UNITED STATES PATENT AND TRADEMARK OFFICE

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Address: COMMISSIONER FOR PATENTS
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/989,297	01/24/2008	Carmeli Adahan	ADAHAN16	4766

191043 7590 10/04/2023

Whitestone Law, PLLC
1850 Towers Crescent Plaza, Suite 550
Tysons, VA 22182

EXAMINER	
TREYGER, ILYA Y	

ART UNIT	PAPER NUMBER
3761	

NOTIFICATION DATE	DELIVERY MODE
10/04/2023	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):

astewart@whitestone.law
elund@whitestone.law
info@whitestone.law

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
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In re Patent No. 8,506,554	:	
Issue Date: August 13, 2013	:	NOTICE
Application No. 11/989,297	:	
Filed: January 24, 2008	:	
Attorney Docket No. ADAHAN16		

This is a Notice regarding the request for acceptance of a fee deficiency submission under 37 CFR 1.28(c) filed July 25, 2023.

The Office no longer investigates or rejects original or reissue applications under 37 CFR 1.56. 1098 Off. Gaz. Pat. Office 502 (January 3, 1989). Therefore, nothing in this Notice is intended to imply that an investigation was done.

The fee deficiency submission under 37 CFR 1.28(c) is **ACCEPTED**. Accordingly, status as a small entity has been removed and any future fee(s) submitted must be paid at the undiscounted rate.

Since the address in the present request differs from the correspondence address of record, a courtesy copy of this Notice is being mailed to the address given in the request. However, applicant should note that a change in the correspondence address will not affect the fee address. Therefore, if applicant desires to receive future correspondence which **may** be mailed, regarding maintenance fees, for the above-identified patent, a "Fee Address Indication" form and/or a "Request for Customer Number" form(s) should be submitted (See USPTO form numbers PTO/SB/47 and/or PTO/SB/125).

Inquiries related to this communication should be directed to Jamice Brantley at (571) 272-3814.

/JAMICE T BRANTLEY/
Jamice T Brantley
Paralegal Specialist, Office of Petitions

Cc :Erik N. Lund
Whitestone Law, PLLC
11718 Bowman Green Dr., Suite 200
Reston, VA 20190

Transmittal Communication on Petition	Application/Control No. 11/989,297	Applicant(s)/Patent Under Reexamination Adahan, Carmeli	
	Deciding Official TREYGER, ILYA Y	Office of Petitions OPET	

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

(ADDITIONAL PARTY'S CORRESPONDENCE ADDRESS)

Erik N. Lund
Whitestone Law, PLLC
11718 Bowman Green Dr., Suite 200
Reston, VA 20190

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above-identified Application/Patent.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	
Carmeli ADAHAN	Art Unit: 3761
Application No.: 11/989,297	Examiner: Ilya Y. TREYGER
Filing Date: 01/24/2008	Atty. Ref. No.: ADAHAN16
Title: WOUND CLOSURE AND DRAINAGE	Confirmation No.: 4766

PETITION FOR ACCEPTANCE OF MAINTENANCE FEE BALANCE DUE TO CHANGE IN ENTITY STATUS UNDER 37 C.F.R. § 1.28(c)

Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Assignee/Applicant's assertion that Assignee/Applicant is a large entity via the Private PAIR Administration was accepted on July 6, 2023 for the above referenced patent. Assignee/Applicant asserts that small entity status was previously established in good faith, and the Office was not notified of a loss of entitlement to small entity status through error. See 37 CFR 1.28(c).

Assignee/Applicant respectfully requests acceptance of the payment of $3,080 as a deficiency payment as required by 37 CFR 1.28(c)(2). Assignee/Applicant's **Fee Deficiency Payment Itemization** begins at page 2 of this paper.

Respectfully submitted,
WHITESTONE LAW, PLLC

By: /Erik N. Lund/
Erik N. Lund
Registration No. 77,473

U.S.P.T.O. Customer Number 191043
WHITESTONE LAW, PLLC
11718 Bowman Green Dr, STE 200
Reston, VA 20190
703.261.9084 (direct)
703.261.9101 (main)
Deposit Account 60-4958

Date: July 6, 2023

NOTIFICATION OF LOSS OF ENTITY STATUS

Application or Patent No.: 8,506,554	First Named Inventor: Carmeli ADAHAN
Filing Date: 01/24/2008	Title of Invention: WOUND CLOSURE AND DRAINAGE SYSTEM

Applicant or patentee hereby notifies the Office that micro entity status is no longer appropriate in this application or patent. Applicant or patentee asserts that:

☐ Applicant/patentee is entitled to small entity status for this application or patent. See 37 CFR 1.27.

OR

☑ Applicant/patentee will pay undiscounted fees in this application or patent.

FEE DEFICIENCY PAYMENT

(please complete this section if you are correcting prior payments that were erroneously made in the micro entity amount)

☑ Applicant or patentee asserts that micro entity status was previously established in good faith, and that micro entity status either was established in error, or the Office was not notified of a loss of entitlement to micro entity status through error.

Fee Description or Type	Current Fee Amount✧	Amount Previously Paid	Date Previously Paid	Deficiency Owed
3.5 yr Maintenance Fee	$2,000	$800	02/13/2017	$1,200
7.5 yr Maintenance Fee	$3,760	$1880	02/15/2021	$1,880
		Total Deficiency Owed (*sum of all entries in "Deficiency Owed" column*)		$3,080

✧ The "current fee amount" refers to the small entity or undiscounted rate (whichever is applicable) listed on the fee schedule as currently in force at the time this paper is submitted and the deficiency is paid in full. The USPTO fee schedule is available at https://www.uspto.gov/Fees. For more information about submitting fee deficiencies, see MPEP 509.04(f). The MPEP is available at https://www.uspto.gov/MPEP.

NOTIFICATION OF LOSS OF ENTITY STATUS

FEE DEFICIENCY PAYMENT (CONT.)

If you owe a fee deficiency, you must enclose payment for the total fee deficiency amount for prior payments erroneously made in the micro entity amount in this application or patent. Do NOT combine payment for multiple applications or patents. If you owe a fee deficiency in multiple applications or patents, you must submit a separate form and payment for each application or patent.

Please check the applicable box for the form of payment, and follow the corresponding instructions for submitting your form and payment.

☐ A check or U.S. Postal Service money order is enclosed. Please make payable to "Director of the USPTO", and mail this form with the check or money order to:

Mail Stop Petition
Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

☐ Payment by credit card. Do NOT provide credit card information on this form. Instead, enclose a completed Credit Card Payment Form (Form PTO-2038), which is available at https://www.uspto.gov/sites/default/files/documents/PTO-2038.pdf. Submit both forms either by facsimile to (571) 273-8300, or by mail to the address shown above.

☑ The Director is hereby authorized to charge $ 3,080 to USPTO Deposit Account No. 60-4958. If you select this option, this form must be signed by someone who is an authorized user of the deposit account, and who is permitted to sign in accordance with 37 CFR 1.33. If you are paying by deposit account, you may submit this form via the USPTO's patent electronic filing systems (EFS-Web or Patent Center), by facsimile to (571) 273-8300, or by mail to the address shown above.

For more information on accepted payment methods, please see https://www.uspto.gov/learning-and-resources/fees-and-payment/accepted-payment-methods. Payment must be made in U.S. dollars, and if payment is made from a foreign country, the payment must be payable and immediately negotiable in the United States for the full amount of the fee required.

SIGNATURE

This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications.

If applicant or patentee is a juristic entity (e.g., an LLC or corporation), this form must be signed by a registered practitioner. See 37 CFR 1.31.

If applicant or patentee is a person or persons, this form may be signed by either a registered practitioner, or the applicant or patentee. Note that if multiple people together are the applicant or patentee (e.g., there are joint inventors who together are the applicant), then a signature is required from each person who is an applicant or patentee. *Submit multiple forms if more than one signature is required, see below*.*

Signature	Date
/Erik N. Lund/	07-06-23
Name (Print/Typed)	Practitioner Registration Number (if applicable)
Erik N. Lund	77,473

☐ * Total of _____ forms are submitted.

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 #
11/989,297	**07/25/2023 11:26:28 PM ET**	**ADAHAN16**

Title of Invention

WOUND CLOSURE AND DRAINAGE SYSTEM

Application Information

APPLICATION TYPE	Utility - U.S. National Stage under 35 USC 371	PATENT #	8506554
CONFIRMATION #	4766	FILED BY	Erik Lund
PATENT CENTER #	62504470	FILING DATE	01/24/2008
CUSTOMER #	191043	FIRST NAMED INVENTOR	Carmeli Adahan
INTL. APPLICATION #	-	INTL. FILING DATE	-
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	-

Documents

TOTAL DOCUMENTS: 1

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
Petition_deficency_payment.pdf	3	Petition for review by the Office of Petitions	257 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
Petition_deficency_payment.pdf	8BEB1438234EC997B024C283E34BE552C6CA7872A54914FEBC0CBE978610BE65112D16FB322A826440B755ACFE58FA929B1DCF1CD7E557C3AFBC37266E765312

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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ACKNOWLEDGEMENT OF LOSS OF ENTITLEMENT TO ENTITY STATUS DISCOUNT

APPLICATION #	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET #	REQUEST ID
11/989,297	01/24/2008	Carmeli Adahan	ADAHAN16	91887

The entity status change request below filed through Patent Center on 07/06/2023 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 #
/Erik N . Lund/	Erik Lund	77473

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
11/989,297	01/24/2008	Carmeli Adahan	ADAHAN16

CONFIRMATION NO. 4766

1444
Browdy and Neimark, PLLC
1625 K Street, N.W.
Suite 550
Washington, DC 20006

POWER OF ATTORNEY NOTICE

OC000000058740927

Date Mailed: 06/28/2023

NOTICE REGARDING CHANGE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 06/26/2023.

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

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

/tawashington/

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
11/989,297	01/24/2008	Carmeli Adahan	ADAHAN16

CONFIRMATION NO. 4766

191043
Whitestone Law, PLLC
11718 Bowman Green Dr., Suite 200
Reston, VA 20190

POA ACCEPTANCE LETTER

OC000000058740997

Date Mailed: 06/28/2023

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 06/26/2023.

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

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

/tawashington/

POWER OF ATTORNEY BY APPLICANT

I hereby revoke all previous powers of attorney given in the application identified in the attached transmittal letter.

I hereby appoint:

☒ Practitioners associated with the Customer Number identified in the box at right as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter (form PTO/AIA/82A or equivalent):

191043

Please recognize or change the correspondence address for the application identified in the attached transmittal letter to:

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

I am the:

☐ Applicant.

☒ Assignee or Person to Whom the Inventor is Under an Obligation to Assign and am authorized to act on behalf of all assignees.

☐ Legal Representative of a Deceased or Legally Incapacitated Inventor.

☐ Person Who Otherwise Shows Sufficient Proprietary Interest (*e.g.*, a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document).

SIGNATURE of Applicant for Patent

Signature: _____ Date: _____

Name (printed): Carmeli Adahan

Telephone: 972-50-6406-000

Title and Company: _____

M.E.A.C. ENGINEERING LTD.

PTO/AIA/96 (08-12)
Approved for use through 01/31/2013. 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.

STATEMENT UNDER 37 CFR 3.73(c)

Applicant/Patent Owner: M.E.A.C. ENGINEERING LTD.

Application No./Patent No.: 11/989,297 - 8,506,554 Filed/Issue Date: 01/24/2008 - 08/13/2013

Titled: WOUND CLOSURE AND DRAINAGE SYSTEM

M.E.A.C. ENGINEERING LTD., a corporation

(Name of Assignee) (Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that, for the patent application/patent identified above, it is (choose **one** of options 1, 2, 3 or 4 below):

1. ☑ The assignee of the entire right, title, and interest.

2. ☐ An assignee of less than the entire right, title, and interest (check applicable box):

   ☐ The extent (by percentage) of its ownership interest is _____%. Additional Statement(s) by the owners holding the balance of the interest must be submitted to account for 100% of the ownership interest.

   ☐ There are unspecified percentages of ownership. The other parties, including inventors, who together own the entire right, title and interest are:

   Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

3. ☐ The assignee of an undivided interest in the entirety (a complete assignment from one of the joint inventors was made). The other parties, including inventors, who together own the entire right, title, and interest are:

   Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

4. ☐ The recipient, via a court proceeding or the like (*e.g.*, bankruptcy, probate), of an undivided interest in the entirety (a complete transfer of ownership interest was made). The certified document(s) showing the transfer is attached.

The interest identified in option 1, 2 or 3 above (not option 4) is evidenced by either (choose **one** of options A or B below):

A. ☐ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.

B. ☑ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as follows:

1. From: ADAHAN, CARMEL To: M.E.A.C. ENGINEERING LTD.

   The document was recorded in the United States Patent and Trademark Office at
   Reel 040196, Frame 0564, or for which a copy thereof is attached.

2. From: ADAHAN, CARMELI To: M.E.A.C. ENGINEERING LTD.

   The document was recorded in the United States Patent and Trademark Office at
   Reel 040555, Frame 0928, or for which a copy thereof is attached.

This collection of information is required by 37 CFR 3.73(b). 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. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450**.

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

PTO/AIA/96 (08-12)
Approved for use through 01/31/2013. 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.

STATEMENT UNDER 37 CFR 3.73(c)

3. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

4. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

5. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

6. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

☐ Additional documents in the chain of title are listed on a supplemental sheet(s).

☐ As required by 37 CFR 3.73(c)(1)(i), the documentary evidence of the chain of title from the original owner to the assignee was, or concurrently is being, submitted for recordation pursuant to 37 CFR 3.11.

[NOTE: A separate copy (i.e., a true copy of the original assignment document(s)) must be submitted to Assignment Division in accordance with 37 CFR Part 3, to record the assignment in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

/Erik N. Lund/	06-26-2023
Signature	Date
Erik N. Lund	77,473
Printed or Typed Name	Title or Registration Number

Privacy Act Statement

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

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

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

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 #
11/989,297	**06/26/2023 01:24:49 PM ET**	**ADAHAN16**

Title of Invention

WOUND CLOSURE AND DRAINAGE SYSTEM

Application Information

APPLICATION TYPE	Utility - U.S. National Stage under 35 USC 371	PATENT #	8506554
CONFIRMATION #	4766	FILED BY	Madeline Nguyen
PATENT CENTER #	62335781	FILING DATE	01/24/2008
CUSTOMER #	1444	FIRST NAMED INVENTOR	Carmeli Adahan
INTL. APPLICATION #	-	INTL. FILING DATE	-
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Erik Lund

Documents

TOTAL DOCUMENTS: 2

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
MEAC_ENGINEERING_LTD_POA.pdf	1	Power of Attorney	179 KB

Warning: The attached file contains comments or annotations. Comments are not recommended and may cause processing problems with the document.

Statement_under_37_CFR_373.pdf	3	Assignee showing of ownership per 37 CFR 3.73	307 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
MEAC_ENGINEERING_LTD_POA.pdf	A64420602ADB9B2ABDD98D7840E5A85CE7B33CDF1DE562D2C4AE2CAFD5EBCE2A9C01873AB255817338BF75E4BD23CFDD04F52AB0580BC05ABA386AB1D5BCDA95
Statement_under_37_CFR_373.pdf	EB259F19576C6077A6A0938D5A414BF4B50D38A19D9413BFF48C9044A5E2E285AD5B6657B3232152A8CB39270141F6B00DCD4A52D850B95BDEDB9DF1CC030E53

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

CERTIFICATE OF CORRECTION

PATENT NO. : 8,506,554 B2
APPLICATION NO. : 11/989297
DATED : August 13, 2013
INVENTOR(S) : Carmeli Adahan

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In the Claims

Column 6, lines 17-28, Claim 1 should read

1. An enclosure for applying negative pressure to a wound, the enclosure being attachable to the wound circumference so as to define a confined volume, and comprising a tube and a venting arrangement, the enclosure having an enclosure outlet connectable to a vacuum source via said tube so that negative pressure can be selectively created in said volume, said venting arrangement located outside said enclosure and comprising a flow restrictor to restrict flow through said venting arrangement such that ambient air can enter said tube via said venting arrangement and flow to said vacuum source without having to enter said enclosure.;

Column 6, line 31, Claim 3, delete "of claim";

Column 7, lines 10-13, Claim 12, rewrite these lines to read:

12. A vacuum system for applying negative pressure to a wound, the vacuum system comprising:

an enclosure and a vacuum source, the enclosure being attachable to the wound circumference so as to define a confined volume;

Column 8, line 37, Claim 24, delete "vacuum system" and insert --enclosure--;

Column 8, line 43, Claim 27, delete "enclosure" and insert --vacuum system--;

Column 8, line 47, Claim 29, delete "enclosure" and insert --vacuum system--.

This certificate supersedes the Certificate of Correction issued June 3, 2014.

Signed and Sealed this
Ninth Day of September, 2014

Michelle K. Lee

Michelle K. Lee
Deputy Director of the United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE
U.S. Patent and Trademark Office
Address : COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450

APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
11/989,297	24 January, 2008	ADAHAN, CARMELI	ADAHAN16

		EXAMINER	
Browdy and Neimark, PLLC 1625 K Street, N.W. Suite 1100 Washington, DC 20006		ILYA TREYGER	
		ART UNIT	PAPER
		3761	20140812

DATE MAILED:

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

Commissioner for Patents

Certificate of Correction is approved.

/TATYANA ZALUKAEVA/ Supervisory Patent Examiner, Art Unit 3761	/ILYA TREYGER/ Examiner, Art Unit 3761

PTO-90C (Rev.04-03)

SPE RESPONSE FOR CERTIFICATE OF CORRECTION

DATE : 08/12/14

TO SPE OF : ART UNIT: _3761_____ Examiner: __ TREYGER, ILYA
SUBJECT : Request for Certificate of Correction for Appl. No.: 11989297 Patent No.: 8506554

CofC mailroom date: 06/23/14

Please respond to this request for a certificate of correction within 7 days.

FOR IFW FILES:

Please review the requested changes/corrections as shown in the **COCIN** document(s) in the IFW application image. No new matter should be introduced, nor should the scope or meaning of the claims be changed.

Please complete the response (see below) and forward the completed response to scanning using document code **COCX**.

FOR PAPER FILES:

Please review the requested changes/corrections as shown in the attached certificate of correction. Please complete this form (see below) and forward it with the file to:

Certificates of Correction Branch (CofC)
Randolph Square – 9D10-A
Palm Location 7580
You can fax the Directors/SPE response to 571-273-3421

Note: Please check Claims 24, 27and 29
Should the changes to the claims be approved?

Lamonte Newsome

Certificates of Correction Branch

571-272-3421

Thank You For Your Assistance

The request for issuing the above-identified correction(s) is hereby:
Note your decision on the appropriate box.

Medela LLC and Medela AG
Exhibit 1008
Page #20

SPE RESPONSE FOR CERTIFICATE OF CORRECTION

❑ **Approved**	**All** changes apply.
❑ **Approved in Part**	Specify below which changes **do not** apply.
❑ **Denied**	State the reasons for denial below.

Comments: _____

_____

_____

_____

_____

_____ _____

SPE **Art Unit**

Medela LLC and Medela AG
Exhibit 1008
Page #21

OK to enter. /I.T./

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Atty. Docket: ADAHAN16

In re Patent of:	)	Conf. No.: 4766
Carmeli ADAHAN	)	
U.S. Pat. No. 8,506,554	)	Washington, D.C.
Issued: August 13, 2013	)	June 23, 2014
For: WOUND CLOSURE AND DRAINAGE SYSTEM	)	ATTN: Certificate of Correction Division

REQUEST FOR CERTIFICATE OF CORRECTION UNDER 37 C.F.R. §1.323

Honorable Commissioner for Patents
U.S. Patent and Trademark Office
Randolph Building, Mail Stop Post Issue
401 Dulany Street
Alexandria, VA 22314

Sir:

In checking over the printed copy of the above-identified patent, we have found the following errors, at least some of which are mistakes on the part of the applicant. It is respectfully requested that these errors be corrected in accordance with 37 C.F.R. §1.323. The errors to be corrected are listed below.

When these changes are considered, it will be clear that all of these errors are of a typographical or clerical error in nature and/or of minor character, which occurred in good faith. Correction thereof does not involve such a change in the patent as would constitute "new matter" or would require further examination.

At claim 1, column 6, lines 25-26, delete "located outside said enclosure and comprising a flow restrictor".

In the Examiner's Amendment of April 10, 2013, the examiner made a clerical or typographical error by repeating the words "located outside said enclosure and comprising a flow restrictor." That this was an obvious clerical or typographical error made by the examiner in the Examiner's Amendment, is evidenced by the Applicants' Interview Summary, summarizing the telephone interview of April 3, 2013, which was filed on May 10, 2013. This contains the paragraph:

> The undersigned further advised the examiner that the amendment filed with the RCE inadvertently removed the language "to restrict flow through said venting arrangement" after "flow restrictor." The examiner stated that if the case were found to otherwise be in consideration for allowance, he would add back these words to claims 11 and 42 in an examiner's amendment.

In the Applicant-Initiated Interview Summary provided by the examiner for the same telephone interview, the examiner wrote, "Applicant authorized the Examiner to include words 'to restrict flow through said venting arrangement' after words 'flow restrictor' in claims 11 and 42. The examiner correctly added these words in claim 42 (patent claim 12), but inadvertently duplicated the words "located outside said enclosure and comprising a flow restrictor" in the rewritten claim 11 (patent claim 1).

At claim 3, column 6, line 31, delete "of claim". These obviously extraneous words are a typographical error introduced into the claims by applicant in its amendment of application claim 14 (patent claim 3) submitted on February 14, 2011.

At claim 12, column 7, line 11, delete the semicolon (;) and insert a colon (:). Following the colon, start a new paragraph beginning with "an enclosure and a vacuum source..."

This is another error introduced by the examiner at the time of the Examiner's Amendment of April 10, 2013. As discussed above, the Applicant's Interview Summary of May 10, 2013, and the Applicant-Initiated Interview Summary issued April 10, 2013, the only changes authorized to application claim 42 (patent claim 12) was the addition of the words "to restrict flow through said venting arrangement" after "flow restrictor." No changes to the preamble were authorized or intended. The previously appearing copy of claim 42, as appearing in the amendment of January 8, 2013, properly showed the preamble ending with a colon and the first paragraph starting with "an enclosure and a vacuum source …" Thus, this was an obvious typographical error on the part of the examiner.

At claim 24, column 8, line 37, delete "vacuum system" and insert "enclosure". Patent claim 24 corresponds to application claim 54, originally introduced by applicant in its amendment of February 13, 2012. However, claim 54 was dependent on claim 11, directed to an enclosure, not a vacuum system (as in independent claim 12, for example). Thus the term "vacuum system" at the beginning of this claim should have read "enclosure," so as to correspond with the wording of the preamble in the claim from which it depends. This is an obvious clerical or typographical error on the part of applicant, the correction of which does not require further examination. The examiner clearly understood claim 54 as having been intended to have been directed to the enclosure of claim 11, rather than the "vacuum system" of claim 11, as claim 11 is not directed to a "vacuum system."

At claim 27, column 8, line 43, delete "enclosure" and substitute "vacuum system". Patent claim 27 corresponds to application claim 57, originally introduced by applicant in its amendment of January 8, 2013. However, claim 57 was dependent on claim 56, directed to a vacuum system, not an enclosure. Thus the term "enclosure" at the

beginning of this claim should have read "vacuum system," so as to correspond with the wording of the preamble in the claim from which it depends. This is an obvious clerical or typographical error on the part of applicant, the correction of which does not require further examination. The examiner clearly understood claim 57 as having been intended to have been directed to the vacuum system of claim 56, rather than the "enclosure" of claim 56, as claim 56 is not directed to an "enclosure."

At claim 29, column 8, line 47, delete "enclosure" and insert "vacuum system". Patent claim 29 corresponds to application claim 59, originally introduced by applicant in its amendment of January 8, 2013. However, claim 59 was dependent on claim 58, directed to a vacuum system, not an enclosure. Thus, the term "enclosure" at the beginning of this claim should have read "vacuum system," so as to correspond with the wording of the preamble in the claim from which it depends. This is an obvious clerical or typographical error on the part of applicant, the correction of which does not require further examination. The examiner clearly understood claim 59 as having been intended to have been directed to the vacuum system of claim 58, rather than the "enclosure" of claim 58, as claim 58 is not directed to an "enclosure."

Attached is a Certificate of Correction form showing the above-identified corrections. The present proposed changes will require no additional examination on the part of the examiner as the corrections are merely the correction of typographical errors.

Submitted herewith is a credit card authorization in the amount of $100.00 to cover the appropriate fee for corrections under 37 CFR §1.323. If insufficient fees are specifically authorized, please charge same to Deposit Account No. 02-4035.

Granting of this request is earnestly solicited.

Please note that a certificate of correction of claim 1 was issued on June 3, 2014, with respect to patent claim 1. However, this corrected claim 1 was identical to claim 1 of the patent and thus changed nothing. The present certificate of correction as to claim 1 is intended to supersede the certificate issued on June 3, 2014.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.
Attorneys for Applicant(s)

By /rlb/
Roger L. Browdy
Registration No. 25,618

RLB:jhw
Telephone No.: (202) 628-5197
Facsimile No.: (202) 737-3528
G:\BN\C\cohn\Adahan16\Pto\2014-06-03CertificateofCorrection1323ADAHAN16.doc

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PTO/SB/44 (09-07)
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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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UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : US8506554
APPLICATION NO.: US2009264837
ISSUE DATE : August 13, 2013
INVENTOR(S) : Carmeli Adahan

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Abstract:
A vacuum system for draining an open wound from liquids exuded therefrom, comprising an enclosure sealable to the wound circumference, a vacuum pump including a disposable pump unit detachably attachable to a non-disposable drive unit, and a waste container for collection of drained liquids. The enclosure has an outlet connected by means of a tube to an inlet of the pump unit and the waste container is connected to an outlet of the pump unit, such that when the vacuum pump is operated the drained liquids flow through the vacuum pump. The enclosure has one or more bleeding holes provided therethrough or adjacent to its outlet so that ambient air may enter the tube and flow together with the drained liquids. The enclosure and the waste container are disposable so that the drained liquids contact only disposable elements and may be disposed of together with all disposable elements.

MAILING ADDRESS OF SENDER (Please do not use customer number below):
Carmeli Adahan
11 Netivei Am street
Jerusalem Israel 97552

This collection of information is required by 37 CFR 1.322, 1.323, and 1.324. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1.0 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: Attention Certificate of Corrections Branch, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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

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PTO/SB/44 (09-07)
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UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : US8506554

APPLICATION NO.: 11/989,297

ISSUE DATE : 8-13-2013

INVENTOR(S) : Carmeli Adahan

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

1. An enclosure for applying negative pressure to a wound, the enclosure being attachable to the wound circumference so as to define a confined volume, and comprising a tube and a venting arrangement, the enclosure having an enclosure outlet connectable to a vacuum source via said tube so that negative pressure can be selectively created in said volume, said venting arrangement located outside said enclosure and comprising a flow restrictor to restrict flow through said venting arrangement located outside said enclosure and comprising a flow restrictor such that ambient air can enter said tube via said venting arrangement and flow to said vacuum source without having to enter said enclosure.

It appears that the text " located outside said enclosure and comprising a flow restrictor " is repeated in the claim.

MAILING ADDRESS OF SENDER (Please do not use customer number below):

11 Netivei Am
Jerusalem, Israel 97552

This collection of information is required by 37 CFR 1.322, 1.323, and 1.324. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1.0 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: Attention Certificate of Corrections Branch, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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(Also Form PTO-1050)

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 8506554

APPLICATION NO.: 11989297

ISSUE DATE : August 13, 2013

INVENTOR(S) : Carmeli ADAHAN

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

At column 6, lines 17-28, Claim 1 should read:

1. An enclosure for applying negative pressure to a wound, the enclosure being attachable to the wound circumference so as to define a confined volume, and comprising a tube and a venting arrangement, the enclosure having an enclosure outlet connectable to a vacuum source via said tube so that negative pressure can be selectively created in said volume, said venting arrangement located outside said enclosure and comprising a flow restrictor to restrict flow through said venting arrangement such that ambient air can enter said tube via said venting arrangement and flow to said vacuum source without having to enter said enclosure.

At claim 3, column 6, line 31, delete “of claim”;
At claim 12, column 7, lines 10-13, rewrite these lines to read:

12. A vacuum system for applying negative pressure to a wound, the vacuum system comprising:
an enclosure and a vacuum source, the enclosure being attachable to the wound circumference so as to define a confined volume;

At claim 24, column 8, line 37, delete “vacuum system” and insert --enclosure--;
At claim 27, column 8, line 43, delete “enclosure” and insert --vacuum system--;
At claim 29, column 8, line 47, delete “enclosure” and insert --vacuum system--;

MAILING ADDRESS OF SENDER (Please do not use customer number below):

BROWDY AND NEIMARK, P.L.L.C.
1625 K. Street N.W. Suite 1100
Washington, D.C. 20006

This collection of information is required by 37 CFR 1.322, 1.323, and 1.324. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1.0 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: Attention Certificate of Corrections Branch, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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

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

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

SPE RESPONSE FOR CERTIFICATE OF CORRECTION

DATE : 08/12/14

TO SPE OF : ART UNIT: 3761 Examiner: TREYGER, ILYA
SUBJECT : Request for Certificate of Correction for Appl. No.: 11989297 Patent No.: 8506554

CofC mailroom date: 06/23/14

Please respond to this request for a certificate of correction within 7 days.

FOR IFW FILES:

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Please complete the response (see below) and forward the completed response to scanning using document code **COCX**.

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Randolph Square – 9D10-A
Palm Location 7580
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Note: **Please check Claims 24, 27and 29**
Should the changes to the claims be approved?

Lamonte Newsome

Certificates of Correction Branch

571-272-3421

Thank You For Your Assistance

The request for issuing the above-identified correction(s) is hereby:
Note your decision on the appropriate box.

Medela LLC and Medela AG
Exhibit 1008
Page #31

SPE RESPONSE FOR CERTIFICATE OF CORRECTION

☐ **Approved** — **All** changes apply.

☐ **Approved in Part** — Specify below which changes **do not** apply.

☐ **Denied** — State the reasons for denial below.

Comments: _____

_____

_____

_____

_____

_____ _____

SPE **Art Unit**

Medela LLC and Medela AG
Exhibit 1008
Page #32

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Atty. Docket: ADAHAN16

In re Patent of:	)	Conf. No.: 4766
Carmeli ADAHAN	)	
U.S. Pat. No. 8,506,554	)	Washington, D.C.
Issued: August 13, 2013	)	June 23, 2014
For: WOUND CLOSURE AND DRAINAGE SYSTEM	)	ATTN: Certificate of Correction Division

REQUEST FOR CERTIFICATE OF CORRECTION UNDER 37 C.F.R. §1.323

Honorable Commissioner for Patents
U.S. Patent and Trademark Office
Randolph Building, Mail Stop Post Issue
401 Dulany Street
Alexandria, VA 22314

Sir:

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When these changes are considered, it will be clear that all of these errors are of a typographical or clerical error in nature and/or of minor character, which occurred in good faith. Correction thereof does not involve such a change in the patent as would constitute "new matter" or would require further examination.

At claim 1, column 6, lines 25-26, delete "located outside said enclosure and comprising a flow restrictor".

In the Examiner's Amendment of April 10, 2013, the examiner made a clerical or typographical error by repeating the words "located outside said enclosure and comprising a flow restrictor." That this was an obvious clerical or typographical error made by the examiner in the Examiner's Amendment, is evidenced by the Applicants' Interview Summary, summarizing the telephone interview of April 3, 2013, which was filed on May 10, 2013. This contains the paragraph:

> The undersigned further advised the examiner that the amendment filed with the RCE inadvertently removed the language "to restrict flow through said venting arrangement" after "flow restrictor." The examiner stated that if the case were found to otherwise be in consideration for allowance, he would add back these words to claims 11 and 42 in an examiner's amendment.

In the Applicant-Initiated Interview Summary provided by the examiner for the same telephone interview, the examiner wrote, "Applicant authorized the Examiner to include words 'to restrict flow through said venting arrangement' after words 'flow restrictor' in claims 11 and 42. The examiner correctly added these words in claim 42 (patent claim 12), but inadvertently duplicated the words "located outside said enclosure and comprising a flow restrictor" in the rewritten claim 11 (patent claim 1).

At claim 3, column 6, line 31, delete "of claim". These obviously extraneous words are a typographical error introduced into the claims by applicant in its amendment of application claim 14 (patent claim 3) submitted on February 14, 2011.

At claim 12, column 7, line 11, delete the semicolon (;) and insert a colon (:). Following the colon, start a new paragraph beginning with "an enclosure and a vacuum source..."

This is another error introduced by the examiner at the time of the Examiner's Amendment of April 10, 2013. As discussed above, the Applicant's Interview Summary of May 10, 2013, and the Applicant-Initiated Interview Summary issued April 10, 2013, the only changes authorized to application claim 42 (patent claim 12) was the addition of the words "to restrict flow through said venting arrangement" after "flow restrictor." No changes to the preamble were authorized or intended. The previously appearing copy of claim 42, as appearing in the amendment of January 8, 2013, properly showed the preamble ending with a colon and the first paragraph starting with "an enclosure and a vacuum source …" Thus, this was an obvious typographical error on the part of the examiner.

At claim 24, column 8, line 37, delete "vacuum system" and insert "enclosure". Patent claim 24 corresponds to application claim 54, originally introduced by applicant in its amendment of February 13, 2012. However, claim 54 was dependent on claim 11, directed to an enclosure, not a vacuum system (as in independent claim 12, for example). Thus the term "vacuum system" at the beginning of this claim should have read "enclosure," so as to correspond with the wording of the preamble in the claim from which it depends. This is an obvious clerical or typographical error on the part of applicant, the correction of which does not require further examination. The examiner clearly understood claim 54 as having been intended to have been directed to the enclosure of claim 11, rather than the "vacuum system" of claim 11, as claim 11 is not directed to a "vacuum system."

At claim 27, column 8, line 43, delete "enclosure" and substitute "vacuum system". Patent claim 27 corresponds to application claim 57, originally introduced by applicant in its amendment of January 8, 2013. However, claim 57 was dependent on claim 56, directed to a vacuum system, not an enclosure. Thus the term "enclosure" at the

beginning of this claim should have read "vacuum system," so as to correspond with the wording of the preamble in the claim from which it depends. This is an obvious clerical or typographical error on the part of applicant, the correction of which does not require further examination. The examiner clearly understood claim 57 as having been intended to have been directed to the vacuum system of claim 56, rather than the "enclosure" of claim 56, as claim 56 is not directed to an "enclosure."

At claim 29, column 8, line 47, delete "enclosure" and insert "vacuum system". Patent claim 29 corresponds to application claim 59, originally introduced by applicant in its amendment of January 8, 2013. However, claim 59 was dependent on claim 58, directed to a vacuum system, not an enclosure. Thus, the term "enclosure" at the beginning of this claim should have read "vacuum system," so as to correspond with the wording of the preamble in the claim from which it depends. This is an obvious clerical or typographical error on the part of applicant, the correction of which does not require further examination. The examiner clearly understood claim 59 as having been intended to have been directed to the vacuum system of claim 58, rather than the "enclosure" of claim 58, as claim 58 is not directed to an "enclosure."

Attached is a Certificate of Correction form showing the above-identified corrections. The present proposed changes will require no additional examination on the part of the examiner as the corrections are merely the correction of typographical errors.

Submitted herewith is a credit card authorization in the amount of $100.00 to cover the appropriate fee for corrections under 37 CFR §1.323. If insufficient fees are specifically authorized, please charge same to Deposit Account No. 02-4035.

Granting of this request is earnestly solicited.

Please note that a certificate of correction of claim 1 was issued on June 3, 2014, with respect to patent claim 1. However, this corrected claim 1 was identical to claim 1 of the patent and thus changed nothing. The present certificate of correction as to claim 1 is intended to supersede the certificate issued on June 3, 2014.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.
Attorneys for Applicant(s)

By _/rlb/_____
Roger L. Browdy
Registration No. 25,618

RLB:jhw
Telephone No.: (202) 628-5197
Facsimile No.: (202) 737-3528
G:\BN\C\cohn\Adahan16\Pto\2014-06-03CertificateofCorrection1323ADAHAN16.doc

PTO/SB/44 (09-07)
Approved for use through 08/31/2013. OMB 0651-0033
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(Also Form PTO-1050)

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 8506554

APPLICATION NO.: 11989297

ISSUE DATE : August 13, 2013

INVENTOR(S) : Carmeli ADAHAN

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

At column 6, lines 17-28, Claim 1 should read:

1. An enclosure for applying negative pressure to a wound, the enclosure being attachable to the wound circumference so as to define a confined volume, and comprising a tube and a venting arrangement, the enclosure having an enclosure outlet connectable to a vacuum source via said tube so that negative pressure can be selectively created in said volume, said venting arrangement located outside said enclosure and comprising a flow restrictor to restrict flow through said venting arrangement such that ambient air can enter said tube via said venting arrangement and flow to said vacuum source without having to enter said enclosure.

At claim 3, column 6, line 31, delete “of claim”;
At claim 12, column 7, lines 10-13, rewrite these lines to read:

12. A vacuum system for applying negative pressure to a wound, the vacuum system comprising:
an enclosure and a vacuum source, the enclosure being attachable to the wound circumference so as to define a confined volume;

At claim 24, column 8, line 37, delete “vacuum system” and insert --enclosure--;
At claim 27, column 8, line 43, delete “enclosure” and insert --vacuum system--;
At claim 29, column 8, line 47, delete “enclosure” and insert --vacuum system--;

MAILING ADDRESS OF SENDER (Please do not use customer number below):

BROWDY AND NEIMARK, P.L.L.C.
1625 K. Street N.W. Suite 1100
Washington, D.C. 20006

This collection of information is required by 37 CFR 1.322, 1.323, and 1.324. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1.0 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: Attention Certificate of Corrections Branch, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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

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

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

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

Electronic Patent Application Fee Transmittal

Application Number:	11989297
Filing Date:	24-Jan-2008
Title of Invention:	WOUND CLOSURE AND DRAINAGE SYSTEM
First Named Inventor/Applicant Name:	Carmeli Adahan
Filer:	Roger Lowen Browdy/Jason Williams
Attorney Docket Number:	ADAHAN16

Filed as Large Entity

U.S. National Stage under 35 USC 371 Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Certificate of Correction	1811	1	100	100
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
		Total in USD ($)		**100**

Electronic Acknowledgement Receipt

EFS ID:	19375836
Application Number:	11989297
International Application Number:	
Confirmation Number:	4766
Title of Invention:	WOUND CLOSURE AND DRAINAGE SYSTEM
First Named Inventor/Applicant Name:	Carmeli Adahan
Customer Number:	1444
Filer:	Roger Lowen Browdy/Jason Williams
Filer Authorized By:	Roger Lowen Browdy
Attorney Docket Number:	ADAHAN16
Receipt Date:	23-JUN-2014
Filing Date:	24-JAN-2008
Time Stamp:	10:58:51
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$100
RAM confirmation Number	8730
Deposit Account	
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)

1	Request for Certificate of Correction	2014-06-23RequestCertificateofCorrection1323_ADAHAN16.pdf	106364 ba8839fe0d1cee212eed55416772ddd401da137e	no	5
Warnings:					
Information:					
2	Request for Certificate of Correction	2014-06-23CertificateofCorrectionForm-ADAHAN16.pdf	165552 a782d26e4205533333071f0fb4d7083511adb7be	no	2
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	30158 ae6cb3c817b825c8a306f5e4e70ab23a6f4c40b1	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	302074		

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<u>New Applications Under 35 U.S.C. 111</u>
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

<u>National Stage of an International Application under 35 U.S.C. 371</u>
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.

<u>New International Application Filed with the USPTO as a Receiving Office</u>
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

CERTIFICATE OF CORRECTION

PATENT NO. : 8,506,554 B2
APPLICATION NO. : 11/989297
DATED : August 13, 2013
INVENTOR(S) : Carmeli Adahan

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In the Claims

Column 6, lines 17-28, Claim 1 should read

1. An enclosure for applying negative pressure to a wound, the enclosure being attachable to the wound circumference so as to define a confined volume, and comprising a tube and a venting arrangement, the enclosure having an enclosure outlet connectable to a vacuum source via said tube so that negative pressure can be selectively created in said volume, said venting arrangement located outside said enclosure and comprising a flow restrictor to restrict flow through said venting arrangement located outside said enclosure and comprising a flow restrictor such that ambient air can enter said tube via said venting arrangement and flow to said vacuum source without having to enter said enclosure.

Signed and Sealed this
Third Day of June, 2014

Michelle K. Lee

Michelle K. Lee
Deputy Director of the United States Patent and Trademark Office

PTO/SB/44 (09-07)
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UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : US8506554

APPLICATION NO.: 11/989,297

ISSUE DATE : 8-13-2013

INVENTOR(S) : Carmeli Adahan

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

1. An enclosure for applying negative pressure to a wound, the enclosure being attachable to the wound circumference so as to define a confined volume, and comprising a tube and a venting arrangement, the enclosure having an enclosure outlet connectable to a vacuum source via said tube so that negative pressure can be selectively created in said volume, said venting arrangement located outside said enclosure and comprising a flow restrictor to restrict flow through said venting arrangement located outside said enclosure and comprising a flow restrictor such that ambient air can enter said tube via said venting arrangement and flow to said vacuum source without having to enter said enclosure.

It appears that the text " located outside said enclosure and comprising a flow restrictor " is repeated in the claim.

MAILING ADDRESS OF SENDER (Please do not use customer number below):

11 Netivei Am
Jerusalem, Israel 97552

This collection of information is required by 37 CFR 1.322, 1.323, and 1.324. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1.0 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: Attention Certificate of Corrections Branch, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 8,506,554 B2
APPLICATION NO. : 11/989297
DATED : August 13, 2013
INVENTOR(S) : Carmeli Adahan

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Title Page, Item (57) Abstract should read:

A vacuum system for draining an open wound from liquids exuded therefrom, comprising an enclosure sealable to the wound circumference, a vacuum pump including a disposable pump unit detachably attachable to a non-disposable drive unit, and a waste container for collection of drained liquids. The enclosure has an outlet connected by means of a tube to an inlet of the pump unit and the waste container is connected to an outlet of the pump unit, such that when the vacuum pump is operated the drained liquids flow through the vacuum pump. The enclosure has one or more bleeding holes provided therethrough or adjacent to its outlet so that ambient air may enter the tube and flow together with the drained liquids. The enclosure and the waste container are disposable so that the drained liquids contact only disposable elements and may be disposed of together with all disposable elements.

Signed and Sealed this
Fifteenth Day of April, 2014

Michelle K. Lee

Michelle K. Lee
Deputy Director of the United States Patent and Trademark Office

PTO/SB/44 (09-07)
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UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : US8506554
APPLICATION NO.: US2009264837
ISSUE DATE : August 13, 2013
INVENTOR(S) : Carmeli Adahan

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Abstract:
A vacuum system for draining an open wound from liquids exuded therefrom, comprising an enclosure sealable to the wound circumference, a vacuum pump including a disposable pump unit detachably attachable to a non-disposable drive unit, and a waste container for collection of drained liquids. The enclosure has an outlet connected by means of a tube to an inlet of the pump unit and the waste container is connected to an outlet of the pump unit, such that when the vacuum pump is operated the drained liquids flow through the vacuum pump. The enclosure has one or more bleeding holes provided therethrough or adjacent to its outlet so that ambient air may enter the tube and flow together with the drained liquids. The enclosure and the waste container are disposable so that the drained liquids contact only disposable elements and may be disposed of together with all disposable elements.

MAILING ADDRESS OF SENDER (Please do not use customer number below):
Carmeli Adahan
11 Netivei Am street
Jerusalem Israel 97552

This collection of information is required by 37 CFR 1.322, 1.323, and 1.324. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1.0 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: Attention Certificate of Corrections Branch, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/989,297	08/13/2013	8506554	ADAHAN16	4766

1444 7590 07/24/2013

Browdy and Neimark, PLLC
1625 K Street, N.W.
Suite 1100
Washington, DC 20006

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

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

The Patent Term Adjustment is 585 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

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

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

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

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

Carmeli Adahan, Jerusalem, ISRAEL;

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PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

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

1444 7590 04/10/2013
Browdy and Neimark, PLLC
1625 K Street, N.W.
Suite 1100
Washington, DC 20006

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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 facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/989,297	01/24/2008	Carmeli Adahan	ADAHAN16	4766

TITLE OF INVENTION: WOUND CLOSURE AND DRAINAGE SYSTEM

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$890	$300	$0	$1190	07/10/2013

EXAMINER	ART UNIT	CLASS-SUBCLASS
TREYGER, ILYA Y	3761	604-540000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 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 Browdy and Neimark, PLLC
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 has been filed for recordation as set forth in 37 CFR 3.11. 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. The following fee(s) are submitted:
- ☐ Issue Fee
- ☐ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
- ☐ A check is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

PTOL-85 (Rev. 02/11)

Medela LLC and Medela AG
Exhibit 1008
Page #49

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 form 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: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature  Date July 10, 2013

Typed or printed name Allen C. Yun Registration No. 37,971

This collection of information 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 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, 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.

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Medela LLC and Medela AG
Exhibit 1008
Page #50

Electronic Patent Application Fee Transmittal

Application Number:	11989297
Filing Date:	24-Jan-2008
Title of Invention:	WOUND CLOSURE AND DRAINAGE SYSTEM
First Named Inventor/Applicant Name:	Carmeli Adahan
Filer:	Roger Lowen Browdy/Darryl Whitehurst
Attorney Docket Number:	ADAHAN16

Filed as Small Entity

U.S. National Stage under 35 USC 371 Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Utility Appl Issue Fee	2501	1	890	890
Publ. Fee- Early, Voluntary, or Normal	1504	1	300	300

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**1190**

Electronic Acknowledgement Receipt	
EFS ID:	16275680
Application Number:	11989297
International Application Number:	
Confirmation Number:	4766
Title of Invention:	WOUND CLOSURE AND DRAINAGE SYSTEM
First Named Inventor/Applicant Name:	Carmeli Adahan
Customer Number:	1444
Filer:	Roger Lowen Browdy/Darryl Whitehurst
Filer Authorized By:	Roger Lowen Browdy
Attorney Docket Number:	ADAHAN16
Receipt Date:	10-JUL-2013
Filing Date:	24-JAN-2008
Time Stamp:	14:15:35
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$1190
RAM confirmation Number	602
Deposit Account	
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)

1	Issue Fee Payment (PTO-85B)	2013-07-10IFFtransmittal.pdf	150564 08e2bf8c518d7fb219e2041cb0dcc904d110ff8c	no	2
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	32285 29d42f0cd5228a0c16243f20fe540c5cab911cc5	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	182849		

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New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

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

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	11989297
	Filing Date	2008-01-24
	First Named Inventor	Carmeli ADAHAN
	Art Unit	3761
	Examiner Name	ILYA Y. TREYGER
	Attorney Docket Number	ADAHAN=16

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	1	5578006	A	1996-11-26	STEVENS	
	2	6817996	B2	2004-11-16	FARD et al.	

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	1	20050148913	A1	2005-07-07	WESTON	

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	1	240188	RU		1947-11-03			☒
	2	9748427	WO	A2	1997-12-24	C.R. BARD INC.		☐

EFS Web 2.1.17

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Receipt date: 04/30/2013	Application Number	11989297	11989297 - GAU: 3761
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2008-01-24	
	First Named Inventor	Carmeli ADAHAN	
	Art Unit	3761	
	Examiner Name	ILYA Y. TREYGER	
	Attorney Docket Number	ADAHAN=16	

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	1	Worth et al., "PRELIMINARY REPORT The Effectiveness of Bacterial Filtration In Vented Wound Drains" Journal of Surgical Research 27(6):405-407 (1979)	☐
	2	Levite et al., "POSSIBILITIES FOR DUAL-LUMEN DRAINAGES IN SURGERY" Body of the RSFSR Ministry of Public Health, Monthly Scientific and Practical Journal, pages 39-41. (1987)	☐
	3	Notice of opposition to European patent EP2127690, dated March 20, 2013	☐
	4	Facts and Submissions in Opposition of EP 2127690, dated March 20, 2013	☐
	5	Edlich et al., "Evaluation of a New, Improved Surgical Drainage System" NEW INSTRUMENTS, 149:295-298 (February 1985)	☐
	6	Communication of a notice of opposition of EP 2127690, dated April 8, 2013	☐

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Examiner Signature	/Ilya Treyger/	Date Considered	05/07/2013

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Receipt date: 04/30/2013	Application Number	11989297	11989297 - GAU: 3761
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2008-01-24	
	First Named Inventor	Carmeli ADAHAN	
	Art Unit	3761	
	Examiner Name	ILYA Y. TREYGER	
	Attorney Docket Number	ADAHAN=16	

CERTIFICATION STATEMENT

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

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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.

☐ None

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	/rlb/	Date (YYYY-MM-DD)	2013-04-30
Name/Print	Roger L. Browdy	Registration Number	25,618

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

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

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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.

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

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

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Exhibit 1008
Page #58

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/989,297	01/24/2008	Carmeli Adahan	ADAHAN16	4766

1444 7590 05/14/2013

Browdy and Neimark, PLLC
1625 K Street, N.W.
Suite 1100
Washington, DC 20006

EXAMINER	
TREYGER, ILYA Y	
ART UNIT	PAPER NUMBER
3761	

MAIL DATE	DELIVERY MODE
05/14/2013	PAPER

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

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

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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
11/989,297	24 January, 2008	ADAHAN, CARMELI	ADAHAN16

Browdy and Neimark, PLLC
1625 K Street, N.W.
Suite 1100
Washington, DC 20006

EXAMINER	
ILYA TREYGER	
ART UNIT	PAPER
3761	20130507

DATE MAILED:

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Commissioner for Patents

IDS submitted 04/30/2013 has been fully considered and attached. Presented references alone or in combination do not constitute potential 102 or 103 rejections.

/Tatyana Zalukaeva/ Supervisory Patent Examiner, Art Unit 3761	/Ilya Y Treyger/ Examiner, Art Unit 3761

PTO-90C (Rev.04-03)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

		Atty. Docket: ADAHAN=16
In re Application of:	)	Conf. No.: 4766
	)	
Carmeli ADAHAN	)	Art Unit: 3761
	)	
Appln. No.: 11/989,297	)	Examiner: Ilya Y. Treyger
	)	
Filed: January 24, 2008	)	Washington, D.C.
	)	
For: WOUND CLOSURE AND DRAINAGE SYSTEM	)	May 10, 2013
	)	

APPLICANT'S INTERVIEW SUMMARY

Honorable Commissioner for Patents
U.S. Patent and Trademark Office
Randolph Building, Mail Stop
401 Dulany Street
Alexandria, VA 22314

Sir:

The interview between Examiner Treyger and the undersigned attorney for applicant on April 3, 2013, is hereby gratefully acknowledged. In this interview the undersigned discussed the claim changes made in the amendment accompanying the RCE filed after receipt of the Notice of Allowance of October 9, 2012. The undersigned explained that the only substantive change was changing "calibrated orifice" to "flow restrictor," which should not change the previously indicated allowability of the claims. The examiner said that he had noticed that and he considered them to be the same except that

"flow restrictor" is a little broader, so he was expanding his search.

The undersigned further advised the examiner that the amendment filed with the RCE inadvertently removed the language "to restrict flow through said venting arrangement" after "flow restrictor." The examiner stated that if the case were found to otherwise be in consideration for allowance, he would add back these words to claims 11 and 42 in an examiner's amendment.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.
Attorneys for Applicant(s)

By /rlb/
Roger L. Browdy
Registration No. 25,618

RLB:jhw
Telephone No.: (202) 628-5197
Facsimile No.: (202) 737-3528
G:\BN\C\cohn\Adahan16\Pto\2013-05-10ApplicantsInterviewSummary.doc

Medela LLC and Medela AG
Exhibit 1008
Page #62

Electronic Acknowledgement Receipt

EFS ID:	15744055
Application Number:	11989297
International Application Number:	
Confirmation Number:	4766
Title of Invention:	WOUND CLOSURE AND DRAINAGE SYSTEM
First Named Inventor/Applicant Name:	Carmeli Adahan
Customer Number:	1444
Filer:	Roger Lowen Browdy/Jason Williams
Filer Authorized By:	Roger Lowen Browdy
Attorney Docket Number:	ADAHAN16
Receipt Date:	10-MAY-2013
Filing Date:	24-JAN-2008
Time Stamp:	13:18:08
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Applicant summary of interview with examiner	2013-05-10ApplicantsInterviewSummary.pdf	70728 30ed5c6c081aca753111acf737c4ac2076343c97	no	2

Warnings:	
Information:	

Total Files Size (in bytes):	70728

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PTO/SB/08a (01-10)
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	Examiner Name	ILYA Y. TREYGER
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	2	9748427	WO	A2	1997-12-24	C.R. BARD INC.		☐

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T5
	1	Worth et al., "PRELIMINARY REPORT The Effectiveness of Bacterial Filtration In Vented Wound Drains" Journal of Surgical Research 27(6):405-407 (1979)	☐
	2	Levite et al., "POSSIBILITIES FOR DUAL-LUMEN DRAINAGES IN SURGERY" Body of the RSFSR Ministry of Public Health, Monthly Scientific and Practical Journal, pages 39-41. (1987)	☐
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	5	Edlich et al., "Evaluation of a New, Improved Surgical Drainage System" NEW INSTRUMENTS, 149:295-298 (February 1985)	☐
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	Filing Date	2008-01-24
	First Named Inventor	Carmeli ADAHAN
	Art Unit	3761
	Examiner Name	ILYA Y. TREYGER
	Attorney Docket Number	ADAHAN=16

CERTIFICATION STATEMENT

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☐ See attached certification statement.

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

☐ None

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	/rlb/	Date (YYYY-MM-DD)	2013-04-30
Name/Print	Roger L. Browdy	Registration Number	25,618

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

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

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

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

Translation of description / claims of RU 240188

WOUND OR BLISTER DRESSING DEVICE

[column 1]

The known wound or blister dressing devices that contain a cylindrical aspiration handpiece tip that is connected to the rarefaction source are intended for sucking out various liquids and do not provide for the mechanical separation of tissues with simultaneous removal of the failing tissues.

The proposed device differs in that the aspiration handpiece tip is equipped with an air suction valve and the working edge of the aspirator is situated in a single plane. This makes it possible to perform evacuation, the mechanical separation of tissues and the simultaneous removal of the failing tissues and traumatic discharge.

Furthermore, in order to ensure more aggressive ablation of pathologically changed tissues, the end of the aspiration handpiece tip can have a sharp cutting edge full-circle or in its arc.

The end of the aspiration handpiece tip may be designed to be blunt, e.g., by polishing or flaring, which ensures prevailing tissue evacuation alongside with attenuated mechanical processing.

Shown on Figure 1 is the wound or blister dressing device discussed herein, in two projections: Figure 2 shows the aspiration handpiece tip.

The device includes a cylindrical aspiration handset *1*, which

[column 2]

uses a hose system *2* and intermediate vessels *3* and *4*, is connected to a vacuum pump *5*. The device is equipped with a movable table *6* and a control panel *7* with measurement instruments. The vessel *3* is half-filled with water and acts as a water filter, while the vessel *4* is intended to receive the traumatic discharge. Furthermore, the device has a fabric filter *8* and an oil filter *9*. The aspiration handpiece tip is equipped with an air suction valve *10*, and the working edge of the aspirator is situated in a single plane.

The device package includes a number of types of removable aspiration handpiece tips *1*, which are used depending on the purpose of the surgery.

If necessary, in order to ensure more aggressive ablation of pathologically changed tissues, the end of the aspiration handset is designed with a sharp cutting edge full-circle or in its arc. In order to ensure prevailing evacuation of tissues alongside with their attenuated mechanical processing, an aspiration handset is used with a sharp (polished or flared) end.

Subject of Invention

1. A wound or blister dressing device comprising a cylindrical aspiration

[column 3]

handpiece tip that can be connected to the rarefaction source, *characterized by* the fact that in order to ensure evacuation, mechanical ablation of tissues and simultaneous removal of the failing tissues and traumatic discharge, the aspiration handset tip is equipped with an air suction valve, and the working edge of the aspirator is situated in a single plane.

2. The device discussed in paragraph 1 *is characterized* by the fact that in order to ensure more aggressive ablation

[column 4]

of pathologically changed tissues, the end of the aspiration handpiece tip has a sharp cutting edge full-circle or in its arc.

3. The device discussed in paragraph 1 is *characterized by* the fact that in order to ensure prevailing evacuation of tissues alongside with their attenuated mechanical processing, the aspiration handset is designed to be blunt, e.g., polished or flared.

библиотека ЦИПА

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Заявитель —

УСТРОЙСТВО ДЛЯ ОБРАБОТКИ РАН ИЛИ ЯЗВ

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Известные устройства для обработки ран или язв, содержащие цилиндрический наконечник-аспиратор, подключаемый к источнику разрежения, предназначены для отсоса различных жидкостей и не предусматривают возможности механического отслоения тканей с одновременным удалением отторгаемых тканей.

Предлагаемое устройство отличается тем, что наконечник-аспиратор снабжен клапаном подсоса воздуха, а рабочая кромка аспиратора расположена в одной плоскости. Это позволяет осуществлять вакуумирование, механическое отслоение тканей и одновременное удаление отторгаемых тканей и раневого отделяемого.

Кроме того, для более активного отторжения патологически измененных тканей торец наконечника-аспиратора может иметь острый режущий край по окружности или по ее дуге.

Торец наконечника-аспиратора может быть выполнен тупым, например, путем шлифовки или развальцовки, что обеспечивает преобладающее вакуумирование тканей при щадящей механической обработке.

На фиг. 1 изображено описываемое устройство для обработки ран или язв, в двух проекциях; на фиг. 2 — наконечник-аспиратор.

Устройство содержит цилиндрический наконечник-аспиратор *1*, который с помощью

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системы шлангов *2* и промежуточных емкостей *3* и *4* подключен к вакуум-насосу *5*. Устройство снабжено передвижным столиком *6* и щитом управления *7* с контрольно-измерительными приборами. Емкость *3* залита наполовину водой и выполняет роль водяного фильтра, а емкость *4* предназначена для приема раневого отделяемого. Кроме того, в устройстве имеются марлевый *8* и масляный *9* фильтры. Наконечник-аспиратор снабжен клапаном *10* подсоса воздуха, а рабочая кромка аспиратора расположена в одной плоскости.

В комплект устройства входит несколько различных типов съемных наконечников-аспираторов *1*, применяемых в зависимости от цели операции.

При необходимости более активного отторжения патологически измененных тканей торец наконечника-аспиратора выполняется с острым режущим краем по окружности или по ее дуге. Для преобладающего вакуумирования тканей при щадящей механической обработке применяется наконечник-аспиратор с тупым (отшлифованным или развальцованным) торцом.

Предмет изобретения

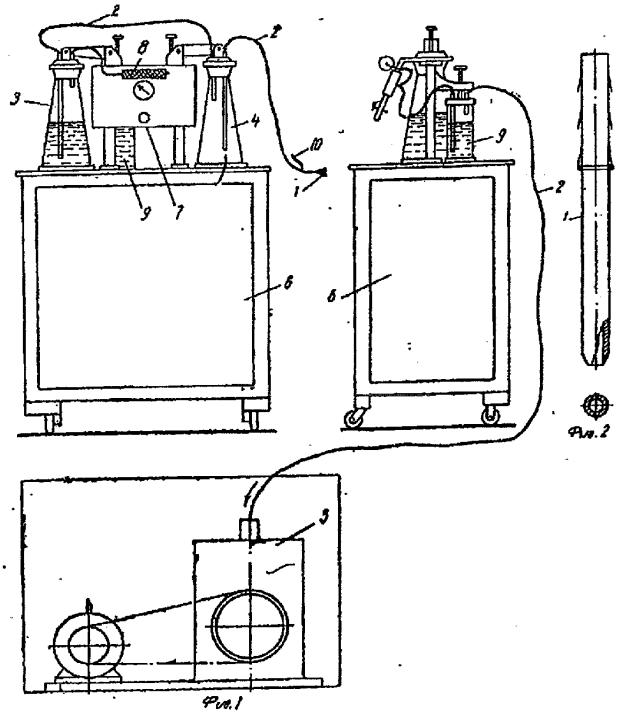
1. Устройство для обработки ран или язв, содержащее цилиндрический наконечник-ас-

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пиратор, подключаемый к источнику разрежения, *отличающееся* тем, что, с целью вакуумирования, механического отслоения тканей и одновременного удаления отторгаемых тканей и раневого отделяемого, наконечник-аспиратор снабжен клапаном подсоса воздуха, а рабочая кромка аспиратора расположена в одной плоскости.

2. Устройство по п. 1, *отличающееся* тем, что, с целью более активного отторжения патологических измененных тканей, торец наконечника-аспиратора имеет острый режущий край по окружности или по ее дуге.

3. Устройство по п. 1, *отличающееся* тем, что, с целью преобладающего вакуумирования тканей при щадящей механической обработке, торец наконечника-аспиратора выполнен тупым, например, отшлифован или имеет развальцовку.



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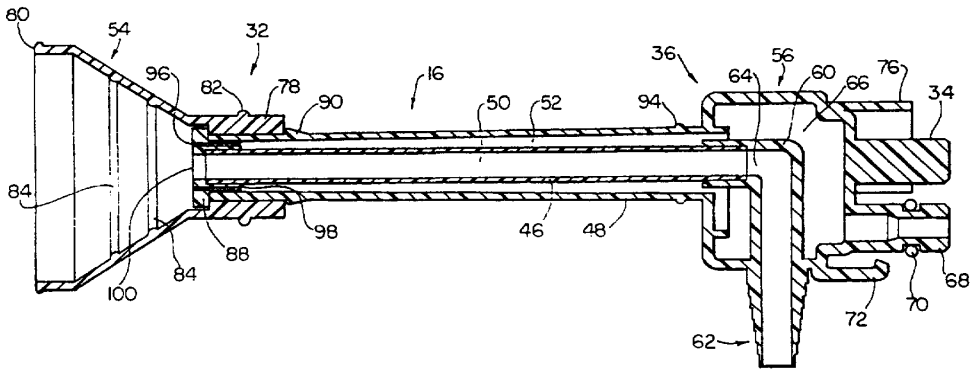
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(57) Abstract

A medical suction and irrigation apparatus includes a suction/irrigation tip removably connected to a conventional suction/irrigation handpiece. Suction is provided through a suction tube which has a bypass conduit in the tip. The bypass conduit is directly connectable to a suction source so that aspirated debris passes through the tip to the suction source. The suction tube thus prevents aspirated debris from entering the conventional suction tube in the handpiece and contaminating the handpiece. The suction tube is also designed to have a maximum size to prevent the tip from clogging. The tip also has an irrigation tube for directing irrigation liquid to the irrigation site, and a connector which connects the irrigation tube to the handpiece so that the handpiece pumps fluid through the tip in a conventional manner. A flexible splash shield, slidably mounted to the irrigation tube, confines irrigation fluid to the local site.

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SUCTION AND IRRIGATION HANDPIECE AND TIP

Field of the Invention

This invention relates generally to medical irrigation systems and, more particularly, to hand-held medical irrigation devices that have a tip with suction and irrigation channels.

Background of the Invention

Irrigation devices are in common use in a variety of non-surgical environments, such as nursing homes and other long-term care facilities, where they are used to treat bed sores and other injuries that are accessible externally about a patient. These devices generally comprise an irrigation handpiece and accompanying irrigation tip that direct irrigation liquid from an irrigation source to an irrigation site. Effective treatment often requires that the injured site be irrigated several times.

Conventional irrigation and suction devices have a combination suction and irrigation tip that can be detachably connected to a handpiece having both irrigation and suction lumens. The free end of the tip has a conical splash shield that, during use, is pressed against and about the irrigated region to confine irrigation liquid (e.g., saline) to that region. A typical tip is shown in U.S. Patent No. 4,692,140 (Olson). The Olson tip has an outer (suction) tube, an inner (irrigation) tube coaxially aligned with the suction tube, and a web (referred to as "pegs" in Olson) that supports the distal end of the irrigation tube within the suction tube. The annular space between the tubes provides a suction pathway for biological debris aspirated from the irrigation site. Aspirated biological debris is drawn through the suction pathway to the suction lumen in the handpiece, from which it flows through a connecting tube to a debris collection chamber.

One problem with such devices is that the biological debris ingested into the handpiece suction lumen (from the irrigation site) may contain infectious bacteria that could contaminate the handpiece. The handpiece can thus become septic and may create an undesirable risk of reinfection to the patient if it is reused. Accordingly, although irrigation handpieces with detachable tips are available, there has been a resistance to their use because the handpieces are relatively expensive and can only be used once. The preferred treatment is to to bathe the patient in a warm whirlpool bath instead of locally irrigating the injury with an irrigation handpiece and tip. This alternative treatment method is inefficient, however, since it is time consuming and treats both injured and uninjured parts of the patient's body.

Another difficulty with the foregoing coaxial tip is that the suction pathway can clog easily with aspirated biological debris because it has a relatively small cross-sectional dimension. The web also appears to further obstruct debris drawn toward the annular suction pathway since it partially covers the open distal end of the pathway.

A flexible splash shield that is permanently fastened to the distal end of the outer suction tube also presents problems. More particularly, when the irrigation tip must be positioned very close to the irrigation site, it may be necessary to cut off the end of the shield along one of several circumferential ring guides. In addition to being time consuming and cumbersome, the structure of the tip is permanently altered. A new tip must be used to irrigate a larger local injury site.

In addition, it is common during use for irrigation fluid and biological debris to escape from the splash shield because, for example, the irrigation surface may not be smooth or the attendant may inadvertently move the handpiece while irrigating. This can cause the debris and irrigation liquid to splash onto the handpiece and/or attendant, consequently contaminating the handpiece and exposing the attendant to infection.

It therefore is among the general objects of the invention to provide an improved suction/irrigation tip that avoids contamination of the handpiece.

Summary of the Invention

In accordance with one aspect of the invention, the suction lumen in a detachable suction and irrigation tip is configured so that aspirated fluid and debris are passed directly to an external suction source when the tip is used with a conventional handpiece having both suction and irrigation lumens. No portion of the suction lumen in the tip is in fluid communication with the suction lumen in the handpiece. However, the irrigation lumen in the handpiece is in fluid communication with the irrigation lumen in the tip so that irrigation can pass through the handpiece and tip in normal fashion.

In accordance with another aspect of the invention, the suction and irrigation lumens in the tip are arranged coaxially with the inner tube defining the suction lumen and the annular lumen between the inner and outer tubes defining the irrigation lumen. The annular lumen terminates in an annular end wall that includes a number of circumferentially spaced outlet apertures through which irrigation liquid is emitted. Since the cross-sectional dimension of the

suction lumen is greater than the radial dimension of the surrounding annular lumen, the risk of that lumen being clogged by debris is reduced.

In accordance with yet another aspect of the invention, a flexible splash shield is slidably mounted on the tip. This enables the distal end of the suction and irrigation tubes to be positioned directly against the irrigation site without having to cut the shield.

In accordance with still another aspect of the invention, the tip is provided with a protective covering having one end that is heat sealed to the tip and another end that is open. When the tip is connected to a handpiece, the covering is sized to fit loosely about the handpiece and may extend past the bottom of the handpiece. The covering protects the handpiece and the attendant from debris that may splash from the irrigation site.

It is among the objects of the invention to provide combination suction and irrigation tip that it detachably connectible to a handpiece and in which biological debris aspirated through the suction lumen bypasses the handpiece.

Another object of the invention is to provide an improved combination suction and irrigation tip that may be detachably connected to an irrigation handpiece in which the risk of the handpiece becoming contaminated with biological debris is reduced.

Brief Description of the Drawings

The foregoing and other objects and advantages of the invention will be appreciated more fully from the following further description thereof with reference to the accompanying drawings wherein:

Figure 1 is a perspective view of the irrigation system in accordance with the invention;

Figure 2 is a perspective view of the suction irrigation tip with the splash shield retracted;

Figure 3 is a longitudinal cross section of the suction irrigation tip along line 3-3 of Figure 1;

Figure 4 is a perspective view of the suction irrigation tip showing the rear and side components of the tip;

Figure 5 is a bottom perspective view of the rear portion of the suction irrigation tip;

Figure 6 is a front perspective view of the suction irrigation tip;

Figure 7 is a perspective view of the suction irrigation tip and handpiece with the polymeric envelope extending just past the bottom of the handpiece; and

Figure 8 is a perspective view of the suction irrigation tip and handpiece with the polymeric envelope extending to the attendant's elbow.

Description of the Illustrative Embodiment

Figure 1 illustrates the main components of the suction and irrigation system, which includes a conventional handpiece 10 connected to a reservoir bag 12 by flexible irrigation tubing 14, and a combination suction and irrigation tip 16 detachably connectible to the handpiece 10. Such a handpiece may also include a suction tube 19 extending into the interior of the handpiece 10 which can be connected to a suction source 18 (e.g., wall suction) to aspirate debris. As described in detail below, when the inventive tip 16 is connected to the handpiece 10, a suction bypass is provided that diverts aspirated debris away from the interior of the handpiece 10, thus reducing the risk of contaminating the handpiece 10. Irrigation fluid (e.g., saline) is provided by the bag 12, from which it is pumped through the handpiece 10 and tip 16, to the irrigation site.

The handpiece 10 may be a Simpulse Solo™ suction irrigator (available from C.R. Bard, Inc. of Murray Hill, N.J.) which has a self contained pump, battery, and motor, (omitted for clarity) such as that described in more detail in co-pending U.S. patent application No. 08/389,155, assigned to C.R. Bard, Inc. A suction lumen 22 and an irrigation lumen 24, shown in phantom, extend through the entire length of the handpiece. The suction lumen 22 is connectible to the suction source 18 at one end and terminates at a suction port 28 at the other end. The irrigation lumen 24 is connectible to the irrigation source 12 at one end and terminates at an irrigation port 30 at the other end. Both ports 28 and 30 are formed through a fitting 26 at the distal end of the handpiece 10.

In accordance with principles of the invention, a special tip (i.e. tip 16) is provided for use with the conventional handpiece 10. The proximal end of the tip 16 is configured to detachably mate with the fitting 26. When the tip 16 is connected to the handpiece 10 and the handpiece 10 is energized (by squeezing a trigger 31), irrigation fluid passes through the irrigation port 30 and into the tip 16. The irrigation fluid is emitted in a pulsatile liquid stream from the distal end 32 of the tip at a pulsating frequency that is controllable by the trigger 31. However, the suction port 28 is plugged by a plug 34 extending from the tip proximal end 36. When the tip 16 is not connected to the handpiece 10, a plug 38 having two projections 40, 44

preferably is inserted into the ports 28 and 30 to prevent entry of contaminants into the handpiece.

The tip 16, illustrated in cross section in FIG. 3, may be made from a hard, substantially transparent plastic. The tip 16 includes an inner (suction) tube 46 coaxially aligned within an outer (irrigation) tube 48, a flexible, funnel-shaped splash shield 54, and a connector 56. The suction tube 46 provides a direct pathway 50 for suction from the tip distal end 32 to a suction source (schematically illustrated as source 18 in Figure 1). Aspirated debris therefore never enters the handpiece 10. The annular space 52 between the suction and irrigation tubes 46 and 48 provides a pathway for irrigation fluid. The splash shield 54, slidably mounted to the irrigation tube 48, enables treatment to be confined to a localized treatment site. The connector 56 at the tip proximal end 36 removably connects the tip 16 to the handpiece 10.

The suction tube 46 is supported within the irrigation tube 48 at one end by an outlet nozzle 58, and at the other end by an elbow shaped conduit 60. The outlet nozzle 58 is in the form of a plurality of circumferentially spaced openings formed in an annular end wall. The elbow shaped conduit 60 extends into and downwardly through the connector 56, terminating at a tapered lower end 62 having a plurality of annular ridges 63 (figure 5). The suction tube 46 is sealed to both the outlet nozzle 58 and elbow-shaped conduit 60 to form a continuous suction lumen 64 from the tip distal end 32 to the tapered lower end 62 of the elbow 60 to which the suction tubing 20 from a suction source may be connected.

Although the elbow shaped conduit 60 is shown as extending from the proximal end of the suction tube 46, it may depend from any part of the suction tube 46. In an alternative embodiment, for example, the suction tube 46 is about half the size as it is in the preferred embodiment and the elbow shaped conduit 60 may connect to the suction tube 46 within the irrigation tube 48. The tapered end 62 of the elbow shaped conduit 60 extends through a wall of the irrigation tube 48 for connection with the flexible suction tubing 20.

The connector 56 has an irrigation fluid chamber 66 that receives fluid from the handpiece irrigation port 30 through an irrigation connector 68. After the fluid is received in the fluid chamber 66, the fluid chamber 66 directs it to the annular space 52, which then directs it through the outlet nozzle 58. An O-ring 70 may encircle the irrigation connector 68 to seal the connection between the irrigation connector 68 and the irrigation port 30 on the handpiece. A flexible clip 72 may be molded integrally with the connector 56 for engagement with a lip 74 formed along the underside of the handpiece fitting 26.

As shown in figures 4 and 5, a hood 76 extends proximally from the connector 56 to shield the suction and irrigation ports 28 and 30 from irrigation fluid and debris that, in use, may splash back toward the handpiece 10. The hood 76 preferably has a partially oblong shape, approximating the shape of the handpiece fitting 26. It extends downwardly about the tip plug 34 and partially about the irrigation connector 68. When the tip 16 is connected to the handpiece 10, the hood 76 covers the top portion of the fitting 26, thus further reducing the risk of splashed fluids contaminating the ports 28 and 30. The rounded top of the hood 76 causes fluids to drip past the sides of the nozzle 26.

The flexible shield 54 includes a proximal collar 78 and a conical body that diverges in a distal direction to a distal rim 80. The collar 78 is slidably mounted to the irrigation tube 48 and has an annular gripping ridge 82 to facilitate gripping the collar 78. A plurality of circumferential ridges 84 (e.g., three) may be included on the inner surface of the shield 54 to serve as cutting guides for cutting shield 54. Vent holes 86 formed in the side of the shield 54 prevent the shield 54 from collapsing under suction and also enable air to mix with the debris aspirated from the site to avoid stagnation of the debris within the shield 54. The shield 54 may be made from a flexible, substantially clear plastic that may be shaped during use to conform to the shape and contour of the irrigation site.

The collar 78 may be secured to the distal end of the tip 16 by both an annular flange 88 (shown in figures 2 and 3) and a discontinuous circumferential ridge 90 formed on the irrigation tube 48. The ridge 90 has two discontinuities 92 that enable the shield 54 to be easily forced over the securing ridge 90. The shield 54 may be retracted proximally (FIG 2), over the securing ridge 90, by applying a proximal force to either the rim 54 or to the gripping ridge on the collar 78. The irrigation tube 48 may be tapered slightly toward the tip distal end 32 to increase the resistance to proximally retracting the shield 54. A stop ridge 94 may circumscribe the proximal end of the irrigation tube 48 to prevent the splash shield 54 from being retracted into contact with the connector 56.

The shower head nozzle 58 is fastened to the tip distal end 32 and includes an end wall 97 and a cylindrical wall 98 extending proximally from the end wall. The nozzle 58 serves a number of important functions. In addition to partially securing the splash shield 54 to the tip 16 and securing the suction tube 46 coaxially within the irrigation tube 48, it can be configured to emit irrigation fluid from the tip 16 in a specialized spray pattern. To that end, the shower head nozzle 58 has a plurality of irrigation holes 96 (e.g., nine) longitudinally formed through the

cylindrical wall 98 and end wall 97, and a central suction hole 100. The diameter of the central suction hole 100 should have approximately the same diameter as the inner diameter of the suction tube 46 such as, for example, 0.1875 inches. The number, shape, and size of the irrigation holes 96 are selected both to provide a specialized spray pattern for the irrigation fluid and to regulate the force with which the irrigation fluid is emitted from the tip 16. Accordingly, the suction/irrigation tip 16 may be customized to be usable with certain handpieces only. For example, when irrigating an externally exposed wound (e.g., a bed sore), it is preferred that the irrigation fluid be emitted from the tip 16 at a force not exceeding 15 p.s.i.. When the tip 16 is used with the Simpulse Solo™ suction irrigation handpiece, nine round holes having a diameter of 0.040 inches have produced satisfactory results. Similarly, when used with the Simpulse Plus™ suction irrigation handpiece, also available from C.R. Bard, Inc., four round holes having a diameter of 0.040 inches have produced satisfactory results.

During the irrigation procedure, it therefore is important that the attendant easily select the tip 16 that corresponds with a specific handpiece 10. Accordingly, it is preferred that the tip 16 have a simple identification means that quickly and easily indicates the tip 16 that corresponds to the handpiece 10 being used. To that end, the tip connector 56 may be color coded to correlate with the handpiece 10. For example, the tip connector 56 to be used with the Simpulse Solo™ may be colored purple, while the tip connector 56 to be used with the Simpulse Plus ™ may be colored green. As a further means for ensuring proper tip use, the tip connector 56 may be specially shaped to mate only with the fitting 26 of the handpiece 10 with which it is to be used. Therefore, the wrong tip 16 cannot fit into the wrong pump/handpiece 10. To that end, either the irrigation connector 68 or the tip plug 34 may be provided with a ridge 101 (Fig. 4) or other irregularity, and the corresponding handpiece suction port 28 or irrigation port 30 may be molded to that complimentary shape. The connector 56 may only be connected to the corresponding port for a fluid tight fit.

Fig. 7 illustrates an arrangement by which the handpiece 10 is protected from irrigation fluid and other biological debris that may splash from the irrigation site during use. To that end, the tip 16 is provided with an protective covering 102 having one end 104 that is heat sealed to the connector 56 and another end 106 that is open. The protective covering 102 is sized to fit loosely about the handpiece 10. The length of the protective covering 102 preferably is long enough to extend to the bottom end of the handpiece 10. This ensures that the handpiece 10 will remain protected by the protective covering 102 even though the protective covering 102 might

shift somewhat relative to the handpiece 10. An elastic band may be connected about the protective covering open end 106 to provide a secure fit about the bottom end of the handpiece 10. The protective covering 102 is can be made from a thin, flexible, substantially transparent polymeric material, such as a low density polyethylene having a thickness of about 0.001 inch. It is dimensioned so that it will maintain a loose fit about the handpiece 10. The flexibility and transparent nature of the polymeric protective covering 102 enables the attendant to effectively operate all the controls on the handpiece 10 through the protective covering.

Fig. 8 shows a second arrangement by which both the handpiece 10 and attendant's arm are protected from debris that splashes from the site. To that end, the tip 16 is provided with a long protective covering 108 having one end 110 that is heat sealed to the connector 56 and another end 112 that is open. The long protective covering 108 is sized to fit loosely about the handpiece 10 so that the attendant may operate the handpiece 10 from within the long protective covering 108 The length of the protective covering 108 preferably is three times the length of the handpiece 10 so that the open end 112 will extend approximately to the attendant's elbow 114. This ensures that both the handpiece 10 and attendant's arm will be protected from debris that splashes from the site. The long protective covering 108 may be made from a thin, flexible, substantially transparent polymeric material, such as a low density polyethylene having a thickness of about 0.001 inch. It is dimensioned so that the attendant's hand will easily fit inside the protective covering 108 to operate the handpiece 10. The flexibility and transparent nature of the long protective covering 108 enables the attendant to effectively operate all the controls on the handpiece 10 from inside and outside the protective covering 108.

When in use, the tip 16 is connected to the handpiece 10 and the flexible suction tubing 20 is connected to the tapered lower end 62 of the elbow shaped conduit 60. The handpiece suction tube 22 remains unused. Since the tip 16 is connected to the handpiece 10, the tip plug 34 sealingly connects to the handpiece suction port 28 and the irrigation connector 68 connects to the handpiece irrigation port 30. The shield 54 may be positioned at the tip distal end 32 and the rim 80 may positioned at the local irrigation site. If desired, either of the flexible protective coverings 102 or 108 may be disposed over and about the handpiece 10. The user may then simultaneously irrigate and aspirate the site. The attendant may retract the shield 54 to put the shower head nozzle 58 directly against, or very close proximity to, the irrigated site. The large cross-sectional area of the suction tube 46 reduces the possibility of clogging. After use, the tip 16 and protective covering 102 or 108 are discarded and the two prong plug 38 is inserted into

the suction and irrigation ports 28, 30 to ensure that the handpiece 10 remains aseptic. The handpiece 10 may be reused at a later time by removing the two prong plug 38 and inserting a new suction irrigation tip 16.

It should be understood that the foregoing description of the invention is intended merely to be illustrative thereof and that other modifications and embodiments may be apparent to those skilled in the art without departing from its spirit.

CLAIMS

1. A detachable suction tip for use with a suction handpiece, the handpiece having an suction lumen extending therethrough for removing irrigation fluid from an irrigation site, the tip comprising:

a suction tube for aspirating irrigation fluid from the irrigation site, the suction tube having a fluid bypass path within the detachable tip which channels aspirated irrigation fluid directly to a suction source so that aspirated fluid within the suction tube does not communicate with the handpiece suction lumen; and

a connector for mechanically connecting the tip to the handpiece, the connector also having a plug for sealing the suction lumen in the handpiece.

2. A tip as defined in claim 1 further comprising an irrigation tube for directing the irrigation fluid to the irrigation site.

3. A tip as defined in claim 2 wherein the connector connects the irrigation tube to the handpiece irrigation lumen to provide fluid communication therebetween.

4. A tip as defined in claim 2 wherein the suction tube is within the irrigation tube.

5. A detachable suction and irrigation tip for use with an irrigation handpiece, the handpiece having a suction lumen and an irrigation lumen extending therethrough, the irrigation lumen directing irrigation fluid to an irrigation site, the tip comprising:

an irrigation tube for directing the irrigation fluid to the irrigation site;

a connector for detachably connecting the irrigation tube to the handpiece to provide fluid communication therebetween and for sealing the suction lumen in the handpiece; and

a suction tube for aspirating irrigation fluid from the irrigation site, the suction tube having a fluid bypass path within the detachable tip which channels aspirated irrigation fluid directly to a suction source so that aspirated fluid within the suction tube does not communicate with the handpiece.

6. The tip as defined by claim 5 wherein the connector has an adjacent chamber for directing the irrigation fluid to the irrigation tube and wherein the fluid bypass path passes through the chamber.

7. The tip as defined by claim 5 wherein the irrigation tube and suction tube are coaxially aligned.

8. The tip as defined by claim 5 wherein the suction tube is disposed in the irrigation tube.

9. The tip as defined by claim 8 wherein the fluid bypass path passes through the irrigation tube.

10. The tip as defined by claim 5 further including a splash shield slidably mounted on the tip.

11. The tip as defined by claim 5 further including a fluid deflecting hood extending from the connector to deflect splashed irrigation fluid away from the handpiece.

12. The tip as defined by claim 5 further including a protective covering fastened to the tip and covering the handpiece.

13. The tip as defined by claim 5 wherein the fluid bypass path terminates at an open end suitable for connection to a suction source.

14. The tip as defined by claim 5 wherein the suction tube has a tube segment that diverts aspirated fluid away from the distal end of the handpiece.

15. A method of irrigating an irrigation site, the method comprising the steps of:

(a) providing a handpiece defining a handpiece irrigation lumen and a handpiece suction lumen;

(b) connecting the handpiece irrigation lumen to an irrigation fluid source;

(c) detachably connecting a tip to the distal end of the handpiece, the tip having a tip irrigation tube in fluid communication with the handpiece irrigation lumen, a tip suction tube for aspirating fluid from the site and a bypass fluid path in fluid communication with the tip suction tube, and

(d) connecting the bypass fluid path to a suction source.

16. The method of irrigating the irrigation site as defined by claim 15 wherein step © comprises the step of plugging the handpiece suction lumen.

17. The method of irrigating the irrigation site as defined by claim 15 further comprising the steps of:

(e) removing the tip from the handpiece;

(f) inserting a plug in the handpiece suction lumen; and

(g) inserting a plug in the handpiece irrigation lumen.

18. The method of irrigating the irrigation site as defined by claim 15 further comprising the steps of:

(h) removing the plug from the handpiece suction lumen;

(i) removing the plug from the handpiece irrigation lumen; and

(j) connecting a second tip to the handpiece, the second tip having a tip irrigation tube, and a tip suction tube that prevents aspirated fluid from communicating with the handpiece suction lumen.

19. An apparatus for irrigating an irrigation site comprising:

a handpiece having an irrigation lumen extending therethrough; and

a tip comprising:

an irrigation tube;

a suction tube for aspirating fluid from the irrigation site; and

a connector for detachably connecting the irrigation tube to the handpiece;

the suction tube being in communication with a bypass fluid path contained within the tip, which bypass fluid path bypasses the handpiece to prevent the aspirated fluid within the suction tube from communicating with the interior of the handpiece.

20. The apparatus as defined by claim 19 wherein the connector comprises a connecting tube in fluid communication with the irrigation tube, and a connecting plug,

the connecting tube removably connecting the irrigation tube to the irrigation lumen in the handpiece, and the connecting plug sealing the suction lumen in the handpiece.

21. An apparatus for irrigating an irrigation site comprising:

a handpiece having a lower end;

a tip connected to the handpiece and having a proximal end; and

a flexible protective covering connected to the tip, the protective covering disposed about and surrounding the proximal end of the tip and the handpiece, the protective covering extending at least to the lower end of the handpiece.

22. The apparatus as defined by claim 21 wherein the protective covering has a length of approximately three times the length of the handpiece.

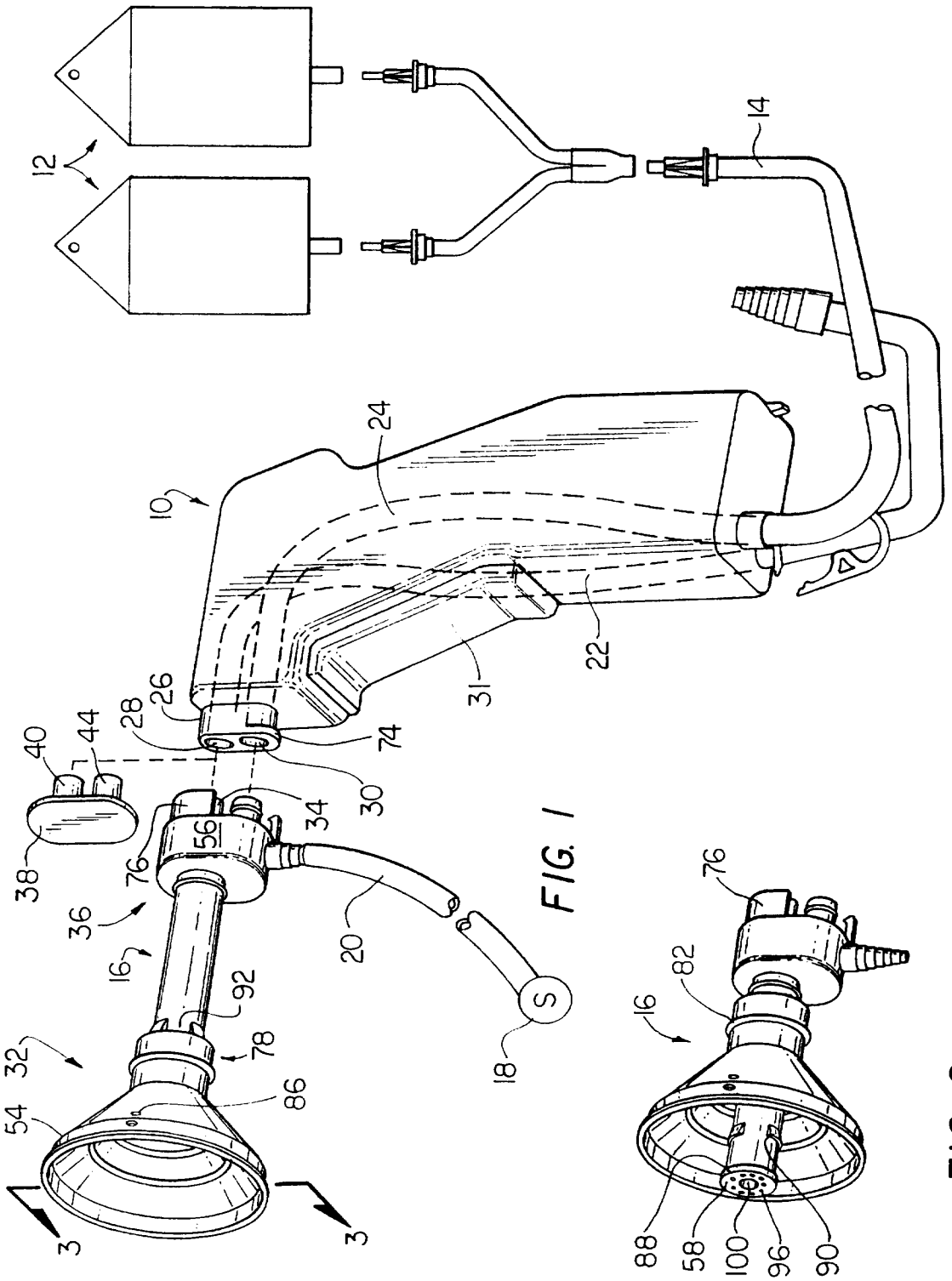


FIG. 1

FIG. 2

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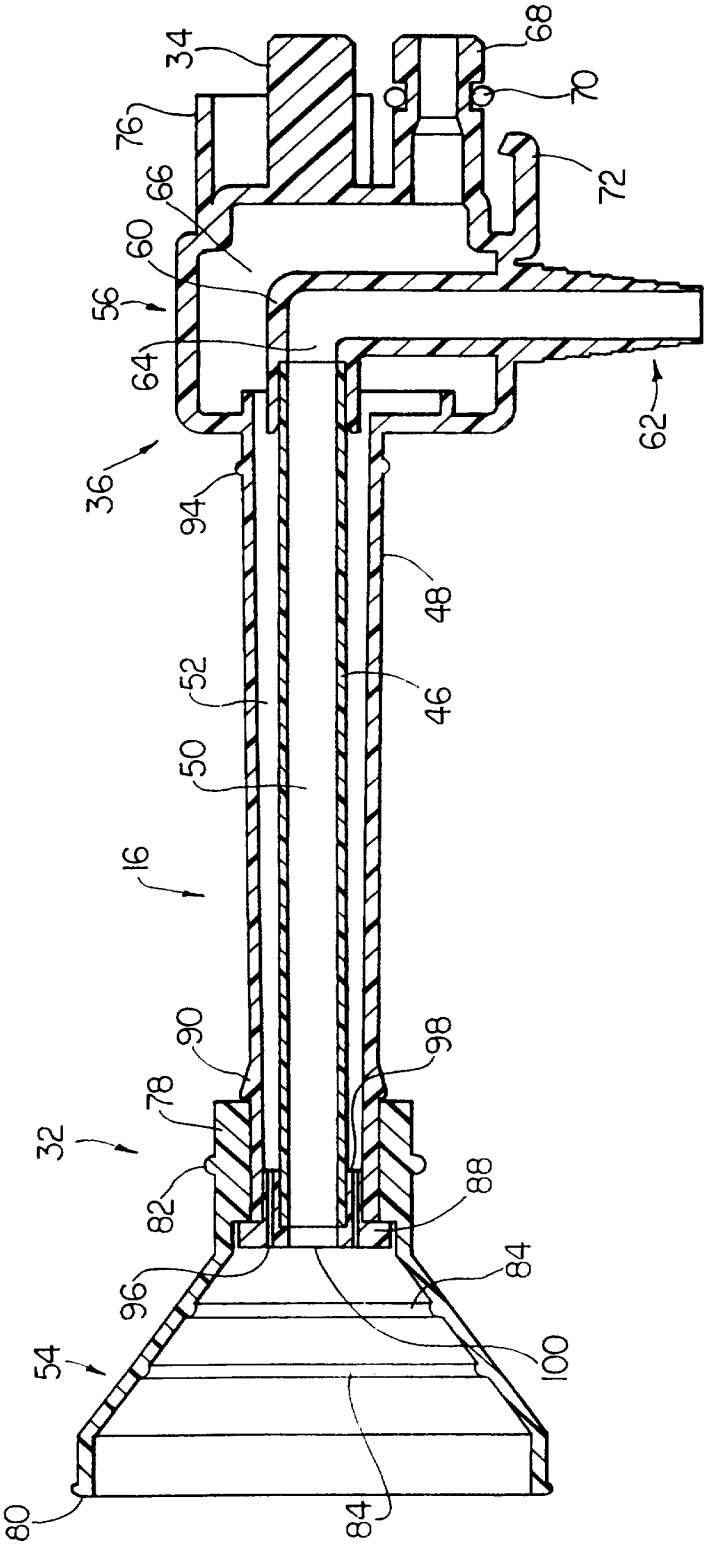


FIG. 3

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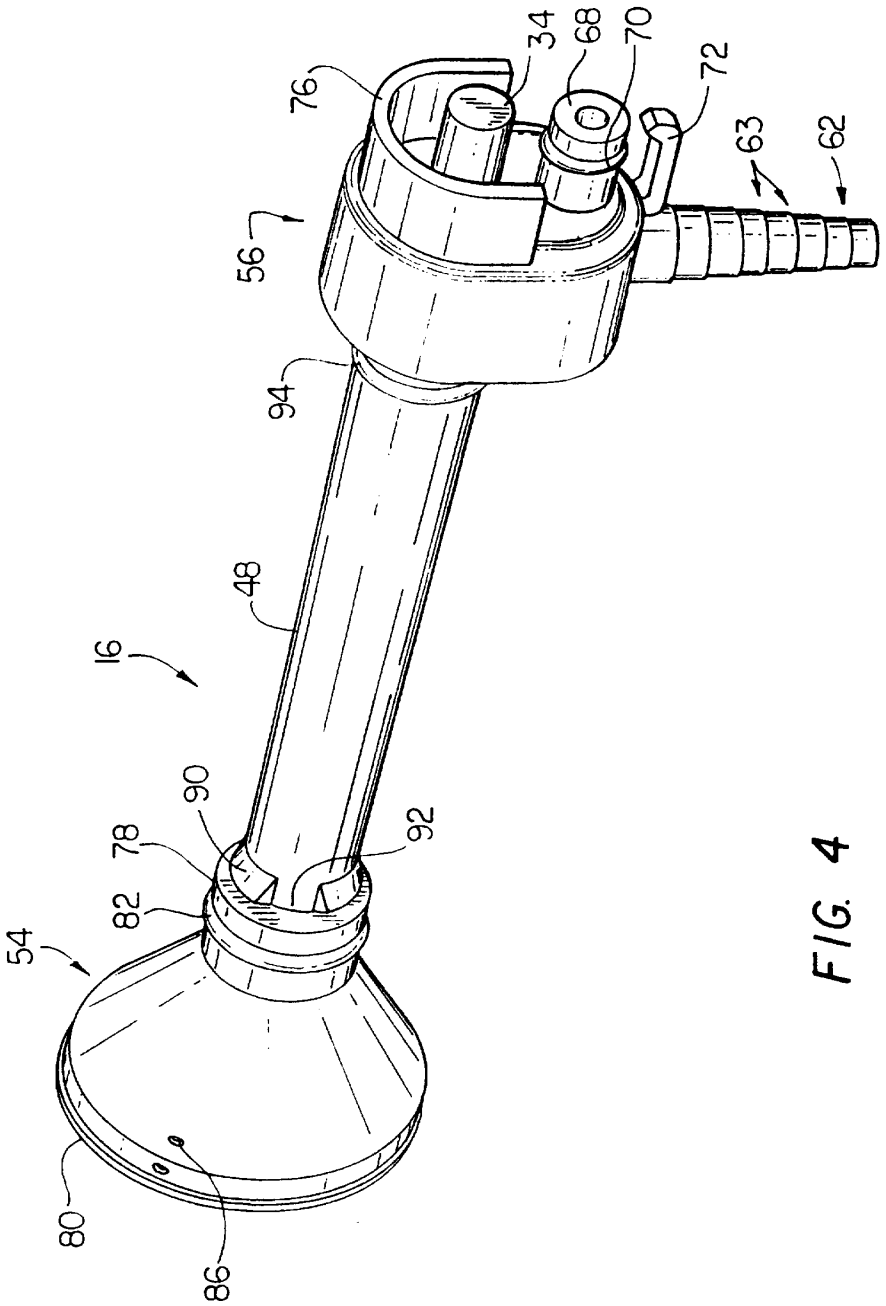


FIG. 4

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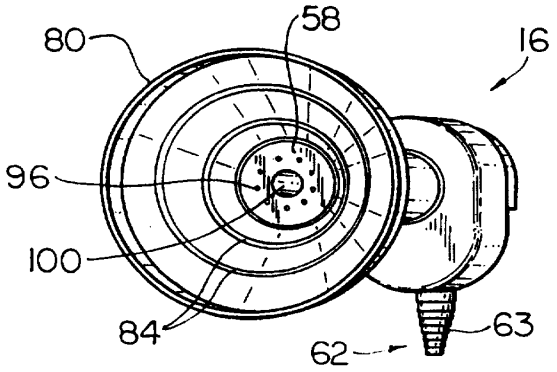


FIG. 6

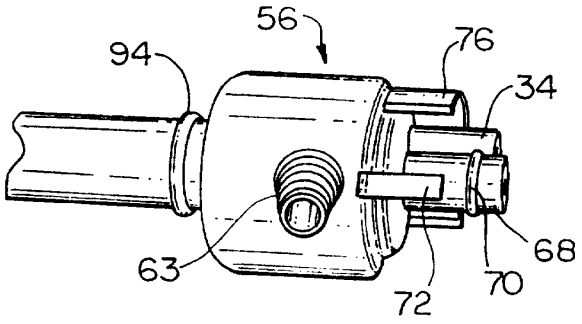


FIG. 5

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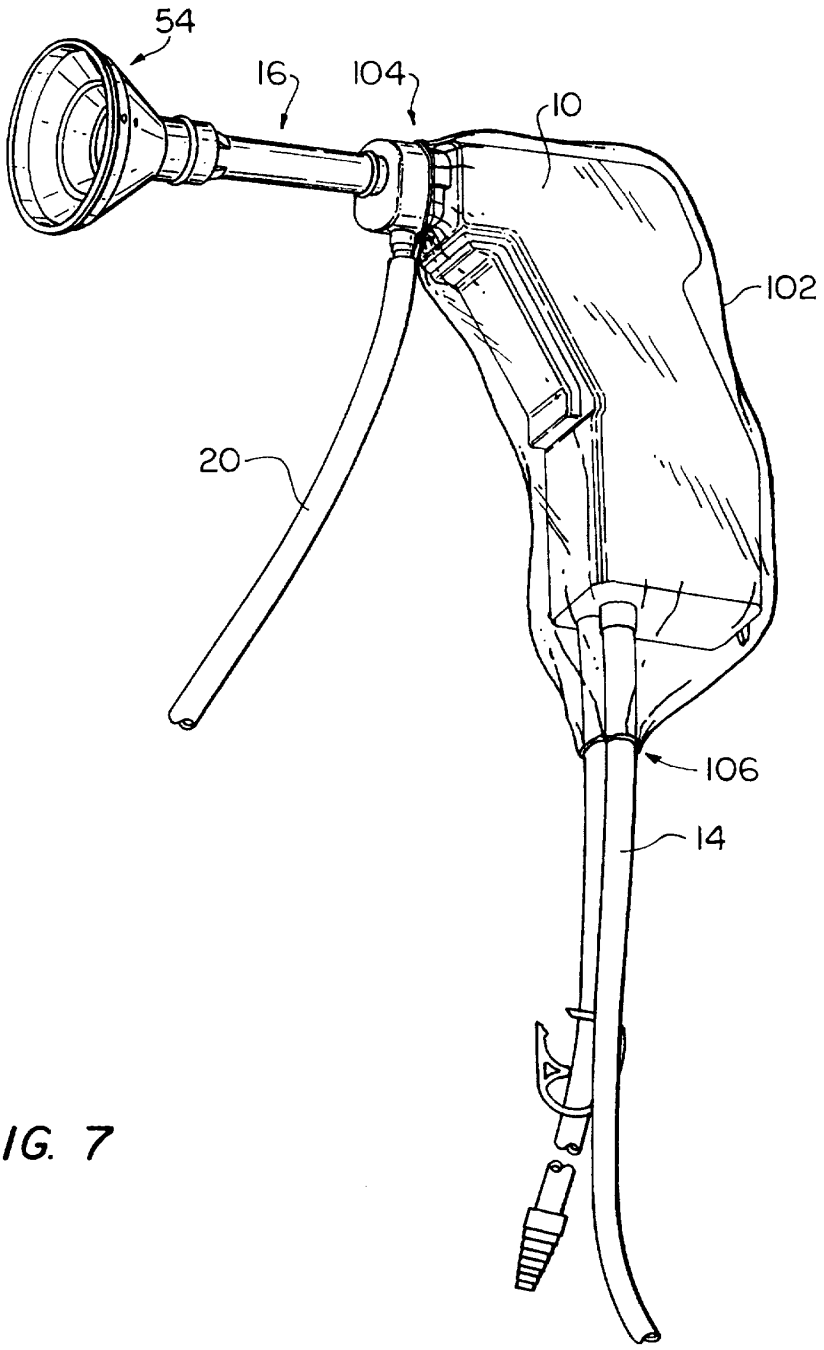


FIG. 7

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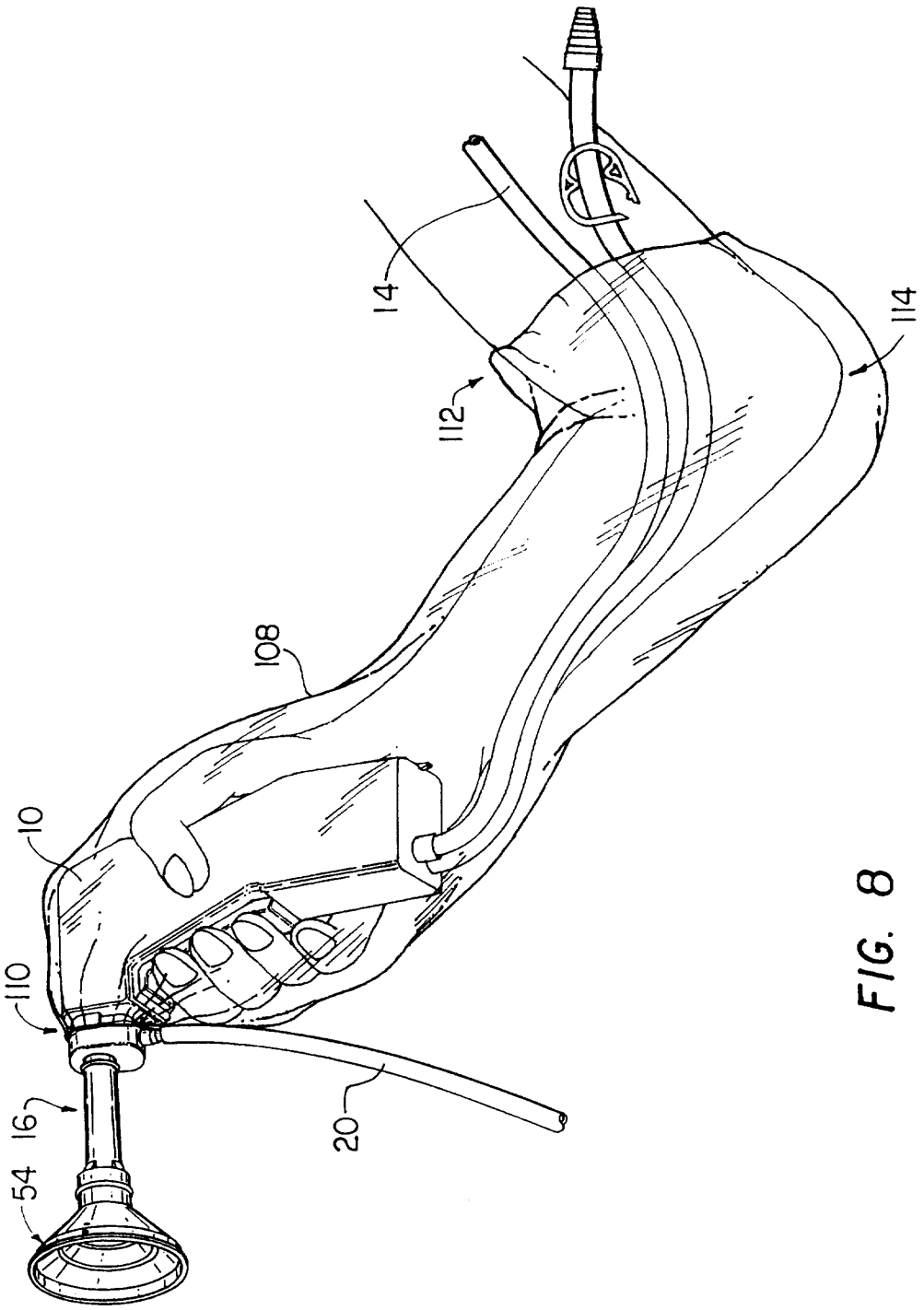


FIG. 8

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Electronic Patent Application Fee Transmittal

Application Number:	11989297
Filing Date:	24-Jan-2008
Title of Invention:	WOUND CLOSURE AND DRAINAGE SYSTEM
First Named Inventor/Applicant Name:	Carmeli Adahan
Filer:	Roger Lowen Browdy/Jason Williams
Attorney Docket Number:	ADAHAN16

Filed as Large Entity

U.S. National Stage under 35 USC 371 Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
		Total in USD ($)		**180**

Electronic Acknowledgement Receipt

EFS ID:	15648947
Application Number:	11989297
International Application Number:	
Confirmation Number:	4766
Title of Invention:	WOUND CLOSURE AND DRAINAGE SYSTEM
First Named Inventor/Applicant Name:	Carmeli Adahan
Customer Number:	1444
Filer:	Roger Lowen Browdy/Jason Williams
Filer Authorized By:	Roger Lowen Browdy
Attorney Docket Number:	ADAHAN16
Receipt Date:	30-APR-2013
Filing Date:	24-JAN-2008
Time Stamp:	13:19:12
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$180
RAM confirmation Number	12054
Deposit Account	
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)

1	Information Disclosure Statement (IDS) Form (SB08)	2013-04-30IDSForm__.pdf	612982 1a89b6423cad0ac1ea5edcde8ac3abac462089c8	no	4
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Information:					
2	Foreign Reference	RU240188withEnglTrans.pdf	597962 b5e11624da6fb2fc32a86c0111e797b4a229910a	no	4
Warnings:					
Information:					
3	Foreign Reference	WO9748427.pdf	815221 fe3600b0d91e6838bcf4bc8f6cb910110c1fdd9c	no	21
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5	Non Patent Literature	Levite1987.pdf	1289723 fcfa97c379d6ffa020c98d60e05702ad8f259771	no	7
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6	Non Patent Literature	2013-03-20NoticeofOppositon.pdf	161627 cacb8902e6c461e873128960ae7f8a14038a668c	no	8
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Warnings:					
Information:					
			Total Files Size (in bytes):	5822852	

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New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

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

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

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NOTICE OF ALLOWANCE AND FEE(S) DUE

1444 7590 04/10/2013

Browdy and Neimark, PLLC
1625 K Street, N.W.
Suite 1100
Washington, DC 20006

EXAMINER
TREYGER, ILYA Y

ART UNIT	PAPER NUMBER
3761	

DATE MAILED: 04/10/2013

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/989,297	01/24/2008	Carmeli Adahan	ADAHAN16	4766

TITLE OF INVENTION: WOUND CLOSURE AND DRAINAGE SYSTEM

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$890	$300	$0	$1190	07/10/2013

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

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

HOW TO REPLY TO THIS NOTICE:

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

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

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

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

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

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

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PTOL-85 (Rev. 02/11)

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Page #99

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

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

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

1444 7590 04/10/2013
Browdy and Neimark, PLLC
1625 K Street, N.W.
Suite 1100
Washington, DC 20006

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 facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/989,297	01/24/2008	Carmeli Adahan	ADAHAN16	4766

TITLE OF INVENTION: WOUND CLOSURE AND DRAINAGE SYSTEM

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$890	$300	$0	$1190	07/10/2013

EXAMINER	ART UNIT	CLASS-SUBCLASS
TREYGER, ILYA Y	3761	604-540000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
- ❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 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 has been filed for recordation as set forth in 37 CFR 3.11. 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. The following fee(s) are submitted:
- ❑ Issue Fee
- ❑ Publication Fee (No small entity discount permitted)
- ❑ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
- ❑ A check is enclosed.
- ❑ Payment by credit card. Form PTO-2038 is attached.
- ❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

PTOL-85 (Rev. 02/11)

Medela LLC and Medela AG
Exhibit 1008
Page #100

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 form 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: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

This collection of information 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 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, 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.

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Exhibit 1008
Page #101

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/989,297	01/24/2008	Carmeli Adahan	ADAHAN16	4766

1444 7590 04/10/2013

Browdy and Neimark, PLLC
1625 K Street, N.W.
Suite 1100
Washington, DC 20006

EXAMINER	
TREYGER, ILYA Y	

ART UNIT	PAPER NUMBER
3761	

DATE MAILED: 04/10/2013

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

The Patent Term Adjustment to date is 391 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 391 day(s).

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

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

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

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Page #102

Privacy Act Statement

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

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

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

Notice of Allowability	Application No.	Applicant(s)	
	11/989,297	ADAHAN, CARMELI	
	Examiner	Art Unit	
	ILYA TREYGER	3761	

-- 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 *01/08/2013*.
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 *11,13,14 and 34-59*.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   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. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ 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).
7. ☐ 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. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 01/08/2013
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *04/03/2013* .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

/Ilya Y Treyger/ Examiner, Art Unit 3761	/Michele M Kidwell/ Primary Examiner, Art Unit 3761

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Applicant-Initiated Interview Summary	**Application No.** 11/989,297	**Applicant(s)** ADAHAN, CARMELI	
	Examiner ILYA TREYGER	**Art Unit** 3761	

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

(1) *ILYA TREYGER*. (3)_____.

(2) *Roger Browdy*. (4)_____.

Date of Interview: *03 April 2013*.

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

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

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

Claim(s) discussed: *11 and 42*.

Identification of prior art discussed: _____.

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

Applicant authorized the Examiner to include words "to restrict flow through said venting arrangement" after words "flow restrictor" in claims 11 and 42 .

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview

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

☐ Attachment

/Ilya Y Treyger/ Examiner, Art Unit 3761	

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Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:
1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. 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 allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). 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, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 01/08/2013 has been entered.

2. Claims 11, 34, 42 and 48 are amended.

3. Claims 55-59 are new.

4. Claims 11, 13, 14 and 34-59 are examined on the merits.

Examiner's Comment

5. IDS submitted 10/31/2012 has been fully considered. Presented references alone or in combination do not constitute potential 102 or 103 rejections.

Examiner's Amendment

6. 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.

7. Authorization for this examiner's amendment was given in a telephone interview with Mr. Browdy on 04/03/2013.

8. The application has been amended as follows:

9. Claim 11 is rewritten as follows:

10. Claim 11. ------- An enclosure for applying negative pressure to a wound, the enclosure being attachable to the wound circumference so as to define a confined volume, and comprising a tube and a venting arrangement, the enclosure having an enclosure outlet connectable to a vacuum source via said tube so that negative pressure can be selectively created in said volume, said venting arrangement located outside said enclosure and comprising a flow restrictor to restrict flow through said venting arrangement located outside said enclosure and comprising a flow restrictor such that ambient air can enter said tube via said venting arrangement and flow to said vacuum source without having to enter said enclosure.------

11. Claim 42 is rewritten as follows:

12. Claim 42. -------A vacuum system for applying negative pressure to a wound, the vacuum system comprising.; an enclosure and a vacuum source, the enclosure being attachable to the wound circumference so as to define a confined volume;

a tube;

a venting arrangement comprising a flow restrictor to restrict flow through said venting arrangement, the enclosure having an enclosure outlet connectable to said vacuum source via said tube so that negative pressure can be created in said volume, said venting arrangement located outside said enclosure such that ambient air can enter said tube via said venting arrangement without entering said enclosure; and

a waste container in fluid communication with said vacuum source. -------

ALLOWABLE CLAIMS

13. Claims 11, 13, 14 and 34-59 are allowed over the prior art of record.

REASONS FOR ALLOWANCE

14. The following is an examiner's statement of reasons for allowance: The closest Prior Art of record US 200110029956 and US 3,516,160 fail to teach, suggest or render obvious a flow restrictor restricting flow through the venting arrangement located outside of the enclosure that prevents the overvacuum conditions during the medical procedure.

15. Newly discovered WO 2008/039223 and WO 2008/039314 disclose the flow restrictors used in different situations that would render obvious claimed limitation, but the mentioned references are not applicable by the failing date.

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 ILYA TREYGER whose telephone number is (571)270-3217. The examiner can normally be reached on 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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

/Ilya Y Treyger/
Examiner, Art Unit 3761

/Michele M Kidwell/
Primary Examiner, Art Unit 3761

Notice of References Cited	Application/Control No. 11/989,297	Applicant(s)/Patent Under Reexamination ADAHAN, CARMELI	
	Examiner ILYA TREYGER	Art Unit 3761	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-			
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N	WO 2008/039314 A2	09-2006	US	Karpowicz et al.	
	O	WO 2008/039223 A1	01-2007	US	Karpowicz et al.	
	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.

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Page #111

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

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

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

Application Number	11989297
Filing Date	2008-01-24
First Named Inventor	ADAHAN, Carmeli
Art Unit	3761
Examiner Name	TREYGER, Ilya Y.
Attorney Docket Number	067913.000085

U.S.PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

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

U.S.PATENT APPLICATION PUBLICATIONS

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

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

FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	01/34223	WO	A1	2001-05-17	HEATON, Keith Patrick		☐
	2	2005/061025	WO	A1	2005-07-07	LARSSON, Michael		☐
	3	00/21586	WO	A1	2000-04-20	Hunt, Kenneth William et al.		☐

EFS Web 2.1.17

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /I.T./

Receipt date: 01/08/2013	Application Number	11989297 11989297 - GAU: 3761
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2008-01-24
	First Named Inventor	ADAHAN, Carmeli
	Art Unit	3761
	Examiner Name	TREYGER, Ilya Y.
	Attorney Docket Number	067913.000085

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

NON-PATENT LITERATURE DOCUMENTS

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

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

EXAMINER SIGNATURE

Examiner Signature	/Ilya Treyger/	Date Considered	04/03/2013

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

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

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /I.T./

Receipt date: 01/08/2013	Application Number	11989297 11989297 - GAU: 3761
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2008-01-24
	First Named Inventor	ADAHAN, Carmeli
	Art Unit	3761
	Examiner Name	TREYGER, Ilya Y.
	Attorney Docket Number	067913.000085

CERTIFICATION STATEMENT

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

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

OR

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

☐ See attached certification statement.

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

☒ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/William L. Klima/	Date (YYYY-MM-DD)	2013-01-08
Name/Print	William L. Klima	Registration Number	32,422

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

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /I.T./

Privacy Act Statement

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

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

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

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

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

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

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

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

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

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

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

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /I.T./

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Exhibit 1008
Page #115

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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
3 April 2008 (03.04.2008)

PCT

(10) International Publication Number
WO 2008/039223 A1

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

(21) International Application Number:
PCT/US2007/000984

(22) International Filing Date: 12 January 2007 (12.01.2007)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/847,221 26 September 2006 (26.09.2006) US

(71) Applicant *(for all designated States except US)*: **BOEHRINGER LABORATORIES INC.** [US/US]; 500 E. Washington Street, P.o. Box 870, Norristown, PA 19404 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **KARPOWICZ, John, R.** [US/US]; 1435 Yellow Springs Road, Chester Springs, PA 19425 (US). **KLOCEK, Kevin, P.** [US/US]; 401 Parkview Drive, Wynnewood, PA 19096 (US). **RADL, Christopher, L.** [US/US]; 530 Clothier Springs Road, Malvern, PA 19355 (US).

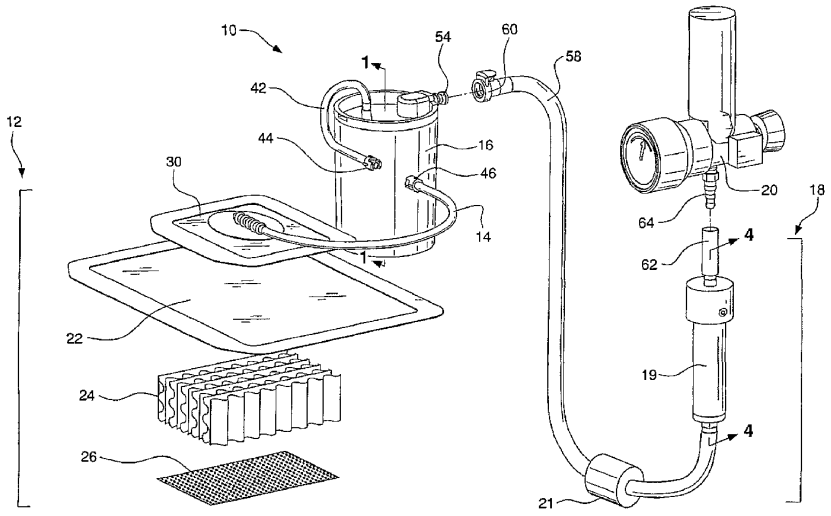
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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

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(54) Title: PUMP SYSTEM FOR NEGATIVE PRESSURE WOUND THERAPY



(57) Abstract: A portable suction pump for producing negative pressure in a system for applying suction to a wound, in which the pump has a pressure control circuit for controlling the operation of the pump to maintain the pressure between upper and lower limits around a pre-selected pressure, and a fault detection system to detect deviations in the level of negative pressure applied to the wound; wherein the fault detection system can operate independent of the pressure control circuit. In a preferred embodiment, the fault detection system uses deviation from a reference airflow to detect system faults.

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PUMP SYSTEM FOR NEGATIVE PRESSURE WOUND THERAPY

Reference to Related Application

[0001] This application claims priority of U.S. Provisional Patent Application No. 60/847,221, filed September 26, 2006.

Field of the Invention

[0002] The invention is related to the general field of wound treatment, and to the more specific field of devices for wound drainage and treatment with suction.

Background of the Invention

[0003] It is well known to treat wounds by applying suction under airtight wound covers. The suction can be used to aspirate wound exudate and other liquids from the wound and/or the wound packing materials, and the suction can be applied as a healing modality for its well known antiseptic and tissue regeneration effects.

[0004] A primary concern in using suction assisted wound therapy is maintaining consistent suction pressure at the wound. It is increasingly recognized that once suction wound dressings are applied, the suction should be maintained at certain levels. Loss of suction to the wound can result if leaks or blockages occur in the system.

[0005] Leaks can occur through breach of the airtight seals surrounding the wound. The earliest devices merely ran a tube under the edge of a wound cover and applied an adhesive or paste around the tube and cover to maintain an airtight seal. The other end of the tube was connectable to a waste collection reservoir and suction regulator of a hospital suction system, and the pressure selected at the regulator was assumed to be the approximate pressure communicated to the wound area under the cover. The test for leakage was visual observance of the cover contracting and the absence of whistling noise when negative pressure was applied. See, e.g., M. E. Chariker, et al, "Effective Management of Incisional and Cutaneous Fistulae with Closed Suction Wound Drainage", *Contemporary Surgery,* vol. 34, June 1989, pages 59-63. This initial check for an airtight seal did not, however, provide any warning if the system developed a leak or if blockage occurred in the collection circuit after hours of use.

[0006] The adhesive seal around the suction tube or other tubes which run under the edge of the wound cover in these prior wound dressings is vulnerable to cracking and breaching the airtight seal, creating air leakage into the cover. Improvements have been made to suction wound therapy devices to reduce the likelihood of leakage. For example, U.S. Application No. 11/181,128, filed July 14, 2005 and commonly assigned with this application, discloses a tube attachment patch to allow the suction tube to be terminated outside of the primary cover and thus reduce the risk of breaking the adhesive seal to the skin. While these newer tube attachment devices provide more seal integrity, there is still the potential for breach of the airtight seals, due to patient movement in bed for example.

[0007] Blockage of suction to the wound can occur for several reasons. A waste collector for wound exudate is usually positioned somewhere in the suction line between the wound and the suction source. Waste collectors incorporate shut-off mechanisms that will shut off suction to the wound when the collector is overfilled. Another potential blockage is kinking or crimping of the suction line itself. Blockage due to debris from the wound and clotting is also a concern. The suction source may also be inadvertently turned off, a line may be inadvertently clamped, or the suction regulator may be misadjusted after the dressing is applied. Since suction wound dressings are intended to last for long periods without changing, usually 24 hours or greater, a leak or blockage could develop unnoticed and not be detected for a duration sufficient to negate the beneficial healing effect of suction as well as increase the risk of infection. There are currently devices to sense when a waste collector canister is filled and provide a warning signal to empty it. None of the devices, however, provides a comprehensive and reliable monitoring of system operation, nor cover the full range of fault possibilities with leakage or blockage.

[0008] In their efforts to improve over these prior art devices, the present inventors designed a suction wound dressing monitoring system as described in U.S. Patent Application Serial No. 11/268,212. In so doing, they considered the impracticality of locating expensive pressure transducers in any of the system components that should be single-use disposable items due to contamination by body fluids. The designers considered that the same basic system should preferably be effective in detecting and

indicating both leaks and system blockage, and that the detection of leaks or blockage should preferably be effective regardless of where the leak or blockage occurs in the system. They considered that the system should preferably provide clear visual indication of both normal and abnormal operation, and could usefully provide aural indication and auto-recording of abnormalities. They also considered that the suction monitoring capability should be easily convertible from use with a stationary suction system, as typically found in hospital care rooms, to use with a portable suction pump.

Summary of the Invention

[0009] In the present invention, the inventors further considered that when using a portable pump as the suction source it would be advantageous to use a microprocessor in the pump's flow monitoring system to detect deviation from the reference airflow and provide corresponding indicators and/or alarms. The use of a microprocessor would also enable other useful functions, such as recording and accumulating various parameters in time units and providing reports of such time records.

[0010] For safety and redundancy, however, the inventors considered that it would be advantageous to provide the pump with pressure control circuitry that is independent of the microprocessor controlled airflow monitoring. This would allow the pump to control pressure to an operator selected pressure set-point without needing to rely on signals from the microprocessor. However, the pressure control circuitry could provide to the microprocessor data related to pump operation, such as the detection of an open circuit, a faulty pressure transducer or a run away pump condition. Moreover, the microprocessor could be used to reset the selected pressure for the pump control circuitry, such as for intermittent operation or to create a line clearing pressure pulse if the airflow deviation was beginning to indicate a conduit occlusion.

[0011] The inventors also considered that it would be useful for the airflow monitoring system to be coupled to a display system on the pump for convenient indication of status conditions related to air flow, such as: normal operation, low level leak, high level leak, line occlusion and a filled waste collection canister. They also considered that it would be useful for the pump to have a separate error indicating display for convenient indication of error conditions that are not related to air flow;

such as overpressure detection by the pressure transducer, pressure transducer failure, waste collection canister not attached, low battery voltage, attachment of incorrect power supply, and low operating time remaining.

[0012] Although the waste collection canister could be located anywhere between the wound dressing and the vacuum source, the inventors considered that when using a portable pump vacuum source, it would be advantageous for the pump to provide a docking station for a waste collection canister, such that the canister can be securely attached to the pump housing. In that configuration, the pump may also include a level detector for detecting and indicating the fill status of the canister. For example, the pump may have a level sensor, such as a capacitance sensor, to detect a filled waste collection canister based upon indications other than pressure differential across a hydrophobic membrane in the canister. If so, the level detector signal may be moderated by an algorithm in the microprocessor to reduce the likelihood of false indications of a full canister caused by splashing when the pump/canister is moved.

[0013] Thus, the invention provides a system for applying suction to a wound in which a reference airflow rate is used for monitoring system operation. The basic components of a wound treatment system using suction include an airtight wound dressing, a suction conduit having one end operatively associated with the wound dressing to communicate suction to the wound, and an opposite end operatively connected with a source of suction, The invention provides a reference airflow rate (or "controlled leak") to the suction source when the system is in operation, such that deviation from the reference airflow can be monitored as an indication of a change in operation. In a preferred embodiment of the invention, a portable pump is used as the suction source. The pump has a flow rate monitoring system to monitor airflow through the conduit from a wound dressing to the pump as indicative of the level of negative pressure applied to the wound. Deviation from the reference flow rate can be used as an indication of abnormal condition such as leakage of the wound dressing or occlusion in the conduit. The flow rate monitoring system is controlled by a microprocessor, which also provides additional functions of providing status and error displays and time keeping and reporting. To compensate for variations in the set point

pressure selected at the pump, the microprocessor can have a look up table for flow rates that compensate for different selected negative pressures.

[0014] For safety and redundancy, the pump has pressure control circuitry that uses solid state electronics and a pressure transducer that can operate independently of the microprocessor and flow monitoring. A user operable pressure selector enables a user to select a negative pressure pump output within a range of negative pressure set-points; and the pressure transducer and a pressure control circuit control the operation of the pump to maintain the pressure sensed by the transducer between upper and lower limits around the selected pressure.

[0015] The microprocessor provides signals to an annunciator, preferably a bar meter that is color coded and graduated to provide a visual indication of air flow through the pump. The annunciator indicates when the airflow through the pump is within a range of the reference air flow that is associated with normal system operation and conversely indicates when a deviation from the reference airflow is associated with an abnormal operation.

[0016] The pump also includes an error indicator display for displaying a visual warning of system errors that are not associated with deviation of airflow through the pump from reference airflow, such as overpressure detection by the pressure transducer, pressure transducer failure, waste collection canister not attached, low battery voltage, attachment of incorrect power supply, and low operating time remaining. The error indicator is preferably controlled by the microprocessor.

[0017] Although the pressure control circuitry generally operates independently of the microprocessor to maintain a selected pressure, the microprocessor can be used to take over supervision of the pump in certain conditions. For example, the microprocessor can re-set the selected set point, such as between a higher and lower pressure level when intermittent pressure therapy is desired. In another example, the microprocessor can be programmed to directly turn on the pump or increase the pump speed when the deviation from reference air flow begins to indicate an occlusion to cause a pressure pulse output from the pump to clear the line between the patient and the collection canister.

[0018] The microprocessor also includes timing programming to record and accumulate the time units based upon inputs from other sensors, and a time reporting routine for providing reports of the time units that the pump is running. The reports may include a record of run-time intervals, a record of the date and duration of run-time intervals, a record of total accumulated run-time, a record of accumulated compliant run time, and a record of run time remaining on a pre-set run time period.

[0019] The system includes a waste collector, disposed in the suction line between the wound dressing and the source of suction, for collecting fluids aspirated from the wound. The preferred collector is an upright transparent plastic canister with fill level markings on the outside surface. The collection canister may also have a residual suction capacity to draw fluid through the line when the pump is shut down.

[0020] The canister may be prevented from overfilling by a hydrophobic membrane filter at the top of the canister that shuts off the airflow when the canister is full. The liquids aspirated from the wound may be turned into a gel, for ease of disposal and to prevent spilling, by a gelling agent in the disposable canister. To keep the waste in the canister level, the gelling agent is preferably provided in stacked disks. The canister has an inlet connector for the suction tube from the wound dressing, and an outlet connector for connecting to a portable pump or to a flow monitoring instrument for use with stationary or hospital wall suction. The outlet connector is preferably a proprietary (non-standard) connector that will not connect directly to the standard appliance fitting of a stationary suction system, to prevent anyone from mistakenly connecting directly to the suction system.

[0021] The pump may also provide a docking station for the waste collector, such that the collector can be securely attached to the pump housing. Preferably the waste collector is a transparent plastic canister having right circular cylinder profile and fill-level markings in a band extending along the height of the cylinder, and having a connection fitting with an O-ring seal. The pump has a docking station with a concave profile conforming to a half section of the canister to support the canister, and a releasable latch fitting adapted to receive the connection fitting of the canister.

[0022] The pump may have a sensor proximate to the canister docking station for detecting when the level of waste in the canister exceeds a level which indicates a filled canister condition. A preferred sensor is a capacitance detector. The sensor sends a signal representing a level of waste collected in the canister to the microprocessor, which includes an algorithm to be applied to the signal to reduce the likelihood of an erroneous indication of a full canister caused by liquid sloshing inside the canister.

[0023] The pump may also have an activated charcoal air filter disposed between the releasable latch fitting and the pump's air discharge port for reducing odors from the pump. The pump may also have a desiccant with the filter. The pump may also utilize a controlled backpressure to lessen the noise inherent in the operation of the valves in a positive displacement pump, such as a leaf spring sound damper disposed over the pump outlet.

[0024] In a preferred embodiment, a calibrated vent in the suction conduit near the wound dressing establishes the reference airflow. Preferably the vent is located in the tube just outside of the wound cover. The vent may be an aperture in the tube sealed with a porous material having specific flow rate characteristics. The reference flow rate may be in a preferred range of 50-300 cc per minute. Higher flows such as 1000 cc/min are possible, but practical limitations on the capacity of the suction source as well as the magnitude of a leak in the dressing suggest that is preferable to use a flow below 1000 cc per minute.

[0025] By locating the vent in the conduit close to the wound, the reference airflow also serves to purge the conduit of fluids. The purging effect minimizes the likelihood of reflux of contaminated fluid back into the wound, and the risk of infection attendant to such reflux. Since the fluid does not reside in the conduit for an extended time, the purge effect also reduces the likelihood of blood clotting in the line. The pump system may also provide a pressure pulse generator to clear the collection line of serial slugs of fluid if a reduction in flow is detected.

[0026] The pump is preferably a portable battery-powered positive displacement pump in which flow rate is proportional to motor rpm allowing the airflow rate of the system to be indicated indirectly by the motor speed or pump speed. An algorithm may

be used to correct motor and pump speed to flow for compressibility effect. Thus a motor speed indicator or tachometer may be the preferred monitoring instrument. However, other flow rate monitoring instruments could be used, such as, but not limited to, target meters, rotometers, turbine meters, mass flow meters, differential pressure (Dp) cells and hot wire anemometers.

[0027] Although the term "airflow" is used herein for consistency, it should be apparent that it is not limited to the composition of ambient air. It is common in medical settings to alter the composition of airflow to a wound, such as by increased oxygen or therapeutic aerosols or other beneficial medications. The flow of any of these mixed gases or aerosol suspensions should be considered airflow for purpose of this description.

[0028] These and other advantages and aspects of the invention will become apparent upon reading the detailed description and drawings that follow.

Brief Description of the Drawings

[0029] Figure 1 is an exploded perspective view of a system for suction wound therapy.

[0030] Figure 2 is a view of a suction tube attachment device showing an air vent in the suction tube to create a controlled reference airflow rate to the suction source.

[0031] Fig 3 is a cross-section view of the waste collection canister showing the shut off membrane and gel agents.

[0032] Figure 4 is a cross section view of the wound monitor airflow indicator.

[0033] Figure 5A is an exploded perspective view of a preferred embodiment of a system for suction wound therapy using a portable suction pump.

[0034] Figure 5B is a perspective view from the top front of a portable pump which may be used in the system of Figure 5A.

[0035] Figure 6A is a schematic diagram of positive displacement pump embodiment measuring motor speed as a surrogate of airflow.

[0036] Figure 6B is a schematic diagram of a positive displacement pump embodiment using a microprocessor for flow monitoring and reporting, and for other timing, control and status display functions.

[0037] Figure 7 is a schematic view of a target meter flow indicator alternative.

[0038] Figure 8 is an exploded perspective view of a portion of an alternative embodiment of a system for suction wound therapy according to the invention using a therapeutic fluid delivery to the wound.

Detailed Description of the Invention

[0039] Figure 1 shows an embodiment of a system (10) for suction wound therapy as described in commonly owned U.S. Patent Application Serial No. 11/268,212. The components include a wound dressing subsystem (12), a suction tube (14), a waste collection canister (16), a flow monitor instrument (18) and a wall suction regulator (20) of a stationary suction source.

The Wound Dressing

[0040] The typical wound dressing (12) includes a wound cover (22) and wound packing material (24), and may include a special wound contact layer (26). It will have a suction tube (14) running under the edge of the primary cover or through the cover, or will terminate outside of the cover and communicate with a nozzle or slot in the cover. There is a wide variety of each of these components. The wound dressing (12) shown in the drawings and described herein uses presently preferred components, but the invention is not intended to be limited to these components.

[0041] The primary wound cover (22) is preferably an airtight wound cover that is vapor permeable. It is preferred to use a thin film transparent commercial bandage, such as medical grade Tegaderm™ manufactured by 3M, that is impermeable to liquids but permeable to water vapor and oxygen. The term "airtight" means that the material is sufficiently occlusive to resist airflow through the cover to maintain suction under the cover while suction is being applied. There are many other thin-film commercial bandages that have similar properties. Highly impermeable materials could also be used. However, since it is beneficial in wound therapy to allow water vapor to escape

and oxygen to migrate into the wound, semi-permeable covers of film material such as Tegaderm™ are preferred. In some instances, the primary cover could also be a rigid or semi-rigid enclosure placed over the wound. The primary wound cover is generally sealed to the skin surrounding the wound with an adhesive (not shown) incorporated in the cover, and gap filler paste (not shown) may be used where needed.

[0042] Before the primary cover (22) is applied, the wound is generally packed with a wound packing (24). Simple gauze or foam pads can be used, or other materials commercially sold as wound packings. The presently preferred wound packing, however, is polyester fibers or comparable resilient fibers in a corrugated layer pattern configured to form a resilient compressible structure, as described in U.S. Patent Application No. 10/981,119, commonly assigned with this application.

[0043] The wound packing (24) may also be attached to a wound contact layer (26). The presently preferred wound contact layer (26) has a special construction that provides a wound contact surface, with depressions formed into the surface, to work in conjunction with the suction to encourage more rapid tissue regeneration, as described in U.S. Application No. 10/982,346, commonly assigned with this application. The contact surface is configured such that voids formed by the depressions remain above the wound surface in the presence of moisture, compressive forces and suction, encouraging local tissue deflection.

[0044] The wound dressing includes a suction tube (14) attached to the wound cover. The dressing may have other tubes (28, in Figure 2) for medication supply or wound flushing. The tube(s) may pass under the edge of the cover or through it, but a presently preferred arrangement uses a tube attachment patch (30) to allow the suction tube to be terminated outside of the primary cover and reduce the risk of breaking the adhesive seal to the skin, as described in U.S. Application No. 11/181,128, commonly assigned with this application.

[0045] As shown in Figure 2, the distal end of the suction tube (14) in this embodiment has a vent hole (32) that is sealed with a porous plug (34) that provides a controlled leak, or reference airflow, for the airflow monitoring devices described hereafter. It is preferable to locate the vent (32, 34) as close to the wound cover as

possible. Having the tube attachment outside of the primary cover allows the use of this controlled leak reference airflow without drying out of the wound, as might occur if the vent were under the cover near the wound. While it is feasible to place the controlled leak in the actual wound space, consideration would need to be given to avoid excessive drying of the wound tissue due to the introduced airflow. In addition, it is possible with the type of tube attachment patch (30) shown in Figure 2 and described in U.S. Application No. 11/181,128 to provide the vent as an aperture in the patch (30).

[0046] The reference airflow rate from the calibrated vent is used for monitoring system operation. The controlled leak rate should be low to maintain a proper suction at the wound site and a moist healing environment. Preferably the reference airflow is in the range of 50-300 cubic centimeters per minute. This flow is low enough to minimize drying and does not significantly alter the suction applied at the wound. Additionally, the flow is low enough to minimize the use of battery power where a portable pump is used as the suction source. A flow of this magnitude is readily obtained by providing a vent hole (32) in the suction tube that is sealed sterile with a porous plug (34), as described above. A suitable seal material is a porous plastic manufactured by Porex from sintered high density polyethylene. Such porous materials are routinely employed to admit air into medical fluid lines at a suitable flow while maintaining an efficient sterile filtration barrier against microbes.

[0047] The wound therapist applies the wound dressing (12) to the patient and attaches the system to suction. The therapist remedies leaks in the dressing by smoothing out creases or wrinkles in the wound cover and addressing gaps due to folds in the patient's anatomy. It has at times been useful to address specific areas of difficult anatomy by using a gap filling paste, as is common in ostomy care, such as coloplast. The airflow monitoring instruments described hereafter facilitate the initial dressing set up process by providing active feedback to the therapist on the integrity of the seal around the wound cover and tubes.

The Waste Collector

[0048] Since a primary function of suction therapy is to drain liquids from the wound, the system normally includes a waste collector (16) for collecting fluids aspirated from the wound. As in the embodiment shown in Figure 3, the collector (16) may be an upright plastic canister (36) with a right circular cylinder profile that may have fill level markings in a band extending along the height of the cylinder on the outside of the canister. The markings may be on a paper label adhesively glued to the canister. The canister is preferably a disposable, single-use device. The canister has a lid (38) incorporating a fitting (40) passing through the lid for the attachment of an inlet tube (42). The inlet tube (42) may be an end of the suction tube (14) leading from the wound, or be a short section of tube that terminates with a connector fitting (44) for mating with a matching connector (46) on the end of the suction tube (14).

[0049] Airflow and any blood or other fluid aspirated from the wound passes through the fitting (40) in the lid and into the canister (36). The liquid is retained in the canister, while the air rises and is drawn through a hydrophobic membrane (50) sealed to the inside of the lid. The membrane (50) acts as a bacteria filter, and can be used as a shut off mechanism to prevent the canister from overflowing and to prevent contamination from flowing out of the container toward the suction source.

[0050] The lid defines an air channel from the outlet port (52) to another connector (54) for connecting the canister to a portable pump or to a tube running to a stationary wall suction system. The second connector (54), however, is preferably a proprietary (non-standard) connector that will not connect directly to the standard appliance fitting of a stationary suction system. This is to prevent anyone from mistakenly connecting directly to the suction system without the flow monitoring instrument and pressure release features described hereafter, with the attendant risk of applying too great a suction to the wound. The mating receptacle in the portable pump configuration described hereafter is configured to receive the proprietary connector. The connector (54) includes a sealing element such as an O-ring seal. This arrangement provides that a fresh O-ring is preferably used with each disposable canister, as contrasted with other pump connectors where the sealing element is in the pump and will ultimately wear out and cause the system to fail because of leakage.

[0051] The air passage through the canister thus forms a part of a suction conduit between the wound and the suction source. In one embodiment of the system described herein, the canister (36) is prevented from overfilling by the hydrophobic membrane (50). If the canister (36) is allowed to fill high enough for the contents to contact the membrane, the membrane occludes and blocks airflow from passing through the canister. This blockage prevents suctioning more waste from the wound, and as described hereafter, the blockage of reference airflow is detected as an indication of an abnormal operating condition. In other embodiments described hereafter, the level of waste product in the canister can be detected by a capacitance sensor or other detector on the pump, and the detection used to prevent overfill.

[0052] Preferably the liquid waste sucked from the wound is turned into a gel for ease of disposal and to prevent spilling or splashing. Although the gelling agent could be provided in porous bags, it is preferred to use disks (56) of laminated fiber sheets containing a gelling agent, such as provided by Gelok International. The disks (56) are cut to fit inside of the jar and stacked on top of each other. The stacked disks cause the liquid to turn to a level surface gel in the canister.

[0053] The system may also include a filter/drier unit (21) disposed between the waste collection canister and the wound flow monitor (18). The filter element provides additional protection against contaminated particles entering the suction source, and the drier removes moisture from the air that may effect the calibration of the flow monitoring instrument.

Use of Controlled Reference Airflow to Indicate Normal Operation

[0054] While prior art suction dressing systems either do not monitor system operation at all, or do so less than optimally by trying to sense pressures directly, the system described herein uses a reference airflow, as may be provided by the air vent (32) described above, to indicate when the system is in normal operation, and also to detect deviation from the reference airflow as an indication of abnormal operation. Higher airflow than the reference flow indicates leakage, while lower airflow indicates blockage.

[0055] The range of flows suitable for reference flow are bound by the permeability of the wound cover on the lower end and suction limits on the upper end. When the wound cover is a semi permeable material, there will be a natural low level background airflow from air molecules passing through the cover. This permeation airflow could serve as the reference flow if the flow monitoring instrument were very sensitive. However, the permeation flow is usually too low and too erratic to be a good reference. The area of the cover and the possibility of it being obstructed by surgical drapes and fluid from the wound can cause the permeation flow to be erratic. Thus, the vent provides a larger and more stable flow rate that masks variation in the permeation flow and provides a good reference. For example, Tegaderm® bandage will allow a diffusion of water on the order of 800 grams/square meter/day, which correlates to a flow rate of about 0.5 cc/min over a square meter. Typical wound cover area would be less than a tenth of a square meter, so in approximate terms, the semi permeable material contributes 0.05 cc/min, or less than .1% of a reference flow of 50 cc/min. Thus, any variation in the background permeation flow is masked by the larger reference flow.

[0056] The indicator sub-system may be embodied in two devices as depicted and described below; a wound monitor flow instrument for use with a stationary suction source and a portable pump with a flow sensing system. Other types of flow indicating devices, such as target meters or hot wire anemometers could also be used.

The Flow Monitor

[0057] In the wound suction system of Figure 1, the flow rate monitor is a float meter (19) that includes a suction conduit (58) between the waste collection canister (16) and a stationary suction source. One end of the conduit includes a mating connector (60) to the proprietary connector (54) of the canister. The flow monitor (18) is preferably located at the other end of the conduit (58) and attaches directly to an appliance connection fitting (64) associated with an adjustable suction regulator (20) as commonly found on stationary suction systems.

[0058] The flow monitor (18) is designed to provide a visual indication of the flow rate through the system. Once the flow rate stabilizes at the controlled reference airflow following initial application, the maintenance of this visual indication of

reference flow is an indication of normal operation free of leaks or blockage, and hence an acceptable level of suction at the wound cover. Deviation to a higher airflow indicates leakage, and drop to lower or no airflow indicates blockage in the collection circuit.

[0059] Figure 4 is a cross section of the float meter (19). A standard connector (63) on the top end of the meter attaches to a short conduit (62) connectable to the appliance fitting (64) of the adjustable suction regulator (20). At the bottom end of the flow meter, a standard connector (59) is attached to the suction conduit (58). It is typical to use suction in the range of 25-200 mm Hg in wound therapy. The flow indicator incorporates a flow restrictor (66) having an orifice (67) that is calibrated to restrict suction airflow to be less than 20 liters per minute when a controlled level of suction of 100 mm Hg is applied by the suction regulator (20).

[0060] As shown in Figure 4, the flow indicator has progressive sections (68, 70, 72, 74) with different inside diameters, having the narrowest section (68) at the bottom and progressively larger diameters in the three additional sections (70, 72, 74) progressing to the top. The outside barrel (76) of the clear tube has graduated markings (not shown) to indicate airflow rates. A float (78) serves as an indicator of flow through the system. When there is no airflow, the float will rest in the lowest section (68). This area is color coded red to indicate a blockage condition, such as a full canister or any occlusion in the fluid path. When the flow into the meter is low, preferably between about 50 cubic centimeters per minute to 300 cubic centimeters per minute, the clearance between the float and the bottom section of the indicator is such that the flow around the float will cause the float to rise into the next section (70). Thus, normal reference airflow will cause the float to rise a discernable amount into the next section. This area of normal operation is color coded green, indicating an acceptable condition.

[0061] The mass of the float works in cooperation with the clearance between the outside of the float and the inside of the tube. The float responds to airflow rate and fluid density and will rise to a level where the dynamic forces are in equilibrium. Typical flow indicators for other applications have continuously increasing inner diameters. Slight changes in flow rate cause the float to chatter up and down around a

height indicative of the flow rate. The use of discrete sections of uniform diameters, but increasing in progression, as the four sections (68, 70, 72, 74) in this indicator reduces the chatter and causes the float to move upward in stages. These stages are selected for discrete flows that provide key reference information regarding the suction applied to the wound.

[0062] If flow through the system increases beyond an acceptable level due to a leak in the wound dressing, the clearance around the float in the normal position may no longer be adequate to allow the float to remain in this position, and the increased flow will lift the float to a higher section in the indicator where the internal diameter is stepped up. Graduated labeling (not shown) on the outside of the indicator provides a visual indication of a moderate leak condition. Additional stepped up diameter sections are provided to indicate higher leak conditions. The stepped up diameters require a significant change in flow before the float will jump from one position to a higher one. This eliminates the jumpiness that would be encountered with a continuous taper inner diameter as common in flow meters for other applications. The stepped diameter sections reduce user interpretation, thus enhancing ease of use and safety.

[0063] The wound monitor instrument also incorporates a safety valve (80) that limits maximum suction to guard against the accidental application of excessively high levels of suction. It is typical to use suction in the range of 25-200 mm Hg for wound drainage and therapy. Consequently, the suction limiting feature may be set to limit the suction to approximately 200 mm Hg. A suction pressure relief chamber (84) is formed between the first flow restrictor (66) and a second flow restrictor (82) having an orifice (83) the same size as the first restrictor. A resilient valve mechanism (86) in the relief chamber serves as a release against the application of high levels of suction. The valve mechanism is spring loaded to a predetermined suction setting, such as 200 mm Hg. If the suction pressure in the relief chamber exceeds the predetermined setting, the valve mechanism will open and allow vent air to be drawn from a relief port (69) into the metering orifice to prevent excess suction from being applied to the patient.

[0064] Protrusions (75) may be provided on the top underside of the interior of the float meter adjacent the first flow restriction orifice to prevent the float from completely blocking the orifice entry to the pressure relief chamber, thus allowing air

passage even if a major leak occurs. This allows some suction to communicate through the system even at high airflow rates. Alternatively, the protrusions could be located on the top surface of the float.

[0065] The wound flow monitor instrument is also protected from sources of potential contamination in the form of particulate matter, aerosols and humidity by an air filter/dryer (21) located in the conduit between the instrument and the canister. The filter/dryer unit includes a particle filter for removing airborne dust as may be encountered when the wound monitor is disconnected from the collection canister for periodic changeover. It is also anticipated that a desiccant or other means of humidity control can be placed in the filter/dryer unit as required.

[0066] While this system has been described in the context of a hospital wall suction system, it can also be used with suction pumps. Some medical buildings may use electrical power pumps to provide suction for wound therapy. These can be moved, since the only restriction is the location of electrical outlets and the length of the power cord, but they are not truly portable. A system using portable battery powered pump is described below.

Portable Pump

[0067] In a portable pump embodiment (100) of the suction system as shown in Figures 5A, the suction source is a portable suction pump unit (102) instead of a stationary suction source. The pump connects to the same wound dressing subassembly (12) and waste collection canister (16) as were described above.

[0068] The pump (102) operates with low voltage DC and has an onboard (battery) power source. The pump will also run on wall power with a suitable ac/dc power converter, which may be combined with a battery charger to recharge the battery during use.

[0069] The pump is configured to produce controlled levels of negative pressure. As shown in Fig. 5B, the pump has an On/Off/Intermittent control switch (112) and pressure level selector dial (113) on its top panel. The pump power is turned ON using the control switch (112). A prescribed pressure setting is selected on the pressure selector dial, which allows set-point choices between 30 and 75 mm Hg.

[0070] In the schematic diagram of Figure 6A, the portable pump embodiment includes a positive displacement air pump (103), a variable speed DC motor (104), a tachometer (105), pressure control circuitry (106) and a fault detection/alarm system (108). In this embodiment the pump pressure control circuitry and the fault detection/alarm system may be hard wired solid state electric devices.

[0071] In the schematic diagram of a preferred embodiment in Figure 6B, the fault detection and alarm system includes a microprocessor (200). A suitable processor is a Microchip 16 Series, part number 16F688, although other similar programmable logic devices could be used.

The Independent Pressure Control System

[0072] Regardless of whether the pump uses a microprocessor or not, the pump's pressure control system is independent of the air flow monitoring function. The pressure control system functions similar to a standard compressor circuit. A pressure transducer (not shown) monitors the negative pressure produced at the pump, and is preferably located in the conduit between the waste collection canister (16) and the pump (102). The compressor control circuit (106) includes a solid state logic device. The user selects a pressure setting using the selector dial (113) to change the resistance of a variable resistor and produce an electrical signal representing the selected pressure. The control circuit (106) receives the selected pressure setting as an input, and sets an upper and lower limit of pressure that is related to the selected pressure. This range between upper and lower limits is selected to provide a reasonably stable suction level while minimizing the on-off cycling of the pump motor. A range of approximately 10 mm Hg is preferred for patient comfort and to minimize noise. The control circuit (106) will function to maintain the pressure sensed by the transducer between the two limits. Such control circuits are commonly employed in industrial applications as well as in hospital central suction systems.

[0073] When the pump is initially turned on by the On/Off/Intermittent switch (112), the control circuit (106) starts the pump running until the transducer detects pressure at or exceeding the upper limit of the pressure range set by the control circuit. The pressure control circuit (106) has a comparator (not shown) that is continually comparing the pressure signal from the pressure transducer to the set point limit signals

as chosen by the operator via the pressure selector dial (113). Once the upper limit is reached, the pressure control circuit (106) turns the pump Off. Normal reference air flow in the conduit will cause pressure at the transducer to decay towards the lower limit of the control range. Once the detected pressure has reached the lower control limit, the control circuit (106) will turn the pump back On, and the process is repeated. Thus, the pressure transducer senses the current negative pressure and the control circuit (106) turns the pump On and Off accordingly to maintain negative pressures that are within the selected desired range.

[0074] The motor (104) is preferably a variable speed DC brushless motor, however other styles of DC motors are acceptable, as well as AC motors that can be equipped with variable outputs. With the variable speed motor, the speed is controlled via a pulse width modulation (PWM) feature of the control circuit (106). The variable speed control allows for efficient use of DC power.

[0075] The positive displacement pump (102) in the preferred embodiment uses a DC diaphragm style pump with inlet and outlet check valves. The diaphragm pump crankshaft is operationally connected to the shaft of the variable speed motor. Other positive displacement pumps may be used, such as peristaltic, piston, syringe or rocking piston pumps.

[0076] A tachometer (105) can be used to indicate motor or pump shaft rpm. For example, Hall sensors are commonly employed on DC brushless motors, as well as encoders, to indicate rpm. It is also possible to sense back EMF in brush versions of DC motors to determine motor shaft rotation speed. In an AC pump, an oscillating bar with a magnet mounted to an end is excited by an AC coil, thus driving a diaphragm. In that case a count of the oscillations delivered by the coil can be used as an indicator of pump speed. Each of these and other forms of pump or motor speed sensors is included in the generic term tachometer, and can be used as the flow rate monitoring instrument, where pump speed or displacement is measured as a surrogate for direct airflow measurement with a positive displacement pump.

[0077] As described above, the pressure control circuitry (106) will run the pump as necessary to maintain suction sensed by the transducer within the desired range of

the selected negative pressure set point. The pump's On-time duration is increased or decreased as required by the pump control circuitry (106), at an efficient motor speed as determined by the pulse width modulation feature of the control circuitry, to maintain the negative pressure in the range established by the selected set point. Thus, the pressure control circuit operates on sensed pressure, and not on sensed air flow. This allows the pressure control to be independent of the flow detection and monitoring and flow status display capability of the system.

The Flow Detection System

[0078] As shown in Fig 6A, a fault detection system (108) can be a circuit that is adapted to monitor pump activity as an indicator of the flow rate of air through the wound therapy and waste collection lines, coupled with an annunciator (114) to provide audible and visual indication of status of operation. This fault detection circuit (108) is a separate circuit that is independent of the compressor control (106). Preferably the fault detection system includes sensors of pump motor activity that provide input to a microprocessor which determines a flow rate based upon the motor activity input, identifies deviations from reference flow rate, and provides the annunciator signal identifying abnormal status of operation. In a preferred embodiment as described below, the fault detection circuit can include a microprocessor.

[0079] A preferred embodiment of portable pump unit (200) is depicted in the schematic diagram of Fig 6B. The pump (203) is as described above, a diaphragm style positive displacement pump with inlet and outlet check valves, and is powered by a variable speed brushless DC motor (204). The unit can be powered by wall outlet power with a power cord (205) supplying electrical power through a power converter and battery charger module (207) which also contains a 12 volt battery. The unit can receive DC power either from the converter or from the battery when used un-plugged. The pressure control circuitry (206) operates as described above to maintain pressure selected at the selector dial (213).

[0080] The unit also includes a microprocessor (210) that is involved in the flow monitoring and system status detection functions. In this embodiment, motor or pump revolutions are counted as an indication of the air volume that has passed through the positive displacement pump and provide an input to the microprocessor (210). A

discrimination algorithm in the microprocessor programming takes the count of motor revolutions and determines a flow rate. This flow rate is compared to the known reference flow rate to determine fault conditions. The flow rate is converted into a signal that illuminates a display bar on the flow rate annunciator (214). A flow rate that is less than the reference flow is indicated as abnormal operation on the annunciator as an occlusion in the circuit, most commonly a full canister. A flow rate that is comparable to the reference flow rate produces an annunciator indication of normal operation. Flow rates that are higher than the reference flow rate will produce abnormal annunciator indications that the circuit is leaking to alert the caregiver to address the seal of the wound cover.

[0081] Where the pump is independently turned On and Off by the pressure control circuit to maintain set point pressure, the pressure sensed by the transducer will oscillate between the upper and lower control limits. The period of this oscillation is related to the leakage in the wound dressing. The higher the leakage, the shorter the period. Thus, the time intervals between the pump turning On or Off could be detected by the microprocessor and used as a rough measure of air flow rate. Where the motor speed is also controlled via a pulse width modulation (PWM) control to make the use of DC power more efficient, however, the microprocessor can also correlate the On/Off intervals with pulse rate to determine airflow rate. In normal operation, the positive displacement pump will output a given number of pulses for each revolution of the pump. The pulse signals can be supplied as an input to the microprocessor. These pulse signals are used to determine the number of pumping strokes the pump has output and are a very close approximation of pump volume. The flow monitoring programming in the microprocessor continually counts the pulses being output from the pump to represent volume of air flow. When taken in combination with a time measurement, these pulses per unit time represent airflow rate. In a presently preferred embodiment, the time measurement is based on the Off cycles of the pump motor. From the time the pump turns Off, until the next time the pump turns Off, the microprocessor counts the pulses and divides by the time between each motor OFF condition to determine the flow rate in the conduit.

[0082] It is sometimes desirable to provide suction in an intermittent fashion to benefit the healing process. Prior processes involve allowing the system to vent to atmospheric pressure for a period of time to allow for reperfusion of tissue. Allowing the system to completely vent to atmosphere results in the complete loss of suction on the dressing system and any benefit that suction could play in maintaining an air tight seal around the wound. The present invention solves this problem by varying the suction between two distinct levels; a first level selected by the pressure selection dial (113) and a second level of 20-25 mm Hg. The selected higher level is used to apply the beneficial therapeutic effects of suction. The second reduced level is below capillary bed pressure, so reperfusion of tissues will occur in this lower stage, while the wound dressing maintains at least some level of suction to help keep the dressing seals in place and to maintain the reference airflow and prevent reflux and clotting in the lines. With this type of intermittent pump operation, the reference airflow should be selected such that it is maintained even at the reduced level, or else the alarms associated with low airflow should be disarmed by the microprocessor during reduced suction intervals as well as the ramp-up and ramp-down intervals.

[0083] The microprocessor (210) can rest the selected pressure to cause intermittent suction. When the On/Off/Intermittent switch is set to Intermittent mode, the programming in the microprocesor uses a time interval for switching between normal selected pressure and the lower level. To enter the lower pressure cycle of the intermittent mode, the microcontroller activates a transistor that adds a resistance to the compressor comparator circuit. In effect, the microcontroller has re-set the pressure control circuitry to a lower selected pressure. Thus, while the microprocessor does not directly control the pressure control system, the microprocessor can re-set the selected pressures between the higher and lower levels at timing intervals selected by input to the microprocessor.

[0084] Faults in the suction therapy system are detected as deviations from the expected flow through the system. The flow detection system uses the reference airflow produced by the calibrated vent on the end of the suction tube calibrated to approximately 50 - 100 cc/min to provide a flow signal indicative of normal operation. If the flow detection system determines the pump is not running at a normal duration to

maintain set-point negative pressure, it will alert the caregiver via a visual and audible alarm.

[0085] An increase in the On time of the motor is proportional to increase of air flow in the system. The microprocessor uses an algorithm to correct the airflow based on the actual pressure in the circuit. Any leak in the dressing system will be compensated for by an increase in the On time of the pump. As the On time increases to equate to a flow of approximately 3 liters per minute, an indicator will light on the flow annunciator display (214) of the unit to alert the caregiver to the fact that the dressing system has a leak. If the caregiver is able to correct the leaking dressing, the indicator will turn off. If the fault condition is not addressed (by re-sealing the wound site) within a one-minute timeframe, the microprocessor will activate an audible alert. Even when a leak condition exists, however, the pump will continue to run under the control of the pressure control system, delivering some level of suction until the condition is corrected or the pump is turned off.

[0086] The flow detection system will also sense the loss or drop of the reference airflow. There are a number of fault conditions which will cause the reference air flow to be reduced, including the lines to the waste canister becoming clogged with wound exudates, or being crimped shut by bending or squeezing. These conditions also result in the loss of negative pressure at the wound. This reduced reference air flow results in reduced motor on time that is sensed by the flow detection system and causes a visual indicator to indicate blockage condition.

[0087] The pump may also have an onboard compliance monitor as part of the timing function of the microprocessor. A compliance indication (159) alerts the caregiver to deviations from the normal application of suction to the wound over time and is a useful adjunct to the application of negative pressure wound therapy. The compliance monitor may compute the number of hours that suction has been within ±5 mmHg of a set point. Medical experience has shown that suction should be applied for 22 of any 24 continuous hours to be effective. This readout can be presented a number of ways to show the number or percentage of compliant hours of suction therapy.

Waste Collection Canister and Fill Indicator

[0088] The pump unit (102) also includes a docking station (160) for the waste collector located between the wound dressing and the pump for collecting liquids aspirated from the wound. As presently preferred, the waste collector is a transparent plastic canister (16) having right circular cylinder profile and fill-level markings in a band (170) extending along the height of the cylinder, and having a connection fitting (54) with an O-ring seal. The portable pump docking station (160) supports the canister. The docking station has a concave profile conforming to a half section of the canister and a semi-circular base (162) to support the canister when one is docked. The pump has a releasable latch fitting (164) in the middle of its upper wall that is adapted to receive the connection fitting (54) of the canister. The canister fitting is inserted into the latch fitting (164) and locked in place by the latch. The canister may be released and removed by depressing the canister release button portion (166) of the latch.

[0089] The pump also provides the ability to detect a filled canister without the need to measure differential pressures across a membrane. Differential pressure measurement can be problematic in that partially clogged membranes can lead to erroneous readings and interpretations. In this embodiment, the pump (102) employs positive level detection as a direct indication of the fill status of the canister. The pump may include a level detector sensor (218 in FIG 6B) proximate to the canister docking station for detecting when the level of waste in the canister exceeds a level which indicates a filled canister condition. A level sensor can take many forms, including a capacitance detector such as a Model# BC 10-QF5 sensor manufactured by Turck, Inc. This detector can be positioned in the pump housing at a desired level and has the ability to read a change in capacitance as caused by the presence of an ionic fluid. The detector can sense this changed environment through the pump housing, so there are no exposed elements. Capacitance type detection is also tolerant to conditions such as mist or fogging. Other positive level sensing mechanisms can be used such as optical, ultrasonic, contact wire, float systems and the like.

[0090] Since the patients may be mobile or need to be transported, there is a potential that agitation and motion can create an artifact where fluid may splash and create a false positive indication of a filled canister and subsequently trigger an

unwarranted signal or alarm. A software algorithm may be used by the microprocessor to minimize the likelihood of this false indication. The algorithm incorporates a time delay and a sampling rate. A sampling rate of 10 milliseconds and a delay of 4 seconds is an effective set of parameters that reduces false full indications due to a motion artifact. Preferably the algorithm is programmed into the microprocessor pump control.

[0091] The direct level detector also allows the system to distinguish between a filled canister and an occluded condition caused by other blockage in the conduit that is detected by deviation from reference airflow. The direct level sensor provides a signal that can illuminate a different array of visual and audible alarms than a lower than normal air flow indication. Providing the clinician a distinction between canister filled condition and an occlusion simplifies operation and makes the system easier to use and less prone to user error.

Timing Subsystem

[0092] The pump unit may have a timing subsystem for recording and accumulating time units corresponding to periods of time when the pump is running. Preferably the timing subsystem uses programming in the microprocessor (210) to record and accumulate the time units based upon inputs from other sensors. For example, the timing can be started and stopped by signals from the ON/OFF/Intermittent power switch, or signals that can detect when the pump is running from a tachometer or other sensor. The timing subsystem or programming in the microprocessor preferably also includes a time reporting routine for providing reports of the time units that the pump is running. The time reports may include a record of run-time intervals, a record of the date and duration of run-time intervals, a record of total accumulated run-time, a record of accumulated compliant run time, and a record of run time remaining on a pre-set run time period.

[0093] The timing subsystem may also be tied into alarms which indicate abnormal operating condition due to leak or occlusion. This will allow the timing subsystem to detect and record total pump operation time and compliant operation time. Compliant operation my be defined by therapeutic convention. For example, compliant time is sometimes identified as normal suction application for 22 hrs of a 24 hour period. The

time reporting subsystem may produce reports of complaint operation time in addition to pump run-time.

[0094] The timing subsystem may also be used to indicate time remaining to scheduled maintenance or cleaning, or to indicate time used or remaining on a billing plan where the payments for usage are based upon time units either on return or pre-paid in advance. When the pump is sold or leased in this manner, the timing subsystem has the ability to record and accumulate time units corresponding to periods of time when the pump is running and for providing reports of run-time, including compliant run time when the wound treatment system is operating normally.

Status Indicators and Alarms

[0095] The system status annunciator may be in the form of a bar meter (114) color coded and graduated to provide a visual indication that the flow through the pump is within a range required to maintain the reference airflow when the system is in normal operation; and conversely indicate that the pump is running faster than required to maintain the reference airflow, indicating air leakage in the system, or is running slower than required to maintain the reference airflow, indicating air blockage in the system. The pump may also provide an audible indication of abnormal operation, such as a beeper tone.

Error Detection and Display

[0096] The pump may also have warning or caution lights (116, 118, 120) indicating pump operating parameters, or errors other than those that are detected from reference airflow such as low battery charge. Electronic controls provide the ability to enable numerous combinations of visual and audible indications of flow detection faults and other errors. In the microprocessor embodiment of Fig 6B, a visual error indicator display (216) that is separate from the flow rate annunciator (214) provides additional trouble shooting assistance. These errors are detected by signals from sensors to the microprocessor. The microprocessor in turn sends signals as an alphanumeric display to the error display (214) that correlate to the following errors: overpressure, missing canister, transducer failure, low battery, low operating time remaining, and attachment of incorrect power supply.

[0097] Overpressure is the condition where a runaway pump could cause potentially high pressures to be delivered to the patient. The microprocessor's error detection software continually polls the output of the pressure transducer and compares it to a stored maximum allowable pressure. If the maximum allowable pressure is exceeded for a predetermined time period, then the microprocessor shuts the pump down and an Overpressure error is indicated on the error display.

[0098] A missing canister condition occurs if the pump is activated without a waste collection canister connected to the fitting. This condition can occur at start-up, and is detected by the error detection software as air flow through the system exceeding a certain level without a corresponding minimal increase in pressure. The detection flow rate for missing canister is typically set to be greater than the increased flow that would be expected from a wound dressing that was removed or compromised. When so detected, a Missing Canister error is indicated on the error display.

[0099] A pressure transducer failure can take two forms: an open circuit (no pressure reading) or an excessively high reading indicative of high vacuum. The latter is straightforward since it would be interpreted as an Overpressure (described above) and result in a fail-safe deactivation of the pump. The open circuit failure appears as zero pressure output. Therefore, if the error detection system software detects air flow but zero pressure, a Transducer Failure error is indicated on the error display.

[0100] A low battery charge is determined by the error detection software polling the battery output voltage when the pump is not plugged into an external electrical source. When a threshold low voltage level is crossed, a Low Battery error is indicated on the error display.

[0101] Low operating time remaining is associated with the timing feature of the pump when it is used to indicate time remaining until scheduled maintenance service or time remaining on a pre-paid rental plan. The timing system constantly accumulates run time and time remaining to a target time, such as the number of pre-paid hours. The error detection system can be set to a time remaining threshold, such that when the accumulated time indicates that time remaining has dropped below the threshold, a Low Time error is indicated on the error display.

[0102] Incorrect power supply detection is to guard against providing excessive voltage to the system. This is accomplished by comparing the input voltage to a set maximum level and detecting if voltage exceeds the maximum level. The system software detects the excess voltage and shuts down the pump, and an Incorrect Power error is indicated on the error display.

Collection Line Pulse System

[0103] The collection line pulse feature is intended to ensure that the collection line is maintained as clear as practical to minimize the amount of fluid in the line and ensure accurate delivery of the negative pressure. When the deviation from reference air flow begins to indicate an occlusion, the microprocessor motor controller can re-set the selected pressure to a higher level, which causes the pressure control circuitry to start the pump or increases pump speed. This pump activation causes a pressure pulse of transient high negative pressure output from the pump to clear the line between the patient and the collection canister. The microprocessor is programmed such that the pressure pulse is initiated prior to the illumination of an occlusion indication. The occlusion indication will not illuminate if the pressure pulse is followed by decay in the pressure reading on the pressure transducer. Decay in the pressure reading is indicative of a clearing collection line and therefore eliminates the concern of occlusion.

Safety Elements

[0104] System redundancy and therefore enhanced safety is accomplished by making the pressure control system operate independently of the monitoring and error detecting software. The pressure transducer is employed in a conventional compressor circuit to control the level of applied negative pressure. Should the compressor circuit fail, then the software has the ability to shut down the system and should the software fail, the independent pressure control will provide controlled suction to the patient.

[0105] The pump may have a charcoal filter element for controlling odors that may emanate from the patient through the pump. This element is placed on the outlet of the pump and can be readily changed and replaced. Also, desiccants can be used in conjunction with the filter to minimize moisture in the exhaust from the pump.

[0106] Positive displacement pumps typically employ check valves which make noise. The pump employs a backpressure device in the form of a leaf spring that is placed over the outlet of the pump to reduce the noise emanating from the pump.

Target Meter Alternative

[0107] There are other devices for determining the flow through the system that could be employed as leak detection devices in a wound dressing system operating with a reference airflow. These devices measure airflow directly, and thus can be used with non positive displacement pumps and wall vacuum sources as well as with positive displacement pumps. As shown in Figure 7, a target meter (120) is a reliable device for flow detection that is insensitive to changes in pressure. The target meter (120) employs an inlet orifice (122) and a target (124) typically placed in close proximity to the orifice. The target is attached to a shaft (126) and pivots on points (128) or an armature. A light torsion spring (not shown) may be used to keep the target in close proximity to the orifice. The extension of the shaft is placed outside of the flow path. As airflow enters the orifice, the target is forced away from the orifice. A proximity sensor, such as a reed switch (130) is so placed as to detect the positions of a magnet (132) on the end of the shaft extension and thus the presence or absence of flow in the circuit as well as measuring flow rate. A target meter could be placed between the waste collection canister and the pump or at the outlet of the pump, or between the waste collection canister and a stationary suction source to provide analogous flow rate information as previously described.

Flow Measurement Alternatives

[0108] Other flow detection devices that could be used alone or in conjunction with a suction source include a hot wire anemometer that determines flow as a function of the cooling of a wire in a flowing air stream, a rotameter with an optical detector that senses the position of a float, a turbine meter that rotates when flow is applied. These flow detection systems are generally insensitive to changes in pressure. A hot wire anemometer could be placed between the waste collection canister and the pump or at the inlet of the pump, or between the waste collector and or a stationary suction source. These alternative flow sensors allow the use of other styles of pumps that are not positive displacement, such as vane pumps and scroll pumps. Almost any flow

instrument could be used, including, for example, differential pressure (DP) cells that provide an indirect measure of flow rate.

[0109] When any fault condition is determined within the system, the pump will continue to run, delivering a sub-optimal level of suction, until the condition is corrected or the user powers the system off, since a sub-optimum level of suction applied to the wound is preferable to no suction at all.

Therapeutic Fluid Delivery and Reference Flow

[0110] In the embodiments described above, the reference flow for discerning between normal and abnormal operation has been ambient air supplied to the suction conduit through a vent. A reference airflow could be provided, however, in the form of a therapeutic mixture, such as oxygen enriched air, nitric oxide, heated humidified air or an aerosol containing medication droplets or particles. Such a configuration is shown in Figure 8. A source of therapeutic mixture (115), such as an oxygen regulator or a nebulizer, is connected to a conduit (117) leading to the wound. The mixture is conveyed through the conduit under or through the wound cover (152) and released into the wound packing (154) adjacent the wound contact material (156). Part of this mixture will be absorbed, but enough could be returned through the suction conduit (157) to provide a reference airflow when the flow has settled into equilibrium.

[0111] While the airflow monitor could be associated with a portable pump or in front of the appliance fitting of a suction regulator, as described above, an airflow monitor (119) could be provided between the therapeutic mixture source (115) and the wound cover (122). Since the part of the conduit beneath the cover would be contaminated in use, a detachable disposable tube (121) would be used for the section of conduit from the monitor to the wound packing. Thus, the invention can provide for the maintenance of suction therapy on a wound as well as the ability to monitor the application and removal of therapeutic substances to the wound.

[0112] Although the invention has been described and illustrated with respect to several embodiments described above, it should be understood the invention may be embodied in other forms without departing from its scope or attributes. Hence, the

scope of the invention should be derived from the claims that follow, recognizing that the claim language may literally encompass structure not specifically described.

Claims:

We claim.

1. A portable suction pump for producing negative pressure in a system for applying suction to a wound, the pump comprising;

(a) a flow rate monitoring system to monitor airflow through a conduit from a wound dressing to the pump as indicative of the level of negative pressure applied to the wound and to detect deviation from a reference flow rate, such that the deviation from the reference flow can be used as an indication of abnormal condition such as leakage of the wound dressing or occlusion in the conduit;

(b) a user operable pressure selector to enable a user to select a negative pressure pump output within a range of negative pressures; and

(c) a pressure transducer and a pressure control circuit for controlling the operation of the pump to maintain the pressure sensed by the transducer between upper and lower limits around the selected pressure, wherein the pressure control circuit can operate to control operation of the pump without input from the flow rate monitoring system.

2. A pump as in claim 1, wherein the flow rate monitoring system is controlled by a microprocessor.

3. A pump as in claim 2, wherein the pressure control circuit uses solid state electronic devices that can control the operation of the pump reference without input from the microprocessor.

4. A pump as in claim 2, further comprising:

a waste collector canister located in the conduit between the wound dressing and the pump for collecting liquids aspirated from the wound, the canister having a connection fitting; and

the pump having a docking station to support the canister and a fitting adapted to receive the connection fitting of the canister.

5. A pump as in claim 4, wherein the pump fitting includes a releasable latch.

6. A pump as in claim 4, further including a canister-fill sensor in the pump proximate to the canister docking station for detecting when the level of waste in the canister exceeds a level which indicates a filled canister condition.

7. A pump as in claim 6, wherein the canister-fill sensor is a capacitance detector.

8. A pump as in claim 6, wherein the canister-fill sensor provides to the microprocessor a signal representing a level of waste collected in the canister and the microprocessor includes an algorithm to be applied to the signal to reduce the likelihood of an erroneous indication of a full canister.

9. A pump as in claim 4, wherein the microprocessor provides signals to an annunciator for displaying a visual indication of airflow through the pump.

10. A pump as in claim 9, wherein the annunciator is a bar meter that is color coded and graduated to provide a visual indication of air flow through the pump.

11. A pump as in claim 10, wherein the annunciator indicates when the airflow through the pump is within a range of the reference air flow that is associated with normal system operation and conversely indicates when a deviation from the reference airflow is associated with an abnormal operation.

12. A pump as in claim 11, further including an error indicator display for displaying a visual warning of one or more system errors that are not associated with deviation of airflow through the pump from reference airflow.

13. A pump as in claim 12, wherein the system errors are chosen from the group consisting of: overpressure detection by the pressure transducer, pressure transducer failure, waste collection canister not attached, low battery voltage, attachment of incorrect power supply, and low operating time remaining.

14. A pump as in claim 2, further comprising the microprocessor having programming to reset the selected pressure between a higher and lower pressure level when intermittent pressure therapy is desired.

15. A pump as in claim 14, wherein the microprocessor has programming to increase the selected pressure when the deviation from reference air flow begins to indicate an occlusion to cause the pressure control circuit to start the pump or increases pump speed to cause a pressure pulse output from the pump to clear the line between the patient and the collection canister.

16. A pump as in claim 15, wherein the microprocessor is programmed such that the pressure pulse is initiated prior to the illumination of the occlusion indicator, and the occlusion indicator will not illuminate if the pressure pulse is followed by decay in the pressure reading on the pressure transducer.

17. A pump as in claim 2, wherein the microprocessor includes timing programming to record and accumulate the time units based upon inputs from other sensors.

18. A pump as in claim 17, wherein the timing programming also has a time reporting routine for providing reports of the time units that the pump is running.

19. A pump as in claim 18, wherein the reports include one or more reports chosen from the group consisting of: a record of run-time intervals, a record of the date and duration of run-time intervals, a record of total accumulated run-time, a record of accumulated compliant run time, and a record of run time remaining on a pre-set run time period.

20. A system for applying suction to a wound, comprising;

(a) a wound dressing, including a wound cover that is sealable to skin surrounding a wound;

(b) a conduit having one end operatively associated with the wound dressing to communicate suction to the wound, and an opposite end operatively associated with a suction pump;

(c) a transparent plastic waste collector canister located in the conduit between the wound and the pump for collecting liquids aspirated from the wound, the canister having right circular cylinder profile and fill-level markings in a band extending along the height of the cylinder, and having a connection fitting with an O-ring seal; and

(d) the pump being a portable pump having a docking station to support the canister, wherein the docking station has a concave profile conforming to a half section of the canister and a releasable latch fitting adapted to receive the connection fitting of the canister.

21. A system as in claim 20, further including a sensor in the pump proximate to the canister docking station for detecting when the level of waste in the canister exceeds a level which indicates a filled canister condition.

22. A system as in claim 21, wherein the sensor is a capacitance detector.

23. A system as in claim 21, further including the pump having a microprocessor, and the sensor providing to the microprocessor a signal representing a level of waste collected in the canister, and the microprocessor including an algorithm to be applied to the signal to reduce the likelihood of an erroneous indication of a full canister caused by liquid sloshing inside the canister.

24. A system as in claim 23, further including the pump having a charcoal air filter disposed between the releasable latch fitting and an air discharge port from the pump.

25. A system as in claim 23, further including the pump having a leaf spring sound damper disposed between the releasable latch fitting and an air discharge port from the pump.

26. A portable suction pump for producing negative pressure in a system for applying suction to a wound, the pump comprising;

(a) a pressure control circuit for controlling the operation of the pump to maintain the pressure between upper and lower limits around a pre-selected pressure, and;

(b) a fault detection system to detect deviations in the level of negative pressure applied to the wound; wherein the fault detection system can operate independent of the pressure control circuit.

27. A portable suction pump as in claim 26, wherein the fault detection system includes a flow rate monitoring system to monitor airflow through a conduit from a wound dressing to the pump as indicative of the level of negative pressure applied to the wound and to detect deviation from a reference flow rate, such that the deviation from the reference flow can be used as an indication of abnormal condition such as leakage of the wound dressing or occlusion in the conduit.

28. A portable suction pump as in claim 27, where the degree of abnormality is indicated by a color coded display.

29. A portable suction pump as in claim 26, further including a microprocessor programmed to increase the pump pressure when the deviation from reference air flow begins to indicate an occlusion by starting the pump or increasing pump speed to cause a pressure pulse output from the pump to clear the line between the patient and the collection canister.

30. A portable suction pump as in claim 30, wherein the pump has a visual occlusion indicator and microprocessor is programmed such that the pressure pulse is initiated prior to the illumination of the occlusion indicator, and the occlusion indicator will not illuminate if the pressure pulse is followed by decay in the pressure reading on the pressure transducer.

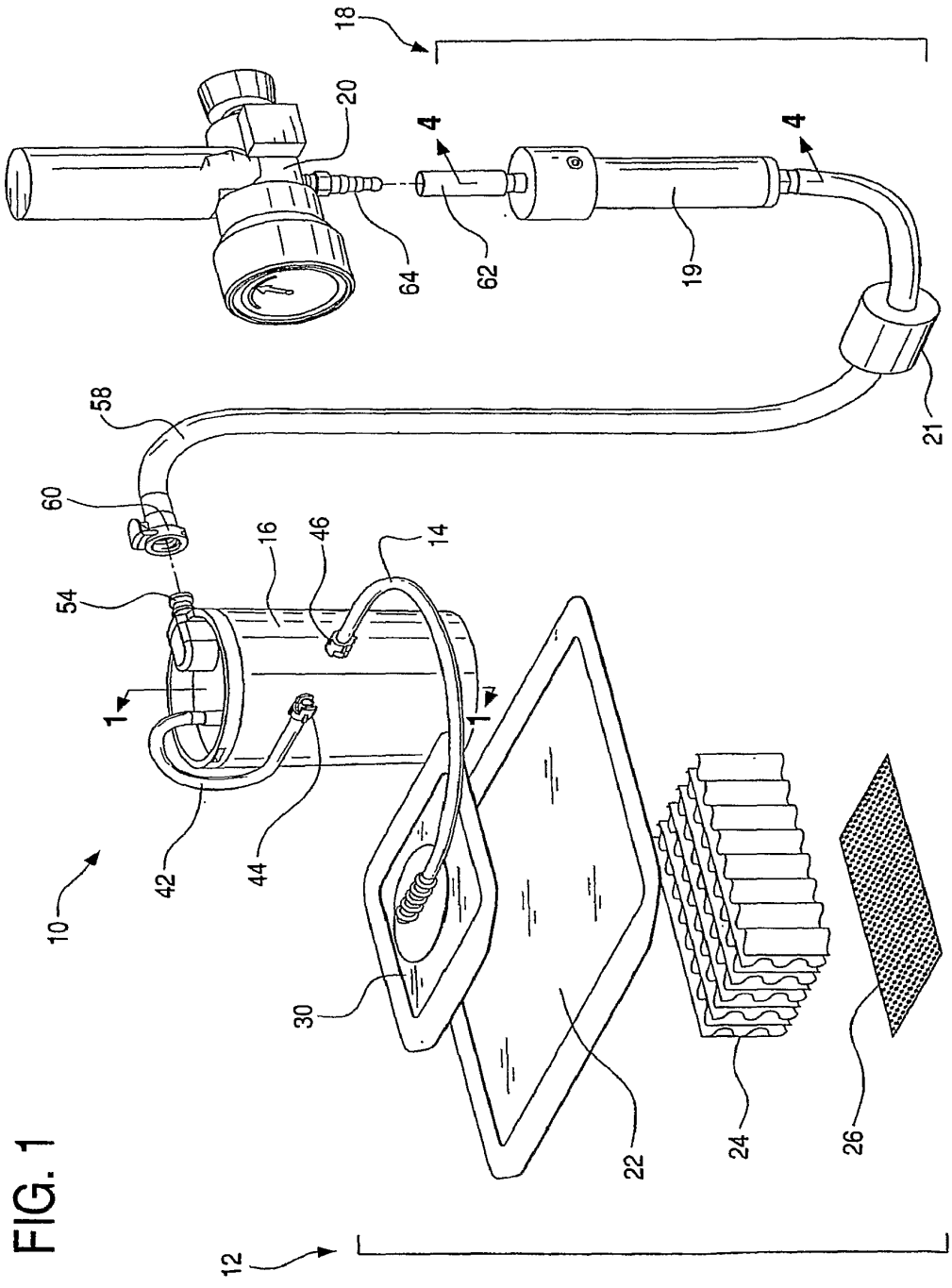


FIG. 1

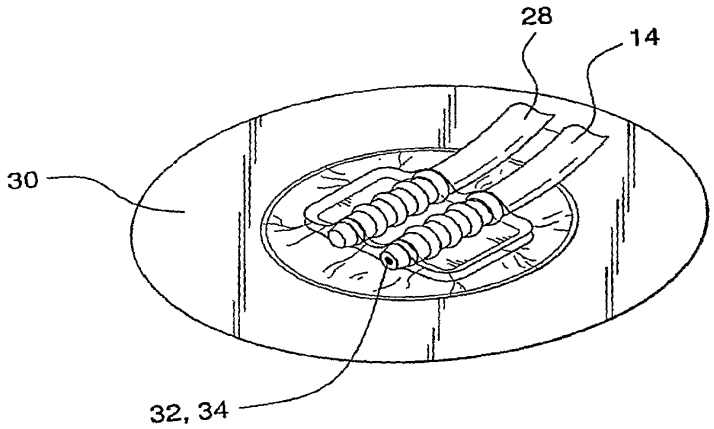


FIG. 2

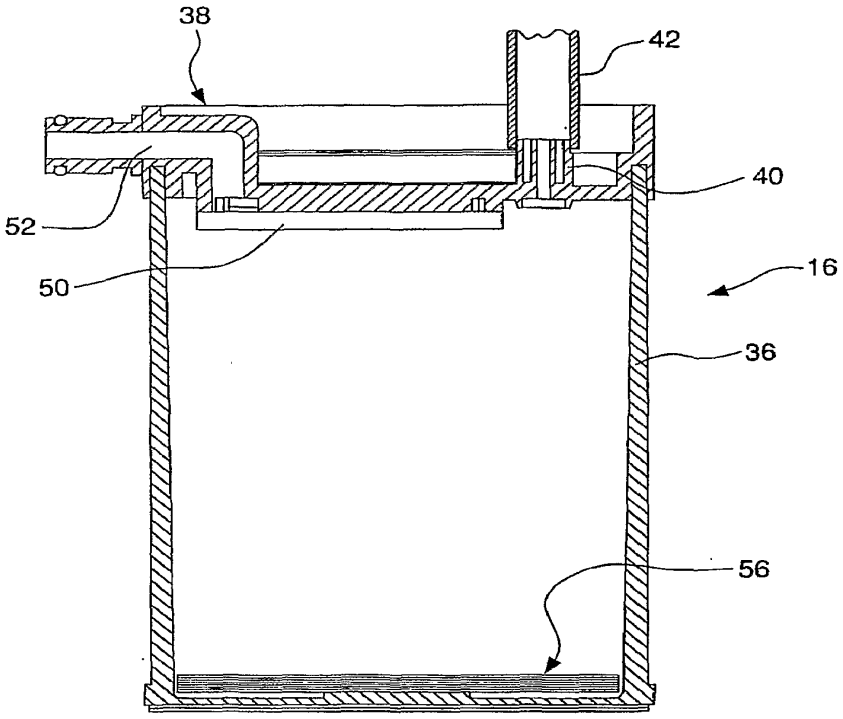


FIG. 3

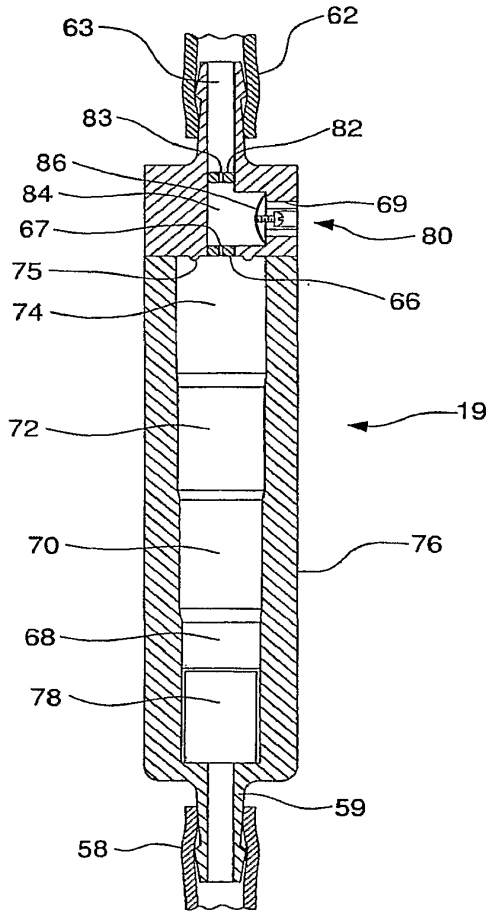


FIG. 4

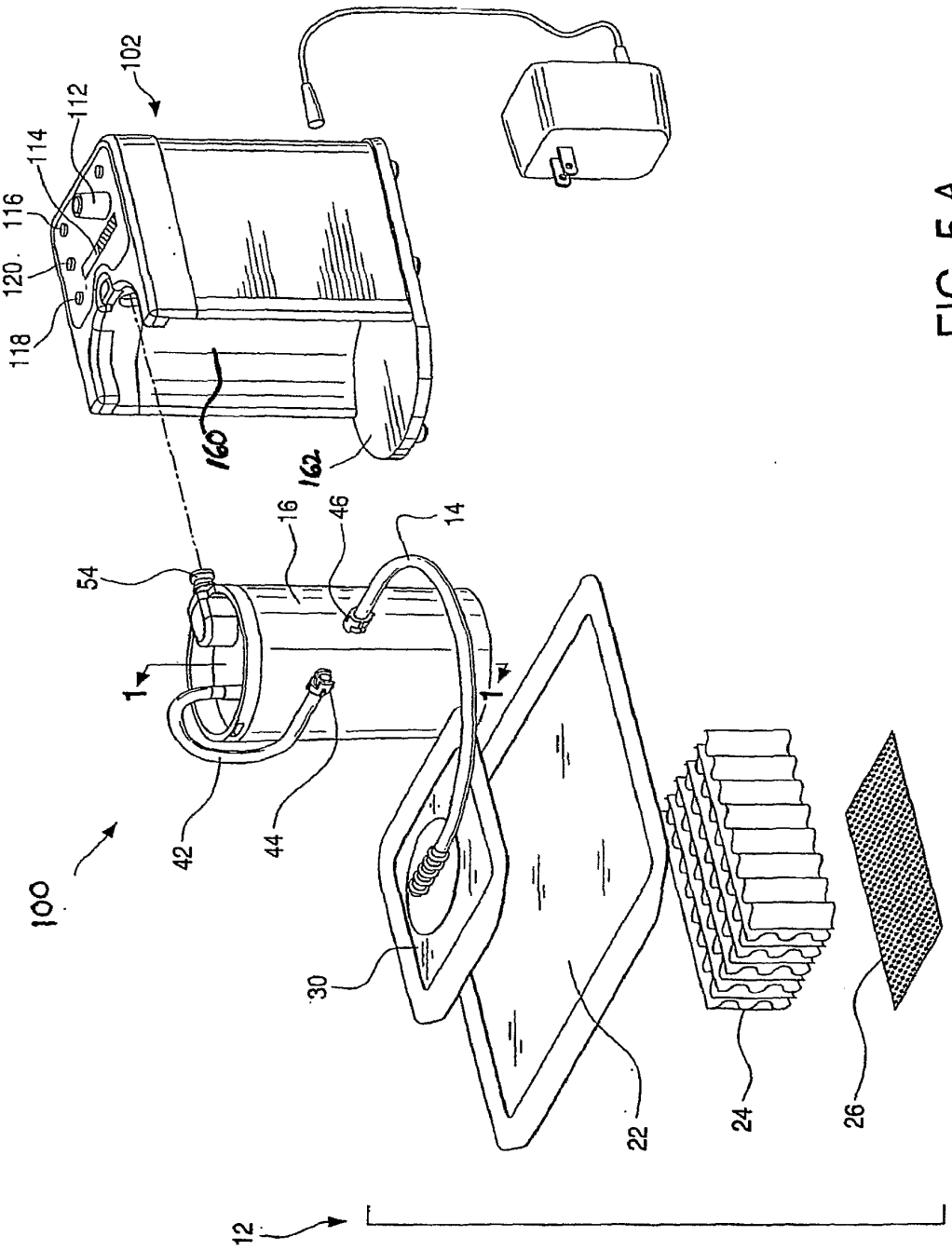

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FIG. 5A

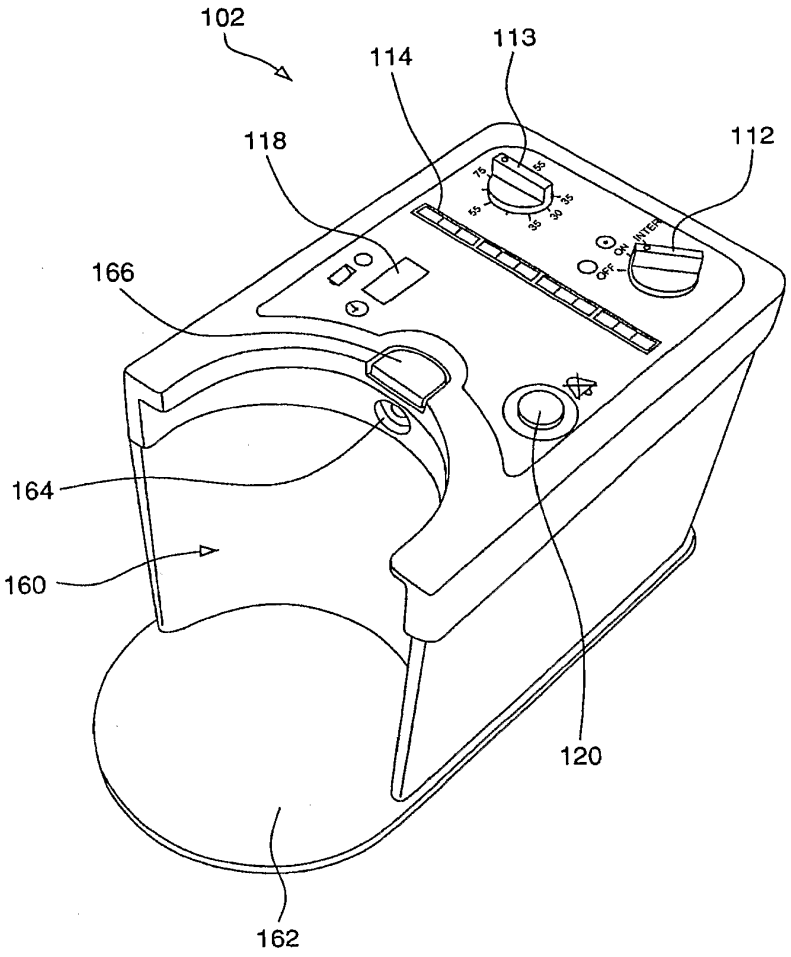


FIG. 5B

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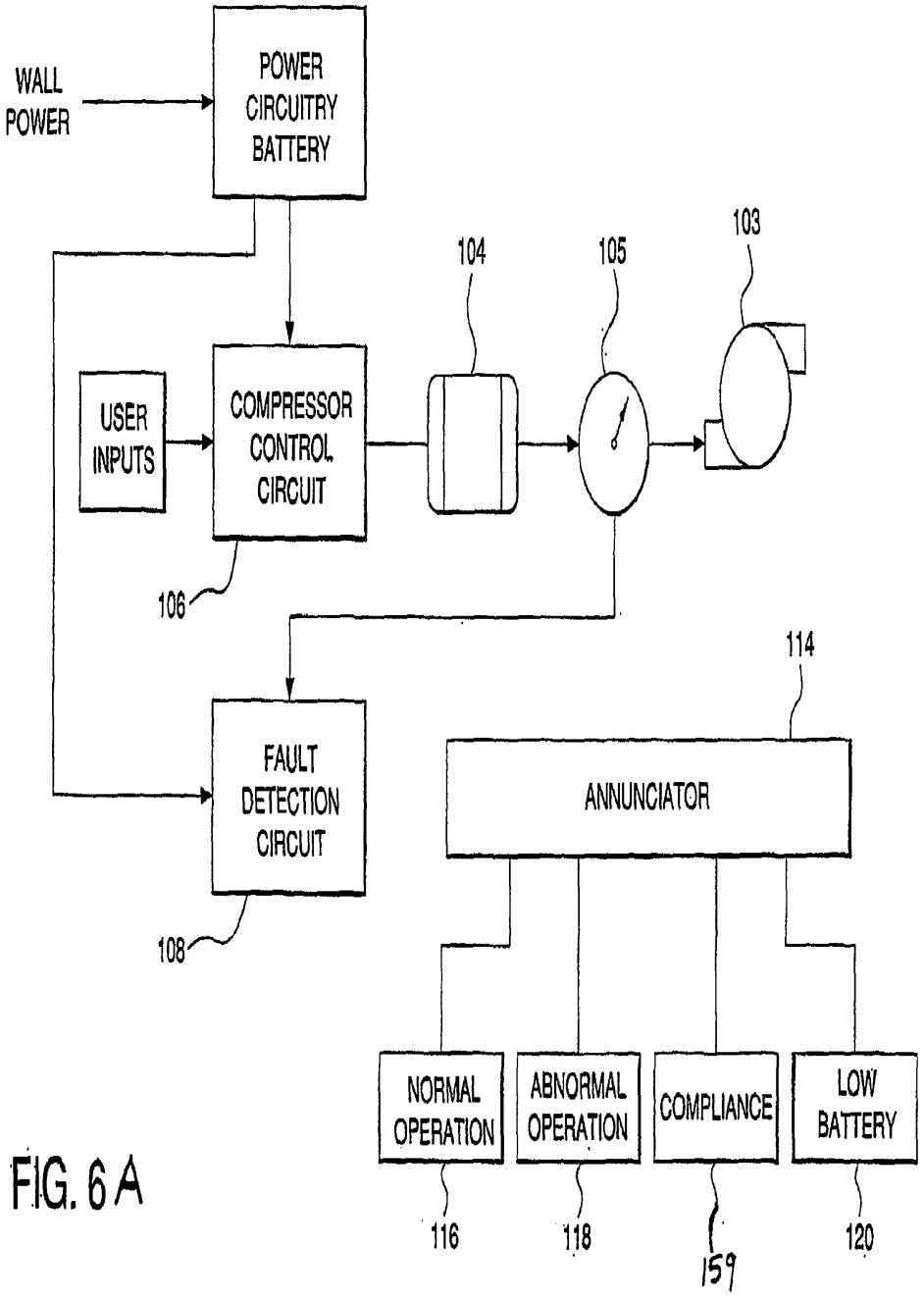

WALL POWER
POWER CIRCUITRY BATTERY
USER INPUTS
COMPRESSOR CONTROL CIRCUIT
104
105
103
106
FAULT DETECTION CIRCUIT
108
114
ANNUNCIATOR
NORMAL OPERATION
ABNORMAL OPERATION
COMPLIANCE
LOW BATTERY
116
118
159
120

FIG. 6A

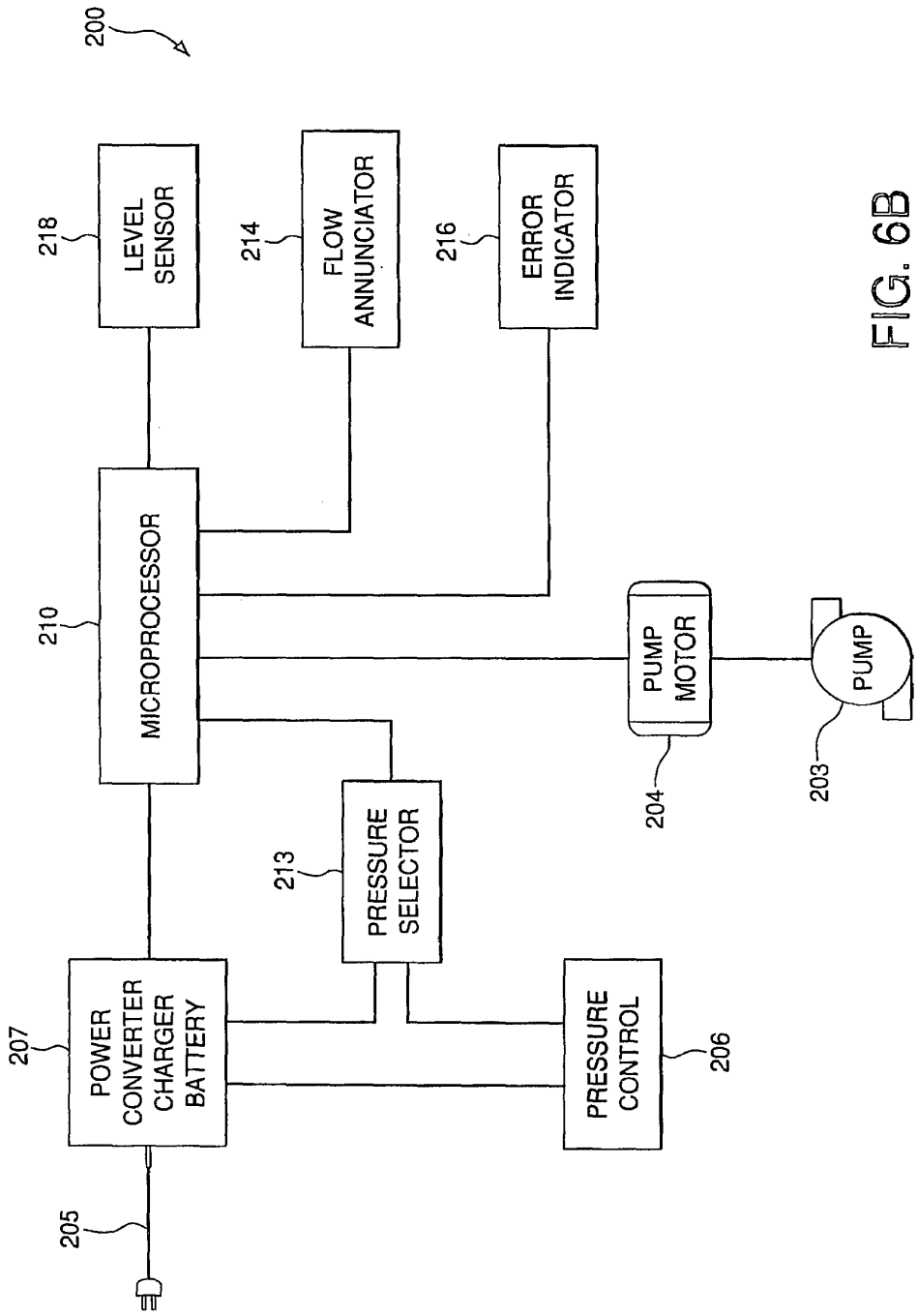


FIG. 6B

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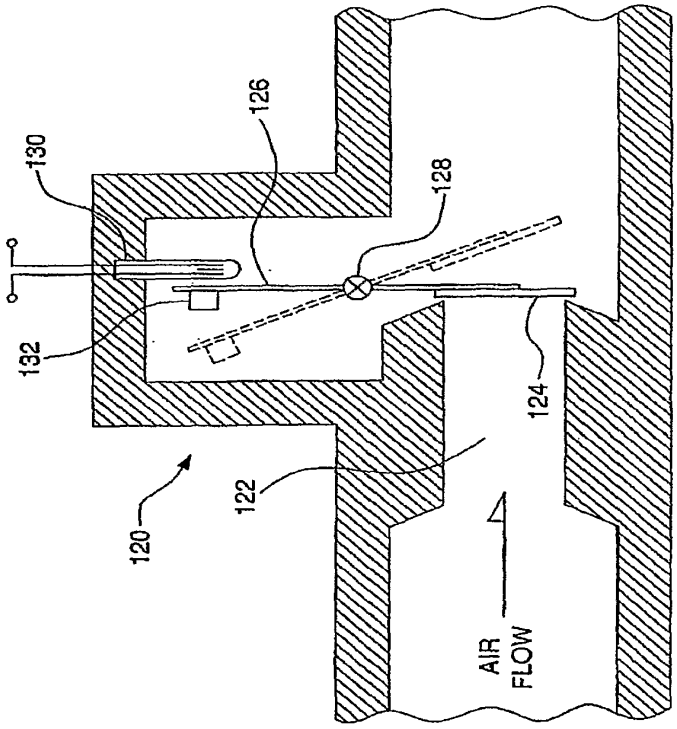


FIG. 7

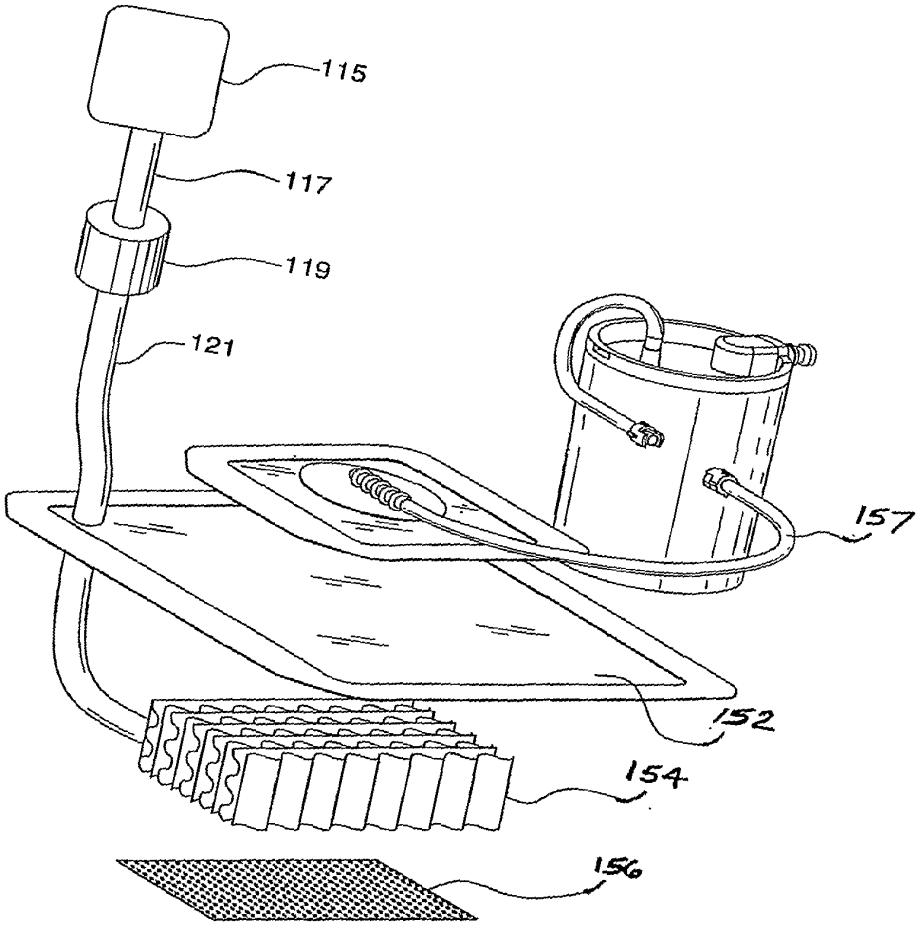


FIG. 8

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(54) Title: PUMP SYSTEM FOR NEGATIVE PRESSURE WOUND THERAPY

(57) Abstract: A pump system for applying negative pressure to a wound, including a flow monitor capable of detecting a deviation from a reference airflow rate provided by a controlled leak to determine whether the system is operating normally or abnormally, and a flow status annunciator to indicate a normal operating condition or whether an abnormal condition is a leak or an occluded line in the system. The pump system further includes a pressure controller for regulating operation of a pump to control pressure in the system at a range around a user-selected setpoint. The pump system may also include a waste collector and a level sensor for detecting when the collector is full.

PUMP SYSTEM FOR NEGATIVE PRESSURE WOUND THERAPY

Reference to Related Applications

[0001] This application is a continuation in part of U.S. Patent Application No. 11/268,212 which was filed on November 7, 2005 and which claims priority of U.S. Provisional Application No. 60/699,218, filed July 14, 2005. This application also claims priority of U.S. Provisional Application No. 60/792,187 filed April 14, 2006, and of U.S. Provisional Application No. 60/847,221, filed September 26, 2006.

Field of the Invention

[0002] The invention relates to the general field of wound treatment, and to the more specific field of devices for wound drainage and treatment with suction.

Background of the Invention

[0003] It is well known to treat wounds by applying suction under airtight wound covers. The suction can be used to aspirate wound exudate and other liquids from the wound and/or the wound packing materials, and the suction can be applied as a healing modality for its well known antiseptic and tissue regeneration effects.

[0004] A primary concern in using suction assisted wound therapy is maintaining consistent suction pressure at the wound. It is increasingly recognized that once suction wound dressings are applied, the suction should be maintained at certain levels. Loss of suction to the wound can result if leaks or blockages occur in the system.

[0005] Leaks can occur through breach of the airtight seals surrounding the wound. The earliest devices merely ran a tube under the edge of a wound cover and applied an adhesive or paste around the tube and cover to maintain an airtight seal. The other end of the tube was connectable to a waste collection reservoir and suction regulator of a hospital suction system, and the pressure selected at the regulator was assumed to be the approximate pressure communicated to the wound area under the cover. The test for leakage was visual observance of the cover contracting and the absence of whistling noise when negative pressure was applied. See, e.g., M. E. Chariker, et al, "Effective Management of Incisional and Cutaneous Fistulae with Closed Suction Wound Drainage", *Contemporary Surgery,*

vol. 34, June 1989, pages 59-63. This initial check for an airtight seal did not, however, provide any warning if the system developed a leak or if blockage occurred in the collection circuit after hours of use.

[0006] The adhesive seal around the suction tube or other tubes which run under the edge of the wound cover in these prior wound dressings is vulnerable to cracking and breaching the airtight seal, creating air leakage into the cover. Improvements have been made to suction wound therapy devices to reduce the likelihood of leakage. For example, U.S. Patent Application No. 11/181,128, filed July 14, 2005 and commonly assigned with this application, discloses a tube attachment patch to allow the suction tube to be terminated outside of the primary cover and thus reduce the risk of breaking the adhesive seal to the skin. While these newer tube attachment devices provide more seal integrity, there is still the potential for breach of the airtight seals due to external causes such as patient movement in bed.

[0007] Blockage of suction to the wound can occur for several reasons. A waste collector for wound exudate is usually positioned somewhere in the suction line between the wound and the suction source. Waste collectors incorporate shut-off mechanisms that will shut off suction to the wound when the collector is overfilled. Another potential blockage is kinking or crimping of the suction line itself. Other potential blockage causes may be debris from the wound, clotting, or drying of wound exudates (particularly where the volume of wound exudates is small relative to the reference airflow). The suction source may also be inadvertently turned off, a line may be inadvertently clamped, or the suction regulator may be misadjusted after the dressing is applied. Since suction wound dressings are intended to last for long periods without changing, usually 24 hours or greater, a leak or blockage could develop unnoticed and not be detected for a duration sufficient to negate the beneficial healing effect of suction as well as increase the risk of infection. There are currently devices to sense when a waste collector canister is filled and provide a warning signal to empty it. None of the devices, however, provides a comprehensive and reliable monitoring of system operation, nor cover the full range of fault possibilities with leakage or blockage.

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[0008] In their efforts to improve over these prior art devices, the present inventors designed a suction wound dressing monitoring system as described in U.S. Patent Application No. 11/268,212. In doing so, they consider the impracticality of locating expensive pressure transducers in any of the system components that should be single-use disposable items due to contamination by body fluids. The designers considered that the same basic system should preferably be effective in detecting and indicating both leaks and system blockage, and that the detection of leaks or blockage should preferably be effective regardless where the leak or blockage occurs in the system. They considered that the system should preferably provide clear visual indication of both normal and abnormal operation, and could usefully provide aural indication and auto-recording of abnormalities. They also considered that the suction monitoring capability should be easily convertible from use with a stationary suction system, as typically found in hospital care rooms, to use with a portable suction pump.

[0009] The inventors considered that particularly when using a stationary suction source, it would be advantageous for the monitoring system to include an air dryer or dehumidifier to remove moisture from the air suctioned from the wound. Often, the air within the system is saturated with moisture (i.e., 100% relative humidity) such that formation of water droplets due to condensation is common and likely. However, such water droplets can potentially interfere with the proper functioning of a flow monitor in the system, and may further increase the likelihood of contamination in the system. Accordingly, a dehumidifier to reduce the humidity of the air would prevent the formation of water droplets and improve the functioning of the system and help to prevent contamination.

[0010] Conversely, the inventors considered that at other times, the system is not saturated and drying of wound exudates may occur in the system conduit, causing or aggravating blockages. Therefore, in some circumstances, it may be advantageous to humidify the air being suctioned from the wound.

[0011] In addition, the inventors have considered that when using a portable pump as the suction source it would be advantageous to use an electronic flow monitor in the monitoring system to detect deviation from a reference airflow and to provide

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corresponding indicators and/or alarms. An embodiment of the electronic flow monitor could be a microprocessor that is further capable of other useful functions, such as recording and accumulating various parameters in time units and providing reports of such time records.

[0012] For safety and redundancy, the inventors considered that it would be advantageous to provide the pump with a pressure controller that is independent of the flow monitor such that the pump can control pressure to a user-selected pressure setpoint without the need to receive or rely on a signal from the flow monitor. However, the pressure controller could provide to the flow monitor data related to pump operation, such as the detection of a faulty pressure transducer or a runaway pump condition. Moreover, a signal from the flow monitor could be used to periodically or temporarily reset the pressure setpoint for the pressure controller to a second pressure lower or higher than the selected pressure, such as for intermittent operation or to create a line clearing pressure pulse if a fluid flow deviation begins to indicate a conduit occlusion.

[0013] The inventors considered that it would be useful for the flow monitor to be coupled to an annunciator on the pump unit, the annunciator including visual and/or auditory indicators, for convenient indication of status conditions related to fluid flow, such as: normal operation, low level leak, high level leak, line occlusion, and filled waste collector, as well as an indication of patient compliant use. They also considered that it would be useful for the pump to have a separate error indicator for convenient indication of error conditions that are not related to fluid flow such as overpressure detection by the pressure transducer, pressure transducer failure, waste collector canister not attached, low battery voltage, attachment of incorrect power supply, low operating time remaining, collection canister full, and pump motor not operational.

[0014] Although the waste collector could be located anywhere between the wound dressing and the vacuum source, the inventors considered that when using a portable pump vacuum source, it would be advantageous for the pump unit to provide a docking station for the waste collector, such that the collector canister can be securely attached to the pump unit. In that configuration, the pump unit may also include a level detector for detecting and indicating the fill status of the waste collector. For example, the pump unit may have a

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level sensor, such as a capacitance sensor, to detect a filled waste collector based upon indications other than pressure differential across a hydrophobic membrane in the collector. If so, the level detector signal may be moderated by an algorithm in the flow monitor to reduce the likelihood of false indications of a full collector caused by sloshing when the pump unit with the waste collector is moved.

Brief Summary of the Invention

[0015] The invention provides a wound treatment system for applying negative pressure or suction therapy to a wound. A reference airflow rate is used for monitoring system operation. The negative pressure wound treatment system includes an airtight wound dressing and a suction conduit having one end operatively associated with the wound dressing to communicate suction to the wound and an opposite end operatively connected with a source of suction. The system preferably includes a waste collector disposed in the suction conduit between the wound dressing and the source of suction for collecting fluids aspirated from the wound. The waste collector may have a residual suction capacity to draw fluid through the conduit when the suction source is shut down. The invention provides a reference airflow rate (or "controlled leak") to the suction source when the system is in operation, such that deviation from the reference airflow can be detected as an indication of a change in operation.

[0016] In a preferred embodiment of the invention, a portable pump unit is used as the suction source. The pump unit has a flow monitor to monitor airflow through the conduit from the wound dressing to the pump as indicative of the level of negative pressure applied to the wound. Deviation from the reference airflow rate can be used as an indication of an abnormal condition such as leakage of the wound dressing or occlusion in the conduit. The flow monitor may be controlled by a microprocessor or by solid state circuitry capable of also providing additional functions including indicating system status and system errors, and further tracking and reporting time histories of system operation. To compensate for variations in the pump volumetric efficiency at a selected setpoint pressure, the flow monitor can have a look-up table to correlate between measured and actual flow rates for a range of negative pressures.

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[0017] For safety and redundancy, the pump unit has a pressure transducer and a pressure controller that can operate independently from the flow monitor. The pressure controller may use solid state circuitry or may be controlled by a microprocessor or may be a simple mechanical-type device. A user-operable pressure selector enables a user to select a negative pressure pump output within a range of negative pressure setpoints. The pressure controller controls the operation of the pump to maintain the pressure sensed by the pressure transducer between upper and lower limits around the selected setpoint pressure.

[0018] The flow monitor provides signals to an annunciator including a flow indicator, preferably a bar meter that is color coded and gradated to provide a visual indication of fluid flow through the pump, and hence through the system conduit. The annunciator indicates when the air flow through the pump is within a range of the reference airflow that is associated with normal system operation, and conversely indicates when a deviation from the reference airflow is associated with an abnormal operation. Compliant time (i.e., the time during which system operation is normal) is accumulated so that the caregiver can make reasonable assessments as to the effectiveness of the therapy.

[0019] The pump also includes an error detector and an error indicator for displaying a visual warning of system errors that are not associated with a deviation of the flow rate through the pump from the reference airflow. Such errors may include overpressure detection by the pressure transducer, pressure transducer failure, waste collector canister not attached, low battery voltage, attachment of incorrect power supply, low operating time remaining, collection canister full, and pump motor not operational. The error detector and error indicator are preferably controlled by a microprocessor or by solid state circuitry, although other mechanisms may be used to control error detection and indication.

[0020] Although the pressure controller may operate independently to maintain the setpoint pressure, a therapy timing controller or the flow monitor can be used to reset the pressure setpoint. For example, the therapy timing controller may periodically reset the pressure setpoint between a higher selected pressure and a second lower pressure when intermittent pressure therapy is desired. For another example, the flow monitor may temporarily increase the setpoint pressure when a deviation from the reference airflow rate begins to indicate an occlusion, such that pressure controller causes the pump to start or to

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increase in speed, creating a vacuum pressure pulse capable of clearing the conduit between the wound dressing and the waste collector.

[0021] The pump may also include a timing subsystem to record and accumulate the time units based upon inputs from other sensors, and to provide reports of the time units that the pump is running. The reports may include a record of runtime intervals, a record of the date and duration of runtime intervals, a record of total accumulated runtime, a record of accumulated compliant runtime, and a record of runtime remaining on a preset runtime period.

[0022] Various waste collectors may be constructed for collecting wound exudates under negative pressure conditions, including, for example, a flexible bag having an internal support. A preferred waste collector is a disposable upright cylindrical transparent plastic canister with fill level markings on an outside surface. The waste collector canister may be prevented from overfilling by a hydrophobic membrane filter at the top of the canister that shuts off the air flow when the canister is full. The liquids aspirated from the wound may be turned into a gel, for ease of disposal and to prevent spilling, by a gelling agent in the disposable canister. To keep the waste in the canister level, the gelling agent is preferably provided in stacked disks. The waste collector has an inlet connector for a suction tube coming from the wound dressing, and an outlet connector for connecting to a portable pump, a dehumidifier, or a flow monitor. The outlet connector is preferably a proprietary (non-standard) connector that will not connect directly to the standard appliance fitting of a stationary suction system, to prevent the wound from being subjected to excessive suction if the conduit were to be mistakenly connecting directly to the suction system without pressure regulation.

[0023] The pump unit may provide a docking station for the waste collector, such that the collector can be securely attached to the pump. The pump unit preferably has a docking station with a profile conforming to an outer surface of the waste collector and a releasable latch fitting adapted to receive the outlet connector of the waste collector.

[0024] The pump unit may have a sensor proximate to the collector docking station for detecting the level of waste in the canister, the level sensor preferably being a capacitance

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detector. The flow monitor is capable of receiving a signal from the level sensor indicating a full collector canister, and the flow monitor may include an algorithm to be applied to the signal to reduce the likelihood of an erroneous indication of a full canister caused by liquid sloshing inside the canister.

[0025] The negative pressure wound therapy system may include a dryer or dehumidifier disposed in the conduit between the waste collector and the suction source, and preferably between the waste collector and the flow monitor, for reducing the tendency of condensate droplets to form in the system.

[0026] Some applications may necessitate adding moisture to the wound for therapeutic purposes, to maintain a clear collection conduit, or to prevent drying of wound exudates within the conduit. Moisture in the form of humidity and/or a liquid may be added to the wound via a separate conduit or directly into a calibrated vent.

[0027] The pump is preferably a portable battery-powered positive displacement pump in which flow rate is approximately proportional to pump speed, such that the flow rate of the system can be detected indirectly by measuring the motor speed or pump speed. A pressure transducer combined with an algorithm or look-up table may be used to correct motor and pump speed to flow for compressibility effect. Thus a motor speed indicator or tachometer may be the preferred monitoring instrument to provide input to the flow monitor. However, other flow rate monitoring instruments could be used, including but not limited to target meters, rotometers, turbine meters, mass flow meters, differential pressure cells, and hot wire anemometers.

[0028] The pump unit may have an activated charcoal air filter disposed at an air discharge port of the pump for reducing odors emanating from the pump. The filter may also include a desiccant. The pump may utilize a controlled backpressure to lessen the noise inherent in the operation of the check valves in a positive displacement pump, such as a leaf spring sound damper disposed over the pump outlet.

[0029] In a preferred embodiment, a calibrated vent in the suction conduit or tube near the wound dressing establishes the reference airflow by effectively providing a controlled leak rate. The calibrated vent may include, but is not limited to, an orifice, a needle valve,

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or a sintered porous element. Preferably the vent is located in the tube just outside of the wound cover. The vent may be an aperture in the tube sealed with a porous material having specific flow rate characteristics. The reference airflow rate may be in a preferred range of 50-300 cubic centimeters per minute (cc/min). Higher flows such as 1000 cc/min are possible, but practical limitations on the capacity of the suction source and line losses inherent in small diameter tubing, as well as the ability to detect the typical magnitude of a leak in the wound dressing, suggest that is preferable to use a flow below 1000 cc/min.

[0030] By locating the vent in the conduit close to the wound dressing, the reference airflow also serves to purge the conduit of fluids and other wound exudates. The purging effect minimizes the likelihood of reflux of contaminated fluid back into the wound, and the risk of infection attendant to such reflux. Since the fluid does not reside in the conduit for an extended time, the purge effect also reduces the likelihood of blood clotting in the line. The pump system may also provide a pressure pulse generator to clear the collection line of serial slugs of fluid if a reduction in flow is detected.

[0031] Although the term "airflow" is used herein for consistency, it should be apparent that it is not limited to the composition of ambient air. It is common in medical settings to alter the composition of airflow to a wound, such as by increased oxygen or therapeutic aerosols or other beneficial medications. It is also understood that in addition to air, the suction source will draw wound exudates and bodily fluids through the suction conduit. The flow of any of these mixed gases or aerosol suspensions, any of which may include wound exudates, should be considered airflow for purpose of this description. The term "fluid flow" is sometimes used interchangeably with "airflow" to more generally indicate a flow of air, possibly including liquid exudates, in the system.

[0032] These and other advantages and aspects of the invention will become apparent upon reading the detailed description and drawings that follow.

Brief Description of the Drawings

[0033] Figure 1 is an exploded prospective view of an embodiment of a system for negative pressure wound therapy.

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[0034] Figure 2 is a perspective view of a suction tube attachment device showing an air vent in the suction tube to create a controlled reference airflow rate to the suction source.

[0035] Figure 3 is a cross-sectional view of a waste collector of Figure 1, taken through section 3-3, showing the shutoff membrane and gel agents.

[0036] Figure 4 is a cross-sectional view of a flow monitor of Figure 1, taken through section 4-4.

[0037] Figure 5A is an enlarged perspective view of a preferred embodiment of a system for negative pressure wound therapy using a portable suction pump.

[0038] Figure 5B is a prospective view of the top front of a portable pump unit that may be used in the system of Figure 5A.

[0039] Figure 6 is a control schematic diagram corresponding to an embodiment of a pump unit.

[0040] Figure 7 is a schematic view of an alternate flow monitor using a target meter.

[0041] Figure 8 is an exploded perspective view of a portion of an alternate embodiment of a system for negative pressure wound therapy including therapeutic fluid delivery to the wound.

[0042] Figure 9 is an exploded perspective view of an embodiment of a system for negative pressure wound therapy including a dehumidifier.

[0043] Figure 10 is a schematic cross-sectional view of the dehumidifier of the system of Figure 9.

[0044] Figure 11A is a front view of the dehumidifier.

[0045] Figure 11B is a cross-sectional view of the dehumidifier of Figure 11A taken through section 11B-11B.

[0046] Figure 11C is a top view of the dehumidifier of Figure 11A.

Detailed Description of the Invention

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[0047] Figure 1 shows an embodiment of a system (10) for negative pressure (suction) wound therapy. The system (10) includes a wound dressing (12), a flow monitoring device (18), and a suction regulator (20) for regulating vacuum from a stationary suction source. Figure 5A shows an alternate embodiment of a system (10) for negative pressure wound therapy where a portable suction pump unit (102) is used in place of the suction regulator (20) and the stationary suction source.

Wound Dressing

[0048] The wound dressing (12) typically includes a primary wound cover (22) and wound packing material (24), and may include a special wound contact layer (26). A suction tube (14) communicates with the wound packing material (24) by running under the edge of the wound cover (22), by extending through the wound cover (22), or by terminating outside of the wound cover (22) and communicating with a nozzle or slot in the wound cover (22). Various wound dressings (12) may be used comprising a wide variety of wound covers (22), wound packing materials (24), optional wound contact layers (26), and means for communicating the suction tube (14) with the packing material (24). The wound dressing (12) shown in the drawings and described herein uses presently preferred components, but the invention is generally applicable to any wound dressing subsystem (12) and is not intended to be limited to any particular components.

[0049] The primary wound cover (22) is preferably an airtight wound cover that is vapor permeable. The term "airtight" means that the material is sufficiently occlusive to resist airflow through the cover to maintain suction under the cover while suction is being applied. It is preferred to use a thin film transparent commercial bandage, such as medical grade Tegaderm™ manufactured by 3M, that is impermeable to liquids but permeable to water vapor and oxygen. There are many other thin-film commercial bandages that have similar properties. Highly impermeable materials could also be used. However, since it is beneficial in wound therapy to allow water vapor to escape and oxygen to migrate into the wound, semi-permeable covers of film material such as Tegaderm™ are preferred. In some instances, the primary wound cover (22) could also be a rigid or semi-rigid enclosure placed over the wound. The primary wound cover (22) is generally sealed to the skin surrounding the wound with an adhesive (not shown) incorporated in the wound cover (22), and gap filler paste (not shown) may be used where needed.

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[0050] Before the wound cover (22) is applied, the wound is generally packed with a wound packing (24). The wound packing (24) may include simple gauze or foam pads or other materials commercially sold as wound packings. The presently preferred wound packing (24) is polyester fibers or comparable resilient fibers in a corrugated layer pattern configured to form a resilient compressible structure, as described in U.S. Patent Application No. 10/981,119, commonly assigned with this application.

[0051] The wound packing (24) may also be attached to a wound contact layer (26). The presently preferred wound contact layer (26) has a special construction that provides a wound contact surface, with depressions formed into the surface, to work in conjunction with the suction to encourage more rapid tissue regeneration, as described in U.S. Patent Application No. 10/982,346, commonly assigned with this application. The contact surface is configured such that voids formed by the depressions remain above the wound surface in the presence of moisture, compressive forces, and suction, thus encouraging local tissue deflection.

[0052] The wound dressing (12) has a suction tube (14) attached to the wound cover (22), as shown in Figure 2. The wound dressing (12) may have one or more other tubes (28) for medication supply or wound flushing. The tube(s) (14, 28) may pass through the wound cover (22) or under the edge thereof, but a presently preferred arrangement uses a tube attachment patch (30) to allow the suction tube (14) to be terminated outside of the primary wound cover (12) to reduce the risk of breaking the adhesive seal to the skin, as described in U.S. Patent Application No. 11/181,128, commonly assigned with this application.

[0053] A distal end of the suction tube (14) in this embodiment has a vent hole (32) that is sealed with a porous plug (34). The porous plug (34) provides a controlled leak, or reference airflow, for flow monitoring devices described hereafter, including the flow monitoring device (18). The vent (32, 34) should be located outside the primary wound cover (22) but is preferably located as close to the wound cover (22) as possible. An advantage of having the suction tube (14) connected to the tube attachment patch (30) outside of the wound cover (22) is that controlled leak reference airflow may be used without drying out the wound, as might occur if the suction tube (14) passed under the

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wound cover (22) near the wound. While it is feasible to route the suction tube (14) under the wound cover (22) while the controlled leak vent (32, 34) is outside of the actual wound space, it would be important to avoid excessive drying of the wound tissue due to the introduced airflow. In addition, it is possible with the type of tube attachment patch (30) shown in Figure 2 and described in U.S. Patent Application No. 11/181,128 to provide the porous vent (32, 34) as an aperture in the patch (30).

[0054] A wound therapist applies the wound dressing (12) to the patient and attaches the system to suction. The therapist remedies leaks in the dressing by smoothing out creases or wrinkles in the wound cover and addressing gaps due to folds in the patient's anatomy. It has at times been useful to address specific areas of difficult anatomy by using a gap filling paste, as is common in ostomy care, such as moldable strip paste from Coloplast. The airflow monitoring instruments described hereafter facilitate the initial dressing set up process by providing active feedback to the therapist on the integrity of the seal around the wound dressing and tubes.

Waste Collector

[0055] Since a primary function of negative pressure or suction therapy is to drain liquids from the wound, a system (10) normally includes a waste collector (16) for collecting fluids aspirated from the wound. As shown in the embodiment of Figure 1, the air passage through the collector or container (16) forms a part of a suction conduit between the wound and the suction source. As shown in cross-section in Figure 3, the collector (16) may be an upright canister (36) with a right circular cylinder profile. The canister (36) is preferably made of a transparent or semi-transparent material such as plastic that enables viewing of the level of liquid contained therein. The canister (36) may have fill level markings in a band extending vertically along the outside of the canister. The markings may be on a paper label adhesively glued to the canister (36) or may be marked, embossed, or etched directly onto the canister (36). The fill level markings may also be created on the pump unit (102). The canister (36) is preferably a disposable, single-use device. The canister (36) has a lid (38) incorporating a fitting (40) passing through the lid (38) for the attachment of an inlet tube (42). The inlet tube (42) may be an end of the suction tube (14) leading from the wound or a short section of tube that terminates with a connector fitting (44) for mating with a matching connector fitting (46) on the end of the suction tube (14).

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[0056] Airflow and any blood or other fluid aspirated from the wound passes through the fitting (40) in the lid and into the canister (36). The liquid is retained in the canister (36), while the air rises and is drawn through a hydrophobic membrane (50) sealed to the inside of the lid (38). The upstream side of the membrane (50) interfaces with the interior of the canister (36) and the downstream side of the membrane (50) interfaces with an outlet air channel (52). The membrane (50) acts as a bacteria filter. Because the membrane (50) is hydrophobic, it can be used as a shut off mechanism to prevent the canister (36) from overflowing and to prevent contamination from flowing out of the collector (16) toward the suction source. If the canister (36) is allowed to fill high enough for the contents to contact the membrane (50), the membrane (50) occludes and blocks airflow from passing through the collector (16). Blockage of the membrane (50) prevents suctioning more waste from the wound, and as described hereafter, the blockage of reference airflow is detected as an indication of an abnormal operating condition. In other embodiments described hereafter, the level of waste product in the canister (36) can be detected by a capacitance sensor or other detector on the pump unit (102), and the detection used to prevent overfill of the canister (36).

[0057] The lid (38) defines the outlet air channel (52) extending from the downstream side of the membrane (50) to a connector (54) for connecting the collector (16) to the portable pump unit (102) or to a tube (58) running to a stationary wall suction system. However, the connector (54) is preferably a proprietary (non-standard) connector that will not connect directly to the standard appliance fitting of a stationary suction system, in order to prevent the collector (16) from being mistakenly connected directly to the suction system without the flow monitoring device (18) and pressure release features described hereafter; connecting the collector (16) directly to a suction system could risk applying too great a suction to the wound. The mating receptacle in the portable pump configuration described hereafter is configured to receive the proprietary connector. The connector (54) includes a sealing element such as an o-ring seal. This arrangement provides that a fresh o-ring is preferably used with each disposable collector (16), as contrasted with other pump connectors where the sealing element is in the pump and will ultimately wear out and cause the system to fail because of leakage.

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[0058] Preferably the liquid waste sucked from the wound is turned into a gel for ease of disposal and to prevent spilling or splashing. Although the gelling agent could be provided in porous bags, it is preferred to use disks (56) of laminated fiber sheets containing a gelling agent, such as provided by Gelok International. The disks (56) are cut to fit inside of the canister (36) and are stacked on top of each other. The stacked disks (56) cause the liquid to turn to a level surface gel in the canister (36).

Controlled Reference Airflow

[0059] Some prior art negative pressure wound therapy systems do not monitor the flow of fluid (air and effluents) being suctioned from the wound dressing (12), while others do so less than optimally by trying to directly sense pressures at the wound. In contrast, the system described herein uses a reference airflow, as may be provided by a calibrated orifice, valve, or filter or by the controlled leak air vent (32, 34), to indicate whether the system is in normal or abnormal operation. The porous plug (34) is calibrated to provide a known reference airflow or controlled leak. A flow rate at or near the reference airflow indicates normal operation, while a flow rate that deviates appreciably (either higher or lower) from the reference airflow indicates abnormal operation. A flow rate higher than the reference airflow indicates leakage, while a flow rate lower than the reference airflow indicates blockage or occlusion or a full waste collector (16).

[0060] The reference airflow rate from the calibrated vent (32, 34) is used for monitoring fluid flow and thus for assessing overall system operation. The controlled leak rate should be low to maintain a proper suction at the wound site and a moist healing environment. Preferably the reference airflow is in the range of 50-300 cubic centimeters per minute (cc/min). More preferably, the reference airflow is approximately 100 cc/min. A flow of 50-300 cc/min is low enough to minimize drying and does not significantly alter the suction applied at the wound. Additionally, the flow is low enough to minimize the use of battery power where a portable pump is used as the suction source. A flow of this magnitude is readily obtained by providing a vent hole (32) in the suction tube that is sealed sterile with a porous plug (34). A suitable seal material for the porous plug (34) is a porous plastic manufactured by Porex from sintered high density polyethylene. Such porous materials are routinely employed to admit air into medical fluid lines at a sufficient flow rate to maintain an efficient sterile filtration barrier against microbes.

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[0061] An advantage of providing the reference airflow is that the tube (14) between the wound packing (12) and the waste collector (16) remains relatively clear of fluids since the continuous flow will encourage rapid movement of a plug of fluid from the wound packing (13) to the collector (16). Liquid aspirated from a wound may contain sufficient blood materials that it could be prone to clotting in a collection tube, lumen, or conduit if allowed to sit in a stationary condition for a period of time, and a clot in a collection line would result in loss of suction being applied to the wound. The reference airflow eliminates this potential problem. Typically, it is expected that the tube (14) could be cleared by the reference airflow in less than ten seconds, depending on the distance.

[0062] The range of flows suitable for a reference airflow rate are bounded at the lower end by the permeability of the wound cover (22) and at the upper end by the suction capacity of the suction source or pump. When the wound cover (22) is a semi-permeable material, there will be a natural low level background airflow from air molecules passing through the wound cover (22). This permeation airflow could serve as the reference airflow if the flow monitoring instrument were very sensitive. However, the permeation flow is usually too low and too erratic to be a good reference. Variations in the area of the cover and the possibility of the cover being obstructed by drapes and fluid from the wound can cause the permeation flow to be erratic. Thus, a calibrated vent, such as the porous vent (32, 34) is a preferred reference because it provides a larger and more stable flow rate that masks variations in the permeation flow. For example, Tegaderm® bandage will allow a diffusion of water on the order of 800 grams per square meter per day, which correlates to a flow rate of about 0.5 cc/min over a square meter. Typical wound cover area would be less than a tenth of a square meter, so in approximate terms, the semi-permeable material contributes 0.05 cc/min, or less than 0.1% of a reference airflow of 50 cc/min. Thus, any variation in the background permeation flow is masked by the larger reference airflow.

Flow Monitoring Device for Use with Stationary Suction Source

[0063] At least two embodiments of the flow monitoring device (18) may be used: a gradated mechanical indicating float meter (19) as shown in detail in Figure 4 and an electronic non-numerical indicator (232) as shown in detail in Figure 5B. The float meter (19) would preferably be used in conjunction with a stationary suction source (20) while the non-numerical indicator (232) would preferably be used with a portable pump unit (102)

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having a flow monitor (206). Other types of flow monitoring and indicating devices, such as target meters or hot wire anemometers could also be used.

[0064] In the system (10) of Figure 1, the flow monitoring device (18) comprises a float flow meter (19) that includes a suction conduit (58) interconnecting between the waste collector (16) and the stationary suction source. One end of the conduit (58) includes a mating connector (60) adapted to receive a proprietary connector (54) on the collector (16). The flow monitoring device (18) is preferably located at the opposed end of the conduit (58) from the collector (16) and attaches directly to an appliance connection fitting (64) associated with the adjustable suction regulator (20) as commonly found on stationary suction systems.

[0065] The flow meter (19) provides a visual indication of the flow rate through the system (10). During normal operation, once the flow rate has stabilized following an initial application of suction, the flow meter (19) provides a visual indication corresponding to the reference airflow rate. As long as the flow meter (19) maintains a visual indication of reference airflow rate, the system (10) is operating normally and is free of leaks or blockage, and hence the wound dressing (12) is subject to an acceptable level of suction. When the flow meter (19) provides a visual indication of a deviation to a higher air flow, the system (10) is operating abnormally because a higher air flow indicates leakage. The flow meter (19) may include one or more gradations of flow rates higher than reference airflow to indicate the magnitude of a leak. When the flow meter (19) provides a visual indication of a deviation to a lower air flow, the system (10) is operating abnormally because a lower air flow indicates occlusion or blockage in the system between the wound dressing (12) and the flow meter (19).

[0066] Figure 4 shows a cross-sectional view of the float meter (19). A standard connector (63) on the top end of the indicator attaches to a short conduit (62) connectable to the appliance fitting (64) of the adjustable suction regulator (20). At the bottom end of the flow indicator a standard connector (59) is attached to the suction conduit (58).

[0067] As shown in Figure 4, the flow meter (19) includes a clear tube (76) gradated into progressive sections (68, 70, 72, 74), each section having a different inside diameter.

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The narrowest section (68) is disposed at the bottom of the flow meter (19) and each successive section (70, 72, 74) moving upwards through the tube (76) is progressively larger in diameter. The gradated markings (not shown) indicate an airflow rate corresponding to various vertical locations along the tube (76). A float (78) is disposed within the tube (76) and serves as an indicator of flow rate through the flow meter (19) and thus through the system (10). Each section (68, 70, 72, 74) indicates a range of flow rates at which the float (78) will reside in that respective section.

[0068] The mass of the float (78) works in cooperation with the density (i.e., the pressure) of the flowing fluid and the clearance between the outside of the float (78) and the inside wall of the tube (76). It is typical to use suction in the range of 25-200 mm Hg in wound therapy. Accordingly, the flow monitoring device (18) incorporates a first flow restrictor (66) having an orifice (67) that is calibrated to restrict suction airflow to be less than 20 liters per minute when a controlled level of suction of 100 mm Hg is applied by the suction regulator (20). The density of the float (78) and the inside dimensions of the tube (76) are preferably calibrated for flow at a pressure of 100 mm Hg, although the indicated flow rates at different pressures are readily calculated. Additionally, the response of the float (78) to various flow rates and pressures through the same tube (76) can be changed by changing the density of the float (78).

[0069] The float (78) responds to airflow rate and will rise to a level where the dynamic forces are in equilibrium, balancing the upward force of the flow against the downward force of gravity. The gradated tube (76) is in contrast to typical flow indicators for other applications which have tubes with continuously increasing inner diameters. In those types of meters, slight changes in flow rate cause the float to chatter up and down around a height indicative of the flow rate. The use of discrete sections of uniform diameters, but increasing in progression, as the four sections (68, 70, 72, 74) in the tube (76) of the preferred flow indicator (19), reduces the chatter and causes the float (78) to move upward in stages. These stages are selected for discrete flows that provide easily interpreted reference information regarding the suction applied to the wound.

[0070] When there is no air flow, or an air flow rate less than the reference airflow, the float (78) rests at the bottom of the tube (76) in the lowest section (68). The lowest section

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(68) is preferably color-coded blue to indicate a blockage condition, such as a full collector (16) or an occlusion in the fluid path such as a blocked vacuum tube (14). When the flow into the flow meter (19) corresponds to the reference airflow, preferably between about 50 cc/min to about 300 cc/min, the clearance between the float (78) and the bottom section (68) of the tube (76) is such that the flow around the float (78) will cause the float (78) to rise into the next progressively wider section (70). Thus, normal reference airflow will cause the float (78) to rise a discernable amount into the next section (70). The section (70) of normal operation is color-coded green, indicating an acceptable condition.

[0071] When flow through the system (10) increases beyond an acceptable level due to a leak in the wound dressing (12), the clearance around the float in the normal position (70) may no longer be adequate to allow the float (70) to remain in this position, and the increased flow will lift the float (78) to a higher section in the tube (76) where the internal diameter is stepped up. The gradated labeling on the outside of the tube (76) provides a visual indication of the extent of the leak condition. The tube (76) includes at least one section (72) of increased diameter to indicate a leak condition and preferably includes two sections (72, 74) to indicate two levels of leak conditions, wherein the lower level leak condition section (72) is disposed immediately above the normal operation section (70), the section (72) having a larger diameter than the section (70), and the higher level leak condition section (74) is disposed immediately above the lower level leak condition section (72), the section (74) having a larger diameter than the section (72). The lower level leak condition section (72) is color-coded yellow, indicating a minor leak requiring repair. The higher level leak condition section (74) is color-coded red, indicating a major leak requiring immediate repair. The stepped up diameters require a significant change in flow before the float (78) will jump from one position to a higher one, thus eliminating the jumpiness that would be encountered with a continuous taper inner diameter as common in flow meters for other applications. Further, the stepped diameter sections (68, 70, 72, 74) reduce user interpretation, thus enhancing ease of use and safety. Additional stepped up diameter sections may be provided to indicate higher leak conditions or finer gradations in the level of leak.

[0072] The flow monitoring device (18) also incorporates a safety valve (80) that limits the maximum suction that may be applied through the system (10), guarding against the

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accidental application of excessively high levels of suction to the wound. It is typical to use suction in the range of 25-200 mm Hg for wound drainage and therapy. Accordingly, the suction limiting feature may preferably be set to limit the suction to no more than approximately 200 mm Hg. The safety valve (80) includes a suction pressure relief chamber (84) formed between the first flow restrictor (66) and a second flow restrictor (82) having an orifice (83). The orifice (83) is preferably about the same size as the orifice (67) in the first flow restrictor (66) to prevent the flow capability of the suction regulator (20) or the pump (103) from overpowering the relief capability of the safety valve (80). A resilient valve mechanism (86) in the relief chamber (84) serves as a release against the application of high levels of suction. The valve mechanism (86) is spring loaded to a predetermined suction setting, such as 200 mm Hg. If the suction pressure in the relief chamber (84) exceeds the predetermined setting, the valve mechanism (86) will open and allow vent air to be drawn into the system (10) from a relief port (69) to prevent excess suction from being applied to the patient's wound.

[0073] Protrusions (75) may be provided on the top underside of the interior of the float meter (19) adjacent to the first flow restriction orifice (67) to prevent the float (78) from completely blocking the orifice entry (67) to the pressure relief chamber (84), thus allowing the continued flow of fluid through the system (10) even if a major leak occurs. This allows continued communication of some suction to the wound even at high airflow rates. Alternatively, the protrusions could be located on the top surface of the float (78).

[0074] While the flow monitoring device (18) using a float meter (19) has been described in the context of a hospital wall suction system, it can also be used with suction pumps such as the portable pump unit (102), as is described below.

Dehumidifier

[0075] The negative pressure wound therapy system may include an air filter/dryer or dehumidifier (21) to protect the downstream components, and in particular the suction source, from potential contamination in the form of particulate matter, aerosols, and humidity. The dehumidifier (21) is preferably disposed in a system conduit between the waste collector (16) and the flow meter (19). Figure 9 illustrates an embodiment of the

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negative pressure wound therapy system including the air dryer or dehumidifier (21) conveniently integrated into a mount for the waste collector (16).

[0076] The dehumidifier (21) may include a particle filter (68) for removing airborne dust as may be encountered when the flow meter (19) is disconnected from the collector (16) for periodic changeover. Humid air exits the waste collector (16) after any liquids have been substantially removed from the wound exudates, but sufficient moisture may remain in the air such that the relative humidity is at or near 100%. At such a high relative humidity, any drop in temperature or pressure may cause condensate to drop out of the air. Accordingly, the dehumidifier (21) removes moisture from the humid air that could otherwise effect the calibration of the flow meter (19). A desiccant or other means of humidity control can be placed in the dehumidifier (21), as required.

[0077] The dehumidifier (21) may also operate by removing moisture from the humid air exiting the waste collector (16) by causing the humid air to pass across one side of a membrane (260) that is impermeable to air but is permeable to water vapor, and concomitantly causing ambient room air, at a relative humidity level much less than 100%, to pass across an opposite side of the membrane (260). Figure 10 schematically illustrates operation of the dehumidifier (21). Due to the properties of the air-impermeable, water vapor-permeable membrane (260), moisture from the higher humidity system air is transferred to the lower humidity room air. The lowered humidity of the system air exiting the dehumidifier (21), at a relative humidity below 100%, prevents the formation of condensation droplets in downstream components such as the flow meter (19) or the suction source.

[0078] The dryer or dehumidifier (21) includes two separate airflow paths (A) and (B) separated by the generally air-impermeable, water vapor-permeable membrane (260). Because the flow meter (19) is a precise device that indicates the quantity of system fluid flow, the dehumidifier is constructed so that the membrane (260) is air tight and air-impermeable such that air from the room side (B) cannot mix with air on the system side (A). At the same time, the membrane (260) should have good water transport properties to remove water from the system air. The membrane (260) is ideally a Dupont Nafion membrane with known water vapor transport properties, although other similar or

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equivalent membrane materials may be used. System air (a), having high humidity, flows from the waste collector (16) into a dehumidifier inlet (262). System air (a) flows across a surface (264) of the membrane (260) and then out a dehumidifier outlet (266) after passing through a particulate filter (268). System air then flows to the flow meter (19). Ambient air (b) enters the a dehumidifier inlet (270) and flows across a surface (272) of the membrane (260). Ambient air (b) exits a dehumidifier outlet (274) and is drawn into the suction source via a conduit (61).

[0079] System air (a) exiting the waste collector (16) is generally very humid (up to 100% relative humidity) due to the liquids that are being collected from the wound. Ambient air (b) is generally less humid; most hospital environments may have relative humidity in the 50% range, depending of course upon the prevailing outside temperature and weather conditions. The resultant moisture gradient across the membrane (260) causes water vapor (c) to be transported through the membrane (260) from the system air flowpath (A) to the ambient air flowpath (B), thus removing water vapor from the system air. As a result, the relative humidity of the system air is reduced to less than 100%, preventing condensation droplets from forming in the flow meter (19) and minimizing the chance that the flow meter (19) will malfunction due to water droplet formation.

[0080] Figures 11A, 11B, and 11C illustrate the dehumidifier (21) in more detail. In a preferred embodiment, as shown, the dehumidifier (21) also serves as a mount for the waste collector (16). The system air inlet (262) serves to accept the outlet connection fitting (54) of the collector (16), which may be secured to the dehumidifier (21) by a spring-loaded latch (280). A set of extending nubs (282) support the membrane (260) inside the dehumidifier (21) and provide flow channels for the system air to pass on the (A) side and position the membrane (260) to provide a flow passage for ambient air to pass on the (B) side.

Portable Pump Unit for Use as the Suction Source

[0081] The system (10) described herein may be used in conjunction with a stationary suction source as provided in most medical buildings, or may be used in conjunction with electrical power pumps to provide suction for wound therapy. However stationary suction sources, and even electric power pumps that may be moved from outlet to outlet, have

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limited portability. Accordingly, an embodiment of the system (100) provides a truly portable battery powered pump unit (102). In a portable pump embodiment (100) of the suction system, as shown in Figure 5A, the suction source is a portable suction pump unit (102) instead of a stationary suction source. Additionally, the use of an electronically controlled suction pump, for example by using a pump unit controller (200) as illustrated in Figure 6, provides the ability to incorporate further advanced control, monitoring, and alerting features into the negative pressure wound treatment system (100).

[0082] The pump unit (102) connects to the same patient circuit, including the wound dressing (12) and the waste collector (16), as described in regard to the negative pressure wound therapy system (10). The pump unit (102) preferably operates on low voltage DC power and has an onboard power source (222) such as a 12 volt battery. The pump unit (102) may also be adapted to be powered through a power cord from a standard AC power socket using a suitable AC/DC power converter (220), which may be combined with a battery charger to recharge the battery (222) during use. The pump unit (102) can receive DC power either from the converter (220), when plugged in, or from the battery (222), when used un-plugged.

[0083] The pump unit (102) is configured to produce controlled levels negative pressure. As shown in detail in Figure 5B and schematically in Figure 6, the pump unit (102) has a Mode Selector switch (204) to select between On, Off, and Intermittent control modes, and a pressure selector dial (206). A prescribed pressure setting is selected using the pressure selector dial (206). The available range of setpoints is preferably between about 30 mm Hg and 100 mm Hg, and is more preferably between about 30 mm Hg and 75 mm Hg. In one embodiment, discrete pressure setpoints of 20, 30, 40, 50, 60, 70, and 75 mm Hg are offered. Additionally, setpoint choices of 100, 125, 150, 175, and 200 mm Hg may be offered. The pump power may be placed into a On state, an Off state, or an Intermittent state using the Mode Selector switch (204). In the Off state, the pump unit (102) will not operate. In the On state, the pump unit (102) will operate based on the selected pressure setpoint. In the Intermittent state, the pump unit (102) will operate cyclically between a higher pressure setpoint selected by the selector dial (206) and a prescribed lower pressure setpoint, as will described in greater detail below.

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[0084] Referring to the schematic diagram of Figure 6, the portable pump unit (102) preferably includes a positive displacement air pump (103), a variable speed DC motor (104), a tachometer (212), a pressure transducer (208), a level sensor (214), a pump unit controller (200), and an annunciator (230). The pump unit controller (200) comprises a pressure controller (202), a flow monitor (210), an error detector (216), a therapy timing controller (224), and a timing subsystem (218). The annunciator (230) comprises a flow status indicator (232), an error indicator (234), a compliance indicator (236), and an audible alarm (238). The flow status indicator (232) is capable of indicating normal or abnormal flow conditions, and the error indicator (234) is capable of indicating other status, fault, or alarm conditions. In the depicted embodiment, the pump unit controller (200) may include one or more of a microprocessor, solid state electronic device, electromechanical devices, mechanical or pneumatic devices, or other equivalent control elements. If a microprocessor is used for performing functions including pressure control, flow monitoring, error detection, and status and alarm annunciation, a suitable processor is a Microchip 16 Series, part number 16F688, it being understood that other similar programmable logic devices could be used.

Vacuum Pressure Control

[0085] Referring to the embodiment schematically illustrated Figure 6, the pump unit controller (200) includes a vacuum or suction pressure controller (202) for maintaining a negative pressure in the wound. The pressure controller (202) is independent of the flow monitor (210), regardless whether the pressure controller (202) and/or flow monitor (210) use a microprocessor or an alternative means such as solid state control circuit. The pressure controller (202) regulates operation of the pump unit (102) based on a signal from a pressure transducer (208) that monitors the negative pressure produced at the suction side of pump (103). The pressure transducer (208) is preferably located in a conduit between the waste collector (16) and the pump (103). Alternatively, a low-cost pressure transducer (208) may be placed directly within the wound cavity and the signal from the transducer (208) conducted via wires to the pressure controller (202).

[0086] The pressure controller (202) receives a setpoint from the user positionable pressure selector dial (206). In an embodiment, the pressure controller (202) includes a solid state logic device and the selector dial (206) changes the resistance of a variable

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resistor to produce an electrical signal representing the selected pressure setpoint. The pressure controller (202) receives the selected pressure setting as an input, and sets an upper limit and a lower limit in a range above and below the selected pressure setpoint. The range between upper limit and the lower limit is selected to provide a reasonably stable suction level while minimizing the on-off cycling of the pump motor (104). A range of approximately 10 mm Hg is preferred to optimize patient comfort and to minimize noise. The pressure controller (202) will function to maintain the pressure sensed by the transducer (208) between the two limits defining the range about the pressure setpoint. Such control circuits are commonly employed in industrial applications as well as in hospital central suction systems.

[0087] When the pump unit (102) is initially turned On by the Mode Selector switch (204), the pressure controller (202) causes the pump motor (104) to start running, driving the positive displacement pump (103). The pump motor (104) continues to run until the pressure transducer (208) detects pressure at or exceeding the upper vacuum limit of the pressure range set by the pressure controller (202) in response to the pressure setpoint on the selector dial (206). The pressure controller (202) continually compares the pressure signal from the pressure transducer (208) to the setpoint limits bounding the range about the operator-selected pressure setpoint. Once the upper control limit is reached, the pressure controller (202) turns off the pump (103). Normal reference airflow in the system (10) will cause pressure at the transducer (208) to decay towards the lower limit of the control range. Once the detected pressure has reached the lower control limit, the pressure controller (202) will turn the pump (103) back on, and the process is repeated cyclically. Thus, the pressure transducer (208) senses the current negative pressure in the system (10) and the pressure controller (202) turns the pump (103) on and off accordingly to maintain negative pressures that are within the selected desired range.

[0088] The motor (104) is preferably a variable speed DC brushless motor. However other styles of DC motors are acceptable, as well as AC motors that can be equipped with variable outputs. When a variable speed motor is used, the speed is controlled via a pulse width modulation (PWM) feature of the pressure controller (202). Variable speed control allows for efficient use of DC power. When a constant speed motor is employed, the on/off time is varied such that the motor is cycled on and off at the most efficient operating speed.

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[0089] The positive displacement pump (103) preferably uses a diaphragm style pump with inlet and outlet check valves. The diaphragm pump crankshaft is operationally connected to the shaft of the variable speed motor (104). Other positive displacement pumps may be used, such as peristaltic, piston, lobe, syringe or rocking piston pumps.

[0090] The tachometer (212) can be used to indicate the rotational speed of the motor (104) or pump shaft. Within the generic term "tachometer" various forms of motor or pump speed sensors may be used. For example, Hall sensors and encoders are commonly employed on DC brushless motors to indicate motor RPM (revolutions per minute). It is also possible to sense back-EMF in brush versions of DC motors to determine motor shaft rotation speed. In an AC motor driven pump, an oscillating bar with a magnet mounted to an end may be excited by an AC coil, thus driving a diaphragm, and a count of the oscillations delivered by the coil can be used as an indicator of pump speed. Regardless the type of tachometer, such a tachometer can be used to infer or determine the flow rate of fluid displaced by the pump unit (102). Because there is a direct correlation between the speed of the positive displacement pump (103) and the actual volume of fluid displaced at a given operating pressure, a measurement of the pump speed combined with a measurement of pressure at inlet of the pump (103), as measured by the pressure transducer (208), can be used to calculate flow rate. Thus, measuring the speed of the positive displacement pump (103) is a surrogate for direct airflow measurement.

[0091] As described above, the pressure controller (202) will cause the pump (103) to run as necessary to maintain the level of vacuum pressure sensed by the transducer (208) within the desired range of the selected negative pressure setpoint. The pressure controller (202) may modulate the on-time duration of the pump (103) to maintain the negative pressure in the desired range. The on-time duration of the pump (103) can be increased or decreased as required by the pump controller (202) to achieve greater or lesser suction, respectively. When a variable speed motor (104) is used, the motor speed can also be adjusted by pulse width modulation, separately from or in combination with the on-time duration, to operate the motor (104) at an efficient speed. Accordingly, the pressure controller (202) can adjust either or both the on-time duration and pump speed to maintain the negative pressure in the range established by the selected pressure setpoint. Thus, the pressure controller (202) operates based on sensed pressure, and not on sensed air flow.

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This allows the pressure controller (202) to function independently from the mechanisms for detecting, monitoring, and displaying the status of flow in the system (10) that are embodied in the flow monitor (210) and the error detector (216).

Flow Monitor and Flow Status Indicator

[0092] As shown in Figure 6, the flow monitor (210) can be adapted to monitor pump activity (i.e., on-time duration and speed) as an indicator of the flow rate of air through the negative pressure wound therapy system (10). The flow monitor (210) is coupled with the flow status indicator (232) in the annunciator (230) to provide audible and visual indication of the status of operation of the system (10) by comparing the fluid flow rate to the reference airflow rate and annunciating indicators of normal or abnormal operation. The flow monitor (210) functions independently from the pressure controller (202). Preferably the flow monitor (210) receives input from sensors that detect pump motor activity, determines a flow rate based upon the motor activity sensor inputs, identifies deviations from the reference airflow rate, and provides a signal to the flow status indicator (232) identifying either a normal state of operation or one of at least two abnormal states of operation.

[0093] The flow monitor (210) is capable of performing flow monitoring functions necessary to compare the fluid flow rate to the reference airflow rate and determine normal or abnormal operational status. To monitor flow rate, revolutions of the motor (104) or positive displacement pump (103) are counted over a period of time, and the count, along with the pressure transducer (208) measurement, is provided as input to the flow monitor (210). An algorithm in the flow monitor (210) correlates the rate of motor revolutions (i.e., count per time), adjusted for pressure, to determine the volumetric flow rate of air passing through the pump (103). The flow monitor (210) compares the calculated flow rate to the known reference airflow rate to determine fault conditions.

[0094] The flow rate detected by the flow monitor (210) is converted into a signal that illuminates a display bar on the flow status indicator (232). A flow rate that is less than the reference airflow rate is displayed as abnormal operation on the flow status indicator (232), indicating an occlusion in the negative pressure system (10). Most commonly, a low flow rate condition is caused by a full waste collector (16), but other causes may include a

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pinched or blocked tube (14) or blockage of the controlled vent (32, 34). A user can distinguish between a full collector (16) condition and a blocked tube (14) condition by viewing the flow status indicator (232) in combination with the error indicator (234) to determine if the level sensor (214) has indicated a full collector (16), as will be discussed below. A flow rate that is comparable to the reference airflow rate is displayed as normal operation on the flow status indicator (232), indicating an acceptable flow rate. For purposes of determining normal operation, a range is established about the reference airflow rate, such that a flow within that range is deemed normal and a deviation upward or downward outside that range is deemed abnormal. A flow rate that is higher than the reference airflow rate is displayed as abnormal operation on the flow status indicator (232), indicating a leak in the negative pressure system (10). Preferably, two levels of leak condition are indicated, a low level leak and a high level leak, to provide a gradated alert to the caregiver indicating the urgency with which the seal of the wound cover (22) must be addressed.

[0095] Referring particularly to Figure 5B, a preferred flow status indicator (232) for use in conjunction with the flow monitor (210) comprises a color-coded bar display having four differently colored regions to indicate four different status conditions. In particular, the bar display preferably includes regions to indicate low flow, normal reference airflow, low-level leak, and high-level leak. In the depicted embodiment, the bar display includes a region of blue LEDs (240) to indicate a flow rate lower than the reference airflow rate range, a region of green LEDs (242) to indicate a flow rate within the reference airflow rate range, a region of yellow LEDs (244) to indicate a flow rate at a low level above the reference airflow rate range, and a region of red LEDs (246) to indicate a flow rate at a high level above the reference airflow rate range. It is readily apparent that a wide variety of non-numerical indicators may be used to display three, four, or more status conditions, including but not limited to an arrow translating up and down a linear scale with demarcated regions, an arrow rotating around a circular scale with demarcated regions, a series of lights such that the number of illuminated lights indicates the status condition, one or more blinking lights such that the frequency of blinking indicates the status condition, and illuminated symbols representative of said flow ranges. Additionally, an audible indicator or alarm (238) may be used to indicate an abnormal operating condition, separately from or

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in combination with a visual indicator. For example, a beeping or continuous tone may be used to indicate abnormal operation, with a different tone pitch, tone duration, or beeping frequency used to indicate each different abnormal condition, while a normal condition would be indicated by the absence of an alarm tone. An alarm silencer or alarm acknowledge button (239) is provided to silence the audible alarm (238) until the abnormal condition has been corrected.

[0096] The gradation of ranges of the flow status indicator (232) may be linear or non-linear and may be adjusted depending on the particular conditions in which the negative pressure wound treatment system is applied. In one embodiment, the reference airflow rate range is preferably defined as a ±10% band about the reference airflow rate, a low flow rate is defined as less than 90% of the reference airflow rate, a low-level leak flow rate is preferably defined as between 110% and 125% of the reference airflow rate, and a high-level leak flow rate is preferably defined as greater than 125% of the reference airflow rate. In another embodiment, where tighter flow rate control is desirable and possible, the reference airflow rate range is defined as a ±5% band about the reference airflow rate, a low flow rate is defined as less than 95% of the reference airflow rate, a low-level leak flow rate is defined as between 105% and 115% of the reference airflow rate, and a high-level leak flow rate is defined as greater than 115% of the reference airflow rate. Tighter flow control may be required, for example, where the wound being treated is smaller such that a low-level leak would be more likely to compromise the vacuum being applied to the wound dressing (12). In yet another embodiment, where less tight flow rate control is desirable and possible, the reference airflow rate range is defined as a ±15% band about the reference airflow rate, a low flow rate is defined as less than 85% of the reference airflow rate, a low-level leak flow rate is defined as between 115% and 130% of the reference airflow rate, and a high-level leak flow rate is defined as greater than 130% of the reference airflow rate. Less tight flow control may be desired, for example, where the wound being treated is larger such that a low-level leak would be less likely to compromise the vacuum being applied to the wound dressing (12). It is readily appreciated that each of the status condition ranges may be adjusted independently to optimize the characteristics of the flow status indicator (232) for a particular application.

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[0097] In the embodiment shown in Figure 6, when the pump (103) is independently turned on and off by the pressure controller (202) to maintain setpoint pressure, the pressure sensed by the transducer (208) will oscillate between the upper control limit and the lower control limit. The period of this oscillation is related to the reference airflow rate, the normal rate of permeation through the wound cover (22), and any leakage in the wound dressing (12). Because the reference airflow rate and the normal rate of permeation through the wound cover (22) should be relatively constant, the higher the leakage in the wound dressing (12), the shorter the period of oscillation will be. Thus, the time intervals between the pump turning on or off can be detected by the flow monitor (210) and used as a rough measure of fluid flow rate through the system.

[0098] Where the pump motor speed is also controlled via a pulse width modulation (PWM) control to make the use of DC power more efficient, the flow monitor (210) can also correlate the on/off intervals with pulse rate to determine flow rate. In normal operation, the positive displacement pump (103) will output a given number of pulses for each revolution of the pump. The pulse signals can be supplied as an input to the flow monitor (210). These pulse signals can be used to determine the number of pumping strokes the pump (103) has performed over a period of time, and combined with the known volume of each pump stroke, can provide very close approximation of the pumped volume per time (i.e., volumetric flow rate). The flow monitor (210) continually counts the pulses being output from the pump (103), combined with the pressure measured by the transducer (208), to calculate the volume of air flow. When taken in combination with a time measurement, pump pulses per unit time represent the airflow rate. In a presently preferred embodiment, the time measurement is based on the off cycles of the pump motor: from the time the pump (103) turns off, until the next time the pump turns off, the flow monitor (210) counts the pulses and divides by the time between each motor off condition to determine the flow rate through the negative pressure system (10).

[0099] As discussed previously, abnormal conditions in the suction therapy system are detected as deviations from the expected flow (i.e., the reference airflow rate) through the system. In yet another embodiment, the reference airflow rate range is calibrated to a tolerance within approximately 50-100 cc/min higher or lower than the airflow produced by the calibrated vent (32, 34) on the end of the suction tube (14). A flow rate within this

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range is denoted as normal operation. If the flow monitor (210) determines that the pump is not running at a normal duration to maintain the setpoint negative pressure, the flow status indicator (232) of the annunciator (230) provides a visual indicator and audible alarm to alert the caregiver. For a PWM controlled pump (103), an increase in the on-time of the motor (104) is proportional to increase of air flow in the system (10). The flow monitor (210) uses an algorithm to correct the air flow rate based on the actual pressure in the system (10). Any leak in the wound dressing (12) will require more flow to maintain the require suction level, such that the leak will be compensated for by an increase in the on-time of the pump (103). When the on-time increases to equate to a flow of approximately 3 liters per minute, the flow status indicator (232) provides a visual indicator to alert the caregiver to inspect and repair the leak in the wound dressing (12). If the caregiver is able to correct the leak, the visual indicator will turn off. If the fault condition is not addressed (by resealing the wound site) within a prescribed timeframe, preferably about one minute, the flow monitor (210) will cause the flow status indicator (232) to activate the audible alarm (238). Nevertheless, even when a leak condition exists, the pump (103) will continue to run as directed by the pressure controller (202), delivering some level of suction until the condition is corrected or the pump unit (102) is turned off.

[0100] The flow monitor (210) can also sense the loss or drop of flow below the reference airflow range. A drop in flow may be caused by various fault conditions, including the tubing (14) to the waste collector (16) becoming clogged with wound exudates, the tubing (14) being crimped shut by bending or squeezing, the waste collector (16) becoming full, and the filter (50) becoming occluded. These conditions also result in the loss of negative pressure at the wound. When a reduction in flow below the reference airflow range is sensed, and the flow status indicator (232) activates a visual indicator to alert the caregiver of a blockage condition.

Intermittent Suction Regime

[0101] It is sometimes desirable to provide suction in an intermittent fashion to benefit the healing process. Prior processes involve allowing the negative pressure system to vent to atmospheric pressure for a period of time to allow for reperfusion of tissue. However, allowing the system to completely vent to atmosphere results in a complete loss of suction on the wound dressing (12) and the resultant loss of any benefit that suction could play in

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maintaining an airtight seal around the wound. The present invention solves this problem by varying the suction between two distinct levels: a first higher vacuum level selected by the pressure selector dial (206) and a second reduced vacuum level of 20-25 mm Hg. The selected higher level is used to apply the beneficial therapeutic effects of suction. The second reduced level is below capillary bed pressure, so reperfusion of tissues will occur in this lower setting, while the wound dressing (12) maintains at least some level of suction to help keep the dressing seals in place and to maintain the reference airflow, thus preventing reflux (by ensuring continuous one-way flow) and clotting in the system tubing. With this type of intermittent pump operation, the reference airflow should be selected such that it is maintained even at the reduced level, or else any annunciator (230) outputs associated with low airflow should be disarmed by the flow monitor (210) during reduced suction intervals as well as the ramp-up and ramp-down intervals.

[0102] To effect intermittent suction, the pressure controller (202) can cyclically reset the pressure setpoint between the selected pressure and the second reduced pressure. When the Mode Selector switch (204) is set to Intermittent mode, the programming in the therapy timing controller (224) uses a time interval for switching the pressure setpoint provided to the pressure controller (202) back and forth between the selected pressure and the second reduced pressure. In an embodiment, to enter the reduced pressure cycle of the intermittent mode, the therapy timing controller (224) activates a transistor that adds a resistance to the pressure controller circuitry, effectively resetting the pressure setpoint to the second reduced pressure.

Waste Collector Docking Station and Fill Indicator

[0103] As illustrated in the embodiment of Figures 5A and 5B, the pump unit (102) includes a docking station (160) for supporting the waste collector (16) which collects liquids aspirated from the wound. The waste collector (16) is disposed in the system between the wound dressing (12) and the pump (103). The waste collector (16) preferably comprises a transparent plastic canister (36) having right circular cylinder profile and fill-level markings along the height of the cylinder. The inlet connection (40) of the waste collector (16) is interconnected to the tubing (14) extending from the wound dressing (12), and the outlet fitting (54) of the waste collector (16) has an o-ring seal. The portable pump docking station (160) supports the waste collector (16). The docking station (160) has a

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concave profile conforming to an external section of the collector (16) and a generally circular base (162) to support the waste collector (16) when docked. The pump unit (102) includes a releasable latch fitting (164) in an upper wall of the docking station (160) that is adapted to receive the connection fitting (54) of the waste collector (16). The fitting (54) is inserted into the latch fitting (164) and latched in place. The waste collector (16) may be released and removed from the docking station (160) by depressing the release button (166) to release the fitting (54) from the latch fitting (164).

[0104] The pump unit (102) provides the ability to detect a filled waste collector (16) without the need to measure differential pressures across the membrane (50), as is required in existing systems. Differential pressure measurement can be problematic because partially clogged membranes can lead to erroneous readings and interpretations. In a preferred embodiment, the pump unit (102) employs positive level detection as a direct indication of the fill status of the waste collector (16). In particular, the pump unit (102) may include a level sensor (214) proximate to the docking station (160) for detecting when the level of waste in the collector (16) equals or exceeds a level which indicates a filled collector condition. The level sensor (214) can take many forms, such as capacitance, optical, ultrasonic, contact wire, float, and others similar sensing mechanisms. A preferred level sensor (214) is a capacitance detector such as a Model# BC 10-QF5 sensor manufactured by Turck, Inc. The level sensor (214) can be positioned in the pump unit (102) at a desired level proximate to the docking station (160) and has the ability to read a change in capacitance as caused by the presence of an ionic fluid. A capacitance level sensor is capable of sensing capacitance through surfaces such as the wall of the canister (36), so no elements of the sensor (214) are exposed to the wound exudate. Capacitance type detection is also tolerant to conditions such as mist or fogging.

[0105] Direct level detection by the level sensor (214) also allows differentiation between a filled waste collector (16) and an occluded condition such as blockage in the tubing (14) that may result in a deviation from the reference airflow range. Based on a signal provided by the direct level sensor (214) to the error detector (216), the error indicator (234) of the annunciator (230) can illuminate a visual indicator and/or an audible alarm distinct from the flow status indicator (232) used to display normal or abnormal flow

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conditions. Providing the clinician a distinction between filled waste collector condition and an occlusion makes the system easier to use and less prone to user error.

[0106] Since the patients may be mobile or need to be transported, there is a potential that agitation and motion can create artifact where fluid may splash and cause a false positive indication of a filled waste collector (16) and subsequently trigger an unwarranted signal or alarm. An algorithm may be used by the error detector (216) to minimize the likelihood of this false indication. The algorithm incorporates a time delay and a sampling rate. For example, a sampling rate of 10 milliseconds and a delay of 4 seconds has been shown to be an effective set of parameters for reducing false full indications due to the motion artifact. Preferably the algorithm is programmed into the error detector (216) of the pump unit controller (200).

Timing Subsystem and Compliance Monitor

[0107] The pump unit controller (200) may have a timing subsystem (218) for recording and accumulating time units corresponding to periods of time when the pump (103) is running. Preferably the timing subsystem (218) records and accumulates the pump operating time units based upon inputs from various sensors. For example, the timing can be started and stopped by signals from the Mode Selector switch (204), or signals that can detect when the pump is running from the tachometer (212) or other sensor. The timing subsystem (218) preferably is capable of providing time reports of the time history of operation of the pump (103). The time reports may include a record of runtime intervals, a record of the date and duration of runtime intervals, a record of total accumulated runtime, a record of accumulated compliant runtime, and a record of runtime remaining on a preset runtime period.

[0108] The timing subsystem (218) of the pump unit controller (200) may include an onboard compliance monitor as part of the timing function. A compliance indicator (236) alerts the caregiver to deviations from the normal application of suction to the wound over time and is a useful adjunct to the application of negative pressure wound therapy. The compliance monitor may compute the number of hours that suction has been within ±5 mm Hg of a pressure setpoint. Medical experience has shown that suction is preferably applied for 22 of any 24 continuous hours to be effective. The compliance indicator (236) can show

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and record in numerous ways the number or percentage of compliant hours of suction therapy for a given therapy period.

[0109] The timing subsystem (218) may be connected to alarms which indicate abnormal operating conditions due to leak or occlusion. The timing subsystem (218) may also be used to indicate time remaining until scheduled maintenance or cleaning, or to indicate time used or remaining on a billing plan where the payments for usage are based upon time units either on return or pre-paid in advance. When the pump unit (102) is sold or leased in this manner, the timing subsystem (218) has the ability to record and accumulate time units corresponding to periods of time when the pump (103) is running and for providing reports of runtime, including compliant runtime when the wound treatment system (10) is operating normally.

Error Detection and Display

[0110] The pump unit (102) may include warning or caution lights indicating pump operating parameters, or errors other than those that are detected by deviations from the reference airflow rate. Numerous combinations of visual and audible indicators may be sued to display such status, fault, or error conditions. In the schematic embodiment of Figure 6, a visual error indicator (234), separate from the flow status indicator (232), provides additional trouble shooting assistance. Various errors may be detected based on sensor signals received by the error detector (216). The error indicator (234) preferably includes an alphanumeric error display, and the error detector (216) can cause the error display to provide indications that correlate to at least following errors: overpressure (i.e., suction exceeding a prescribed limit), missing waste collector, pressure transducer failure, low battery, low operating time remaining, and attachment of incorrect power supply.

[0111] Overpressure is the condition where a runaway pump (103) could cause potentially high negative pressures to be delivered to the patient. The error detector (216) continually polls the output of the pressure transducer (208) and compares it to a stored maximum allowable pressure. If the maximum allowable pressure is exceeded for a predetermined time period, then the pressure controller (202) causes the pump (103) to stop operating and an overpressure error is indicated on the error indicator (234).

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[0112] A missing waste collector condition occurs if the pump (103) is activated without a waste collector (16) installed in the docking station (160) and connected to the latch fitting (164). This condition can occur at startup or during operation, and is detected by the error detector (216) as flow through the system exceeding a certain level without a corresponding minimal increase in pressure. The threshold flow rate for detecting a missing waste collector is typically set to be greater than the increased flow that would be expected from a wound dressing that was removed or compromised. When so detected, a missing waste collector error is indicated on the error indicator (234).

[0113] A pressure transducer failure can take two forms: an excessively high reading indicative of high vacuum or an open circuit (no pressure reading). A high vacuum reading would be interpreted as an overpressure condition, as described above, and would result in a fail-safe deactivation of the pump (103). An open circuit failure appears as zero pressure output, so if the error detector (216) detects air flow but zero pressure, a transducer failure error is indicated on the error indicator (234).

[0114] A low battery charge is determined by the error detector (216) polling the battery output voltage when the pump unit (102) is not plugged into an external electrical power source. When a threshold low voltage level is crossed, a low battery error is indicated on the error indicator (234).

[0115] Low operating time remaining is associated with the timing feature of the pump unit controller (200) when it is used to indicate time remaining until scheduled maintenance service or time remaining on a pre-paid rental plan. The timing system (218) constantly accumulates runtime and time remaining to a target time, such as the number of pre-paid hours. The error detector (216) can be set to a time remaining threshold, such that when the accumulated time indicates that time remaining has dropped below the threshold, a low time error is indicated on the error indicator (234).

[0116] Incorrect power supply detection is to guard against providing excessive voltage to the system. This is accomplished by comparing the input voltage to a set maximum level and detecting if voltage exceeds the maximum level. The error detector (216) detects the

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excess voltage and shuts down the pump (103), and an incorrect power error is indicated on the error indicator (234).

Collection Line Pulse System

[0117] The pump unit (102) may include a collection line pulse feature to ensure that the collection line is maintained as clear as practical to minimize the amount of fluid in the line and ensure accurate delivery of the negative pressure. When the flow monitor (210) begins to detect a deviation from the reference airflow rate so as to indicate an occlusion, the pressure controller (202) can temporarily reset the pressure setpoint temporarily to a pressure higher than the selected pressure, causing the pump (103) to start or to increase in speed. This pump activation or acceleration causes a pressure pulse of transient high negative pressure in the system conduit to clear the tube (14) between the wound dressing (12) and the waste collector (16). The pressure pulse is initiated prior to the illumination of an occlusion indication on the flow status indicator (232). An occlusion indication will not occur if the pressure pulse is followed by decay in the pressure measured by the pressure transducer (208), because a decay in pressure would indicate a cleared collection line and the absence of an occlusion. Once the flow monitor (210) again detects a normal fluid flow rate, the pressure controller (202) resets the pressure setpoint to the selected pressure.

Additional Features

[0118] In order to enhance safety of the negative pressure wound therapy system (10), the pressure controller (202) can operate independently of the flow monitor (210) and error detector (216) in the pump unit controller (200). This provides a measure of system redundancy in the event that one or the other function should fail. Should the pressure controller (202) fail, the flow monitor (210) and/or error detector (216) are capable of shutting down the pump unit (102), and should the flow monitor (210) fail, the pressure controller (202) will continue to provide suction to the wound.

[0119] The pump unit (102) may have a charcoal filter element (not shown) for controlling odors that may emanate from the patient through the pump (103). This element is placed on the outlet of the pump (103) and can be readily changed and replaced. Also, desiccants can be used in conjunction with the filter to minimize moisture in the exhaust from the pump (103).

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[0120] Positive displacement pumps typically employ check valves which make noise. Accordingly, the pump unit (102) may employ a backpressure device in the form of a leaf spring (not shown) that is placed over the outlet of the pump (103) to reduce the noise emanating from the pump check valves.

Flow Measurement Alternatives

[0121] There are other devices for determining the flow through the system that could be employed as leak detection devices in a wound dressing system operating with a reference airflow. These devices measure flow directly, and thus can be used with non-positive displacement pumps and wall vacuum sources as well as with positive displacement pumps. As shown in Figure 7, a target meter (120) is a reliable device for flow detection that is insensitive to changes in pressure. The target meter (120) employs an inlet orifice (122) and a target (124) typically placed in close proximity to the orifice. The target is attached to a shaft (126) and pivots on points (128) or an armature. A light torsion spring (not shown) may be used to keep the target in close proximity to the orifice. The extension of the shaft is placed outside of the flow path. As flow enters the orifice, the target is forced away from the orifice. A proximity sensor, such as a reed switch (130) is so placed as to detect the positions of a magnet (132) on the end of the shaft extension and thus the presence or absence of flow in the circuit as well as measuring flow rate. A target meter could be placed between the waste collection canister and the pump or at the outlet of the pump, or between the waste collection canister and a stationary suction source to provide analogous flow rate information as previously described.

[0122] Other flow detection devices that could be used alone or in conjunction with a suction source include a hot wire anemometer that determines flow as a function of the cooling of a wire in a flowing air stream, a rotameter with an optical detector that senses the position of a float, a turbine meter that rotates when flow is applied. These flow detection systems are generally insensitive to changes in pressure. A hot wire anemometer could be placed between the waste collector (16) and the pump (103) or at the inlet of the pump (103), or between the waste collector (16) and or a stationary suction source. These alternative flow sensors allow the use of other styles of pumps that are not positive displacement, such as vane pumps and scroll pumps. Almost any flow instrument could be

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used, including, for example, differential pressure (DP) cells that provide an indirect measure of flow rate.

[0123] When any fault condition is determined within the system, the pump (103) will continue to run, delivering a sub-optimal level of suction, until the condition is corrected or the user powers the system off, since a sub-optimum level of suction applied to the wound is preferable to no suction at all.

Therapeutic Fluid Delivery and Reference Airflow

[0124] In the embodiments described above, the reference airflow for discerning between normal and abnormal operation has been ambient air supplied to the suction conduit through a vent. A reference airflow could be provided, however, in the form of a therapeutic mixture, such as oxygen enriched air, nitric oxide, heated humidified air or an aerosol containing medication droplets or particles. Such a configuration is shown in Figure 8. A source of therapeutic mixture (150), such as an oxygen regulator or a nebulizer, is connected to a conduit (152) leading to the wound. The mixture is conveyed through the conduit under or through the wound cover (122) and released into the wound packing (124) adjacent the wound contact material (126). Part of this mixture will be absorbed, but enough could be returned through the suction conduit (114) to provide a reference airflow when the flow has settled into equilibrium.

[0125] While a flow monitor (210) could be associated with a portable pump unit (102) or in front of the appliance fitting of a suction regulator (20), as described above, an airflow monitor (154) could be provided between the therapeutic mixture source (150) and the wound cover (122). Since the part of the conduit beneath the cover would be contaminated in use, a detachable disposable tube (156) would be used for the section of conduit from the monitor (154) to the wound packing (112). Thus, the invention can provide for the maintenance of suction therapy on a wound as well as the ability to monitor the application and removal of therapeutic substances to the wound.

[0126] Although the invention has been described and illustrated with respect to several embodiments described above, it should be understood the invention may be embodied in other forms without departing from its scope or attributes. Hence, the scope of the

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invention should be derived from the claims that follow, recognizing that the claim language may literally encompass structure not specifically described.

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Claims

We claim:

1. A pump for applying suction to a wound in a negative pressure wound therapy system, the pump comprising a flow monitor to monitor fluid flow rate in a system conduit from a wound dressing to the pump as indicative of a level of negative pressure applied to a wound, the flow monitor detecting whether or not the flow rate deviates from a reference airflow rate, the flow monitor comprising a gradated non-numerical visual annunciator to indicate flow conditions including that the flow rate is below the reference airflow rate range so as to indicate an occlusion in the system, that the flow rate is within the reference airflow rate range so as to indicate normal operation, that the flow rate is at a first level above the reference airflow rate range so as to indicate a first level of leakage in the system, or that the flow rate is at a second level above the reference airflow rate range so as to indicate a second higher level of leakage in the system, the second level being a greater deviation from the reference airflow than the first level.

2. A pump as in claim 1, wherein the gradated annunciator comprises a color-coded bar meter for displaying a different color corresponding to each flow condition.

3. A pump as in claim 1, wherein the pump is a positive displacement pump.

4. A pump as in claim 1, further including:

an error detector for detecting one or more system errors that are not associated with a deviation of flow rate from the reference airflow; and

an error indicator for displaying a visual warning of system errors detected by the error detector.

5. A pump as in claim 1, further comprising:

a pressure transducer for sensing pressure in the system; and

a pressure controller for controlling the pump to maintain the system pressure between an upper limit and a lower limit around a pressure setpoint, wherein the pressure controller can control the pump without input from the flow monitor.

6. A pump as in claim 5, the pressure controller further comprising a timer for periodically resetting the pressure setpoint between a user-selected pressure and a second

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pressure lower than the user-selected pressure for providing intermittent negative pressure therapy to the wound.

7. A pump as in claim 5, wherein the pressure controller further receives an input from the flow monitor when the flow monitor begins to detect a deviation of the flow rate below the reference airflow rate that indicates an occlusion in the system, such that the pressure controller causes the pressure setpoint to temporarily increase above the user-selected pressure, causing the pump to start or to increase in speed to create a negative pressure pulse capable of clearing the system conduit between the wound dressing and the waste collector.

8. A pump as in claim 7, wherein the pressure pulse is initiated prior to the gradated indicator providing indication of an occlusion, and wherein the gradated indicator will not provide an indication of an occlusion if the negative pressure pulse is followed by a decay in the pressure.

9. A pump as in claim 1, further comprising:

a waste collector located in the system between the wound dressing and the flow monitor for collecting liquids aspirated from the wound;

a docking station for releasably supporting the collector; and

a level sensor proximate to the docking station for detecting the level of waste in the collector.

10. A pump as in claim 9, wherein the level sensor is a capacitance detector.

11. A pump as in claim 9, wherein the level sensor is an optical detector.

12. A pump as in claim 9, wherein the level sensor provides a signal representing a level of waste in the collector and an algorithm is applied to the signal to reduce the likelihood of an erroneous indication of a full collector when the collected waste is sloshed.

13. A pump as in claim 9, wherein the gradated annunciator is further capable of providing visual indication of a full collector.

14. A pump as in claim 1, further comprising a timing subsystem to record and accumulate time units based upon inputs from various sensors.

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15. A pump as in claim 14, wherein the timing subsystem is further capable of providing reports of time histories of pump operation including one or more reports chosen from the group consisting of: a record of runtime intervals, a record of the date and duration of runtime intervals, a record of total accumulated runtime, a record of accumulated compliant runtime, and a record of runtime remaining on a preset runtime period.

16. A system for applying negative pressure therapy to a wound, comprising:

a wound dressing including a wound cover that is sealable to skin surrounding a wound;

a portable suction pump powered by a battery or by an alternating current electrical power supply, the pump comprising a flow monitor to detect the flow rate in the conduit;

a conduit having an end operatively associated with the wound dressing and an opposite end operatively associated with the suction pump, to communicate suction to the wound; and

a waste collector disposed in the conduit between the wound dressing and the suction pump for collecting liquids aspirated from the wound, the waste collector being releasably supported by a docking station on the pump;

wherein the pump includes a sensor proximate to the docking station for detecting the level of waste in the collector; and

wherein the flow monitor comprises a non-numerical annunciator capable of providing visual indications of flow conditions including that the flow rate is below the reference airflow rate range so as to indicate an occlusion in the system, that the flow rate is within the reference airflow rate range so as to indicate normal operation, that the flow rate is at a first level above the reference airflow rate range so as to indicate a first level of leakage in the system, that the flow rate is at a second level above the reference airflow rate range so as to indicate a second higher level of leakage in the system, the second level being a greater deviation from the reference airflow rate than the first level, or that the waste collector is full.

17. A system as in claim 16, further comprising:

a pressure transducer for sensing pressure in the system; and

a pressure controller for controlling the pump to maintain the system pressure between an upper limit and a lower limit around a pressure setpoint.

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18. A system as in claim 16, further including an error indicator for displaying a visual warning of one or more system errors that are not associated with a deviation of flow rate through the pump from the reference airflow rate, wherein the system errors are chosen from the group consisting of: overpressure detected by the pressure transducer, pressure transducer failure, waste collection canister not attached, low battery voltage, attachment of incorrect power supply, low operating time remaining, collection canister full, and pump motor not operational.

19. A method for applying suction to a wound in a negative pressure wound therapy system comprising:

providing a suction pump;

providing a pressure transducer for sensing pressure in the system;

controlling the pump to maintain the system pressure between an upper limit and a lower limit around a pressure setpoint;

providing a flow monitor to monitor fluid flow rate in the system and to detect whether the flow rate deviates from a reference airflow rate; and

providing a gradated non-numerical visual annunciator to indicate flow conditions including that the flow rate is below the reference airflow rate range so as to indicate an occlusion in the system, that the flow rate is within the reference airflow rate range so as to indicate normal operation, that the flow rate is at a first level above the reference airflow rate range so as to indicate a first level of leakage in the system, or that the flow rate is at a second level above the reference airflow rate range so as to indicate a second higher level of leakage in the system, the second level being a greater deviation from the reference airflow than the first level.

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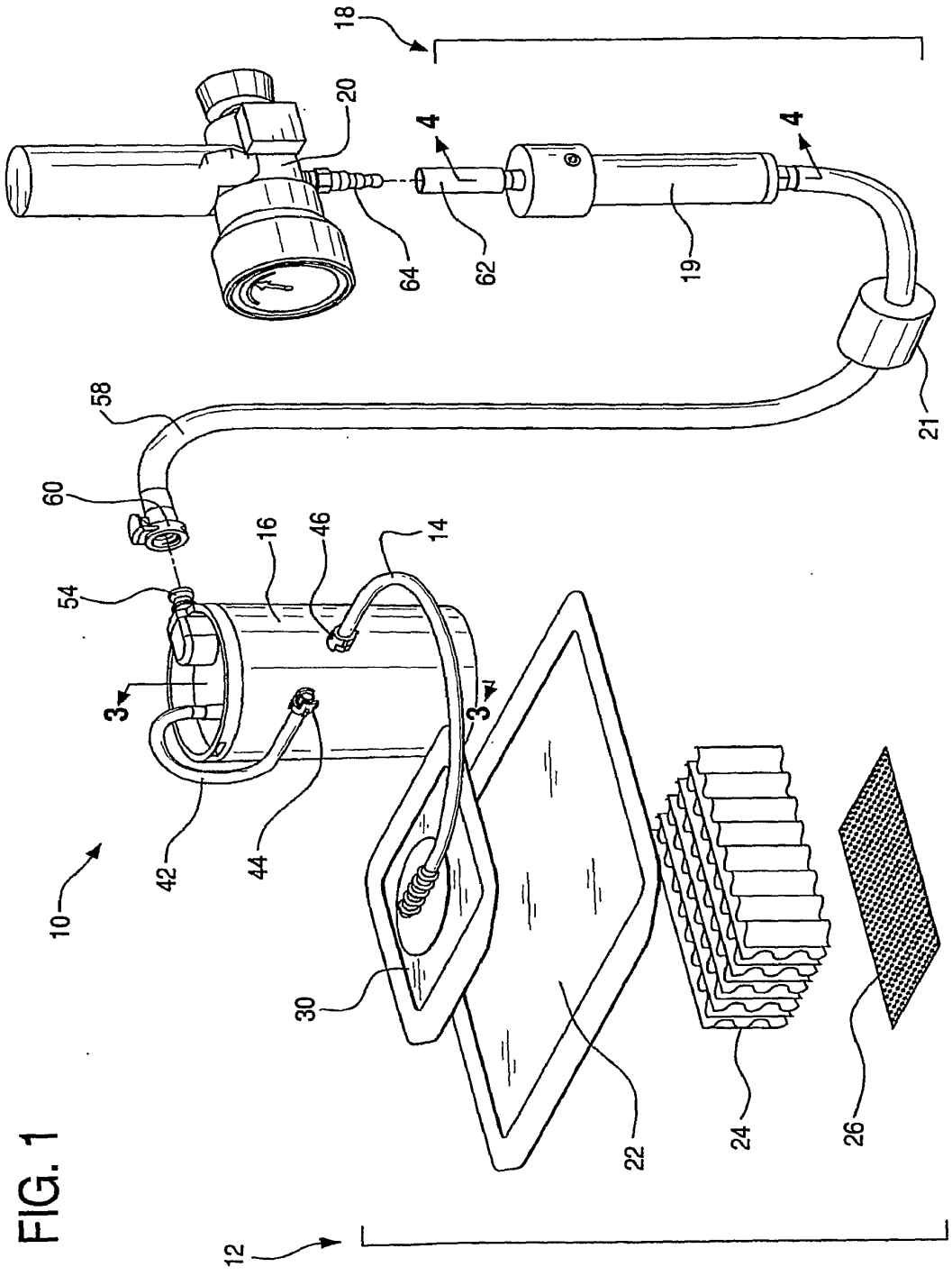


FIG. 1

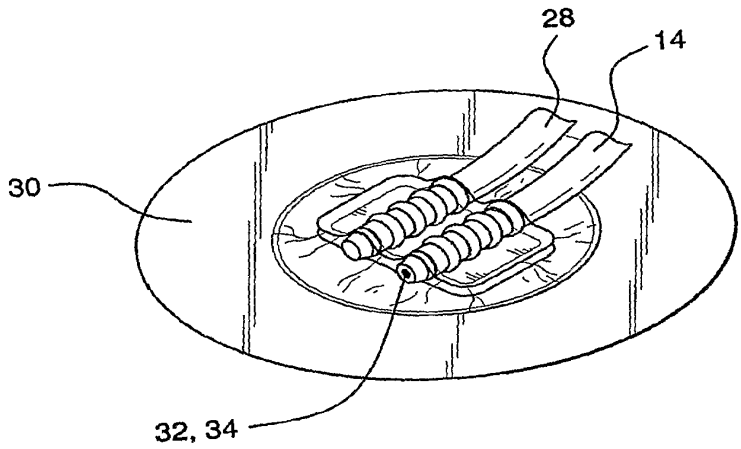


FIG. 2

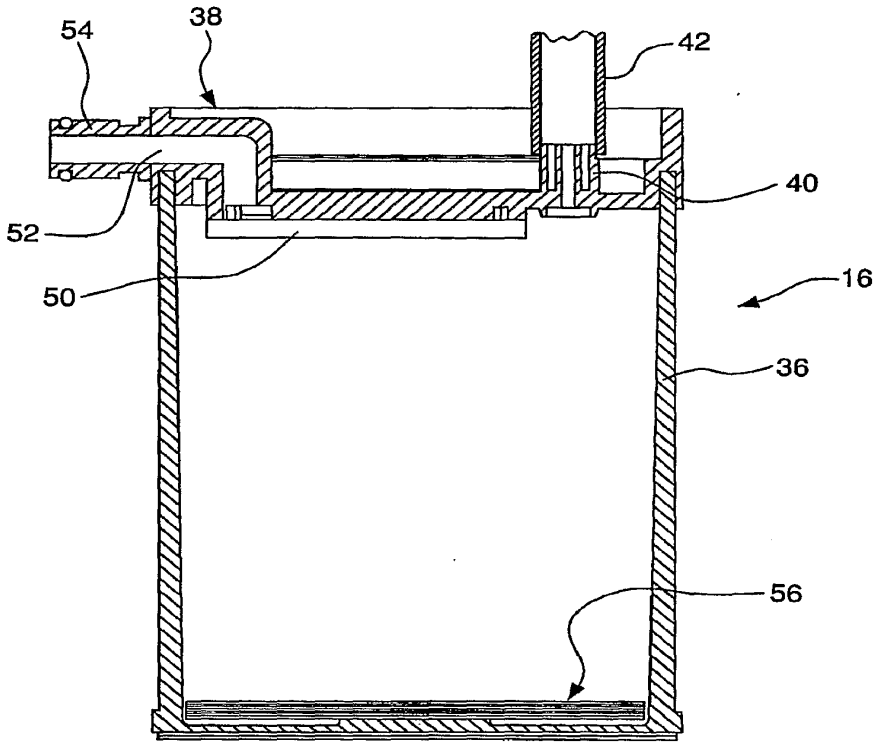


FIG. 3

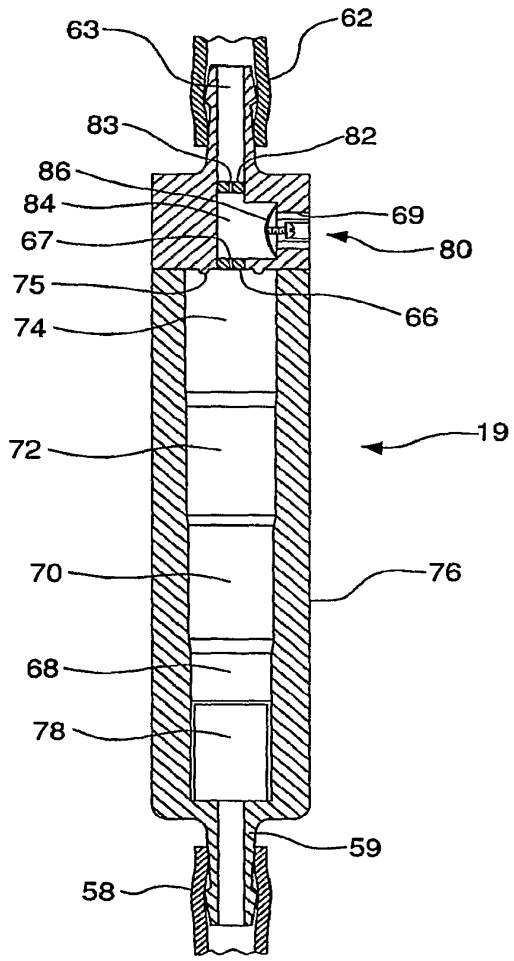


FIG. 4

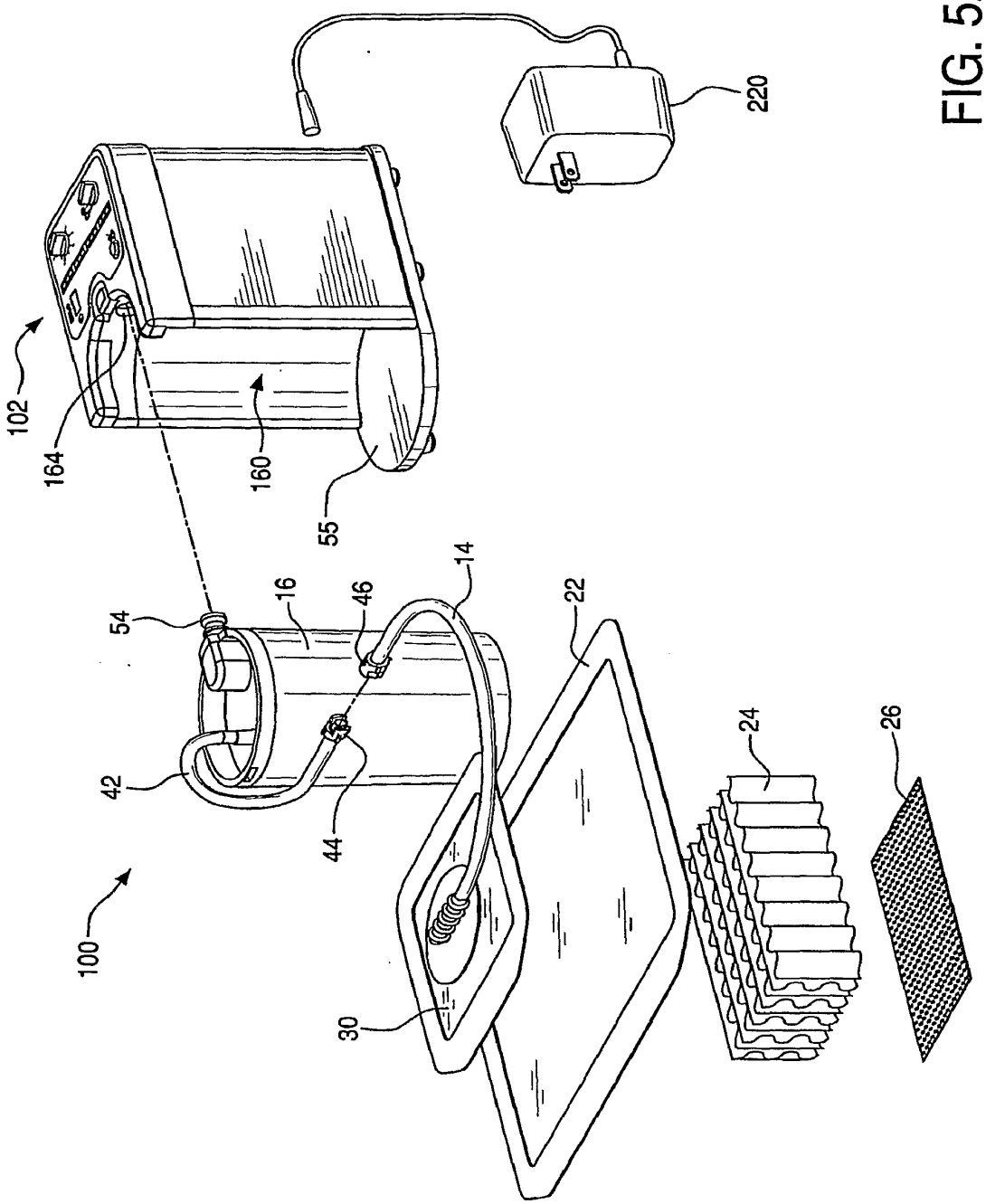


FIG. 5A

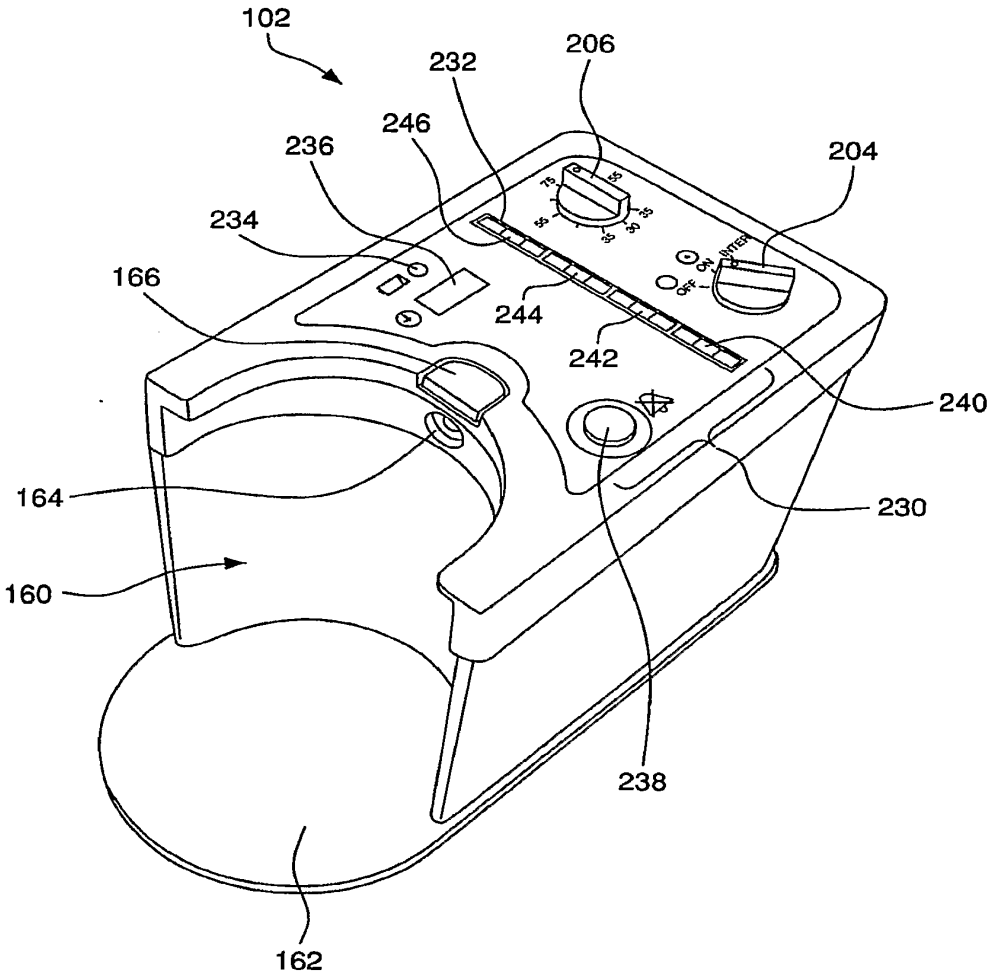


FIG. 5B

FIG. 6

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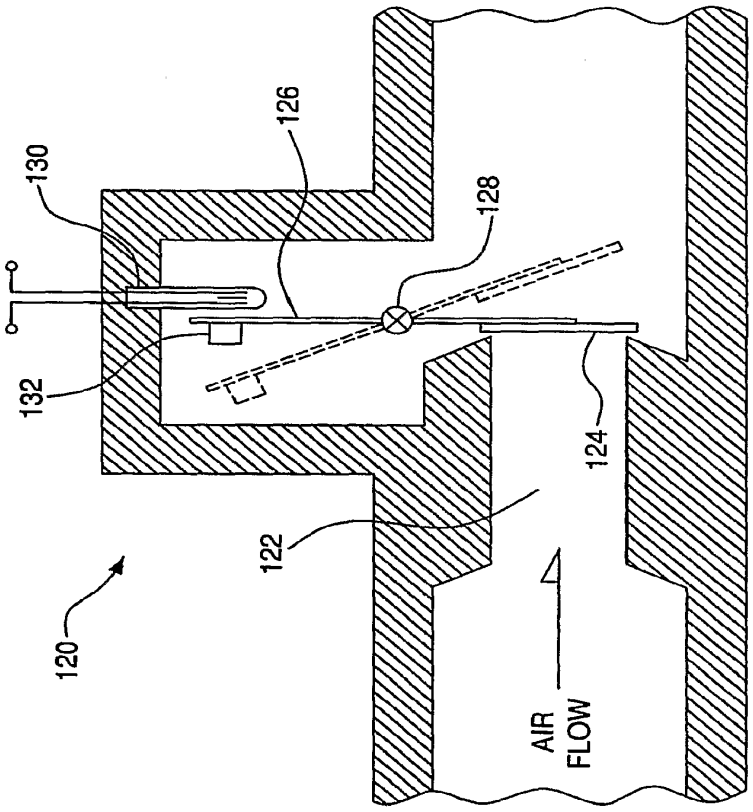


FIG. 7

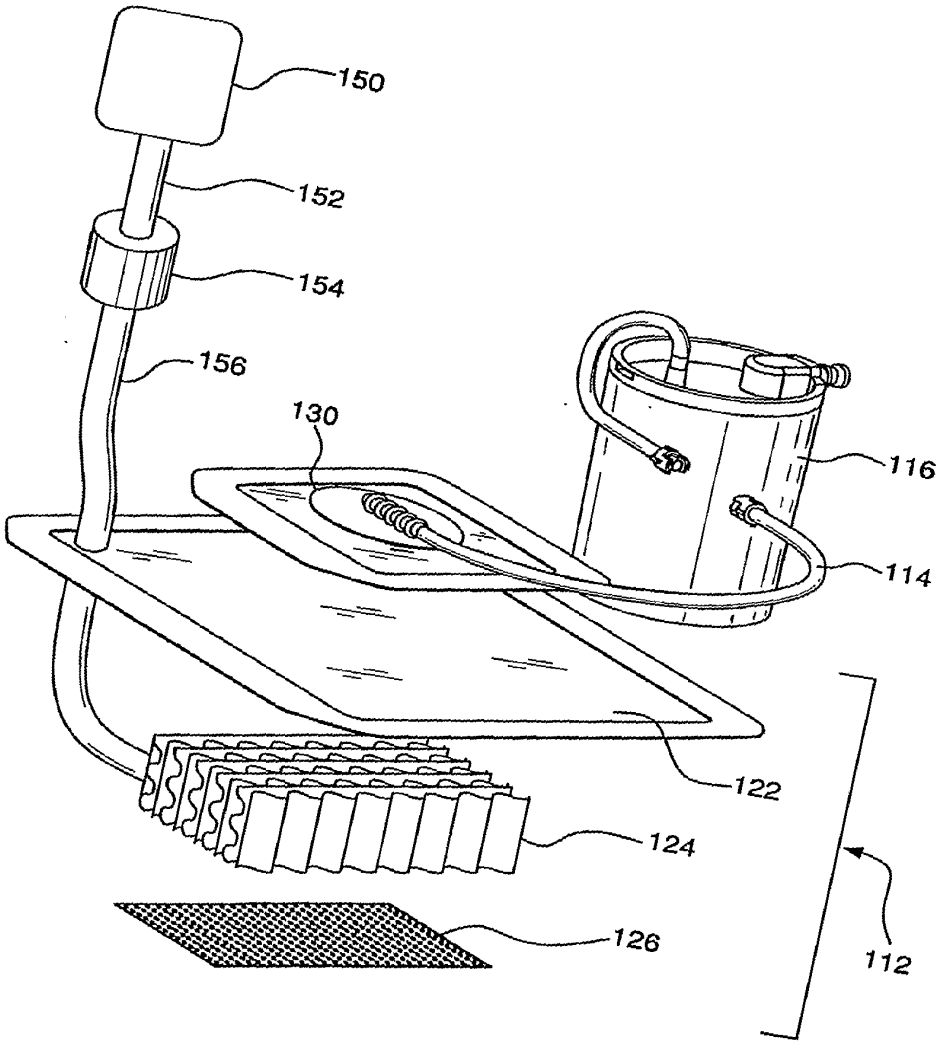


FIG. 8

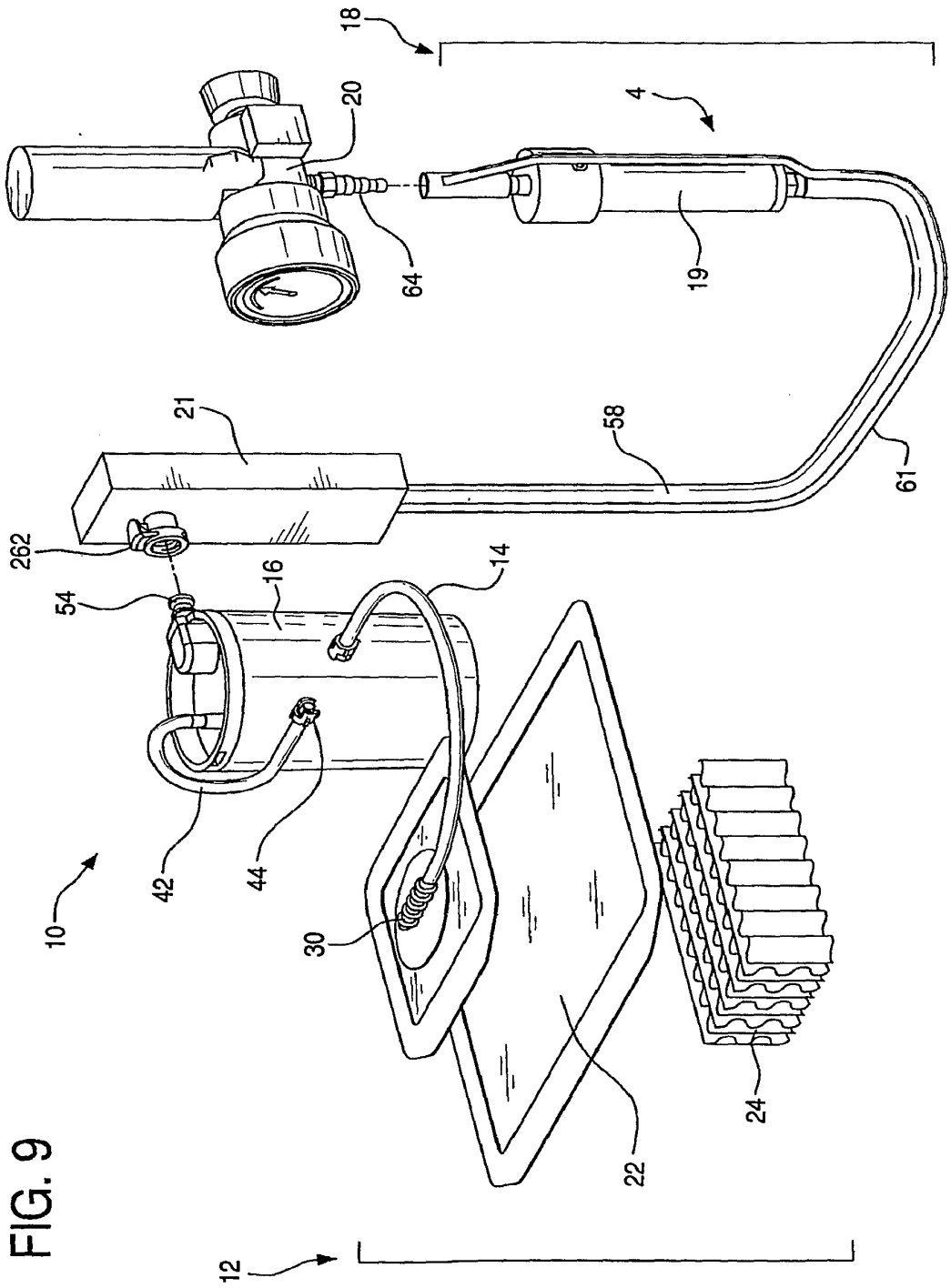


FIG. 9

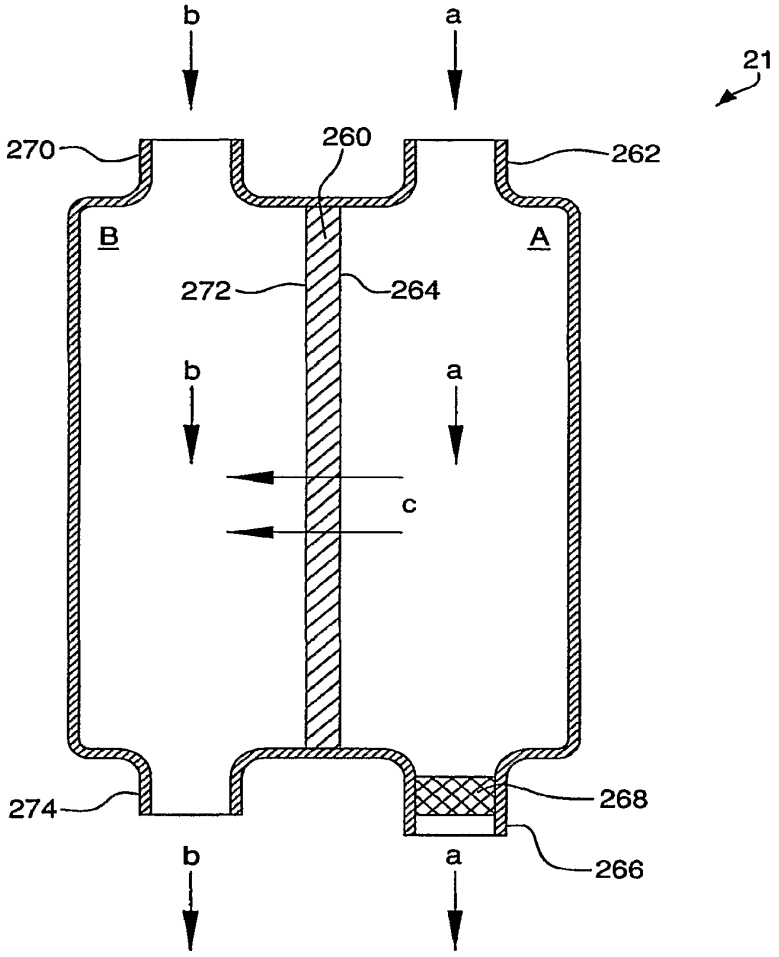


FIG. 10

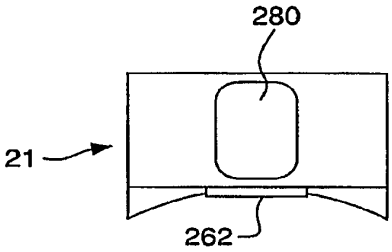
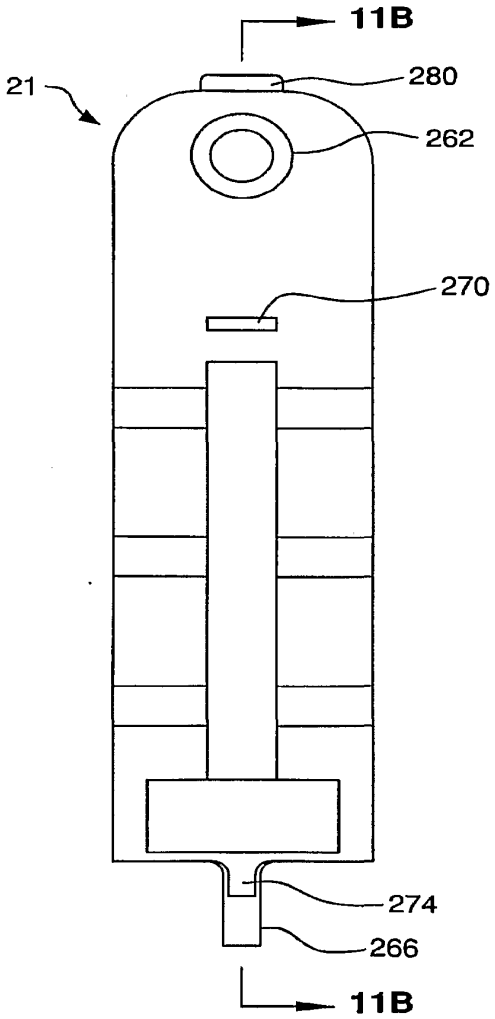


FIG. 11C



IG. 11A

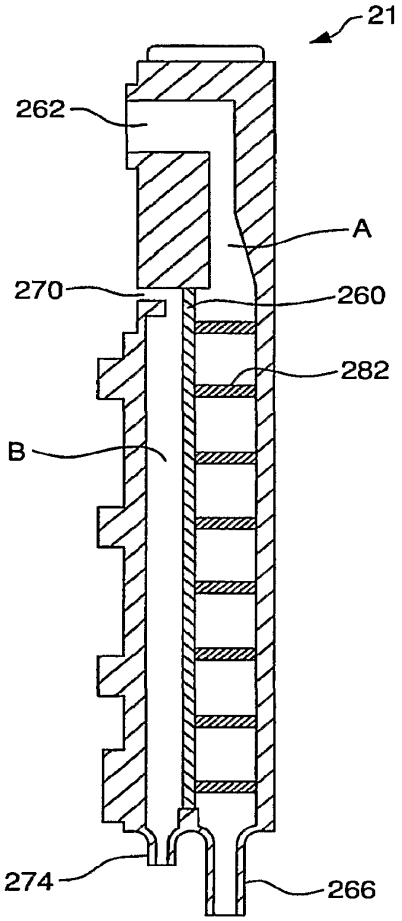


FIG. 11B

Issue Classification

Application/Control No.	Applicant(s)/Patent Under Reexamination
1198929711989297	ADAHAN, CARMELIADAHAN, CARMELI
Examiner	**Art Unit**
ILYA TREYGERILYA TREYGER	37613761

CPC		
Symbol	**Type**	**Version**

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

US ORIGINAL CLASSIFICATION	
CLASS	**SUBCLASS**
604	540

CROSS REFERENCE(S)					
CLASS	**SUBCLASS (ONE SUBCLASS PER BLOCK)**				
604	35	305	306	307	308
604	313	317	318	319	320
604	321	322	323	540	541
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606	131				

INTERNATIONAL CLASSIFICATION										
CLAIMED					**NON-CLAIMED**					
A	6	1	M	1 / 00						

/ILYA TREYGER/ Examiner.Art Unit 3761	04/03/2013	**Total Claims Allowed:** 29	
(Assistant Examiner)	(Date)		
(Primary Examiner)	(Date)	O.G. Print Claim(s) 1	O.G. Print Figure 1

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Issue Classification

Application/Control No.	Applicant(s)/Patent Under Reexamination
1198929711989297	ADAHAN, CARMELIADAHAN, CARMELI
Examiner	**Art Unit**
ILYA TREYGERILYA TREYGER	37613761

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

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
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/ILYA TREYGER/ Examiner.Art Unit 3761	04/03/2013	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	29	
		O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1

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Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11989297	ADAHAN, CARMELI
	Examiner	**Art Unit**
	ILYA TREYGER	3761

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

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

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Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11989297	ADAHAN, CARMELI
	Examiner	**Art Unit**
	ILYA TREYGER	3761

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

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

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EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	59	((CARMELI) near2 (ADAHAN)).INV.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:34
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L4	940	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:34
L5	409	(604/313).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:34
L6	2428	(604/317-323).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:34
L7	1726	(604/540-544).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:34
L8	256	(604/902).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:34
L9	596	(606/131).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:34
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L14	201	L2 and L7	US-PGPUB;	OR	OFF	2013/04/03

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L19	175	("4743232" | "5230350").PN. OR ("5344415").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:34
L20	333	("1355846" | "2547758" | "2632443" | "2682873" | "2969057" | "3367332" | "3648692" | "3682180" | "3826254" | "4080970" | "4096853" | "4139004" | "4165748" | "4245630" | "4261363" | "4275721" | "4297995" | "4333468" | "4373519" | "4382441" | "4392853" | "4392858" | "4419097" | "4475909" | "4480638" | "4525166" | "4525374" | "4540412" | "4543100" | "4551139" | "4569348" | "4605399" | "4608041" | "4640688" | "4655754" | "4733659" | "4743232" | "4787888" | "4826949" | "4838883" | "4840187" | "4863449" | "4872450" | "4878901" | "4897081" | "4906233" | "4906240" | "4919654" | "4941882" | "4953565" | "4969880" | "4985019" | "5037397" | "5100396" | "5149331" | "5167613" | "5176663" | "5261893" | "5298015" | "5344415" | "5358494" | "5556375" | "5607388" | "5636643" | "5645081").PN. OR ("6071267").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:34
L21	59	((CARMELI) near2 (ADAHAN)).INV.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:34
L22	14871	wound and (suction vacuum) and (enclosure dressing) and ((bleeding hole) (vacuum breaker))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L23	990	(604/35).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:34

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L24	940	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:34
L25	409	(604/313).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:34
L26	2428	(604/317-323).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:34
L27	1726	(604/540-544).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:34
L28	256	(604/902).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:34
L29	596	(606/131).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:34
L30	39	L22 and L23	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L31	191	L22 and L24	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L32	252	L22 and L25	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L33	415	L22 and L26	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L34	201	L22 and L27	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L35	9	L22 and L28	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L36	9	L22 and L29	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L37	130	("1251258" | "3171410" | "3486504").PN. OR ("3874387").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:34
L38	246	("3026874" | "3486504" | "4540412" | "4759354" | "4969880").PN. OR	US-PGPUB; USPAT;	OR	OFF	2013/04/03 13:34

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		("5149331").URPN.	USOCR			
L39	175	("4743232" | "5230350").PN. OR ("5344415").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:34
L40	333	("1355846" | "2547758" | "2632443" | "2682873" | "2969057" | "3367332" | "3648692" | "3682180" | "3826254" | "4080970" | "4096853" | "4139004" | "4165748" | "4245630" | "4261363" | "4275721" | "4297995" | "4333468" | "4373519" | "4382441" | "4392853" | "4392858" | "4419097" | "4475909" | "4480638" | "4525166" | "4525374" | "4540412" | "4543100" | "4551139" | "4569348" | "4605399" | "4608041" | "4640688" | "4655754" | "4733659" | "4743232" | "4787888" | "4826949" | "4838883" | "4840187" | "4863449" | "4872450" | "4878901" | "4897081" | "4906233" | "4906240" | "4919654" | "4941882" | "4953565" | "4969880" | "4985019" | "5037397" | "5100396" | "5149331" | "5167613" | "5176663" | "5261893" | "5298015" | "5344415" | "5358494" | "5556375" | "5607388" | "5636643" | "5645081").PN. OR ("6071267").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:34
L41	59	((CARMELI) near2 (ADAHAN)).INV.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:34
L42	14871	wound and (suction vacuum) and (enclosure dressing) and ((bleeding hole) (vacuum breaker))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L43	990	(604/35).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:34
L44	940	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:34
L45	409	(604/313).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:34
L46	2428	(604/317-323).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:34
L47	1726	(604/540-544).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:34
L48	256	(604/902).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:34
L49	596	(606/131).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:34
L50	39	L42 and L43	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L51	191	L42 and L44	US-PGPUB; USPAT; USOCR;	OR	OFF	2013/04/03 13:34

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			EPO; JPO; DERWENT; IBM_TDB			
L52	252	L42 and L45	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L53	415	L42 and L46	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L54	201	L42 and L47	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L55	9	L42 and L48	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L56	9	L42 and L49	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L57	130	("1251258" | "3171410" | "3486504").PN. OR ("3874387").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:34
L58	246	("3026874" | "3486504" | "4540412" | "4759354" | "4969880").PN. OR ("5149331").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:34
L59	175	("4743232" | "5230350").PN. OR ("5344415").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:34
L60	333	("1355846" | "2547758" | "2632443" | "2682873" | "2969057" | "3367332" | "3648692" | "3682180" | "3826254" | "4080970" | "4096853" | "4139004" | "4165748" | "4245630" | "4261363" | "4275721" | "4297995" | "4333468" | "4373519" | "4382441" | "4392853" | "4392858" | "4419097" | "4475909" | "4480638" | "4525166" | "4525374" | "4540412" | "4543100" | "4551139" | "4569348" | "4605399" | "4608041" | "4640688" | "4655754" | "4733659" | "4743232" | "4787888" | "4826949" | "4838883" | "4840187" | "4863449" | "4872450" | "4878901" | "4897081" | "4906233" | "4906240" | "4919654" | "4941882" | "4953565" | "4969880" | "4985019" | "5037397" | "5100396" | "5149331" | "5167613" | "5176663"	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:34

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		"5261893" | "5298015" | "5344415" | "5358494" | "5556375" | "5607388" | "5636643" | "5645081").PN. OR ("6071267").URPN.				
L61	59	((CARMELI) near2 (ADAHAN)).INV.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:34
L62	14871	wound and (suction vacuum) and (enclosure dressing) and ((bleeding hole) (vacuum breaker))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L63	990	(604/35).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:34
L64	940	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:34
L65	409	(604/313).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:34
L66	2428	(604/317-323).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:34
L67	1726	(604/540-544).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:34
L68	256	(604/902).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:34
L69	596	(606/131).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:34
L70	39	L62 and L63	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L71	191	L62 and L64	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L72	252	L62 and L65	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L73	415	L62 and L66	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L74	201	L62 and L67	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L75	9	L62 and L68	US-PGPUB;	OR	OFF	2013/04/03

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			USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB			13:34
L76	9	L62 and L69	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L77	130	("1251258" | "3171410" | "3486504").PN. OR ("3874387").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:34
L78	246	("3026874" | "3486504" | "4540412" | "4759354" | "4969880").PN. OR ("5149331").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:34
L79	175	("4743232" | "5230350").PN. OR ("5344415").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:34
L80	333	("1355846" | "2547758" | "2632443" | "2682873" | "2969057" | "3367332" | "3648692" | "3682180" | "3826254" | "4080970" | "4096853" | "4139004" | "4165748" | "4245630" | "4261363" | "4275721" | "4297995" | "4333468" | "4373519" | "4382441" | "4392853" | "4392858" | "4419097" | "4475909" | "4480638" | "4525166" | "4525374" | "4540412" | "4543100" | "4551139" | "4569348" | "4605399" | "4608041" | "4640688" | "4655754" | "4733659" | "4743232" | "4787888" | "4826949" | "4838883" | "4840187" | "4863449" | "4872450" | "4878901" | "4897081" | "4906233" | "4906240" | "4919654" | "4941882" | "4953565" | "4969880" | "4985019" | "5037397" | "5100396" | "5149331" | "5167613" | "5176663" | "5261893" | "5298015" | "5344415" | "5358494" | "5556375" | "5607388" | "5636643" | "5645081").PN. OR ("6071267").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:34
L82	59	((CARMELI) near2 (ADAHAN)).INV.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:34
L83	14871	wound and (suction vacuum) and (enclosure dressing) and ((bleeding hole) (vacuum breaker))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L84	990	(604/35).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:34
L85	940	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:34
L86	409	(604/313).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:34
L87	2428	(604/317-323).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:34

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L88	1726	(604/540-544).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:34
L89	256	(604/902).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:34
L90	596	(606/131).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:34
L91	39	L83 and L84	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L92	191	L83 and L85	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L93	252	L83 and L86	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L94	415	L83 and L87	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L95	201	L83 and L88	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L96	9	L83 and L89	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L97	9	L83 and L90	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L98	130	("1251258" | "3171410" | "3486504").PN. OR ("3874387").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:34
L99	246	("3026874" | "3486504" | "4540412" | "4759354" | "4969880").PN. OR ("5149331").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:34
L100	175	("4743232" | "5230350").PN. OR ("5344415").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:34
L101	333	("1355846" | "2547758" | "2632443" | "2682873" | "2969057" | "3367332" |	US-PGPUB; USPAT;	OR	OFF	2013/04/03 13:34

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		"3648692" | "3682180" | "3826254" | "4080970" | "4096853" | "4139004" | "4165748" | "4245630" | "4261363" | "4275721" | "4297995" | "4333468" | "4373519" | "4382441" | "4392853" | "4392858" | "4419097" | "4475909" | "4480638" | "4525166" | "4525374" | "4540412" | "4543100" | "4551139" | "4569348" | "4605399" | "4608041" | "4640688" | "4655754" | "4733659" | "4743232" | "4787888" | "4826949" | "4838883" | "4840187" | "4863449" | "4872450" | "4878901" | "4897081" | "4906233" | "4906240" | "4919654" | "4941882" | "4953565" | "4969880" | "4985019" | "5037397" | "5100396" | "5149331" | "5167613" | "5176663" | "5261893" | "5298015" | "5344415" | "5358494" | "5556375" | "5607388" | "5636643" | "5645081").PN. OR ("6071267").URPN.	USOCR			
L102	59	((CARMELI) near2 (ADAHAN)).INV.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:34
L103	14871	wound and (suction vacuum) and (enclosure dressing) and ((bleeding hole) (vacuum breaker))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L104	990	(604/35).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:34
L105	940	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:34
L106	409	(604/313).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:34
L107	2428	(604/317-323).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:34
L108	1726	(604/540-544).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:34
L109	256	(604/902).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:34
L110	596	(606/131).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:34
L111	39	L103 and L104	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L112	191	L103 and L105	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L113	252	L103 and L106	US-PGPUB; USPAT; USOCR; EPO; JPO;	OR	OFF	2013/04/03 13:34

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			DERWENT; IBM_TDB			
L114	415	L103 and L107	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L115	201	L103 and L108	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L116	9	L103 and L109	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L117	9	L103 and L110	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L118	130	("1251258" | "3171410" | "3486504").PN. OR ("3874387").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:34
L119	246	("3026874" | "3486504" | "4540412" | "4759354" | "4969880").PN. OR ("5149331").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:34
L120	175	("4743232" | "5230350").PN. OR ("5344415").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:34
L121	333	("1355846" | "2547758" | "2632443" | "2682873" | "2969057" | "3367332" | "3648692" | "3682180" | "3826254" | "4080970" | "4096853" | "4139004" | "4165748" | "4245630" | "4261363" | "4275721" | "4297995" | "4333468" | "4373519" | "4382441" | "4392853" | "4392858" | "4419097" | "4475909" | "4480638" | "4525166" | "4525374" | "4540412" | "4543100" | "4551139" | "4569348" | "4605399" | "4608041" | "4640688" | "4655754" | "4733659" | "4743232" | "4787888" | "4826949" | "4838883" | "4840187" | "4863449" | "4872450" | "4878901" | "4897081" | "4906233" | "4906240" | "4919654" | "4941882" | "4953565" | "4969880" | "4985019" | "5037397" | "5100396" | "5149331" | "5167613" | "5176663" | "5261893" | "5298015" | "5344415" | "5358494" | "5556375" | "5607388" | "5636643" | "5645081").PN. OR ("6071267").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:34
L122	59	((CARMELI) near2 (ADAHAN)).INV.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:34

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L123	14871	wound and (suction vacuum) and (enclosure dressing) and ((bleeding hole) (vacuum breaker))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L124	990	(604/35).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:34
L125	940	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:34
L126	409	(604/313).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:34
L127	2428	(604/317-323).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:34
L128	1726	(604/540-544).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:34
L129	256	(604/902).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:34
L130	596	(606/131).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:34
L131	39	L123 and L124	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L132	191	L123 and L125	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L133	252	L123 and L126	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L134	415	L123 and L127	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L135	201	L123 and L128	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L136	9	L123 and L129	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L137	9	L123 and L130	US-PGPUB; USPAT; USOCR;	OR	OFF	2013/04/03 13:34

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			EPO; JPO; DERWENT; IBM_TDB			
L138	130	("1251258" | "3171410" | "3486504").PN. OR ("3874387").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:34
L139	246	("3026874" | "3486504" | "4540412" | "4759354" | "4969880").PN. OR ("5149331").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:34
L140	175	("4743232" | "5230350").PN. OR ("5344415").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:34
L141	333	("1355846" | "2547758" | "2632443" | "2682873" | "2969057" | "3367332" | "3648692" | "3682180" | "3826254" | "4080970" | "4096853" | "4139004" | "4165748" | "4245630" | "4261363" | "4275721" | "4297995" | "4333468" | "4373519" | "4382441" | "4392853" | "4392858" | "4419097" | "4475909" | "4480638" | "4525166" | "4525374" | "4540412" | "4543100" | "4551139" | "4569348" | "4605399" | "4608041" | "4640688" | "4655754" | "4733659" | "4743232" | "4787888" | "4826949" | "4838883" | "4840187" | "4863449" | "4872450" | "4878901" | "4897081" | "4906233" | "4906240" | "4919654" | "4941882" | "4953565" | "4969880" | "4985019" | "5037397" | "5100396" | "5149331" | "5167613" | "5176663" | "5261893" | "5298015" | "5344415" | "5358494" | "5556375" | "5607388" | "5636643" | "5645081").PN. OR ("6071267").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:34
L142	59	((CARMELI) near2 (ADAHAN)).INV.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:34
L143	14871	wound and (suction vacuum) and (enclosure dressing) and ((bleeding hole) (vacuum breaker))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L144	990	(604/35).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:34
L145	940	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:34
L146	409	(604/313).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:34
L147	2428	(604/317-323).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:34
L148	1726	(604/540-544).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:34
L149	256	(604/902).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:34
L150	596	(606/131).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:34
L151	39	L143 and L144	US-PGPUB;	OR	OFF	2013/04/03

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			USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB			13:34
L152	191	L143 and L145	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L153	252	L143 and L146	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L154	415	L143 and L147	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L155	201	L143 and L148	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L156	9	L143 and L149	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L157	9	L143 and L150	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L158	130	("1251258" | "3171410" | "3486504").PN. OR ("3874387").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:34
L159	246	("3026874" | "3486504" | "4540412" | "4759354" | "4969880").PN. OR ("5149331").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:34
L160	175	("4743232" | "5230350").PN. OR ("5344415").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:34
L161	333	("1355846" | "2547758" | "2632443" | "2682873" | "2969057" | "3367332" | "3648692" | "3682180" | "3826254" | "4080970" | "4096853" | "4139004" | "4165748" | "4245630" | "4261363" | "4275721" | "4297995" | "4333468" | "4373519" | "4382441" | "4392853" | "4392858" | "4419097" | "4475909" | "4480638" | "4525166" | "4525374" | "4540412" | "4543100" | "4551139" |	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:34

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		"4569348" | "4605399" | "4608041" | "4640688" | "4655754" | "4733659" | "4743232" | "4787888" | "4826949" | "4838883" | "4840187" | "4863449" | "4872450" | "4878901" | "4897081" | "4906233" | "4906240" | "4919654" | "4941882" | "4953565" | "4969880" | "4985019" | "5037397" | "5100396" | "5149331" | "5167613" | "5176663" | "5261893" | "5298015" | "5344415" | "5358494" | "5556375" | "5607388" | "5636643" | "5645081").PN. OR ("6071267").URPN.				
L162	39	L98 and (vent venting ventillation)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L163	55	L99 and (vent venting ventillation)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L164	27	L100 and (vent venting ventillation)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L165	67	L101 and (vent venting ventillation)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L166	75	"4108574" "4208171"	US-PGPUB; USPAT; EPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L167	0	L166 and (air adj hole)	US-PGPUB; USPAT; EPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L168	6	L166 and (vent venting)	US-PGPUB; USPAT; EPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L169	6	"20040015042" "20050180868"	US-PGPUB; USPAT; EPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L170	67	"4552552"	US-PGPUB; USPAT; EPO; DERWENT;	OR	OFF	2013/04/03 13:34

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			IBM_TDB			
L171	36	L170 and (vent venting)	US-PGPUB; USPAT; EPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L172	0	L170 and (air adj hole)	US-PGPUB; USPAT; EPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L173	26	"5116206" "7503910"	US-PGPUB; USPAT; EPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:34
L174	7	L173 and (vent venting)	US-PGPUB; USPAT; EPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L176	940	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:35
L177	990	(604/35).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:35
L178	59	((CARMELI) near2 (ADAHAN)).INV.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:35
L179	14871	wound and (suction vacuum) and (enclosure dressing) and ((bleeding hole) (vacuum breaker))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L180	990	(604/35).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:35
L181	940	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:35
L182	409	(604/313).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:35
L183	2428	(604/317-323).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:35
L184	1726	(604/540-544).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:35
L185	256	(604/902).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:35
L186	596	(606/131).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:35
L187	39	L179 and L180	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L188	191	L179 and L181	US-PGPUB; USPAT; USOCR; EPO; JPO;	OR	OFF	2013/04/03 13:35

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			DERWENT; IBM_TDB			
L189	252	L179 and L182	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L190	415	L179 and L183	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L191	201	L179 and L184	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L192	9	L179 and L185	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L193	9	L179 and L186	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L194	130	("1251258" | "3171410" | "3486504").PN. OR ("3874387").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:35
L195	246	("3026874" | "3486504" | "4540412" | "4759354" | "4969880").PN. OR ("5149331").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:35
L196	175	("4743232" | "5230350").PN. OR ("5344415").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:35
L197	333	("1355846" | "2547758" | "2632443" | "2682873" | "2969057" | "3367332" | "3648692" | "3682180" | "3826254" | "4080970" | "4096853" | "4139004" | "4165748" | "4245630" | "4261363" | "4275721" | "4297995" | "4333468" | "4373519" | "4382441" | "4392853" | "4392858" | "4419097" | "4475909" | "4480638" | "4525166" | "4525374" | "4540412" | "4543100" | "4551139" | "4569348" | "4605399" | "4608041" | "4640688" | "4655754" | "4733659" | "4743232" | "4787888" | "4826949" | "4838883" | "4840187" | "4863449" | "4872450" | "4878901" | "4897081" | "4906233" | "4906240" | "4919654" | "4941882" | "4953565" | "4969880" | "4985019" | "5037397" | "5100396" | "5149331" | "5167613" | "5176663" | "5261893" | "5298015" | "5344415" |	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:35

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		"5358494" | "5556375" | "5607388" | "5636643" | "5645081").PN. OR ("6071267").URPN.				
L198	59	((CARMELI) near2 (ADAHAN)).INV.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:35
L199	14871	wound and (suction vacuum) and (enclosure dressing) and ((bleeding hole) (vacuum breaker))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L200	990	(604/35).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:35
L201	940	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:35
L202	409	(604/313).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:35
L203	2428	(604/317-323).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:35
L204	1726	(604/540-544).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:35
L205	256	(604/902).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:35
L206	596	(606/131).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:35
L207	39	L199 and L200	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L208	191	L199 and L201	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L209	252	L199 and L202	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L210	415	L199 and L203	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L211	201	L199 and L204	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L212	9	L199 and L205	US-PGPUB; USPAT;	OR	OFF	2013/04/03 13:35

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			USOCR; EPO; JPO; DERWENT; IBM_TDB			
L213	9	L199 and L206	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L214	130	("1251258" | "3171410" | "3486504").PN. OR ("3874387").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:35
L215	246	("3026874" | "3486504" | "4540412" | "4759354" | "4969880").PN. OR ("5149331").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:35
L216	175	("4743232" | "5230350").PN. OR ("5344415").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:35
L217	333	("1355846" | "2547758" | "2632443" | "2682873" | "2969057" | "3367332" | "3648692" | "3682180" | "3826254" | "4080970" | "4096853" | "4139004" | "4165748" | "4245630" | "4261363" | "4275721" | "4297995" | "4333468" | "4373519" | "4382441" | "4392853" | "4392858" | "4419097" | "4475909" | "4480638" | "4525166" | "4525374" | "4540412" | "4543100" | "4551139" | "4569348" | "4605399" | "4608041" | "4640688" | "4655754" | "4733659" | "4743232" | "4787888" | "4826949" | "4838883" | "4840187" | "4863449" | "4872450" | "4878901" | "4897081" | "4906233" | "4906240" | "4919654" | "4941882" | "4953565" | "4969880" | "4985019" | "5037397" | "5100396" | "5149331" | "5167613" | "5176663" | "5261893" | "5298015" | "5344415" | "5358494" | "5556375" | "5607388" | "5636643" | "5645081").PN. OR ("6071267").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:35
L218	59	((CARMELI) near2 (ADAHAN)).INV.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:35
L219	14871	wound and (suction vacuum) and (enclosure dressing) and ((bleeding hole) (vacuum breaker))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L220	990	(604/35).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:35
L221	940	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:35
L222	409	(604/313).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:35
L223	2428	(604/317-323).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:35
L224	1726	(604/540-544).CCLS.	US-PGPUB;	OR	OFF	2013/04/03

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			USPAT			13:35
L225	256	(604/902).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:35
L226	596	(606/131).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:35
L227	39	L219 and L220	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L228	191	L219 and L221	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L229	252	L219 and L222	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L230	415	L219 and L223	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L231	201	L219 and L224	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L232	9	L219 and L225	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L233	9	L219 and L226	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L234	130	("1251258" | "3171410" | "3486504").PN. OR ("3874387").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:35
L235	246	("3026874" | "3486504" | "4540412" | "4759354" | "4969880").PN. OR ("5149331").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:35
L236	175	("4743232" | "5230350").PN. OR ("5344415").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:35
L237	333	("1355846" | "2547758" | "2632443" | "2682873" | "2969057" | "3367332" | "3648692" | "3682180" | "3826254" |	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:35

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		"4080970" | "4096853" | "4139004" | "4165748" | "4245630" | "4261363" | "4275721" | "4297995" | "4333468" | "4373519" | "4382441" | "4392853" | "4392858" | "4419097" | "4475909" | "4480638" | "4525166" | "4525374" | "4540412" | "4543100" | "4551139" | "4569348" | "4605399" | "4608041" | "4640688" | "4655754" | "4733659" | "4743232" | "4787888" | "4826949" | "4838883" | "4840187" | "4863449" | "4872450" | "4878901" | "4897081" | "4906233" | "4906240" | "4919654" | "4941882" | "4953565" | "4969880" | "4985019" | "5037397" | "5100396" | "5149331" | "5167613" | "5176663" | "5261893" | "5298015" | "5344415" | "5358494" | "5556375" | "5607388" | "5636643" | "5645081").PN. OR ("6071267").URPN.				
L238	59	((CARMELI) near2 (ADAHAN)).INV.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:35
L239	14871	wound and (suction vacuum) and (enclosure dressing) and ((bleeding hole) (vacuum breaker))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L240	990	(604/35).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:35
L241	940	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:35
L242	409	(604/313).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:35
L243	2428	(604/317-323).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:35
L244	1726	(604/540-544).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:35
L245	256	(604/902).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:35
L246	596	(606/131).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:35
L247	39	L239 and L240	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L248	191	L239 and L241	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L249	252	L239 and L242	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT;	OR	OFF	2013/04/03 13:35

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			IBM_TDB			
L250	415	L239 and L243	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L251	201	L239 and L244	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L252	9	L239 and L245	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L253	9	L239 and L246	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L254	130	("1251258" | "3171410" | "3486504").PN. OR ("3874387").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:35
L255	246	("3026874" | "3486504" | "4540412" | "4759354" | "4969880").PN. OR ("5149331").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:35
L256	175	("4743232" | "5230350").PN. OR ("5344415").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:35
L257	333	("1355846" | "2547758" | "2632443" | "2682873" | "2969057" | "3367332" | "3648692" | "3682180" | "3826254" | "4080970" | "4096853" | "4139004" | "4165748" | "4245630" | "4261363" | "4275721" | "4297995" | "4333468" | "4373519" | "4382441" | "4392853" | "4392858" | "4419097" | "4475909" | "4480638" | "4525166" | "4525374" | "4540412" | "4543100" | "4551139" | "4569348" | "4605399" | "4608041" | "4640688" | "4655754" | "4733659" | "4743232" | "4787888" | "4826949" | "4838883" | "4840187" | "4863449" | "4872450" | "4878901" | "4897081" | "4906233" | "4906240" | "4919654" | "4941882" | "4953565" | "4969880" | "4985019" | "5037397" | "5100396" | "5149331" | "5167613" | "5176663" | "5261893" | "5298015" | "5344415" | "5358494" | "5556375" | "5607388" | "5636643" | "5645081").PN. OR ("6071267").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:35
L258	59	((CARMELI) near2 (ADAHAN)).INV.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:35

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L259	14871	wound and (suction vacuum) and (enclosure dressing) and ((bleeding hole) (vacuum breaker))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L260	990	(604/35).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:35
L261	940	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:35
L262	409	(604/313).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:35
L263	2428	(604/317-323).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:35
L264	1726	(604/540-544).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:35
L265	256	(604/902).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:35
L266	596	(606/131).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:35
L267	39	L259 and L260	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L268	191	L259 and L261	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L269	252	L259 and L262	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L270	415	L259 and L263	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L271	201	L259 and L264	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L272	9	L259 and L265	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L273	9	L259 and L266	US-PGPUB; USPAT; USOCR;	OR	OFF	2013/04/03 13:35

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			EPO; JPO; DERWENT; IBM_TDB			
L274	130	("1251258" | "3171410" | "3486504").PN. OR ("3874387").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:35
L275	246	("3026874" | "3486504" | "4540412" | "4759354" | "4969880").PN. OR ("5149331").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:35
L276	175	("4743232" | "5230350").PN. OR ("5344415").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:35
L277	333	("1355846" | "2547758" | "2632443" | "2682873" | "2969057" | "3367332" | "3648692" | "3682180" | "3826254" | "4080970" | "4096853" | "4139004" | "4165748" | "4245630" | "4261363" | "4275721" | "4297995" | "4333468" | "4373519" | "4382441" | "4392853" | "4392858" | "4419097" | "4475909" | "4480638" | "4525166" | "4525374" | "4540412" | "4543100" | "4551139" | "4569348" | "4605399" | "4608041" | "4640688" | "4655754" | "4733659" | "4743232" | "4787888" | "4826949" | "4838883" | "4840187" | "4863449" | "4872450" | "4878901" | "4897081" | "4906233" | "4906240" | "4919654" | "4941882" | "4953565" | "4969880" | "4985019" | "5037397" | "5100396" | "5149331" | "5167613" | "5176663" | "5261893" | "5298015" | "5344415" | "5358494" | "5556375" | "5607388" | "5636643" | "5645081").PN. OR ("6071267").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:35
L278	59	((CARMELI) near2 (ADAHAN)).INV.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:35
L279	14871	wound and (suction vacuum) and (enclosure dressing) and ((bleeding hole) (vacuum breaker))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L280	990	(604/35).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:35
L281	940	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:35
L282	409	(604/313).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:35
L283	2428	(604/317-323).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:35
L284	1726	(604/540-544).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:35
L285	256	(604/902).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:35
L286	596	(606/131).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:35
L287	39	L279 and L280	US-PGPUB;	OR	OFF	2013/04/03

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			USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB			13:35
L288	191	L279 and L281	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L289	252	L279 and L282	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L290	415	L279 and L283	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L291	201	L279 and L284	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L292	9	L279 and L285	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L293	9	L279 and L286	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L294	130	("1251258" | "3171410" | "3486504").PN. OR ("3874387").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:35
L295	246	("3026874" | "3486504" | "4540412" | "4759354" | "4969880").PN. OR ("5149331").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:35
L296	175	("4743232" | "5230350").PN. OR ("5344415").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:35
L297	333	("1355846" | "2547758" | "2632443" | "2682873" | "2969057" | "3367332" | "3648692" | "3682180" | "3826254" | "4080970" | "4096853" | "4139004" | "4165748" | "4245630" | "4261363" | "4275721" | "4297995" | "4333468" | "4373519" | "4382441" | "4392853" | "4392858" | "4419097" | "4475909" | "4480638" | "4525166" | "4525374" | "4540412" | "4543100" | "4551139" |	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:35

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		"4569348" | "4605399" | "4608041" | "4640688" | "4655754" | "4733659" | "4743232" | "4787888" | "4826949" | "4838883" | "4840187" | "4863449" | "4872450" | "4878901" | "4897081" | "4906233" | "4906240" | "4919654" | "4941882" | "4953565" | "4969880" | "4985019" | "5037397" | "5100396" | "5149331" | "5167613" | "5176663" | "5261893" | "5298015" | "5344415" | "5358494" | "5556375" | "5607388" | "5636643" | "5645081").PN. OR ("6071267").URPN.				
L298	59	((CARMELI) near2 (ADAHAN)).INV.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:35
L299	14871	wound and (suction vacuum) and (enclosure dressing) and ((bleeding hole) (vacuum breaker))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L300	990	(604/35).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:35
L301	940	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:35
L302	409	(604/313).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:35
L303	2428	(604/317-323).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:35
L304	1726	(604/540-544).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:35
L305	256	(604/902).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:35
L306	596	(606/131).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:35
L307	39	L299 and L300	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L308	191	L299 and L301	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L309	252	L299 and L302	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L310	415	L299 and L303	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT;	OR	OFF	2013/04/03 13:35

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			IBM_TDB			
L311	201	L299 and L304	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L312	9	L299 and L305	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L313	9	L299 and L306	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L314	130	("1251258" | "3171410" | "3486504").PN. OR ("3874387").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:35
L315	246	("3026874" | "3486504" | "4540412" | "4759354" | "4969880").PN. OR ("5149331").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:35
L316	175	("4743232" | "5230350").PN. OR ("5344415").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:35
L317	333	("1355846" | "2547758" | "2632443" | "2682873" | "2969057" | "3367332" | "3648692" | "3682180" | "3826254" | "4080970" | "4096853" | "4139004" | "4165748" | "4245630" | "4261363" | "4275721" | "4297995" | "4333468" | "4373519" | "4382441" | "4392853" | "4392858" | "4419097" | "4475909" | "4480638" | "4525166" | "4525374" | "4540412" | "4543100" | "4551139" | "4569348" | "4605399" | "4608041" | "4640688" | "4655754" | "4733659" | "4743232" | "4787888" | "4826949" | "4838883" | "4840187" | "4863449" | "4872450" | "4878901" | "4897081" | "4906233" | "4906240" | "4919654" | "4941882" | "4953565" | "4969880" | "4985019" | "5037397" | "5100396" | "5149331" | "5167613" | "5176663" | "5261893" | "5298015" | "5344415" | "5358494" | "5556375" | "5607388" | "5636643" | "5645081").PN. OR ("6071267").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:35
L318	59	((CARMELI) near2 (ADAHAN)).INV.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:35
L319	14871	wound and (suction vacuum) and (enclosure dressing) and ((bleeding hole) (vacuum breaker))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35

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L320	990	(604/35).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:35
L321	940	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:35
L322	409	(604/313).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:35
L323	2428	(604/317-323).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:35
L324	1726	(604/540-544).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:35
L325	256	(604/902).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:35
L326	596	(606/131).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:35
L327	39	L319 and L320	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L328	191	L319 and L321	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L329	252	L319 and L322	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L330	415	L319 and L323	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L331	201	L319 and L324	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L332	9	L319 and L325	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L333	9	L319 and L326	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L334	130	("1251258" | "3171410" | "3486504").PN. OR ("3874387").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:35

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L335	246	("3026874" | "3486504" | "4540412" | "4759354" | "4969880").PN. OR ("5149331").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:35
L336	175	("4743232" | "5230350").PN. OR ("5344415").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:35
L337	333	("1355846" | "2547758" | "2632443" | "2682873" | "2969057" | "3367332" | "3648692" | "3682180" | "3826254" | "4080970" | "4096853" | "4139004" | "4165748" | "4245630" | "4261363" | "4275721" | "4297995" | "4333468" | "4373519" | "4382441" | "4392853" | "4392858" | "4419097" | "4475909" | "4480638" | "4525166" | "4525374" | "4540412" | "4543100" | "4551139" | "4569348" | "4605399" | "4608041" | "4640688" | "4655754" | "4733659" | "4743232" | "4787888" | "4826949" | "4838883" | "4840187" | "4863449" | "4872450" | "4878901" | "4897081" | "4906233" | "4906240" | "4919654" | "4941882" | "4953565" | "4969880" | "4985019" | "5037397" | "5100396" | "5149331" | "5167613" | "5176663" | "5261893" | "5298015" | "5344415" | "5358494" | "5556375" | "5607388" | "5636643" | "5645081").PN. OR ("6071267").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/04/03 13:35
L338	39	L274 and (vent venting ventillation)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L339	55	L275 and (vent venting ventillation)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L340	27	L276 and (vent venting ventillation)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L341	67	L277 and (vent venting ventillation)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L342	75	"4108574" "4208171"	US-PGPUB; USPAT; EPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L343	0	L342 and (air adj hole)	US-PGPUB; USPAT; EPO;	OR	OFF	2013/04/03 13:35

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			DERWENT; IBM_TDB			
L344	6	L342 and (vent venting)	US-PGPUB; USPAT; EPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L345	6	"20040015042" "20050180868"	US-PGPUB; USPAT; EPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L346	67	"4552552"	US-PGPUB; USPAT; EPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L347	36	L346 and (vent venting)	US-PGPUB; USPAT; EPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L348	0	L346 and (air adj hole)	US-PGPUB; USPAT; EPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L349	26	"5116206" "7503910"	US-PGPUB; USPAT; EPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L350	7	L349 and (vent venting)	US-PGPUB; USPAT; EPO; DERWENT; IBM_TDB	OR	OFF	2013/04/03 13:35
L351	940	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:35
L352	990	(604/35).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/04/03 13:35
S1	53	((CARMELI) near2 (ADAHAN)).INV.	US-PGPUB; USPAT; USOCR	OR	OFF	2010/10/05 16:32
S2	11641	wound and (suction vacuum) and (enclosure dressing) and ((bleeding hole) (vacuum breaker))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/10/05 16:47
S3	851	(604/35).CCLS.	US-PGPUB; USPAT	OR	OFF	2010/10/05 16:48
S4	746	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2010/10/05 16:48
S5	266	(604/313).CCLS.	US-PGPUB; USPAT	OR	OFF	2010/10/05 16:48
S6	1805	(604/317-323).CCLS.	US-PGPUB; USPAT	OR	OFF	2010/10/05 16:49

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S7	1255	(604/540-544).CCLS.	US-PGPUB; USPAT	OR	OFF	2010/10/05 16:49
S8	250	(604/902).CCLS.	US-PGPUB; USPAT	OR	OFF	2010/10/05 16:49
S9	505	(606/131).CCLS.	US-PGPUB; USPAT	OR	OFF	2010/10/05 16:49
S10	17	S2 and S3	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/10/05 16:49
S11	119	S2 and S4	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/10/05 16:50
S12	126	S2 and S5	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/10/05 16:50
S13	117	S2 and S6	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/10/05 16:50
S14	109	S2 and S7	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/10/05 16:50
S15	7	S2 and S8	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/10/05 16:50
S16	4	S2 and S9	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/10/05 16:50
S17	63	("1251258" | "3171410" | "3486504").PN. OR ("3874387").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2010/10/05 16:51
S18	99	("3026874" | "3486504" | "4540412" | "4759354" | "4969880").PN. OR ("5149331").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2010/10/05 16:52
S19	73	("4743232" | "5230350").PN. OR ("5344415").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2010/10/05 16:52
S20	154	("1355846" | "2547758" | "2632443" | "2682873" | "2969057" | "3367332" |	US-PGPUB; USPAT;	OR	OFF	2010/10/05 16:52

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		"3648692" | "3682180" | "3826254" | "4080970" | "4096853" | "4139004" | "4165748" | "4245630" | "4261363" | "4275721" | "4297995" | "4333468" | "4373519" | "4382441" | "4392853" | "4392858" | "4419097" | "4475909" | "4480638" | "4525166" | "4525374" | "4540412" | "4543100" | "4551139" | "4569348" | "4605399" | "4608041" | "4640688" | "4655754" | "4733659" | "4743232" | "4787888" | "4826949" | "4838883" | "4840187" | "4863449" | "4872450" | "4878901" | "4897081" | "4906233" | "4906240" | "4919654" | "4941882" | "4953565" | "4969880" | "4985019" | "5037397" | "5100396" | "5149331" | "5167613" | "5176663" | "5261893" | "5298015" | "5344415" | "5358494" | "5556375" | "5607388" | "5636643" | "5645081").PN. OR ("6071267").URPN.	USOCR			
S21	54	((CARMELI) near2 (ADAHAN)).INV.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/04/15 11:54
S22	12345	wound and (suction vacuum) and (enclosure dressing) and ((bleeding hole) (vacuum breaker))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 11:54
S23	881	(604/35).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 11:54
S24	784	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 11:54
S25	290	(604/313).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 11:54
S26	1923	(604/317-323).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 11:54
S27	1341	(604/540-544).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 11:54
S28	251	(604/902).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 11:54
S29	521	(606/131).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 11:54
S30	18	S22 and S23	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 11:54
S31	135	S22 and S24	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 11:54
S32	149	S22 and S25	US-PGPUB; USPAT; USOCR; EPO; JPO;	OR	OFF	2011/04/15 11:54

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			DERWENT; IBM_TDB			
S33	169	S22 and S26	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 11:54
S34	125	S22 and S27	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 11:54
S35	7	S22 and S28	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 11:54
S36	4	S22 and S29	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 11:54
S37	74	("1251258" | "3171410" | "3486504").PN. OR ("3874387").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/04/15 11:54
S38	114	("3026874" | "3486504" | "4540412" | "4759354" | "4969880").PN. OR ("5149331").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/04/15 11:54
S39	82	("4743232" | "5230350").PN. OR ("5344415").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/04/15 11:54
S40	174	("1355846" | "2547758" | "2632443" | "2682873" | "2969057" | "3367332" | "3648692" | "3682180" | "3826254" | "4080970" | "4096853" | "4139004" | "4165748" | "4245630" | "4261363" | "4275721" | "4297995" | "4333468" | "4373519" | "4382441" | "4392853" | "4392858" | "4419097" | "4475909" | "4480638" | "4525166" | "4525374" | "4540412" | "4543100" | "4551139" | "4569348" | "4605399" | "4608041" | "4640688" | "4655754" | "4733659" | "4743232" | "4787888" | "4826949" | "4838883" | "4840187" | "4863449" | "4872450" | "4878901" | "4897081" | "4906233" | "4906240" | "4919654" | "4941882" | "4953565" | "4969880" | "4985019" | "5037397" | "5100396" | "5149331" | "5167613" | "5176663" | "5261893" | "5298015" | "5344415" | "5358494" | "5556375" | "5607388" | "5636643" | "5645081").PN. OR ("6071267").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/04/15 11:54
S41	54	((CARMELI) near2 (ADAHAN)).INV.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/04/15 12:53

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S42	12345	wound and (suction vacuum) and (enclosure dressing) and ((bleeding hole) (vacuum breaker))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 12:53
S43	881	(604/35).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 12:53
S44	784	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 12:53
S45	290	(604/313).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 12:53
S46	1923	(604/317-323).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 12:53
S47	1341	(604/540-544).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 12:53
S48	251	(604/902).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 12:53
S49	521	(606/131).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 12:53
S50	18	S42 and S43	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 12:53
S51	135	S42 and S44	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 12:53
S52	149	S42 and S45	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 12:53
S53	169	S42 and S46	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 12:53
S54	125	S42 and S47	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 12:53
S55	7	S42 and S48	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 12:53
S56	4	S42 and S49	US-PGPUB; USPAT; USOCR;	OR	OFF	2011/04/15 12:53

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			EPO; JPO; DERWENT; IBM_TDB			
S57	74	("1251258" | "3171410" | "3486504").PN. OR ("3874387").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/04/15 12:53
S58	114	("3026874" | "3486504" | "4540412" | "4759354" | "4969880").PN. OR ("5149331").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/04/15 12:53
S59	82	("4743232" | "5230350").PN. OR ("5344415").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/04/15 12:53
S60	174	("1355846" | "2547758" | "2632443" | "2682873" | "2969057" | "3367332" | "3648692" | "3682180" | "3826254" | "4080970" | "4096853" | "4139004" | "4165748" | "4245630" | "4261363" | "4275721" | "4297995" | "4333468" | "4373519" | "4382441" | "4392853" | "4392858" | "4419097" | "4475909" | "4480638" | "4525166" | "4525374" | "4540412" | "4543100" | "4551139" | "4569348" | "4605399" | "4608041" | "4640688" | "4655754" | "4733659" | "4743232" | "4787888" | "4826949" | "4838883" | "4840187" | "4863449" | "4872450" | "4878901" | "4897081" | "4906233" | "4906240" | "4919654" | "4941882" | "4953565" | "4969880" | "4985019" | "5037397" | "5100396" | "5149331" | "5167613" | "5176663" | "5261893" | "5298015" | "5344415" | "5358494" | "5556375" | "5607388" | "5636643" | "5645081").PN. OR ("6071267").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/04/15 12:53
S61	54	((CARMELI) near2 (ADAHAN)).INV.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/04/15 12:53
S62	12345	wound and (suction vacuum) and (enclosure dressing) and ((bleeding hole) (vacuum breaker))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 12:53
S63	881	(604/35).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 12:53
S64	784	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 12:53
S65	290	(604/313).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 12:53
S66	1923	(604/317-323).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 12:53
S67	1341	(604/540-544).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 12:53
S68	251	(604/902).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 12:53
S69	521	(606/131).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 12:53
S70	18	S62 and S63	US-PGPUB;	OR	OFF	2011/04/15

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			USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB			12:53
S71	135	S62 and S64	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 12:53
S72	149	S62 and S65	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 12:53
S73	169	S62 and S66	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 12:53
S74	125	S62 and S67	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 12:53
S75	7	S62 and S68	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 12:53
S76	4	S62 and S69	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 12:53
S77	74	("1251258" | "3171410" | "3486504").PN. OR ("3874387").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/04/15 12:53
S78	114	("3026874" | "3486504" | "4540412" | "4759354" | "4969880").PN. OR ("5149331").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/04/15 12:53
S79	82	("4743232" | "5230350").PN. OR ("5344415").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/04/15 12:53
S80	174	("1355846" | "2547758" | "2632443" | "2682873" | "2969057" | "3367332" | "3648692" | "3682180" | "3826254" | "4080970" | "4096853" | "4139004" | "4165748" | "4245630" | "4261363" | "4275721" | "4297995" | "4333468" | "4373519" | "4382441" | "4392853" | "4392858" | "4419097" | "4475909" | "4480638" | "4525166" | "4525374" | "4540412" | "4543100" | "4551139" |	US-PGPUB; USPAT; USOCR	OR	OFF	2011/04/15 12:53

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		"4569348" | "4605399" | "4608041" | "4640688" | "4655754" | "4733659" | "4743232" | "4787888" | "4826949" | "4838883" | "4840187" | "4863449" | "4872450" | "4878901" | "4897081" | "4906233" | "4906240" | "4919654" | "4941882" | "4953565" | "4969880" | "4985019" | "5037397" | "5100396" | "5149331" | "5167613" | "5176663" | "5261893" | "5298015" | "5344415" | "5358494" | "5556375" | "5607388" | "5636643" | "5645081").PN. OR ("6071267").URPN.				
S84	55	((CARMELI) near2 (ADAHAN)).INV.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/09/26 13:57
S85	12846	wound and (suction vacuum) and (enclosure dressing) and ((bleeding hole) (vacuum breaker))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S86	902	(604/35).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S87	815	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S88	308	(604/313).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S89	2020	(604/317-323).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S90	1424	(604/540-544).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S91	253	(604/902).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S92	529	(606/131).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S93	21	S85 and S86	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S94	150	S85 and S87	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S95	164	S85 and S88	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S96	214	S85 and S89	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT;	OR	OFF	2011/09/26 13:57

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			IBM_TDB			
S97	137	S85 and S90	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S98	8	S85 and S91	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S99	5	S85 and S92	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S100	88	("1251258" | "3171410" | "3486504").PN. OR ("3874387").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/09/26 13:57
S101	133	("3026874" | "3486504" | "4540412" | "4759354" | "4969880").PN. OR ("5149331").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/09/26 13:57
S102	94	("4743232" | "5230350").PN. OR ("5344415").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/09/26 13:57
S103	200	("1355846" | "2547758" | "2632443" | "2682873" | "2969057" | "3367332" | "3648692" | "3682180" | "3826254" | "4080970" | "4096853" | "4139004" | "4165748" | "4245630" | "4261363" | "4275721" | "4297995" | "4333468" | "4373519" | "4382441" | "4392853" | "4392858" | "4419097" | "4475909" | "4480638" | "4525166" | "4525374" | "4540412" | "4543100" | "4551139" | "4569348" | "4605399" | "4608041" | "4640688" | "4655754" | "4733659" | "4743232" | "4787888" | "4826949" | "4838883" | "4840187" | "4863449" | "4872450" | "4878901" | "4897081" | "4906233" | "4906240" | "4919654" | "4941882" | "4953565" | "4969880" | "4985019" | "5037397" | "5100396" | "5149331" | "5167613" | "5176663" | "5261893" | "5298015" | "5344415" | "5358494" | "5556375" | "5607388" | "5636643" | "5645081").PN. OR ("6071267").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/09/26 13:57
S104	55	((CARMELI) near2 (ADAHAN)).INV.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/09/26 13:57
S105	12846	wound and (suction vacuum) and (enclosure dressing) and ((bleeding hole) (vacuum breaker))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57

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S106	902	(604/35).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S107	815	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S108	308	(604/313).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S109	2020	(604/317-323).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S110	1424	(604/540-544).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S111	253	(604/902).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S112	529	(606/131).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S113	21	S105 and S106	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S114	150	S105 and S107	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S115	164	S105 and S108	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S116	214	S105 and S109	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S117	137	S105 and S110	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S118	8	S105 and S111	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S119	5	S105 and S112	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S120	88	("1251258" | "3171410" | "3486504").PN. OR ("3874387").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/09/26 13:57

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S121	133	("3026874" | "3486504" | "4540412" | "4759354" | "4969880").PN. OR ("5149331").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/09/26 13:57
S122	94	("4743232" | "5230350").PN. OR ("5344415").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/09/26 13:57
S123	200	("1355846" | "2547758" | "2632443" | "2682873" | "2969057" | "3367332" | "3648692" | "3682180" | "3826254" | "4080970" | "4096853" | "4139004" | "4165748" | "4245630" | "4261363" | "4275721" | "4297995" | "4333468" | "4373519" | "4382441" | "4392853" | "4392858" | "4419097" | "4475909" | "4480638" | "4525166" | "4525374" | "4540412" | "4543100" | "4551139" | "4569348" | "4605399" | "4608041" | "4640688" | "4655754" | "4733659" | "4743232" | "4787888" | "4826949" | "4838883" | "4840187" | "4863449" | "4872450" | "4878901" | "4897081" | "4906233" | "4906240" | "4919654" | "4941882" | "4953565" | "4969880" | "4985019" | "5037397" | "5100396" | "5149331" | "5167613" | "5176663" | "5261893" | "5298015" | "5344415" | "5358494" | "5556375" | "5607388" | "5636643" | "5645081").PN. OR ("6071267").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/09/26 13:57
S124	55	((CARMELI) near2 (ADAHAN)).INV.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/09/26 13:57
S125	12846	wound and (suction vacuum) and (enclosure dressing) and ((bleeding hole) (vacuum breaker))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S126	902	(604/35).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S127	815	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S128	308	(604/313).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S129	2020	(604/317-323).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S130	1424	(604/540-544).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S131	253	(604/902).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S132	529	(606/131).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S133	21	S125 and S126	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S134	150	S125 and S127	US-PGPUB;	OR	OFF	2011/09/26

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			USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB			13:57
S135	164	S125 and S128	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S136	214	S125 and S129	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S137	137	S125 and S130	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S138	8	S125 and S131	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S139	5	S125 and S132	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S140	88	("1251258" | "3171410" | "3486504").PN. OR ("3874387").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/09/26 13:57
S141	133	("3026874" | "3486504" | "4540412" | "4759354" | "4969880").PN. OR ("5149331").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/09/26 13:57
S142	94	("4743232" | "5230350").PN. OR ("5344415").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/09/26 13:57
S143	200	("1355846" | "2547758" | "2632443" | "2682873" | "2969057" | "3367332" | "3648692" | "3682180" | "3826254" | "4080970" | "4096853" | "4139004" | "4165748" | "4245630" | "4261363" | "4275721" | "4297995" | "4333468" | "4373519" | "4382441" | "4392853" | "4392858" | "4419097" | "4475909" | "4480638" | "4525166" | "4525374" | "4540412" | "4543100" | "4551139" | "4569348" | "4605399" | "4608041" | "4640688" | "4655754" | "4733659" | "4743232" | "4787888" | "4826949" | "4838883" | "4840187" | "4863449" | "4872450" | "4878901" | "4897081" | "4906233" | "4906240" | "4919654" | "4941882" | "4953565" | "4969880" |	US-PGPUB; USPAT; USOCR	OR	OFF	2011/09/26 13:57

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		"4985019" | "5037397" | "5100396" | "5149331" | "5167613" | "5176663" | "5261893" | "5298015" | "5344415" | "5358494" | "5556375" | "5607388" | "5636643" | "5645081").PN. OR ("6071267").URPN.				
S144	55	((CARMELI) near2 (ADAHAN)).INV.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/09/26 13:57
S145	12846	wound and (suction vacuum) and (enclosure dressing) and ((bleeding hole) (vacuum breaker))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S146	902	(604/35).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S147	815	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S148	308	(604/313).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S149	2020	(604/317-323).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S150	1424	(604/540-544).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S151	253	(604/902).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S152	529	(606/131).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S153	21	S145 and S146	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S154	150	S145 and S147	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S155	164	S145 and S148	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S156	214	S145 and S149	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S157	137	S145 and S150	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57

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S158	8	S145 and S151	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S159	5	S145 and S152	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S160	88	("1251258" | "3171410" | "3486504").PN. OR ("3874387").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/09/26 13:57
S161	133	("3026874" | "3486504" | "4540412" | "4759354" | "4969880").PN. OR ("5149331").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/09/26 13:57
S162	94	("4743232" | "5230350").PN. OR ("5344415").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/09/26 13:57
S163	200	("1355846" | "2547758" | "2632443" | "2682873" | "2969057" | "3367332" | "3648692" | "3682180" | "3826254" | "4080970" | "4096853" | "4139004" | "4165748" | "4245630" | "4261363" | "4275721" | "4297995" | "4333468" | "4373519" | "4382441" | "4392853" | "4392858" | "4419097" | "4475909" | "4480638" | "4525166" | "4525374" | "4540412" | "4543100" | "4551139" | "4569348" | "4605399" | "4608041" | "4640688" | "4655754" | "4733659" | "4743232" | "4787888" | "4826949" | "4838883" | "4840187" | "4863449" | "4872450" | "4878901" | "4897081" | "4906233" | "4906240" | "4919654" | "4941882" | "4953565" | "4969880" | "4985019" | "5037397" | "5100396" | "5149331" | "5167613" | "5176663" | "5261893" | "5298015" | "5344415" | "5358494" | "5556375" | "5607388" | "5636643" | "5645081").PN. OR ("6071267").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/09/26 13:57
S164	26	S100 and (vent venting ventillation)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 14:02
S165	32	S101 and (vent venting ventillation)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 14:02
S166	15	S102 and (vent venting ventillation)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT;	OR	OFF	2011/09/26 14:02

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			IBM_TDB			
S167	36	S103 and (vent venting ventillation)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 14:02
S168	70	"4108574" "4208171"	US-PGPUB; USPAT; EPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 14:22
S169	0	S168 and (air adj hole)	US-PGPUB; USPAT; EPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 14:23
S170	5	S168 and (vent venting)	US-PGPUB; USPAT; EPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 14:23
S171	6	"20040015042" "20050180868"	US-PGPUB; USPAT; EPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 14:24
S172	55	"4552552"	US-PGPUB; USPAT; EPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 14:24
S173	28	S172 and (vent venting)	US-PGPUB; USPAT; EPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 14:25
S174	0	S172 and (air adj hole)	US-PGPUB; USPAT; EPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 14:25
S175	18	"5116206" "7503910"	US-PGPUB; USPAT; EPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 14:26
S176	3	S175 and (vent venting)	US-PGPUB; USPAT; EPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 14:27
S178	858	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/05/24 16:07
S179	929	(604/35).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/05/24 16:07
S180	56	((CARMELI) near2 (ADAHAN)).INV.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25

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S181	14131	wound and (suction vacuum) and (enclosure dressing) and ((bleeding hole) (vacuum breaker))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S182	959	(604/35).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
S183	879	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
S184	371	(604/313).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
S185	2276	(604/317-323).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
S186	1612	(604/540-544).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
S187	255	(604/902).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
S188	579	(606/131).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
S189	33	S181 and S182	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S190	172	S181 and S183	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S191	217	S181 and S184	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S192	348	S181 and S185	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S193	176	S181 and S186	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S194	9	S181 and S187	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S195	8	S181 and S188	US-PGPUB; USPAT; USOCR;	OR	OFF	2012/09/14 12:25

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			EPO; JPO; DERWENT; IBM_TDB			
S196	119	("1251258" | "3171410" | "3486504").PN. OR ("3874387").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
S197	210	("3026874" | "3486504" | "4540412" | "4759354" | "4969880").PN. OR ("5149331").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
S198	147	("4743232" | "5230350").PN. OR ("5344415").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
S199	288	("1355846" | "2547758" | "2632443" | "2682873" | "2969057" | "3367332" | "3648692" | "3682180" | "3826254" | "4080970" | "4096853" | "4139004" | "4165748" | "4245630" | "4261363" | "4275721" | "4297995" | "4333468" | "4373519" | "4382441" | "4392853" | "4392858" | "4419097" | "4475909" | "4480638" | "4525166" | "4525374" | "4540412" | "4543100" | "4551139" | "4569348" | "4605399" | "4608041" | "4640688" | "4655754" | "4733659" | "4743232" | "4787888" | "4826949" | "4838883" | "4840187" | "4863449" | "4872450" | "4878901" | "4897081" | "4906233" | "4906240" | "4919654" | "4941882" | "4953565" | "4969880" | "4985019" | "5037397" | "5100396" | "5149331" | "5167613" | "5176663" | "5261893" | "5298015" | "5344415" | "5358494" | "5556375" | "5607388" | "5636643" | "5645081").PN. OR ("6071267").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
S200	56	((CARMELI) near2 (ADAHAN)).INV.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
S201	14131	wound and (suction vacuum) and (enclosure dressing) and ((bleeding hole) (vacuum breaker))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S202	959	(604/35).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
S203	879	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
S204	371	(604/313).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
S205	2276	(604/317-323).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
S206	1612	(604/540-544).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
S207	255	(604/902).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
S208	579	(606/131).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
S209	33	S201 and S202	US-PGPUB;	OR	OFF	2012/09/14

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			USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB			12:25
S210	172	S201 and S203	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S211	217	S201 and S204	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S212	348	S201 and S205	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S213	176	S201 and S206	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S214	9	S201 and S207	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S215	8	S201 and S208	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S216	119	("1251258" | "3171410" | "3486504").PN. OR ("3874387").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
S217	210	("3026874" | "3486504" | "4540412" | "4759354" | "4969880").PN. OR ("5149331").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
S218	147	("4743232" | "5230350").PN. OR ("5344415").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
S219	288	("1355846" | "2547758" | "2632443" | "2682873" | "2969057" | "3367332" | "3648692" | "3682180" | "3826254" | "4080970" | "4096853" | "4139004" | "4165748" | "4245630" | "4261363" | "4275721" | "4297995" | "4333468" | "4373519" | "4382441" | "4392853" | "4392858" | "4419097" | "4475909" | "4480638" | "4525166" | "4525374" | "4540412" | "4543100" | "4551139" |	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25

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		"4569348" | "4605399" | "4608041" | "4640688" | "4655754" | "4733659" | "4743232" | "4787888" | "4826949" | "4838883" | "4840187" | "4863449" | "4872450" | "4878901" | "4897081" | "4906233" | "4906240" | "4919654" | "4941882" | "4953565" | "4969880" | "4985019" | "5037397" | "5100396" | "5149331" | "5167613" | "5176663" | "5261893" | "5298015" | "5344415" | "5358494" | "5556375" | "5607388" | "5636643" | "5645081").PN. OR ("6071267").URPN.				
S220	56	((CARMELI) near2 (ADAHAN)).INV.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
S221	14131	wound and (suction vacuum) and (enclosure dressing) and ((bleeding hole) (vacuum breaker))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S222	959	(604/35).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
S223	879	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
S224	371	(604/313).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
S225	2276	(604/317-323).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
S226	1612	(604/540-544).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
S227	255	(604/902).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
S228	579	(606/131).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
S229	33	S221 and S222	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S230	172	S221 and S223	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S231	217	S221 and S224	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S232	348	S221 and S225	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT;	OR	OFF	2012/09/14 12:25

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			IBM_TDB			
S233	176	S221 and S226	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S234	9	S221 and S227	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S235	8	S221 and S228	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S236	119	("1251258" | "3171410" | "3486504").PN. OR ("3874387").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
S237	210	("3026874" | "3486504" | "4540412" | "4759354" | "4969880").PN. OR ("5149331").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
S238	147	("4743232" | "5230350").PN. OR ("5344415").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
S239	288	("1355846" | "2547758" | "2632443" | "2682873" | "2969057" | "3367332" | "3648692" | "3682180" | "3826254" | "4080970" | "4096853" | "4139004" | "4165748" | "4245630" | "4261363" | "4275721" | "4297995" | "4333468" | "4373519" | "4382441" | "4392853" | "4392858" | "4419097" | "4475909" | "4480638" | "4525166" | "4525374" | "4540412" | "4543100" | "4551139" | "4569348" | "4605399" | "4608041" | "4640688" | "4655754" | "4733659" | "4743232" | "4787888" | "4826949" | "4838883" | "4840187" | "4863449" | "4872450" | "4878901" | "4897081" | "4906233" | "4906240" | "4919654" | "4941882" | "4953565" | "4969880" | "4985019" | "5037397" | "5100396" | "5149331" | "5167613" | "5176663" | "5261893" | "5298015" | "5344415" | "5358494" | "5556375" | "5607388" | "5636643" | "5645081").PN. OR ("6071267").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
S240	56	((CARMELI) near2 (ADAHAN)).INV.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
S241	14131	wound and (suction vacuum) and (enclosure dressing) and ((bleeding hole) (vacuum breaker))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25

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S242	959	(604/35).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
S243	879	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
S244	371	(604/313).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
S245	2276	(604/317-323).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
S246	1612	(604/540-544).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
S247	255	(604/902).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
S248	579	(606/131).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
S249	33	S241 and S242	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S250	172	S241 and S243	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S251	217	S241 and S244	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S252	348	S241 and S245	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S253	176	S241 and S246	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S254	9	S241 and S247	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S255	8	S241 and S248	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S256	119	("1251258" | "3171410" | "3486504").PN. OR ("3874387").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25

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S257	210	("3026874" | "3486504" | "4540412" | "4759354" | "4969880").PN. OR ("5149331").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
S258	147	("4743232" | "5230350").PN. OR ("5344415").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
S259	288	("1355846" | "2547758" | "2632443" | "2682873" | "2969057" | "3367332" | "3648692" | "3682180" | "3826254" | "4080970" | "4096853" | "4139004" | "4165748" | "4245630" | "4261363" | "4275721" | "4297995" | "4333468" | "4373519" | "4382441" | "4392853" | "4392858" | "4419097" | "4475909" | "4480638" | "4525166" | "4525374" | "4540412" | "4543100" | "4551139" | "4569348" | "4605399" | "4608041" | "4640688" | "4655754" | "4733659" | "4743232" | "4787888" | "4826949" | "4838883" | "4840187" | "4863449" | "4872450" | "4878901" | "4897081" | "4906233" | "4906240" | "4919654" | "4941882" | "4953565" | "4969880" | "4985019" | "5037397" | "5100396" | "5149331" | "5167613" | "5176663" | "5261893" | "5298015" | "5344415" | "5358494" | "5556375" | "5607388" | "5636643" | "5645081").PN. OR ("6071267").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
S260	56	((CARMELI) near2 (ADAHAN)).INV.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
S261	14131	wound and (suction vacuum) and (enclosure dressing) and ((bleeding hole) (vacuum breaker))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S262	959	(604/35).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
S263	879	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
S264	371	(604/313).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
S265	2276	(604/317-323).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
S266	1612	(604/540-544).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
S267	255	(604/902).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
S268	579	(606/131).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
S269	33	S261 and S262	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S270	172	S261 and S263	US-PGPUB;	OR	OFF	2012/09/14

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			USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB			12:25
S271	217	S261 and S264	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S272	348	S261 and S265	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S273	176	S261 and S266	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S274	9	S261 and S267	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S275	8	S261 and S268	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S276	119	("1251258" | "3171410" | "3486504").PN. OR ("3874387").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
S277	210	("3026874" | "3486504" | "4540412" | "4759354" | "4969880").PN. OR ("5149331").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
S278	147	("4743232" | "5230350").PN. OR ("5344415").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
S279	288	("1355846" | "2547758" | "2632443" | "2682873" | "2969057" | "3367332" | "3648692" | "3682180" | "3826254" | "4080970" | "4096853" | "4139004" | "4165748" | "4245630" | "4261363" | "4275721" | "4297995" | "4333468" | "4373519" | "4382441" | "4392853" | "4392858" | "4419097" | "4475909" | "4480638" | "4525166" | "4525374" | "4540412" | "4543100" | "4551139" | "4569348" | "4605399" | "4608041" | "4640688" | "4655754" | "4733659" | "4743232" | "4787888" | "4826949" | "4838883" | "4840187" | "4863449" | "4872450" | "4878901" | "4897081" | "4906233" | "4906240" | "4919654" | "4941882" | "4953565" | "4969880" |	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25

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		"4985019" | "5037397" | "5100396" | "5149331" | "5167613" | "5176663" | "5261893" | "5298015" | "5344415" | "5358494" | "5556375" | "5607388" | "5636643" | "5645081").PN. OR ("6071267").URPN.				
S280	56	((CARMELI) near2 (ADAHAN)).INV.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
S281	14131	wound and (suction vacuum) and (enclosure dressing) and ((bleeding hole) (vacuum breaker))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S282	959	(604/35).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
S283	879	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
S284	371	(604/313).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
S285	2276	(604/317-323).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
S286	1612	(604/540-544).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
S287	255	(604/902).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
S288	579	(606/131).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
S289	33	S281 and S282	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S290	172	S281 and S283	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S291	217	S281 and S284	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S292	348	S281 and S285	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S293	176	S281 and S286	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25

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S294	9	S281 and S287	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S295	8	S281 and S288	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S296	119	("1251258" | "3171410" | "3486504").PN. OR ("3874387").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
S297	210	("3026874" | "3486504" | "4540412" | "4759354" | "4969880").PN. OR ("5149331").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
S298	147	("4743232" | "5230350").PN. OR ("5344415").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
S299	288	("1355846" | "2547758" | "2632443" | "2682873" | "2969057" | "3367332" | "3648692" | "3682180" | "3826254" | "4080970" | "4096853" | "4139004" | "4165748" | "4245630" | "4261363" | "4275721" | "4297995" | "4333468" | "4373519" | "4382441" | "4392853" | "4392858" | "4419097" | "4475909" | "4480638" | "4525166" | "4525374" | "4540412" | "4543100" | "4551139" | "4569348" | "4605399" | "4608041" | "4640688" | "4655754" | "4733659" | "4743232" | "4787888" | "4826949" | "4838883" | "4840187" | "4863449" | "4872450" | "4878901" | "4897081" | "4906233" | "4906240" | "4919654" | "4941882" | "4953565" | "4969880" | "4985019" | "5037397" | "5100396" | "5149331" | "5167613" | "5176663" | "5261893" | "5298015" | "5344415" | "5358494" | "5556375" | "5607388" | "5636643" | "5645081").PN. OR ("6071267").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
S300	56	((CARMELI) near2 (ADAHAN)).INV.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
S301	14131	wound and (suction vacuum) and (enclosure dressing) and ((bleeding hole) (vacuum breaker))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S302	959	(604/35).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
S303	879	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
S304	371	(604/313).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
S305	2276	(604/317-323).CCLS.	US-PGPUB;	OR	OFF	2012/09/14

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			USPAT			12:25
S306	1612	(604/540-544).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
S307	255	(604/902).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
S308	579	(606/131).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
S309	33	S301 and S302	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S310	172	S301 and S303	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S311	217	S301 and S304	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S312	348	S301 and S305	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S313	176	S301 and S306	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S314	9	S301 and S307	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S315	8	S301 and S308	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S316	119	("1251258" | "3171410" | "3486504").PN. OR ("3874387").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
S317	210	("3026874" | "3486504" | "4540412" | "4759354" | "4969880").PN. OR ("5149331").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
S318	147	("4743232" | "5230350").PN. OR ("5344415").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
S319	288	("1355846" | "2547758" | "2632443" |	US-PGPUB;	OR	OFF	2012/09/14

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		"2682873" | "2969057" | "3367332" | "3648692" | "3682180" | "3826254" | "4080970" | "4096853" | "4139004" | "4165748" | "4245630" | "4261363" | "4275721" | "4297995" | "4333468" | "4373519" | "4382441" | "4392853" | "4392858" | "4419097" | "4475909" | "4480638" | "4525166" | "4525374" | "4540412" | "4543100" | "4551139" | "4569348" | "4605399" | "4608041" | "4640688" | "4655754" | "4733659" | "4743232" | "4787888" | "4826949" | "4838883" | "4840187" | "4863449" | "4872450" | "4878901" | "4897081" | "4906233" | "4906240" | "4919654" | "4941882" | "4953565" | "4969880" | "4985019" | "5037397" | "5100396" | "5149331" | "5167613" | "5176663" | "5261893" | "5298015" | "5344415" | "5358494" | "5556375" | "5607388" | "5636643" | "5645081").PN. OR ("6071267").URPN.	USPAT; USOCR			12:25
S320	56	((CARMELI) near2 (ADAHAN)).INV.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
S321	14131	wound and (suction vacuum) and (enclosure dressing) and ((bleeding hole) (vacuum breaker))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S322	959	(604/35).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
S323	879	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
S324	371	(604/313).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
S325	2276	(604/317-323).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
S326	1612	(604/540-544).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
S327	255	(604/902).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
S328	579	(606/131).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
S329	33	S321 and S322	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S330	172	S321 and S323	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S331	217	S321 and S324	US-PGPUB; USPAT; USOCR;	OR	OFF	2012/09/14 12:25

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			EPO; JPO; DERWENT; IBM_TDB			
S332	348	S321 and S325	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S333	176	S321 and S326	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S334	9	S321 and S327	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S335	8	S321 and S328	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S336	119	("1251258" | "3171410" | "3486504").PN. OR ("3874387").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
S337	210	("3026874" | "3486504" | "4540412" | "4759354" | "4969880").PN. OR ("5149331").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
S338	147	("4743232" | "5230350").PN. OR ("5344415").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
S339	288	("1355846" | "2547758" | "2632443" | "2682873" | "2969057" | "3367332" | "3648692" | "3682180" | "3826254" | "4080970" | "4096853" | "4139004" | "4165748" | "4245630" | "4261363" | "4275721" | "4297995" | "4333468" | "4373519" | "4382441" | "4392853" | "4392858" | "4419097" | "4475909" | "4480638" | "4525166" | "4525374" | "4540412" | "4543100" | "4551139" | "4569348" | "4605399" | "4608041" | "4640688" | "4655754" | "4733659" | "4743232" | "4787888" | "4826949" | "4838883" | "4840187" | "4863449" | "4872450" | "4878901" | "4897081" | "4906233" | "4906240" | "4919654" | "4941882" | "4953565" | "4969880" | "4985019" | "5037397" | "5100396" | "5149331" | "5167613" | "5176663" | "5261893" | "5298015" | "5344415" | "5358494" | "5556375" | "5607388" | "5636643" | "5645081").PN. OR ("6071267").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
S340	34	S276 and (vent venting ventillation)	US-PGPUB; USPAT;	OR	OFF	2012/09/14 12:25

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			USOCR; EPO; JPO; DERWENT; IBM_TDB			
S341	43	S277 and (vent venting ventillation)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S342	19	S278 and (vent venting ventillation)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S343	53	S279 and (vent venting ventillation)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S344	73	"4108574" "4208171"	US-PGPUB; USPAT; EPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S345	0	S344 and (air adj hole)	US-PGPUB; USPAT; EPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S346	6	S344 and (vent venting)	US-PGPUB; USPAT; EPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S347	6	"20040015042" "20050180868"	US-PGPUB; USPAT; EPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S348	63	"4552552"	US-PGPUB; USPAT; EPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S349	33	S348 and (vent venting)	US-PGPUB; USPAT; EPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S350	0	S348 and (air adj hole)	US-PGPUB; USPAT; EPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S351	21	"5116206" "7503910"	US-PGPUB; USPAT; EPO;	OR	OFF	2012/09/14 12:25

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			DERWENT; IBM_TDB			
S352	4	S351 and (vent venting)	US-PGPUB; USPAT; EPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
S353	879	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
S354	959	(604/35).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L81	0	pressure and regulating and device and sealed and vial and wheath and cap and connector and positioned and within and bag and interior and surface and outer and adapted and expanded and unfolded and compensat and changes and volume and medical and fluid and move and first and orientation and portion and partially and unexpanded and folded and second and lubricant and layer and impermeable and impeding and passage and between and regulates and withdrawn and equilibrate and opposite and reduces and friction.clm.	US-PGPUB	OR	OFF	2013/04/03 13:34
L175	0	pressure and regulating and device and sealed and vial and wheath and cap and connector and positioned and within and bag and interior and surface and outer and adapted and expanded and unfolded and compensat and changes and volume and medical and fluid and move and first and orientation and portion and partially and unexpanded and folded and second and lubricant and layer and impermeable and impeding and passage and between and regulates and withdrawn and equilibrate and opposite and reduces and friction.clm.	US-PGPUB	OR	OFF	2013/04/03 13:35
L353	0	pressure and regulating and device and sealed and vial and wheath and cap and connector and positioned and within and bag and interior and surface and outer and adapted and expanded and unfolded and compensat and changes and volume and medical and fluid and move and first and orientation and portion and partially and unexpanded and folded and second and lubricant and layer and impermeable and impeding and passage and between and regulates and withdrawn and equilibrate and opposite and reduces and friction.clm.	US-PGPUB	OR	OFF	2013/04/03 13:35
L354	0	pressure and regulating and device and sealed and vial and wheath and cap and connector and positioned and within and bag and interior and surface and outer and adapted and expanded and unfolded and compensat and changes and volume and	US-PGPUB	OR	OFF	2013/04/03 13:35

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		medical and fluid and move and first and orientation and portion and partially and unexpanded and folded and second and lubricant and layer and impermeable and impeding and passage and between and regulates and withdrawn and equilibrate and opposite and reduces and friction.clm.				
L355	0	enclosure and applying and negative and pressure and wound and attachable and circumference and confined and volume and tube and outlet and connectable and vacuum and source and venting and arrangement and calibrated and orifice and restrict and flow and ambient and air.clm.	USPAT; UPAD	OR	OFF	2013/04/03 13:35
L356	1	enclosure and applying and negative and pressure and wound and attachable and circumference and confined and volume and tube and outlet and connectable and vacuum and source and venting and arrangement and calibrated and orifice and restrict and flow and ambient and air.clm.	US-PGPUB	OR	OFF	2013/04/03 13:35
S81	0	pressure and regulating and device and sealed and vial and wheath and cap and connector and positioned and within and bag and interior and surface and outer and adapted and expanded and unfolded and compensat and changes and volume and medical and fluid and move and first and orientation and portion and partially and unexpanded and folded and second and lubricant and layer and impermeable and impeding and passage and between and regulates and withdrawn and equilibrate and opposite and reduces and friction.clm.	US-PGPUB	OR	OFF	2011/04/15 13:00
S177	0	pressure and regulating and device and sealed and vial and wheath and cap and connector and positioned and within and bag and interior and surface and outer and adapted and expanded and unfolded and compensat and changes and volume and medical and fluid and move and first and orientation and portion and partially and unexpanded and folded and second and lubricant and layer and impermeable and impeding and passage and between and regulates and withdrawn and equilibrate and opposite and reduces and friction.clm.	US-PGPUB	OR	OFF	2011/09/26 13:57
S355	0	pressure and regulating and device and sealed and vial and wheath and cap and connector and positioned and within and bag and interior and surface and outer and adapted and expanded and unfolded and compensat and changes and volume and medical and fluid and move and first and orientation and portion and partially and unexpanded and folded and second and lubricant and layer and impermeable and impeding and passage and between and regulates and withdrawn and equilibrate and opposite and reduces and friction.clm.	US-PGPUB	OR	OFF	2012/09/14 12:25
S356	0	pressure and regulating and device and sealed and vial and wheath and cap and	US-PGPUB	OR	OFF	2012/09/14 12:25

Medela LLC and Medela AG
Exhibit 1008
Page #282

		connector and positioned and within and bag and interior and surface and outer and adapted and expanded and unfolded and compensat and changes and volume and medical and fluid and move and first and orientation and portion and partially and unexpanded and folded and second and lubricant and layer and impermeable and impeding and passage and between and regulates and withdrawn and equilibrate and opposite and reduces and friction.clm.				
S357	0	enclosure and applying and negative and pressure and wound and attachable and circumference and confined and volume and tube and outlet and connectable and vacuum and source and venting and arrangement and calibrated and orifice and restrict and flow and ambient and air.clm.	USPAT; UPAD	OR	OFF	2012/09/14 12:30
S358	1	enclosure and applying and negative and pressure and wound and attachable and circumference and confined and volume and tube and outlet and connectable and vacuum and source and venting and arrangement and calibrated and orifice and restrict and flow and ambient and air.clm.	US-PGPUB	OR	OFF	2012/09/14 12:30

4/3/2013 1:44:45 PM
C:\Users\itreyger\Documents\EAST\Workspaces\11989297.wsp

Medela LLC and Medela AG
Exhibit 1008
Page #283

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

BIB DATA SHEET

CONFIRMATION NO. 4766

SERIAL NUMBER	FILING or 371(c) DATE RULE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
11/989,297	01/24/2008	604	3761	29068U

APPLICANTS
Carmeli Adahan, Jerusalem, ISRAEL;

**** CONTINUING DATA ************************* I.T. 06/22/2010**
This application is a 371 of PCT/IL2005/000784 07/24/2005

**** FOREIGN APPLICATIONS ************************* I.T. 06/22/2010**

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED **** ** SMALL ENTITY **
07/08/2009

Foreign Priority claimed ☑ Yes ☐ No 35 USC 119(a-d) conditions met ☐ Yes ☐ No Verified and Acknowledged /ILYA Y TREYGER/ Examiner's Signature	☐ Met after Allowance Initials	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
		ISRAEL	2	33	5

ADDRESS

THE NATH LAW GROUP
112 South West Street
Alexandria, VA 22314
UNITED STATES

TITLE

Wound closure and drainage system

FILING FEE RECEIVED		
1000	FEES: Authority has been given in Paper No._____ to charge/credit DEPOSIT ACCOUNT No._____ for following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11989297	ADAHAN, CARMELI
	Examiner	Art Unit
	ILYA Y TREYGER	3761

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
604	540-544	10/5/2010	I. T.

SEARCH NOTES		
Search Notes	Date	Examiner
EAST Search attached	10/5/2010	I. T.
Search updated	4/15/2011	I. T.
Search updated	9/26/2011	I. T.
Search updated	5/22/2012	I. T.
Search updated	9/14/2012	I. T.
Search updated	4/3/2013	I. T.

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
604	540-544	9/14/2012	I. T.
	PGPUB Searched	9/14/2012	I. T.
	All updated	4/3/2013	I. T.

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www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
11/989,297	01/24/2008	Carmeli Adahan	ADAHAN

CONFIRMATION NO. 4766

1444
Browdy and Neimark, PLLC
1625 K Street, N.W.
Suite 1100
Washington, DC 20006

POA ACCEPTANCE LETTER

OC000000059977934

Date Mailed: 03/27/2013

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 03/14/2013.

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

/ttkim/

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

Medela LLC and Medela AG
Exhibit 1008
Page #286

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
11/989,297	01/24/2008	Carmeli Adahan	067913.000085

CONFIRMATION NO. 4766

20230
VORYS, SATER, SEYMOUR & PEASE LLP
1909 K St., NW
9th Floor
WASHINGTON, DC 20006-1152

POWER OF ATTORNEY NOTICE

OC000000059977918

Date Mailed: 03/27/2013

NOTICE REGARDING CHANGE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 03/14/2013.

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

/ttkim/

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

179704.2

PTO/SB/81 (01-09)
Approved for use through 11/30/2011. OMB 0651-0035
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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POWER OF ATTORNEY OR REVOCATION OF POWER OF ATTORNEY WITH A NEW POWER OF ATTORNEY AND CHANGE OF CORRESPONDENCE ADDRESS

Application Number	11/969,297
Filing Date	2008-01-24
First Named Inventor	C. ADAHAN
Title	WOUND CLOSURE AND DRAINAGE SYSTEM
Art Unit	3761
Examiner Name	TREYGER, ILYA Y
Attorney Docket Number	ADAHAN

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

☐ A Power of Attorney is submitted herewith.

OR

☒ I hereby appoint Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith: 01444

OR

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

Practitioner(s) Name	Registration Number

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

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

OR

☐ The address associated with Customer Number:

OR

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

I am the:

☒ Applicant/Inventor.

OR

☐ Assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) (Form PTO/SB/96) submitted herewith or filed on _____.

SIGNATURE of Applicant or Assignee of Record

Signature	X Carmel Adahan	Date	X MARCH 8, 13
Name	Carmeli ADAHAN	Telephone	
Title and Company			

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☒ *Total of 1 forms are submitted.

This collection of information is required by 37 CFR 1.31, 1.32 and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: **Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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

Electronic Acknowledgement Receipt

EFS ID:	15220103
Application Number:	11989297
International Application Number:	
Confirmation Number:	4766
Title of Invention:	WOUND CLOSURE AND DRAINAGE SYSTEM
First Named Inventor/Applicant Name:	Carmeli Adahan
Customer Number:	20230
Filer:	Roger Lowen Browdy/Erin Geraghty
Filer Authorized By:	Roger Lowen Browdy
Attorney Docket Number:	067913.000085
Receipt Date:	14-MAR-2013
Filing Date:	24-JAN-2008
Time Stamp:	12:14:28
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Power of Attorney	2013-03-08poa.pdf	852593 8be85f88bf4cc2ff7e676290be8f85af38ad981b	no	1

Warnings:	
Information:	

Total Files Size (in bytes):	852593

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

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

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

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

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	11989297
	Filing Date	2008-01-24
	First Named Inventor	ADAHAN, Carmeli
	Art Unit	3761
	Examiner Name	TREYGER, Ilya Y.
	Attorney Docket Number	067913.000085

U.S.PATENTS						
Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					
If you wish to add additional U.S. Patent citation information please click the Add button.						

U.S.PATENT APPLICATION PUBLICATIONS						
Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					
If you wish to add additional U.S. Published Application citation information please click the Add button.						

FOREIGN PATENT DOCUMENTS								
Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	01/34223	WO	A1	2001-05-17	HEATON, Keith Patrick		☐
	2	2005/061025	WO	A1	2005-07-07	LARSSON, Michael		☐
	3	00/21586	WO	A1	2000-04-20	Hunt, Kenneth William et al.		☐

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	11989297
	Filing Date	2008-01-24
	First Named Inventor	ADAHAN, Carmeli
	Art Unit	3761
	Examiner Name	TREYGER, Ilya Y.
	Attorney Docket Number	067913.000085

If you wish to add additional Foreign Patent Document citation information please click the Add button			
NON-PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1		☐
If you wish to add additional non-patent literature document citation information please click the Add button			

EXAMINER SIGNATURE			
Examiner Signature		Date Considered	

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

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	11989297
	Filing Date	2008-01-24
	First Named Inventor	ADAHAN, Carmeli
	Art Unit	3761
	Examiner Name	TREYGER, Ilya Y.
	Attorney Docket Number	067913.000085

CERTIFICATION STATEMENT

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

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

OR

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

☐ See attached certification statement.

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

☒ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/William L. Klima/	Date (YYYY-MM-DD)	2013-01-08
Name/Print	William L. Klima	Registration Number	32,422

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

Privacy Act Statement

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

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

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

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

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

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

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

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

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

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

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

Electronic Patent Application Fee Transmittal

Application Number:	11989297
Filing Date:	24-Jan-2008
Title of Invention:	WOUND CLOSURE AND DRAINAGE SYSTEM
First Named Inventor/Applicant Name:	Carmeli Adahan
Filer:	William Leonard Klima/Regina Williams
Attorney Docket Number:	067913.000085

Filed as Small Entity

U.S. National Stage under 35 USC 371 Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Request for continued examination	2801	1	465	465
		Total in USD ($)		**465**

Electronic Acknowledgement Receipt	
EFS ID:	14645123
Application Number:	11989297
International Application Number:	
Confirmation Number:	4766
Title of Invention:	WOUND CLOSURE AND DRAINAGE SYSTEM
First Named Inventor/Applicant Name:	Carmeli Adahan
Customer Number:	20230
Filer:	William Leonard Klima/Regina Williams
Filer Authorized By:	William Leonard Klima
Attorney Docket Number:	067913.000085
Receipt Date:	08-JAN-2013
Filing Date:	24-JAN-2008
Time Stamp:	16:33:25
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$465
RAM confirmation Number	3296
Deposit Account	220585
Authorized User	WILLIAMS, REGINA L
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees) Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)	

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)					
File Listing:					
Document Number	**Document Description**	**File Name**	**File Size(Bytes)/ Message Digest**	**Multi Part /.zip**	**Pages (if appl.)**
1	Amendment Submitted/Entered with Filing of CPA/RCE	11989297_Amendment.pdf	137759 8e43bbabc192f14707e942762945e56ea388204d	no	11
Warnings:					
Information:					
2	Request for Continued Examination (RCE)	11989297_RCE.pdf	1030882 18db873cdab97b2fc1ab8f48af7597d57ca230c9	no	3
Warnings:					
This is not a USPTO supplied RCE SB30 form.					
Information:					
3	Information Disclosure Statement (IDS) Form (SB08)	11989297_IDS.pdf	1350989 43ff791e012ac8a4ad6ecfb5bbed718c82a0f1e2	no	4
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
4	Fee Worksheet (SB06)	fee-info.pdf	30518 9aac765f42e2145d80d9c25c84a6bbe22987e635	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	2550148		

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.

<u>New Applications Under 35 U.S.C. 111</u>
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

<u>National Stage of an International Application under 35 U.S.C. 371</u>
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.

<u>New International Application Filed with the USPTO as a Receiving Office</u>
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.

Mail Stop RCE
Attorney Docket No. 067913.000085

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Carmeli ADAHAN	Conf. No.: 4766
Application No.: 11/989,297	Examiner: TREYGER, ILYA Y.
Filed: January 24, 2008	Group Art Unit: 3761

For: WOUND CLOSURE AND DRAINAGE SYSTEM

AMENDMENT

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

Dear Commissioner:

Prior to the payment of the Issue and Publication Fees, please enter the following amendments:

Amendments to the Claims begins on page 2 of this paper.

Remarks begin on page 10 of this paper.

A **Conclusion** appears at page 11 of this paper.

AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions and listings of claims in the application:

Listing of Claims:

1-10. (Canceled)

11. (Currently Amended) An enclosure for applying negative pressure to a wound, the enclosure being attachable to the wound circumference so as to define a confined volume, and comprising a tube and a venting arrangement, the enclosure having an enclosure outlet connectable to a vacuum source via said tube so that negative pressure [[may]] can be selectively created in said volume, ~~said tube comprising a venting arrangement comprising a calibrated orifice to restrict flow through~~ said venting arrangement located outside said enclosure and comprising a flow restrictor[[,]] such that ambient air can enter said tube via said venting arrangement and flow to said vacuum source without ~~entering~~ having to enter said enclosure.

12. (Canceled)

13. (Previously Presented) The enclosure according to claim 11, wherein said venting arrangement comprises one or more bleeding holes.

14. (Previously Presented) The enclosure according to claim of claim 11, wherein said venting arrangement is provided in the form of a porous body.

15-33. (Canceled)

34. (Currently Amended) The enclosure according to claim 11, wherein said venting arrangement acts ~~as a flow restrictor~~ to provide, under the action of the vacuum source, a restricted flow of ambient air therethrough and along said tube.

35. (Previously Presented) The enclosure according to claim 11, wherein said enclosure facilitates drainage of fluids exuded from the wound, wherein the ambient air can enter said tube via said venting arrangement and flow together with the exuded liquids under the action of the negative pressure.

36. (Previously Presented) The enclosure according to claim 11, wherein said venting arrangement provides for ambient air to enter said enclosure via said tube and for ambient pressure to be restored in said confined volume when the vacuum source is not operating.

37. (Previously Presented) The enclosure according to claim 11, wherein in operation of the enclosure, ambient air enters the tube directly via said venting arrangement

without entering said enclosure when negative pressure is being applied to the wound via said enclosure.

38. (Previously Presented) A disposable assembly for applying negative pressure to a wound, the assembly comprising an enclosure as defined in claim 11 attachable to the wound circumference so as to define a confined volume, a vacuum pump unit of the vacuum pump connected to said enclosure so that negative pressure may be created in said volume, said vacuum pump unit being configured for being detachably attached to a drive unit of the vacuum pump for operating the pump unit, and a waste container connected to said vacuum pump unit, wherein said enclosure is connected to an inlet of said vacuum pump unit via said tube and said waste container is connected to an outlet of said vacuum pump unit.

39. (Previously Presented) A disposable assembly according to claim 38, wherein said assembly further operates to drain the wound from fluids exuded therefrom, wherein the ambient air can enter said tube via said venting arrangement and flow together with the exuded liquids under the action of the negative pressure, and facilitates draining of the exuded fluids to said waste container.

40. (Previously Presented) The disposable assembly according to claim 38, wherein said venting arrangement comprises one or more bleeding holes.

41. (Previously Presented) The disposable assembly according to claim 38, wherein said venting arrangement is provided in the form of a porous body.

42. (Currently Amended) A vacuum system for applying negative pressure to a wound, the vacuum system comprising:

an enclosure and a vacuum source, the enclosure being attachable to the wound circumference so as to define a confined volume;

a tube;

a venting arrangement comprising a flow restrictor, the enclosure having an enclosure outlet connectable to said vacuum source via said tube so that negative pressure [[may]] can be created in said volume, ~~said tube comprising a venting arrangement comprising a calibrated orifice to restrict flow through~~ said venting arrangement located ~~adjacent to said enclosure outlet and~~ outside said enclosure such that ambient air can enter said tube via said venting arrangement without entering said enclosure; and

a waste container in fluid communication with said vacuum source.

43. (Previously Presented) The vacuum system of claim 42, wherein said vacuum system further operates to drain the wound from fluids exuded therefrom, wherein the ambient air can enter said tube via said venting arrangement and flow together with the exuded liquids under the action of the negative pressure, and facilitates draining of the exuded fluids to said waste container.

44. (Previously presented) The vacuum system according to claim 42, wherein said vacuum source includes a disposable pump unit detachably attachable to a non-disposable drive unit, said enclosure and said waste container being disposable so that the ambient air that enters said tube via said venting arrangement contacts only the disposable elements and said drained liquids may be disposed of together with said disposable elements.

45. (Previously Presented) The vacuum system according to claim 44, wherein said pump unit and said drive unit are adapted for attaching and detaching by simple hand manipulations.

46. (Previously Presented) The vacuum system according to claim 42, wherein said venting arrangement comprises one or more bleeding holes.

47. (Previously Presented) The vacuum system according to claim 42, wherein said venting arrangement is provided in the form of a porous body.

48. (Currently Amended) A vacuum system for applying a negative pressure to a wound, the vacuum system comprising an enclosure and a vacuum source, the enclosure being attachable to the wound circumference so as to define a confined volume, and comprising a tube, the enclosure having an enclosure outlet connectable

to said vacuum source via said tube so that negative pressure may be created in said volume, said tube comprising a venting arrangement comprising a ~~calibrated orifice~~ flow restrictor to restrict flow through said venting arrangement located adjacent to said enclosure outlet and outside said enclosure such that ambient air can enter said tube via said venting arrangement and flow to said vacuum source without entering said enclosure, wherein said vacuum pump comprises a collection chamber upstream of a pump inlet of said vacuum source, and wherein said tube is connected to an inlet of said collection chamber.

49. (Previously Presented) The vacuum system of claim 48, wherein said vacuum system further operates to drain the wound from fluids exuded therefrom, wherein the ambient air can enter said tube via said venting arrangement and flow together with the exuded liquids under the action of the negative pressure, and facilitates draining of the exuded fluids to said waste container.

50. (Previously Presented) The vacuum system according to claim 48, wherein said vacuum source includes a disposable pump unit detachably attachable to a non-disposable drive unit, said enclosure and said collection chamber being disposable so that the ambient air that enters said tube via said venting arrangement contacts only the disposable elements and said drained liquids may be disposed of together with said disposable elements.

51. (Previously Presented) The vacuum system according to claim 50, wherein said pump unit and said drive unit are adapted for attaching and detaching by simple hand manipulations.

52. (Previously Presented) The vacuum system according to claim 48, wherein said venting arrangement comprises one or more bleeding holes.

53. (Previously Presented) The vacuum system according to claim 48, wherein said venting arrangement is provided in the form of a porous body.

54. (Previously Presented) The vacuum system according to claim 11, wherein the venting arrangement is a tube orifice.

55. (New) The enclosure according to claim 54, said orifice having a smaller opening than a cross-section of the tube.

56. (New) The vacuum system according to claim 42, wherein the venting arrangement is a tube orifice.

57. (New The enclosure according to claim 56, said orifice having a smaller opening than a cross-section of the tube.

58. (New) The vacuum system according to claim 48, wherein the venting arrangement is a tube orifice.

59. (New) The enclosure according to claim 58, said orifice having a smaller opening than a cross-section of the tube.

REMARKS

Claims 11, 13, 14, and 34-54 are pending in the application.

Claims 11, 34, 42, and 48 are amended above.

Claims 1–10, 12, and 15-33 were previously canceled without prejudice or disclaimer of the subject matter contained therein.

Claims 55--59 are newly added.

Applicant, by amending any claims herein, makes no admission as to the validity of any rejection made by the Examiner against any claim. Applicant reserves the right to reassert any of the claims canceled or the original scope of any claim amended herein, in a continuing application.

It is respectfully submitted that the above amendments to the claims introduce no new matter within the meaning of 35 U.S.C. §132. Accordingly, Applicant requests reconsideration and timely withdrawal of the pending rejections for the reasons discussed below.

CONCLUSION

In view of the foregoing, Applicants respectfully submit that the application is in condition for examination on the merits. The Examiner is invited to contact the undersigned attorney if it is believed that such contact will expedite the prosecution of the application.

Respectfully submitted,

VORYS, SATER, SEYMOUR AND PEASE LLP
/William L. Klima/
William L. Klima
Reg. No. 32,422
Customer No. 20230

January 8, 2013

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~~1/07/2013 15537688~~ 1/08/2013 15537688

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

PTO/SB/30EFS (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
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REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL
(Submitted Only via EFS-Web)

Application Number	11/989,297	Filing Date	2008-01-24	Docket Number (if applicable)	067913.000085	Art Unit	4766
First Named Inventor	ADAHAN, Carmeli			Examiner Name	TREYGER, Ilya Y.		

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 220585

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

☒ Patent Practitioner Signature

☐ Applicant Signature

PTO/SB/30EFS (07-09)
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Signature of Registered U.S. Patent Practitioner			
Signature	/William L. Klima/	Date (YYYY-MM-DD)	2013-01-08
Name	William L. Klima	Registration Number	32422

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.

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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.

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Page #312

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PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
11/989,297	01/24/2008	

APPLICATION AS FILED – PART I

	(Column 1)	(Column 2)	SMALL ENTITY ☒		OR	OTHER THAN SMALL ENTITY	
FOR	NUMBER FILED	NUMBER EXTRA	RATE ($)	FEE ($)		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 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			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT		(Column 1)		(Column 2)	(Column 3)	SMALL ENTITY		OR	OTHER THAN SMALL ENTITY	
	01/08/2013	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 29	Minus	** 33	= 0	X $31 =	0	OR	X $ =	
	Independent (37 CFR 1.16(h))	* 3	Minus	***5	= 0	X $125 =	0	OR	X $ =	
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE	

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

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
/LYNNELL JOHNSON/

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.**

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NOTICE OF ALLOWANCE AND FEE(S) DUE

20230 7590 10/09/2012
VORYS, SATER, SEYMOUR & PEASE LLP
1909 K St., NW
9th Floor
WASHINGTON, DC 20006-1152

EXAMINER
TREYGER, ILYA Y

ART UNIT	PAPER NUMBER
3761	

DATE MAILED: 10/09/2012

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/989,297	01/24/2008	Carmeli Adahan	067913.000085	4766

TITLE OF INVENTION: WOUND CLOSURE AND DRAINAGE SYSTEM

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$885	$300	$0	$1185	01/09/2013

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 SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

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

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

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PTOL-85 (Rev. 02/11)

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Page #314

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

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

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

20230 7590 10/09/2012
VORYS, SATER, SEYMOUR & PEASE LLP
1909 K St., NW
9th Floor
WASHINGTON, DC 20006-1152

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 facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/989,297	01/24/2008	Carmeli Adahan	067913.000085	4766

TITLE OF INVENTION: WOUND CLOSURE AND DRAINAGE SYSTEM

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$885	$300	$0	$1185	01/09/2013

EXAMINER	ART UNIT	CLASS-SUBCLASS
TREYGER, ILYA Y	3761	604-540000

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

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

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 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 has been filed for recordation as set forth in 37 CFR 3.11. 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. The following fee(s) are submitted:

❑ Issue Fee

❑ Publication Fee (No small entity discount permitted)

❑ Advance Order - # of Copies _____

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❑ A check is enclosed.

❑ Payment by credit card. Form PTO-2038 is attached.

❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

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

❑ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

❑ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/989,297	01/24/2008	Carmeli Adahan	067913.000085	4766

20230 7590 10/09/2012

VORYS, SATER, SEYMOUR & PEASE LLP
1909 K St., NW
9th Floor
WASHINGTON, DC 20006-1152

EXAMINER	
TREYGER, ILYA Y	
ART UNIT	PAPER NUMBER
3761	

DATE MAILED: 10/09/2012

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

The Patent Term Adjustment to date is 391 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 391 day(s).

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

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

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

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Privacy Act Statement

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

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

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

Notice of Allowability	Application No.	Applicant(s)	
	11/989,297	ADAHAN, CARMELI	
	Examiner	Art Unit	
	ILYA TREYGER	3761	

-- 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 *09/14/2012*.
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 *11,13,14 and 34-54*.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   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. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ 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).
7. ☐ 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. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *09/06/2012* .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

/Ilya Y Treyger/
Examiner, Art Unit 3761

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Applicant-Initiated Interview Summary	Application No.	Applicant(s)	
	11/989,297	ADAHAN, CARMELI	
	Examiner	Art Unit	
	ILYA TREYGER	3761	

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

(1) *ILYA TREYGER*. (3) *William Klima*.

(2) *Tayana Zalukaeva*. (4)_____.

Date of Interview: *06 September 2012*.

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

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

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

Claim(s) discussed: *11,42 and 48*.

Identification of prior art discussed: *US 200110029956 and US 3,516,160*.

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

Applicant proposed the amendment: to include the limitation of "comprising a calibrated orifice to restrict flow through the venting arrangement located outside said enclosure" into the claims 1, 42 and 48.
Examiner agreed that the proposed amendment places the Application in condition for allowance. .

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview

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

☐ Attachment

/Ilya Y Treyger/ Examiner, Art Unit 3761	/Tatyana Zalukaeva/ Supervisory Patent Examiner, Art Unit 3761

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Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:
1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

EXAMINER'S AMENDMENT

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

Authorization for this examiner's amendment was given in a personal interview with Mr. Klima on 06/09/2012.

The application has been amended as follows:

2. Claim 11 is rewritten as follows:

3. Claim 11. ------- An enclosure for applying negative pressure to a wound, the enclosure being attachable to the wound circumference so as to define a confined volume, and comprising a tube, the enclosure having an enclosure outlet connectable to a vacuum source via said tube so that negative pressure may be created in said volume, said tube comprising a venting arrangement comprising a calibrated orifice to restrict flow through said venting arrangement located outside said enclosure, such that ambient air can enter said tube via said venting arrangement and flow to said vacuum source without entering said enclosure. -------

4. Claim 42 is rewritten as follows:

Claim 42. ------- A vacuum system for applying negative pressure to a wound, the vacuum system comprising an enclosure and a vacuum source, the enclosure being attachable to the wound circumference so as to define a confined volume; a tube, the enclosure having an enclosure outlet connectable to said vacuum source via said tube so that negative pressure may be created in said volume, said tube comprising a venting arrangement comprising a calibrated

orifice to restrict flow through said venting arrangement located adjacent to said enclosure outlet and outside said enclosure such that ambient air can enter said tube via said venting arrangement ; and a waste container in fluid communication with said vacuum source. -------

5. Claim 48 is rewritten as follows:

Claim 48. ------- A vacuum system for applying a negative pressure to a wound, the vacuum system comprising an enclosure and a vacuum source, the enclosure being attachable to the wound circumference so as to define a confined volume, and comprising a tube, the enclosure having an enclosure outlet connectable to said vacuum source via said tube so that negative pressure may be created in said volume, said tube comprising a venting arrangement comprising a calibrated orifice to restrict flow through said venting arrangement located adjacent to said enclosure outlet and outside said enclosure such that ambient air can enter said tube via said venting arrangement and flow to said vacuum source without entering said enclosure, wherein said vacuum pump comprises a collection chamber upstream of a pump inlet of said vacuum source, and wherein said tube is connected to an inlet of said collection chamber. -------

ALLOWABLE CLAIMS

6. **Claims 11, 13, 14 and 34-54 are allowed over the prior art of record.**

REASONS FOR ALLOWANCE

7. The following is an examiner's statement of reasons for allowance: The closest Prior Art of record US 200110029956 and US 3,516,160 fail to teach, suggest or render obvious a calibrated orifice restricting flow through the venting arrangement located outside of the enclosure that prevents the overvacuum conditions during the medical procedure.

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 ILYA TREYGER whose telephone number is (571)270-3217. The examiner can normally be reached on 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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

/Ilya Y Treyger/
Examiner, Art Unit 3761
/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11989297	ADAHAN, CARMELI
	Examiner	Art Unit
	ILYA Y TREYGER	3761

SEARCHED			
Class	Subclass	Date	Examiner
604	540-544	10/5/2010	I. T.

SEARCH NOTES		
Search Notes	Date	Examiner
EAST Search attached	10/5/2010	I. T.
Search updated	4/15/2011	I. T.
Search updated	9/26/2011	I. T.
Search updated	5/22/2012	I. T.
Search updated	9/14/2012	I. T.

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner
604	540-544	9/14/2012	I. T.
	PGPUB Searched	9/14/2012	I. T.

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BIB DATA SHEET

CONFIRMATION NO. 4766

SERIAL NUMBER	FILING or 371(c) DATE RULE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
11/989,297	01/24/2008	604	3761	29068U

APPLICANTS
Carmeli Adahan, Jerusalem, ISRAEL;

**** CONTINUING DATA ************************* I.T. 06/22/2010**
This application is a 371 of PCT/IL2005/000784 07/24/2005

**** FOREIGN APPLICATIONS ************************* I.T. 06/22/2010**

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED **** ** SMALL ENTITY **
07/08/2009

Foreign Priority claimed ☑ Yes ☐ No 35 USC 119(a-d) conditions met ☐ Yes ☐ No Verified and Acknowledged /ILYA Y TREYGER/ Examiner's Signature	☐ Met after Allowance Initials	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
		ISRAEL	2	33	5

ADDRESS

THE NATH LAW GROUP
112 South West Street
Alexandria, VA 22314
UNITED STATES

TITLE

Wound closure and drainage system

FILING FEE RECEIVED		
1000	FEES: Authority has been given in Paper No._____ to charge/credit DEPOSIT ACCOUNT No._____ for following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	56	((CARMELI) near2 (ADAHAN)).INV.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
L2	14131	wound and (suction vacuum) and (enclosure dressing) and ((bleeding hole) (vacuum breaker))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L3	959	(604/35).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
L4	879	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
L5	371	(604/313).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
L6	2276	(604/317-323).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
L7	1612	(604/540-544).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
L8	255	(604/902).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
L9	579	(606/131).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
L10	33	L2 and L3	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L11	172	L2 and L4	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L12	217	L2 and L5	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L13	348	L2 and L6	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L14	176	L2 and L7	US-PGPUB;	OR	OFF	2012/09/14

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			USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB			12:25
L15	9	L2 and L8	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L16	8	L2 and L9	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L17	119	("1251258" | "3171410" | "3486504").PN. OR ("3874387").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
L18	210	("3026874" | "3486504" | "4540412" | "4759354" | "4969880").PN. OR ("5149331").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
L19	147	("4743232" | "5230350").PN. OR ("5344415").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
L20	288	("1355846" | "2547758" | "2632443" | "2682873" | "2969057" | "3367332" | "3648692" | "3682180" | "3826254" | "4080970" | "4096853" | "4139004" | "4165748" | "4245630" | "4261363" | "4275721" | "4297995" | "4333468" | "4373519" | "4382441" | "4392853" | "4392858" | "4419097" | "4475909" | "4480638" | "4525166" | "4525374" | "4540412" | "4543100" | "4551139" | "4569348" | "4605399" | "4608041" | "4640688" | "4655754" | "4733659" | "4743232" | "4787888" | "4826949" | "4838883" | "4840187" | "4863449" | "4872450" | "4878901" | "4897081" | "4906233" | "4906240" | "4919654" | "4941882" | "4953565" | "4969880" | "4985019" | "5037397" | "5100396" | "5149331" | "5167613" | "5176663" | "5261893" | "5298015" | "5344415" | "5358494" | "5556375" | "5607388" | "5636643" | "5645081").PN. OR ("6071267").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
L21	56	((CARMELI) near2 (ADAHAN)).INV.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
L22	14131	wound and (suction vacuum) and (enclosure dressing) and ((bleeding hole) (vacuum breaker))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L23	959	(604/35).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25

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L24	879	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
L25	371	(604/313).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
L26	2276	(604/317-323).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
L27	1612	(604/540-544).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
L28	255	(604/902).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
L29	579	(606/131).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
L30	33	L22 and L23	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L31	172	L22 and L24	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L32	217	L22 and L25	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L33	348	L22 and L26	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L34	176	L22 and L27	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L35	9	L22 and L28	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L36	8	L22 and L29	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L37	119	("1251258" | "3171410" | "3486504").PN. OR ("3874387").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
L38	210	("3026874" | "3486504" | "4540412" | "4759354" | "4969880").PN. OR	US-PGPUB; USPAT;	OR	OFF	2012/09/14 12:25

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		("5149331").URPN.	USOCR			
L39	147	("4743232" | "5230350").PN. OR ("5344415").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
L40	288	("1355846" | "2547758" | "2632443" | "2682873" | "2969057" | "3367332" | "3648692" | "3682180" | "3826254" | "4080970" | "4096853" | "4139004" | "4165748" | "4245630" | "4261363" | "4275721" | "4297995" | "4333468" | "4373519" | "4382441" | "4392853" | "4392858" | "4419097" | "4475909" | "4480638" | "4525166" | "4525374" | "4540412" | "4543100" | "4551139" | "4569348" | "4605399" | "4608041" | "4640688" | "4655754" | "4733659" | "4743232" | "4787888" | "4826949" | "4838883" | "4840187" | "4863449" | "4872450" | "4878901" | "4897081" | "4906233" | "4906240" | "4919654" | "4941882" | "4953565" | "4969880" | "4985019" | "5037397" | "5100396" | "5149331" | "5167613" | "5176663" | "5261893" | "5298015" | "5344415" | "5358494" | "5556375" | "5607388" | "5636643" | "5645081").PN. OR ("6071267").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
L41	56	((CARMELI) near2 (ADAHAN)).INV.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
L42	14131	wound and (suction vacuum) and (enclosure dressing) and ((bleeding hole) (vacuum breaker))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L43	959	(604/35).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
L44	879	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
L45	371	(604/313).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
L46	2276	(604/317-323).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
L47	1612	(604/540-544).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
L48	255	(604/902).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
L49	579	(606/131).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
L50	33	L42 and L43	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L51	172	L42 and L44	US-PGPUB; USPAT; USOCR;	OR	OFF	2012/09/14 12:25

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			EPO; JPO; DERWENT; IBM_TDB			
L52	217	L42 and L45	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L53	348	L42 and L46	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L54	176	L42 and L47	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L55	9	L42 and L48	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L56	8	L42 and L49	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L57	119	("1251258" | "3171410" | "3486504").PN. OR ("3874387").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
L58	210	("3026874" | "3486504" | "4540412" | "4759354" | "4969880").PN. OR ("5149331").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
L59	147	("4743232" | "5230350").PN. OR ("5344415").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
L60	288	("1355846" | "2547758" | "2632443" | "2682873" | "2969057" | "3367332" | "3648692" | "3682180" | "3826254" | "4080970" | "4096853" | "4139004" | "4165748" | "4245630" | "4261363" | "4275721" | "4297995" | "4333468" | "4373519" | "4382441" | "4392853" | "4392858" | "4419097" | "4475909" | "4480638" | "4525166" | "4525374" | "4540412" | "4543100" | "4551139" | "4569348" | "4605399" | "4608041" | "4640688" | "4655754" | "4733659" | "4743232" | "4787888" | "4826949" | "4838883" | "4840187" | "4863449" | "4872450" | "4878901" | "4897081" | "4906233" | "4906240" | "4919654" | "4941882" | "4953565" | "4969880" | "4985019" | "5037397" | "5100396" | "5149331" | "5167613" | "5176663" |	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25

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		"5261893" | "5298015" | "5344415" | "5358494" | "5556375" | "5607388" | "5636643" | "5645081").PN. OR ("6071267").URPN.				
L61	56	((CARMELI) near2 (ADAHAN)).INV.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
L62	14131	wound and (suction vacuum) and (enclosure dressing) and ((bleeding hole) (vacuum breaker))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L63	959	(604/35).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
L64	879	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
L65	371	(604/313).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
L66	2276	(604/317-323).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
L67	1612	(604/540-544).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
L68	255	(604/902).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
L69	579	(606/131).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
L70	33	L62 and L63	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L71	172	L62 and L64	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L72	217	L62 and L65	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L73	348	L62 and L66	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L74	176	L62 and L67	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L75	9	L62 and L68	US-PGPUB;	OR	OFF	2012/09/14

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			USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB			12:25
L76	8	L62 and L69	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L77	119	("1251258" | "3171410" | "3486504").PN. OR ("3874387").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
L78	210	("3026874" | "3486504" | "4540412" | "4759354" | "4969880").PN. OR ("5149331").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
L79	147	("4743232" | "5230350").PN. OR ("5344415").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
L80	288	("1355846" | "2547758" | "2632443" | "2682873" | "2969057" | "3367332" | "3648692" | "3682180" | "3826254" | "4080970" | "4096853" | "4139004" | "4165748" | "4245630" | "4261363" | "4275721" | "4297995" | "4333468" | "4373519" | "4382441" | "4392853" | "4392858" | "4419097" | "4475909" | "4480638" | "4525166" | "4525374" | "4540412" | "4543100" | "4551139" | "4569348" | "4605399" | "4608041" | "4640688" | "4655754" | "4733659" | "4743232" | "4787888" | "4826949" | "4838883" | "4840187" | "4863449" | "4872450" | "4878901" | "4897081" | "4906233" | "4906240" | "4919654" | "4941882" | "4953565" | "4969880" | "4985019" | "5037397" | "5100396" | "5149331" | "5167613" | "5176663" | "5261893" | "5298015" | "5344415" | "5358494" | "5556375" | "5607388" | "5636643" | "5645081").PN. OR ("6071267").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
L82	56	((CARMELI) near2 (ADAHAN)).INV.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
L83	14131	wound and (suction vacuum) and (enclosure dressing) and ((bleeding hole) (vacuum breaker))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L84	959	(604/35).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
L85	879	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
L86	371	(604/313).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
L87	2276	(604/317-323).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25

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L88	1612	(604/540-544).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
L89	255	(604/902).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
L90	579	(606/131).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
L91	33	L83 and L84	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L92	172	L83 and L85	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L93	217	L83 and L86	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L94	348	L83 and L87	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L95	176	L83 and L88	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L96	9	L83 and L89	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L97	8	L83 and L90	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L98	119	("1251258" | "3171410" | "3486504").PN. OR ("3874387").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
L99	210	("3026874" | "3486504" | "4540412" | "4759354" | "4969880").PN. OR ("5149331").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
L100	147	("4743232" | "5230350").PN. OR ("5344415").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
L101	288	("1355846" | "2547758" | "2632443" | "2682873" | "2969057" | "3367332" |	US-PGPUB; USPAT;	OR	OFF	2012/09/14 12:25

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		"3648692" | "3682180" | "3826254" | "4080970" | "4096853" | "4139004" | "4165748" | "4245630" | "4261363" | "4275721" | "4297995" | "4333468" | "4373519" | "4382441" | "4392853" | "4392858" | "4419097" | "4475909" | "4480638" | "4525166" | "4525374" | "4540412" | "4543100" | "4551139" | "4569348" | "4605399" | "4608041" | "4640688" | "4655754" | "4733659" | "4743232" | "4787888" | "4826949" | "4838883" | "4840187" | "4863449" | "4872450" | "4878901" | "4897081" | "4906233" | "4906240" | "4919654" | "4941882" | "4953565" | "4969880" | "4985019" | "5037397" | "5100396" | "5149331" | "5167613" | "5176663" | "5261893" | "5298015" | "5344415" | "5358494" | "5556375" | "5607388" | "5636643" | "5645081").PN. OR ("6071267").URPN.	USOCR			
L102	56	((CARMELI) near2 (ADAHAN)).INV.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
L103	14131	wound and (suction vacuum) and (enclosure dressing) and ((bleeding hole) (vacuum breaker))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L104	959	(604/35).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
L105	879	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
L106	371	(604/313).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
L107	2276	(604/317-323).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
L108	1612	(604/540-544).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
L109	255	(604/902).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
L110	579	(606/131).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
L111	33	L103 and L104	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L112	172	L103 and L105	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L113	217	L103 and L106	US-PGPUB; USPAT; USOCR; EPO; JPO;	OR	OFF	2012/09/14 12:25

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			DERWENT; IBM_TDB			
L114	348	L103 and L107	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L115	176	L103 and L108	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L116	9	L103 and L109	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L117	8	L103 and L110	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L118	119	("1251258" | "3171410" | "3486504").PN. OR ("3874387").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
L119	210	("3026874" | "3486504" | "4540412" | "4759354" | "4969880").PN. OR ("5149331").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
L120	147	("4743232" | "5230350").PN. OR ("5344415").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
L121	288	("1355846" | "2547758" | "2632443" | "2682873" | "2969057" | "3367332" | "3648692" | "3682180" | "3826254" | "4080970" | "4096853" | "4139004" | "4165748" | "4245630" | "4261363" | "4275721" | "4297995" | "4333468" | "4373519" | "4382441" | "4392853" | "4392858" | "4419097" | "4475909" | "4480638" | "4525166" | "4525374" | "4540412" | "4543100" | "4551139" | "4569348" | "4605399" | "4608041" | "4640688" | "4655754" | "4733659" | "4743232" | "4787888" | "4826949" | "4838883" | "4840187" | "4863449" | "4872450" | "4878901" | "4897081" | "4906233" | "4906240" | "4919654" | "4941882" | "4953565" | "4969880" | "4985019" | "5037397" | "5100396" | "5149331" | "5167613" | "5176663" | "5261893" | "5298015" | "5344415" | "5358494" | "5556375" | "5607388" | "5636643" | "5645081").PN. OR ("6071267").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
L122	56	((CARMELI) near2 (ADAHAN)).INV.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25

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L123	14131	wound and (suction vacuum) and (enclosure dressing) and ((bleeding hole) (vacuum breaker))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L124	959	(604/35).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
L125	879	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
L126	371	(604/313).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
L127	2276	(604/317-323).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
L128	1612	(604/540-544).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
L129	255	(604/902).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
L130	579	(606/131).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
L131	33	L123 and L124	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L132	172	L123 and L125	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L133	217	L123 and L126	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L134	348	L123 and L127	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L135	176	L123 and L128	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L136	9	L123 and L129	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L137	8	L123 and L130	US-PGPUB; USPAT; USOCR;	OR	OFF	2012/09/14 12:25

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			EPO; JPO; DERWENT; IBM_TDB			
L138	119	("1251258" | "3171410" | "3486504").PN. OR ("3874387").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
L139	210	("3026874" | "3486504" | "4540412" | "4759354" | "4969880").PN. OR ("5149331").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
L140	147	("4743232" | "5230350").PN. OR ("5344415").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
L141	288	("1355846" | "2547758" | "2632443" | "2682873" | "2969057" | "3367332" | "3648692" | "3682180" | "3826254" | "4080970" | "4096853" | "4139004" | "4165748" | "4245630" | "4261363" | "4275721" | "4297995" | "4333468" | "4373519" | "4382441" | "4392853" | "4392858" | "4419097" | "4475909" | "4480638" | "4525166" | "4525374" | "4540412" | "4543100" | "4551139" | "4569348" | "4605399" | "4608041" | "4640688" | "4655754" | "4733659" | "4743232" | "4787888" | "4826949" | "4838883" | "4840187" | "4863449" | "4872450" | "4878901" | "4897081" | "4906233" | "4906240" | "4919654" | "4941882" | "4953565" | "4969880" | "4985019" | "5037397" | "5100396" | "5149331" | "5167613" | "5176663" | "5261893" | "5298015" | "5344415" | "5358494" | "5556375" | "5607388" | "5636643" | "5645081").PN. OR ("6071267").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
L142	56	((CARMELI) near2 (ADAHAN)).INV.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
L143	14131	wound and (suction vacuum) and (enclosure dressing) and ((bleeding hole) (vacuum breaker))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L144	959	(604/35).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
L145	879	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
L146	371	(604/313).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
L147	2276	(604/317-323).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
L148	1612	(604/540-544).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
L149	255	(604/902).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
L150	579	(606/131).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
L151	33	L143 and L144	US-PGPUB;	OR	OFF	2012/09/14

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			USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB			12:25
L152	172	L143 and L145	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L153	217	L143 and L146	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L154	348	L143 and L147	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L155	176	L143 and L148	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L156	9	L143 and L149	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L157	8	L143 and L150	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L158	119	("1251258" | "3171410" | "3486504").PN. OR ("3874387").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
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L160	147	("4743232" | "5230350").PN. OR ("5344415").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25
L161	288	("1355846" | "2547758" | "2632443" | "2682873" | "2969057" | "3367332" | "3648692" | "3682180" | "3826254" | "4080970" | "4096853" | "4139004" | "4165748" | "4245630" | "4261363" | "4275721" | "4297995" | "4333468" | "4373519" | "4382441" | "4392853" | "4392858" | "4419097" | "4475909" | "4480638" | "4525166" | "4525374" | "4540412" | "4543100" | "4551139" |	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/14 12:25

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Page #339

		"4569348" | "4605399" | "4608041" | "4640688" | "4655754" | "4733659" | "4743232" | "4787888" | "4826949" | "4838883" | "4840187" | "4863449" | "4872450" | "4878901" | "4897081" | "4906233" | "4906240" | "4919654" | "4941882" | "4953565" | "4969880" | "4985019" | "5037397" | "5100396" | "5149331" | "5167613" | "5176663" | "5261893" | "5298015" | "5344415" | "5358494" | "5556375" | "5607388" | "5636643" | "5645081").PN. OR ("6071267").URPN.				
L162	34	L98 and (vent venting ventillation)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L163	43	L99 and (vent venting ventillation)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L164	19	L100 and (vent venting ventillation)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L165	53	L101 and (vent venting ventillation)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L166	73	"4108574" "4208171"	US-PGPUB; USPAT; EPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L167	0	L166 and (air adj hole)	US-PGPUB; USPAT; EPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L168	6	L166 and (vent venting)	US-PGPUB; USPAT; EPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L169	6	"20040015042" "20050180868"	US-PGPUB; USPAT; EPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L170	63	"4552552"	US-PGPUB; USPAT; EPO; DERWENT;	OR	OFF	2012/09/14 12:25

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			IBM_TDB			
L171	33	L170 and (vent venting)	US-PGPUB; USPAT; EPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L172	0	L170 and (air adj hole)	US-PGPUB; USPAT; EPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L173	21	"5116206" "7503910"	US-PGPUB; USPAT; EPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L174	4	L173 and (vent venting)	US-PGPUB; USPAT; EPO; DERWENT; IBM_TDB	OR	OFF	2012/09/14 12:25
L176	879	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25
L177	959	(604/35).CCLS.	US-PGPUB; USPAT	OR	OFF	2012/09/14 12:25

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L81	0	pressure and regulating and device and sealed and vial and wheath and cap and connector and positioned and within and bag and interior and surface and outer and adapted and expanded and unfolded and compensat and changes and volume and medical and fluid and move and first and orientation and portion and partially and unexpanded and folded and second and lubricant and layer and impermeable and impeding and passage and between and regulates and withdrawn and equilibrate and opposite and reduces and friction.clm.	US-PGPUB	OR	OFF	2012/09/14 12:25
L175	0	pressure and regulating and device and sealed and vial and wheath and cap and connector and positioned and within and bag and interior and surface and outer and adapted and expanded and unfolded and compensat and changes and volume and medical and fluid and move and first and orientation and portion and partially and unexpanded and folded and second and lubricant and layer and impermeable and impeding and passage and between and regulates and withdrawn and equilibrate and opposite and reduces and friction.clm.	US-PGPUB	OR	OFF	2012/09/14 12:25
L178	0	enclosure and applying and negative and pressure and wound and attachable and circumference and confined and volume and tube and outlet and connectable and vacuum	USPAT; UPAD	OR	OFF	2012/09/14 12:30

Medela LLC and Medela AG
Exhibit 1008
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		and source and venting and arrangement and calibrated and orifice and restrict and flow and ambient and air.clm.				
L179	1	enclosure and applying and negative and pressure and wound and attachable and circumference and confined and volume and tube and outlet and connectable and vacuum and source and venting and arrangement and calibrated and orifice and restrict and flow and ambient and air.clm.	US-PGPUB	OR	OFF	2012/09/14 12:30

9/14/2012 12:31:39 PM
C:\Users\itreyger\Documents\EAST\Workspaces\11989297.wsp

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Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11989297	ADAHAN, CARMELI
	Examiner	**Art Unit**
	ILYA Y TREYGER	3761

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

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

CLAIM		DATE								
Final	Original	10/05/2010	04/15/2011	09/26/2011	05/22/2012	09/14/2012				
	1	-	-	-	-	-				
	2	-	-	-	-	-				
	3	-	-	-	-	-				
	4	-	-	-	-	-				
	5	-	-	-	-	-				
	6	-	-	-	-	-				
	7	-	-	-	-	-				
	8	-	-	-	-	-				
	9	-	-	-	-	-				
	10	-	-	-	-	-				
1	11	✓	✓	✓	✓	=				
	12	✓	✓	-	-	-				
2	13	✓	✓	✓	✓	=				
3	14	✓	✓	✓	✓	=				
	15	-	-	-	-	-				
	16	-	-	-	-	-				
	17	-	-	-	-	-				
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	31	-	-	-	-	-				
	32	-	-	-	-	-				
	33	-	-	-	-	-				
4	34		✓	✓	✓	=				
5	35		✓	✓	✓	=				
6	36		✓	✓	✓	=				

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Exhibit 1008
Page #343

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11989297	ADAHAN, CARMELI
	Examiner	**Art Unit**
	ILYA Y TREYGER	3761

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

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

CLAIM		DATE								
Final	Original	10/05/2010	04/15/2011	09/26/2011	05/22/2012	09/14/2012				
7	37		✓	✓	✓	=				
8	38		✓	✓	✓	=				
9	39		✓	✓	✓	=				
10	40		✓	✓	✓	=				
11	41		✓	✓	✓	=				
12	42		✓	✓	✓	=				
13	43		✓	✓	✓	=				
14	44		✓	✓	✓	=				
15	45		✓	✓	✓	=				
16	46		✓	✓	✓	=				
17	47		✓	✓	✓	=				
18	48		✓	✓	✓	=				
19	49		✓	✓	✓	=				
20	50		✓	✓	✓	=				
21	51		✓	✓	✓	=				
22	52		✓	✓	✓	=				
23	53		✓	✓	✓	=				
24	54				✓	=				

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Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11989297	ADAHAN, CARMELI
	Examiner	**Art Unit**
	ILYA TREYGER	3761

ORIGINAL		INTERNATIONAL CLASSIFICATION									
CLASS	SUBCLASS	CLAIMED					NON-CLAIMED				
604	540	A	6	1	M	1 / 00 (2006.01.01)					

CROSS REFERENCE(S)					
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)				
604	35	305	306	307	308
604	313	317	318	319	320
604	321	322	323	541	542
604	543	544	902		

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

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	11	17	47												
2	13	18	48												
3	14	19	49												
4	34	20	50												
5	35	21	51												
6	36	22	52												
7	37	23	53												
8	38	24	54												
9	39														
10	40														
11	41														
12	42														
13	43														
14	44														
15	45														
16	46														

/ILYA TREYGER/ Examiner.Art Unit 3761	09/14/2012	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	24	
/TATYANA ZALUKAEVA/ Supervisory Patent Examiner.Art Unit 3761	09/21/2012	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1

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UNITED STATES DEPARTMENT OF COMMERCE
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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/989,297	01/24/2008	Carmeli Adahan	067913.000085	4766

20230 7590 09/14/2012

VORYS, SATER, SEYMOUR & PEASE LLP
1909 K St., NW
9th Floor
WASHINGTON, DC 20006-1152

EXAMINER	
TREYGER, ILYA Y	

ART UNIT	PAPER NUMBER
3761	

NOTIFICATION DATE	DELIVERY MODE
09/14/2012	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):

patlaw@vorys.com

Applicant-Initiated Interview Summary	**Application No.**	**Applicant(s)**	
	11/989,297	ADAHAN, CARMELI	
	Examiner	**Art Unit**	
	ILYA TREYGER	3761	

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

(1) *ILYA TREYGER*. (3) *William Klima*.

(2) *Tayana Zalukaeva*. (4)_____.

Date of Interview: *06 September 2012*.

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

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

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

Claim(s) discussed: *11,42 and 48*.

Identification of prior art discussed: *US 200110029956 and US 3,516,160*.

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

Applicant proposed the amendment: to include the limitation of "comprising a calibrated orifice to restrict flow through the venting arrangement located outside said enclosure" into the claims 1, 42 and 48.
Examiner agreed that the proposed amendment places the Application in condition for allowance. .

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview

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

☐ Attachment

/Ilya Y Treyger/ Examiner, Art Unit 3761	/Tatyana Zalukaeva/ Supervisory Patent Examiner, Art Unit 3761

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Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:
1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

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.
11/989,297	01/24/2008	Carmeli Adahan	067913.000085	4766

20230 7590 06/11/2012

VORYS, SATER, SEYMOUR & PEASE LLP
1909 K St., NW
9th Floor
WASHINGTON, DC 20006-1152

EXAMINER	
TREYGER, ILYA Y	
ART UNIT	PAPER NUMBER
3761	

NOTIFICATION DATE	DELIVERY MODE
06/11/2012	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):

patlaw@vorys.com

Office Action Summary	Application No.	Applicant(s)	
	11/989,297	ADAHAN, CARMELI	
	Examiner	Art Unit	
	ILYA TREYGER	3761	

-- 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* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, 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 *13 February 2012*.

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

3)☐ 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

4)☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above claim(s) *1-10,12 and 15-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11,13,14 and 34-54* is/are rejected.

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

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

Application Papers

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

10)☒ The drawing(s) filed on *24 January 2008* 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).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

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).

a)☐ All b)☐ Some * c)☐ None of:

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) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02/21/2012*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claim 54 is new.

2. Claims 11, 13, 14 and 34-54 are examined on the merits.

Response to Arguments

3. With respect to claims 11, 42 and 48, Applicant argues that supplying the suction tube of Lockwood with the venting arrangement of Leffler would destroy the operation of Lockwood's device, and intended use thereof.

This argument is found persuasive and the reference of Lockwood has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Argenta et al. (US 200110029956).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) 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.

6. Claims 11, 13, 14 and 34-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Argenta et al. (US 200110029956) in view of Leffler (US 3,516,160).

7. In Re claims 11, 13, 34-37, 40, 44, 46, 52 and 542, Argenta discloses an enclosure 58 (fig. 2) for applying negative pressure to a wound (page 5, [0042], lines 5-6), the enclosure being attachable to the wound circumference so as to define a confined volume A (fig. 2), and comprising a tube 52 (page 5, [0042], line 28; fig2), the enclosure having an enclosure outlet 54 (page 5, [0042], line 27) connectable to the vacuum source 30 (page 5, [0042], line 29; fig. 2) so that negative pressure may be created in said volume.

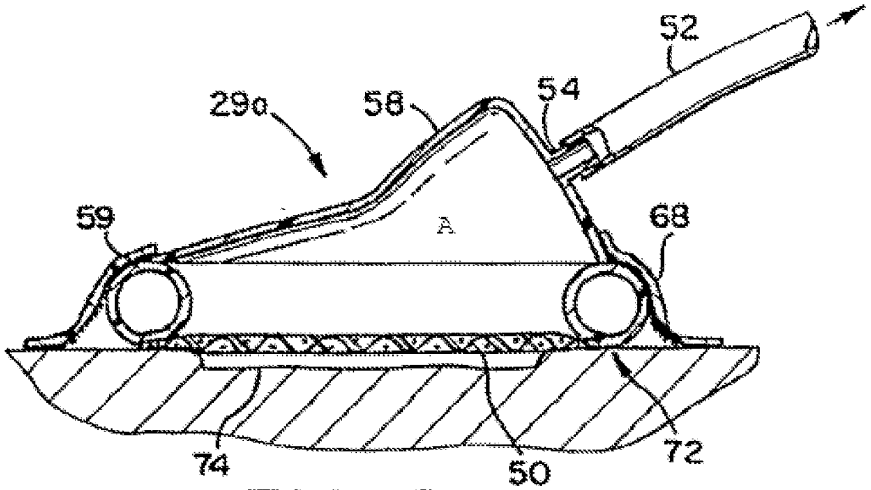


FIG. 2

Argenta does not expressly disclose the system, wherein the suction tube comprises a venting arrangement outside the enclosure such that ambient air can enter the tube via the venting arrangement and flow to the vacuum source without entering the enclosure.

Leffler teaches a medical suction apparatus (see Title) wherein the suction tube 26 (fig. 1) comprises a venting port 20 (col. 3, line 69; fig. 1) that is a bleeding hole outside of the wound

area allowing the flow to the vacuum source without entering the wound area, wherein the vent arrangement necessarily provides a restricted flow of ambient air therethrough and along the suction tube and is in the form of tube orifice.

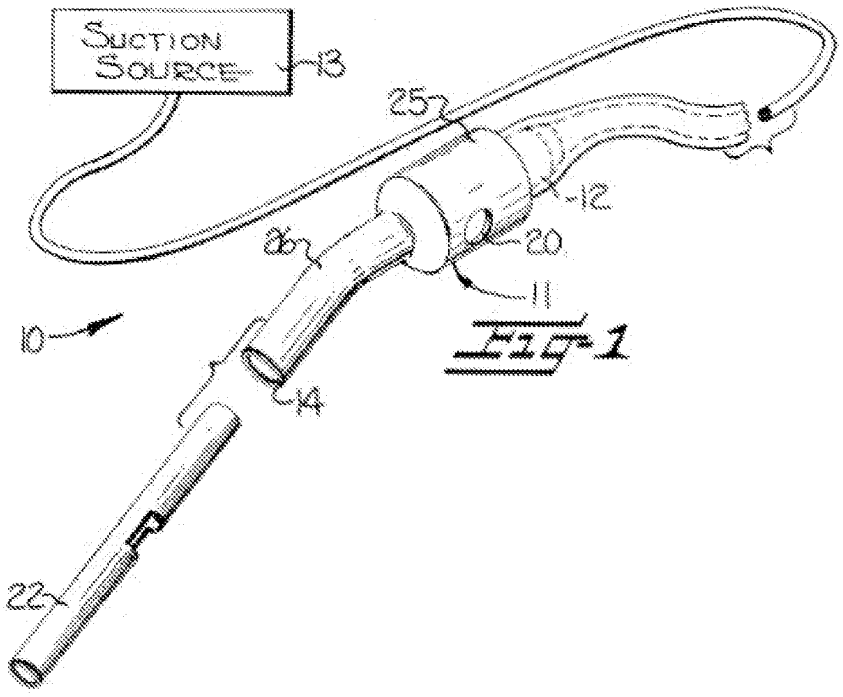


Fig. 1

It would have been obvious to one having ordinary skill in the art at the time the invention was made to supply the suction tube of Argenta with the venting arrangement, as taught by Leffler in order to control the flow in the tube, as motivated by Leffler (col. 4, lines 35-40).

8. In Re claims 14, 41, 47 and 53, Argenta in view of Leffler disclose the invention discussed above, but do not expressly disclose the structure, wherein the bleeding holes are provided in the form of a porous body.

Since the porous body is a material comprising plurality of holes, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the plurality of holes in the form of porous body in order to simplify the production process by using the material known in the art.

9. In Re claims 38, 39, 43 and 49, Argenta in view of Leffler disclose the invention discussed above, as applied to claim 11, wherein the apparatus comprises a collecting vessel connected to the vacuum source (Argenta, page 4, [0036]), but do not expressly disclose the apparatus, wherein the waste container is connected to an outlet of the vacuum pomp unit.

Since shifting the position of the container would not have modified the operation of the device, it would have been obvious to one having ordinary skill in the art at the time the invention was made to connect the waste container to the outlet of the pump in order to position the container remotely from the patient, since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70 (MPEP 2144.04 (VI-C)).

10. In Re claims 42, 45, 48, 50 and 51, Argenta discloses an enclosure 58 (fig. 2) for applying negative pressure to a wound (page 5, [0042], lines 5-6), the enclosure being attachable to the wound circumference so as to define a confined volume A (fig. 2), and comprising a tube 52 (page 5, [0042], line 28; fig2), the enclosure having an enclosure outlet 54 (page 5, [0042], line 27) connectable to the vacuum source 30 (page 5, [0042], line 29; fig. 2) so that negative pressure may be created in said volume;

a collecting vessel in fluid communication with the wound and connected to the vacuum source (page 4, [0036]), wherein all elements of the device are fully capable of being disposed.

Argenta does not expressly disclose the system, wherein the suction tube comprises a venting arrangement outside the enclosure such that ambient air can enter the tube via the venting arrangement and flow to the vacuum source without entering the enclosure.

Leffler teaches a medical suction apparatus (see Title) wherein the suction tube 26 (fig. 1) comprises a venting port 20 (col. 3, line 69; fig. 1) that is a venting arrangement that is a bleeding hole outside of the wound area allowing the flow to the vacuum source without entering the wound area, wherein the vent arrangement necessarily provides a restricted flow of ambient air therethrough and along the suction tube.

The rationale of obviousness rejection discussed above in claim 11 is incorporated herein in its entirety.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILYA TREYGER whose telephone number is (571)270-3217. The examiner can normally be reached on 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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

/Ilya Y Treyger/
Examiner, Art Unit 3761

/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11989297	ADAHAN, CARMELI
	Examiner	Art Unit
	ILYA Y TREYGER	3761

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

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

CLAIM		DATE								
Final	Original	10/05/2010	04/15/2011	09/26/2011	05/22/2012					
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	3	-	-	-	-					
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	10	-	-	-	-					
	11	✓	✓	✓	✓					
	12	✓	✓	-	-					
	13	✓	✓	✓	✓					
	14	✓	✓	✓	✓					
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	35		✓	✓	✓					
	36		✓	✓	✓					

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Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11989297	ADAHAN, CARMELI
	Examiner	Art Unit
	ILYA Y TREYGER	3761

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

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

CLAIM		DATE								
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	40		✓	✓	✓					
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	52		✓	✓	✓					
	53		✓	✓	✓					
	54				✓					

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	11989297
	Filing Date	2008-01-24
	First Named Inventor	Carmeli ADAHAN
	Art Unit	3761
	Examiner Name	TREYGER, ILYA Y
	Attorney Docket Number	29068U

U.S.PATENTS						Remove
Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4583970		1986-04-22	KIRCHNER	
	2	5947923	A	1999-09-07	UEHARA, et al.	
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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /I.T./

Receipt date: 02/21/2012	Application Number	11989297 11989297 - GAU: 3761
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2008-01-24
	First Named Inventor	Carmeli ADAHAN
	Art Unit	3761
	Examiner Name	TREYGER, ILYA Y
	Attorney Docket Number	29068U

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

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

EXAMINER SIGNATURE

Examiner Signature	/Ilya Treyger/	Date Considered	05/22/2012

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

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

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /I.T./

Receipt date: 02/21/2012	Application Number	11989297	11989297 - GAU: 3761
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99**)	Filing Date	2008-01-24	
	First Named Inventor	Carmeli ADAHAN	
	Art Unit	3761	
	Examiner Name	TREYGER, ILYA Y	
	Attorney Docket Number	29068U	

CERTIFICATION STATEMENT

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

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

OR

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

☐ See attached certification statement.

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

☐ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/Susanne M. Hopkins/	Date (YYYY-MM-DD)	2012-02-21
Name/Print	Susanne M. Hopkins	Registration Number	33247

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

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Privacy Act Statement

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

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

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

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

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

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

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

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

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

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

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

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EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S1	53	((CARMELI) near2 (ADAHAN)).INV.	US-PGPUB; USPAT; USOCR	OR	OFF	2010/10/05 16:32
S2	11641	wound and (suction vacuum) and (enclosure dressing) and ((bleeding hole) (vacuum breaker))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/10/05 16:47
S3	851	(604/35).CCLS.	US-PGPUB; USPAT	OR	OFF	2010/10/05 16:48
S4	746	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2010/10/05 16:48
S5	266	(604/313).CCLS.	US-PGPUB; USPAT	OR	OFF	2010/10/05 16:48
S6	1805	(604/317-323).CCLS.	US-PGPUB; USPAT	OR	OFF	2010/10/05 16:49
S7	1255	(604/540-544).CCLS.	US-PGPUB; USPAT	OR	OFF	2010/10/05 16:49
S8	250	(604/902).CCLS.	US-PGPUB; USPAT	OR	OFF	2010/10/05 16:49
S9	505	(606/131).CCLS.	US-PGPUB; USPAT	OR	OFF	2010/10/05 16:49
S10	17	S2 and S3	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/10/05 16:49
S11	119	S2 and S4	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/10/05 16:50
S12	126	S2 and S5	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/10/05 16:50
S13	117	S2 and S6	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/10/05 16:50
S14	109	S2 and S7	US-PGPUB;	OR	OFF	2010/10/05

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			USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB			16:50
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S18	99	("3026874" | "3486504" | "4540412" | "4759354" | "4969880").PN. OR ("5149331").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2010/10/05 16:52
S19	73	("4743232" | "5230350").PN. OR ("5344415").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2010/10/05 16:52
S20	154	("1355846" | "2547758" | "2632443" | "2682873" | "2969057" | "3367332" | "3648692" | "3682180" | "3826254" | "4080970" | "4096853" | "4139004" | "4165748" | "4245630" | "4261363" | "4275721" | "4297995" | "4333468" | "4373519" | "4382441" | "4392853" | "4392858" | "4419097" | "4475909" | "4480638" | "4525166" | "4525374" | "4540412" | "4543100" | "4551139" | "4569348" | "4605399" | "4608041" | "4640688" | "4655754" | "4733659" | "4743232" | "4787888" | "4826949" | "4838883" | "4840187" | "4863449" | "4872450" | "4878901" | "4897081" | "4906233" | "4906240" | "4919654" | "4941882" | "4953565" | "4969880" | "4985019" | "5037397" | "5100396" | "5149331" | "5167613" | "5176663" | "5261893" | "5298015" | "5344415" | "5358494" | "5556375" | "5607388" | "5636643" | "5645081").PN. OR ("6071267").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2010/10/05 16:52
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S22	12345	wound and (suction vacuum) and (enclosure dressing) and ((bleeding hole) (vacuum breaker))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 11:54
S23	881	(604/35).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 11:54

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S24	784	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 11:54
S25	290	(604/313).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 11:54
S26	1923	(604/317-323).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 11:54
S27	1341	(604/540-544).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 11:54
S28	251	(604/902).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 11:54
S29	521	(606/131).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 11:54
S30	18	S22 and S23	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 11:54
S31	135	S22 and S24	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 11:54
S32	149	S22 and S25	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 11:54
S33	169	S22 and S26	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 11:54
S34	125	S22 and S27	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 11:54
S35	7	S22 and S28	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 11:54
S36	4	S22 and S29	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 11:54
S37	74	("1251258" | "3171410" | "3486504").PN. OR ("3874387").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/04/15 11:54
S38	114	("3026874" | "3486504" | "4540412" | "4759354" | "4969880").PN. OR	US-PGPUB; USPAT;	OR	OFF	2011/04/15 11:54

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		("5149331").URPN.	USOCR			
S39	82	("4743232" | "5230350").PN. OR ("5344415").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/04/15 11:54
S40	174	("1355846" | "2547758" | "2632443" | "2682873" | "2969057" | "3367332" | "3648692" | "3682180" | "3826254" | "4080970" | "4096853" | "4139004" | "4165748" | "4245630" | "4261363" | "4275721" | "4297995" | "4333468" | "4373519" | "4382441" | "4392853" | "4392858" | "4419097" | "4475909" | "4480638" | "4525166" | "4525374" | "4540412" | "4543100" | "4551139" | "4569348" | "4605399" | "4608041" | "4640688" | "4655754" | "4733659" | "4743232" | "4787888" | "4826949" | "4838883" | "4840187" | "4863449" | "4872450" | "4878901" | "4897081" | "4906233" | "4906240" | "4919654" | "4941882" | "4953565" | "4969880" | "4985019" | "5037397" | "5100396" | "5149331" | "5167613" | "5176663" | "5261893" | "5298015" | "5344415" | "5358494" | "5556375" | "5607388" | "5636643" | "5645081").PN. OR ("6071267").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/04/15 11:54
S41	54	((CARMELI) near2 (ADAHAN)).INV.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/04/15 12:53
S42	12345	wound and (suction vacuum) and (enclosure dressing) and ((bleeding hole) (vacuum breaker))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 12:53
S43	881	(604/35).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 12:53
S44	784	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 12:53
S45	290	(604/313).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 12:53
S46	1923	(604/317-323).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 12:53
S47	1341	(604/540-544).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 12:53
S48	251	(604/902).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 12:53
S49	521	(606/131).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 12:53
S50	18	S42 and S43	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 12:53
S51	135	S42 and S44	US-PGPUB; USPAT; USOCR;	OR	OFF	2011/04/15 12:53

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			EPO; JPO; DERWENT; IBM_TDB			
S52	149	S42 and S45	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 12:53
S53	169	S42 and S46	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 12:53
S54	125	S42 and S47	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 12:53
S55	7	S42 and S48	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 12:53
S56	4	S42 and S49	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 12:53
S57	74	("1251258" | "3171410" | "3486504").PN. OR ("3874387").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/04/15 12:53
S58	114	("3026874" | "3486504" | "4540412" | "4759354" | "4969880").PN. OR ("5149331").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/04/15 12:53
S59	82	("4743232" | "5230350").PN. OR ("5344415").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/04/15 12:53
S60	174	("1355846" | "2547758" | "2632443" | "2682873" | "2969057" | "3367332" | "3648692" | "3682180" | "3826254" | "4080970" | "4096853" | "4139004" | "4165748" | "4245630" | "4261363" | "4275721" | "4297995" | "4333468" | "4373519" | "4382441" | "4392853" | "4392858" | "4419097" | "4475909" | "4480638" | "4525166" | "4525374" | "4540412" | "4543100" | "4551139" | "4569348" | "4605399" | "4608041" | "4640688" | "4655754" | "4733659" | "4743232" | "4787888" | "4826949" | "4838883" | "4840187" | "4863449" | "4872450" | "4878901" | "4897081" | "4906233" | "4906240" | "4919654" | "4941882" | "4953565" | "4969880" | "4985019" | "5037397" | "5100396" | "5149331" | "5167613" | "5176663" |	US-PGPUB; USPAT; USOCR	OR	OFF	2011/04/15 12:53

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		"5261893" | "5298015" | "5344415" | "5358494" | "5556375" | "5607388" | "5636643" | "5645081").PN. OR ("6071267").URPN.				
S61	54	((CARMELI) near2 (ADAHAN)).INV.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/04/15 12:53
S62	12345	wound and (suction vacuum) and (enclosure dressing) and ((bleeding hole) (vacuum breaker))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 12:53
S63	881	(604/35).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 12:53
S64	784	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 12:53
S65	290	(604/313).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 12:53
S66	1923	(604/317-323).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 12:53
S67	1341	(604/540-544).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 12:53
S68	251	(604/902).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 12:53
S69	521	(606/131).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 12:53
S70	18	S62 and S63	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 12:53
S71	135	S62 and S64	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 12:53
S72	149	S62 and S65	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 12:53
S73	169	S62 and S66	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 12:53
S74	125	S62 and S67	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 12:53
S75	7	S62 and S68	US-PGPUB;	OR	OFF	2011/04/15

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			USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB			12:53
S76	4	S62 and S69	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 12:53
S77	74	("1251258" | "3171410" | "3486504").PN. OR ("3874387").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/04/15 12:53
S78	114	("3026874" | "3486504" | "4540412" | "4759354" | "4969880").PN. OR ("5149331").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/04/15 12:53
S79	82	("4743232" | "5230350").PN. OR ("5344415").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/04/15 12:53
S80	174	("1355846" | "2547758" | "2632443" | "2682873" | "2969057" | "3367332" | "3648692" | "3682180" | "3826254" | "4080970" | "4096853" | "4139004" | "4165748" | "4245630" | "4261363" | "4275721" | "4297995" | "4333468" | "4373519" | "4382441" | "4392853" | "4392858" | "4419097" | "4475909" | "4480638" | "4525166" | "4525374" | "4540412" | "4543100" | "4551139" | "4569348" | "4605399" | "4608041" | "4640688" | "4655754" | "4733659" | "4743232" | "4787888" | "4826949" | "4838883" | "4840187" | "4863449" | "4872450" | "4878901" | "4897081" | "4906233" | "4906240" | "4919654" | "4941882" | "4953565" | "4969880" | "4985019" | "5037397" | "5100396" | "5149331" | "5167613" | "5176663" | "5261893" | "5298015" | "5344415" | "5358494" | "5556375" | "5607388" | "5636643" | "5645081").PN. OR ("6071267").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/04/15 12:53
S84	55	((CARMELI) near2 (ADAHAN)).INV.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/09/26 13:57
S85	12846	wound and (suction vacuum) and (enclosure dressing) and ((bleeding hole) (vacuum breaker))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S86	902	(604/35).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S87	815	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S88	308	(604/313).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S89	2020	(604/317-323).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57

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S90	1424	(604/540-544).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S91	253	(604/902).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S92	529	(606/131).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S93	21	S85 and S86	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S94	150	S85 and S87	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S95	164	S85 and S88	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S96	214	S85 and S89	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S97	137	S85 and S90	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S98	8	S85 and S91	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S99	5	S85 and S92	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S100	88	("1251258" | "3171410" | "3486504").PN. OR ("3874387").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/09/26 13:57
S101	133	("3026874" | "3486504" | "4540412" | "4759354" | "4969880").PN. OR ("5149331").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/09/26 13:57
S102	94	("4743232" | "5230350").PN. OR ("5344415").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/09/26 13:57
S103	200	("1355846" | "2547758" | "2632443" | "2682873" | "2969057" | "3367332" |	US-PGPUB; USPAT;	OR	OFF	2011/09/26 13:57

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		"3648692" | "3682180" | "3826254" | "4080970" | "4096853" | "4139004" | "4165748" | "4245630" | "4261363" | "4275721" | "4297995" | "4333468" | "4373519" | "4382441" | "4392853" | "4392858" | "4419097" | "4475909" | "4480638" | "4525166" | "4525374" | "4540412" | "4543100" | "4551139" | "4569348" | "4605399" | "4608041" | "4640688" | "4655754" | "4733659" | "4743232" | "4787888" | "4826949" | "4838883" | "4840187" | "4863449" | "4872450" | "4878901" | "4897081" | "4906233" | "4906240" | "4919654" | "4941882" | "4953565" | "4969880" | "4985019" | "5037397" | "5100396" | "5149331" | "5167613" | "5176663" | "5261893" | "5298015" | "5344415" | "5358494" | "5556375" | "5607388" | "5636643" | "5645081").PN. OR ("6071267").URPN.	USOCR			
S104	55	((CARMELI) near2 (ADAHAN)).INV.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/09/26 13:57
S105	12846	wound and (suction vacuum) and (enclosure dressing) and ((bleeding hole) (vacuum breaker))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S106	902	(604/35).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S107	815	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S108	308	(604/313).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S109	2020	(604/317-323).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S110	1424	(604/540-544).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S111	253	(604/902).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S112	529	(606/131).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S113	21	S105 and S106	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S114	150	S105 and S107	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S115	164	S105 and S108	US-PGPUB; USPAT; USOCR; EPO; JPO;	OR	OFF	2011/09/26 13:57

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			DERWENT; IBM_TDB			
S116	214	S105 and S109	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S117	137	S105 and S110	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S118	8	S105 and S111	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S119	5	S105 and S112	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S120	88	("1251258" | "3171410" | "3486504").PN. OR ("3874387").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/09/26 13:57
S121	133	("3026874" | "3486504" | "4540412" | "4759354" | "4969880").PN. OR ("5149331").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/09/26 13:57
S122	94	("4743232" | "5230350").PN. OR ("5344415").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/09/26 13:57
S123	200	("1355846" | "2547758" | "2632443" | "2682873" | "2969057" | "3367332" | "3648692" | "3682180" | "3826254" | "4080970" | "4096853" | "4139004" | "4165748" | "4245630" | "4261363" | "4275721" | "4297995" | "4333468" | "4373519" | "4382441" | "4392853" | "4392858" | "4419097" | "4475909" | "4480638" | "4525166" | "4525374" | "4540412" | "4543100" | "4551139" | "4569348" | "4605399" | "4608041" | "4640688" | "4655754" | "4733659" | "4743232" | "4787888" | "4826949" | "4838883" | "4840187" | "4863449" | "4872450" | "4878901" | "4897081" | "4906233" | "4906240" | "4919654" | "4941882" | "4953565" | "4969880" | "4985019" | "5037397" | "5100396" | "5149331" | "5167613" | "5176663" | "5261893" | "5298015" | "5344415" | "5358494" | "5556375" | "5607388" | "5636643" | "5645081").PN. OR ("6071267").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/09/26 13:57
S124	55	((CARMELI) near2 (ADAHAN)).INV.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/09/26 13:57

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S125	12846	wound and (suction vacuum) and (enclosure dressing) and ((bleeding hole) (vacuum breaker))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S126	902	(604/35).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S127	815	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S128	308	(604/313).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S129	2020	(604/317-323).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S130	1424	(604/540-544).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S131	253	(604/902).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S132	529	(606/131).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S133	21	S125 and S126	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S134	150	S125 and S127	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S135	164	S125 and S128	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S136	214	S125 and S129	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S137	137	S125 and S130	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S138	8	S125 and S131	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S139	5	S125 and S132	US-PGPUB; USPAT; USOCR;	OR	OFF	2011/09/26 13:57

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			EPO; JPO; DERWENT; IBM_TDB			
S140	88	("1251258" | "3171410" | "3486504").PN. OR ("3874387").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/09/26 13:57
S141	133	("3026874" | "3486504" | "4540412" | "4759354" | "4969880").PN. OR ("5149331").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/09/26 13:57
S142	94	("4743232" | "5230350").PN. OR ("5344415").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/09/26 13:57
S143	200	("1355846" | "2547758" | "2632443" | "2682873" | "2969057" | "3367332" | "3648692" | "3682180" | "3826254" | "4080970" | "4096853" | "4139004" | "4165748" | "4245630" | "4261363" | "4275721" | "4297995" | "4333468" | "4373519" | "4382441" | "4392853" | "4392858" | "4419097" | "4475909" | "4480638" | "4525166" | "4525374" | "4540412" | "4543100" | "4551139" | "4569348" | "4605399" | "4608041" | "4640688" | "4655754" | "4733659" | "4743232" | "4787888" | "4826949" | "4838883" | "4840187" | "4863449" | "4872450" | "4878901" | "4897081" | "4906233" | "4906240" | "4919654" | "4941882" | "4953565" | "4969880" | "4985019" | "5037397" | "5100396" | "5149331" | "5167613" | "5176663" | "5261893" | "5298015" | "5344415" | "5358494" | "5556375" | "5607388" | "5636643" | "5645081").PN. OR ("6071267").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/09/26 13:57
S144	55	((CARMELI) near2 (ADAHAN)).INV.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/09/26 13:57
S145	12846	wound and (suction vacuum) and (enclosure dressing) and ((bleeding hole) (vacuum breaker))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S146	902	(604/35).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S147	815	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S148	308	(604/313).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S149	2020	(604/317-323).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S150	1424	(604/540-544).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S151	253	(604/902).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S152	529	(606/131).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S153	21	S145 and S146	US-PGPUB;	OR	OFF	2011/09/26

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			USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB			13:57
S154	150	S145 and S147	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S155	164	S145 and S148	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S156	214	S145 and S149	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S157	137	S145 and S150	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S158	8	S145 and S151	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S159	5	S145 and S152	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
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S161	133	("3026874" | "3486504" | "4540412" | "4759354" | "4969880").PN. OR ("5149331").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/09/26 13:57
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		"4569348" | "4605399" | "4608041" | "4640688" | "4655754" | "4733659" | "4743232" | "4787888" | "4826949" | "4838883" | "4840187" | "4863449" | "4872450" | "4878901" | "4897081" | "4906233" | "4906240" | "4919654" | "4941882" | "4953565" | "4969880" | "4985019" | "5037397" | "5100396" | "5149331" | "5167613" | "5176663" | "5261893" | "5298015" | "5344415" | "5358494" | "5556375" | "5607388" | "5636643" | "5645081").PN. OR ("6071267").URPN.				
S164	26	S100 and (vent venting ventillation)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 14:02
S165	32	S101 and (vent venting ventillation)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 14:02
S166	15	S102 and (vent venting ventillation)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 14:02
S167	36	S103 and (vent venting ventillation)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 14:02
S168	70	"4108574" "4208171"	US-PGPUB; USPAT; EPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 14:22
S169	0	S168 and (air adj hole)	US-PGPUB; USPAT; EPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 14:23
S170	5	S168 and (vent venting)	US-PGPUB; USPAT; EPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 14:23
S171	6	"20040015042" "20050180868"	US-PGPUB; USPAT; EPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 14:24
S172	55	"4552552"	US-PGPUB; USPAT; EPO; DERWENT;	OR	OFF	2011/09/26 14:24

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			IBM_TDB			
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S174	0	S172 and (air adj hole)	US-PGPUB; USPAT; EPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 14:25
S175	18	"5116206" "7503910"	US-PGPUB; USPAT; EPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 14:26
S176	3	S175 and (vent venting)	US-PGPUB; USPAT; EPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 14:27

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S81	0	pressure and regulating and device and sealed and vial and wheath and cap and connector and positioned and within and bag and interior and surface and outer and adapted and expanded and unfolded and compensat and changes and volume and medical and fluid and move and first and orientation and portion and partially and unexpanded and folded and second and lubricant and layer and impermeable and impeding and passage and between and regulates and withdrawn and equilibrate and opposite and reduces and friction.clm.	US-PGPUB	OR	OFF	2011/04/15 13:00
S177	0	pressure and regulating and device and sealed and vial and wheath and cap and connector and positioned and within and bag and interior and surface and outer and adapted and expanded and unfolded and compensat and changes and volume and medical and fluid and move and first and orientation and portion and partially and unexpanded and folded and second and lubricant and layer and impermeable and impeding and passage and between and regulates and withdrawn and equilibrate and opposite and reduces and friction.clm.	US-PGPUB	OR	OFF	2011/09/26 13:57

5/22/2012 3:24:06 PM
C:\Users\itreyger\Documents\EAST\Workspaces\11989297.wsp

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BIB DATA SHEET

CONFIRMATION NO. 4766

SERIAL NUMBER	FILING or 371(c) DATE RULE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
11/989,297	01/24/2008	604	3761	29068U

APPLICANTS
Carmeli Adahan, Jerusalem, ISRAEL;

**** CONTINUING DATA ************************* I.T. 06/22/2010**
This application is a 371 of PCT/IL2005/000784 07/24/2005

**** FOREIGN APPLICATIONS ************************* I.T. 06/22/2010**

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED **** ** SMALL ENTITY **
07/08/2009

Foreign Priority claimed ☑ Yes ☐ No 35 USC 119(a-d) conditions met ☐ Yes ☐ No Verified and Acknowledged /ILYA Y TREYGER/ Examiner's Signature	☐ Met after Allowance Initials	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
		ISRAEL	2	33	5

ADDRESS

THE NATH LAW GROUP
112 South West Street
Alexandria, VA 22314
UNITED STATES

TITLE

Wound closure and drainage system

FILING FEE RECEIVED		
1000	FEES: Authority has been given in Paper No._____ to charge/credit DEPOSIT ACCOUNT No._____ for following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11989297	ADAHAN, CARMELI
	Examiner	Art Unit
	ILYA Y TREYGER	3761

SEARCHED			
Class	Subclass	Date	Examiner
604	540-544	10/5/2010	I. T.

SEARCH NOTES		
Search Notes	Date	Examiner
EAST Search attached	10/5/2010	I. T.
Search updated	4/15/2011	I. T.
Search updated	9/26/2011	I. T.
Search updated	5/22/2012	I. T.

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
11/989,297	01/24/2008	Carmeli Adahan	29068U

CONFIRMATION NO. 4766

20529
THE NATH LAW GROUP
112 South West Street
Alexandria, VA 22314

POWER OF ATTORNEY NOTICE

OC000000053532501

Date Mailed: 04/10/2012

NOTICE REGARDING CHANGE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 03/29/2012.

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

/hgray/

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

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
11/989,297	01/24/2008	Carmeli Adahan	067913.000085

CONFIRMATION NO. 4766

20230
VORYS, SATER, SEYMOUR & PEASE LLP
1909 K St., NW
9th Floor
WASHINGTON, DC 20006-1152

POA ACCEPTANCE LETTER

OC000000053532515

Date Mailed: 04/10/2012

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 03/29/2012.

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

/hgray/

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

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Exhibit 1008
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REVOCATION OF POWER OF ATTORNEY WITH A NEW POWER OF ATTORNEY
AND
CHANGE OF CORRESPONDENCE ADDRESS

I hereby revoke all previous powers of attorney given in the applications identified in Appendix A.

I hereby appoint Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s) to prosecute the applications identified in Appendix A, and to transact all business in the United States Patent and Trademark Office connected therewith:

CUSTOMER NUMBER: 20230

Please recognize or change the correspondence address for the applications identified in Appendix A to the address associated with:

CUSTOMER NUMBER: 20230

I am the:

Applicant / Inventor

SIGNATURE OF APPLICANT / INVENTOR

Signature [signature] Date March 11, 2012

Name Caswell Austin Telephone 9562640600

Title and Company CEO of Engineering

Signatures of all assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

Total of _____ forms are submitted.

Electronic Acknowledgement Receipt

EFS ID:	12419756
Application Number:	11989297
International Application Number:	
Confirmation Number:	4766
Title of Invention:	Wound closure and drainage system
First Named Inventor/Applicant Name:	Carmeli Adahan
Customer Number:	20529
Filer:	Susanne M. Hopkins/Lisa Elliott
Filer Authorized By:	Susanne M. Hopkins
Attorney Docket Number:	29068U
Receipt Date:	29-MAR-2012
Filing Date:	24-JAN-2008
Time Stamp:	09:36:02
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Miscellaneous Incoming Letter	AppendixA.pdf	68602 050dd4de2b644a65061d458d33fc836f724ad8cd	no	3
Warnings:					
Information:					

2	Power of Attorney	Rev.pdf	283941 fdba52b86dfeecab4c58c2b4177714ba81e8c685	no	1
Warnings:					
Information:					
			Total Files Size (in bytes):	352543	

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New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

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

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

APPENDIX A

CARMELI ADAHAN

1	Appl. Number:	11989297
	Filing Date:	01/24/2008
	Publ. Number:	20090264837
	Publ. Date:	10/22/2009
	Patent Number:	n/a
	Issue Date:	n/a
	First Named Inventor:	Carmeli ADAHAN
	Title:	Wound Closure and Drainage System
	Art Unit:	3761
	Examiner Name:	TREYGER, ILYA Y
	Attorney Docket Number:	067913.000085

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APPENDIX A

CARMELI ADAHAN

2	Appl. Number:	12223473
	Filing Date:	07/31/2008
	Publ. Number:	20090030402
	Publ. Date:	01/29/2009
	Patent Number:	n/a
	Issue Date:	n/a
	First Named Inventor:	Carmeli ADAHAN
	Title:	Suctioning System, Method and Kit
	Art Unit:	3761
	Examiner Name:	TREYGER, ILYA Y
	Attorney Docket Number:	067913.000101

Medela LLC and Medela AG
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Page #386

APPENDIX A

CARMELI ADAHAN

3	Appl. Number:	12451335
	Filing Date:	11/06/2009
	Publ. Number:	20100063483
	Publ. Date:	03/11/2010
	Patent Number:	n/a
	Issue Date:	n/a
	First Named Inventor:	Carmeli ADAHAN
	Title:	Suction System
	Art Unit:	3761
	Examiner Name:	TREYGER, ILYA Y
	Attorney Docket Number:	067913.000220

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Page #387

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	11989297
Filing Date	2008-01-24
First Named Inventor	Carmeli ADAHAN
Art Unit	3761
Examiner Name	TREYGER, ILYA Y
Attorney Docket Number	29068U

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4583970		1986-04-22	KIRCHNER	
	2	5947923	A	1999-09-07	UEHARA, et al.	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	11989297
	Filing Date	2008-01-24
	First Named Inventor	Carmeli ADAHAN
	Art Unit	3761
	Examiner Name	TREYGER, ILYA Y
	Attorney Docket Number	29068U

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

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EXAMINER SIGNATURE

Examiner Signature		Date Considered	

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	11989297
	Filing Date	2008-01-24
	First Named Inventor	Carmeli ADAHAN
	Art Unit	3761
	Examiner Name	TREYGER, ILYA Y
	Attorney Docket Number	29068U

CERTIFICATION STATEMENT

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

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

OR

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

☐ See attached certification statement.

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

☐ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/Susanne M. Hopkins/	Date (YYYY-MM-DD)	2012-02-21
Name/Print	Susanne M. Hopkins	Registration Number	33247

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

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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.

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

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

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

Electronic Acknowledgement Receipt

EFS ID:	12115378
Application Number:	11989297
International Application Number:	
Confirmation Number:	4766
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First Named Inventor/Applicant Name:	Carmeli Adahan
Customer Number:	20529
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1	Information Disclosure Statement (IDS) Form (SB08)	IDS.pdf	612317 4f61f2511928a9779efa77024bc3e48ab37203de	no	4
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If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

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

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

New International Application Filed with the USPTO as a Receiving Office

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

Mail Stop AMENDMENT
Attorney Docket No. 29068U

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Carmeli Adahan	Conf. No.: 4766
Application No.: 11/989,297	Examiner: TREYGER, ILYA Y.
Filed: January 24, 2008	Group Art Unit: 3761

For: WOUND CLOSURE AND DRAINAGE SYSTEM

AMENDMENT AND RESPONSE

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

Dear Commissioner:

This paper is submitted responsive to the non-final Official Action dated October 11, 2011, along with a Petition for a one (1) month extension of time, making a response due on or before February 13, 2012 (Monday). Accordingly, this paper is timely filed.

Amendments to the Specification begins on page 2 of this paper.

Amendments to the Claims begins on page 3 of this paper.

Remarks begin on page 10 of this paper.

A **Conclusion** appears at page 25 of this paper.

AMENDMENTS TO THE SPECIFICATION:

Please amend the specification as follows.

Page 6, line 5-15,

Suction tube 16 is connected to nipple 38 of the enclosure 12 which covers wound area of the body 34 such that suction of air through tube 16 creates negative pressure in the volume above the wound area of the body 34. A bleeding orifice 35 is provided within the enclosure 12, or adjacent to it as a tube orifice 37 (i.e. venting arrangement), allowing ambient air to flow into and through suction tube 16, rendering enclosure 12 non-air tight, or vented. This feature, unlike conventional sealed closures, provides for quick movement of exudate entering suction tube 16, toward the vacuum pump 14, and into the waste bag 31, before it dries up or coagulates and occludes the tube. This feature also provides for introduction of ambient pressure to the wound area of the body 34 whenever the vacuum pump stops pumping, allowing cyclic negative pressure application to the wound, by cycling the vacuum pump on and off alternately.

AMENDMENTS TO THE CLAIMS:

Please amend the claims as follows. This listing of claims replaces all prior versions of the claims in this application.

1-10. (Canceled)

11. (Previously presented) An enclosure for applying negative pressure to a wound, the enclosure being attachable to the wound circumference so as to define a confined volume, and comprising a tube, the enclosure having an enclosure outlet connectable a vacuum source via said tube so that negative pressure may be created in said volume, said tube comprising a venting arrangement, outside said enclosure, such that ambient air can enter said tube via said venting arrangement and flow to said vacuum source without entering said enclosure.

12. (Canceled)

13. (Previously presented) The enclosure according to claim 11, wherein said venting arrangement comprises one or more bleeding holes.

14. (Previously presented) The enclosure according to claim of claim 11, wherein said venting arrangement is provided in the form of a porous body.

15-33. (Canceled)

34. (Previously presented) The enclosure according to claim 11, wherein said venting arrangement acts as a flow restrictor to provide, under the action of the vacuum source, a restricted flow of ambient air therethrough and along said tube.

35. (Previously presented) The enclosure according to claim 11, wherein said enclosure facilitates drainage of fluids exuded from the wound, wherein the ambient air can enter said tube via said venting arrangement and flow together with the exuded liquids under the action of the negative pressure.

36. (Previously presented) The enclosure according to claim 11, wherein said venting arrangement provides for ambient air to enter said enclosure via said tube and for ambient pressure to be restored in said confined volume when the vacuum source is not operating.

37. (Previously presented) The enclosure according to claim 11, wherein in operation of the enclosure, ambient air enters the tube directly via said venting arrangement without entering said enclosure when negative pressure is being applied to the wound via said enclosure.

38. (Previously presented) A disposable assembly for applying negative pressure to a wound, the assembly comprising an enclosure as defined in claim 11 attachable to the wound circumference so as to define a confined volume, a vacuum pump unit of the vacuum pump connected to said enclosure so that negative pressure may be created in said volume, said vacuum pump unit being configured for being detachably attached to a drive unit of the vacuum pump for operating the pump unit, and a waste container connected to said vacuum pump unit, wherein said enclosure is connected to an inlet of said vacuum pump unit via said tube and said waste container is connected to an outlet of said vacuum pump unit.

39. (Previously presented) A disposable assembly according to claim 38, wherein said assembly further operates to drain the wound from fluids exuded therefrom, wherein the ambient air can enter said tube via said venting arrangement and flow together with the exuded liquids under the action of the negative pressure, and facilitates draining of the exuded fluids to said waste container.

40. (Previously presented) The disposable assembly according to claim 38, wherein said venting arrangement comprises one or more bleeding holes.

41. (Previously presented) The disposable assembly according to claim 38, wherein said venting arrangement is provided in the form of a porous body.

42. (Previously presented) A vacuum system for applying negative pressure to a wound, the vacuum system comprising an enclosure and a vacuum source, the enclosure being attachable to the wound circumference so as to define a confined volume, and comprising a tube, the enclosure having an enclosure outlet connectable to said vacuum source via said tube so that negative pressure may be created in said volume, said tube comprising a venting arrangement adjacent to said enclosure outlet, outside said enclosure, such that ambient air can enter said tube via said venting arrangement, and further comprising a waste container in fluid communication with said vacuum source.

43. (Previously presented) The vacuum system of claim 42, wherein said vacuum system further operates to drain the wound from fluids exuded therefrom, wherein the ambient air can enter said tube via said venting arrangement and flow together with the exuded liquids under the action of the negative pressure, and facilitates draining of the exuded fluids to said waste container.

44. (Previously presented) The vacuum system according to claim 42, wherein said vacuum source includes a disposable pump unit detachably attachable to a non-disposable drive unit, said enclosure and said waste container being disposable so that the ambient air that enters said tube via said venting arrangement contacts only the disposable elements and said drained liquids may be disposed of together with said disposable elements.

45. (Previously presented) The vacuum system according to claim 44, wherein said pump unit and said drive unit are adapted for attaching and detaching by simple hand manipulations.

46. (Previously presented) The vacuum system according to claim 42, wherein said venting arrangement comprises one or more bleeding holes.

47. (Previously presented) The vacuum system according to claim 42, wherein said venting arrangement is provided in the form of a porous body.

48. (Previously presented) A vacuum system for applying negative pressure to a wound, the vacuum system comprising an enclosure and a vacuum source, the enclosure being attachable to the wound circumference so as to define a confined volume, and comprising a tube, the enclosure having an enclosure outlet connectable to said vacuum source via said tube so that negative pressure may be created in said volume, said tube comprising a venting arrangement adjacent to said enclosure outlet, outside said enclosure, such that ambient air can enter said tube via said venting arrangement and flow to said vacuum source without entering said enclosure, wherein said vacuum pump comprises a collection chamber upstream of a pump inlet of said vacuum source, and wherein said tube is connected to an inlet of said collection chamber.

49. (Previously presented) The vacuum system of claim 48, wherein said vacuum system further operates to drain the wound from fluids exuded therefrom, wherein the ambient air can enter said tube via said venting arrangement and flow together with the exuded liquids under the action of the negative pressure, and facilitates draining of the exuded fluids to said waste container.

50. (Previously presented) The vacuum system according to claim 48, wherein said vacuum source includes a disposable pump unit detachably attachable to a non-disposable drive unit, said enclosure and said collection chamber being disposable so that the ambient air that enters said tube via said venting arrangement contacts only the disposable elements and said drained liquids may be disposed of together with said disposable elements.

51. (Previously presented) The vacuum system according to claim 50, wherein said pump unit and said drive unit are adapted for attaching and detaching by simple hand manipulations.

52. (Previously presented) The vacuum system according to claim 48, wherein said venting arrangement comprises one or more bleeding holes.

53. (Previously presented) The vacuum system according to claim 48, wherein said venting arrangement is provided in the form of a porous body.

54. (New) The vacuum system according to claim 11, wherein the venting arrangement is a tube orifice.

REMARKS

Claims 11, 13, 14, and 34-53 are pending in the application. Claims 11, 13, 14, and 34-53 are rejected.

Claims 1–10, 12, and 15-33 were previously canceled without prejudice or disclaimer of the subject matter contained therein.

Claim 54 is newly added to recite that the "venting arrangement" is a "tube orifice." Support for the above amendments appears throughout the originally filed specification, claims, and drawings. Further, the specification has been amended to recite the "venting arrangement."

Applicant, by amending any claims herein, makes no admission as to the validity of any rejection made by the Examiner against any claim. Applicant reserves the right to reassert any of the claims canceled or the original scope of any claim amended herein, in a continuing application.

It is respectfully submitted that the above amendments to the claims introduce no new matter within the meaning of 35 U.S.C. §132. Accordingly, Applicant requests reconsideration and timely withdrawal of the pending rejections for the reasons discussed below.

Applicant thanks Examiner Ilya Treyger and Supervisor Patent Examiner Tatyana Zalukaeva for their time and consideration provided during the in-person interview held on February 6, 2012, with Applicant's undersigned representative.

I. Claims 11, 13, 14, and 34-37 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Lockwood et al. ("Lockwood", US 2005/0004534) in view of Leffler (US 3,516,160) as set forth in paragraph 8 on page 3 of the Official Action.

The Examiner asserts that "[It] would have been obvious to one having ordinary skill in the art at the time the invention was made to supply the suction tube of Lockwood with the venting arrangement, as taught by Leffler in order to control the flow in the tube, as motivated by Leffler (col. 4, lines 35-40).

To establish an obviousness rejection under 35 U.S.C. § 103(a), four factual inquiries must be examined. The four factual inquiries include (a) determining the scope and contents of the prior art; (b) ascertaining the differences between the prior art and the claims in issue; (c) resolving the level of ordinary skill in the pertinent art; and (d) evaluating evidence of secondary consideration. *Graham v. John Deere*, 383 U.S. 1, 17-18 (1966). In view of these four factors, the analysis supporting a rejection under 35 U.S.C. 103(a) should be made explicit, and should "identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements" in the manner claimed. *KSR Int'l. Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1741 (2007). Furthermore, even if the prior art may be combined, there must be a reasonable expectation of success, and the reference or references, when combined, must disclose or suggest all of the claim limitations. *See In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Lockwood discloses a vented vacuum bandage, including a vent 19 connected via tube 20 to vacuum bandage 14 (Figs. 1 and 3). A vacuum source 16 is connected via tube 74, switch valve 50, tube 52, vent 19, and tube 20 to vacuum bandage 14. In addition, an

irrigation source 18 is also connected via tube 76, switch valve 50, tube 52, vent 19, and tube 20 to vacuum bandage 14.

Thus, Lockwood discloses a configuration that provides both vacuum and irrigation to the vacuum bandage 14.

Leffler discloses a dental aspirating cuspidor 10, including a tubular ejecting member 22 provided with open venting ports 20 and 21 "for avoiding excessive and discomforting suction to the patient's mouth when the aspirating cuspidor is placed therein." *See* column 3, lines 30-32.

Again, the Examiner's rejection is "to supply the suction tube of Lockwood with the venting arrangement, as taught by Leffler in order to control the flow in the tube, as motivated by Leffler (col. 4, lines 35-40)."

Supplying the suction tube of Lockwood with the venting arrangement of Leffler would destroy the operation of Lockwood's device, and intended use thereof. Specifically, providing a vent in the tubing sections 20 or 52 would preclude the device of Lockwood from being used during the irrigation mode. Specifically, the irrigation fluid would spray out of the vent under pressure and defeat the irrigation function of the vacuum bandage 14. Clearly, such a modification of the device of Lockwood as asserted by the Examiner is not suggested, and in fact is taught away.

Further, providing a vent in the tubing section 74 of Lockwood would further destroy the operation and intended use of the device of Lockwood. Specifically, the ports 20 and 21 are "open" ports (i.e. no means for closing ports 20 and 21) during operation and use of the aspirating cuspidor of Leffler. This arrangement reduces the vacuum level and air flow,

especially, if applied to the vented vacuum bandage of Lockwood significantly reducing the air flow over the wound. *See* paragraph [0007] in Lockwood. Clearly such a modification of the device of Lockwood as asserted by the Examiner is not suggested, and in fact taught away.

It is pointed out that the open end of the tubular ejecting member 22 in Leffler is open to the atmosphere, and not restricted, for example, with a vacuum bandage and venting arrangement according to the claimed combination. It is also noted that an important object for providing the ports 20 and 21 in Leffler is to avoid creating a vacuum in close proximity or with the surface of the mouth tissue (i.e. to avoid clogging or blocking the open end of tubular ejecting member 22). Thus, the object of providing ports 20 and 21 in Leffler is the opposite to the object of Lockwood of creating a vacuum and resulting air flow over the wound teaching away from adding a port of Leffler to one of the tubing sections in Lockwood. Only through improper hindsight would there exist any motivation to try to add the port to one of tubing sections in Loodwood.

CLAIM 11

Claim 11 is currently recited as follows:

> *11. An enclosure for applying negative pressure to a wound, the enclosure being attachable to the wound circumference so as to define a confined volume, and comprising a tube, the enclosure having an enclosure outlet connectable to a vacuum source via said tube so that negative pressure may be created in said volume, said*

tube comprising a venting arrangement, outside said enclosure, such that ambient air can enter said tube via said venting arrangement and flow to said vacuum source without entering said enclosure.

In the obviousness rejection, the Examiner states:

> "*Lockwood does not expressly disclose the system, wherein the suction tube comprises a venting arrangement outside the enclosure such that ambient air can enter the tube via the venting arrangement and flow to the vacuum source without entering the enclosure.*
>
> *Leffler teaches a medical suction apparatus (see Title) wherein the suction tube 26 (fig.1) comprises a venting port 20 (col. 3, line 69; fig. 1) that is a venting arrangement outside of the wound area allowing the flow to the vacuum source without entering the wound area."*

Applicant further submits that there is no motivation to combine the Lockwood and Leffler references, that there is no reasonable expectation of success even if the references are combined, further rending any such combination non-obvious. Furthermore, Applicant submits that even if combined the combination of references does not disclose nor suggest claim 11.

Motivation to Combine

In the first place, the Examiner expressly relies on **Leffler**, the secondary reference, to provide motivation to combine this reference with Lockwood, which is the primary reference. Such a combination is not suggested.

Secondly, Leffler is directed to a completely different field of technology from Lockwood. Lockwood is directed to a vacuum bandage for a **wound**, in which it is desired to maintain a vacuum within a sealed environment over the wound, and in particular it is desired to create a flow of air over the wound to promote healing, and alternately to irrigate the wound (Abstract, paragraphs [0002], [0010]). In stark contrast, Leffler is concerned with aspirating the **intraoral cavity** for removing saliva during a dental procedure, in which there is no intention of, nor desire in, sealing the mouth, nor in creating a vacuum therein, nor in providing an airflow thereto from another inlet.

Thirdly, Leffler expressly teaches away from low flow rates through the suction tubing, and teaches large tubing cross-sections (column 4, lines 3 to 11), and further teaches away from high suction pressure, creating instead low level suction (column 1, lines 19-24; column 4, lines 51 to 55; column 4, lines 9-11). In contrast, Lockwood is directed in the opposite direction, teaching relatively small tube lumens (paragraph [0071]) and providing a “vacuum” within the wound bandage.

Fourthly, the wound environment in Lockwood is expected to be maintained in sterile conditions, while this is not a priority in the saliva aspiration provided by Leffler.

The above would render it rather unlikely for one of ordinary skill in the art to consider Leffler when desiring to improve on Lockwood, and it is respectfully submitted that there is no motivation to combine the references.

Reasonable Expectation of Success

The combination of Lockwood with Leffler would have little expectation of success.

(a) Increased flow over the wound.

Lockwood is very concerned with providing an **increased airflow over the wound**, and this is accomplished via vent 19, outer lumen 24 and out of end 21 of tube 20, which is positioned under sealing film 13, to communicate with the wound. *See p*aragraph [0068], lines 6 to 9:

> *"Venting provides for **increased air flow** through bandage 14 and above or adjacent the wound while vacuum source 16 applies suction to the wound"*

Paragraph [0069], lines 1 to 8:

> "*Ventilation of the system 10, while drawing a negative pressure over the wound, acts to prevent the system 10 from becoming static by drawing air in from the surrounding atmosphere through vent 19, to bandage 14 to create air flow above the wound, and out through a vacuum tube in communication with vacuum source 14. **Therefore**, venting the system 10 **increases air flow** above the wound while vacuum source 16 applies suction to the wound."*

Paragraph [0081], lines 2 to 4:

"As mentioned before, vent 19 ***provides increased air flow*** *through bandage 14 and above the wound."*

Paragraph [0124], lines 2 to 5:

"As mentioned before with respect to vents 19 and 119, vent 219 ***provides increased air flow*** *through bandage 14 and above wound 200."*

Combining Leffler with Lockwood would result, as the Examiner states, in having a vent between the wound and the vacuum source, which would necessarily reduce the actual vacuum pressure that is provided at the wound site. In turn, the weaker vacuum at the wound site would result in a reduction of airflow in to the would site via the original vent 19 that is upstream of the wound site, resulting in a **diminished** air flow over the wound, as compared with not combining Lockwood with Leffler, which directly opposite to the stated intention of Lockwood.

Thus, clearly, this combination of references is against the principles established by *In re Gordon* (733 F.2d 900, 221 USPQ 1125 (Fed Cir 1984)), in which if the proposed modification of the prior art would render the prior art invention being modified unsatisfactory for its intended purpose then the teachings of the references are not sufficient to render the claims prima facie obvious.

Arguably, the vacuum source 16 in Lockwood could possibly be modified to increase suction to bring back the airflow over the wound to the "increased" levels before Leffler was combined with Lockwood. However, such a modification of Lockwood is also not obvious

and goes against the principles established by *In re Mills* (916 F.2d 680. 16 USPQ2d 1430-(Fed Cir 1990)), in which the mere fact that references can be modified or combined does not of itself render the resultant modification or combination obvious.

Furthermore, given the relatively large lumen sizes of Leffler compared with the smaller lumen sizes of Lockwood (discussed briefly above), such a combination may result in the venting ports 20, 21 of Leffler being larger than vent 19 of Lockwood. In addition, the location of the venting ports 20, 21 of Leffler being downstream of the wound site while vent 19 is upstream of the wound site, and providing a filter in vent 19, while none is provided in the venting ports 20, 21, may result in ambient air being preferentially sucked in via the venting ports 20, 21 rather than vent 19, further decreasing the airflow over the wound, detrimentally to Lockwood. Such a combination of references should then change the principle of operation of Lockwood, which desires an increased airflow over the wound, and such a combination of references is against the principles established by *In re Ratti* (270 F.2d 810, 123USPQ 349 (CCPA 1959)), in which if the proposed combination of the prior art would change the principle of operation of the prior art invention being modified then the teachings of the references are not sufficient to render the claims prima facie obvious.

(b)Irrigation Function

Lockwood discloses an irrigation source 18 that is connected to switch valve 50 via tube 76, vacuum source 16 being connected to switch valve 50 via tube 74. Vacuum/irrigation passageway 42 provides communication between the switch valve 50 and the wound site via single lumen tube 52, inner lumen 22 of tube 20, and connector 15

of bandage 14. The switch valve 50 enables the user to selectively switch between providing irrigation at the wound from the irrigation source 18, or providing a vacuum at the wound site from vacuum source 16, each time via the same vacuum/irrigation passageway 42.

Leffler discloses (column 3, lines 11 to 45) an aspirating cuspidor 10 comprising an ejecting member 22 on which is connected housing 11 which includes venting ports 20 and 21. The ejector is of short dimensions and adapted to be held in the mouth by the patient or dental assistant:

> "*A suitable example of an ejecting member 22 is a short drinking straw of plastic of other types of materials*." Column 4, lines 43 to 45.
>
> "*The aspirating cuspidor 10 comprises an open-ended, tubular housing 11 adapted to be held by the patient or dental assistant* …" column 3, liners 14 to 16.

Combining Leffler with Lockwood would place housing 11 with vent ports 20, 21 in fluid communication with the vacuum/irrigation passageway 42, a short distance from the wound site. On consideration of Fig. 1 of Lockwood, this location would probably be in tube 20, between the vent 19 and the wound site, since Leffler teaches a short distance, comparable to a short drinking straw, between the housing 11 and the end of the ejecting member 22. However, the vacuum/irrigation passageway 42 is defined in the inner lumen of tube 20, and thus to work as suggested by the Examiner, the housing 11 of Leffler must

be modified to provide fluid communication between the venting ports 20, 21 of Leffler and the inner lumen of tube 20 of Lockwood, while being sealed off from the outer lumen of tube 20. Such a modification is not obvious from Lockwood nor from Leffler.

Arguably, the housing 11 of Leffler can be located in tube 52 of Lockwood, but this is against the teachings of Leffler, since comparatively placing the housing so far from the end of the ejecting member 22 of Leffler would not allow the user in Leffler to hold the aspirating cuspidor 10 comfortably in the mouth of a dental patient and to selectively close the ports 20, 21:

> "*For this purpose **the patient or dental assistant** may simply put his **fingers** over the venting ports…*" column 4, lines 46 to 47.

These fingers are of course of the same hand that is holding the aspirating cuspidor 10:

> "*The aspirating cuspidor 10 comprises an open-ended, tubular housing 11 adapted to be **held by the patient or dental assistant** …*" column 3, lines 14 to 16.

It is also self-evident that the efficacy of the venting ports 20, 21 in Leffler to create "*an aspirating suction…and for avoiding excessive and discomforting suction to the patient's mouth*" (column 2, lines 55 to 60), will diminish the further away from the mouth-end of the ejecting member 22 the venting ports 20, 21 are located.

Thus, locating the housing of Leffler in tube 52 (and more so in tube 74) would be detrimental to the operation of the housing 11 and venting ports 20, 21 disclosed by Leffler, and thus, this is also against the principles established by *In re Gordon*, briefly discussed above.

In any case, locating the housing 11 and venting ports 20, 21 of Leffler in tube 20 or tube 52 would result, when switching the switch valve 50 to irrigation source 18, in irrigation liquid passing out of the vents 20, 21 of Leffler, and onto the patient, bed and possible attendants in Lockwood, which is highly undesirable in Lockwood. While the housing 20 in Leffler allegedly "*prevent[s] leakage of the saliva, water and foreign matter as it passes through the ejecting passageway15 in the housing 11*" (column 4, lines 33 to 40, Leffler), consideration of Fig. 3 of Leffler clearly indicates that a flow in the reverse direction would unavoidably leak through ports 20, 21. Thus such a combination of references would also be also against the principles established by *In re Gordon*, briefly discussed above, with respect to either one of Lockwood or Leffler.

(c) Sterility

Lockwood is directed to a wound site and requires sterile conditions to be observed. For example, a filter is provided in vent 19 of Lockwood.

In contrast, venting ports 20, 21 of Leffler are open, and thus combining these venting ports with Lockwood would be detrimental in the device of Lockwood, as the venting ports 20, 21 could allow unwanted micro-organisms to obtaining access to the wound site, for example when the vacuum source is not operating.

While ports 20, 21 could also arguably be provided with filters, doing so is not reasonably suggested by Leffler, However, such a modification of Lockwood is also not obvious and goes against the principles established by *In re Mills*, briefly discussed above.

Combination of References vs. Claim 11

In claim 11, the venting arrangement (i.e. orifice) acts as a bleed hole, which by clearing the suction tube allows having the same vacuum level for the full tube length up to the pump. Thus by controlling the vacuum at the pump end of the tube, a controlled vacuum level is maintained over the wound site. Thus, claim 11 enables to control the vacuum remotely by bleeding air to clear the tube. Leffler requires a high flow, to collect and extract saliva and debris, without any vacuum control function at the suction tip. Accordingly, even a combination of these two references does not accomplish the function of controlling distal vacuum by maintaining a tube clear of exudates.

Thus, not only is such a combination of references not obvious, but there is also no reasonable expectation of success, and it is therefore respectfully submitted that claim 11 is novel and non-obvious over Lockwood in view of Leffler. For at least this reason, the claims that depend from claim 11 are also novel and non-obvious over these references.

In view of the foregoing, it is submitted that nothing in Lockwood and Leffler, alone or in combination, renders the presently claimed subject matter obvious within the meaning of 35 U.S.C. §103. Accordingly, the Examiner is respectfully requested to withdraw this rejection of the pending claims.

II. Claims 38-53 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Lockwood et al. ("Lockwood", US 2005/0004534) in view of Leffler (US 3,516,160), as applied to claim 11 above, and further in view of Argenta et al. ("Argenta", US 2001/0029956) as set forth in paragraph 12 on page 5 of the Official Action.

The Examiner asserts that "[It] would have been obvious to one having ordinary skill in the art at the time the invention was made to supply the apparatus of Lockwood/Leffler with the collection vessel, as taught by Argenta in order to store the exudates, as motivated by Argenta (page 4, [0036], lines 21-22." This rejection is respectfully traversed.

Lockwood and ***Leffler*** are discussed in detail in the response set forth in paragraph I above. ***Argenta*** does not add any relevant teach regarding the base claimed subject matter.

CLAIMS 42, 48

Claim 42 is recited as follows:

42. A vacuum system for applying a negative pressure to a wound, the vacuum system comprising an enclosure and a vacuum source, the enclosure being attachable to the wound circumference so as to define a confined volume, and comprising a tube, the enclosure having an enclosure outlet connectable to a vacuum source via said tube so that negative pressure may be created in said volume, said tube comprising a venting arrangement adjacent to said enclosure outlet, outside said enclosure, such that ambient air can enter said tube via said venting arrangement and further comprising a waste container in fluid communication with said vacuum source.

Claim 49 is recited as follows:

> *49. A vacuum system for applying a negative pressure to a wound, the vacuum system comprising an enclosure and a vacuum source, the enclosure being attachable to the wound circumference so as to define a confined volume, and comprising a tube, the enclosure having an enclosure outlet connectable to a vacuum source via said tube so that negative pressure may be created in said volume, said tube comprising a venting arrangement adjacent to said enclosure outlet, outside said enclosure, such that ambient air can enter said tube via said venting arrangement and flow to said vacuum source without entering said enclosure, wherein said vacuum pump comprises a collection chamber upstream of a pump inlet of said vacuum source, and wherein said tube is connected to an inlet of said collection chamber.*

The Examiner rejected independent claims 42, 49 as being obvious over Lockwood in view of Leffler and further in view of Argenta. The arguments provided above regarding claim 11 apply, *mutatis mutandis*, to claims 42 and 49. While not addressing whether or not such a combination is proper, it is to be noted that, as de facto agreed to by the Examiner, Argenta does not cure the deficiencies in Lockwood regarding claim 11.

In view of the foregoing, it is submitted that nothing in Lockwood, Leffler, and Argenta, alone or in combination, renders the presently claimed subject matter obvious within the meaning of 35 U.S.C. §103. Accordingly, the Examiner is respectfully requested to withdraw this rejection of the pending claims.

CONCLUSION

Applicant asserts that the claims are in condition for immediate allowance and early notice to that effect is earnestly solicited. Should the Examiner deem that any further action by Applicant's undersigned representative is desirable and/or necessary, the Examiner is invited to telephone the undersigned at the number set forth below.

In the event this paper is not timely filed, Applicant petitions for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,
THE NATH LAW GROUP

/William L. Klima/
Susanne M. Hopkins
Reg. No. 33,247
William L. Klima
Reg. No. 32,422
Customer No. 20529

February 13, 2012
THE NATH LAW GROUP
112 South West Street
Alexandria, Virginia 22314
Tel: 703- 548-6284

PTO/SB/22 (09-11)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARMENT 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.

PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)	Docket Number (Optional) 29068U
Application Number 11/989,297	Filed January 24, 2008
For WOUND CLOSURE AND DRAINAGE SYSTEM	
Art Unit 3761	Examiner TREYGER, ILYA Y.

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	
☑ One month (37 CFR 1.17(a)(1))	$150	$75	$ 75
☐ Two months (37 CFR 1.17(a)(2))	$560	$280	$
☐ Three months (37 CFR 1.17(a)(3))	$1270	$635	$
☐ Four months (37 CFR 1.17(a)(4))	$1980	$990	$
☐ Five months (37 CFR 1.17(a)(5))	$2690	$1345	$

☑ Applicant claims small entity status. See 37 CFR 1.27.

☐ 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 14-0112.

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.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) is enclosed (Form PTO/SB/96).

☑ attorney or agent of record. Registration Number 32,422

☐ attorney or agent under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____

/William L. Klima/	February 13, 2012
Signature	Date
William L. Klima	703-548-6284
Typed or printed name	Telephone Number

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

☑ Total of one (1) forms are submitted.

This collection of information is required by 37 CFR 1.136(a). 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 6 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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

Privacy Act Statement

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

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

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

Electronic Patent Application Fee Transmittal

Application Number:	11989297
Filing Date:	24-Jan-2008
Title of Invention:	Wound closure and drainage system
First Named Inventor/Applicant Name:	Carmeli Adahan
Filer:	Susanne M. Hopkins/William Klima
Attorney Docket Number:	29068U

Filed as Small Entity

U.S. National Stage under 35 USC 371 Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Extension - 1 month with $0 paid	2251	1	75	75

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
		Total in USD ($)		**75**

Electronic Acknowledgement Receipt

EFS ID:	12066277
Application Number:	11989297
International Application Number:	
Confirmation Number:	4766
Title of Invention:	Wound closure and drainage system
First Named Inventor/Applicant Name:	Carmeli Adahan
Customer Number:	20529
Filer:	Susanne M. Hopkins/William Klima
Filer Authorized By:	Susanne M. Hopkins
Attorney Docket Number:	29068U
Receipt Date:	13-FEB-2012
Filing Date:	24-JAN-2008
Time Stamp:	19:12:40
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$75
RAM confirmation Number	6353
Deposit Account	
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)

1		2012_02_12_RNFOA.pdf	158844 cbd88527047205912e3f5e19f76ec9fcb0dc472d	yes	25

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1
	Specification	2	2
	Claims	3	9
	Applicant Arguments/Remarks Made in an Amendment	10	25

Warnings:

Information:

2	Extension of Time	sb0022.pdf	286662 05f2b5a95f5f17feeb1139d1416afa7900d69775	no	2

Warnings:

Information:

3	Fee Worksheet (SB06)	fee-info.pdf	29922 793a9f48cace20aaae234e7d1144c3321b3d7bbf	no	2

Warnings:

Information:

Total Files Size (in bytes):	475428

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

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

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

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

PTO/SB/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
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PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
11/989,297	01/24/2008	

APPLICATION AS FILED – PART I

	(Column 1)	(Column 2)	SMALL ENTITY ☒		OR	OTHER THAN SMALL ENTITY	
FOR	NUMBER FILED	NUMBER EXTRA	RATE ($)	FEE ($)		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 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			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT		(Column 1)		(Column 2)	(Column 3)	SMALL ENTITY		OR	OTHER THAN SMALL ENTITY	
	02/13/2012	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 12	Minus	** 33	= 0	X $30 =	0	OR	X $ =	
	Independent (37 CFR 1.16(h))	* 3	Minus	***5	= 0	X $125 =	0	OR	X $ =	
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE	

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

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
/KIMBERLY WHITE/

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.
11/989,297	01/24/2008	Carmeli Adahan	29068U	4766

20529 7590 02/08/2012

THE NATH LAW GROUP
112 South West Street
Alexandria, VA 22314

EXAMINER	
TREYGER, ILYA Y	
ART UNIT	PAPER NUMBER
3761	
MAIL DATE	DELIVERY MODE
02/08/2012	PAPER

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.

Applicant-Initiated Interview Summary	Application No.	Applicant(s)	
	11/989,297	ADAHAN, CARMELI	
	Examiner	Art Unit	
	ILYA TREYGER	3761	

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

(1) *ILYA TREYGER*.

(2) *Tatyana Zalukaeva*.

(3) *William L. Klima*.

(4) *Yehuda Seruya*.

Date of Interview: *06 February 2012*.

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

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

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

Claim(s) discussed: *11,42 and 48*.

Identification of prior art discussed: *US 2005/0004534, US 3,516,160, and US 2001/0029956*.

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

Applicant argues that the combination of Lockwood and Leffler is improper because application of venting structure of Leffler completely destroys the irrigation function of the Lockwood's apparatus.
Examiner will reread the reference of Lockwood in view of Applicat's arguments. The official response to the last office action is required .

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview

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

☐ Attachment

/Ilya Y Treyger/ Examiner, Art Unit 3761	/Tatyana Zalukaeva/ Supervisory Patent Examiner, Art Unit 3761

Medela LLC and Medela AG
Exhibit 1008
Page #427

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:
1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

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.
11/989,297	01/24/2008	Carmeli Adahan	29068U	4766

20529 7590 10/11/2011

THE NATH LAW GROUP
112 South West Street
Alexandria, VA 22314

EXAMINER	
TREYGER, ILYA Y	
ART UNIT	PAPER NUMBER
3761	
MAIL DATE	DELIVERY MODE
10/11/2011	PAPER

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.

Medela LLC and Medela AG
Exhibit 1008
Page #429

Office Action Summary	Application No.	Applicant(s)	
	11/989,297	ADAHAN, CARMELI	
	Examiner	Art Unit	
	ILYA TREYGER	3761	

-- 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* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, 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 *22 August 2011*.

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

3)☐ 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

4)☒ Claim(s) *1-53* is/are pending in the application.

4a) Of the above claim(s) *1-10,12 and 15-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11,13,14 and 34-53* is/are rejected.

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

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

Application Papers

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

10)☒ The drawing(s) filed on *24 January 2008* 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).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

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).

a)☐ All b)☐ Some * c)☐ None of:

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) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date : 11/16/2010; 08/23/2011; 05/16/2011; 05/04/2011.

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Page #431

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. 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 01/24/2008 has been entered.

2. Claims 11 and 48 are amended.

3. Claim 12 is canceled.

4. Claims 11, 13, 14 and 34-53 are examined on the merits.

Response to Arguments

5. Applicant's arguments are substantially based on the fact that the reference of Lockwood does not disclose the venting arrangement capable of performing claimed functions.

This argument is found persuasive and rejection under 35 U.S.C. 102(b) has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Leffler (US 3,516,160).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) 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.

8. Claimы 11, 13 and 14 and 34-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lockwood et al. (US 2005/0004534) in view of Leffler (US 3,516,160).

9. In Re claims 11, 14 and 35-37, Lockwood discloses an enclosure for applying negative pressure to a wound, the enclosure being attachable to the wound circumference so as to define a confined volume (Abstract, lines 2-6), and comprising a tube 20 (page 5, [0070]; fig. 1), the enclosure having an enclosure outlet connectable to the vacuum source (Abstract, lines 9-10) via tube 20 (fig. 1) so that negative pressure may be created in said volume (Abstract, lines 5-6).

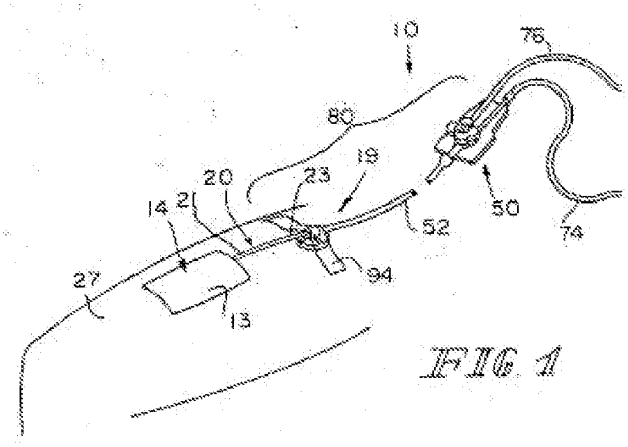


FIG. 1

Lockwood does not expressly disclose the system, wherein the suction tube comprises a venting arrangement outside the enclosure such that ambient air can enter the tube via the venting arrangement and flow to the vacuum source without entering the enclosure.

Leffler teaches a medical suction apparatus (see Title) wherein the suction tube 26 (fig. 1) comprises a venting port 20 (col. 3, line 69; fig. 1) that is a venting arrangement outside of the wound area allowing the flow to the vacuum source without entering the wound area.

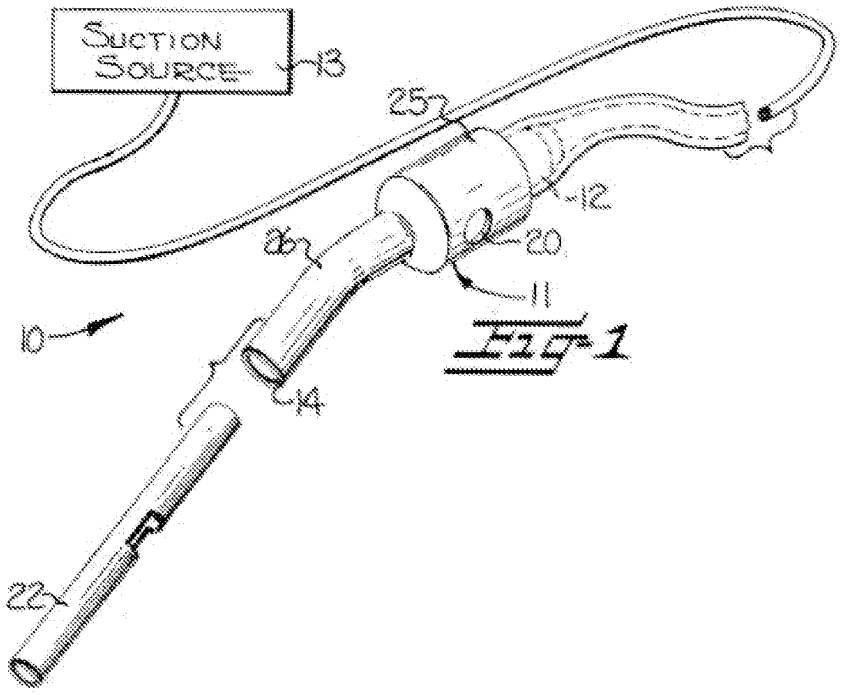


Fig. 1

It would have been obvious to one having ordinary skill in the art at the time the invention was made to supply the suction tube of Lockwood with the venting arrangement, as taught by Leffler in order to control the flow in the tube, as motivated by Leffler (col. 4, lines 35-40).

10. In Re claim 13, Lockwood discloses the venting arrangement 19 (fig. 1) necessarily comprising a bleeding hole, since it has been disclosed as communicating with the surrounding atmosphere (Abstract, lines 7-8).

In Re claim 14, Lockwood discloses the invention discussed above, but does not expressly disclose the structure, wherein the bleeding holes are provided in the form of a porous body.

Since the porous body is a material comprising plurality of holes, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the plurality of holes in the form of porous body in order to simplify the production process by using the material known in the art.

11. In Re claim 34, since the vent arrangement has been disclosed as being in communication with the ambient air, Lockwood discloses the vent arrangement that necessarily provides a restricted flow of ambient air therethrough and along the tube 20.

12. Claims 38-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lockwood et al. (US 2005/0004534) in view of Leffler (US 3,516,160), as applied to claim 11 above, and further in view of Argenta et al. (US 2001/0029956).

13. In Re claim 38, 39, 43 and 49, Lockwood in view of Leffler disclose the invention discussed above but do not expressly disclose the system comprising a waste container.

Argenta teaches a wound treatment apparatus comprising a collecting vessel in fluid communication with the wound and connected to the vacuum source (page 4, [0036]).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to supply the apparatus of Lockwood/ Leffler with the

collection vessel, as taught by Argenta in order to store the exudate, as motivated by Argenta (page 4, [0036], lines 21-22).

Lockwood in view of Argenta do not expressly disclose the apparatus wherein the waste container is connected to an outlet of the vacuum pomp unit.

Since shifting the position of the container would not have modified the operation of the device, it would have been obvious to one having ordinary skill in the art at the time the invention was made to connect the waste container to the outlet of the pump in order to position the container remotely from the patient, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse,* 86 USPQ 70 (**MPEP 2144.04 (VI-C)**).

14. In Re claims 40, 44, 46 and 52, Lockwood discloses an enclosure for applying negative pressure to a wound, the enclosure being attachable to the wound circumference so as to define a confined volume (Abstract, lines 2-6), and comprising a tube 20 (page 5, [0070]; fig. 1), the enclosure having an enclosure outlet connectable to the vacuum source (Abstract, lines 9-10) via tube 20 (fig. 1) so that negative pressure may be created in said volume (Abstract, lines 5-6).

Lockwood does not expressly disclose the assembly, wherein the venting arrangement comprises one or more bleeding holes.

Leffler teaches a medical suction apparatus (see Title) wherein the suction tube 26 (fig. 1) comprises a venting port 20 (col. 3, line 69; fig. 1) that is a venting arrangement made in the form of bleeding hole.

The rationale of obviousness rejection discussed above in claim 11 is incorporated herein in its entirety.

In Re claims 41, 47 and 53, Lockwood in view of Leffler, and further in view of Argenta disclose the invention discussed above, as applied to claim 38, but do not expressly disclose the apparatus, wherein the bleeding holes are provided in the form of a porous body.

The rationale of obviousness rejection discussed above in claim 14 is incorporated herein in its entirety.

15. In Re claims 42, 45, 48 and 51, Lockwood discloses an enclosure for applying negative pressure to a wound, the enclosure being attachable to the wound circumference so as to define a confined volume (Abstract, lines 2-6), and comprising a tube 20 (page 5, [0070]; fig. 1), the enclosure having an enclosure outlet connectable to the vacuum source (Abstract, lines 9-10) via tube 20 (fig. 1) so that negative pressure may be created in said volume (Abstract, lines 5-6).

Lockwood does not expressly disclose the system, wherein the suction tube comprises a venting arrangement outside the enclosure such that ambient air can enter the tube via the venting arrangement and flow to the vacuum source without entering the enclosure.

Leffler teaches a medical suction apparatus (see Title) wherein the suction tube 26 (fig. 1) comprises a venting port 20 (col. 3, line 69; fig. 1) that is a venting arrangement outside of the wound area allowing the flow to the vacuum source without entering the wound area.

The rationale of obviousness rejection discussed above in claim 11 is incorporated herein in its entirety.

Lockwood in view of Leffler do not expressly disclose the system comprising a waste container.

Argenta teaches a wound treatment apparatus comprising a collecting vessel in fluid communication with the wound and connected to the vacuum source (page 4, [0036]).

The rationale of obviousness rejection discussed above in claim 38 is incorporated herein in its entirety.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILYA TREYGER whose telephone number is (571)270-3217. The examiner can normally be reached on 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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

/Ilya Y Treyger/
Examiner, Art Unit 3761

/Tatyana Zalukaeva/
Supervisory Patent Examiner, Art Unit 3761

Notice of References Cited	Application/Control No. 11/989,297	Applicant(s)/Patent Under Reexamination ADAHAN, CARMELI	
	Examiner ILYA TREYGER	Art Unit 3761	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-3,516,160	06-1970	LEFFLER DENNIS F	433/95
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
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FOREIGN PATENT DOCUMENTS

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	N					
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	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
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	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.

Medela LLC and Medela AG
Exhibit 1008
Page #439

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11989297	ADAHAN, CARMELI
	Examiner	Art Unit
	ILYA Y TREYGER	3761

SEARCHED			
Class	Subclass	Date	Examiner
604	540-544	10/5/2010	I. T.

SEARCH NOTES		
Search Notes	Date	Examiner
EAST Search attached	10/5/2010	I. T.
Search updated	4/15/2011	I. T.
Search updated	9/26/2011	I. T.

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner

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Exhibit 1008
Page #440

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CONFIRMATION NO. 4766

SERIAL NUMBER	FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
11/989,297	01/24/2008 RULE	604	3761	29068U

APPLICANTS
Carmeli Adahan, Jerusalem, ISRAEL;

**** CONTINUING DATA ************************* I.T. 06/22/2010**
This application is a 371 of PCT/IL2005/000784 07/24/2005

**** FOREIGN APPLICATIONS ************************* I.T. 06/22/2010**

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED **** ** SMALL ENTITY **
07/08/2009

Foreign Priority claimed ☑ Yes ☐ No 35 USC 119(a-d) conditions met ☐ Yes ☐ No Verified and Acknowledged /ILYA Y TREYGER/ Examiner's Signature	☐ Met after Allowance Initials	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
		ISRAEL	2	33	5

ADDRESS

THE NATH LAW GROUP
112 South West Street
Alexandria, VA 22314
UNITED STATES

TITLE

Wound closure and drainage system

FILING FEE RECEIVED		
1000	FEES: Authority has been given in Paper No._____ to charge/credit DEPOSIT ACCOUNT No._____ for following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit

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Application Number	11989297
Filing Date	2008-01-24
First Named Inventor	ADAHAN
Art Unit	3761
Examiner Name	TREYGER
Attorney Docket Number	29068U

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4552552		1985-11-12	POLASCHEGG, et al.	corresponds to DE 32 05 449 C2

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	1	32 05 445	DE	A1	1983-08-25	Fa. Wilhelm Schade	English Abstract attached separately	☒
	2	32 05 449	DE	C2	1983-09-01	Fresenius AG	corresponds to US 4,552,552	☐

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Receipt date: 05/04/2011	Application Number	11989297 11989297 - GAU: 3761
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2008-01-24
	First Named Inventor	ADAHAN
	Art Unit	3761
	Examiner Name	TREYGER
	Attorney Docket Number	29068U

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
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Examiner Signature	/Ilya Treyger/	Date Considered	09/26/2011

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	11989297
	Filing Date	2008-01-24
	First Named Inventor	ADAHAN
	Art Unit	3761
	Examiner Name	TREYGER
	Attorney Docket Number	29068U

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4108574		1978-08-22	BARTLEY, et al.	
	2	4208171		1980-06-17	JONSSON	
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	1	20040015042	A1	2004-01-22	VINCENT, et al.	
	2	20050180868	A1	2005-08-18	MILLER	
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Receipt date: 05/16/2011	Application Number	11989297	11989297 - GAU: 3761
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2008-01-24	
	First Named Inventor	ADAHAN	
	Art Unit	3761	
	Examiner Name	TREYGER	
	Attorney Docket Number	29068U	

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	Filing Date	2008-01-24
	First Named Inventor	ADAHAN
	Art Unit	3761
	Examiner Name	TREYGER
	Attorney Docket Number	29068U

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	1	6257847	B1	2001-07-10	SILVER, et al.	
	2	7255681	B1	2007-08-14	SILVER, et al.	
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Receipt date: 08/23/2011	Application Number	11989297 11989297 - GAU: 3761
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2008-01-24
	First Named Inventor	ADAHAN
	Art Unit	3761
	Examiner Name	TREYGER
	Attorney Docket Number	29068U

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
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Examiner Signature	/Ilya Treyger/	Date Considered	09/26/2011

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99**)	Filing Date	2008-01-24	
	First Named Inventor	ADAHAN	
	Art Unit	3761	
	Examiner Name	TREYGER	
	Attorney Docket Number	29068U	

CERTIFICATION STATEMENT

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

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

OR

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

☐ See attached certification statement.

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

☒ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/Susanne M. Hopkins/	Date (YYYY-MM-DD)	2011-08-23
Name/Print	Susanne M. Hopkins	Registration Number	33247

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

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Privacy Act Statement

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

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

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

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

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

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

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

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

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

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

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

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Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11989297	ADAHAN, CARMELI
	Examiner	Art Unit
	ILYA Y TREYGER	3761

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

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

CLAIM		DATE								
Final	Original	10/05/2010	04/15/2011	09/26/2011						
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	2	-	-	-						
	3	-	-	-						
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	9	-	-	-						
	10	-	-	-						
	11	✓	✓	✓						
	12	✓	✓	-						
	13	✓	✓	✓						
	14	✓	✓	✓						
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	35		✓	✓						
	36		✓	✓						

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Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11989297	ADAHAN, CARMELI
	Examiner	**Art Unit**
	ILYA Y TREYGER	3761

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

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

CLAIM		DATE								
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	43		✓	✓						
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	51		✓	✓						
	52		✓	✓						
	53		✓	✓						

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EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S1	53	((CARMELI) near2 (ADAHAN)).INV.	US-PGPUB; USPAT; USOCR	OR	OFF	2010/10/05 16:32
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S3	851	(604/35).CCLS.	US-PGPUB; USPAT	OR	OFF	2010/10/05 16:48
S4	746	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2010/10/05 16:48
S5	266	(604/313).CCLS.	US-PGPUB; USPAT	OR	OFF	2010/10/05 16:48
S6	1805	(604/317-323).CCLS.	US-PGPUB; USPAT	OR	OFF	2010/10/05 16:49
S7	1255	(604/540-544).CCLS.	US-PGPUB; USPAT	OR	OFF	2010/10/05 16:49
S8	250	(604/902).CCLS.	US-PGPUB; USPAT	OR	OFF	2010/10/05 16:49
S9	505	(606/131).CCLS.	US-PGPUB; USPAT	OR	OFF	2010/10/05 16:49
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S11	119	S2 and S4	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/10/05 16:50
S12	126	S2 and S5	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/10/05 16:50
S13	117	S2 and S6	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/10/05 16:50

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S14	109	S2 and S7	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/10/05 16:50
S15	7	S2 and S8	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/10/05 16:50
S16	4	S2 and S9	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/10/05 16:50
S17	63	("1251258" | "3171410" | "3486504").PN. OR ("3874387").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2010/10/05 16:51
S18	99	("3026874" | "3486504" | "4540412" | "4759354" | "4969880").PN. OR ("5149331").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2010/10/05 16:52
S19	73	("4743232" | "5230350").PN. OR ("5344415").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2010/10/05 16:52
S20	154	("1355846" | "2547758" | "2632443" | "2682873" | "2969057" | "3367332" | "3648692" | "3682180" | "3826254" | "4080970" | "4096853" | "4139004" | "4165748" | "4245630" | "4261363" | "4275721" | "4297995" | "4333468" | "4373519" | "4382441" | "4392853" | "4392858" | "4419097" | "4475909" | "4480638" | "4525166" | "4525374" | "4540412" | "4543100" | "4551139" | "4569348" | "4605399" | "4608041" | "4640688" | "4655754" | "4733659" | "4743232" | "4787888" | "4826949"	US-PGPUB; USPAT; USOCR	OR	OFF	2010/10/05 16:52

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S24	784	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 11:54
S25	290	(604/313).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 11:54
S26	1923	(604/317-323).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 11:54
S27	1341	(604/540-544).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 11:54
S28	251	(604/902).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 11:54
S29	521	(606/131).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 11:54
S30	18	S22 and S23	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 11:54
S31	135	S22 and S24	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 11:54

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S32	149	S22 and S25	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 11:54
S33	169	S22 and S26	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 11:54
S34	125	S22 and S27	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 11:54
S35	7	S22 and S28	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 11:54
S36	4	S22 and S29	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 11:54
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S44	784	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 12:53
S45	290	(604/313).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 12:53
S46	1923	(604/317-323).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 12:53
S47	1341	(604/540-544).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 12:53
S48	251	(604/902).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 12:53
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S53	169	S42 and S46	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 12:53
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S55	7	S42 and S48	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 12:53
S56	4	S42 and S49	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 12:53
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S68	251	(604/902).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 12:53
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S87	815	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S88	308	(604/313).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S89	2020	(604/317-323).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S90	1424	(604/540-544).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S91	253	(604/902).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S92	529	(606/131).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S93	21	S85 and S86	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S94	150	S85 and S87	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S95	164	S85 and S88	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S96	214	S85 and S89	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S97	137	S85 and S90	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57

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S98	8	S85 and S91	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S99	5	S85 and S92	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
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S102	94	("4743232" | "5230350").PN. OR ("5344415").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/09/26 13:57
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S107	815	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S108	308	(604/313).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S109	2020	(604/317-323).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S110	1424	(604/540-544).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S111	253	(604/902).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S112	529	(606/131).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S113	21	S105 and S106	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S114	150	S105 and S107	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S115	164	S105 and S108	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57

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S118	8	S105 and S111	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S119	5	S105 and S112	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
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S121	133	("3026874" | "3486504" | "4540412" | "4759354" | "4969880").PN. OR ("5149331").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/09/26 13:57
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S123	200	("1355846" | "2547758" | "2632443" | "2682873" | "2969057" | "3367332" | "3648692" | "3682180" | "3826254" | "4080970" | "4096853" | "4139004" | "4165748" | "4245630" | "4261363" | "4275721" | "4297995" | "4333468" | "4373519" | "4382441" | "4392853" | "4392858" | "4419097" | "4475909" | "4480638" | "4525166" | "4525374" | "4540412" | "4543100" | "4551139" | "4569348" |	US-PGPUB; USPAT; USOCR	OR	OFF	2011/09/26 13:57

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S128	308	(604/313).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S129	2020	(604/317-323).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S130	1424	(604/540-544).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S131	253	(604/902).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S132	529	(606/131).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S133	21	S125 and S126	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57

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S136	214	S125 and S129	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S137	137	S125 and S130	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S138	8	S125 and S131	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S139	5	S125 and S132	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
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S149	2020	(604/317-323).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S150	1424	(604/540-544).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S151	253	(604/902).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
S152	529	(606/131).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/09/26 13:57
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S154	150	S145 and S147	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S155	164	S145 and S148	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S156	214	S145 and S149	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S157	137	S145 and S150	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
S158	8	S145 and S151	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 13:57
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S160	88	("1251258" | "3171410" | "3486504").PN. OR ("3874387").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/09/26 13:57
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S163	200	("1355846" | "2547758" | "2632443" | "2682873" | "2969057" | "3367332" | "3648692" | "3682180" | "3826254" | "4080970" | "4096853" | "4139004" | "4165748" | "4245630" | "4261363" | "4275721" | "4297995" | "4333468" | "4373519" | "4382441" | "4392853" | "4392858" | "4419097" | "4475909" | "4480638" | "4525166" | "4525374" | "4540412" | "4543100" | "4551139" | "4569348" | "4605399" | "4608041" | "4640688" | "4655754" | "4733659" | "4743232" | "4787888" | "4826949" | "4838883" | "4840187" | "4863449" | "4872450" | "4878901" | "4897081" | "4906233" | "4906240" | "4919654" | "4941882" | "4953565" | "4969880" | "4985019" | "5037397" | "5100396" | "5149331" | "5167613" | "5176663" | "5261893" | "5298015" | "5344415" | "5358494" | "5556375" | "5607388"	US-PGPUB; USPAT; USOCR	OR	OFF	2011/09/26 13:57

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		| "5636643" | "5645081").PN. OR ("6071267").URPN.				
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S165	32	S101 and (vent venting ventillation)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 14:02
S166	15	S102 and (vent venting ventillation)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 14:02
S167	36	S103 and (vent venting ventillation)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 14:02
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S170	5	S168 and (vent venting)	US-PGPUB; USPAT; EPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 14:23
S171	6	"20040015042" "20050180868"	US-PGPUB; USPAT; EPO; DERWENT; IBM_TDB	OR	OFF	2011/09/26 14:24
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EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
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		impermeable and impeding and passage and between and regulates and withdrawn and equilibrate and opposite and reduces and friction.clm.				

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PTO/SB/08a (01-10)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	11989297
Filing Date	2008-01-24
First Named Inventor	ADAHAN
Art Unit	3761
Examiner Name	TREYGER
Attorney Docket Number	29068U

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5370610	A	1994-12-06	REYNOLDS	
	2	5662599	A	1997-09-02	REICH, et al.	
	3	6471982	B1	2002-10-29	LYDON, et al.	
	4	5636643	A	1997-06-10	ARGENTA, et al.	
	5	7128735	B2	2006-10-31	WESTON	
	6	6824533	B2	2004-11-30	RISK, JR., et al.	
	7	6562013	B1	2003-05-13	MARASCO, JR.	
	8	4447226		1984-05-08	MAYORAL	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /I.T./

Receipt date: 11/16/2010	Application Number	11989297	11989297 - GAU: 3761
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99**)	Filing Date	2008-01-24	
	First Named Inventor	ADAHAN	
	Art Unit	3761	
	Examiner Name	TREYGER	
	Attorney Docket Number	29068U	

	9	4611627		1986-09-16	EIDSVOOG, et al.	
	10	1599899		1926-09-14	KETTERING, et al.	
	11	6071267	A	2000-06-06	ZAMICROWSKI	
	12	0599333		1898-02-22	HULSE	
	13	3416461		1968-12-17	McFARLAND	
	14	5419687	A	1995-05-30	ADAHAN	
	15	6042560	A	2000-03-28	NIEDERBERGER	
	16	6648862	B2	2003-11-18	WATSON	
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	18	4930997		1990-06-05	BENNETT	
	19	4661093		1987-04-28	BECK, et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /I.T./

Receipt date: 11/16/2010	Application Number	11989297	11989297 - GAU: 3761
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2008-01-24	
	First Named Inventor	ADAHAN	
	Art Unit	3761	
	Examiner Name	TREYGER	
	Attorney Docket Number	29068U	

	20	5645081	A	1997-07-08	ARGENTA, et al.	
	21	5776119	A	1998-07-07	BILBO, et al.	

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20050004534	A1	2005-01-06	LOCKWOOD, et al.	
	2	20040039243	A1	2004-02-26	BEARNSON, et al.	
	3	20030014022	A1	2003-01-16	LOCKWOOD, et al.	
	4	20010029956	A1	2001-10-18	ARGENTA, et al.	
	5	20040199840	A1	2004-10-07	TAKEOKA, et al.	
	6	20050192548	A1	2005-09-01	DOLLIVER, et al.	
	7	20040064132	A1	2004-04-01	BOCHRINGER, et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /I.T./

Receipt date: 11/16/2010	Application Number	11989297	11989297 - GAU: 3761
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date	2008-01-24	
(**Not for submission under 37 CFR 1.99)**	First Named Inventor	ADAHAN	
	Art Unit	3761	
	Examiner Name	TREYGER	
	Attorney Docket Number	29068U	

	8	20020151826	A1	2002-10-17	RAMEY, et al.	
	9	20040059284	A1	2004-03-25	NASH, et al.	
	10	20030097100	A1	2003-05-22	WATSON	
	11	20030040687	A1	2003-02-27	BOYNTON, et al.	
	12	20030050594	A1	2003-03-13	ZAMICROWSKI	

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	1	03/030966	WO	A1	2003-04-17	HILL-ROM SERVICES, INC.		☐
	2	97/18007	WO	A1	1997-05-22	KCI MEDICAL LIMITED		☐
	3	102 15 896	DE	A1	2003-10-23	LEYBOLD VAKUUM GMBH	ABSTRACT	☒
	4	03/016719	WO	A1	2003-02-27	ADAHAN		☐

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Receipt date: 11/16/2010	Application Number	11989297	11989297 - GAU: 3761
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2008-01-24	
	First Named Inventor	ADAHAN	
	Art Unit	3761	
	Examiner Name	TREYGER	
	Attorney Docket Number	29068U	

	5	24 01 643	DT	A1	1975-07-17	TUCHENHAGEN	ABSTRACT	☒
	6	0 156 211	EP	A2	1985-10-02	FRESENIUS AG	ABSTRACT	☒
	7	00/02016	WO	A1	2000-01-13	DEKA PRODUCTS LIMITED PARTNERSHIP		☐
	8	96/05873	WO	A1	1996-02-29	MEDISCUS PRODUCTS LIMITED		☐
	9	2 378 734	GB	A	2003-02-19	ADAHAN		☐
	10	2 307 180	GB	A	1997-05-21	KCI MEDICAL LIMITED		☐
	11	03/057070	WO	A2	2003-07-17	HILL-ROM SERVICES INC.		☐

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Receipt date: 11/16/2010	Application Number	11989297	11989297 - GAU: 3761
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	First Named Inventor	ADAHAN	
	Art Unit	3761	
	Examiner Name	TREYGER	
	Attorney Docket Number	29068U	

EXAMINER SIGNATURE			
Examiner Signature	/Ilya Treyger/	Date Considered	04/15/2011

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

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PTO/SB/08a (01-10)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	11989297
Filing Date	2008-01-24
First Named Inventor	ADAHAN
Art Unit	3761
Examiner Name	TREYGER
Attorney Docket Number	29068U

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	6257847	B1	2001-07-10	SILVER, et al.	
	2	7255681	B1	2007-08-14	SILVER, et al.	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	11989297
	Filing Date	2008-01-24
	First Named Inventor	ADAHAN
	Art Unit	3761
	Examiner Name	TREYGER
	Attorney Docket Number	29068U

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
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[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	11989297
	Filing Date	2008-01-24
	First Named Inventor	ADAHAN
	Art Unit	3761
	Examiner Name	TREYGER
	Attorney Docket Number	29068U

CERTIFICATION STATEMENT

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

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

OR

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

☐ See attached certification statement.

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

☒ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/Susanne M. Hopkins/	Date (YYYY-MM-DD)	2011-08-23
Name/Print	Susanne M. Hopkins	Registration Number	33247

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

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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.

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Medela LLC and Medela AG
Exhibit 1008
Page #482

Electronic Acknowledgement Receipt

EFS ID:	10792150
Application Number:	11989297
International Application Number:	
Confirmation Number:	4766
Title of Invention:	Wound closure and drainage system
First Named Inventor/Applicant Name:	Carmeli Adahan
Customer Number:	20529
Filer:	Susanne M. Hopkins/Lisa Elliott
Filer Authorized By:	Susanne M. Hopkins
Attorney Docket Number:	29068U
Receipt Date:	23-AUG-2011
Filing Date:	24-JAN-2008
Time Stamp:	12:17:43
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	SB08.pdf	611628 a738ee10e3e97c585b5339185077803d14e9f7d0	no	4

Warnings:	
Information:	

Total Files Size (in bytes):	611628

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

New Applications Under 35 U.S.C. 111

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

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

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

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

PTO/SB/30EFS (07-09)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL
(Submitted Only via EFS-Web)

Application Number	11/989,297	Filing Date	2008-01-24	Docket Number (if applicable)	29068U	Art Unit	3761
First Named Inventor	Carmeli ADAHAN			Examiner Name	TREYGER, ILYA Y.		

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 _____

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

☒ Patent Practitioner Signature

☐ Applicant Signature

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Signature of Registered U.S. Patent Practitioner			
Signature	/William L. Klima/	Date (YYYY-MM-DD)	2011-08-22
Name	William L. Klima	Registration Number	32422

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.

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

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).

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

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

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

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

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Exhibit 1008
Page #487

Mail Stop AFTER FINAL
Attorney Docket No. 29068U

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Carmeli Adahan	Conf. No.: 4766
Application No.: 11/989,297	Examiner: TREYGER, ILYA Y.
Filed: January 24, 2008	Group Art Unit: 3761

For: WOUND CLOSURE AND DRAINAGE SYSTEM

AMENDMENT AND RESPONSE

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

Dear Commissioner:

This paper is submitted responsive to the final Official Action dated April 20, 2011, along with a Request for Continued Examination (RCE) and a Petition for a one (1) month extension of time to extend the period to respond to August 22, 2011. Accordingly, this paper is timely filed.

Amendments to the Claims begins on page 2 of this paper.

Remarks begin on page 9 of this paper.

A **Conclusion** appears at page 19 of this paper.

AMENDMENTS TO THE CLAIMS

Please amend the claims as follows. This listing of claims replaces all prior version of the claims in this application.

1-10. (Canceled)

11. (Currently amended) An enclosure for applying negative pressure to a wound, the enclosure being attachable to the wound circumference so as to define a confined volume, and comprising a tube, the enclosure having an enclosure outlet connectable a vacuum source via said tube so that negative pressure may be created in said volume, said tube comprising a venting arrangement, outside said enclosure, such that ambient air can enter said tube via said venting arrangement and flow to said vacuum source without entering said enclosure.

12. (Canceled)

13. (Previously presented) The enclosure according to claim 11, wherein said venting arrangement comprises one or more bleeding holes.

14. (Previously presented) The enclosure according to claim of claim 11, wherein said venting arrangement is provided in the form of a porous body.

15-33. (Canceled)

34. (Previously presented) The enclosure according to claim 11, wherein said venting arrangement acts as a flow restrictor to provide, under the action of the vacuum source, a restricted flow of ambient air therethrough and along said tube.

35. (Previously presented) The enclosure according to claim 11, wherein said enclosure facilitates drainage of fluids exuded from the wound, wherein the ambient air can enter said tube via said venting arrangement and flow together with the exuded liquids under the action of the negative pressure.

36. (Previously presented) The enclosure according to claim 11, wherein said venting arrangement provides for ambient air to enter said enclosure via said tube and for ambient pressure to be restored in said confined volume when the vacuum source is not operating.

37. (Previously presented) The enclosure according to claim 11, wherein in operation of the enclosure, ambient air enters the tube directly via said venting arrangement without entering said enclosure when negative pressure is being applied to the wound via said enclosure.

38. (Previously presented) A disposable assembly for applying negative pressure to a wound, the assembly comprising an enclosure as defined in claim 11 attachable to the wound circumference so as to define a confined volume, a vacuum pump unit of the vacuum pump connected to said enclosure so that negative pressure may be created in said volume, said vacuum pump unit being configured for being detachably attached to a drive unit of the vacuum pump for operating the pump unit, and a waste container connected to said vacuum pump unit, wherein said enclosure is connected to an inlet of said vacuum pump unit via said tube and said waste container is connected to an outlet of said vacuum pump unit.

39. (Previously presented) A disposable assembly according to claim 38, wherein said assembly further operates to drain the wound from fluids exuded therefrom, wherein the ambient air can enter said tube via said venting arrangement and flow together with the exuded liquids under the action of the negative pressure, and facilitates draining of the exuded fluids to said waste container.

40. (Previously presented) The disposable assembly according to claim 38, wherein said venting arrangement comprises one or more bleeding holes.

41. (Previously presented) The disposable assembly according to claim 38, wherein said venting arrangement is provided in the form of a porous body.

42. (Previously presented) A vacuum system for applying negative pressure to a wound, the vacuum system comprising an enclosure and a vacuum source, the enclosure being attachable to the wound circumference so as to define a confined volume, and comprising a tube, the enclosure having an enclosure outlet connectable to said vacuum source via said tube so that negative pressure may be created in said volume, said tube comprising a venting arrangement adjacent to said enclosure outlet, outside said enclosure, such that ambient air can enter said tube via said venting arrangement, and further comprising a waste container in fluid communication with said vacuum source.

43. (Previously presented) The vacuum system of claim 42, wherein said vacuum system further operates to drain the wound from fluids exuded therefrom, wherein the ambient air can enter said tube via said venting arrangement and flow together with the exuded liquids under the action of the negative pressure, and facilitates draining of the exuded fluids to said waste container.

44. (Previously presented) The vacuum system according to claim 42, wherein said vacuum source includes a disposable pump unit detachably attachable to a non-disposable drive unit, said enclosure and said waste container being disposable so that the ambient air that enters said tube via said venting arrangement contacts only the disposable elements and said drained liquids may be disposed of together with said disposable elements.

45. (Previously presented) The vacuum system according to claim 44, wherein said pump unit and said drive unit are adapted for attaching and detaching by simple hand manipulations.

46. (Previously presented) The vacuum system according to claim 42, wherein said venting arrangement comprises one or more bleeding holes.

47. (Previously presented) The vacuum system according to claim 42, wherein said venting arrangement is provided in the form of a porous body.

48. (Currently amended) A vacuum system for applying negative pressure to a wound, the vacuum system comprising an enclosure and a vacuum source, the enclosure being attachable to the wound circumference so as to define a confined volume, and comprising a tube, the enclosure having an enclosure outlet connectable to said vacuum source via said tube so that negative pressure may be created in said volume, said tube comprising a venting arrangement adjacent to said enclosure outlet, outside said enclosure, such that ambient air can enter said tube via said venting arrangement and flow to said vacuum source without entering said enclosure, wherein said vacuum pump comprises a collection chamber upstream of a pump inlet of said vacuum source, and wherein said tube is connected to an inlet of said collection chamber.

49. (Previously presented) The vacuum system of claim 48, wherein said vacuum system further operates to drain the wound from fluids exuded therefrom, wherein the ambient air can enter said tube via said venting arrangement and flow together with the exuded liquids under the action of the negative pressure, and facilitates draining of the exuded fluids to said waste container.

50. (Previously presented) The vacuum system according to claim 48, wherein said vacuum source includes a disposable pump unit detachably attachable to a non-disposable drive unit, said enclosure and said collection chamber being disposable so that the ambient air that enters said tube via said venting arrangement contacts only the disposable elements and said drained liquids may be disposed of together with said disposable elements.

51. (Previously presented) The vacuum system according to claim 50, wherein said pump unit and said drive unit are adapted for attaching and detaching by simple hand manipulations.

52. (Previously presented) The vacuum system according to claim 48, wherein said venting arrangement comprises one or more bleeding holes.

53. (Previously presented) The vacuum system according to claim 48, wherein said venting arrangement is provided in the form of a porous body.

REMARKS

Claims 11-13, 14, and 34-53 are pending in the application. Claims 11-14, and 34-53 are rejected.

Claim 12 is canceled above without prejudice or disclaimer of the subject matter contained therein. Claims 1–10, and 15-33 were previously canceled without prejudice or disclaimer of the subject matter contained therein. Claims 11 and 48 are amended above.

Support for the above amendments appears throughout the originally filed specification, claims, and drawings. Specifically, claims 11 and 48 have been amended to incorporate the subject matter of claim 12.

Applicant, by amending any claims herein, makes no admission as to the validity of any rejection made by the Examiner against any claim. Applicant reserves the right to reassert any of the claims canceled or the original scope of any claim amended herein, in a continuing application.

It is respectfully submitted that the above amendments to the claims introduce no new matter within the meaning of 35 U.S.C. §132. Accordingly, Applicant requests reconsideration and timely withdrawal of the pending rejections for the reasons discussed below.

I. Claims 11-13, and 35-37 stand rejected under 35 U.S.C. §102(e) as being anticipated by Lockwood et al. ("Lockwood", US 2005/0004534)as set forth in paragraph 7 on page 2 of the Official Action.

The Examiner asserts that claims 11-13, and 35-37 are anticipated under 35 U.S.C. §102(e) by Lockwood. This rejection is respectfully traversed.

"Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration." *W.L. Gore & Assocs. V. Garlock*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). Further, "when evaluating the scope of a claim, every limitation in the claim must be considered. U.S.P.T.O. personnel may not dissect a claimed invention into discrete elements and then evaluate the elements in isolation. Instead, the claim as a whole must be considered." *U.S.P.T.O. Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility*, page 9, October 26, 2005. As the Federal Circuit stated, "[a]nticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim." *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Col.*, 730 F.2d 1452, 221 USPQ 481, 485 (Fed. Cir. 1984) (citing *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983)).

Claim 11 currently recites the limitation of the venting arrangement (which is outside of the enclosure) is such that "*ambient air can enter said tube via said venting arrangement and flow to said vacuum source* ***without entering said enclosure***."

Thus air sucked in through the venting arrangement goes **directly** to the pump under suction ***without passing through the enclosure***, and tends to dislodge any blockage in the tube, if present there.

The Examiner contends on page 3 of the Official Action that in Lockwood (US 2005/00045534) "*ambient air necessarily enters the tube 20 via the venting arrangement and flows to the vacuum source without entering the enclosure if negative pressure is applied…*".

Applicant respectfully submits that this is a fundamental misreading of Lockwood, which does not disclose or suggest such a feature at all.

Quite the contrary, Lockwood ***teaches away*** from the claimed subject matter recited in claim 11, the disclosed apparatus in Lockwood being structurally and functionally configured for ensuring that the ambient air is drawn in via vent 19 **has to flow over the wound** via the bandage 14 before flowing to the vacuum source, as supported by at least the following sections of Lockwood:

Paragraph [0068], lines 6 to 9:

> *"Venting provides for increased air* ***flow through bandage 14 and above or adjacent the wound*** *while vacuum source 16 applies suction to the wound"*

Paragraph [0069], lines 1 to 8:

"*Ventilation of the system 10, while drawing a negative pressure over the wound, acts to prevent the system 10 from becoming static by drawing air in from the surrounding atmosphere through vent 19, to bandage 14* ***to create air flow above the wound, and out through a vacuum tube*** *in communication with vacuum source 14. Therefore, venting the system 10* ***increases air flow above the wound while vacuum source 16 applies suction to the wound.***"

Paragraph [0081], lines 2 to 4:

"*As mentioned before, vent 19 provides increased air flow* ***through bandage 14 and above the wound***."

Paragraph [0124], lines 2 to 5:

"*As mentioned before with respect to vents 19 and 119, vent 219 provides increased* ***air flow through bandage 14 and above wound 200***."

Structurally, and referring to paragraph [0072] and Fig. 3 in particular, the bandage 14 includes a wound dressing member 12 having connector 15 coupled to tube 20 by a barbed tube coupler 11. Member 12 lies adjacent to and generally conforms to the wound

surface. Sealing film 13 is placed over member 12 and sealed around tube 20 to the patient's healthy skin 27 surrounding the wound, as shown in FIG. 1. Connector 15 is in communication with the wound by a plurality of passageways 66 of member 12 and a plurality of holes 67, each in communication with one of the passageways 66, formed in a bottom surface 68 of member 19. Tube coupler 11 connects inner lumen 22 of tube 20 with connector 15.

Each outer lumen 24 is open at an end 21 of tube 20, **this end 21 being positioned under sealing film 13 to communicate the end 21 with the wound** (paragraph [0081], lines 13 to 13). This allows air to be drawn in from the atmosphere through vent 19, to flow through outer lumens 24 and exit tube 20 at end 21, to circulate around member 12 to the wound surface, and to flow through the holes 67 and passageways 66 of member 12 into a vacuum/irrigation passageway 42 formed in part by lumen 22. The negative pressure created by vacuum source 16 causes air to flow through system 10 in this manner.

The flow path from the vent to the vacuum source is explicitly disclosed as follows in paragraph [0081], lines 5 to 19:

> *"The air flow path while vacuuming the system begins as **air is drawn in from the surrounding atmosphere into filter housing 40 of vent 19** and through filter 34. The air then travels through opening 46 into annular space 45 defined by outer conduit 38 and through outer lumens 24 of multi-lumen tube 20. The **air travels through the outer lumens 24 from vent end 23 of tube 20 to end 21 of tube 20, a portion of which is positioned under sealing film 13, to communicate with***

the wound. ***Vacuum source 16 then draws the air around wound dressing member 12*** *through passageways 66 at an open peripheral edge of member 12 and through holes 67 into passageways 66. Air is then drawn from passageways 66 into connector 15 of member 12, through barb 11, and through inner lumen 22 of multi-lumen tube 20* ***toward vacuum source 14.*** *"*

Thus, it is abundantly clear Lockwood teaches away from claim 11, which in contrast requires the ambient air to enter the tube via the venting arrangement and flow to the vacuum source ***without entering the enclosure***.

It is therefore respectfully submitted that claim 11 is not anticipated by Lockwood. For at least the reason that claim 11 is not anticipated by Lockwood, all claims depending from claim 11, directly or indirectly, are also submitted to be novel and inventive over this reference.

In view of the above, it is submitted that Lockwood does not teach each and every element of claims 11-13, and 35-37 are required for anticipation under 35 U.S.C. §102. Thus, the Examiner is respectfully requested to withdraw this rejection.

II. Claim 14 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Lockwood et al. ("Lockwood", US 2001/0004534), as set forth in paragraph 12 on page 4 of the Official Action.

The Examiner asserts that "it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the plurality of holes in the form of porous body in order to simplify the production process, since it has been held to be within the general skill of a worker in the art to select a know material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin, 125USPQ416.*" This rejection is respectfully traversed.

To establish an obviousness rejection under 35 U.S.C. § 103(a), four factual inquiries must be examined. The four factual inquiries include (a) determining the scope and contents of the prior art; (b) ascertaining the differences between the prior art and the claims in issue; (c) resolving the level of ordinary skill in the pertinent art; and (d) evaluating evidence of secondary consideration. *Graham v. John Deere*, 383 U.S. 1, 17-18 (1966). In view of these four factors, the analysis supporting a rejection under 35 U.S.C. 103(a) should be made explicit, and should "identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements" in the manner claimed. *KSR Int'l. Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1741 (2007). Furthermore, even if the prior art may be combined, there must be a reasonable expectation of success, and the reference or references, when combined, must disclose or suggest all of the claim limitations. *See In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Lockwood is discussed in detail in the response set forth in paragraph 1 above.

Again, Lockwood does not teach or suggest the claimed subject matter, and teaches away therefrom.

In view of the foregoing, it is submitted that nothing in Lockwood renders the presently claimed subject matter obvious within the meaning of 35 U.S.C. §103. Accordingly, the Examiner is respectfully requested to withdraw this rejection of the pending claims.

III. Claims 38-53 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Lockwood et al. ("Lockwood", US 2001/0004534) in view of Argenta et al. ("Argenta", US 2001/0029956), as set forth in paragraph 13 on page 4 of the Official Action.

The Examiner asserts that "[It] would have been obvious to one having ordinary skill in the art at the time the invention was made to supply the apparatus of Lockwood with the collection vessel, as taught by Argenta in order to store the exudates, as motivated by Argenta (page 4, [0036), lines 21-22).

The Examiner further asserts that "it would have been obvious to one having ordinary skill in the art at the time the invention was made to connect the waste container to the outlet of the pump in order to position the container remotely from the patient, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse,* 86 USPQ 70 (MPEP 2144.04 (VI-C)). These rejections are respectfully traversed.

Lockwood is discussed in detail in the response set forth in paragraph 1 above.

Argenta was cited, in combination with Lockwood, for obviousness in some of the claims that depend from claim11, and such rejections are therefore moot in view of the above. While not addressing whether or not such a combination is proper, it is to be noted that, as de facto agreed to by the Examiner, Argenta does ***not*** cure the deficiencies in Lockwood regarding claim 11.

Claim 48 has been amended in a similar manner to claim 11, and therefore the arguments above apply, *mutatis mutandis*, to claim 48 as well. It is therefore respectfully submitted that claim 48 is novel and inventive over Lockwood.

The combination of Lockwood and Argenta was also cited for obviousness in original claim 48. Argenta is relied on by the Examiner as disclosing a collection chamber, but as discussed above, Argenta does not cure the deficiencies in Lockwood regarding the feature that the "*ambient air can enter said tube via said venting arrangement and flow to said vacuum source* ***without entering said enclosure***".

It is therefore respectfully submitted that claims 38-53, in particular independent claim 48, are ***not*** taught or suggested by the combination of Lockwood and Argenta.

In view of the foregoing, it is submitted that nothing in Lockwood and Argenta, taken alone or together, render the presently claimed subject matter obvious within the meaning of 35 U.S.C. §103. Accordingly, the Examiner is respectfully requested to withdraw this rejection of the pending claims.

GENERAL COMMENTS

It is to be noted that the feature "*ambient air can enter said tube via said venting arrangement and flow to said vacuum source* ***without entering said enclosure***" was already present in the claims (i.e. claim 12) and therefore was already considered and searched by the Examiner. In view of the above the application should now be in condition for allowance, and no further searching or consideration is required.

CONCLUSION

Applicant asserts that the claims are in condition for immediate allowance and early notice to that effect is earnestly solicited. Should the Examiner deem that any further action by Applicant's undersigned representative is desirable and/or necessary, the Examiner is invited to telephone the undersigned at the number set forth below.

In the event this paper is not timely filed, Applicant petitions for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,
THE NATH LAW GROUP

/William L. Klima/
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Reg. No. 32,422
Customer No. 20529

Date: August 22, 2011
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Tel: 703- 548-6284

PTO/SB/22 (07-09)
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PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a) **FY 2009** ***(Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).)***	Docket Number (Optional) 29068U
Application Number 11/989,297	Filed January 24, 2008
For WOUND CLOSURE AND DRAINAGE SYSTEM	
Art Unit 3761	Examiner TREYGER, ILYA Y.

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	
☑ One month (37 CFR 1.17(a)(1))	$130	$65	$ 65
☐ Two months (37 CFR 1.17(a)(2))	$490	$245	$
☐ Three months (37 CFR 1.17(a)(3))	$1110	$555	$
☐ Four months (37 CFR 1.17(a)(4))	$1730	$865	$
☐ Five months (37 CFR 1.17(a)(5))	$2350	$1175	$

☑ Applicant claims small entity status. See 37 CFR 1.27.

☐ 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 14-0112.

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.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) is enclosed (Form PTO/SB/96).

☑ attorney or agent of record. Registration Number 32,422

☐ attorney or agent under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____

/William L. Klima/ — Signature

August 22, 2011 — Date

William L. Klima — Typed or printed name

703-548-6284 — Telephone Number

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

☑ Total of one (1) forms are submitted.

This collection of information is required by 37 CFR 1.136(a). 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 6 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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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:

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3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
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8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Patent Application Fee Transmittal

Application Number:	11989297
Filing Date:	24-Jan-2008
Title of Invention:	Wound closure and drainage system
First Named Inventor/Applicant Name:	Carmeli Adahan
Filer:	Susanne M. Hopkins/William Klima
Attorney Docket Number:	29068U

Filed as Small Entity

U.S. National Stage under 35 USC 371 Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Extension - 1 month with $0 paid	2251	1	65	65

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Request for continued examination	2801	1	405	405
		Total in USD ($)		**470**

Electronic Acknowledgement Receipt

EFS ID:	10787143
Application Number:	11989297
International Application Number:	
Confirmation Number:	4766
Title of Invention:	Wound closure and drainage system
First Named Inventor/Applicant Name:	Carmeli Adahan
Customer Number:	20529
Filer:	Susanne M. Hopkins/William Klima
Filer Authorized By:	Susanne M. Hopkins
Attorney Docket Number:	29068U
Receipt Date:	22-AUG-2011
Filing Date:	24-JAN-2008
Time Stamp:	17:01:37
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$470
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Deposit Account	
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)

1	Request for Continued Examination (RCE)	sb0030e_fill.pdf	797962 d2481f38b203dd91268731018 03b823f6bed85b4	no	3
Warnings:					
Information:					
2		2011_08_22_ROA.pdf	139466 73794b4c7f7bcd1570b1818f6620bc611deb3ceb	yes	19
	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Amendment After Final		1	1	
	Claims		2	8	
	Applicant Arguments/Remarks Made in an Amendment		9	19	
Warnings:					
Information:					
3	Extension of Time	sb0022.pdf	312959 368fe43b79bf1538d9b93aa05b27d747a5bfd824	no	2
Warnings:					
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4	Fee Worksheet (SB06)	fee-info.pdf	31923 a2381abf12002e3efea18fa71335216da55238a0	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	1282310		

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

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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.

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PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
11/989,297	01/24/2008	

APPLICATION AS FILED – PART I

	(Column 1)	(Column 2)	SMALL ENTITY ☒		OR	OTHER THAN SMALL ENTITY	
FOR	NUMBER FILED	NUMBER EXTRA	RATE ($)	FEE ($)		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 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			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT 08/22/2011	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 23	Minus	** 33	= 0	X $26 =	0	OR	X $ =	
Independent (37 CFR 1.16(h))	* 3	Minus	***5	= 0	X $110 =	0	OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE	

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

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
/LYNNELL JOHNSON/

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.**

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	11989297
Filing Date	2008-01-24
First Named Inventor	ADAHAN
Art Unit	3761
Examiner Name	TREYGER
Attorney Docket Number	29068U

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4108574		1978-08-22	BARTLEY, et al.	
	2	4208171		1980-06-17	JONSSON	

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20040015042	A1	2004-01-22	VINCENT, et al.	
	2	20050180868	A1	2005-08-18	MILLER	

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	11989297
	Filing Date	2008-01-24
	First Named Inventor	ADAHAN
	Art Unit	3761
	Examiner Name	TREYGER
	Attorney Docket Number	29068U

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	1		☐

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CERTIFICATION STATEMENT

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☐ See attached certification statement.

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

☐ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/Susanne M. Hopkins/	Date (YYYY-MM-DD)	2011-05-16
Name/Print	Susanne M. Hopkins	Registration Number	33247

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

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

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

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

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

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Medela LLC and Medela AG
Exhibit 1008
Page #518

Electronic Patent Application Fee Transmittal

Application Number:	11989297
Filing Date:	24-Jan-2008
Title of Invention:	Wound closure and drainage system
First Named Inventor/Applicant Name:	Carmeli Adahan
Filer:	Susanne M. Hopkins/Lisa Elliott
Attorney Docket Number:	29068U

Filed as Small Entity

U.S. National Stage under 35 USC 371 Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
		Total in USD ($)		**180**

Electronic Acknowledgement Receipt

EFS ID:	10092022
Application Number:	11989297
International Application Number:	
Confirmation Number:	4766
Title of Invention:	Wound closure and drainage system
First Named Inventor/Applicant Name:	Carmeli Adahan
Customer Number:	20529
Filer:	Susanne M. Hopkins/Lisa Elliott
Filer Authorized By:	Susanne M. Hopkins
Attorney Docket Number:	29068U
Receipt Date:	16-MAY-2011
Filing Date:	24-JAN-2008
Time Stamp:	15:04:07
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$180
RAM confirmation Number	1293
Deposit Account	
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)

1	Information Disclosure Statement (IDS) Filed (SB/08)	sb0008.pdf	611789 84bd40b6f41fc018528b3351d8de25c0b36d60cc	no	4
Warnings:					
Information:					
2	Fee Worksheet (PTO-875)	fee-info.pdf	29990 3185e502da8559101343c1b172128d59dc084e3d	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	641779	

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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.

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First Named Inventor	ADAHAN
Art Unit	3761
Examiner Name	TREYGER
Attorney Docket Number	29068U

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4552552		1985-11-12	POLASCHEGG, et al.	corresponds to DE 32 05 449 C2

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	1	32 05 445	DE	A1	1983-08-25	Fa. Wilhelm Schade	English Abstract attached separately	☒
	2	32 05 449	DE	C2	1983-09-01	Fresenius AG	corresponds to US 4,552,552	☐

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
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Signature	/Susanne M. Hopkins/	Date (YYYY-MM-DD)	2011-05-04
Name/Print	Susanne M. Hopkins	Registration Number	33247

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Page #526

ABSTRACT

Source: DE3205445A [EN]

The invention relates to a tilt and slide cover in a vehicle roof. The tilt and slide cover comprises a cover and a frame, which is supported in lateral guides of a roof opening. The special feature of the tilt and slide cover lies in the fact that the cover is arranged relatively moveable in relation to the frame and can be locked to and released from this. The frame comprises a plastic section, into which the slide guide and other fittings such as slide cheek holders or the like can be integrated in one piece. It is also possible to fix the rear water collection channel directly on the frame.

(19) BUNDESREPUBLIK DEUTSCHLAND

DEUTSCHES PATENTAMT

(12) **Offenlegungsschrift**

(11) **DE 3205445 A1**

(51) Int. Cl. 3:
B60G 7/04

(21) Aktenzeichen: P 32 05 445.9
(22) Anmeldetag: 16. 2. 82
(43) Offenlegungstag: 25. 8. 83

DE 3205445 A1

(71) Anmelder:
Fa. Wilhelm Schade, 5970 Plettenberg, DE

(72) Erfinder:
Strunk, Harald, 5970 Plettenberg, DE

Patentanwälte

(54) Fahrzeugdach mit einem im Bereich einer Dachöffnung angeordneten Hebe-Schiebedeckel

Die Erfindung betrifft einen Hebe-Schiebedeckel bei einem Fahrzeugdach. Der Hebe-Schiebedeckel besteht aus einer Abdeckung und einem Rahmen, der in Seitenführungen einer Dachöffnung gelagert ist. Das besondere des Hebe-Schiebedeckels besteht darin, daß die Abdeckung gegenüber dem Rahmen relativ beweglich angeordnet und mit diesem ver- und entriegelbar ist. Der Rahmen besteht aus einem Kunststoffteil, in das die Kulissenführung und sonstige Beschlagteile, wie Gleitbackenhalter o.dgl., einstückig integriert werden können. Auch ist es möglich, die hintere Wasserauffangrinne unmittelbar am Rahmen zu befestigen. (32 05 445)

DE 3205445 A1

BUNDESDRUCKEREI 07. 83 308 034/306 15/50

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Ansprüche

1. Fahrzeugdach mit einem im Bereich einer Dachöffnung angeordneten Hebe-Schiebedeckel, der eine Abdeckung und einen in Seitenführungen der Dachöffnung beweglich gelagerten Rahmen aufweist, dadurch gekennzeichnet, daß die Abdeckung (4) gegenüber dem Rahmen (5) relativ beweglich angeordnet und mit diesem ver- und entriegelbar ist.

2. Fahrzeugdach nach Anspruch 1, dadurch gekennzeichnet, daß die Abdeckung am Rahmen verschwenkbar angeordnet ist.

3. Fahrzeugdach nach den Ansprüchen 1 bis 3, dadurch gekennzeichnet, daß die Schwenklagergelenke (6) in dem Bereich zwischen der Unterseite (7) der Abdeckung nahe deren Vorderkante (8) und der zu der Unterseite parallelen Ebene des tiefsten dem Fahrzeuginneren (9) zugewandten Punktes des Rahmens angeordnet sind.

4. Fahrzeugdach nach den Ansprüchen 1 bis 3, dadurch gekennzeichnet, daß die Schwenklagergelenke (6) als gesonderte Teile an den Rändern der Abdeckung (4) befestigt sind.

5. Fahrzeugdach nach den Ansprüchen 1 bis 3, dadurch gekennzeichnet, daß die Schwenklagergelenke einstückig an die Abdeckung angeformt sind.

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6. Fahrzeugdach nach den Ansprüchen 1 bis 5, dadurch gekennzeichnet, daß die Abdeckung mit einer zumindest bereichsweise deren Ränder übergreifenden Einfassung (11) versehen ist, an der die Lagergelenke (6) befestigt bzw. einstückig angeformt sind.

7. Fahrzeugdach nach Anspruch 6, dadurch gekennzeichnet, daß die Einfassung (11) einen die Ränder der Abdeckung umfassenden etwa U-förmigen Querschnitt besitzt und Versteifungsrippen (12) aufweist.

8. Fahrzeugdach nach den Ansprüchen 4 bis 6, dadurch gekennzeichnet, daß die Einfassung mit der Abdeckung verklebt ist.

9. Fahrzeugdach nach den Ansprüchen 1 bis 8, dadurch gekennzeichnet, daß der Rahmen als gespritztes, gegossenes oder gepreßtes Element ausgebildet ist und daß zu beiden Längsseiten des Rahmens je eine die Hebe- und Verschiebebewegung ermöglichende Kulissenführung (15) und / oder sonstige Beschlagteile, wie Gleitbackenhalter (16) o. dgl., einstückig an den Rahmen angeformt ist.

10. Fahrzeugdach nach dem Anspruch 9, dadurch gekenn-

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zeichnet, daß der Rahmen durch nach dessen Montage in der Dachöffnung in Kulissenführungen (15,25) einsetzbare Bolzen (17) an einem am Fahrzeugdach (3) verschiebbar in Seitenführungen (20) gelagerten Gleitstück (18) befestigbar ist und daß die Kulissenführungen (15,25) und das Gleitstück im Querschnitt gesehen parallel nebeneinander angeordnet sind.

11. Fahrzeugdach nach den Ansprüchen 1 bis 10, dadurch gekennzeichnet, daß dem Hebe-Schiebedeckel (4,5) an seinem im Bereich der Dachöffnungs-Hinterkante gelegenen Ende eine sich quer zur Fahrzeuglängsachse erstreckende Wasserauffangrinne (31) zugeordnet ist und daß die Wasserauffangrinne im Bereich dessen hinteren Endes am Rahmen (4) befestigt ist.

12. Fahrzeugdach nach Anspruch 11, dadurch gekennzeichnet, daß die Wasserauffangrinne an den Rahmen angeschraubt, angeklebt und angeschweißt ist.

13. Fahrzeugdach nach Anspruch 11, dadurch gekennzeichnet, daß die Wasserauffangrinne und der Rahmen als einstückige Einheit hergestellt sind.

14. Fahrzeugdach nach den Ansprüchen 1 bis 13, dadurch

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gekennzeichnet, daß der Rahmen (5) eine umlaufende Spaltdichtung (13) aufweist, auf der die Ränder der Abdeckung in der Schließstellung des Hebe-Schiebedeckels derart aufliegen, daß einerseits die Abdeckung gegenüber dem Rahmen und andererseits die Deckeleinheit (4,5) gegenüber dem Dachausschnitt abgedichtet ist.

15. Fahrzeugdach nach den Ansprüchen 1 bis 14, dadurch gekennzeichnet, daß an den beiden Längsseiten der Abdeckung (4) je eine die Hebe- und Verschiebebewegung der Abdeckung ermöglichende Kulissenführung (25) angeordnet ist, die in der Zusammenbaustellung des Hebe-Schiebedeckels eine Stellung zwischen den einander zugewandten Gleitflächen (30) der Kulissenführung (15) für den Rahmen (5) und der Gleitfläche (28) des Gleitstücks (18) einnimmt.

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Page #532

PA/Wa 2

Anmelder: Firma
Wilhelm Schade
Postfach 1549

D-5970 Plettenberg

Fahrzeugdach mit einem im Bereich einer Dachöffnung angeordneten Hebe-Schiebedeckel.

Die Erfindung bezieht sich auf ein Fahrzeugdach mit einem im Bereich einer Dachöffnung angeordneten Hebe-Schiebedeckel, der eine Abdeckung und einen in Seitenführungen der Dachöffnung beweglich gelagerten Rahmen aufweist.

Bei einem aus der Praxis bekannten Hebe-Schiebedeckel dieser Art ist die als transparente Scheibe ausgebildete Abdeckung mit dem die Scheibe tragenden Rahmen an ihren Rändern verklebt, so daß Abdeckung und Rahmen eine untereinander fest verbundene Einheit bilden. In seinem in Fahrtrichtung vorderen Bereich ist der Rahmen an seinen beiden Längsseiten durch einen an der Rahmenunterseite befestigten Hebel abgestützt, dessen der Rahmenunterseite abgewandtes Ende in einem Gleitschuh verschwenkbar gelagert ist. Der Gleitschuh dient einerseits als Lagerstelle für die Deckeleinheit zum Ausstellen aus ihrer Geschlossenstellung in die Hebestellung und zum anderen als Gleitführung beim Verschieben der Deckeleinheit. Außerdem ist der Hebe-Schiebedeckel über Gleit-

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bolzen in Kulissenführungen gelagert, die als von dem Deckel getrennte Einzelteile an seitlichen Führungsschienen angeschraubt sind. Die Führungsschienen sind im Bereich der Dachöffnung an der Karosserie befestigt. Bei der Montage werden zunächst die Kulissenführungen mit mehreren Schrauben an die seitlichen Führungsschienen angeschraubt und die Gleitbolzen in den Kulissenführungen vormontiert, bevor die Deckeleinheit in die Dachöffnung eingesetzt und an den Beschlagteilen befestigt wird.

Im Bereich der in Fahrtrichtung hinteren Dacheinschnittkante ist bei der bekannten Ausführung zusätzlich eine sich quer zur Dachöffnung erstreckende, verfahrbare Wasserauffangrinne vorgesehen, die in der Geschlossenstellung des Hebe-Schiebedeckels auf der Fahrzeuginnenseite den Dichtungsspalt zwischen der Hinterkante des Deckels und der dieser gegenüberliegenden Anschlagkante der Dachöffnung überbrückt. Wird der Deckel in die hintere Schiebestellung geschoben, nimmt er über besondere Mitnehmerteile die Wasserauffangrinne während seiner gesamten Öffnungsbewegung unterhalb der Dachhaut mit, so daß Wasser oder Feuchtigkeitsrückstände in jeder beliebigen Stellung vom Deckel über dessen Hinterkante in die Auffangrinne gelangen. Entsprechendes gilt für die entgegengesetzte Deckelbewegung beim Zurückfahren aus der Öffnungsstellung

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in die Geschlossenstellung.

Bei dieser bekannten Hebe-Schiebedach-Konstruktion ist es nachteilig, daß der den Schwenkpunkt für den Deckel enthaltende Gleitschuh einen relativ großen Abstand sowohl von der Längsmittelebene des Hebe-Schiebedeckels als auch von der Vorderkante der Dachöffnung haben muß, um einen genügend großen Bewegungsspielraum für den Deckel zuzulassen. Dies führt dazu, daß der Querspalt zwischen der Deckel-Vorderkante und der Vorderkante der Dachöffnung unverhältnismäßig breit sein muß und dadurch die den Querspalt abdeckende Dichtungsleiste durch die relativ weit ausladende Kippbewegung überbeanprucht wird. Dadurch besteht die Gefahr einer frühzeitigen Materialermüdung, die die Bildung von Leckstellen nach sich zieht. Außerdem unterstützt der breite Dichtungsspalt die Erhöhung von Windgeräuschen. Ein weiterer wichtiger Nachteil besteht bei der bekannten Ausführung darin, daß beim Ausstellen des Deckels in die Hebestellung die die Deckelränder umlaufend eng umfassenden Dichtungsleisten an den Rändern des Dachausschnittes entlangschleifen und diese nach außen, oder beim Schließen des Deckels nach innen zu drücken suchen. Durch diese ständig wechselnden Kräfteeinwirkungen ist es in der Praxis unvermeidbar, daß sich das relativ dünne, instabile Karosserieblech der Dachhaut besonders im Be-

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reich der Hinterkante leicht ausbeult und über längere Zeit sogar bleibend verformt.

Dadurch, daß die bekannte Hebe-Schiebedach-Konstruktion aus zahlreichen Einzelteilen besteht, wie gesonderten Kulissenführungen, vorzumontierenden Gleitbolzen, Befestigungsschrauben zum Anschrauben der Kulissenführungen an Seiten-Führungsschienen, eine getrennte verschiebbare Wasserauffangrinne u.s.w., stellt sich die Montage sehr zeitaufwendig und kostspielig. Zudem kann die Montage nur von ausgebildeten Fachkräften vorgenommen werden.

Aufgabe der Erfindung ist es, unter Vermeidung der genannten Nachteile ein baulich einfaches und funktionssicheres Hebe-Schiebedach der eingangs genannten Art, vorzuschlagen, das außerdem eine wesentliche Montageerleichterung ermöglicht.

Dies wird nach der Erfindung dadurch erreicht, daß die Abdeckung gegenüber dem Rahmen relativ beweglich angeordnet und mit diesem ver- und entriegelbar ist. Durch die erfindungsgemäße Trennung der Abdeckung von dem Rahmen ist es möglich, die Dichtungsspalte zwischen dem Hebe-Schiebedeckel und den Rändern des Dachausschnittes sehr eng zu halten, so daß neben einer Verringerung der

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Windgeräusche eine durchlaufend gute Abdichtung der Spalte erreicht wird. Dadurch, daß nicht der gesamte Rahmen nach oben aus der Dachöffnung ausgehoben zu werden braucht - die Hebefunktion wird bei dem Erfindungsgegenstand allein von der Abdeckung übernommen - tritt eine Überbelastung und damit eine unerwünschte Ausbeulung der Karosserieränder nicht auf. Vielmehr wird die Dachhaut im Bereich der Ränder des Dachausschnittes umlaufend gleichmäßig stabilisiert. Durch den Vorschlag nach der Erfindung wurden außerdem die Voraussetzungen dafür geschaffen, daß die Zahl der einzelnen Beschlagteile sehr gering gehalten werden kann und damit eine wesentliche Montageerleichterung erzielt wird. Zudem ist es nun erstmalig auch bei Hebe-Schiebedeckeln möglich, die Wasserauffangrinne an dem Rahmen starr zu befestigen, so daß jegliche bisher notwendige Beschlagteile zur Sicherung des Bewegungsablaufes der Auffangrinne entfallen können.

Zweckmäßig ist die Abdeckung am Rahmen schwenkbar angeordnet. Vorzugsweise sind die Schwenklagergelenke in dem Bereich zwischen der Unterseite der Abdeckung nahe deren Vorderkante und der zu der Unterseite parallelen Ebene des tiefsten dem Fahrzeuginneren zugewandten Umrißpunktes des Rahmens angeordnet. Auf einen besonderen Abstand der Lagerachsen von der Dachfläche oder von der Vorderkante

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der Dachöffnung braucht keine Rücksicht genommen zu werden, so daß die Gefahr einer Überbeanspruchung der Dichtungsleisten beim Ausstellen der Abdeckung nicht besteht. Die Schwenklagergelenke können nach der Erfindung dabei als gesonderte Teile an den Kändern der Abdeckung befestigt sein. Alternativ dazu können sie auch einstückig an die Abdeckung angeformt sein.

In vorteilhafter Weiterentwicklung des Erfindungsgegenstandes ist die Abdeckung mit einer zumindest bereichsweise deren Ränder übergreifenden Einfassung versehen, an der die Lagergelenke befestigt bzw. einstückig angeformt sind. Vorzugsweise besitzt die Einfassung einen die Ränder der Abdeckung umfassenden etwa U-förmigen Querschnitt und weist Versteifungsrippen auf. Vorteilhaft ist die Einfassung mit der Abdeckung verklebt.

In weiterer bevorzugter Ausgestaltung des Erfindungsgegenstandes ist der Rahmen als gespritztes, gegossenes oder gepreßtes Element ausgebildet, wobei die die Hebe- und Verschiebebewegung ermöglichende Kulissenführung und/oder sonstige Beschlagteile, wie Gleitbackennalter o.dgl. einstückig an den Rahmen angeformt sind. Da nach diesem Vorschlag die Kulissenführungen und dgl. als Einzelteile fortfallen, weil sie bei dem Erfindungsgegenstand aufgrund der vernachlässigbaren Toleranzprobleme durch die Trennung der Abdeckung von den Rahmen unmittelbar in den Rah-

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men integriert werden können, sind durch die Erfindung nunmehr die Voraussetzungen gegeben, den Hebe-Schiebedeckel mit wenigen Handgriffen auch von ungelernten Kräften in die Dachöffnung einzusetzen und dort zu lagern. Zweckmäßig ist dazu der Rahmen durch vorzugsweise zwei, nach dessen Montage in der Dachöffnung, in die Kulissenführung einsetzbare Bolzen an einem am Fahrzeugdach verschiebbar in Seitenführungen gelagerten Gleitstück befestigbar, wobei die Bolzen gleichzeitig als Kulissenbolzen dienen. Auf diese Weise ist es möglich, daß der gesamte Hebe-Schiebedeckel allein von den Kulissenbolzen getragen wird.

In Weiterentwicklung der Erfindung ist dem Hebe-Schiebedeckel an seinem im Bereich der Dachöffnungs-Hinterkante gelegenen Ende eine sich quer zur Fahrzeuglängsachse erstreckende Wasserauffangrinne zugeordnet, die im Bereich des hinteren Endes des Rahmens befestigt ist. Die Wasserauffangrinne kann an den Rahmen angeschraubt, angeklebt, angeschweißt oder sonstwie befestigt werden. Alternativ dazu kann sie in bevorzugter Weise auch mit dem Rahmen als einstückige Einheit hergestellt sein. Die Entscheidung, ob eine mit dem Rahmen einstückige oder getrennte Ausführung der Wasserauffangrinne gewählt wird, ist in der Praxis jeweils davon abhängig, aus welchem Material der Rahmen und die Rinne hergestellt werden.

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Die Erfindung ist nachstehend anhand mehrerer in der Zeichnung dargestellter Ausführungsbeispiele näher beschrieben.

In der Zeichnung zeigen:

Fig. 1: eine teilweise geschnittene Draufsicht auf den in einen Dachausschnitt eingebauten Hebe-Schiebedeckel,

Fig. 2: einen Schnitt nach der Linie II-II in Figur 1,

Fig. 3: einen Schnitt entsprechend Figur 2, jedoch mit ausgestellter Abdeckung,

Fig. 4: einen Schnitt nach der Linie IV-IV in Figur 1 mit einem an eine Einfassung der Abdeckung angeformten Schwenklagergelenk,

Fig. 4a: einen Schnitt entsprechend Figur 4, jedoch mit einem unmittelbar an die Abdeckung angeformten Schwenklagergelenk,

Fig. 4b: einen Schnitt entsprechend Figur 4, bei dem das Schwenklagergelenk als gesondertes Beschlagteil an der Einfassung befestigt ist,

Fig. 5: einen Schnitt entsprechend Fig. 4 mit ausgestellter Abdeckung,

Fig. 6: einen Schnitt nach der Linie VI-VI in Fig. 1,

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Fig. 7: einen Schnitt entsprechend Fig. 6, mit teilweise nach hinten eingeschobenem Hebe-Schiebedeckel,

Fig. 8: einen Schnitt nach der Linie VIII-VIII in Fig. 1,

Fig. 9: einen Schnitt nach der Linie IX-IX in Fig. 1, mit geschlossenem Hebe-Schiebedeckel,

Fig. 10: einen Schnitt entsprechend Fig. 9 mit ausgestellter Abdeckung,

Fig. 11: einen Schnitt nach der Linie XI-XI in Fig. 1,

Fig. 12,12a, 12b: eine vereinfachte Schnittansicht nach der Linie XII-XII in Fig. 1, jeweils in verschiedenen Öffnungsstellungen des Hebe-Schiebedeckels.

Der Hebe-Schiebedeckel 1 ist in einem Dachausschnitt 2 eines Kraftfahrzeugdaches 3 montiert. Er weist eine Abdeckung 4 und einen Rahmen 5 auf. Die Abdeckung besteht vorzugsweise aus einer transparenten Scheibe, kann aber auch als eine undurchsichtige Metall- oder Kunststofftafel ausgebildet sein. Sie ist gegenüber dem Rahmen relativ beweglich angeordnet und mit diesem ver- und entriegelbar. Bei dem gewählten Beispiel ist die Abdeckung am Rahmen verschwenkbar angelenkt. Dazu besitzt sie Schwenk-

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lagergelenke 6, die im Bereich zwischen der Unterseite 7 der Abdeckung nahe deren Vorderkante 8 und der zu der Unterseite parallelen Ebene des tiefsten dem Fahrzeuginnern 9 zugewandten Punktes des Rahmens 5 angeordnet ist. Da bei dem gezeigten Ausführungsbeispiel der tiefste Punkt der Rahmenquerholme von deren ebener Unterseite gebildet ist, liegen die Schwenklagergelenke 6 in dem Abstandsraum zwischen der Ebene der Holmunterseite 5' und der dazu parallelen Unterseite 7 der Abdeckung 4. Die Schwenklagergelenke 6 können als gesonderte Teile 10 (Fig. 4b) an dem Rand der Abdeckung befestigt, z. B. angeschraubt oder angeklebt sein. Auch können sie einstückig (Fig. 4a) an den Rand der Abdeckung angeformt werden. Alternativ dazu ist auch eine getrennte Befestigung oder einstückige Anformung an einer Einfassung 11 möglich, wie aus Figur 4 ersichtlich.

Die Einfassung 11 übergreift die Ränder der Abdeckung 4 und besteht aus einem um die Abdeckung durchgehend umlaufenden, profilierten Blechstreifen. Die Einfassung 11 besitzt einen die Ränder ober- und unterseitig umfassenden U-förmigen Querschnitt, der durch Versteifungsrippen 12 (Fig. 4) verstärkt ist. Sie ist mit dem Rand der Abdeckung verklebt und kann z.B. aus einem Metall- oder einem Kunststoffteil bestehen. Statt der umlaufenden Ausführung ist es auch möglich, im Abstand voneinander auf

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die Ränder der Abdeckung aufgesetzte Teilstücke zu verwenden. Das entsprechende, über je einen auf beiden Seiten des Deckels vorgesehenen Lagerbolzen 6' verbundene Gegenstück für die an der Abdeckung befestigten Lagergelenke befindet sich jeweils am Rahmen selbst, der zusätzlich noch besonders profilierte Dichtungsleisten 13 trägt, die auf Vorsprünge 13' der Rahmenholme 4 aufgesteckt sind und die den Spalt 14 zwischen den Rändern des Dachausschnittes 2 und den diesen zugewandten Rändern der Abdeckung 4 und des Rahmens 5 umlaufend abdichten.

Dadurch, daß der Rahmen als von der Abdeckung getrenntes Teil ausgebildet ist und damit die bei den bisher bekannten Hebe-Schiebedeckeln auftretenden Toleranzprobleme nicht mehr gegeben sind, ist es bei dem dargestellten Ausführungsbeispiel möglich, den Rahmen 5 als einstückig gespritztes, gegossenes oder gepreßtes Kunststoffteil auszubilden und die Kulissenführungen 15 (Fig. 9,10) beidseits des Rahmens in den Rahmen einzuformen, so daß Rahmen und Kulissenführungen eine einstückige Einheit bilden. In gleicher Weise sind die Gleitbackenhalter 16 (Fig. 11) an den Rahmen unmittelbar angeformt. Die Aufhängung des kompletten Hebe-Schiebedeckels in der Dachöffnung erfolgt über zwei Bolzen 17, die beidseits des Rahmens jeweils durch eine in zugeordneten Gleitstücken 18 vorgesehene Bohrung 19 gesteckt werden.

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Die Gleitstücke 18 sind über in Seitenführungen 20 des Daches eingreifende Gleitfüße 21,22 parallel zur Ebene des Dachausschnittes verschiebbar gelagert. Die Bohrungen 19 in dem Gleitstück 18 decken sich mit länglichen Führungsausnehmungen 23,24, von denen die Führungsausnehmungen 23 in den in den Rahmen integrierten, jeweils zugeordneten Kulissenführungen 15 und die Ausnehmungen 24 in Kulissenführungen 25 vorgesehen sind, die mit der Einfassung 11 an der Unterseite 7 der Abdeckung 4 mittels Schrauben 26 starr verbunden sind. Die Kulissenführungen 25 sind im Querschnitt gesehen jeweils zwischen den Kulissenführungen 15 des Rahmens und den Gleitstücken 18 so angeordnet, daß die Seitenflächen 27 der Kulisse 25 die ihnen jeweils zugewandte Seitenfläche 28 des Gleitstückes 18 und die Seitenfläche 29 der Kulisse 25 die Seitenfläche 30 der Kulissenführung 15 des Rahmens mit Gleitsitz berührt. Wie ersichtlich, wird der gesamte Hebe-Schiebedeckel von den Bolzen 17 getragen, über die der Kraftfluß von den Kulissenführungen 15, 25 auf die Gleitstücke 18 übertragen wird.

Wie in den Figuren 6 und 7 verdeutlicht, ist an der Unterseite des hinteren Rahmenholmes eine sich quer zur Fahrzeug-Längsachse erstreckende Wasserauffangrinne 31 befestigt, z.B. angeschraubt, angeklebt oder angeschweißt.

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Ist der Rahmen als ein Kunststoffteil ausgebildet, bietet sich ebenfalls die Herstellung der Wasserauffangrinne als einstückige Einheit mit dem Rahmen an.

Wie aus Figur 12a ersichtlich, in der der Hebe-Schiebedeckel die Schließstellung entsprechend der Darstellung in Figur 9 einnimmt, befindet sich der Bolzen 17 in einer mittleren Anschlagstellung, in der er mit seinem die Ausnehmungen 23, 24 der Kulissenführungen 15,25 durchgreifenden Schaftende an Übergängen 32,33 der Ausnehmungen 23,24 anliegt. Bei der über einen nicht dargestellten Getriebemechanismus auf das Gleitstück 18 ausgeübten Bewegung in Pfeilrichtung 34 bleiben die Kulissenführungen 15,25 solange in Ruhestellung, bis die Bolzen den Übergang 35 der im wesentlichen horizontal verlaufenden Teilstrecke 36 der Ausnehmung 24 erreicht haben, weil sich auf dem Weg zwischen den Übergängen 32,35 der Verlauf der Teilstrecke 36 mit einer entsprechenden Teilstrecke 37 der Ausnehmung 23 in der Kulissenführung 15 des Rahmens 4 deckt. Überschreitet der Bolzen während der Bewegung des Gleitstücks 18 in Pfeilrichtung 34 den Übergang 35 der Ausnehmung 24, so bewirkt er zwangsläufig eine Auslenkbewegung der die Abdeckung 4 tragenden Kulissenführung 25 nach oben (Pfeil 38), weil die an den Übergang 35 anschließende Teilstrecke 39 der

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Ausnehmung 24 aus der horizontalen Ebene bis zum äußeren Auslaufende 40 schräg nach unten abgewinkelt ist, während die Teilstrecke 37 der Ausnehmung 23 der Kulissenführung 15 bis zu ihrem Auslaufende 41 hin geradlinig weiterverläuft. Gleichzeitig mit der Auslenkung wird die Abdeckung um die Achsen 6' der Lager 6 verschwenkt. In Figur 12 b ist die Öffnungsstellung der Abdeckung 4 dargestellt, die der Öffnungsstellung in Figur 10 entspricht, aus der deutlich wird, daß sich die Kulissenführung 25 gegenüber der in ihrer Grundstellung (Fig.9) unverändert gebliebenen Kulissenführung 15 in Pfeilrichtung 38 nach oben verlagert hat.

Bei einer dem Pfeil 34 entgegengesetzten Bewegung des Gleitwagens 18 überführen die Bolzen 17 im umgekehrten Bewegungsablauf die Abdeckung 4 zunächst in die Schließstellung (Fig. 9 und 12a). Nach Überschreiten der Übergänge 32,33 der Ausnehmungen 24,23 durch die Bolzen 17 werden sowohl die Kulissenführungen 25 der Abdeckung 4 als auch die Kulissenführungen 15 des Rahmens 5 gleichzeitig entgegen dem Pfeil 38 nach unten verlagert, weil die sich an die Übergänge 32,33 anschließenden Teilstrecken 43 bzw. 44 der Ausnehmungen 24 bzw. 23 aus der Horizontalen schräg nach oben abgewinkelt sind und sich bis zu den Auslaufenden 45,46 hin decken. Hierdurch wird der Rahmen 5 zusammen mit der Abdeckung 4 zwangsläufig in eine Stellung unterhalb der Dachhaut, wie in Figur 7 angedeutet, verlagert, in der der Hebe-Schiebedeckel bei seiner weiteren

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Bewegung nach hinten in eine nicht dargestellte Öffnungsstellung ausgefahren werden kann.

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Leerseite

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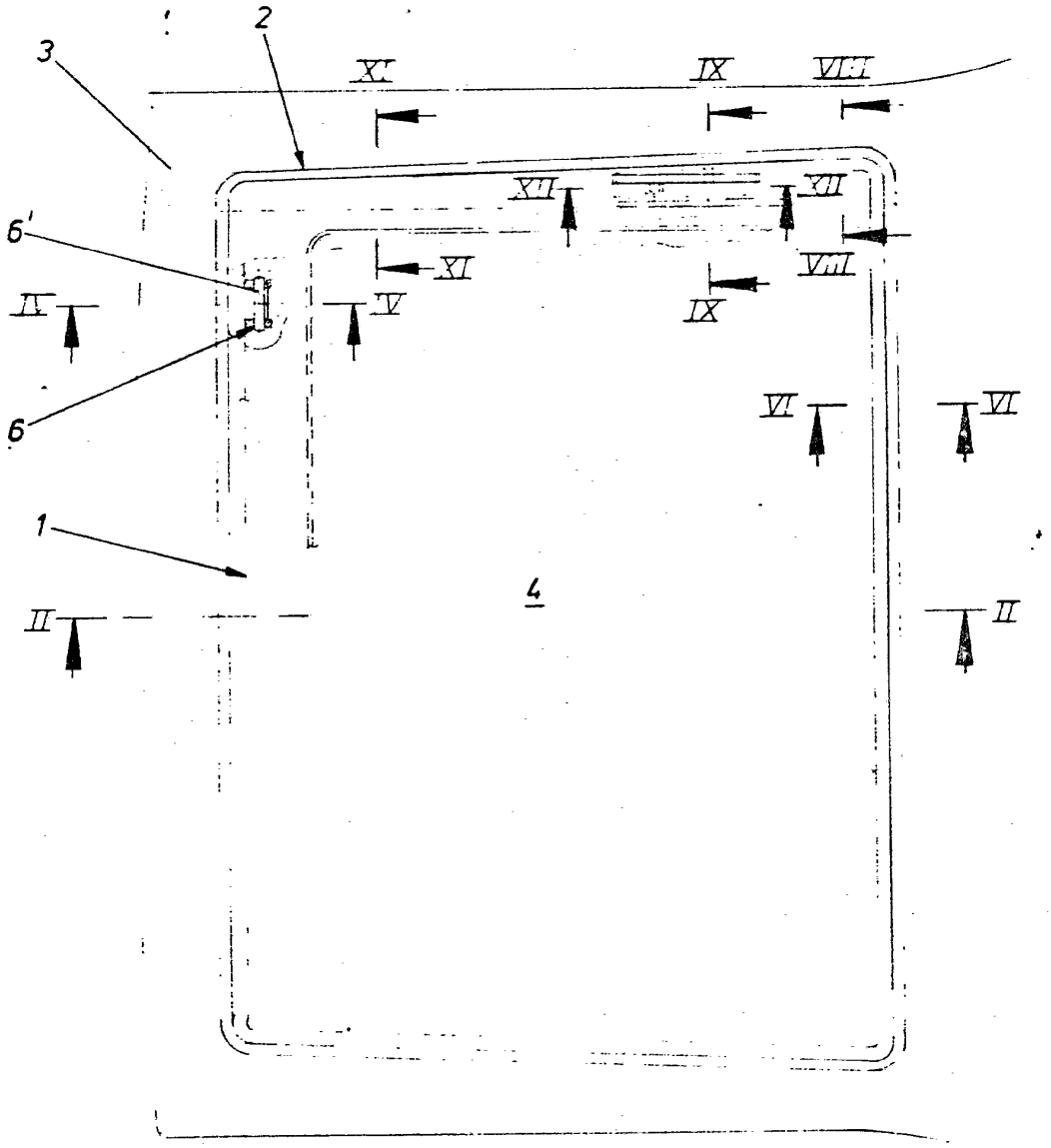


Fig. 1

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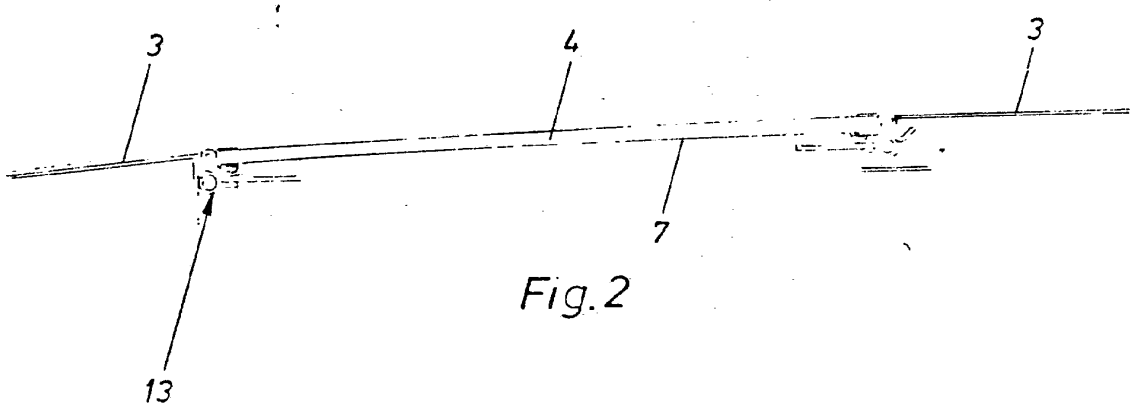


Fig. 2

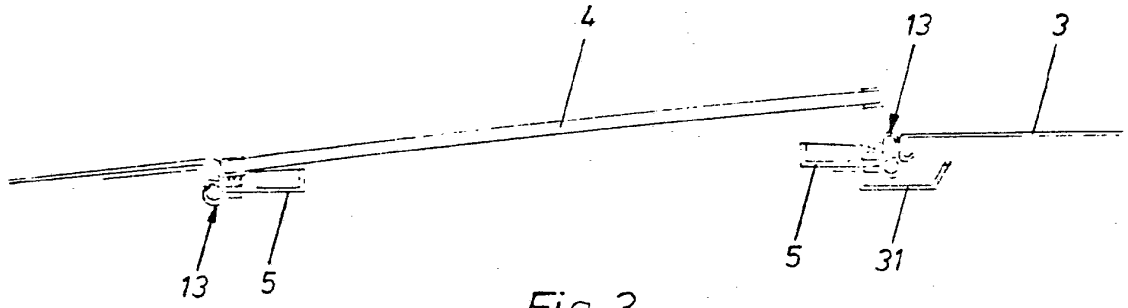


Fig. 3

nungsstellung ausgeführen werden kann.

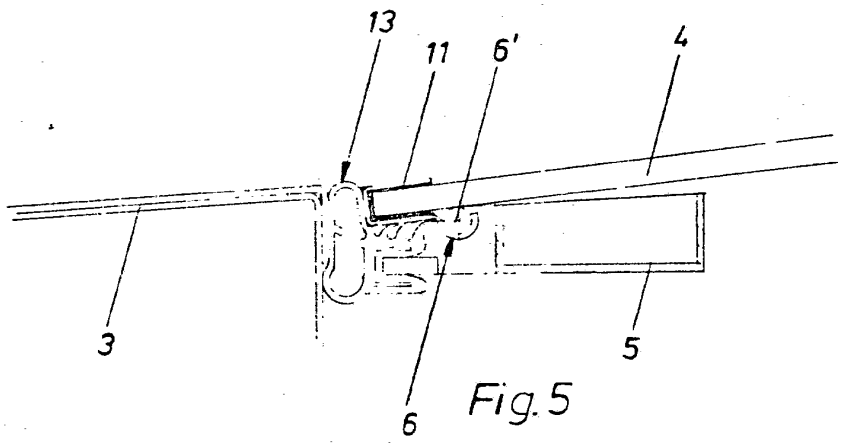


Fig. 5

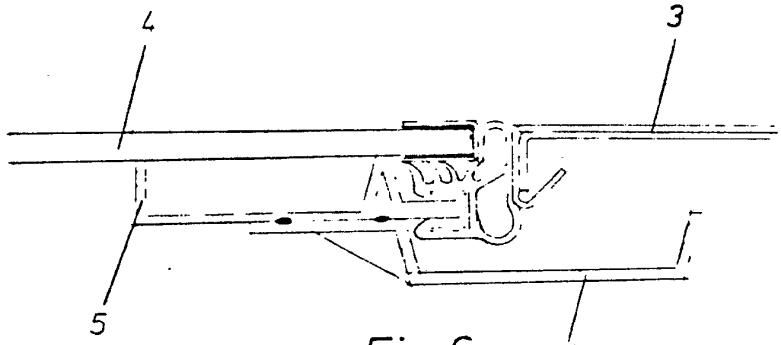


Fig. 6

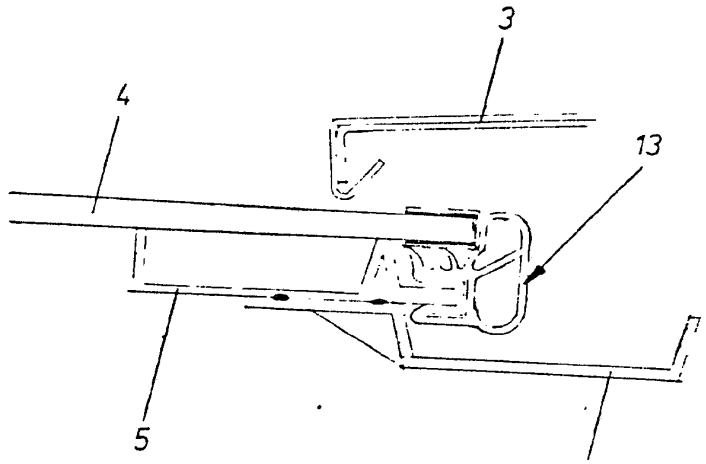


Fig. 7

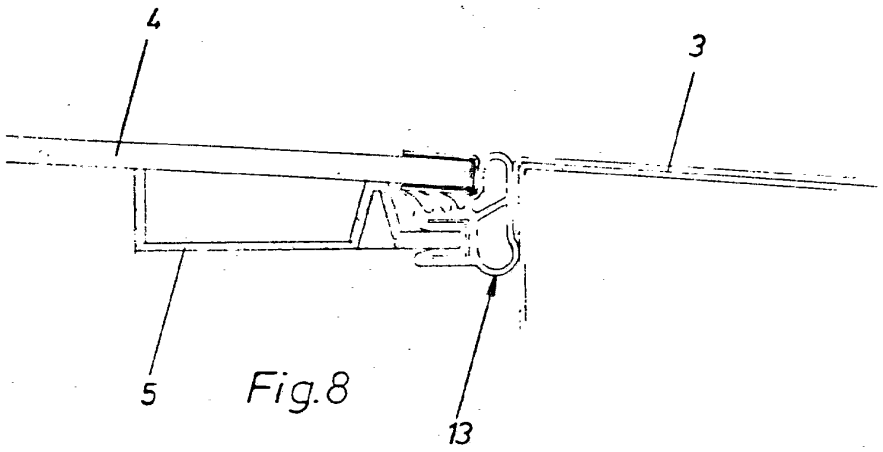


Fig.8

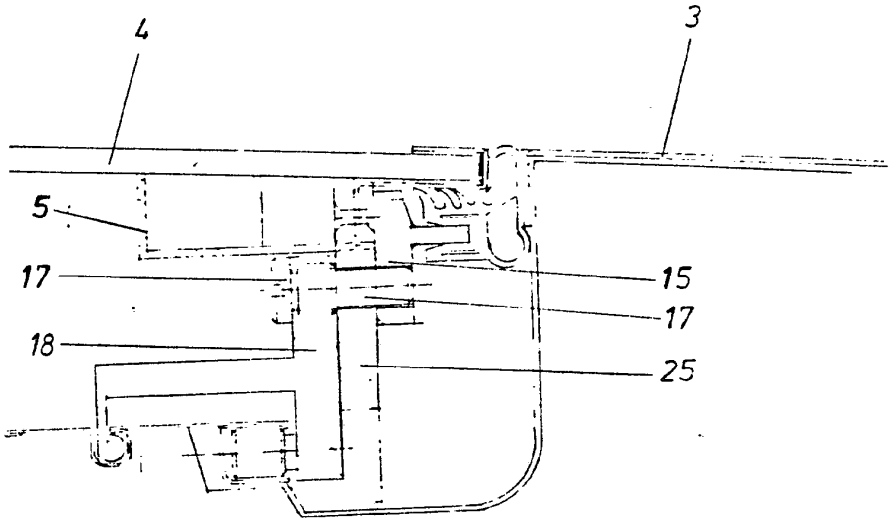


Fig. 9

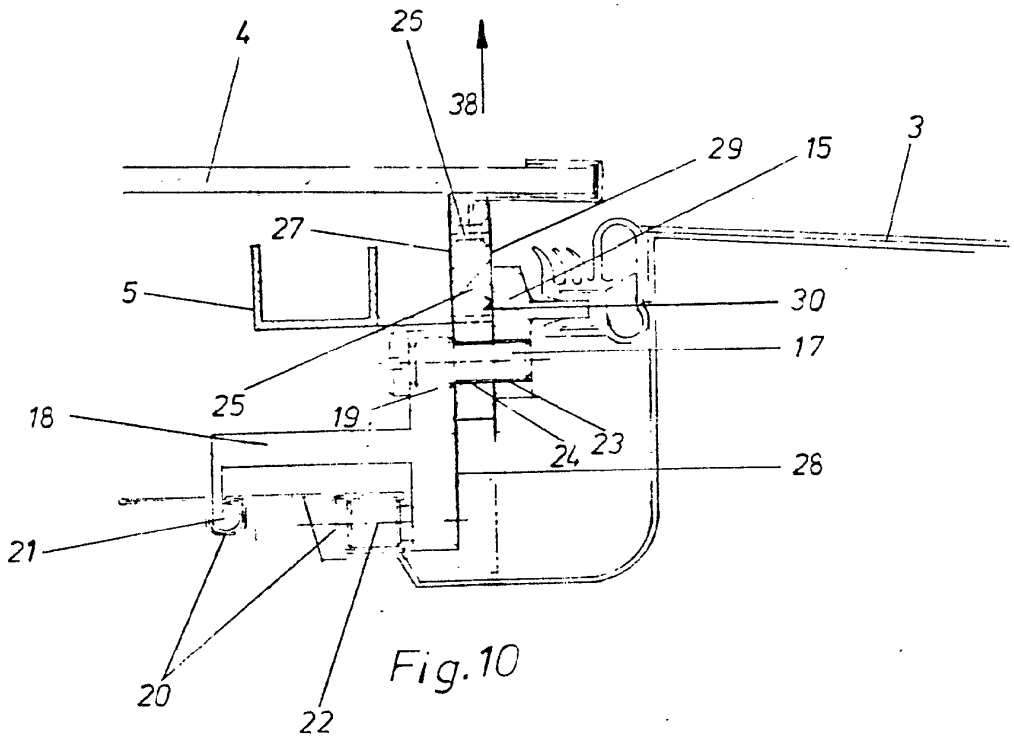


Fig. 10

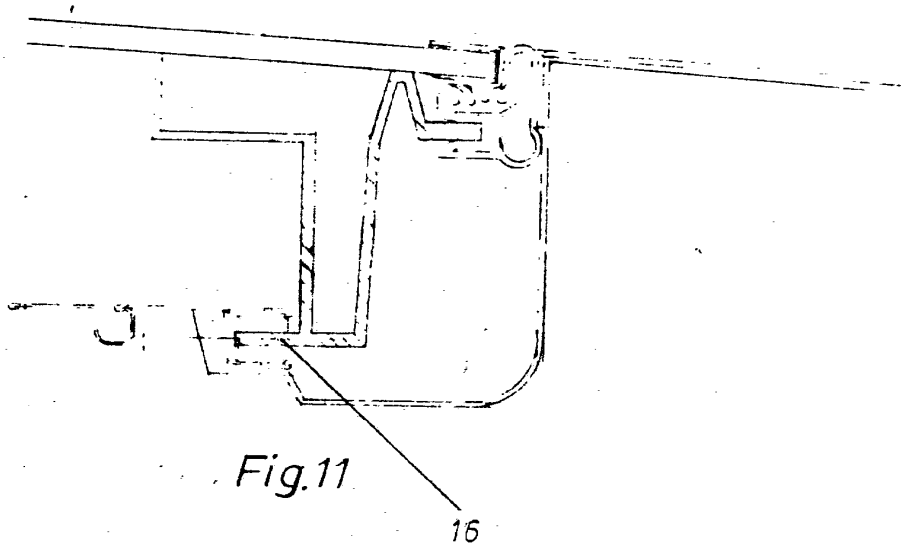


Fig.11

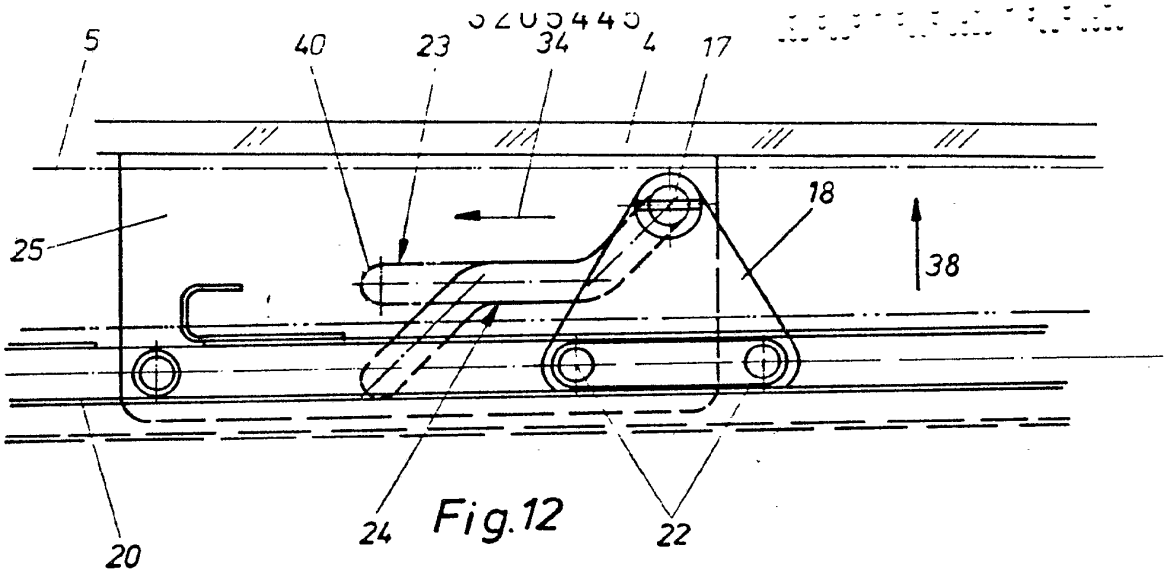


Fig.12

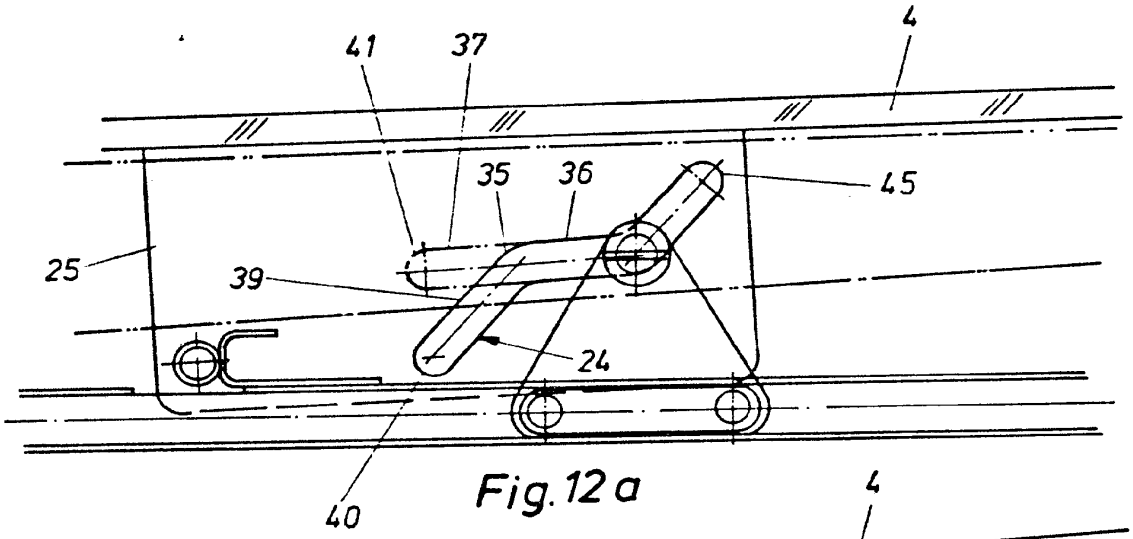


Fig.12a

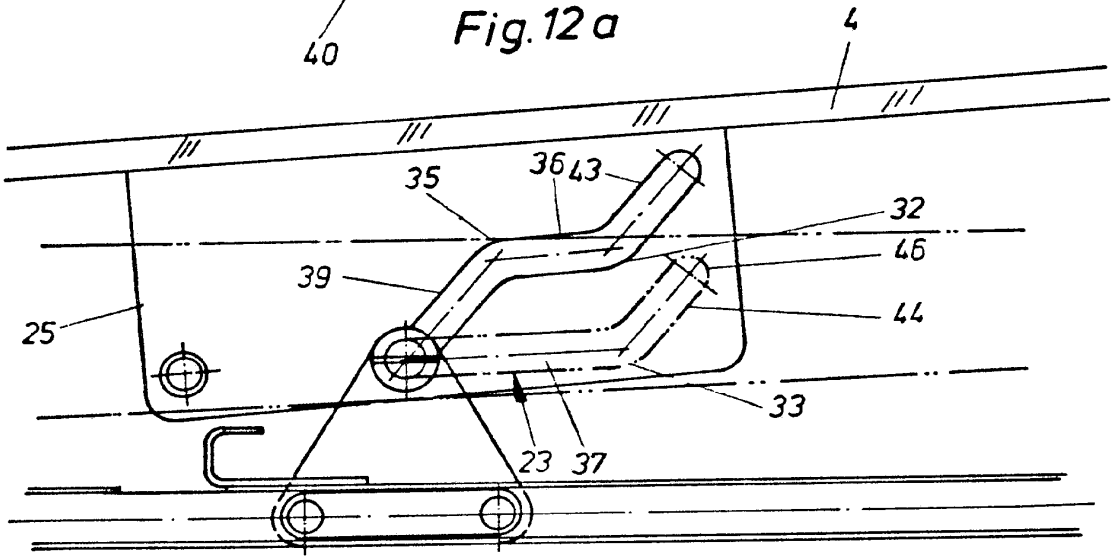


Fig.12b

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(56) Im Prüfungsverfahren entgegengehaltene Druckschriften nach § 44 PatG:

DE-OS 26 19 324
DE-OS 24 55 917
DE-OS 21 49 026
US 38 11 800
US 37 91 787

DE-Z.: Medizinal-Markt/Acta Mediotechnica 26 (1978) 12, S.381-383;

(54) Vorrichtung zum Reinigen des Blutes von Stoffwechselprodukten

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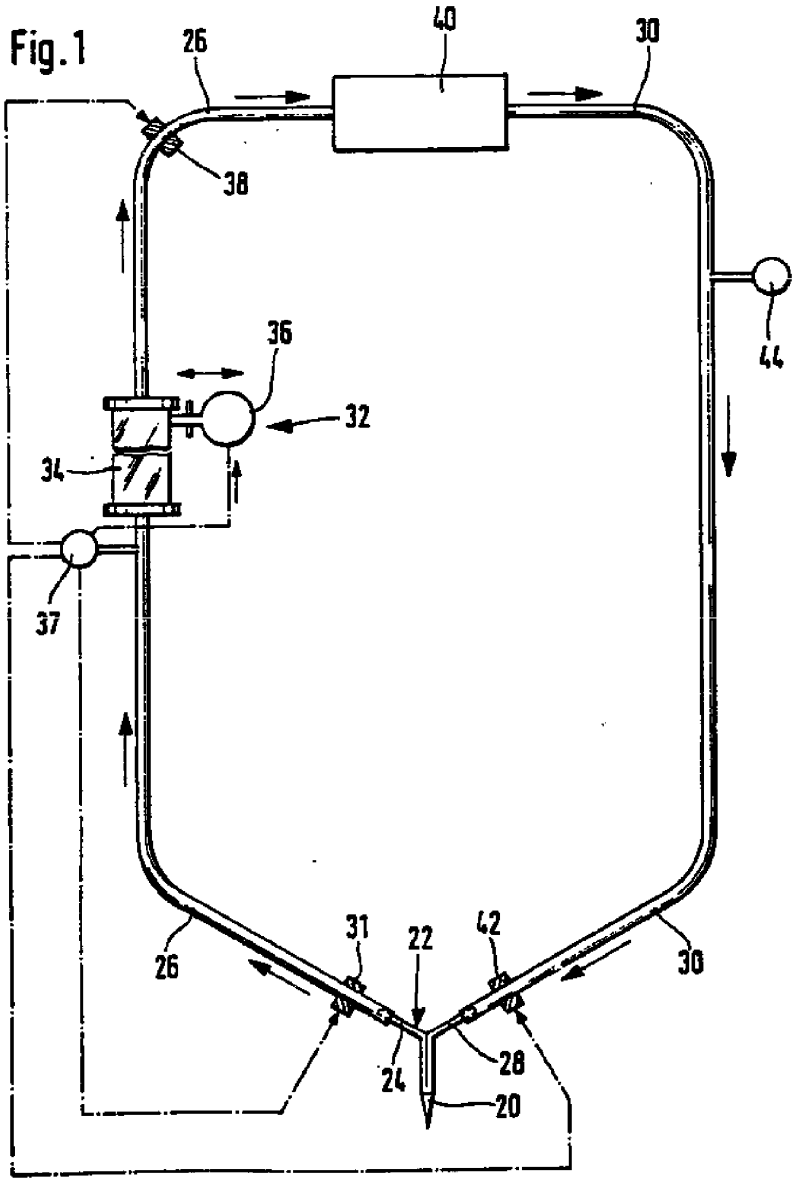
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ZEICHNUNGEN BLATT 1

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Fig. 1



Patentansprüche:

1. Vorrichtung zum Reinigen des Blutes von Stoffwechselprodukten, insbesondere Single-Needle-Dialysevorrichtung, mit einem Dialysator mit einem Dialysatkreislauf und einem Blutkreislauf, der bluteingangs- und blutausgangsseitig über eine Zuleitung und eine Ableitung mit wenigstens einem Blutanschluß verbunden ist, bei der die Zuleitung eine Pumpe und jeweils ein stromauf und stromab der Pumpe angeordnetes Absperrorgan aufweist, wobei die Pumpe ein im wesentlichen starres Gehäuse und eine flexible, innerhalb des Gehäuses angeordnete Membran aufweist, die den Innenraum des Gehäuses in eine erste mit Blut beaufschlagbare Kammer und eine zweite Kammer trennt, die über eine Leitung mit einer als Antrieb dienenden Hubkolbenpumpe verbunden ist, dadurch gekennzeichnet, daß das Antriebsmedium ein Gas ist und der Gasraum mittels Überdruck- und Unterdruckventilen (128, 132) mit der Umgebung in Verbindung steht.

2. Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, daß das Hubvolumen der Hubkolbenpumpe (124) größer ist als das Speichervolumen der Pumpe (34).

3. Vorrichtung nach Anspruch 2, dadurch gekennzeichnet, daß das Hubvolumen bis zu 20% größer ist als das Speichervolumen.

4. Vorrichtung nach einem der Ansprüche 1–3, dadurch gekennzeichnet, daß in der die Pumpe (34) und die Hubkolbenpumpe (36, 124) verbindenden Leitung (116) eine hydrophobe, gasdurchlässige Membran (132) vorgesehen ist, die den Innenquerschnitt der Leitung (116) abdeckt.

5. Vorrichtung nach einem der Ansprüche 1–4, dadurch gekennzeichnet, daß die Hubkolbenpumpe (36, 124) zwangsgesteuert ist und an ihren Umkehrpunkten die Absperrorgane (31, 38, 42) umgeschaltet werden.

6. Vorrichtung nach einem der Ansprüche 1–5, dadurch gekennzeichnet, daß die Ventile (128, 132) und die Hubkolbenpumpe (36, 124) mit einer Überwachungseinrichtung (131) verbunden sind.

7. Vorrichtung nach Anspruch 6, dadurch gekennzeichnet, daß mit der Überwachungseinrichtung (131) die Pumpgeschwindigkeit gesteuert, die zeitliche oder phasengebundene Abfolge der Ventilzustände registriert oder ein Alarmsignal abgegeben wird.

8. Vorrichtung nach einem der Ansprüche 1–7, dadurch gekennzeichnet, daß in der Pumpleitung (122) ein Drucksensor angeordnet ist, mit dem über die Überwachungseinrichtung (131) die Änderung der Druckabfolge registriert wird.

Die Erfindung betrifft eine Vorrichtung zum Reinigen des Blutes von Stoffwechselprodukten, insbesondere Single-Needle-Dialysevorrichtung, mit einem Dialysator mit einem Dialysatkreislauf und einem Blutkreislauf, der bluteingangs- und blutausgangsseitig über eine Zuleitung und eine Ableitung mit wenigstens einem Blutanschluß verbunden ist, bei der die Zuleitung eine Pumpe und jeweils ein stromauf und stromab der Pumpe

angeordnetes Absperrorgan aufweist, wobei die Pumpe ein im wesentlichen starres Gehäuse und eine flexible, innerhalb des Gehäuses angeordnete Membran aufweist, die den Innenraum des Gehäuses in eine erste mit Blut beaufschlagbare Kammer und eine zweite Kammer trennt, die über eine Leitung mit einer als Antrieb dienenden Hubkolbenpumpe verbunden ist.

Die US-PS 37 91 767 beschreibt eine Vorrichtung der eingangs erwähnten Art, die eine Pumpanordnung in einem Single-Needle-Dialysesystem aufweist. Bei dieser Pumpanordnung wird das Blut in eine schlauchförmige, flexible Speicherkammer in einem ersten Schritt eingepumpt und aus dieser im nächsten Schritt abgepumpt. Diese flexible Speicherkammer ist in einem starren Gehäuse angeordnet und bildet in diesem einen Ringraum, in den durch Pumpen eine Flüssigkeit als Pumpfluid gefördert wird.

Die Pumpe gemäß US-PS weist einen mit einem Balg verbundenen Kolben auf, der gegen die Kraft einer Feder bewegt wird. Da sich das Balginnenvolumen verändert und hierdurch ein Unterdruck erzeugt wird, erfolgt ein Ansaugen der Flüssigkeit aus dem Ringraum des Speichers. Das Blut wird dabei solange angesaugt, bis sich der Schlauch an die Speicherwand angelegt hat, ohne daß er jedoch erweitert worden wäre.

Das Blutvolumen ist durch die in der Pumpanordnung befindliche Flüssigkeitsmenge und das Innenvolumen des nicht elastisch erweiterbaren Schlauchs begrenzt.

Um das Blut aus dem Schlauch abzupumpen, wird der Solenoid, der den Balg bewegt, abgeschaltet. Durch die Rückschnellkraft der Feder wird der Balg anschließend zusammengepreßt, so daß die Pumpflüssigkeit in den Speicher zurückgepumpt wird.

Da dieses System volumenkonstant ist, ergeben sich einige schwerwiegende Nachteile.

Zunächst sind die auf das Blut einwirkenden Unter- und Überdrücke nicht beliebig einstellbar, da sie weitgehend von der Auslegung der einzelnen Pumpelemente festgelegt sind. So stellt die Feder infolge ihrer konstanten Federkraft grundsätzlich den Balg und somit die Pumpflüssigkeit mit konstantem Druck zurück, die wegen der Inkompressibilität diesen Druck an das Blut weitergibt. Da für den Solenoid ähnliche Betriebsbedingungen gelten, ist davon auszugehen, daß keine Drucksteuerung vorliegt. Dies führt dazu, daß das zu pumpende Flüssigkeitsvolumen relativ genau eingestellt werden muß, um die Pumpe effektiv auszunutzen.

Weiterhin fördert der Balg zwar die Pumpflüssigkeit zurück, erzeugt jedoch keinen steuerbaren Unterdruck im Pumpsystem, da das Blut ohne einen Strömungswiderstand in den Schlauch nachströmt und der Schlauch selbst aus seinem kollabierten Zustand ohne Unterdruck in den expandierten, jedoch immer noch drucklosen Zustand, überführt wird.

Ein bedeutender Nachteil dieser Pumpanordnung besteht darin, daß bei Betriebsbeginn die Phasenlage zwischen dem Speicher einerseits und der Balgpumpe andererseits übereinstimmen muß, damit die Pumpanordnung überhaupt funktionieren kann. Eine solche Übereinstimmung läßt sich jedoch regelmäßig nicht oder nur schwer erzielen, mit der Folge, daß nur noch eine unvollständige Füllung der Speicherkammer mit Blut stattfindet. Dies gilt insbesondere bei der Verwendung eines inkompressiblen Mediums als Pumpfluid. Da sich weiterhin die Pumpverhältnisse während des Betriebs ändern können, beispielsweise die Phasenlage zwischen der Speicherkammer und der Pumpe verschoben wird, variiert in entsprechender Weise das Pumpergebnis, das

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regelmäßig nicht zufriedenstellend ist.

Diese bekannte Pumpanordnung weist also weder in der Anlaufphase noch während der normalen Betriebsphase ein völlig zufriedenstellendes Pumpergebnis auf, was darauf zurückzuführen ist, daß außer der Menge der Pumpflüssigkeit sämtliche Betriebsparameter praktisch konstant und somit nicht mehr steuerbar sind.

Die US-PS 38 11 800 beschreibt ein weitgehend ähnliches System, bei dem wiederum ein sich nach dem Zusammendrücken in die Ausgangslage zurückstellender, jedoch nicht erweiterbarer Schlauch als Speicherelement eingesetzt wird. Auf diesen Schlauch wirkt ein weiterer Schlauch ein, der mit einem hydraulischen Pumpfluid gefüllt ist. Durch eine Erweiterung dieses Schlauchs wird der mit Blut gefüllte Schlauch zusammengedrückt und das im Schlauch befindliche Blut abgepumpt. Der Blutschlauch wird anschließend beim Zurückziehen der Pumpflüssigkeit zurückgestellt und füllt sich somit bei entsprechender Steuerung der Klemmen, die den Blutschlauch abschließen und öffnen.

Es wird also mit einer hydraulisch angetriebenen Pumpe gepumpt, die innerhalb eines starren Gehäuses untergebracht ist. Das Volumen dieses Gehäuses ist dabei geringer als das Volumen der beiden Schläuche. So kommt es daher ständig zu einer Kollabierung eines der beiden Schläuche.

Derartige hydraulische Systeme weisen Probleme bei der Drucksteuerung auf, da der Kompressionsdruck nicht durch eine einfach zu gewährleistende Sicherheitsmaßnahme begrenzt werden kann.

Weiterhin kann die Blutansauggeschwindigkeit nicht geregelt werden, da sie durch die Rückschnellkraft des Blutschlauchs sowie die Eigenschaften des Pumpschlauches und des angeschlossenen Systems bestimmt ist. Eine weitere Regelung ist nicht möglich.

Die DE-OS 24 55 917 beschreibt einen extrakorporalen Kreislauf in Form eines Single-Needle-Dialysesystems, das wiederum eine Pumpe zum Umpumpen von Blut mit einem veränderlichen Innenvolumen aufweist. Zum Einsatz kommen die bereits als nachteilig beschriebenen Schlauchpumpen oder eine rohrförmige Membran und Ventile aufweisende Membranpumpen, die ein gesteuertes Einlaß- und Auslaßventil aufweisen. Derartige Pumpen sind als Ventrikelpumpen bekannt, die grundsätzlich selbstansaugend sind und den Blutfluß in eine Richtung steuern.

Ähnliche Pumpsysteme sind weiterhin aus den DE-OS 21 49 026 und 26 19 234 bekannt, die als Blutpumpen eingesetzt werden sollen. Dabei handelt es sich um passiv betriebene Ausdehnungsgefäße, die sich regelmäßig selbsttätig füllen, ohne daß eine optimale Pumpleistung durch das Antriebselement erreicht werden kann.

Weiterhin ist ein solches balgartiges Ausdehnungsgefäß, das unmittelbar mit Blut beaufschlagt wird, in Medizinalmarkt/Acta Medicotechnica 26, (1978) Bd. 12, S. 381–383 beschrieben. Eine solche mechanisch angetriebene Balgpumpe hat den Nachteil, daß sie nicht per se den Überdruck oder Unterdruck einschränkt. Sie benötigt daher einen zusätzlichen, in das Blutzuführungssystem integrierten Druckaufnehmer, der wiederum die externe Pumpe bzw. die Vorschubgeschwindigkeit steuert, mit der der Balg zusammen- oder auseinandergezogen wird.

Demgemäß kann also nur festgehalten werden, daß die vorstehend erläuterten Pumpsysteme entweder einer volumenkonstanten Zwangssteuerung unterzogen sind oder aber eine mit der Pumpkammer gekoppelte Drucksteuerung aufweisen. Darüber hinaus können solche Blutpumpen zu Beginn ihrer Tätigkeit bei unbestimmter Phasenlage nur schwierig und mit einem speziellen Füllprogramm odef speziellen Einrichtungen hierfür betrieben werden.

Der Erfindung liegt daher die Aufgabe zugrunde, eine Vorrichtung der eingangs erwähnten Art zur Verfügung zu stellen, bei der die Pumpe in jeder Betriebsart sicher gefüllt und entleert werden kann, ohne daß die Hubkolbenpumpe über mit der Pumpe oder dem Blutzuführungssystem verbundene Druckaufnehmer geregelt werden muß.

Die Lösung der Aufgabe erfolgt dadurch, daß das Antriebsmedium ein Gas ist und der Gasraum mittels Überdruck- und Unterdruckventilen mit der Umgebung in Verbindung steht.

Erfindungsgemäß erfolgt die Regelung der Hubkolbenpumpe unabhängig von einer mit der Pumpe in Verbindung stehenden Regeleinrichtung, d. h. die Pumpe regelt sich selbsttätig, wenn ein bestimmter an die Pumpe angelegter Überdruck oder Unterdruck erreicht wird. Dabei öffnen sich die Ventile, so daß der auf die Pumpe einwirkende Druck nicht mehr erhöht oder abgesenkt wird.

Eine derartige Betriebsweise ist mit den eingangs erwähnten hydraulischen Pumpen nur schwierig durchzuführen, da die Pumpflüssigkeiten infolge ihres inkompressiblen Charakters regelmäßig in Pumpanordnungen mit konstantem Volumen untergebracht sind, d. h. Pumpe und Antrieb werden regelmäßig zwangsgesteuert.

Erfindungsgemäß kann jeder beliebige Über- und Unterdruck in der pneumatisch betriebenen Pumpe eingestellt werden, ohne daß diese beschädigt wird.

Weiterhin ist es vorteilhaft, daß die erfindungsgemäße Pumpanordnung zu Beginn ohne jegliche Schwierigkeit gefüllt werden kann, da sie von der Phasenlage unabhängig ist. Die Pumpe saugt nämlich Blut solange an, bis sich die elastische Membran an das starre Pumpgehäuse angelegt hat und dadurch der Druck abfällt. Wenn ein bestimmter Unterdruck erreicht ist, öffnet sich das Unterdruckventil und hält diesen Unterdruck solange konstant, bis die Pumpe den Umkehrpunkt erreicht. Ist dieser Umkehrpunkt erreicht, so schließt sich das Unterdruckventil und es wird die Pumpe entleert. Nach dem Entleeren steigt der Überdruck an und wird bei einem bestimmten Wert dadurch konstant gehalten, daß das Überdruckventil sich öffnet.

Die Pumpe arbeitet jedoch weiter und kehrt erst an ihrem anderen Umkehrpunkt zum Saugbetrieb zurück. An diesem Punkt hat sie nun die richtige Phasenlage erreicht.

Sie benötigt daher lediglich einen Zyklus, um zu der jeweils angestrebten Phasenlage zu kommen, die einen optimalen Pumpbetrieb garantiert.

In einer besonders bevorzugten Ausführungsform ist das Innnenvolumen der Pumpe und der Hubkolbenpumpe korreliert und somit das Verhältnis dieser Volumina begrenzt. Demzufolge unterliegt auch der Druck einer bestimmten Begrenzung in diesem pneumatisch betriebenen System, so daß u. U. auch der Ausfall der Druckbegrenzungsventile toleriert werden kann.

Weitere Einzelheiten, Vorteile und Ausführungsformen sind in der nachfolgenden Beschreibung unter Bezugnahme auf die Zeichnung erläutert. Es zeigt

Fig. 1 schematisch eine Single-Needle-Dialysenanordnung mit dem erfindungsgemäßen Pumpsystem,

Fig. 2 einen Längsschnitt durch eine erste Ausführungsform des erfindungsgemäßen Pumpspeichers,

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Fig. 3 einen Längsschnitt durch eine zweite Ausführungsform des erfindungsgemäßen Pumpspeichers,

Fig. 4 eine Druck/Volumen-Charakteristik der in Fig. 2 gezeigten Ausführungsform beim Befüllen,

Fig. 5 eine Membranpumpe für das in Fig. 1 gezeigten Pumpsystem,

Fig. 6—8 jeweils den Endabschnitt weiterer Ausführungsformen von Pumpspeichern im Längsschnitt, wobei eine weitere zylindrische Außenwand des Pumpspeichers skizziert angedeutet ist und

Fig. 9 eine schematische Darstellung eines kontinuierlich pumpenden Systems mit zwei Pumpspeichern.

Gemäß Fig. 1 wird einem Patienten über eine Hohlkanüle 20 Blut entnommen, die in ein Blutgefäß eingeschoben wird. Diese Hohlkanüle 20 weist an ihrem Ende einen y-förmigen Anschluß 22 auf, bei dem der eine Anschluß 24 mit der Arterienleitung 26 verbunden ist, während der andere Ast 28 mit der Venenleitung 30 verbunden ist. Die Hohlkanüle kann als Biflownadel ausgebildet sein, d. h. sie besteht aus zwei ineinander koaxial angeordneten Kanülen, bei denen die äußere Kanüle um wenige Millimeter zurückgesetzt ist, um einen Vermischungseffekt zu vermeiden. Andererseits kann jedoch auch der geringe Vermischungseffekt bei der vorzugsweise eingesetzten y-förmigen Nadel 20 hingenommen werden.

In der Arterienleitung 26 ist im Anschluß an die y-förmige Hohlnadel 20 ein Absperrorgan 31 vorgesehen, mit der die Arterienleitung geöffnet und abgeschlossen werden kann. An dieses Absperrorgan 31 schließt sich ein Pumpsystem 32 an, das mit der Arterienleitung 26 in Verbindung steht und im wesentlichen die Pumpe 34 und die damit in Verbindung stehende Hubkolbenpumpe 36 aufweist. Stromab des Pumpsystems 32 ist in der Arterienleitung 26 ein weiteres Absperrorgan 38 angeordnet, das vorteilhafterweise entweder als Klemme oder aber als Rückschlagventil ausgebildet ist.

Stromab des Absperrorgans 38 ist die Arterienleitung 26 mit dem Dialysator 40 verbunden, in dem das zu reinigende Blut von den Stoffwechselprodukten und überschüssiger Flüssigkeit befreit wird. Dieser Dialysator 40 ist mit einer nicht gezeigten Dialysenanordnung verbunden, die die Dialyseflüssigkeit mit ebenfalls nicht gezeigten Zu- und Ableitungen durch den Dialysator 40 fördert.

An diesen Dialysator 40 schließt sich die Venenleitung 30 mit dem Leitungsast 28 an, der zur y-förmigen Kanüle 20 geführt ist. Vor der Kanüle 20 ist ein weiteres Absperrorgan 42 vorgesehen, mit der die Venenleitung 30 geöffnet und geschlossen werden kann.

Weiterhin kann vorteilhafterweise in der Venenleitung 30 ein Drucksensor 44 angeordnet sein, der den Druck anzeigt, der sich in dem Leitungsabschnitt zwischen dem Schließorgan 38 und der Klemme 42 aufbaut.

Die in Fig. 1 gezeigte erste Ausführungsform wird folgendermaßen betrieben:

Das Blut wird über die Hohlkanüle 20 mittels des in Fig. 5 näher gezeigten und nachstehend beschriebenen Pumpsystems 32 angesaugt, wobei das Organ 38 und die Klemme 42 geschlossen und das Absperrorgan geöffnet sind. Über die Arterienleitung 26 wird das Blut in die Pumpe 34 mittels der Hubkolbenpumpe 36 gepumpt, wobei die anhand Fig. 2 nachstehend näher erläuterte schlauchförmig ausgebildete Pumpe 34 zunächst drucklos aufgefüllt wird. Anschließend erweitern sich unter sprunghaftem Druckanstieg die Außenwände, ähnlich dem Zustand, in dem ein Ballon aufgeblasen wird. Bereits eine geringe Menge zusätzliches Blut reicht aus, um diesen sprunghaften Druckanstieg in ein nur noch geringfügig ansteigendes Druckplateau umzuwandeln, d. h. daß bei der weiteren Einspeisung von Blut in die Pumpe 34 der Druck in der Pumpe 34 im wesentlichen nur noch geringfügig ansteigt oder sogar konstant bleibt, ohne zunächst wieder sprunghaft anzusteigen. Dieser Anstieg erfolgt dann, wenn ein Grenzzustand erreicht wird, bei dem sich die elastischen Eigenschaften der Speicherwand verändern. Diese Druckcharakteristik ist in der Fig. 4 gezeigt.

In Fig. 2 ist die erste Ausführungsform der erfindungsgemäßen Pumpe 34 im Längsschnitt gezeigt. Diese Pumpe 34 weist im wesentlichen kreisförmige Endplatten 46 und 48 auf, in die ringförmige Nuten 50, 52, 54 und 56 eingelassen sind. Beide Endplatten 46 und 48 weisen weiterhin eine Öffnung 58 und 60 auf, die jeweils von den Anschlußstutzen 62 und 64 umgeben sind. Auf diese Anschlußstutzen 62 und 64 sind die Leitungen 26 aufgesteckt oder aufgeklebt.

Beide Endplatten 46 und 48 sind miteinander über den erweiterbaren Schlauch 66 und die zylinderförmige Speicherwand 68 verbunden. Der Schlauch 66 ist in seinem Endbereich 70 und 72 quergespannt und in die ringförmigen Nuten 50 und 54 der Endplatten 46 und 48 eingelassen und dort befestigt. In seinem mittleren Bereich ist er jedoch nicht quergespannt, sondern allenfalls vorteilhafterweise in Längsrichtung etwas vorgespannt. In die zweiten ringförmigen Nuten 52 und 56 der Endplatten 46 und 48 ist die Speicherwand 68 fest eingesetzt, was beispielsweise durch Kleben oder mechanisches Klemmen vorgenommen werden kann.

Wie aus Fig. 2 ersichtlich, ist der Innenraum 74 des Schlauchs 66 mit der Öffnung 58 und somit der Arterienleitung 26 in Verbindung und wird beim Betrieb mit Blut gefüllt. Hierdurch erfolgt eine Erweiterung der Wand des elastischen Schlauchs 66 solange, bis sich dieser an die Speicherwand 68 vollständig angelegt hat, wie dies durch die strichpunktierte Linie 76 angedeutet ist.

Um eine derartige elastische Erweiterung des Schlauchs 66 zu erreichen, muß natürlich auf die Außenwand des Schlauchs 66 ein Unterdruck ausgeübt werden, der in dem im wesentlichen ringförmigen Raum 78 angelegt wird, der zwischen dem Schlauch 66 und der Speicherwand 68 gebildet wird. Hierzu ist in der Speicherwand 68 wenigstens eine Öffnung 80 vorgesehen, die über eine Zuleitung 82 mit der Hubkolbenpumpe 36 in Verbindung steht, die in Fig. 5 näher dargestellt und erläutert ist. Diese Hubkolbenpumpe 36 pumpt über die Zuleitung 82 und die Öffnung 80 Luft aus bzw. in den ringförmigen Raum 78, was entweder zur Erweiterung oder zum Kollabieren des Schlauchs 66 führt.

Infolge seiner hochelastischen Eigenschaften kollabiert der Schlauch 66 in seinem in Fig. 2 gezeigten aufgespannten Zustand nicht vollständig, so daß zum völligen Abpumpen von Blut aus dem Innenraum 74 ein zusätzlicher Überdruck durch die Hubkolbenpumpe 36 erzeugt werden muß.

Für die Zuführung von Blut ist ein Unterdruck von etwa 150 und max. 500 mm Hg-Säule notwendig, der mit den Sensoren 37, 44, 84 oder 88 gemessen werden kann, wobei letztere mit dem ringförmigen Raum 78 und/oder der Zuleitung 82 über die Leitung 86 bzw. 90 in Verbindung stehen.

Als Material für diesen Schlauch 66 werden hochelastische Materialien eingesetzt, beispielsweise organische Polymere und deren Gemische, wie Polyurethane Kautschuke, Silikonkautschuke, Latex, Gummi, regenerierter Gummi u. dgl. Vorzugsweise wird Latex einge-

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setzt, das ggf. übliche Zusatz- und die Elastizität verbessernde Mittel aufweist. Ein derartiger Schlauch 66 kann wenigstens um das Fünffache seines Lumens, insbesondere um das Zehnfache ausgedehnt werden, so daß er also — wenigstens in der bevorzugten Ausführungsform — das Zehnfache seines Innenvolumens zusätzlich aufnehmen kann.

Die Wandstärke eines derartigen Schlauches 66 liegt in einem Bereich von etwa 0,05—0,5, vorzugsweise 0,1—0,4 mm. Sie wird in Abhängigkeit von der gewünschten Druckcharakteristik und der Volumenerweiterung der einzusetzenden Pumpe 34 gewählt. Je dicker die Wandstärke des Schlauches 66 ist, desto höher ist der Anfangsdruck, der aufzuwenden ist, um zu dem über einen weiten Volumenbereich führenden Druckplateau zu kommen. Vorzugsweise wird die Wandstärke so gewählt, daß das Druckplateau oberhalb des in der Vene herrschenden Druckes, vorzugsweise über 20 mm Hg liegt. Dieser Druck muß also in der Venenleitung vorliegen, um überhaupt Blut in die Vene überführen zu können.

Das Schlauchvolumen und die Länge des Schlauches 66 richten sich nach dem Einsatzzweck sowie der Auslegung der Dialysevorrichtung. Üblicherweise wird der Durchmesser eines Schlauchs 66 in einem Bereich von 5—15, vorzugsweise etwa 8 mm liegen, während die Länge des Schlauchs 10—20, vorzugsweise ca. 15 cm betragen kann. Es sind jedoch aber auch kürzere oder längere Abmessungen denkbar, sofern dies der Einsatzzweck erfordert. Wenn nur geringe Blutvolumina befördert werden, wird man eine entsprechend geringer dimensionierte Pumpe mit einem entsprechend kleineren Schlauch einsetzen als bei größeren Blutumsätzen.

Bei der ersten in Fig. 2 gezeigten Ausführungsform weist der Schlauch 66 eine von der einen Endplatte 48 zur anderen Endplatte 46 abnehmende Wandstärke auf. Vorzugsweise nimmt die Wandstärke über die Gesamtlänge der Pumpe 34 um bis zu 50% ab. Ein derartig über seine Gesamtlänge im wesentlichen stetig in seiner Wanddicke abnehmender Schlauch kann dadurch erzeugt werden, daß man einen Stab in eine flüssige Latexmasse eintaucht und diesen Stab anschließend aus der flüssigen Latexmasse herauszieht. Durch den flüssigen Zustand dieser Latexmasse fließt ein Teil der an dem Schlauch hängenden Masse herunter, so daß die Wandstärke des dadurch hergestellten Schlauchs von einem Schlauchende zum anderen Schlauchende stetig zunimmt. Hierdurch steigt das Druckplateau, das sich beim Aufblähen des Schlauches 66 ergibt, nach dem abrupten Anstieg, wie aus Fig. 4 ersichtlich, ebenfalls stetig an.

Eine derartige in Fig. 2 dargestellte Anordnung eines Schlauches 66 mit abnehmender Wanddicke zieht die Anordnung der Öffnung 80, die mit der Hubkolbenpumpe 36 über die Zuleitung 82 in Verbindung steht, in der Nähe des Schlauchbereichs 72 nach sich, in dem der Schlauch 66 seine größte Wandstärke besitzt. Der Schlauch wird sich nämlich dort zuerst aufblähen, wo die Wandstärke des Schlauchs am geringsten ist, d. h. im Bereich der Endplatte 46. Dabei legt sich dieser Endbereich an die Speicherwand 68 an und füllt sich unter Bildung einer Wellenfront in Richtung auf das die größte Wandstärke aufweisende Schlauchende.

In Fig. 3 ist eine weitere Ausführungsform gezeigt, wobei für gleiche Teile die gleichen in Fig. 2 verwendeten Bezugszeichen eingesetzt werden. In dieser Ausführungsform kommt vorzugsweise ein Schlauch 66 zum Einsatz, dessen Wandstärke über seine Gesamtlänge im wesentlichen gleich ist. Die Verwendung dieser Ausführungsform ist jedoch nicht auf einen Schlauch mit im wesentlichen gleicher Wandstärke beschränkt, so daß auch Schläuche mit abnehmender Wandstärke, wie in Fig. 2 gezeigt, eingesetzt werden können.

Die Ausführungsform gem. Fig. 3 unterscheidet sich von der in Fig. 2 gezeigten Ausführungsform im wesentlichen dadurch, daß die Speicherwand 68 eine Vielzahl von Öffnungen 92 aufweist, die beliebig über dem Umfang und die Länge dieser Speicherwand 68 vorgesehen sind. Über diese Öffnungen 92 kann die Luft, die von der Hubkolbenpumpe 36 ab- oder zugepumpt wird, entweder entweichen oder aber zufließen.

Weiterhin ist bei der zweiten Ausführungsform eine weitere Außenwand 94 vorgesehen, deren Durchmesser größer ist als der Durchmesser der Speicherwand 68 und die im wesentlichen die gleiche Form wie die Speicherwand besitzt. Somit wird bei einer Zylinderform der beiden Wände 68 und 94 ein ringförmiger Raum 96 zwischen diesen beiden Wänden gebildet, der über die Öffnungen 92 mit dem ringförmigen Raum 78 in Verbindung steht. Die Außenwand 94 ist jeweils in ihrem Endbereich 98 und 100 mit den Endplatten 46 und 48 fest verbunden, wobei die gesamte Anordnung bis auf die in der Außenwand 94 vorgesehene Öffnung 102 als gasdicht anzusehen ist. Diese Öffnung 102 kann an beliebiger Stelle in der Außenwand 94 vorliegen, da sich der Schlauch 66 nur an die Speicherwand 68 anlegen kann und durch die Vielzahl der Öffnungen 92 sichergestellt ist, daß der Schlauch 66 beim Abpumpen der Luft nicht die Abströmöffnung zusetzt und dadurch ein weiteres Abpumpen von Luft verhindert.

Eine solche Ausführungsform ist insbesondere bei einem Schlauch mit gleichbleibender Wandstärke zweckdienlich, da dieser in aller Regel keine von einem Schlauchende zum anderen Schlauchende ablaufende Wellenbewegung mitmacht, sondern sich beim Füllen mit Blut an einer beliebigen Stelle erweitern kann. Durch diese Anordnung wird sichergestellt, daß auch hier eine gleichmäßige Füllung des Schlauches 66 bis zum Anlegen an die Speicherwand 68 erfolgt, wobei sich der Schlauch 66 über seine gesamte Länge an die Speicherwand 68 anlegen kann.

Die Öffnung 102 ist wiederum über die Leitung 104 mit der Hubkolbenpumpe 36 in Verbindung. Weiterhin sind ebenfalls wie in der ersten Ausführungsform Sensoren 84 und 88 vorgesehen, die über Leitungen 106 und 108 und entsprechende Öffnungen in der Außenwand 94 mit dem ringförmigen Raum 96 in Verbindung stehen.

Zweckmäßigerweise werden die Abmessungen des Schlauchs 66 so gewählt, daß der Raum 74 etwa 50—80 ml beträgt, während der elastische Schlauch 66 im drucklosen Zustand etwa 10—15 ml faßt.

Hinzuzufügen ist, daß als Material für den elastischen Schlauch 66 alle wasserundurchlässigen Materialien in Frage kommen, die eine entsprechend große Bruchdehnung (> 200%) aufweisen, wozu die vorstehend genannten Materialien gehören.

Als Material für die Speicherwand 68 und die Außenwand 94 kommen Materialien in Frage, die im wesentlichen starr sind. So sind beispielsweise Polymerisate, wie Polyethylen, Acrylglas, PVC u. dgl. einsetzbar.

Als Fluid für die ringförmigen Räume 78 und 96 setzt man üblicherweise Luft ein.

Wenn bei den vorstehend geschilderten Ausführungsformen Blut in den Schlauch 66 durch Erzeugung von Unterdruck mittels der Hubkolbenpumpe 36 eingepumpt wird, steigt der Druck anfangs nur geringfügig

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an, da der Schlauch 66 sich unter geringer Dehnung füllt und dabei das Volumen nur geringfügig zunimmt. Danach bläht sich der Schlauch 66 zunächst an der Stelle auf, die die geringste Wandstärke besitzt. Er legt sich dabei an die Speicherwand 68 solange an, bis die Luft aus dem gesamten Raum 78 verdrängt ist. Während bei der ersten Ausführungsform mit der abnehmenden Wandstärke des Schlauchs 66 die Dehnungsfronten sich in axialer Richtung ausbreiten und der aufzuwendende Unterdruck im wesentlichen gleich bleibt, verändert sich dieser stetig mit dem gemäß der zweiten Ausführungsform eingesetzten Schlauch 66, der eine im wesentlichen gleiche Wandstärke besitzt.

Wenn die Luft vollständig aus dem Raum 78 verdrängt ist, so daß der Schlauch 66 entsprechend der Linie 76 an der Speicherwand 68 anliegt, steigt der Druck sehr rasch an, da sich der Schlauch 66 nicht mehr verformen läßt.

In Fig. 4 ist die Druck/Volumen-Charakteristik eines Beispiels des ersten Druckspeichers in durchgezogener Linie gezeigt, während in gestrichelter Linie das Idealverhalten eines Druckspeichers mit gleichbleibender Wandstärke dargestellt ist. Das Diagramm bezieht sich natürlich auf das Blutvolumen, das bereits einem bei Normaldruck gefüllten Schlauch 66 zugeführt wird. Der gemäß der ersten Ausführungsform eingesetzte Schlauch ist durch Tauchen eines Stabes in ein Latexbad und langsames Herausziehen dieses Stabes hergestellt worden, was aus der stetig ansteigenden Druckcharakteristik in Abhängigkeit von zugeführten Blutvolumen zu ersehen ist.

Da sich im elastischen Schlauch 66 sowohl die Druck- als auch die Volumenverhältnisse verändern, können beide Parameter zur Steuerung der Pumpe 34 unabhängig voneinander oder zusammen eingesetzt werden.

In Fig. 5 ist eine spezielle Pumpanordnung mit 110 bezeichnet, die sowohl für die erste als auch die zweite Ausführungsform einsetzbar ist. Dabei ist die Wand 112, die der Speicherwand 68 bzw. der Außenwand 94 entspricht, mit einer Öffnung 114 durchsetzt, an die sich auf der Innenseite der Wand 112 der ringförmige Raum 78 bzw. 96 anschließt. Auf der Außenseite der Wand 112 steht die Öffnung 114 mit der Leitung 116 in Verbindung, die der Leitung 82 bzw. 104 entspricht.

Diese Leitung 116 weist an ihrem anderen Ende ein Paßstück 118, beispielsweise einen Flansch oder einen Luer-Konus auf, mit dem die Pumpe 34 mit einem weiteren Paßstück 120 gasdicht verbunden werden kann. An dieses weitere Paßstück schließt sich die Leitung 122 an, die mit der Balgpumpe 124 verbunden ist.

Unter Balgpumpe wird eine Pumpe mit konstantem Hubvolumen verstanden. Bevorzugt ist eine Balgpumpe 124, deren Hubvolumen größer ist als das Speichervolumen der Pumpe 34. Besonders bevorzugt ist eine Balgpumpe 124, deren Volumen bis zu 20% größer ist als das Speichervolumen der Pumpe 34.

Mittels dieser Balgpumpe 124 wird die Luft aus dem Innenbereich der Pumpe 34 abgesaugt und in den Balg 126 überführt.

Bei der Zwangssteuerung, bei der die Hubkolbenpumpe zwischen einem oberen und unteren Totpunkt, d. h. einem Höchst- und Tiefstdruckwert pendelt, sind diese Sensoren 84 und 88 nicht zwangsläufig notwendig. Setzt man nämlich eine Balgpumpe 124 mit konstantem Fördervolumen und konstanter, zuvor bestimmter Pumpgeschwindigkeit ein, so kann in der Leitung 122 ein Unterdruckventil 128 vorgesehen sein, das sich öffnet, wenn ein bestimmter Unterdruck in dieser Leitung erreicht ist. Vorzugsweise wird man dieses Unterdruckventil 128 so einstellen, daß dieses umschaltet, wenn sich der Schlauch 66 vollständig mit Blut angefüllt hat und sich an die Speicherwand 68 angelegt hat. Die Balgpumpe 124 schaltet dann selbsttätig am Totpunkt in ihrer Pumpfunktion um und schaltet zugleich an diesem Punkt die Klemmen 31, 38 und 42.

Es erfolgt darauf das Abpumpen von Blut aus dem Schlauch 66 entweder mittels der Balgpumpe 124 selbst oder aber durch Belüften der Leitung 122 durch ein nicht gezeigtes Ventil, wobei sich der Schlauch 66 infolge seiner elastischen Eigenschaften selbst entlädt.

Ist der Schlauch 66 völlig zusammengedrückt, so steigt der Druck in der Außenkammer stark an, sofern die Pumpe 126 weiterhin komprimiert, was der Fall ist, wenn das Hubvolumen der Pumpe größer ist als das Speichervolumen der Pumpe 34. In diesem Fall ist vorteilhafterweise ein Überdruckventil 132 in der Leitung 122 vorgesehen, über das die überschüssige Luft entweichen kann, so daß ein bestimmter Höchstdruckwert im System nicht überschritten wird. Am unteren Totpunkt der Balgpumpe 124 wird dann die Klemme 38 sowie die Venenklemme 42 geschlossen und die Arterienklemme 31 geöffnet.

Aus der vorstehenden Ausführung ist ersichtlich, daß kein Sensor zum Umsteuern der Hubkolbenpumpe benötigt wird. Dabei kann im Fehlerfall, d. h. bei Versagen einer Klemme oder beim Verstopfen der Leitungen kein Druck im Blutsystem auftreten, der größer ist als der durch das Überdruckventil 132 in der Pumpleistung bestimmte Maximaldruck. Da die Balgpumpe 124, sofern deren Hubvolumen größer ist als das Füllvolumen der Pumpe 34, immer mit einem Überschuß an Luft arbeitet, wird auch bei einer Undichtigkeit in der Pumpleitung 122 zwischen Balg 126 und dem Ausdehnungsraum 78 immer das volle Füllvolumen des Ausdehnungsraumes 78 gepumpt. Auf diese Weise erreicht man ein Pumpvolumen, das pro Hub dem Füllvolumen der Pumpe 34 entspricht. Aus der Zahl der Hübe, die man mittels eines nicht gezeigten Zählgeräts bestimmen kann, läßt sich direkt durch Multiplikation mit dem Pumpvolumen die durchgesetzte Menge bestimmen und anzeigen sowie aus derem zeitlichen Differential auch die Pumprate.

Bei der gesamten Anordnung ist es wenigstens nützlich festzustellen, ob eine Unterbrechung, beispielsweise ein Verstopfen oder Lösen der Leitung, an irgendeiner Stelle aufgetreten ist. Dies kann einerseits durch Überprüfung des Druckes in der Venen- oder Arterienleitung mittels der Drucksensoren 37 oder 44 erfolgen. Dieser Druck wird nämlich Schwankungen unterliegen, die aufgrund des Strömungswiderstandes der Leitung 26 bzw. 30 und der Nadel 20 unter Förderung von Blut in den entsprechenden Leitungen 26 und 30 auftreten. Diese Drucksensoren 37 und 44 sind mit einer nicht gezeigten zeitgesteuerten Überwachungseinrichtung in Verbindung, die bei einem unerwünschten Druckwert die gesamte Anlage ausschaltet.

Eine entsprechende Überwachungseinrichtung 131 kann jedoch auch bei dem gemäß Fig. 5 gezeigten Pumpsystem angeordnet sein. Diese Überwachungseinrichtung ist sowohl mit den Ventilen 128 und 132 als auch mit der Balg-Pumpe 124 verbunden. Dabei ersetzt diese Überwachungseinrichtung eine nicht gezeigte Einrichtung, die das Öffnen der Ventile 128 und 132 anzeigen kann. Ist beispielsweise eine der Leitungen 26 oder 30 blockiert, so wird der Ausdehnungsraum 78 nur mit einem bestimmten Blutvolumen gefüllt sein und sich ansonsten jedoch inkompressibel verhalten, da ja auf-

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grund der Blockierung Blut weder zu- noch abgeführt werden kann. Infolgedessen wird sich das Über- bzw. Unterdruckventil 128 bzw. 132 nicht bei dem vorgesehenen Bruchteil der Hubbewegung des Balges 126 bzw. nicht zum dafür vorgesehenen Zeitintervall in Abhängigkeit vom Zeitpunkt des Umschaltvorganges öffnen, sondern schon weit früher. In einem solchen Fall schaltet die Überwachungseinrichtung 131 die gesamte Anlage ab.

In einer weiteren Ausführungsform können die Drucksensoren 37 und 44 zu einem einzigen Drucksensor zusammengefaßt sein, der vorteilhafterweise in der Nähe des Y-Stücks 22 zwischen den Klemmen 31 und 42 liegt. Dieser Sensor kann wiederum mit der Überwachungseinrichtung 131 verbunden sein, wobei man in der Ansaugphase den dadurch hervorgerufenen negativen Druck ablesen kann, andererseits in der Druckphase den Überdruck bestimmen kann.

Die vorstehend erläuterte Anordnung läßt weiterhin die folgende Überwachungsautomatik für das Einregulieren der Pumpengeschwindigkeit zu: Ist die Ergiebigkeit des Shunts oder der Nadel 20 nicht groß genug im Vergleich zur eingestellten Pumpgeschwindigkeit, so wird bei der Expansion des Balges 126 ein Unterdruck auftreten, der wesentlich über einem für die Kombination aus Schlauchsystem und Nadel charakteristischen Wert liegt. Dies kann durch einen Drucksensor, beispielsweise den Sensor 37 oder 84 detektiert werden. Dieser Wert kann jedoch aber auch bei Vorhandensein eines Unterdruckventiles 128 durch den Öffnungszeitpunkt dieses Ventiles detektiert werden. Vorteilhafterweise kann man schließlich aber auch auf eine Detektion dieses Zustandes völlig verzichten, wobei man das Unterdruckventil bzw. den Umsteuerungssensor auf einen Wert stellt, der aufgrund der Daten des Schlauchsystems und der Nadel berechnet bzw. zuvor empirisch bestimmt werden kann. Ist die Ergiebigkeit des Shunts groß genug, so wird der Unterdruck diesen Wert erst überschreiten, wenn der Ausdehnungsraum 78 vollgefüllt ist. Ist dies nicht der Fall, so wird der Unterdruck diesen Wert bereits vorher überschreiten, wobei das Unterdruckventil 128 geöffnet und dadurch das Pumpvolumen und die Pumprate beschränkt werden. Somit erhält man eine Pumpvorrichtung, die mit einfachen Mitteln verfahrenstechnisch sicher ist, wobei die Pumpgeschwindigkeit optimal der Leistungsfähigkeit des Shunts angebracht ist. In diesem Fall wird man die Balgpumpe 124 mit hoher Geschwindigkeit arbeiten lassen und auf eine vollständige Füllung des Ausdehnungsraums 78 verzichten. Ein Ablesen der geförderten Blutmenge aus der Zahl der Pumphübe ist dann allerdings nicht mehr möglich.

Im übrigen ist zu bemerken, daß die Anordnung eines Drucksensors in der Blutleitung wesentlich kritischer ist als im Pumpensystem selbst. An der Pumpleitung 122 kann der Drucksensor fest angeschlossen werden, wobei die Gefahr von Undichtigkeiten im wesentlichen vernachlässigbar ist. Im übrigen kann der Sensor mit Umgebungsluft beaufschlagt werden, ohne daß hierdurch Kontaminationsgefahren entstehen. Insofern kann natürlich ein ungeschützter Sensor verwendet werden.

Um sicherzustellen, daß bei einem Platzen des Schlauchs 66 kein Blut in die Hubkolbenpumpe 36 dringt, weist in einer bevorzugten Ausführungsform jede von der Wand 68 und 94 abzweigende Leitung eine hydrophobierte Membran 136 auf, wie dies in Fig. 5 dargestellt ist. Eine derartige hydrophobierte Membran, beispielsweise auf der Basis von PTFE mit einer Dicke von 10—50 µm und einem Porendurchmesser von unterhalb 1 µm, hält das Blut bei den verwendeten Drükken von einem Ausströmen aus der Pumpe 34 zurück gestattet jedoch den ungehinderten Durchtritt von Luft.

Über eine derartige Drucksteuerung läßt sich natürlich die in der Pumpe 34 gespeicherte Blutmenge beliebig feststellen, sofern die eingesetzten Sensoren vorher entsprechend justiert und geeicht wurden. Weiterhin kann hierdurch eine bestimmte Blutmenge zyklisch durch den Dialysator 40 gepumpt werden, wobei die Pumpe 34 nicht vollgepumpt werden muß.

Das in Fig. 1 gezeigte Absperrorgan 38 kann wahlweise einen konstanten Öffnungsquerschnitt oder aber auch einen variablen Öffnungsquerschnitt aufweisen, was von der durchzulassenden Blutmenge abhängt. Bei im wesentlichen konstanten Druckplateau wird man ein Absperrorgan 38 mit konstantem Öffnungsquerschnitt einsetzen, um gleiche Förder- und Druckverhältnisse in der Venenleitung 30 herzustellen. Andererseits wird man bei einem ansteigenden Druckplateau, also bei über die Öffnungszeit der Absperrorgane 38 variierenden Druck- und Förderverhältnissen eine Klemme mit variierbarem Öffnungsquerschnitt einsetzen, um die durch die Venenleitung 30 geförderten Mengen im wesentlichen konstant zu halten. Dieser Öffnungsquerschnitt wird durch eine nicht gezeigte Steuerungseinrichtung, die druck- oder volumengesteuert sein kann, variiert.

Eine derartige Anordnung hat den Vorteil, daß der an dem Dialysator anliegende Druck nicht identisch ist mit dem Pumpdruck in der Pumpe 34, so daß der Dialysator mit erheblich niedrigeren, beliebig gegenüber dem Speicherdruck einstellbaren Drücken betrieben werden kann.

Die Pumpe 34 kann natürlich auch hinter dem Dialysator 40, d. h. in der Venenleitung 30 angeordnet sein, wobei natürlich das Absperrorgan 38 entfällt.

Weiterhin kann auch stromab des Dialysators eine zusätzliche Klemme angeordnet sein, die vorzugsweise einen variierbaren Öffnungsquerschnitt besitzt. In Verbindung mit dem Absperrorgan 38 kann somit in diesem Zweig, der den Dialysator umfaßt, ein beliebiger unterhalb dem sonstigen Betriebsdruck liegender Druck eingestellt werden.

In Fig. 6—8 sind weitere Ausführungsformen der erfindungsgemäßen Pumpe 34 gezeigt, in denen speziell die Befestigung des aufblähbaren Schlauchs 66 an den Endplatten 46 und 48 erläutert ist. Gemäß Fig. 6 ist der Innenschlauch 66 an der Endplatte 46 mit Hilfe eines Klemmrings 160 befestigt, der vorzugsweise eine konusförmige Gestalt zum leichteren Einschieben dieser Anordnung in die Ausnehmung 162 der Endplatte 46 aufweist. Der Durchmesser des Klemmrings 160 ist dabei so bemessen, daß der aufgeweitete Schlauch 66 sicher in der Ausnehmung 162 gehalten wird.

Beim Einsetzen wird zunächst der Schlauch 66 geweitet und über den Klemmring 160 gezogen. Anschließend wird diese Anordnung in der Endplatte 46 festgeklemmt. Die Speicherwand 68 läßt sich dann in die entsprechende ringförmige Nut 52 einsetzen. Danach wird der Schlauch 66 durch die Speicherwand 68 durchgezogen und mit einem entsprechenden Klemmring in die Endplatte 48 eingesetzt.

In Fig. 7 ist eine weitere Befestigungsart des Innenschlauchs 66 gezeigt. Dabei weist die Platte 46 auf ihrer Innenseite eine weite ringförmige Nut 164 auf, während die ringförmige Nut 52 für die Speicherwand 68 beibe-

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halten wird. Auf den durch die ringförmige Nut 164 in der Endplatte 46 gebildeten Rohransatz 166 wird der Schlauch 66 mit Hilfe eines Klemmrings 168 befestigt, wobei wiederum die aus dem Schlauch 66 und dem Klemmring 168 bestehende Anordnung auf diesen Rohransatz 166 formschlüssig aufgeschoben wird.

In Fig. 8 ist eine Abwandlung der in Fig. 7 erläuterten Ausführungsform dargestellt. Dabei weist der Rohransatz 166 an seinem unteren Ende einen olivenförmigen Wulst 170 auf, dessen Außenumfang etwas größer ist als der Innenumfang des Klemmrings 168. Dieser Klemmring 168 ist jedoch so elastisch, daß er zusammen mit dem Schlauch 66 über den Wulst 170 geschoben werden kann und durch den Wulst 170 fest in Stellung gehalten wird.

Die in Fig. 6–8 gezeigte Pumpe 34 kann natürlich auch die in Fig. 3 gezeigte Außenwand 94 aufweisen, was durch die strichpunktierten Linien angedeutet ist.

Weiterhin ist es bevorzugt, daß der Schlauch 66 axial in der Pumpe 34 vorliegt. Vorteilhafterweise wird der Schlauch 66 um mindestens etwa 10% seiner Gesamtlänge in Axialrichtung gedehnt, um ein Zusammenfallen zu verhindern. In Verbindung mit der vorstehend beschriebenen Querdehnung im Endbereich wird dadurch ein voll aufgespannter Schlauch 66 in der Pumpe 34 erhalten. Hierdurch erreicht man eine bessere Aufblähbarkeit des Schlauchs 66 im Betrieb. Zugleich wird ein Zusammenkleben der Schlauchwände durch fortschreitende Vulkanisierung im Lagerzustand vermieden.

Die erfindungsgemäße Pumpe 34 läßt sich ohne Probleme sterilisieren und wird bereits in Verbindung mit dem Schlauchsystem einsatzbereit dem Patienten zur Verfügung gestellt. Bettseitig muß lediglich noch die Hubkolbenpumpe an die Pumpe 34 angeschlossen werden.

In Fig. 9 ist schematisch ein Pumpensystem 180 gezeigt, das für eine übliche Vorrichtung zur Hämodialyse eingesetzt werden kann, die mit zwei Nadeln arbeitet. In einem solchen System wird kontinuierlich Blut aus der Arterie über die Leitung 26 abgepumpt und über die Leitung 30 wieder der Vene zugeführt. Da jedoch die Pumpe 34 nicht kontinuierlich beladen und zugleich entladen werden kann, sind entsprechend der in Fig. 10 gezeigten Ausführungsform wenigstens zwei Pumpen 182 und 184 vorgesehen, die durch die Pumpen 186 und 188 angetrieben werden.

Dabei können die Pumpen 182 und 184 den Pumpen gemäß Fig. 2 oder Fig. 3 entsprechen, während die zum Einsatz kommenden Pumpen 186 und 188 in Form der vorstehend beschriebenen Hubkolbenpumpen vorliegen können.

Die Zuführungsleitung 26 verzweigt sich stromauf der beiden Pumpen 182 und 184 in wenigstens zwei Leitungsäste 190 und 192 und führt stromab der Pumpen 182 und 184 über zwei Leitungsäste 194 und 196 in die Leitung 30 zurück. An den Verzweigungspunkten ist jeweils eine Schalteinrichtung 200 und 202 vorgesehen mit der wechselweise die Leitungen 26 bzw. 30 mit einer der Leitungen 190 oder 192 bzw. 194 oder 196 verbunden werden können. Vorzugsweise sind die Schalteinrichtungen gegenläufig geschaltet, d. h., daß beim Füllen des einen Zweiges der andere Zweig geleert werden kann und umgekehrt.

Als Schalteinrichtungen 200 und 202 können Drei-Wege-Ventile, Doppelklemmen usw. in Frage kommen, die mit dem Umsteuerungszeitpunkt der Pumpen 186 und 188 synchronisiert sind. So können diese Schalteinrichtungen entweder durch Sensoren umgeschaltet werden, die zugleich die Pumpen umschalten, oder aber zwangsläufig am Totpunkt der Balgpumpen geschaltet werden.

Weiterhin kann es vorteilhaft sein, daß die Pumpen 186 und 188 zu einer Pumpe zusammengefaßt sind, beispielsweise zu einer Balgpumpe, die mit einer Kolbenstange zwei Bälge gegenläufig betätigt.

Es muß nicht hinzugefügt werden, daß bei dem in Fig. 9 gezeigten Pumpensystem eine Druck- und Zwangssteuerung möglich sind.

Die Ventile oder Absperrorgane 128 und 132 können in einer weiteren Ausführungsform auch ohne elektrische Verbindung mit der Balgpumpe 124 allein durch eine mechanische Betätigung, beispielsweise durch nicht gezeigte Nocken, die auf dem Balg oder vorteilhafterweise auf dem Kolben der Balgpumpe angebracht sind, gesteuert werden. Durch eine entsprechende Verschiebbarkeit dieser Nocken kann der zweckmäßige Öffnungszeitpunkt und damit der Druckwert in der Leitung 122 eingestellt werden.

Besonders zu beachten ist weiterhin, daß bei Alarm, insbesondere beim Lösen der Förderleitung 26, neben dem Abschalten der wichtigsten Organe auch die Arterienklemme 31 geschlossen wird, so daß die vollständige Sicherheit des Patienten hergestellt ist.

Hierzu 5 Blatt Zeichnungen

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ZEICHNUNGEN BLATT 2

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Veröffentlichungstag: 17. Oktober 1985

Fig. 2

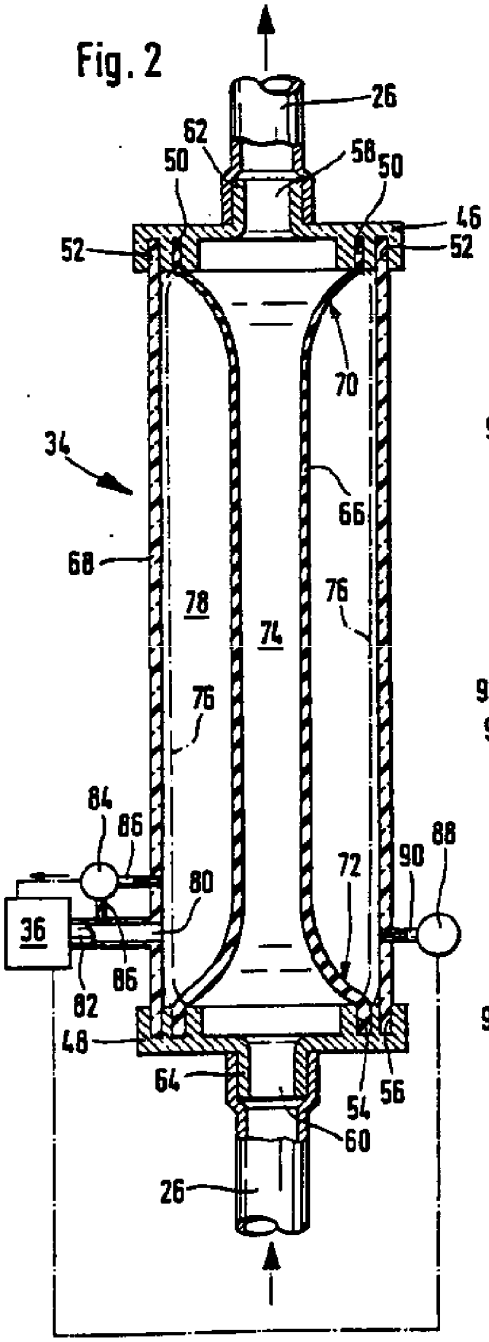
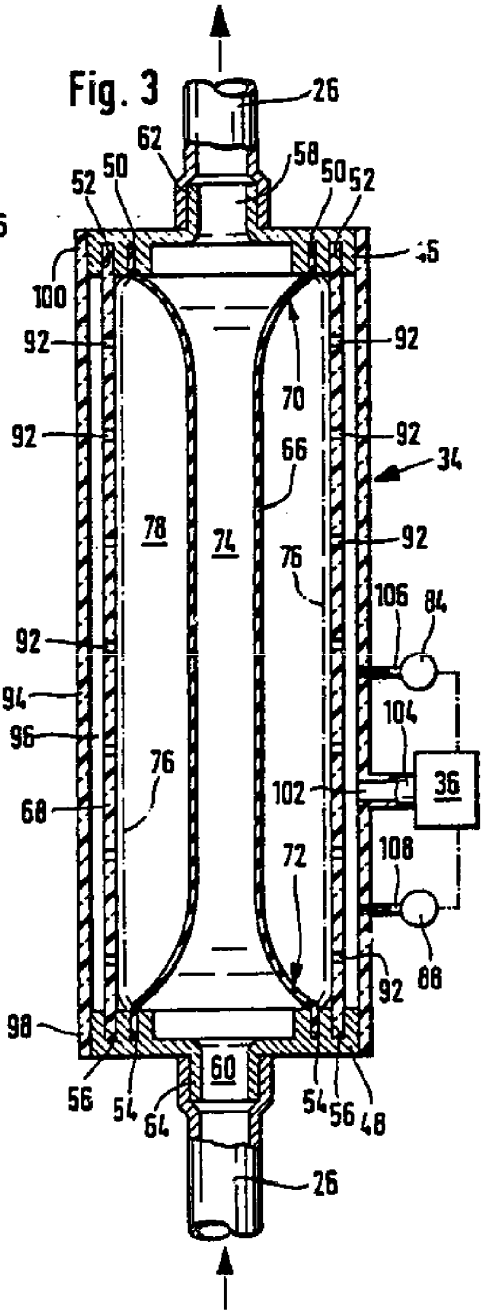


Fig. 3



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Page #567

ZEICHNUNGEN BLATT 3

Nummer: 32 05 449
Int. Cl.³: A 61 M 1/30
Veröffentlichungstag: 17. Oktober 1985

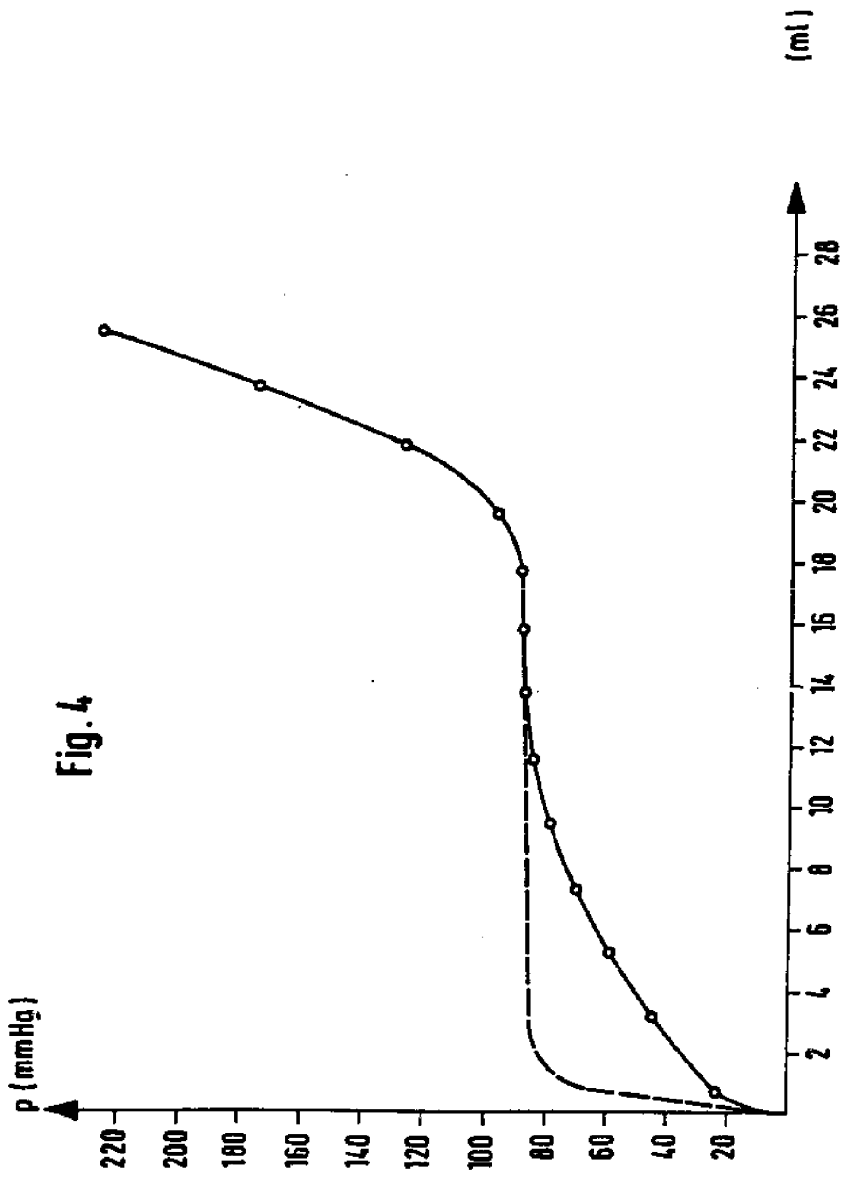


Fig. 4

Nummer: 32 05 449
Int. Cl.³: A 61 M 1/30
Veröffentlichungstag: 17. Oktober 1985

Fig. 5

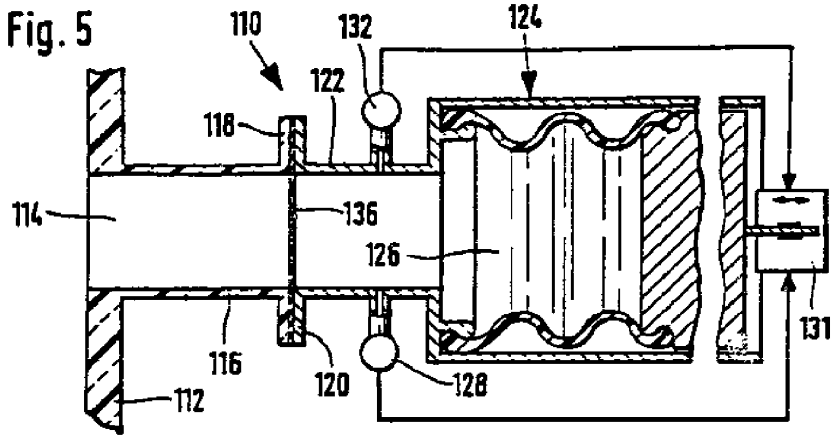


Fig. 6

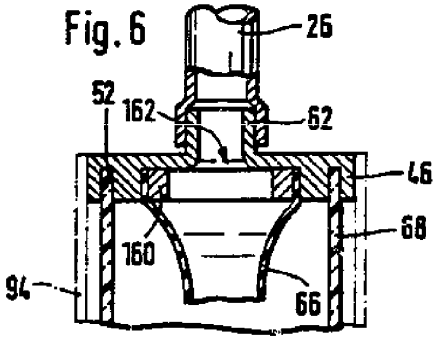


Fig. 7

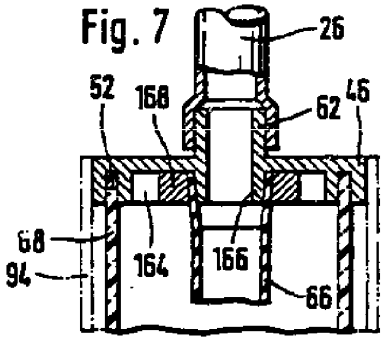
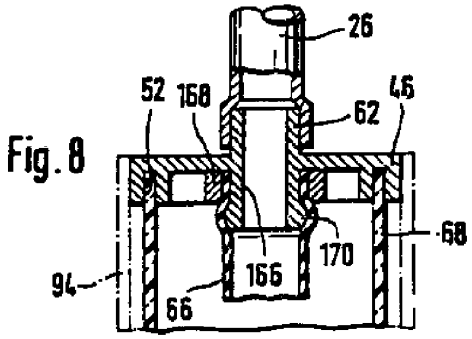


Fig. 8

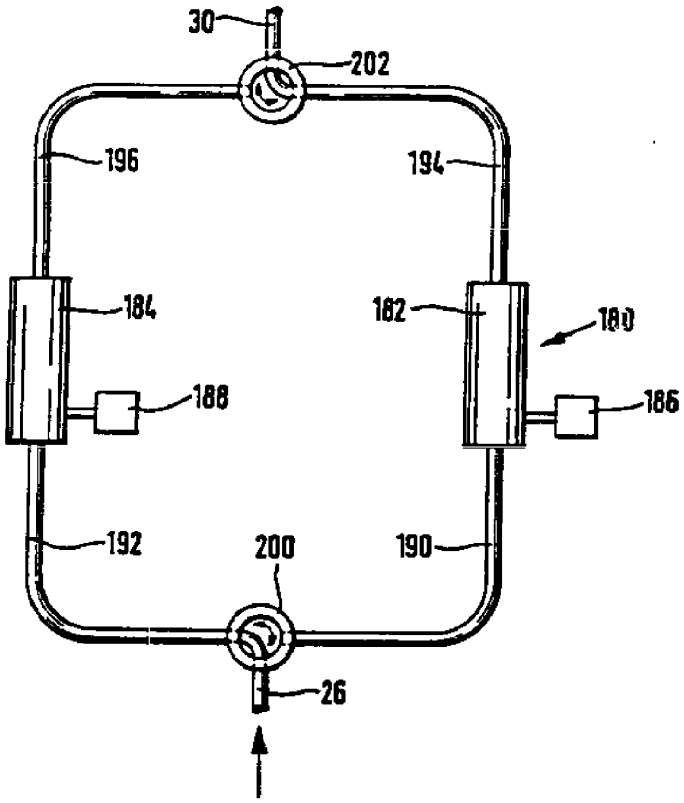


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Page #569

ZEICHNUNGEN BLATT 5

Nummer: 32 05 449
Int. Cl.³: A 61 M 1/30
Veröffentlichungstag: 17. Oktober 1985

Fig. 9



Electronic Patent Application Fee Transmittal

Application Number:	11989297
Filing Date:	24-Jan-2008
Title of Invention:	Wound closure and drainage system
First Named Inventor/Applicant Name:	Carmeli Adahan
Filer:	Susanne M. Hopkins/Lisa Elliott
Attorney Docket Number:	29068U

Filed as Small Entity

U.S. National Stage under 35 USC 371 Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
		Total in USD ($)		**180**

Electronic Acknowledgement Receipt

EFS ID:	10015761
Application Number:	11989297
International Application Number:	
Confirmation Number:	4766
Title of Invention:	Wound closure and drainage system
First Named Inventor/Applicant Name:	Carmeli Adahan
Customer Number:	20529
Filer:	Susanne M. Hopkins/Lisa Elliott
Filer Authorized By:	Susanne M. Hopkins
Attorney Docket Number:	29068U
Receipt Date:	04-MAY-2011
Filing Date:	24-JAN-2008
Time Stamp:	16:12:04
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$180
RAM confirmation Number	2879
Deposit Account	
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)

1	Information Disclosure Statement (IDS) Filed (SB/08)	sb0008.pdf	611796 0134ec3887bffa207ee473d57ca0043c3d066a66	no	4
Warnings:					
Information:					
2	Abstract	ABSTRACT_DE3205445.pdf	64563 261c47698b07950d1bf35ea243ed9265d8b4d1b0	no	1
Warnings:					
Information:					
3	Foreign Reference	DE3205445.pdf	881229 8dc2f6215d2ee6b7f84f5710cd1053199998 45f8	no	30
Warnings:					
Information:					
4	Foreign Reference	DE3205449.pdf	800451 2d550117f6fdd9af02dc022321238d9ea23e4544	no	13
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5	Fee Worksheet (PTO-875)	fee-info.pdf	29989 f1d17b6c4de87f21be2a552678ff08ad6490c754	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	2388028		

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.

<u>New Applications Under 35 U.S.C. 111</u>
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

<u>National Stage of an International Application under 35 U.S.C. 371</u>
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.

<u>New International Application Filed with the USPTO as a Receiving Office</u>
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.
11/989,297	01/24/2008	Carmeli Adahan	29068U	4766

20529 7590 04/20/2011

THE NATH LAW GROUP
112 South West Street
Alexandria, VA 22314

EXAMINER	
TREYGER, ILYA Y	
ART UNIT	PAPER NUMBER
3761	
MAIL DATE	DELIVERY MODE
04/20/2011	PAPER

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

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

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Page #575

Office Action Summary	Application No.	Applicant(s)	
	11/989,297	ADAHAN, CARMELI	
	Examiner	Art Unit	
	ILYA Y. TREYGER	3761	

-- 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* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, 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 *14 February 2011*.

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

3)☐ 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

4)☒ Claim(s) *1-53* is/are pending in the application.

4a) Of the above claim(s) *1-10 and 15-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-14 and 34-53* is/are rejected.

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

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

Application Papers

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

10)☒ The drawing(s) filed on *24 January 2008* 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).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

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).

a)☐ All b)☐ Some * c)☐ None of:

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) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/16/2010; 01/03/2011; 02/25/2011*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

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Exhibit 1008
Page #576

DETAILED ACTION

1. Claims 11-14 are amended representing new limitations.

2. Claims 34-53 are new representing new limitations.

3. Claims 11-14 and 34-53 are examined on the merits.

Response to Arguments

4. Applicant's arguments with respect to claims 11-14 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 11-13 and 34-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Lockwood et al. (US 2005/0004534).

7. In Re claims 11, 12, and 35-37, Lockwood discloses an enclosure for applying negative pressure to a wound, the enclosure being attachable to the wound circumference so as to define a confined volume (Abstract, lines 2-6), and comprising a tube 20 (page 5, [0070]; fig. 1), the enclosure having an enclosure outlet connectable to the vacuum source (Abstract, lines 9-10) via tube 20 (fig. 1) so that negative pressure may be created in said volume (Abstract, lines 5-6). The tube 20 comprises a venting arrangement 19 (Abstract, lines 7-8); page 5, [0069]; fig. 1) such that ambient air can enter said tube via the venting arrangement, wherein the ambient air

necessarily enters the tube 20 via the venting arrangement and flow to the vacuum source without entering the enclosure if the negative pressure is applied, and wherein the ambient air can flow together with the exuded liquids under the action of the negative pressure.

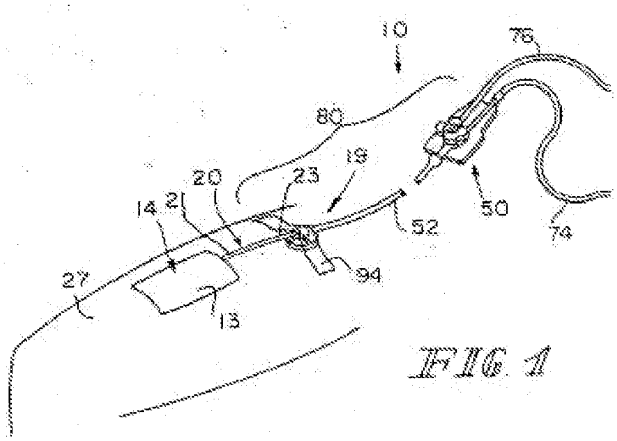


FIG. 1

8. In Re claim 13, Lockwood discloses the venting arrangement 19 (fig. 1) necessarily comprising a bleeding hole, since it has been disclosed as communicating with the surrounding atmosphere (Abstract, lines 7-8).

9. In Re claim 34, since the vent arrangement has been disclosed as being in communication with the ambient air, Lockwood discloses the vent arrangement that necessarily provides a restricted flow of ambient air therethrough and along the tube 20.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) 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.

12. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lockwood et al. (US 2005/0004534)

Lockwood discloses the invention discussed above, but does not expressly disclose the structure, wherein the bleeding holes are provided in the form of a porous body.

Since the porous body is a material comprising plurality of holes, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the plurality of holes in the form of porous body in order to simplify the production process, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin,* 125 USPQ 416.

13. Claims 38-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lockwood et al. (US 2005/0004534) in view of Argenta et al. (US 2001/0029956).

14. In Re claim 38, Lockwood discloses the invention discussed above but does not expressly disclose the system comprising a waste container.

Argenta teaches a wound treatment apparatus comprising a collecting vessel in fluid communication with the wound and connected to the vacuum source (page 4, [0036]).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to supply the apparatus of Lockwood with the collection vessel, as taught by Argenta in order to store the exudate, as motivated by Argenta (page 4, [0036], lines 21-22).

Lockwood in view of Argenta do not expressly disclose the apparatus wherein the waste container is connected to an outlet of the vacuum pomp unit.

Since shifting the position of the container would not have modified the operation of the device, it would have been obvious to one having ordinary skill in the art at the time the invention was made to connect the waste container to the outlet of the pump in order to position the container remotely from the patient, since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70 (**MPEP 2144.04 (VI-C)**).

15. In Re claims 39, 43 and 49, Lockwood discloses the assembly wherein the apparatus operates to drain the wound from fluids exuded therefrom, wherein the ambient air can enter said tube via said venting arrangement and flow together with the exuded liquids under the action of the negative pressure, a wherein the exuded fluid is fully capable of being stored in the waste container (Abstract, lines 1-10).

16. In Re claims 40, 44, 46 and 52, Lockwood discloses the venting arrangement necessarily comprising a bleeding hole, since it has been disclosed as communicating with the surrounding atmosphere (Abstract, lines 7-8).

17. In Re claims 41, 47 and 53, Lockwood in view of Argenta disclose the invention discussed above, as applied to claim 38, but do not expressly disclose the apparatus, wherein the bleeding holes are provided in the form of a porous body.

The rationale of obviousness rejection discussed above in claim 14 is incorporated herein in its entirety.

18. In Re claims 42 and 45, Lockwood discloses a vacuum system comprising an enclosure for applying negative pressure to a wound, the enclosure being attachable to the wound circumference so as to define a confined volume (Abstract, lines 2-6), and comprising a tube 20 (page 5, [0070]; fig. 1), the enclosure having an enclosure outlet connectable to the vacuum source (Abstract, lines 9-10) via tube 20 (fig. 1) so that negative pressure may be created in said volume (Abstract, lines 5-6). The tube 20 comprises a venting arrangement 19 (Abstract, lines 7-8); page 5, [0069]; fig. 1) such that ambient air can enter said tube via the venting arrangement, wherein the ambient air necessarily enters the tube 20 via the venting arrangement and flow to the vacuum source without entering the enclosure if the negative pressure is applied, wherein the ambient air can flow together with the exuded liquids under the action of the negative pressure, and wherein the vacuum source is fully capable of being detached from the system.

Lockwood does not expressly disclose the system comprising a waste container.

Argenta teaches a wound treatment apparatus comprising a collecting vessel in fluid communication with the wound and connected to the vacuum source (page 4, [0036]).

The rationale of obviousness rejection discussed above in claim 38 is incorporated herein in its entirety.

19. In Re claims 48, 50 and 51, Lockwood discloses a vacuum system comprising an enclosure for applying negative pressure to a wound, the enclosure being attachable to the wound circumference so as to define a confined volume (Abstract, lines 2-6), and comprising a tube 20 (page 5, [0070]; fig. 1), the enclosure having an enclosure outlet connectable to the vacuum source (Abstract, lines 9-10) via tube 20 (fig. 1) so that negative pressure may be created in said volume (Abstract, lines 5-6). The tube 20 comprises a venting arrangement 19 (Abstract, lines 7-8); page 5, [0069]; fig. 1) such that ambient air can enter said tube via the venting arrangement, wherein the ambient air necessarily enters the tube 20 via the venting arrangement and flow to the vacuum source without entering the enclosure if the negative pressure is applied, wherein the ambient air can flow together with the exuded liquids under the action of the negative pressure, and wherein the vacuum source is fully capable of being detached from the system.

Lockwood does not expressly disclose the system wherein the vacuum pump comprises a collection chamber upstream of a pump inlet of said vacuum source, and wherein said tube is connected to an inlet of said collection chamber.

Argenta teaches an apparatus wherein the vacuum pump comprises a collection chamber upstream of a pump inlet of said vacuum source, and wherein said tube is connected to an inlet of said collection chamber (page 4, [0036]; fig. 1).

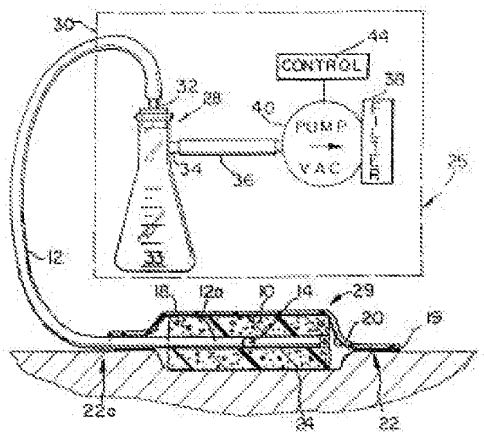


FIG. 1

The rationale of obviousness rejection discussed above in claim 14 is incorporated herein in its entirety.

Conclusion

20. 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 ILYA Y. TREYGER whose telephone number is (571)270-3217. The examiner can normally be reached on 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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

/Ilya Y Treyger/
Examiner, Art Unit 3761

/Michele Kidwell/
Primary Examiner, Art Unit 3761

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BIB DATA SHEET

CONFIRMATION NO. 4766

SERIAL NUMBER	FILING or 371(c) DATE RULE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
11/989,297	01/24/2008	604	3761	29068U

APPLICANTS
Carmeli Adahan, Jerusalem, ISRAEL;

**** CONTINUING DATA ************************* I.T. 06/22/2010**
This application is a 371 of PCT/IL2005/000784 07/24/2005

**** FOREIGN APPLICATIONS ************************* I.T. 06/22/2010**

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED **** ** SMALL ENTITY **
07/08/2009

Foreign Priority claimed ☑ Yes ☐ No 35 USC 119(a-d) conditions met ☐ Yes ☐ No Verified and Acknowledged /ILYA Y TREYGER/ Examiner's Signature	☐ Met after Allowance Initials	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
		ISRAEL	2	33	5

ADDRESS

THE NATH LAW GROUP
112 South West Street
Alexandria, VA 22314
UNITED STATES

TITLE

Wound closure and drainage system

FILING FEE RECEIVED		
1000	FEES: Authority has been given in Paper No._____ to charge/credit DEPOSIT ACCOUNT No._____ for following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	54	((CARMELI) near2 (ADAHAN)).INV.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/04/15 11:54
L2	12345	wound and (suction vacuum) and (enclosure dressing) and ((bleeding hole) (vacuum breaker))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 11:54
L3	881	(604/35).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 11:54
L4	784	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 11:54
L5	290	(604/313).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 11:54
L6	1923	(604/317-323).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 11:54
L7	1341	(604/540-544).CCLS.	US-PGPUB; USPAT	OR	OFF	2011/04/15 11:54
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Medela LLC and Medela AG
Exhibit 1008
Page #586

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L14	125	L2 and L7	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 11:54
L15	7	L2 and L8	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 11:54
L16	4	L2 and L9	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/15 11:54
L17	74	("1251258" | "3171410" | "3486504").PN. OR ("3874387").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/04/15 11:54
L18	114	("3026874" | "3486504" | "4540412" | "4759354" | "4969880").PN. OR ("5149331").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/04/15 11:54
L19	82	("4743232" | "5230350").PN. OR ("5344415").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/04/15 11:54
L20	174	("1355846" | "2547758" | "2632443" | "2682873" | "2969057" | "3367332" | "3648692" | "3682180" | "3826254" | "4080970" | "4096853" | "4139004" | "4165748" | "4245630" |	US-PGPUB; USPAT; USOCR	OR	OFF	2011/04/15 11:54

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		"4261363" | "4275721" | "4297995" | "4333468" | "4373519" | "4382441" | "4392853" | "4392858" | "4419097" | "4475909" | "4480638" | "4525166" | "4525374" | "4540412" | "4543100" | "4551139" | "4569348" | "4605399" | "4608041" | "4640688" | "4655754" | "4733659" | "4743232" | "4787888" | "4826949" | "4838883" | "4840187" | "4863449" | "4872450" | "4878901" | "4897081" | "4906233" | "4906240" | "4919654" | "4941882" | "4953565" | "4969880" | "4985019" | "5037397" | "5100396" | "5149331" | "5167613" | "5176663" | "5261893" | "5298015" | "5344415" | "5358494" | "5556375" | "5607388" | "5636643" | "5645081").PN. OR ("6071267").URPN.					

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EAST Search History (Interference)

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Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11989297	ADAHAN, CARMELI
	Examiner	Art Unit
	ILYA Y TREYGER	3761

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

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

CLAIM		DATE								
Final	Original	10/05/2010	04/15/2011							
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	11	✓	✓							
	12	✓	✓							
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	14	✓	✓							
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	34		✓							
	35		✓							
	36		✓							

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Page #590

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	Examiner	**Art Unit**
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CLAIM		DATE								
Final	Original	10/05/2010	04/15/2011							
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	39		✓							
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	46		✓							
	47		✓							
	48		✓							
	49		✓							
	50		✓							
	51		✓							
	52		✓							
	53		✓							

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	11989297	ADAHAN, CARMELI
	Examiner	Art Unit
	ILYA Y TREYGER	3761

SEARCHED			
Class	Subclass	Date	Examiner
604	540-544	10/5/2010	I. T.

SEARCH NOTES		
Search Notes	Date	Examiner
EAST Search attached	10/5/2010	I. T.
Search updated	4/15/2011	I. T.

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner

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

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	11989297
	Filing Date	2008-01-24
	First Named Inventor	ADAHAN
	Art Unit	3761
	Examiner Name	TREYGER
	Attorney Docket Number	29068U

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5116206	A	1992-05-26	ADAHAN	
	2	7503910	B2	2009-03-17	ADAHAN	

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Receipt date: 01/03/2011	Application Number	11989297 11989297 - GAU: 3761
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2008-01-24
	First Named Inventor	ADAHAN
	Art Unit	3761
	Examiner Name	TREYGER
	Attorney Docket Number	29068U

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	11989297
	Filing Date	2008-01-24
	First Named Inventor	Adahan
	Art Unit	3761
	Examiner Name	Treyger
	Attorney Docket Number	29068U

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	1	2002035111	JP	A	2002-02-05	Pigeon Corp	With English Abstract	☒
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Receipt date: 02/25/2011	Application Number	11989297	11989297 - GAU: 3761
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2008-01-24	
	First Named Inventor	Adahan	
	Art Unit	3761	
	Examiner Name	Treyger	
	Attorney Docket Number	29068U	

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Application Number	11989297
Filing Date	2008-01-24
First Named Inventor	ADAHAN
Art Unit	3761
Examiner Name	TREYGER
Attorney Docket Number	29068U

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5370610	A	1994-12-06	REYNOLDS	
	2	5662599	A	1997-09-02	REICH, et al.	
	3	6471982	B1	2002-10-29	LYDON, et al.	
	4	5636643	A	1997-06-10	ARGENTA, et al.	
	5	7128735	B2	2006-10-31	WESTON	
	6	6824533	B2	2004-11-30	RISK, JR., et al.	
	7	6562013	B1	2003-05-13	MARASCO, JR.	
	8	4447226		1984-05-08	MAYORAL	

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Receipt date: 11/16/2010	Application Number	11989297	11989297 - GAU: 3761
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99**)	Filing Date	2008-01-24	
	First Named Inventor	ADAHAN	
	Art Unit	3761	
	Examiner Name	TREYGER	
	Attorney Docket Number	29068U	

	9	4611627		1986-09-16	EIDSVOOG, et al.	
	10	1599899		1926-09-14	KETTERING, et al.	
	11	6071267	A	2000-06-06	ZAMICROWSKI	
	12	0599333		1898-02-22	HULSE	
	13	3416461		1968-12-17	McFARLAND	
	14	5419687	A	1995-05-30	ADAHAN	
	15	6042560	A	2000-03-28	NIEDERBERGER	
	16	6648862	B2	2003-11-18	WATSON	
	17	4739791		1988-04-26	ADAHAN	
	18	4930997		1990-06-05	BENNETT	
	19	4661093		1987-04-28	BECK, et al.	

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	First Named Inventor	ADAHAN	
	Art Unit	3761	
	Examiner Name	TREYGER	
	Attorney Docket Number	29068U	

	20	5645081	A	1997-07-08	ARGENTA, et al.	
	21	5776119	A	1998-07-07	BILBO, et al.	

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	1	20050004534	A1	2005-01-06	LOCKWOOD, et al.	
	2	20040039243	A1	2004-02-26	BEARNSON, et al.	
	3	20030014022	A1	2003-01-16	LOCKWOOD, et al.	
	4	20010029956	A1	2001-10-18	ARGENTA, et al.	
	5	20040199840	A1	2004-10-07	TAKEOKA, et al.	
	6	20050192548	A1	2005-09-01	DOLLIVER, et al.	
	7	20040064132	A1	2004-04-01	BOCHRINGER, et al.	

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Receipt date: 11/16/2010	Application Number	11989297	11989297 - GAU: 3761
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date	2008-01-24	
(**Not for submission under 37 CFR 1.99)**	First Named Inventor	ADAHAN	
	Art Unit	3761	
	Examiner Name	TREYGER	
	Attorney Docket Number	29068U	

	8	20020151826	A1	2002-10-17	RAMEY, et al.	
	9	20040059284	A1	2004-03-25	NASH, et al.	
	10	20030097100	A1	2003-05-22	WATSON	
	11	20030040687	A1	2003-02-27	BOYNTON, et al.	
	12	20030050594	A1	2003-03-13	ZAMICROWSKI	

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	1	03/030966	WO	A1	2003-04-17	HILL-ROM SERVICES, INC.		☐
	2	97/18007	WO	A1	1997-05-22	KCI MEDICAL LIMITED		☐
	3	102 15 896	DE	A1	2003-10-23	LEYBOLD VAKUUM GMBH	ABSTRACT	☒
	4	03/016719	WO	A1	2003-02-27	ADAHAN		☐

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Receipt date: 11/16/2010	Application Number	11989297 11989297 - GAU: 3761
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	First Named Inventor	ADAHAN
	Art Unit	3761
	Examiner Name	TREYGER
	Attorney Docket Number	29068U

	5	24 01 643	DT	A1	1975-07-17	TUCHENHAGEN	ABSTRACT	☒
	6	0 156 211	EP	A2	1985-10-02	FRESENIUS AG	ABSTRACT	☒
	7	00/02016	WO	A1	2000-01-13	DEKA PRODUCTS LIMITED PARTNERSHIP		☐
	8	96/05873	WO	A1	1996-02-29	MEDISCUS PRODUCTS LIMITED		☐
	9	2 378 734	GB	A	2003-02-19	ADAHAN		☐
	10	2 307 180	GB	A	1997-05-21	KCI MEDICAL LIMITED		☐
	11	03/057070	WO	A2	2003-07-17	HILL-ROM SERVICES INC.		☐

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	First Named Inventor	ADAHAN
	Art Unit	3761
	Examiner Name	TREYGER
	Attorney Docket Number	29068U

EXAMINER SIGNATURE			
Examiner Signature	/Ilya Treyger/	Date Considered	04/15/2011

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	1	2002035111	JP	A	2002-02-05	Pigeon Corp	With English Abstract	☒

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	Filing Date	2008-01-24
	First Named Inventor	Adahan
	Art Unit	3761
	Examiner Name	Treyger
	Attorney Docket Number	29068U

CERTIFICATION STATEMENT

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

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OR

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☐ See attached certification statement.

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

☐ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/Susanne M. Hopkins/	Date (YYYY-MM-DD)	2011-02-25
Name/Print	Susanne M. Hopkins	Registration Number	33,247

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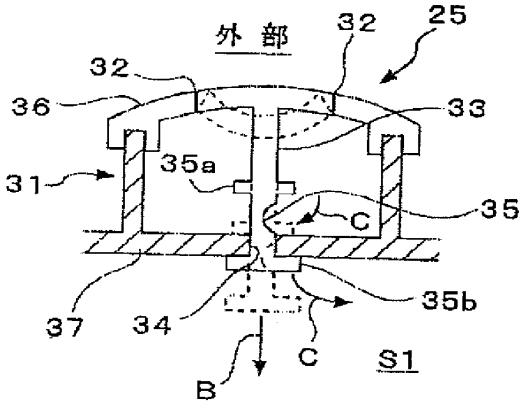
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(54)【発明の名称】　脈動搾乳器

(57)【要約】
【課題】　脈動における圧力変化を小さくして、使用に無理のない圧力変化を実現できる脈動搾乳器を提供すること。
【解決手段】　フードの開口を塞いだ状態で真空引き手段により陰圧が形成される陰圧形成空間を備える脈動型搾乳器１０であって、この陰圧形成空間と外部空間との間に設けられる小部屋３１と、前記外部空間と前記小部屋とを開閉する小部屋開閉手段３２及びこの小部屋３１と前記陰圧形成空間とを開閉する内部開閉手段とを備えており、前記真空引き手段が連続吸引した状態で、前記陰圧形成空間の陰圧が一定以上の大きさとなると、前記小部屋３１内の空気を前記陰圧形成空間に導く構成とした陰圧調整手段２５を有する。



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【特許請求の範囲】

【請求項１】　フードの開口を塞いだ状態で真空引き手段により陰圧が形成される陰圧形成空間を備える脈動型搾乳器であって、

この陰圧形成空間と外部空間との間に設けられる小部屋と、

前記外部空間と前記小部屋とを開閉する小部屋開閉手段及びこの小部屋と前記陰圧形成空間とを開閉する内部開閉手段とを備えており、

前記真空引き手段が連続吸引した状態で、前記陰圧形成空間の陰圧が一定以上の大きさとなると、前記小部屋内の空気を前記陰圧形成空間に導く構成とした陰圧調整手段を有することを特徴とする、脈動搾乳器。

【請求項２】　前記フードの内部空間が前記陰圧形成空間と連通しており、

前記フードに前記陰圧調整手段を設けたことを特徴とする、請求項１に記載の脈動搾乳器。

【請求項３】　前記弁手段の小部屋開閉手段と内部開閉手段とが択一的に開閉される構成としたことを特徴とする、請求項１または２のいずれかに記載の脈動搾乳器。

【請求項４】　前記真空引き手段が連続吸引した状態で、前記陰圧形成空間の陰圧が一定以上の大きさとなると、前記内部開閉手段を開いて小部屋内の空気を前記陰圧形成空間に導き、陰圧形成空間の陰圧が小さくなると、小部屋開閉手段を開いて小部屋内に外部の空気を導入することを特徴とする、請求項１ないし３のいずれかに記載の脈動搾乳器。

【請求項５】　一端が開放されたフード部と、

このフード部の他端が接続され、前記フード部の内部空間と連続した空間を有する本体部と、

この本体部に設けられ、本体の空間を陰圧形成空間とする真空引き手段と、

この本体部もしくは前記フード部に設けられる陰圧調整手段と

を有しており、

前記陰圧調整手段が、

前記陰圧形成空間と外部空間との間に設けられる小部屋と、

前記外部空間と前記小部屋とを開閉する小部屋開閉手段と、

この小部屋と前記陰圧形成空間とを開閉する内部開閉手段とを備えており、

前記真空引き手段が連続吸引した状態で、前記陰圧形成空間の陰圧が一定以上の大きさとなると、前記小部屋内の空気を前記陰圧形成空間に導く構成とされており、

かつ前記本体部には、母乳の収容容器が接続され、

前記本体部と前記母乳の収容容器の間を開閉する陰圧空間の限定手段を備えることを特徴とする、脈動搾乳器。

【請求項６】　前記小部屋が、フード部の側面から一体に起立される壁部と、

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この壁部の上端を塞ぐ柔軟な材料で形成した蓋部と、

この蓋部の裏面から小部屋内に延びており、先端がフード部の側面を貫通して貫通孔を開閉する拡径部を有するタクト部とを備えることを特徴とする、請求項５に記載の脈動搾乳器。

【請求項７】　前記小部屋が、フード部の側面から一体に起立される壁部と、

この壁部の上端を塞ぐ蓋部と、

この蓋部の裏面から小部屋内に延びており、先端がフード部の側面を貫通し、他端が前記蓋部を貫通するタクト部とを有しており、

前記内部空間の陰圧の大きさに対応して、前記タクト部が移動することにより、タクト部の前記各端部が前記内部開閉手段と小部屋開閉手段を択一的に開閉することを特徴とする、請求項５に記載の脈動搾乳器。

【発明の詳細な説明】

【０００１】

【発明の属する技術分野】この発明は、母乳を搾乳するための搾乳器に係り、特に、簡単な構成で脈動動作を行うことができる脈動搾乳器に関するものである。

【０００２】

【従来の技術】従来、この種の脈動搾乳器としては、例えば、本出願人による特公平３－６２１０６号に記載のものが知られている。すなわち、この搾乳器は、乳房を当てる開口を備えたフードに往復運動する弁手段を備えた圧力調整手段が設けられている。

【０００３】そして、フード内を真空引きすることで、フード内の陰圧が大きくなると、上記弁体の動作により、フード内が大気開放されるのようになっている。この動作を繰り返し行うことにより、脈動的に母乳を吸引することができるようにされているとともに、上記弁体の動作トルクを調整することで、脈動の圧力を変化させることができるようにされたものである。

【０００４】

【発明が解決しようとする課題】しかしながら、このような従来の脈動搾乳器においては、フード内の空間と外部の空間の直接的に開閉する弁手段を用いていることから、大気開放した時に流入する空気量が一定せず、精密な圧力調整が困難であるという問題がある。すなわち、フード内等の陰圧空間へ流入する空気量は、脈動における負圧の大きさの変化と関係し、脈動時の負圧の変化幅が大きいと、搾乳器を使用する母親の乳房への刺激が大きくなってしまう。

【０００５】また、従来の搾乳器において、圧力調整手段の弁体の動作トルクを調整する機構を設けることは、圧力調整手段の構造を複雑にし、故障の原因となるとともに、使い慣れない母親等にとっては、自分で自己に適する圧力に調整することは困難があるという欠点があった。

【０００６】本発明は、このような問題を解決するため

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になされたもので、脈動における圧力変化を小さくして、使用に無理のない圧力変化を実現できる脈動搾乳器を提供すること目的としている。

【０００７】

【課題を解決するための手段】上記目的は、請求項１の発明によれば、フードの開口を塞いだ状態で真空引き手段により陰圧が形成される陰圧形成空間を備える脈動型搾乳器であって、この陰圧形成空間と外部空間との間に設けられる小部屋と、前記外部空間と前記小部屋とを開閉する小部屋開閉手段及びこの小部屋と前記陰圧形成空間とを開閉する内部開閉手段とを備えており、前記真空引き手段が連続吸引した状態で、前記陰圧形成空間の陰圧が一定以上の大きさとなると、前記小部屋内の空気を前記陰圧形成空間に導く構成とした陰圧調整手段を有する、脈動搾乳器により、達成される。

【０００８】請求項１の構成によれば、陰圧形成空間と外部空間との間に小部屋を設けて、陰圧形成空間内には、この小部屋を介して空気が流れこむようにされている。これにより、脈動動作における圧力変化の際に、陰圧形成空間へ流れ込む空気量を小部屋の大きさにより制限することができる。このため、陰圧が増大した状態から、外部に直接大気開放される場合と比べて、空気が流れ込む量が少なくしかも一定しているので、脈動動作における圧力変化を小さくすることができるとともに、安定させることができる。したがって、従来のように、大きな圧力変化により使用者が痛みを覚えることがなく、また、圧力変化も一定しているので、この点においても、不安定な圧力変化による不意の痛みや不快感を防止することができる。

【０００９】請求項２の発明は、請求項１の構成において、前記フードの内部空間が前記陰圧形成空間と連通しており、前記フードに前記陰圧調整手段を設けたことを特徴とする。請求項２の構成によれば、陰圧調整手段を例えば、真空引き手段等を内蔵する本体内でなくフード部に設けることから、構成が簡単になり、故障を起こしにくく、さらに、動作不良の際等にもフードを交換することにより修理できる利点がある。

【００１０】請求項３の発明は、請求項１または２の構成において、前記弁手段の小部屋開閉手段と内部開閉手段とが択一的に開閉される構成としたことを特徴とする。

【００１１】請求項３の構成によれば、前記陰圧形成空間に、正確に小部屋の容積分だけの空気を送り込むことができるので、圧力変化をより正確に一定に保つことができる。

【００１２】請求項４の発明は、請求項１ないし３のいずれかの構成において、前記真空引き手段が連続吸引した状態で、前記陰圧形成空間の陰圧が一定以上の大きさとなると、前記内部開閉手段を開いて小部屋内の空気を前記陰圧形成空間に導き、陰圧形成空間の陰圧が小さくなると、小部屋開閉手段を開いて小部屋内に外部の空気を導入することを特徴とする。

【００１３】請求項４の構成によれば、真空引き手段は、連続動作するだけで、正確な脈動を行うことができる。

【００１４】また、上記目的は、請求項５の発明によれば、一端が開放されたフード部と、このフード部の他端が接続され、前記フード部の内部空間と連続した空間を有する本体部と、この本体部に設けられ、本体の空間を陰圧形成空間とする真空引き手段と、この本体部もしくは前記フード部に設けられる陰圧調整手段とを有しており、前記陰圧調整手段が、前記陰圧形成空間と外部空間との間に設けられる小部屋と、前記外部空間と前記小部屋とを開閉する小部屋開閉手段と、この小部屋と前記陰圧形成空間とを開閉する内部開閉手段とを備えており、前記真空引き手段が連続吸引した状態で、前記陰圧形成空間の陰圧が一定以上の大きさとなると、前記小部屋内の空気を前記陰圧形成空間に導く構成とされており、かつ前記本体部には、母乳の収容容器が接続され、前記本体部と前記母乳の収容容器の間を開閉する陰圧空間の限定手段を備える、脈動搾乳器により、達成される。

【００１５】請求項５の構成によれば、脈動動作における圧力変化の際に、フード部の内部空間へ流れ込む空気量を小部屋の大きさにより制限することができる。このため、陰圧が増大した状態から、外部に直接大気開放される場合と比べて、空気が流れ込む量が少なく、しかも一定しているので、脈動動作における圧力変化を小さくすることができるとともに、安定させることができる。しかも、本体部の真空引き手段は、連続動作するだけで、正確な脈動を行うことができる。そして、この脈動動作が開始されるに際して、陰圧空間の限定手段により、陰圧を形成すべき空間が小さく限定されることで、脈動の立ち上がりが速やかに行われる。

【００１６】請求項６の発明は、請求項５の構成において、前記小部屋が、フード部の側面から一体に起立される壁部と、この壁部の上端を塞ぐ柔軟な材料で形成した蓋部と、この蓋部の裏面から小部屋内に延びており、先端がフード部の側面を貫通して貫通孔を開閉する拡径部を有するタクト部とを備えることを特徴とする。

【００１７】請求項７の発明は、請求項５の構成において、前記小部屋が、フード部の側面から一体に起立される壁部と、この壁部の上端を塞ぐ蓋部と、この蓋部の裏面から小部屋内に延びており、先端がフード部の側面を貫通し、他端が前記蓋部を貫通するタクト部とを有しており、前記内部空間の陰圧の大きさに対応して、前記タクト部が移動することにより、タクト部の前記各端部が前記内部開閉手段と小部屋開閉手段を択一的に開閉することを特徴とする。

【００１８】

【発明の実施の形態】以下、この発明の好適な実施形態

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を添付図面を参照しながら、詳細に説明する。尚、以下に述べる実施形態は、本発明の好適な具体例であるから、技術的に好ましい種々の限定が付されているが、本発明の範囲は、以下の説明において特に本発明を限定する旨の記載がない限り、これらの態様に限られるものではない。

【００１９】図１は、本発明の実施形態による脈動搾乳器の全体構成を示す概略断面図である。図において、脈動搾乳器１０（以下、「搾乳器１０」と略称する）は、母乳の収容容器として、例えば、哺乳瓶の瓶本体１５に取り付けた状態が示されている。すなわち、搾乳器１０は、本体部１１とフード部１２とを有している。フード部１２は一端が拡径された広口の開口１２ａを備えており、斜めに延びる筒状の内部空間Ｓ１を備えている。フード部１２の他端側は、容器の方向へ向かうように曲げられた通路１２ｂを備えている。

【００２０】フード部１２の下端はリング状の蓋体１３とされており、この蓋体１３の内周に形成されたメネジが、瓶本体１５の上端開口の周囲に形成されたオネジと螺合されている。尚、この搾乳器１０は、哺乳瓶だけでなく、蓋体１３と接続できるあらゆる形態の容器に取り付けることができる。また、瓶本体１５の上端開口内側には、短い筒状の部材１９が配置されており、この部材は後述する陰圧空間の限定手段を構成している。この筒状の部材１９は、その上端のフランジ部１９ａがフード部１２の段部と瓶本体１５の上端との間に挟み込まれるようにして着脱自在に取付けられてる。この陰圧空間限定手段１９の下端は、開閉蓋１８が形成されており、この開閉蓋１８を図示の実線のように閉めた状態では、瓶本体１５の内部空間Ｓ４との間に仕切りとなって内部空間Ｓ３を閉じることになる。

【００２１】フード部１２の通路１２ｂに隣接して、垂直な筒状の接合部１４が一体に設けられており、内部空間Ｓ２が形成された本体１１がこの接合部１４に取り付けられている。本体１１の図において上部の筐体には、図示しないバッテリや、このバッテリにより駆動されるモータ等と、これにより駆動されるダイヤフラム等の電動部が収容されており、内部空間Ｓ２を真空引きするための手段１１ａを構成している。この真空引き手段１１ａは、連結部２２を介して、空気通路となった接続部２３に接続されており、上記内部空間Ｓ２に連通している。

【００２２】また、真空引き手段１１ａの下には、上記内部空間Ｓ２に接続された圧力開放ボタン１６が配置されている。圧力開放ボタン１６は、頭部１６と頭部１６の裏側中心部から貫通孔１６ｃを通って内部空間Ｓ２に入り込む弁体１６ａと、弁体１６ａの先端に形成され、内部空間Ｓ２に位置する閉止部１６ｂを有している。

【００２３】また、圧力開放ボタン１６は、頭部１６の裏側周縁に沿って複数設けられ、頭部１６の裏側周縁と本体側との間に配置された付勢手段１７，１７を有している。付勢手段１７，１７は例えば、弾性を有するバネ状の部材で、頭部１６が、使用者の手指等により、矢印Ａの方向に押し込まれると変形して弁体１６ａを内部空間Ｓ２の方向に移動させて、その閉止部１６ｂが外気と連通した上記貫通孔１６ｃを開放する。これにより、内部空間Ｓ２には外部の空気が入り込む。また、手指を離すと、付勢手段１７，１７はその弾性に基づいて、図示されているように延びるから、弁体１６ａを内部空間Ｓ２から離れる方向に移動させ、図示されているように閉止部１６ｂは貫通孔１６ｃを塞いで、内部空間Ｓ２を密閉するようになっている。

【００２４】かくして、搾乳器１０では、フード部１２の開口に、例えば母親等が乳房（図示せず）を当てて、本体１１の電動部の図示しないスイッチをオンさせることにより、真空引き手段１１ａが作動して、内部空間Ｓ２と、この内部空間Ｓ２が連通している内部空間Ｓ３と、この内部空間Ｓ３が連通しているフード部１２の内部空間Ｓ１内の空気を吸引して陰圧空間とするようになっている。この陰圧により母親の乳房から絞られた母乳は、フード部１２の内部空間Ｓ１を通り、通路１２ｂから下に導かれて、筒状の部材１９（陰圧空間の限定手段）内に一時貯留される。そして、開閉蓋１８を図示の点線のように開くと、母乳は瓶本体１５内に落下して貯留されるようになっている。すなわち、陰圧空間の限定手段１９は、瓶本体１５の内側に図示するように装着される有底筒体でなっており、この底部が開閉蓋１８となっている。この底部は、例えば、ある程度弾性を備えた筒体の底部をその周方向に沿って、一部を残して切り離した構成であり、この切り離されていない一部がヒンジとして機能する。これにより、開閉蓋１８は構造的には、その剛性に基づいて閉じており、内部空間Ｓ３内の陰圧が高まると、開閉蓋１８を閉じる力は大きくなる。しかしながら、開閉蓋１８が閉じた状態で、搾乳された母乳が筒状の部材１９内にある程度貯留されると、その重さにより、開閉蓋１８は開かれる。尚、陰圧空間の限定手段の開閉蓋１８が開かれていると、真空引き手段１１ａは、瓶本体１５の内部空間Ｓ４を含む広い容積の空間を真空引きする必要がある。

【００２５】ここで、搾乳器１０では、フード部１２の側面に陰圧調整手段２５を備えることにより、上記陰圧が一定周期で変化する脈動をつくり出すことができる。次に、この陰圧調整手段２５の構成を説明する。ここで、陰圧調整手段は、フード部１２の側面だけでなく、陰圧を形成する空間であるＳ２，Ｓ３のいずれの箇所に対応して設けてもよい。しかしながら、この実施形態では、フード部１２が搾乳器１０の本体１１と取り外しができることや、フード部１２が外部に大きく突出して、広い側面を持つので、陰圧調整手段はの取り付けが簡単であること等から、構成が簡単となり、故障の際の修理

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等も容易となる。

【００２６】図２及び図３は、陰圧調整手段の第１の実施形態を示しており、図２はその上面図、図３は図２のＢ－Ｂ線概略断面図である。図において陰圧調整手段２５は、外部空間に突出するように設けられた小部屋３１を有している。小部屋３１は、比較的小さな容積の部屋であって、外部空間と陰圧形成空間であるフード１２の内部空間Ｓ１との間に設けられる。小部屋の容積は、搾乳器１０の構造によって変わるが、この実施形態では、例えば、小部屋３１は、陰圧が形成される空間の２０パーセントである程度の容量とされている。

【００２７】小部屋３１を形成する円筒状の壁の上端は、柔軟な屋根状の蓋部３６により塞がれている。この蓋部３６は、合成ゴム材料等により上方に凸となるようなドーム状の形成でなり、柔軟な性質を備えている。蓋部３６には、図２に示されているように、例えば２箇所の十字状の切り込み部３２，３２が設けられており、図示の状態では、切り込み部３２，３２は閉じている。この実施形態では、この切り込み部３２，３２が、外部空間と前記小部屋とを開閉する小部屋開閉手段を構成している。蓋部３６の裏面の切り込み部３２，３２の開のほぼ中心付近には、図３に示されているように、小部屋３１の内部空間に向かって、柱状のロッドもしくはタクト部３３が一体に延びている。タクト部３３の下端は、フード部１２の壁３７を貫通する貫通孔３４を通って内部空間Ｓ１と連通している。タクト部３３の下端には、第１の拡径部３５ｂが形成されており貫通孔３４の内部空間Ｓ１側周縁に対して、この第１の拡径部３５ｂが当接することにより、貫通孔３４を塞ぐとともに、タクト部３３の下端も貫通孔３４から外側に抜けないようになっている。

【００２８】タクト部３３の第１の拡径部３５ｂよりも上の位置で、少なくともフード部１２の壁３７の厚み分よりも離れた箇所には、タクト部３３の軸状の側面を切り欠いて形成された縮径部３５が設けられている。この縮径部３５よりも上方には、第２の拡径部３５ａが形成されている。この実施形態では、この縮径部３５と貫通孔３４とで、小部屋と陰圧形成空間とを開閉する内部開閉手段を構成している。

【００２９】陰圧調整手段の第１の実施形態は以上のように構成されており、図１で説明したように、真空引き手段１１ａの動作により、フード１２の内部空間Ｓ１の空気が連続的に吸引されて陰圧とされる。この陰圧が一定以上大きくなると、タクト部３３が矢印Ｂの方向に引かれる。これにより、第１の拡径部３５ｂが下に引かれて、貫通孔３４の周縁から離れると同時に、この貫通孔３４の位置には、タクト部３３の縮径部３５が移動してくるので、貫通孔３４は開放される。これにより、小部屋３１内の空気は、矢印Ｃに示すように、内部空間Ｓ１に導入される。そして、貫通孔３４にタクト部３３に設けられた第２の拡径部３５ａが当たり、縮径部３５が内部空間Ｓ１内に入り込んで、貫通孔３４が閉じると、蓋部３３の切り込み部３２，３２との間の領域がタクト部３３に引っ張られて点線で示すように変形する。このため、切り込み部３２，３２は開いて、外部の空気が小部屋３１内に侵入する。

【００３０】この動作により、フード１２内の内部空間Ｓ１へは、小部屋３１の収容していた空気が流れ込むことから、陰圧が小さくなり、タクト部３３を下に引く力が弱まるから、蓋部３６の弾性に基づいて、図３の実線の状態に戻る。そして、真空引き手段１１ａが、再び内部空間Ｓ１の陰圧を大きくすると、上記の動作を繰り返すことになり、後述するような脈動が生じて、フード部１２内の陰圧は周期的に変化し、この周期的変化に基づいて、母乳が吸引される。

【００３１】図４ないし図７は、陰圧調整手段の第２の実施形態を示しており、図４はその外部空間と前記小部屋とを開閉する小部屋開閉手段を開いた状態の上面図、図５は図４のＣ－Ｃ線概略断面図、図６はその外部空間と前記小部屋とを開閉する小部屋開閉手段を閉じた状態の上面図、図７は図６のＣ－－Ｃ線概略断面図である。これらの図において陰圧調整手段４０は、外部空間に突出するように設けられた小部屋４１を有している。小部屋４１は比較的小さな容積の部屋であって、外部空間と陰圧形成空間であるフード１２の内部空間Ｓ１との間に設けられる。

【００３２】小部屋４１を形成する円筒状の壁の上端は、柔軟な屋根状の蓋部４６により塞がれている。この蓋部４６は、合成ゴム材料等により上方に凸となるようなドーム状の形成でなり、柔軟な性質を備えている。蓋部４６には、図４に示されているように、やや偏心した位置に湾曲した切り込み部４２が設けられており、図４の状態では、切り込み部４２は開いており、図６の状態では、切り込み部４２は閉じている。

【００３３】この実施形態では、この切り込み部４２が、外部空間と前記小部屋とを開閉する小部屋開閉手段を構成している。蓋部４６の裏面の切り込み部４２よりも中心によった位置には、図５に示されているように、小部屋４１の内部空間に向かって、柱状のロッドもしくはタクト部４３が一体に延びている。タクト部４３の下端は、フード部１２の壁３７を貫通する貫通孔３４を通って内部空間Ｓ１と連通している。タクト部４３の下端には、拡径部４７が形成されており貫通孔３４の内部空間Ｓ１側周縁に対して、この拡径部４７が当接することにより、貫通孔３４を塞ぐとともに、タクト部４３の下端も貫通孔３４から外側に抜けないようになっている。

【００３４】タクト部４３の拡径部４７より上には、少なくともフード部１２の壁３７の厚み分より離れて、タクト部４３の軸状の側面を切り欠いて形成された縮径部４５が設けられている。この実施形態では、この縮径部

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４５と貫通孔３４とで、小部屋と陰圧形成空間とを開閉する内部開閉手段を構成している。

【００３５】陰圧調整手段の第２の実施形態は以上のように構成されており、図１で説明したように、真空引き手段１１ａの動作により、フード１２の内部空間Ｓ１の空気が連続的に吸引されて陰圧とされる。この陰圧が一定以上大きくなると、図７に示されているように、タクト部４３が矢印Ｆの方向に引かれる。これにより、拡径部４７が下に引かれて、貫通孔３４の周縁から離れると同時に、この貫通孔３４の位置には、タクト部４３の縮径部４５が移動してくるので、貫通孔３４は開放される。これにより、小部屋４１内の空気は、矢印Ｅに示すように、内部空間Ｓ１に導入される。これと同時に、蓋部４３の切り込み部４２のある領域はタクト部４３に引っ張られて、図７に示されているように内側に凸となるような変形が生じる。このため、切り込み部４２は閉じていて外部部の空気は小部屋４１内に侵入しない。

【００３６】この動作により、フード１２内の内部空間Ｓ１へは、小部屋４１の収容していた空気が流れ込むことから、陰圧が小さくなり、タクト部４３を下に引く力が弱まるから、蓋部４６の弾性に基づいて、図５の状態に戻る。これにより、切り込み部４２は開いて、矢印Ｄに示されているように、外部の空気が小部屋４１内に導入される。そして、真空引き手段１１ａが、再び内部空間Ｓ１の陰圧を大きくすると、上記の動作を繰り返すことになり、後述するような脈動が生じて、フード部１２内の陰圧は周期的に変化し、この周期的変化に基づいて、母乳が吸引される。

【００３７】図８ないし図１１は、陰圧調整手段の第３の実施形態を示しており、図８はその上面図、図９ないし図１１は、図８のＤ－Ｄ線概略断面図を示しており、この図９ないし図１１は動作の各段階を示している。これらの図において陰圧調整手段５０は、外部空間に突出するように設けられた小部屋５１を有している。小部屋５１は比較的小さな容積の部屋であって、外部空間と陰圧形成空間であるフード１２の内部空間Ｓ１との間に設けられる。

【００３８】小部屋５１を形成する筒状の壁の上端は、蓋部５６により塞がれている。この蓋部５６は、下面の小部屋５１内に突起５６ｂを備えており、他の実施形態のように変形しない。蓋部５６の図８に示されているやや端部によった位置に貫通孔５６ａが形成されおり、この貫通孔５６ａの真下には、フード部１２の壁面（側面）３７に貫通孔５４が形成されている。

【００３９】上記各貫通孔５６ａと５４を貫通するように、柱状のロッドもしくはタクト部５３が挿通されている。タクト部５３は、小部屋５１の壁面３７ａに沿って上下に摺動されるように設けられている。小部屋５１内の空間内において、タクト部５３の途中からは水平に一体に延びる掛止片５７が設けられており、掛止片５７とフード部１２の壁面（側面）３７の間には、付勢手段として例えばコイルスプリングが挿入されている。また、タクト部５３の上部には、上端よりやや下の位置から上記掛止片５７の上面までの間に第１の切り欠き部５９が形成されており、この第１の切り欠き部５９は上段部５９ａと下段部５９ｂを備えている。この第１の切り欠き部５９の上下方向の大きさは、少なくとも蓋部５６の厚みより大きくされている。この実施形態では、貫通孔５６ａと第１の切り欠き部５９が、外部空間と前記小部屋とを開閉する小部屋開閉手段を構成している。

【００４０】上記タクト部５３の下部には、下端部よりやや上の位置に第２の切り欠き部５５が形成されており、この第２の切り欠き部５５は上段部５５ａと下段部５５ｂを備えている。この第２の切り欠き部５５の上下方向の大きさは、少なくともフード部１２の側面３７の厚みよりも大きく設定されている。さらに、第１に切り欠き部５９の上段部５９ａと第２の切り欠き部５５の下段部５５ｂまでの距離は、各貫通孔５６ａと５４の外縁部の間の距離を越えないように設定されている。そして、この実施形態では、貫通孔５４とタクト部５３の第２の切り欠き部５５が、小部屋と陰圧形成空間とを開閉する内部開閉手段を構成している。

【００４１】陰圧調整手段の第３の実施形態は以上のように構成されており、搾乳器１０の使用を開始する時には、フード部１２の内部空間Ｓ１は大気圧で、陰圧を生じていない。このため、図９に示すように、タクト部５３は上端に位置しており、掛止片５７の上面が蓋部５６の突起５６ｂと当接されている。タクト部５３の第１の切り欠き部５９の上段部５９ａは、貫通孔５６ａの上端よりも上に位置して、外部空間と小部屋５１の内部とは連通しており、外部空間から矢印Ｇに示すように、小部屋５１内に空気が導入される。

【００４２】次いで、図１で説明したように、真空引き手段１１ａの動作により、フード１２の内部空間Ｓ１の空気が連続的に吸引されて陰圧とされる。この陰圧が一定以上大きくなると、図１０に示されているように、タクト部５３がコイルスプリング５８の付勢力に抗して、矢印の方向に次第に引かれる。これにより、タクト部５３の第１の切り欠き部５９の上段部５９ａが貫通孔５６ａの上端を越えて下に位置して貫通孔５６ａを塞ぐ。同時に、タクト部５３の第２の切り欠き部５５の下段部５５ｂも、貫通孔５４の下端を越えて下降していないので、図１０の状態では、貫通孔５６ａも貫通孔５４も塞がれている。

【００４３】次いで、内部空間Ｓ１の陰圧がさらに大きくなると、タクト部５３がコイルスプリング５８の付勢力に抗して、矢印の方向にさらに引かれる。これにより、タクト部５３の第１の切り欠き部５９の上段部５９ａが貫通孔５６ａの下端を越えて下に位置して貫通孔５６ａを塞ぐ状態を継続する。一方、タクト部５３の第２

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の切り欠き部５５の下段部５５ｂは、貫通孔５４の下端を越えて下降する。これにより、図１１の状態では、貫通孔５６ａは塞がれているが、貫通孔５４は第２の切り欠き部５５により、小部屋５１の内部と連通するので、小部屋５１内の空気だけが、性格に内部空間Ｓ１に導入される。

【００４４】この動作により、フード１２内の内部空間Ｓ１へは、小部屋５１の収容していた空気だけが流れ込むことから、陰圧が小部屋５１の容積の空気分だけ正確に小さくなり、タクト部５３を下に引く力が弱まるから、コイルスプリング５８の付勢力に抗しきれなくなり、タクト部５３は上昇されて図９の状態に戻り、外部の空気が小部屋５１内に導入される。そして、真空引き手段１１ａが、再び内部空間Ｓ１の陰圧を大きくすると、上記の動作を繰り返すことになり、後述するような脈動が生じて、フード部１２内の陰圧は周期的に変化し、この周期的変化に基づいて、母乳が吸引される。

【００４５】かくして、この第３の実施形態は、他の実施形態と比べて、図１０で説明したように、第１の切り欠き部５９と第２の切り欠き部５５とが、それぞれ外部空間と内部空間Ｓ１とに確実に択一的に開放されるから、上記脈動の振幅がきわめて正確になされることになる。

【００４６】図１２は、本実施形態の搾乳器１０の全体の動作の一例を簡単に説明するためのフローチャートと、各ステップにおける陰圧の関係を示している。図において、使用者である授乳者が自己の乳房にフード部１２の開口１２ａを当てる（ＳＩ１）。ここで、通常は、図１の陰圧空間の限定手段１９の開閉蓋１８を実線のように閉じられている。次に、図示しないスイッチをオンして電動部を作動させ（ＳＴ２）、真空引き手段の一部であるダイヤフラム（図示せず）を作動させると、真空引き手段１１ａが陰圧形成空間である内部空間Ｓ２、Ｓ３、Ｓ１の空気を吸引することで、これらの空間を真空引きして陰圧を生じさせる（ＳＴ３）。この状態では、陰圧は形成されたばかりであり、弱い（小さい）。

【００４７】真空引き手段１１ａの動作が継続して、この陰圧が一定以上大きくなると（ＳＴ４，）、ここから、脈動による搾乳動作に入る。上述の各実施形態で説明したように、各陰圧形成手段が動作されて、小部屋と内部空間との間の内部開閉手段が開くと、小部屋の空気が内部空間に入り込むので、陰圧は弱まる（ＳＴ５）。ここで、搾乳動作により、搾乳された母乳が内部空間Ｓ１からＳ３に導かれて、筒状の部材である陰圧空間の限定手段１９内に一時貯留され、ある程度の量が溜まったら、開閉蓋１８が開かれる（ＳＴ６，ＳＴ７）。これに対して、母乳が一定量溜まらない間は、ＳＴ８に進む（ＳＴ６，ＳＴ８）。すなわち、陰圧空間の限定手段１９内で、母乳が一定量に到達しない間は、開閉蓋１８を開くことができないので、ＳＴ８に進んで、内部開閉手段が閉じられ、陰圧が大きくなる（ＳＴ８）。また、ＳＴ６で母乳が一定量溜まって、開閉蓋１８が開かれると、母乳は直ちに瓶本体１５内に落下して貯留され、開閉蓋１８は直ぐに閉じられて、ＳＴ８に進む。次いで、搾乳作業が終了しない限りは、ＳＴ５に戻って、作業者が瓶本体１５に貯留された母乳の量や出方を見ながら、搾乳作業が終了しないうちは、上記の動作が繰り返される。また、作業者が瓶本体１５に貯留された母乳の量を見ながら、母乳が目的の量だけ貯留されたり、あるいは母乳が出なくなって、搾乳作業が終了したと判断したら（ＳＴ９）、ＳＴ１０に進んで、圧力開放ボタン１６の頭部１６ａを図１の矢印Ａの方向に押し込んで、各内部空間Ｓ２，Ｓ３，Ｓ１を大気圧とし（ＳＴ１０）、図示しない電源スイッチをオフにして、使用を終了する（ＳＴ１１）。

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【００４８】図１３は、本実施形態の搾乳器１０と従来の脈動型搾乳器の搾乳動作における脈動の様子を示すグラフである。図示のＡは、本実施形態の搾乳器１０によるもの、Ｂは図１の構成中において、限定手段１８を設けないか、開閉蓋１８ａを開いて使用したもの、Ｃは従来の脈動型搾乳器である。

【００４９】図示されているように、本実施形態の搾乳器１０は、陰圧調整手段を備えているので、使用開始からの陰圧形成において、一定の大きさの陰圧になるまでの立ち上がりのスピードが早く、しかも、従来と比べて、小さな振幅による正確な脈動を実現できる。これにより、使用者の乳房に与える刺激がきわめて少なく、不快感のない使用が可能であるとともに、乳幼児の授乳動作における脈動にきわめて近似した搾乳動作を実現することができる。しかも、陰圧調整手段は、このような脈動を行う陰圧を自動的に実現することができ、構成が簡単で、その分故障もすくなく、確実な動作を行うことができる。

【００５０】本発明は、上述の実施形態に限定されるものではなく、上記しない構成を付加することもできる。また、上記実施形態の各構成は、その一部を省略することができるし、相互に組み合わせてもよい。

【００５１】

【発明の効果】以上述べたように、本発明によれば、脈動における圧力変化を小さくして、使用に無理のない圧力変化を実現できる脈動搾乳器を提供することができる。

【図面の簡単な説明】

【図１】本発明の実施形態に係る脈動搾乳器の構成を示す概略断面図である。

【図２】図１の脈動搾乳器の陰圧調整手段の第１の実施形態を示す上面図である。

【図３】図２のＢ－Ｂ線概略断面図である。

【図４】図１の脈動搾乳器の陰圧調整手段の第２の実施形態の外部空間と前記小部屋とを開閉する小部屋開閉手

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段を開いた状態の上面図である。

【図５】図４のＣ－Ｃ線概略断面図である。

【図６】図４の陰圧調整手段の外部空間と小部屋とを開閉する小部屋開閉手段を閉じた状態の上面図である。

【図７】図６のＣ－Ｃ線概略断面図である。

【図８】図１の脈動搾乳器の陰圧調整手段の第３の実施形態を示す上面図である。

【図９】図８のＤ－Ｄ線概略断面図であり、外部空間と前記小部屋とを開閉する小部屋開閉手段を開いた状態の上面図である。

【図１０】図８のＤ－Ｄ線概略断面図であり、外部空間と前記小部屋とを開閉する小部屋開閉手段を閉じ、小部屋と陰圧形成空間とを開閉する内部開閉手段も閉じた状態の図である。

【図１１】図８のＤ－Ｄ線概略断面図であり、外部空間と前記小部屋とを開閉する小部屋開閉手段を開いた状態＊

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＊の図である。

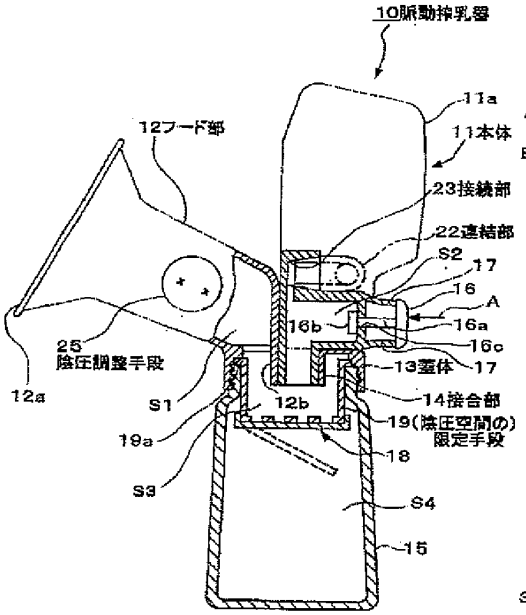
【図１２】図１の脈動搾乳器の動作の一例を示すフローチャートである。

【図１３】図１の脈動搾乳器の脈動動作と従来の脈動搾乳の脈動動作を比較したグラフである。

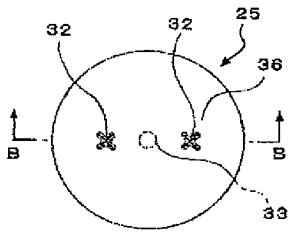
【符号の説明】

１０・・・脈動搾乳器、１１・・・本体、１２・・・本体、１３・・・蓋体、１５・・・瓶本体、１６・・・圧力開放ボタン、１８・・・開閉蓋、１９・・・（陰圧空間の）限定手段、２５・・・陰圧調整手段、３１・・・小部屋、３２・・・切り込み、３５・・・タクト部、３６・・・蓋部、４０・・・陰圧調整手段、４１・・・小部屋、４２・・・切り込み、４３・・・タクト部、４６・・・蓋部、５０・・・陰圧調整手段、５１・・・小部屋、５３・・・タクト部、５６・・・蓋部、Ｓ１，Ｓ２，Ｓ３，Ｓ４・・・内部空間

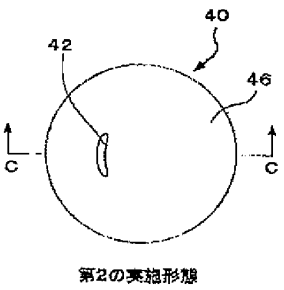
【図１】



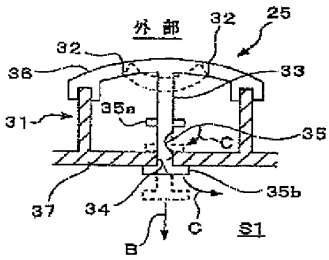
【図２】



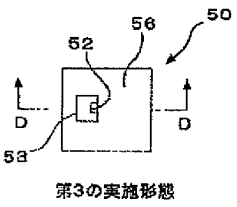
【図４】



【図３】

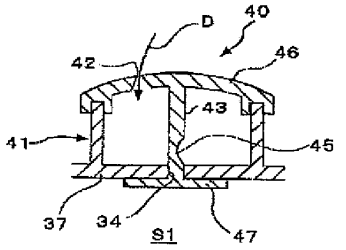


【図８】

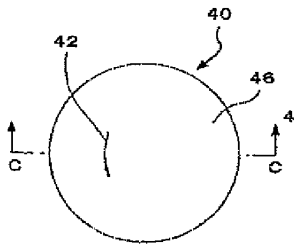


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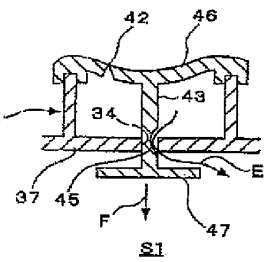
【図５】



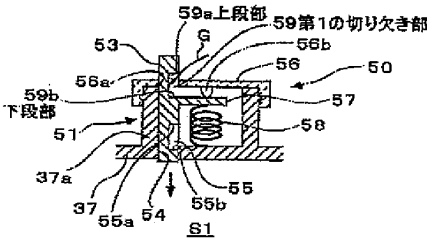
【図６】



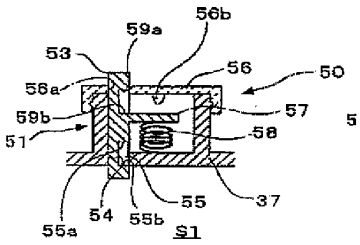
【図７】



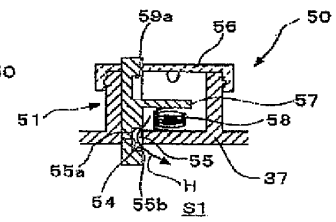
【図９】



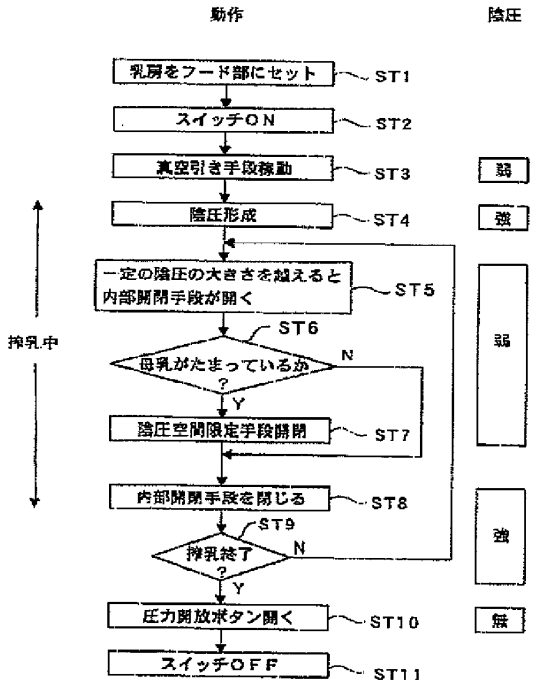
【図１０】



【図１１】

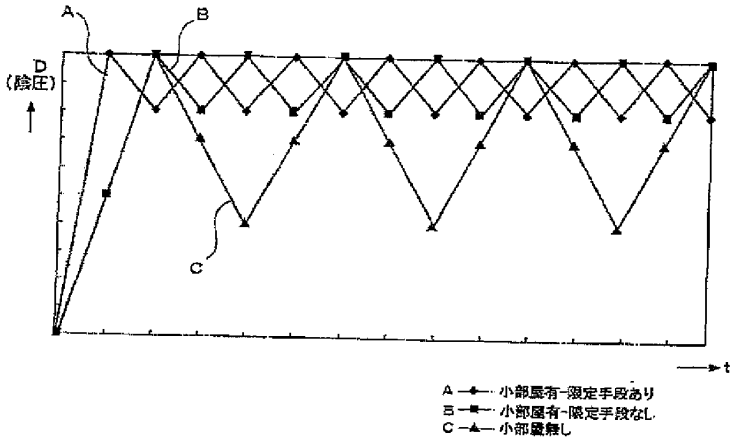


【図１２】



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【図１３】



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(71) Applicant: PIGEON CORP

(72) Inventor: OMURA KENJI
OOUSHI YOSHIYUKI

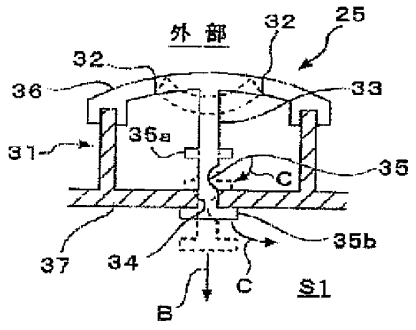
(54) PULSATIVE BREAST PUMP

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(57) Abstract:

PROBLEM TO BE SOLVED: To provide a pulsative breast pump which can realize such a pressure change that allows the pump to be used reasonably by making the pressure change in pulsation smaller

SOLUTION: This pulsative breast pump 10 provided with a negative pressure forming space in which a negative pressure is formed by means of an evacuating means in a state where the opening of a hood is closed is also provided with a small room 31 between the negative pressure forming space and an external space, a small room opening/closing means 32 which opens and closes the external space and room 31, and an internal opening/closing means which opens and closes the room 31 and negative pressure forming space. In addition, the pump 10 is also provided with a negative pressure adjusting means 25 which guides the air in the room 31 to the negative pressure forming space when the negative pressure in the space becomes a fixed value or higher after the evacuating means continuously evacuates the space



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Confirmation Number:	4766
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First Named Inventor/Applicant Name:	Carmeli Adahan
Customer Number:	20529
Filer:	Susanne M. Hopkins/Howard Kline
Filer Authorized By:	Susanne M. Hopkins
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1	Information Disclosure Statement (IDS) Filed (SB/08)	updated_IDS.pdf	612249 2c4f528adc5369097e0896e489f354054ffd5581	no	4

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

Mail Stop AMENDMENT
Attorney Docket No. 29068U

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Carmeli Adahan	Conf. No.: 4766
Application No.: 11/989,297	Examiner: TREYGER, ILYA Y.
Filed: January 24, 2008	Group Art Unit: 3761

For: **WOUND CLOSURE AND DRAINAGE SYSTEM**

AMENDMENT AND RESPONSE

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

Dear Commissioner:

This paper is submitted responsive to the non-final Official Action dated October 14, 2010, along with a Petition for a one (1) month extension of time to extend the period to respond to February 14, 2011. Accordingly, this paper is timely filed.

A **Listing of the Claims** begins on page **2** of this paper.

Remarks begin on page **10** of this paper.

A **Conclusion** appears at page **20** of this paper.

AMENDMENTS TO THE CLAIMS

Please amend the claims as follows. This listing of claims replaces all prior version of the claims in this application.

Claims 1-10 (Canceled)

11. (currently amended) An enclosure for applying negative pressure to ~~draining an open~~ a wound ~~from liquids exuded therefrom~~ , the enclosure being attachable to the wound circumference so as to define a confined volume, and comprising a tube, the enclosure having an enclosure outlet connectable ~~by means of a tube~~ to ~~an inlet of~~ a vacuum ~~pump~~ source via said tube so that negative pressure may be created in said volume, said tube comprising a venting arrangement, ~~wherein one or more bleeding holes are provided in the enclosure or adjacent to its outlet~~ outside said enclosure, such that ambient air can enter said tube via said venting arrangement ~~and flow together with the exuded liquids under the action of the negative pressure, and the ambient pressure may be restored in said confined volume when said vacuum pump is not operating~~.

12. (Currently amended) The enclosure ~~of Claim~~ according to claim 11, ~~having a nipple for connecting to said tube~~ wherein ambient air can enter said tube via said venting arrangement and flow to said vacuum source without entering said enclosure.

13. (Currently amended) The enclosure ~~of Claim~~ according to claim 11, wherein said venting arrangement comprises ~~a plurality of~~ one or more bleeding holes ~~is provided in the form of a porous body mounted in said enclosure~~.

14. (Currently amended) The enclosure ~~of Claim~~ according to claim of claim 11, ~~completed with a tube connected to said outlet, for connection to said vacuum pump inlet, wherein said one or more bleeding holes are provided in the tube, adjacent to said outlet~~ wherein said venting arrangement is provided in the form of a porous body.

Claims 15-33 (Canceled)

34. (New) The enclosure according to claim 11, wherein said venting arrangement acts as a flow restrictor to provide, under the action of the vacuum source, a restricted flow of ambient air therethrough and along said tube.

35. (New) The enclosure according to claim 11, wherein said enclosure facilitates drainage of fluids exuded from the wound, wherein the ambient air can enter said tube via said venting arrangement and flow together with the exuded liquids under the action of the negative pressure.

36. (New) The enclosure according to claim 11, wherein said venting arrangement provides for ambient air to enter said enclosure via said tube and for ambient pressure to be restored in said confined volume when the vacuum source is not operating.

37. (New) The enclosure according to claim 11, wherein in operation of the enclosure, ambient air enters the tube directly via said venting arrangement without entering said enclosure when negative pressure is being applied to the wound via said enclosure.

38. (New) A disposable assembly for applying negative pressure to a wound, the assembly comprising an enclosure as defined in claim 11 attachable to the wound circumference so as to define a confined volume, a vacuum pump unit of the vacuum pump connected to said enclosure so that negative pressure may be created in said volume, said vacuum pump unit being configured for being detachably attached to a drive unit of the vacuum pump for operating the pump unit, and a waste container connected to said vacuum pump unit, wherein said enclosure is connected to an inlet of said vacuum pump unit via said tube and said waste container is connected to an outlet of said vacuum pump unit.

39. (New) A disposable assembly according to claim 38, wherein said assembly further operates to drain the wound from fluids exuded therefrom, wherein the ambient air can enter said tube via said venting arrangement and flow together with the exuded liquids under the action of the negative pressure, and facilitates draining of the exuded fluids to said waste container.

40. (New) The disposable assembly according to claim 38, wherein said venting arrangement comprises one or more bleeding holes.

41. (New) The disposable assembly according to claim 38, wherein said venting arrangement is provided in the form of a porous body.

42. (New) A vacuum system for applying negative pressure to a wound, the vacuum system comprising an enclosure and a vacuum source, the enclosure being attachable to the wound circumference so as to define a confined volume, and comprising a tube, the enclosure having an enclosure outlet connectable to said vacuum source via said tube so that negative pressure may be created in said volume, said tube comprising a venting arrangement adjacent to said enclosure outlet, outside

said enclosure, such that ambient air can enter said tube via said venting arrangement, and further comprising a waste container in fluid communication with said vacuum source.

43. (New) The vacuum system of claim 42, wherein said vacuum system further operates to drain the wound from fluids exuded therefrom, wherein the ambient air can enter said tube via said venting arrangement and flow together with the exuded liquids under the action of the negative pressure, and facilitates draining of the exuded fluids to said waste container.

44. (New) The vacuum system according to claim 42, wherein said vacuum source includes a disposable pump unit detachably attachable to a non-disposable drive unit, said enclosure and said waste container being disposable so that the ambient air that enters said tube via said venting arrangement contacts only the disposable elements and said drained liquids may be disposed of together with said disposable elements.

45. (New) The vacuum system according to claim 44, wherein said pump unit and said drive unit are adapted for attaching and detaching by simple hand manipulations.

46. (New) The vacuum system according to claim 42, wherein said venting arrangement comprises one or more bleeding holes.

47. (New) The vacuum system according to claim 42, wherein said venting arrangement is provided in the form of a porous body.

48. (New) A vacuum system for applying negative pressure to a wound, the vacuum system comprising an enclosure and a vacuum source, the enclosure being attachable to the wound circumference so as to define a confined volume, and comprising a tube, the enclosure having an enclosure outlet connectable to said vacuum source via said tube so that negative pressure may be created in said volume, said tube comprising a venting arrangement adjacent to said enclosure outlet, outside said enclosure, such that ambient air can enter said tube via said venting arrangement, wherein said vacuum pump comprises a collection chamber upstream of a pump inlet of said vacuum source, and wherein said tube is connected to an inlet of said collection chamber.

49. (New) The vacuum system of claim 48, wherein said vacuum system further operates to drain the wound from fluids exuded therefrom, wherein the ambient air can enter said tube via said venting arrangement and flow together with the exuded liquids under the action of the negative pressure, and facilitates draining of the exuded fluids to said waste container.

50. (New) The vacuum system according to claim 48, wherein said vacuum source includes a disposable pump unit detachably attachable to a non-disposable drive unit, said enclosure and said collection chamber being disposable so that the ambient air that enters said tube via said venting arrangement contacts only the disposable elements and said drained liquids may be disposed of together with said disposable elements.

51. (New) The vacuum system according to claim 50, wherein said pump unit and said drive unit are adapted for attaching and detaching by simple hand manipulations.

52. (New) The vacuum system according to claim 48, wherein said venting arrangement comprises one or more bleeding holes.

53. (New) The vacuum system according to claim 48, wherein said venting arrangement is provided in the form of a porous body.

REMARKS

Claims 1-33 are pending in the application, claims 1-10 and 15-33 are withdrawn from consideration, and claims 11-14 are rejected in the outstanding Official Action.

After entry of the above amendments, claims 1–10, and 15-33 are canceled without prejudice or disclaimer of the subject matter contained therein, and claims 11-14 are amended.

Support for the above amendments appears throughout the originally filed specification, claims, and drawings.

Applicants, by amending any claims herein, make no admission as to the validity of any rejection made by the Examiner against any claim. Applicants reserve the right to reassert any of the claims canceled or the original scope of any claim amended herein, in a continuing application.

It is respectfully submitted that the above amendments to the claims introduce no new matter within the meaning of 35 U.S.C. §132. Accordingly, Applicant requests reconsideration and timely withdrawal of the pending rejections for the reasons discussed below.

I. Claims 11 and 12 stand rejected under 35 U.S.C. §102(b) as being anticipated by Lerman (U.S. Patent No. 5,941,859)as set forth in paragraph 4 on page 2 of the Official Action.

The Examiner asserts that claims 11 and12 are anticipated under 35 U.S.C. §102(b) by Lerman. This rejection is respectfully traversed.

Applicants respectfully submit that the rejection of claims 11 and 12 must be withdrawn because the cited reference to Lerman does not disclose, teach, and/or suggest all of the features of the currently claimed subject matter.

"Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration." *W.L. Gore & Assocs. V. Garlock*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). Further, "when evaluating the scope of a claim, every limitation in the claim must be considered. U.S.P.T.O. personnel may not dissect a claimed invention into discrete elements and then evaluate the elements in isolation. Instead, the claim as a whole must be considered." *U.S.P.T.O. Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility*, page 9, October 26, 2005. As the Federal Circuit stated, "[a]nticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim." *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Col.*, 730 F.2d 1452, 221 USPQ 481, 485 (Fed. Cir. 1984) (citing *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983)).

Lerman discloses a wound irrigation shield with fluid scavenging. Lerman describes that the "perimeter of the shield has a group of cutouts or vacuum breaks 22, shown as three in number, but fewer or more can be used. Vacuum breaks 22 and suction tube 16 are disposed approximately 180 degrees opposite each other around an imaginary

symmetrical axis which passes through the apex of the shield." *See column 4, lines 13-18.*

Further, Lerman describes the "[V]acuum breaks 22 prevent excessive suction from being applied to the wound itself and allow air to enter the shield so that there is greater air flow directed toward the suction tube." *See column 4, lines 43-46.*

Independent claim 11 currently recites:

> An enclosure for applying negative pressure to a wound, the enclosure being attachable to the wound circumference so as to define a confined volume, and comprising a tube, the enclosure having an enclosure outlet connectable to a vacuum source via said tube so that negative pressure may be created in said volume, said tube comprising a venting arrangement, outside said enclosure, such that ambient air can enter said tube via said venting arrangement.

Lerman does ***not*** describe the claimed combination comprising "said tube comprising a venting arrangement, outside said enclosure, such that ambient air can enter said tube via said venting arrangement."

In view of the above, it is submitted that Lerman does not teach each and every element of the claims as required for anticipation under 35 U.S. C. §102. Thus, Applicant respectfully requests the Examiner to withdraw this rejection.

It is noted that claim 12 depends on independent claim 11, thus claim 12 is also not anticipated by Lerman.

II. Claims 13 and 14 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Lerman (U.S. Patent No. 5,941,859) in paragraph 7 on page 6 of the Official Action.

The Examiner asserts that "it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the plurality of holes in the form of porous body in order to simplify the production process, since it has been held to be within the general skill of a worker in the art to select a know material on the basis of its suitability for the intended use as a matter of obvious design choice." Further, the Examiner asserts that "it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide bleeding holes on the vacuum tubing in order convenience the treatment procedure, since it has been held that rearranging parts of an invention involves only routine skill in the art." These rejections are respectfully traversed.

To establish an obviousness rejection under 35 U.S.C. § 103(a), four factual inquiries must be examined. The four factual inquiries include (a) determining the scope and contents of the prior art; (b) ascertaining the differences between the prior art and the claims in issue; (c) resolving the level of ordinary skill in the pertinent art; and (d) evaluating evidence of secondary consideration. *Graham v. John Deere*, 383 U.S. 1, 17-18 (1966). In view of these four factors, the analysis supporting a rejection under 35 U.S.C. 103(a) should be made explicit, and should "identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements" in the manner claimed. *KSR Int'l. Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1741 (2007). Furthermore, even if the prior art may be combined, there must be a reasonable expectation of success, and the reference or references, when combined, must disclose or suggest all of the claim limitations. *See In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Lerman discloses a wound irrigation shield with fluid scavenging. Lerman describes that the "perimeter of the shield has a group of cutouts or vacuum breaks 22, shown as three in number, but fewer or more can be used. Vacuum breaks 22 and suction tube 16 are disposed approximately 180 degrees opposite each other around an imaginary symmetrical axis which passes through the apex of the shield." *See column 4, lines 13-18.*

Further, Lerman describes the "[V]acuum breaks 22 prevent excessive suction from being applied to the wound itself and allow air to enter the shield so that there is greater air flow directed toward the suction tube." *See column 4, lines 43-46.*

Independent claim 11 currently recites:

> *An enclosure for applying negative pressure to a wound, the enclosure being attachable to the wound circumference so as to define a confined volume, and comprising a tube, the enclosure having an enclosure outlet connectable to a vacuum source via said tube so that negative pressure may be created in said volume, said tube comprising a venting arrangement, outside said enclosure, such that ambient air can enter said tube via said venting arrangement.*

Lerman does ***not*** describe the claimed combination comprising ***"said tube comprising a venting arrangement, outside said enclosure, such that ambient air can enter said tube via said venting arrangement."***

The Examiner agrees that such a venting arrangement is novel and not disclosed in Lerman, but argues that it would have been obvious to provide the "bleeding holes" of Lerman in the tubing 26, since:

1. tubing 26 and enclosure 10 form a common confined volume;

2. shifting the position of the holes would not have modified operation of the device; and

3. re-arranging parts of an invention involves only routine skill in the art.

The Examiner suggests that it would have been obvious to provide the bleeding holes in the suction tube "*to convenience the procedure since it has been held that rearranging parts of an invention involves only routine skill in the art*". It is not entirely clear what the Examiner means by "convenience", and how this would be an improvement over the disclosed position of the holes in the shield.

Lerman is directed to a wound irrigation device for use with a standard syringe and suction trap comprises a shield 10 which incorporates an irrigation tube 12 and nozzle 14 to deliver fluid at high pressure to a wound.

As clearly stated in the Abstract and elsewhere in Lerman, the intended purpose of the shield in Lerman is to ***protect the operator from splashback***, and includes a suction tube 16 to scavenge effluent, thus preventing spillage back into the wound or onto the patient and environs.

Regarding item 1 above, the tubing 26 is connected to the shield 10, and the internal volume of the tube is nominally in fluid communication with the internal volume of the shield. However, it is the ***other*** end of the tube that is connected to the pump, and thus, in operation of the pump, fluid is meant to flow only in one direction, i.e. from the shield to the tube, but not vice versa.

Furthermore, if the position of the holes is changed, then the fluid dynamics changes from a situation in which the flow through the holes and the shield and to the suction tube are essentially "in series" when the holes are in shield, to a situation in which the flow through the holes and the shield and to the suction tube are essentially "in parallel" when the holes are in the suction tube.

Regarding item 3, it is clear from the figures of Lerman, that the sum total of cross-sectional flow areas through the vacuum breaks in each of the illustrated embodiments could easily exceed the cross-sectional flow area of the suction tube. In such case, it is not entirely clear how one skilled in the art would go about transferring these "holes" to the suction tube, and still ensure that there is still a fluid flow from the shield to the suction tube.

Regarding item 2, it is respectfully submitted that the position of the holes 22 in Lerman ***does*** affect the operation of the device, particularly when shifting the position of the holes from being on the shield to being on the tube, as suggested by the Examiner.

Vacuum breaks 22, referred to by the Examiner (and thus herein as well) as "holes" are provided to "*prevent excessive suction from being applied to the wound itself **and** allow air to **enter the shield** so that there is greater air flow **toward** the suction tube*" (column 4, lines 44-46).

Thus, when, as actually disclosed in Lerman, the holes 22 are provided ***on the shield 10 itself***, the effect is to provide greater air flow ***towards*** the suction tube, ***through*** the enclosed volume of the shield. This forces the ambient air to pass over the wound, and the flow of air over the wound enhances drainage of the wound.

Placing ***any*** of the "holes" on tube 26 instead of on the shield would ***not*** "*allow air to* ***enter the shield***" through these holes, contrary to the stated purpose of the "holes" in column 4, lines 44-46 of Lerman, since the tube is downstream of the shield and the suction provided by the vacuum pump would result in ambient air entering the tube via these holes and going straight to the pump, bypassing the shield. This is self evident.

It is also to be noted that operation of the device 28 in Lerman would be substantially different in at least some circumstances, according to the position of the holes, for example where the suction port of the suction tube to the shield were to be blocked during pumping. In such circumstances, and with the "holes" located on the shield, the device 28 would increase suction significantly due to the blockage, and the user may be easily alerted to this (the motor would sound strained, for example), enabling the user to check the shield and to unblock the suction opening, and then continue as normal. On the other hand, with the holes transferred to the suction tube, such a blockage at the suction tube port would result in more ambient air being sucked through the holes and the suction tube, but no significant increase in suction. The operator would not realize that there is a blockage as the device would continue to work at the more or less normal suction levels, and moreover the collection reservoir would show that no fluid is being collected. This could give the wrong indication to the user that there is no more wound fluid to collect, while the reality would be that more and more fluid is being deposited in the shield. Thus, when the shield is removed, the fluids therein would, unexpected by the user, splash and contaminate the environment, contrary to the purpose of the device.

Furthermore, having the holes in the shield, as disclosed in Lerman, induces entrainment of fluids in the shield and increases the air flow ***through*** the shield and ***towards*** the suction tube (column 4, lines 44-46). However, placing the holes in the suction tube instead of on the shield can actually have the ***opposite*** effect, since the direct suction of ambient air through the suction tube hole actually results in there being less suction available for the shield itself (since now the suction is being shared by the fluid flow coming from the shield and the fluid flow coming from the holes (these two flows now being "in parallel" rather than "in series")), and thus less air and fluids are actually sucked through the shield and towards the suction tube via the shield. In fact, if the total flow area through the holes is close to or exceeds the cross-sectional flow area through the suction tube itself, then effectively no suction is applied to the shield at all, and there is only direct fluid flow from ambient to the suction tube via these holes.

Thus, by having the "holes" on the tube rather than on the shield this modification can actually render the Lerman device unsatisfactory for its intended purpose, contrary to the principle established in *In re Gordon* (733 F.2d 900, 221 USPQ 1125 (Fed Cir 1984)).

Moreover, and given that in Fig. 2 the tube 26 is gravitationally below the shield 10 (it makes sense to use the device in this manner to enhance drainage of fluids), it is not inconceivable that if the device is switched off while there are still wound fluids in the tube (for example due to a power shortage, malfunction, overfull reservoir, etc), these fluids could easily leak out and contaminate the environment via the suction tube holes (this

would not happen with the vacuum breaks 22 in their disclosed positions on the shield). This is of course contrary to the purpose of the device in Lerman, and also contrary to In re Gordon.

In fact, the intention in Lerman is to place the holes ***as far away as possible from the suction tube***, and mentions over and over again that the "*vacuum breaks 22 and the suction tube 16 are disposed approximately 180 degrees from one another with respect to the shield*" (see column 4, lines 15-18; column 6, lines 6-9 and 24-29). Thus, Lerman clearly ***teaches away*** from claim 11.

In view of the foregoing, it is submitted that nothing in the applied reference, renders the presently claimed subject matter obvious within the meaning of 35 U.S.C. §103. Accordingly, the Examiner is respectfully requested to withdraw this rejection of the pending claims.

The above arguments apply to newly submitted independent claims 42, and 48, and it is similarly respectfully submitted that these claims are patentable over the cited reference.

CONCLUSION

Applicants assert that the claims are in condition for immediate allowance and early notice to that effect is earnestly solicited. Should the Examiner deem that any further action by Applicants' undersigned representative is desirable and/or necessary, the Examiner is invited to telephone the undersigned at the number set forth below.

In the event this paper is not timely filed, Applicants petition for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

THE NATH LAW GROUP

/William L. Klima/
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Customer No. 20529

Date: February 14, 2011

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PTO/SB/22 (07-09)
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PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a) **FY 2009** ***(Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).)***	Docket Number (Optional) 29068U
Application Number 11/989,297	Filed January 24, 2008
For WOUND CLOSURE AND DRAINAGE SYSTEM	
Art Unit 3761	Examiner TREYGER, ILYA Y.

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	
☑ One month (37 CFR 1.17(a)(1))	$130	$65	$ 65
☐ Two months (37 CFR 1.17(a)(2))	$490	$245	$
☐ Three months (37 CFR 1.17(a)(3))	$1110	$555	$
☐ Four months (37 CFR 1.17(a)(4))	$1730	$865	$
☐ Five months (37 CFR 1.17(a)(5))	$2350	$1175	$

☑ Applicant claims small entity status. See 37 CFR 1.27.

☐ 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 14-0112.

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.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) is enclosed (Form PTO/SB/96).

☑ attorney or agent of record. Registration Number 32,422

☐ attorney or agent under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____

/William L. Klima/ — Signature

February 14, 2011 — Date

William L. Klima — Typed or printed name

703-548-6284 — Telephone Number

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

☑ Total of one (1) forms are submitted.

This collection of information is required by 37 CFR 1.136(a). 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 6 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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

Privacy Act Statement

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

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

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

Electronic Patent Application Fee Transmittal

Application Number:	11989297
Filing Date:	24-Jan-2008
Title of Invention:	Wound closure and drainage system
First Named Inventor/Applicant Name:	Carmeli Adahan
Filer:	Susanne M. Hopkins/William Klima
Attorney Docket Number:	29068U

Filed as Small Entity

U.S. National Stage under 35 USC 371 Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Extension - 1 month with $0 paid	2251	1	65	65

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
		Total in USD ($)		**65**

Electronic Acknowledgement Receipt

EFS ID:	9443966
Application Number:	11989297
International Application Number:	
Confirmation Number:	4766
Title of Invention:	Wound closure and drainage system
First Named Inventor/Applicant Name:	Carmeli Adahan
Customer Number:	20529
Filer:	Susanne M. Hopkins/William Klima
Filer Authorized By:	Susanne M. Hopkins
Attorney Docket Number:	29068U
Receipt Date:	14-FEB-2011
Filing Date:	24-JAN-2008
Time Stamp:	23:05:39
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$65
RAM confirmation Number	6954
Deposit Account	
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)

1		2011_02_14_ROA.pdf	142665 41a7b9a5154daac591c1169cbec46b524ac6facd	yes	20
	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Amendment/Req. Reconsideration-After Non-Final Reject		1	1	
	Claims		2	9	
	Applicant Arguments/Remarks Made in an Amendment		10	20	
Warnings:					
Information:					
2	Extension of Time	sb0022.pdf	312922 26f237393ff912b7037c93ac8989bcd1e704501b	no	2
Warnings:					
Information:					
3	Fee Worksheet (PTO-875)	fee-info.pdf	30036 8882fe1ee43eee5d52f75ee57fe017976af8596f	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	485623		

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

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

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

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

PTO/SB/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
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PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
11/989,297	01/24/2008	

APPLICATION AS FILED – PART I

	(Column 1)	(Column 2)	SMALL ENTITY ☒		OR	OTHER THAN SMALL ENTITY	
FOR	NUMBER FILED	NUMBER EXTRA	RATE ($)	FEE ($)		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 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			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT	02/14/2011	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 24	Minus	** 33	= 0	X $26 =	0	OR	X $ =	
	Independent (37 CFR 1.16(h))	* 3	Minus	***5	= 0	X $110 =	0	OR	X $ =	
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE	

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

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
/RUTH M. LLOYD/

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.

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	11989297
	Filing Date	2008-01-24
	First Named Inventor	ADAHAN
	Art Unit	3761
	Examiner Name	TREYGER
	Attorney Docket Number	29068U

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5116206	A	1992-05-26	ADAHAN	
	2	7503910	B2	2009-03-17	ADAHAN	

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

U.S.PATENT APPLICATION PUBLICATIONS Remove

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

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FOREIGN PATENT DOCUMENTS Remove

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

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NON-PATENT LITERATURE DOCUMENTS Remove

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	11989297
	Filing Date	2008-01-24
	First Named Inventor	ADAHAN
	Art Unit	3761
	Examiner Name	TREYGER
	Attorney Docket Number	29068U

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

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EXAMINER SIGNATURE

Examiner Signature		Date Considered	

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

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	11989297
	Filing Date	2008-01-24
	First Named Inventor	ADAHAN
	Art Unit	3761
	Examiner Name	TREYGER
	Attorney Docket Number	29068U

CERTIFICATION STATEMENT

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

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

OR

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

☐ See attached certification statement.

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

☐ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/Susanne M. Hopkins/	Date (YYYY-MM-DD)	2011-01-03
Name/Print	Susanne M. Hopkins	Registration Number	33247

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

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

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

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

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

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

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

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

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

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

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

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

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Exhibit 1008
Page #650

Electronic Acknowledgement Receipt

EFS ID:	9147955
Application Number:	11989297
International Application Number:	
Confirmation Number:	4766
Title of Invention:	Wound closure and drainage system
First Named Inventor/Applicant Name:	Carmeli Adahan
Customer Number:	20529
Filer:	Susanne M. Hopkins/Lisa Elliott
Filer Authorized By:	Susanne M. Hopkins
Attorney Docket Number:	29068U
Receipt Date:	03-JAN-2011
Filing Date:	24-JAN-2008
Time Stamp:	17:13:12
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Filed (SB/08)	sb0008-IDS.pdf	611757 e1cfaa48f51cb09bdcce025a520c78f55e442483	no	4

Warnings:	
Information:	

Total Files Size (in bytes):	611757

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New Applications Under 35 U.S.C. 111

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

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

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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.

PTO/SB/08a (01-10)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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

Application Number	11989297
Filing Date	2008-01-24
First Named Inventor	ADAHAN
Art Unit	3761
Examiner Name	TREYGER
Attorney Docket Number	29068U

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5370610	A	1994-12-06	REYNOLDS	
	2	5662599	A	1997-09-02	REICH, et al.	
	3	6471982	B1	2002-10-29	LYDON, et al.	
	4	5636643	A	1997-06-10	ARGENTA, et al.	
	5	7128735	B2	2006-10-31	WESTON	
	6	6824533	B2	2004-11-30	RISK, JR., et al.	
	7	6562013	B1	2003-05-13	MARASCO, JR.	
	8	4447226		1984-05-08	MAYORAL	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	Filing Date	2008-01-24
	First Named Inventor	ADAHAN
	Art Unit	3761
	Examiner Name	TREYGER
	Attorney Docket Number	29068U

	9	4611627		1986-09-16	EIDSVOOG, et al.	
	10	1599899		1926-09-14	KETTERING, et al.	
	11	6071267	A	2000-06-06	ZAMICROWSKI	
	12	0599333		1898-02-22	HULSE	
	13	3416461		1968-12-17	McFARLAND	
	14	5419687	A	1995-05-30	ADAHAN	
	15	6042560	A	2000-03-28	NIEDERBERGER	
	16	6648862	B2	2003-11-18	WATSON	
	17	4739791		1988-04-26	ADAHAN	
	18	4930997		1990-06-05	BENNETT	
	19	4661093		1987-04-28	BECK, et al.	

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Exhibit 1008
Page #654

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	11989297
	Filing Date	2008-01-24
	First Named Inventor	ADAHAN
	Art Unit	3761
	Examiner Name	TREYGER
	Attorney Docket Number	29068U

	20	5645081	A	1997-07-08	ARGENTA, et al.	
	21	5776119	A	1998-07-07	BILBO, et al.	

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20050004534	A1	2005-01-06	LOCKWOOD, et al.	
	2	20040039243	A1	2004-02-26	BEARNSON, et al.	
	3	20030014022	A1	2003-01-16	LOCKWOOD, et al.	
	4	20010029956	A1	2001-10-18	ARGENTA, et al.	
	5	20040199840	A1	2004-10-07	TAKEOKA, et al.	
	6	20050192548	A1	2005-09-01	DOLLIVER, et al.	
	7	20040064132	A1	2004-04-01	BOCHRINGER, et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	11989297
	Filing Date	2008-01-24
	First Named Inventor	ADAHAN
	Art Unit	3761
	Examiner Name	TREYGER
	Attorney Docket Number	29068U

	8	20020151826	A1	2002-10-17	RAMEY, et al.	
	9	20040059284	A1	2004-03-25	NASH, et al.	
	10	20030097100	A1	2003-05-22	WATSON	
	11	20030040687	A1	2003-02-27	BOYNTON, et al.	
	12	20030050594	A1	2003-03-13	ZAMICROWSKI	

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

FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	03/030966	WO	A1	2003-04-17	HILL-ROM SERVICES, INC.		☐
	2	97/18007	WO	A1	1997-05-22	KCI MEDICAL LIMITED		☐
	3	102 15 896	DE	A1	2003-10-23	LEYBOLD VAKUUM GMBH	ABSTRACT	☒
	4	03/016719	WO	A1	2003-02-27	ADAHAN		☐

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	11989297
	Filing Date	2008-01-24
	First Named Inventor	ADAHAN
	Art Unit	3761
	Examiner Name	TREYGER
	Attorney Docket Number	29068U

	5	24 01 643	DT	A1	1975-07-17	TUCHENHAGEN	ABSTRACT	☒
	6	0 156 211	EP	A2	1985-10-02	FRESENIUS AG	ABSTRACT	☒
	7	00/02016	WO	A1	2000-01-13	DEKA PRODUCTS LIMITED PARTNERSHIP		☐
	8	96/05873	WO	A1	1996-02-29	MEDISCUS PRODUCTS LIMITED		☐
	9	2 378 734	GB	A	2003-02-19	ADAHAN		☐
	10	2 307 180	GB	A	1997-05-21	KCI MEDICAL LIMITED		☐
	11	03/057070	WO	A2	2003-07-17	HILL-ROM SERVICES INC.		☐

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NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T5
	1		☐

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Exhibit 1008
Page #657

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	11989297
	Filing Date	2008-01-24
	First Named Inventor	ADAHAN
	Art Unit	3761
	Examiner Name	TREYGER
	Attorney Docket Number	29068U

EXAMINER SIGNATURE			
Examiner Signature		Date Considered	

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

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

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	First Named Inventor	ADAHAN
	Art Unit	3761
	Examiner Name	TREYGER
	Attorney Docket Number	29068U

CERTIFICATION STATEMENT

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

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

OR

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

☐ See attached certification statement.

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

☒ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/Susanne M. Hopkins/	Date (YYYY-MM-DD)	2010-11-16
Name/Print	Susanne M. Hopkins	Registration Number	33247

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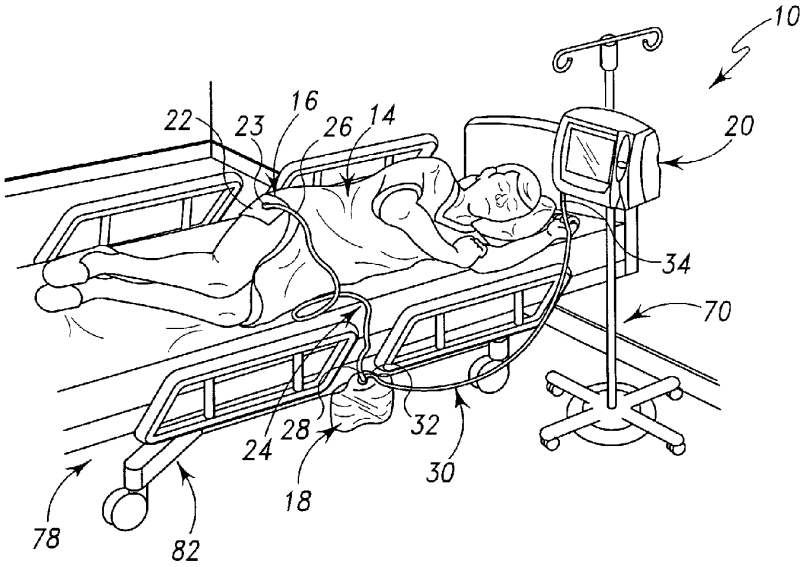
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(54) Title: WASTE CONTAINER FOR NEGATIVE PRESSURE THERAPY



(57) Abstract: A system (10) for treating a patient (14) with a wound comprises a bandage (16), a receptacle (18), and a vacuum source (21). The bandage (16) comprises a cover (22) to seal about the wound and to define a space above the wound in which a vacuum is to be formed. The bandage (16) further comprises a port (23) providing communication with the space. The receptacle (18) is connected to the port (23) to receive exudate from the wound and is provided to be placed below)the wound. The vacuum source (21) is spaced apart from the receptacle (18), is connected to the receptacle (18), and is effective to provide a vacuum in the receptacle (18) and in the space.

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WASTE CONTAINER FOR NEGATIVE PRESSURE THERAPY

FIELD OF THE INVENTION

The present invention relates to a wound treatment system and specifically to a vacuum therapy wound treatment system for surface wounds. More specifically, the present invention relates to the drainage and collection of exudate from the wound surface through vacuum therapy.

BACKGROUND FO THE DISCLOSURE

Medical professionals, such as nurses and doctors, routinely treat patients having surface wounds of varying size, shape, and severity. It is known that controlling the topical atmosphere adjacent a wound can enhance the healing process. For example, by applying medicinal agents or even water over a wound, dirt and bacteria are either killed or washed away, thereby promoting healing. In addition, applying a negative pressure or vacuum to a wound draws out exudate, which might contain dirt and bacteria, from the wound to further promote healing.

A vacuum bandage is a bandage having a cover for sealing about the outer perimeter of the wound and under which a vacuum is established to act on the wound surface. This vacuum applied to the wound surface accelerates healing of chronic wounds. Typically, suction tubes are provided for drawing exudate away from the wound. If the cover is a flexible cover, which is typically more comfortable for the patient, a porous packing may be provided under the cover to provide the space in which the vacuum is formed. The following U.S. Patents establish the nature of vacuum treatment bandages and devices: 6,095,992; 6,080,189; 6,071,304; 5,645,081; 5,636,643; 5,358,494; 5,298,015; 4,969,880; 4,655,754; 4,569,674; 4,382,441; and 4,112,947. All of such references are incorporated herein by reference for purposes of disclosing the nature of such vacuum treatment of wounds.

As shown, for example, in U.S. Patent No. 5,645,081 (hereinafter the '081 patent), a method of treating tissue damage is provided by applying negative pressure to a wound. The negative pressure is provided in sufficient duration and magnitude to promote tissue migration in order to facilitate the closure of the wound. Fig. 1 of the '081 patent discloses an open cell polyester foam section covering the wound, a flexible hollow tube inserted into the foam section at one end and attached

to a vacuum pump at another end, an adhesive sheet overlying the foam section, and tubing to adhere to the skin surrounding the wound in order to form a seal that allows the creation of a vacuum when the suction pump is operating. The '081 patent further teaches use of negative pressure between about 0.1 and 0.99 atmospheres, and that the pressure can be substantially continuous, wherein the pressure is relieved only to change the dressing on the wound. Alternatively, the '081 patent teaches use of a cyclic application of pressure in alternating periods of application and non-application. In a preferred embodiment, pressure is applied in 5-minute periods of application and non-application.

Various other prior art references teach the value of the vacuum bandage or the provision of vacuum to the surface of a chronic wound. Several Russian language articles exist that establish the efficacy of vacuum therapy. Examples of such prior art articles, each of which discusses the use of application of vacuum to a wound to promote healing, are as follows: "Vacuum therapy in the treatment of acute suppurative diseases of soft tissues and suppurative wound", Davydov, et al. Vestn. Khir., Sept. 1988 (the Sept. 1988 article); "Pathenogenic mechanism of the effect of vacuum therapy on the course of the wound process", Davydov, et al. Khirurigiia, June 1990 (the June 1990 article); and "Vacuum therapy in the treatment of suppurative lactation mastitis", Davydov, et al., Vestn. Khir., Nov. 1986 (the Nov. 1986 article).

The Russian articles distinguish wound drainage from the use of vacuum therapy for healing. The Russian authors report that vacuum therapy resulted in faster cleansing of the wound and more rapid detoxification than with the traditional incision-drainage method. The Nov. 1986 article describes the vacuum therapy techniques as a reduction of 0.8 - 1.0 atmosphere for 20 minutes at the time of surgery, and subsequent 1.5 to 3 hour treatments at a reduced pressure of 0.1 to 0.15 from atmosphere, twice daily. These Russian articles teach the use of negative pressure to effect healing. The articles describe using several sessions per day, each lasting up to one hour, with a vacuum of 76-114 mmHg.

The Russian articles teach using this vacuum method to decrease the number of microbes in the wound. The June 1990 article teaches that vacuum therapy provides a significant antibacterial effect. The June 1990 article describes the stepped up inflow of blood to the zone around the wound, which leads to an increase in the

number of leukocytes reaching the focus of inflammation. Subsequent articles and patents further develop the benefits obtained with vacuum therapy. The prior art, therefore, teaches the benefit and value of a vacuum bandage.

SUMMARY OF THE DISCLOSURE

Accordingly, a vacuum therapy system for treating a patient with a wound is provided. The system includes a vacuum bandage comprising a cover to seal about the wound. The cover also defines a space above the wound in which a vacuum is to be formed. The bandage further comprises a port which provides communication with the space. The system further includes a receptacle to be placed below the wound. The receptacle is connected to the port to receive exudate from the wound. Finally, the system includes a vacuum source spaced apart from the receptacle and connected to the receptacle. The vacuum source is effective to provide a vacuum in the receptacle and in the space above the wound.

Illustratively, the system may comprise one or more of the following features alone or in combination with each other: a first tube coupled to the port of the bandage and the receptacle, a second tube coupled to the vacuum source and the receptacle, a means for attaching the receptacle to a support below the wound, a means for supporting the vacuum source away from the receptacle, and/or a control dominating the vacuum source to establish the amount of vacuum applied to the space and the time when the vacuum is applied to the space.

Further illustratively, the receptacle of the system may comprise one or more of the following features alone or in combination with each other: an anti-microbial filter, an air vent to allow an inner area of the receptacle to communicate with the surrounding atmosphere, a mounting portion, and an upper portion and a lower portion coupled to the upper portion. The anti-microbial filter may be hydrophobic, and the upper portion of the receptacle may be made of a rigid material while the lower portion pf the receptacle may be made of a flexible material.

The vacuum source of the system may comprise a vacuum pump and associated controls and/or a flow sensor to be connected to a vacuum line. Illustratively, the flow sensor may be configured to determine the level of vacuum present in the receptacle.

A method for treating a wound on a patient is also provided including the steps of sealing a bandage having a port about the wound to define a space above the wound in which a vacuum can be formed, placing a receptacle below the wound, and placing a vacuum source spaced away from the receptacle. The method further includes the steps of connecting the receptacle to the port of the bandage, connecting the vacuum source to the receptacle, and operating the vacuum source to evacuate the receptacle and provide a vacuum in the space above the wound. The method further includes the step of controlling the level of vacuum applied to the space and the time of application of the vacuum.

Additional features and advantages of the apparatus will become apparent to those skilled in the art upon consideration of the following detailed descriptions exemplifying the best mode of carrying out the apparatus as presently perceived.

BRIEF DESCRIPTION OF THE DRAWINGS

The detailed description particularly refers to the accompanying figures in which:

Figs. 1-4 are perspective views of a vacuum therapy system and a patient undergoing vacuum therapy treatment showing a vacuum bandage of the system coupled to the patient, a waste drainage container or receptacle coupled to the vacuum bandage by a first tube and a housing including a vacuum source coupled to the receptacle by a second tube, and also showing the receptacle positioned below the wound and spaced apart from housing;

Fig. 1 is a perspective view showing the housing mounted on a mobile IV pole;

Fig. 2 is a perspective view similar to Fig. 1 showing the housing positioned on a bedside cabinet;

Fig. 3 is a perspective view similar to Figs. 1 and 2 showing the housing mounted to an on-bed IV pole;

Fig. 4 is a perspective view similar to Figs. 1-3 showing the housing mounted on a footboard of the patient's hospital bed;

Fig. 5 is a sectional view of an illustrative receptacle showing the first tube coupled to an inlet port of the receptacle and showing the second tube coupled to

an outlet port of the receptacle and also showing a hydrophobic filter positioned at the outlet port of the receptacle;

Fig. 6 is a perspective view of another illustrative waste receptacle of the present invention showing a mounting portion of the receptacle for mounting the receptacle to a bed frame of the hospital bed, as shown in Figs. 1-4; and

Fig. 7 is a perspective view of yet another illustrative waste receptacle of the present invention showing an alternative mounting portion of the receptacle for mounting the receptacle to the bed frame of the hospital bed.

DETAILED DESCRIPTION OF THE DRAWINGS

A vacuum therapy system 10 is provided for use with a wound on a patient 14, as shown in Figs. 1-4. System 10 comprises a vacuum bandage 16, a waste container or receptacle 18 coupled to the bandage 16, and a housing 20 coupled to the receptacle 18. Housing 20 includes a vacuum source 21 (shown in Fig. 5) for applying negative pressure to the wound to draw exudate from the wound in order to facilitate healing. Receptacle 18 is provided to collect the exudate drawn from the wound and is placed below the wound to facilitate the drainage of exudate from the wound by gravity as well as suction. Housing 20, which includes the vacuum source 21, is spaced apart from receptacle 18 in order to allow a caregiver to place the housing 20 in any convenient location while still benefiting from the gravitational effects gained by maintaining the receptacle 18 at a level below the wound.

Illustrative vacuum bandages and vacuum and irrigation systems are disclosed in U.S. Publication No. US-2002-0065494-A1 published May 30, 2002, to Lockwood, et al. titled "VACUUM THERAPY AND CLEANSING DRESSING FOR WOUNDS", PCT Publication No. WO 01/37922 published May 31, 2001, to Risk et al. titled "WOUND TREATMENT APPARATUS", and U.S. Patent No. 6,458,109 issued October 1, 2002, to Henley et al. titled "WOUND TREATMENT APPARATUS". Each of these publications, and patents are owned b the same applicant as the present application and are specifically incorporated herein by reference.

Vacuum bandage 16 includes a cover 22 to seal about the wound. The bandage 16 operates to define a space above the wound to which negative pressure can be applied to form a vacuum. The bandage 16 further includes a port 23 in

communication with the space above the wound. The port 23 is coupled to receptacle 18 by a first tube 24 of the system 10. First tube 24 includes a first end 26 coupled to the port 23 and a second end 28 coupled to the receptacle 18. System 10 further includes a second tube 30 coupled at a first end 32 to the receptacle 18 and coupled at a second end 34 to the vacuum source 21 which may be contained within housing 20.

Illustrative receptacle 18 of the vacuum therapy system 10 includes a body 40 which forms an interior cavity 42 for collecting exudate 62 (shown in Fig. 5) and fluid drawn from the wound therein. Although receptacle 18 is illustratively shown in Fig. 5, the height, width, and shape of receptacle 18 may take various forms. Body 40 includes an upper portion 44 and a lower portion 46 coupled to the upper portion 44. Upper portion 44 defines an inlet port 48 coupled to the first tube 24, and an outlet port 50 coupled to the second tube 26. In illustrative embodiments, upper portion 44 of the receptacle 18 is formed from a rigid material and the lower portion 46 of the receptacle 18 is also formed from a rigid material and is integral with the upper portion 44, as shown, for example, in Figs. 5-7. However, it is within the scope of this disclosure to include a receptacle having a lower portion 46 made from a flexible material as well. For example, lower portion 46 may be a flexible bag removably coupled to the upper portion 44 of receptacle 18.

As shown in Fig. 5, receptacle 18 further includes a hydrophobic filter 60 in communication with second tube 30 and thus the vacuum source 21. Illustratively, filter 60 is a 0.2-micron hydrophobic anti-microbial filter. Upper portion 44 of receptacle 18 further defines an air vent 64 to provide communication between interior cavity 42 of receptacle 18 and the outside atmosphere. Preferably, as shown in Fig. 5, hydrophobic filter 60 is positioned over air vent 64 to prevent bacteria, etc. in the surrounding atmosphere from entering receptacle 18.

As mentioned above, first end 32 of second tube 30 is coupled to outlet port 50 of receptacle 18 and second end 34 of second tube 30 is coupled to vacuum source 21. Vacuum source 21 may be contained within housing 20 or may be external to the housing 20. For example, most medical facilities have vacuum ports near where patients are treated, such as in-wall vacuum ports, for example. Each port is served by a system vacuum pump to provide negative pressure. Vacuum source 21 is also defined to include any type of mechanism for providing negative pressure such as an electrically operated or manual pump, for example. Housing 20 is configured to

be a portable unit allowing a caregiver to move housing 20 to wherever the patient is located within close proximity to the wound or wounds. For example, as shown in Figs. 1-4, the housing 20 is shown to be coupled to a mobile IV pole 70, positioned on a bedside cabinet 72, coupled to an on-bed IV pole 74, and coupled to a footboard 76 of the hospital bed 78. Each of the mobile IV pole 70, cabinet 72, in-bed IV pole 74, and footboard 76 illustrate an example of a means for supporting the housing 20 and vacuum source 21 away from receptacle 18. The housing 20 and its vacuum source 21 may be placed above, at generally the same level, or below the receptacle 18. Preferably, the receptacle 18 will be placed below the wound.

In addition to the vacuum source 21, it is also within the scope of the disclosure for housing 20 to include a controller (not shown) for controlling the amount and rate of negative pressure to be applied to the wound, for example. Housing 20 may also include an irrigation system and such other devices and components as disclosed in PCT Publication No. WO 01/37922 referenced above and incorporated herein.

As described above, the components of system 10 (vacuum bandage 16, first tube 24, receptacle 18, second tube 30, and vacuum source 21) are coupled to each other in series. The port of vacuum bandage 16 is coupled to the receptacle 18 by first tube 24. First tube 24 is coupled to inlet port 48 of receptacle 18 and receptacle 18 is coupled to the housing 20, or more specifically, to the vacuum source 21, by second tube 30. First end 32 of second tube 30 is coupled to outlet port 50 of receptacle 18 and second end 34 of second tube 30 is coupled to vacuum source 21 . By this series configuration, the vacuum source 21 is thus in fluid communication with the receptacle 18 through the second tube 3, and the space above the wound created by vacuum bandage 16 is in fluid communication with receptacle 18 through first tube 24. Therefore, the vacuum source 21 operates to create negative pressure, or a vacuum, in the space above the wound, in the first tube 24, in receptacle 18, and in second tube 30.

Illustratively, a flow sensor (not shown) may be coupled to second tube 30 between receptacle 18 and vacuum source 21 for monitoring the fluid flow from receptacle 18 to vacuum source 21. The flow sensor may then provide feedback to the controller, for example, located within housing 20. If, for example, the flow

sensor detects no fluid flow, the feedback sent to the controller would signal the vacuum source 21 to turn off or cease running.

In operation, it is possible that at a period of time after negative pressure is created above the wound, system 10 may become relatively static due to a lack of fluid flow through system 10. As mentioned above, this lack of fluid flow could cause the vacuum source 21 to be turned off. However, it may still be beneficial to provide a vacuum above the wound in order to draw blood up to the surface of the wound. Air vent 64 is provided in receptacle 18 in order to maintain a small amount of fluid flow to prevent the flow sensor from detecting a static system. Once system 10 has become relatively static and there is little to no fluid flow from bandage 16 through first tube 24 and to receptacle 18, vacuum source 21 is still able to pull air through air vent 64 thus allowing the flow sensor to detect a fluid flow in order to keep the vacuum source 21 running. Once the level of exudate 62 collected within receptacle 18 reaches air vent 64 and/or outlet port 50, hydrophobic filter 60 will prevent liquid to pass therethrough and the flow sensor will sense that the flow has become static. The flow sensor will send a signal to the controller which will, in turn, tell the vacuum source 21 to turn off.

In use, receptacle 18 is positioned below the vacuum bandage 16 and the patient's wound to which the vacuum bandage 16 is attached. As shown in Figs. 1-4, placing receptacle 18 below the wound facilitates the drainage of exudate from the wound through gravity. Therefore, exudate is drawn from the wound through the use of a negative pressure supplied by vacuum source 21 and through the use of gravity. Receptacle 18 is also spaced apart from vacuum source 21 and/or the housing 20, as shown in Figs. 1-4. As stated above, vacuum source 21 is often provided within housing 20. Therefore, spacing receptacle 18 apart from the vacuum source 21 allows the housing 20 to be placed at any desired location or level while still maintaining use of gravity for the collection of exudate within receptacle 18.

In illustrative embodiments, receptacle 18 includes a mounting portion 80 coupled to the body 40, as shown in Figs. 6 and 7. Mounting portion 80 is provided to allow a caregiver to mount the receptacle 18 to hospital bed 78 below the patient 14 and thus below the wound in order to facilitate the drainage of the exudate from the wound by gravity. Hospital beds 78 often to include a hook (not shown) or a type of mount or support coupled to a bed frame 82 of the bed 78. Urine bags, for

example, are often hung by the caregiver from these hooks to facilitate drainage through the use of gravity alone.

Mounting portion 80 of receptacle 18, as shown in Fig. 6, is in the shape of a handle to define an aperture 84 for receiving the hook or mount coupled to bed frame 82. Mounting portion 80 is coupled to a top wall 86 of body 40 to cooperate with body 40 and form aperture 84. Mounting portion 80 includes a first generally vertical member 88 coupled to top wall 86, a second generally vertical member 90 coupled to top wall 86, and a generally horizontal member 92 spaced-apart from top wall 86 and coupled to and positioned to extend between each of the first and second generally vertical members 88, 90.

Another illustrative mounting portion 180 is shown in Fig. 7. Alternate mounting portion 180 is hook-shaped and includes a single curved member coupled to the top wall 86 of the receptacle 18 to define a hook-receiving space 182 for receiving a hook or mount of the bed frame 82. Although mounting portion 80 and alternate mounting portion 180 are disclosed and described herein, it is within the scope of this disclosure to include a receptacle having a mounting portion adapted to cooperate with the bed frame of the hospital bed in order to support the receptacle below the wound of the patient being treated.

Although the invention has been described in detail with reference to certain preferred embodiments, variations and modifications exist within the scope and spirit of the invention.

CLAIMS:

1. A system for treating a patient with a wound, the system comprising:

(a) a bandage comprising a cover to seal about the wound and define a space above the wound in which a vacuum is to be formed, and a port providing communication with the space,

(b) a receptacle to be placed below the wound and connected to the port to receive exudate from the wound, and

(c) a vacuum source spaced apart from the receptacle and connected to the receptacle, the vacuum source being effective to provide a vacuum in the receptacle and in the space.

2. The system of claim 1, further including a first tube coupled to the port of the bandage and the receptacle and a second tube coupled to the vacuum source and the receptacle.

3. The system of claim 2, wherein the receptacle further includes an inlet port coupled to the first tube and an outlet port coupled to the second tube.

4. The system of claim 3, wherein the receptacle further includes an anti-microbial filter adjacent the outlet port.

5. The system of claim 4, wherein the filter is hydrophobic.

6. The system of claim 1, wherein the receptacle includes an air vent to allow an inner area of the receptacle to communicate with the surrounding atmosphere.

7. The system of claim 1, wherein the receptacle includes an upper portion and a lower portion coupled to the upper portion, and wherein the upper portion of the receptacle is formed from a rigid material.

8. The system of claim 7, wherein the upper portion of the receptacle includes an inlet port coupled to the bandage and an outlet port coupled to the vacuum source.

9. The system of claim 7, wherein the lower portion of the receptacle is formed from a flexible material.

10. The system of claim 1, wherein the vacuum bandage, receptacle, and vacuum source are configured to operate in series with each other.

11. The system of claim 1, further including a mounting portion coupled to the receptacle.

12. The system of claim 1, comprising a control dominating the vacuum source, the control being configured to establish the amount of vacuum applied to the space.

13. The system of 12, wherein the control is configured to establish the time when vacuum is applied to the space.

14. The system of claim 1, comprising means for attaching the receptacle to a support below the wound.

15. The system of claim 1, comprising means for supporting the vacuum source away from the receptacle.

16. A system for creating a vacuum above a wound and drawing exudate away from the wound, the system comprising:

(a) a vacuum bandage to place over and seal about the wound on a patient to provide a vacuum space above the wound and a port communicating with the space,

(b) a receptacle configured to be placed below the wound, the receptacle being in communication through the port with the vacuum space, and

(c) a vacuum source positioned away from the receptacle and connected to the receptacle to provide a vacuum in the receptacle and in the vacuum space, thereby subjecting a surface of the wound to vacuum therapy.

17. The system of claim 16, wherein the vacuum source comprises a vacuum pump and associated controls, the pump being connected to the receptacle.

18. The system of claim 17, wherein the vacuum source is positioned above the receptacle.

19. The system of claim 16, wherein the vacuum source is positioned above the receptacle.

20. The system of claim 16, wherein the vacuum source comprises a flow sensor to be connected to a vacuum line, the flow sensor being configured to determine the level of vacuum present in the receptacle.

21. The system of claim 16, comprising means for supporting the receptacle below the wound.

22. The system of claim 16, comprising means for supporting the vacuum source above the receptacle.

23. A method for treating a wound on a patient, the method comprising the steps of:

(a) sealing a bandage having a port about the wound to define a space above the wound and in communication with the port in which a vacuum can be formed,

(b) placing a receptacle below the wound,

(c) placing a vacuum source spaced away from the receptacle,

(d) connecting the receptacle to the port of the bandage,

(e) connecting the vacuum source to the receptacle, and

(f) operating the vacuum source to evacuate the receptacle and provide a vacuum in the space above the wound.

24. The method of claim 23, comprising the step of controlling the level of vacuum applied to the space and the time of application of the vacuum.

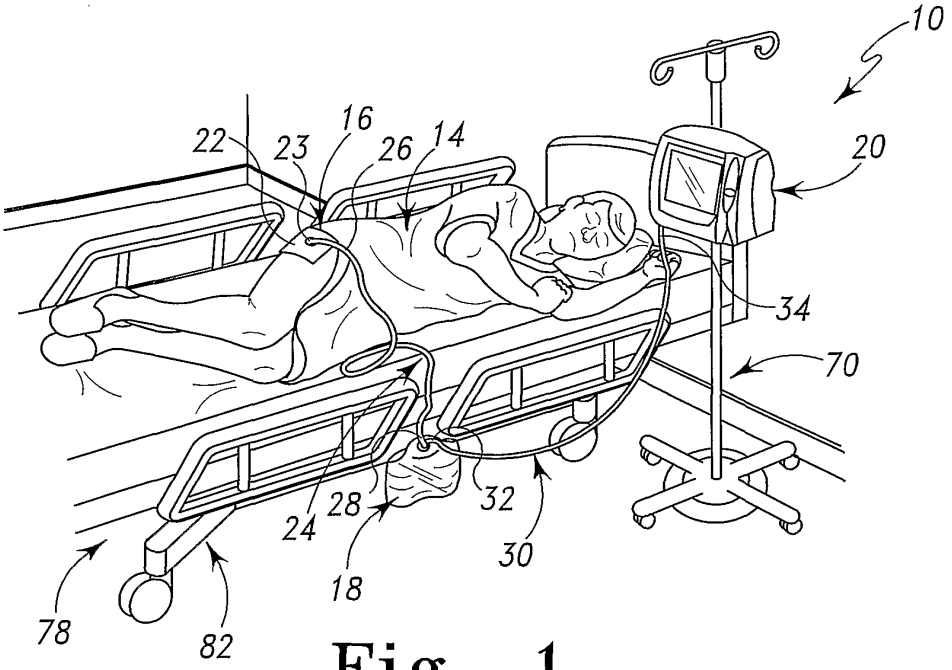

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Fig. 1

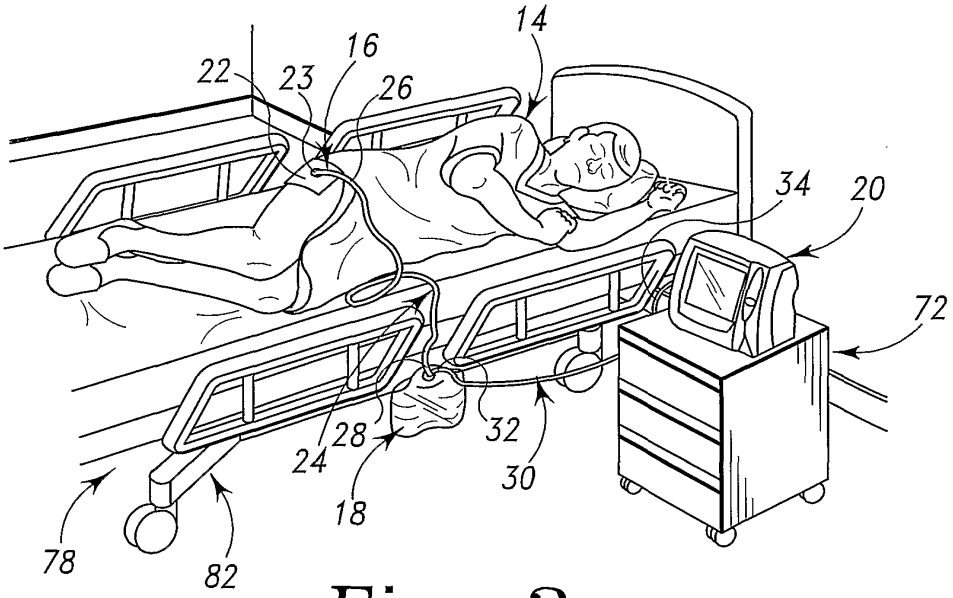

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Fig. 2

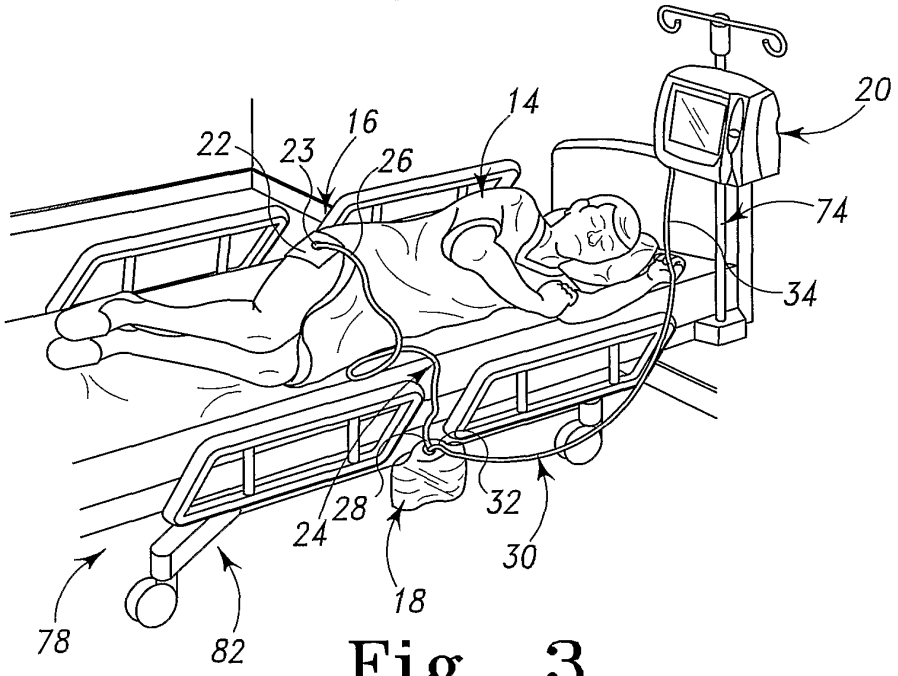

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Fig. 3

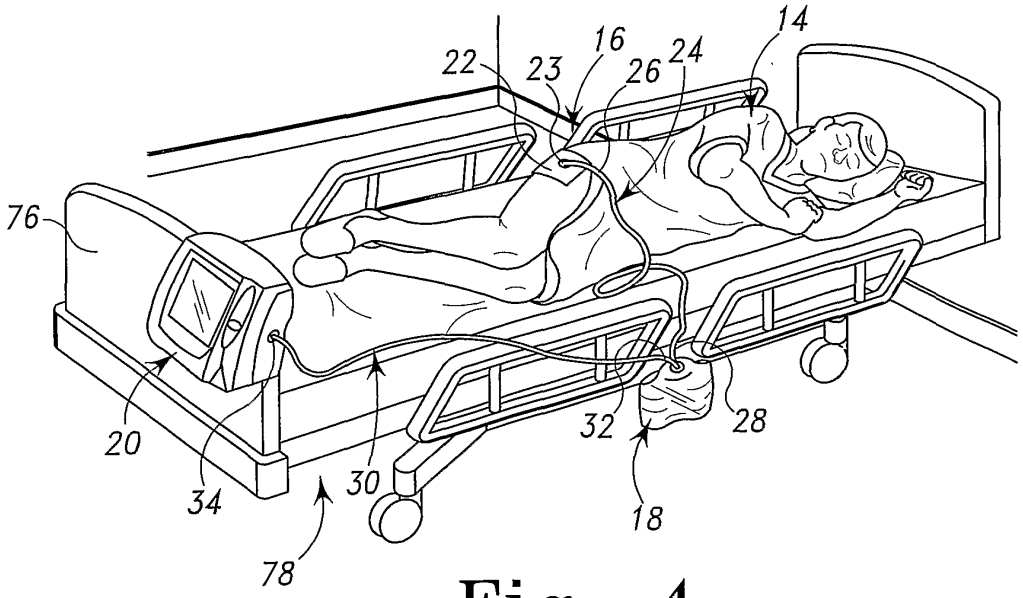

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Fig. 4

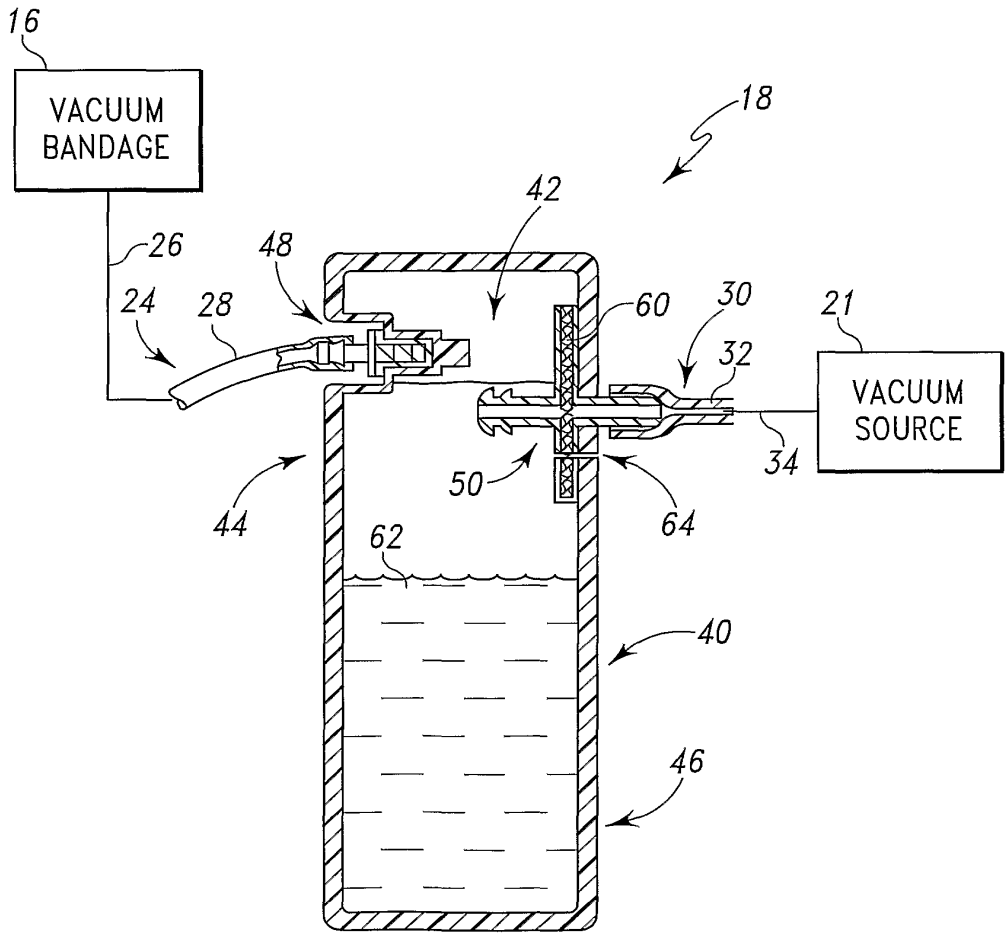

16
VACUUM BANDAGE
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42
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VACUUM SOURCE
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Fig. 5

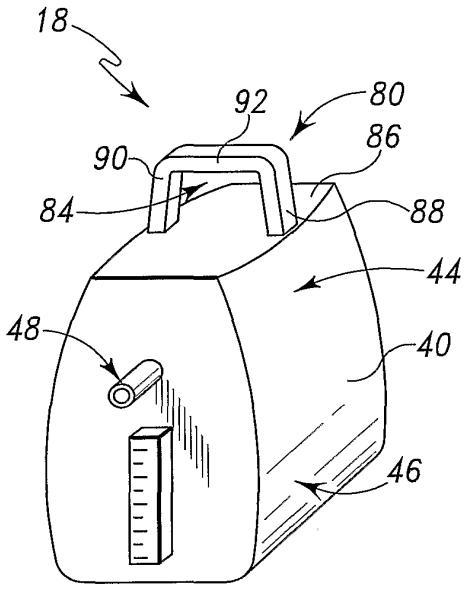


Fig. 6

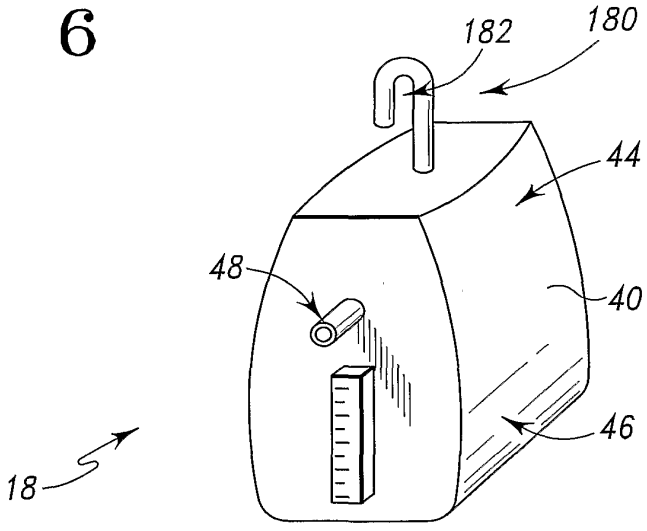


Fig. 7

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 02/32221

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M1/00 A61M27/00

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 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, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 636 643 A (ARGENTA LOUIS C ET AL) 10 June 1997 (1997-06-10) cited in the application column 6, line 19 - line 45; figure 1 column 8, line 65 -column 9, line 19; figure 8 column 8, line 20 - line 26	1-5,7,8, 10-13, 15-22
Y	---	6
Y	WO 01 34223 A (KCI MEDICAL LTD ;HEATON KEITH PATRICK (GB)) 17 May 2001 (2001-05-17) page 5, last paragraph	6

	-/--	

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

[X] Patent family members are listed in annex.

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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
29 January 2003	05/02/2003

Name and mailing address of the ISA	Authorized officer
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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	WO 01 37922 A (HENLEY ALAN WAYNE ;PETROSENKO ROBERT (US); SANDERSON RONALD LESLIE) 31 May 2001 (2001-05-31) cited in the application page 9, paragraph 4; figure 6 ---	4,5,20
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 02/32221

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 23 24
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

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INTERNATIONAL SEARCH REPORT

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International Application No
PCT/US 02/32221

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
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A1

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(30) Priority Data:
9523253.4 14 November 1995 (14.11.95) GB

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(74) Agent: WOODCRAFT, David, Charles; Brookes & Martin, High Holborn House, 52/54 High Holborn, London WC1V 6SE (GB).

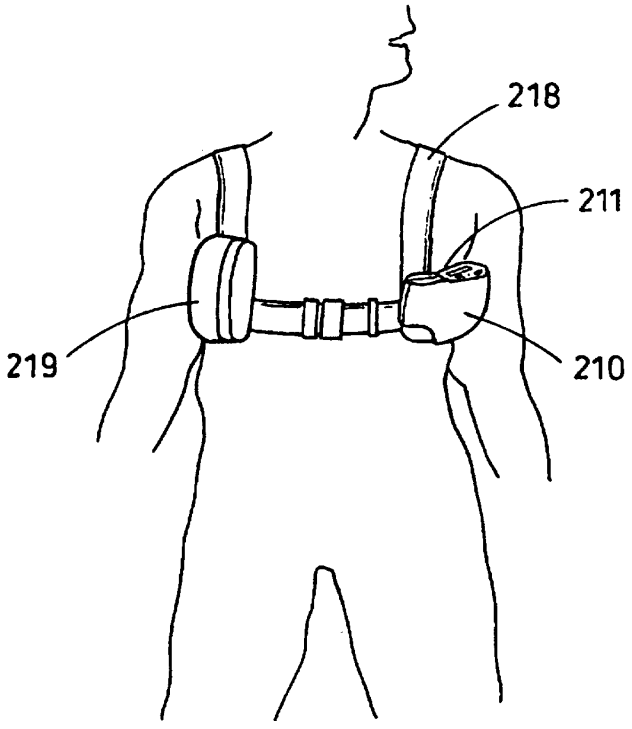
(81) Designated States: CA, DE, JP, US, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
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Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: PORTABLE WOUND TREATMENT APPARATUS

(57) Abstract

The invention relates to a portable wound treatment apparatus for stimulating the healing of superficial wounds. The apparatus comprises a housing (210) containing a suction pump and a canister for containing fluids drawn from the wound. The housing is supported on a harness or belt (216, 218) worn by the patient and is connected to a porous dressing at the wound site by a catheter.



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PORTABLE WOUND TREATMENT APPARATUS

This invention relates to the healing of wounds and, more particularly, to apparatus for stimulating the healing of superficial wounds.

PCT Application No. GB95/01983 (WO 96/05873) describes apparatus for stimulating the healing of wounds comprising a porous pad which is permeable to fluids for introduction into the wound, a dressing for covering the wound and providing an air-tight seal around the wound, a drainage tube connecting the pad to a suction pump so that negative pressure can be applied to the wound to draw fluids therefrom, and a canister for collecting fluids sucked from the wound. The apparatus described in the above application has proved to be clinically effective but there are some limitations in its use.

The apparatus described in the above PCT application is effective for treating a wide variety of different types and sizes of wounds. However, it may require the patient to undergo treatment on the apparatus for a long period. In cases where the patient is confined to bed this may not be a major problem, but where the patient is mobile it means that he or she would be confined for long periods while the treatment takes place.

An object of this invention is therefore to provide apparatus which can be used more conveniently, especially by patients who are reasonably mobile, and which has certain further advantages which will become apparent from the following description.

According to one aspect of the present invention there is provided a portable therapeutic apparatus for stimulating the healing of superficial wounds in a person, which comprises a housing containing a suction pump and a canister for containing fluids drawn from the wound by said pump, said canister including

means for connection to a dressing in the region of the wound and a harness or belt for supporting the housing on the person.

Typically, the housing will have a curved surface on the side intended to be supported against the person's body so as to make the apparatus more comfortable to wear. In addition, controls and indicators indicating the status of the treatment being applied to the wound are preferably located on the upper side of the housing so that the patient can easily see, e.g. the level of suction pressure being applied and the programme for such treatment.

The suction pump is conveniently driven by an electric motor and batteries for such motor may be contained within the housing. However, it is generally more convenient to provide a separate housing for the batteries since these can be placed on the belt or harness in such a way as to balance the weight of the housing, preferably in a housing shaped similarly to the housing for the pump and canister. The canister should be removably mounted within the housing, e.g. by means of a latch or similar release mechanism, so that the canister can be readily removed and replaced when full.

In a portable therapeutic apparatus (in contrast with a static apparatus of the kind described in the above PCT application which cannot be easily carried by the patient), it is less easy to determine the pressure prevailing at the wound site being treated. This is because the pressure will depend, in part, upon the hydrostatic height between the pump and the wound being treated and this height may vary during the treatment, depending upon the patient's movements. Apparatus in accordance with the invention overcomes this problem by providing an additional conduit connecting the wound site or an area close thereto to a pressure-detecting means, preferably located in the housing. The pressure-detecting means can be linked to a microprocessor programmed to maintain such pressure within a

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predetermined range irrespective of the movement of the patient. This can be done by, for example, signalling the pump to increase its speed where the hydrostatic pressure increases between the pump and the wound site or, conversely, reducing its speed where the hydrostatic pressure is reduced. This feature can also be used in a static therapeutic apparatus of the kind described in the above-mentioned PCT application.

In the apparatus described in the above PCT application, the level of liquid in the canister is monitored by capacitance measurement. It has now been found that a simpler way of determining when the canister is filled is by measuring or detecting the pressure drop across the canister. The pressure drop can be increased by providing a filter barrier in the region of the outlet end of the canister. Thus, when the liquid reaches a level within the canister so as to substantially occlude the filter, a sharp pressure change occurs in the conduit between the canister and the pump. By monitoring this pressure change, the point at which the canister is filled can be accurately determined.

Additional advantages and features of the present application will become apparent from the following description and accompanying drawings, in which:-

Figure 1 is a schematic layout of the apparatus in accordance with the invention,

Figure 2A and B are pictorial representations of the housing of the pump and canister,

Figure 3A and B are pictorial representations of the apparatus supported on a belt and harness respectively,

Figure 4 is an exploded view of the housing showing the contents,

Figures 5A to F show various views of a preferred form of the canister and a section of a multi-lumen tube, and

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Figures 6A to D show various views of a foam dressing connector for connecting the housing to the dressing,

Figure 6E shows a section of a modified multi-lumen tube,

Figures 7A & 7B show a plan and perspective view of a surgical drape for use with the apparatus.

Referring to the drawings, the portable therapeutic apparatus comprises a housing 210 (best shown in Figures 2A and 2B), having rounded corners and a side 211 which is concavely curved in order to fit comfortably to the wearer's body. The shaping of the housing with curved surfaces is to avoid sharp corners or edges which could dig in to the user or his carer. The upper surface 212 is generally flat and has an LCD screen 213 on which details such as applied pressure can be displayed. Control buttons 214 are provided to adjust pressures and treatment intervals. Provision is made for housing a canister within the housing and a snap release cover 215 is arranged for removing or introducing the canister.

Figures 3A and 3B show schematically ways in which the housing 210 may be supported on the patient's body. In Figure 3A the housing 210 is supported on a belt 216 and its weight is balanced by a similarly rounded casing 217 containing a rechargeable battery pack. Figure 3B shows an alternative arrangement in which the housing is supported on a harness 218 and again a battery pack is contained in a housing 219, also supported on the harness.

Figure 4 shows an exploded view of the housing 210 indicating the main components within the housing. The housing consists of front and rear shell mouldings 1 and 2 having an external belt clip 21 for attachment to a belt or harness.

Within housing shell 1 is located a suction pump 6 with associated electric motor 6A and the pump is connected by a silicon rubber tube 103 to a canister

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spigot 7A in a compartment 20 for the canister 100. Also connected to a second canister spigot 7B via a tube 10 is a pressure relief valve 8 and both tubes 103 and 10 are connected via T-connectors T to pressure transducers (not shown). A microprocessor 4 is mounted on a PCB board 5 and a membrane assembly 3 incorporates an LCD indicator and control buttons.

The apparatus may include means for recording pressures and treatment conditions given to a particular patient which may be printed out subsequently by the physician. Alternatively, the equipment may include a modem and a telephone jack so that the conditions under which the patient has been treated can be interrogated by the physician from a distant station.

Canister 100 is a push fit into the cavity 20 and its lower end is supported in a cover 30. The cover 30 incorporates fingers 31 which are releasably engageable with lips 32 to hold the canister in position. The canister and the latch mechanism is arranged so that when the latch is engaged, the spigots 7A and 7B are in sealing engagement or abutment with tubular protrusions 33 and 34 formed in the top of the canister.

The method of operation of the apparatus can be appreciated from the schematic layout in Figure 1, in which the canister 100 is connected via tube 101 to a porous dressing 102 at the wound site. Suction is applied to the wound site via the canister by a tube 103, connected to the pump 6. The pressure in the tube 103 is detected by the transducer 105.

A second tube 106 is connected to the wound site 102 at one end, and also to a pressure relief valve 8 and to a second transducer 108. Tubes 106 and 101 can be combined in a multi-partitioned tube in manner to be described later. By means of tube 106 and transducer 108 the pressure at the wound site can be measured or monitored. A filter 109 is placed at or close to the outlet end of the

canister 100 to prevent liquid or solid particles from entering the tube 103. The filter is a bacterial filter which is hydrophobic and preferably also lypophobic. Thus, aqueous and oily liquids will bead on the surface of the filter. During normal use there is sufficient air flow through the filter such that the pressure drop across the filter is not substantial.

As soon as the liquid in the canister reaches a level where the filter is occluded, a much increased negative pressure occurs in tube 103 and this is detected by transducer 105. Transducer 105 is connected to circuitry which interprets such a pressure change as a filled canister and signals this by means of a message on the LCD and/or buzzer that the canister requires replacement. It may also automatically shut off the working of the pump.

In the event that it is desired to apply intermittent suction to the wound site, a pressure relief valve 8 enables the pressure at the wound site to be brought to atmospheric pressure rapidly. Thus, if the apparatus is programmed, for example, to relieve pressure at 10 minute intervals, at these intervals valve 8 will open for a specified period, allow the pressure to equalise at the wound site and then close to restore the suction. It will be appreciated that when constant suction (or negative pressure) is being applied to the wound site, valve 8 remains closed and there is no leakage from atmosphere. In this state, it is possible to maintain negative pressure at the wound site without running the pump continuously, but only from time to time, to maintain a desired level of negative pressure (i.e. a desired pressure below atmospheric), which is detected by the transducer 105. This saves power and enables the appliance to operate for long periods on its battery power supply.

Instead of running two separate tubes to the wound site, it is preferable to contain tubes 106 and 101 in a single tube which is connected through the canister. Thus, for example, tubes 103 and 101 may comprise an internal tube surrounded by

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an annular space represented by tube 106. This is illustrated in Figures 5A to 5F and in a modified form in Figure 6E.

In an alternative embodiment, the multi-lumen tube may be constructed as shown in Figure 6E. In this embodiment, the internal bore 606 comprises the line 101 (see Figure 1) and is used to extract fluids from the wound site. Air flow (represented by line 106 in Figure 1) passes down conduits 607 located within the walls of the tube. By spacing the conduits 607 at 90° intervals around the tube, the risk of arresting the air flow by kinking or twisting the multi-lumen tube is minimised.

Figure 5E is a plan view of the top of a preferred shape of canister, the generally triangular shape in section being chosen to fit better the space within cavity 20 (see Figure 4). Tubular protrusions on the top of the canister are connected internally of the canister with respectively conduits 124 and 121 (see sectional view of Figure 5B), thus maintaining a separation between the tubes which are represented by lines 103 and 106 in Figure 1. At the base of the canister, a moulding 125 facilitates connection to a multi-partitioned tube 126 shown in Figure 5F. Tube 126 has a central bore 127 which is sized to fit over a spigot 128 in moulding 125. At the same time, the external wall of tube 126 seals against the inner wall 129 of moulding 125. Thus, compartment 124 will connect with central bore 127 and the compartment 121 will connect with the annular spaces 130 of tube 126. In this way, a conduit 130 corresponds with line 106 and central bore 127 with line 101 as shown in Figure 1.

The partitioned tube need not continue all the way to the wound site 102, but can be connected to a short section of single bore tube close to the wound site.

In the event of an air leak in the dressing at the wound site 102, this can be detected by both transducers 105 and 108 reading insufficient negative pressure for

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a specific time period, and then triggering a leak alarm, i.e. a message on the LCD, preferably also with an audible warning.

Typically, the pump 6 is a diaphragm pump but other types of pumps and equivalent components to those specifically employed may be substituted.

Figures 6A~6D show various views of a connector for attaching the multi-lumen tube at the wound site. Figures 7A and 7B show a plan and perspective view of a surgical drape for attaching the connector to a porous dressing at the wound site. The connector comprises a moulded plastics disc-like cup 601 having a centrally positioned spout 602. The spout 602 is sized to accept, as a closely sliding fit, the end of a multi-lumen tube e.g. of the kind shown in Figures 5F or 6E. In use, a porous dressing is cut to correspond with the extent of the wound and pressed onto the wound as shown in Figure 10 of our above cited PCT application WO 96/05873. Instead of introducing the lumen into the foam dressing, the cup 601 is pressed onto the porous dressing and secured by a surgical drape. However, if desired, the end of the lumen can be passed into the spout and additionally pressed into the foam. A surgical drape such as shown in Figures 7A and 7B, can be used to secure the connector, lumen and dressing. The drape comprises a polyurethane film 701 coated on one side with a pressure-sensitive acrylic resin adhesive. A hole 702 is cut through all layers of the drape and the hole is dimensioned to correspond approximately with the outer cross-section of the spout 602. Film 701 has an overall size which allows it to be adhered to the patient's skin around the wound site, while at the same time, securing the connector to the porous dressing. A sufficient overlap around the wound is provided so that an air-tight cavity is formed around the wound.

In an alternative form, the drape can be made in two parts, e.g. by cutting along the line X-X in Figure 7A. With this arrangement, the wound can be sealed

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by overlapping two pieces of surgical drape so that they overlap each other along a line Y-Y as shown in Figure 6D.

The surgical drape may include a protective film 703, e.g. of polyethylene, and a liner 704 which is stripped off prior to use to expose the pressure-sensitive adhesive layer. The polyurethane film may also include handling bars 705,706, which are not coated with adhesive, to facilitate stretching of the film over the wound site. The dressing is preferably a pad of porous, flexible plastics foam, e.g. reticulated, open intercommunicating cellular flexible polyurethane foam, especially of the kind described in the above-mentioned PCT application WO 96/05873.

Alternatively, a reticulated intercommunicating cellular foam made from flexible polyvinylacetate or polyvinylalcohol foam may be used. The latter is advantageous because it is hydrophilic. Other hydrophilic open celled foams may be used.

In another method of therapy, the foam dressing may be sutured into a wound after surgery and the foam dressing connected to the pump unit by the multi-lumen catheter. Negative pressure can then be applied continuously or intermittently for a period determined by the surgeon, e.g. from about 6 hours to 4 to 5 days. After this period, the dressing is removed and the wound re-sutured. This therapy improves the rate of granulation and healing of wounds after surgery.

CLAIMS:-

1. A portable therapeutic apparatus for stimulating the healing of a superficial wound in a person, which comprises a housing containing a suction pump and a canister for containing fluids drawn from the wound by said pump, said canister including means for connection to a dressing in the region of the wound and a harness or belt for supporting the housing on the person.

2. Apparatus as claimed in claim 1 wherein the housing has a curved surface on the side intended to be supported against the person's body, and controls located on an upper side of the housing.

3. Therapeutic apparatus for stimulating healing of a wound in mammals which comprises a porous pad, which is permeable to liquids for introduction into the wound, a dressing for covering the wound and providing a substantially air-tight seal around the wound, a drainage tube connecting the pad to a suction pump so that suction can be applied to the wound to draw liquids therefrom, said tube being connected to the pump via a canister for collecting liquids sucked from the wound and a filter barrier located in the canister at the outlet side, and pressure detecting means arranged to detect pressure changes in the tube between the canister and the pump and to signal a pressure change when liquid in the canister covers a substantial part of the filter barrier, thus indicating a full canister.

4. Apparatus as claimed in claim 3 wherein the filter barrier covers the entire outlet from the canister and the dimensions of the pores in said barrier are such that when liquid covers substantially the whole of the filter barrier, said pressure detecting means signals a sharp increase in negative pressure in the tube connecting the canister with the pump.

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5. Therapeutic apparatus for stimulating healing of a wound in mammals which comprises a porous pad, which is permeable to liquids for introduction into the wound, a dressing for covering the wound and providing a substantially air-tight seal around the wound, a drainage tube connecting the pad to a suction pump so that suction can be applied to the wound to draw liquids therefrom, said tube being connected to the pump via a canister for collecting liquids sucked from the wound and at least one filter interposed between the canister and the pump, said apparatus including an additional conduit connecting the porous pad to pressure detecting means whereby the pressure substantially at the wound site can be monitored.

6. Apparatus as claimed in claim 5 which includes a relief valve for admitting air to the additional conduit and means for controlling the operation of the valve so that intermittent suction can be applied to the wound site.

7. Apparatus as claimed in claim 5 or 6 in which a single tube links the porous pad with the housing, said tube being longitudinally partitioned to provide a conduit for applying suction and an additional conduit for connection to said pressure detecting means.

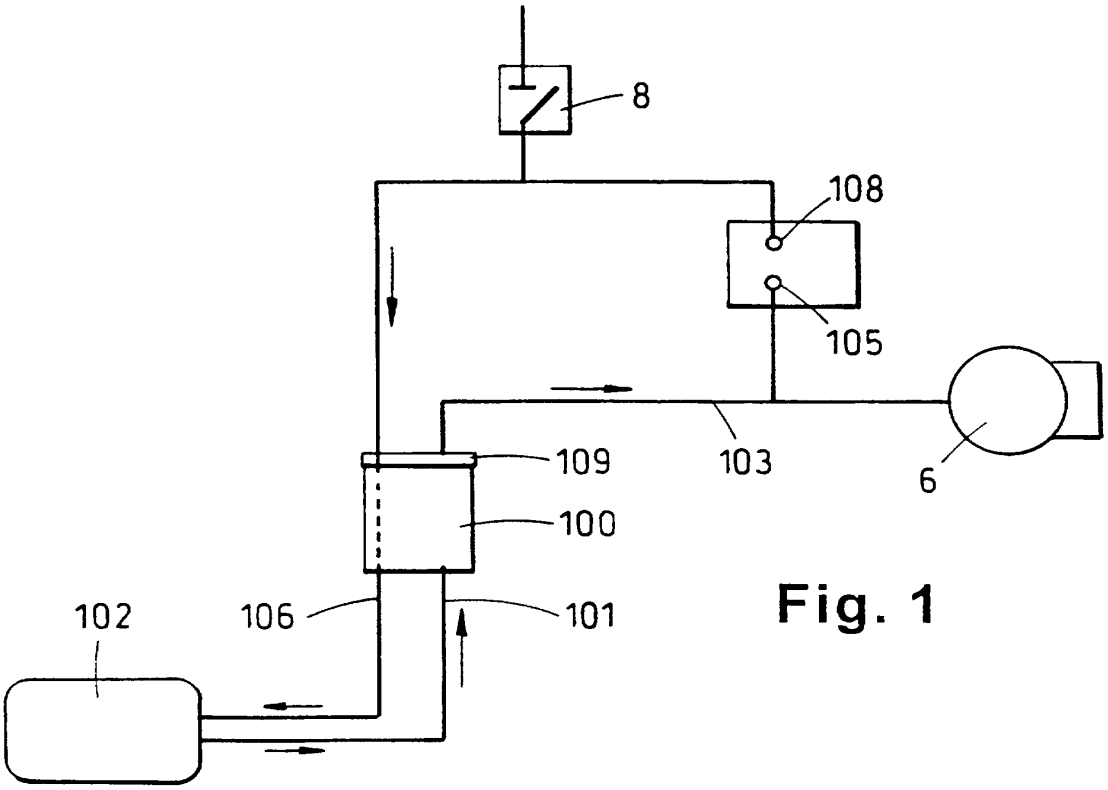


Fig. 1

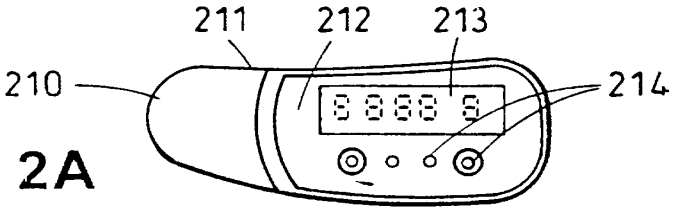


Fig. 2A

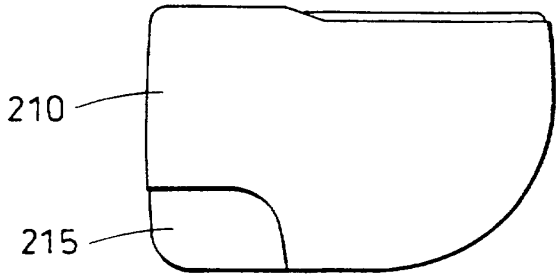


Fig. 2B

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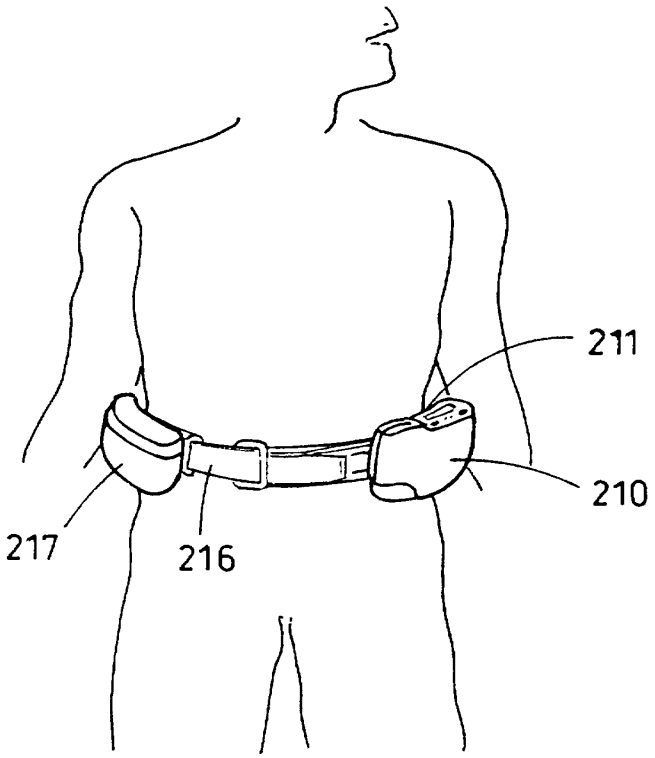


Fig. 3A

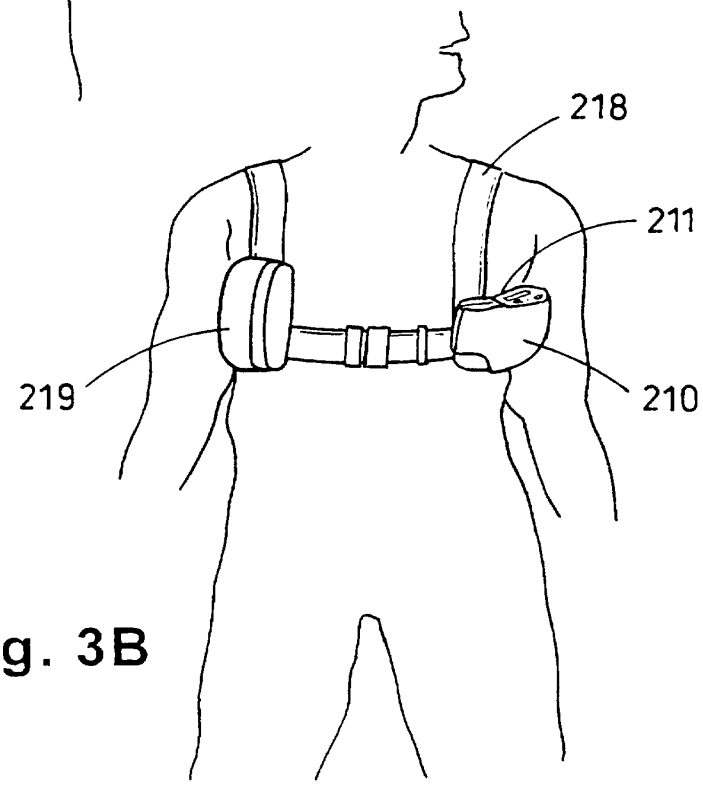


Fig. 3B

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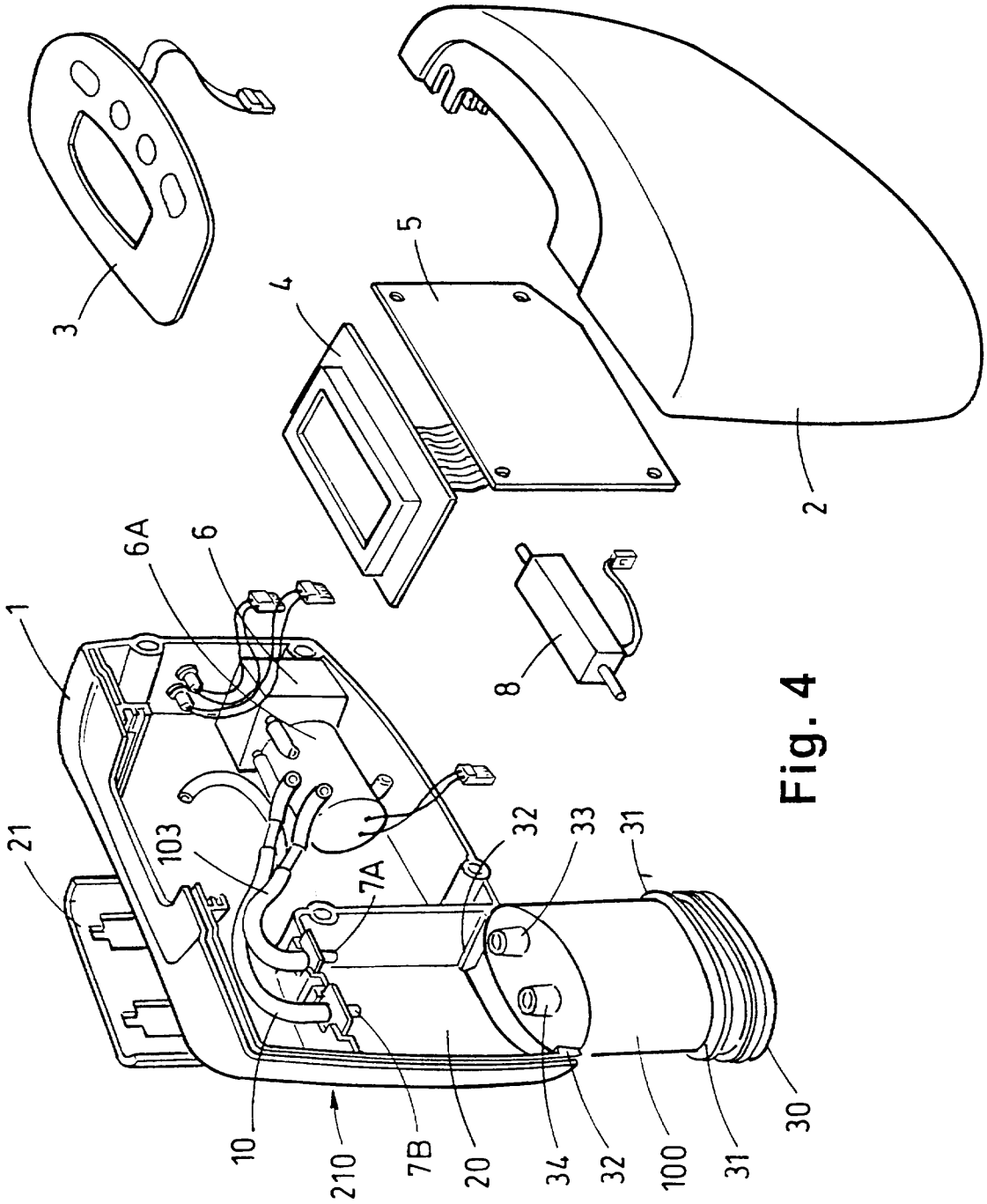


Fig. 4

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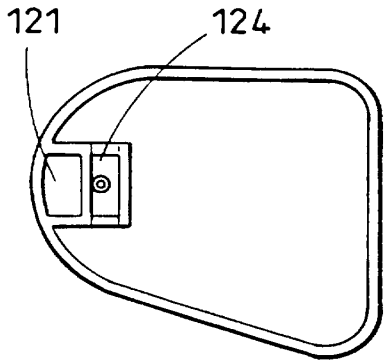


Fig. 5A

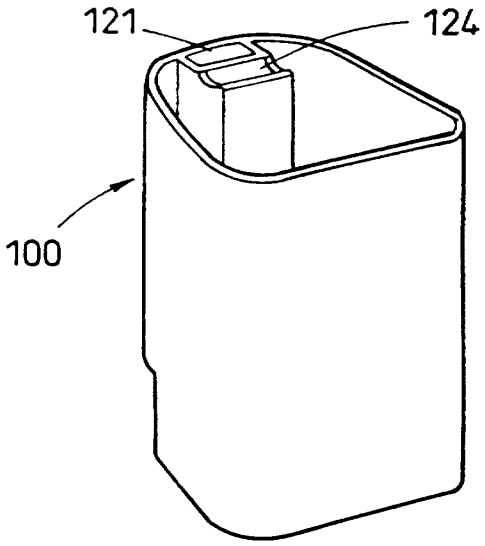


Fig. 5D

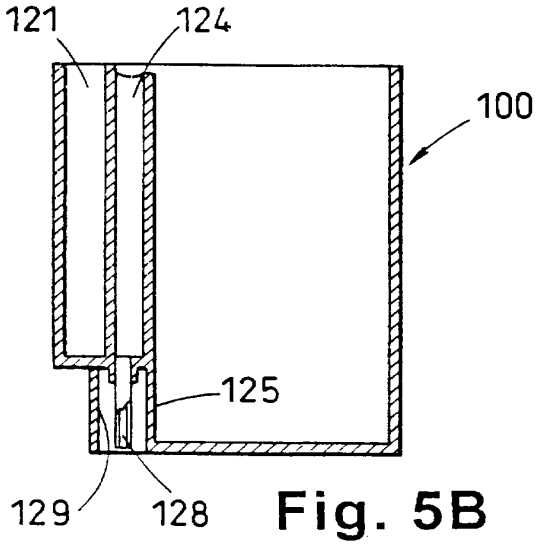


Fig. 5B

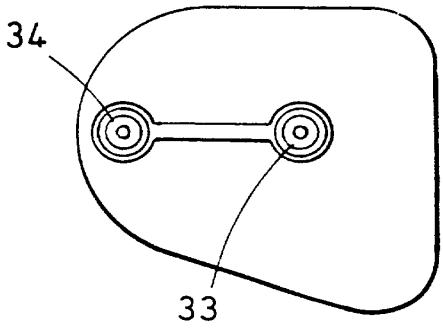


Fig. 5E

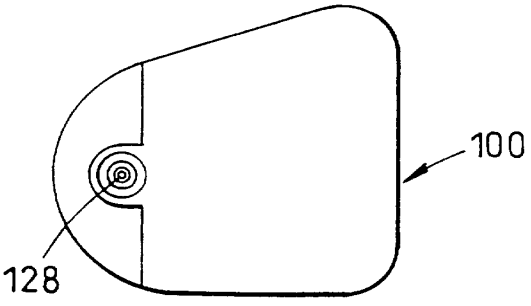


Fig. 5C

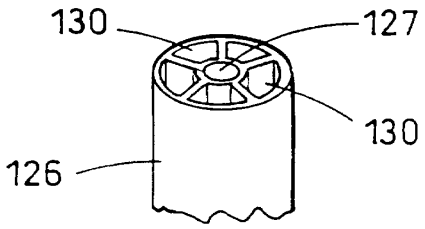


Fig. 5F

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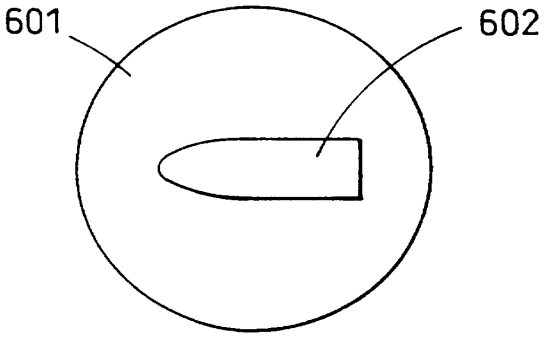


Fig. 6A

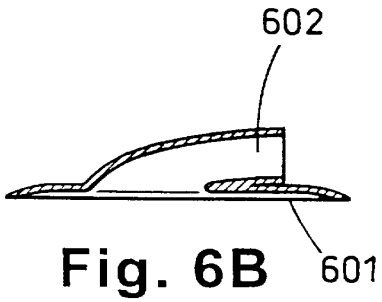


Fig. 6B

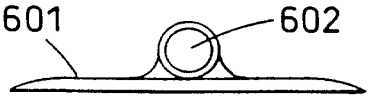


Fig. 6C

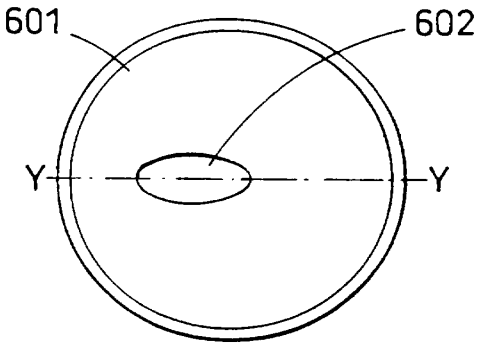


Fig. 6D

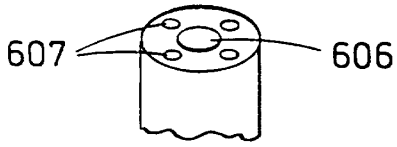


Fig. 6E

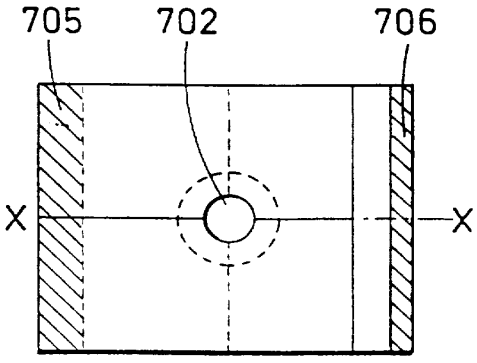


Fig. 7A

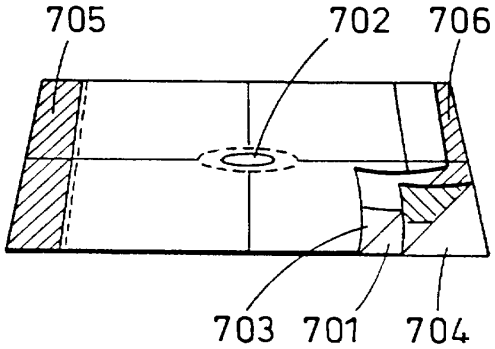


Fig. 7B

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INTERNATIONAL SEARCH REPORT

I ational Application No
PCT/GB 96/02802

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M27/00 A61M1/00

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 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.
X	US 5 134 994 A (SAY) 4 August 1992 see column 1, line 7 - line 9 see column 2, line 6 - column 4, line 2 see figures 1,4-8	1
Y	---	2
Y	WO 80 02182 A (MOSS) 16 October 1980 see page 4, line 23 - line 31 see figure 1	2

X	US 4 710 165 A (MCNEIL ET AL.) 1 December 1987 see column 5, line 1 - line 56	1

	-/--	

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

[X] Patent family members are listed in annex.

* Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

1

Date of the actual completion of the international search	Date of mailing of the international search report
17 April 1997	29.04.97
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl, Fax (+ 31-70) 340-3016	**Authorized officer** Schönleben, J

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

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/GB 96/02802

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 94 20041 A (WAKE FOREST UNIVERSITY) 15 September 1994 see page 12, line 8 - page 17, line 8 see page 18, line 2 - line 35 see figures 1,8	3-7
A		5
Y	DE 295 04 378 U (MTG) 14 September 1995 see the whole document	3,4
Y	DE 43 06 478 A (WAGNER) 8 September 1994 see column 2, line 8 - line 16 see column 4, line 66 - column 5, line 65 see figures 1-5	5-7
A	GB 2 220 357 A (SMITHS INDUSTRIES) 10 January 1990 see page 7, line 1 - page 8, line 20 see figure 1	3
A	GB 2 235 877 A (ANTONIO TALLURI) 20 March 1991 see page 4, line 12 - page 5, line 18 see figures 2-4	3
A	US 3 066 672 A (CROSBY ET AL.) 4 December 1962 see column 1, line 67 - column 2, line 35 see figures 1,3	6

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

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INTERNATIONAL SEARCH REPORT

.ternational applicauon No.
PCT/GB 96/02802

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Arucle 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 II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

SEE ANNEX

1. ☒ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searches without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☒ No protest accompanied the payment of additional search fees.

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INTERNATIONAL SEARCH REPORT

Information on patent family members

national Application No
PCT/GB 96/02802

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5134994 A	04-08-92	NONE	
WO 8002182 A	16-10-80	US 4266545 A	12-05-81
		EP 0026226 A	08-04-81
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US 4710165 A	01-12-87	NONE	
WO 9420041 A	15-09-94	AU 6360894 A	26-09-94
		EP 0688189 A	27-12-95
DE 29504378 U	14-09-95	NONE	
DE 4306478 A	08-09-94	WO 9420152 A	15-09-94
		EP 0692987 A	24-01-96
GB 2220357 A	10-01-90	EP 0358302 A	14-03-90
GB 2235877 A	20-03-91	NONE	
US 3066672 A	04-12-62	NONE	

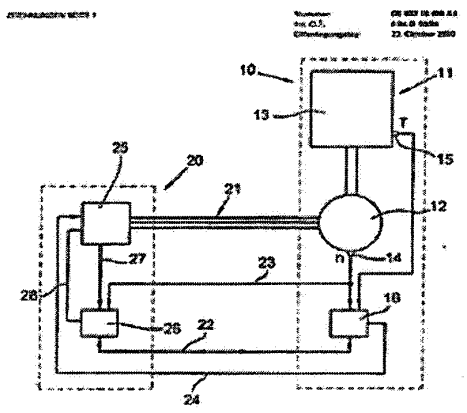
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© PatBase

1) Family number: 29153066 (WO03085268A)

Title: VACUUM PUMP
VAKUUMPUMPE POMPE A VIDE

Abstract:
Source: WO03085268A Disclosed is a vacuum pump comprising a pump unit (10) and a control device (20),which are interconnected by means of cables. A microcontroller (26) that is providedin the control device (20) controls an inverter (25) supplying motor power tothe turbomolecular pump (11). A microcontroller (16) which is disposed insidethe pump unit (10) monitors operation of the pump and also stores device-specificdata and event-related data of the turbomolecular pump. The microcontrollers(16, 26) mutually monitor each other and monitor the security of data communicationand the intactness of the transmission channels.



Die Vakuumpumpe enthaelt eine Pumpeneinheit (10) und ein Steuergeraet(20), die durch Kabel miteinander verbunden sind. Ein Steuer-Mikrocontroller(26) im Steuergeraet (20) steuert einen Wechselrichter (25), der den Motorstromder Turbo-Molekular-pumpe (11) liefert. Der Pumpenbetrieb wird von einem ueberwachungs-Mikrocontroller(16) ueberwacht, der in der Pumpeneinheit (10) positioniert ist. Der ueberwachungs-Mikrocontroller(16) speichert ausserdem geraetebezogene Daten und ereignisbezogeneDaten der Turbo-Molekularpumpe. Die Mikrocontroller (16, 26) ueberwachensich wechselseitig und sie ueberwachen auch die Sicherheit der Datenkommunikationund die Intaktheit der uebertragungskanaele. L'invention concerne une pompe a vide comprenant une unitepompe (10) et un appareil de commande (20) qui sont relies par un cable.Un microcontroleur de commande (26), loge dans l'appareilde commande (20), commande un onduleur (25) qui delivre le courant de moteura la pompe turbomoleculaire (11). Le mode de fonctionnement de lapompe est surveille par un microcontroleur de surveillance (16)qui est place dans l'unite pompe (10). Par ailleurs, le microcontroleurde surveillance (16) enregistre les donnees specifiques appareilet des donnees specifiques evenement de la pompe turbomoleculaire.Les microcontroleurs (16, 26) se surveillent mutuellement et surveillentegalement la securite de la communication des donneeset le bon etat des canaux de transmission.

(19) BUNDESREPUBLIK DEUTSCHLAND

DEUTSCHES PATENT- UND MARKENAMT

(12) **Offenlegungsschrift**

(10) **DE 102 15 896 A 1**

(51) Int. Cl.[7]:
F 04 D 19/04
H 02 H 7/093
F 04 D 27/00

(21) Aktenzeichen: 102 15 896.7
(22) Anmeldetag: 11. 4. 2002
(43) Offenlegungstag: 23. 10. 2003

DE 102 15 896 A 1

(71) Anmelder:
Leybold Vakuum GmbH, 50968 Köln, DE

(74) Vertreter:
Patentanwälte von Kreisler, Selting, Werner et col., 50667 Köln

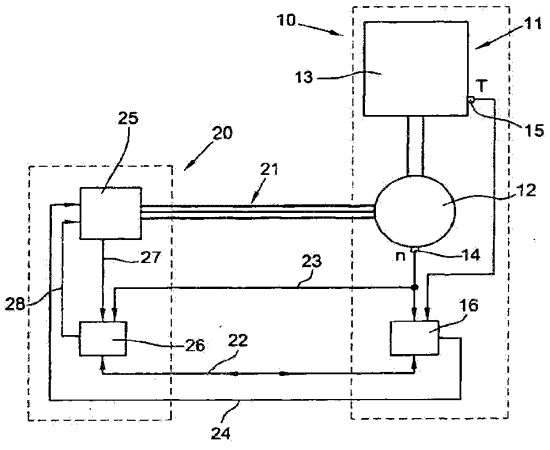
(72) Erfinder:
Harig, Christian, 51105 Köln, DE; Kieffer, Manfred, 50389 Wesseling, DE

(56) Für die Beurteilung der Patentfähigkeit in Betracht zu ziehende Druckschriften:
DE 42 37 971 A1
JP 2221698 A., In: Patent Abstracts of Japan;;
JP 10289001 A., In: Patent Abstracts of Japan;;

Die folgenden Angaben sind den vom Anmelder eingereichten Unterlagen entnommen

(54) Vakuumpumpe

(57) Die Vakuumpumpe enthält eine Pumpeneinheit (10) und ein Steuergerät (20), die durch Kabel miteinander verbunden sind. Ein Steuer-Mikrocontroller (26) im Steuergerät (20) steuert einen Wechselrichter (25), der den Motorstrom der Turbo-Molekularpumpe (11) liefert. Der Pumpenbetrieb wird von einem Überwachungs-Mikrocontroller (16) überwacht, der in der Pumpeneinheit (10) positioniert ist. Der Überwachungs-Mikrocontroller (16) speichert außerdem gerätebezogene Daten und ereignisbezogene Daten der Turbo-Molekularpumpe. Die Mikrocontroller (16, 26) überwachen sich wechselseitig und sie überwachen auch die Sicherheit der Datenkommunikation und die Intaktheit der Übertragungskanäle.



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Beschreibung

[0001] Die Erfindung betrifft eine Vakuumpumpe mit einer eine Turbo-Molekularpumpe enthaltenden Pumpeneinheit und einem einen Wechselrichter enthaltenden Steuergerät, welches den Motorstrom für die Pumpeneinheit liefert.

[0002] Turbo-Molekularpumpen, wie sie beispielsweise in US 6,184,640 B1 oder in EP 0 836 009 B1 beschrieben sind, bestehen aus einer Pumpeneinheit und einem daran angeschlossenen Steuergerät. Die zur Pumpeneinheit gehörende Turbo-Molekularpumpe hat eine hohe Betriebsdrehzahl von über 10.000 U/min. Der Rotor dieser Pumpe hat also im Betrieb eine sehr hohe kinetische Energie. Im Fehlerfall, insbesondere bei einem. Rotor-Stator-Kontakt, werden Teile des Rotors nach außen geschleudert. Dies kann zum Bersten des Gehäuses der Turbo-Molekularpumpe führen und ein Lösen der gesamten Pumpe von der Befestigung zur Folge haben. Bei größeren Turbo-Molekularpumpen mit entsprechend großem Rotor-Trägheitsmoment ist es praktisch unmöglich, alle denkbaren Gefahrenmomente durch entsprechend stark ausgelegte Gehäusekomponenten auszuschließen.

[0003] Eine wesentliche Gefahrenquelle bildet ein Versagen oder eine Fehlfunktion des Wechselrichters, der die Betriebsströme für den Pumpenmotor erzeugt. Der Pumpenmotor ist in der Regel ein bürstenloser Gleichstrommotor, dessen Rotor mit Permanentmagneten ausgestattet ist. Der Stator enthält Wicklungen, in denen ein um die Achse rotierendes Magnetfeld erzeugt wird. Ein fehlerhafter Wechselrichter kann dazu führen, dass die Pumpe mit einer zu hohen Drehzahl betrieben wird.

[0004] Der Erfindung liegt die Aufgabe zugrunde, eine aus einer Pumpeneinheit und einem Steuergerät bestehende Vakuumpumpe zu schaffen, bei der eine zuverlässige redundante Drehzahlüberwachung unter ständiger Prüfung der Signalwege mit geringem Aufwand erfolgt.

[0005] Die Lösung dieser Aufgabe erfolgt erfindungsgemäß mit den im Patentanspruch 1 angegebenen Merkmalen. Hiernach enthält die Pumpeneinheit einen Überwachungs-Mikrocontroller, dem die Signale des Drehzahlsensors der Pumpeneinheit zugeführt werden und der im Falle des Überschreitens einer vorgespeicherten maximalen Drehzahl den Wechselrichter abschaltet. Außerdem ist vorgesehen, dass der im Steuergerät enthaltene Steuer-Mikrocontroller und der in der Pumpeneinheit vorgesehene Überwachungs-Mikrocontroller zum Datenabgleich miteinander kommunizieren.

[0006] Dadurch, dass der Überwachungs-Mikrocontroller in der Pumpeneinheit angeordnet ist, kann er zwei unterschiedliche Funktionen erfüllen, nämlich einerseits die Speicherung der Pumpenparameter, zu denen unter anderem die höchstzulässige Pumpendrehzahl gehört, und zum anderen die Überwachungs- und Abschaltaufgabe. Der Überwachungs-Mikrocontroller führt mit dem Steuer-Mikrocontroller einen Dialog zum Datenabgleich. Dadurch werden zugleich die Datenwege überprüft. Das Signal des Drehzahlsensors, das die aktuelle Pumpendrehzahl repräsentiert, wird beiden Mikrocontrollern zugeführt, so dass in beiden Mikrocontrollern jeweils unabhängig beurteilt wird, ob die Pumpendrehzahl im zulässigen Bereich liegt. Sofern die maximale Pumpendrehzahl von der Betriebstemperatur der Pumpe abhängig ist, kann außerdem das Signal eines Temperatursensors an die Mikrocontroller geliefert werden.

[0007] Wenn der Steuer-Mikrocontroller versagt und daher die Pumpendrehzahl über den zulässigen Wert ansteigt, wird dies von dem Überwachungs-Mikrocontroller erkannt und dieser bewirkt über einen eigenen Kanal die sofortige Abschaltung des Wechselrichters.

[0008] Wenn bei der Kommunikation der beiden Mikrocomputer während des Datenabgleichs festgestellt wird, dass die zu vergleichenden Daten voneinander abweichen, folgt eine Fehlermeldung bzw. eine Beendigung des Pumpenbetriebes.

[0009] Dadurch, dass der Überwachungs-Mikrocontroller in der Pumpeneinheit angeordnet ist und außer der Überwachungsfunktion auch die Funktion der Speicherung der Pumpendaten und ihre Übertragung an den Steuer-Mikrocontroller wahrnimmt, hat der Überwachungs-Mikrocontroller eine Doppelfunktion. Üblicherweise werden für die drei Funktionen Steuerung, Überwachung und Speicherung drei Mikrocontroller eingesetzt. Demgegenüber sind bei der erfindungsgemäßen Vakuumpumpe für die genannten drei Funktionen nur zwei Mikrocontroller erforderlich.

[0010] Ein Mikrocontroller im Sinne der vorliegenden Erfindung ist ein Mikroprozessor mit den zugehörigen Speichern und anderen Hilfskomponenten, also ein kompletter Computer, der imstande ist, eine Speicherung und Verarbeitung von Daten selbständig vorzunehmen und einen Dialog mit anderen Rechnern zu führen.

[0011] Im Folgenden wird unter Bezugnahme auf die einzige Figur der Zeichnung ein Ausführungsbeispiel der Erfindung näher erläutert.

[0012] In der Zeichnung ist ein schematisches Blockschaltbild der Vakuumpumpe dargestellt.

[0013] Die Vakuumpumpe weist eine Pumpeneinheit **10** auf, die eine Turbo-Molekularpumpe **11** enthält. Die Turbo-Molekularpumpe **11** besteht aus einem Motor **12**, der hier als bürstenloser Gleichstrommotor ausgebildet ist, und einem Pumpenteil **13**. Der Motor **12** treibt den Pumpenteil **13** direkt an, also ohne Zwischenschaltung eines Übersetzungsgetriebes. Der Motor **12** ist ein schnelllaufender Motor mit Drehzahlen über 10.000 U/min.

[0014] Ein Drehzahlsensor **14** ermittelt die Drehzahl des Motors **12** bzw. die Drehzahl des Rotors des Pumpenteils **13**. Der Drehzahlsensor **14** ist beispielsweise eine Spule, die auf einen mit der Welle rotierenden Magneten anspricht und bei jedem Durchlauf des Magneten einen Impuls erzeugt. Ferner ist ein Temperatursensor **15** vorgesehen, der die Temperatur T des Pumpenteils **13** misst.

[0015] Die Pumpeneinheit **10** enthält ferner einen Überwachungs-Mikrocontroller **16**. Dieser empfängt die Signale des Drehzahlsensors **14** und des Temperatursensors **15**. Er enthält einen Speicher, in dem Kenndaten der Turbo-Molekularpumpe **11** gespeichert sind, wie die höchstzulässige Drehzahl, das Herstellungsdatum, die Maschinennummer und ähnliches. Außerdem werden in dem Speicher Ereignisse gespeichert, wie das Auftreten einer Überdrehzahl, die Wartungsdaten des Gerätes oder auch Angaben über das Steuergerät, mit welchem die Pumpeneinheit kombiniert wurde.

[0016] Der Betrieb der Pumpeneinheit wird von dem Steuergerät **20** gesteuert, das auch die Stromversorgung liefert. Das Steuergerät ist über Kabel mit der Pumpeneinheit verbunden. Das Kabel enthält eine dreiphasige Versorgungsleitung **21** sowie Daten- oder Signalleitungen **22**, **23**.

[0017] Das Steuergerät **20** enthält einen Wechselrichter **25**, der die für den Betrieb des Motors **12** erforderlichen Phasenspannungen der entsprechenden Frequenz liefert, und einen Steuer-Mikrocontroller **26**. Der Steuer-Mikrocontroller **26** empfängt über eine Leitung **27** ein Signal über die aktuelle Frequenz der Motor-Betriebssignale, also ein Signal, das der Soll-Drehzahl entspricht. Über die Leitung **23** erhält der Steuer-Mikrocontroller **26** das Ist-Signal der Motordrehzahl n. Weichen diese beiden Signale voneinander ab, dann bewirkt der Steuer-Mikrocontroller **26** über eine Leitung **28** die Abschaltung des Wechselrichters **25**.

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[0018] Der Überwachungs-Mikrocontroller **16** kann über die Leitung **24** ebenfalls den Wechselrichter **25** ausschalten. Dies geschieht beispielsweise dann, wenn die vom Drehzahlsensor **14** gemessene Drehzahl über der maximal zulässigen Drehzahl liegt.

[0019] Auf der Leitung **22** können die Mikrocontroller **16** und **26** bidirektional untereinander kommunizieren. Beispielsweise teilt der Überwachungs-Mikrocontroller **16** dem Steuer-Mikrocontroller **26** die maximal zulässige Drehzahl der Turbo-Molekularpumpe **11** mit. Die Datenübertragung erfolgt unter Anwendung üblicher Sicherheitstechniken mit Fehlererkennung, beispielsweise nach dem CRC-Verfahren (Cyclic Redundancy Check). Dadurch wird die Datenübertragung insbesondere auf der Leitung **22** gesichert.

[0020] Der Überwachungs-Mikrocontroller **16** überwacht den Steuer-Mikrocontroller **26** und prüft außerdem, ob die Datenwege intakt sind. Wird ein Fehler festgestellt, so schaltet der Überwachungs-Mikrocontroller **16** über Leitung **27** den Wechselrichter **25** ab und bewirkt eine Alarmerzeugung. Ferner wird in gewissen Zeitabständen der Wechselrichter für kurze Zeit (einige Millisekunden) abgeschaltet und geprüft, ob und mit welcher Charakteristik der Motorstrom absinkt.

[0021] Die Überprüfung der Datenwege erfolgt in der Weise, dass das Ausbleiben von Daten auf einer der Leitungen **22, 23** zu einer Abschaltung führt. Auf diese Weise werden sowohl Unterbrechungen als auch Signalverfälschungen oder abnorme Situationen sicher festgestellt.

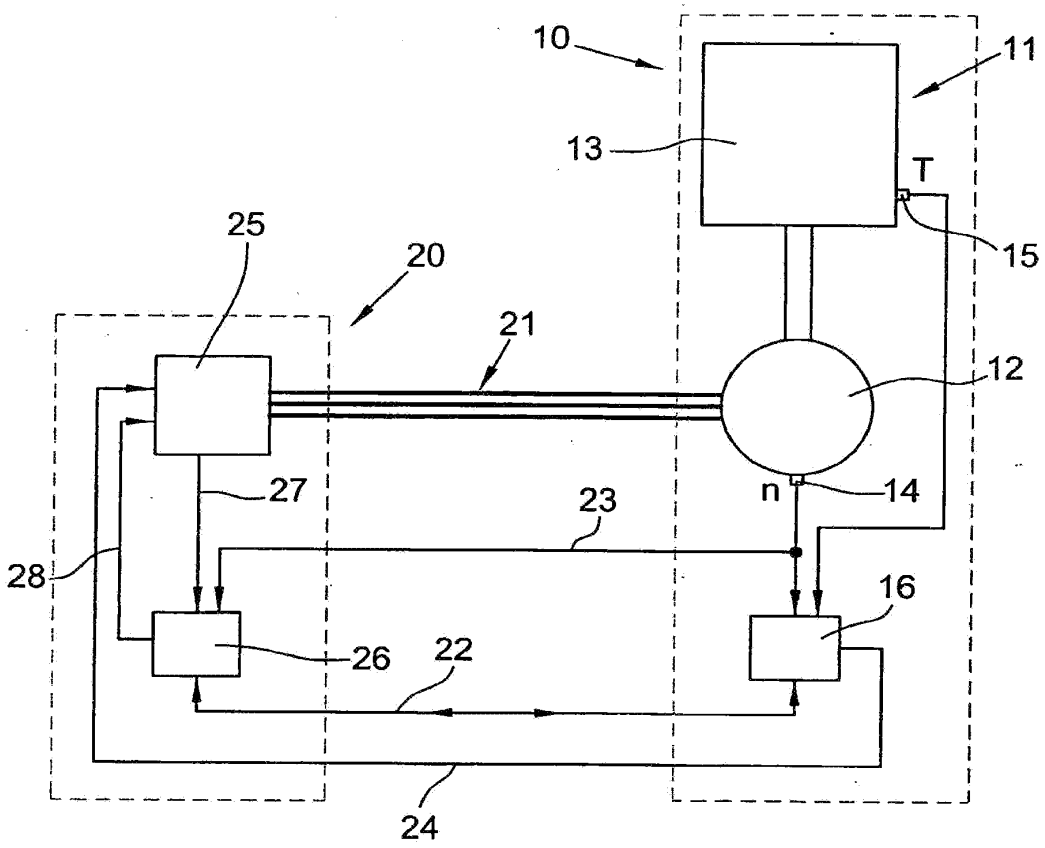
Patentansprüche

1. Vakuumpumpe mit einer eine Turbo-Molekularpumpe (**11**) enthaltenden Pumpeneinheit (**10**) und einem einen Wechselrichter (**25**) enthaltenden Steuergerät (**20**), welches den Motorstrom für die Pumpeneinheit liefert, wobei die Pumpeneinheit (**10**) einen Drehzahlsensor (**14**) enthält, dessen Signal einem Steuer-Mikrocontroller (**26**) des Steuergerätes (**20**) zugeführt wird, welcher im Falle einer unzulässigen Drehzahl den Wechselrichter (**25**) abschaltet, **dadurch gekennzeichnet** dass die Pumpeneinheit (**10**) einen Überwachungs-Mikrocontroller (**16**) enthält, dem ebenfalls die Signale des Drehzahlsensors (**14**) zugeführt werden und der im Falle des Überschreitens einer vorgespeicherten maximalen Drehzahl den Wechselrichter (**25**) abschaltet, und dass der Steuer-Mikrocontroller (**26**) und der Überwachungs-Mikrocontroller (**16**) zum Datenabgleich miteinander kommunizieren.
2. Vakuumpumpe nach Anspruch 1, dadurch gekennzeichnet, dass der Überwachungs-Mikrocontroller (**16**) die Signale mindestens eines an der Turbo-Molekularpumpe (**11**) vorgesehenen Temperatursensors (**15**) empfängt und an den Steuer-Mikrocontroller (**26**) mitteilt.
3. Vakuumpumpe nach Anspruch 1 oder 2, dadurch gekennzeichnet, dass der Überwachungs-Mikrocontroller (**16**) einen Speicher zur Aufnahme von gerätebezogenen Daten der Turbo-Molekularpumpe (**11**) und zur Aufnahme von ereignisbezogenen Daten der Turbo-Molekularpumpe enthält.

Hierzu 1 Seite(n) Zeichnungen

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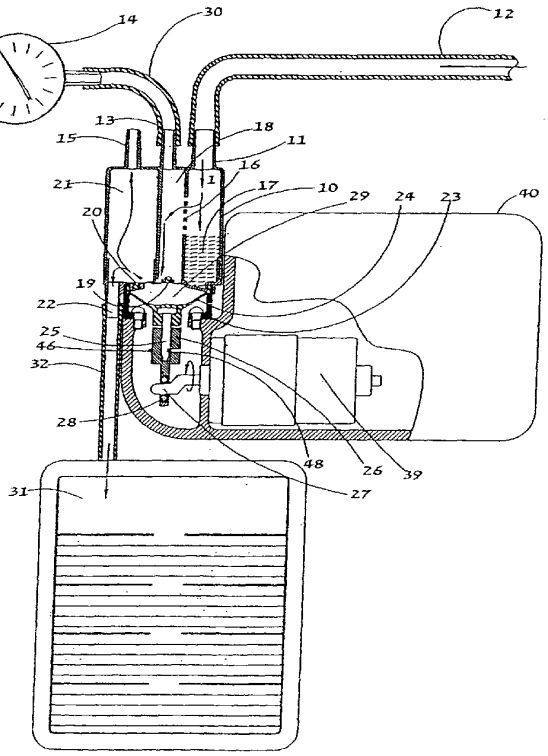
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(54) Title: A COMPACT VACUUM PUMP



(57) Abstract: A vacuum pump capable of pumping solid, liquid and gas, or any combination thereof, including a drive (40) and a manually disengageable pumping system connected thereto. The pumping system is composed of a two- or three-chambered canister (1, 18, 21) within which solids, liquids, and gases can be separated from one another. A highly flexible diaphragm (24), attached to the canister and sealed against it circumferentially, facilitates this separation, when reciprocating and pumping. The components of the pumping system are designed to be disposable, and the two- or three-chambered canister provides for a highly efficient pumping system that is significantly smaller in size than those previously known. The pump is particularly useful for medical applications.

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A COMPACT VACUUM PUMP

The present invention relates to a vacuum pump, especially useful in the field of medicine. More specifically, the pump disclosed herein includes a drive and a disposable pumping system that can be easily disengaged from the drive after use to allow for easy disposal of all pump components which come into contact with the matter being suctioned, together with the contained matter. The pump is not limited in the volume of matter it is capable of suctioned while maintaining uninterrupted vacuum pressure. During medical surgery or emergency airway clearing body fluids, such as blood or emesis, are suctioned. Vacuum pumps are utilized to generate vacuum inside a suction canister into which the body fluids are drawn through a tube, called a "suction catheter." Conventional vacuum pumps, also termed "aspirators" in medicine, contain rigid vacuum canisters into which the suctioned fluids are collected that maintain their shape and stiffness under high vacuum pressure. Some suction canisters are disposable and others can be removed for cleaning, disinfection, and re-use.

Aspirators of the type described above are characterized by a number of disadvantages, including the following:

1. When a large volume of fluid is collected, the suction canisters have to be relatively large in volume. Most commonly a canister of up to five liters in volume is used. Large canisters slow the vacuum rise rate because of the large air volume to be removed from the canister before a vacuum is created in the canister strong enough to draw the suctioned matter.
2. Since the air in the suction canister is drawn through the pump, it is very difficult to prevent contamination of the non-disposable pump components, such as the diaphragm, valves, cylinder or piston, even when the suction canister is disposed of after use. Contaminated pumps are a health hazard as the air flowing through them is exhausted to the atmosphere.
3. Aspirators are used for drawing body fluids and emesis, which may contain solids. Air is also drawn into the pump, during aspiration. Vacuum pumps are generally efficient in pumping either air or fluids, but most pumps are inefficient in pumping all three types of matter.

Thus, conventional vacuum devices are large, bulky, costly and inefficient in performing their function.

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In the present invention the term "pumping system" generally refers to a system having the following components: a suction canister, a suction inlet, a waste outlet, and integral means for creating suction. The term "disposable vacuum pump" generally refers to a pump in which all components other than the drive are inexpensive, and therefore may be disposed of. One wishing to re-use the disposable components (or use similar, non-disposable components) may, however, do so. The term "drive" generally refers to a pump component included of an electric motor, or to other means by which a pump piston, or a diaphragm, may be caused to reciprocate while contained within a housing. The term "body fluids" refers to blood, emesis or mucus. The term "three types of matter," "three types of media," and "three states of matter" refer to liquid, solid and gas. The terms "matter," "media," and "material" are used interchangeably to refer to the material being suctioned.

Embodiments of the invention may provide an improved vacuum pump capable of pumping air or gas, liquid and solids, and capable of separating the three types of matter to allow efficient pumping while collecting the liquid in a low cost bag.

Further embodiments may provide a pump in which all components that come in contact with body matter, or any other pumped media, can be easily disconnected and removed from the pump's drive means to be sterilized or disposed of. This leaves the non-disposable drive free from contamination. In prior-art pumps that have disposable canisters, the suctioned air is drawn through the pump, bringing the inside of the pump in contact with air that may be contaminated. The inside of the pump is traditionally not accessible for cleaning.

Embodiments of the present invention may further provide a vacuum pump which is extremely fast in generating a high vacuum or suction pressure yet do so with a relatively small vacuum canister and a low capacity pump.

It is further desirable to provide a physically compact vacuum pump with performance and capacity that are independent of its dimensions and are significantly higher than those of physically larger vacuum pumps. In addition, it is desirable to provide a vacuum pump which generates uninterrupted vacuum, independent of the volume of the vacuum canister that does not fill up as do conventional vacuum canisters.

The vacuum pump includes a drive and a disposable pumping system connected to this drive and adapted to be manually disengaged therefrom, wherein the disposable pumping system includes:

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(a) a three-chambered canister, wherein an inlet leads into the first chamber, and the first chamber has means for retaining solids and preventing their passage from the first chamber to the second chamber; and the second chamber has a one-way valve at its exit, the valve allowing passage of liquid and gas out of the second chamber; and the third chamber has an outlet for the discharge of air, and an additional outlet for the discharge of liquid; and the third chamber further has a one-way valve at its inlet allowing entry of liquid and gas through the valve while preventing exit of matter through the valve;

(b) a highly flexible diaphragm, attached to the three-chambered canister, sealing against it circumferentially, wherein the flexible diaphragm is attached to a partition with the three-chambered canister, in which the valves are installed;

(c) a drive member attached to the diaphragm, wherein reciprocation of the drive member induces reciprocation of the diaphragm; and

(d) means for mounting and engaging the disposable pumping system to the housing of a drive, wherein the means are capable of simultaneously coupling the pump drive member to the drive.

The drive is coupled to the drive member, and the drive includes an electric motor rotating a crank, the crank being connected to reciprocating means, in such a way that activation of the drive induces reciprocation of the crank and of the drive member. The pumping system is capable of being attached or detached from the drive in a rapid and facile manner (in the preferred embodiment, accomplished by a single, simple, wrist twist motion).

According to preferred embodiment of the present invention, the three-chambered canister has a volume of approximately 100 cc.

Further according to a preferred embodiment of the present invention, the pump includes a vacuum port outlet present in the second chamber, the outlet connected by tubing to an external vacuum gauge for the purpose of monitoring the pressure inside the first and second chambers.

Additionally, according to a preferred embodiment of the present invention, the means for retaining solids in the first chamber are included of a sieve.

Moreover, according to preferred embodiment of the present invention, the highly flexible diaphragm is capable of yielding or stretching when large quantities of fluid are contained within it. When subjected to high loads, the diaphragm is capable of stretching to effectively reciprocate only a fraction of its area (such as 50%) while the remainder of its surface remains stationary.

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Still further, according to preferred embodiments of the present invention, the vacuum pump additionally includes means for sealing the three-chambered canister and preventing leakage of air or materials into or out of the canister, as well as further preventing loss of vacuum in first and second chambers.

According to embodiments of the present invention, the pump additionally includes a disposable waste container for collection of discharged liquid that is attached to the liquid outlet of the third chamber. In a preferred embodiment, the disposable waste container is a waste bag, having any appropriate size. In some preferred embodiments, the capacity of the waste bag is between 500 cc and 5 liters. The waste-collection bag is a low cost waste container, at ambient pressure, which is easily disposed of along with the body fluids it contains, together with the pumping system.

Furthermore, according to the preferred embodiment of the present invention, the means for mounting and engaging the pumping system to the drive housing include a mounting base protruding from the lower portion of the three-chambered canister, the mounting base adapted for mating and attaching to the drive housing. In the preferred embodiment, twisting of the mounting base against the drive housing or mating portion thereof couples the two physically.

Still further yet, according to the preferred embodiment of the present invention, the drive rotates a crank, and a reciprocating rod receptacle is connected to the crank, and the rod receptacle is adapted to mate with the drive member. In the preferred embodiment, a lock clip secures the drive member to the rod receptacle. Coupling the mounting base to the drive housing is affected simultaneously with the securing of the drive member to the rod receptacle, in a single operation.

Additionally, the pumping system and the drive may be portable and may be operated on battery power.

Moreover, the pumping system additionally includes means for sealing the pumping system, for facilitating disposal of the pumping system, with all pumped matter contained.
Further according to preferred embodiments of the present invention, the pump is capable of generating continuous flow of matter therethrough, while maintaining uninterrupted vacuum pressure.

The pump may be capable of generating a vacuum pressure of approximately 650 mm of Mercury as measured in the first and second chambers.

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Additionally, in a preferred embodiment, the pump further includes suction catheter tubing attached to the inlet present in the first chamber, allowing entry of matter into the three-chambered canister.

Unlike common diaphragm pumps, the diaphragm in this invention is flexible and not restrained by a rigid piston. The flexibility of the diaphragm allows it to stretch and conform to the pumped matter, irrespective of the reciprocal motion of the rigid drive member. Thus, when the diaphragm encounters resistance it stretches and yields, allowing uninterrupted motion of the reciprocating drive member.

The three-chambered canister, the diaphragm and the one-way valves advantageously include an integral pumping system that can easily be attached to a drive that causes the drive member to reciprocate. Such a drive, as described, may be an electric motor, whose output shaft has a crank to which the drive member is connected. The electric motor will thus, when powered, affect pumping from one chamber of the canister to the other. The pumping system can easily be disengaged from the drive after use, and be sterilized or disposed of. The ability to completely separate the heart of the pump and its associated chambers and tubing conduits from the drive motor allows disposal or sterilization of all pump components that come in contact with pumped matter. It would be obvious to those skilled in the art that means other than an electric motor may be utilized to induce the reciprocal motion of the drive member.

The three-chambered canister is constructed in a manner such that the solids entering the chamber are trapped and prevented from entering further into the pump and affecting its performance by blocking the valves and tubing. It would be obvious to those skilled in the art that when the pumped matter is not likely to include solids, there would be no need to prevent them from reaching the pump's one-way valves, and thus the pumping system hereby described would function equally well without the first chamber. A pump having only two chambers, to be used in such case, is thus described below as well. Additionally, the pumped air is separated from the fluid and released to the atmosphere so that liquid, and not air, is collected in the waste bag, thereby utilizing the volume of the waste bag efficiently. Thus, the capacity of the pump to suck or collect fluids is not limited by the size of the chamber into which the fluid is drawn, and even a small chamber can be utilized to pump large volumes of fluid, limited only by the capacity of the waste bag. This is in contrast to pumps of the prior art in which the canister or chamber size limits the amount of matter that may be suctioned, and when large canisters are used to overcome this limitation evacuating the large canister by the pump then becomes a slow process.

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The present invention can be utilized in the field of medicine, to aspirate body fluids, emesis and mucous; however, the scope of the invention is not limited to medical use alone, and the vacuum pump may be utilized in other fields as well. An important feature of the pump is the ability to easily and economically remove and replace all components that come in contact with the materials being pumped, thus preventing any harmful contamination. The pump can therefore find application in the field of chemistry as well, where prior art pumps are difficult to clean after use.

In addition, there is provided in an alternative aspect of the present invention a vacuum pump for the pumping of liquid and gas (preferably not for use in pumping of solids), including a drive, and a manually disengageable disposable pumping system connected to the drive, wherein the disposable pumping system includes:

a) a dual-chambered canister, wherein the first chamber has an inlet and a one-way valve at the exit of the first chamber, the valve allowing passage of liquid and gas out of the first chamber; and the second chamber has an outlet for the discharge of air, and an additional outlet for the discharge of liquid; and the second chamber is further connected via a one-valve, allowing entrance of liquid or gas through the valve, while preventing exit of liquid or gas through the valve;

b) a highly flexible diaphragm, attached to the dual-chambered canister sealing against it circumferentially, wherein the flexible diaphragm is attached to a partition with the dual-chambered canister in which the valves are installed;

c) a drive member attached to the diaphragm, reciprocation of the drive member inducing reciprocation of the diaphragm; and

d) means for mounting and engaging the disposable pumping system to the housing of a drive, wherein the means are capable of simultaneously coupling the drive member to the drive.

In the vacuum pump the drive is coupled to the pumping system so that activation of the drive induces reciprocation of the flexible diaphragm, and the pumping system is capable of being attached or detached from the drive in a rapid and facile manner.

It will be clear to those skilled in the art that while the preferred embodiment of the invention includes several features, partial application of the disclosed features of the invention does not limit the scope of the invention. For instance, the diaphragm may be

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substituted by a piston for pumping, the discharge port may function in the absence of the waste bag and the liquid and gas outlets may be combined into a single outlet.

BRIEF DESCRIPTION OF THE DRAWINGS

For a better understanding of the invention, embodiments of it will now be described by way of example, with reference to the accompanying drawings in which:

Fig. 1 is a cross-sectional view of a preferred disposable vacuum pump having a three-chambered canister connected to a waste bag, wherein the suction is created by reciprocating a diaphragm by an electric motor drive;

Fig. 2 is a cross-sectional view of the "pumping system" disengaged from the "drive", to be disposed of as one integral unit;

Fig. 3 is a view of a mounting base, with a bayonet arrangement for quick – twist engagement and disengagement of the disposable components; and

Fig. 4 is a cross-sectional view of the locking mechanism, utilized to attach the pump drive member to the receptacle rod of the electric motor.

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DETAILED DESCRIPTION OF THE INVENTION

It is appreciated that the detailed description that follows is intended only to illustrate certain preferred embodiments of the present invention. It is in no way intended to limit the scope of the invention, as set out in the claims.

Referring now to Fig. 1, there is provided a vacuum pump containing a three-chambered canister 10, which is employed for the performance of several different functions. The three-chambered canister 10 has an inlet 11 in its first chamber 1. A suction tube catheter 12 is connected to the inlet 11. In the second chamber 18 a vacuum outlet port 13 is connected to a vacuum gauge 14 . In the third chamber 21 an air discharge outlet 15 is present, which is open to the atmosphere. The first chamber 1 contains a sieve 16, utilized to prevent solids 17 from entering the second chamber 18, also termed the "liquid chamber." Two one-way umbrella valves 19 and 20 are present in the bottom of the second chamber 18 and the third chamber 21, respectively. The third chamber 21 is at ambient pressure, and has a liquid outlet 22. To the bottom of the three-chambered canister 10 there is attached a mounting base 23, used to mount the canister and its associated tubing 12 onto the drive housing 40 or on a docking means connected to the drive housing. The mounting base 23 is also utilized to secure a diaphragm 24 to the underside of the three-chambered canister 10. The diaphragm 24 has an integral rod-shaped drive member 25, which is inserted into a corresponding cavity in a receptacle rod 26, pivotally attached to motor 39, via a crank 27 coupled to a bearing 28. Upon activation of the motor 39, the crank 28 is rotated by motor 39, which reciprocates the receptacle rod 26, causing the diaphragm 24 to increase and decrease the volume of the cavity 29 that it forms. This creates a vacuum therein, capable of drawing towards it, and thus pumping, air or fluid that passes through the one-way umbrella valves 19 and 20.

While the preferred embodiment describes a motor-crank combination as the means by which to reciprocate diaphragm 24, it would be apparent that other drive means may be used to create the reciprocal movement of the diaphragm.

Air, liquid and solids may enter the three-chambered canister 10 through a suction tube 12, which may, by way of example, be inserted into a patient's mouth for the removal of emesis. The three states of matter being pumped enter the three-chambered canister 10 through the inlet 11. Solids 17 are prevented from moving further than the first chamber 1 by means of sieve 16. Liquids and air enter the second chamber (liquid chamber) 18, which is under vacuum when diaphragm 24 reciprocates, driving them past one-way umbrella valve 20 into the third chamber 21. The vacuum level in liquid chamber 18 is monitored by a vacuum

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gauge 14, connected to the vacuum outlet port 13 via a conduit 30. The air and liquid entering the third chamber 21 are separated, whereupon the liquid is drained into waste bag 31 through a drain tube 32, and the air is driven out to atmosphere through an air discharge outlet 15.

From the description above, it is clear that the three-chambered canister 10 is the heart of the pump, to which the diaphragm 24 is attached to perform the pump function together with the one-way umbrella valves 19 and 20. Out of the three-chambers that make up the three-chambered canister, only one, the liquid chamber 18, is under vacuum. The three-chambered canister is partitioned by the sieve 16; the first chamber 1 and the third chamber 21 are essentially at ambient pressure.

The pump hereby described is distinct in its capability to suck liquid, solids and air or any mixture of the three, and to separate each of the three matter types into their respective destinations. The three types of matter are separated in order to prevent clogging of the pump by suctioned solids, and in order to collect only fluid for disposal, and not gas, thus minimizing the volume of the waste material for disposal, and of the canister that holds this waste material. It is also of particular importance to note that air and liquid can be pumped through the pump continuously at any volume, limited only by the volume of the waste bag 31 to contain the pumped liquids.

The pump's ability to pump air and liquid is unlike conventional pumps that are efficient in pumping only one type of matter, and is enhanced by the flexibility of the diaphragm 24. Unlike conventional pump diaphragms, which are rigidified by a piston or ribbing to prevent them from excessive flexing which reduces displacement, the diaphragm 24 described in this invention is particularly flexible so it can yield when encountering heavy loads such as those present when pumping liquid. This diaphragm flexibility also provides an additional substantial advantage: when the vacuum in pumping volume 29 is high the diaphragm 24 stretches to allow the reciprocation of the receptacle rod 26 to occur at minimal burden to the "drive," which in the preferred embodiment includes an electric motor 39.

In order to obtain high vacuum levels it is necessary to extract all air from pumping cavity 29 when the diaphragm 24 is at its upper travel extremity, as illustrated in Fig. 2. This function, in a conventional vacuum pump, will cause damage to the pump when liquid or solids enter the pumping chamber, as they cannot be expelled through the pump's outlet valve fast enough. In the disclosed invention, the flexibility of the diaphragm 24 will allow it to yield, or bulge, when encountering resistance as a result of liquid or solid presence, preventing excessive forces and the ensuing damage.

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An additional important function of the flexibility of diaphragm 24 is its ability to stretch and yield, so that when the vacuum level in the pumping cavity 29 is high, only a smaller effective area of diaphragm 24 reciprocates, and stretches, requiring less power from motor 39 to effect reciprocation.

In Figure 2, drive housing 40 that contains the motor 39, crank 27 and reciprocating receptacle rod 26, is shown disengaged from all other parts since the drive will be re-used while all other parts, which have directly contacted the matter being pumped, are slated for disposal and are termed the "disposable pumping system." The disposable pumping system, essentially including the canister, the diaphragm, associated valves, the disposable waste bag, and associated tubing, are shown in Figure 2 after all outlets have been sealed for disposal. The suction tube 12 is plugged with a plug 33 to prevent any liquid from leaking out of it. The conduit 30 is disengaged from the vacuum gauge 14 (Fig. 1) and attached to the air discharge outlet 15, sealing all possible leak paths from three-chambered canister 10.

It will be appreciated by persons skilled in the art that the drive 40, which is the only non-disposable hardware in the preferred embodiment, does not come into contact with any of the pumped media. This is unlike conventional aspirators or suction pumps that pass the suctioned air through them and may thus be contaminated by infectious air.

The method and means for attachment and mounting of the disposable pumping system to drive 40 is illustrated in Figs. 2 and 3, whereby the mounting base 23 is placed on top of retainers 41 as shown in Fig. 2. The retainers 41 protrude from a shelf- or step-like part of the drive 40 and have large mushroom-shaped heads, which pass through larger openings 42 in a flange of the base 23, seen also in Fig. 3. When the three-chambered canister 10 is rotated clockwise with its mounting base 23, the large heads of the retainers 41 engage slots 45 (Fig. 3), attaching the mounting base 23 to the drive 40 in a bayonet-type fastening action using a 45-degree twist. This action is similar to attaching a cap to a glass jar. The drive member 25, shown in Figs. 1 and 2, is inserted into the receptacle rod 26 simultaneously with the attachment of the mounting base 23 to drive housing 40.

Referring to Figure 4, a spring-loaded lock-clip 46 keys and locks the drive member 25 to the receptacle rod 26, when the lock clip engages pre-aligned slots 48 present in the drive member 25 and the receptacle rod 26. The disengagement of the mounting base 23 from the drive 40 is effected, simultaneously with disengagement of the drive member 25 from the receptacle rod 26 , when both are rotated counterclockwise, by drive member 25 pushing lock clip 46 out of its slot 47, as illustrated in Fig. 4,, eliminating the keying between drive member

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25 and receptacle rod 26. This action is similar to the removal of a cap from a jar by twisting counterclockwise and lifting.

While only one form of engagement of canister 10 to drive 40 was described in the preferred embodiment of this invention, it would be clear to those skilled in the art that other similar methods for quick fastening of these parts can be utilized effectively.

The above-described method of engagement has, however, an important feature that should be noted. Since the receptacle rod 26 may be at its lower position at the time when the drive member 25 is inserted into it, slots 47 and 48 may come into alignment only when motor 39 is powered and crank 27 (Figs. 1 and 2) raises receptacle rod 26 allowing lock clip 46 to key slots 47 and 48. Thus, the insertion of drive member 25 into receptacle rod 26 enables engagement, rather than fastening the two together.

It will be appreciated by persons skilled in the art that the present invention is not limited by what has been shown and described hereinabove, merely by way of example. Rather, the scope of the present invention is limited solely by the claims, which follow:

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CLAIMS

1. A vacuum pump capable of pumping solid, liquid and gas, or any combination thereof, including a drive and a manually disengageable disposable pumping system connected to said drive, wherein said disposable pumping system includes:

a three-chambered canister, wherein the first chamber has an inlet, and means are provided for retaining solids and preventing their passage from said first chamber to the second chamber; and said second chamber having a one-way valve at its exit, said valve allowing passage of liquid or gas out of said second chamber; and the third chamber having an outlets for the discharge of gas or liquid or any combination thereof; and said third chamber further being connected via a one-way valve, allowing entrance of liquid or gas through said valve, while preventing exit of liquid or gas through said valve;

integral means for pumping or displacement of gas and liquid, effective when coupled to said drive means and attached to a partition with said three-chambered canister, in which said valves are installed and sealing against it circumferentially;

a drive member attached to said pumping means, reciprocation of said drive member inducing reciprocation of said pumping means; and

means for mounting and engaging said disposable pumping system to the housing of said drive, said means being capable of simultaneously coupling said drive member to said drive;

wherein, in said assembled vacuum pump said drive is coupled to said pumping system in such a way that activation of said drive induces reciprocation of said pumping means, and said pumping system is capable of being attached or detached from said drive in a rapid and facile manner.

2. A vacuum pump according to claim 1, wherein said three-chambered canister has a volume of approximately 100 cc.

3. A vacuum pump according to claim 1 or 2, additionally including a vacuum outlet port, present in said second chamber, said outlet connected by tubing to an external vacuum gauge for the purpose of monitoring the pressure inside said first and second chambers.

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4. A vacuum pump according to any preceding claim, wherein said means for retaining solids in said first chamber are included of a sieve.

5. A vacuum pump according to claim 1, wherein said pumping means are included of a highly flexible diaphragm.

6. A vacuum pump according to any preceding claim, wherein said highly flexible diaphragm is capable of yielding or stretching when exposed to high load or resistance.

7. A vacuum pump according to any preceding claim, wherein said highly flexible diaphragm, when subjected to high loads, is capable of stretching to effectively reciprocate only a fraction of its area while the remainder of its surface remains stationary.

8. A vacuum pump according to any preceding claim, additionally including a disposable waste container for collection of discharged liquid, attached to the liquid discharge outlet of said third chamber.

9. A vacuum pump, according to claim 7, wherein said disposable waste container is a waste bag, having any appropriate size.

10. A vacuum pump according to claim 8, wherein the capacity of said waste bag is between 500 cc and 5 liters.

11. The vacuum pump according to any preceding claim, wherein the means for mounting and engaging said pumping system to said drive include a mounting base protruding from the lower portion of said three-chambered canister, said mounting base adapted for mating and attaching to said drive housing.

12. A vacuum pump according to any preceding claim, wherein drive rotates a crank, and said drive is coupled to said drive member via a reciprocating member connected to said crank, and said member is adapted to be coupled with said drive member.

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13. A vacuum pump according to claim 12, wherein coupling said mounting base to said drive housing, is affected simultaneously with the securing of said drive member to said reciprocating member in a single operation.

14. A vacuum pump according to claim 12 or 13, additionally including a lock clip, capable of securing said drive member to said reciprocating member.

15. A vacuum pump according to any preceding claim, wherein said pumping system additionally including means for sealing said pumping system, for facilitating disposal of said pumping system, while containing the pumped waste.

16. A vacuum pump according to any preceding claim, wherein said pump is capable of maintaining an unlimited flow of matter therethrough, while maintaining uninterrupted vacuum pressure.

17. A vacuum pump according to any preceding claim, wherein said pump is capable of generating a vacuum pressure of approximately 650 mm of Mercury as measured in said first and second chambers.

18. A vacuum pump according to any preceding claim, wherein said pump is capable of continuously suctioning an unlimited volume of matter therethrough.

19. A vacuum pump according to any preceding claim, additionally including a suction catheter tube attached to said inlet present in said first chamber, for allowing entry of matter into said three-chambered canister.

20. A vacuum pump capable of pumping liquid and gas, having a drive, and a manually disengageable disposable pumping system connected to the drive, wherein said disposable pumping system includes:

a dual-chambered canister, wherein the first chamber has an inlet and a one-way valve at the exit of the first chamber, said valve allowing passage of liquid and gas out of said first chamber; and the second chamber having outlets for the discharge of liquid and gas; said

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chamber further being connected via a one-way valve, allowing entrance of liquid or gas through said valve, while preventing exit of liquid or gas through said valve;

pumping means, attached to said dual-chambered canister sealing against it circumferentially, wherein said pumping means are attached to a partition with said dual-chambered canister in which said valves are installed;

a drive member attached to said diaphragm, reciprocation of said drive member inducing reciprocation of said pumping means; and

means for mounting and engaging said disposable pumping system on the housing of the drive, wherein said means are capable of simultaneously coupling the drive member to the drive;

wherein in the assembled vacuum pump, the drive is coupled to said pumping system, such that activation of the drive induces reciprocation of said pumping means; and wherein said pumping system is capable of being attached or detached from said drive in a rapid and facile manner.

21. A vacuum pump capable of pumping liquid and gas, having a drive and a disengageable disposable pumping system connected to the drive, wherein the disposable pumping system includes:

a first chamber having an inlet and a first one-way valve at its exit, allowing passage of liquid and gas through said first chamber; and a second chamber having an outlet for the discharge of air and an outlet for the discharge of liquid; and an inlet via a second one-way valve, allowing entrance of liquid or gas through said valve while preventing exit of liquid or gas through said valve;

a flexible diaphragm sealing against the exterior of said chambers so as to define a pump cavity whose inlet is said first one-way valve and whose outlet is said second one-way valve; and

a drive member attached to said diaphragm, reciprocation of which induces reciprocation of said diaphragm,

said pump further including means for mounting said disposable pumping system on the housing of the drive, and for coupling said drive member to the drive.

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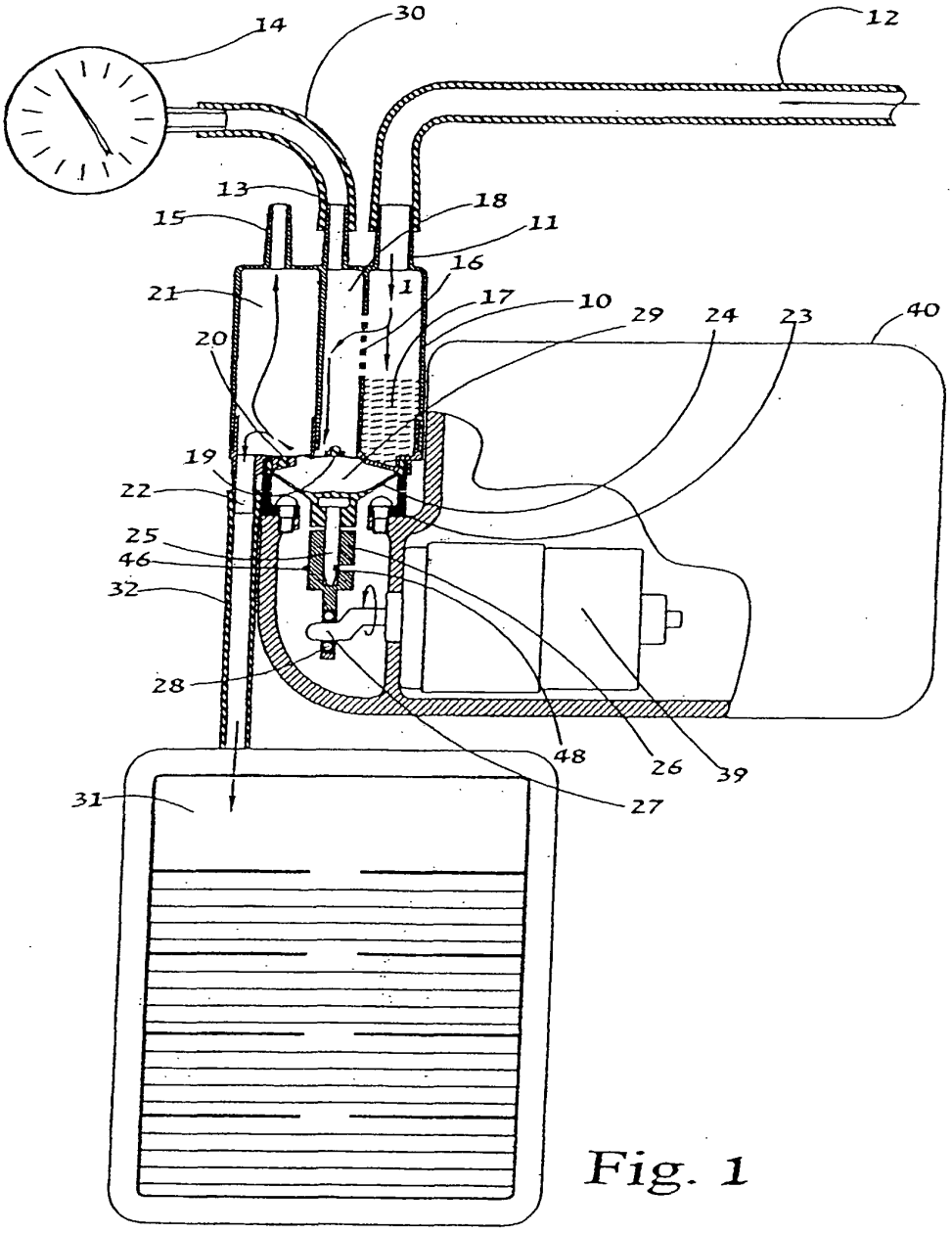

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Fig. 1

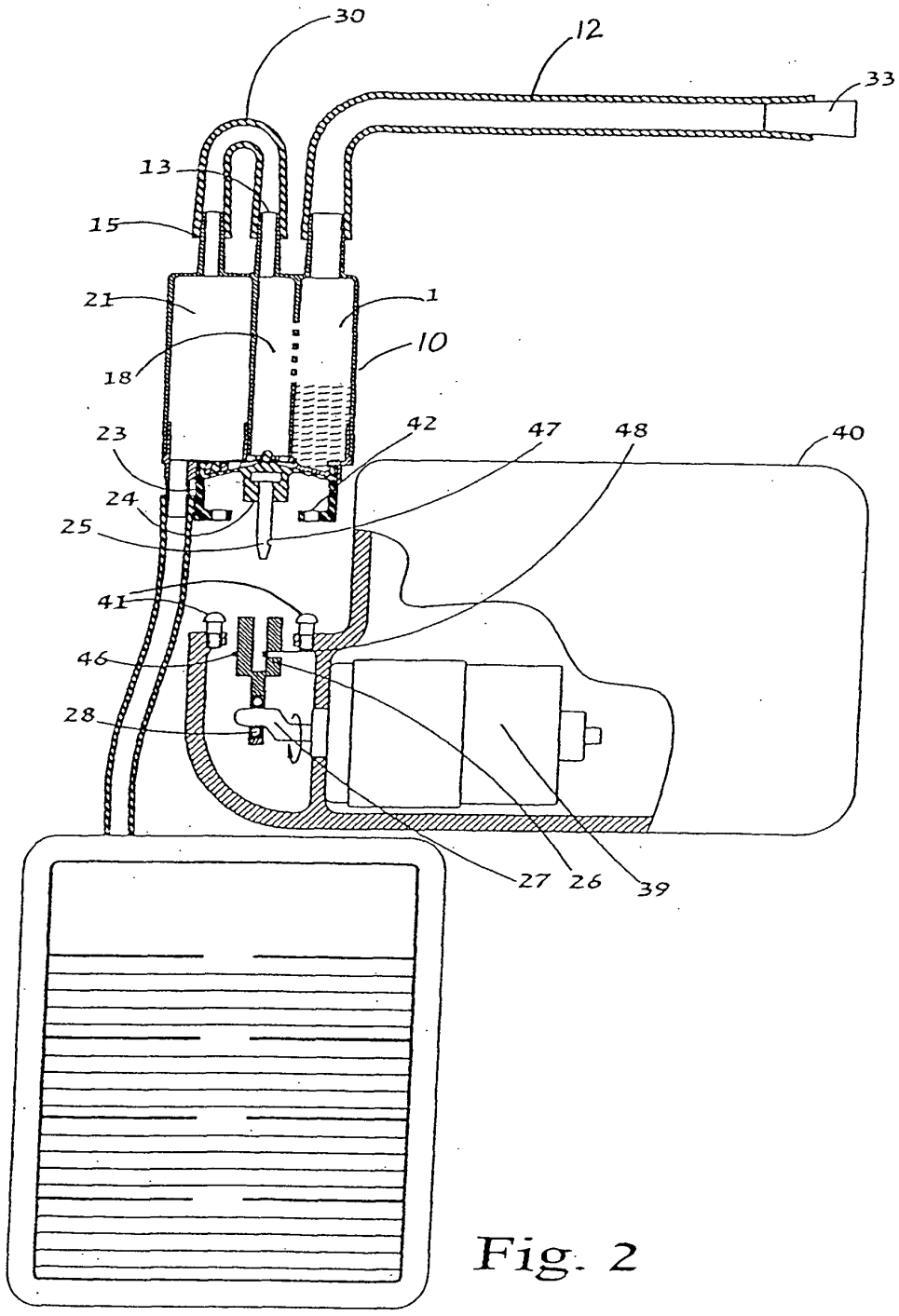


Fig. 2

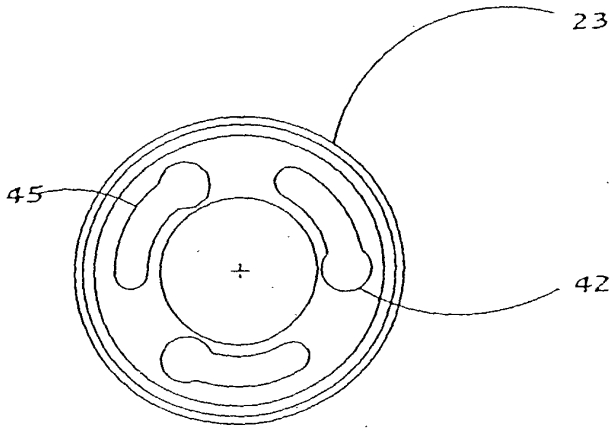


Fig.3

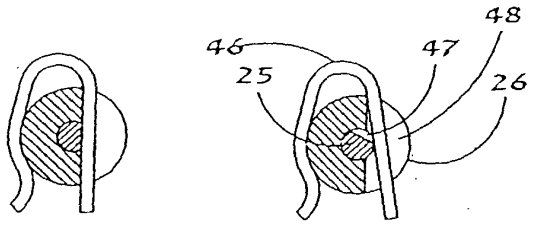


Fig.4

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL02/00661

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : F04B 23/00,17/00; A61M 1/00
US CL : 417/313, 413.1, 360; 604/319

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. : 417/313, 413.1, 360; 604/319, 149, 222, 223, 224, 226; 92/103R, 103SD, 99, 90, 92, 78, 79

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)
Please See Continuation Sheet

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,466,229 (ELSON et al) 14 November 1995 (14.11.1995), whole document. Figure 4b.	1, 2, 20-21
A	US 4,747,843 (FELIX et al) 31 May 1988 (31.05.1988), whole document.	1, 20-21
A	US 5,173,033 (ADAHAN) 22 December 1992 (22.12.1992), whole document.	1, 20-21
A	US 4,883,476 (KURTZ et al) 28 November 1989 (28.11.1989), column 4, lines 60-65.	1, 20-21

☐ 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 published on or after the international filing date

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
10 December 2002 (10.12.2002)	31 JAN 2003
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 Timothy S. Thorpe J. Thurley for Telephone No. 703-308-0861

Form PCT/ISA/210 (second sheet) (July 1998)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL02/00661

Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claim Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claim 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. ☒ Claim Nos.: 4, 6-19
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest
☐ The additional search fees were accompanied by the applicant's protest.
☐ No protest accompanied the payment of additional search fees.

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Continuation of B. FIELDS SEARCHED Item 3:
USPAT, US-PGPUB, EPO, JPO, DERWENT
vacuum or suction pump, solid, liquid, gas, disposable, chambers or canisters, valve, reciprocate

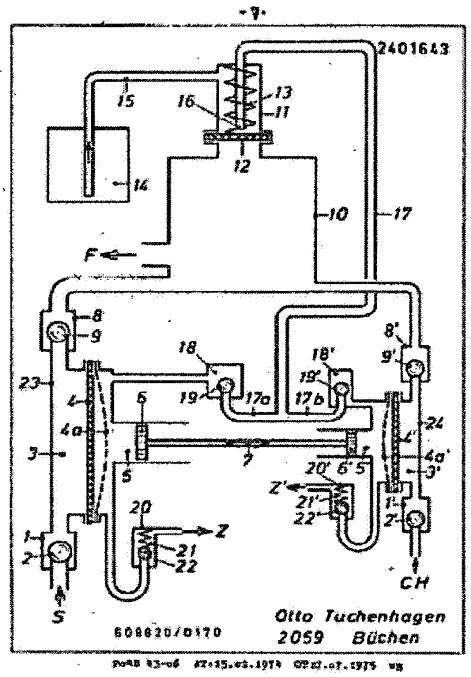
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© PatBase

1) Family number: 2007819 (DE2401643 A1)

Title: VERFAHREN ZUR PROPORTIONALEN ZUDOSIERUNG IN SCHLAMMPUMPEN, DIE AUF FILTERPRESSEN ARBEITEN

Abstract:
Source: DE2401643A1 PATENTAN5PR ue C H E 1 Verfahren zur proportionalen Zudosierung in Schlamm pumpen, die auf Filterpressen arbeiten, bei dem zwei Kolb en-Membran-Pumpen gleichgeschaltet laufen, wobei eine Kolben-Nembran-Pumpe (23) das Schmutzwasser foerdert und eine zweite Kolben-Membran-Pumpe (24) Aufbereitungschemikalien foerdert, und zwar beide in den gleichen Schmutzwasserdruckraum (10), dadurch gekennzeichnet, dass beide Nolben-Membran-Pumpen (23 u.



Machine translation: PATENTAN5PR ue C H E 1 procedure for proportional metering to mud pump, which works on Filterpressen, with which two Kolb EN diaphragm pumps coordinated run, whereby a piston Nembran pump (23) promotes the waste water and promotes a second piston diaphragm pump (24) preparation chemicals, both into the same waste water pressure chamber (10), by the fact characterized that both Nolben diaphragm pumps (23 u.

International class (IPC 8): F04B13/02 F04B43/02 F04B43/067 (Advanced/Invention); F04B13/00 F04B43/02 F04B43/06 (Core/Invention)
International class (IPC 1-7): F04B43/06
European class: F04B13/02 F04B43/02P3 F04B43/067

Family:	Publication number	Publication date	Application number	Application date
	DE2401643 A1	19750717	DE19742401643	19740115
	DE2401643 C2	19820401	DE19742401643	19740115

Priority: DE19742401643 19740115

Assignee(s): (std): LIGHT WILLIAM ANDREW ROCHESTER N Y ; TUCHENHAGEN OTTO

(51) Int. Cl. 2: F 04 B 43-06

(19) BUNDESREPUBLIK DEUTSCHLAND

DEUTSCHES PATENTAMT

DT 24 01 643 A1

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(43) Offenlegungstag: 17. 7. 75

(30) Unionspriorität:

(32) (33) (31) —

(54) Bezeichnung: Verfahren zur proportionalen Zudosierung in Schlammpumpen, die auf Filterpressen arbeiten

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(72) Erfinder: Stahlkopf, Friedrich, 2059 Büchen

DT 24 01 643 A1

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Büchen, den 11. Jan. 1974

2401643

P A T E N T A N M E L D U N G

Anmelder:

Otto Tuchenhagen, Ingenieur

2059 Büchen, Berliner Str.

Verfahren zur proportionalen Zudosierung in Schlammpumpen, die auf Filterpressen arbeiten

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Schlammhaltige Substanzen werden bekanntlich über Filterpressen geleitet. Die Feststoffe werden im Filter zurückgehalten, die Flüssigkeit fließt ab. Die schlammhaltige Substanz wird aufbereitet durch Zusatz von Chemikalien. Die schlammhaltige Substanz wird in die Filterpresse hineingepreßt. Solange der Filter sauber ist, hat man einen verhältnismäßig hohen Durchsatz und mit allmählichem Zuwachsen des Filters sinkt auch naturgemäß die Durchsatzmenge, weil der Maximaldruck der vorgesetzten Pumpe festliegt.

Die Aufbereitungs-Chemikalien müssen also dieser variablen Durchsatzmenge angepaßt werden; bei hohem Durchsatz also mehr und bei allmählicher Verstopfung des Filters weniger Aufbereitungs-Chemikalien. Nach dem jetzigen Stand der Technik werden diese variablen Aufbereitungs-Chemikalien bei Filterpressen durch verschiedenste Verfahren mechanisch oder elektrisch gesteuert. Die elektrischen Verfahren, die teilweise induktiv arbeiten, sind sehr störanfällig und die mechanischen Verfahren sind sehr kostenaufwendig, abgesehen davon, daß die Chemikalien nicht schonend genug behandelt werden.

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Dieser Erfindung liegt die Aufgabe zugrunde, ein Verfahren zur proportionalen Zudosierung in Schlammpumpen, die auf Filterpressen arbeiten, in einfachster und sicherster Weise zu gewährleisten. Diese Aufgabe wird dadurch gelöst, daß man grundsätzlich bei diesem Verfahren mit Kolben-Membran-Pumpen arbeitet, bei denen bekanntlich eine Membrane auf einer Seite mit Steuerflüssigkeit beaufschlagt wird, um auf der anderen Seite Schlamm zu pumpen. Die Steuerflüssigkeit erhält ihren Impuls bekanntlich durch eine Kolbenpumpe. Der Druck der Steuerflüssigkeit wird über ein Überström-Ventil begrenzt. Der Kolben mit seinem Hub ist so ausgelegt, daß er über ein Rückschlag-Ventil immer mehr Steuerflüssigkeit ansaugt als zur Betätigung der Membrane erforderlich ist. Diese Mehransaugung von Steuerflüssigkeit wird über eine Drossel-Membrane gesteuert, die in Abhängigkeit von der Schmutzwasserdruckseite arbeitet. Wird also der Druck auf der Schmutzwasserseite höher, so wird von der Schmutzwasserseite her die Steuerflüssigkeit abgedrosselt, so daß der Kolben entsprechend geringere bzw. gar keine überschüssige Menge mehr bekommt. Beim Druckhub findet nun die Förder-Membrane bei verstopftem Filter einen höheren Druck, und auf der Steuerwasserseite strömt entsprechend diesem entstehenden Gegendruck die Steuerflüssigkeit über ein Überström-Ventil ab. Die Füllung im Steuerwasserraum wird also allmählich kleiner und der Membranhub entsprechend. Das verschlammte Schmutzwasser wird also entsprechend dem Membranhub verringert, also entsprechend der Durchsatzmöglichkeit im Filter. Die Steuerung dieser proportionalen Förderung wird erfindungsgemäß durch ein Regel-Ventil erzielt, das in Druckabhängigkeit des Schmutzwasserraumes die Zufuhr von Steuerflüssigkeit zur Kolbenseite der Kolben-Membran-Pumpe bestimmt, so daß der Steuerwasserraum entsprechend weniger Steuerflüssigkeit erhält, wobei sich dann naturgemäß die Membrane mit steigendem Druck im Schmutzwasserraum gegen ein gelochtes Stützblech legt und bis zur Null-Grenze herunter an diesem Blech liegen bleibt. Man hat also durch

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diese Kolben-Membran-Pumpe einen druckabhängigen, proportionalen Filterdurchsatz.

Nach der vorliegenden Erfindung wird nun eine Kolben-Membran-Pumpe gleicher Art als Dosierpumpe für die Zudosierung von Schlamm-Aufbereitungs-Chemikalien verwendet, die mit der vorstehend beschriebenen Förderpumpe in Abhängigkeit läuft, wobei erfindungsgemäß die Menge der Steuerflüssigkeit vom gleichen Schmutzwasserraum und vom gleichen Regelventil geregelt wird. Die Zudosierung von Schlamm-Aufbereitungs-Chemikalien ist also im gleichen Verhältnis wie der Durchsatz des Schmutzwassers und ist bei der Vorschaltung bei einer Filterpresse proportional zum Durchsatz.

In der beiliegenden Zeichnung ist eine Ausführungsform veranschaulicht.

Die Förderpumpe 23 erhält das verschlammte Schmutzwasser bei S über das Saug-Ventil 1 mit der Rückschlagkugel 2. Es gelangt in den Schmutwasserraum 3. Die Förder-Membrane 4 wird über den Steuerwasserraum 5 durch den Kolben 6 mit seiner Kolbenstange 7 angetrieben. Beim Saughub des Kolbens 6 legt sich die Förder-Membrane 4 voll gegen ein gelochtes Stützblech 4a. Der Kolben 6 holt mit seinem Saughub zusätzliche Steuerflüssigkeit heran, und zwar aus dem Steuerwasserbehälter 14 über die Leitung 15 und das Regel-Ventil 11 mit seiner Drossel-Membrane 12, seinem Sitz 16 und seiner Feder 13. Das zusätzliche Steuerwasser gelangt dann durch die Verbindungsleitung 17 über die Leitung 17a in das Rückschlag-Ventil 18 mit seiner Rückschlagkugel 19 in den Steuerwasserraum 5.

Beim Druckhub des Kolbens 6 geht die Förder-Membrane 4 nach vorn und das verschlammte Schmutzwasser gelangt über das Druck-Ventil 8 mit der Rückschlagkugel 9 in den Schmutzwasserdruckraum 10, aus dem es bei F austritt, um von hier in die Filter-

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presse zu gelangen.

Mit allmählicher Verstopfung des Filters wird der Druck in dem Schmutzwasserdruckraum 10 entsprechend höher, die Drossel-Membrane 12 mit der Feder 13 wird entsprechend beaufschlagt und verringert den Durchsatz zum Sitz 16, so daß beim folgenden Saughub der Kolben 6 entsprechend weniger Steuerflüssigkeit erhält. Beim folgenden Druckhub geht die Förder-Membrane 4 nach vorn, wobei die Beaufschlagung vom Schmutzwasserraum her den Membranhub mindert, weil das Überström-Ventil 20 mit der Feder 21 und der Sitzkugel 22 die Ableitung der Steuerflüssigkeit bei Z vornimmt. Die Förder-Membrane 4 wird sich in ihrer Bewegung also dem Druck im Schmutzwasserraum 3 anpassen, wobei die überschüssige Steuerflüssigkeit entsprechend der Feder 21 bei Z abfließt. Die Fördermembrane 4 wird sich also bei zunehmendem Druck im Schmutzwasserraum 3 immer weniger von dem gelochten Stützblech 4a abheben und der Kolben 6 durch die Drossel-Membrane 12 immer weniger Wasser zum Abführen über das Überströmventil 20 erhalten.

Erfindungsgemäß ist am gleichen Schmutzwasserraum die Förderpumpe 23 die Dosierpumpe 24 angeschlossen, die erfindungsgemäß über das gleiche Regelventil 11, über die Verbindungsleitung 17 und 17b gesteuert wird, und zwar durch das Rückschlagventil 18', mit seiner Rückschlagkugel 19', wirkend auf den Steuerwasserraum 5'.

Beim Druckhub des Kolbens 6', der über die Kolbenstange 7 mit der Förderpumpe 23 synchron läuft, geht die Fördermembrane 4' nach vorn und die bei CH über die Rückschlagkugel 2' im Saugventil 1' eintretenden Chemikalien gelangen in den Chemikalienraum 3', die von hier aus über das Druckventil 8' mit der Rückschlagkugel 9' in den Schmutzwasserraum 10 gelangen.

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Mit allmählicher Verstopfung des Filters wird der Druck entsprechend höher, die Drossel-Membrane 12 mit der Feder 13 wird entsprechend beaufschlagt und verringert den Durchsatz zum Sitz 16, so daß beim folgenden Saughub die Kolben 6 und 6' entsprechend weniger Flüssigkeit erhalten. Beim folgenden Druckhub gehen die Förder-Membrane 4 und 4' nach vorn, wobei die Beaufschlagung vom Schmutzwasserraum her die Membranhübe mindert, weil die Überströmventile 20 und 20' mit den Federn 21 und 21' und den Sitzkugeln 22 und 22' die Ableitung der Steuerflüssigkeit bei Z bzw. Z' vornehmen. Die Förder-Membranen 4 und 4' werden sich in ihrer Bewegung also dem Druck im Schmutzwasserraum 3 und im Chemikalienraum 3' anpassen, wobei die überschüssige Steuerflüssigkeit entsprechend den Federn 21 und 21' bei Z bzw. Z' abfließt. Die Fördermembranen 4 und 4' werden sich also bei zunehmendem Druck im Schmutzwasserraum 3' immer weniger von den gelochten Stützblechen 4a und 4a' abheben und die Kolben 6 und 6' durch die Drosselmembrane 12 immer weniger Wasser zum Abführen über die Überströmventile 20 und 20' erhalten. Am gleichen Schmutzwasserdruckraum 10 der Förderpumpe 23 ist die Dosierpumpe 24 angeschlossen, und zwar so, daß erfindungsgemäß ein gemeinsames Regelventil 11 am gemeinsamen Schmutzwasserdruckraum 10 angeschlossen ist und daß dieses gemeinsame Regelventil 11 auf die Förderpumpe 23 und die Dosierpumpe 24 regelnd wirkt. Als erfinderischer Vorteil ist bei dieser Anordnung noch berücksichtigt, daß eine gemeinsame Kolbenstange 7 mit zwei Kolben 6 und 6' versehen ist, die auf den Steuerwasserraum 5 und 5' wirken.

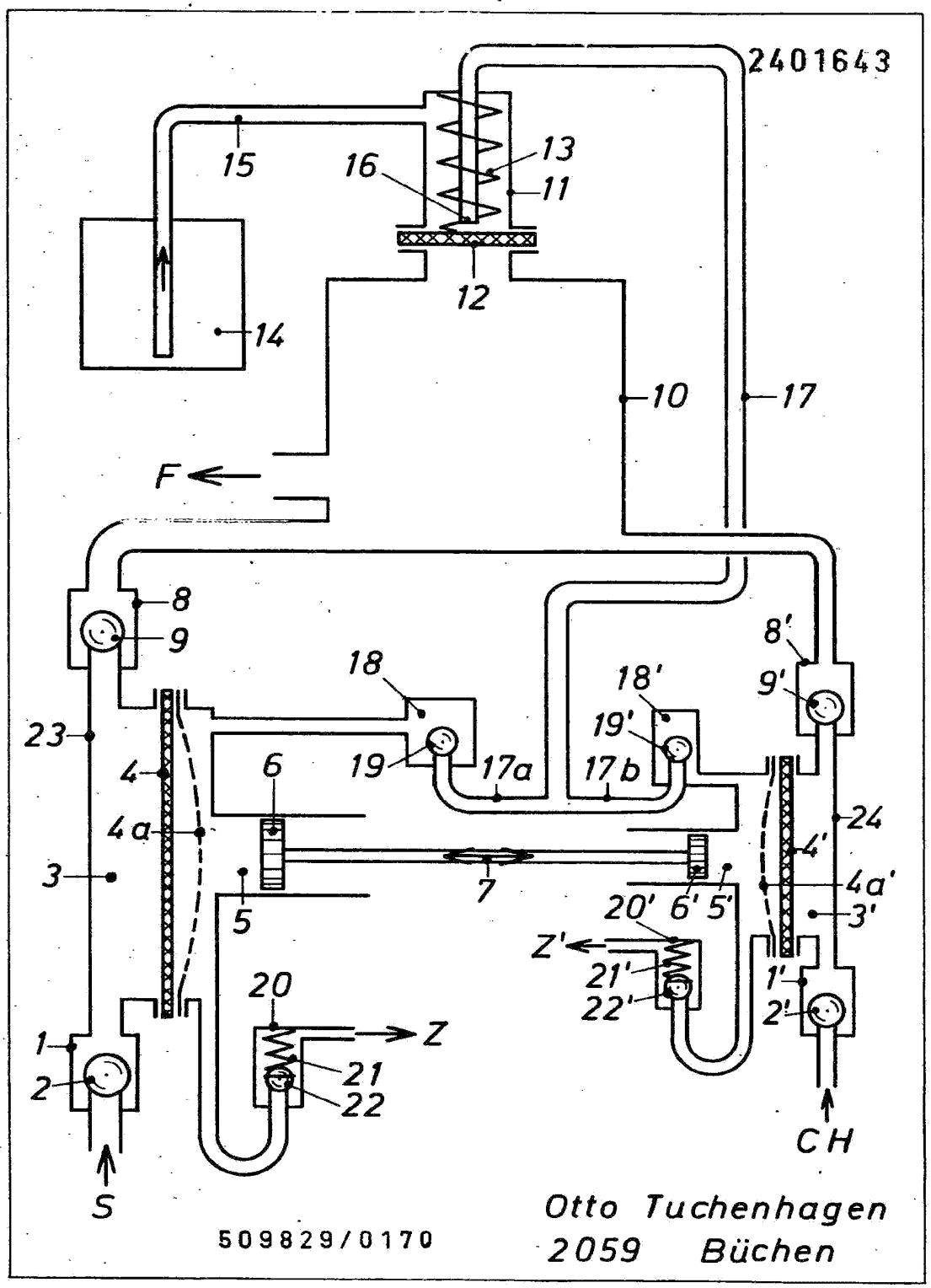
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PATENTANSPRÜCHE

1. Verfahren zur proportionalen Zudosierung in Schlammpumpen, die auf Filterpressen arbeiten, bei dem zwei Kolben-Membran-Pumpen gleichgeschaltet laufen, wobei eine Kolben-Membran-Pumpe (23) das Schmutzwasser fördert und eine zweite Kolben-Membran-Pumpe (24) Aufbereitungschemikalien fördert, und zwar beide in den gleichen Schmutzwasserdruckraum (10), dadurch gekennzeichnet, daß beide Kolben-Membran-Pumpen (23 u. 24) auf der Steuerwasserseite Flüssigkeit erhalten, deren Zufluß nach den beiden Pumpen (23 und 24) über ein gemeinsames Regelventil (11) geregelt wird.

2. Verfahren zur proportionalen Zudosierung in Schlammpumpen, die auf Filterpressen arbeiten, nach Anspruch 1, dadurch gekennzeichnet, daß die Förderpumpe (23) und die Dosierpumpe (24) über eine gemeinsame Kolbenstange (7) angetrieben werden.

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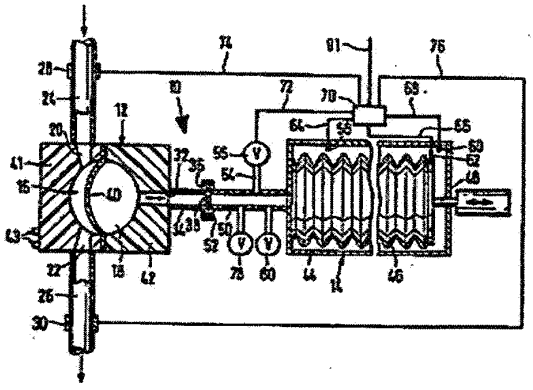
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1) Family number: 3714277 (US4634430A)

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Title: Pump arrangement for medical purposes

Abstract:
Source: US4634430A Pump arrangement (10) for medical purposes, in particular blood or infusion pump, comprising a pump housing (12) having two pump chambers (16, 18), of which the work chamber (16) is subjected to the liquid to be pumped while the drive chamber (18) is connected via a connecting conduit to a pneumatic pump (14) of restricted pumping volume. This connecting conduit (50) comprises a valve (56) which is opened at the respective changeover point (top and bottom dead-center) of the pump (14) to set the entire pump arrangement (16) to atmospheric pressure.



International class (IPC 8): A61M1/00 A61M1/10 A61M5/14 F04B43/06 F04B43/067 (Advanced/Invention);
A61M1/00 A61M1/10 A61M5/14 F04B43/06 (Core/Invention)
International class (IPC 1-7): A61M1/00 A61M1/10 A61M37/00 A61M5/14 A61M5/16 F04B43/06
European class: A61M1/10E4H F04B43/06 F04B43/067
US class: 128/DIG12 417/395 604/141 604/153 604/4 604/6.11

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Cited documents: US4552552, US4303376, US4265600, US3568214, US3449767, US3213804, US2855144, US2311229, GB716399, FR2304357, EP0088900, DE3205449,

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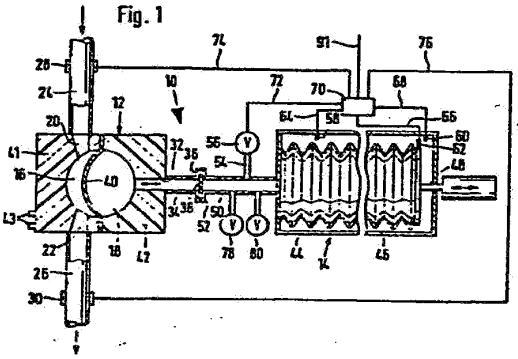
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(54) **Pumpanordnung für medizinische Zwecke.**

(57) Pumpanordnung (10) für medizinische Zwecke, insbesondere Blut- oder Infusionspumpe, bestehend aus einem Pumpengehäuse (12), das zwei durch eine Pumpenmembran (40) getrennte Pumpkammern (16, 18) aufweist, von denen die Arbeitskammer (16) mit der zu pumpenden Flüssigkeit beaufschlagt wird, während die Antriebskammer (18) über eine Verbindungsleitung mit einer in ihrem Pumpvolumen begrenzten, pneumatischen Pumpe (14) verbunden ist.

Diese Verbindungsleitung (50) weist ein Ventil (56) auf, das am jeweiligen Umschaltpunkt (oberer und unterer Totpunkt) der Pumpe (14) geöffnet wird, um die gesamte Pumpanordnung (16) auf Atmosphärendruck zu stellen.

Fig. 1



EP 0 156 211 A2

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55 FR08 40 4

Pumpanordnung für medizinische Zwecke

Die Erfindung betrifft eine Pumpanordnung für medizinische Zwecke, insbesondere eine Blut- oder Infusionspumpe,mit wenigstens einem Pumpengehäuse, das einen Raum aufweist, der von einer undurchlässigen Membran in einer Arbeitskammer und in eine Antriebskammer unterteilt ist, wobei die Arbeitskammer mit wenigstens einer Öffnung zur Zu- und Abführung des zu fördernden Fluids versehen ist und die Antriebskammer mit Luft als Pumpfluid beaufschlagbar und mit einer ein begrenztes Pumpvolumen aufweisenden Pumpe verbunden ist, und mit einem mit der Antriebskammer verbundenen Ventil für den Druckausgleich bei Hubwechsel der Pumpe.

Eine Pumpanordnung der eingangs erwähnten Art ist aus der DE-OS 32 05 449 bekannt. Sie besteht im wesentlichen aus einem Speichergefäß, das in zwei Kammern unterteilt ist. Die eine Kammer kann dabei mit dem zu pumpenden Fluid, insbesondere Blut, gefüllt und entleert werden, während die andere Kammer alternierend hierzu mit Luft als Pumpfluid beaufschlagt wird. Zwischen beiden Kammern ist eine elastisch erweiterbare, undurchlässige Membran vorgesehen, die gemäß dieser DE-OS in

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Form eines elastischen Schlauchs ausgebildet ist. Beide Kammern sind von einem starren, luftundurchlässigen Pumpengehäuse umgeben, das für die das Pumpfluid aufweisende Kammer eine Öffnung besitzt, die über eine Rohrleitung mit der ein begrenztes Pumpvolumen aufweisenden Pumpe verbunden ist. Diese Pumpe ist als Balgpumpe ausgebildet, die beim Pumpbetrieb zwischen dem oberen und unteren Totpunkt jeweils hin- und herpendelt.

Die mit dem Pumpfluid beaufschlagbare Kammer bzw. der das Pumpfluid aufweisende Raum ist über Unter- und Überdruckventile mit der Umgebung verbunden. Diese Ventile haben die Aufgabe, einen bestimmten Druckwert, nämlich einen bestimmten Überdruck und Unterdruck beim Betrieb der Pumpe einzuhalten. Wird beispielsweise die Pumpe blockiert oder treten die üblichen Anlaufschwierigkeiten auf, so erfolgt lediglich ein Zu- oder Abpumpen des Pumpfluids bis zu dem durch die Ventile gesteuerten Druckwert, die üblicherweise selbsttätig arbeiten.

In der Regel erfolgt der Pumpenbetrieb jedoch so, daß die Über- und Unterdruckventile nicht betätigt werden. Bei einer solchen Arbeitsweise wird also das Pumpfluid bei der Entleerung der Pumpenkammer zusammengepreßt (Überdruck) und bei der Füllung der Pumpenkammer expandiert(Unterdruck). Hier stellen sich jedoch Probleme beim Betrieb der Pumpanordnung ein, die sich vor allen Dingen auf die Pumpkapazität dieser Anordnung auswirken.

Nachstehend wird die Wirkungsweise der bekannten Pumpe und deren Problematik erläutert.

Wie bereits vorstehend festgestellt, wird der Druck in der Pumpe zwischen einem unteren Druckwert p_{min} und einem oberen Druckwert p_{max} schwanken, wobei gerade noch nicht die Ventile sich öffnen werden.

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Nun wird abhängig vom Einsatz der Pumpe ein bestimmter Ansaugdruck p_E bzw. Förderdruck p_K benötigt, die an die Pumpanordnung anzulegen sind.

Setzt man nun voraus, daß man für die Membran keine Kraft zur Expansion benötigt, dann gilt für den Grenzfall $p_E = p_{min}$ bzw. $p_K = p_{max}$.

Das Pumpverhalten der bekannten Pumpe wird nun an folgendem Beispiel erläutert:

$p_E = -400$ mbar und $p_K = +600$ mbar, während das Innenvolumen der Pumpenkammer $V_1 = 50$ cm^3 und das Balgvolumen der Balgpumpe $V_2 = 30$ cm^3 betragen sollen.

Im Ausgangszustand ist V_1 (komprimiert) = 0 cm^3 und V_2 = 30 cm^3, während $p = p_{max} = +600$ mbar absolut = 1.600 mbar. ist.

Anschließend wird angesaugt, wobei V_1 gegen 50 cm^3 und V_2 gegen 0 cm^3 geht. Somit wird das Volumen von 30 auf 50 cm^3 expandiert.

Über die Beziehung P x V = constant folgt:

$1.600 \times 30 = p_E \times 50$

$p_E = 960$ mbar.

Demzufolge beträgt also der Expansionsunterdruck P_E lediglich -40 mbar abs., was zum Betrieb der Pumpe nicht zufriedenstellend ist.

Sollen nunmehr bei der Expansion der Balgpumpe -400 mbar erreicht werden, so wird lediglich - wie nachstehend erläutert - ein geringeres Pumpvolumen erzielt. Denn über die vorstehende Beziehung ergibt sich:

$1.600 \times 30 = 600 \times V_T$ (V_T= erforderliches Balgvolumen)

$V_T = 80$ cm^3

d.h. im Grenzfall kann zwar gerade der Ansaugunterdruck

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erreicht werden, wobei jedoch allerdings das Balgvolumen von 50 cm^3 für ein vollständiges Abpumpen nicht ausreicht. Hierzu würden 80 cm^3 benötigt.

Eine weitere Pumpanordnung ist aus der US-PS 35 68 214 bekannt, bei der zwei Pumpkammern wechselseitig von einer Pumpe mit Pumpfluid beaufschlagt werden, wobei als Pumpfluid isotomische Kochsalzlösung und Quecksilber eingesetzt werden. Die bei solchen Systemen auftretende Verschiebung der Phasenlage bei Hubwechsel der Pumpe, beeinflußt die Wirkung der Pumpe erheblich und läßt sich im allgemeinen nicht in den Griff bekommen, so daß sich diese Pumpe in der Praxis als nicht einsetzbar erwiesen hat.

Der Erfindung liegt daher die Aufgabe zugrunde, eine Pumpanordnung der eingangs erwähnten Art zur Verfügung zu stellen, die innerhalb der eingestellten Druckgrenzen die Pumpenkammer im Betrieb vollständig füllt und entleert.

Die Lösung der Aufgabe erfolgt dadurch, daß ein Steuergerät vorgesehen ist, das vor jedem Hubwechsel der Pumpe das Ventil öffnet und nach Druckausgleich auf Umgebungsdruck schließt und danach den nächsten Hub der Pumpe einleitet.

Die erfindungsgemäße Pumpanordnung weist gegenüber der bekannten Pumpanordnung den Vorteil auf, daß bei gegebenen Volumina des Pumpengehäuses und der Pumpe (also dem Innenvolumen des Pumpgehäuses und des Balgvolumens) die vorgegebenen Druckgrenzen zwangsläufig erreicht werden, also die Pumpe völlig zufriedenstellend arbeitet.

Dies ist darauf zurückzuführen, daß der jeweilige Ausgangsdruck der Atmosphärendruck, also 1000 mbar, ist.

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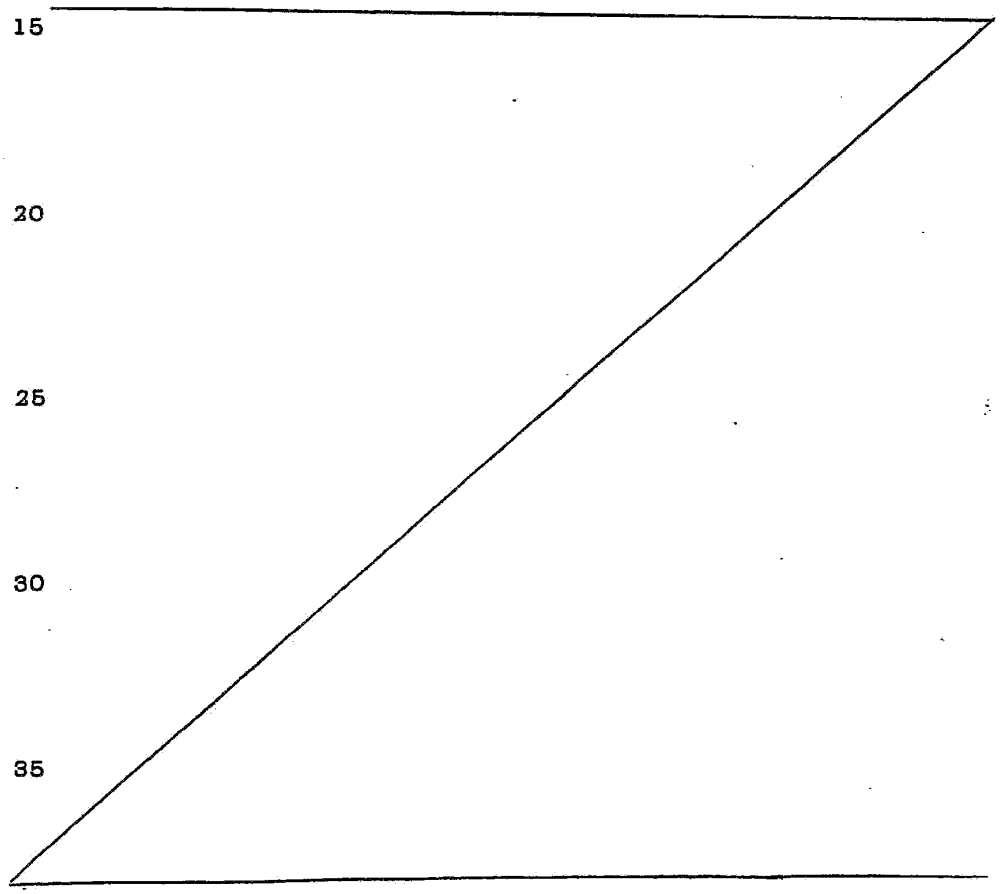
Demzufolge wird bei den eingangs erwähnten Maßnahmen (V_1 = 50, V_2 = 30, p_{min} = -400 mbar und p_{max} = 600 mbar) folgendes Pumpergebnis erzielt:

a) Pumpe am unteren Totpunkt
V_1 = 0 cm^3
V_2 = 30 cm^3
p = p abs. = 1000 mbar.

Beim Expandieren ergibt sich dann folgender Expansionsdruck: p_E

p 30 x 1000 = 50 x p_E

p_E = 600 mbar abs. = -400 mbar rel.



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b) Pumpe am oberen Totpunkt

$V_1 = 50\ cm^3$

$V_2 = 0$

$p = 1000$ mbar

Bei der Kompression wird folgender Kompressionsdruck p_K erhalten:

$1000 \times 50 = p_K \times 30$

$p_K = 1.665$ mbar abs., somit 665 mbar rel.

Mit der erfindungsgemäßen Pumpanordnung wird somit ein günstiges Verhältnis von Pump- und Balgvolumen erreicht. Zusätzlich sind die erzeugbaren Drücke durch das Verhältnis der Volumina vorgegeben und somit begrenzt.

Insofern läßt sich die gesamte Pumpanordnung wesentlich kleiner bauen und ist dennoch beim Betrieb völlig zufriedenstellend.

Die erfindungsgemäße Pumpanordnung kann vorteilhafterweise über- und/oder unterdruckkontrolliert werden, wobei die bekannten Ventile hierzu eingesetzt werden. Zusätzlich kann über die Beobachtung des gesamten Druckverhaltens, das vorteilhafterweise in einem Speicher gespeichert wird, die gesamte Anlage überwacht und ggf. abgeschaltet werden.

Weitere Einzelheiten, Vorteile und Merkmale sind in der nachfolgenden Beschreibung unter Bezugnahme auf die Zeichnungen erläutert.

Es zeigen

Fig. 1 eine Pumpanordnung im Querschnitt,

Fig. 2 schematisch eine Infusionsvorrichtung mit der Pumpanordnung,

Fig. 3 schematisch eine weitere Infusionsanordnung mit mehreren Pumpengehäusen und einer Balgpumpe und

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Fig. 4 eine spezielle Ausführungsform eines Pumpengehäuses.

Aus Fig. 1 ist die erfindungsgemäße Pumpanordnung mit 10 ersichtlich. Diese Pumpanordnung 10 besteht im wesentlichen aus einem Pumpengehäuse 12 und einer ein begrenztes Pumpvolumen aufweisenden Pumpe 14, insbesondere einer Kolbenpumpe oder einer Balgpumpe. Letztere ist in Fig. 1 dargestellt.

Das Pumpengehäuse weist zwei Kammern auf, nämlich eine Arbeitskammer 16 für die zu pumpende Flüssigkeit und eine Antriebskammer 18 für das von der Pumpe 16 ein- und auszupumpende Fluid, insbesondere Luft.

Die Arbeitskammer 16 weist wenigstens eine erste Öffnung auf, wobei in Fig. 1 zwei Öffnungen 20 und 22 dargestellt sind, durch die die zu pumpende Flüssigkeit in die erste Pumpkammer eingepumpt und aus dieser herausgepumpt werden kann. Die beiden Öffnungen 20 und 22 sind jeweils mit Schlauchleitungen 24 und 26 verbunden, die mit nicht gezeigten Speichergefäßen bzw. nachgeschalteten Einrichtungen, die mit der zu pumpenden Flüssigkeit beaufschlagt werden, weiter verbunden sind.

Diese Schlauchleitungen 24 und 26 sind mit Absperreinrichtungen 28 und 30, vorzugsweise elektromagnetischen Schlauchklemmen absperrbar, die im Gegentakt betätigt werden. Wenn man davon ausgeht, daß die Leitung 24 als Flüssigkeitszuführleitung und die Leitung 26 als Flüssigkeitsabführleitung dienen soll, so ist die Absperreinrichtung 28 in der Füllphase geöffnet, während die Absperreinrichtung 30 gesperrt ist. In der Entleerungsphase wird dann entsprechend umgeschaltet, also die Klemme 30 geöffnet und die Klemme 28 geschlossen.

Die Antriebskammer 18 ist ebenfalls mit einer zweiten Öffnung 32, die wie die übrigen Öffnungen 20 und 22 das Pumpengehäuse durchsetzt, nach außen hin geöffnet, so daß durch

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diese Öffnung 32 ein Pumpfluid ein- und ausgepumpt werden kann.

An diese Öffnung 32 schließt sich eine im wesentlichen starre Leitung 34 an, die vorteilhafterweise an ihrem Ende einen Flansch 36 aufweist. Diesen Flansch 36 überspannte vorteilhafterweise eine hydrophobe Membran 38, deren Poren so bemessen sind, daß hierdurch keine Keime in die Leitung 34 und somit in die Antriebskammer 18 eintreten kann. Hierdurch wird sichergestellt, daß bei einem Bruch der nachstehend erläuterten Pumpmembran 40 nicht die üblicherweise steril zu haltende wässrige Flüssigkeit durch die Leitung 34 abfließt und dabei unsteril wird. Somit dient die Membran 38 als Sicherheitseinrichtung für einen Bruch der Pumpenmembran 40.Eine derartige Anordnung ist in der DE-OS 32 05 449 umschrieben.

Diese Pumpenmembran 40 teilt die beiden Pumpkammern 16 und 18 und kann vorteilhafterweise eine bereits vorgeformte gekrümmte Gestalt besitzen. In dieser Ausführungsform kann sie sich ohne Erweiterung jeweils an die Wandungen der Kammern anlegen. In einer weiteren Ausführungsform besitzt die Pumpenmembran 40 eine ebene Ausbildung und kann vorteilhafterweise bereits um einen bestimmten Betrag vorgespannt im Pumpengehäuse 12 angeordnet sein. In diesem Fall erweitert sich die Membran elastisch beim Pumpbetrieb und neigt dazu, bei Entlastung, beispielsweise bei Entlüftung der Pumpe 14 oder Öffnen der Klemmen 28 und 30 in den Ausgangszustand zurückzukehren.

Vorteilhafterweise besteht das Pumpengehäuse 12 aus zwei Gehäusehälften 41 und 42, zwischen die bei der Herstellung die Membran zunächst eingelegt wird und die anschließend miteinander verklebt oder verschweißt werden. Als Material für das Pumpengehäuse wird üblicherweise ein leicht formbares Kunststoffmaterial, beispielsweise PVC, Polyacrylglas oder Polycarbonat gewählt, während als Material für die Pumpenmembran Weich-PVC, Polyethylen oder dgl., sofern die

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Membran unelastisch ist, oder gummielastische Materialien, wie Silikongummi u.dgl., eingesetzt werden.

Das Pumpvolumen V_1 wird durch die Volumina der beiden Kammern 16 und 18 bestimmt. Vorteilhafterweise wird man unterschiedliche Normvolumina einsetzen, je nachdem, welche Pumpraten erzeugt werden sollen.

Weiterhin ist es bevorzugt, daß das Pumpengehäuse 12 einschließlich der mit ihr verbundenen Schläuche 24 und 26 und der Leitung 34 als sog. Wegwerfteil zum Einsatz kommt, das bereits im sterilen Zustand die Produktionsstätte verläßt.

In einer ersten zweckmäßigen Ausführungsform ist die Kontur der Kammern 16 und 18 identisch, wie dies in Fig. 1 gezeigt ist.

Andererseits können jedoch in einer weiteren Ausführungsform die Konturen der Kammern 16 und 18 asymmetrisch sein. In Beispiel 2 ist eine solche asymmetrische Anordnung gezeigt, bei der vorteilhafterweise als Pumpenmembran 40 eine elastische Pumpenmembran eingesetzt wird. In der in Fig. 2 gezeigten Ausführungsform liegt die ebene Membran direkt an der Kammerwand an, so daß praktisch eine zweite Pumpkammer entfällt und die zweite Pumpkammer - wie vorstehend erläutert - wiederum mit der Pumpe 14 in Verbindung ist. Eine derartige Pumpe wird, sofern eine ausreichend elastische Membran gewählt wird, als selbstentleerend bezeichnet.

Andererseits kann jedoch auch die Kontur der Kammern 16 und 18 derart ausgebildet sein, daß die Pumpanordnung 10 als selbstansaugend angesehen wird. Eine derartige Ausbildung ist in Fig. 3 in der mittleren Pumpanordnung gezeigt. In diesem Fall liegt die Membran auf der Seite der Pumpe 14 an der ebenen Wand an, so daß die Antriebskammer 18 im nichtbelasteten Zustand entfällt. In einer

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solchen Ausführungsform wird ebenfalls eine elastische, ggf. vorgespannte Pumpenmembran 40 eingesetzt.

Wie bereits vorstehend festgestellt, kann die Pumpanordnung 10 ein variables Innenvolumen V_1 aufweisen. Zur Festlegung der Pumprate wird entweder diese Größe in ein Steuergerät in Verbindung mit dem zu fördernden Volumen eingetippt oder aber das Pumpengehäuse 12 weist in Abhängigkeit von dem Volumen V_1 spezielle Kennmarken in Form von Vorsprüngen 43 an der Außenwand auf, die beim Einlegen des Pumpengehäuses 12 in eine nicht gezeigte Steuereinrichtung einen bestimmten Kontakt auslösen, der zur Speicherung des Pumpvolumens V_1 im Steuergerät führt. Dies ist insbesondere bei sog. Kassetten der Fall, die in ein derartiges Steuergerät eingelegt werden.

Die Pumpe 14 ist, wie in Fig. 1 gezeigt, als Balgpumpe ausgebildet und besteht demzufolge aus einem Gehäuse 44, in dem ein Balg 46 angeordnet ist, der mittels eines sich hin und her bewegenden Stößels 48 zusammengepreßt oder auseinandergedrückt wird. Das Ende dieses Balges 46 ist über eine starre Leitung 50, deren Ende einen Flansch 52 aufweist, mit dem Pumpengehäuse 12 in Verbindung zu bringen, insbesondere mit der Leitung 34, wobei die beiden Flansche 36 und 52 aneinander befestigt werden.

Vorteilhafterweise ist die Leitung 50 im nicht gekuppelten Zustand verschlossen, so daß hierdurch keine Luft entweichen kann. Dies ist insbesondere dann von Interesse, wenn die Pumpe 14 mit mehreren Pumpengehäusen 12 über ein Leitungssystem verbunden ist, wie dies in Fig. 3 gezeigt ist. In einem solchen Fall ist vorteilhafterweise jeweils die Leitung 50 automatisch geschlossen; wenn keine Verbindung mit einem Pumpengehäuse 12 vorliegt, jedoch geöffnet, was vorteilhafterweise durch eine selbsttätig wirkende Ventilanordnung, wie dies nachstehend erläutert ist, erreicht wird, wenn die Verbindung hergestellt ist.

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Von der Leitung 50 geht eine weitere Leitung 54 ab, die mit einem Ventil 56 verschlossen ist. Über dieses Ventil 56 kann die gesamte Pumpanordnung 10 belüftet werden, so daß der jeweils in der Pumpanordnung 10 herrschende Unter- oder Überdruck beseitigt und die gesamte Anordnung auf den Atmosphärendruck eingestellt wird.

Eine besonders bevorzugte Ausführungsform der Erfindung liegt darin, daß die Belüftung der Pumpanordnung 10 jeweils am oberen und unteren Totpunkt der Pumpe 14 vorgenommen wird.

Zu diesem Zweck ist das Gehäuse 44 der Pumpe 14 mit Kontakten 58 und 60 ausgerüstet, die mit einem Kontakt 62 zusammenwirken, der auf dem Balg 46 angeordnet ist. Diese Kontakte sind über Leitungen 64, 66, 68 mit einem Steuergerät 70 verbunden, das wiederum über eine Leitung 72 mit dem Ventil 56 verbunden ist.

Weiterhin ist das Steuergerät über eine Leitung 74 und eine Leitung 76 mit der Absperreinrichtung 28 bzw. 30 verbunden.

Vorteilhafterweise im unteren Totpunkt (komprimierter Balg 46) und im oberen Totpunkt (expandierter Balg) schaltet die Steuereinrichtung 70 jeweils die Klemmen 28 und 30 um, d.h. zum Füllen der Kammer 16 wird die Klemme 28 geöffnet und die Klemme 30 geschlossen, während zum Entleeren der Kammer 16 die Klemme 28 geschlossen und die Klemme 30 geöffnet wird.

Zugleich wird vorteilhafterweise - wie vorstehend erwähnt - jeweils an diesen Totpunkten die Pumpanordnung 10, insbesondere die Antriebskammer 18 und der Innenraum des Balgs 46 durch Öffnen des Ventils 56, was ebenfalls das Steuergerät 70 durch Schließen der Kontakte 56 - 60 veranlaßt, solange geöffnet, bis die Pumpanordnung 10 druckausgeglichen ist. Vorteilhafterweise sind während dieser Öffnungs-

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phase die beiden Klemmen 28 und 30 geschlossen.

Vorteilhafterweise wird die Pumpanordnung mit bestimmten Grenzdrücken sowohl im Unterdruckbereich als auch im Überdruckbereich gefahren. Werden diese Grenzwerte überschritten, dann öffnen die Druckbegrenzungsventile 78 und 80, die einen bestimmten festgelegten Druckgrenzwert während der Pumpphase der Pumpe 14 aufrechterhalten. Diese Druckbegrenzungsventile 78 und 80 werden automatisch geschlossen, wenn die Pumpe ihren oberen oder unteren Totpunkt erreicht hat. Im übrigen ist eine derartige Druckbegrenzungsanordnung in der DE-OS 32 05 449 beschrieben, auf deren Offenbarung ausdrücklich Bezug genommen wird.

In dieser Druckschrift ist ein weiteres Pumpengehäuse beschrieben, bei dem anstelle einer flächigen Pumpenmembran 40 eine schlauchförmige Pumpenmembran eingesetzt wird. Auf die Offenbarung dieser Pumpenmembran sowie der Befestigung dieser Membran in dem Pumpengehäuse wird wiederum Bezug genommen.

Wie bereits eingangs erläutert, hängt bei dieser Anordnung der zu erreichende Unterdruck bzw. Überdruck im wesentlichen vom Verhältnis des Pumpvolumens V_1 und des Volumens V_2 des ausgezogenen Balges 46 ab. Insofern ist es leicht, den Druckgrenzwert der Druckbegrenzungsventile 78 und 80 festzulegen, der vorteilhafterweise wenigstens 10 % über den jeweiligen Druckgrenzwerten liegt, die aufgrund der gewählten Anordnung festgelegt sind.

Diese Grenzdruckwerte werden so gewählt, daß die eingesetzten Materialien diese Drücke ohne weiteres aushalten können. Sie liegen insofern in einem Bereich von 100 mbar - 3 bar, vorzugsweise 400 mbar - 2 bar.

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Andererseits können jedoch aber auch diese Bereiche überschritten werden, sofern entsprechend feste Materialien eingesetzt werden.

Die in Fig. 1 gezeigte Pumpanordnung 10 wird auf folgende Weise betrieben:

Über die Leitung 24 wird von einem nicht gezeigten Behälter das zu fördernde Fluid, beispielsweise Blut oder eine Infusionslösung, dem Pumpengehäuse 12 zugeführt. Hierzu ist die Klemme 28 offen, während die Klemme 30 geschlossen ist. Weiterhin befindet sich die Balgpumpe am unteren Totpunkt, d.h. am linken Anschlag gemäß der in Fig. 1 gezeigten Ausführungsform. Der Druck ist ebenfalls auf Normaldruck gestellt. Anschließend wird der Balg expandiert, d. h. nach rechts bewegt, wobei durch die expandierte Luft die Pumpenmembran 40 ebenfalls nach rechts mitgenommen wird. Hierdurch wird ein Unterdruck im System erzeugt, der zum Einpumpen des Fluids in die Arbeitskammer 16 führt. Die Pumpphase ist dann beendet, wenn das Kammervolumen V_1 vollständig mit Fluid gefüllt ist, d.h. wenn sich die Pumpenmembran 40 an die rechte Kammerwand angelegt hat. Beim Anlegen bewegt sich jedoch noch der Balg 46 weiter nach rechts, bis der obere Totpunkt erreicht wird. Sollte hierbei der bestimmte Grenzdruckwert überschritten werden, öffnet automatisch das Druckbegrenzungsventil 78, um einen bestimmten Grenzüberdruckwert konstant zu halten.

Im oberen Totpunkt schaltet dann das Steuergerät 70 zunächst die Klemme 28 zu, öffnet das Ventil 56 zur Einstellung des Drucks auf den Normaldruckwert und öffnet dann die Klemme 30. Zugleich wird die Phasenlage der Pumpe 14 umgeschaltet, die dann in die Kompressionsphase, d.h. in die Abpumpphase überführt wird. Hierdurch wird durch den entstehenden Überdruck die Pumpenmembran solange nach links bewegt, bis sie sich an die Wand der linken Kammerhälfte 16 angelegt hat, d.h. bis der Zustand der völligen Entleerung erreicht ist.

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Sollte hier ein bestimmter Überdruck noch während der Pumpphase erreicht werden, öffnet das andere Überdruckbegrenzungsventil 80 und hält diesen Überdruck konstant.

Bei Erreichen des unteren Totpunkts wird dann wiederum das Ventil 56 zur Einstellung auf den Atmosphärendruckwert betätigt.

Anschließend beginnt erneut die Füllphase.

In Fig. 2 ist eine spezielle Infusionsvorrichtung mit 82 gezeigt, wobei für gleiche Teile die gleichen Bezugsziffern wie in Fig. 1 gezeigt werden.

Diese Infusionsvorrichtung 82 weist einen Infusionsbeutel 84 auf, der über die Leitung 24 mit dem Pumpengehäuse 85 verbunden ist, die jedoch nur eine Öffnung 20 aufweist, die zugleich als Zuführ- und Abführöffnung dient. Eine solche Ausführungsform mit nur einer Öffnung gehört zu den bevorzugten Ausführungsformen.

Dementsprechend verzweigt sich also die Leitung 24 bei dem Verzweigungspunkt 86, von dem die Leitung 88, die mit der Öffnung 20 verbunden ist, und die Leitung 26 abgeht.

Gemäß der in Fig. 2 gezeigten Pumpanordnung weist das Pumpengehäuse 85 eine Antriebskammer 18 auf, die der in Fig. 1 gezeigten Antriebskammer 18 entspricht. Ebenfalls entspricht die Pumpenmembran 40 der in Fig. 1 gezeigten Pumpenmembran 40. Es fehlt jedoch vollständig die Arbeitskammer 16 gem. Fig. 1. Demzufolge liegt die ebene Membran 40 völlig an der Wand der Gehäusehälfte 41 an.

Vorteilhafterweise wird in dieser Ausführungsform eine derart elastische Membran gewählt, daß diese durch den hydrostatischen Druck zwangsläufig geöffnet wird, sofern

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die Flüssigkeitssäule bis in den Beutel 84 reicht. Die elastische Rückstellkraft soll jedoch so bemessen sein, daß sich die Pumpenmembran erst dann erweitert, wenn die Wassersäule wenigstens 10 cm beträgt. Vorteilhafterweise ist dabei die Klemme 28 noch unterhalb dieses Grenzwerts, d.h. unterhalb etwa 10 cm angeordnet, so daß sich keine Luftblasen in dem Pumpsystem bilden können, was gerade bei der Infusion von besonderer Bedeutung ist. Die Infusionsvorrichtung 82 gem. Fig. 2 wird auf folgende Weise betrieben:

Bei geöffneter Klemme 28 drückt die im Beutel 84 befindliche Flüssigkeit die vorteilhafterweise elastische Pumpenmembran 40 solange nach rechts, bis sich die Membran 40 an die Wand der rechten Kammerhälfte 42 angelegt hat.

Während dieser Füllphase kann gemäß einer ersten Ausführungsform die Balgpumpe 14 den Füllvorgang unterstützen, wobei das Ventil 56 gemäß der in Fig. 1 beschriebenen Betriebsweise betätigt wird, d.h. nur an den oberen und unteren Totpunkten geöffnet wird. Gemäß einer zweiten Ausführungsform kann jedoch das Ventil 56 auch während der Füllphase, d.h. Expansion des Balges 46, geöffnet sein, wobei es zu einem selbsttätigen Füllvorgang durch den Druck der Wassersäule kommt. Diese Ausführungsform ist bei der in Fig. 2 gezeigten Infusionsvorrichtung 82 besonders bevorzugt.

Nach erfolgter Füllung wird dann der Balg 46 bei geschlossenem Ventil 56 komprimiert und am unteren Totpunkt belüftet. Hierauf beginnt wiederum die selbsttätige Füllphase.

Es muß nicht besonders hinzugefügt werden, daß anstelle des asymmetrischen Pumpengehäuses gemäß Fig. 2 das symmetrische Pumpengehäuse gemäß Fig. 1 eingesetzt werden kann, sofern die Membran die gleichen elastischen Eigenschaften besitzt. Allerdings kann hier die Rückstellkraft

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der Membran zu einer Einschleppung von Luftblasen in die Arbeitskammer 16 führen, so daß an der Leitung 28 vorteilhafterweise Luftsensoren 90 angebracht sind, die über die Leitung 91 mit dem Steuergerät 70 verbunden sind und die gesamte Vorrichtung abschalten können.

In Fig. 3 ist eine Pumpvorrichtung 92 gezeigt, die vier Anschlüsse für je vier Pumpengehäuse besitzt, von denen nur drei belegt sind.

Von der Pumpe 14 geht wiederum die Leitung 50 ab, in die über die Leitung 54 das Ventil 56 eingeschaltet ist. Die Leitung 50 weist gemäß der in Fig. 3 gezeigten Ausführungsform vier Verzweigungen 96 auf, von denen Leitungen 98 abgehen, deren Ende jeweils Anschlüsse 100 aufweisen. Diese Anschlüsse 100 sind vorteilhafterweise mit einem Sperrventil 102 ausgerüstet, das beim Konnektieren mit der Leitung 34 geöffnet wird.

Wie in Fig. 3 gezeigt, weist die Pumpvorrichtung 92 zwei Pumpengehäuse 12, wie in Fig. 1 gezeigt, und ein asymmetrisches Pumpengehäuse 104 auf, das nachstehend erläutert wird.

Derartige Pumpvorrichtungen 92 werden besonders vorteilhaft in der Intensivmedizin eingesetzt, bei der der Patient mit mehreren Infusionsleitungen versehen ist.

Sollten jeweils gleiche Infusionsraten erzielt werden, so werden vorteilhafterweise Pumpengehäuse 12, 104 mit gleichem Innenvolumen V_1 eingesetzt, wobei die Pumpe entsprechen der gewünschten Rate mit der entsprechenden Geschwindigkeit betrieben wird.

In Abhängigkeit vom Balgvolumen V_2 steigt die Pumpengröße V_1 vorteilhafterweise entweder um die Faktoren 2, 4, 8 usw. oder um die Faktoren 4, 16, 32 usw. Dabei sollen die Volumina V_1 und V_2 so ausgelegt sein, daß generell eine kontinuierliche Pumprate ohne größere Pausenzeiten erzielt

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werden kann.

Wenn jedoch unterschiedliche Pumpraten, d.h. unterschiedliche Infusionsflüssigkeitsmengen dem Patienten verabreicht werden sollen, so können teilweise Pumpengehäuse 12, 104 mit unterschiedlichen Volumina eingesetzt werden, teilweise Pumpengehäuse 12 mit gleichen Volumina zur Anwendung kommen, sofern die Pausenzeiten nicht zu groß sind und spezielle Vorkehrungen zur Verminderung der Pumprate getroffen werden. Bei dieser Betriebsweise ist natürlich die Infusionsrate mit der höchsten Pumpenfrequenz geschwindigkeits- und steuerungsbestimmend. Sofern also diese Pumpenfrequenz zu einer überhöhten und somit unerwünschten Pumprate führt, können folgende Vorkehrungen getroffen werden:

Soll beispielsweise die Infusionsflüssigkeit, die in das obere Pumpengehäuse 12 gem. Fig. 3 eingeführt wird, in geringeren Mengen infundiert werden, so ist vorteilhafterweise in der Leitungsverbindung 98 bzw. 34 ein Absperrorgan 106 vorgesehen, das diese Leitungen entsprechend sperrt. So können bestimmte Hübe des Balgs 46 und somit bestimmte Pumpschritte dadurch ausgelassen werden, daß das Absperrorgan 106, vorzugsweise ein Ventil oder eine Schlauchklemme, sofern ein elastischer Schlauch eingesetzt wird, am unteren Totpunkt der Pumpe 14 für einen bestimmten Zeitraum geschlossen wird, beispielsweise solange, bis die Pumpe 14 den oberen Totpunkt erreicht hat.

Anstelle des Absperrorgans 106 kann in einer anderen Ausführungsform die Klemme 30 geschlossen bleiben, wobei bei geöffneter Klemme 28 in den Beutel zurückgepumpt wird oder bei ebenfalls geschlossener Klemme 28 lediglich ein erhöhter Unterdruck im Pumpengehäuse 12 erzeugt wird.

In einer weiteren Ausführungsform ist es auch denkbar, daß beim Expandieren des Balges 46 das Absperrorgan 28 geschlossen bleibt, während das Absperrorgan 30 geöffnet

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wird. In einem solchen Fall ist jedoch darauf zu achten, daß es zu keinem Rücksaugvorgang von den anderen Abführleitungen der übrigen Pumpengehäuse kommt.

Als Absperrorgane 28 und 30 bzw. 106 kommen die üblichen magnetischen oder mechanischen Klemmen in Frage, wobei kombinierte Klemmen für beide Absperreinrichtungen 28 und 30 bevorzugt sind. Derartige Kombinationsklemmen, bei denen immer nur eine der Klemmen offen ist, während die andere zwangsläufig geschlossen ist, ist mit 108 in Fig. 3 gezeigt. Diese Klemme 108 gem. Fig. 3 wird linear zwischen den beiden Anlagepunkten bewegt. Denkbar ist jedoch auch eine Nocke, die an einer Scheibe angebracht ist, die jeweils um einen bestimmten Betrag von der einen Schließposition in die andere Schließposition überführt wird.

Diese Ventile können also - wie vorstehend erläutert - zwangsgeführt werden oder aber auch gesteuert werden, sofern elektromagnetische Ventile eingesetzt werden.

In Fig. 4 ist vergrößert das asymmetrische Pumpengehäuse 104 gem. Fig 3 gezeigt. Dieses Pumpengehäuse 104 weist eine zweite Kammerhälfte 110 und eine erste Kammerhälfte 112 auf, wobei die Kammerhälfte 110 in Form einer ebenen Platte ausgebildet ist, während die Kammerhälfte 112 eine halbkugelförmige Aushöhlung 114 aufweist. Beide Kammerhälften sind von der Pumpenmembran 116 getrennt. Zusätzlich weisen beide Kammerhälften 110 und 112 Öffnungen 118 und 120 auf.

Gemäß dieser Ausführungsform ist die Öffnung 118 mit der Leitung 34 verbunden, während die Öffnung 120 mit der Leitung 88 verbunden ist.

Wie bereits vorstehend erläutert, ist diese Pumpenform, sofern eine elastisch erweiterbare Membran 116 eingesetzt wird, selbst zurückstellend, wenn sich die Membran 116 völlig an die Innenwand des Pumpengehäuses 112 angelegt

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hat und die Pumpe 14 komprimiert ist.

In dieser Betriebsweise wird das Ventil 56 vorteilhafterweise am unteren Totpunkt geöffnet, was zur Folge hat, daß sich die Membran 116 in die Ausgangslage zurückbegibt. Hierdurch füllt sich der Raum 114 selbsttätig mit der Pumpflüssigkeit. Somit handelt es sich hier um eine selbst-ansaugende Pumpe.

Falls jedoch die Öffnung 120 mit der Pumpe 14 über die Leitung 34 verbunden ist und die Öffnung 118 mit dem Behälter der zu pumpenden Flüssigkeit über die Leitung 88 verbunden ist, wird die Membran 116 beim Expandieren der Pumpe nach hinten solange mitgenommen, bis sie sich an die Innenwand der Aushöhlung 114 angelegt hat. Im oberen Totpunkt der Pumpe 14 (Balgpumpe oder Kolbenpumpe) erfolgt dann die Belüftung des Systems durch Öffnen des Ventils 56 mit der Folge, daß sich die Membran 116 in ihre Ausgangslage aufgrund ihrer elastischen Rückstellkraft zurückbegibt und die gespeicherte Flüssigkeit durch die Öffnung 118 abdrückt. Somit handelt es sich hier um eine selbst-abfördernde Pumpe.

Die erfindungsgemäßen Pumpanordnungen können vorteilhafterweise mit einer mikroprozessorgesteuerten Auswertungs- und/oder Steuereinheit verbunden sein. Hier können die Verhältnisse der zu fördernden Mengen und die tatsächlichen Mengen programmierbar sein. Weiterhin können diese Einheiten durch die Markierungen 43 bereits auf die speziellen Pumpengehäusetypen programmierbar sein, und zwar unabhängig davon, ob symmetrische oder asymmetrische Pumpengehäuse eingesetzt werden.

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Patentansprüche

1. Pumpanordnung für medizinische Zwecke, insbesondere eine Blut- oder Infusionspumpe, mit wenigstens einem Pumpgehäuse, das einen Raum aufweist, der von einer undurchlässigen Membran in einer Arbeitskammer und in eine Antriebskammer unterteilt ist, wobei die Arbeitskammer mit wenigstens einer Öffnung zur Zu- und Abführung des zu fördernden Fluids versehen ist und die Antriebskammer mit Luft als Pumpfluid beaufschlagbar und mit einer ein begrenztes Pumpvolumen aufweisenden Pumpe verbunden ist, und mit einem mit der Antriebskammer verbundenen Ventil für den Druckausgleich bei Hubwechsel der Pumpe, dadurch gekennzeichnet, daß ein Steuergerät (70) vorgesehen ist, das vor jedem Hubwechsel der Pumpe (14) das Ventil (56) öffnet und nach Druckausgleich auf Umgebungsdruck schließt und danach den nächsten Hub der Pumpe(14)einleitet.

2. Pumpanordnung nach Anspruch 1, dadurch gekennzeichnet, daß das Ventil (56) mit einem Steuergerät (70) verbunden ist, das durch Schalten der Endkontakte (58, 60) mit dem Schaltkontakt (56) angesteuert wird, die an der Pumpe (14) angeordnet sind.

3. Pumpanordnung nach Anspruch 2, dadurch gekennzeichnet, daß das Steuergerät (70) mit einer stromauf der Arbeitskammer (16) angeordneten Absperreinrichtung (28) und einer stromab der Arbeitskammer (16) angeordneten Absperreinrichtung (30) verbunden ist und diese getaktet öffnet bzw. schließt.

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4. Pumpanordnung nach Anspruch 3, dadurch gekennzeichnet, daß die Absperreinrichtung (28) im unteren bzw. oberen Totpunkt der Pumpe (14) geschlossen bzw. geöffnet wird, während die Absperreinrichtung (30) umgekehrt geöffnet bzw. geschlossen wird.

5. Pumpanordnung nach einem der Ansprüche 1 - 4, dadurch gekennzeichnet, daß die Pumpe (14) mit Unterdruck- und Überdruckbegrenzungsventilen (78, 80) ausgerüstet ist.

6. Pumpanordnung nach einem der Ansprüche 1 - 5, dadurch gekennzeichnet, daß die Verbindungsleitung zwischen der Antriebskammer (18) des Pumpengehäuses (12) mit der Pumpe (14) durch ein Absperrorgan (106) gesteuert geöffnet bzw. geschlossen wird.

7. Pumpanordnung nach einem der Ansprüche 1 - 6, dadurch gekennzeichnet, daß das Pumpengehäuse (12, 85, 104) aus einer ersten und einer zweiten Gehäusehälte (41 bzw. 42; 112 bzw. 110) besteht.

8. Pumpanordnung nach Anspruch 7, dadurch gekennzeichnet, daß die erste Gehäusehälfte (41; 112) wenigstens eine erste Öffnung (20, 22, 120) für die Zu- und Abführung der zu pumpenden Flüssigkeit aufweist und die zweite Gehäusehälfte (42) eine andere Öffnung (32, 118) für das Pumpfluid aufweist.

9. Pumpanordnung nach Anspruch 8, dadurch gekennzeichnet, daß die andere Öffnung (32, 118) mit einer im wesentlichen starren Leitung (34) verbunden ist, deren Ende mit einer hydrophoben, Keime nicht durchlassenden Membran (38) verschlossen ist.

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10. Pumpanordnung nach einem der Ansprüche 1 - 9, dadurch gekennzeichnet, daß das Pumpengehäuse (12, 104) ein Kunststoffwegwerfteil ist und volumenabhängige Kennmarken aufweist.

11. Pumpanordnung nach einem der Ansprüche 1 - 10, dadurch gekennzeichnet, daß die Pumpe (14) über eine Leitung (50) mit dem Pumpengehäuse (12, 104) verbindbar ist, die ein Absperrventil (102) aufweist, das im ungekuppelten Zustand die Leitung (50) verschließt.

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Fig. 1

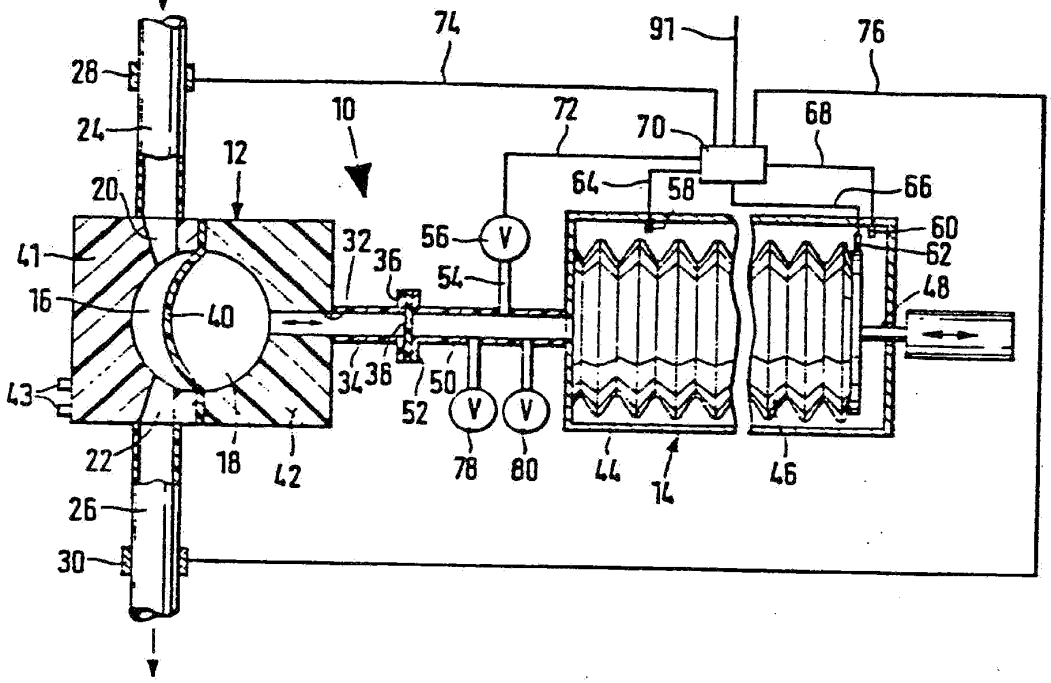


Fig. 2

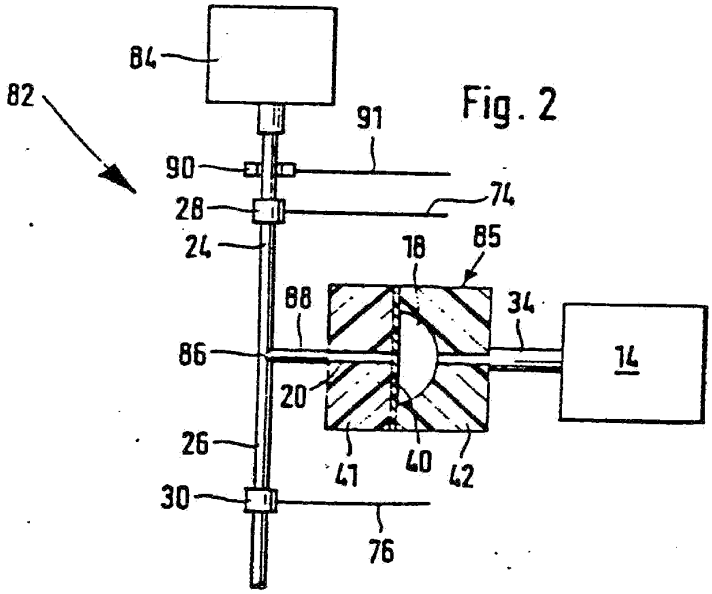
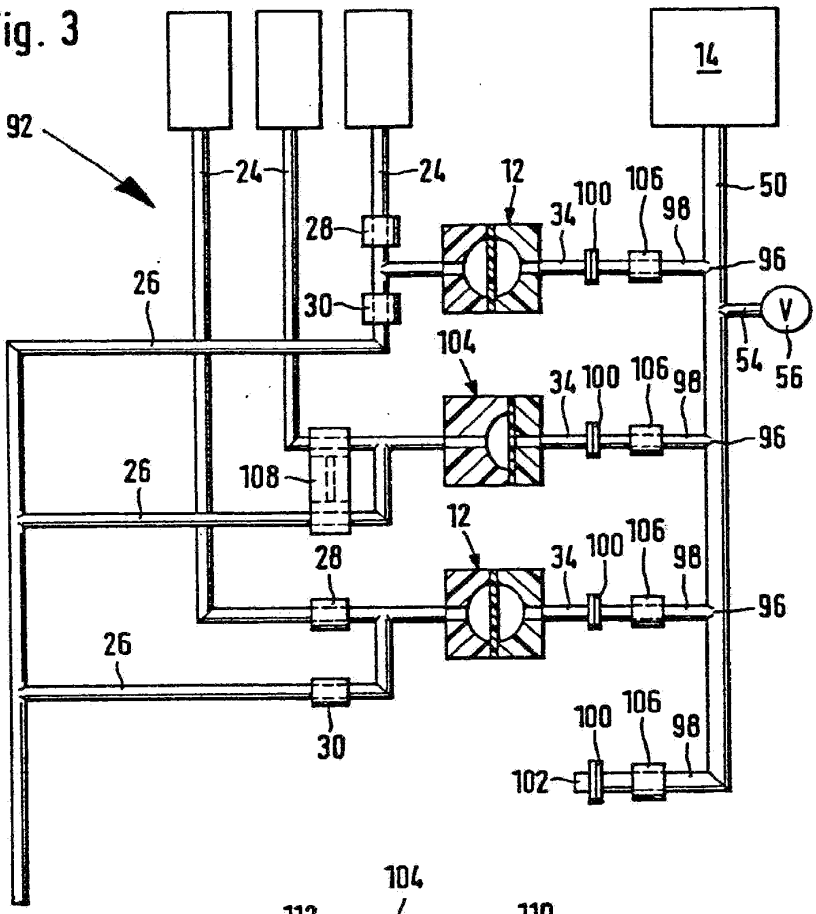


Fig. 3



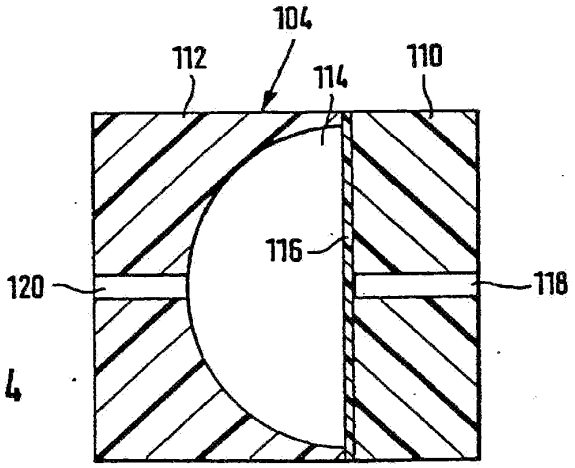


Fig. 4

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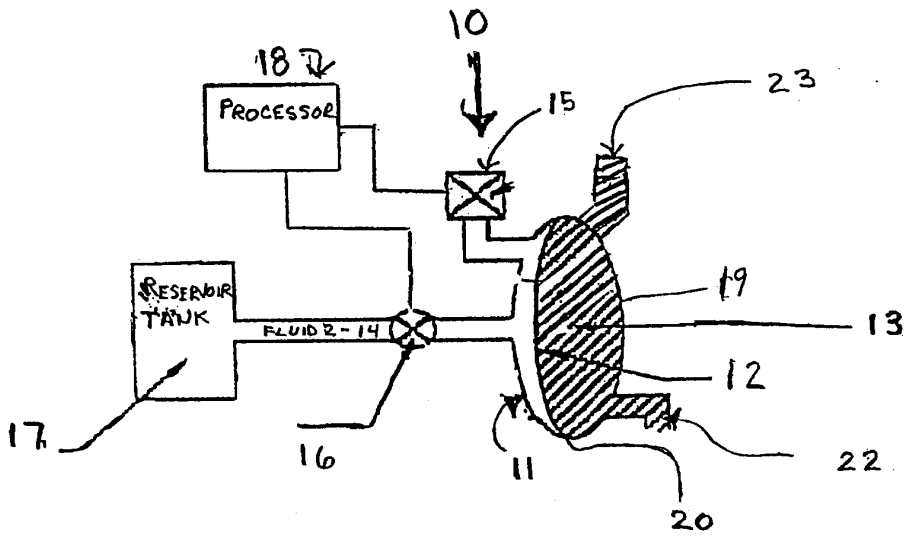
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(57) **Abstract**

The time derivated pressure variation in a second fluid, separated from a first (13) by a pumping membrane (12), is measured (15) in response to energy (16, 17) applied in a time–varying manner to the second fluid. After low pass filtering, below a threshold, a stop is indicated.

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DETERMINING WHEN FLUID HAS STOPPED FLOWING WITHIN AN ELEMENT

Technical Field

The present invention relates to fluid systems and, more specifically, to determining whether fluid has stopped flowing within a line.

Background Art

In fluid management systems, a problem is the inability to rapidly detect an occlusion in a fluid line. If a patient is attached to a fluid dispensing machine, the fluid line may become bent or flattened and therefore occluded. This poses a problem since the patient may require a prescribed amount of fluid over a given amount of time and an occlusion, if not rapidly detected, can cause the rate of transport to be less than the necessary rate. One solution in the art, for determining if a line has become occluded, is volumetric measurement of the transported fluid. In some dialysis machines, volumetric measurements occur at predesignated times to check if the patient has received the requisite amount of fluid. In this system both the fill and delivery strokes of a pump are timed. This measurement system provides far from instantaneous feedback. If the volumetric measurement is different from the expected volume over the first time period, the system may cycle and remeasure the volume of fluid sent. In that case, at least one additional period must transpire before a determination can be made as to whether the line was actually occluded. Only after at least two timing cycles can an alarm go off declaring a line to be occluded.

Summary of the Invention

A method for determining when a first fluid having a pressure has stopped flowing within a line is disclosed. In accordance with one embodiment, the method is formed from the following steps: applying a time varying amount of energy to a second fluid separated from the first fluid by a membrane, measuring a pressure of the second fluid, and determining whether the first fluid has stopped flowing, at least based on the pressure of the second fluid. In another embodiment the method contains the steps of:

modulating a pressure of a second fluid separated from the first fluid by a membrane;

measuring the pressure of the second fluid;

determining a value corresponding to the derivative with respect to a timing period of the pressure of the second fluid creating a derivative value;

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a determining a value corresponding to the magnitude of the derivative value creating a magnitude derivative;

determining a value corresponding to low pass filtering the magnitude derivative creating a low pass output; and

comparing the low pass output to a threshold value, for determining that the first fluid has stopped flowing when the low pass output is below the threshold. In yet another embodiment, the method adds the steps of taking the difference between the pressure of the second fluid and a target value and varying an inlet valve in response to the difference between the pressure of the second fluid and the target value for changing the pressure of the second fluid toward the target value.

In another embodiment, the target value comprises a time varying component having an amplitude and it is superimposed on a DC component. The amplitude of the time varying component is less than the DC component.

In an embodiment in accordance with the invention, a fluid management system dispenses an amount of a first fluid and monitors a state of flow of the first fluid. The system has a chamber, an energy imparter, a transducer and a processor. The chamber has an inlet and an outlet and a septum separating the first fluid and a second fluid. The energy imparter applies a time varying amount of energy on the second fluid. The transducer is used for measuring a pressure of the second fluid within the chamber and creating a signal of the pressure. The processor is used for determining whether the first fluid has stopped flowing based on the signal.

In another embodiment, the fluid management system has the components of a chamber, a reservoir tank, a membrane, a transducer, and a processor. The reservoir tank contains a second fluid in fluid communication with the chamber and the tank has a valve disposed between the reservoir tank and the chamber. The membrane is disposed within the chamber between the first fluid and the second fluid and it is used for pumping the first fluid in response to a pressure differential between the first fluid and the second fluid. The transducer is used for measuring the pressure of the second fluid within the chamber and creating a pressure signal. The processor performs multiple steps constituting: i) reading the pressure signal, ii) determining a value corresponding to the derivative with respect to

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a timing period of the pressure signal creating a derivative value, iii) determining a value corresponding to the magnitude of the derivative value creating a magnitude derivative, iv) determining a value corresponding to low pass filtering the magnitude derivative creating a low pass output, v) comparing the low pass output to a threshold value, for determining that the first fluid has stopped flowing when the low pass output is below the threshold and

vi) causing an indicator signal if the first fluid has stopped flowing. In another related embodiment, the processor controls the opening and closing of a valve in response to the difference between the pressure of the second fluid and a target value, the opening and closing of the valve adjusting the pressure of the second fluid toward the target value. In yet other embodiments, the first fluid may be dialysis fluid or blood and the second fluid may be air or a gas.

Brief Description of The Drawings

The foregoing features of the invention will be more readily understood by reference to the following detailed description taken with the accompanying drawings:

Fig. 1 is a schematic drawing of a simplified embodiment of the invention, showing a chamber, reservoir tank and processor.

Fig. 2A shows a flow chart of a method for computing whether a fluid has stopped flowing in a line, in accordance with an embodiment of the invention.

Fig. 2B shows a graphical representation of step 202 of Fig. 2A which is the pressure signal of the second fluid graphed with respect to time.

Fig. 2C shows a graphical representation of step 204 of Fig. 2A which is the derivative of step 202 graphed with respect to time.

Fig. 2D shows a graphical representation of step 206 of Fig. 2A which is the magnitude of step 204 graphed with respect to time.

Fig. 2E shows a graphical representation of step 208 of Fig. 2A which is step 206 low pass filtered and graphed with respect to time.

Fig. 3 shows a flow chart of a control feedback loop for setting the pressure within the chamber of Fig. 1, in accordance with an embodiment of the invention.

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Detailed Description of Specific Embodiments

Referring now to FIG. 1, a fluid management system is designated generally by numeral **10**. The fluid management system is of the kind that uses the pressure of one fluid to move another fluid. The invention will be described generally with reference to the fluid management system shown in FIG. 1, however it is to be understood that many fluid systems, such as dialysis machines and blood transport machines, may similarly benefit from various embodiments and improvements which are subjects of the present invention. In the following description and claims, the term "line" includes, but is not limited to, a vessel, chamber, holder, tank, conduit and, more specifically, pumping chambers for dialysis machines and blood transport machines. In the following description and claims the term "membrane" shall mean anything, such as a septum, which separates two fluids so that one fluid does not flow into the other fluid. Any instrument for converting a fluid pressure to an electrical, hydraulic, optical or digital signal will be referred to herein as a "transducer." In the following description and claims the term "energy imparter" shall refer to any device that might impart energy into a system. Some examples of energy imparters are pressurized fluid tanks, heating devices, pistons, actuators and compactors.

Overview of the System and Method of Determining if a Fluid is Flowing within a Line

The system and method provides a way for quickly determining if a fluid has ceased flowing within a line. In a preferred embodiment the line is a chamber **11.** The method determines if a fluid management system's pumping mechanism is at the end of its stroke and a fluid, referred to as a "first fluid", has stopped flowing. In one embodiment, the system and method are part of a fluid management system for transporting dialysis fluid **13** wherein the first fluid is moved through a disposable chamber **11** by a pumping mechanism which may be a flexible membrane **12**. The first fluid **13** may be blood, dialysis fluid, liquid medication, or any other fluid. The fluid which is on the opposite side of the membrane from the first fluid is known as the second fluid. The second fluid **14** is preferably a gas, but may be any fluid and in a preferred embodiment the air is the second fluid.

The flexible membrane **12** moves up and down within chamber **11** in response to

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pressure changes of the second fluid. When membrane **12** reaches its lowest point it has come into contact with the bottom wall **19** of disposable chamber **11**. When membrane **12** contacts bottom wall **19** it is said to be at the bottom or end of its stroke. The end of stroke is one indication that first fluid **13** has stopped flowing. To determine if pumping mechanism **12** is at the end of its stroke, the pressure of the second fluid is continuously measured. The pressure of the second fluid is measured for determining if the first fluid has stopped flowing.

The pressure measurement is performed within the chamber or line by a transducer **15**. Transducer **15** sends an output signal to a processor **18** which applies the remaining steps and controls the system. The signal is differentiated by processor **18**, then the absolute value is taken, the signal is then low pass filtered, and finally the signal is compared to a threshold. If the signal is below the threshold, fluid has stopped flowing. The absolute value of the derivative may be referred to as the "absolute value derivative" and either the absolute value, the magnitude or a value indicating the absolute value may be used. Once it is determined that first fluid **13** has stopped flowing, the system is capable of ascertaining whether an occlusion in an exit line **22** or entrance line **23** has occurred or whether the source of fluid is depleted. Because the algorithm detects rapidly when fluid flow has stopped, the delay for detecting whether exit line **22** or entrance line **23** is occluded may be reduced by an order of magnitude with respect to the prior art for such a system. A more detailed description of this method and its accompanying system will be found below. This system for determining when fluid has stopped flowing may also be operated in unison with a control system.

In a preferred embodiment, the closed loop control system regulates the pressure within the container. It attempts to adjust the pressure of the second fluid to a target pressure by comparing the measured pressure signal of the second fluid to the target pressure and controlling the opening and closing of an inlet valve **16** to adjust the pressure of the second fluid. The term "attempts" is used in a controls-theoretical sense. The inlet valve **16** connects the chamber to a pressurized fluid reservoir tank **17**.

Detailed Description of the System for Determining if a Fluid is Flowing

Further referring to Fig. 1, in accordance with a preferred embodiment, fluid flows

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through line **11** in which pumping mechanism **12** is located. The mechanism may be of a flexible membrane **12** which divides the line **11** and is attached to the inside of the line's inner sides **20**. Membrane **12** can move up or down in response to pressure changes within chamber **11** and is the method by which fluid is transported through chamber **11**. The membrane **12** is forced toward or away from the chamber's wall by a computer controlled pneumatic valve **16** which delivers positive or negative pressure to various ports (not shown) on the chamber **11**. The pneumatic valve **16** is connected to a pressurized reservoir tank **17**. By "pressurized", it is meant that the reservoir tank contains a fluid **14** which is at a pressure greater than the fluid **13** being transported.

Pressure control in line **11** is accomplished by variable sized pneumatic valve **16** under closed loop control. Fluid **13** flows through the chamber in response to the pressure differential between first fluid **13** being transported and second fluid **14** which is let into the line from the reservoir tank. The reservoir tank **17** releases a time varying amount of second fluid **14** into the chamber. As the pressure of the fluid from the reservoir tank becomes greater, membrane **12** constricts the volume in which the transported fluid **13** is located, forcing transported fluid **13** to be moved. The flow of the fluid is regulated by processor **18** which compares the pressure of the second fluid to a target pressure signal and regulates the opening and closing of valve **16** accordingly. When fluid **13** flow stops, valve **16** will close after the pressure is at its target. This indicates either that the membrane or pumping mechanism **12** is at the end of its stroke or the fluid line is occluded. After the fluid flow ceases, the pressure within line **11** will remain at a constant value. Thus, when the pressure signal is differentiated, the differentiated value will be zero. With this information a system has been developed to determine if the fluid flow has stopped.

Description of the Control System and the Feedback Loop

For the following section refer to the flow chart of Fig. 3 and to Fig. 1. The control system operates in the following manner in a preferred embodiment. The second fluid/air pressure is measured within the chamber through transducer **15 (step 302)**. The pressure signal that is produced is fed into processor **18** that compares the signal to the target pressure signal and then adjusts valve **16** that connects pressurized fluid reservoir tank **17**

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and chamber **11** so that the pressure of the second fluid/air in chamber **11** moves toward the target pressure **(step 304)**. The target pressure in the closed loop system is a computer simulated DC target value with a small time varying component superimposed. In the preferred embodiment, the time varying component is an AC component and it is a very small fraction of the DC value. The time varying component provides a way to dither the pressure signal about the desired target value until the stroke is complete. Since the target pressure has the time varying signal superimposed, the difference or differential between the pressure signal and the target value will never remain at zero when fluid is flowing in the line. The target pressure will fluctuate from time period to time period which causes the difference between the pressure and the target pressure to be a value other than zero while fluid is flowing.

When a higher pressure is desired, indicating that the pressure in the disposable chamber **11** is below the target pressure, valve **16** opens allowing the pressurizing fluid, which may be air **14** in a preferred embodiment, to flow from the reservoir tank to the disposable chamber **(step 306)**. The reservoir tank need not be filled with air. The reservoir tank **17** can be filled with any fluid, referred to as the second fluid **14**, which is stored at a greater pressure than the first fluid **13**, which is the fluid being transported. For convenience of the description the second fluid will be referred to as "air". As long as there is fluid flow of first fluid **13**, valve **16** must remain open to allow air **14** to flow into disposable chamber **11** so that constant pressure is maintained. When a lower pressure is targeted, which indicates that the pressure is greater than the target pressure, valve **16** does not open as much **(step 308)**. When fluid stops moving valve **16** closes completely. Fluid is allowed to enter or exit chamber **11** depending on the change in pressure.

Detailed Description of the System and Method of Measuring Whether Fluid Flow has Stopped

Referring to Fig. 2A the method for determining when a fluid has stopped flowing in a line is described in terms of the apparatus shown in Fig. 1. First in one embodiment, he pressure of the second fluid is measured within the chamber by the transducer which takes a pressure reading **(step 202)**. Fig. 2B shows a graphical representation of **step 202** of Fig. 2A which is the pressure signal of the second fluid graphed with respect to time.

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Each period, the pressure of the second fluid changes so long as membrane **12** is not at the end of its stroke due to the AC component that is superimposed upon the DC target pressure. The AC component causes valve **16** to open and close from period to period, so that the pressure of the second fluid **11** mimics the AC component of the target pressure and is modulated. The pressure change between periods will not be equal to zero, so long as fluid continues to flow.

The measured pressure is sent to processor **18** which stores the information and differentiates the measured pressure signal with respect to the set time interval **(step 204)**. Fig. 2C shows a graphical representation of step 204 of Fig. 2A which is the derivative of step 202 graphed with respect to time.

Because the AC component of the target pressure causes inlet valve **16** to adjust the actual pressure of the air/second fluid **14** within chamber **11** during the stroke, the pressure differential will change between each time interval in a likewise manner. When pumping mechanism/membrane **12** reaches the end of stroke the pressure differential (dp) per time interval will approach zero, when the fluid stops flowing.

Processor **18** then takes the absolute value of the differentiated pressure signal **(step 206)**. Fig. 2D shows a graphical representation of step 206 of Fig. 2A which is the magnitude of step 204 graphed with respect to time.

The absolute value is applied to avoid the signal from crossing through zero. During periods of fluid flow, the superimposed time varying signal on the target pressure may cause the target value be larger during one period than the actual pressure and then smaller than the actual pressure in the next period. These changes will cause the valve to open and close so that the actual pressure mimics the time varying component of the target pressure. From one period to the next the differential of the actual pressure signal, when it is displayed on a graph with respect to time may cross through zero. Since a zero pressure reading indicates that fluid has stopped flowing, a zero crossing would indicate that fluid has stopped flowing even when it had not. When the absolute value is applied the agnitude f the signal results and this limits the signal results to positive values.

The pressure signal is then low pass filtered to smooth the curve and to remove any high frequency noise **(step 208)**. The filter prevents the signal from approaching zero

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until the end of stroke occurs. Fig. 2E shows a graphical representation of step 208 of Fig. 2A which is step 206 low pass filtered and graphed with respect to time.

If the filtered signal falls below a predetermined threshold the fluid has stopped flowing and either the membrane has reached the end of its stroke or the fluid line is occluded **(step 210)**. The threshold value is used as a cutoff point for very small flow rates. Low flow rates are akin to an occluded line. The threshold is set at a value that is above zero and at such a level that if the signal is above the threshold, false indications that the fluid has stopped will not occur. The threshold is determined through various measurement tests of the system and is system dependent.

Indicating if a Fluid Line is Occluded

In a preferred embodiment, when the end of stroke is indicated by processor **18,** the system may then determine if one of fluid lines **22,23** is occluded. This can be accomplished through a volumetric fluid measurement. The air volume is measured within line **11**. The ideal gas law can be applied to measure the fluid displaced by the system. Since pressure change is inversely proportional to the change in volume within a fixed space, air volume in pumping chamber **11** can be measured using the following equation.

$Va=Vb(Pbi-Pbf)/(Paf-Pai)$

Where

Va=pump chamber air volume

Vb= reference air volume (which is known)

Pbi=initial pressure in reference volume

Pbf=final pressure in reference volume

Paf=final pressure in pump chamber

Pai=initial pressure in pump chamber

Once the volume of air is calculated the value of the air volume at the beginning of the stroke is then recalled. The differential between the previous and current volume measurements equates to the volume of fluid **13** that is displaced. If the amount of fluid **3** that is displaced is less than half of what is expected, entrance or exit line **22,23** is considered occluded and an alarm can be sent either visually or through sound or both. The entire process may be performed in less than five seconds as opposed to the prior art which

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may take upwards of thirty seconds to determine if a fluid line is occluded. The algorithm is very robust over a wide range of fill and delivery pressures and is intolerant to variations in the valve used to control pressure.

It is possible to use the ideal gas law to create a system to measure a no flow condition based on parameters beside pressure. If energy is allowed to enter the system through the second fluid in a time varying manner the change in volume, or temperature may be measured with respect to the second fluid. If the change approaches zero for the volume or temperature the first fluid will have stopped flowing.

Although various exemplary embodiments of the invention have been disclosed, it should be apparent to those skilled in the art that various changes and modifications can be made which will achieve some of the advantages of the invention without departing from the true scope of the invention. These and other obvious modifications are intended to be covered by the appended claims.

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What is claimed is:

1. A method for determining when a first fluid having a pressure has stopped flowing within a line, the method comprising:

applying a time varying amount of energy to a second fluid separated from the first fluid by a membrane;

measuring a pressure of the second fluid in response to the applied energy; and

determining whether the first fluid has stopped flowing based at least on the pressure of the second fluid.

2. A method according to claim 1, wherein the second fluid is a gas.

3. A method according to claim 1, wherein the second fluid is air.

4. A method according to claim 1, wherein the first fluid is blood.

5. A method according to claim 1, wherein the first fluid is dialysis fluid.

6. A method according to claim 1, wherein the step of determining whether the first fluid has stopped flowing includes:

determining a value corresponding to the derivative with respect to a timing period of the pressure of the second fluid creating a derivative value;

determining a value corresponding to the magnitude of the derivative value creating a magnitude derivative;

low pass filtering the magnitude derivative creating a low pass output; and

comparing the low pass output to a threshold value for determining that the first fluid has stopped flowing when the low pass output is below the threshold.

7. A method according to claim 6, further comprising: taking the difference between the pressure of the second fluid and a target value; and

varying an inlet valve in response to the difference between the pressure of the

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second fluid and the target value for changing the pressure of the second fluid toward the target value.

8. A method according to claim 7, wherein the target value comprises a time varying component having an amplitude and a DC component, the amplitude of the time varying component being less than the DC component.

9. A fluid management system for dispensing an amount of a first fluid and monitoring a state of flow of the first fluid, the system comprising:

a chamber having an inlet and an outlet and a septum separating the first fluid and a second fluid;

an energy imparter for applying a time varying amount of energy on the second fluid;

a transducer for measuring a pressure of the second fluid within the chamber and creating a signal of the pressure; and

a processor for determining whether the first fluid has stopped flowing based on the signal.

10. The system according to claim 9, wherein the second fluid is a gas.

11. The system according to claim 9, wherein the second fluid is air.

12. The system according to claim 9, wherein the first fluid is dialysis fluid.

13. The system according to claim 9, wherein the first fluid is blood.

14. A fluid management system for dispensing an amount of a first fluid and monitoring a state of flow of the first fluid, the system comprising:

a chamber having an inlet and an outlet;

a reservoir tank containing a second fluid in fluid communication with the hamber,

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valve disposed between the reservoir tank and the chamber;

a membrane disposed within the chamber between the first fluid and the second fluid for pumping the first fluid in response to a pressure differential between the first fluid and the second fluid;

a transducer for measuring a pressure of the second fluid within the chamber and creating a signal of the pressure; and

a processor for determining whether the first fluid has stopped flowing based at least on the signal.

15. A system according to claim 14, further including an indicator activated if the first fluid has stopped flowing.

16. A system according to claim 14, wherein the processor further controls opening and closing of the valve.

17. A system according to claim 14, wherein the pressure measured by the transducer is pressure.

18. A fluid management system for dispensing an amount of a first fluid and monitoring a state of flow of the first fluid, the system comprising:

a chamber having an inlet and an outlet;

a reservoir tank containing a second fluid in fluid communication with the chamber, the tank having a valve disposed between the reservoir tank and the chamber;

a membrane disposed within the chamber between the first fluid and the second fluid for pumping the first fluid in response to a pressure differential between the first fluid and the second fluid;

transducer for measuring the pressure of the second fluid within the chamber and creating a pressure signal; and

a processor for

i) receiving the pressure signal;

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ii) determining a value corresponding to the derivative with respect to a timing period of the pressure signal creating a derivative value;

iii) determining a value corresponding to the magnitude of the derivative value creating an magnitude derivative;

iv) low pass filtering the magnitude derivative creating a low pass output;

v) comparing the low pass output to a threshold value for determining that the first fluid has stopped flowing when the low pass output is below the threshold and

vi) causing an indicator signal if the first fluid has stopped flowing.

19. The system according to claim 18, wherein the processor controls the opening and closing of a valve in response to the difference between the pressure of the second fluid and a target value, the opening and closing of the valve adjusting the pressure of the second fluid toward the target value.

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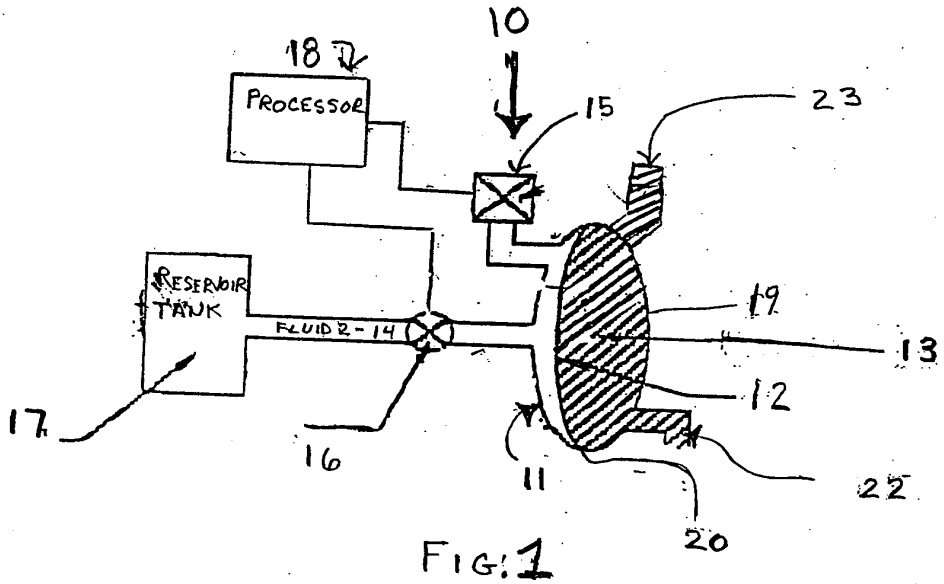
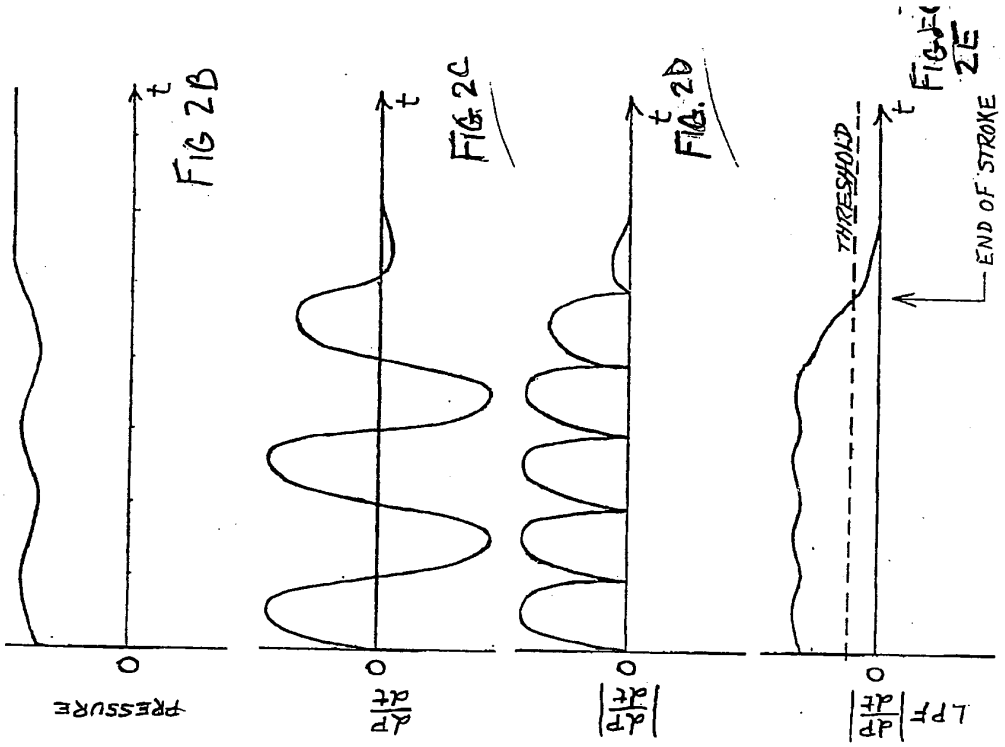

10
18
PROCESSOR
15
23
RESERVOIR TANK
FLUID 2 - 14
19
13
12
17
16
11
22
20

FIG: 1


PRESSURE
0
t
FIG 2B
$\frac{dP^2}{dt^2}$
0
t
FIG 2C
$\left|\frac{dP^2}{dt^2}\right|$
0
t
FIG. 2D
LPF $\left|\frac{dP^2}{dt^2}\right|$
0
THRESHOLD
END OF STROKE
t
FIG. 2E

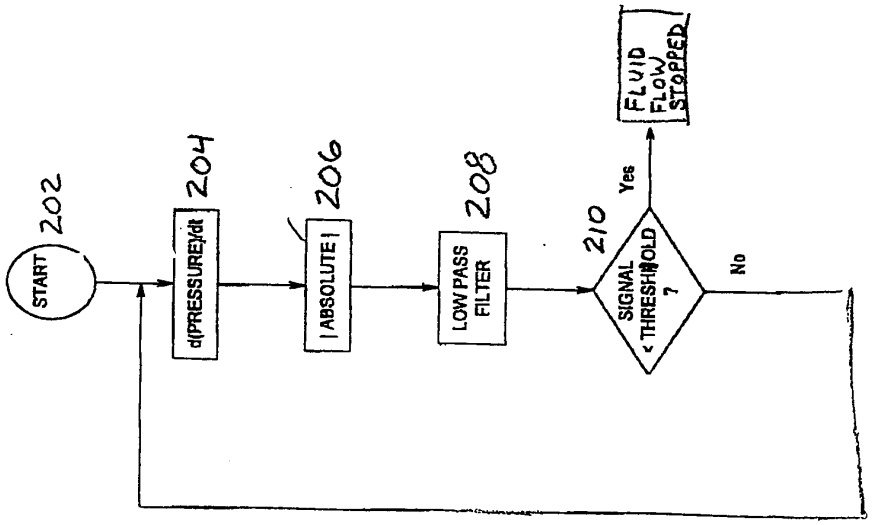

START
202
d(PRESSURE)/dt
204
| ABSOLUTE |
206
LOW PASS FILTER
208
SIGNAL < THRESHOLD ?
210
Yes
No
FLUID FLOW STOPPED

FIG. 2A

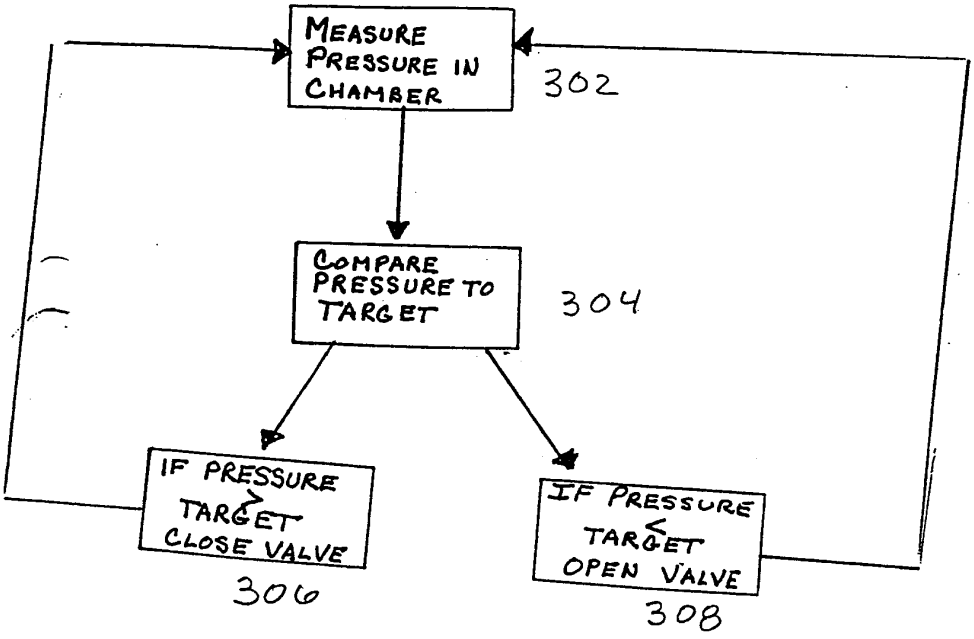


FIG. 3

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INTERNATIONAL SEARCH REPORT

Inter nal Application No
PCT/US 99/14513

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 G01F1/34 G01F25/00 A61M1/14 F04B43/00

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 G01F G01P 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 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	US 4 976 162 A (D.L.KAMEN) 11 December 1990 (1990-12-11) figure 1	1,9,14, 18
A	US 4 431 425 A (QUEST MEDICAL) 14 February 1984 (1984-02-14) column 2, line 50 - column 3, line 16; figure 2	1,9,14, 18
A	US 4 662 540 A (ROBOTICS) 5 May 1987 (1987-05-05) column 1, line 52 - column 2, line 2; figure 1	1,9,14, 18
A	US 4 072 934 A (WYLAIN) 7 February 1978 (1978-02-07) column 2, line 24 - line 35; figures 1,2	1,9,14, 18

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

☒ Patent family members are listed in annex.

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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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"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

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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
23 September 1999	05/10/1999

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	Mielke, W

1

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INTERNATIONAL SEARCH REPORT

Information on patent family members

Interr nal Application No
PCT/US 99/14513

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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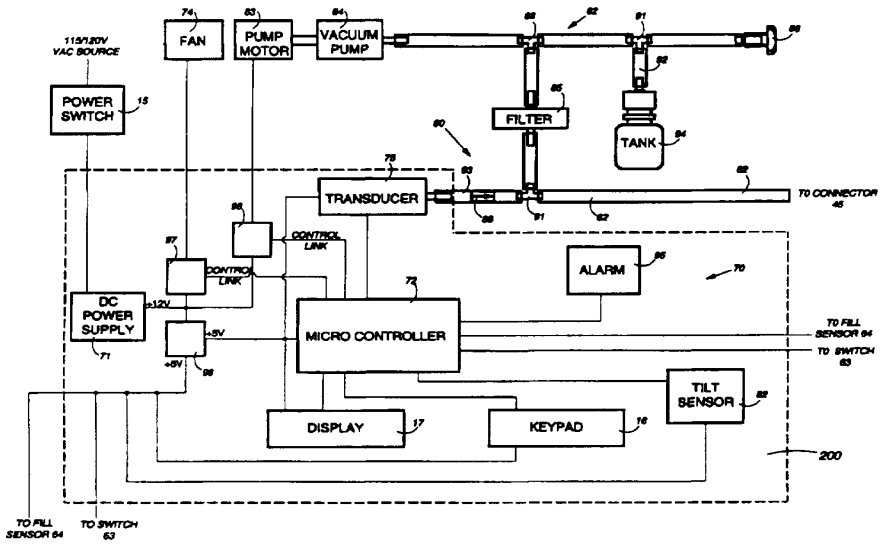
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With international search report.

(54) Title: WOUND DRAINAGE EQUIPMENT



(57) Abstract

A therapeutic apparatus is disclosed for stimulating healing of a wound in mammals. The apparatus comprises a porous foamed pad (36) connected by a tube (37, 38) to a canister (19). A vacuum pump is located within a housing having a recess (18) for receiving the canister. A bacterial filter (46) positioned over the outlet of the canister protects the vacuum pump from contamination by wound drainage fluids sucked into the canister.

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WOUND DRAINAGE EQUIPMENT

The present invention relates to the healing of wounds and, more particularly, but not by way of limitation, to an apparatus for closing wounds that is compact, self-contained, and includes a disposable wound fluids canister.

Wound closure involves epithelial and subcutaneous tissue adjacent the wound migrating towards the centre of the wound until it closes. Unfortunately, closure is difficult with large wounds or wounds that have become infected. In such wounds, a zone of stasis (i.e. an area in which localized swelling of tissue restricts the flow of blood to the tissues) forms near the surface of the wound. Without sufficient blood flow, the epithelial and subcutaneous tissues surrounding the wound not only receive diminished oxygen and nutrients, but are also less able to successfully fight bacterial infection and, thus are less able to close the wound naturally. Such wounds have presented difficulties to medical personnel for many years.

The most common technique for closing open wounds has been the use of sutures or staples. Although such mechanical closure techniques are widely practised and often effective, they suffer a major disadvantage by providing tension on the skin tissue adjacent the wound. That is, the tensile force required to achieve closure using sutures or staples causes very high localized stresses at the suture or staple insertion point. Such stresses commonly result in the rupture of the tissue at those points, which can eventually cause dehiscence in wounds, providing additional tissue loss.

Moreover, some wounds harden and inflame to such a degree due to infection that closure by stapling or suturing is not feasible. Wounds not reparable by suturing or stapling generally require prolonged hospitalisation,

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with its attendant high cost, and major surgical procedures, such as grafts of surrounding tissues. Examples of wounds not readily treatable with staples or suturing include large, deep, open wounds, decubitus ulcers, ulcers resulting from chronic osteomyelitis, and partial thickness burns that subsequently develop into full thickness burns.

The above problem is discussed in WO 93/09727 which proposes as a solution a procedure for draining the wound by applying a continuous negative pressure to the wound over an area sufficient to promote migration of epithelial and subcutaneous tissue toward the wound. Although WO 93/09727 deals in some detail with the clinical considerations of this kind of treatment, the apparatus described has certain practical shortcomings.

One problem with the apparatus described in the above prior document is that no means are disclosed for avoiding spread of infection from one patient to another or re-infection of the patient being treated.

In accordance with the present invention, there is provided a therapeutic apparatus for stimulating healing of wounds, said apparatus including a housing that contains a vacuum pump and a chamber for holding a disposable wound drainage collection canister. The canister preferably resides within the chamber and connects at an outlet with the vacuum pump and at an inlet with a porous pad. The pad is placed over a wound and adhesively secured thereto to create a sealed environment at the wound. Thus, when the vacuum pump activates, it evacuates air from the canister and thence the wound environment, resulting in the application of negative pressure to the wound, which in turn tends to promote drainage of fluids flowing from the wound into the canister. After the canister is filled, it is removed from the chamber, disposed of, and replaced with another canister to continue therapy.

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Although the vacuum pump is designed to be reusable because of its more costly components, the apparatus utilizes a removable and disposable canister adapted to prevent contamination of the vacuum pump or the remainder of the apparatus. If the vacuum pump or other parts of the housing or the tubing leading to the pump from the canister became contaminated, the wound closure apparatus would have to be completely disassembled, thoroughly cleaned and possibly discarded. Disassembly and cleaning of the wound closure apparatus is extremely time and labour intensive, while disposal of the wound closure apparatus is expensive. Consequently, a removable and disposable canister prevents either of the above undesirable circumstances from occurring.

It is, therefore, an object of the present invention to provide a wound closure apparatus that closes wounds without stressing the surrounding skin.

It is another object of the present invention to render technology like that disclosed in WO 93/09727 available in a convenient, compact and self-contained, efficient and economically feasible system. It is also an object to optimize the safety and effectiveness of such a device, particularly from an infection control standpoint.

It is a further object of the present invention to provide a wound closure apparatus that includes a removable and disposable wound fluids collection canister to protect the wound closure apparatus from contamination.

Still other objects, features and advantages of the present invention will become evident to those skilled in the art in light of the following.

Figure 1 is a perspective view depicting the vacuum pump unit of a wound closure apparatus constructed according to the teachings of the present invention.

Figure 2 is a right side plan view depicting the vacuum pump unit of Figure 1.

Figure 2A is a detail view of the latch 26 portion of Figure 2, partially cut-away to eliminate guide (or "key") 29 from the view and to show portions of latch 26 in sagital cross section.

Figure 3 is a perspective view depicting a wound drainage collection canister for use in conjunction with the vacuum pump unit of Figure 1.

Figure 4 is a rear plan view depicting the wound drainage collection canister of Figure 3.

Figure 5 is a perspective view depicting the connection of a wound drainage collection canister of Figure 3 to a wound pad.

Figure 6 is a front plan view in partial cross section depicting the connection of the wound drainage collection canister of Figure 3 within the housing of the vacuum pump of Figure 1.

Figure 6A is a partial view of the apparatus shown in Figure 6 except the canister is removed.

Figure 7 is a perspective view depicting the filter carrier of the wound drainage collection canister.

Figure 8 is a top plan view depicting the filter cap of the wound drainage collection canister.

Figure 9 is a schematic view depicting the control system for a wound closure apparatus constructed according to the teachings of the present invention, and

Figure 10 is a section through a wound showing the wound pad in place.

As illustrated in Figures 1 and 2, front housing 11 and rear housing 12 connect together using any suitable means such as screws and fasteners to

provide wound closure vacuum pump 10 with a small, compact, and easily portable carrying case. Consequently, front housing 11 and rear housing 12 connect together to form handle 13 that permits easy carrying of wound closure apparatus 10. Except as maybe otherwise evident from this description, the carrying case of vacuum pump 10 is substantially as described and shown in WIPO Design No. DM/032185.

Front housing 11 includes power switch 15 that is movable between an on and off position to permit user control of the delivery of power to wound closure apparatus 10. Keypad 16 and liquid crystal display (LCD) 17 mount to front housing 11 to permit the programming of wound closure apparatus 10. Chamber 18 is defined by integrally formed interior side walls 100 and 101, top wall 102, bottom wall 103 and rear wall 104. Side wall 100 is dependently attached to the interior of front housing 11 by standard mounting hardware (not shown). The would fluids collection canister, illustrated in Figures 3-5, is received within chamber 18. Side walls 100 and 101 each include a key 29 and 30, respectively, the aid in the alignment of wound fluids collection canister 19 within chamber 18. Furthermore, front housing 11 includes latch 26 to secure the wound fluids collection canister within chamber 18.

Rear housing 12 includes arm 14 pivotally mounted to it within recess 110. An identical arm pivotally mounts to the opposite side of rear housing 12 within an identical recess. Arm 14 and its corresponding arm mounted on the opposite side of rear housing 12 pivot from within their recesses to a position where they support wound closure apparatus 10 at an angle. Arm 14 and its corresponding arm angularly support wound closure apparatus 10 to permit easier user access to keypad 16. Arm 14 and its corresponding arm may also be used to permit hanging of apparatus 10 from a hospital bed foot board.

Canister 19 has a shape as shown in Figures 3 to 6. As illustrated in Figures 3 to 6, canister 19 includes sidewalls 20 and 21, top wall 23, bottom wall 24, back wall 22 and front wall 25 that define the rectangular chamber for receiving blood, pus, and other fluids emitted from a wound. Sidewalls 20 and 21 include keyways 27 and 31 respectively, that receive a respective one of keys 29 and 30 to provide easy alignment of canister 19 within chamber 18. Furthermore, keyway 27 includes recess 28 that receives latch 26 to fasten canister 19 within chamber 18.

Front wall 25 of canister 19 includes raised portion 32 extending therefrom to furnish a window that permits a user to determine the level of wound fluids within canister 19. Accordingly, raised portion 32 is transparent so that the level of wound fluids within canister 19 may be visually determined. Raised portion 32 includes sidewalls 110 and 111, top wall 112, bottom wall 113, and front face 114 that define a chamber which opens into the chamber defined by sidewalls 20 and 21, top wall 23, bottom wall 24, back wall 22 and front wall 25 of canister 19. Front face 114 of raised portion 32 includes graduations that demarcate the volume of wound fluid within canister 19. Additionally, sidewalls 110 and 111 of raised portion 32 include ridges that provide a gripping surface for the user during the insertion and removal of canister 19 from chamber 18.

Although raised portion 32 is transparent to permit the determination of the level of wound fluids within canister 19, sidewalls 20 and 21, back wall 22, top wall 23, bottom wall 24, and front wall 25 are opaque or textured so that they are only translucent. As an alternative, the portions of canister 19 surrounding filter 46 may also be transparent. This enables a user to visually check for signs of contamination of filter 46. In this preferred embodiment,

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sidewalls 20 and 21, back wall 22, top wall 23, bottom wall 24, front wall 25, and raised portion 32 of canister 19 are fabricated from a plastics material.

Canister 19 includes inlet 35 that is formed integrally with top wall 112 of raised portion 32. Inlet 35 is cylindrical in shape and communicates with the interior of canister 19 to permit the transfer of wound fluids into canister 19. In this preferred embodiment, inlet 35 is also fabricated from a plastics material.

In order to prevent liquids sucked into the canister from splashing directly onto cap 49, which masks the outlet 44, and to reduce foaming within the canister, inlet 35 has a blind inner end. Inlet 35 has a slot 35A so that drainage fluid is deflected downwardly into the raised handle portion 32 of the canister. Handle portion 32 may communicate with the main part of the canister through one or more holes in wall 25. It is desirable to avoid foaming because this can give a false reading when a capacitance sensing device is used to sense when the canister is filled. An anti-foaming material, e.g. a silicone may be added to the canister, e.g. by coating the interior walls. It may also be advantageous to include a gel-forming substance, e.g. a polyacrylamide or modified starch in order to immobilise the drainage fluid. This is particularly useful if the apparatus is likely to be tilted.

Wound fluids (i.e. drainage) are communicated through inlet 35 into canister 19 via pad 36 and hoses 37 and 38. In this preferred embodiment, pad 36 is fabricated from an open cell polyurethane or polyether foam. Hose 37 is inserted within pad 36 by making an incision in pad 36 and inserting the end of hose 37. Hose 37 can then be secured within pad 36 using any suitable means such as an adhesive or a flange. Preferably, the foam pad is moulded or formed with an elongated hole for the drainage tube which is an interference fit with the tube. The hoses are preferably made from medical grade PVC tube. Hose 38

mounts within inlet 35 using any suitable means such as an adhesive or welding. Hoses 37 and 38 include luer lock connectors 39 and 40, respectively, (or the equivalent such as any known quick disconnect type coupling) that attach together to permit communication between hoses 37 and 38. Furthermore, hoses 37 and 38 include pinch clamps 41 and 42, respectively, that are capable of sealing their respective hose 37 or 38 to prevent the flow of wound fluids. The foam pad is preferably packaged in a sterile container together with its connector and clamp. When packaged, the clamps will be in their open condition.

The communication of wound fluids into canister 19 requires the securing of pad 36 over a wound. Pad 36 is secured over a wound using cover 43 which is fabricated from a plastics material and includes an adhesive on one side that sticks to human skin. Wound cover 43 is conveniently a surgical drape material comprising a sheet of elastomeric material coated peripherally or overall with a pressure-sensitive adhesive, such as an acrylic adhesive. The elastomeric or rubbery nature of the wound cover is important because it accommodates changes in pressure in the wound area during intermittent operation of the vacuum pump. The wound cover is preferably a polyurethane film with a removable backing sheet, i.e. of polythene to protect the adhesive surface.

A high degree of reticulation in the polymer foam is desirable to achieve good permeability when the foam is under suction. Foams having at least 90% and especially at least 95% of interconnecting cells are preferred.

In use, the foam pad is cut to a size which corresponds closely to the edge of the wound with the objective of packing the foam into the wound cavity 210 so that it contacts the surface of the cavity, rather than bridging the cavity.

As depicted in Figure 10, the cavity may be extensive and there may be little or no tissue coverage to the bone 212. This is illustrated diagrammatically in Figure 10. Figure 10 is a cross-section through a wound showing the foam pad 36 packed into the wound cavity 210. It is important that the foam should be firmly packed into the recesses of the wound cavity. Drainage tube 37 terminates within the centre of the foam pad 36. Surgical drape 43 extends over the foam pad and is adhered to intact skin 211 around the periphery of the wound. Drape 43 is also firmly adhered around the tube 37 to prevent leakage of air. A wound cover is then adhered to the surrounding skin and around the drainage tube to provide an air-tight seal around the wound.

As illustrated in Figures 2, 4 and 6, canister 19 includes outlet 44 that mounts over port 45 to permit wound closure apparatus 10 to draw wound fluids into canister 19. Outlet 44 is cylindrically shaped and formed as an integral part of back wall 22 by outer wall 33 and inner wall 50 which are interconnected by end wall 34. Passageway 52, defined in part by interior wall 50 and in part by filter cap 49, provides the actual conduit for outlet 44 between the interior and exterior of canister 19. The placement of canister 19 within recess 18 such that outlet 44 resides over port 45 couples canister 19 to a vacuum pump. The vacuum pump removes air from canister 19 to create vacuum pressure within canister 19. That vacuum pressure is then transmitted to a wound site through hoses 37 and 38, thereby not only enabling therapeutic use of system 10, but also tending to promote wound drainage. Any wound drainage fluid is then drawn through pad 36 and hoses 37 and 38 into canister 19.

Outlet 44 resides near top wall 23 of canister 19 to ensure efficient operation of the vacuum pump. That is, the vacuum pump removes the most

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air from canister 19 when the air does not have to first bubble through wound fluids contained in canister 19. Consequently, with outlet 44 positioned near the top of canister 19, the vacuum pump removes air directly from canister 19, and it is only during the final filling of canister 19 that air must bubble through wound fluids. Preferably, as described below, the apparatus includes detecting and warning means which operates before the level of the drainage fluid reaches either the inlet or outlet tube so that a fresh canister can be installed.

In removing fluids from a wound utilizing wound closure apparatus 10, a major safety concern is preventing wound fluids from contaminating the vacuum pump. Accordingly, filter 46 mounts over outlet 44 utilizing filter carrier 48 and filter cap 49 to block the flow of wound fluids to outlet 44 so that wound fluids remain within canister 19 and do not flow into the vacuum pump. In this preferred embodiment, filter 46 is a 0.2 micron hydrophobic membrane filter providing a bacterial barrier, although other filters may be substituted as appropriate.

As illustrated in Figure 7, filter carrier 48 includes face 53 formed integrally with lip 54. Face 53 includes groove 56 formed therein, while lip 54 supports brace 55 in its interior. Filter 46 fits within groove 56 of face 54 and is supported within filter carrier 48 by brace 55 of lip 54. An 'O' ring 53A is fitted in peripheral recess of filter carrier 48 to accommodate manufacturing tolerances and ensure a fluid tight seal in filter cap 49.

As illustrated in Figures 6 and 8, filter cap 49 includes cylindrical portions 57 and 58 which are formed integrally (with annulus 57' spanning therebetween), to hold filter carrier 48 within passageway 52 of outlet 44. To mount filter 46 over passageway 52, filter 46 is first placed within filter carrier 48 as described above. Filter carrier 48 is then positioned within filter cap 49

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such that face 53 abuts annulus 57' of filter cap 49 and lip 54 of filter carrier 48 resides within annular lip 50' of outlet 44. Accordingly, when cylindrical portion 57 of filter cap 49 mounts over outlet 44, the front face 53 of filter carrier 48 and the outer edges of filter 46 abut annulus 57' to secure filter 46 within passageway 52. Filter cap 49 attaches to outlet 44 using any suitable means such as an adhesive or welding. Filter cap 49 is completely sealed except for aperture 51 positioned on top of filter cap 49. Aperture 51 communicates with port 45 via passageway 52 of outlet 44 to permit the vacuum pump to draw air from the interior of canister 19.

As illustrated in Figures 2 and 6, port 45 includes O-ring 59 mounted thereabout to provide a fluid tight seal between port 45 and inner wall 50 of outlet 44. Port 45 mounts through rear wall 104 of chamber 18 using any suitable means such as nuts 60 and 61. Furthermore, hose 62 attaches to the rear of port 45 using any suitable means such as a clamp to couple port 45 to the vacuum pump.

Switch 63 protrudes through rear wall 104 of chamber 18 to produce a signal indicating when canister 19 properly and securely resides within chamber 18. In this preferred embodiment, switch 63 is a normally open push button switch that mounts on rear wall 104 of chamber 18 using any suitable means such as a bracket. When canister 19 is properly positioned within chamber 18, its rear wall 22 presses the head of switch 63, closing switch 63 so that it provides a signal indicating that canister 19 properly resides within chamber 18.

Fill sensor 64 resides adjacent side wall 101, exterior to chamber 18. Fill sensor 64 provides a signal that indicates when canister 19 is filled with wound debris. In this preferred embodiment, fill sensor 64 is a capacitive sensor that mounts on side wall 101 of chamber 18 using any suitable means such as a

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bracket or appropriate adhesive material. Fill sensor 64 has a sensing profile 64A which determines the point at which the capacitance measurement is made. When wound fluids have reached the level within canister 19 which corresponds to the location of the sensing profile 64A, the capacitance within canister 19 as 'seen' by fill sensor 64 changes, resulting in fill sensor 64 outputting a signal indicating that canister 19 is filled with wound fluids to the level at which the sensing profile is located. The position of this sensing profile behind wall 101 can be changed (see Figure 6A) to provide an optimum balance of space and volume utility.

As illustrated in Figure 2A, latch 26 generally comprises latch pin 65, handle 66 latch guide sleeve 68A and spring 67. Latch pin 65 comprises a proximal end 65A and distal end 65B. Latch guide sleeve 68A abuts the inner surface of front housing 11 and is held securely in place from the outer side of front housing 11 by nut 68B. Handle 66 screws onto the proximal end 65A of latch pin 65 and is locked in position by nut 69A. In the preferred embodiment, cover 68 over nuts 69A and 68B provides a surface against which handle 66 abuts, thus preventing end 65B from excessively entering chamber 18 as will be understood further herein. Cover 68 also provides aesthetic enclosure of nuts 69A and 68B. Dependent attachment of side wall 100 (chamber 18), as described hereinabove, is such that side wall 100 abuts latch guide sleeve 68A on the side distal front housing 11. Further, this arrangement causes distal end 65B of latch pin 65 to project into chamber 18 under the force of spring 67 (shown partially cut away). Spring 67 resides circumferentially about latch pin 65 within an axial bore of latch pin guide 68A. Spring 67 exerts force between distal end 65B of latch pin 65 and an annulus within the axial bore of latch pin guide 68A. A transverse slot in the distal end of latch pin guide 68A receives

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end 65B of latch pin 65, providing rotational alignment of end 65B and further recess for end 65B when a user "pulls" handle 66 in an axial direction.

Latch 26 operates to ensure canister 19 remains secured within chamber 18. End 65B of latch 26 terminates in a point that protrudes through key 29 into chamber 18. During the placing of canister 19 within chamber 18, key way 27 of canister 19 forces the point 65B of the latch pin within key 29. However, once canister 19 has been properly positioned within chamber 18, recess 28 resides below latch pin end 65B so that spring 67 biases the point 65B of latch pin 65 into recess 28 to prevent the removal of canister 19 from chamber 18. The removal of canister 19 from chamber 18 is accomplished by grasping handle 66 and pulling the point 65B of latch pin 65 from recess 28. With the point of latch pin 65 no longer within recess 28, canister 19 may be pulled from chamber 18 using its raised portion 32.

As illustrated in Figure 9, wound closure apparatus 10 preferably plugs into a standard 115/120 VAC power source (e.g. an outlet) to supply power to control system 70. Alternative embodiments (not shown, although similar) are readily adapted for 220 VAC power by changing the power cord and appropriately re-wiring the tops of the transformer within the DC power supply 71 as is readily know in the art. The application of power to control system 70 is regulated by power switch 15 which is a standard push button on/off switch. With power switch 15 depressed, DC power supply 71 receives the 115/120 VAC signal and converts it into a 12 VDC signal for use by fan 74 and motor 83. A conventional voltage regulator 96 steps down the voltage to +5V or 12V for use by each of the other DC components 63, 16, 17, 82, 72 and 75. Voltage regulator 96 connects to keypad 16, LCD 17, switch 63, microcontroller 72, transducer 75, and tilt sensor 82 to supply each of them with the +5V DC

signal. Microcontroller 72 links to solid state relays (MOSFETs) 97 and 98 for controlling the provision of the 12 VDC power supply to fan 74, pump motor 83 and fill sensor 64, respectively.

As illustrated in Figure 1, once power switch 15 is depressed, a user employs keypad 16 and LCD 17 to select the operating parameters for wound closure apparatus 10. Wound closure apparatus 10 stores the previously selected operating parameters so that upon power initialization, LCD 17 displays the phrase "NEW PATIENT" with the word "NO" over arrow button 76, and the word "YES" over arrow button 77. If the user presses arrow button 76 to answer no, wound closure apparatus 10 will operate at the previously selected parameters. After answering no, the user presses on/off button 78 to begin operation of wound closure apparatus 10.

Conversely, if the user presses arrow button 77 to indicate a new patient, wound closure apparatus 10 will operate either under default values or allow the user to select the operating parameters. To operate under default parameters, the user presses on/off button 78 after pressing arrow button 77. However, to select his or her own values, the user presses option button 79 after pressing arrow button 77.

Upon the pressing of option buttons 79, LCD 17 displays a bar graph representing the spectrum of available vacuum pump pressures and a numerical representation of the vacuum pump pressure presently displayed by the bar graph. The user changes vacuum pump pressure using arrow buttons 76 and 77. The pressing of arrow button 76 reduces vacuum pump pressure, while the pressing of arrow button 77 increases vacuum pump pressure. After selecting the desired vacuum pump pressure, the user presses option button 79 to save the selected vacuum pump pressure.

Once the selected vacuum pump pressure has been saved, LCD 17 displays the pump operation times available to the user. The user may program wound closure apparatus 10 to pump either continuously or intermittently. Thus, LCD 17 displays the word "CONTINUOUS" over arrow button 76 and "INTERMITTENT" over arrow button 77. The user selects continuous operation by pressing arrow button 76 followed by on/off button 78 to activate the vacuum pump. In its continuous mode, wound closure apparatus 10 runs its vacuum pump continuously until on/off button 78 is pressed again.

If the user presses arrow button 77 to select intermittent operation, LCD 17 displays a bar graph or figures representing the minimum and maximum on times for the vacuum pump. LCD 17 also displays the phrase "ON TIME" and the numerical value presently displayed. A user decreases the on time of the vacuum pump by pressing arrow button 76 and increases the on time of the vacuum pump by pressing arrow button 77. After selecting the desired on time, the user presses options button 79 to save the selected on time value.

LCD 17 then displays a second bar graph or figures representing the off time for the vacuum pump with the phrase "OFF TIME" and the numerical value presently depicted by the bar graph. Again, arrow buttons 76 and 77 are pressed to increase or decrease, respectively, the off time for the vacuum pump. After selecting the off time, the user presses options button 79 followed by on/off button 78 to operate wound closure apparatus 10 using the selected parameters.

Keypad 16 includes setting button 80 to permit the user to sequentially display the currently selected operating parameters of wound closure apparatus 10. Keypad 16 further includes delay button 81 to permit the user to deactivate an alarm sounded in response to an improper operating condition of wound

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closure apparatus 10. Delay button 81 provides the user with the ability to silence alarms so that the alarm will not have to be listened to during the correction of the problem.

Any new alarm conditions occurring within the fifteen minute period ("delay period") after the pressing of delay button 81 will not be indicated by an audible alarm. However, the pump will still be deactivated when appropriate, even during the delay period.

Again referring to Figure 9, microcontroller 72 is a multi-port microprocessor with a eight-bit analog to digital (A/D) converter having associated memory that stores the program directing microcontroller 72 during its control of wound closure apparatus 10. After receiving and storing the user selected operational parameters and receiving an on signal due to the pressing of on/off button 78, microcontroller 72 activates pump motor 83 which, in turn, drives vacuum pump 84 to begin the removal of air from canister 19.

As vacuum pump 84 operates, it draws air from within canister 19, into hose 62 via outlet 44 of canister 19 and port 45. Hose 62 connects to filter 85 and transducer 75 via T-junction 91. Filter 85 is similar to filter 46 and thus ensures no wound fluids contaminate vacuum pump 84. Filter 85 communicates with pump 84 via T-junction 88 and one arm of the latter is connected to bleed valve 86. Bleed valve 86 communicates with the atmosphere to release pressure developed within line 62 by vacuum pump 84 after microcontroller 72 deactivates vacuum pump 84. Bleed valve 86 is sufficiently small to ensure that it generally does not affect the vacuum pressure levels achieved by vacuum pump 84 as it evacuates air from canister 19, except to prevent over pressurisation beyond 250 mmHg and to prevent erratic operation of the vacuum pump at very low pressure settings..

In the preferred embodiment, an orifice of 0.5 mm diameter is especially preferred for bleed valve 86. Valve 86 or the equivalent is particularly important for enabling intermittent application of negative pressure, as the orifice allows for gradual release of the negative pressure (over a period of about fifteen seconds) when the pump motor 83 is de-actuated. Bleed valve 86 is positioned outside housing 11 to facilitate un-clogging of aperture 86 in the event of a blockage. An aperture is provided in bleed valve 86, which is machined from stainless steel. Flow control orifices would be alternatives.

Line 62 also includes T-connector 91 to connect it with line 92. Line 92 is connected to tank 94 which acts as a damper to pressure changes in line 62. This dampening effect, facilitated by restrictor 89 in line 93 between transducer 75 and T-junction 91, causes the pressure measured by transducer 75 to be an accurate indication of actual wound site pressure. Transducer 75 communicates with line 62 via line 93 to measure tank 94 pressure and produce an electrical signal representative of that pressure. Transducer 75 outputs its pressure signal to microcontroller 72.

Microcontroller 72 utilizes the pressure signal to control the speed of pump motor 83. As previously described, the user selects either a default vacuum pump pressure or a desired vacuum pump pressure for the operation of wound closure apparatus 10. After receiving the wound pressure signal from transducer 75, microcontroller 72 compares the wound pressure with the user selected pressure. If the wound pressure is higher than the user selected vacuum pump pressure, microcontroller 72 reduces pump motor speed to decrease vacuum pump pressure and thus the pressure at the wound. Conversely, if the wound pressure is less than the user selected vacuum pump

pressure, microcontroller 72 increases the speed of pump motor 83 resulting in an increase in the vacuum pressure applied at the wound.

Microcontroller 72 controls pump motor 83 by varying the amount of voltage received by pump motor 83. That is, microcontroller 72 receives the 12V DC signal from DC power supply 71 and outputs a voltage between 0 and 12V DC to pump motor 83 to control its speed in accordance with the user selected vacuum pump pressure value. Accordingly, microcontroller 72 employs feedback to ensure that the wound experiences the user selected vacuum pump pressure. If the target pressure is not reached after a period of five minutes, microcontroller 72 deactivates motor 83 and sounds the audible alarm. Additionally, the feedback signal prevents maximum vacuum pump pressure from being exceeded. If the wound pressure measured by transducer 75 exceeds a maximum safe vacuum pump pressure, microcontroller 72 deactivates pump motor 83.

Wound closure apparatus 10 includes fan 74 to cool pump motor 83 and printed circuit board or chassis 200 during the operation of the wound closure apparatus 10. In the preferred embodiment, microcontroller 72 controls fan 74 to always operate while power is being supplied. In alternative embodiments, however, microcontroller 72 controls fan 74 to operate only in relation to motor 83, because it is only necessary for fan 74 to operate if motor 83 is also operating. In such alternative, as long as pump motor 83 operates, microcontroller 72 runs fan 74. However, when microcontroller 72 deactivates pump motor 83 it also deactivates fan 74.

Control system 70 includes fill sensor 64 to provide a signal to microcontroller 72 that indicates when canister 19 is completely filled with wound fluids. After receiving a signal from fill sensor 64, microcontroller 72

deactivates pump motor 83 and fan 74 and activates alarm 95 to signal the user that canister 19 must be replaced.

Control system 70 includes switch 63 to prevent users from operating wound closure apparatus 10 without a canister properly installed. If a canister is not properly installed, switch 63 remains open and therefore outputs no signal to microcontroller 72. If microcontroller 72 receives no signal from switch 63, indicating no canister within chamber 18, it will not supply power to pump motor 83 even after a user has pressed on/off button 78. Furthermore, microcontroller 72 activates alarm 95 to signal the user that either a canister is not properly installed or is improperly installed within chamber 18 when therapy is activated. Microcontroller 72 operates pump motor 83 only if switch 63 is depressed to provide a signal indicating the proper placement of a canister within chamber 18.

Control system 70 includes tilt sensor 82 to prevent operation of wound closure apparatus 10 if it is tilted excessively. Excessive tilting of wound closure apparatus 10 during operation diminishes the efficiency of removal of wound fluids and, more importantly, might result in either the contamination of vacuum pump 84 or the spilling of wound fluids. Thus, if wound closure apparatus 10 tilts along any of its axes beyond a predetermined angle (approximately 45° in this preferred embodiment), tilt sensor 82 outputs a signal to microcontroller 72. In response, microcontroller 72 deactivates pump motor 83 and activates alarm 95 to signal the user of the excessive tilt situation. In this preferred embodiment, tilt sensor 82 may be implemented with any standard mercury switch. The tilt circuiting and alarm operates as follows. If therapy is in progress and the pump unit is tilted, the alarm will sound and the liquid crystal display 17 will state 'unit tilted'. Therapy is automatically stopped.

When the unit is returned to the vertical, therapy will be automatically reinstated after a time delay (e.g. about 30 seconds) has elapsed..

CLAIMS:-

1. A therapeutic apparatus for stimulating healing of a wound in mammals which comprises a porous pad which is permeable to fluids for introduction into the wound, a dressing for covering the wound and providing an air-tight seal around the wound, a drainage tube connecting the pad to a suction pump so that negative pressure can be applied to the wound, to draw fluids therefrom, said tube being connected to the pump via a canister for collecting fluids sucked from the wound, and at least one filter being interposed between the canister and the pump.

2. Apparatus as claimed in claim 1 wherein said filter is located in the canister.

3. Apparatus as claimed in claim 1 or 2 wherein the canister is removably attached to a housing for the pump.

4. Apparatus as claimed in claim 3 wherein the canister is removably received in a recess in the housing.

5. Apparatus as claimed in any one of the preceding claims which includes means for detecting when said canister is substantially full with fluid.

6. Apparatus as claimed in claim 5 wherein said means comprises capacitance sensing means arranged to sense a change of capacitance as said canister fills with liquid.

7. Apparatus as claimed in any one of the preceding claims wherein said pad is a polymer foam having interconnecting cells.

8. Apparatus as claimed in claim 7 wherein the foam is a reticulated foam having at least 90% of interconnecting cells.

9. Apparatus as claimed in claim 8 wherein said foam has at least 95% of interconnecting cells.

10. Apparatus as claimed in claim 7, 8 or 9, wherein said drainage tube is fitted into the interior of the foam as an interference fit.

11. Apparatus as claimed in any one of claims 7 to 10 wherein said foam is a polyether foam.

12. Apparatus as claimed in any one of the preceding claims in which said dressing is an elastomeric film which is coated at least in the peripheral areas with a pressure-sensitive adhesive.

13. Apparatus as claimed in claim 12 wherein said film is a polyurethane film.

14. Apparatus as claimed in any one of the preceding claims which is adapted to apply continuous or intermittent suction to the wound.

15. Apparatus as claimed in claim 14 wherein a bleed device is provided between the canister and the pump to permit release of negative pressure during intermittent operation.

16. A sterile pack for use in conjunction with a vacuum pump and canister for stimulating wound healing by drainage, said pack comprising a polymer foam pad of reticulated open-celled foam having a drainage tube sealed within the foam.

17. A pack as claimed in claim 16 wherein said foam comprises more than about 95% interconnecting cells.

18. A pack as claimed in claim 16 or 17 which includes connector means for connecting the tube to said canister or to a tube attached to said canister.

19. A pack according to any one of the preceding claims wherein the tube is fitted into the foam by an interference fit.

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20. A canister for use in the apparatus as claimed in any one of claims 1 to 15 which comprises a moulded plastics container having an inlet for connection to a wound dressing pad and an outlet for connection to a suction pump, said outlet incorporating a bacterial filter.

21. A canister as claimed in claim 20 which includes deflector means for deflecting liquid sucked through the inlet in a direction towards the bottom of the canister.

22. A canister as claimed in claim 20 or 21 which includes an anti-foaming substance.

23. A canister as claimed in any one of claims 20 to 22 which includes a gel-forming substance, which is capable of immobilising drainage fluids within the canister.

24. Therapeutic apparatus is claimed in any one of the preceding claims which includes a tilt sensor adapted to give an audible and/or visual alarm when the apparatus is tilted beyond a predetermined angle from vertical.

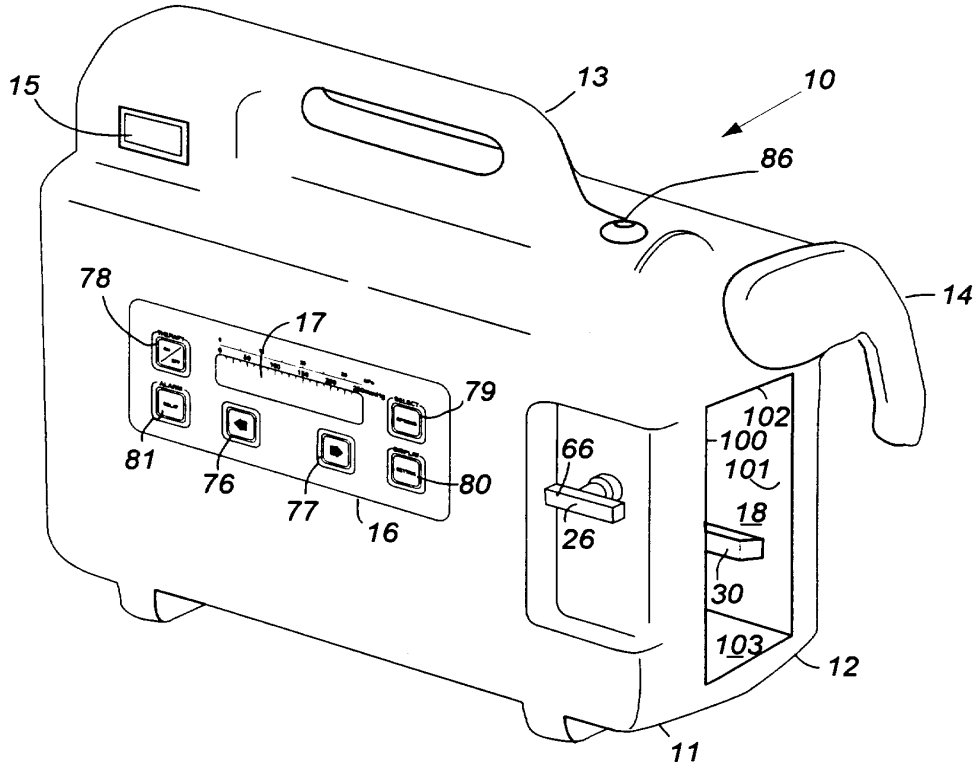


FIG.1

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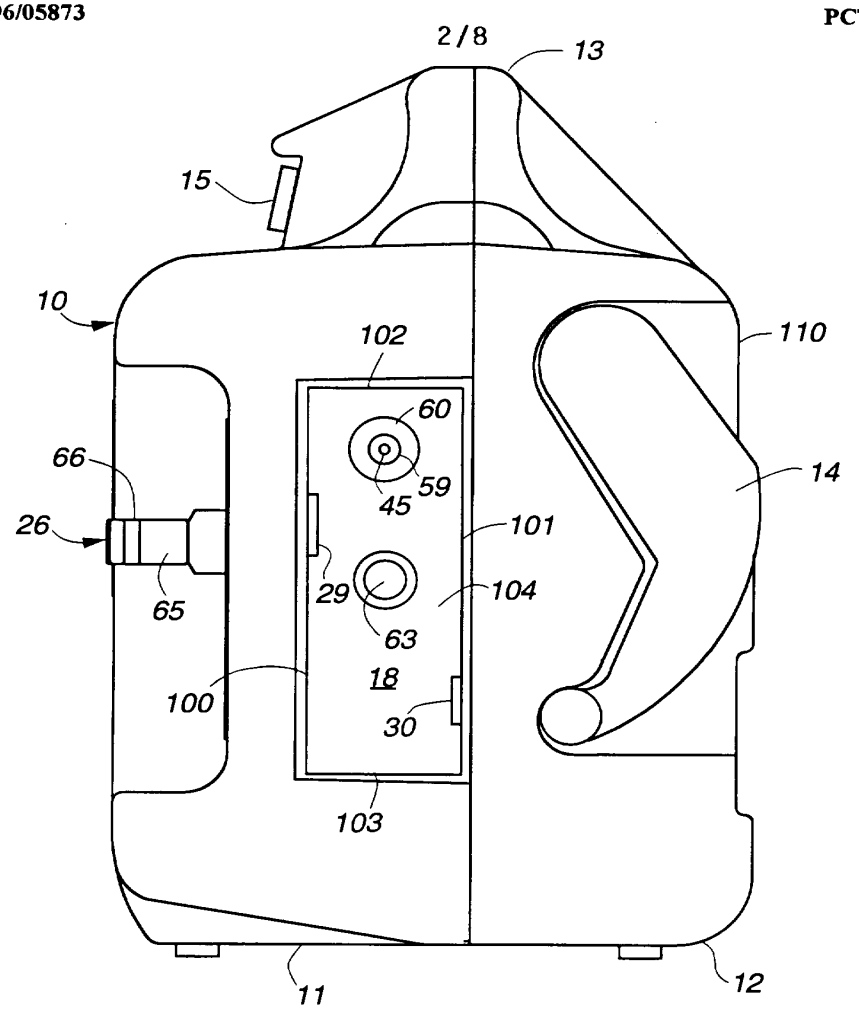


FIG.2

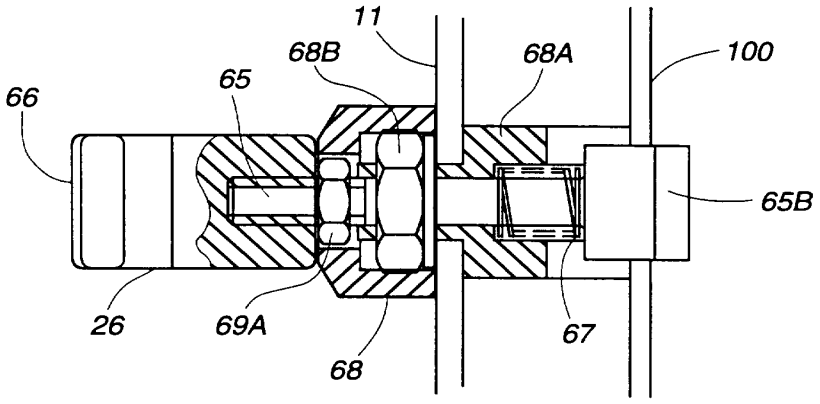


FIG.2A

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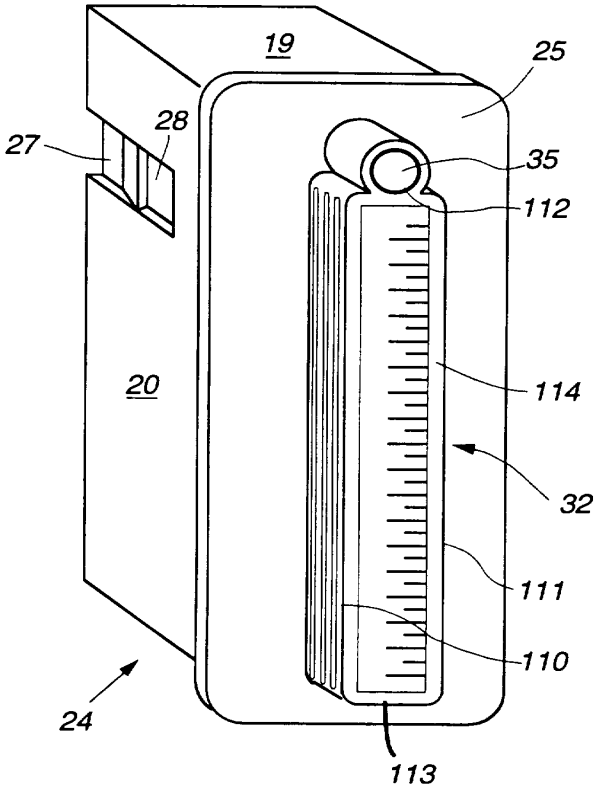


FIG.3

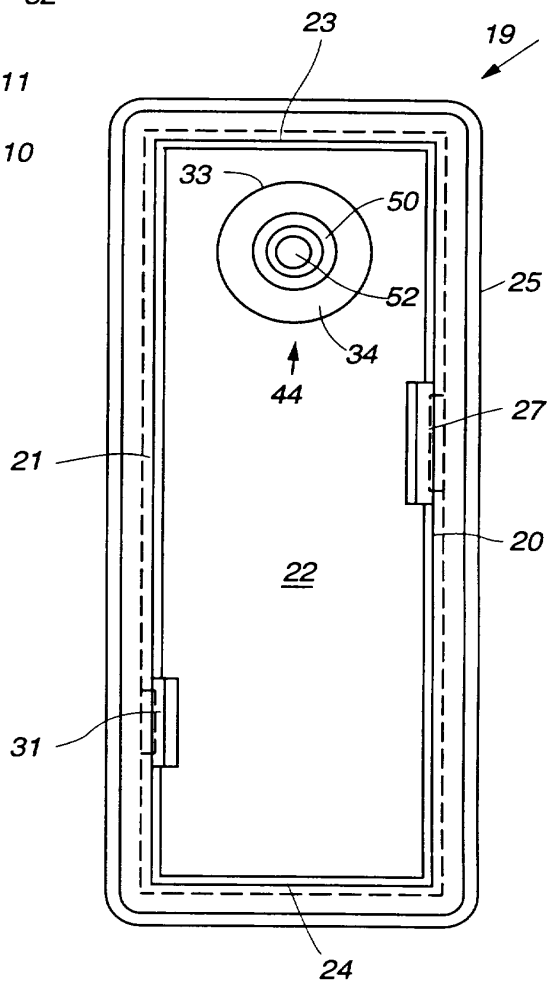


FIG.4

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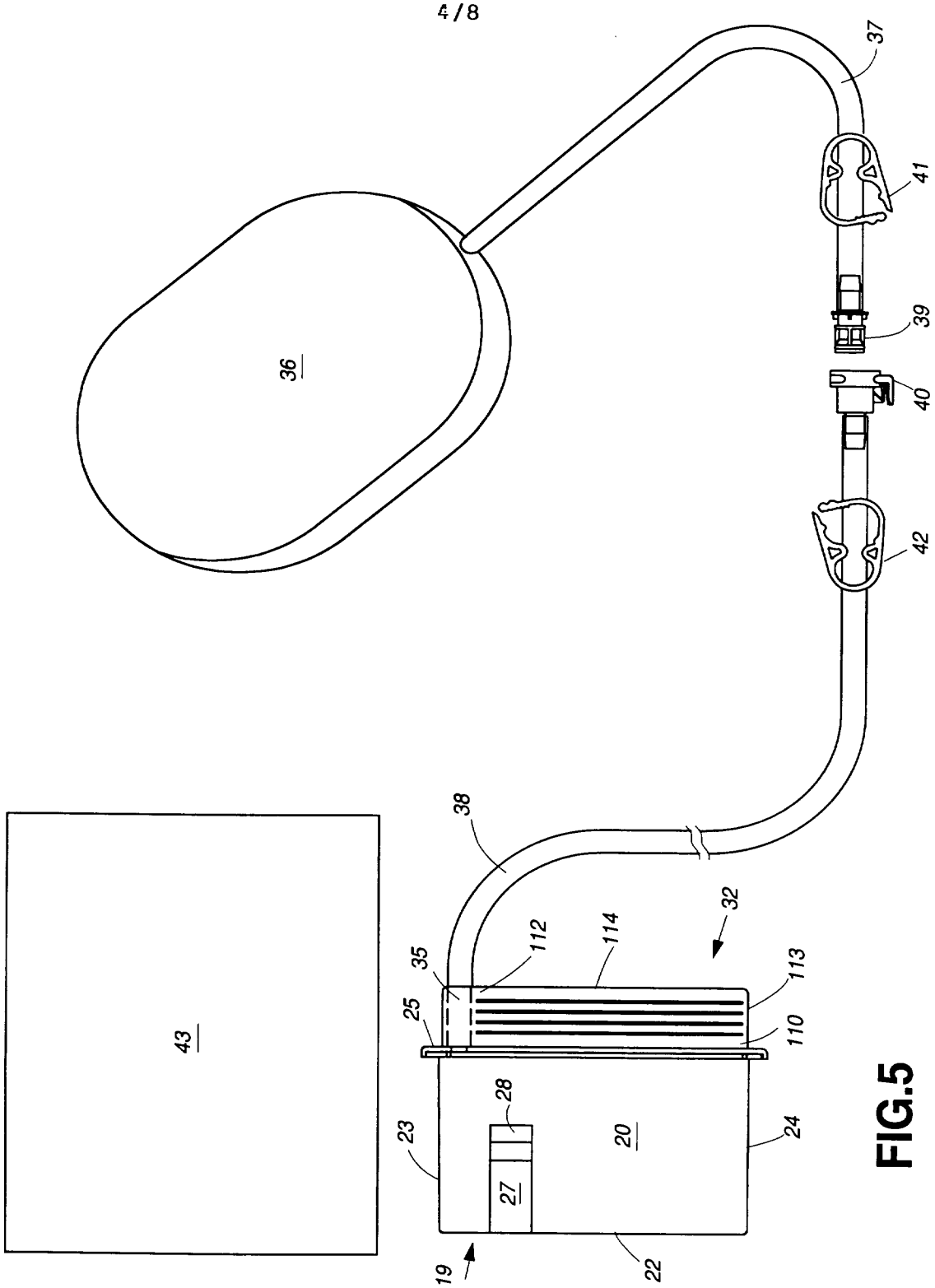


FIG.5

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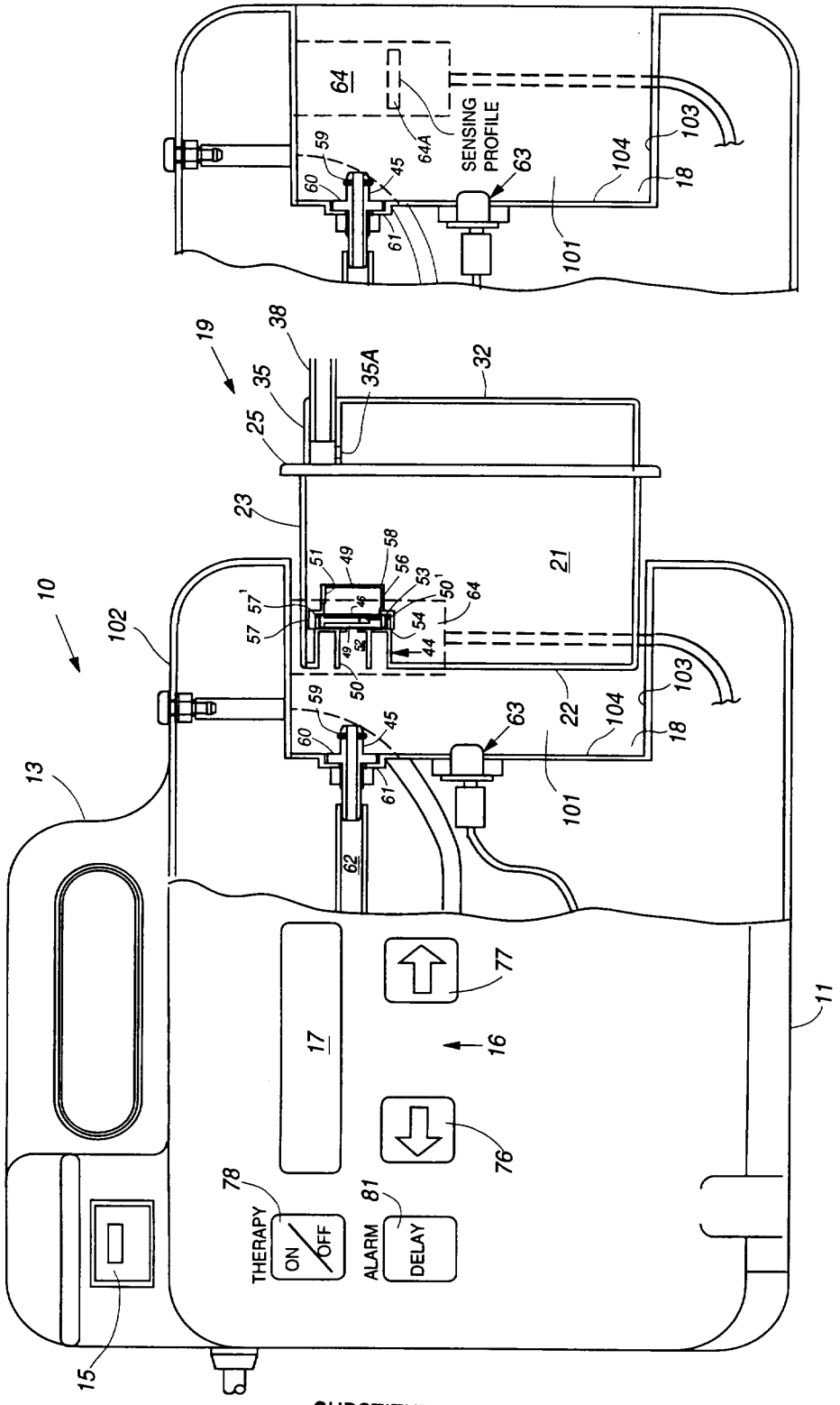


FIG.6A

FIG.6

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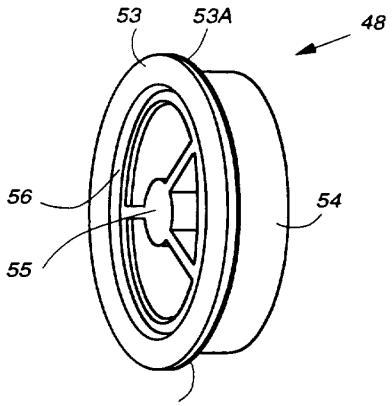


FIG.7

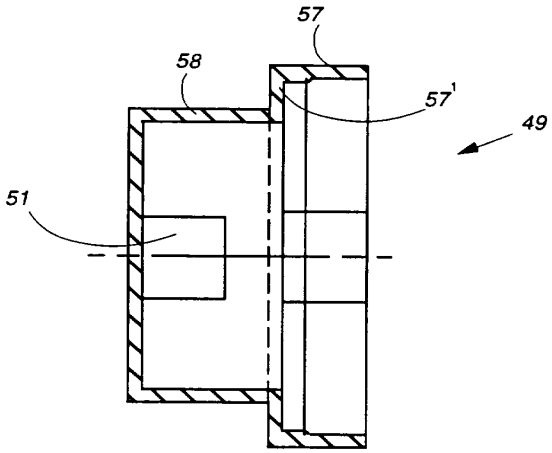


FIG.8

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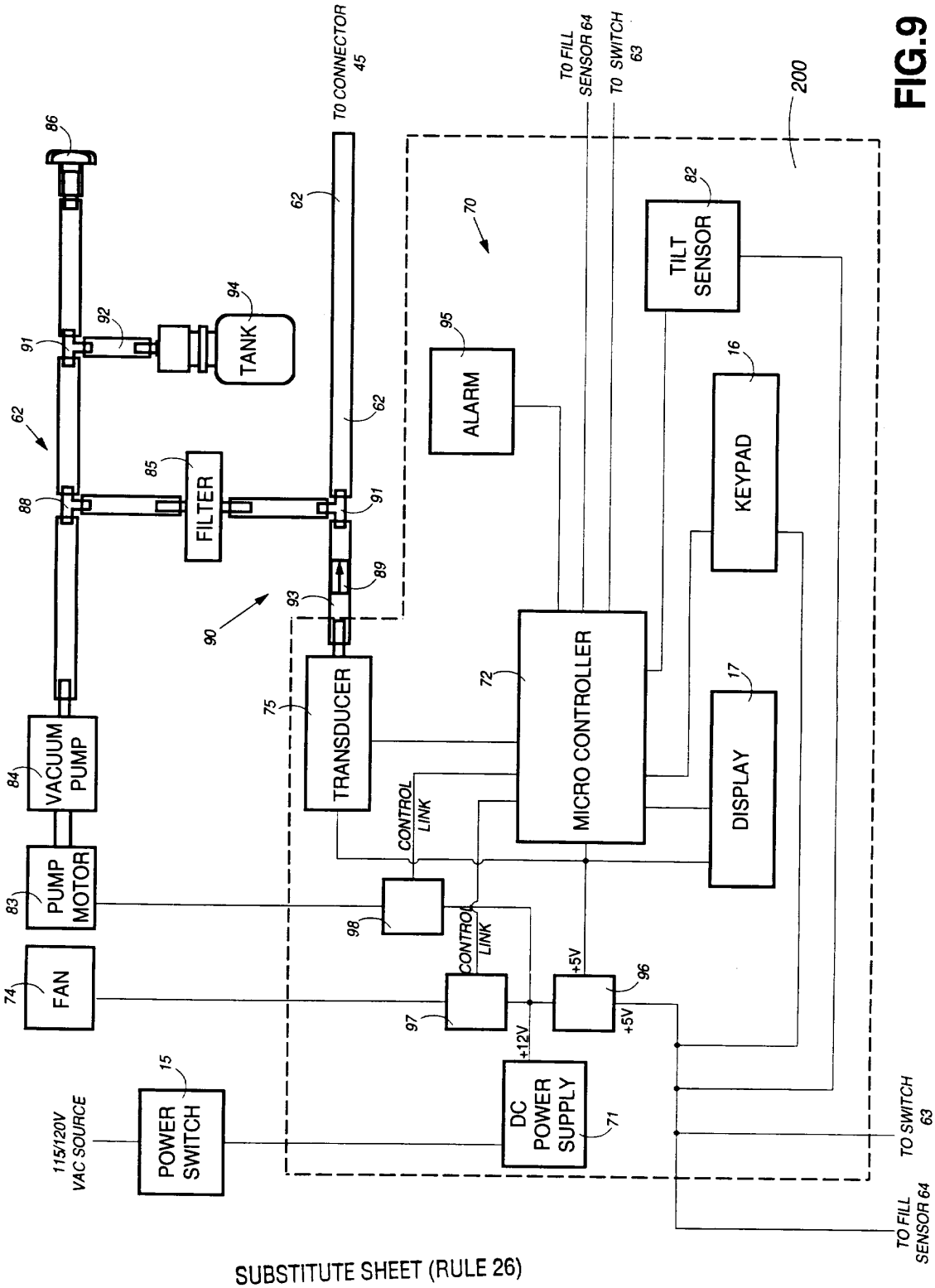


FIG.9

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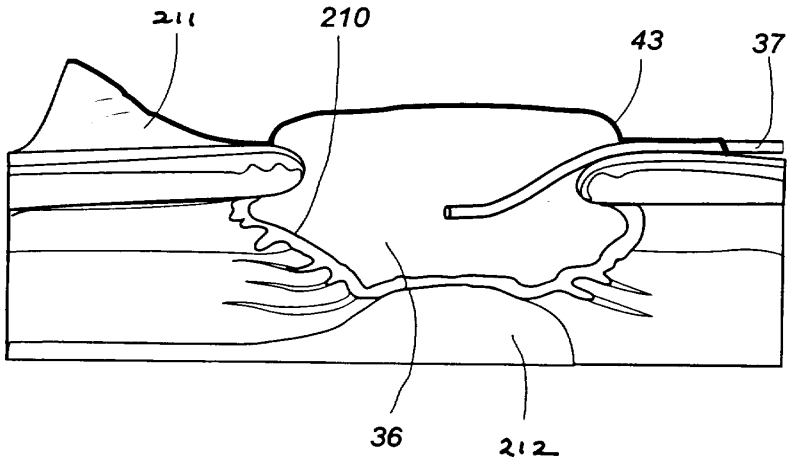


FIG.10

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INTERNATIONAL SEARCH REPORT

Inte onal Application No
PCT/GB 95/01983

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M1/00

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 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.
X Y	US,A,3 520 300 (FLOWER GUILES JR) 14 July 1970 see column 2, line 10 - column 3, line 16; figures ---	1,7-13, 16-19 2-6,14, 15,22-24
Y A	US,A,4 758 220 (SUNDBLOM LEIF J ET AL) 19 July 1988 see abstract; figures 3,6A see column 5, line 3 - line 34 see column 12, line 48 - line 50 ---	3,4,14, 15 5
Y	DE,A,26 40 413 (WOLF GMBH RICHARD) 9 March 1978 see claims 1,6,7; figure 1 ---	5,6
A	US,A,5 279 550 (HABIB MAGDI F ET AL) 18 January 1994 see abstract; figures 1,3 --- -/--	15

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

[X] Patent family members are listed in annex.

* Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

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Date of the actual completion of the international search	Date of mailing of the international search report
9 November 1995	23. 11. 95
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+ 31-70) 340-3016	Authorized officer Zeinstra, H

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INTERNATIONAL SEARCH REPORT

Int. ional Application No
PCT/GB 95/01983

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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X	EP,A,0 358 302 (SMITHS INDUSTRIES PLC) 14 March 1990	20,21
Y	see abstract; figures 1,4	2,22,23
A	see column 2, line 26 - column 4, line 34	1
Y	GB,A,2 197 789 (SMITHS INDUSTRIES PUBLIC LIMITED COMPANY) 2 June 1988 see abstract; figures see page 5, line 1 - line 13	22
Y	US,A,5 092 858 (BENSON C DAVID ET AL) 3 March 1992 see abstract; figures 1-6 see column 4, line 33 - column 5, line 27	23
Y	PATENT ABSTRACTS OF JAPAN vol. 016 no. 394 (C-0976) ,21 August 1992 & JP,A,04 129536 (TERUMO CORP) 30 April 1992, see abstract	24
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INTERNATIONAL SEARCH REPORT

Information on patent family members

Int. .onal Application No
PCT/GB 95/01983

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(12) UK Patent Application (19) GB (11) 2 378 734 (13) A

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(22) Date of Filing 14.08.2001

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(51) INT CL[7]
F04B 17/00 // A61M 1/00

(52) UK CL (Edition V)
F1W WCA WDX
A5R RCEB

(56) Documents Cited
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US 4639245 A

(58) Field of Search
UK CL (Edition T) A5R RCEB, F1W WCA WDL WDM WDX
INT CL[7] A61M 1/00, F04B 9/02 17/00 17/03 35/00 39/16 53/22
Other: ONLINE: WPI; EPODOC; JAPIO

(54) Abstract Title
Disposable pump with detachable motor

(57) A vacuum pump comprises a drive 40 and a manually disengageable, disposable pumping system connected thereto. The pumping system comprises a two or three chambered cannister 1, 18, 21 in which solids liquids and gases can be separated from one another. A pumping means such as a diaphragm 24 is attached to the cannister and sealed against it cicumferentially. Activation of the drive means causes reciprocation of the pumping means to produce the pumping action.

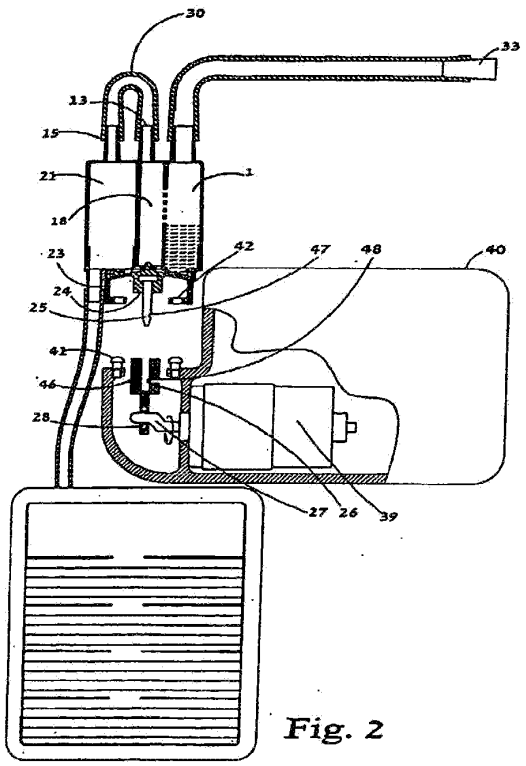


Fig. 2

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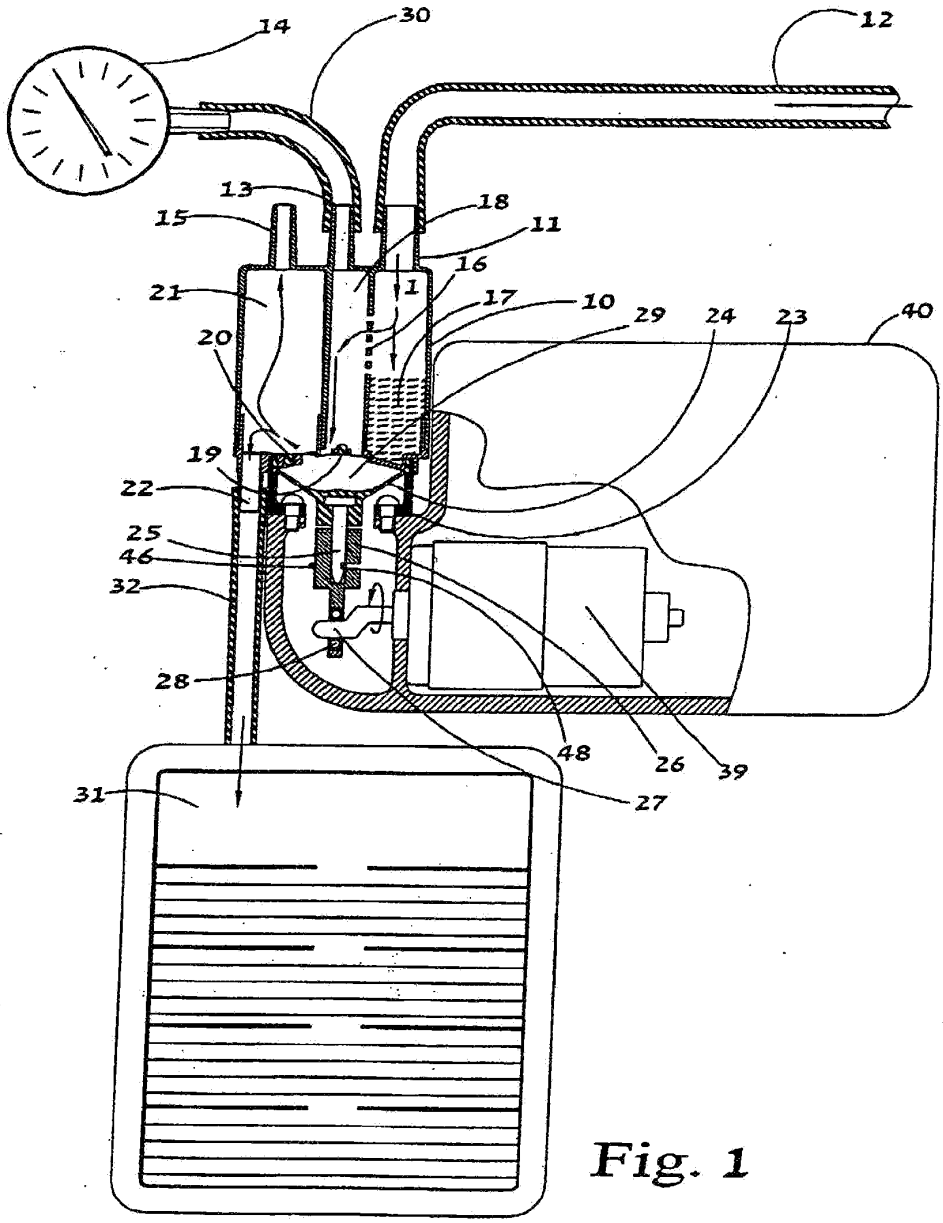

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Fig. 1

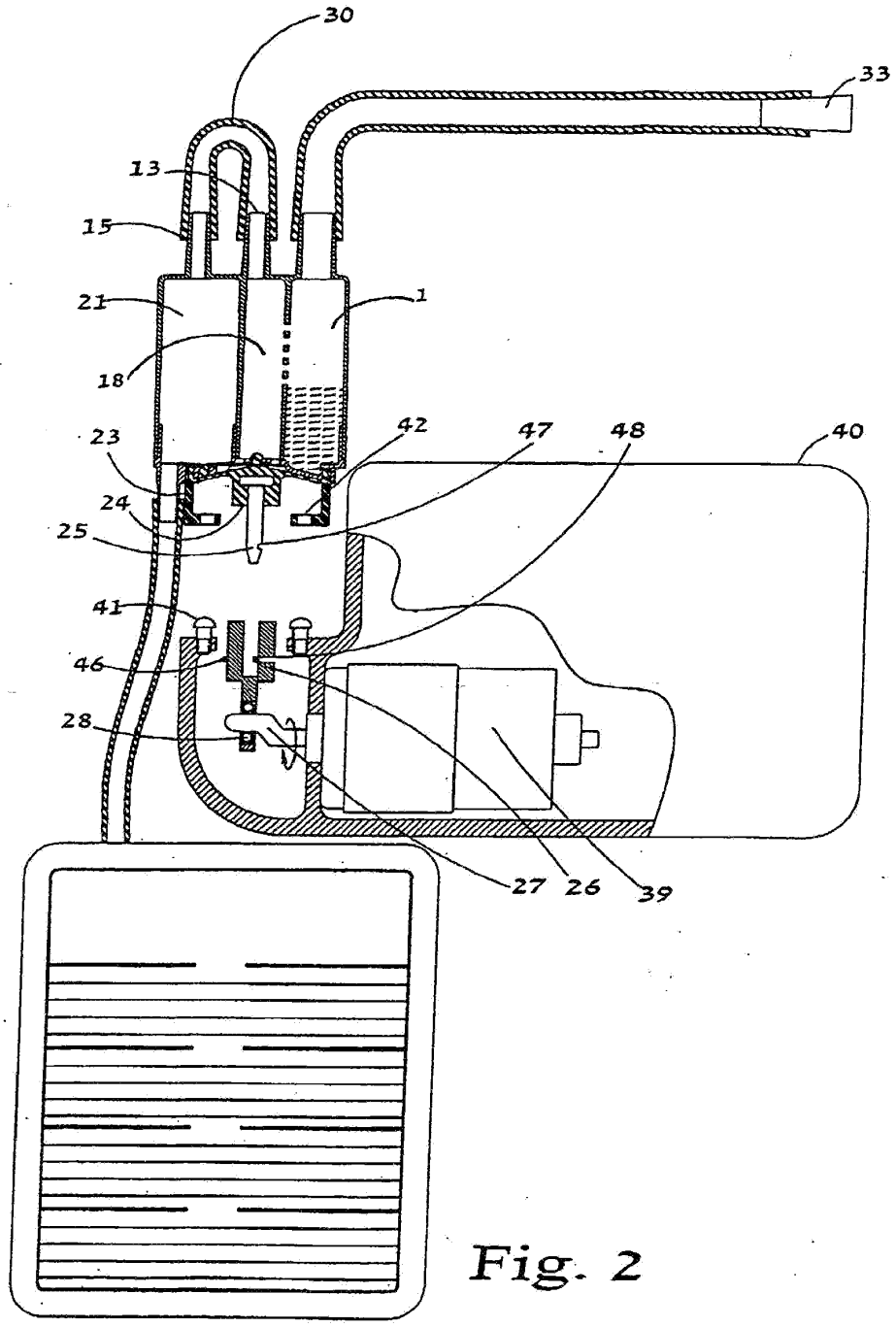


Fig. 2

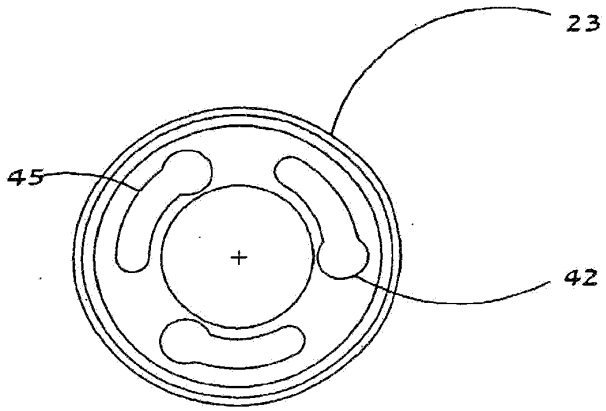


Fig. 3

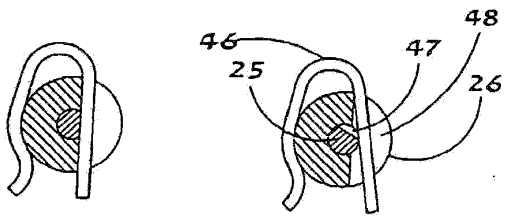


Fig.4

A COMPACT VACUUM PUMP

The present invention relates to a vacuum pump, especially useful in the field of medicine. More specifically, the pump disclosed herein comprises a drive, and a disposable pumping system that can be easily disengaged from the drive after use, to allow for easy disposal of all pump components which come in contact with the matter being sucked, together with the contained matter. The pump should not be limited in the volume of matter it is capable of sucking, while maintaining uninterrupted vacuum pressure.

During medical surgery or emergency airway clearing, body fluids such as blood, or emesis, are subjected to suction. Vacuum pumps are utilized to generate vacuum inside a suction canister, into which the body fluids are drawn through a tube, called a "suction catheter". Conventional vacuum pumps, also termed "aspirators" in medicine, contain rigid vacuum canisters into which the suctioned fluids are collected, which maintain their shape and stiffness under high vacuum pressure. Some suction canisters are disposable and others can be removed for cleaning, disinfection, and re-use.

Aspirators of the type described above are characterized by a number of disadvantages, including the following:

1. When a large volume of fluid is collected, the suction canisters have to be relatively large in volume. Most commonly, a canister of up to five liters in volume is used. Large canisters slow the vacuum rise rate, because of the large air volume to be removed from the canister before a vacuum is created in the canister strong enough to draw the suctioned

matter.

2. Since the air in the suction canister is drawn through the pump, it is very difficult to prevent contamination of the non-disposable pump components, such as the diaphragm, valves, cylinder or piston, even when the suction canister is disposed of after use. Contaminated pumps are a health hazard, as the air flowing through them is exhausted to the atmosphere.

3. Aspirators are used for drawing body fluids and emesis, which may contain solids. Air is also drawn into the pump, during aspiration. Vacuum pumps are generally efficient in pumping either air or fluids, but most pumps are inefficient in pumping all three types of matter.

Thus, conventional vacuum devices are large, bulky, costly and inefficient in performing their function.

In the present invention, the term "pumping system" generally refers to a system having at least the following components: a suction canister, a suction inlet, a waste outlet, and integral means for creating suction. The term "disposable vacuum pump" generally refers to a pump in which all components other than the drive are inexpensive, and therefore may be disposed of. One wishing to re-use the disposable components (or use similar, non-disposable components) may, however do so. The term "drive" generally refers to a pump component comprising of an electric motor, or other means by which a pump piston, or a diaphragm, may be caused to reciprocate, contained within a housing. The term "body fluids" refers typically to blood, emesis or mucus. The terms "three types of matter", "three types of media", and "three states of matter", refer to liquid, solid and gas. The terms "matter",

"media", and "material" are used interchangeably to refer to the material being suctioned. The term "load", or "high load", refers to the quantity and weight of the material being suctioned or pumped.

Embodiments of the invention may provide an improved vacuum pump, capable of pumping air or gas, liquid and solids, and capable of separating the three types of matter, to allow efficient pumping, while collecting the liquid in a low cost bag.

Further embodiments may provide a pump in which all components that come in contact with body matter, or any other pumped media, can be easily disconnected and removed from the pump's drive means, to be sterilized or disposed of. This leaves the non-disposable drive free from contamination. In prior-art pumps that have disposable canisters, the suctioned air is drawn through the pump, bringing the inside of the pump in contact with air which may be contaminated. The inside of the pump is traditionally not accessible for cleaning.

Embodiments of the present invention may further provide a vacuum pump which is extremely fast in generating a high vacuum or suction pressure, yet doing so with a relatively small vacuum canister and a low-capacity pump.

It is further desirable to provide a physically compact vacuum pump, with performance and capacity which are independent of its dimensions, and are significantly higher than those of physically larger vacuum pumps and moreover to provide a vacuum pump which generates uninterrupted vacuum, independent of the volume of the vacuum canister, which does not fill up as do conventional vacuum canisters.

The vacuum pump comprises a drive, and a disposable pumping system connected to this drive (but designed to

be manually disengaged therefrom), wherein the disposable pumping system comprises:

a) a three-chambered canister, wherein an inlet leads into the first chamber, and the first chamber has means for retaining solids and preventing their passage from said first chamber to the second chamber; and the second chamber has a one-way valve at its exit, said valve allowing passage of liquid and gas out of said second chamber; and the third chamber has an outlet for the discharge of air, and an additional outlet for the discharge of liquid; and said third chamber further has a one-way valve, at its inlet, allowing entry of liquid and gas through said valve, while preventing exit of matter through said valve;

b) a highly flexible diaphragm, attached to said three-chambered canister, sealing against it circumferentially, wherein said flexible diaphragm is attached to a partition with said three-chambered canister, in which said valves are installed;

c) a drive member attached to said diaphragm, wherein reciprocation of said drive member induces reciprocation of said diaphragm; and

d) means for mounting and engaging said disposable pumping system to the housing of a drive, wherein said means are capable of simultaneously coupling the pump drive member to said drive.

The drive is coupled to the drive member, and the drive includes an electric motor rotating a crank, said crank being connected to reciprocating means, in such a way that activation of the drive induces reciprocation of the crank and of the drive member. The pumping

system is capable of being attached to or detached from the drive in a rapid and facile manner (in the preferred embodiment, accomplished by a single, simple, wrist twist motion).

According to a preferred embodiment of the present invention, the three-chambered canister has a volume of approximately 100 cc.

Further according to a preferred embodiment of the present invention, the pump includes a vacuum port outlet present in the second chamber, said outlet connected by tubing to an external vacuum gauge for the purpose of monitoring the pressure inside the first and second chambers.

Additionally according to preferred embodiment of the present invention, the means for retaining solids in the first chamber includes a sieve.

Moreover according to preferred embodiment of the present invention, the highly flexible diaphragm is capable of yielding or stretching when large quantities of fluid are contained within it. When subjected to high loads, the diaphragm is capable of stretching to effectively reciprocate only a fraction of its area (such as 50%) while the remainder of its surface remains stationary.

Still further according to preferred embodiments of the present invention, the vacuum pump additionally comprises means for sealing said three-chambered canister and preventing leakage of air or materials into or out of said canister; and further preventing loss of vacuum in first and second chambers.

According to embodiments of the present invention, the pump additionally comprises a disposable waste container, for collection of discharged liquid, attached to the liquid outlet of said third chamber. In a preferred embodiment, the disposable waste

container is a waste bag, having any appropriate size. In some preferred embodiments, the capacity of said waste bag is between 500 cc and 5 liters. The waste-collection bag is a low cost waste container, at ambient pressure, which is easily disposed of along with the body fluids it contains, together with the pumping system.

Furthermore, according to the preferred embodiment of the present invention, the means for mounting and engaging the pumping system to the drive housing comprise a mounting base protruding from the lower portion of the three-chambered canister, said mounting base adapted for mating and attaching to the drive housing. In the preferred embodiment, twisting of the mounting base against the drive housing or mating portion thereof couples the two physically.

Still further yet, according to the preferred embodiment of the present invention, the drive rotates a crank, and a reciprocating rod receptacle is connected to said crank, and said rod receptacle is adapted to mate with said drive member. In the preferred embodiment, a lock clip secures the drive member to the rod receptacle. Coupling said mounting base to said drive housing is affected simultaneously with the securing of said drive member to the rod receptacle, in a single operation.

Additionally, the pumping system and the drive may be portable and may be operated on battery power. Moreover, the pumping system may additionally comprise means for sealing said pumping system, for facilitating disposal of said pumping system, with all pumped matter contained.

Further according to preferred embodiments of the present invention, the pump is capable of generating continuous unlimited flow of matter therethrough, while maintaining uninterrupted vacuum pressure. The

pump may be capable of generating a vacuum pressure of approximately 650 mm of Mercury as measured in the first and second chambers.

Additionally, in a preferred embodiment, the pump further comprises suction catheter tubing attached to the inlet present in said first chamber, allowing entry of matter into the three-chambered canister.

Unlike common diaphragm pumps, the diaphragm in this invention is flexible and not restrained by a rigid piston. The flexibility of the diaphragm allows it to stretch and conform to the pumped matter, irrespective of the reciprocal motion of the rigid drive member. Thus, when the diaphragm encounters resistance it stretches and yields, allowing uninterrupted motion of the reciprocating drive member.

The three-chambered canister, the diaphragm and the one-way valves advantageously comprise an integral pumping system, which can easily be attached to a drive, which causes the drive member to reciprocate. Such a drive, as described, may be an electric motor, whose output shaft has a crank to which the drive member is connected. The electric motor will thus, when powered, affect pumping from one chamber of the canister to the other. The pumping system can easily be disengaged from the drive after use, and be sterilized or disposed of. The ability to completely separate the heart of the pump and its associated chambers and tubing conduits, from the drive motor allows disposal or sterilization of all pump components that come in contact with pumped matter. It would be obvious to those skilled in the art that means other than an electric motor may be utilized to induce the reciprocal motion of the drive member.

The three-chambered canister is constructed in a manner such that the solids entering the chamber are

trapped and prevented from entering further into the pump and affecting its performance by blocking the valves and tubing. It would be obvious to those skilled in the art that when the pumped matter is not likely to include solids, there would be no need to prevent them from reaching the pump one-way valves, and thus the pumping system hereby described would function equally well without the first chamber. A pump having only two chambers, to be used in such case, is thus described below as well. Additionally, the pumped air is separated from the fluid, and released to the atmosphere, so that liquid, and not air, is collected in the waste bag, thereby utilizing the volume of the waste bag efficiently. Thus, the capacity of the pump to suck or collect fluids is not limited by the size of the chamber into which the fluid is drawn, and even a small chamber can be utilized to pump large volumes of fluid, limited only by the capacity of the waste bag. This is in contrast to pumps of the prior art, in which the canister or chamber size limits the amount of matter that may be suctioned, and when large canisters are used to overcome this limitation, evacuating the large canister by the pump becomes a slow process.

The present invention can be utilized in the field of medicine, to aspirate body fluids, emesis and mucus; however, the scope of the invention is not limited to medical use alone, and the vacuum pump may be utilized in other fields as well. An important feature of the pump is the ability easily and economically to remove and replace all components that come in contact with the materials being pumped, preventing any harmful contamination. The pump can therefore, find application in the field of chemistry as well, where prior art pumps are difficult to clean after use.

In addition, there is thus provided in an alternative aspect of the present invention, a vacuum

pump for the pumping of liquid and gas, (preferably not for use in pumping of solids), comprising a drive, and a manually disengageable disposable pumping system connected to said drive, wherein said disposable pumping system comprises:

a) a dual-chambered canister, wherein the first chamber has an inlet and a one-way valve at the exit of said first chamber, said valve allowing passage of liquid and gas out of said first chamber; and the second chamber has an outlet for the discharge of air, and an additional outlet for the discharge of liquid; and said second chamber is further connected via a one-way valve, allowing entrance of liquid or gas through said valve, while preventing exit of liquid or gas through said valve;

b) a highly flexible diaphragm, attached to said dual-chambered canister, sealing against it circumferentially, wherein said flexible diaphragm is attached to a partition with said dual-chambered canister in which said valves are installed;

c) a drive member attached to said diaphragm, reciprocation of said drive member inducing reciprocation of said diaphragm; and

d) means for mounting and engaging said disposable pumping system to the housing of a drive, wherein said means are capable of simultaneously coupling the drive member to said drive.

In the vacuum pump the drive is coupled to the pumping system so that activation of said drive induces reciprocation of said flexible diaphragm; and the pumping system is capable of being

attached to or detached from said drive in a rapid and facile manner.

BRIEF DESCRIPTION OF THE DRAWINGS

For a better understanding of the invention embodiments of it will now be described, by way of example, with reference to the accompanying drawings, in which:

Fig. 1 is a cross-sectional view of a preferred disposable vacuum pump having a three-chambered canister connected to a waste bag, wherein the suction is created by reciprocating a diaphragm by an electric motor drive;

Fig. 2 is a cross-sectional view of the "pumping system" disengaged from the "drive", to be disposed of as one integral unit;

Fig. 3 is a view of a mounting base, with a bayonet arrangement for quick - twist engagement and disengagement of the disposable components; and

Fig. 4 is a cross-sectional view of the locking mechanism, utilized to attach the pump drive member to the receptacle rod of the electric motor.

DETAILED DESCRIPTION OF THE INVENTION

It is appreciated that the detailed description that follows is intended only to illustrate certain preferred embodiments of the present invention. It is in no way intended to limit the scope of the invention, as set out in the claims.

Referring now to **Fig. 1**, there is provided a vacuum pump containing a three-chambered canister 10, which is employed for the performance of several different functions. The three-chambered canister 10 has an inlet 11 in its first chamber 1. A suction tube

catheter 12 is connected to the inlet 11. In the second chamber 18 a vacuum outlet port 13 is connected to a vacuum gauge 14. In the third chamber 21 an air discharge outlet 15 is present, which is open to the atmosphere. The first chamber 1 contains a sieve 16, utilized to prevent solids 17 from entering the second chamber 18, also termed the "liquid chamber". Two one-way umbrella valves 19 and 20 are present in the bottom of the second chamber 18 and the third chamber 21, respectively. The third chamber 21 is at ambient pressure, and has a liquid outlet 22. To the bottom of the three-chambered canister 10 there is attached a mounting base 23, used to mount the canister and its associated tubing 12 on the drive housing 40 or on a docking means connected to the drive housing. The mounting base 23 is also utilized to secure a diaphragm 24 to the underside of the three-chambered canister 10. The diaphragm 24 has an integral rod-shaped drive member 25, which is inserted into a corresponding cavity in a receptacle rod 26, pivotally attached to a drive 40, via a crank 27 coupled to a bearing 28. Upon activation of the motor 39, the crank 28 is rotated by the motor 39, which reciprocates the receptacle rod 26, causing the diaphragm 24 to increase and decrease the volume of the cavity 29 it forms. This creates a vacuum therein, capable of drawing towards it, and thus pumping, air or fluid that pass through the one-way umbrella valves 19 and 20.

While the preferred embodiment describes a motor-crank combination as the means by which to reciprocate diaphragm 24, it would be apparent that other drive means may be used to create the reciprocal movement of the diaphragm.

Air, liquid and solids may enter the three-chambered canister 10 through a suction tube 12, which may, by way of example, be inserted into a patient's

mouth, for the removal of emesis. The three states of matter being pumped enter the three-chambered canister 10 through the inlet 11. Solids 17 are prevented from moving further than the first chamber 1, by sieve 16. Liquids and air enter the second chamber (liquid chamber) 18, which is under vacuum when diaphragm 24 reciprocates, driving them past one-way umbrella valve 20, into the third chamber 21. The vacuum level in the liquid chamber 18 is monitored by a vacuum gauge 14, connected to the vacuum outlet port 13 via a conduit 30. The air and liquid entering the third chamber 21 are separated, whereupon the liquid is drained into a waste bag 31 through a drain tube 32, and the air is driven out to atmosphere through an air discharge outlet 15.

From the description above, it is clear that the three-chambered canister 10 is the heart of the pump, to which the diaphragm 24 is attached to perform the pumping function together with the one-way umbrella valves 19 and 20. Out of the three chambers that make up the three-chambered canister, only one, the liquid chamber 18, is under vacuum. The three-chambered canister is partitioned by the sieve 16; the first chamber 1 and the third chamber 21 are essentially at ambient pressure.

The pump hereby described is distinct in its capability to suck liquid, solids and air or any mixture of the three, and to direct each of the three matter types to their respective destination while separating them. The three types of matter are separated in order to prevent clogging of the pump by solids suctioned, and in order to collect only fluid to dispose of, and not gas, and thus minimize the volume of the waste material for disposal, and of the canister which holds this waste material. It is also of particular importance to note that air and liquid can

be pumped through the pump continuously, at any volume, limited only by the volume of the waste bag 31 to contain the pumped liquids.

The pump's ability to pump air and liquid, unlike conventional pumps, which are efficient in pumping only one type of matter, is enhanced by the flexibility of the diaphragm 24. Unlike conventional pump diaphragms, which are rigidified by a piston or ribbing, to prevent them from excessive flexing, which reduces displacement, the diaphragm 24 described in this embodiment is particularly flexible, so it can yield when encountering heavy loads, such as those present when pumping liquid. This diaphragm flexibility also provides an additional substantial advantage: when the vacuum in the pumping cavity 29 is high, the diaphragm 24 stretches to allow the reciprocation of the receptacle rod 26 to occur, at minimal burden to the "drive", which in the preferred embodiment comprises an electric motor 39.

Referring to **Figure 2**, to obtain high vacuum levels it is necessary to extract all air from the pumping cavity 29 when the diaphragm 24 is at its upper travel extremity, as illustrated in Fig. 2. This function, in a conventional vacuum pump, will cause damage to the pump when liquid or solids enter the pumping chamber, as they cannot be expelled through the pump's outlet valve fast enough. In the disclosed invention, the flexibility of the diaphragm 24 will allow it to yield, or bulge, when encountering resistance as a result of liquid or solid presence, preventing excessive forces and the ensuing damage.

An additional important function of the flexibility of the diaphragm 24 is its ability to stretch and yield, so that when the vacuum level in the pumping cavity 29 is high, only a smaller effective area of the diaphragm 24 reciprocates, and stretches,

requiring less power from the motor 39 to effect reciprocation.

In Figure 2, the drive 40, which contains the motor 39, crank 27 and reciprocating receptacle rod 26, is shown disengaged from all other parts, since the drive will be re-used, while all other parts, which have directly contacted the matter being pumped, are slated for disposal, and are termed the "disposable pumping system". The disposable pumping system, essentially comprising the canister, the diaphragm, associated valves, the disposable waste bag, and associated tubing, are shown in Figure 2 after all outlets have been sealed for disposal. The suction tube 12 is plugged with a plug 33 to prevent any liquid from leaking out of it. The conduit 30 is disengaged from the vacuum gauge 14 and attached to the air discharge outlet 15, sealing all possible leak paths from three-chambered canister 10.

It will be appreciated by persons skilled in the art that the drive 40, which is the only non-disposable hardware in the preferred embodiment, does not come in contact with any of the pumped media, unlike conventional aspirators or suction pumps, which pass the suctioned air through them, and may thus be contaminated by infectious air.

The method and means for attachment and mounting of the disposable pumping system to drive 40 is illustrated in **Figs. 2 and 3**, whereby the mounting base 23 is placed on top of retainers 41, shown in Fig. 2. The retainers 41 protrude from a shelf- or step-like part of the drive 40 and have a large mushroom-shaped head, which passes through large openings 42 in a flange of the base 23, as shown in Fig. 3. When the three-chambered canister 10 is rotated clockwise, with its mounting base 23, the large heads of the retainers 41 engage slots 45, attaching the mounting

base 23 to the drive 40, in a bayonet-type fastening action using a 45-degree twist. This action is similar to attaching a cap to a glass jar. The drive member 25, shown in Figs. 1, 2, is inserted into the receptacle rod 26, simultaneously with the attachment of the mounting base 23 to the housing of the drive 40.

Referring to **Figure 4**, a spring-loaded lock-clip 46 keys and locks the drive member 25 to the receptacle rod 26, when the lock clip engages pre-aligned slots 48 present in the drive member 25 and the receptacle rod 26. The disengagement of the mounting base 23 from the drive 40 is effected, simultaneously with disengagement of the drive member 25 from the receptacle rod 26, when both are rotated counterclockwise, as illustrated in Fig. 4, by drive member 25 pushing lock clip 46 out of its slot 47, eliminating the keying between drive member 25 and receptacle rod 26. This action is similar to the removal of a cap from a jar, by twisting counterclockwise and lifting.

While only one form of engagement of canister 10 to drive 40 was described in the preferred embodiment of this invention, it would be clear to those skilled in the art, that other similar methods for quick fastening of these parts, can be utilized effectively.

The above-described method of engagement has, however, an important feature that should be noted. Since the receptacle rod 26 may be at its lower position at the time when the drive member 25 is inserted into it, slots 47 and 48 may come into alignment only when motor 39 is powered and crank 27 raises receptacle rod 26 allowing lock clip 46 to key slots 47 and 48. Thus, the insertion of the drive member 25 into the receptacle rod 26 enables engagement, rather than fastening the two together.

CLAIMS

1. A vacuum pump capable of pumping solid, liquid and gas, or any combination thereof, especially useful for suctioning body liquids, comprising a drive and a manually disengageable disposable pumping system connected to said drive, wherein said disposable pumping system comprises:

a three-chambered canister, wherein the first chamber has an inlet, and means are provided for retaining solids and preventing their passage from said first chamber to the second chamber; the second chamber having a one-way valve at its exit, said valve allowing passage of liquid and gas out of said second chamber; the third chamber having an outlet for the discharge of air, and having an additional outlet for the discharge of liquid; and said third chamber further being connected via a one-way valve, allowing entrance of liquid or gas through said valve, while preventing exit of liquid or gas through said valve;

a highly flexible diaphragm, attached to said three-chambered canister, sealing against it circumferentially, said flexible diaphragm being attached to a partition with said three-chambered canister in which said valves are installed;

a drive member attached to said diaphragm, reciprocation of said drive member inducing reciprocation of said diaphragm; and

means for mounting and engaging said disposable pumping system to the housing of a drive, these means being capable of simultaneously

coupling the drive member to the drive;

wherein, in the assembled vacuum pump, the drive is coupled to the pumping system in such a way that activation of the drive induces reciprocation of said flexible diaphragm, and the pumping system is capable of being attached or detached from drive in a rapid and facile manner.

2. A vacuum pump according to claim 1, wherein the three-chambered canister has a volume of approximately 100 cc.

3. A vacuum pump according to claim 1 or 2, additionally comprising a vacuum outlet port, present in said second chamber, said outlet connected by tubing to an external vacuum gauge for the purpose of monitoring the pressure inside the first and second chambers.

4. A vacuum pump according to any preceding claim, wherein said means for retaining solids in the first chamber are comprised of a sieve.

5. A vacuum pump according to any preceding claim, wherein said highly flexible diaphragm is capable of yielding or stretching when exposed to high load or resistance.

6. A vacuum pump according to any preceding claim, wherein said highly flexible diaphragm, when subjected to high loads, is capable of stretching to effectively reciprocate only a fraction of its area while the remainder of its surface remains stationary.

7. A vacuum pump according to any preceding

claim, additionally comprising a disposable waste container, for collection of discharged liquid, attached to the liquid discharge outlet of said third chamber;

8. A vacuum pump according to claim 7, wherein said disposable waste container is a waste bag, having any appropriate size.

9. A vacuum pump according to claim 8, wherein the capacity of said waste bag is between 500 cc and 5 liters.

10. The vacuum pump according to any preceding claim, wherein the means for mounting and engaging said pumping system to said drive comprise a mounting base protruding from the lower portion of the three-chambered canister, said mounting base adapted for mating and attaching to said drive housing.

11. A vacuum pump according to any preceding claim, wherein said drive rotates a crank, and said drive is coupled to said drive member via a reciprocating rod receptacle connected to said crank, and said rod receptacle is adapted to mate with said drive member.

12. A vacuum pump according to claim 11, wherein coupling said mounting base to said drive housing, is affected simultaneously with the securing of said drive member to the rod receptacle, in a single operation.

13. A vacuum pump according to claim 11 or 12, additionally comprising a lock clip, capable of securing the drive member to the rod receptacle.

14. A vacuum pump according to any preceding claim, wherein said pumping system and said drive are portable and may be operated on battery power.

15. A vacuum pump according to any preceding claim, wherein said pumping system additionally comprising means for sealing said disposable pumping system, for facilitating disposal of said pumping system, while containing the pumped waste.

16. A vacuum pump according to any preceding claim, wherein said pump is capable of maintaining an unlimited flow of matter therethrough, while maintaining uninterrupted vacuum pressure.

17. A vacuum pump according to any preceding claim, wherein said pump is capable of generating a vacuum pressure of approximately 650 mm of Mercury as measured in the first and second chambers.

18. A vacuum pump according to any preceding claim, wherein said pump is capable of suctioning, continuously, an unlimited volume of matter therethrough.

19. A vacuum pump according to any preceding claim, additionally comprising a suction catheter tube attached to the inlet present in said first chamber, for allowing entry of matter into said three-chambered canister.

20. A vacuum pump capable of pumping liquid and gas, comprising a drive, and a manually disengageable disposable pumping system connected to said drive, wherein said disposable pumping system comprises:

a dual-chambered canister, wherein the first chamber

has an inlet and a one-way valve at the exit of the first chamber, said valve allowing passage of liquid and gas out of said first chamber; and the second chamber having an outlet for the discharge of air and an additional outlet for the discharge of liquid; said second chamber further being connected via a one-way valve, allowing entrance of liquid or gas through said valve, while preventing exit of liquid or gas through said valve;

a highly flexible diaphragm, attached to said dual-chambered canister, sealing against it circumferentially, wherein said flexible diaphragm is attached to a partition with said dual-chambered canister in which said valves are installed;

a drive member attached to said diaphragm, reciprocation of said drive member inducing reciprocation of said diaphragm; and

means for mounting and engaging said disposable pumping system on the housing of a drive, wherein said means are capable of simultaneously coupling the drive member to said drive;

wherein in the assembled vacuum pump, said drive is coupled to said pumping system, such that activation of said drive induces reciprocation of said flexible diaphragm; and wherein said pumping system is capable of being attached or detached from said drive in a rapid and facile manner.

21. A vacuum pump capable of pumping liquid and gas, comprising a drive and a disengageable disposable pumping system connected to the drive, wherein the disposable pumping system comprises:

a first chamber having an inlet and a first one-way

valve at its exit, allowing passage of liquid and gas out of the first chamber; and a second chamber having an outlet for the discharge of air and an outlet for the discharge of liquid; and an inlet via a second one-way valve, allowing entrance of liquid or gas through the valve while preventing exit of liquid or gas through the valve;

a flexible diaphragm sealing against the exterior of the chambers so as to define a pump cavity whose inlet is the first one-way valve and whose outlet is the second one-way valve; and

a drive member attached to the diaphragm, reciprocation of which induces reciprocation of the diaphragm;

the pump further comprising means for mounting the disposable pumping system on the housing of the drive, and for coupling the drive member to the drive.

22. A pump system substantially as described herein with reference to the attached drawings.

Amendments to the claims have been filed as follows

CLAIMS

1. A vacuum pump capable of pumping solid, liquid and gas, or any combination thereof, comprising a drive, and a manually disengageable disposable pumping system connected to said drive, wherein said disposable pumping system is comprised:

a three-chambered canister, wherein the first chamber has an inlet, and means are provided for retaining solids and preventing their passage from said first chamber to the second chamber; and the second chamber having a one-way valve at its exit, said valve allowing passage of liquid or gas out of said second chamber; and the third chamber having an outlet for the discharge of air, and having an additional outlet for the discharge of liquid; and said third chamber further being connected via a one-way valve, allowing entrance of liquid or gas through said valve, while preventing exit of liquid or gas through said valve;

a highly flexible diaphragm, attached to said three chambered canister, sealing it circumferentially, said flexible diagram being attached to a partition with said three-chambered canister, in which said valves are installed;

a drive member attached to said diaphragm, reciprocation of said drive member inducing reciprocation of said diaphragm; and

a bayonet arrangement for selectably simultaneously coupling said disposable pumping system to the housing of a drive and said drive member to the drive, and for selectably simultaneously decoupling said disposable pumping system from the housing of said drive and said drive member from said drive.

2. A vacuum pump according to claim 1, wherein the three-chambered canister has a volume of approximately 100 cc.

3. A vacuum pump according to claim 1 or 2, additionally comprising a vacuum outlet port, present in said second chamber, said outlet connected by tubing to an external vacuum gauge for the purpose of monitoring the pressure inside the first and second chambers.

4. A vacuum pump according to any of the preceding claims, wherein said means for retaining solids in the first chamber are comprised of a sieve.

5. A vacuum pump according to any of the preceding claims, wherein said highly flexible diaphragm is capable of yielding or stretching when exposed to high load or resistance.

6. A vacuum pump according to any of the preceding claims, wherein said highly flexible diaphragm, when subjected to high loads, is capable of stretching to effectively reciprocate only a fraction of its area while the remainder of its surface remains stationary.

7. A vacuum pump according to any of the preceding claims, additionally comprising a disposable waste container, for collection of discharged liquid, attached to the liquid discharge outlet of said third chamber.

8. A vacuum pump, according to claim 7, wherein said disposable waste container is a waste bag, having any appropriate size.

9. A vacuum pump according to claim 8, wherein the capacity of said waste bag is between 500 cc and 5 liters.

10. The vacuum pump according to any of the preceding claims, wherein the means for mounting and engaging said pumping system to drive comprise a mounting base protruding from the lower portion of the three-chambered canister, said mounting base adapted for mating and attaching to said drive housing.

11. A vacuum pump according to any of the preceding claims, wherein said drive rotates a crank, and said drive is coupled to said drive member via a reciprocating member connected to said crank, and said member is adapted to be coupled with said drive member.

12. A vacuum pump according to claim 11, wherein coupling said mounting base to said drive housing, is effected simultaneously with the securing of said drive member to the reciprocating member, in a single operation.

13. A vacuum pump according to claim 11 or 12, additionally comprising a lock clip, capable of securing the drive member to the reciprocating member.

14. A vacuum pump according to any of the preceding claims, wherein said pumping system additionally comprising means for sealing said pumping system, for facilitating disposal of said pumping system, while containing the pumped waste.

15. A vacuum pump according to any of the preceding claims, wherein said pump is capable of generating a vacuum pressure of approximately 650 mm of Mercury as measured in the first and second chambers.

16. A vacuum pump according to any of the preceding claims, additionally comprising a suction catheter tube attached to the inlet present in said first chamber, for allowing entry of matter into said three-chambered canister.

17. A vacuum pump capable of pumping liquid and gas, comprising a drive, and a manually disengageable disposable pumping system connected to said drive, wherein said disposable pumping system comprises:

a dual-chambered canister, wherein the first chamber has an inlet and a one-way valve at the exit of the first chamber, said valve allowing passage of liquid and gas out of said first chamber; and the second chamber having an outlet for the discharge of air and an additional outlet for the discharge of liquid, said chamber further being connected via a one-way valve, allowing entrance of liquid or gas through said valve, while preventing exit of liquid or gas through said valve;
a highly flexible diaphragm, attached to said dual-chambered canister, sealing against it circumferentially, wherein said flexible diaphragm is attached to a partition with said dual-chambered canister in which said valves are installed;
a drive member attached to said diaphragm, reciprocation of said drive member inducing reciprocation of said flexible diaphragm; and

a bayonet arrangement for selectably simultaneously coupling said disposable pumping system to the housing of a drive and said drive member to the drive, and for selectably simultaneously decoupling said disposable pumping system from the housing of said drive and said drive member from said drive.

18. A vacuum pump capable of pumping liquid and gas, comprising a drive and a disengageable disposable pumping system connected to the drive, wherein the disposable pumping system comprises:

a first chamber having an inlet and a first one-way valve at its exit, allowing passage of liquid and gas through the first chamber; and a second chamber having an outlet for the discharge of air and an outlet for the discharge of liquid; and an inlet via a second one-way valve, allowing entrance of liquid or gas through the valve while preventing exit of liquid or gas through the valve;

a flexible diaphragm sealing against the exterior of the chambers so as to define a pump cavity whose inlet is the first one-way valve and whose outlet is the second one-way valve; and

a drive member attached to the diaphragm, reciprocation of which induces reciprocation of the diaphragm;

the pump further comprising means for mounting the disposable pumping system on the housing of the drive, and for coupling the drive member to the drive.

19. A pump system substantially as described herein with reference to the attached drawings.

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Application No: GB 0119811.8 **Examiner:** David Hotchkiss
Claims searched: 1 - 20 **Date of search:** 4 April 2002

Patents Act 1977
Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.T): F1W (WCA, WDX, WDL, WDM); A5R (RCEB)

Int Cl (Ed.7): F04B (9/02, 17/00, 17/03, 35/00, 39/16, 53/22); A61M (1/00)

Other: Online: WPI; EPODOC;JAPIO

Documents considered to be relevant:

Category	Identity of document and relevant passage		Relevant to claims
A	GB 2124712 A	(MEDTRONIC INC) See especially screws 30 & 32 in figures 1 and 2, which could be unscrewed to detach the motor	
A	EP 1045146 A2	(CLEMENS MICHELER) See English abstract	
A	EP 0494375 A1	(IWAKI CO LTD) See especially column 4 lines 45 - 46	
A	US 4842584	(ABBOTT LAB) See especially column 1, paragraph 2 and chambers 90, 82 & 22	
A	US 4798589	(FISHER SCIENT GROUP INC) See especially column 2 line 35 - column 4 line 59	
A	US 4639245	(OXIMETRIX) See especially figure 1	

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.

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Page #856

(12) UK Patent Application (19) GB (11) 2 307 180 (13) A

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A61M 1/00

(52) UK CL (Edition O)
A5R RCEB

(56) Documents Cited
GB 2277035 A EP 0080179 A1 WO 96/05873 A1
WO 93/09727 A1 WO 80/02182 A1 US 4392858 A

(58) Field of Search
UK CL (Edition O) A5R RCEA RCEB RCED RCEX
INT CL[6] A61B 19/00 , A61F 13/00 , A61M 1/00
ONLINE: WPI

(54) Portable pump for draining fluid from a wound dressing

(57) Wound healing is stimulated by applying a porous dressing from which fluid is drawn into canister 100 via a catheter using portable suction pump 6 which is contained in housing 210 and is worn on a harness or belt. Overfilling of canister 100 is prevented by a filter contained in the canister and a pressure sensor which detects pressure reductions in tube 103 between canister 100 and pump 6 which occur when drainage liquid covers the filter. Contamination of pump 6 is prevented by a further filter placed between pump 6 and canister 100 and pressure at the wound site is monitored by a conduit connected to the porous dressing.

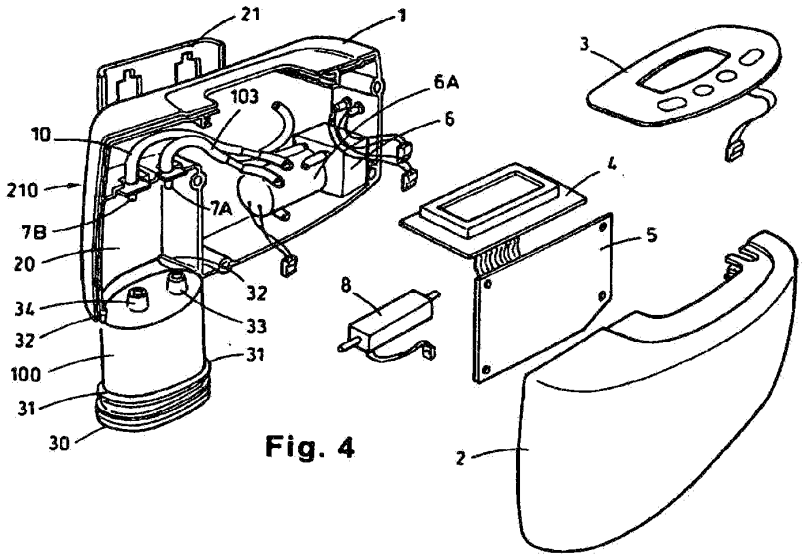


Fig. 4

GB 2 307 180 A

At least one drawing originally filed was informal and the print reproduced here is taken from a later filed formal copy.

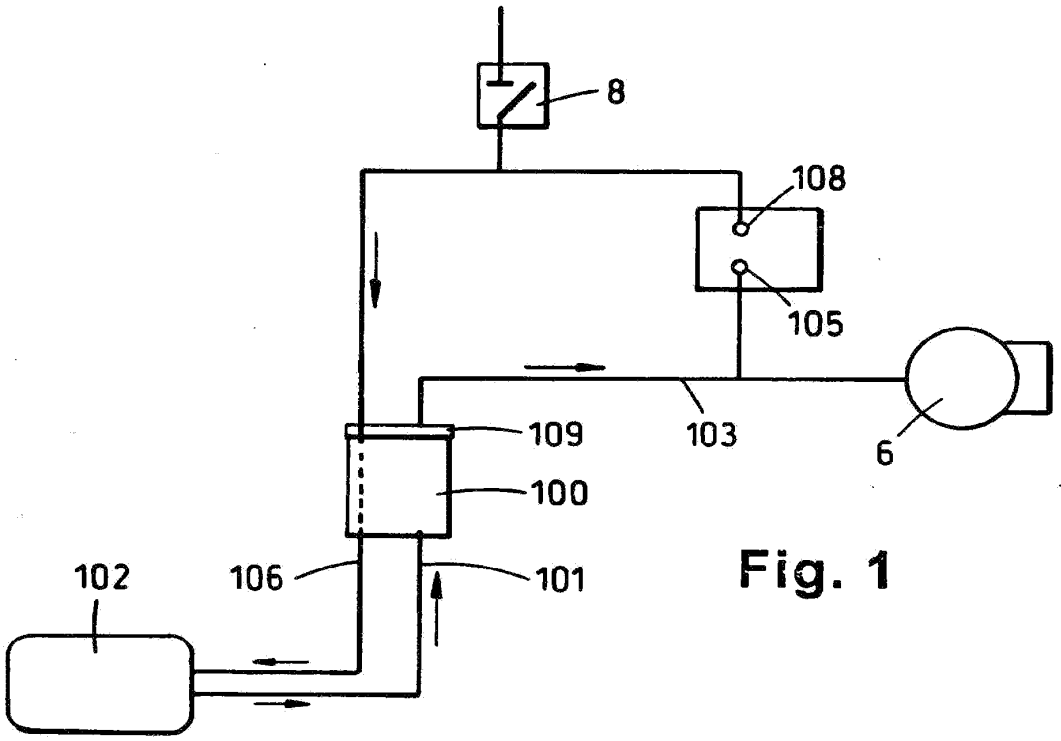


Fig. 1

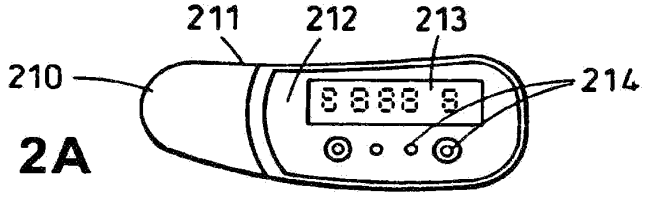


Fig. 2A

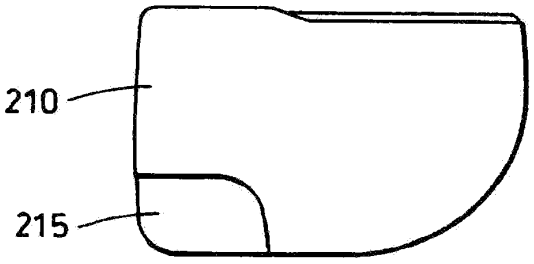


Fig. 2B

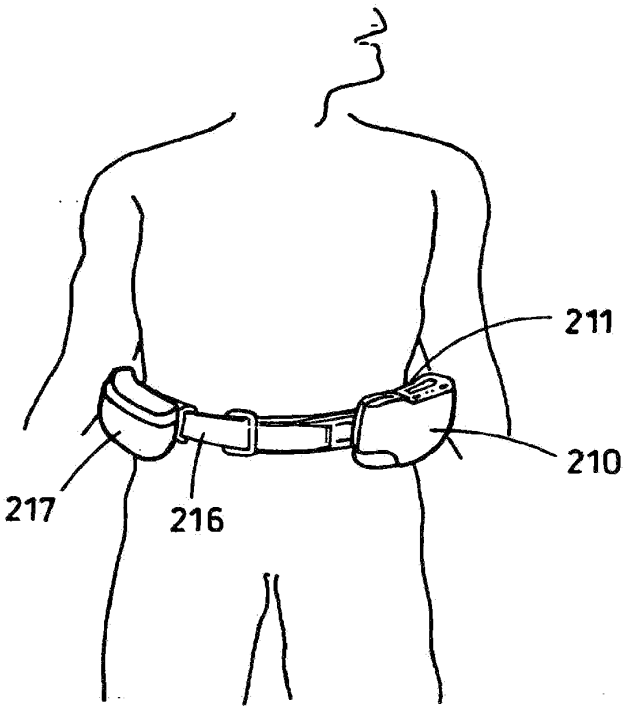


Fig. 3A

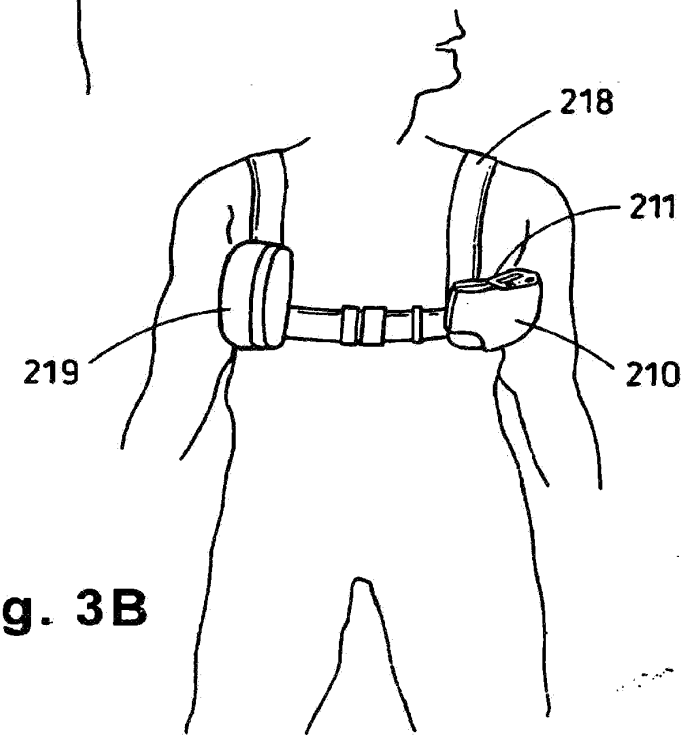


Fig. 3B

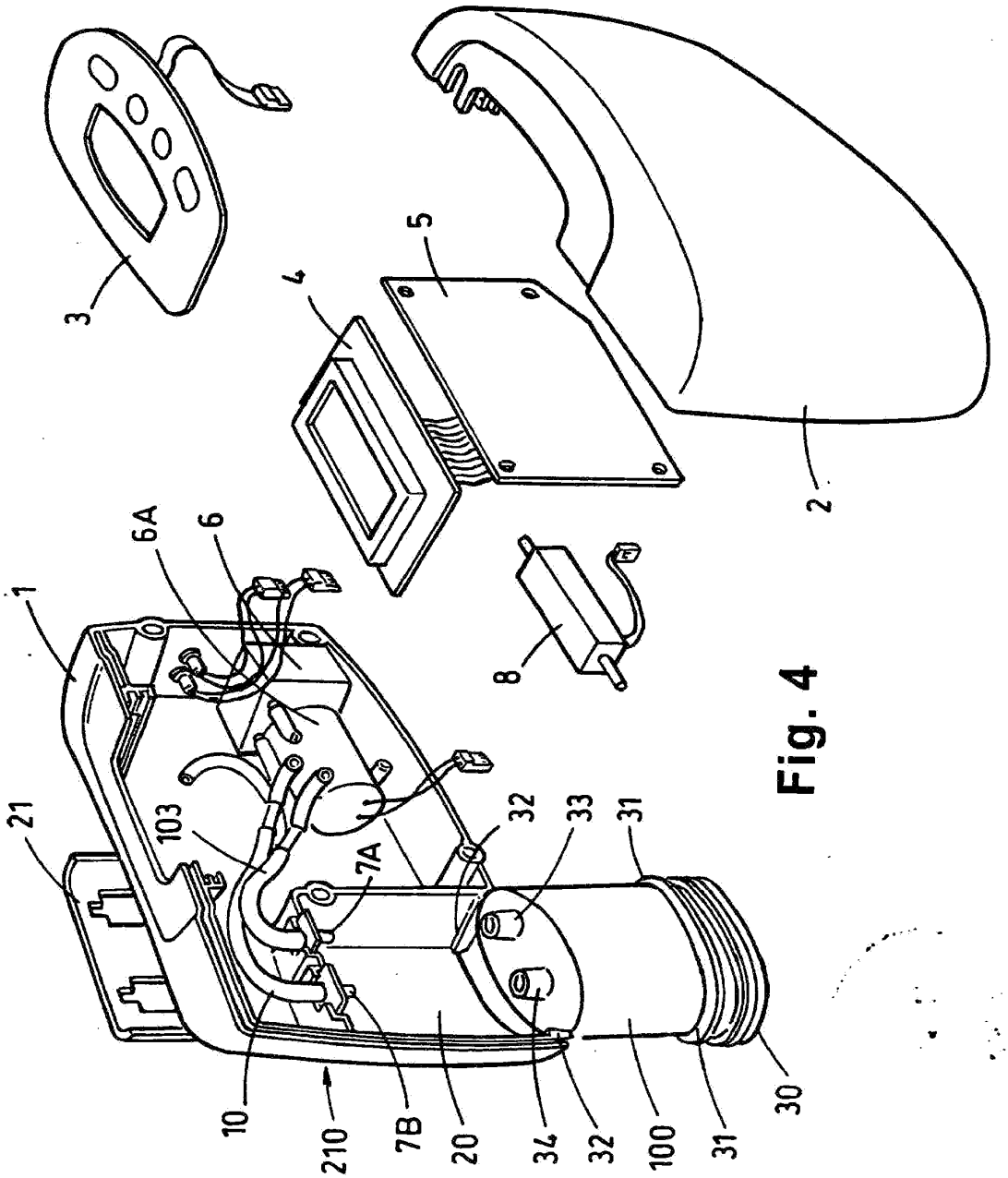


Fig. 4

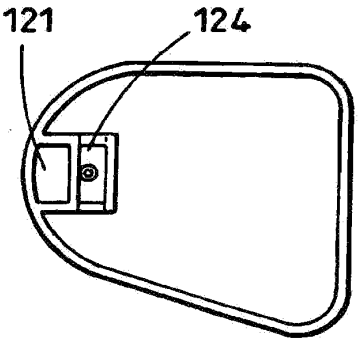


Fig. 5A

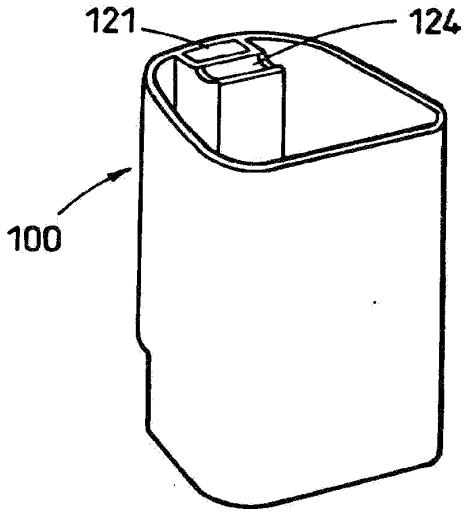


Fig. 5D

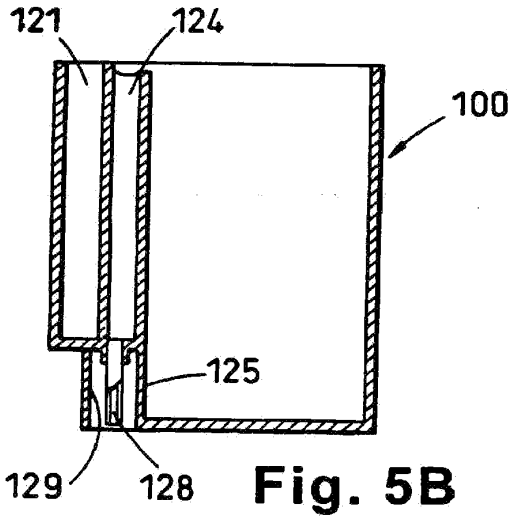


Fig. 5B

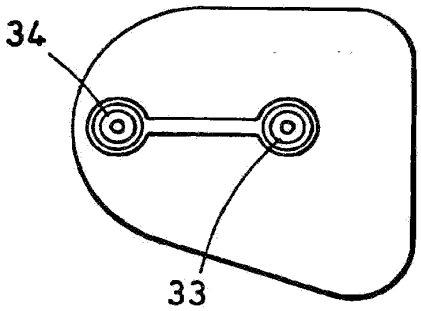


Fig. 5E

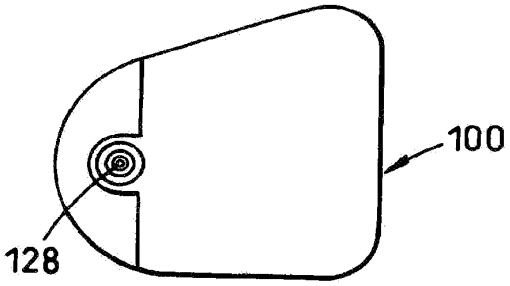


Fig. 5C

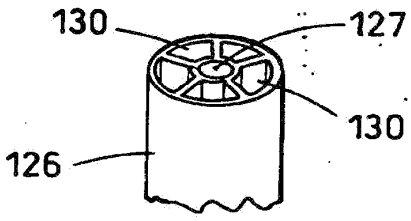


Fig. 5F

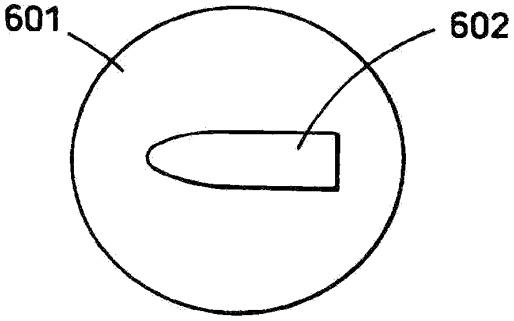


Fig. 6A

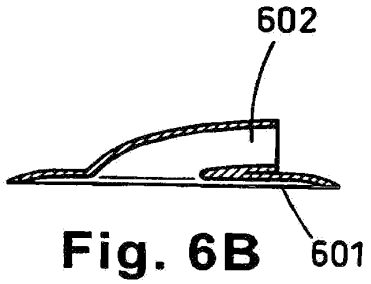


Fig. 6B



Fig. 6C

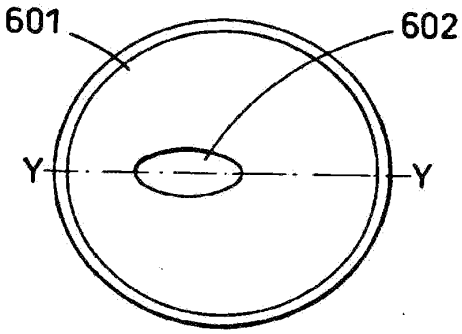


Fig. 6D

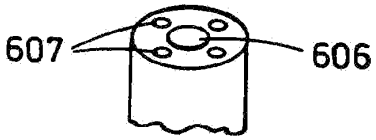


Fig. 6E

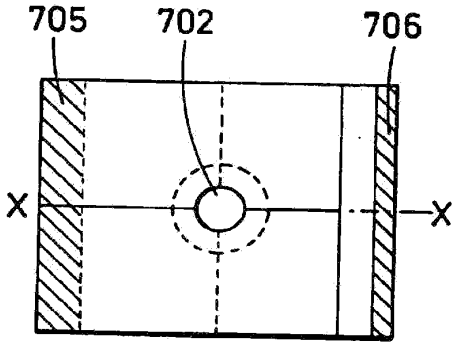


Fig. 7A

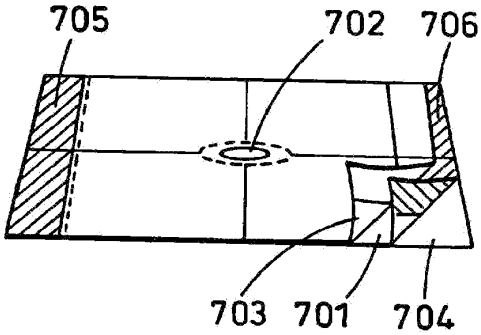


Fig. 7B

2307180

PORTABLE WOUND TREATMENT APPARATUS

This invention relates to the healing of wounds and, more particularly, to apparatus for stimulating the healing of superficial wounds.

PCT Application No. GB95/01983 (WO 96/05873) describes apparatus for stimulating the healing of wounds comprising a porous pad which is permeable to fluids for introduction into the wound, a dressing for covering the wound and providing an air-tight seal around the wound, a drainage tube connecting the pad to a suction pump so that negative pressure can be applied to the wound to draw fluids therefrom, and a canister for collecting fluids sucked from the wound. The apparatus described in the above application has proved to be clinically effective but there are some limitations in its use.

The apparatus described in the above PCT application is effective for treating a wide variety of different types and sizes of wounds. However, it may require the patient to undergo treatment on the apparatus for a long period. In cases where the patient is confined to bed this may not be a major problem, but where the patient is mobile it means that he or she would be confined for long periods while the treatment takes place.

An object of this invention is therefore to provide apparatus which can be used more conveniently, especially by patients who are reasonably mobile, and which has certain further advantages which will become apparent from the following description.

According to one aspect of the present invention there is provided a portable therapeutic apparatus for stimulating the healing of superficial wounds in a person, which comprises a housing containing a suction pump and a canister for containing fluids drawn from the wound by said pump, said canister including

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means for connection to a dressing in the region of the wound and a harness or belt for supporting the housing on the person.

Typically, the housing will have a curved surface on the side intended to be supported against the person's body so as to make the apparatus more comfortable to wear. In addition, controls and indicators indicating the status of the treatment being applied to the wound are preferably located on the upper side of the housing so that the patient can easily see, e.g. the level of suction pressure being applied and the programme for such treatment.

The suction pump is conveniently driven by an electric motor and batteries for such motor may be contained within the housing. However, it is generally more convenient to provide a separate housing for the batteries since these can be placed on the belt or harness in such a way as to balance the weight of the housing, preferably in a housing shaped similarly to the housing for the pump and canister. The canister should be removably mounted within the housing, e.g. by means of a latch or similar release mechanism, so that the canister can be readily removed and replaced when full.

In a portable therapeutic apparatus (in contrast with a static apparatus of the kind described in the above PCT application which cannot be easily carried by the patient), it is less easy to determine the pressure prevailing at the wound site being treated. This is because the pressure will depend, in part, upon the hydrostatic height between the pump and the wound being treated and this height may vary during the treatment, depending upon the patient's movements. Apparatus in accordance with the invention overcomes this problem by providing an additional conduit connecting the wound site or an area close thereto to a pressure-detecting means, preferably located in the housing. The pressure-detecting means can be linked to a microprocessor programmed to maintain such pressure within a

predetermined range irrespective of the movement of the patient. This can be done by, for example, signalling the pump to increase its speed where the hydrostatic pressure increases between the pump and the wound site or, conversely, reducing its speed where the hydrostatic pressure is reduced. This feature can also be used in a static therapeutic apparatus of the kind described in the above-mentioned PCT application.

In the apparatus described in the above PCT application, the level of liquid in the canister is monitored by capacitance measurement. It has now been found that a simpler way of determining when the canister is filled is by measuring or detecting the pressure drop across the canister. The pressure drop can be increased by providing a filter barrier in the region of the outlet end of the canister. Thus, when the liquid reaches a level within the canister so as to substantially occlude the filter, a sharp pressure change occurs in the conduit between the canister and the pump. By monitoring this pressure change, the point at which the canister is filled can be accurately determined.

Additional advantages and features of the present application will become apparent from the following description and accompanying drawings, in which:-

Figure 1 is a schematic layout of the apparatus in accordance with the invention,

Figure 2A and B are pictorial representations of the housing of the pump and canister,

Figure 3A and B are pictorial representations of the apparatus supported on a belt and harness respectively,

Figure 4 is an exploded view of the housing showing the contents,

Figures 5A to F show various views of a preferred form of the canister and a section of a multi-lumen tube, and

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Figures 6A to D show various views of a foam dressing connector for connecting the housing to the dressing,

Figure 6E shows a section of a modified multi-lumen tube,

Figures 7A & 7B show a plan and perspective view of a surgical drape for use with the apparatus.

Referring to the drawings, the portable therapeutic apparatus comprises a housing 210 (best shown in Figures 2A and 2B), having rounded corners and a side 211 which is concavely curved in order to fit comfortably to the wearer's body. The shaping of the housing with curved surfaces is to avoid sharp corners or edges which could dig in to the user or his carer. The upper surface 212 is generally flat and has an LCD screen 213 on which details such as applied pressure can be displayed. Control buttons 214 are provided to adjust pressures and treatment intervals. Provision is made for housing a canister within the housing and a snap release cover 215 is arranged for removing or introducing the canister.

Figures 3A and 3B show schematically ways in which the housing 210 may be supported on the patient's body. In Figure 3A the housing 210 is supported on a belt 216 and its weight is balanced by a similarly rounded casing 217 containing a rechargeable battery pack. Figure 3B shows an alternative arrangement in which the housing is supported on a harness 218 and again a battery pack is contained in a housing 219, also supported on the harness.

Figure 4 shows an exploded view of the housing 210 indicating the main components within the housing. The housing consists of front and rear shell mouldings 1 and 2 having an external belt clip 21 for attachment to a belt or harness.

Within housing shell 1 is located a suction pump 6 with associated electric motor 6A and the pump is connected by a silicon rubber tube 103 to a canister

spigot 7A in a compartment 20 for the canister 100. Also connected to a second canister spigot 7B via a tube 10 is a pressure relief valve 8 and both tubes 103 and 10 are connected via T-connectors T to pressure transducers (not shown). A microprocessor 4 is mounted on a PCB board 5 and a membrane assembly 3 incorporates an LCD indicator and control buttons.

The apparatus may include means for recording pressures and treatment conditions given to a particular patient which may be printed out subsequently by the physician. Alternatively, the equipment may include a modem and a telephone jack so that the conditions under which the patient has been treated can be interrogated by the physician from a distant station.

Canister 100 is a push fit into the cavity 20 and its lower end is supported in a cover 30. The cover 30 incorporates fingers 31 which are releasably engageable with lips 32 to hold the canister in position. The canister and the latch mechanism is arranged so that when the latch is engaged, the spigots 7A and 7B are in sealing engagement or abutment with tubular protrusions 33 and 34 formed in the top of the canister.

The method of operation of the apparatus can be appreciated from the schematic layout in Figure 1, in which the canister 100 is connected via tube 101 to a porous dressing 102 at the wound site. Suction is applied to the wound site via the canister by a tube 103, connected to the pump 6. The pressure in the tube 103 is detected by the transducer 105.

A second tube 106 is connected to the wound site 102 at one end, and also to a pressure relief valve 8 and to a second transducer 108. Tubes 106 and 101 can be combined in a multi-partitioned tube in manner to be described later. By means of tube 106 and transducer 108 the pressure at the wound site can be measured or monitored. A filter 109 is placed at or close to the outlet end of the

canister 100 to prevent liquid or solid particles from entering the tube 103. The filter is a bacterial filter which is hydrophobic and preferably also lypophobic. Thus, aqueous and oily liquids will bead on the surface of the filter. During normal use there is sufficient air flow through the filter such that the pressure drop across the filter is not substantial.

As soon as the liquid in the canister reaches a level where the filter is occluded, a much increased negative pressure occurs in tube 103 and this is detected by transducer 105. Transducer 105 is connected to circuitry which interprets such a pressure change as a filled canister and signals this by means of a message on the LCD and/or buzzer that the canister requires replacement. It may also automatically shut off the working of the pump.

In the event that it is desired to apply intermittent suction to the wound site, a pressure relief valve 8 enables the pressure at the wound site to be brought to atmospheric pressure rapidly. Thus, if the apparatus is programmed, for example, to relieve pressure at 10 minute intervals, at these intervals valve 8 will open for a specified period, allow the pressure to equalise at the wound site and then close to restore the suction. It will be appreciated that when constant suction (or negative pressure) is being applied to the wound site, valve 8 remains closed and there is no leakage from atmosphere. In this state, it is possible to maintain negative pressure at the wound site without running the pump continuously, but only from time to time, to maintain a desired level of negative pressure (i.e. a desired pressure below atmospheric), which is detected by the transducer 105. This saves power and enables the appliance to operate for long periods on its battery power supply.

Instead of running two separate tubes to the wound site, it is preferable to contain tubes 106 and 101 in a single tube which is connected through the canister. Thus, for example, tubes 103 and 101 may comprise an internal tube surrounded by

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an annular space represented by tube 106. This is illustrated in Figures 5A to 5F and in a modified form in Figure 6E.

In an alternative embodiment, the multi-lumen tube may be constructed as shown in Figure 6E. In this embodiment, the internal bore 606 comprises the line 101 (see Figure 1) and is used to extract fluids from the wound site. Air flow (represented by line 106 in Figure 1) passes down conduits 607 located within the walls of the tube. By spacing the conduits 607 at 90° intervals around the tube, the risk of arresting the air flow by kinking or twisting the multi-lumen tube is minimised.

Figure 5E is a plan view of the top of a preferred shape of canister, the generally triangular shape in section being chosen to fit better the space within cavity 20 (see Figure 4). Tubular protrusions on the top of the canister are connected internally of the canister with respectively conduits 124 and 121 (see sectional view of Figure 5B), thus maintaining a separation between the tubes which are represented by lines 103 and 106 in Figure 1. At the base of the canister, a moulding 125 facilitates connection to a multi-partitioned tube 126 shown in Figure 5F. Tube 126 has a central bore 127 which is sized to fit over a spigot 128 in moulding 125. At the same time, the external wall of tube 126 seals against the inner wall 129 of moulding 125. Thus, compartment 124 will connect with central bore 127 and the compartment 121 will connect with the annular spaces 130 of tube 126. In this way, a conduit 130 corresponds with line 106 and central bore 127 with line 101 as shown in Figure 1.

The partitioned tube need not continue all the way to the wound site 102, but can be connected to a short section of single bore tube close to the wound site.

In the event of an air leak in the dressing at the wound site 102, this can be detected by both transducers 105 and 108 reading insufficient negative pressure for

a specific time period, and then triggering a leak alarm, i.e. a message on the LCD, preferably also with an audible warning.

Typically, the pump 6 is a diaphragm pump but other types of pumps and equivalent components to those specifically employed may be substituted.

Figures 6A~6D show various views of a connector for attaching the multi-lumen tube at the wound site. Figures 7A and 7B show a plan and perspective view of a surgical drape for attaching the connector to a porous dressing at the wound site. The connector comprises a moulded plastics disc-like cup 601 having a centrally positioned spout 602. The spout 602 is sized to accept, as a closely sliding fit, the end of a multi-lumen tube e.g. of the kind shown in Figures 5F or 6E. In use, a porous dressing is cut to correspond with the extent of the wound and pressed onto the wound as shown in Figure 10 of our above cited PCT application WO 96/05873. Instead of introducing the lumen into the foam dressing, the cup 601 is pressed onto the porous dressing and secured by a surgical drape. However, if desired, the end of the lumen can be passed into the spout and additionally pressed into the foam. A surgical drape such as shown in Figures 7A and 7B, can be used to secure the connector, lumen and dressing. The drape comprises a polyurethane film 701 coated on one side with a pressure-sensitive acrylic resin adhesive. A hole 702 is cut through all layers of the drape and the hole is dimensioned to correspond approximately with the outer cross-section of the spout 602. Film 701 has an overall size which allows it to be adhered to the patient's skin around the wound site, while at the same time, securing the connector to the porous dressing. A sufficient overlap around the wound is provided so that an air-tight cavity is formed around the wound.

In an alternative form, the drape can be made in two parts, e.g. by cutting along the line X-X in Figure 7A. With this arrangement, the wound can be sealed

by overlapping two pieces of surgical drape so that they overlap each other along a line Y-Y as shown in Figure 6D.

The surgical drape may include a protective film 703, e.g. of polyethylene, and a liner 704 which is stripped off prior to use to expose the pressure-sensitive adhesive layer. The polyurethane film may also include handling bars 705,706, which are not coated with adhesive, to facilitate stretching of the film over the wound site. The dressing is preferably a pad of porous, flexible plastics foam, e.g. reticulated, open intercommunicating cellular flexible polyurethane foam, especially of the kind described in the above-mentioned PCT application WO 96/05873.

Alternatively, a reticulated intercommunicating cellular foam made from flexible polyvinylacetate or polyvinylalcohol foam may be used. The latter is advantageous because it is hydrophilic. Other hydrophilic open celled foams may be used.

In another method of therapy, the foam dressing may be sutured into a wound after surgery and the foam dressing connected to the pump unit by the multi-lumen catheter. Negative pressure can then be applied continuously or intermittently for a period determined by the surgeon, e.g. from about 6 hours to 4 to 5 days. After this period, the dressing is removed and the wound re-sutured. This therapy improves the rate of granulation and healing of wounds after surgery.

CLAIMS:-

1. A portable therapeutic apparatus for stimulating the healing of a superficial wound in a person, which comprises a housing containing a suction pump and a canister for containing fluids drawn from the wound by said pump, said canister including means for connection to a dressing in the region of the wound and a harness or belt for supporting the housing on the person.

2. Apparatus as claimed in claim 1 wherein the housing has a curved surface on the side intended to be supported against the person's body, and controls located on an upper side of the housing.

3. Therapeutic apparatus for stimulating healing of a wound in mammals which comprises a porous pad, which is permeable to liquids for introduction into the wound, a dressing for covering the wound and providing a substantially air-tight seal around the wound, a drainage tube connecting the pad to a suction pump so that suction can be applied to the wound to draw liquids therefrom, said tube being connected to the pump via a canister for collecting liquids sucked from the wound and a filter barrier located in the canister at the outlet side, and pressure detecting means arranged to detect pressure changes in the tube between the canister and the pump and to signal a pressure change when liquid in the canister covers a substantial part of the filter barrier, thus indicating a full canister.

4. Apparatus as claimed in claim 3 wherein the filter barrier covers the entire outlet from the canister and the dimensions of the pores in said barrier are such that when liquid covers substantially the whole of the filter barrier, said pressure detecting means signals a sharp increase in negative pressure in the tube connecting the canister with the pump.

5. Therapeutic apparatus for stimulating healing of a wound in mammals which comprises a porous pad, which is permeable to liquids for introduction into the wound, a dressing for covering the wound and providing a substantially air-tight seal around the wound, a drainage tube connecting the pad to a suction pump so that suction can be applied to the wound to draw liquids therefrom, said tube being connected to the pump via a canister for collecting liquids sucked from the wound and at least one filter interposed between the canister and the pump, said apparatus including an additional conduit connecting the porous pad to pressure detecting means whereby the pressure substantially at the wound site can be monitored.

6. Apparatus as claimed in claim 5 which includes a relief valve for admitting air to the additional conduit and means for controlling the operation of the valve so that intermittent suction can be applied to the wound site.

7. Apparatus as claimed in claim 5 or 6 in which a single tube links the porous pad with the housing, said tube being longitudinally partitioned to provide a conduit for applying suction and an additional conduit for connection to said pressure detecting means.

The Patent Office

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Claims searched: 1 and 2 **Date of search:** 11 February 1997

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Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.O): A5R (RCEA, RCEB, RCED, RCEX)

Int Cl (Ed.6): A61B 19/00, A61F 13/00, A61M 1/00,

Other: ONLINE: WPI

Documents considered to be relevant:

Category	Identity of document and relevant passage		Relevant to claims
Y	GB 2277035 A	(UNITED SURGICAL SERVICES) see page 6 lines 8 to 18 and the figures, particularly Figure 1.	1
Y	EP 0080179 A1	(INTERMEDICAT) 01.06.83 (see the figures and also WPI Abstract Accession No. 83-54112K/23)	1
P,A	WO 96/05873 A1	(MEDISCUS PRODUCTS) see page 4 line 27 to page 12 line 9 and the figures.	-
Y	WO 93/09727 A1	(WAKE FOREST UNIVERSITY) see the examples, particularly Examples 4 to 8 and the figures.	1
Y	WO 80/02182 A1	(MOSS) see page 2 lines 18 to 33, page 4 lines 16 to 31 and the figures, particularly Figure 1.	1
Y	US 4392858	(GEORGE & DI PALMA) see column 2 lines 24 to 36 and the figures, particularly Figure 1	1

X Document indicating lack of novelty or inventive step
Y Document indicating lack of inventive step if combined with one or more other documents of same category.
& Member of the same patent family

A Document indicating technological background and/or state of the art.
P Document published on or after the declared priority date but before the filing date of this invention.
E Patent document published on or after, but with priority date earlier than, the filing date of this application.

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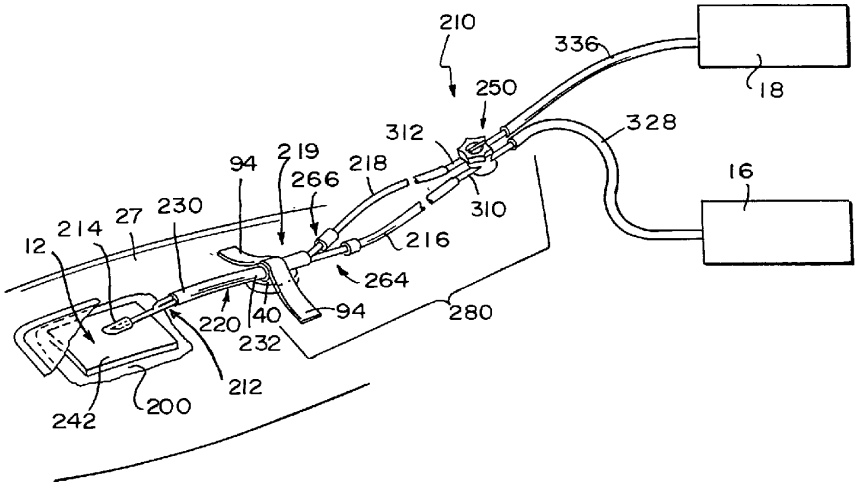
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[Continued on next page]

(54) Title: VENTED VACUUM BANDAGE AND METHOD



(57) Abstract: A ventilated bandage system (10, 210, 400) is provided for use with a wound (200). The system (10, 210, 400) includes a bandage (14, 410) positioned adjacent the wound (200) to create a sealed environment around the wound (200). A vacuum source (16) of the system (10, 210, 400) is in communication with the bandage (14, 410) to create negative pressure between the bandage (14, 410) and the wound (200). The system (10, 210, 400) may also include a first passageway or vent (19, 119, 219, 460) in communication with the bandage (14, 410) and with the surrounding atmosphere, and a second passageway in communication with the bandage and with the vacuum source (16).

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Declarations under Rule 4.17:

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for the following designations 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, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW, 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, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)*

— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii)) for the following designations 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, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW, 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, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)*

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VENTED VACUUM BANDAGE AND METHOD

BACKGROUND OF THE INVENTION

The present disclosure relates to vacuum therapy wound treatment systems including a vacuum bandage coupled to a vacuum source and an irrigation source.

The prior art contemplates that chronic wounds may be treated by providing a vacuum in the space above the wound to promote healing. A number of prior art references teach the value of the vacuum bandage or the provision of vacuum in the space above the surface of a chronic wound.

A vacuum bandage is a bandage having a cover for sealing about the outer perimeter of the wound and under which a vacuum is established to act on the wound surface. Applying vacuum to the wound surface promotes healing of chronic wounds. Typically, suction tubes are provided for drawing exudate away from the wound and for creating a vacuum under the cover. The following U.S. Patents establish the nature of vacuum treatment bandages and devices: 6,095,992; 6,080,189; 6,071,304; 5,645,081; 5,636,643; 5,358,494; 5,298,015; 4,969,880; 4,655,754; 4,569,674; 4,382,441; and 4,112,947. All of such references are incorporated herein by reference.

Further, the prior art contemplates that wounds may be treated by providing irrigation in the space above the wound. Typically, a tube is provided in communication with the wound surface of the wound at one end and with an irrigation source an another end. The fluid from the irrigation source travels through the tube to the wound surface.

The prior art further contemplates the use of stopcocks for use in intravenous injections and infusions. Stopcocks may be designed to include multiple ports for directing fluid flow along various paths or channels. The following U.S. Patents establish the nature of stopcocks: 6,158,467; 3,586,049; 2,485,842; 2,842,124; and U.S. Patent Application Publication No. US 2001/00 13370 A1.

SUMMARY OF THE INVENTION

The present invention comprises one or more of the following features or combinations thereof:

A wound care bandage system is provided for use with a wound. The system, among other things, may be capable of ventilating the wound. The system may include a vacuum source, an irrigation source, a vent in communication with the surrounding atmosphere and with the wound, and a bandage. The vacuum source creates negative pressure above the wound and the irrigation source irrigates the wound. As is herein defined, the term "vent" is or includes any passageway to the atmosphere, unless noted otherwise.

The bandage is configured to lie adjacent the wound to create a sealed environment about the wound. The vent may be positioned between the bandage and the vacuum source. A vacuum passageway of the system may extend between the bandage and the vacuum source, and a vent passageway of the system may extend from the bandage to the vent in communication with the surrounding atmosphere. The vacuum passageway may extend through the vent to the vacuum source.

The system may also include a multi-lumen tube which forms the vacuum passageway and the vent passageway, and a wound dressing member coupled to the multi-lumen tube configured to lie adjacent the wound. The multi-lumen tube may be configured to couple to the vacuum bandage and may include a venting lumen in communication with the surrounding atmosphere and another vacuum/irrigation lumen in communication with either or both of the vacuum source and the irrigation source. Further, the multi-lumen tube may include a vacuum lumen and a separate irrigation lumen distinct from the vacuum lumen.

The system may also include a vent-valve apparatus having the vent or a portion of the vent passageway formed therein. The apparatus provides selective communication between the wound and either the vacuum source or the irrigation source. The apparatus may include a multi-lumen connector configured to communicate with the bandage. The multi-lumen connector may include at least one inner conduit in communication with the vacuum source and/or the irrigation source and at least one outer conduit in communication with the atmosphere. The apparatus may further include a vacuum connector coupled to the vacuum source and an irrigation connector coupled to the irrigation source. An opening of the apparatus may be provided to communicate with the atmosphere and with the outer conduit of the multi-lumen connector.

In one embodiment, the apparatus may include a vent having the multi-

lumen connector, and a stopcock coupled to the vent and including the vacuum connector and the irrigation connector. The vent may include a single-lumen connector coupled to the inner conduit of the multi-lumen connector. The vent may further include a housing and a filter housed within the housing. The filter may be in communication with the surrounding atmosphere and with the outer conduit of the multi-lumen connector through the opening.

The stopcock may include a single-lumen connector coupled to the single-lumen connector of the vent and a diverter to selectively couple the single-lumen connector of the stopcock with either the vacuum connector or with the irrigation connector. The stopcock may further include a body and the diverter may be coupled to the body for rotational movement relative to the body. The diverter may include a cut-out portion to selectively communicate the vacuum connector or the irrigation connector with the vent.

In another embodiment, the apparatus may include a body or outer shell defining an aperture and a diverter or inner barrel received within the aperture. The diverter may rotate relative to the outer shell to selectively communicate with the vacuum source or the irrigation source. The outer shell may include the multi-lumen connector, the vacuum connector, and the irrigation connector. The diverter may include a first set of passageways and a second set of passageways formed therethrough. The first set of passageways communicates with the inner conduit of the multi-lumen connector, the vacuum connector, and the irrigation connector. The second set of passageways may communicate with the outer conduit of the multi-lumen connector through a groove or channel formed in the outer shell between the outer conduit and the second set of passageways. The outer shell illustratively includes the opening of the apparatus and the second set of passageways is in selective communication with the opening. A filter may be coupled to the opening.

In yet another embodiment, the apparatus may include a vent and a stopcock coupled to the vent. The vent may include a multi-lumen connector and a first and second single-lumen connector. The stopcock may include a vacuum connector and an irrigation connector. The vacuum connector may include a first portion coupled to the first single-lumen connector of the vent and a second portion coupled to the vacuum source. The irrigation connector may include a first portion coupled to the second single-lumen connector of the vent and a second portion

coupled to the irrigation source.

The inner conduit of the multi-lumen connector may be a vacuum conduit and the multi-lumen connector may further include an irrigation conduit. Each of the vacuum and irrigation conduits may be positioned within the outer conduit. The vacuum conduit may be coupled to the first single-lumen connector of the vent and the irrigation conduit may be coupled to the second single-lumen connector of the vent. The vent further may include a housing coupled to the multi-lumen connector and a filter within the housing. The filter may be in communication with the surrounding atmosphere and with the opening through a passageway of the housing.

The stopcock may include a body coupled to the vacuum and irrigation connectors and a diverter received within an aperture of the body. Each of the first and second portions of the vacuum and irrigation connectors may communicate with the aperture of the body. The vacuum connector may illustratively lie in a first horizontal plane and the irrigation connector may illustratively lie in a second horizontal plane.

The diverter may include a first cut-out portion for communication with the vacuum connector and a second cut-out portion for communication with the irrigation connector. The diverter may rotate relative to the body to connect the first and second portions of the vacuum connector with each other and to connect the first and second portions of the irrigation connector with each other to selectively communicate the vacuum source and the irrigation source to the wound.

Other features of the invention will become apparent to those skilled in the art upon consideration of the following detailed description of the preferred embodiments exemplifying the best mode of carrying out the invention as presently perceived.

BRIEF DESCRIPTION OF THE DRAWINGS

The detailed description particularly refers to the accompanying figures in which:

Figs. 1-8 illustrate components of a wound care bandage system of the present disclosure which provides suction, irrigation, and ventilation to a wound;

Fig. 1 is a part perspective, part diagrammatic view of the wound care

bandage system located on the leg of a patient and coupled to a vent and to vacuum and irrigation sources through the use of a stopcock or a switch valve;

Fig. 2 is a perspective view of the vent of the system showing a multi-lumen connector for communication with the wound via a multi-lumen tube, a single-lumen connector for communication with the switch valve, and a circular housing holding a filter (in phantom) in communication with the surrounding atmosphere;

Fig. 3 is a side view of the vent, with portions broken away, showing the multi-lumen connector aligned for coupling to the multi-lumen tube, the single-lumen connector aligned for coupling to a single lumen tube, a passageway of the vent extending between outer lumens of the multi-lumen tube and the filter of the vent, and further showing a thin, flexible wound dressing member of the bandage coupled to the multi-lumen tube by a barbed coupler;

Fig. 4 is a sectional view of the multi-lumen tube taken along line 4-4 of Fig. 3 showing an inner lumen of the tube for communication with the vacuum source and the irrigation source of the system and four outer lumens of the tube for communication with the filter and surrounding atmosphere to aspirate an area above the wound;

Fig. 5 is an exploded perspective view of the switch valve and vent of the system showing a vent connector of the valve aligned for coupling to the single-lumen connector of the vent, a vacuum connector for communication with the vacuum source, an irrigation connector for communication with the irrigation source, and a handle or diverter for providing selective communication between the vent connector and either the vacuum source or the irrigation source;

Figs. 6a and 6b are perspective views of the handle of the switch valve showing a grip and a stem of the handle and further showing a cut-out portion of the stem for selective communication between the vent, vacuum, and irrigation connectors of the switch valve;

Fig. 7 is a sectional view taken along line 7-7 of Fig. 5 showing the handle of the switch valve in an irrigation position so that the cut-out portion provides a passageway between the irrigation connector and the vent connector to permit fluid from the irrigation source to run through the switch valve to the wound;

Fig. 8 is a sectional view similar to Fig. 7 showing the handle of the switch valve in a vacuum position so that the cut-out portion provides a passageway

between the vacuum connector and the vent connector to permit the vacuum source to draw fluid and exudate from the wound;

Figs. 9-16 illustrate components of another wound care bandage system in accordance with the present disclosure which also provides suction, irrigation, and ventilation to the wound;

Fig. 9 is a part perspective, part diagrammatic view similar to Fig. 1 showing the wound care bandage system of Figs. 9-16 including a two-level stopcock or switch valve in selective communication with the bandage, vacuum source, and irrigation source of the system, and further showing the two-level stopcock including a vent coupled to a filter;

Fig. 10 is an exploded view of the two-level stopcock showing an inner barrel or handle and an outer shell, with portions broken away, and further showing the inner barrel having a grip and a stem including an upper level of ports for communication with either the vacuum source or the irrigation source, depending on the position of the inner barrel relative to the outer shell, and a lower level of ports for communication with the vent, and further showing an inner vent groove of the outer shell for providing communication between the outer lumens of the multi-lumen tube and the lower level ports of the barrel;

Figs. 11-16 show three positions of the two-level stopcock provided by moving the inner barrel relative to the outer shell to selectively align certain upper level ports of the inner barrel with the vacuum and irrigation connectors of the outer shell and to selectively align certain lower level ports with the vent of the outer shell;

Figs. 11 and 12 show the two-level stopcock in a vented vacuum position so that the vacuum source and vent are in communication with the wound to create a negative pressure adjacent the wound while drawing air into the system through the vent and over the wound to aspirate the passageways of the system;

Fig. 11 is a top view of the two-level stopcock in the vented vacuum position showing a passageway (in phantom) connecting the vacuum connector and the multi-lumen tube connector;

Fig. 12 is a sectional view taken along line 13-13 of Fig. 9 when the two-level stopcock is in the vented vacuum position showing venting passageways of the inner barrel and showing one passageway connecting the vent groove of the outer shell with the vent;

Figs. 13 and 14 show the two-level stopcock in a vacuum position where only the vacuum source is in communication with the wound to create a negative pressure adjacent the wound;

Fig. 13 is a top view similar to Fig. 11 of the stopcock in the vacuum position after the handle has been turned clockwise from the vented vacuum position shown in Fig. 11, and showing a passageway (in phantom) between the vacuum connector and the multi-lumen tube connector;

Fig. 14 is a sectional view similar to Fig. 12 showing the two-level stopcock in the vacuum position where none of the venting passageways of the inner barrel connect the vent groove of the outer shell with the vent;

Figs. 15 and 16 show the two-level stopcock in a vented irrigation position where the irrigation source and the vent are in communication with the wound;

Fig. 15 is a top view similar to Figs. 11 and 13 showing the two-level stopcock in the vented irrigation position after the handle has been turned clockwise from the vacuum position shown in Fig. 13, and showing a passageway (in phantom) between the irrigation connector and the multi-lumen connector;

Fig. 16 is a sectional view similar to Figs. 12 and 14 showing the two-level stopcock in the vented irrigation position and showing a passageway of the inner barrel connecting the vent groove of the outer shell with the vent;

Figs. 17-19 show a multi-lumen tube coupler according to the present disclosure for use with either of the systems illustrated in Figs. 1-8 and Figs. 9-16 described above for coupling two multi-lumen tubes together;

Fig. 17 is a part perspective, part diagrammatic view of the multi-lumen tube coupler in use with the system shown in Figs. 9-16;

Fig. 18 is a perspective view of the multi-lumen tube coupler showing an inner passageway for communication with each inner lumen of the multi-lumen tubes and an outer passageway for communication with each outer lumen of the multi-lumen tubes, and also showing a contoured upper surface and a flat bottom surface of the tube coupler;

Fig. 19 is a sectional view of the multi-lumen tube coupler coupled to two multi-lumen tubes showing a flow path of fluids through the multi-lumen tubes and the coupler;

Figs. 20 -28 illustrate components of yet another wound care bandage system in accordance with the present disclosure for providing suction, irrigation, and ventilation to the wound;

Fig. 20 is a part perspective, part diagrammatic view similar to Fig. 1 showing the wound care bandage system of Figs. 20-28 including a vent coupled to the bandage via a multi-lumen tube (shown in Fig. 21) and a stopcock or switch valve coupled to the vent (via two single-lumen tubes) to provide selective communication between the bandage and the irrigation and vacuum sources;

Fig. 21 is an end view of the multi-lumen tube of the system shown in Figs. 20-28 showing the tube including a vacuum lumen, an irrigation lumen, and four outer vent lumens formed within a body of the tube;

Fig. 22 is a perspective view of a "Y-connecter" of the system shown in Figs. 20-28 for coupling the wound dressing member of the bandage with the multi-lumen tube shown in Fig. 21 showing a bandage portion of the connector for insertion within a connector of the member, a vacuum portion for insertion within the vacuum lumen of the multi-lumen tube, and an irrigation portion for insertion within the irrigation lumen of the multi-lumen tube;

Fig. 23 is a perspective view of the vent of the system shown in Fig. 20 showing a multi-lumen connector for coupling with the multi-lumen tube of Fig. 21, a vacuum connector for communication with the vacuum source via a single-lumen tube, an irrigation connector for communication with the irrigation source via a separate single-lumen tube, and also showing a filter housing coupled to the multi-lumen connector for communication with the venting lumens of the multi-lumen tube and with the atmosphere;

Fig. 24 is a sectional view of the vent coupled to the multi-lumen tube and the two single-lumen tubes showing a filter of the vent (in phantom), the separate vacuum, irrigation, and vent passageways formed through the vent, and also showing the Y-connecter of the system coupled to the multi-lumen tube and to the member;

Fig. 25 is an exploded perspective view of the stopcock or switch valve of the system shown in Figs. 20-28 showing two separate passageways through a body of the stopcock for separate communication with the vacuum source and the irrigation source, and showing a handle or diverter, having two cut-out portions, to be received within the body of the stopcock;

Figs. 26-28 are sectional views showing the stopcock in an irrigation position, a vacuum position, and an off position;

Fig. 26 is a sectional view of the stopcock showing the stopcock in the vacuum position so that a first cut-out portion of the handle creates a passageway between first and second portions of a vacuum conduit of the stopcock;

Fig. 27 is a sectional view similar to Fig. 26 showing the stopcock in the irrigation position where the handle has been rotated in a clockwise direction from that shown in Fig. 26 so that a second cut-out portion (shown in phantom) connects first and second portions of an irrigation conduit with each other;

Fig. 28 is a sectional view similar to Figs. 26 and 27 showing the stopcock in the off position where the handle has been rotated 180 degrees from that shown in Fig. 27 so that neither the first nor the second cut-out portions connect the first and second portions of either of the vacuum conduit or the irrigation conduit;

Figs. 29-31 illustrate components of still another vacuum bandage system of the present disclosure which provides suction, irrigation, and ventilation to a wound;

Fig. 29 is a part perspective and part diagrammatic view of a vacuum bandage system of the present disclosure showing a wound dressing member of the bandage including a cover having a port and a wound contacting layer having a wound contacting surface and channels formed in an opposite surface to cooperate with the cover and form passageways of the member in communication with the port and a vacuum source and/or an irrigation source, and also showing a vent line or tube having a first end for communication with the passageways and a second end in communication with the surrounding atmosphere through a filter and a cap;

Fig. 30 is a sectional view of the bandage of Fig. 29 positioned within a wound and showing a sealing film of the bandage providing a sealed vacuum space above the wound, the first end of the vent line in communication with the vacuum space, and the second end of the vent line coupled to the filter and to the cap outside of the vacuum space;

Fig. 31 is a sectional view taken along line 31-31 of Fig. 30 showing the vent line and a vacuum tube coupled to each other by a coupler;

Fig. 32 is a sectional view of an alternative vent line and vacuum tube showing a multi-lumen tube having a vent passageway and a vacuum tube

passageway formed therein and separated by a partition; and

Fig. 33 is a sectional view of yet another vent line and vacuum tube combination showing an outer wall of the vent line and an outer wall of the vacuum tube integrally coupled to one another to form a single multi-lumen tube.

DETAILED DESCRIPTION OF THE DRAWINGS

A wound care bandage system is provided which has the capability to create negative pressure adjacent the wound, to irrigate the wound, and to ventilate the wound. A vent of the system is provided to communicate with the wound and with the surrounding atmosphere. In some embodiments, a vent-valve apparatus or a vent and valve combination of the system is in communication with the wound and with a vacuum source and an irrigation source of the wound. The vent-valve apparatus includes the vent which is in communication with the surrounding atmosphere and a diverter to provide selective communication between the wound and the irrigation source or between the wound and the vacuum source, as is described in greater detail below.

One embodiment of a wound care bandage system 10 is shown in Figs. 1-8 and is provided to allow a caregiver to create a negative pressure above a wound surface (not shown) of a wound 200 (see Fig. 20) through the use of an illustrative vacuum bandage 14 and a vacuum source 16, as shown in Fig. 1. System 10 further allows a caregiver to irrigate the wound surface through the use of an irrigation source 18. Additionally, system 10 ventilates the wound during the application of negative pressure to the wound and irrigation of the wound through use of a vent 19 in communication with the surrounding atmosphere.

The system 10 further includes a stopcock or switch valve 50 coupled to vent 19. Switch valve 50 allows a caregiver to selectively provide communication between the wound and either vacuum source 16 or irrigation source 18. As is herein defined, the terms switch valve and stopcock are used interchangeably to describe an apparatus for selectively controlling and/or diverting fluid flow therethrough. As shown in Fig. 1, switch valve 50 is coupled to vent 19 via a single-lumen tube 52. However, switch valve 50 may also be coupled directly to vent 19, as shown in Fig. 5 and described in more detail below. The vent 19 and switch valve 50 (and tube 52, if used) cooperate to create a vent-valve assembly 80 to allow a caregiver to toggle

between different modes such as vented vacuum therapy and vented irrigation therapy. The system 10 incorporates two separate fluid lines. One fluid line selectively provides vacuum suction or irrigation to the wound while the other fluid line vents the system 10 by providing communication between the wound and the surrounding atmosphere to create air flow above the wound.

Vacuum bandage 14, as shown in Fig. 1, is provided for use with the wound and is sealed about the wound by a cover or sealing film 13 of bandage 14 to create a sealed environment between the wound and sealing film 13 in which a negative pressure can be established. Bandage 14 is selectively coupled to both vacuum source 16 and irrigation source 18 through the use of switch valve 50, as is described in more detail below.

Bandage 14 promotes the healing of the wound by providing vacuum therapy to the wound to promote blood flow and remove exudate from the wound surface and by providing for irrigation of the wound with fluids such as saline, for example. An illustrative wound treatment apparatus having a wound temperature control system, a medicine delivery system, and a drainage system is disclosed in U.S. Patent No. 6,458,109. An illustrative vacuum and irrigation system is disclosed in U.S. Patent Publication No. US 2002/0161317 A1. Additionally, an illustrative vacuum bandage is disclosed in U.S. Patent Publication No. US 2002/0065494 A1. Alternative vacuum bandages are disclosed in U.S. Patent Publication No. US 2002/0082567 A1. Further, a vacuum bandage system including a controller of the system is disclosed in U.S. Patent Application No. 10/159,583 filed on May 31, 2002, titled WOUND TREATMENT APPARATUS and in U.S. Patent Application No. 10/159,720 filed on May 31, 2002, titled WOUND TREATMENT APPARATUS. All of these applications are hereby incorporated herein by reference.

As mentioned above, system 10 incorporates two separate fluid lines to provide vented vacuum therapy and vented irrigation therapy to the wound. Venting of bandage 14 is disclosed in U.S. Patent Application Serial No. 60/344,588 filed on December 26, 2001. This application is hereby incorporated herein by reference. Venting provides for increased air flow through bandage 14 and above or adjacent the wound while vacuum source 16 applies suction to the wound. System 10 is also vented while irrigation source 18 provides fluid to the wound. Without providing for ventilation of the system 10 during operation of vacuum source 16, a generally closed

system is created between vacuum bandage 14 and vacuum source 16. For example, in bandages without a ventilation system, once the requisite amount of air has been removed by the vacuum source 16 to create a predetermined negative pressure at the wound surface, it is possible for the system to become generally static, inhibiting much, if any, fluid flow from the wound surface. In some embodiments disclosed herein, static conditions may be created at the wound surface.

Ventilation of the system 10, while drawing a negative pressure over the wound, acts to prevent the system 10 from becoming static by drawing air in from the surrounding atmosphere through vent 19, to bandage 14 to create air flow above the wound, and out through a vacuum tube in communication with vacuum source 14. Therefore, venting the system 10 increases air flow above the wound while vacuum source 16 applies suction to the wound.

The two fluid lines for ventilation and vacuum/irrigation of the wound are provided in multi-lumen tube 20, shown in cross-section in Fig. 4. As shown in Fig. 3, tube 20 is coupled to a connector 15 of bandage 14, and is therefore in communication with the wound at one end 21 and is coupled to vent 19 at the other end 23. Tube 20 includes an inner lumen 22 for selective communication with the vacuum source 16 and the irrigation source 18 and outer lumens 24 formed in a body or outer wall 25 of tube 20 for communication with the surrounding atmosphere through vent 19. Inner lumen 22 thus defines a portion of a vacuum/irrigation passageway 42 and outer lumens 24 each define a portion of a ventilation passageway 44.

As shown in Fig. 4, tube 20 includes four outer lumens 24 spaced about inner lumen 22. It is within the scope of this disclosure, however, to include a multi-lumen tube having one or more outer lumens in communication with the surrounding atmosphere and one or more inner lumens in selective communication with the vacuum source 16 and the irrigation source 18. Illustratively, the outer diameter 26 of tube 20 is 0.250 inch (6.300 mm), the inner diameter 28 of tube 20 (the diameter of inner lumen 22) is 0.125 inch (3.150 mm), and the diameter 29 of each outer or peripheral lumen is 0.014 inch (0.353 mm). Although tube 20 includes the above dimensions, it is within the scope of this disclosure to provide any suitable multi-lumen tube having lumens of any suitable size.

As shown in Fig. 3, bandage 14 illustratively includes a thin, flexible

wound dressing member 12 having connector 15 coupled to tube 20 by a barbed tube coupler 11. Member 12 lies adjacent to and generally conforms to the wound surface. Sealing film 13 is placed over member 12 and sealed around tube 20 to the patient's healthy skin 27 surrounding the wound, as shown in Fig. 1. Illustratively, connector 15 is in communication with the wound by a plurality of passageways 66 of member 12 and a plurality of holes 67, each in communication with one of the passageways 66, formed in a bottom surface 68 of member 19. Tube coupler 11 connects inner lumen 22 of tube 20 with connector 15. Each outer lumen 24 is open at an end 21 of tube 20. This allows air to be drawn in from the atmosphere through vent 19, to flow through outer lumens 24 and exit tube 20 at end 21, to circulate around member 12 to the wound surface, and to flow through the holes 67 and passageways 66 of member 12 into a vacuum/irrigation passageway 42 formed in part by lumen 22. The negative pressure created by vacuum source 16 causes air to flow through system 10 in this manner.

Although bandage 14 is described above, it is within the scope of this disclosure for the system 10, and other alternative systems described below, to include any suitable bandage or wound dressing member coupled to the vacuum source 16 to communicate negative pressure from the vacuum source 16 to the wound. Bandage 14, therefore, is merely an illustrative bandage of the wound care bandage systems disclosed herein.

As mentioned above, system 10 further includes vent 19. Vent 19 is coupled to end 23 of tube 20, as shown in Fig. 1, and is illustratively shown to be coupled to patient's healthy skin 27 by tape 94, for example. As shown in Figs. 2 and 3, vent 19 includes a multi-lumen or wound connector 30 for coupling with multi-lumen tube 20 and a single-lumen connector 32 for coupling with single-lumen tube 52 or for coupling directly to switch valve 50, as shown in Fig. 5. Vent 19 further includes a filter 34, shown in phantom in Figs. 2 and 3, housed within a filter housing 40. Multi-lumen connector 30 includes an inner conduit 36 and an outer conduit 38 concentric and coaxial with inner conduit 36 along an axis 39, as shown in Fig. 3. An edge 41 of inner conduit 36 is substantially coplanar with an edge 43 of outer conduit 38. An annular space 45 is defined between a cylindrical inner surface 47 of outer conduit 38 and a cylindrical outer surface 53 of inner conduit 36.

Inner conduit 36 is in communication with vacuum source 16 and

irrigation source 18 through stopcock 50 and defines a portion of the vacuum/irrigation passageway 42. The vacuum/irrigation passageway 42 extends through inner lumen 22, a portion of vent 19 and stopcock 50. Outer conduit 38, or annular space 45, is in communication with the surrounding atmosphere and defines a portion of vent passageway 44. The vent passageway 44 extends through outer lumens 24 and a portion of vent 19 to the surrounding atmosphere.

As shown in Fig. 3, a ridge or stop 59 is coupled to inner surface 47 of outer conduit 38 to prevent tube 20 from being inserted too far within connector 30 and thus sealing off outer lumens 24. Stop 59 prevents vent passageway 44 from becoming closed off and keeps vent passageway 44 open to receive air from the surrounding atmosphere. Vent 19 includes three evenly spaced stops 59 coupled to inner surface 47. It is within the scope of this disclosure, however, to include a vent having any number of stops 59 or the like to prevent vent passageway 44 from becoming closed off.

When connecting multi-lumen tube 20 with vent 19, inner conduit 36 is received within inner lumen 22 of tube 20. Wall 25 of tube 20, which includes outer lumens 24, is received within annular space 45 of connecter 30. Tube 20 is, therefore, press fit into connector 30 and, if desired, may be permanently coupled to connecter 30 through the use of adhesives applied to the appropriate surfaces of connecter 30 and/or tube 20.

Connector 32 is received within single-lumen tube 52 when connecting vent 19 to tube 52. Tube 52 is press fit onto connector 32 so that an end 65 of single-lumen tube 52 abuts an annular shoulder surface 69 of conduit 30. As noted above, vent 19 may also be coupled directly to switch valve 50 through the use of a luer lock connection shown in Fig. 5 and discussed further below.

As shown in Fig. 3, vent 19 includes an opening or passageway 46 leading between outer conduit 38 and filter 34 to connect annular space 45 with the surrounding atmosphere. Opening 46 extends radially away from conduit 30 and is generally perpendicular to axis 39. Opening 46 is defined by cylindrical wall 27. Illustratively, opening 46 has a diameter of 0.100 inch (2.54 mm), however, it is within the scope of this disclosure to include a vent having any suitably sized opening for receiving air from the surrounding atmosphere.

Further illustratively, filter 34, is a 0.2 micron anti-microbial filter for

preventing bacteria and other microorganisms in the atmosphere from entering the vent 19 and traveling along vent passageway 44 below sealing film 13 of bandage 14 to the wound. Such an air filter, for example, is made by W.L. Gore & Associates, Inc. of Elkton, MD. As mentioned above, filter 34 is housed within housing 40. Housing 40 has a circular top wall 31, a cylindrical sidewall 33, and a circular bottom wall (not shown). Filter 34 is a generally circular dish of material sandwiched between top wall 31 and the bottom wall. The bottom wall has apertures, openings, or the like so that filter 34 is in communication with the surrounding atmosphere. Further, the bottom wall is removable so that filter 34 may be replaced if needed. Vent 19 further includes reinforcement ribs 35 appended to top wall 31 of housing 40 and wall 27 defining passageway 46.

In operation, vent 19 is used during both vacuum and irrigation modes of the system. As mentioned before, vent 19 provides increased air flow through bandage 14 and above the wound. Vent 19 also creates an open system and prevents the system from becoming static. The air flow path while vacuuming the system begins as air is drawn in from the surrounding atmosphere into filter housing 40 of vent 19 and through filter 34. The air then travels through opening 46 into annular space 45 defined by outer conduit 38 and through outer lumens 24 of multi-lumen tube 20. The air travels through the outer lumens 24 from vent end 23 of tube 20 to end 21 of tube 20, a portion of which is positioned under sealing film 13, to communicate with the wound. Vacuum source 16 then draws the air around wound dressing member 12 through passageways 66 at an open peripheral edge of member 12 and through holes 67 into passageways 66. Air is then drawn from passageways 66 into connector 15 of member 12, through barb 11, and through inner lumen 22 of multi-lumen tube 20 toward vacuum source 14.

It is also within the scope of the disclosure for the caregiver to close off vent 19 while vacuuming or irrigating the wound. Vent 19 may be closed in a number of ways. For example, a cap or valve (not shown) may be coupled to filter 34 or filter housing 40 to prevent air flow through filter 40. It is within the scope of this disclosure to include a vent having other suitable means of preventing air flow therethrough.

As shown in Fig. 3 and mentioned above, inner conduit 36 and outer conduit 38 form separate passageways through vent 19. Inner conduit 36 is in

communication with and forms a portion of vacuum/irrigation passageway 42 which extends through inner lumen 22, a portion of vent 19 and on to switch valve 50. Outer conduit 38 is in communication with and forms a portion of vent passageway 44, which extends through outer lumens 24 and a portion of vent 19. Vent passageway 44 is in communication with the atmosphere through filter 34.

As shown in Fig. 1, system 10 further includes switch valve 50. Switch valve 50 is positioned between vent 19 and vacuum and irrigation sources 16, 18. Single-lumen tube 52 is coupled to and extends between single-lumen connector 32 of vent 19 and switch valve 50 and forms a portion of vacuum/irrigation passageway 42. Switch valve 50, includes a vent connector 54 which can be coupled either to single-lumen tube 52, as shown in Fig. 1, or directly to connecter 32 of vent 19, as shown in Fig. 5, through the use of a luer lock. Single-lumen connector 32 includes a female thread portion 55 of the luer lock, and vent connector 54 of switch valve 50 includes a male portion 57 of the luer lock so that the two can be coupled together.

As shown in Fig. 5, switch valve 50 includes a body 60 and a handle or diverter 51 coupled to body 60. Body 60 includes vent connector 54, a vacuum connector 56 in communication with vacuum source 16, and an irrigation connector 58 in communication with irrigation source 18. Vent connector 54 forms another portion of vacuum/irrigation passageway 42 and is in selective communication with vacuum source 16 and irrigation source 18. Vacuum/irrigation passageway 42 therefore extends from end 21 of inner lumen 22 of multi-lumen tube 20 to multi-lumen connector 30 of vent 19, through inner conduit 36 of vent 19, out connector 32 of vent 19, to vent connector 54 of switch valve 50 and partially through switch valve 50 to diverter 51 of switch valve 50.

Switch valve 50 includes diverter 51 for selectively providing communication between vacuum source 16 and bandage 14 and between irrigation source 18 and bandage 14. Diverter 51 includes a grip 62 and a stem 64 coupled to grip 62, as show in Figs. 6a and 6b. Diverter 51 is rotatably movable relative to body 60 to selectively provide communication between either vent connector 54 and irrigation connector 58 or between vent connector 54 and vacuum connector 56. A caregiver rotates diverter 51 between an irrigation position shown in Fig. 7 and a vacuum position shown in Fig. 8 depending on whether the wound is to receive

vacuum or irrigation treatment, respectively. Switch valve 50 allows the caregiver to easily switch between communication with vacuum source 16 and irrigation source 18 without the need to disconnect or reconnect various tubes from each of the vacuum source 16 and/or irrigation source 18, for example.

As shown in Figs. 7 and 8, body 60 includes an aperture 61 for receiving stem 64 of diverter 51. Vent connector 54, vacuum connector 56, and irrigation connector 58 each form a respective opening 82, 84, 86 in communication with aperture 61. As diverter 51 is rotated, a cut-out portion 63 of stem 64 provides a passageway between vent connector 54 and vacuum connector 56 when diverter 51 is in the vacuum position, for example. When diverter 51 is in the irrigation position, cut-out portion 63 provides a passageway between vent connector 54 and irrigation connector 64. Diverter 51 is also movable to an off position where cut-out portion 63 does not provide any communication between the connectors 54, 56, 58.

In addition to vacuum/irrigation passageway 42 and vent passageway 44, system 10 further includes a separate vacuum passageway 70 and a separate irrigation passageway 72. Vacuum connector 56 defines a portion of vacuum passageway 70 and irrigation connector 58 defines a portion of irrigation passageway 72. As shown in Fig. 1, vacuum connector 56 is coupled to a vacuum tube 74 which is, in turn, coupled to vacuum source 16. The vacuum passageway 70, therefore, extends from opening 84 of body 60 through vacuum connector 56 and vacuum tube 74 to vacuum source 16.

As shown in Fig. 1, irrigation connector 58 is coupled to an irrigation tube 76 which is, in turn, coupled to irrigation source 18. The irrigation passageway 72, therefore, extends from opening 86 of body 60 through irrigation connector 58 and irrigation tube 76 to irrigation source 18. Thus, at opening 82 of body 60, vacuum/irrigation passageway 42 ends and is split into separate vacuum and irrigation passageways 70, 72.

As shown in Fig. 5, an attachment 88 is coupled to irrigation connector 58. Attachment 88 includes a first inlet 90 for communication with irrigation tube 76 and irrigation source 18 and a second inlet 92 for communication with a hand-held syringe (not shown). Attachment 88 provides two means of introducing fluids into system 10. Second inlet 92 allows a caregiver to manually introduce fluids into system 10 while irrigation source 18 includes automatic controls for introducing

fluids into system 10 through first inlet 90. A slot 96 of irrigation connector 58 receives a portion of second inlet 92 to secure attachment 88 within irrigation connector 58.

As mentioned above, system 10 allows a caregiver to treat the wound using vented vacuum therapy through the use of vent 19 with vacuum source 16 and using vented irrigation therapy through the use of irrigation source 18 and vent 19. To provide vented vacuum therapy to the wound, the caregiver moves diverter 51 to the vacuum position, shown in Fig. 8, so that cut-out portion 63 of stem 64 connects opening 82 of vent connector 54 with opening 84 of vacuum connector 56. Therefore, irrigation connector 58 and irrigation passageway 72 are closed off and vacuum/irrigation passageway 42 is connected with vacuum connector 56 and vacuum passageway 70. Vent passageway 44 is kept open to the surrounding atmosphere. The negative pressure provided by vacuum source 16 above wound 12 acts to draw air in from the atmosphere through filter 34 of vent 19 and outer lumens 24. As mentioned above, vent 19 is provided to aspirate the system 10 by creating an air flow path from the atmosphere to the bandage 14, over the wound, and out through inner lumen 22 in communication with vacuum source 16.

To create vented irrigation of wound 12, a caregiver moves diverter 51 to the irrigation position so that cut-out portion 63 of stem 64 connects opening 82 of vent connector 54 with opening 56 of irrigation connector 58. Therefore, irrigation passageway 72 of the irrigation connector 58 is in communication with the vacuum/irrigation passageway 42 of the vent connector 54. The vacuum passageway 70 is thus cut off from communication with the vacuum/irrigation passageway 42. Irrigation fluid is then dispensed from irrigation source 18 through irrigation passageway 72 of tube 76 and switch valve 50 to the vacuum/irrigation passageway 42 through vent connector 54, tube 52, vent 19, and inner lumen 22 of multi-lumen tube 20 to wound 12. Vent 19 is left in an open position to allow air to flow out of bandage 14 while fluid from irrigation source 18 is channeled to the wound. As mentioned above, it is also within the scope of this disclosure to provide non-vented irrigation of the wound by closing off vent 19 from the surrounding atmosphere while providing fluid to the wound through irrigation source 18.

As mentioned above, the combination of vent 19, and switch valve 50 is defined as vent-valve assembly 80. If desired, assembly 80 may also include tube

52 or another conduit or passageway between vent 19 and switch valve 50. Assembly 80 provides a caregiver with the ability to toggle or selectively switch between the vented vacuum mode of therapy and the vented irrigation mode of therapy for the treatment of the wound. As mentioned above, it is within the scope of this disclosure to include a vent which is able to be closed off from communication with the surrounding atmosphere so that vacuum only and/or irrigation only therapy may be provided as well.

An alternative vent-valve assembly 180 is provided for use with system 10, as shown in Figs. 9-16. Assembly 180 includes a stopcock or valve portion in selective communication with vacuum source 16 and irrigation source 18 and a vent portion in communication with the surrounding atmosphere. Assembly 180 is configured to selectively provide three modes of therapy: vacuum therapy, vented vacuum therapy, and vented irrigation therapy.

As shown in Fig. 9, vent-valve assembly 180 is positioned between illustrative bandage 14 of system 10 and vacuum and irrigation sources 16, 18. Assembly 180 serves a similar function as assembly 80, including vent 19 and stopcock 50, shown in Figs. 1-8. Similar to assembly 80, assembly 180 is in communication with bandage 14, vacuum source 16, and irrigation source 18 of system 10. Assembly 180 is operated by a caregiver during the treatment of a patient to change from mode to mode as desired.

As shown in Fig. 10, assembly 180 includes an outer shell or body 110 and a diverter or inner barrel 112. Inner barrel 112 is normally positioned within outer shell 110, as shown in Fig. 9, and is rotatable relative to outer shell 110 between three different positions which correlate with the three available modes: vacuum, vented vacuum, vented irrigation. Outer shell 110 includes a cylindrical hub 114 having an outer surface 116 and in inner surface 118, shown in Fig. 10. Outer shell 110 further includes a multi-lumen or wound connector 130, a vent 119, a vacuum connector 156, and an irrigation connector 158. Suitable coupling means such as a C-clip (not shown) to fit around inner barrel 112, a pin (not shown) through outer shell 110 and inner barrel 112, for example, are provided to prevent inner barrel or diverter 112 from being inadvertently separated from body 110. Such coupling means are also provided for use with stopcocks 50 and 250 (discussed below) to prevent the handle of each from being inadvertently decoupled from the body of each.

Similar to multi-lumen connector 30 of vent 19, multi-lumen connector 130 of assembly 180 includes inner conduit 36 and outer conduit 38 spaced apart from and concentric with inner conduit 36. Inner conduit 36 defines a portion of vacuum/irrigation passageway 42 and outer conduit 38 defines a portion of vent passageway 44 of system 10. Inner conduit 36 is received within inner lumen 22 of tube 20. Wall 25 of tube 20, which includes outer lumens 24, is received within outer conduit 38 of multi-lumen connector 130. As shown in Fig. 9, inner conduit 36 is coupled to a barb 37. Barb 37 is received within inner lumen 22 as well and helps maintain the connection between tube 20 and multi-lumen connector 130. It is within the scope of this disclosure for multi-lumen connector 30 of vent 19 to have barb 37 formed integrally with inner conduit 36.

As shown in Fig. 10, outer conduit 38 includes a partition 48 having multiple vent holes 49 formed therethrough. Air traveling through lumens 24 also travels through the holes 49 to a vent grove 122 formed in inner surface 118 of hub 114. It is not necessary for outer lumens 24 of tube 20 to align directly with one of the vent holes 49. A stop (not shown), similar to stop 59, is coupled to inner surface 47 of outer conduit 38 to prevent tube 20 from being inserted too far within connecter 130. Vent groove 122 connects outer conduit 38 with vent 119, as is described in more detail below.

Vacuum connector 156 communicates with vacuum source 16 through vacuum tube 74. Vacuum connector 156 includes barb 37 received within tube 74. Vacuum connector 156 and vacuum tube 74 form vacuum passageway 70 of system 10. Irrigation connector 158 communicates with irrigation source 18 through irrigation tube 76, as shown in Fig. 17. Irrigation connector 158 and irrigation tube 76 form the irrigation passageway 72 of system 10. Vacuum connector 156 and irrigation connector 158 are each in selective communication with multi-lumen connector 130, as is described below. As shown in Fig. 9, air filter 34, contained within a housing 124, is coupled to vent 119 and is received within an aperture 120 (shown in Fig. 10) of vent 119. Housing 124 includes an air inlet tube 126 and a connector tube 128 coupled to vent 119 and in communication with aperture 120 of vent 119.

Diverter 112, as shown in Fig. 10, includes a grip 162 and a cylinder or stem 164 coupled to grip 162. Cylinder 164 includes an upper level of holes and a

lower level of holes, as shown in Fig. 10. As shown in phantom in Figs. 11, 13, and 15, the upper level of holes includes first, second, third, fourth, and fifth holes 166, 168, 170, 172, 174, respectively. As shown in Figs. 12, 14, and 16, the lower level of holes includes first, second, third, and fourth holes 182, 184, 186, and 188, respectively. The upper level of holes communicate with inner conduit 36 of multi-lumen connector 130 and with each of the vacuum and irrigation connectors 156, 158. The lower level of holes communicate with outer conduit 38 and aperture 120 of vent 119. The upper holes of cylinder 164 form interconnecting passageways through cylinder 164 to selectively connect inner conduit 36 with vacuum conduit 156 and irrigation conduit 158 and the lower holes form passageways through cylinder 164 to selectively connect outer conduit 38 with vent 119, as is described in more detail below.

As shown in Figs. 11 and 12, assembly 180 is in the vented vacuum position. As shown in Fig. 11, the upper holes are positioned so that hole 166 is in communication with inner conduit 36 and hole 170 is in communication with vacuum connector 156 to provide a passageway between inner conduit 36 and vacuum connector 156. The other holes 168, 172 and 174 are not in communication with any of the connectors 130, 156, 158 of outer shell 110. Looking now to the lower level of holes shown in Fig. 12, hole 182 is in communication with vent groove 122 and hole 186 is in communication with aperture 120 of vent 119 to provide a passageway between vent groove 122 and vent 119 so that outer lumens 24 of tube 20 are in communication with the surrounding atmosphere.

By rotating grip 162 clockwise (as viewed from the top of apparatus 180), a caregiver rotates inner barrel 112 relative to outer shell 110 to move assembly 180 to the vacuum position shown in Figs. 13 and 14. In the vacuum position, upper level hole 174 is in communication with inner conduit 36 of multi-lumen connector 130 and hole 168 is in communication with vacuum connector 156 to provide a passageway between inner conduit 36 and vacuum connector 156. In the vacuum position, however, vent passageway 44 of system 10 is prevented from communicating with the surrounding atmosphere through vent 119. As shown in Fig. 14, for example, none of the lower level holes are in communication with either vent groove 122 or aperture 120 of vent 119.

By rotating grip 162 still further clockwise, a caregiver rotates inner

barrel 112 relative to outer shell 110 to move assembly 180 to the vented irrigation position shown in Figs. 15 and 16. Fig. 15 shows the orientation of the upper level holes of the inner barrel 112 while assembly 180 is in the vented irrigation position. Hole 172 is in communication with inner conduit 36 of multi-lumen connector 130 and hole 166 is in communication with irrigation connector 158 to provide communication between inner conduit 36 and irrigation connector 158. Fig. 16 shows the orientation of the lower level holes when stopcock 180 is in the vented irrigation position. Hole 188 is in communication with vent groove 122 and hole 184 is in communication with aperture 120 of vent 119 so that outer conduit 38 is in communication with vent 119 to allow air from the surrounding atmosphere to enter system 10. It is also within the scope of this disclosure for assembly 180 to be in an "off" position where none of the upper level passageways connect any of the connecters 130, 158, 156 with each other, and where none of the lower level passageways connect the vent grove 122 with the vent 119.

Referring now to Figs. 17-19, a tube coupler 140 is provided for use with system 10. As shown in Fig. 17, coupler 140 is positioned between bandage 14 and assembly 180. It is within the scope of this disclosure, however, to position a tube coupler between bandage 14 and assembly 80 shown in Fig. 1. Coupler 140 connects or couples two multi-lumen tubes together. Coupler 140 allows a caregiver to disconnect a portion of system 10 between bandage 14 and assemblies 80 or 180. As shown in Figs. 17-19, coupler 140 couples multi-lumen tube 20 to another multi-lumen tube 17.

Coupler 140 includes an outer body 142 having a curved upper surface 144 and a generally flat bottom surface 146. Outer body 142 defines a passageway 148 therethrough for receiving a portion of a multi-lumen tube at a first end 136 and at a second end 138. Passageway 148 is defined by an inner surface 149 of body 142. Coupler 140 further includes an inner conduit 150 which defines a portion of vacuum/irrigation passageway 42. Inner conduit 150 is positioned within passageway 148. A portion of vent passageway 44 is annular and is defined between inner surface 149 of body 142 and an outer surface 151 of inner conduit 150. Coupler 140 further includes a central partition 152 formed around conduit 150 and connected to inner surface 149. Partition 152 includes three generally evenly spaced holes 154 for the vented air to flow through.

An end of tube 20 is inserted into first end 136 of coupler 140 and an end of tube 17 is inserted into second end 138 of coupler 140, as shown in Fig. 19, so that inner conduit 150 is received within the inner lumen 22 of each tube 20, 17. As mentioned above, multi-lumen tubes 20, 17 include four outer lumens 24 formed in wall 25. As shown in Fig. 19, tubes 20, 17 are inserted into coupler 140 and are generally spaced-apart from partition 152 so that air flowing through the four outer lumens 24 of tube 17 flows into an open space 155 on the right side of partition 152, as shown in Fig. 19, through holes 154 of partition 152 and into an open space 157 located on the left side of partition 152 into outer lumens 24 of tube 20.

Tube coupler 140 may also be used to aide in effectively securing sealing film 13 of bandage 14 over or around tube 20. For example, coupler 140 may be placed on the patient's healthy skin adjacent the wound. The film 13 may then be placed over curved upper surface 144 of coupler 140 and effect a seal around coupler 140 to create a sealed environment between film 13 and the wound. Coupler 140, therefore, may also act to prevent leaks in the vacuum space created below film 13. Coupler 140 further includes a ridge or stop 153 coupled to inner surface 149 to each of the right and left sides of partition 152 to prevent each respective tube 20, 17 from abutting partition 152 and closing off vent lumens 24 from communication with the surrounding atmosphere. Each open space 155, 157, therefore, is defined between a respective stop 153 and partition 152, as shown in Fig. 19.

Referring now to Figs. 20-28, another illustrative wound care bandage system 210 is provided. System 210 operates similarly to system 10 described above and includes a vent-valve apparatus 280 to provide ventilation while allowing a user to toggle between a vacuum therapy mode and an irrigation therapy mode. As shown in Fig. 20, bandage 14 is coupled to a vent 219 via an alternative multi-lumen tube 220. Specifically, member 12 of bandage 14 is coupled to a "Y-connector" 212 of the system 210 which is coupled to tube 220. Y-connector 212 is shown in more detail in Figs. 22 and 24 and is discussed in more detail below.

Vent-valve apparatus 280 includes a stopcock or switch valve 250 coupled to vent 219 via two single-lumen tubes 216, 218. Switch valve 250 is coupled to both vacuum source 16 and irrigation source 18 to provide selective communication between either the bandage 14 and vacuum source 16 or between bandage 14 and irrigation source 18, as described below.

Vent 219, similar to vent 19, is spaced apart from bandage 14 and is illustratively shown to be coupled to patient's healthy skin 27 by tape 94, for example. Vent 219 is able to provide ventilation to wound 200 (shown in Fig. 20) during the application of negative pressure to wound 200 and during irrigation of wound 200 because vent 219, similar to vents 19 and 119 are in communication with the surrounding atmosphere and with the wound 200.

The wound care bandage system 210 shown in Figs. 20-28 incorporates three separate fluid paths. One fluid path is used exclusively for the purpose of venting the wound 200 with air from the surrounding atmosphere. A second fluid path is used to create a negative pressure adjacent the wound 200, while the third fluid path is used to irrigate the wound 200. Switch valve 250 acts to selectively communicate either the vacuum path or the irrigation path with the wound 200. The three fluid paths for ventilation, vacuum, and irrigation of wound 200 are provided by multi-lumen tube 220.

Multi-lumen tube 220 includes a vacuum lumen 222, an irrigation lumen 224, and four outer venting lumens 226 formed within and defined by a body 228, as shown in Fig. 21. Vacuum lumen 222 is in communication with vacuum source 16, irrigation lumen 224 is in communication with irrigation source 18, and each venting lumen 226 is in communication with the atmosphere through vent 219, as is described below. As shown in Figs. 20 and 24, multi-lumen tube 220 is coupled to an alternative connector 214 of member 12 by Y-connecter 212, and is therefore in communication with the wound 200 at one end 230 and is coupled to vent 260 at another end 232.

Although tube 200 is shown to include four venting lumens 214, it is within the scope of this disclosure to include a multi-lumen tube having one or more venting lumens in communication with the surrounding atmosphere, one or more vacuum lumens in communication with the vacuum source 16, and one or more irrigation lumens in communication with the irrigation source 18. Illustratively, an outer diameter 234 of tube 220 is 0.375 inch (9.53 mm), a diameter 236 of vacuum lumen 222 is 0.125 inch (3.175 mm), a diameter 238 of irrigation lumen 224 is 0.125 inch (3.175 mm), and a diameter 240 of each outer venting lumen 226 is 0.020 inch (0.508 mm). Although tube 220 includes the above dimensions, it is within the scope of this disclosure to provide any suitable multi-lumen tube having lumens of any

suitable size.

As mentioned above, Y-connecter 212 is provided for coupling with alternative connector 214 of vacuum bandage 14. Connector 214 is similar to connector 15 and is in communication with wound 200 through channels 66 and holes 67 of member 12. Connector 214 is different from connector 15 in that connector 214 is positioned at an angle relative to a top surface 242 of member 12 and includes a single angled passageway 244 (as shown in Fig. 24) rather than a vertical passageway connected to a horizontal passageway of connector 15 (as shown in Fig. 3). In the illustrative embodiment, the included angle between an axis along passageway 244 and the top surface 242 of member 12, when member 12 is in a flat configuration, is about 30 degrees.

Illustratively, Y-connecter 212 includes a bandage portion 246, an irrigation portion 248, and a vacuum portion 252, as shown in Fig. 22. Irrigation portion 248 includes a passageway 254 forming a section of the irrigation passageway, vacuum portion 252 includes a passageway 256 forming a section of the vacuum passageway, and bandage portion 246 includes a passageway 258 forming a section of the vacuum/irrigation passageway. The passageway 254 of irrigation portion 248 and the passageway 256 of vacuum portion 252 each merge into passageway 258 of the bandage portion 246. Once bandage portion 246 of Y-connecter 212 splits into the irrigation portion 248 and the vacuum portion 252, the irrigation and vacuum passageways remain separate and distinct passageways through multi-lumen tube 220, vent 219, and switch valve 250 to the respective irrigation source 18 and vacuum source 16.

Bandage portion 246 is press fit into connector 214, as shown in Fig. 24, and includes an angled end 260 to lie adjacent to the top surface 242 of member 12. Irrigation portion 248 is similarly press fit into irrigation lumen 224 of tube 220 and vacuum portion 252 is press fit into vacuum lumen 222 of tube 220. In some embodiments, adhesive or sealant is applied to either or all of portions 246, 248, 252 to further enhance the connection between bandage portion 246 and connector 214 between irrigation portion 248 and tube 220, and between vacuum portion 252 and tube 220. Y-connecter 212 is provided to connect bandage 14 with multi-lumen tube 220 and vent 219.

Referring now to Fig. 23, vent 219 includes a multi-lumen connector

262 for coupling with multi-lumen tube 220, a single-lumen vacuum connector 264 for coupling with a single-lumen tube, such as tube 216, and a single-lumen irrigation connector 266 for coupling with a single-lumen tube, such as tube 218 (as shown in Fig. 20). Tubes 216 and 218 are also coupled to switch valve 250 as shown in Fig. 20 and described in more detail below. It is also within the scope of this disclosure to eliminate the use of tubes 216 and 218 so that vent 219 is coupled directly to switch valve 250. Similar to vents 19, 119, vent 219 further includes filter 34 (shown in phantom), housed within filter housing 40, in communication with multi-lumen connector 262.

Multi-lumen connector 262 includes an outer conduit 272, an inner vacuum conduit 274, and an inner irrigation conduit 276, as shown in Fig. 23. Both vacuum conduit 274 and irrigation conduit 276 are located within outer conduit 272. An edge 278 of outer conduit 272 is substantially coplanar with an edge 281 of vacuum conduit 274 and an edge 282 of irrigation conduit 276. Vacuum conduit 274 is in communication with vacuum source 16 through switch valve 250 and defines a portion of the vacuum passageway. Irrigation conduit 276 is in communication with the irrigation source 18 through switch valve 250 and defines a portion of the irrigation passageway. Outer conduit 252 is in communication with the surrounding atmosphere and defines a portion of the vent passageway.

As shown in Fig. 24, vacuum conduit 274 is received within vacuum lumen 222 of tube 220. Body 228 of tube 220, which includes outer venting lumens 226, is received within a space 284 defined between a cylindrical inner surface 286 of outer conduit 272 and cylindrical outer surfaces 288, 290 of vacuum and irrigation conduits 274, 276, respectively (as shown in Fig. 23). Tube 220 is press fit into the space 284 so that the outer surface of tube 220 abuts cylindrical inner surface 286 of outer conduit 272, so that an inner surface of vacuum lumen 220 abuts the cylindrical outer surface 288 of the vacuum conduit 274, and so that the inner surface of irrigation lumen 224 abuts the cylindrical outer surface 290 of the irrigation conduit 276. In some embodiments, an adhesive material or sealant is applied to the appropriate surfaces of tube 220 and multi-lumen connector 262 to enhance the connection between tube 220 and vent 219.

As shown in Fig. 23, a ridge or stop (not shown) is coupled to and positioned between outer surface 288 of vacuum conduit 274 and outer surface 290 of

irrigation conduit 276 to prevent tube 220 from being inserted too far within connector 262 and thus sealing off outer lumens 226. The stop prevents vent passageway from becoming closed off and keeps vent passageway open to receive air from the surrounding atmosphere. Illustratively, vent 219 includes one stop, however, it is within the scope of this disclosure to include a vent having any number of stops or the like to prevent the vent passageway from becoming closed off from the surrounding atmosphere.

Vacuum connector 264 of vent 219 includes an inner surface 292 defining a portion of the vacuum passageway and an outer surface 294. Vacuum connector 264 is in communication with vacuum conduit 274 of multi-lumen connector 262, as shown in phantom in Figs. 23 and 24. Illustratively, single-lumen tube 216, coupled to vacuum source 16, is press fit into vacuum connector 264, as shown in Fig. 24. Tube 216 may further be permanently or temporarily bonded to vacuum connecter 264 through the use of an adhesive material applied to the appropriate surfaces of tube 216 and connecter 264.

Irrigation connector 266 of vent 219 similarly includes an inner surface 296 defining a portion of the irrigation passageway and an outer surface 298 including a shoulder 300. Irrigation connector 266 is in communication with irrigation conduit 276 of multi-lumen connector 262, also shown in Figs. 23 and 24. Illustratively, single-lumen tube 218 is press-fit into irrigation connector 266, as shown in Fig. 24. Tube 218 may further be permanently or temporarily bonded to irrigation connector 266 through the use of an adhesive material applied to the appropriate surfaces of tube 218 and connector 266. It is within the scope of this disclosure, however, to connect tubes 216 and 218 to the respective irrigation and vacuum connectors 266, 264 through the use of a barb or a luer lock connection, for example.

Outer conduit 272 of multi-lumen connector 262 further includes an opening or aperture 302 in communication with the surrounding atmosphere. Housing 40 for filter 34 is coupled to multi-lumen connector 262 so that a passageway 46 of housing 40 connects space 284 with the filter 34 and the surrounding atmosphere. Passageway 46 extends radially away from outer conduit 272 and is generally perpendicular to an axis running through vacuum conduit 274. Passageway 46 is defined by cylindrical wall 27.

In operation, vent 219 is used during both vacuum and irrigation

modes of the system. As mentioned before with respect to vents 19 and 119, vent 219 provides increased air flow through bandage 14 and above wound 200. Vent 219 also creates an open system and prevents the system from becoming static. Vent 219 further maintains separate vacuum and irrigation passageways. As mentioned before with respect to vents 19, 119, it is within the scope of the disclosure for the caregiver to close off vent 160 while vacuuming or irrigating wound 200. Vent 219 may also be closed in a number of ways. For example, a cap or a valve (not shown) may be coupled to filter 34 or filter housing 40 to prevent air flow through filter 34. It is within the scope of this disclosure to include a vent having other suitable means of preventing air flow therethrough.

Referring now to Figs. 25-28, the stopcock 250 of system 210 includes a diverter or handle 314 and a body 316 defining an aperture 318 for receiving at least a portion of the handle 314. Handle 314 includes a grip 320 and a hub or stem 322 coupled to the grip 320. Hub 322 is received within aperture 318 of body 316. Stopcock or switch valve 250 further includes a vacuum conduit 310 having a first portion 324 coupled to tube 216 and a second portion 326 coupled to a single-lumen tube 328, as shown in Fig. 20. Tube 328, is coupled to vacuum source 16, as shown in Fig. 20. As shown in Figs. 25-28, vacuum conduit 310 defines a portion of the vacuum passageway through body 316. Each single-lumen tube 216, 328 is coupled to the respective first portion 324 and second portion 326 of the stopcock 250 through the use of luer locks (not shown). It is within the scope of this disclosure, however, to connect tubes 216, 328 to stopcock 250 in another suitable manner such as through the use of a barb, by press-fitting each tube 216, 328 onto conduit 310 of stopcock 250, or by slip-fitting each tube 216, 328 into conduit 310, and including the use of adhesive material to permanently or temporarily bond each tube 216, 328 to conduit 310.

Stopcock 250 further includes an irrigation conduit 330 having a first portion 332 coupled to tube 218 and a second portion 334 coupled to a single-lumen tube 336. Tube 336 is coupled to irrigation source 18, as shown in Fig. 20. Irrigation conduit 330 defines a portion of the irrigation passageway through body 316 of stopcock 250. As shown in Fig. 25, irrigation conduit 330 lies below vacuum conduit 310 as indicated by a distance 311 so that the irrigation conduit 330 and vacuum conduit 310 are positioned to lie in separate horizontal planes. Tubes 218, 336 may

be coupled to irrigation conduit 330 by the same or similar means as those discussed above with respect to tubes 216, 328 and vacuum conduit 310.

Hub 322 of handle 314 includes a first or vacuum cut-out portion 340 and a second or irrigation cut-out portion 342. Similar to conduits 310 and 330, cut-out portions 340, 342 do not lie in the same horizontal plane. When hub 322 is received within aperture 318 of body 316, vacuum cut-out portion 340 lies in the same horizontal plane as vacuum conduit 310 and irrigation cut-out portion 342 lies in the same horizontal plane as irrigation conduit 330.

Handle 314, and thus hub 322, is rotatable relative to body 316. Handle 314 is able to be positioned by a caregiver to align the vacuum cut-out portion 340 with the vacuum conduit 310, as shown in Fig. 26, or to align the irrigation cut-out portion 342 with the irrigation conduit 330, as shown in Fig. 27. Further, handle 314 may be rotated to an "off" position where neither cut-out portion 340, 342 is aligned with either of the conduits 310, 330, as shown in Fig. 28. Thus, passageways 344, 346 through conduits 310, 330 each communicate with aperture 318 of body 316.

Referring to Fig. 26, the stopcock 250 is in a vacuum position where vacuum cut-out portion 340 is aligned with vacuum conduit 310, as mentioned above. Vacuum cut-out portion 340 connects first portion 324 of vacuum conduit 310 with second 326 of vacuum conduit 310 so that vacuum source 16 is able to create a negative pressure adjacent the wound 200. When stopcock 250 is in the vacuum position, irrigation cut-out portion 342 is not in communication with the irrigation conduit 330.

Rotating handle 314 about 90 degrees clockwise from the vacuum position aligns irrigation cut-out portion 342 with irrigation conduit 330 in an irrigation position shown in phantom in Fig. 27. Irrigation cut-out portion 342 connects first end 332 of irrigation conduit 330 with second end 334 of irrigation conduit 330 so that the irrigation source 18 is able to send fluids through stopcock 250 to wound 200. When stopcock 250 is in the irrigation position, vacuum cut-out portion 340 is not in communication with the vacuum conduit 310.

To move the stopcock 250 to the "off" position (shown in Fig. 28), the caregiver may either rotate the handle 180 degrees in either direction from the irrigation position (shown in Fig. 27) or the caregiver may rotate the handle 90

degrees in the counter-clockwise direction from the vacuum position (shown in Fig. 26). As mentioned above, neither cut-out portion 340, 342 communicates with either conduit 310, 330 when stopcock 250 is in the "off" position.

As shown in Fig. 25, grip 320 of handle 314 includes an indicator 350 to indicate to the caregiver whether the stopcock 250 is in the vacuum position, irrigation position, or off position. It is within the scope of this disclosure to include a seal, gasket, or o-ring (not shown) between hub 322 and body 316 of stopcock 250 to create a seal between the two components.

Looking now to Figs. 29 and 30, yet another wound care bandage system 400 is provided which has the capability to create negative pressure adjacent wound 200, to irrigate wound 200, and to ventilate wound 200. Ventilated vacuum bandage system 400 is provided for use with wound 200 having a wound surface 413. The system 400 includes a wound dressing member 419 similar to wound dressing member 12, shown in Fig. 24, a vacuum source 16, an irrigation source 18, and a vent 460 in communication with the member 419. The vent 460 is also in communication with the surrounding atmosphere to provide increased air flow above the wound surface 413 and through the member 419 particularly when the vacuum source 16 is operating to create a negative pressure above the wound 200. As is herein defined with respect to all embodiments disclosed herein, the term "vent" is or includes any passageway to the atmosphere, unless noted otherwise.

In one illustrative embodiment, a vacuum bandage 410 is provided for use with wound 200 having wound surface 413, shown in Fig. 30. Bandage 410 includes the wound dressing member 419 and a vent 460 in communication with member 419 as shown in Figs. 29 and 30. Member 419 is illustratively thin and flexible and includes a wound contacting layer 420 and a cover 422 coupled to the layer 420. Member 419 also includes a connector 423 coupled to cover 422 for communication with vacuum source 16 and/or irrigation source 18.

Vacuum bandage 410 is coupled to vacuum source 16 and irrigation source 18 through the use of a switch valve 455, as shown diagrammatically in Fig. 29. Switch valve 455 may be the same as or similar to stopcock 50 and/or assemblies 80, 180, described above, for example. Similar to bandage 14, bandage 410 also promotes the healing of large wound 200 by providing vacuum therapy to the wound 200 to promote blood flow and remove exudate from wound surface 413 and by

providing for irrigation of the wound 200 with fluids such as saline, for example.

Vent 460 of system 400 is provided for increased air flow through bandage 410 and above wound 200 while vacuum source 16 applies suction to wound 200. Without vent 460, a generally closed system is created between vacuum bandage 10 and vacuum source 14. Vent 460, similar to vents 19, 119, 219 discussed above, acts to prevent the system 400 from becoming static by drawing air in from the surrounding atmosphere around bandage 410. Air is drawn through vent 460 to bandage 410 to create airflow above wound 200, through member 419, and out through a vacuum tube 441 coupled to vacuum source 16. A wound care technique disclosing ventilation of the wound is provided in the article "No wound is too big for resourceful nurses" by Margaret Wooding-Scott, RN, CCRN, Barbara Ann Montgomery, RN, ET, and Deborah Coleman, RN, MS, CS as published in the December 1988 edition of the magazine RN.

Referring now to member 419, layer 420, cover 422, and connecter 423 are each made of a medical grade silicone or other type of pliable elastomer. Two companies, for example, which manufacture such medical grade silicone are GE Silicones and NuSil Technology. It is within the scope of this disclosure, however, to include a member made of any suitable type of material. Illustratively, member 419 is made of material that is non-porous and non-foam-like. This thin, flexible material is also generally non-absorptive. For example, materials such as polyvinylchloride (PVC), PVC free of diethylhexyl phthalate (DEHP-free PVC), polyurethane, or polyethylene may be used in the manufacture of member 419. However, as mentioned above, it is within the scope of this disclosure to include a bandage having a member made of any suitable material to communicate the negative pressure from the vacuum source to the wound. Further, layer 420, cover 422, and connecter 423 may each be molded to include anti-microbial constituents. For example, it is within the scope of this disclosure to impregnate member 419 with silver ions which are known anti-microbials.

Illustratively, member 419, including layer 420, cover 422, and connecter 423, is also made of a generally non-adhesive material. Therefore, wound contacting layer 420, which lies generally adjacent to the wound surface 413, does not adhere to the wound surface 413. Further, member 419 is illustratively solid in nature and generally non-compressible. Member 419 is also illustratively transparent.

Therefore, a caregiver or user is able to see the wound 200 through member 419 when member 419 is placed adjacent to wound surface 413. This transparency allows the caregiver to view the progress of the healing of the wound 200.

Layer 420 includes a wound facing surface 424 and an upper or opposite surface 426. Wound facing surface 424, or portions thereof, contact and conform to the wound surface 413. Opposite surface 426 includes a central area 428 and a plurality of channels 430 spaced-apart from and extending radially away from central area 428. Central area 428 is recessed relative to the portions of upper surface 426 between channels 430. As shown in Fig. 29, channels 430 are open at the sides and ends of member 419. Opposite surface 426 further includes concentric channels 431. Illustratively, each channel 430, 431 is 0.030 inch (0.762 mm) wide and 0.030 inch (0.762 mm) deep. It is within the scope of this disclosure, however, to include channels 430, 431 of opposite surface 426 having other suitable widths and depths suitable for the present application. Central area 428 of layer 420 is provided to communicate with the vacuum source 16 and irrigation source 18 through a port 440 of cover 422, as will be described below.

Illustratively, a plurality of radially extending protrusions or bosses 432 are positioned around central area 428. Bosses 432 are positioned between central area 428 and channels 430, 431, as shown in Fig. 29. Bosses 432 are provided to prevent central area 428 from collapsing in on port 440 of cover 422 to form a seal and effectively block air flow through port 440 while suction is applied to the bandage 410. Port 440 communicates with the vacuum source 16 and/or the irrigation source 18 via connecter 423 and tube 441, as shown in Figs. 29 and 30. Tube 441 is coupled to connecter 423 by a barbed tube coupler 498, similar to tube coupler 11 described above. Tube 441 may also be coupled directly to connecter 423.

As mentioned above, port 440 is in communication with central area 428 of layer 420. Illustratively, four bosses 432 are shown in Fig. 29. However, it is within the scope of this disclosure to provide any number of bosses 423 or the like around central area 428 of layer 420 to prevent central area 428 from sealing off port 440 of cover 422 as suction is applied to bandage 410. Further, it is within the scope of this disclosure to include a boss or bosses having any shape in order to prevent central area 428 from sealing off port 440 when vacuum source 16 is running.

Connecter 423, as shown in Figs. 29 and 30 is a tubal port coupled to a

top surface 436 of cover 422 and in communication with port 440 of cover 422. As mentioned before, it is within the scope of this disclosure for connector 423 to be a separate component of member 419 which is coupled to cover 422 or for connecter 423 to be coupled to cover 422 by being molded integrally with cover 422.

Connector 423 includes a passageway formed at a right-angle. Thus, the passageway in connecter 423 has a vertical portion 425 that communicates with port 440 and a horizontal portion 427 that communicates with vertical portion 425. Connector 423 connects with tube 441 through the coupler 498 to provide a horizontal tube attachment for tube 441. Cover 422 includes a bottom surface 434 and top surface 436, as shown in Fig. 29. Bottom surface 434 engages opposite surface 426 of layer 420, as shown in Fig. 30.

In some embodiments, member 419 is formed by heat sealing opposite surface 426 of layer 420 and bottom surface 434 of cover 422 together and by heat sealing connecter 423 to top surface 436 of cover 422. For example, each of connecter 423, cover 422 (or the combination of cover 422 and connecter 423), and layer 420 may be pre-shaped and formed from semi-cured silicone. Once the connecter 423, cover 422, and layer 420 are placed together appropriately, the entire member 419 may be heated to heat seal and cure each of the three components to one another. Alternatively, for example, the cover 422 only may be made from semi-cured silicone while the connecter 423 and layer 420 may be made from fully cured silicone. Once placed together and heated, connecter 423 and layer 420 will heat seal to cover 422. Semi-cured silicone may be bought and pre-molded from a manufacturer such as NuSil Technology, for example.

Although the method of heat sealing the cover 422, connecter, and layer 420 to each other is disclosed, it is within the scope of this disclosure to form member 419 by coupling layer 420, cover 422, and connector 423 together by any other suitable means such as through the use of adhesives, for example. Further, it is within the scope of this disclosure to provide a member 419 where cover 422 lies adjacent to, but is not coupled to, layer 420.

As mentioned above, cover 422 is coupled to layer 420 and connecter 423 is coupled to cover 422 to form member 419. Cover 422 and layer 420 cooperate to form distinct passageways 442 of member 419 defined by channels 430, 431 of layer 420 and lower surface 434 of cover 422. Passageways 442 extend from the

outer edges of member 419 and are in communication with central area 428 of layer 420. Central area 428 of layer 420 is in communication with port 440 of cover 422 which is in communication with the vacuum and/or irrigation sources 16, 18, via connecter 423, and tube 441. Therefore, passageways 442 are in communication with the vacuum and/or irrigation sources 16, 18.

Layer 420 includes through holes 446 which extend from channels 430, 431 to wound facing surface 424, as shown in Fig. 30. Illustratively, holes 446 are distinct and are provided to communicate with channels 430, 431 of layer 420. Holes 446 therefore communicate with passageways 442 of member 419 and the vacuum and/or irrigation sources 16, 18 as well to allow the suction from the vacuum source 16 and/or the fluid from the irrigation source 18 to reach the wound bed surface 413 via the holes 446. Illustratively, holes 46 are 0.020 inch (0.508 mm) in diameter and are spaced approximately 0.500 inch (12.700 mm) apart along channels 430, 431 of layer 420. It is, however, within the scope of the disclosure to include holes having other suitable sized diameters and/or other suitable spacing that allow for the removal of exudate without clogging.

Bandage 410 further includes a sealing layer or film 450 that is placed over cover 422 and around tube 441, as shown in Fig. 30. Film 450 acts as an outer cover of the bandage 410 and covers the entire wound 412 by extending over wound 412 and attaching to the patient's healthy skin 452, also as shown in Fig. 30. Preferably, film 450 is an occlusive or semi-occlusive material which allows water vapor to permeate through. Because of this characteristic, the film 450 is referred to as Moisture Vapor Transmission Rate film or MVTR film. The products TEGADERM® brand sealing film made by 3M Corporation, and OPSITE FLEXIGRID® semi-permeable dressing made by Smith & Nephew can be used for film 450, for example. Film 450 is approximately 0.003 inch (0.076 mm) thick. However, it is within the scope of this disclosure to include any occlusive or semi-occlusive film 450 having another thickness. Film 450 is provided to create a sealed environment below the film 450 and around the wound 200 in which a vacuum or negative pressure can be maintained as provided by vacuum source 16. Film 450 therefore creates a vacuum space 453 below film 450 and above wound surface 413.

As shown in Fig. 30, sealing film 450 is positioned adjacent to top surface 436 of cover 422. It is within the scope of this disclosure, however, for

bandage 410 to further include a packing material or filler such as gauze, for example, positioned between film 450 and member 419.

It is also within the scope of this disclosure to provide a bandage (not shown) having a self-sealing member which seals about the wound 412 to the patient's healthy skin 27 to provide a vacuum space between the member and the wound surface 413. In other words, it is within the scope of this disclosure to include a bandage having a sealing means without the use of sealing film 450. For example, it is within the scope of this disclosure to include a wound contacting layer of the member having an adhesive positioned about the outer perimeter of the wound contacting surface of the layer. The adhesive perimeter would be provided to seal to the patient's healthy skin 27 surrounding wound 200. The adhesive would, therefore, permit the member to be self-sealing such that a vacuum or negative pressure can be created and maintained above wound surface 413 without the use of sealing film 450. It is also within the scope of this disclosure to provide any member having an adhesive for attachment to the patient's healthy skin surrounding the wound so that the member is self-sealing and able to maintain a negative pressure above the wound without the use of a sealing film. For example, the wound contacting layer may be sized smaller than the cover and the bottom surface of the cover may include an outer adhesive perimeter for coupling with the patient's surrounding healthy skin.

As shown in Fig. 30, member 419 of bandage 410 has a smooth wound facing surface 424. Wound facing surface 424 may also be textured or roughened and/or may include ribs, protrusions, channels, or spacers, or a single rib, protrusion, channel or spacer design. By providing member 419 with one or more ribs, protrusions, channels, spacers, etc., a space is created between surface 424 of layer 420 and wound surface 413. Through holes 446 communicate with this space to permit vacuum source 16 to establish a generally uniformly distributed vacuum or negative pressure to the wound surface 413 to draw blood from the body to the wound surface 413 and to draw exudate from the wound 412 through holes 446, into channels 430, 431 and passageways 442, and out port 440 of cover 422.

Although bandage 410 is described above, it is within the scope of this disclosure for the ventilated vacuum bandage system to include any suitable bandage or wound dressing member coupled to the vacuum source 16 to communicate negative pressure from the vacuum source 16 to the wound 412. Bandage 410,

therefore, is merely an illustrative bandage for use with the wound care bandage systems disclosed herein.

The vacuum or negative pressure which draws blood from the body to the wound surface 413 and draws exudate from the wound 200 up through member 419 promotes the healing of wound 200. As wound 200 heals, granulations form along the wound surface 413. Granulations, therefore, are the replacement within the wound bed of tissue lost. As the granulations fill in the wound bed causing the wound 200 to heal, member 419 rides up on the wound surface 413 on top of the granulations which are formed.

As mentioned above, port 440 of cover 422 communicates with vacuum source 16 and/or irrigation source 18 via connecter 423 and tube 441. As shown in Fig. 29, switch valve 455 is provided which allows the caretaker to switch between the use of the vacuum source 16 and the irrigation source 18. It will be appreciated that a mechanism other than the switch valve 455 may be used to selectively couple the vacuum source 16 or the irrigation source 18 to the bandage 410. Simple tube clamps, for example, may be used selectively to open and close the tube set provided with bandage 410. When valve 455 is switched to operate the vacuum source 16, the vacuum suction draws exudate up through holes 446 and radially inwardly through passageways 442 toward port 440 and finally through connecter 423 and tube 441. Although tube 441 has been referred to as vacuum tube 441, tube 441 may also be used as an irrigation tube carrying liquid to the wound 200 from irrigation source 18, as described above.

As mentioned above, bandage 410 includes vent 460 similar to vents 19, 119, 219 described above. Vent 460 also operates to increase air flow through the wound 200 and the passageways 442 of member 419 while vacuum source 16 applies suction to wound 200. Without vent 460 a generally closed system is created between vacuum bandage 410 and vacuum source 414. For example, in bandages without vent 460, once the requisite amount of air in the tubing 441 and below sealing film 450 within vacuum space 453 has been removed by the vacuum source 16 to create a predetermined negative pressure at wound surface 413, it is possible for the system to become generally static inhibiting much, if any, fluid flow from wound surface 413 through passageways 442 and out port 440 and connector 423. Vent 460, however, opens the system to aspirate the passageways 442 and tube 41 of the system which

promotes removal of debris that may be clogging the system.

Vent 60 acts as a first port of bandage 410 and port 440 of member 419 acts as a second port of bandage 410. Bandage 410 , therefore, includes a first port in communication with the surrounding atmosphere above or around bandage 410 and a second port in communication with the vacuum source 16. When vacuum source 16 is running, a pressure differential is initially created as vacuum source 16 draws more air out from beneath sealing film 450 than is drawn in from the surrounding atmosphere through vent 460. Therefore, a negative pressure is created above wound 200. Once a desired negative pressure above wound 200 is reached, that negative pressure may be maintained so that the amount of air flow into the bandage through vent 460 is generally equal to the amount of air flow out of the bandage 410 through connecter 423 and tube 441 by vacuum source 16. The two ports of bandage 410 allow an air flow current to be created beneath the film 450 to generally prevent the bandage 410 and vacuum source 16 system from becoming static.

As shown in Figs. 29 and 30, vent 460 comprises a vent line or tube 462 having a first end 464 and an opposite second end 466. Illustrative vent line 462 runs parallel to tube 441 and is coupled to tube 441 by one or more couplers 468, as shown in Figs. 30 and 31. First end 464 is positioned to lie below sealing film 450 and above member 419. As shown in Fig. 30, first end 464 is adjacent top surface 436 of cover 422 and second end 466 of vent line 462 is positioned outside the vacuum space 453 defined between wound surface 413 and sealing film 450. Thus, second end 466 communicates with the surrounding atmosphere to draw air from the surrounding atmosphere into the system and through passageways 442 of member 419. Although vent 460 is illustrated as a tube, it is within the scope of this disclosure for vent 460 to include any type of conduit or passage which provides communication between the atmosphere surrounding the bandage 410 and the passageways 442 of the bandage 410.

An air filter 470 similar to filter 34, described above, is coupled to second end 466 of vent line 462 as shown in Figs. 29 and 30. Illustratively, air filter 470 is a 0.2 micron anti-microbial filter for preventing bacteria and other microorganisms in the atmosphere from entering the wound space below film 450. Filter 470 is also hydrophobic. Such an air filter, for example, is made by W.L. Gore & Associates, Inc. of Elkton, MD. A cap or a valve 472 is also coupled to

second end 466 of vent line 462. As shown in Figs. 29 and 30, filter 470 is positioned between end 466 and valve 472. Valve 472 allows a user to manually control and adjust the amount of air flow into vent line 462. For example, valve 472 is movable between a fully closed position and a fully opened position. In the fully closed position, no air flow is permitted through valve 472 and the system operates as a closed system. In the fully open position, a maximum amount of air is drawn in through the valve 472 and vent line 462 so that the system operates as an open system to aspirate the passageways 442 of member 419 and create fluid flow throughout the system. The valve 472 is also adjustable to any desired partially open position between the fully closed position and the fully open position. Therefore, the amount of air flow through vent line 462 is adjustable by the caregiver.

While the valve 472 is open or partially open and air is being drawn in through vent line 462, vacuum source 16 will maintain a negative pressure under sealing film 450 while vacuum source 16 is operating. In other words, the vacuum bandage 410 and vacuum source 16 act to initially vent less air into the system than is vacuumed out of the system to create a negative pressure above the wound 200. Once created, the negative pressure above the wound 200 is maintained by vacuum source 16 when vent line 462 is open. For example, even though vent line 462 is open, vacuum source 16 is still able to create a negative pressure above wound 200 as a result of the pneumatic resistance provided by the vent 460. The vent line 462 and air filter 470 create pneumatic resistance to the entry of air from the surrounding atmosphere into the space 453 above the wound 200 when the valve 472 is open, thus enabling the net effect to be a negative pressure above the wound 200 created by the vacuum source 16. In preferred embodiments, vent 460 is open or partially open while the vacuum source 16 is operating. It is within the scope of the disclosure, however, to close the vent 460 while the vacuum source is running.

Although vent line 462 is shown to run parallel to tube 441, it is within the scope of this disclosure to position vent line 462 anywhere so long as first end 464 is positioned below sealing film 450 and second end 466 communicates with the surrounding atmosphere. Vent line 462 of the embodiment of Figs. 29-31 comprises a separate tube formed independently from tube 441 and coupled to tube 441 by couplers 468, such as medical tape wrapped around tube 441 and vent line 462. Figs. 32-33, as well as Fig. 4, described above, illustrate the cross sections of various

alternative vent lines and vacuum/irrigation tube combinations.

The embodiments shown in Figs. 32 and 33 as well as Fig. 4 illustrate parallel vent lines and vacuum/irrigation tubes which do not require a coupler 68, for example, to maintain their parallel relationship. A vent line and vacuum tube combination 480 is shown in Fig. 32. Combination 480 includes vent line passageway 482 and vacuum/irrigation passageway 484 separated from vent line passageway 482 by a partition 486. As shown in Fig. 32, combination 480 has a circular cross-section defined by an outer wall 488. Combination 480 is extruded or manufactured as a single tube having two passages or lumens, whereas vent line 462 and tube 441 of Fig. 31 are extruded or manufactured separately.

Another illustrative vent line and vacuum/irrigation tube combination 490 is shown in Fig. 33. In combination 490, vent line 462 and tube 441 are integrally coupled to each other. As illustrated, vent line 462 includes an outer wall 492 and tube 441 includes an outer wall 494. A portion of outer wall 492 is integrally coupled to a portion of outer wall 494. An external coupler 468, for example, is not required to maintain the parallel relationship of vent line 462 and tube 441 of combination 490. Further, combination 490 is extruded or manufactured as a single tube having two passages or lumens.

Yet another illustrative vent line and vacuum/irrigation tube combination is shown in Fig. 4 as multi-lumen tube 20 and was discussed above with reference to system 10. Multi-lumen tube is a single multi-lumen tube having outer wall 25 and a central, inner lumen or vacuum passageway 22. Passageway 22 may be coupled at one end to either the vacuum source 16 or the irrigation source 18 of system 410 and may be coupled at the other end to connecter 423 of member 419 via the barbed coupler 498, as shown in Fig. 3, and described in more detail below. As mentioned above with respect to system 10, multi-lumen tube 20 further includes four outer lumens or air vent passageways 24. Passageways 24 are formed within outer wall 25 and around central passageway 22. Passageways 24 are in communication with the atmosphere surrounding bandage 410 at one end and are in communication with the vacuum space 453 below sealing film 450. Combination 500 is also extruded or manufactured as a single tube.

As shown in Figs. 29 and 30, barbed tube coupler 498 is received within tube 441 and horizontal passageway 427 of connector 423. Coupler 498

includes ridges 499 for preventing coupler 498 from separating from either tube 441 or connector 423. The vent line and vacuum tube combinations 480, 490 of Figs. 32 and 33 as well as multi-lumen tube 20 of Fig. 4, are also coupled to connector 423 via coupler 498. For example, coupler 498 is received within tube passageway 484 of vent line and vacuum tube combination 480 leaving vent line passageway 482 free to draw air into the bandage 410 from the surrounding atmosphere. Coupler 498 is also received within tube 441 of combination 490 and vacuum passageway 22 of multi-lumen tube 20. It is within the scope of this disclosure to further include combinations 480, 490 where vent line passageway 482 and vent line 462 respectively, extend beyond tube passageway 484 and tube 441 to space first end 464 of vent line passageway 482 and vent line 462 away from tube passageway 484 and tube 441.

Vent 460, shown in Figs. 29 and 30, comprises vent line 462, filter 470, and valve 472 as mentioned above. However, it is within the scope of this disclosure to provide any vent in communication with both vacuum space 453 and passageways 442 and with the surrounding atmosphere. In other words, a vent is provided for communication between an area outside bandage 410 and an area within bandage 410 below film 450 or any other sealing means to permit air to flow through the system to aspirate the passageways 442 of the system and to allow the system to operate as an open system. The vent 460 is provided to create a fluid flow path from outside the sealing means, through the sealing means to the member 419 and finally through the holes 446 and passageways 442 of the member 419 and out port 440 of member 419.

The air from vent 460 flows within the wound space 453 below film 450, or a similar sealing means, and above wound surface 413 of wound 200. For example, some air from the surrounding atmosphere reaches passageways 442 through openings at the peripheral edges of member 419 and some reaches passageways 442 through holes 446 via various gaps which may exist between wound surface 413 of wound 200 and wound facing surface 424 of member 419. Further, ribs, protrusions, nubs, or texturing on wound facing surface 424 act to promote air flow through holes 446 by providing a space between wound surface 413 and wound facing surface 424.

Although vent 460 is provided to create a fluid flow path from the

surrounding atmosphere through the passageways 442 of member 419 and out port 440 of member 419, it is within the scope of this disclosure for vent line 462 of vent 460 to also be used as a separate irrigation line after filter 420 and valve 472 are detached from line 462. This second line may be connected to the irrigation source 18, for example, rather than be exposed to the surrounding atmosphere. It is therefore within the scope of this disclosure to connect second end 466 of vent line 462 to irrigation source 18 to permit irrigation of bandage 410 and wound surface 413 simultaneously with the operation of the vacuum source 16.

Although this invention has been described in detail with reference to certain embodiments, variations and modifications exist within the scope and spirit of the invention as described and defined in the following claims.

CLAIMS:

1. A vacuum bandage connectable to a vacuum source and provided for use with a wound having a wound surface, the bandage comprising:

a wound contacting surface adapted to be in contact with and generally conform to the wound surface,

a plurality of discrete passageways defined by a non-porous material, the passageways being configured for communication with the wound surface and with the vacuum source, and

a vent in communication with the passageways and configured for communication with the atmosphere surrounding the bandage.

2. The bandage of claim 1, wherein the vent comprises a tube and a filter coupled to the vent tube.

3. The bandage of claim 2, wherein the vent comprises a removable cap coupled to the filter.

4. The bandage of claim 2, wherein the vent comprises a tube and a valve coupled to the tube, the valve being movable between a closed position prohibiting air flow through the tube and an open position allowing air flow through the tube.

5. The bandage of claim 1, further including a sealing means to seal about the wound and provide a sealed space above the wound and below the sealing means, and wherein the vent comprises a tube having a first end in communication with the space above the wound and a second end in communication with the air above the sealing means.

6. The bandage of claim 5, wherein the vent includes an air filter and a valve each coupled to the second end of the tube.

7. The bandage of claim 5, wherein the first end of the tube is positioned adjacent to a top surface of the member.

8. A vacuum bandage connectable to a vacuum source and provided for use with a wound having a wound surface, the bandage comprising,

a non-porous member having a wound contacting surface adapted to be in contact with and generally conform to the wound surface, the member further including distinct passageways configured for communication with the wound surface

and configured for communication with the vacuum source,

an outer cover adjacent to the member to create a vacuum space between the cover and the wound surface, the passageways of the member being positioned within the vacuum space, and

a port in communication with the vacuum space and configured to communicate with an area outside the vacuum space to create a fluid flow path from the area outside the vacuum space to the vacuum space.

9. The bandage of claim 8, wherein the port is configured for communication with an irrigation source to pass fluid through the port and into the vacuum space.

10. The bandage of claim 9, further including a second port in communication with the passageways and configured for communication with the vacuum source.

11. The bandage of claim 8, wherein the port includes a first end in communication with the passageways and a second end in communication with the area outside the sealing means, and further including a valve coupled to the second end of the port, the valve being movable between a fully closed and fully opened position.

12. A tubing set for use with a vacuum bandage coupled to a vacuum source, the vacuum bandage having a member including a wound contacting surface adapted to be in contact with and conform to a wound surface, a port in communication with the vacuum source, and a plurality of passageways in communication with the wound surface and the port, the tubing set comprising:

a first tube configured to communicate with the port and the vacuum source,

a second tube configured to communicate with the passageways and the atmosphere surrounding the vacuum bandage to provide air flow from the surrounding atmosphere to the passageways of the vacuum bandage,

an air filter coupled to the second tube, and

a valve coupled to the second tube, the valve being operable between a closed position preventing air flow from the atmosphere to the vacuum bandage and an open position permitting air flow from the atmosphere through the filter to the vacuum bandage.

13. A bandage for use with a wound comprising:

a wound contacting member adapted to be in contact with and generally conform to the surface of the wound,

a vent in communication with the member and with the atmosphere surrounding the bandage to provide a passageway from the atmosphere to the member, and

a filter coupled to the vent and configured to filter the air passing through the vent from the atmosphere to the member.

14. The bandage of claim 13, wherein the passageway is a tube having a first end configured for in communication with the atmosphere and a second end in communication with the member.

15. The bandage of claim 14, wherein the bandage further includes a filter coupled to the first end of the tube.

16. The bandage of claim 13, wherein the member includes a port configured for communication with a vacuum source, holes configured for communication with the wound surface, and a passageway between each hole and the port, and wherein the vent is in communication with the passageways.

17. The bandage of claim 16, wherein the member is generally non-compressible.

18. The bandage of claim 16, wherein the member is generally non-porous.

19. A vacuum bandage for use with a wound and a vacuum source, the bandage comprising:

a wound contacting member adapted to be in contact with and generally conform to a wound surface of the wound,

a cover positioned over the member and configured to seal to the patient's healthy skin surrounding the wound to create a space below the cover and above the wound,

a vent in communication with the space and configured for communication with the atmosphere surrounding the bandage, and

a port in communication with the space and configured for communication with the vacuum source.

20. A method for creating continuous air flow above a wound

surface while maintaining a continuous negative atmosphere above the surface comprising the steps of:

placing a bandage over the wound surface and the bandage having a vacuum port and a vent,

creating a sealed environment above the wound,

connecting the port to a vacuum source, the vent being in communication with the atmosphere surrounding the bandage, and

drawing air in from the atmosphere through the vent of the bandage, over the wound surface, and out the port of the bandage by operation of the vacuum source.

21. A method for applying a negative pressure therapy to a wound surface comprising the steps of:

applying a wound dressing member to the wound surface, the member including a port for communication with a vacuum source, a wound contacting surface having holes formed therein, and passageways communicating between the holes and the port,

applying a cover to establish a vacuum space between the cover and the wound surface,

providing a passageway communicating between the vacuum space and the atmosphere to create an air flow path from the atmosphere to the vacuum space, through the holes and passageways, and out the port of the member, and

operating the vacuum source to create a negative pressure above the wound.

22. The method of claim 21, wherein the passageway is open when the vacuum source is operating

23. A system for ventilating a vacuum bandage covering a wound having a wound surface, and the bandage being connectable to a vacuum source and an irrigation source, the system comprising:

a multi-lumen tube configured to couple to the vacuum bandage, the multi-lumen tube including a first lumen configured to communicate with the vacuum source, a second lumen in communication with the surrounding atmosphere, and a third lumen in communication with the irrigation source, and

a wound dressing member coupled to the multi-lumen tube, the wound

dressing member being provided to communicate negative pressure from the vacuum source to the wound.

24. The system of claim 23, wherein the multi-lumen tube includes four lumens to communicate with the surrounding atmosphere.

25. The system of claim 23, wherein a diameter of each of the first lumen in communication with the vacuum source of the third lumen in communication with the irrigation source is approximately 3.175 mm, and wherein a diameter of the second lumen in communication with the surrounding atmosphere is approximately 0.508 mm.

26. The system of claim 23 wherein the multi-lumen tube includes an outer wall defining the first lumen, and the second and third lumens are formed in the outer wall of the multi-lumen tube.

27. The system of claim 26, wherein the multi-lumen tube further includes four outer lumens formed in the outer wall of the multi-lumen tube and in communication with the surrounding atmosphere.

28. The system of claim 23, further including a vent coupled to the multi-lumen tube and including a passageway between the second lumen and the surrounding atmosphere.

29. The system of claim 28, wherein the vent includes a multi-lumen connector coupled to the multi-lumen tube and a single-lumen connector configured to be coupled to the vacuum source.

30. The system of claim 29, wherein the vent further includes another single-lumen connector configured to be coupled to the irrigation source.

31. The system of claim 30, wherein the multi-lumen connector includes an irrigation conduit coupled to the single-lumen connector configured to be coupled to the irrigation source and a vacuum conduit coupled to the single-lumen connector configured to be coupled to the vacuum source.

32. The system of claim 31, wherein the multi-lumen connector further includes an outer conduit positioned around and spaced-apart from the vacuum and irrigation conduits to create a space in communication with the second lumen and with the surrounding atmosphere.

33. The system of claim 29, wherein the multi-lumen connector includes a vacuum conduit, an irrigation conduit, and an outer conduit positioned

around and spaced-apart from the vacuum and irrigation conduits to create a space, and further wherein the vent includes a filter in communication with the annular space and with the surrounding atmosphere.

34. The system of claim 29, wherein the multi-lumen connector includes an inner conduit in communication with the single-lumen connector and an outer conduit in communication with the passageway and the surrounding atmosphere.

35. The system of claim 34, wherein the vent further includes a filter in communication with the outer conduit.

36. The system of claim 23, wherein the vent includes a multi-lumen connector coupled to the multi-lumen tube, a single lumen connector in communication with the first lumen and configured to communicate with the vacuum source, and a filter in communication with the second lumen.

37. The system of claim 36, wherein the multi-lumen connector includes an inner conduit in communication with the first lumen of the multi-lumen tube, and an outer conduit in communication with the second lumen, and wherein the filter is in communication with the outer conduit.

38. A vent for use with a vacuum bandage in communication with a wound and a vacuum source, the vent comprising:

a multi-lumen connector configured to communicate with the bandage, the multi-lumen connector having an inner conduit defining a vacuum passageway in communication with the vacuum source, and an outer conduit defining a vent passageway in communication with the surrounding atmosphere, and

a single-lumen connector coupled to the vacuum passageway and configured to communicate with the vacuum source.

39. The vent of claim 38, further including an anti-microbial filter in communication with the atmosphere and with the vent passageway.

40. The vent of claim 39, further including a housing for the filter, the housing being coupled to the multi-lumen connector.

41. The vent of claim 39, further including an opening connecting the outer conduit with the filter.

42. The vent of claim 38, wherein the multi-lumen connector further including a second inner conduit defining an irrigation passageway in

communication with the irrigation source, and the vent further including a second single-lumen connector in communication with the second inner conduit.

43. A vented vacuum bandage system for use with a wound and a vacuum source, comprising:

a bandage configured to lie adjacent the wound to create a sealed environment about the wound,

a vent positioned between the bandage and the vacuum source,

a vacuum passageway extending from the bandage, through the vent, to the vacuum source, and

a vent passageway extending from the bandage to the vent in communication with the surrounding atmosphere.

44. The system of claim 43, further including a tube having a first end coupled to the bandage and a second end coupled to the vent, the tube including the vent passageway and a portion of the vacuum passageway from the bandage to the vent.

45. The system of claim 44, wherein the tube further includes an irrigation passageway from the bandage to the vent.

46. The system of claim 44, wherein the tube has an outer body forming an inner lumen defining the vacuum passageway and an outer lumen formed in the outer wall defining the vent passageway.

47. The system of claim 46, wherein the tube has four outer lumens formed in the outer body.

48. The system of claim 44, wherein the vent includes a multi-lumen connector coupled to the tube and a single-lumen connector configured to communicate with the vacuum source.

49. The system of claim 48, wherein the multi-lumen connector includes an inner conduit and an outer conduit around the inner conduit, and further wherein the vacuum passageway is in communication with the inner conduit and the vent passageway is in communication with the outer conduit.

50. The system of claim 49, wherein the vent further includes an opening between the outer conduit and the surrounding atmosphere.

51. The system of claim 49, wherein the inner conduit is in communication with the single-lumen connector and the outer conduit is in

communication with the surrounding atmosphere.

52. The system of claim 50, wherein the vent further includes a filter housing coupled to the outer conduit, and a filter housed within the filter housing and positioned between the opening of the vent and the surrounding atmosphere.

53. The system of claim 52, wherein the filter is a 0.2 micron filter.

54. The system of claim 44, wherein the bandage includes a member having distinct passageways formed therein and distinct holes in communication with the passageways and configured to communicate with the wound, and wherein the second lumen of the tube is in communication with the holes and passageways.

55. A vented vacuum bandage system for use with a wound, a vacuum source, and an irrigation source, the system comprising:

a bandage positioned adjacent the wound to create a sealed environment around the wound,

a vacuum source in communication with the bandage to create a negative pressure between the bandage and the wound,

a first passageway in communication with the bandage and with the surrounding atmosphere,

a second passageway in communication with the bandage and with the vacuum source, and

a third passageway in communication with the bandage and with the irrigation source.

56. The system of claim 55, further including an irrigation source and a third passageway in communication with the bandage and with the irrigation source.

57. The system of claim 56, further including a vent including the first, second, and third passageways.

58. A wound bandage system for use with a wound, a negative pressure source, and an irrigation source, comprising:

a wound bandage, and

a vent apparatus through which ambient atmosphere vents to the wound bandage, through which irrigation fluid flows from the irrigation source to the

wound bandage, and through which negative pressure is communicated to the wound bandage.

59. A vent-valve apparatus for use with a vacuum bandage coupled to a wound to provide selective communication between the wound and either a vacuum source or an irrigation source, comprising:

a vent in communication with the atmosphere and configured to communicate with the wound, and

a stopcock coupled to the vent and in selective communication with the vacuum source and the irrigation source, the stopcock being movable between a vacuum position connecting the wound with the vacuum source and an irrigation position connecting the wound with the irrigation source.

60. The apparatus of claim 59, further including a multi-lumen connector having a first conduit coupled to the vent and a second conduit configured to communicate with one of the vacuum source and the irrigation source.

61. The apparatus of claim 60, wherein the multi-lumen connector further includes a third conduit and wherein the second conduit is configured to communicate with the vacuum source and the third conduit is configured to communicate with the irrigation source.

62. The apparatus of claim 61, wherein the vent includes the multi-lumen connector and a first single-lumen connector coupled to the second conduit of the multi-lumen connector and a second single-lumen connector coupled to the third conduit of the multi-lumen connector.

63. The apparatus of claim 61, wherein the stopcock includes a vacuum connector coupled to the first conduit and an irrigation connector coupled to the second conduit.

64. The apparatus of claim 60, further including a filter coupled to the multi-lumen connector and in communication with the first conduit of the multi-lumen connector.

65. The apparatus of claim 59, wherein the stopcock includes a handle having a first cut-out portion and a second cut-out portion.

66. The apparatus of claim 65, wherein the stopcock includes a vacuum conduit in communication with the first cut-out portion and configured to be coupled to the vacuum source and an irrigation conduit in communication with the

second cut-out portion and configured to be coupled to the irrigation source.

67. The apparatus of claim 66, wherein the stopcock defines an aperture for receiving a portion of the handle, and wherein the vacuum conduit includes a first portion in communication with the aperture and a second portion in communication with the aperture and the irrigation conduit includes a first portion in communication with the aperture and a second portion in communication with the aperture, and further wherein the handle is rotatable within the aperture to selectively align the first cut-out portion with the first and second portions of the vacuum conduit when the stopcock is in the vacuum position and to selectively align the second cut-out portion with the first and second portions of the irrigation conduit when the stopcock is in the irrigation position.

68. The apparatus of claim 66, wherein the first cut-out portion lies in a first plane and the second cut-out portion lies in a second plane parallel to the first plane.

69. A wound bandage system for use with a vacuum bandage on a wound, comprising:

a multi-lumen tube having a first lumen configured to be coupled to a vacuum source, a second lumen configured to be coupled to an irrigation source, and a third lumen in communication with the surrounding atmosphere,

a vent-valve apparatus coupled to the multi-lumen tube, the apparatus having a vent coupled to the third lumen, a filter coupled to the vent, and a valve coupled to the first and second lumens, the vent-valve apparatus provided to selectively communicate negative pressure and irrigation fluids to the wound while exposing the wound to the surrounding atmosphere through the vent,

a first single-lumen tube coupled to the vent-valve apparatus and configured to be coupled to the vacuum source, and

a second single-lumen tube coupled to the vent-valve apparatus and configured to be coupled to the irrigation source.

70. A vent-valve apparatus for use with a vacuum bandage coupled to a wound, a vacuum source coupled to the bandage, and an irrigation source coupled to the bandage, the vent-valve apparatus comprising:

a vacuum conduit configured to be coupled to the vacuum source,

an irrigation conduit configured to be coupled to the irrigation source,

a body having an aperture in communication with the vacuum conduit and the irrigation conduit,

a rotatable handle received in part within the aperture and including a passageway configured to selectively communicate the vacuum conduit and the irrigation conduit with the wound,

a vent in communication with the atmosphere and configured to communicate with the wound.

71. A wound care bandage system for use with a vacuum bandage coupled to a wound, a vacuum source coupled to the bandage, and an irrigation source coupled to the bandage, the system comprising:

a vacuum passageway in communication with the wound and the vacuum source,

an irrigation passageway in communication with the wound and the vacuum source,

a ventilation passageway in communication with the wound and the surrounding atmosphere, and

a valve coupled to the vacuum passageway and the irrigation passageway to selectively communicate the wound with either the vacuum source or the irrigation source.

72. A vent-valve apparatus for use with a vacuum bandage coupled to a wound to provide selective communication between the wound and either a vacuum source or an irrigation source, comprising:

a stopcock having a body including a wound connector configured to communicate with the wound, a vacuum connector configured to communicate with the vacuum source, and an irrigation connector configured to communicate with the irrigation source, and a handle rotatably coupled to the body and movable between a vacuum position connecting the wound connector with the vacuum connector and an irrigation position connecting the wound connector and the irrigation connector, and

a passageway in communication with the surrounding atmosphere and configured to communicate with the wound.

73. The apparatus of claim 72, wherein the apparatus further includes a multi-lumen connector having an outer conduit and an inner conduit.

74. The apparatus of claim 73, wherein the inner conduit is in

communication with the single-lumen connector and the outer conduit is configured to communicate with the surrounding atmosphere.

75. The apparatus of claim 74, further including a filter coupled to the passageway, and wherein the passageway connects the outer conduit with the filter.

76. The apparatus of claim 73, wherein the handle includes a grip and a stem coupled to the grip, and wherein the stem includes a cut-out portion forming a passageway to selectively connect the wound connector with either the vacuum connector or the irrigation connector.

77. The apparatus of claim 76, wherein the body of the stopcock includes an aperture and the stem is received within the aperture.

78. The apparatus of claim 76, wherein the cut-out portion is semi-circular in shape.

79. The apparatus of claim 73, wherein the apparatus includes a vent comprising the passageway and the multi-lumen connector, and wherein the vent further includes a single-lumen connector coupled to the wound connector of the stopcock..

80. The apparatus of claim 72, wherein the wound connector includes an outer conduit in communication with the passageway and an inner conduit in selective communication with the vacuum connector and the irrigation connector.

81. The apparatus of claim 80, wherein the handle includes a grip and a stem coupled to the handle, and wherein the stem includes a passageway to selectively connect the wound connector with either the vacuum connector or the irrigation connector.

82. The apparatus of claim 80, wherein the apparatus further includes a filter and the passageway connects the outer conduit with the filter.

83. The apparatus of claim 72, wherein the stopcock includes an outer shell and an inner barrel rotatably coupled to the outer shell and received within an aperture of the outer shell, and wherein the outer shell includes the wound connector, the vacuum connector, the irrigation connector, and the passageway.

84. The apparatus of claim 83, wherein the wound connector includes an inner conduit in selective communication with vacuum connector and the irrigation connector and an outer conduit in communication with the vent.

85. The apparatus of claim 84, wherein the vent includes a filter.

86. The apparatus of claim 84, wherein the inner barrel includes an upper set of passageways to selectively connect the wound connector with either the vacuum connector or the irrigation connector, and a lower set of passageways to selectively connect the outer conduit with the vent.

87. The apparatus of claim 86, wherein the outer shell includes a groove extending between the outer conduit and the lower set of passageways.

88. A vent-valve apparatus for use with a vacuum bandage coupled to a wound to provide selective communication between the wound and either a vacuum source or an irrigation source, comprising:

a multi-lumen connector configured to communicate with the bandage, the multi-lumen connector including an inner conduit and an outer conduit,

a vacuum connector in selective communication with the inner conduit of the multi-lumen connector and configured to communicate with the vacuum source,

an irrigation connector in selective communication with the inner conduit of the multi-lumen connector and configured to communicate with the irrigation source, and

an opening in communication with the atmosphere and with the outer conduit of the multi-lumen connector.

89. The apparatus of claim 88, further including a handle in communication with and movable relative to the vacuum connector, the irrigation connector, and the multi-lumen connector between a vacuum position where the vacuum connector is in communication with the inner conduit and an irrigation position where the irrigation connector is in communication with the inner conduit.

90. The apparatus of claim 89, wherein the handle includes a grip, a stem, and a passageway through the stem configured to selectively connect the inner conduit with either the vacuum connector or the irrigation connector.

91. The apparatus of claim 90, wherein the handle includes a second passageway in selective communication with the outer conduit and the vent.

92. The apparatus of claim 89, further including a filter coupled to the vent.

93. The apparatus of claim 88, wherein the outer conduit defines a

vent passageway in communication with the surrounding atmosphere and the inner conduit defines a vacuum/irrigation passageway configured to selectively communicate with the vacuum source and the irrigation source.

94. The apparatus of claim 93, further including a vent comprising the multi-lumen connector and the passageway and a stopcock coupled to the vent including the vacuum connector and the irrigation connector.

95. A vent-valve apparatus coupled to a vacuum bandage for providing selective communication between the bandage and either a vacuum source or an irrigation source, comprising:

a vent in communication with the atmosphere and the vacuum bandage,

a valve coupled to the vent,

a vacuum passageway in communication with vacuum source and the valve,

an irrigation passageway in communication with the irrigation source and the valve, and

a vacuum/irrigation passageway in communication with the vacuum bandage and the valve, and in selective communication with the vacuum passageway and the irrigation passageway.

96. A vent-valve apparatus for use with a vacuum bandage coupled to a wound to provide selective communication between the wound and either a vacuum source or an irrigation source, comprising:

an outer body including a central aperture, a vacuum connector in communication with the vacuum source and the aperture, and an irrigation connector in communication with the irrigation source and the aperture,

a handle rotatably received within the aperture, the handle having a passageway formed therein, and

a multi-lumen connector in communication with the wound having an inner conduit in communication with the wound and the handle, and an outer conduit in communication with the wound and the surrounding atmosphere.

97. The apparatus of claim 96, wherein the inner conduit is in selective communication with the vacuum connector and the irrigation connector.

98. The apparatus of claim 97, wherein the handle is rotatable

between a vacuum position wherein the passageway provides communication between the inner conduit and the vacuum connector, and an irrigation position wherein the passageway provides communication between the inner conduit and the irrigation connector.

99. A wound care bandage system provided for use with a wound having a wound surface, a vacuum source, and an irrigation source, comprising:

a bandage configured to lie adjacent the wound surface and seal about the wound surface to provide a sealed environment below the wound surface,

a multi-lumen tube coupled to the bandage and configured for communication with the wound surface, the tube including an inner lumen configured to selectively communicate with the vacuum source and the irrigation source, and an outer lumen in communication with the surrounding atmosphere, and

a vent-valve assembly coupled to the multi-lumen tube and movable between a vacuum position connecting the inner lumen with the vacuum source, and an irrigation position connecting the inner lumen with the irrigation source.

100. The system of claim 99, wherein the multi-lumen tube includes an outer wall and a plurality of outer lumens formed in the outer wall.

101. The system of claim 100, wherein the vent-valve assembly includes a vent in communication with the outer lumens of the multi-lumen tube.

102. The system of claim 101, wherein the vent includes a filter.

103. The system of claim 100, wherein the vent valve assembly includes a multi-lumen connector coupled to the multi-lumen tube, and wherein the multi-lumen connector includes an inner conduit to be received within the inner lumen of the multi-lumen tube and an outer conduit to receive the outer wall of the multi-lumen tube.

104. The system of claim 103 wherein the outer conduit is in communication with the vent.

105. The system of claim 99, wherein the vent-valve assembly includes a body having a vacuum connector, an irrigation connector, and an aperture in communication with the vacuum connector and the irrigation connector.

106. The system of claim 105, wherein the vent-valve assembly further includes a handle rotatably received within the aperture, the handle includes a passageway to selectively connect the vacuum connector with the inner conduit and

the irrigation connector with the inner conduit.

107. The system of claim 106, wherein the handle includes another passageway to selectively connect the vent with the outer conduit of the multi-lumen connector.

108. A method of wound care therapy is provided for wound having a wound surface, comprising the steps of:

applying a bandage over the wound surface to seal about the wound surface,

coupling a multi-lumen tube to the bandage to communication with the wound surface, the multi-lumen tube including an inner lumen and an outer lumen,

coupling the inner lumen of the multi-lumen tube to a multi-lumen connector of an apparatus in selective communication with a vacuum source and an irrigation source,

coupling an outer lumen of the multi-lumen tube to a vent in communication with the atmosphere,

coupling a single lumen tube to an irrigation connector of the apparatus for communication with the irrigation source,

coupling a single lumen tube to a vacuum connector of the apparatus for communication with the vacuum source, and

moving the apparatus between a vacuum position where the vacuum connector is in communication with the inner lumen of the multi-lumen tube and an irrigation position where the vacuum connector is in communication with the inner lumen of the multi-lumen tube.

109. A method of wound care therapy is provided for wound having a wound surface, comprising the steps of:

coupling a bandage to a first fluid line and a second fluid line,

coupling the first fluid line to a vent in communication with the surrounding atmosphere,

coupling the second fluid line to a valve in selective communication with a vacuum source and an irrigation source, and

switching the valve between a vacuum position where the second fluid line is in communication with the vacuum source, and an irrigation position where the second fluid line is in communication with the irrigation source.

110. A wound bandage system for use with a wound, comprising:

a bandage,

an irrigation source,

a negative pressure source,

a vent-valve apparatus,

a first single lumen tube coupled to the irrigation source and the vent-valve apparatus,

a second single lumen tube coupled to the vacuum source and the vent-valve apparatus, and

a multi-lumen tube coupled to the vent-valve apparatus and the bandage.

111. A wound bandage system for use with a wound, a negative pressure source, and an irrigation source, comprising:

a wound bandage, and

a vent-valve apparatus through which ambient atmosphere vents to the wound bandage, through which irrigation fluid flows from the irrigation source, and through which negative pressure is communicated to the wound bandage.

112. The system of claim 111, further including a multi-lumen tube coupled to the wound bandage at a first end and coupled to the vent-valve apparatus at a second end.

113. The system of claim 112, wherein the multi-lumen tube includes an irrigation lumen, a vacuum lumen, and a vent lumen.

114. The system of claim 113, wherein the multi-lumen tube four vent lumens.

115. The system of claim 111, wherein the vent-valve apparatus includes a multi-lumen connector coupled to the multi-lumen tube, and wherein the multi-lumen connector includes an outer conduit formed to receive a portion of a vent lumen of the multi-lumen tube, a vacuum conduit positioned within the outer conduit and received within a vacuum lumen of the multi-lumen tube, and an irrigation conduit positioned within the outer conduit and received within an irrigation lumen of the multi-lumen tube.

116. The system of claim 115, wherein the vent-valve apparatus further includes a passageway from the outer conduit to the surrounding atmosphere,

a filter coupled to the passageway.

117. The system of claim 111, wherein the vent-valve apparatus includes a vacuum conduit configured to be coupled to the vacuum source, an irrigation conduit configured to be coupled to the irrigation source, an aperture defined by a body of the apparatus in communication with the vacuum conduit and the irrigation conduit, and a handle rotatably received within the aperture to selectively provide communication between the wound and the irrigation source or between the wound and the vacuum source.

118. The system of claim 117, wherein the handle includes a first cut-out portion and a second cut-out portion, and wherein the first cut-out portion is aligned with the vacuum conduit when the handle is in a first, vacuum position and wherein the second cut-out portion is aligned with the irrigation conduit when the handle is in the second, irrigation position.

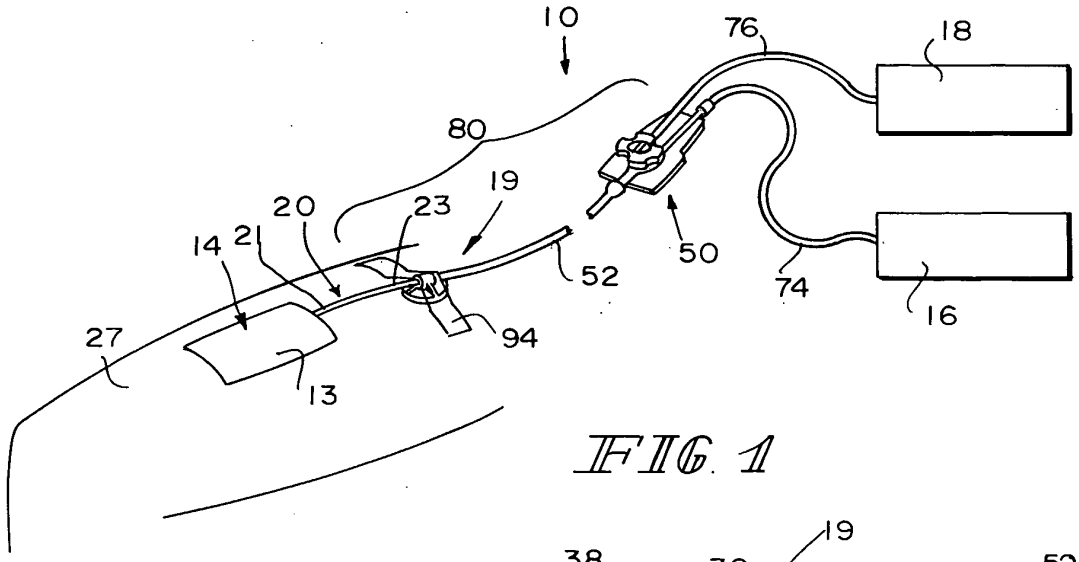


FIG. 1

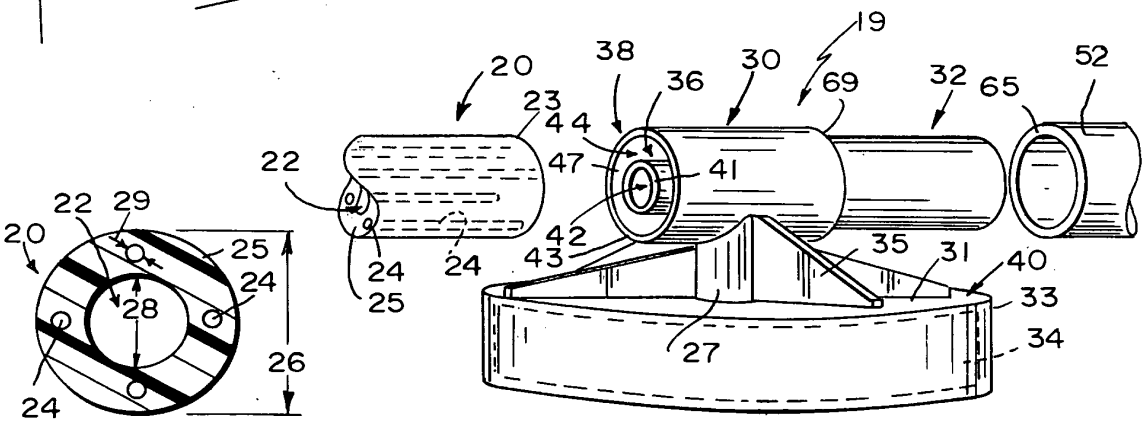


FIG. 4

FIG. 2

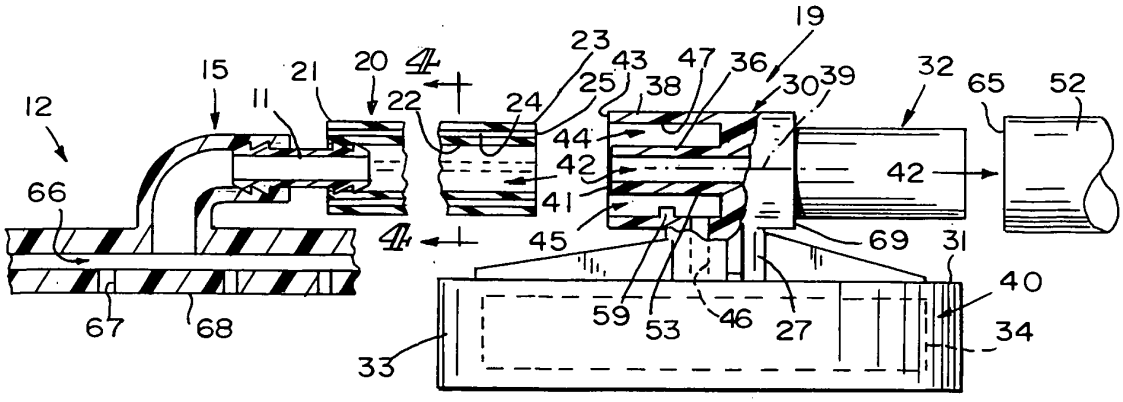


FIG. 3

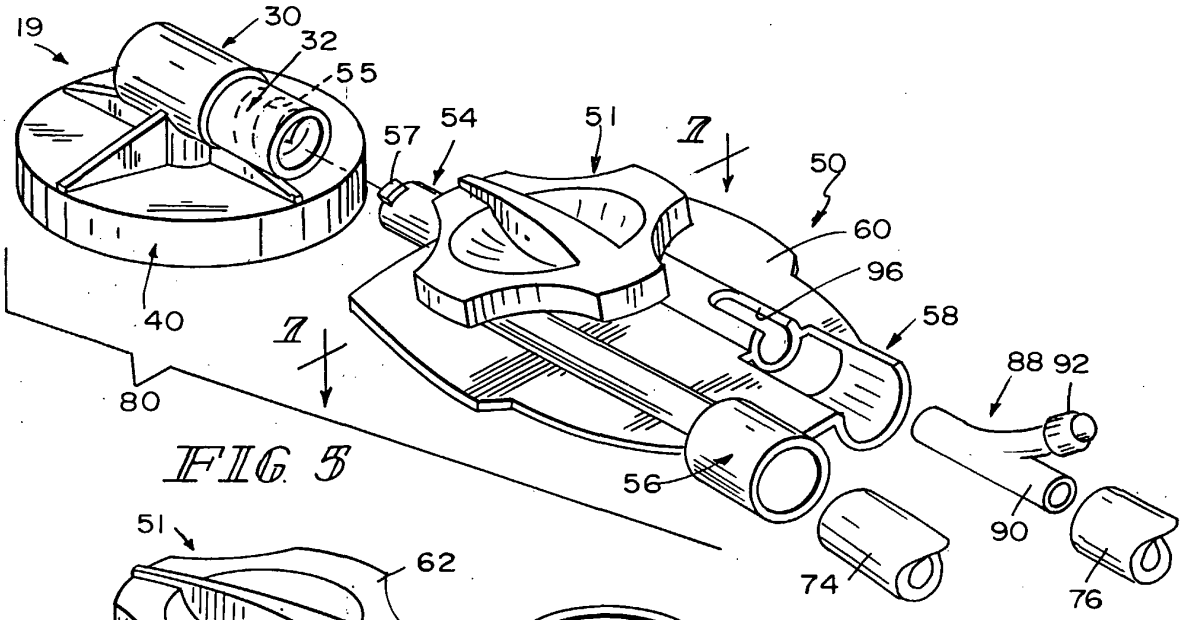


FIG. 5

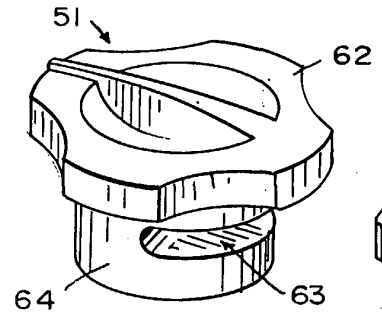


FIG. 6a

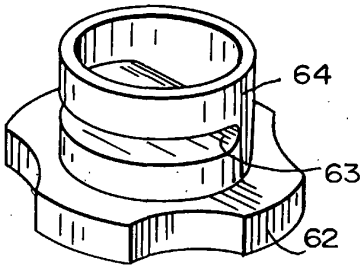


FIG. 6b

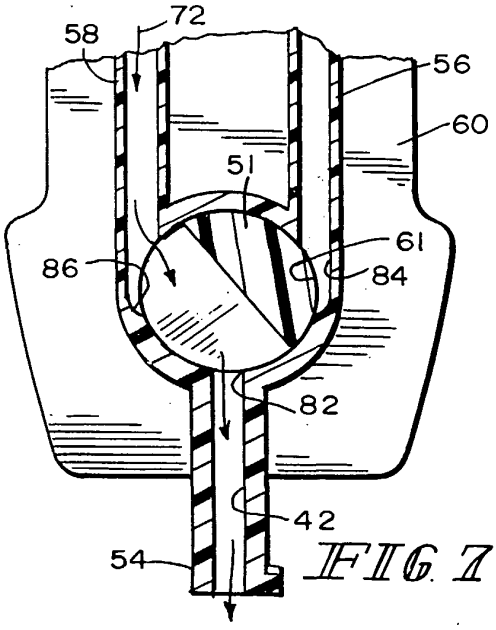


FIG. 7

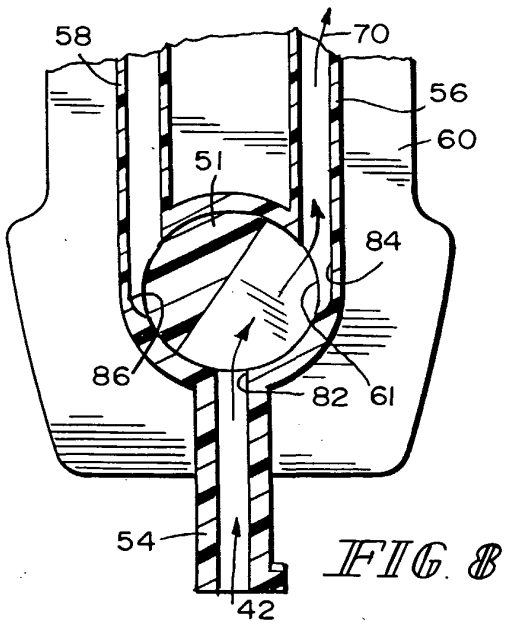


FIG. 8

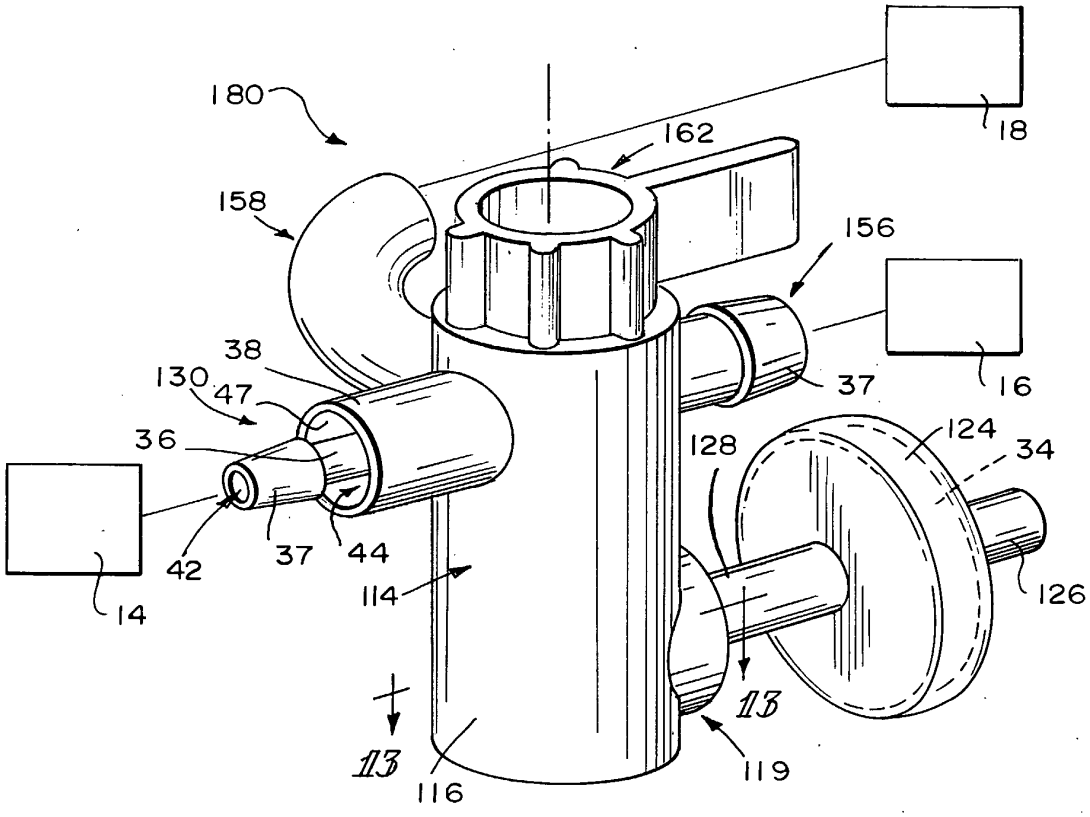

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FIG. 9

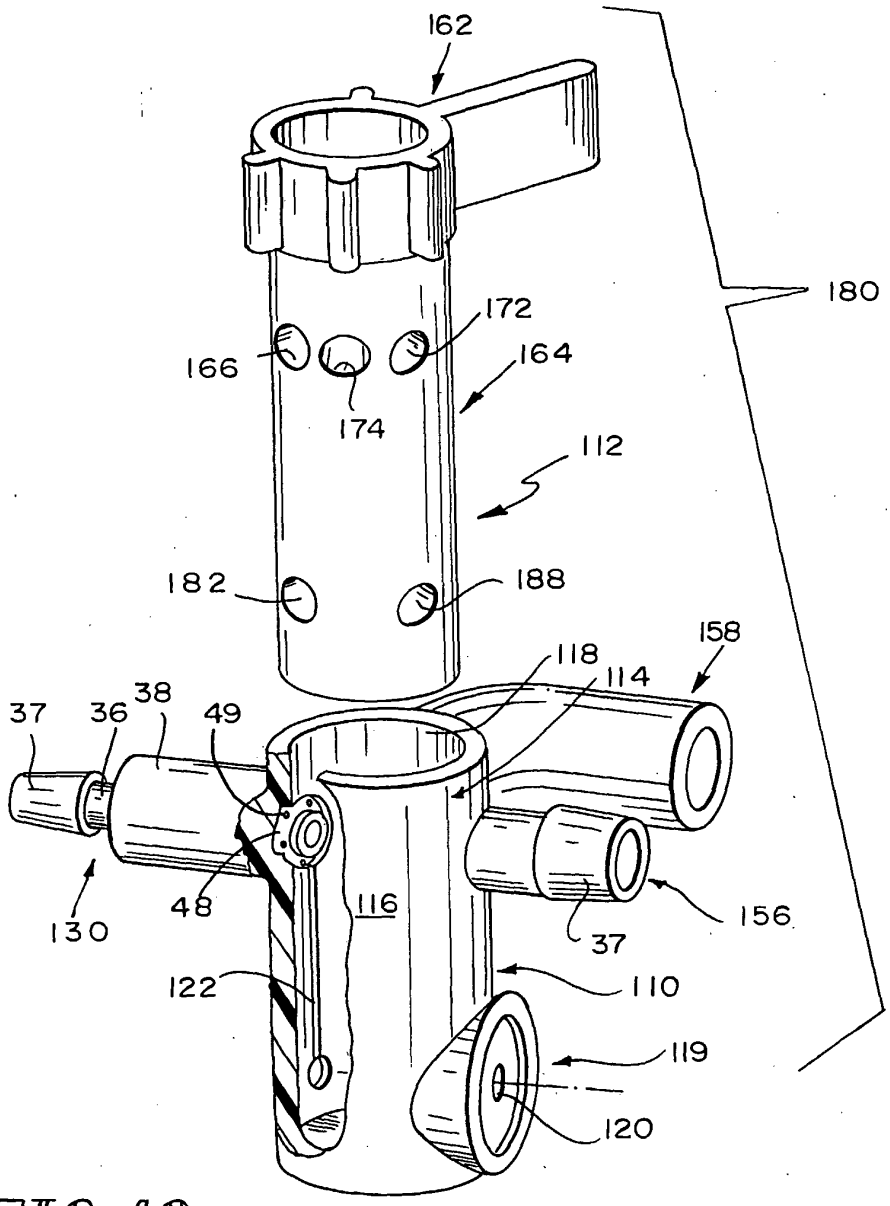

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FIG. 10

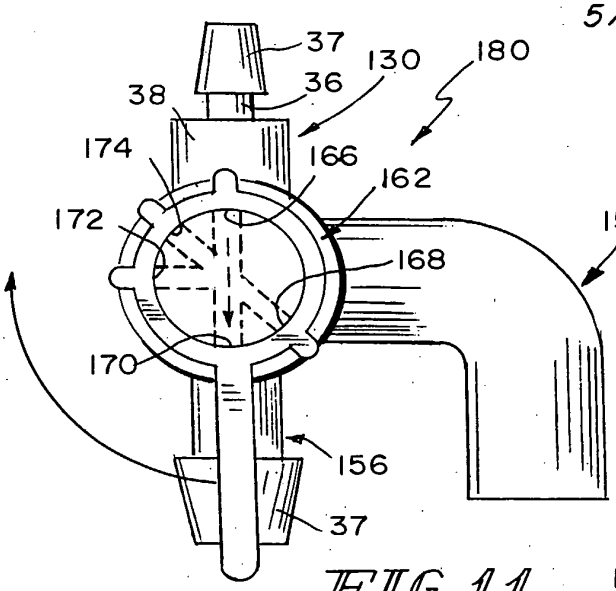


FIG. 11

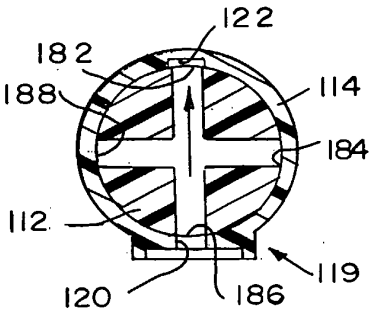


FIG. 12

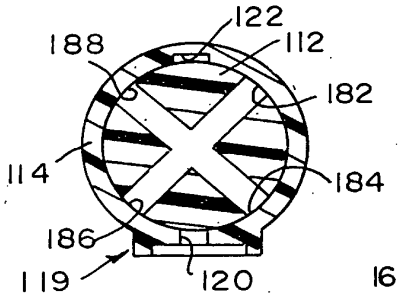


FIG. 14

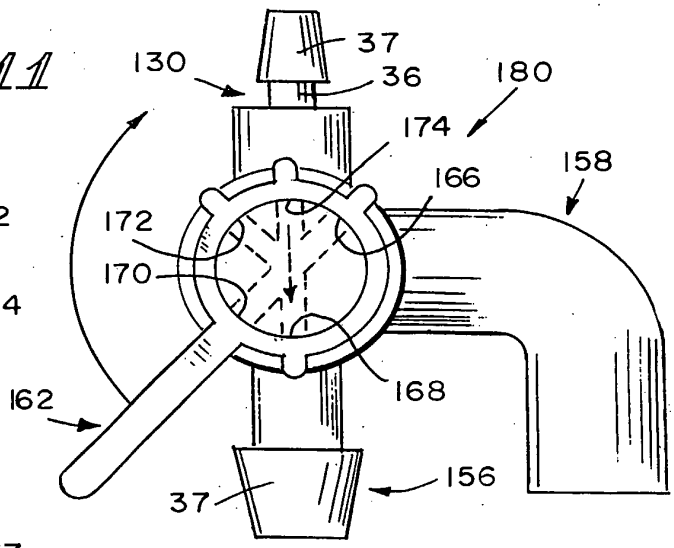


FIG. 13

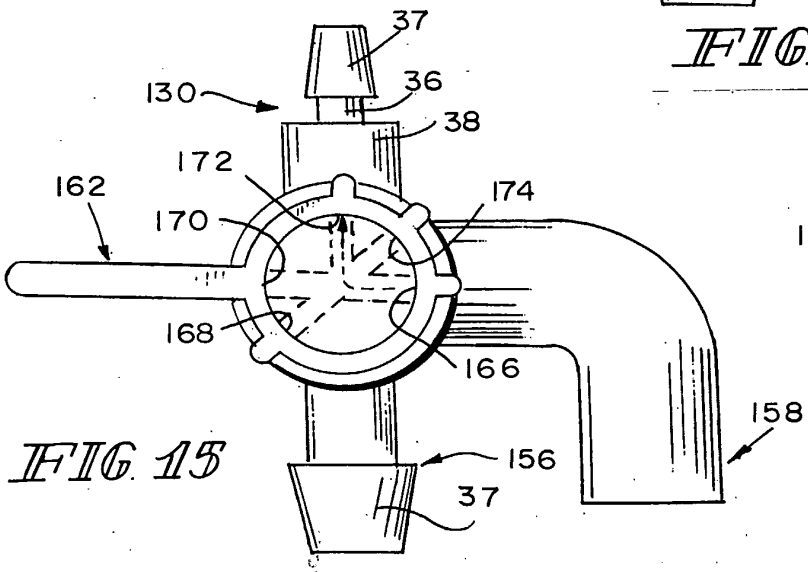


FIG. 15

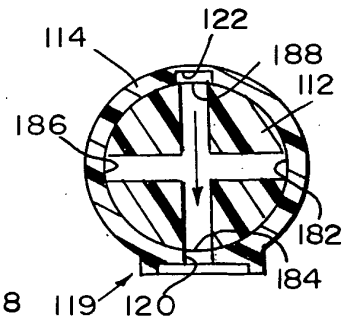


FIG. 16

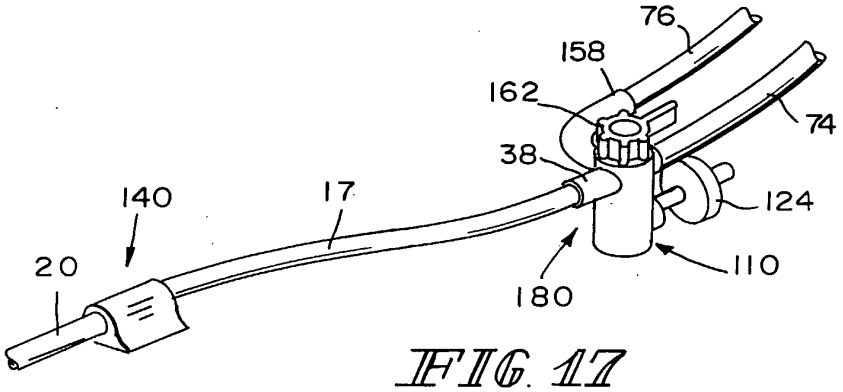


FIG. 17

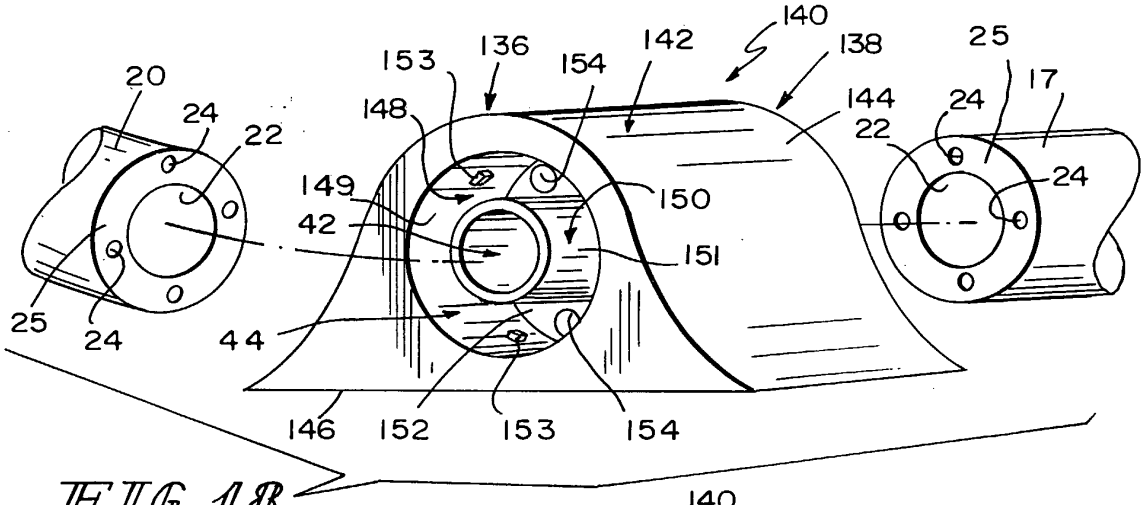


FIG. 18

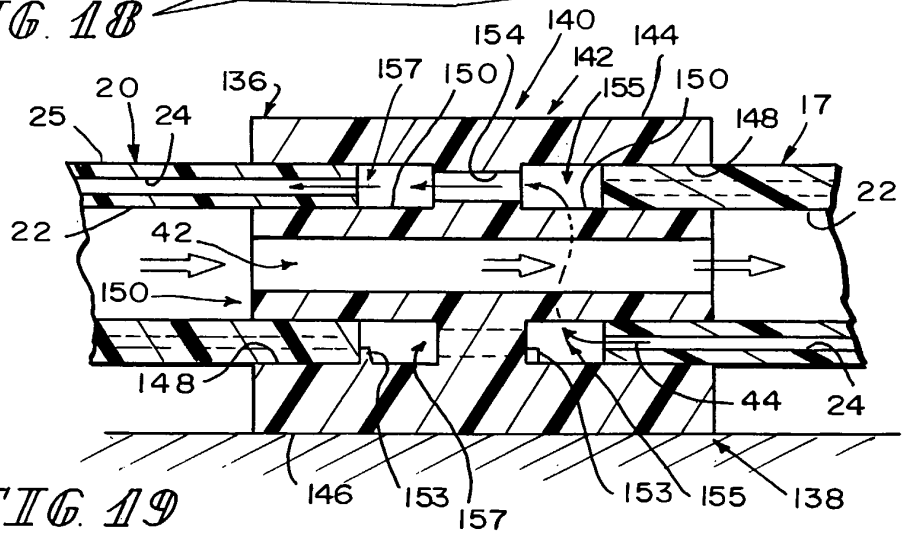


FIG. 19

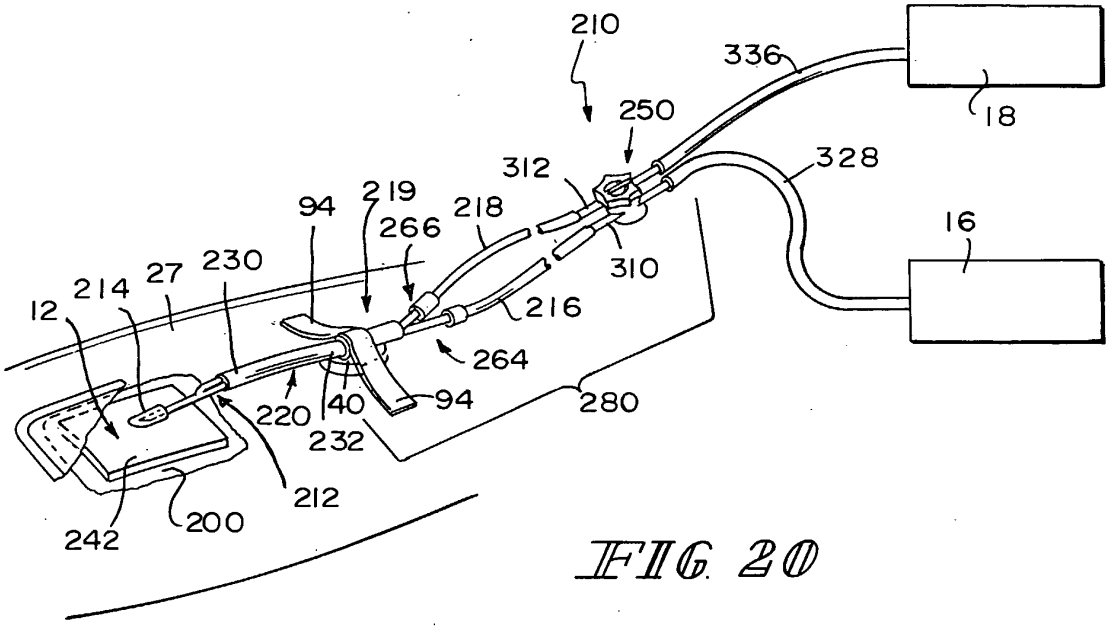


FIG. 20

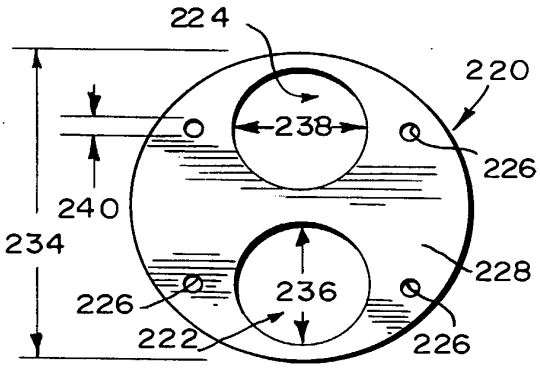


FIG. 21

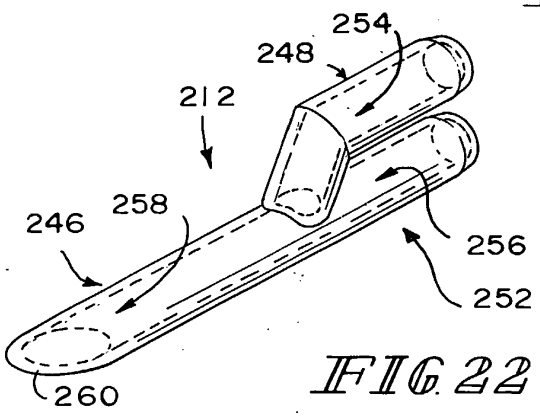


FIG. 22

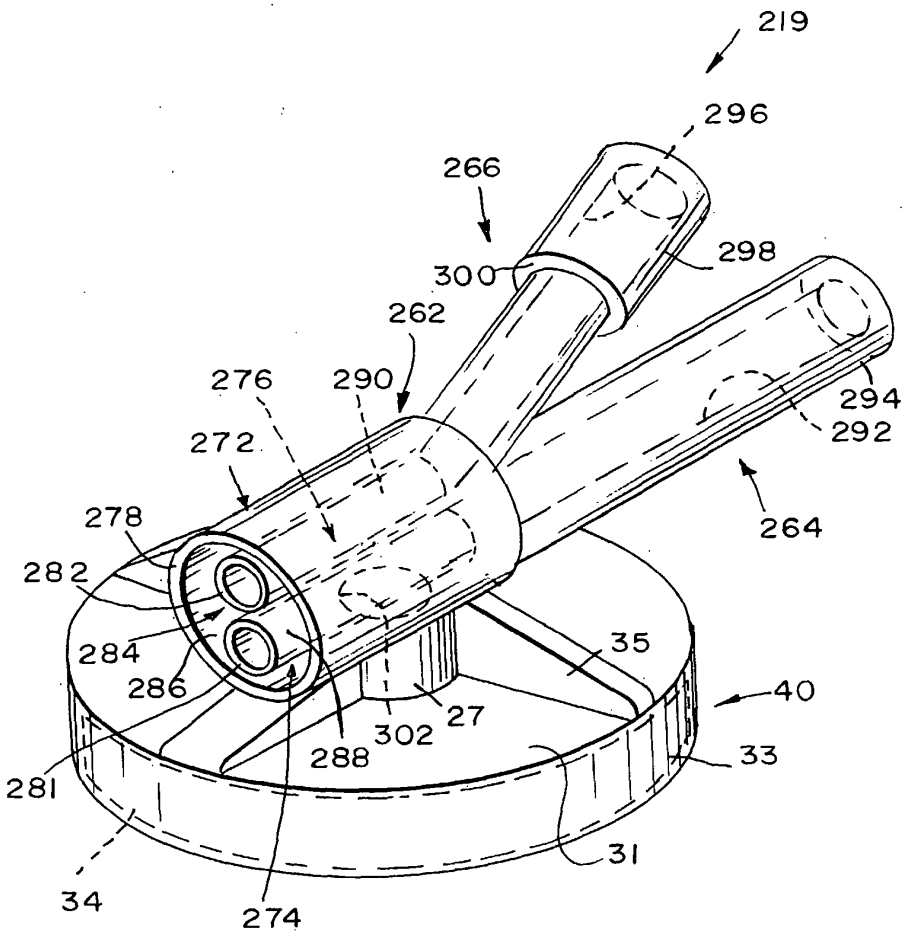

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FIG 23

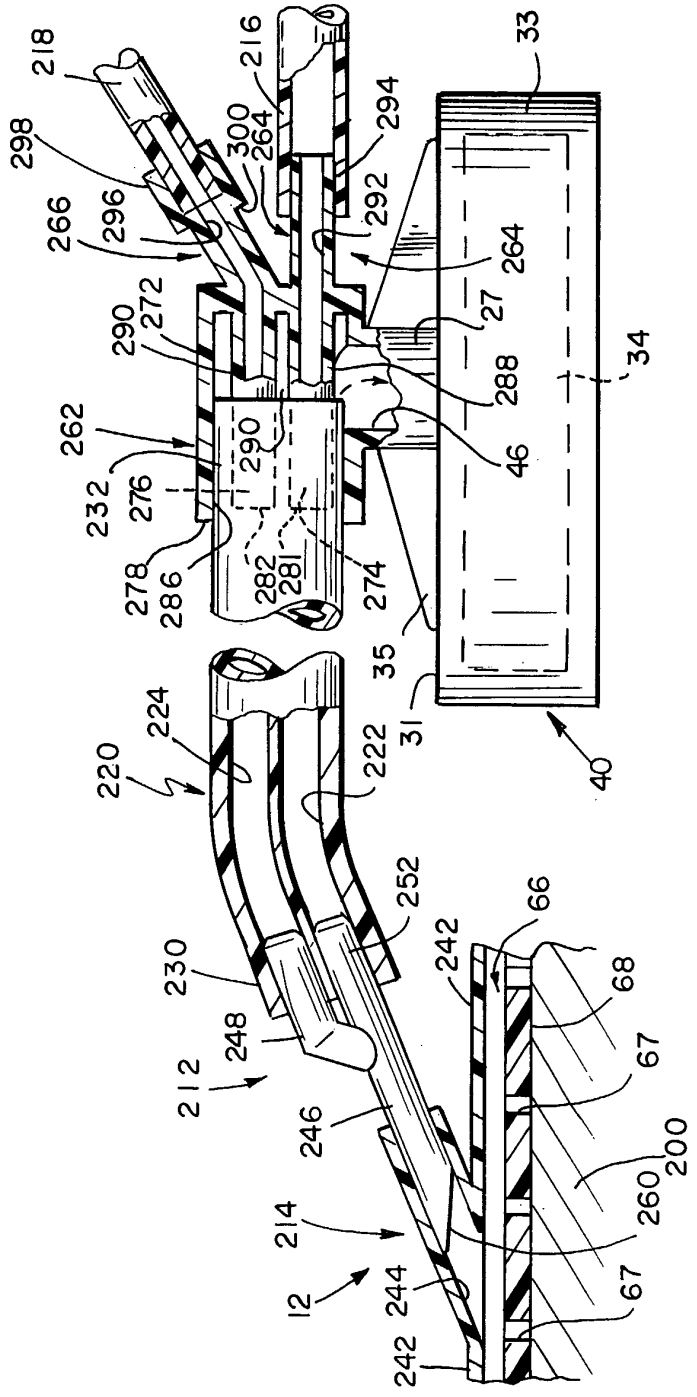


FIG. 24

Medela LLC and Medela AG
Exhibit 1008
Page #944

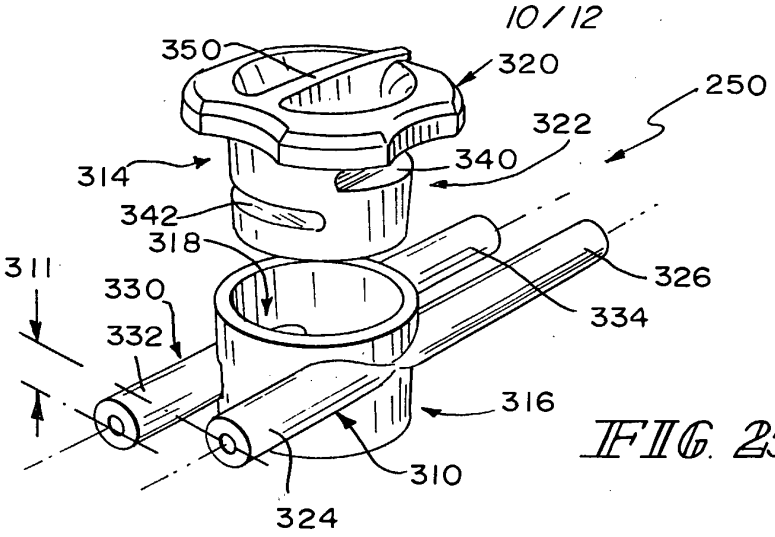


FIG. 25

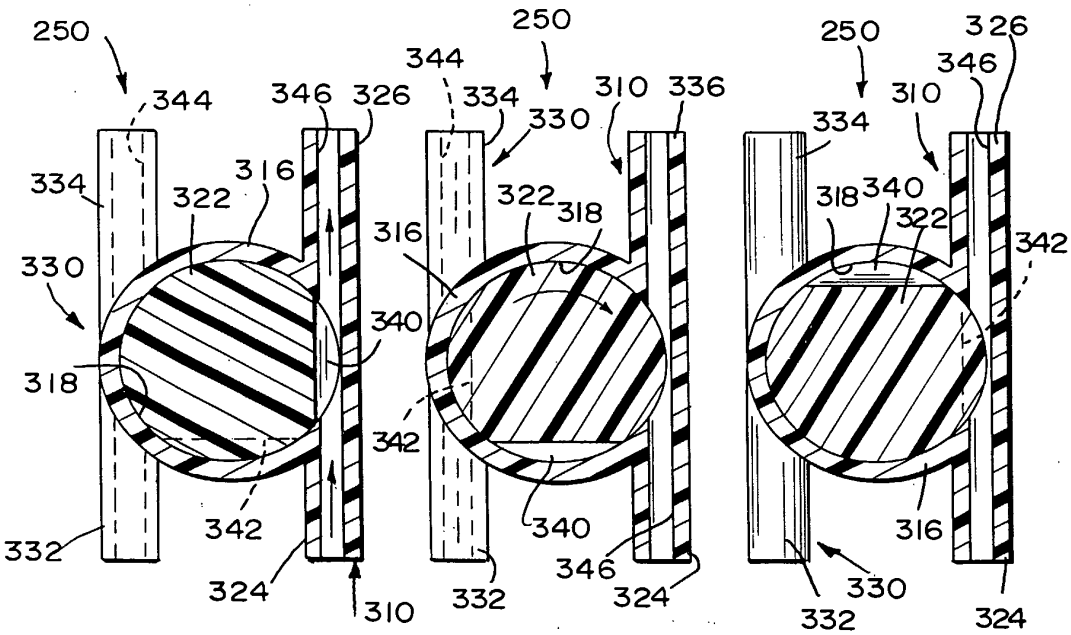


FIG. 26 FIG. 27 FIG. 28

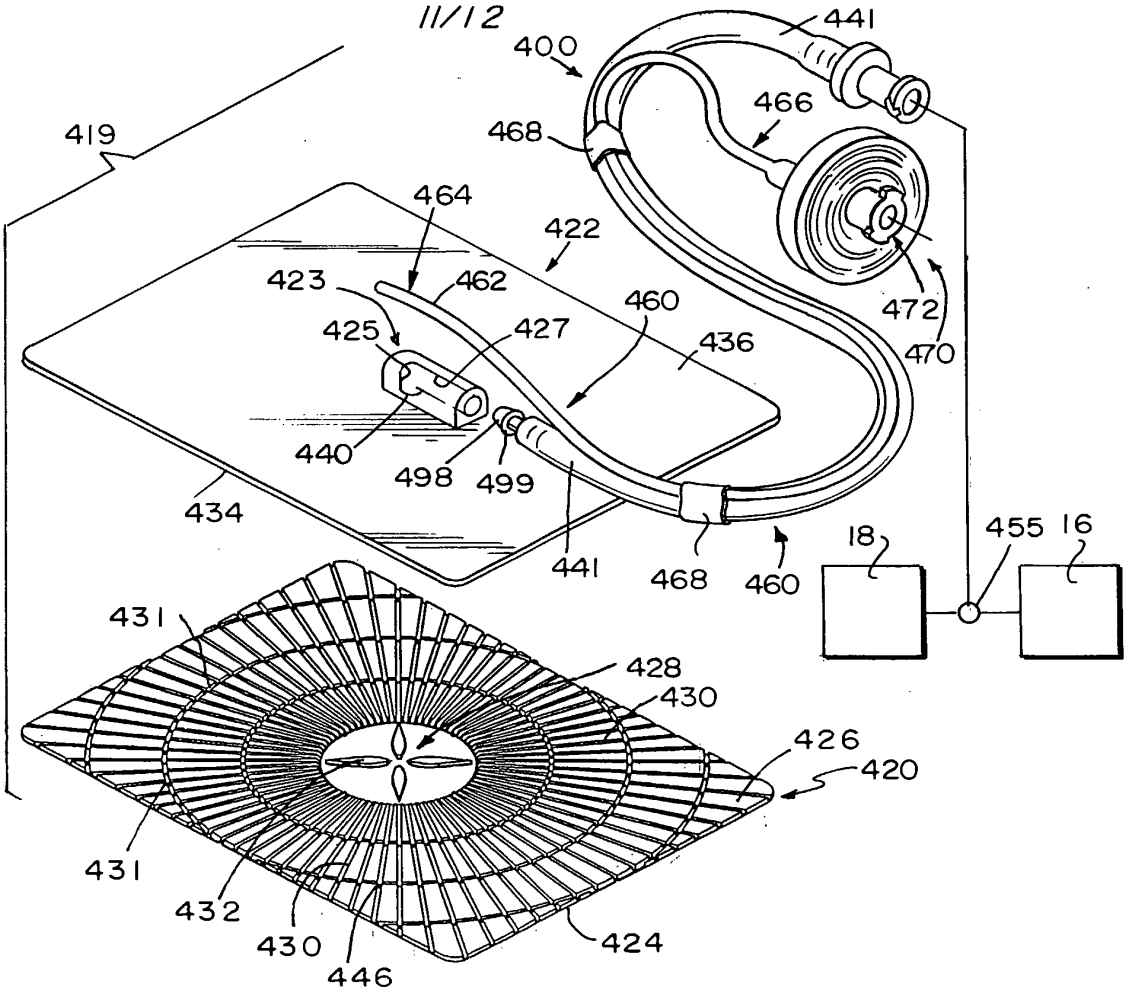

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FIG. 29

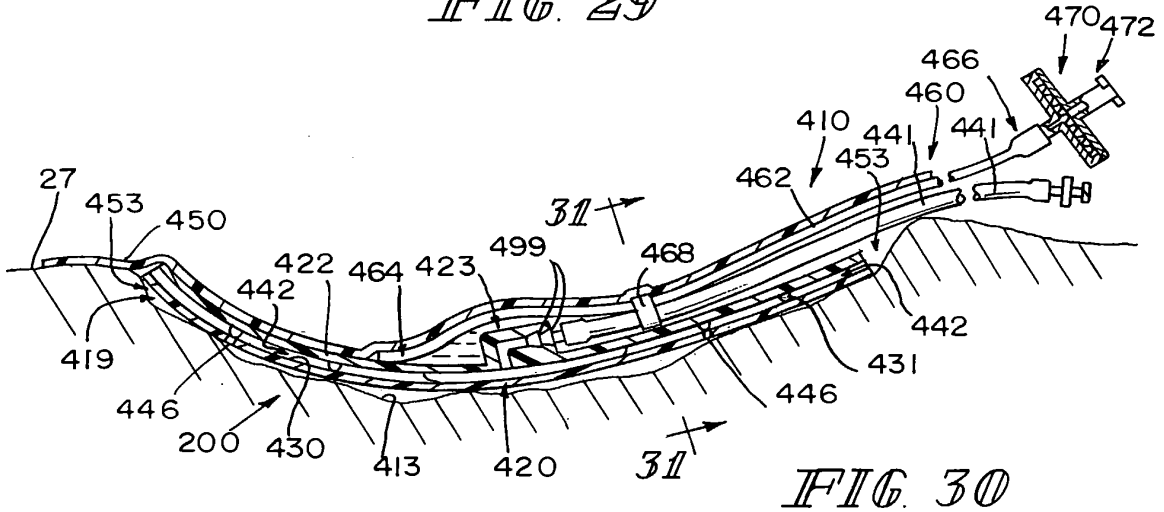

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FIG. 30

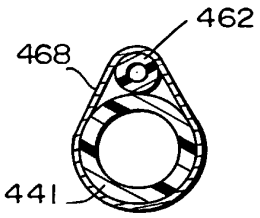


FIG. 31

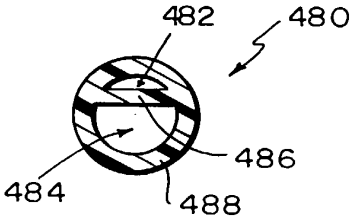


FIG. 32

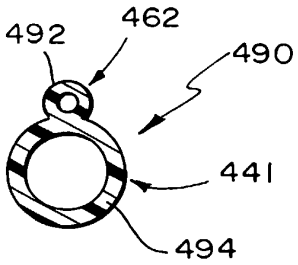


FIG. 33

Electronic Acknowledgement Receipt

EFS ID:	8846114
Application Number:	11989297
International Application Number:	
Confirmation Number:	4766
Title of Invention:	Wound closure and drainage system
First Named Inventor/Applicant Name:	Carmeli Adahan
Customer Number:	20529
Filer:	Susanne M. Hopkins/Lisa Elliott
Filer Authorized By:	Susanne M. Hopkins
Attorney Docket Number:	29068U
Receipt Date:	16-NOV-2010
Filing Date:	24-JAN-2008
Time Stamp:	13:46:47
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Miscellaneous Incoming Letter	Letter_Examiner_relDSpreviouslysubmitted.pdf	69882 da03a6c993c38863c02723e98cc3ca1f6f567cb	no	2
Warnings:					
Information:					

2	Miscellaneous Incoming Letter	STAMPED_FILING_RECEIPT__06-05-2008.pdf	61213 61575f2f97dfa5a6c92110870864c1aed38df56b	no	1
Warnings:					
Information:					
3	Information Disclosure Statement (IDS) Filed (SB/08)	sb0008-IDS.pdf	613378 c47b341eee9ce17d8c3711e88b59a43f706064cf	no	8
Warnings:					
Information:					
4	Foreign Reference	WO_03030966_A1.pdf	1044861 21e2245ec7761462f176a11913431281254 9b3d0	no	23
Warnings:					
Information:					
5	Foreign Reference	WO_97018007_A1.pdf	719315 e31e8a4253d0cdcacc030956602c3d6324a4084e	no	22
Warnings:					
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6	Foreign Reference	DE_10215896_A1.pdf	3548394 b5ec2543598ff79e4714256da4cb39cdada5b1e8	no	5
Warnings:					
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7	Foreign Reference	WO_03016719_A1.pdf	977501 dea83cac35989e419c84e4245f29c816d74ea6d7	no	23
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8	Foreign Reference	DT-DE_2401643_A1.pdf	5109846 38f21c6472ab5082ede4cca792fcdc81671b25b8	no	9
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9	Foreign Reference	EP_0156211_A2.pdf	14490416 dcb8121fa02f43e0c9016325459 90a09a34d63b8	no	26
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10	Foreign Reference	WO_00002016_A1.pdf	839147 517b6086c342cc72a850a24fcf1aa33145cc8f51	no	21
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11	Foreign Reference	WO_96005873_A1.pdf	1168473 ab6bd904d857966bcad8806591e07b7b2f118f15	no	36
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12	Foreign Reference	GB_2378734_A.pdf	16227990 977bb32f6526692478a3923c3e18f3f01f53bc2c	no	31
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13	Foreign Reference	GB_2307180_A.pdf	8865647 03bf7de7776ae900ed7e7301171da3140f24a851	no	18
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14	Foreign Reference	WO_03057070_A2.pdf	3510815 d908a2b9f2e018a7e01be072335aef09ab16597b	no	73
Warnings:					
Information:					
		Total Files Size (in bytes):	57246878		

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

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

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

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

Attorney Docket No. 29068U

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

ADAHAN		Conf. No.:	4766
Appl. No.:	11/989,297	Examiner:	TREYGER
Appl. Filing Date:	January 24, 2008	Art Unit:	3761
Title:	**WOUND CLOSURE AND DRAINAGE SYSTEM**		

LETTER TO THE EXAMINER

ATTN: EXAMINER TREYGER
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Examiner:

The IDS is being filed herewith is to replace the IDS filed on June 5, 2008, of which the 1449 and the references were misplaced within the USPTO.

Evidence of the filing is submitted herewith as the stamped filing receipt, dated June 5, 2008.

As provided in MPEP § 503, a stamped Filing Receipt/Return Postcard is prima facie evidence that the United States Patent and Trademark Office has received all of the items listed on the Filing Receipt. MPEP § 503, provides, in relevant parts that:

> The USPTO will stamp the receipt date on the filing receipt. A filing receipt which itemizes and properly identifies the items which are being filed serves as *prima facie* evidence of receipt in the USPTO of all the items listed thereon on the date stamped thereon by the USPTO. (Emphasis Added).

Applicants respectfully submit that the filing receipt stamped by the United States Patent and Trademark Office on June 5, 2008, clearly and properly identifies all of the items submitted in the filing. Additionally, none of the items were noted as not being received. Accordingly, the stamped Filing Receipt submitted herewith serves as *prima facie* evidence that the Office received the 1449 and references with the filing of June 5, 2008.

The Examiner is respectfully requested to cite the documents listed on the attached Form PTO/SB/08 in the next Official Action. In so doing, the Examiner is respectfully requested to initial in the space adjacent to the listing of each document on the Form PTO/SB/08, and return a copy of the initialed Form PTO/SB/08 with the next communication to Applicants, to confirm that these documents have been considered by the Examiner and made of record in this application.

The Examiner is invited to contact the undersigned attorney at the below-listed telephone number, with regard to any questions that may arise.

Respectfully submitted,

THE NATH LAW GROUP

/Susanne M. Hopkins/

Susanne M. Hopkins
Registration No. 33,247
Customer No. 20529

Date: November 16, 2010

THE NATH LAW GROUP
112 S. West Street, Alexandria, Virginia 22314
Tel: (703) 548-6284; Fax: (703) 683-8396
SMH/le

Attorney Docket No. 29068U

FILING RECEIPT

Date: June 5, 2008

Fees: $ 0.00 Attorney: GMN/JLM/DR

In re Application of:

ADAHAN

Serial No.:	11/989,297	Intl. Appl. No.:	PCT/IL2005/000784
Filed:	January 24, 2008	Intl. Filing Date:	July 24, 2005

For: **WOUND CLOSURE AND DRAINAGE SYSTEM**

DOCUMENTS BEING FILED:
THE PTO STAMP HEREON ACKNOWLEDGES RECEIPT OF:

(1) Transmittal Letter;
(2) Information Disclosure Statement (2 pages); and
(3) PTO Form-1449 (2 pages) with forty-four (44) references cited, and copies of eleven (11) of the forty-four (44) references cited.

THE NATH LAW GROUP
112 S. West Street
Alexandria, VA 22314
(703) 548-6284

FILE CHECK

Prepared by: le
Approved by:
Copy reviewed:
Filed by:



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/989,297	01/24/2008	Carmeli Adahan	29068U	4766

20529 7590 10/14/2010

THE NATH LAW GROUP
112 South West Street
Alexandria, VA 22314

EXAMINER	
TREYGER, ILYA Y	
ART UNIT	PAPER NUMBER
3761	
MAIL DATE	DELIVERY MODE
10/14/2010	PAPER

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.

Medela LLC and Medela AG
Exhibit 1008
Page #954

Office Action Summary	Application No.	Applicant(s)	
	11/989,297	ADAHAN, CARMELI	
	Examiner	Art Unit	
	ILYA Y. TREYGER	3761	

-- 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* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, 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 *13 September 2010*.

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

3)☐ 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

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) *1-10 and 15-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-14* is/are rejected.

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

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

Application Papers

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

10)☒ The drawing(s) filed on *24 January 2008* 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).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

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).

a)☐ All b)☐ Some * c)☐ None of:

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) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/27/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Medela LLC and Medela AG
Exhibit 1008
Page #955

DETAILED ACTION

Election/Restrictions

1. Claims 1-10 and 15-33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 09/13/2010.

2. Claims 11-14 are examined on the merits.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 11 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Lerman (US 5,941,859).

Lerman discloses a wound irrigation shield 10 (Abstract, line 2; fig. 1) that is an enclosure attachable to the wound 58 (col. 4, line 4; fig. 1) circumference so as to define a confined volume (fig. 1), having an outlet 18 (col. 4, line 11; fig. 1) made in the form of suction tube 16 (col. 4, line 10; fig. 1) that is a nipple (in re claim 12), wherein the nipple 16 is connectable by means of a suction tubing 26 (col. 5, lines 10-11; fig. 2) to the vacuum source 50 (col. 5, lines 11-12; fig. 2), wherein plurality of vacuum breaks (bleeding holes) 22 are provided in the enclosure (col. 4, lines 13-18; fig. 4).

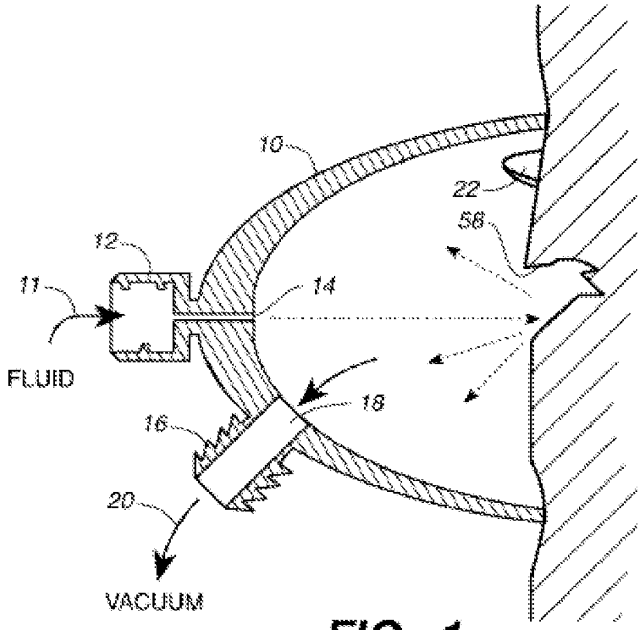


FIG._1

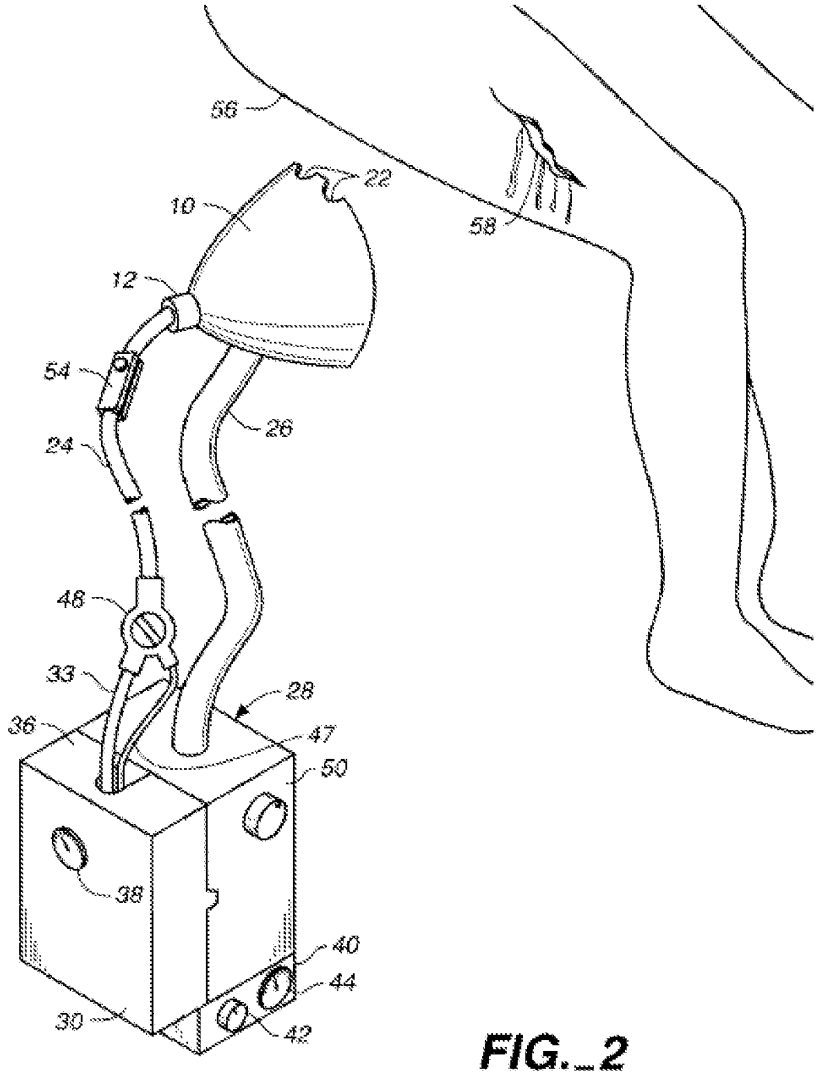


FIG._2

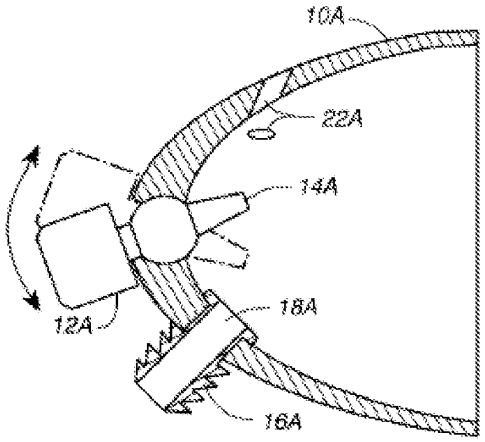


FIG._4

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) 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.

7. Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lerman (US 5,941,859).

8. In Re claim 13, Lerman discloses the invention discussed above, wherein the enclosure comprises a plurality of bleeding holes, but does not expressly disclose the structure, wherein the bleeding holes are provided in the form of a porous body.

Since the porous body is a material comprising plurality of holes, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the plurality of holes in the form of porous body in order to simplify the production process, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin,* 125 USPQ 416. In Re claim 14, Lerman discloses the invention discussed above but does not expressly disclose the enclosure, wherein the bleeding holes are located on the tube connected to the nipple.

Since both the vacuum tubing 26 and the enclosure 10 are forming common confined volume, shifting the position of bleeding holes would not have modified the operation of the device. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide bleeding holes on the vacuum tubing in order to convenience the treatment procedure, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse,* 86 USPQ 70 (**MPEP 2144.04 (VI-C)**).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILYA Y. TREYGER whose telephone number is (571)270-3217. The examiner can normally be reached on 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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

/Ilya Y Treyger/
Examiner, Art Unit 3761

/Tatyana Zalukaeva/
Supervisory Patent Examiner, Art Unit 3761

Notice of References Cited	Application/Control No. 11/989,297	Applicant(s)/Patent Under Reexamination ADAHAN, CARMELI	
	Examiner ILYA Y. TREYGER	Art Unit 3761	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-5,941,859	08-1999	Lerman, Benjamin S.	604/289
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
www.uspto.gov

BIB DATA SHEET

CONFIRMATION NO. 4766

SERIAL NUMBER	FILING or 371(c) DATE RULE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
11/989,297	01/24/2008	604	3761	29068U

APPLICANTS
Carmeli Adahan, Jerusalem, ISRAEL;

**** CONTINUING DATA ************************* I.T. 06/22/2010**
This application is a 371 of PCT/IL2005/000784 07/24/2005

**** FOREIGN APPLICATIONS ************************* I.T. 06/22/2010**

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED **** ** SMALL ENTITY **
07/08/2009

Foreign Priority claimed ☑ Yes ☐ No 35 USC 119(a-d) conditions met ☐ Yes ☐ No Verified and Acknowledged /ILYA Y TREYGER/ Examiner's Signature	☐ Met after Allowance Initials	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
		ISRAEL	2	33	5

ADDRESS

THE NATH LAW GROUP
112 South West Street
Alexandria, VA 22314
UNITED STATES

TITLE

Wound closure and drainage system

FILING FEE RECEIVED		
1000	FEES: Authority has been given in Paper No._____ to charge/credit DEPOSIT ACCOUNT No._____ for following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11989297	ADAHAN, CARMELI
	Examiner	Art Unit
	ILYA Y TREYGER	3761

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

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

CLAIM		DATE								
Final	Original	10/05/2010								
	1	-								
	2	-								
	3	-								
	4	-								
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Medela LLC and Medela AG
Exhibit 1008
Page #964

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11989297	ADAHAN, CARMELI
	Examiner	Art Unit
	ILYA Y TREYGER	3761

SEARCHED			
Class	Subclass	Date	Examiner
604	540-544	10/5/2010	I. T.

SEARCH NOTES		
Search Notes	Date	Examiner
EAST Search attached	10/5/2010	I. T.

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner

Medela LLC and Medela AG
Exhibit 1008
Page #965

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	53	((CARMELI) near2 (ADAHAN)).INV.	US-PGPUB; USPAT; USOCR	OR	OFF	2010/10/05 16:32
L2	11641	wound and (suction vacuum) and (enclosure dressing) and ((bleeding hole) (vacuum breaker))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/10/05 16:47
L3	851	(604/35).CCLS.	US-PGPUB; USPAT	OR	OFF	2010/10/05 16:48
L4	746	(604/305-308).CCLS.	US-PGPUB; USPAT	OR	OFF	2010/10/05 16:48
L5	266	(604/313).CCLS.	US-PGPUB; USPAT	OR	OFF	2010/10/05 16:48
L6	1805	(604/317-323).CCLS.	US-PGPUB; USPAT	OR	OFF	2010/10/05 16:49
L7	1255	(604/540-544).CCLS.	US-PGPUB; USPAT	OR	OFF	2010/10/05 16:49
L8	250	(604/902).CCLS.	US-PGPUB; USPAT	OR	OFF	2010/10/05 16:49
L9	505	(606/131).CCLS.	US-PGPUB; USPAT	OR	OFF	2010/10/05 16:49
L10	17	2 and 3	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/10/05 16:49
L11	119	2 and 4	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/10/05 16:50
L12	126	2 and 5	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/10/05 16:50

Medela LLC and Medela AG
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Page #966

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L14	109	2 and 7	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/10/05 16:50
L15	7	2 and 8	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/10/05 16:50
L16	4	2 and 9	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/10/05 16:50
L17	63	("1251258" | "3171410" | "3486504").PN. OR ("3874387").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2010/10/05 16:51
L18	99	("3026874" | "3486504" | "4540412" | "4759354" | "4969880").PN. OR ("5149331").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2010/10/05 16:52
L19	73	("4743232" | "5230350").PN. OR ("5344415").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2010/10/05 16:52
L20	154	("1355846" | "2547758" | "2632443" | "2682873" | "2969057" | "3367332" | "3648692" | "3682180" | "3826254" | "4080970" | "4096853" | "4139004" | "4165748" | "4245630" |	US-PGPUB; USPAT; USOCR	OR	OFF	2010/10/05 16:52

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Page #967

		"4261363" | "4275721" | "4297995" | "4333468" | "4373519" | "4382441" | "4392853" | "4392858" | "4419097" | "4475909" | "4480638" | "4525166" | "4525374" | "4540412" | "4543100" | "4551139" | "4569348" | "4605399" | "4608041" | "4640688" | "4655754" | "4733659" | "4743232" | "4787888" | "4826949" | "4838883" | "4840187" | "4863449" | "4872450" | "4878901" | "4897081" | "4906233" | "4906240" | "4919654" | "4941882" | "4953565" | "4969880" | "4985019" | "5037397" | "5100396" | "5149331" | "5167613" | "5176663" | "5261893" | "5298015" | "5344415" | "5358494" | "5556375" | "5607388" | "5636643" | "5645081").PN. OR ("6071267").URPN.					

Medela LLC and Medela AG
Exhibit 1008
Page #968

EAST Search History (Interference)

<This search history is empty>

10/5/2010 4:53:11 PM

Medela LLC and Medela AG
Exhibit 1008
Page #969

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	11989297
	Filing Date	2008-01-24
	First Named Inventor	Carmeli ADAHAN
	Art Unit	3761
	Examiner Name	ILYA Y. TREYGER
	Attorney Docket Number	29068U

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	7229422	B2	2007-06-12	Klobe	

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	0865304	EP	B1	2001-07-18	KCI Medical Ltd.		☐
	2	8401904	WO	A1	1984-05-24	Gunnar Swanbeck		☐
	3	2002541978	JP	A	2002-12-10		This corresponds with International Publication No. WO 00/64394	☒

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /I.T./

Receipt date: 08/27/2010	Application Number	11989297	11989297 - GAU: 3761
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2008-01-24	
	First Named Inventor	Carmeli ADAHAN	
	Art Unit	3761	
	Examiner Name	ILYA Y. TREYGER	
	Attorney Docket Number	29068U	

	4	0064394	WO	A1	2000-11-02	KCI Medical Limited		☐

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

NON-PATENT LITERATURE DOCUMENTS [Remove]

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

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

EXAMINER SIGNATURE

Examiner Signature	/Ilya Treyger/	Date Considered	10/05/2010

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

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

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /I.T./

Mail Stop Amendment
Attorney Docket No. **29068U**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Carmeli ADAHAN		Conf. No.:	4766
Appl. No.:	**11/989,297**	Examiner:	Ilya Y. Treyger
Filed:	January 24, 2008	Art Unit:	3761
Intl. Appl. No.:	PCT/IL2005/000784		
Intl. Filing Date:	July 24, 2005		

For: **WOUND CLOSURE AND DRAINAGE SYSTEM**

RESPONSE TO RESTRICTION REQUIREMENT

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

Dear Commissioner:

This Response is filed responsive to the Official Action dated August 13, 2010 making a response due on or before September 13, 2010. Accordingly, this Response is timely filed.

Remarks begin on page 2 of this paper.

A **Conclusion** appears at page 3 of this paper.

I. Restriction Requirement Summary

The Office Action requires election of a single invention in accordance with 35 U.S.C. §§ 121 and 372 for prosecution on the merits. The application is held to contain four patentably distinct inventions defined by the following Groups:

Group I: Claims 1 – 10 and 15 – 23, drawn to a vacuum system and a method for draining an open wound;

Group II: Claims 11 – 14, drawn to an enclosure for draining an open wound;

Group III: Claims 24 – 28, drawn to a disposable assembly for draining an open wound; and

Group IV: Claims 29 – 33, drawn to a vacuum system for draining an open wound.

II. Response to Restriction Requirement

Applicant hereby elects claims 11 – 14 of Group II, without traverse. Applicant reserves the right to file one or more divisional applications directed to the non-elected subject matter.

# # # #

CONCLUSION

Having made the required election, examination on the merits is earnestly solicited. Should the Examiner deem that any further action by Applicant's undersigned representative is desirable and/or necessary, the Examiner is invited to telephone the undersigned at the number set forth below.

In the event this paper is not timely filed, Applicant petitions for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,
THE NATH LAW GROUP

Date: September 13, 2010

/Derek Richmond/

_____
Susanne M. Hopkins
Registration No. 33,247
Derek Richmond
Registration No. 45,771
Robert T. Burns
Registration No. 60,545
Customer No. 20259

THE NATH LAW GROUP
112 South West Street
Alexandria, Virginia 22314
Tel: (703) 548-6284
Fax: (703) 683-8396

Electronic Acknowledgement Receipt

EFS ID:	8406648
Application Number:	11989297
International Application Number:	
Confirmation Number:	4766
Title of Invention:	Wound closure and drainage system
First Named Inventor/Applicant Name:	Carmeli Adahan
Customer Number:	20529
Filer:	Robert Thomas Burns Jr.
Filer Authorized By:	
Attorney Docket Number:	29068U
Receipt Date:	13-SEP-2010
Filing Date:	24-JAN-2008
Time Stamp:	16:31:32
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	29068U_TL_RRR_8-13-10.pdf	78475 9aaf3df9319737e45ddfdb843839c950e199d582	no	1

Warnings:	
Information:	

2	Response to Election / Restriction Filed	29068U_RRR_8-13-10.pdf	103584 c5cc7eb976b20bc738c73dbc612d425352ffb165	no	3
Warnings:					
Information:					
			Total Files Size (in bytes):	182059	

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

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

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

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

Mail Stop AMENDMENT
Attorney Docket No. **29068U**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Carmeli ADAHAN — Conf. No.: 4766

Appl. No.: **11/989,297** — Examiner: Ilya Y. Treyger

Filed: January 24, 2008 — Group Art Unit: 3761

Intl. Appl. No.: PCT/IL2005/000784

Intl. Filing Date: July 24, 2005

For: **WOUND CLOSURE AND DRAINAGE SYSTEM**

TRANSMITTAL LETTER

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

Dear Commissioner:

Submitted herewith for filing in the U.S. Patent and Trademark Office is the following:

(1) Transmittal Letter; and
(2) Response to Restriction Requirement.

Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,
THE NATH LAW GROUP

Date: September 13, 2010

/Derek Richmond/

THE NATH LAW GROUP
112 S. West Street
Alexandria, Virginia 22314
Tel: (703) 548-6284
Fax: (703) 683-8396

Susanne M. Hopkins
Registration No. 33,247
Derek Richmond
Registration No. 45,771
Robert T. Burns
Registration No. 60,545
Customer No. 20529

PTO/SB/06 (07-06)
Approved for use through 1/31/2007. 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	Filing Date	☐ To be Mailed
11/989,297	01/24/2008	

APPLICATION AS FILED – PART I

	(Column 1)	(Column 2)	SMALL ENTITY ☒		OR	OTHER THAN SMALL ENTITY	
FOR	NUMBER FILED	NUMBER EXTRA	RATE ($)	FEE ($)		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 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			TOTAL	

APPLICATION AS AMENDED – PART II

		(Column 1)		(Column 2)	(Column 3)	SMALL ENTITY		OR	OTHER THAN SMALL ENTITY	
	09/13/2010	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)		RATE ($)	ADDITIONAL FEE ($)
AMENDMENT	Total (37 CFR 1.16(i))	* 33	Minus	** 33	= 0	X $26 =	0	OR	X $ =	
	Independent (37 CFR 1.16(h))	* 5	Minus	***5	= 0	X $110 =	0	OR	X $ =	
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE	

		(Column 1)		(Column 2)	(Column 3)					
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AMENDMENT	Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =		OR	X $ =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =		OR	X $ =	
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	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
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Application Number	11989297
Filing Date	2008-01-24
First Named Inventor	Carmeli ADAHAN
Art Unit	3761
Examiner Name	ILYA Y. TREYGER
Attorney Docket Number	29068U

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	1	0865304	EP	B1	2001-07-18	KCI Medical Ltd.		☐
	2	8401904	WO	A1	1984-05-24	Gunnar Swanbeck		☐
	3	2002541978	JP	A	2002-12-10		This corresponds with International Publication No. WO 00/64394	☒

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	11989297
	Filing Date	2008-01-24
	First Named Inventor	Carmeli ADAHAN
	Art Unit	3761
	Examiner Name	ILYA Y. TREYGER
	Attorney Docket Number	29068U

	4	0064394	WO	A1	2000-11-02	KCI Medical Limited		☐

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	Filing Date	2008-01-24
	First Named Inventor	Carmeli ADAHAN
	Art Unit	3761
	Examiner Name	ILYA Y. TREYGER
	Attorney Docket Number	29068U

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

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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	/Derek Richmond/	Date (YYYY-MM-DD)	2010-08-27
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EFS ID:	8276315
Application Number:	11989297
International Application Number:	
Confirmation Number:	4766
Title of Invention:	Wound closure and drainage system
First Named Inventor/Applicant Name:	Carmeli Adahan
Customer Number:	20529
Filer:	Susanne M. Hopkins/Jennifer Gray
Filer Authorized By:	Susanne M. Hopkins
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Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Foreign Reference	EP0865304B1.pdf	566348 77c2e8ed3b7afb47b84786082ec1d975e9bf72f7	no	11

Warnings:	
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2	Foreign Reference	WO8401904.pdf	579866 531d2a02769986c6735a3995c8fcb6512c5cf56b	no	16
Warnings:					
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3	Foreign Reference	WO0064394.pdf	335605 ec7cee215e795199f3bc54c0ccdcecb890bc0823	no	16
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4	Foreign Reference	JP2002541978A.pdf	222510 c9d680e1d3a7871fda553c603ea7eb54bd42659d	no	15
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5	Information Disclosure Statement (IDS) Filed (SB/08)	updated_IDS.pdf	611806 30310516413222a920f4f199c2e923169d4a0879	no	4
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(11) EP 0 865 304 B1

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(54) **PORTABLE WOUND TREATMENT APPARATUS**

TRAGBARE WUNDBEHANDLUNGSVORRICHTUNG

APPAREIL PORTATIF DE TRAITEMENT DE BLESSURES

(84) Designated Contracting States:
AT BE CH DE DK ES FI FR GR IE IT LI LU MC NL PT SE

(30) Priority: **14.11.1995 GB 9523253**

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(56) References cited:
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GB-A- 2 220 357
GB-A- 2 235 877
US-A- 3 066 672
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EP 0 865 304 B1

Description

[0001] This invention relates to the healing of wounds and, more particularly, to apparatus for stimulating the healing of superficial wounds.

[0002] PCT Application No. GB95/01983 (WO 96/05873) describes apparatus for stimulating the healing of wounds comprising a porous pad which is permeable to fluids for introduction into the wound, a dressing for covering the wound and providing an air-tight seal around the wound, a drainage tube connecting the pad to a suction pump so that negative pressure can be applied to the wound to draw fluids therefrom, and a canister for collecting fluids sucked from the wound. The apparatus described in the above application has proved to be clinically effective but there are some limitations in its use.

[0003] The apparatus described in the above PCT application is effective for treating a wide variety of different types and sizes of wounds. However, it may require the patient to undergo treatment on the apparatus for a long period. In cases where the patient is confined to bed this may not be a major problem, but where the patient is mobile it means that he or she would be confined for long periods while the treatment takes place.

[0004] Another example of an apparatus for stimulating the healing of superticial wounds is given in WO-A-94R0041. The preamble of claim 1 is based on this document.

[0005] An object of this invention is therefore to provide apparatus which can be used more conveniently, especially by patients who are reasonably mobile, and which has certain further advantages which will become apparent from the following description.

[0006] According to claim 1, there is provided a portable therapeutic apparatus for stimulating the healing of superficial wounds in a person, which comprises a housing containing a suction pump and a canister for containing fluids drawn from the wound by said pump, said canister including means for connection to a dressing in the region of the wound. The device may comprise harness or belt for supporting the housing on the person.

[0007] Typically, the housing will have a curved surface on the side intended to be supported against the person's body so as to make the apparatus more comfortable to wear. In addition, controls and indicators indicating the status of the treatment being applied to the wound are preferably located on the upper side of the housing so that the patient can easily see, e.g. the level of suction pressure being applied and the programme for such treatment.

[0008] The suction pump is conveniently driven by an electric motor and batteries for such motor may be contained within the housing. However, it is generally more convenient to provide a separate housing for the batteries since these can be placed on the belt or harness in such a way as to balance the weight of the housing, preferably in a housing shaped similarly to the housing for the pump and canister. The canister should be removably mounted within the housing, e.g. by means of a latch or similar release mechanism, so that the canister can be readily removed and replaced when full.

[0009] In a portable therapeutic apparatus (in contrast with a static apparatus of the kind described in the above PCT application which cannot be easily carried by the patient), it is less easy to determine the pressure prevailing at the wound site being treated. This is because the pressure will depend, in part, upon the hydrostatic height between the pump and the wound being treated and this height may vary during the treatment, depending upon the patient's movements. Apparatus in accordance with the invention overcomes this problem by providing an additional conduit connecting the wound site or an area close thereto to a pressure-detecting means, preferably located in the housing. The pressure-detecting means can be linked to a microprocessor programmed to maintain such pressure within a predetermined range irrespective of the movement of the patient. This can be done by, for example, signalling the pump to increase its speed where the hydrostatic pressure increases between the pump and the wound site or, conversely, reducing its speed where the hydrostatic pressure is reduced. This feature can also be used in a static therapeutic apparatus of the kind described in the above-mentioned PCT application.

[0010] In the apparatus described in the above PCT application, the level of liquid in the canister is monitored by capacitance measurement. It has now been found that a simpler way of determining when the canister is filled is by measuring or detecting the pressure drop across the canister. The pressure drop can be increased by providing a filter barrier in the region of the outlet end of the canister. Thus, when the liquid reaches a level within the canister so as to substantially occlude the filter, a sharp pressure change occurs in the conduit between the canister and the pump. By monitoring this pressure change, the point at which the canister is filled can be accurately determined.

[0011] Additional advantages and features of the present application will become apparent from the following description and accompanying drawings, in which:-

Figure 1 is a schematic layout of the apparatus in accordance with the invention,

Figure 2A and B are pictorial representations of the housing of the pump and canister,

Figure 3A and B are pictorial representations of the apparatus supported on a belt and harness respectively,

Figure 4 is an exploded view of the housing showing the contents,

Figures 5A to F show various views of a preferred form of the canister and a section of a multi-lumen tube, and

Figures 6A to D show various views of a foam dress-

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ing connector for connecting the housing to the dressing,

Figure 6E shows a section of a modified multi-lumen tube,

Figures 7A & 7B show a plan and perspective view of a surgical drape for use with the apparatus.

[0012] Referring to the drawings, the portable therapeutic apparatus comprises a housing 210 (best shown in Figures 2A and 2B), having rounded corners and a side 211 which is concavely curved in order to fit comfortably to the wearer's body. The shaping of the housing with curved surfaces is to avoid sharp corners or edges which could dig in to the user or his carer. The upper surface 212 is generally flat and has an LCD screen 213 on which details such as applied pressure can be displayed. Control buttons 214 are provided to adjust pressures and treatment intervals. Provision is made for housing a canister within the housing and a snap release cover 215 is arranged for removing or introducing the canister.

[0013] Figures 3A and 3B show schematically ways in which the housing 210 may be supported on the patient's body. In Figure 3A the housing 210 is supported on a belt 216 and its weight is balanced by a similarly rounded casing 217 containing a rechargeable battery pack. Figure 3B shows an alternative arrangement in which the housing is supported on a harness 218 and again a battery pack is contained in a housing 219, also supported on the harness.

[0014] Figure 4 shows an exploded view of the housing 210 indicating the main components within the housing. The housing consists of front and rear shell mouldings 1 and 2 having an external belt clip 21 for attachment to a belt or harness.

[0015] Within housing shell 1 is located a suction pump 6 with associated electric motor 6A and the pump is connected by a silicon rubber tube 103 to a canister spigot 7A in a compartment 20 for the canister 100. Also connected to a second canister spigot 7B via a tube 10 is a pressure relief valve 8 and both tubes 103 and 10 are connected via T-connectors T to pressure transducers (not shown). A microprocessor 4 is mounted on a PCB board 5 and a membrane assembly 3 incorporates an LCD indicator and control buttons.

[0016] The apparatus may include means for recording pressures and treatment conditions given to a particular patient which may be printed out subsequently by the physician. Alternatively, the equipment may include a modem and a telephone jack so that the conditions under which the patient has been treated can be interrogated by the physician from a distant station.

[0017] Canister 100 is a push fit into the cavity 20 and its lower end is supported in a cover 30. The cover 30 incorporates fingers 31 which are releasably engageable with lips 32 to hold the canister in position. The canister and the latch mechanism is arranged so that when the latch is engaged, the spigots 7A and 7B are in sealing engagement or abutment with tubular protrusions 33 and 34 formed in the top of the canister.

[0018] The method of operation of the apparatus can be appreciated from the schematic layout in Figure 1, in which the canister 100 is connected via tube 101 to a porous dressing 102 at the wound site. Suction is applied to the wound site via the canister by a tube 103, connected to the pump 6. The pressure in the tube 103 is detected by the transducer 105.

[0019] A second tube 106 is connected to the wound site 102 at one end, and also to a pressure relief valve 8 and to a second transducer 108. Tubes 106 and 101 can be combined in a multi-partitioned tube in manner to be described later. By means of tube 106 and transducer 108 the pressure at the wound site can be measured or monitored. A filter 109 is placed at or close to the outlet end of the canister 100 to prevent liquid or solid particles from entering the tube 103. The filter is a bacterial filter which is hydrophobic and preferably also lypophobic. Thus, aqueous and oily liquids will bead on the surface of the filter. During normal use there is sufficient air flow through the filter such that the pressure drop across the filter is not substantial.

[0020] As soon as the liquid in the canister reaches a level where the filter is occluded, a much increased negative pressure occurs in tube 103 and this is detected by transducer 105. Transducer 105 is connected to circuitry which interprets such a pressure change as a filled canister and signals this by means of a message on the LCD and/or buzzer that the canister requires replacement. It may also automatically shut off the working of the pump.

[0021] In the event that it is desired to apply intermittent suction to the wound site, a pressure relief valve 8 enables the pressure at the wound site to be brought to atmospheric pressure rapidly. Thus, if the apparatus is programmed, for example, to relieve pressure at 10 minute intervals, at these intervals valve 8 will open for a specified period, allow the pressure to equalise at the wound site and then close to restore the suction. It will be appreciated that when constant suction (or negative pressure) is being applied to the wound site, valve 8 remains closed and there is no leakage from atmosphere. In this state, it is possible to maintain negative pressure at the wound site without running the pump continuously, but only from time to time, to maintain a desired level of negative pressure (i.e. a desired pressure below atmospheric), which is detected by the transducer 105. This saves power and enables the appliance to operate for long periods on its battery power supply.

[0022] Instead of running two separate tubes to the wound site, it is preferable to contain tubes 106 and 101 in a single tube which is connected through the canister. Thus, for example, tubes 103 and 101 may comprise an internal tube surrounded by an annular space represented by tube 106. This is illustrated in Figures 5A to 5F and in a modified form in Figure 6E.

[0023] In an alternative embodiment, the multi-lumen

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tube may be constructed as shown in Figure 6E. In this embodiment, the internal bore 606 comprises the line 101 (see Figure 1) and is used to extract fluids from the wound site. Air flow (represented by line 106 in Figure 1) passes down conduits 607 located within the walls of the tube. By spacing the conduits 607 at 90° intervals around the tube, the risk of arresting the air flow by kinking or twisting the multi-lumen tube is minimised.

[0024] Figure 5E is a plan view of the top of a preferred shape of canister, the generally triangular shape in section being chosen to fit better the space within cavity 20 (see Figure 4). Tubular protrusions on the top of the canister are connected internally of the canister with respectively conduits 124 and 121 (see sectional view of Figure 5B), thus maintaining a separation between the tubes which are represented by lines 103 and 106 in Figure 1. At the base of the canister, a moulding 125 facilitates connection to a multi-partitioned tube 126 shown in Figure 5F. Tube 126 has a central bore 127 which is sized to fit over a spigot 128 in moulding 125. At the same time, the external wall of tube 126 seals against the inner wall 129 of moulding 125. Thus, compartment 124 will connect with central bore 127 and the compartment 121 will connect with the annular spaces 130 of tube 126. In this way, a conduit 130 corresponds with line 106 and central bore 127 with line 101 as shown in Figure 1.

[0025] The partitioned tube need not continue all the way to the wound site 102, but can be connected to a short section of single bore tube close to the wound site.

[0026] In the event of an air leak in the dressing at the wound site 102, this can be detected by both transducers 105 and 108 reading insufficient negative pressure for a specific time period, and then triggering a leak alarm, i.e. a message on the LCD, preferably also with an audible warning.

[0027] Typically, the pump 6 is a diaphragm pump but other types of pumps and equivalent components to those specifically employed may be substituted.

[0028] Figures 6A~6D show various views of a connector for attaching the multi-lumen tube at the wound site. Figures 7A and 7B show a plan and perspective view of a surgical drape for attaching the connector to a porous dressing at the wound site. The connector comprises a moulded plastics disc-like cup 601 having a centrally positioned spout 602. The spout 602 is sized to accept, as a closely sliding fit, the end of a multi-lumen tube e.g. of the kind shown in Figures 5F or 6E. In use, a porous dressing is cut to correspond with the extent of the wound and pressed onto the wound as shown in Figure 10 of our above cited PCT application WO 96/05873. Instead of introducing the lumen into the foam dressing, the cup 601 is pressed onto the porous dressing and secured by a surgical drape. However, if desired, the end of the lumen can be passed into the spout and additionally pressed into the foam. A surgical drape such as shown in Figures 7A and 7B, can be used to secure the connector, lumen and dressing. The drape comprises a polyurethane film 701 coated on one side with a pressure-sensitive acrylic resin adhesive. A hole 702 is cut through all layers of the drape and the hole is dimensioned to correspond approximately with the outer cross-section of the spout 602. Film 701 has an overall size which allows it to be adhered to the patient's skin around the wound site, while at the same time, securing the connector to the porous dressing. A sufficient overlap around the wound is provided so that an air-tight cavity is formed around the wound.

[0029] In an alternative form, the drape can be made in two parts, e.g. by cutting along the line X-X in Figure 7A. With this arrangement, the wound can be sealed by overlapping two pieces of surgical drape so that they overlap each other along a line Y-Y as shown in Figure 6D.

[0030] The surgical drape may include a protective film 703, e.g. of polyethylene, and a liner 704 which is stripped off prior to use to expose the pressure-sensitive adhesive layer. The polyurethane film may also include handling bars 705,706, which are not coated with adhesive, to facilitate stretching of the film over the wound site. The dressing is preferably a pad of porous, flexible plastics foam, e.g. reticulated, open intercommunicating cellular flexible polyurethane foam, especially of the kind described in the above-mentioned PCT application WO 96/05873.

[0031] Alternatively, a reticulated intercommunicating cellular foam made from flexible polyvinylacetate or polyvinylalcohol foam may be used. The latter is advantageous because it is hydrophilic. Other hydrophilic open celled foams may be used.

[0032] In another method of therapy, the foam dressing may be sutured into a wound after surgery and the foam dressing connected to the pump unit by the multi-lumen catheter. Negative pressure can then be applied continuously or intermittently for a period determined by the surgeon, e.g. from about 6 hours to 4 to 5 days. After this period, the dressing is removed and the wound re-sutured. This therapy improves the rate of granulation and healing of wounds after surgery.

Claims

1. Therapeutic apparatus for stimulating healing of a wound in mammals which comprises a porous pad, which is permeable to liquids for introduction into the wound, a dressing (102) for covering the wound and providing a substantially air-tight seal around the wound, a drainage conduit (101) connecting the pad to a suction pump (6) so that suction can be applied to the wound to draw liquids therefrom, said conduit being connected to the pump via a canister (100) for collecting liquids sucked from the wound and at least one filter (109) interposed between the canister and the pump, characterised in that said apparatus includes an additional conduit (106) connecting the porous pad to pressure detecting

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means (108) whereby the pressure substantially at the wound site can be monitored.

2. Apparatus as claimed in claim 1 wherein the pressure detecting means (108) is linked to a microprocessor programmed to maintain pressure at the wound site within a predetermined range irrespective of movement of the patient.

3. Apparatus as claimed in claim 1 or 2 which includes a relief valve (8) for admitting air to the additional conduit (106) and means for controlling the operation of the valve so that intermittent suction can be applied to the wound site.

4. Apparatus as claimed in any one of claims 1 to 3 in which a single tube (126) links the porous pad with the housing, said tube being longitudinally partitioned to provide a drainage conduit (127 or 606) for applying suction and an additional conduit (130 or 607) for connection to said pressure detecting means (108).

5. Apparatus as claimed in any one of the preceding claims wherein the suction pump and canister are contained in a housing (210) adapted to be worn and wherein the housing has a curved side (211) intended to be supported against the body and has controls (214) located on an upper side (212) of the housing.

6. Apparatus as claimed in any one of the preceding claims wherein said filter is located in the canister at the outlet side and pressure detecting means (105) are arranged to detect pressure changes in a conduit (103) connecting the canister and the pump and to signal a pressure change when liquid in the canister covers a substantial part of the filter, thus indicating a full canister.

7. Apparatus as claimed in claim 6 wherein the filter covers the entire outlet from the canister and the dimensions of the pores in the filter are such that when liquid covers substantially the whole of the filter, said pressure detecting means (105) signals a sharp increase in negative pressure in the conduit (103), connecting the canister with the pump.

8. Apparatus as claimed in any one of the preceding claims which includes means for recording pressures and treatment conditions given to a patient.

9. Apparatus as claimed in any one of the preceding claims wherein the porous pad comprises an intercommunicating cellular foam of polyvinyl alcohol.

Patentansprüche

1. Therapeutisches Gerät zur Förderung der Heilung einer Wunde von Säugern, umfassend

   - ein poröses, für Flüssigkeiten durchlässiges Polster zum Einführen in die Wunde,
   - einen Verband (102) zur Abdeckung der Wunde und zum Bereitstellen einer im wesentlichen luftdichten Abdichtung um die Wunde herum,
   - eine das Polster mit einer Saugpumpe (6) verbindende Drainageleitung (101), sodass an der Wunde gesaugt werden kann, um Flüssigkeiten von dort abzuziehen, wobei die Leitung über einen Kanister (100) zum Sammeln von von der Wunde abgesaugter Flüssigkeit mit einer Pumpe verbunden ist und
   - wenigstens einen Filter (109) der zwischen dem Kanister und der Pumpe angeordnet ist,

   dadurch gekennzeichnet, dass
   das Gerät eine zusätzliche Leitung (106) beinhaltet, die das poröse Polster mit einem Druck-Nachweis-Gerät (108) verbindet, wobei der Druck im wesentlichen an der wunden Stelle überwacht werden kann.

2. Gerät nach Anspruch 1, **wobei** das Druck-Nachweis-Gerät (108) mit einem Mikroprozessor verbunden ist, der dazu programmiert ist, den Druck an der wunden Stelle innerhalb eines vorbestimmten Bereichs unabhängig von der Bewegung des Patienten aufrecht zu erhalten.

3. Gerät nach Anspruch 1 oder 2, das ein Entlastungsventil (8) beinhaltet, um Luft in die zusätzliche Leitung (106) einzulassen, und das ein Mittel für die Kontrolle des Betriebs des Ventils beinhaltet, sodass in Abständen an der wunden Stelle gesaugt werden kann.

4. Gerät nach einem der Ansprüche 1 bis 3, bei welchem ein einzelnes Röhrchen (126) das poröse Polster mit dem Gehäuse verbindet, wobei das Röhrchen in Längsrichtung geteilt ist um eine Drainageleitung (127 oder 606) zum Saugen und eine zusätzliche Leitung (130 oder 607) für die Verbindung mit dem Druck-Nachweis-Gerät (108) bereitzustellen

5. Gerät nach einem der vorherigen Ansprüche, **wobei** die Saugpumpe und der Kanister in einem Gehäuse (210) gefasst sind, das dazu angepasst ist getragen zu werden und wobei das Gehäuse eine gewölbte Seite (211) hat, die dazu vorgesehen ist gegen den Körper abgestützt zu sein und das Regler (214) hat, die sich an der oberen Seite (212) des Gehäuses befinden.

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6. Gerät nach einem der vorherigen Ansprüche, **wobei** sich der Filter in dem Kanister an der Ausflussseite befindet und Drucknachweis-Geräte (105) angeordnet sind um Druckänderungen in einer den Kanister und die Pumpe verbindenden Leitung (103) zu ermitteln und eine Druckänderung anzuzeigen, wenn die Flüssigkeit in dem Kanister einen wesentlichen Teil des Filters bedeckt und somit einen vollen Kanister anzudeuten.

7. Gerät nach Anspruch 6, **wobei** der Filter den gesamten Auslass des Kanisters bedeckt und die Dimensionen der Poren in dem Filter so sind, dass das Druck-Nachweis-Gerät (105) eine scharfe Zunahme des Unterdrucks in der den Kanister mit der Pumpe verbindenden Leitung (103) anzeigt, wenn die Flüssigkeit im Wesentlichen den ganzen Filter bedeckt.

8. Gerät nach einem der vorherigen Ansprüche, das Mittel zum Aufzeichnen der Drücke und Behandlungsbedingungen beinhaltet, die dem Patienten erteilt werden.

9. Gerät nach einem der vorherigen Ansprüche, **wobei** das poröse Polster einen verbindenden zellförmigen Schaum aus Polyvinylalkohol beinhaltet.

Revendications

1. Dispositif thérapeutique destiné à stimuler la cicatrisation d'une plaie chez les mammifères qui comprend un tampon poreux, qui est perméable aux liquides, destiné à une introduction dans la plaie, un pansement (102) destiné à recouvrir la plaie et procurant un joint pratiquement étanche à l'air autour de la plaie, un conduit de drainage (101) reliant le tampon à une pompe d'aspiration (6) de sorte qu'une aspiration peut être appliquée à la plaie afin d'aspirer des liquides depuis celle-ci, ledit conduit étant relié à la pompe par l'intermédiaire d'une boîte (100) destinée à recueillir les liquides aspirés depuis la plaie et au moins un filtre (109) interposé entre la boîte et la pompe, caractérisé en ce que ledit dispositif comprend un conduit supplémentaire (106) reliant le tampon poreux à un moyen de détection de la pression (108), d'où il résulte que la pression peut pratiquement être surveillée au niveau du site de la plaie.

2. Dispositif selon la revendication 1, dans lequel le moyen de détection de la pression (108) est relié à un microprocesseur programmé pour maintenir la pression au niveau du site de la plaie à l'intérieur d'une plage prédéterminée indépendamment du mouvement du patient.

3. Dispositif selon l'une quelconque des revendications 1 et 2, qui comprend un clapet de décharge (8) destiné à admettre de l'air vers le conduit supplémentaire (106) et un moyen destiné à commander le fonctionnement du clapet de sorte qu'une aspiration intermittente peut être appliquée au site de la plaie.

4. Dispositif selon l'une quelconque des revendications 1 à 3, dans lequel un tube unique (126) relie le tampon poreux au boîtier, ledit tube étant cloisonné longitudinalement pour procurer un conduit de drainage (127 ou 606) destiné à appliquer une aspiration et un conduit supplémentaire (130 ou 607) destiné au raccordement audit moyen de détection de la pression (108).

5. Dispositif selon l'une quelconque des revendications précédentes, dans lequel la pompe d'aspiration et la boîte sont contenues dans un boîtier (210) conçu pour être porté et dans lequel le boîtier présente un côté incurvé (211) prévu pour être maintenu contre le corps et comporte des commandes (214) situées sur une face supérieure (212) du boîtier.

6. Dispositif selon l'une quelconque des revendications précédentes, dans lequel ledit filtre est situé dans la boîte au niveau du côté de l'orifice de sortie et un moyen de détection de la pression (105) est disposé afin de détecter des changements de pression dans un conduit (103) reliant la boîte et la pompe et pour signaler un changement de pression lorsque le liquide dans la boîte recouvre une partie substantielle du filtre, en indiquant ainsi que la boîte est pleine.

7. Dispositif selon la revendication 6, dans lequel le filtre recouvre complètement l'orifice de sortie de la boîte et les dimensions des pores du filtre sont telles que lorsque le liquide recouvre pratiquement la totalité du filtre, ledit moyen de détection de la pression (105) signale une augmentation brutale de la pression négative dans le conduit (103), reliant la boîte à la pompe.

8. Dispositif selon l'une quelconque des revendications précédentes, lequel comprend un moyen destiné à enregistrer les pressions et les conditions de traitement données à un patient.

9. Dispositif selon l'une quelconque des revendications précédentes, dans lequel le tampon poreux comprend une mousse d'alcool polyvynilique à cellules communiquant entre elles.

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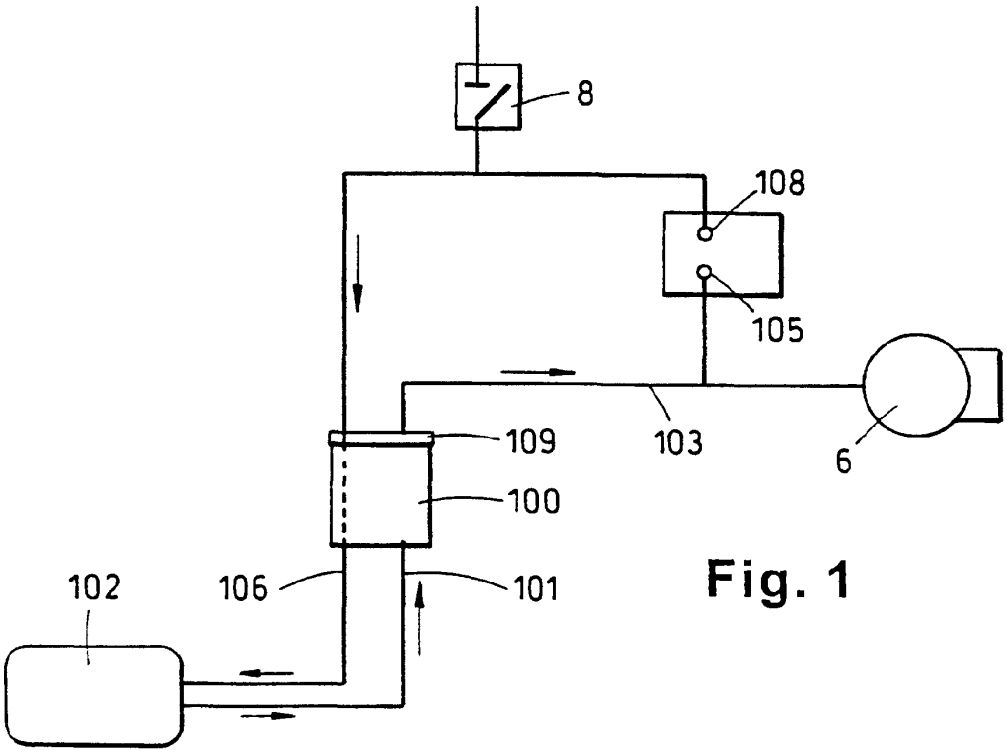


Fig. 1

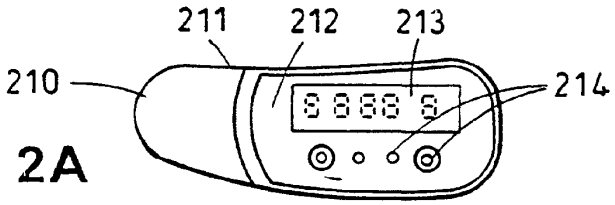


Fig. 2A

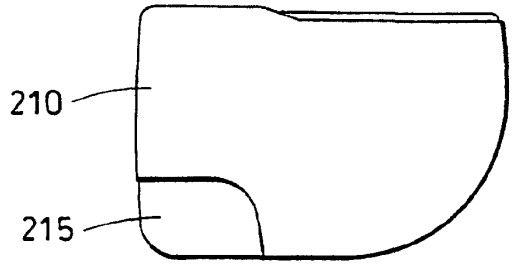


Fig. 2B

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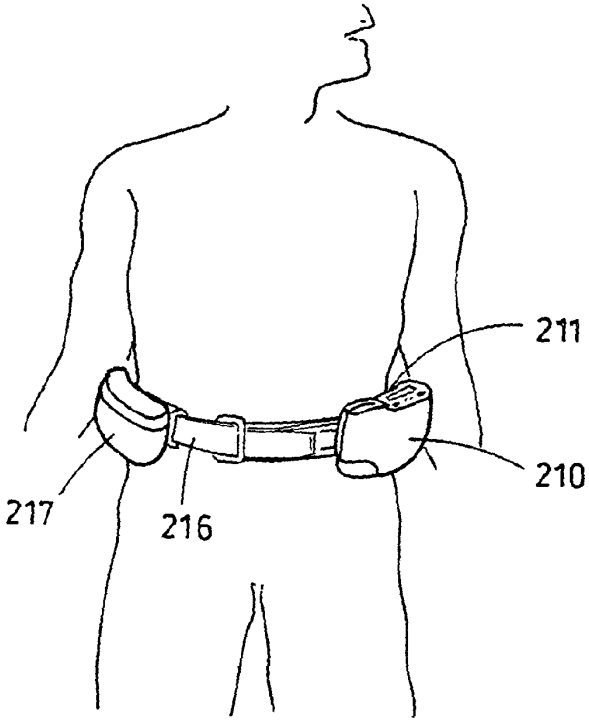


Fig. 3A

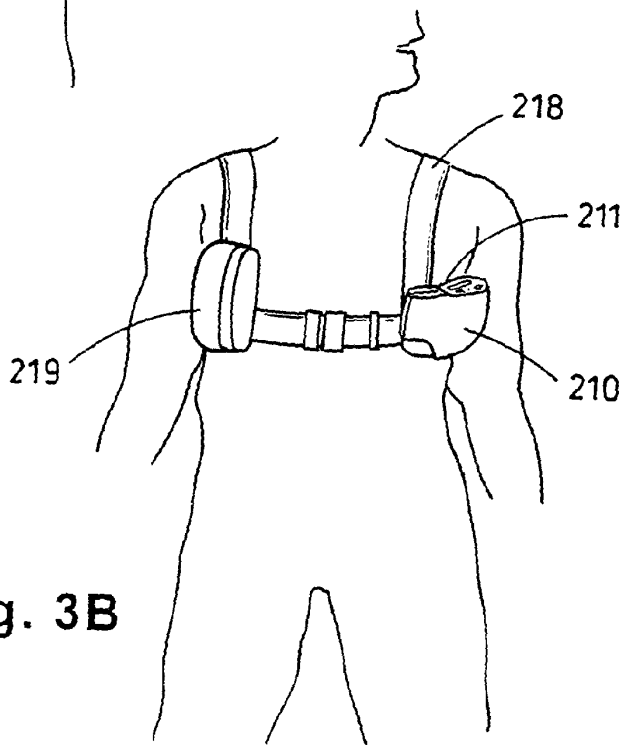


Fig. 3B

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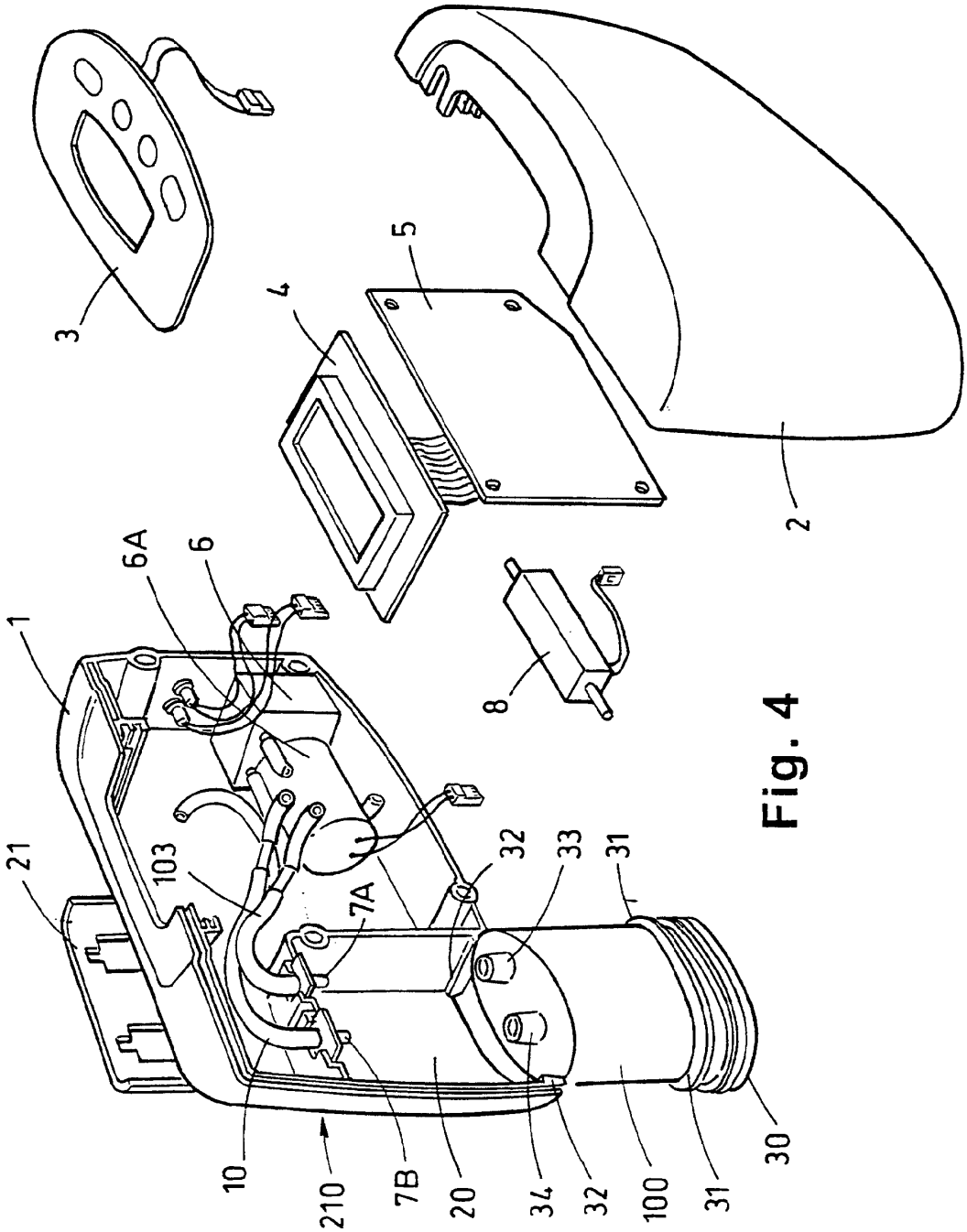


Fig. 4

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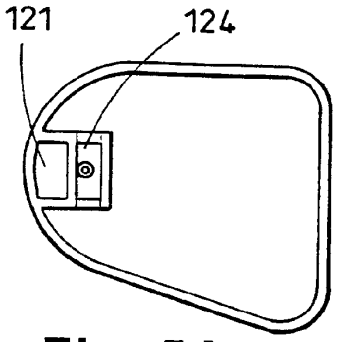


Fig. 5A

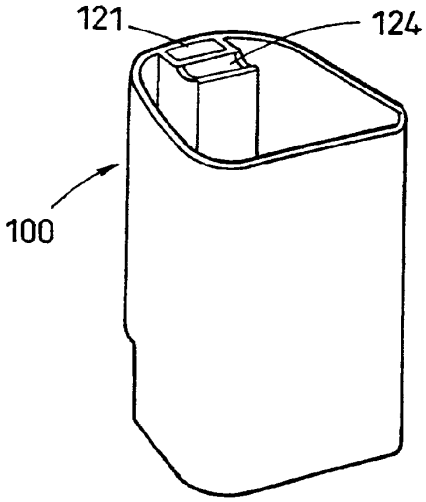


Fig. 5D

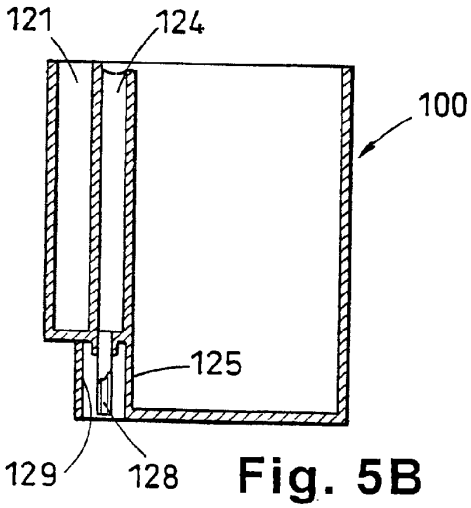


Fig. 5B

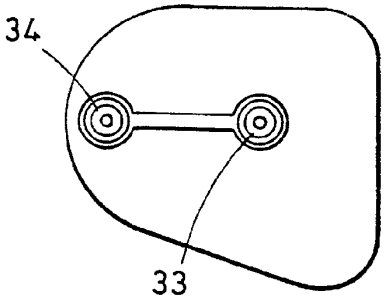


Fig. 5E

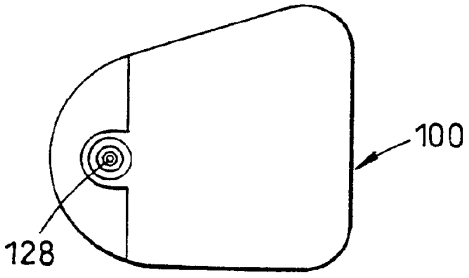


Fig. 5C

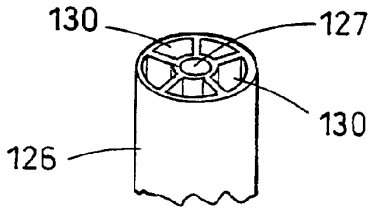


Fig. 5F

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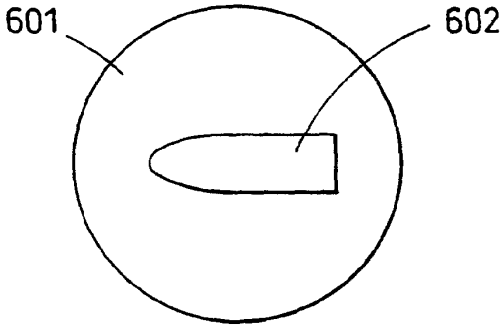


Fig. 6A

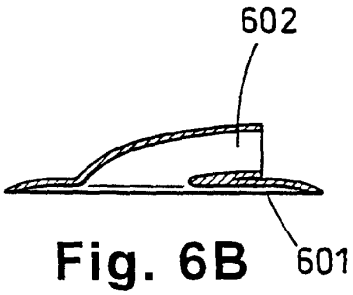


Fig. 6B

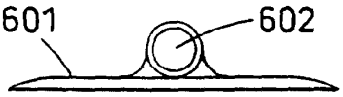


Fig. 6C

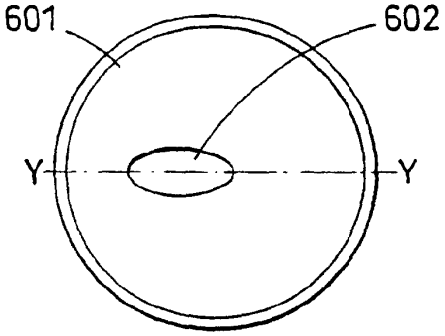


Fig. 6D

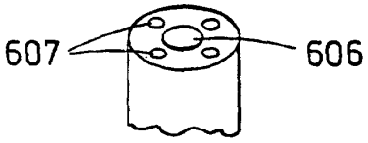


Fig. 6E

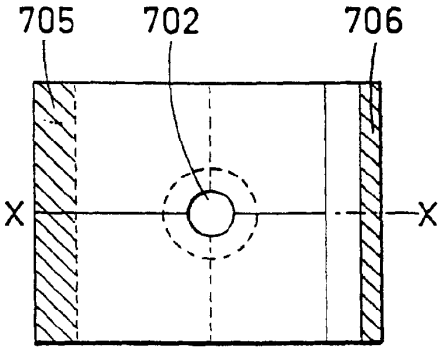


Fig. 7A

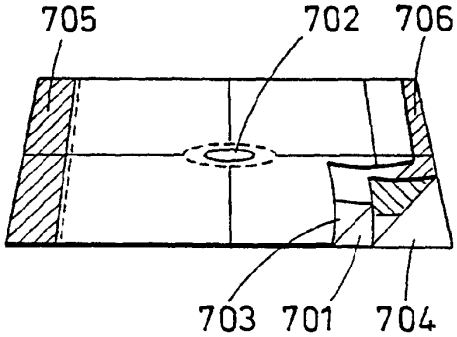


Fig. 7B

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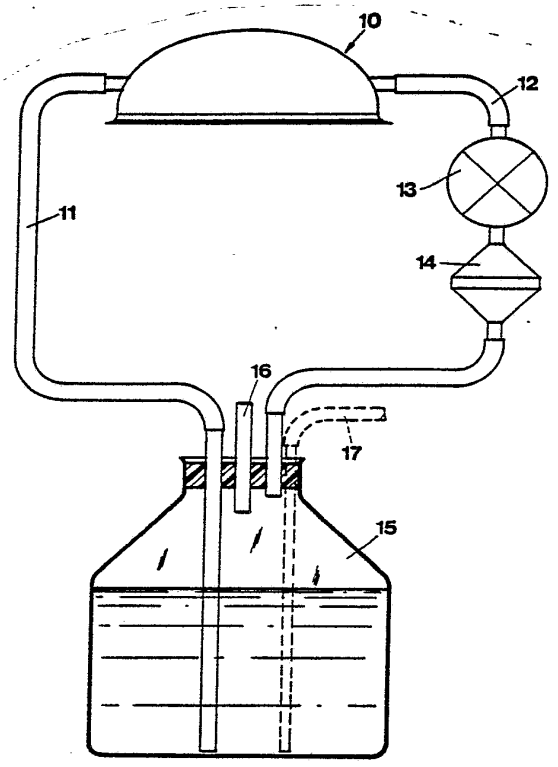
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With amended claims.

(54) Title: A DEVICE FOR RINSING AND TREATING WOUNDS AND INFECTED SKIN PORTIONS

(57) Abstract

A device for rinsing and treating wounds and infected skin portions and comprising a suction cup (10) which is placed over the area to be treated and a vessel (15) for a treatment solution, said vessel by way of a tube connection (11, 12) communicating with the interior of the suction cup. The treatment solution is intended to fill up at least a substantial part of the volume of the suction cup (10). The vessel (15) and suction cup form by way of the tube connection a closed liquid system for the treatment solution. A pump (13) may be arranged to cause the solution to circulate between the suction cup (10) and the vessel (15). A suction effect is created within the cup (10) by keeping this on a level above the vessel (15).



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A device for rinsing and treating wounds and infected skin portions

Technical field

The present invention refers to a device for rinsing and treating wounds and infected skin portions and comprising a cup-shaped member covering the area to be treated and having its opening towards this, said device further comprising a vessel for a treatment solution, said vessel by way of a tube connection communicates with the interior of the cup-shaped member, at which the treatment solution is intended to fill up at least a substantial part of the volume of the cup-shaped member and forming a liquid surface against the area to be treated for exchanging components between this and the treatment solution, and wherein the interior of the cup-shaped member is arranged to be kept at a lower pressure than the atmospheric pressure.

Background of the invention

The conventional method for treating chronical and infected wounds, such as bedsores, leg ulcers etc. is manual washing and moist compresses soaked with a common salt solution and if necessary enzymes for promoting the healing process. In recent years a new medical preparation called Debrisan® consisting of small, dry, porous beads has been used to a limited extent and is declared to have a better absorption capacity as compared to most common salt compresses.

Divices for risning and treating wounds have also been proposed, in which a cup with its opening facing the wound is applied about the wound area, said cup having an inlet and an outlet opening and a liquid is caused to pass through the cup. Said liquid can contain antibiotics and substances which improves the healing process. Bacteria and waste products from

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the wound are washed away with the cleansing slution. Such a device is shown in DE-OS 2,809.828 and US patent No. 2.280.915. Since often long treatment periods are required for obtaining a desired result large volumes of cleansing solution are consumed, which means great expenses especially if the solution contains substances as antibiotics, enzyme preparations, vitamines etc.

The purpose and most important features of the invention

The object of the present invention is to provide a device of the kind mentioned in the introduction, which makes it possible to treat wounds and infected skin portions in an economically justified way even during long periods of time and which improves the healing of the wound and besides in certain cases can compensate for an insufficient blood-circulation, e.g. in leg ulcers.

This has been achieved by the fact that said vessel and cup-shaped member by way of said tube connection form a closed liquid system thereby providing a uniform low pressure within the cup-shaped member, which may be regulated by the level difference between the cup-shaped member and the vessel.

Description of the drawings

The invention will now be further described with reference to the accompanying drawings, where Fig. 1 and 2 schematically show two different embodiments of the invention.

Description fo the embodiments

The device according to Fig 1 comprises a suction cup 10 of rubber, plastic or glass and which has an inlet and an outlet opening, to which a feed and a discharge tube 11 and 12 resp. are connected. The discharge tube 12 leads by way of a pump 13 and a sterilizing filter 14 down into a bottle 15 containing a treatment solution. The pump 13 is preferably a so called

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peristaltic pump. The tube 11 connected to the inlet opening of the suction cup 10 leads from the bottle 15. The interior of the bottle 15 is kept at atmospheric pressure by means of an air tube 16. Oxygen may also be bubbled into the solution by way of a tube 17 to ensure oxygenation of the wound to be treated. The suction cup is applied over the wound area or the infected skin portions to be treated. The solution is caused to circulate through the system and is prevented from leaking out from the suction cup 10 by applying a pressure to the cup. This pressure may be created by an external bandage or by having a somewhat lower pressure inside the cup than in the surrounding atmosphere. This lower pressure may be regulated by the level difference between the bottle and the suction cup. i.e. the hydrostatic pressure difference. It can also be regulated by the flow resistance between the bottle and the suction cup and by the speed of flow. The pressure can also be regulated by a separate pressure regulator.

The low pressure in the suction cup provides besides preventing leaking from the suction cup, that interstitial fluid is sucked out from the wound and facilitates that blood components are transported to the wound and that microorganisms are easier washed away from the wound.

The suction cup may be of different sizes, shapes and materials, such as glass, rubber or plastic etc. The suction cup has an opening towards the skin area to be treated and inlet and outlet openings for the solution. The size of the opening towards the skin may vary from some mm^2 to some dm^2. The volume of the solution may vary from some ml to several liters.

The sterlizing filter 14 which may either be placed between the pump 13 and the bottle 15 or between the suction cup 10 and the pump can have a porosity of about 0.22 micron, to filter out all bacteria, up to about 0.80 micron to get a good degree of cleaning of the solution. The sterilizing filter 14 is however in most cases unnecessary and can thus be

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eliminated.

The bottle 15 with the treatment solution may be placed in a thermostatically regulated water bath to ensure a certain temperature of the treatment solution.

The active ingredients in the solution to be circulated may be a cleaning agent, compounds for nutrition of the tissue including oxygen, vitamins, amino acids and glucose, drugs of different types such as antibiotics, antiinflammatory agents, e.g. cortison, and enzymes for digestion of necrotic tissue, coagulum and pus.

The solution may be of the types used for intravenous infusion or for skin cleaning. It is however possible that a better result may be obtained with new developed solutions for this special pupose.

The circulation of the solution enables a larger volume of the solution and by that a greater amount of nutritives, drugs etc. to come in contact with the wound to be treated and to get a continuous sterilization of the solution if the sterilizing filter 14 is used. The circulation will also give an effective cleaning of the wound as the solution all the time will be flowing over the wound and wash away waste products therefrom. As was mentioned above a continuous oxygenation of the wound may easily be obtained by bubbling oxygen into the treatment solution in the bottle.

Especially at chronic leg ulcers the device according to this invention may be regarded as a substitute for the insufficient blood circulation in the ulcer area.

If a continuous treatment is desired during a long period of time the filter 14 and the treatment solution may be exchanged e.g. by arranging a T-connection with a valve between the bottle 15 and the suction cup 10 and between the pump 13 and the filter 14.

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In the embodiment shown in Fig. 2 the pump is eliminated and th cup 10 is connected to the bottle 15 only by way of the tube 11. The outlet opening 10 of the cup is closable. The solution is caused to raise into the cup 10 through the tube 11 by raising the bottle 15 to a higher level, at which the outlet opening of the cup is open. When the solution starts flowing out through said opening this is closed by a stopper 18 or the like, after which the bottle is lowered to a level below the cup 10. The interior of the cup will then have a negative pressure corresponding to the level difference to the bottle. A certain natural circulation caused by convection will take place within the cup, at which there will be an exchange of components between the wound and the treatment solution.

In practice it may be appropriate to start a treatment with the device according to Fig. 1 and when the healing process has advanced change to the device according to Fig. 2

The most important fields of application for the device according to the invention are:

1. Cleaning of chronic and infected ulcers such as pressure ulcers, leg ulcers etc.

2. Substituting and complementing the blood circulation in arterial- or venous insufficiency of the legs in leg ulcer patients.

3. Administration of drugs such as antibiotics and antiinflammatory compounds in a controlled and exact way in for instance vasculitis ulcers.

4. Treatment of superficial skin infections, such as impetigo, herpes simplex and mycoses. Clinical tests have been performed with the device according to Fig. 1 and the results thereof will be given below.

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Clinical tests

The patients have been treated for approximately two hours daily till the lesions have healed. If pain was felt due to the low pressure the treatment was stopped when the patient so wanted. In one of the patients the treatment was stopped after 45 minutes the first week of treatment. Subsequently the patient could stand treatment for two hours daily. Two patients with leg ulcers due to an established arterial insufficiency, two patients with ulcers due to venous insufficiency, one patient with a diabetic ulcer and one patient with pyoderma gangrenosum have taken part in the preliminary clinical trial. One of the patients with arterial insufficiency had two ulcers that were treated, not simultaneously but in succession.

Case 1. 93-year old woman that after childbirth got problems with varicous veins and subcequently had several deep vein thromboses. Since the age of 80 she suffered from recurrent leg ulcers. Some months before treatment started with external circulation she got several ulcerations on both legs. Oscillometry and systolic ankle and toe pressure gave values indicating threatening gangraene. Treatment with external circulation gave complete epithelialization in nine weeks.

Case 2. 73-year old man who earlier had vein thromboses three times in his left leg. The first leg ulcer came in 1968 and has recurred since then in both legs but mostly in his left leg. In 1980 he was considered having a combined arterial and venous insufficiency causing his leg ulcerations. He was operated for insufficient perforating veins in his left leg the same year. After the operating the surgical wound did not heal. The patient also developed some other ulcerations on the same leg. First we started treating the initial three year old surgical wound with external circulation. After nine weeks when this ulcer was healed, we went on with treating another wound distal and lateral to the surgical wound. After seven

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weeks of treatment the wound was epithelialized over 80 percent of its surface.

Case 3. 65-year old woman with diabetes and hypertension. She had a small traumatic ulceration on the ventral side of the left leg in 1948. The ulceration has recurred several times but since 1978 it had not healed in spite of several types of treatment including reconstructive surgery . In 1982 toe pressure in the first left toe was 30 mmHG indicating arterial insufficiency. After eight weeks of treatment with external circulation the ulcer was healed.

Case 4. 57-year old woman with mild hypertension who had vein thrombosis in her left leg in 1957 and 1973. The patient had a 1.5x2 centimeter ulcer for half a year over the left medial melleolus when treatment with external circulation was started. After three weeks of treatment the ulceration was healed.

Case 5. 63-year old man with recurrent leg ulcerations since 1976. He had no sign of arterial insufficiency. In August 1982 he got a 1 centimeter ulceration on the medial side of his left leg. In February 1983 he got another 1 centimeter ulcer close to the former. Both ulcers were treated simulaneously with external circulation and both were healed in three weeks.

Case 6. 27-year old woman with pyoderma gengrenosum since 1972. The ulceration have mainly appeared on her legs and arms. For the last 18 months she had had ulcerations all the time and refused taking prednisolon. One of her fresh ulcers had a diameter slightly over 1.5 centimeter. After three weeks of treatment the ulcer was heald.

Results

Daily treatment with external circulation of a nutrient solution under low pressure has been effective in healing the seven ulcerations of the six patients. For the three patients

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without arterial insufficiency the healing rate has been considerably shorter than for those with arterial insufficiency on the basis of arteriosclerosis or diabetes mellitus.

When the daily treatment was stopped there was an oedema under the treatment cup. The oedema disappeared within a few hours. Pain was recorded for one patient after the low pressure had been applied for about 45 minutes. After a few weeks of treatment the pain did not appear.

For two patients albumin determination in the circulating nutrient fluid after two hours of treatment was performed. Values corresponding to about 0.5 ml of serum was obtained.

For the patients with arterial insufficiency including the diabetic patient the ulcers healed first with an epithelialization and later on after the treatment had been stopped the dermal defect was filled out. Epitheialization thus seemed to proceed granulation under the conditions of this type of treatment.

The invention is of course not limited to the embodiments shown in the drawings but can be notified within the scope of the claims.

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Claims

1. A device for rinsing and treating wounds and infected skin portions and comprising a cup-shaped member (10) covering the area to be treated and having its opening towards this, said device further comprising a vessel (15) for a treatment solution, said vessel by way of a tube connection communicates with the interior of the cup-shaped member, at which the treatment solution is intended to fill up at least a substantial part of the volume of the cup-shaped member and forming a liquid surface against the area to be treated for exchanging components between this and the treatment solution, and wherein the interior of the cup-shaped member (10) is arranged to be kept at a lower pressure than the atmospheric pressure,
c h a r a c t e r i z e d i n,
that said vessel (15) and cup-shaped member (10) by way of said tube connection (11,12) form a closed liquid system, thereby providing a uniform low pressure within the cup-shaped member, which may be regulated by the level difference between the cup-shaped member and the vessel (15).

2. A device according to claim 1,
c h a r a c t e r i z e d i n,
that a tube connection (11) is arranged between the vessel (15) and an inlet opening in the cup-shaped member (10) and a second tube connection (12) is arranged between an outlet opening in the cup-shaped member and the vessel, and that a pump (13) is provided at said second tube connection for causing the treatment solution to circulate between the cup-shaped member and the vessel.

3. A device according to claim 2,
c h a r a c t e r i z e d i n,
that a sterlizing filter (14) is arranged between said outlet opening and the vessel (15).

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4. A device according to claim 1,
c h a r a c t e r i z e d i n,
that the vessel (15) by way of a tube connection (11) is connected to an opening in the cup-shaped member (10), which has a second closable opening and that in use of the device the tube and at least a substantial part of the cup-shaped member are filled with treatment solution and said second opening is closed, at which the low pressure in the cup-shaped member is maintained and can be regulated by the level difference between the cup-shaped member and the vessel.

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AMENDED CLAIMS
[received by the International Bureau on 24 April 1984 (24.04.84);
original claims 1 to 4 replaced by claims 1 and 2]

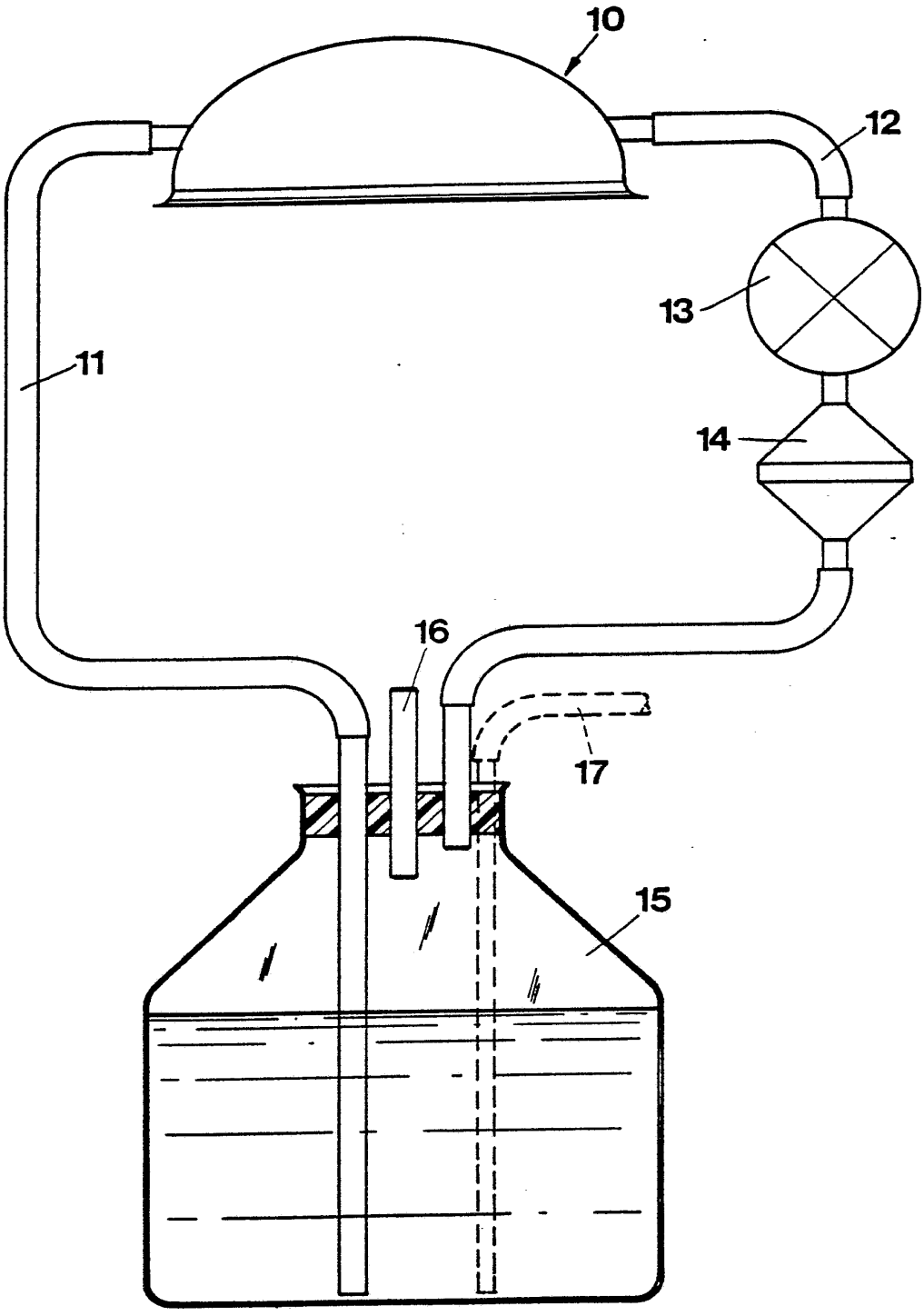
1. A device for rinsing and treating wounds and infected skin portions and comprising a cup-shaped member (10) covering the area to be treated and having its opening towards this and said member having inlet- and outlet openings, said device further comprising a vessel (15) for a treatment solution intended to pass through the cup-shaped member and fill up at least a substantial part of the volume thereof and forming a liquid surface against the area to be treated for exchanging components between this and the treatment solution, and wherein the interior of the cup-shaped member (10) is arranged to be kept at a lower pressure than the atmospheric pressure,
c h a r a c t e r i z e d i n,
that said vessel (15) by way of said tubes (11,12) is connected to both the inlet- and outlet openings of the cup-shaped member (10), so that a closed liquid system is formed between said member and said vessel, and that a pump (13) is provided between said outlet opening and the vessel for causing the treatment solution to circulate in said liquid system.

2. A device according to claim 1,
c h a r a c t e r i z e d i n,
that a sterlizing filter (14) is arranged between said outlet opening and the vessel (15).

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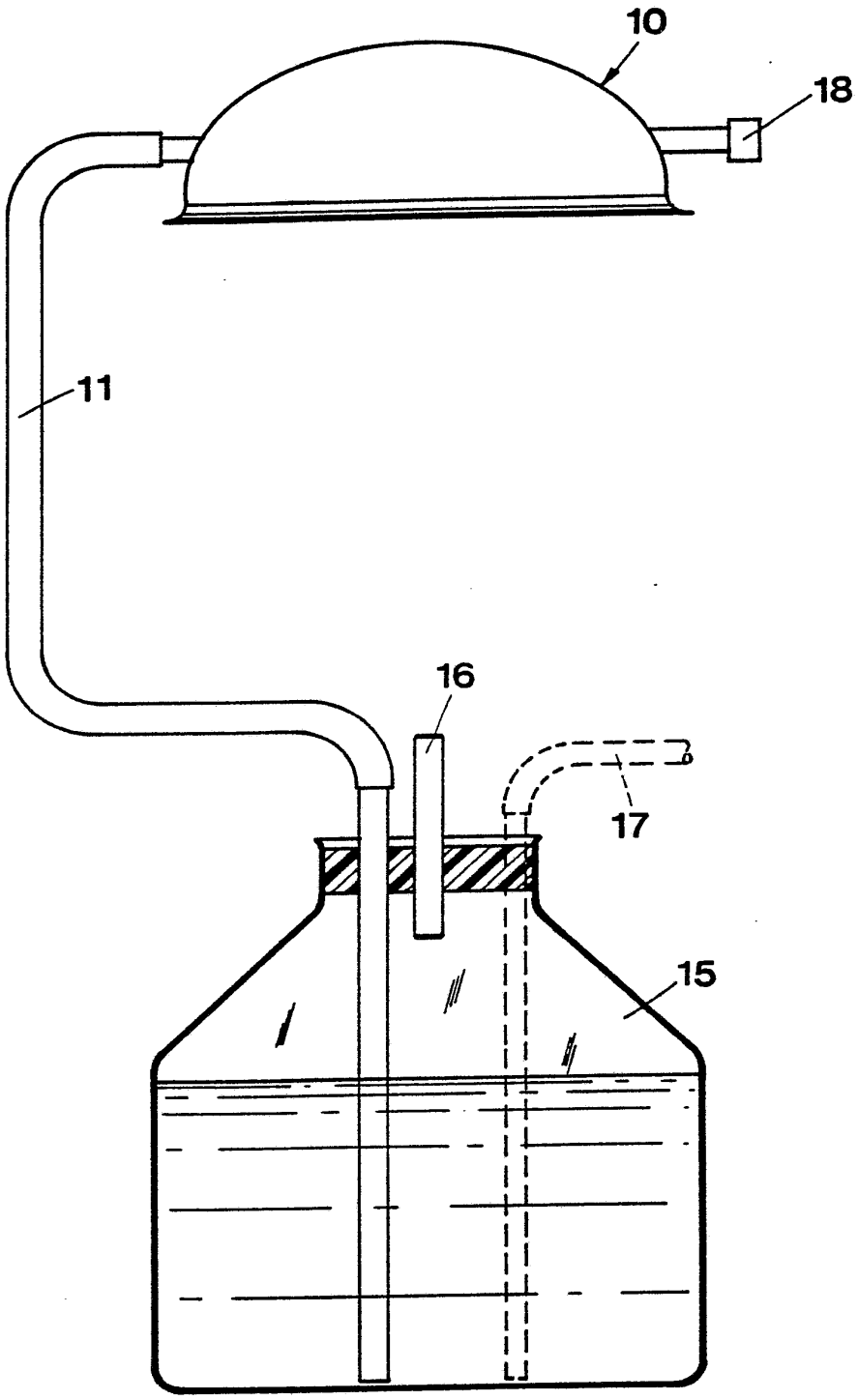
FIG 1



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FIG 2



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INTERNATIONAL SEARCH REPORT

International Application No PCT/SE83/00439

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [3]

According to International Patent Classification (IPC) or to both National Classification and IPC 3

A 61 M 35/00

II. FIELDS SEARCHED

Minimum Documentation Searched [4]

Classification System	Classification Symbols
IPC 3	A 61 F 13/00, A 61 H 33/00, 35/00, A 61 M 35/00, 37/00
US Cl	128:114, 260, 268, 269, 273

Documentation Searched other than Minimum Documentation to the Extent that such Documents are included in the Fields Searched [5]

SE, NO, DK, FI classes as above

III. DOCUMENTS CONSIDERED TO BE RELEVANT [14]

Category [6]	Citation of Document, [16] with indication, where appropriate, of the relevant passages [17]	Relevant to Claim No. [18]
Y X	SE, B, 402 212 (GAMBRO AB) 26 June 1978 & DE 2745347 JP 53048979 US 4191646 SE 7611387	1 2
Y X	SE, B, 422 883 (TAKEDA CHEMICAL INDUSTRIES LTD) 5 April 1982	1 2
Y	WO, A1, 80/01139 (PÅL SVEDMAN) 12 June 1980 & GB 2047543 EP 0020662 US 4382441	1
X	GB, A, 641 061 (J D MAC LAURIN) 2 August 1950	4
Y	US, A, 2 280 915 (J H JOHNSSON) 28 April 1942	1
X	US, A, 3 026 874 (R C STEVENS) 27 March 1962	4

* Special categories of cited documents: [15]

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IV. CERTIFICATION

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1984-02-16	1984 -02- 23
International Searching Authority [1]	**Signature of Authorized Officer** [20]
Swedish Patent Office	Leif Vingård

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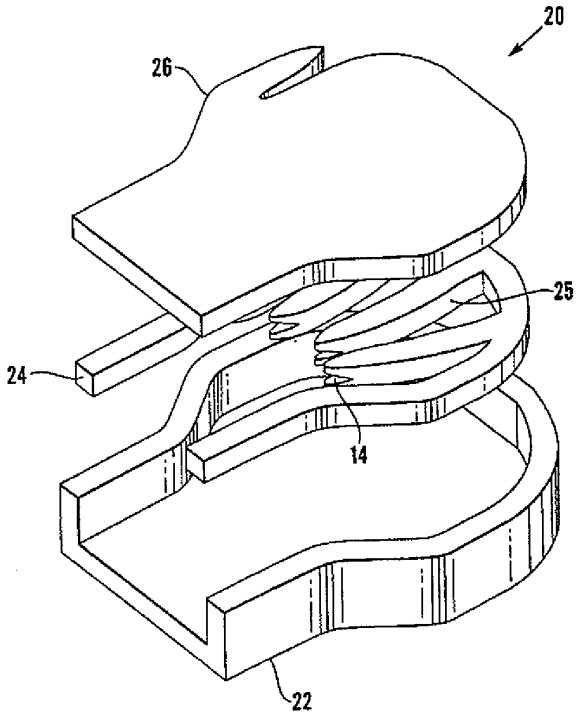
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(54) Title: WOUND TREATMENT APPARATUS EMPLOYING REDUCED PRESSURE

(57) Abstract

Apparatus is described for stimulating healing of wounds, particularly burns, to the hands or feet. The apparatus comprises an envelope for receiving the affected part of the body. The envelope (12) comprises an air–tight cover which contains a porous pad (22, 24, 26) for covering the wound. Means are provided for connecting the interior of the envelope to a source of suction.



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WOUND TREATMENT APPARATUS EMPLOYING REDUCED PRESSURE

The present invention relates to an apparatus for the healing of wounds and more particularly to preventing progression of partial-thickness burns.

Where a person suffers a burn, the dermal and epidermal layers in the region of the wound are damaged. Closure of the resulting wound is important to prevent loss of body fluids and invasion by micro-organisms. In the case of a partial-thickness burn, epithelial and subcutaneous tissue adjacent to the wound will migrate outwards and eventually grow new tissue over the wound. A wide array of wound coverings have been developed to expedite wound closure and allow the natural processes of repairing the damaged tissue to proceed.

The prognosis of a wound caused by a burn depends on the severity of the injury and particularly the depth of the burn. In general, a partial-thickness burn will heal more quickly and with less complications than a deeply penetrating burn. It has been observed that partial-thickness burns often deteriorate and become more serious, deeper burns, if not treated promptly after incurring the burn injury.

The hands more often suffer burn injuries than other parts of the body. Probably, this is due to the natural reaction of attempting to protect the face with the hands and, in many cases, the burn injury is to the backs of the hands. Other parts of the body which more frequently suffer burns may be the arms, feet and legs.

The present invention seeks to provide apparatus for treating injuries to a part of the body, especially injuries caused by burns.

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According to one aspect of the invention there is provided apparatus for stimulating healing of wounds which comprises an envelope for receiving an affected part of the body, said envelope including a substantially air-tight cover and a porous pad within the cover, said cover being adapted to contact the wound surface, and connection means for connecting the interior of the envelope to a source of negative pressure.

By substantially "air-tight" cover is meant one which is sufficiently air-tight that by applying suction to the porous pad, a pressure below ambient can be maintained within the envelope. It is not, however, necessary for the material of the envelope to be totally air occlusive.

It has been found that when negative pressure therapy using the apparatus of the invention is applied to a burn within a relatively short time of incurring the injury (e.g. within about 12 hours), not only is the rate of healing improved but progression of a partial-thickness burn to a deeper injury is arrested.

In one embodiment, the apparatus of the invention the envelope comprises a glove, sleeve or sock. For example, the apparatus may include a glove formed from a flexible plastics or rubber foam which is contained within a cover of low air-porosity. Typically, the flexible plastics foam is a polyurethane or polyvinyl alcohol (pva) foam having intercommunicating cells or a combination of such foams, e.g. as a laminate. In such a laminate, the pva layer may be adjacent the wound.

Additional features of the present application will become apparent from the following description and accompanying drawings, in which:-

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Figure 1 is an exploded perspective view of the porous pad;

Figure 2 is a perspective view when the porous pad is assembled together;

Figure 3 is a perspective view of the porous pad within its cover;

Figures 4a to 4d show various views of a connector for pneumatically connecting the porous pad to a source of negative pressure; and

Figure 5 is a plan view of a modified cover.

The embodiment shown in the accompanying drawings is designed for use in treating burns to the hand.

It will be appreciated that various appropriate modifications are possible for treating burns to other parts of the body, such as feet within the scope of the invention.

Figures 1, 2 and 3 show apparatus (10) for treating wounds to the hands comprising a porous pad having a lower base (22), a middle section (24) and an upper section (26) incorporated within a cover (12) of low air porosity. The porous pad is in the form of a glove or mitten and may be constructed by fixing the upper section (26) to the base (22) while retaining the middle section (24) within the cavity so formed. Typically, the porous pad is a reticulated plastics foam, and may be formed by gluing or welding the separate sections together. When placed inside the pad, the hand is held in place with fingers spread by finger-separators (25) and V-cut type grooves (14). As shown in Figures 2 and 3, the foam may be shaped to provide for a separate supporting compartment (27) for the thumb to aid the attainment of the optimum positions of the fingers and thumb for healing. However, this is not

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essential. The pad is preferably made from a reticulated foam such as polyurethane as described in PCT application WO 96/05873, polyvinylalcohol foam or a combination thereof.

Figure 3 shows the assembled pad after insertion into a cover (12). Cover (12) is an envelope formed from air-impermeable sheet material, e.g. polyurethane or polyolefin film, and is sized to encompass the glove-shaped porous pad. One end of the cover (12) has a large opening which is closable by an easily re-sealable means (4) such as a zip-type seal used on food bags. The other end (8) includes a substantially impermeable pressure-sensitive acrylic resin adhesive (9), ,the underside of which is secured as a tight seal to the patient's skin. The open end (8) may be coated on its inner surface with a pressure-sensitive acrylic resin adhesive (9) in order to seal the cover to the patient's skin, e.g. at the wrist or lower arm. Alternatively, the end (8) may be sealed to the patient's wrist with a separate piece of adhesive tape, such as a polyurethane film coated with a pressure-sensitive adhesive. The open end (8) is open and is tapered as shown. By providing a taper, the open end can be cut to a size such that the opening will fit snugly around the patient's wrist. Attached to the cover (12) in the region of a central part of the porous pad is a connector (100). Connector (100) may be attached to the cover by adhesive.

Figure 5 is a plan view of a cover similar to cover (12) shown in Figure 3. The same reference numerals are used to indicate corresponding parts. The cover shown in Figure 5 differs from that shown in Figure 3 in that the end (8) for attachment at the patient's wrist has a somewhat larger taper and is designed so that

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the end can be trimmed to suit the patient. The connector (100) has a generally circular flange (101) whose underside face (i.e. the face which in use contacts the foam page 20) is formed with small projecting buttons. The construction of this aspect of the connector is as described in GB Patent Application No. 2,333,965. Instead of using a zip lock seal, a seal of the "Velcro" type can be used. In this embodiment, a zip lock seal (4) is formed from polyethylene and this is joined to the rest of the cover, which is formed from polyurethane, by adhesive tape.

Figures 4a to 4d show various views of the connector (100) and it will be seen that it comprises a moulded plastics flange portion (101) and suction port having a centrally positioned spout (102) and aperture (106). The connector (100) is firmly attached to the cover by an adhesive. The spout extends through a hole cut in the cover and the upper surface of the flange 101 is bonded with adhesive to the cover (12). The spout (102) is sized to accept as a closely sliding fit, the end of a single or multi-lumen tube (30) which emerges from beneath the wound cover (12). Tube (30) may be constructed as described in co-pending patent application WO 97/18007. Where a multi-lumen tube is used, one lumen can be used for measuring the pressure at the burn site. It is also within the scope of this invention to irrigate the burn or other wound through one of the lumens or via a separate connector to the foam pad. The connector or connectors can be used to introduce drugs, e.g. antibiotics, to the wound site. The cover drape (12) is preferably made from a flexible film of low air permeability such as polyurethane and may include a protective layer of polyethylene. Suitable materials are described in GB patent application No. 2,333,965.

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In use, the hand of a patient having a burn injury is introduced into the outer cover (12) via the open end (8). Re-sealable opening (4) may then be opened and folded back to expose the injured hand. The hand is then introduced into the porous pad which may be pre-assembled or assembled in situ around the injured hand. In the latter case, it may be convenient to fix the upper section (26) to the lower section (24) by suturing or stapling, rather than gluing or welding the foam. With the foam pad in place encompassing the injured hand, the cover (12) is drawn back over the porous pad and the opening (4) re-sealed. Spout (102) is then connected by a tube to a suction pump, e.g. using the technique described in WO 97/18007. Pulsed, intermittent or continuous negative pressure may be applied to the patient's hand in accordance with a programme which may be controlled automatically by a control device associated with the pump as described in our above patent application. Negative pressure therapy using the apparatus of the invention has been found to stimulate healing of burns and to reduce the progression of cell death beneath a burn injury. Also, by improving blood flow to the wound area, infection is controlled and granulation of the wound is stimulated.

One additional beneficial effect of therapy using the apparatus of this invention is that during therapy, the hand is held firmly in a half-closed position, which is the optimum position for promotion of healing. This can be further encouraged by the introduction of a rigid or semi-rigid splint, e.g. of plastics, which is formed or moulded into the desired shape, the collapsed dressing being strapped to the splint during or

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after application of the suction, so that the desired healing position can be maintained after release of the suction.

The suction pump is preferably controlled by control means including a pressure transducer for monitoring pressure at the wound site as described in our above PCT application. A timer device may also be associated with the pump to provide on/off operation if necessary at selected intervals. The apparatus may also include a canister located between the porous pad and the pump to collect wound exudate. Typically, the pump is a diaphragm pump but other types of pumps and equivalent components, such vacuum bottles, may be substituted. The apparatus may also be used with a wall suction source as described in GB patent application No. 2,342,584.

The terms and expressions which have been employed are used as terms of description and not of limitation. Although the present invention relates mainly to partial-thickness burns, it is understood that the present invention maybe used with open wounds as well as a possible treatment of pressure sores.

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CLAIMS:-

1. Apparatus for stimulating healing of wounds which comprises an envelope for receiving an affected part of the body, said envelope including a substantially air-tight cover and a porous pad within the cover, said pad being adapted to contact the wound surface, and connection means for connecting the interior of the envelope to a source of negative pressure.

2. Apparatus as claimed in claim 1 wherein the envelope comprises a glove, sock or sleeve.

3. Apparatus as claimed in claim 2 which is intended for treating wounds to the hand and comprises a glove formed from a flexible plastics or rubber foam and an external cover of air-impermeable sheet material.

4. Apparatus as claimed in claim 3 wherein the connection means comprises a tube which communicates with the foam within the cover.

5. Apparatus as claimed in any one of the preceding claims wherein the cover has a re-sealable opening which permits the wound to be inspected at intervals.

6. Apparatus as claimed in any one of the preceding claims wherein the source of negative pressure is a suction pump.

7. Apparatus as claimed in any one of the preceding claims which includes a canister for collecting wound exudate.

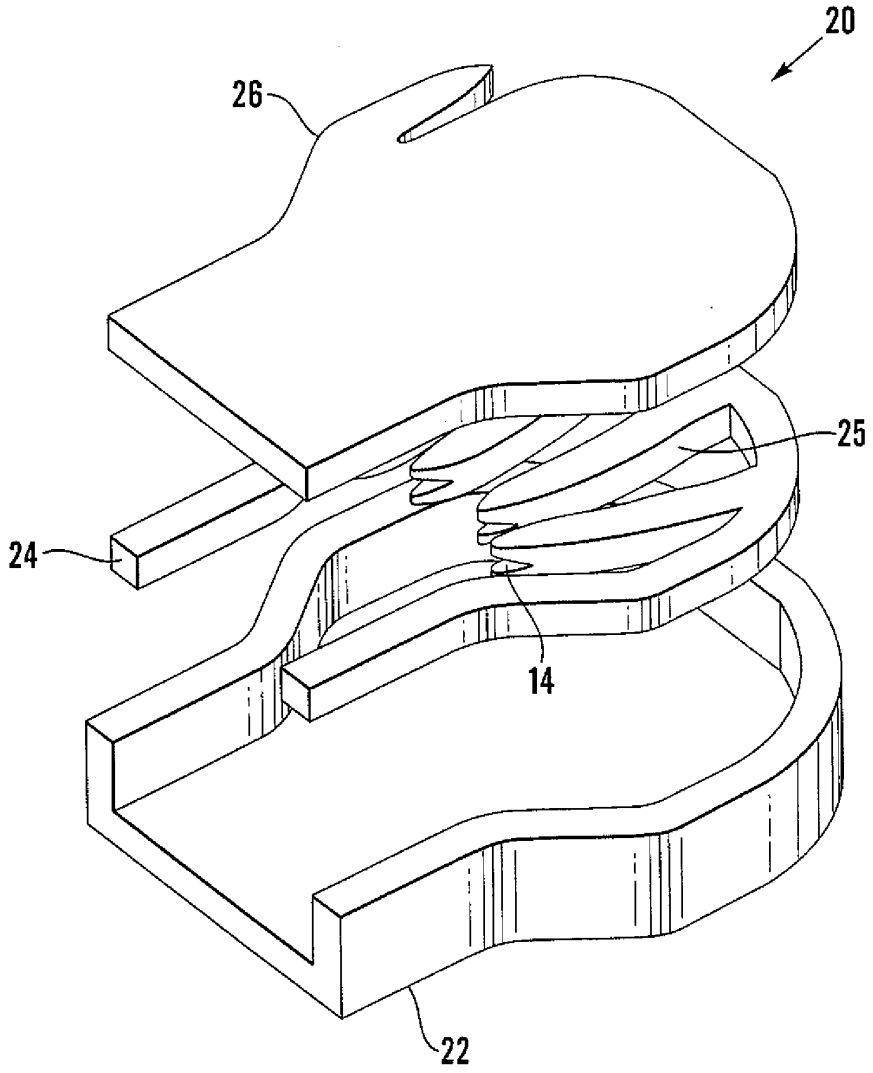


Fig. 1

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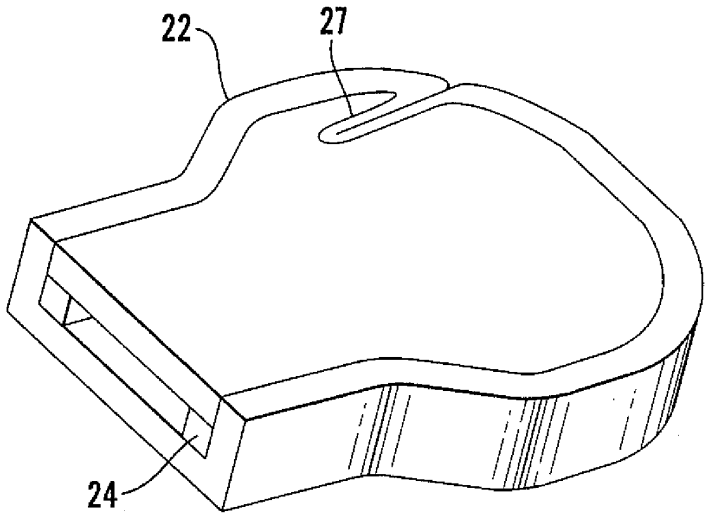


Fig.2

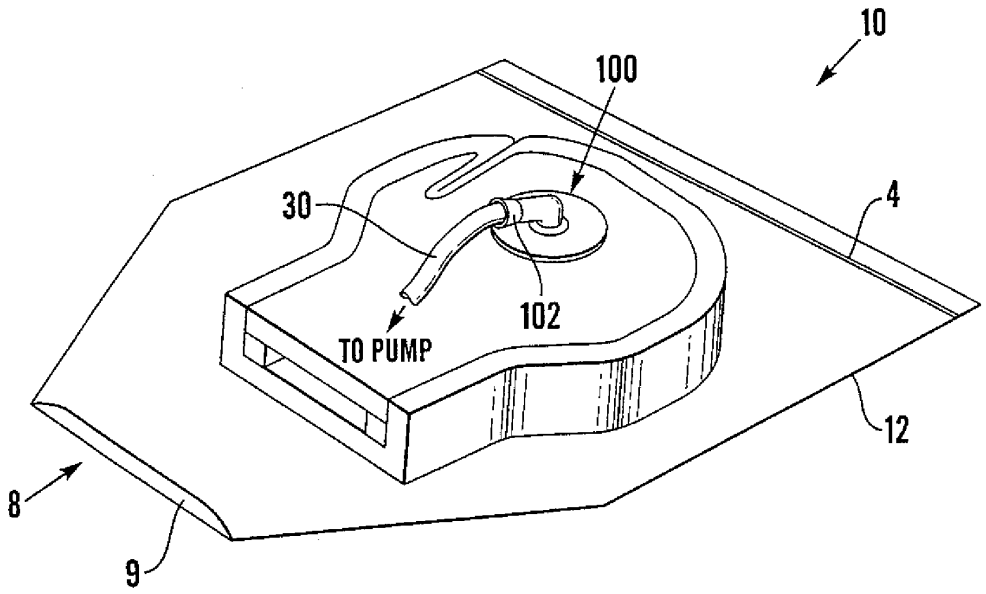


Fig.3

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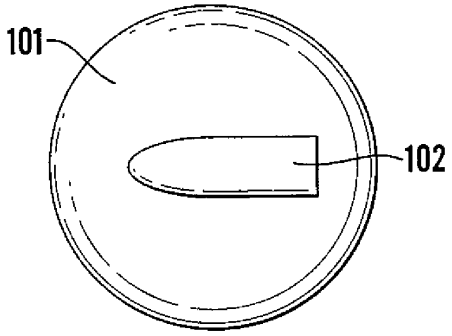


Fig.4A

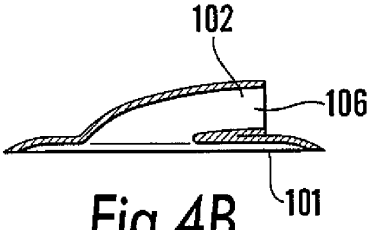


Fig.4B

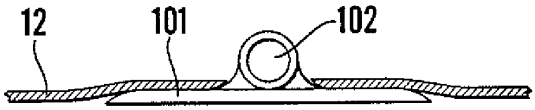


Fig.4C

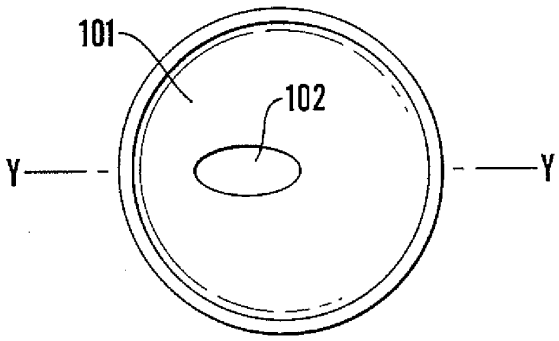


Fig.4D

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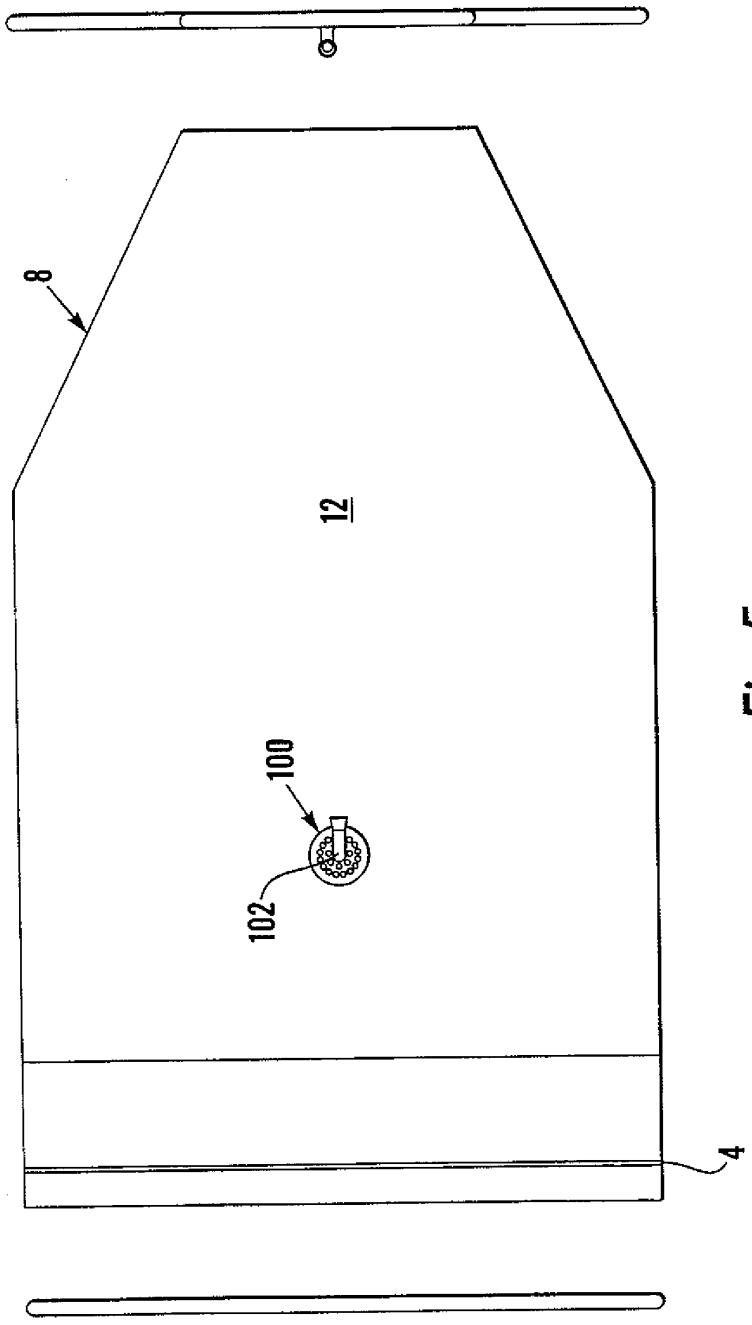


Fig.5

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INTERNATIONAL SEARCH REPORT

Int. ational Application No
PCT/GB 00/01566

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F13/00 A61F13/10

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 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 practical, search terms used)
EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 969 880 A (ZAMIEROWSKI DAVID S) 13 November 1990 (1990-11-13) column 7, line 7 - line 16; figure 8	1,4-7
A	DE 10 93 949 B (DIPL.-ING. ALFRED MAIER) 1 December 1960 (1960-12-01) column 2, line 34 - line 51; figure 1	1-7
A	US 5 527 293 A (ZAMIEROWSKI DAVID S) 18 June 1996 (1996-06-18) claim 1; figure 24	1-7

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

☒ Patent family members are listed in annex.

° Special categories of cited documents :

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"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
13 September 2000	25/09/2000

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	Westermayer, W

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

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INTERNATIONAL SEARCH REPORT

Information on patent family members

Int tional Application No
PCT/GB 00/01566

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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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（Ｐ2002－541978Ａ）
(43)公表日　平成14年12月10日(2002.12.10)

(51)Int.Cl.[7]	識別記号	ＦＩ	ﾃｰﾏｺｰﾄﾞ(参考)
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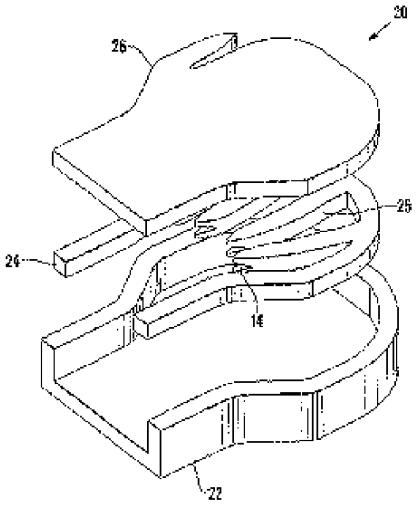
審査請求　未請求　予備審査請求　有　（全 15 頁）

(21)出願番号　特願2000－613396(Ｐ2000－613396)
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(54)【発明の名称】　減圧を使用する創傷部治療装置

(57)【要約】
創傷部、特に手または足の火傷の治癒を促進するための装置が記載されている。この装置は体の患部を収納するための外被を含み、この外被（１２）は創傷部をカバーするための多孔性パッド（２２、２４、２６）を含む気密カバーを備える。外被の内部を吸引源に接続するための手段が設けられている。



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【特許請求の範囲】

【請求項１】　体の患部を収納するための外被を備え、該外被が実質的に気密性のカバーと、このカバー内に設けられた多孔性パッドを含み、前記パッドが創傷部の表面に接触するようになっており、更に前記外被の内部を負圧源に接続するための接続手段を備えた、創傷部の治癒を促進するための装置。

【請求項２】　前記外被が、グローブ、ソックまたはスリーブを含む、請求項１記載の装置。

【請求項３】　可撓性プラスチック発泡体またはゴム発泡体から成形されたグローブと、非通気性シート材料製の外部カバーとを含む、手の創傷部を治療するようになっている、請求項２記載の装置。

【請求項４】　接続手段が前記カバー内の前記発泡体と連通するチューブを含む、請求項３記載の装置。

【請求項５】　前記カバーが創傷部を所定の間隔で検査できるようにする再シール可能な開口部を有する、先の請求項のいずれかに記載の装置。

【請求項６】　前記負圧源が吸引ポンプである、先の請求項のいずれかに記載の装置。

【請求項７】　創傷部の排出物を収集するためのキャニスターを含む、先の請求項のいずれかに記載の装置。

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【発明の詳細な説明】

【０００１】

本発明は、創傷部の治療をするための装置に関し、より詳細には、部分深度火傷の進行を防止することに関する。

【０００２】

人が火傷を負った場合、創傷部の領域にある真皮層および上皮層が損傷を受ける。この結果生じる創傷部を閉じることは、体液が失われること、および微生物の侵入を防止する上で重要である。部分深度火傷の場合、創傷部に隣接する上皮組織および皮下組織が外側に移動し、最終的に創傷部の上に新しい組織として成長する。創傷部の閉鎖を促進し、損傷を受けた組織を補修する自然のプロセスが進行できるようにするための種々の創傷部カバーがこれまで開発されている。

【０００３】

火傷によって生じた創傷部の治療後の経過は損傷の深刻さ、特に火傷の深さに応じて決まる。一般に、部分深度の火傷は深く進んだ火傷よりも、より早く、かつあまり複雑とならないで治癒する。火傷の損傷を受けた後にすぐに治療しない場合、部分深度の火傷はひどくなり、より深刻な深い火傷となることが多いことが判っている。

【０００４】

手は体の他の部分よりも火傷を受けることが多い。恐らくこの理由は、両手で顔を保護しようとする自然な反応によるものであり、多くのケースでは火傷の損傷は手の甲に及んでいる。より頻繁に火傷を受ける体の他の部分は、恐らくは、腕、足および脚部である。

【０００５】

本発明は体の一部の損傷、特に火傷によって生じた損傷を治療するための装置を提供するものである。

【０００６】

本発明の１つの特徴によれば、体の患部を収納するための外被を備え、該外被が実質的に気密性のカバーと、このカバー内に設けられた多孔性パッドを含み、前記パッドが創傷部の表面に接触するようになっており、更に前記外被の内部を

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負圧源に接続するための接続手段を備えた、創傷部の治癒を促進するための装置が提供される。

【０００７】

実質的に「気密な」カバーとは、多孔性パッドに吸引力を加えることにより、外被内に周辺よりも低い圧力を維持できる程度に十分な気密性があることを意味する。しかしながら、外被の材料は完全に空気を閉塞できるものでなくてもよい。

【０００８】

損傷が生じてから比較的短期間（例えば約１２時間）の間に、火傷部に対して本発明の装置を使用した負圧治療を加えると、治癒速度が改善されるだけでなく、部分深度の火傷のより深い損傷への進行も阻止されることが判った。

【０００９】

本発明の装置の一実施例では、外被はグローブ、スリーブまたはソックを含む。例えばこの装置は通気性の低い多孔性のカバー内に収納された、可撓性プラスチック発泡体またはゴム発泡体から形成されたグローブを含むことができる。一般にこの可撓性プラスチック発泡体は相互に連通するセルを有するポリウレタン、またはポリビニールアルコール（ＰＶＡ）発泡体またはラミネートのようなかかる発泡体の組み合わせである。かかるラミネートでは、このＰＶＡ層を創傷部に隣接させることができる。

【００１０】

次の説明および添付図面から、本願の別の特徴が明らかとなろう。

【００１１】

添付図面に示されている実施例は手の火傷を治療するのに使用するようになっている。

【００１２】

本発明の範囲内では、体の他の部分、例えば足の火傷を治療するのに、適当な種々の変形が可能であることが理解できよう。

【００１３】

図１、２および３は通気性の低い多孔性のカバー（１２）内に内蔵された、下

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方の底部（２２）と、中間部分（２４）と、上方部分（２６）とを備えた、手の損傷を治療するための装置（１０）を示す。多孔質パッドはグローブまたはミトン状をしており、ミトン状に形成したキャビティ内に中間部分（２４）を維持しながら、底部（２２）へ上方部分（２６）を固定することによって製造できる。一般に、この多孔質パッドは網目状プラスチック発泡体であり、別々の部分を一体に縫付けまたは溶着によって形成できる。パッド内に手を挿入すると、指セパレータ（２５）およびＶ字カットタイプのグローブ（１４）によって指が広がった状態で、手が所定位置に保持される。図２および３に示されるように、この発泡体は治療のために親指とその他の指を最適な位置に位置させるのを助けるよう、親指用の別個の支持コンパートメント（２７）を提供するような形状とすることができる。しかしながら、このことは本質的なことではない。パッドはＰＣＴ特許出願公開公報WO96/05873号に記載されているようなポリウレタン製の網目状発泡体、ポリビニールアルコール発泡体またはそれらの組み合わせから製造することが好ましい。

【００１４】

図３はカバー（１２）内に挿入した後の組み立ての完了したパッドを示す。カバー（１２）は非通気性シート材料、例えばポリウレタンまたはポリオレフィン膜から形成された外被であって、グローブ状の多孔性パッドを囲むような大きさとなっている。カバー（１２）の一端は大きな開口部を有し、この開口部は容易にシール可能な手段（４）、例えば食品バッグで使用されているジップタイプのシールによって閉鎖できる。他方の端部（８）は実質的に不透過性の感圧性アクリル樹脂接着部（９）を含み、この接着部の下面は気密シールとして患者の皮膚に固定される。例えば手首または下腕の患者の皮膚にカバーをシールするよう、開端部（８）の内側表面には感圧性アクリル樹脂接着剤（９）を塗布できる。これとは異なり、接着テープの別個の部分、例えば感圧性接着剤がコーティングされたポリウレタン膜で患者の手首に端部（８）をシールしてもよい。開端部（８）は開いており、図のごとくテーパーが設けられている。テーパを設けることにより、開口部が患者の手首のまわりに嵌合されるようなサイズに開端部をカットできる。多孔性パッドの中心部分の領域にあるカバー（１２）にはコネクタ（１

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００）が取り付けられている。このコネクタ（１００）は接着剤によってカバーに取り付けてもよい。

【００１５】

図５は、図３に示されたカバー（１２）に類似するカバーの平面図である。対応する部品を示すのに同じ参照番号を使用している。図５に示されたカバーは患者の手首に取り付けるための端部（８）のテーパが多少大きくなっており、この端部（８）を患者に合わせてトリムできるようになっている点が、図３に示されたカバーと異なっている。コネクタ（１００）はほぼ円形のフランジ（１０１）を有し、このフランジの下面（すなわち使用中に発泡パッド２０に接触する面）には小さい突出するボタンが形成されている。このコネクタのこの特徴の構造は英国特許出願第2333965号に記載されている。ジップロックシールを使用する変わりにベルクロタイプのシールを使用することもできる。この実施例では、ジップロックシール（４）はポリエチレンから形成され、このシールはポリウレタンから形成されているカバーの他の部分に接着テープによって接合される。

【００１６】

図４ａ～４ｄはコネクタ（１００）の種々の図を示す。このコネクタは成形されたプラスチックフランジ部分（１０１）と、中心に位置する注ぎ口（１０２）および開口部（１０６）を有する吸引ポートとを含む。コネクタ（１００）は接着剤によりカバーに強固に取り付けられる。この注ぎ口はカバーにカットされた孔を貫通しており、フランジ（１０１）の上部表面は接着剤によってカバー（１２）に接合されている。注ぎ口（１０２）は創傷部カバー（１２）の下方から出ている単一またはマルチルーメンチューブ（３０）の端部を密着スライド嵌合によって受け入れるような寸法となっている。チューブ（３０）は継続中の特許出願公開公報WO97/18007号に記載されているように製造できる。マルチルーメンチューブを使用する場合、火傷部分の圧力を測定するために１本のルーメンを使用できる。ルーメンのうちの１つまたは別個のコネクタを介し、発泡パッドへ火傷部またはその他の創傷部の体液の排出を行うことも、本発明の範囲内である。創傷部へ医薬、例えば抗生物質を注入するのに、コネクタ（単数または複数）を使用できる。カバー滅菌布（１２）は低通気性の可撓性膜、例えばポリウレタン、

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から製造することが好ましく、ポリエチレンの保護膜を含むことができる。英国特許出願第2333965号には、適当な材料が記載されている。

【００１７】

使用に際し、開端部（８）を介して外側カバー（１２）内に火傷創傷部を有する患者の手を挿入する。次に、再シール可能な開口部（４）を開け、損傷を受けた手が露出するように、この開口部を折り戻すことができる。次に、多孔性パッド内に手を挿入する。この多孔性パッドはあらかじめ組み立ておいてもよいし、また使用場所で損傷を受けた手のまわりに組み立ててもよい。後者の場合、発泡体を糊付けまたは溶着するよりも、縫合またはステープリングによって、下方部分（２４）に上方部分（２６）を固定することが好ましい。発泡体パッドが損傷を受けた手を所定場所で囲んでいる場合、多孔性パッド上にカバー（１２）を引き戻し、開口部（４）を再シールする。次に、例えば国際特許出願公開公報WO97/18007号に記載されている技術を使用する吸引ポンプへチューブを用いて注ぎ口（１０２）を接続する。プログラムに従い、患者の手にパルス状、間欠的または連続的な負圧を加えることができ、このプログラムは上記本出願人の出願に記載されているように、ポンプに関連する制御デバイスによって自動的に制御できる。本発明の装置を使用する負圧治療は火傷部の治癒を促進し、火傷損傷部の下方の細胞の死の進行を抑制できることが判っている。更に、創傷部領域への血流を改善することにより、感染を制御し、創傷部の肉芽組織形成を促進できる。

【００１８】

本発明の装置を使用する治療の更に有利な効果として、治療中に治癒を促進できる最適位置である、半閉鎖位置に手を強固に保持できることが挙げられる。このことは、例えばプラスチック製の剛性または半剛性副木を導入することによって更に促進でき、この副木は所望する形状に形成または成形され、吸引力を解放した後に所望する治療位置を維持できるように、吸引力を印加している間、またはその後にスプリントに折りたたまれた滅菌布がストラップされる。

【００１９】

吸引ポンプは本願出願人の上記ＰＣＴ出願に記載されているように、創傷場所における圧力をモニタするための圧力トランスジューサを含む制御手段によって

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制御することが好ましい。必要な場合、選択されたインターバルでオン／オフ動作をするように、ポンプにタイマー装置を連動させることもできる。本発明は創傷部の排出液を収集するよう、多孔性パッドとポンプとの間に設けられたキャニスターを含んでもよい。一般に、ポンプはダイヤフラムタイプのポンプであるが、他のタイプのポンプおよび均等な部品、例えば真空ボトルも代わりに使用できる。本発明は英国特許出願第2342584号に記載されているように、壁吸引ソースと共に使用できる。

【００２０】

これまで本明細書で使用した用語および表現は、発明を説明するための用語であり、発明を限定するためのものではない。本発明は、主に部分深度火傷に関するものであるが、本発明は開放性創傷部だけでなく、とこずれの治療にも使用できると理解できよう。

【図面の簡単な説明】

【図１】

多孔性パッドの分解斜視図である。

【図２】

多孔性パッドを一体に組み立てた時の斜視図である。

【図３】

カバー内に設けられた多孔性パッドの斜視図である。

【図４ａ】

多孔性パッドを負圧源に空気圧的に接続するためのコネクタの図である。

【図４ｂ】

多孔性パッドを負圧源に空気圧的に接続するためのコネクタの図である。

【図４ｃ】

多孔性パッドを負圧源に空気圧的に接続するためのコネクタの図である。

【図４ｄ】

多孔性パッドを負圧源に空気圧的に接続するためのコネクタの図である。

【図５】

変形カバーの平面図である。

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【図１】

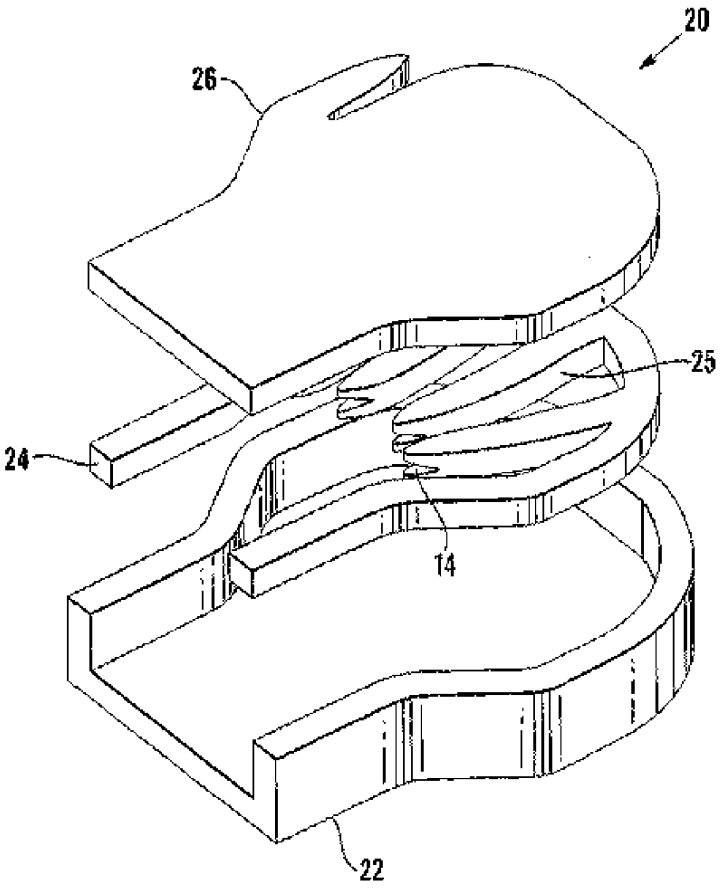


Fig. 1

【図２】

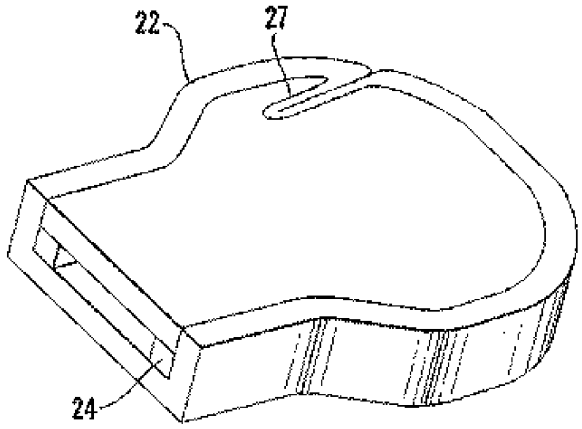
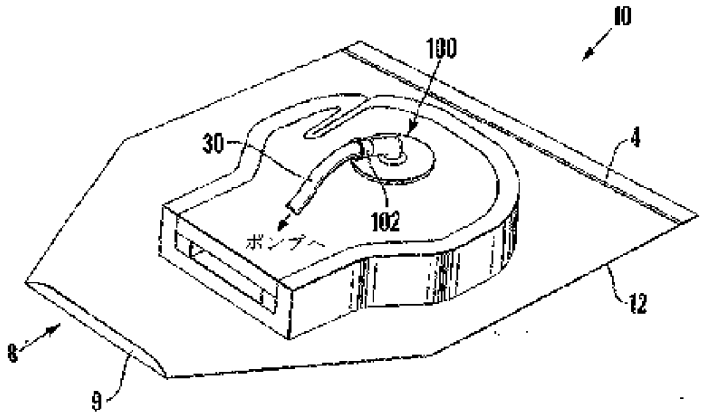


Fig.2

【図３】



【図４Ａ】

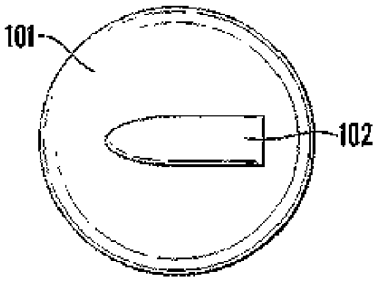


Fig.4A

【図４Ｂ】

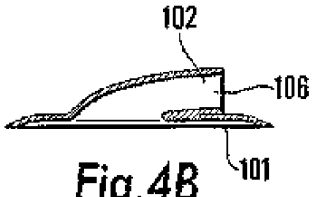


Fig.4B

【図４Ｃ】



Fig.4C

【図４Ｄ】

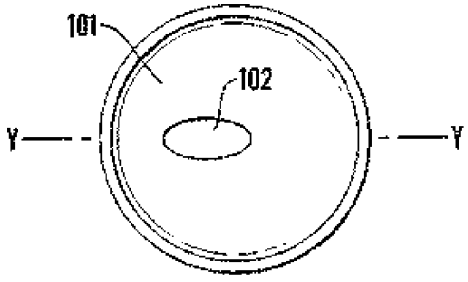


Fig.4D

【図５】

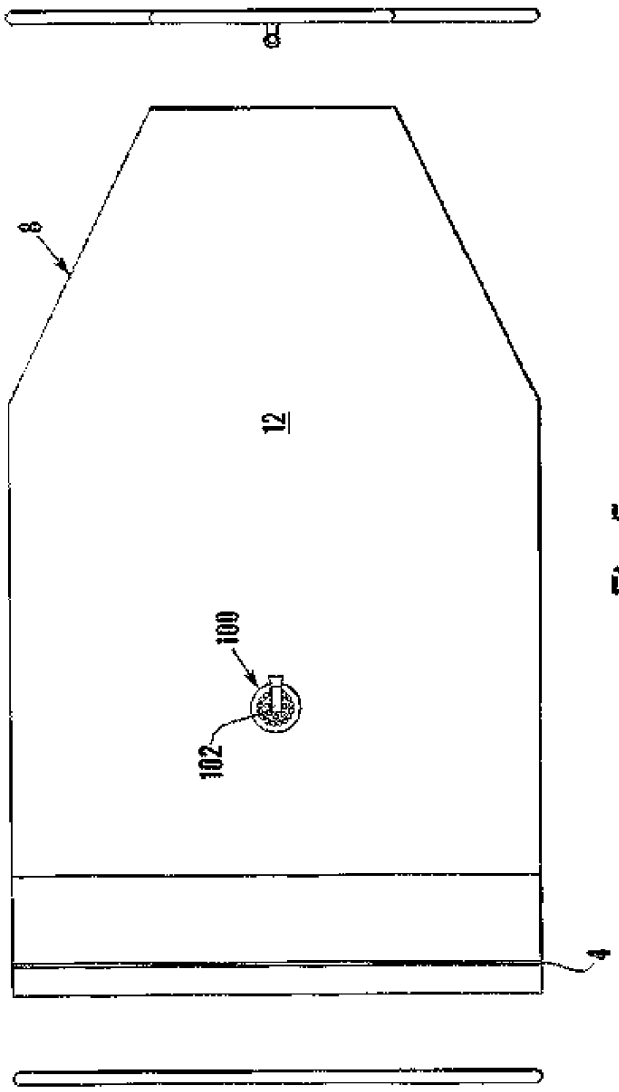


Fig.5

【国際調査報告】

INTERNATIONAL SEARCH REPORT

Int. Tional Application No
PCT/GB 00/01566

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F13/00 A61F13/10

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 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 practical, search terms used)
EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 969 880 A (ZAMIEROWSKI DAVID S) 13 November 1990 (1990-11-13) column 7, line 7 - line 16; figure 8	1,4-7
A	DE 10 93 949 B (DIPL.-ING. ALFRED MAIER) 1 December 1960 (1960-12-01) column 2, line 34 - line 51; figure 1	1-7
A	US 5 627 293 A (ZAMIEROWSKI DAVID S) 18 June 1996 (1996-06-18) claim 1; figure 24	1-7

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

☒ Patent family members are listed in annex.

° Special categories of cited documents:

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
13 September 2000	25/09/2000
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer Westermayer, W

Form PCT/ISA/210 (second sheet) (July 1998)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/GB 00/01566

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
US 4969880	A	13-11-1990	AT	146990 T	15-01-1997
			AU	654468 B	10-11-1994
			AU	5521890 A	05-11-1990
			CA	2049948 A	04-10-1990
			DE	69029578 D	13-02-1997
			DE	69029578 T	05-06-1997
			EP	0465601 A	15-01-1992
			JP	4506011 T	22-10-1992
			WO	9011795 A	18-10-1990
			US	5527293 A	18-06-1996
			US	5100396 A	31-03-1992
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DE 1093949	B		NONE		
US 5527293	A	18-06-1996	US	5261893 A	16-11-1993
			US	5100396 A	31-03-1992
			US	4969880 A	13-11-1990
			AU	2029592 A	30-12-1992
			CA	2103033 A	15-11-1992
			WO	9220299 A	26-11-1992
			AT	146980 T	15-01-1997
			AU	654468 B	10-11-1994
			AU	5521890 A	05-11-1990
			CA	2049948 A	04-10-1990
			DE	69029578 D	13-02-1997
			DE	69029578 T	05-06-1997
			EP	0465601 A	15-01-1992
			JP	4506011 T	22-10-1992
			WO	9011795 A	18-10-1990

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

フロントページの続き

(81)指定国 EP(AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OA(BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG), AP(GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), EA(AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, 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, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/989,297	01/24/2008	Carmeli Adahan	29068U	4766

20529 7590 08/13/2010

THE NATH LAW GROUP
112 South West Street
Alexandria, VA 22314

EXAMINER	
TREYGER, ILYA Y	
ART UNIT	PAPER NUMBER
3761	
MAIL DATE	DELIVERY MODE
08/13/2010	PAPER

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

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

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Office Action Summary	Application No.	Applicant(s)	
	11/989,297	ADAHAN, CARMELI	
	Examiner	Art Unit	
	ILYA Y. TREYGER	3761	

-- 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 *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, 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 *24 January 2008*.

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

3)☐ 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

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

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

8)☒ Claim(s) *1-33* are subject to restriction and/or election requirement.

Application Papers

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

10)☐ The drawing(s) filed on _____ 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).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

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).

a)☐ All b)☐ Some * c)☐ None of:

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) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

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DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-10 and 15-23, drawn to a vacuum system and a method for draining an open wound.
Group II, claim(s) 11-14, drawn to an enclosure for draining an open wound.
Group III, claim(s) 24-28, drawn to a disposable assembly for draining an open wound.
Group IV, claim(s) 29-33, drawn to a vacuum system for draining an open wound.

2. The groups of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Where the group of inventions is claimed in one and the same international application, the requirement for unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "**special technical features**" shall mean those technical features that define a contribution which each of the claimed inventions considered as a whole , **makes over the prior art**. The inventions listed as Groups I, II, III and IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, although they share the special technical feature, this special technical feature does not define a contribution over the prior art for the following reasons: Claim 11 is either obvious or anticipated by the following US 7,229,422. Accordingly, the special technical feature linking the inventions, *an enclosure for draining an open wound being attachable to the wound circumference so as to define a confined volume* does not provide a contribution over the prior art, and no single general inventive concept exists. Therefore the restriction is appropriate.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention or species.

Should applicant traverse on the ground that the inventions have unity of invention (37 CFR 1.475(a)), applicant must provide reasons in support thereof. Applicant may submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. Where such evidence or admission is provided by applicant, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

3. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully

examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILYA Y. TREYGER whose telephone number is (571)270-3217. The examiner can normally be reached on 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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

/Ilya Y Treyger/
Examiner, Art Unit 3761

/Tatyana Zalukaeva/
Supervisory Patent Examiner, Art Unit 3761

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

BIB DATA SHEET

CONFIRMATION NO. 4766

SERIAL NUMBER	FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
11/989,297	01/24/2008 RULE	604	3761	29068U

APPLICANTS
Carmeli Adahan, Jerusalem, ISRAEL;

**** CONTINUING DATA ************************* I.T. 06/22/2010**
This application is a 371 of PCT/IL2005/000784 07/24/2005

**** FOREIGN APPLICATIONS ************************ I.T. 06/22/2010**

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED **** ** SMALL ENTITY **
07/08/2009

Foreign Priority claimed ☑ Yes ☐ No 35 USC 119(a-d) conditions met ☐ Yes ☐ No Verified and Acknowledged /ILYA Y TREYGER/ Examiner's Signature	☐ Met after Allowance Initials	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
		ISRAEL	2	33	5

ADDRESS

THE NATH LAW GROUP
112 South West Street
Alexandria, VA 22314
UNITED STATES

TITLE

Wound closure and drainage system

FILING FEE RECEIVED		
1000	FEES: Authority has been given in Paper No._____ to charge/credit DEPOSIT ACCOUNT No._____ for following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit

Medela LLC and Medela AG
Exhibit 1008
Page #1049

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
11/989,297	01/24/2008	Carmeli Adahan	29068U

CONFIRMATION NO. 4766

20529
THE NATH LAW GROUP
112 South West Street
Alexandria, VA 22314

PUBLICATION NOTICE

OC000000038412023

Title: Wound closure and drainage system

Publication No.US-2009-0264837-A1
Publication Date:10/22/2009

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publically available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently http://www.uspto.gov/patft/.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Office of Public Records. The Office of Public Records can be reached by telephone at (703) 308-9726 or (800) 972-6382, by facsimile at (703) 305-8759, by mail addressed to the United States Patent and Trademark Office, Office of Public Records, Alexandria, VA 22313-1450 or via the Internet.

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

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

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

Medela LLC and Medela AG
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Page #1050

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

U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
11/989,297	Carmeli Adahan	29068U

20529
THE NATH LAW GROUP
112 South West Street
Alexandria, VA 22314

INTERNATIONAL APPLICATION NO.	
PCT/IL2005/000784	
I.A. FILING DATE	PRIORITY DATE
07/24/2005	

CONFIRMATION NO. 4766
371 ACCEPTANCE LETTER

OC000000036846521

Date Mailed: 07/14/2009

NOTICE OF ACCEPTANCE OF APPLICATION UNDER 35 U.S.C 371 AND 37 CFR 1.495

The applicant is hereby advised that the United States Patent and Trademark Office in its capacity as a Designated / Elected Office (37 CFR 1.495), has determined that the above identified international application has met the requirements of 35 U.S.C. 371, and is ACCEPTED for national patentability examination in the United States Patent and Trademark Office.

The United States Application Number assigned to the application is shown above and the relevant dates are:

01/24/2008	01/24/2008
DATE OF RECEIPT OF 35 U.S.C. 371(c)(1), (c)(2) and (c)(4) REQUIREMENTS	DATE OF COMPLETION OF ALL 35 U.S.C. 371 REQUIREMENTS

A Filing Receipt (PTO-103X) will be issued for the present application in due course. **THE DATE APPEARING ON THE FILING RECEIPT AS THE " FILING DATE" IS THE DATE ON WHICH THE LAST OF THE 35 U.S.C. 371 (c)(1), (c)(2) and (c)(4) REQUIREMENTS HAS BEEN RECEIVED IN THE OFFICE. THIS DATE IS SHOWN ABOVE.** *The filing date of the above identified application is the international filing date of the international application (Article 11(3) and 35 U.S.C. 363).* Once the Filing Receipt has been received, send all correspondence to the Group Art Unit designated thereon.

The following items have been received:

- Indication of Small Entity Status
- Copy of the International Application filed on 01/24/2008
- Copy of the International Search Report filed on 01/24/2008
- Information Disclosure Statements filed on 06/05/2008
- Oath or Declaration filed on 01/24/2008
- Request for Immediate Examination filed on 01/24/2008
- U.S. Basic National Fees filed on 01/24/2008

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

KAREN M WILLIAMS

Telephone: (703) 756-1464

FORM PCT/DO/EO/903 (371 Acceptance Notice)

Medela LLC and Medela AG
Exhibit 1008
Page #1051

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
11/989,297	01/24/2008	3761	1000	29068U	33	5

CONFIRMATION NO. 4766

20529
THE NATH LAW GROUP
112 South West Street
Alexandria, VA 22314

FILING RECEIPT

OC000000036846520

Date Mailed: 07/14/2009

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Applicant(s)

Carmeli Adahan, Jerusalem, ISRAEL;

Power of Attorney: The patent practitioners associated with Customer Number 20529

Domestic Priority data as claimed by applicant

This application is a 371 of PCT/IL2005/000784 07/24/2005

Foreign Applications

If Required, Foreign Filing License Granted: 07/08/2009

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 11/989,297**

Projected Publication Date: 10/22/2009

Non-Publication Request: No

Early Publication Request: No
**** SMALL ENTITY ****

Medela LLC and Medela AG
Exhibit 1008
Page #1052

Title

Wound closure and drainage system

Preliminary Class

604

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

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

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as

Medela LLC and Medela AG
Exhibit 1008
Page #1053

set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

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

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

NOT GRANTED

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

OIPE
JUL 10 2009
PATENT & TRADEMARK OFFICE

IAP19 Rec'd PCT/PTO 10 JUL 2009

Mail Stop PCT
Attorney Docket No.: 29068U

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Carmeli ADAHAN		Conf. No.:	4766
Appl. No.:	11/989,297	Examiner:	TBD
Filed:	January 24, 2008	Art Unit:	3761
Intl. Appl. No.:	PCT/IL2005/000784		
Intl. Filing Date:	July 24, 2005		

For: **WOUND CLOSURE AND DRAINAGE SYSTEM**

TRANSMITTAL LETTER

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

Dear Commissioner:

Submitted herewith for filing in the U.S. Patent and Trademark Office is the following:

(1) Transmittal Letter, one (1) page;
(2) Submission of Documents to Supplement Filing Requirements under 35 USC 371, one (1) page; and
(3) Application Data Sheet, four (4) pages.

Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

THE NATH LAW GROUP

Susanne M. Hopkins, Reg. No. 33,247
Customer No. 20529

Date: July 10, 2009

THE NATH LAW GROUP
112 S. West Street, Alexandria, Virginia 22314
Tel: (703) 548-6284; Fax: (703) 683-8396
SMH/le



Mail Stop PCT
Attorney Docket No.: 29068U

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Carmeli ADAHAN		Conf. No.:	4766
Appl. No.:	11/989,297	Examiner:	TBD
Filed:	January 24, 2008	Art Unit:	3761
Intl. Appl. No.:	PCT/IL2005/000784		
Intl. Filing Date:	July 24, 2005		

For: **WOUND CLOSURE AND DRAINAGE SYSTEM**

SUBMISSION OF DOCUMENTS TO SUPPLEMENT FILING REQUIREMENTS UNDER 35 USC 371

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

Dear Commissioner:

In order to supplement the filing documents for the national phase filing under 35 USC 371 commenced on January 24, 2008, Applicant now submits the following document:

(1) Application Data Sheet, four (4) pages.

Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

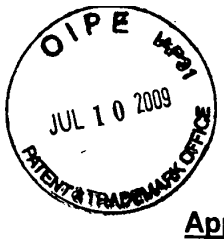
Respectfully submitted,

THE NATH LAW GROUP

Susanne M. Hopkins, Reg. No. 33,247
Customer No. 20529

Date: July 10, 2009

THE NATH LAW GROUP
112 S. West Street, Alexandria, Virginia 22314
Tel: (703) 548-6284; Fax: (703) 683-8396
SMH/le



Application Data Sheet

Application Information

Application Number::	11/989,297
Filing Date::	January 24, 2008
Application Type::	National Phase
Subject Matter::	Utility
Suggested Classification::	
Suggested Group Art Unit::	
CD-ROM or CD-R?::	None
Number of CD disks::	0
Number of copies of CDs::	0
Sequence submission?::	No
Computer Readable Form (CRF)::	No
Number of copies of CRF::	0
Title::	WOUND CLOSURE AND DRAINAGE SYSTEM
Attorney Docket Number::	29068U
Request for Early Publication?::	No
Request for Non-Publication?::	No
Suggested Drawing Figure::	
Total Drawing Sheets::	2
Small Entity?::	Yes
Latin name::	
Variety denomination name::	

Medela LLC and Medela AG
Exhibit 1008
Page #1057

Petition included?::	No
Petition Type::	N/a
Licensed U.S. Govt. Agency::	N/a
Contract or Grant Numbers::	N/a
Secrecy Order in Parent Appl.?::	No

Applicant Information (1)

Applicant Authority type::	Inventor
Primary Citizenship Country::	IL
Status::	Full Capacity
Given Name::	Carmeli
Middle Name::	
Family Name::	ADAHAN
Name Suffix::	
City of Residence::	Jerusalem
State or Province of Residence::	
Country of Residence::	IL
Street of Mailing address::	11 Netivei Am, Ramot
City of mailing address::	Jerusalem
State/Province of mailing address::	
Country of mailing address::	IL
Postal Code of mailing address::	97552

Initial 07/ /09

Medela LLC and Medela AG
Exhibit 1008
Page #1058

Correspondence Information

Correspondence Customer Number::	20529
Name::	THE NATH LAW GROUP
Street of mailing address::	112 S. West Street
City of mailing address::	Alexandria
State or Province of mailing address::	VA
Country of mailing address::	US
Postal or Zip Code of mailing address::	22314
Phone number::	(703) 548-6284
Fax number::	(703) 683-8396
E-Mail address::	ip@nathlaw.com

Representative Information

Representative Customer Number::	20529

Domestic Priority Information

Application::	Continuity Type::	Parent Application::	Parent Filing Date (MM/DD/YY) ::
This Application	National Stage of	PCT/IL2005/000784	07/24/05

Foreign Priority Information

Country::	Application Number::	Filing Date:: (MM/DD/YY)	Priority Claimed::

Initial 07/ /09

Assignee Information
Assignee name::

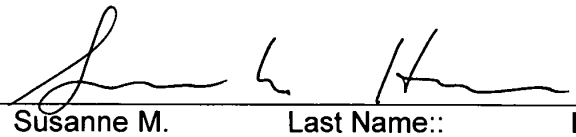
Street of mailing address::

City of mailing address::

State/Province of mailing address::

Country of mailing address::

Postal Code of mailing address::

Signature::
Signature:: 

First Name::	Susanne M.	Last Name::	Hopkins
Registration No.::	33,247	Date (MM/DD/YY)::	07/10/09

PTO/SB/97 (07-06)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
JUN 05 2008
PATENT & TRADEMARK OFFICE

Attorney Docket No. 29068U
MAIL STOP PCT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:		Conf. No.:	4766
ADAHAN			
Serial No.:	11/989,297	Intl. Appl. No.:	PCT/IL2005/000784
Filed:	January 24, 2008	Intl. Filing Date:	July 24, 2005
For:	**WOUND CLOSURE AND DRAINAGE SYSTEM**		

TRANSMITTAL LETTER

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

Sir:

Submitted herewith for filing in the U.S. Patent and Trademark Office is the following:

(1) Information Disclosure Statement (2 pages); and
(2) PTO Form-1449 (2 pages) with forty-four (44) references cited, and copies of eleven (11) of the forty-four (44) references cited.

The Commissioner is hereby authorized to charge any deficiency or credit any excess to Deposit Account Number 14-0112.

Respectfully submitted,
THE NATH LAW GROUP

Date: June 5, 2008

Gary M. Nath
Registration No. 26,965
Jerald L. Meyer
Registration No. 41,194
Derek Richmond
Registration No. 45,771
Customer No. 20529

THE NATH LAW GROUP
112 S. West Street
Alexandria, VA 22314
Tel: (703) 548-6284
Fax: (703) 683-8396



Attorney Docket No. 29068U
MAIL STOP PCT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:		Conf. No.:	3761
ADAHAN			
Serial No.:	11/989,297	Intl. Appl. No.:	PCT/IL2005/000784
Filed:	January 24, 2008	Intl. Filing Date:	July 24, 2005
For:	**WOUND CLOSURE AND DRAINAGE SYSTEM**		

INFORMATION DISCLOSURE STATEMENT

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

Sir:

An Information Disclosure Statement is submitted herewith pursuant to 37 C.F.R. 1.97-1.98. Please note the following particulars:

[NOTE: One only of items a, b, c, and d must be checked.]

a. [X] The enclosed first statement is being filed within three months of the filing date of a national application, or within three months of the date of entry into 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, whichever event occurs last.

b. [ ] The enclosed first statement is being filed after a first action on the merits but before the mailing date of a final action under 37 C.F.R. 1.113, or a notice of allowance under 37 C.F.R. 1.311.

The enclosed first statement is accompanied by [check one]:

[ ] i. a certification in part (e) below as specified in 37 C.F.R. 1.97(e),

or

[ ] ii. a check in the amount required by 37 C.F.R. 1.17(p).

c. [ ] The enclosed first statement is being filed after the mailing date of a final action under 37 C.F.R. 1.113, or a notice of allowance under 37 C.F.R. 1.311, but before payment of the issue fee.

[ ] Certification report(e) below; and

[ ] A check in the amount as required by 1.17(p).

d. [ ] The enclosed first statement is being filed pursuant to 37 C.F.R. 1.97(i), for placement in the file.

e. Certification [Check one] [Certification is required only if box (b)(i) or box (c) is checked.]

[ ] I hereby certify that each item of information contained in the enclosed first Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement,

Medela LLC and Medela AG
Exhibit 1008
Page #1062

or

[ ] I hereby certify that no item of information in the enclosed first Information Disclosure Statement herewith was cited in a communication from a foreign patent office in a counterpart foreign application, or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. 1.56(c) more than three months prior to the filing of this first Information Disclosure Statement.

or

[ ] Appropriate certification is attached.

f. [X] If no check is enclosed and a fee is due in connection with this communication or if the check enclosed is insufficient, the Commissioner is authorized to charge any fee or additional fee due in connection with this communication to Deposit Account No. 14-0112.

g. [X] Copies of the documents are attached herewith with a completed first PTO Form-1449.

or

[ ] Copies of the documents are not attached, with a completed first PTO Form-1449 as allowed under CFR 1.98(d)(1)(2). The earlier application is identified as: _____.

and / or

[X] Copies of US Patents/Publications not attached, with a completed first PTO Form-1449 as allowed in Official Gazette Aug. 5, 2003/ Vol. 1273, no. 1.

The Examiner is respectfully requested to cite the documents listed on the attached first PTO Form-1449 in the next Office Action. In so doing, the Examiner is respectfully requested to initial in the space adjacent to the listing of each document on the first PTO Form-1449, and return a copy of the initialed first PTO Form-1449 with the next communication to Applicants, to confirm that these documents have been considered by the Examiner and made of record in this application.

If the Examiner has any questions or wishes to discuss this application, kindly telephone the undersigned at the below-listed number.

Respectfully submitted,
THE NATH LAW GROUP

Date: June 5, 2008

Gary M. Nath
Registration No. 26,965
Jerald L. Meyer
Registration No. 41,194
Derek Richmond
Registration No. 45,771
Customer No. 20529

THE NATH LAW GROUP
112 S. West Street
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Medela LLC and Medela AG
Exhibit 1008
Page #1063

IAP12 Rec'd PCT/PTO 24 JAN 2008

PTO-1390 (Rev. 09-2007)
Approved for use through 3/31/2007. OMB 0651-0021
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER	
29068U	
APPLICATION NO. (If known, see 37 CFR 1.5)	11/989297
Not Yet Assigned	

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/IL2005/000784	July 24, 2005	(n/a)

TITLE OF INVENTION
WOUND CLOSURE AND DRAINAGE SYSTEM

APPLICANT(S) FOR DO/EO/US
ADAHAN, Carmeli

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☑ This is a **FIRST** submission of items concerning a submission under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a submission under 35 U.S.C. 371.
3. ☑ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. ☑ The US has been elected (Article 31).
5. ☑ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
   a. ☑ is attached hereto (required only if not communicated by the International Bureau).
   b. ☐ has been communicated by the International Bureau.
   c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
   a. ☐ is attached hereto.
   b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☑ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
   a. ☐ are attached hereto (required only if not communicated by the International Bureau).
   b. ☐ have been communicated by the International Bureau.
   c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
   d. ☑ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☑ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11 to 20 below concern document(s) or information included:

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☐ A preliminary amendment.
14. ☐ An Application Data Sheet under 37 CFR 1.76.
15. ☐ A substitute specification.
16. ☑ A power of attorney and/or change of address letter.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13*ter*.2 and 37 CFR 1.821- 1.825.
18. ☐ A second copy of the published International Application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. 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 15 minutes to complete, including gathering information, preparing, and submitting the completed 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: **Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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PTO/SB/01 (1390) (Rev. 09-2007)
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U.S. APPLICATION NO. (if known, see 37 CFR 1.5)	INTERNATIONAL APPLICATION NO.	ATTORNEY'S DOCKET NUMBER
10/589297 Not Yet Assigned	PCT/IL2005/000784	29068U

20. Other items or information:

A1 Publication, Executed Declaration, PCT/ISA/210, Check, Postcard for Serial Number

The following fees have been submitted	CALCULATIONS	PTO USE ONLY
21. ☑ Basic national fee (37 CFR 1.492(a)) $310	$ 310.00	
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TOTAL OF 21, 22 and 23 =	930.00	

☐ Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) in an electronic medium or computer program listing in an electronic medium) (37 CFR 1.492(j)).
The fee is $260 for each additional 50 sheets of paper or fraction thereof.

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	RATE	
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CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	$	
Total claims	33 - 20 =	13	x $ 50	$ 650.00	
Independent claims	5 - 3 =	2	x $210	$ 420.00	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ $370	$	
			TOTAL OF ABOVE CALCULATIONS =	$ 2000.00	
☑ Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by ½.					
			SUBTOTAL =	$ 1000.00	
Processing fee of $130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)). +				$	
			TOTAL NATIONAL FEE =	$ 1000.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). $40.00 per property +				$	
			TOTAL FEES ENCLOSED =	$ 1000.00	
			Amount to be refunded:	$	
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NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:

Customer No. 20529

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Jerald L. Meyer
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41,194
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor: ADAHAN, Carmeli

Appl. No.: Not Yet Assigned

Filing Date: January ___, 2008

Intl. Appl. No.: PCT/IL2005/000784

Intl. Filing Date: July 24, 2005

Title: **WOUND CLOSURE AND DRAINAGE SYSTEM**

TRANSMITTAL LETTER

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

Sir:

Submitted herewith for filing in the U.S. Patent and Trademark Office is the following:

1. Transmittal Letter to U.S. Designated/Elected Office (DO/EO/US) Concerning Filing Under 35 U.S.C. 371;
2. International Publication Number: WO 2007/013049 A1; International Publication Date of March 30, 2006, which consists of 16 pages:
   - 1 page for the Cover Sheet, with the Abstract,
   - 8 pages of Textual Specification,
   - 5 pages of 33 Claims, and
   - 2 sheets of Drawings;
3. Executed Declaration & Power of Attorney;
4. PCT/ISA/210 (International Search Report);
5. Check Nos.: 5718 and 5743 in the aggregate amount of $1000.00 for Basic Filing Fees, for 13 Total Claims over 20, and for 2 Independent Claims over 3, as a small entity; and
6. Postcard for the Request for the Early Notification of the Serial Number.

The Commissioner is hereby authorized to charge any deficiency or credit any excess to Deposit Account No. 14-0112.

Respectfully submitted,
THE NATH LAW GROUP

January 24, 2008

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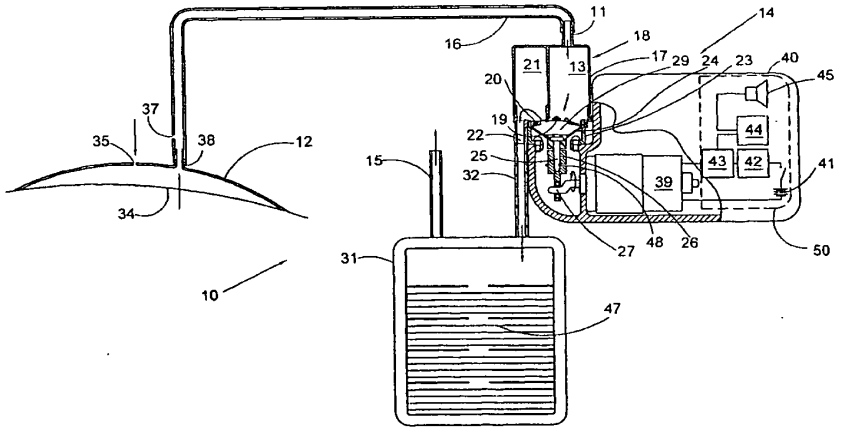
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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: WOUND CLOSURE AND DRAINAGE SYSTEM



(57) Abstract: A vacuum system for draining an open wound from liquids exuded therefrom, comprising an enclosure scalable to the wound circumference, a vacuum pump including a disposable pump unit detachably attachable to a non-disposable drive unit, and a waste container for collection of drained liquids. The enclosure has an outlet connected by means of a tube to an inlet of the pump unit and the waste container is connected to an outlet of the pump unit, such that when the vacuum pump is operated the drained liquids flow through the vacuum pump. The enclosure has one or more bleeding holes provided therethrough or adjacent to its outlet so that ambient air may enter the tube and flow together with the drained liquids. The enclosure and the waste container are disposable so that the drained liquids contact only disposable elements and may be disposed of together with all disposable elements.

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WOUND CLOSURE AND DRAINAGE SYSTEM

FIELD OF THE INVENTION

This invention relates generally to wound healing, and more specifically to healing of wounds by negative pressure drainage.

BACKGROUND OF THE INVENTION

Negative pressure applied to a wound enhances drainage of fluids or exudate from the wound and promotes tissue growth and wound healing. This method of healing (known as "cupping") was exercised since the times of ancient Greek physicians until the 19th century.

WO 96/05873 describes a therapeutic apparatus for stimulating healing of wounds. The apparatus comprises a porous foamed pad which is sealed on the wound and connected by a tube to an inlet of a canister. A vacuum pump is connected to an outlet of the canister. A bacterial filter positioned over the outlet of the canister protects the vacuum pump from contamination by wound drainage fluids sucked into the canister. The pump, the canister and control circuitry are disposed in a case.

WO 97/18007 discloses a portable wound treatment apparatus using a similar arrangement of a porous pad, canister and vacuum pump. The canister and the pump are in one housing which accommodates also the control circuitry and is wearable on a harness or a belt.

US 6,648,862 describes a portable vacuum desiccator using a similar arrangement as above, the canister being formed as a cartridge containing a trapping agent (desiccator). The vacuum pump and the canister may be integrated and detachable from the pump motor and circuitry.

Current negative pressure wound drainage systems such as the ones described above suffer from the following deficiencies:

- Since the negative pressure applied to the wound area is created by pump suction, the flow into the pump is likely to contaminate the pump, or conversely, to

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require costly and complex methods of isolating the pump from the wound exudate such as antibacterial filters.

- The wound exudate is collected in a rigid canister, which must be large enough to prevent it from overflowing, and thus it is bulky and an inconvenient burden for ambulatory patients, who carry a portable system with them.

- Conventional wound drainage systems utilize an air tight seal of the wound, which is helpful in obtaining and maintaining negative pressure, but requires a pressure relief or bleed valve to produce the pressure cycling desirable to obtain accelerated wound closure, as described in WO 96/05873.

- A sealed wound dressing or enclosure, when under negative pressure, will promote migration of the exudate toward the negative pressure source, through the connecting tube, which may occlude, should the exudate coagulate.

- The need to monitor and control the negative pressure level in conventional systems requires the use of a vacuum transducer, gage or relief valve, which must be connected to the suction tube, which is subject to contamination. Cleaning, disinfecting or isolating the negative pressure monitoring or controlling device are complex, costly and un-reliable.

SUMMARY OF THE INVENTION

It is the purpose of this invention to alleviate all the above listed deficiencies, by providing a wound drainage enclosure and vacuum system, which are impervious to contamination and easy to use.

In accordance with a first aspect of the present invention, there is provided an enclosure for draining an open wound from liquids exuded therefrom. The enclosure is attachable to the wound circumference so as to define a confined volume, and has an outlet, for example formed as a nipple, connectable by means of a tube to an inlet of a vacuum pump so that negative pressure may be created in said confined volume. One or more bleeding holes are provided in the enclosure or adjacent to its outlet such that ambient air can enter the tube and flow together with the exuded liquids when negative pressure is present. Ambient pressure may be restored in the confined volume when the vacuum pump is not operating.

The bleeding hole in the enclosure may be a calibrated orifice or other flow restrictors providing for controlled flow of ambient air into the enclosure or into its

outlet. For instance, a hole plugged with open cell foam or an open pore sintered metal plug, which restrict the flow, but are not susceptible to plugging as is a small orifice.

The bleeding hole renders the wound closure vented or non-airtight, as distinguishable from conventional wound closures. The flow of air from the bleeding hole in the wound closure, in response to the negative pressure created by the vacuum pump, facilitates the removal of exudate, which might otherwise coagulate, dry-up and occlude the tubing.

According to another aspect of the present invention, there is provided a method for draining an open wound from liquids exuded therefrom. The method includes:

- providing an enclosure and sealing it to the wound circumference so as to define a confined volume,

- connecting the confined volume to a vacuum pump,

- connecting a waste container for collection of drained liquids to the vacuum pump, and

- operating said vacuum pump to draw the exuded liquids from the wound.

The method is characterized in that the confined volume is connected to an inlet of the vacuum pump and the waste container is connected to an outlet of the vacuum pump such that the drained liquids flow through said vacuum pump.

The method may include employment of an enclosure with bleeding orifices so that ambient air is allowed to enter the tube and flow together with the drained exuded liquids.

Preferably, gases are separated and released from the drained exuded liquids.

According to a further aspect of the present invention, there is provided a vacuum system for practicing the above method. The vacuum system may use a totally disposable vacuum pump, together with a waste collection bag, as disclosed in WO03016719. The vacuum pump is a two-chambered diaphragm pump adapted for pumping gases and liquids and/or any combination thereof. The vacuum pump is capable of pumping air and fluid which enter its inlet port, to a waste bag attached to its outlet port. The waste bag is vented to the atmosphere, such that it collects only the fluids which enter it.

The vacuum system may be adapted to be carried by an ambulatory patient.

According with a next aspect of the present invention, there is provided a disposable assembly for draining an open wound from liquids exuded therefrom. The

assembly comprises an enclosure attachable to the wound circumference so as to define a confined volume, a vacuum pump unit connected to the enclosure so that negative pressure may be created in the confined volume, and a waste container connected to the vacuum pump unit. The vacuum pump unit has means for detachably attaching to a drive unit for operating the pump unit. The enclosure is connected to an inlet of the vacuum pump unit and the waste container is connected to an outlet of the vacuum pump unit, such that when the vacuum pump unit is operated the drained liquids flow therethrough.

Preferably, the pump unit and the drive unit are adapted for attaching and detaching by simple hand manipulations.

The enclosure may have bleeding holes as described above.

The vacuum pump unit is preferably a two-chambered diaphragm pump adapted for pumping gases and liquids and/or any combination thereof.

The waste container may contain a porous media adapted to soak up the drained liquids and may be in the form of a collapsible or foldable bag.

The drained liquids and air contact only the parts of the disposable assembly. The drained exuded liquids may then be disposed of together with the disposable assembly. More specifically, the pump unit is disposed of after use, together with the tubing connected to it, as well as the waste bag connected, with its content, and with the wound closure which may be connected to the pump unit via the tube.

In accordance with yet another aspect of the present invention, there is provided a vacuum system as described above where the vacuum pump has a drive unit and a control block adapted to power the drive unit so that a predetermined level of negative pressure is maintained in the confined volume. The control block has a sensor for sensing working parameters of the drive unit and means for deriving the level of negative pressure in the confined volume from these working parameters, in order to maintain said predetermined level. The sensor has no fluid connection with the confined volume.

For example, the drive unit may comprise a direct current electric motor and the sensor may sense the electric current driving the motor. The same function of negative pressure control may be accomplished by an adjustable torque limiting clutch, placed between the motor output shaft and the pump.

The control block may be provided with alarm means to warn the user if the predetermined level of negative pressure is not maintained.

If the vacuum pump comprises a disposable pump unit and the drive unit is detachably attachable to the pump unit, the control block with monitoring means is preferably associated with the drive unit which is non-disposable.

Thus, indirect means are provided for controlling or monitoring the level of negative pressure applied to the wound, without making any direct connection to a vacuum sensor, transducer or gage to any portion of the system, which has the negative pressure applied to it. The indirect negative pressure monitoring and control result from the need to dispose of any portion of the system, which may come in contact with the pumped media, which is likely to be contaminated or infectious. Accordingly, all the disposable components in the system may be relatively low in cost, to promote discarding them after use. Pressure transducers, vacuum gages or sensors, are relatively costly, and thus not considered disposable.

BRIEF DESCRIPTION OF THE DRAWINGS

In order to understand the invention and to see how it may be applied, a preferred embodiment will now be described, by way of non-limiting example only, with reference to the accompanying drawings, in which:

Fig. 1 is a schematic sectional view of the vacuum system of the present invention applied on a wound.

Fig. 2 shows the disposable portion of the system of Fig. 1.

DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

The present invention provides a system and a method of treating and healing of a body wound, by applying a negative pressure to the wound, over an area sufficient to promote migration of epithelial and subcutaneous tissue toward the wound.

It is appreciated that the detailed description that follows is intended only to illustrate certain preferred embodiments of the present invention. It is in no way intended to limit the scope of the invention, as set out in the claims.

With reference to Fig. 1, in accordance with the present invention, a vacuum system 10 for draining an open wound from liquids exuded therefrom comprises a wound enclosure 12, a vacuum pump 14, and waste collection bag 31. The wound

enclosure 12 is connected by a suction tube 16 to an inlet 11 of the vacuum pump. The waste collection bag 31 is connected to an outlet 22 of the vacuum pump. Thereby, when the vacuum pump 14 is operated, the drained liquids flow through the pump into the waste bag 31.

Suction tube 16 is connected to nipple 38 of the enclosure 12 which covers wound area of the body 34 such that suction of air through tube 16 creates negative pressure in the volume above the wound area of the body 34. A bleeding orifice 35 is provided within the enclosure 12, or adjacent to it as a tube orifice 37, allowing ambient air to flow into and through suction tube 16, rendering enclosure 12 non-air tight, or vented. This feature, unlike conventional sealed closures, provides for quick movement of exudate entering suction tube 16, toward the vacuum pump 14, and into the waste bag 31, before it dries up or coagulates and occludes the tube. This feature also provides for introduction of ambient pressure to the wound area of the body 34 whenever the vacuum pump stops pumping, allowing cyclic negative pressure application to the wound, by cycling the vacuum pump on and off alternately.

Instead of the bleeding orifice 35 in the enclosure, other flow restrictors may be used to provide for controlled flow of ambient air into the enclosure or into the outlet. For instance, a hole plugged with open cell foam or an open pore sintered metal plug, which restrict the flow, but are not susceptible to plugging as is a small orifice.

The vacuum pump 14 comprises a pump unit 18 and a drive unit 40 which are detachably attachable to each other, as explained below. The pump unit 18 includes a two-chambered housing 17 and a diaphragm 24 secured to the underside of the two-chambered housing 17 so as to form a working chamber 29.

The two-chambered housing 17 has a first chamber 13 with the inlet 11 and a second chamber 21 with an outlet 22. The suction tube 16 is connected to the inlet 11. Two one-way valves 19 and 20 are present at the bottom of the first chamber 13 and the second chamber 21, respectively. To the bottom of the two-chambered housing 17 there is attached a mounting base 23, used to mount the housing 17 to the drive unit 40 by means of a bayonet lock.

The diaphragm 24 has an integral rod-shaped drive member 25, which is used for engagement with the drive unit 40.

The drive unit 40 includes an electric motor 39, batteries 41 and a control block 50 described below. The shaft of the motor 39 has a crank 27 coupled to a reciprocating

rod 26. The rod 26 has a receptacle with a cavity adapted to receive and lock therein the drive member 25.

When the pump unit 18 is attached to the drive unit 40 by means of the bayonet lock in the base 23, the drive member 25 is received in the receptacle cavity of the reciprocating rod 26 and then locked therein.

Upon activation of the motor 39, the crank 27 is rotated and reciprocates the receptacle rod 26, causing the diaphragm 24 to expand and contract the working chamber 29. Thus the pump unit 18 pumps air or liquid that passes through the one-way valves 19 and 20.

Air and liquids enter the two-chambered housing 17 through the inlet 11 and suction tube 16 which is connected to the patient's wound enclosure 12, for the removal of exudate. Liquids and air enter the first chamber 13, which is under negative pressure when diaphragm 24 reciprocates, driving them past one-way valve 20, into the second chamber 21. The air and liquid which are pumped through outlet 22, enter waste bag 31.

The pump's ability to pump air and liquid, unlike conventional pumps, which are efficient in pumping only one type of matter, is enhanced by the flexibility of the diaphragm 24 which allows the diaphragm to yield when encountering heavy loads, such as those present when pumping liquid. This diaphragm flexibility also provides an additional substantial advantage: when the negative pressure in working chamber 29 is high, the diaphragm 24 stretches to allow the reciprocation of the receptacle rod 26 to occur, at minimal burden to the electric motor 39.

The waste bag 31 has a vent 15, through which air and gas are discharged to the atmosphere. Accordingly, waste bag 31 will retain only the waste fluids which are pumped into it. The waste bag may contain a porous media 47 adapted to soak up the drained liquids.

It is important to note that waste bag 31 is made of thin plastic sheet, which allow it to be folded or collapsed when not full, providing the convenience of having minimal bulk and minimal inconvenience to the patient using or carrying it.

The drive unit 40 also includes a control block 50 with control circuits such as cycle control 42, which turns the motor pump on and off alternately, motor voltage and current monitoring and control 43, which controls the negative pressure level produced by the pump unit 18, by controlling the voltage and current which drive motor 39. At any given voltage which drives motor 39, the current draw of the motor is directly

related to the negative pressure generated by the pump 18. Accordingly, monitoring of the current which the motor 39 draws allows for indirect monitoring of the negative pressure attained by pump 18. The ability to monitor the negative pressure developed by pump 18, indirectly, precludes the need of making an infectious negative pressure line connection to a pressure transducer or vacuum gage.

For example, if the motor 39 is a direct current electric motor, a sensor may sense the electric current driving the motor. Since the direct current motor output torque is directly related to the current driving the motor, and since the motor output torque is directly related to the negative pressure the pump 18 produces, monitoring the motor current or controlling it, provide for monitoring and controlling the negative pressure produced by the vacuum pump. Motor current monitoring is only one of the available methods of indirect negative pressure monitoring and controlling. The same function of negative pressure control may be accomplished by an adjustable torque limiting clutch placed between the motor output shaft and the crank 27.

The control block 50 also has a negative pressure comparator 44, which compares the desired set negative pressure level obtained by pump 18, and the actual monitored negative pressure level as obtained indirectly from motor voltage and current monitoring and control 43. Comparator 44 will activate audible alarm 45, whenever pump 18 fails to reach the desired pre-set negative pressure level.

Fig. 2 shows the disposable portion of the system as an assembly 60, which includes the pump unit 18, the waste bag 31, the connecting tube 16 and the wound enclosure 12, all separated from the drive unit and from the wound area of the body 34. The assembly 60 may be disposed of in its totality after use, and replaced by a new assembly, thus keeping the costly drive unit 40 free from any contamination. It would be obvious to those skilled in the art, that the present invention alleviates the need for cleaning or disinfecting any portion of drive unit 40 after use, or providing protective means, such as filters, to keep contaminants from reaching the costly drive 40.

CLAIMS:

1. A vacuum system for draining an open wound from liquids exuded therefrom, comprising an enclosure sealable to the wound circumference so as to define a confined volume, a vacuum pump in fluid communication with said confined volume, and a waste container for collection of drained liquids in fluid communication with said vacuum pump,

wherein said confined volume is connected to an inlet of said vacuum pump and said waste container is connected to an outlet of said vacuum pump, such that when said vacuum pump is operated the drained liquids flow through said vacuum pump.

2. The vacuum system of Claim 1, wherein said enclosure has an outlet connected by means of a tube to said inlet of the vacuum pump, and one or more bleeding holes are provided through said enclosure or adjacent to its outlet so that ambient air may enter said tube and flow together with the drained liquids.

3. The vacuum system of Claim 1, wherein said vacuum pump includes a disposable pump unit detachably attachable to a non-disposable drive unit, said enclosure and said waste container being disposable so that the drained liquids, as well as air coming in contact with them, contact only the disposable elements and said drained liquids may be disposed of together with said disposable elements.

4. The vacuum system of Claim 3, wherein said pump unit and said drive unit are adapted for attaching and detaching by simple hand manipulations.

5. The vacuum system of Claim 1, wherein said vacuum pump includes a drive unit and a control block adapted to power said drive unit so that a predetermined level of negative pressure is maintained in said confined volume,

wherein said control block has a sensor for sensing working parameters of said drive unit and means for deriving the level of negative pressure in said confined volume from said working parameters, in order to maintain said predetermined level, said sensor having no fluid communication with said confined volume.

6. The vacuum system of Claim 5, wherein said drive unit comprises an electric motor and said working parameters include the electric current and/or voltage of said motor.

7. The vacuum system of Claim 1, wherein said waste container is vented so as to release gases mixed with said drained liquids.

8. The vacuum system of Claim 1, wherein said waste container is a collapsible bag.

9. The vacuum system of Claim 1, wherein said vacuum pump is a two-chambered diaphragm pump adapted for pumping gases and liquids and/or any combination thereof.

10. The vacuum system of Claim 1, adapted to be worn by an ambulatory patient.

11. An enclosure for draining an open wound from liquids exuded therefrom, the enclosure being attachable to the wound circumference so as to define a confined volume, and having an outlet connectable by means of a tube to an inlet of a vacuum pump so that negative pressure may be created in said volume,

wherein one or more bleeding holes are provided in the enclosure or adjacent to its outlet such that ambient air can enter said tube and flow together with the exuded liquids under the action of the negative pressure, and the ambient pressure may be restored in said confined volume when said vacuum pump is not operating.

12. The enclosure of Claim 11, having a nipple for connecting to said tube.

13. The enclosure of Claim 11, wherein a plurality of bleeding holes is provided in the form of a porous body mounted in said enclosure.

14. The enclosure of Claim 11, completed with a tube connected to said outlet, for connection to said vacuum pump inlet, wherein said one or more bleeding holes are provided in the tube, adjacent to said outlet.

15. A method for draining an open wound from liquids exuded therefrom, including:

- providing an enclosure and sealing it to the wound circumference so as to define a confined volume,

- connecting said confined volume to a vacuum pump,

- connecting a waste container for collection of drained liquids to said vacuum pump,

- operating said vacuum pump to drain the exuded liquids,

wherein

said confined volume is connected to an inlet of said vacuum pump and said waste container is connected to an outlet of said vacuum pump such that the drained liquids and air flow through said vacuum pump.

16. The method of Claim 15, wherein said enclosure has an outlet connected by means of a tube to said inlet of the vacuum pump, and ambient air is allowed to enter into said tube via one or more bleeding holes provided through said enclosure or adjacent to its outlet so that said air flows together with the drained exuded liquids.

17. The method of Claim 15, comprising separating and releasing of gases from the drained exuded liquids.

18. The method of Claim 17, wherein said gases are released through a vent in the waste container.

19. The method of Claim 15, wherein said vacuum pump is a two-chambered diaphragm pump adapted for pumping gases and liquids and/or any combination thereof.

20. The method of Claim 15, wherein said enclosure, said waste container, and at least a part of said vacuum pump which contacts said drained liquids, are disposable, and the method comprises disposing of the disposable elements together with the drained exuded liquids.

21. The method of Claim 20, wherein the disposable part of said vacuum pump is a pump unit detachably attachable to a non-disposable drive unit, the method including attaching the pump unit to the drive unit before draining, and detaching the pump unit before said disposing.

22. The method of Claim 21, wherein said attaching and detaching include only simple hand manipulations.

23. The method of Claim 15, applied to a wound of an ambulatory patient.

24. A disposable assembly for draining an open wound from liquids exuded therefrom, the assembly comprising an enclosure attachable to the wound circumference so as to define a confined volume, a vacuum pump unit connected to said enclosure so that negative pressure may be created in said volume, said vacuum pump unit having means for detachably attaching to a drive unit for operating the pump unit, and a waste container connected to said vacuum pump unit;

wherein said enclosure is connected to an inlet of said vacuum pump unit and said waste container is connected to an outlet of said vacuum pump unit, such that when said vacuum pump unit is operated the drained liquids flow therethrough.

25. The disposable assembly of Claim 24, wherein said enclosure has an outlet connected by means of a tube to said inlet of the vacuum pump unit, and one or more

bleeding holes are provided through said enclosure or adjacent to its outlet so that ambient air may flow through said tube together with the drained exuded liquids.

26. The disposable assembly of Claim 24, wherein said vacuum pump unit is a two-chambered diaphragm pump adapted for pumping gases and liquids and/or any combination thereof.

27. The disposable assembly of Claim 24, wherein said waste container contains a porous media adapted to soak up said drained liquids.

28. The disposable assembly of Claim 24, wherein said waste container is a collapsible bag.

29. A vacuum system for draining an open wound from liquids exuded therefrom, comprising an enclosure sealable to the wound circumference so as to define a confined volume, a vacuum pump in fluid communication with said confined volume, said vacuum pump having a drive unit, and a control block adapted to power said drive unit so that a predetermined level of negative pressure is maintained in said confined volume,

wherein

said control block has a sensor for sensing working parameters of said drive unit and means for deriving the level of negative pressure in said confined volume from said working parameters, in order to maintain said predetermined level, said sensor having no fluid communication with said confined volume.

30. The vacuum system of Claim 29, wherein said drive unit comprises an electric motor and said working parameters include the electric current and/or voltage of said motor.

31. The vacuum system of Claim 29, wherein said control block has alarm means to warn the user if said predetermined level of negative pressure is not maintained.

32. The vacuum system of Claim 29, further comprising a waste container for collection of drained liquids, where said confined volume is in fluid communication with an inlet of said vacuum pump, and said waste container is in fluid communication with an outlet of said vacuum pump such that when said vacuum pump is operated the drained liquids flow therethrough.

33. The vacuum system of Claim 29, wherein said vacuum pump comprises a disposable pump unit including said inlet and said outlet, and said pump unit is

detachably attachable to said drive unit, said control block with said sensor being associated with the drive unit,

and wherein said enclosure and said waste container are disposable, so that said exuded liquids may contact only the disposable elements of the vacuum system and may be disposed of together with said disposable elements after detaching said drive unit.

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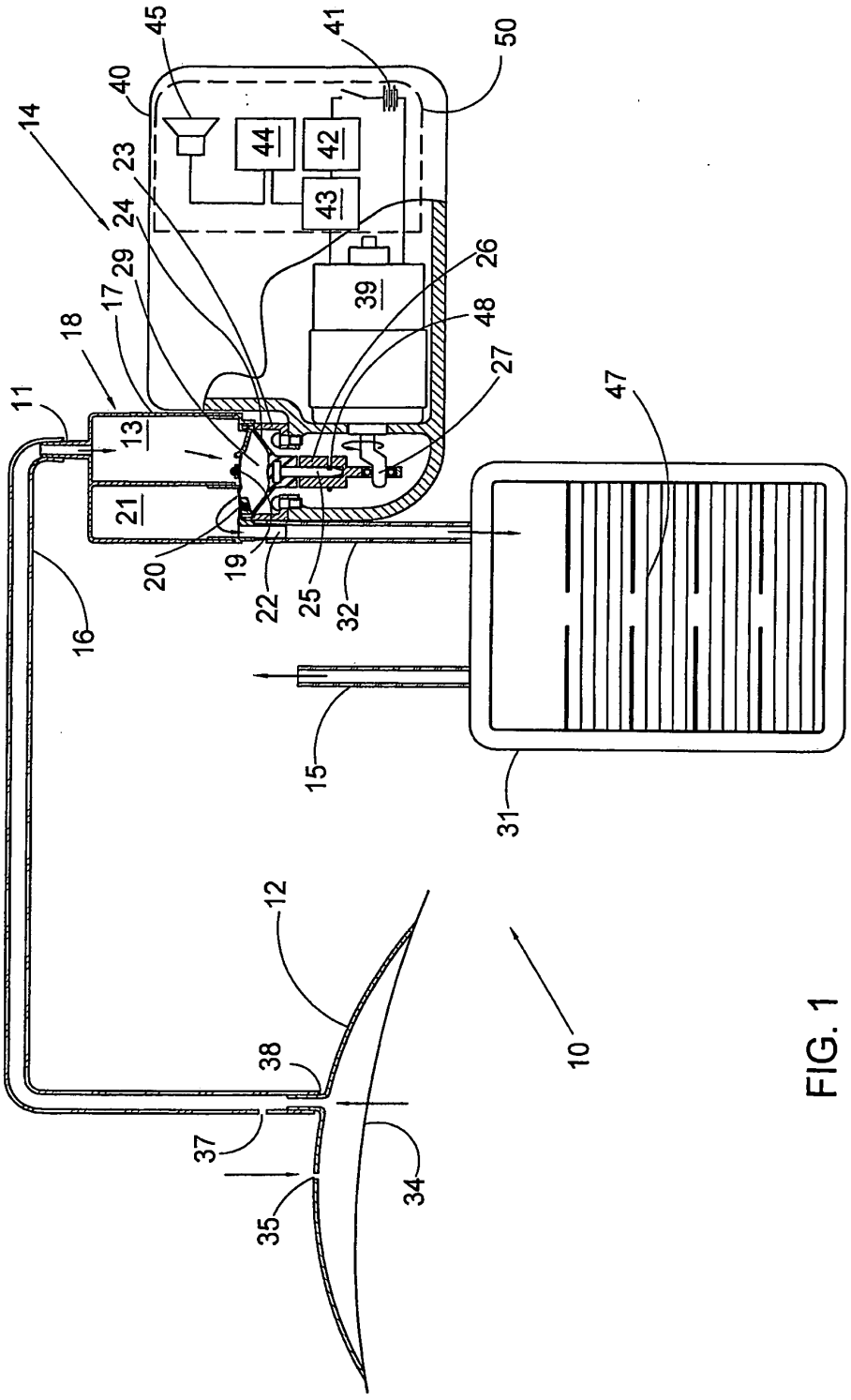

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FIG. 1

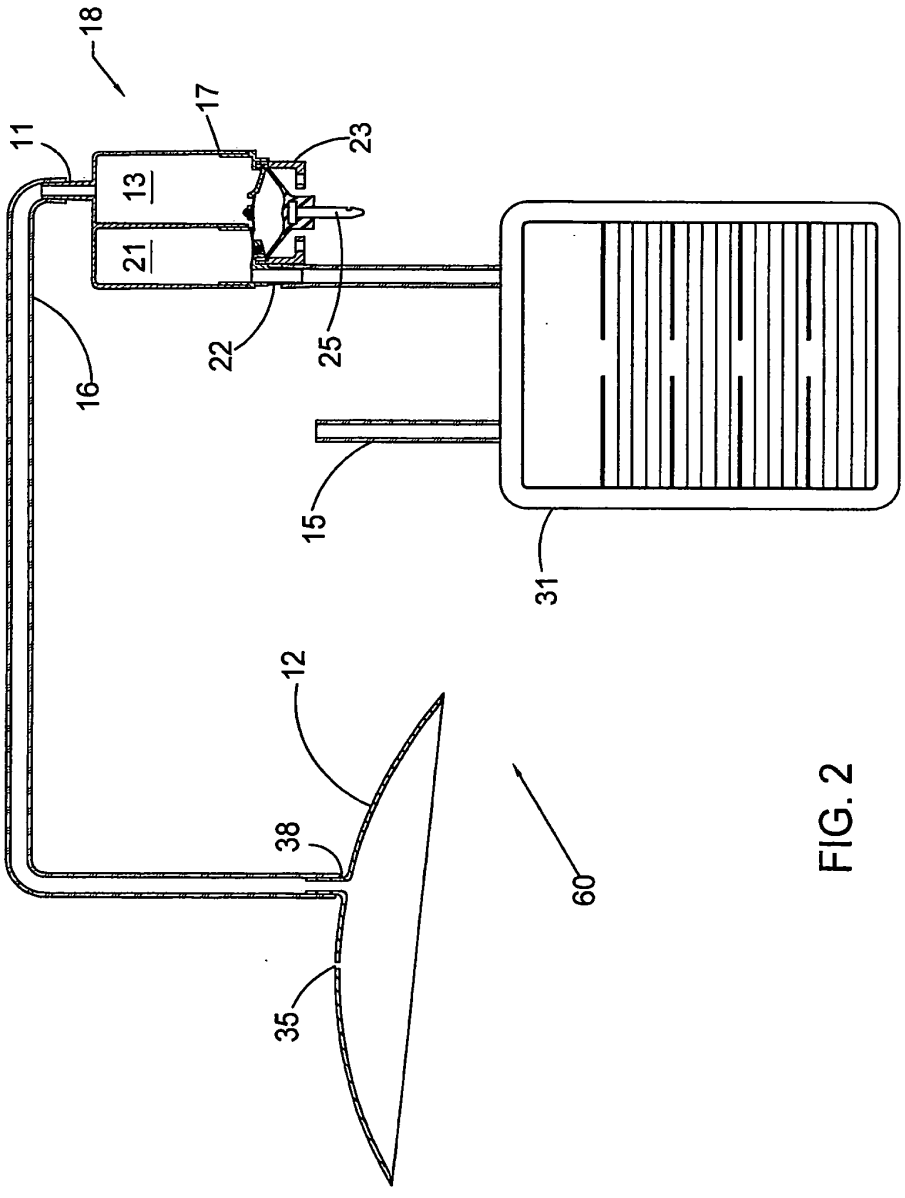


FIG. 2

IT/989297
IAP05Rec'd PCT 24 JAN 2006

Attorney's Docket No.:

COMBINED DECLARATION AND POWER OF ATTORNEY

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled WOUND CLOSURE AND DRAINAGE SYSTEM, the specification of which:

- ☐ is attached hereto.
- ☐ was filed on _____ as Application Serial No. _____ and was amended on _____.
- ☒ was described and claimed in PCT International Application No. PCT/IL2005/000784 filed on July 24, 2005 and as amended under PCT Article on _____

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim the benefit under Title 35, United States Code, §119(e)(1) of any United States provisional application(s) listed below:

U.S. Serial No.	Filing Date	Status

I hereby claim the benefit under 35 U.S.C. §120 of any prior U.S. non-provisional application(s) or under §365(c) of any prior PCT international application(s) designating the U.S., listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in such U.S. or PCT international application in the manner provided by the first paragraph of 35 U.S.C. §112, I acknowledge the duty to disclose to the PTO all information which is material to patentability as defined in 37 C.F.R. §1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

Application Serial No.	Filing Date	Status

I hereby claim foreign priority benefits under 35 U.S.C. §§ 119 (a)-(d) and 365 (b) of any prior foreign application(s) for patent, inventor's or plant breeder's rights certificate(s), or under §365(a) of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed:

Country	Application No.	Filing Date	Priority Claimed
			☐

Attorney's Docket No.:

Combined Declaration and Power of Attorney

I/We hereby appoint the Practitioners associated with the following Customer Number:

Customer Number 20529

Direct Telephone Calls to: Send Correspondence to:

THE NATH LAW GROUP
112 South West Street
Alexandria, VA 22314
U.S.A

Gary M. Nath
(703) 548-6284

The undersigned hereby authorizes the U.S. Attorneys or Agents appointed herein to accept and follow instructions from Reinhold Cohn and Partners as to any action to be taken in the U.S. Patent and Trademark Office regarding this application without direct communication between the U.S. Attorneys or Agents and the undersigned. In the event of a change of the persons from whom instructions may be taken, the U.S. Attorneys or Agents appointed herein will be so notified by the undersigned.

I hereby further 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; and 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 18 U.S.C. §1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full Name of Inventor: Carmeli ADAHAN

Inventor's Signature: _____ Date: Dec. 31. 07

Residence Address: Same as Post Office Address
Citizenship: Israeli
Post Office Address: 11 Netivei Am
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Jerusalem 97552
ISRAEL

INTERNATIONAL SEARCH REPORT

International application No
PCT/IL2005/000784

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M1/00 A61M27/00 F04B43/04 F04B53/22

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 practical, search terms used)
EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2004/064132 A1 (BOEHRINGER JOHN R ET AL) 1 April 2004 (2004-04-01) paragraphs [0037] - [0039]; figure 1	1,7,8,10
Y		9
Y	US 4 930 997 A (BENNETT ET AL) 5 June 1990 (1990-06-05) column 7, line 47 - line 50; figure 4 column 17, line 45 - column 18, line 60	1,5,6, 29-32
A		7,8
Y	US 4 661 093 A (BECK ET AL) 28 April 1987 (1987-04-28) column 5, line 24 - line 60; figures 1,3	1,3,4,24
A		8

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[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 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
13 July 2006	19/07/2006

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, A

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

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INTERNATIONAL SEARCH REPORT

International application No
PCT/IL2005/000784

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 2001/029956 A1 (ARGENTA LOUIS C ET AL) 18 October 2001 (2001-10-18) paragraph [0042]; figure 2	1,3-6, 24,29-32
Y	WO 03/016719 A (ADAHAN, CARMELI) 27 February 2003 (2003-02-27) cited in the application the whole document	9
A		8
A	US 5 645 081 A (ARGENTA ET AL) 8 July 1997 (1997-07-08) column 5, line 23 - line 36; figure 1	1,3,24
A	US 2002/151826 A1 (RAMEY JOHN S ET AL) 17 October 2002 (2002-10-17) paragraph [0061]	1,3,24
A	US 5 776 119 A (BILBO ET AL) 7 July 1998 (1998-07-07) column 2, line 2 - line 5	5,6,29, 30
A	US 2004/059284 A1 (NASH JOHN E ET AL) 25 March 2004 (2004-03-25) column 42	5,6, 29-31

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL2005/000784

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 15-23
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapyRule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [X] 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.:

3-6,24-33

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.

[X] No protest accompanied the payment of additional search fees.

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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, 7-10

A vacuum system with the technical features of claim 1 comprising an enclosure defining a confined volume, a vacuum pump, a waste container, wherein said confined volume is connected to an inlet of said pump and said waste container is connected to an outlet of said pump, such that drained liquids flow through said vacuum pump

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2. claims: 2 (dependent on 1); 11-14

An enclosure with the technical features of claim 11 defining a confined volume having an outlet wherein one or more bleeding holes are provided;
A vacuum system with the technical features of claim 1, the enclosure further comprising an outlet connected by means of a tube to said inlet of the vacuum pump and one or more bleeding holes are provided

---

3. claims: 3,4 (dependent on 1); 24-28

A disposable assembly with the features of claim 24 comprising an enclosure defining a confined volume, a vacuum pump unit, a waste container, wherein said enclosure is connected to an inlet of said pump and said waste container is connected to an outlet of said pump unit, such that drained liquids flow through said vacuum pump unit, said vacuum pump unit having means for detachably attaching to a drive unit for operating the pump unit;
A vacuum system with the technical features of claim 1 the vacuum pump further including a disposable pump unit detachably atttachable to a non-disposable drive unit, said enclosure and said waste container being disposable

---

4. claims: 5,6 (dependent on 1); 29-33

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

A vacuum system with the technical features of claim 29 comprising an enclosure defining a confined volume, a vacuum pump, said vacuum pump having a drive unit and a control block adapted to power said drive unit wherein said control block has a sensor for sensing working parameters of said drive unit and means for deriving the level of negative pressure in said confined volume, said sensor having no fluid communication with said confined volume;
A vacuum system with the technical features of claim 1 said vacuum pump further including a drive unit and a control block adapted to power said drive unit wherein said control block has a sensor for sensing working parameters of said drive unit and means for deriving the level of negative pressure in said confined volume, said sensor having no fluid communication with said confined volume;

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/IL2005/000784

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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PATENT APPLICATION SERIAL NO._____

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE
FEE RECORD SHEET

01/25/2008 GFREY1 00000103 11989297

01 FC:2631	155.00	OP
02 FC:2633	105.00	OP
03 FC:2642	205.00	OP
04 FC:2615	325.00	OP
05 FC:2614	210.00	OP

PTO-1556
(5/87)

*U.S. Government Printing Office: 2002-489-267/69033

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(19) World Intellectual Property Organization
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1 February 2007 (01.02.2007)

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(10) International Publication Number
WO 2007/013049 A1

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A61M 1/00 (2006.01) *F04B 43/04* (2006.01)
A61M 27/00 (2006.01) *F04B 53/22* (2006.01)

(21) International Application Number:
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(22) International Filing Date: 24 July 2005 (24.07.2005)

(25) Filing Language: English

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(71) Applicant and
(72) Inventor: **ADAHAN, Carmeli** [IL/IL]; 11 Netivei Am Ramot, 97552 Jerusalem (IL).

(74) Agent: **REINHOLD COHN AND PARTNERS**; P.O. Box 4060, 61040 Tel Aviv (IL).

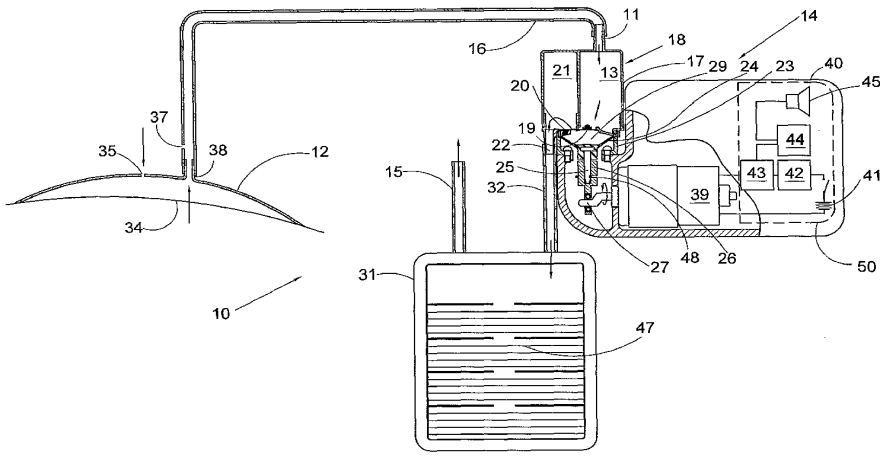
(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

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.

(54) **Title:** WOUND CLOSURE AND DRAINAGE SYSTEM



(57) **Abstract:** A vacuum system for draining an open wound from liquids exuded therefrom, comprising an enclosure sealable to the wound circumference, a vacuum pump including a disposable pump unit detachably attachable to a non-disposable drive unit, and a waste container for collection of drained liquids. The enclosure has an outlet connected by means of a tube to an inlet of the pump unit and the waste container is connected to an outlet of the pump unit, such that when the vacuum pump is operated the drained liquids flow through the vacuum pump. The enclosure has one or more bleeding holes provided therethrough or adjacent to its outlet so that ambient air may enter the tube and flow together with the drained liquids. The enclosure and the waste container are disposable so that the drained liquids contact only disposable elements and may be disposed of together with all disposable elements.

WO 2007/013049 A1

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WOUND CLOSURE AND DRAINAGE SYSTEM

FIELD OF THE INVENTION

This invention relates generally to wound healing, and more specifically to healing of wounds by negative pressure drainage.

BACKGROUND OF THE INVENTION

Negative pressure applied to a wound enhances drainage of fluids or exudate from the wound and promotes tissue growth and wound healing. This method of healing (known as "cupping") was exercised since the times of ancient Greek physicians until the 19th century.

WO 96/05873 describes a therapeutic apparatus for stimulating healing of wounds. The apparatus comprises a porous foamed pad which is sealed on the wound and connected by a tube to an inlet of a canister. A vacuum pump is connected to an outlet of the canister. A bacterial filter positioned over the outlet of the canister protects the vacuum pump from contamination by wound drainage fluids sucked into the canister. The pump, the canister and control circuitry are disposed in a case.

WO 97/18007 discloses a portable wound treatment apparatus using a similar arrangement of a porous pad, canister and vacuum pump. The canister and the pump are in one housing which accommodates also the control circuitry and is wearable on a harness or a belt.

US 6,648,862 describes a portable vacuum desiccator using a similar arrangement as above, the canister being formed as a cartridge containing a trapping agent (desiccator). The vacuum pump and the canister may be integrated and detachable from the pump motor and circuitry.

Current negative pressure wound drainage systems such as the ones described above suffer from the following deficiencies:

- Since the negative pressure applied to the wound area is created by pump suction, the flow into the pump is likely to contaminate the pump, or conversely, to

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require costly and complex methods of isolating the pump from the wound exudate such as antibacterial filters.

- The wound exudate is collected in a rigid canister, which must be large enough to prevent it from overflowing, and thus it is bulky and an inconvenient burden for ambulatory patients, who carry a portable system with them.

- Conventional wound drainage systems utilize an air tight seal of the wound, which is helpful in obtaining and maintaining negative pressure, but requires a pressure relief or bleed valve to produce the pressure cycling desirable to obtain accelerated wound closure, as described in WO 96/05873.

- A sealed wound dressing or enclosure, when under negative pressure, will promote migration of the exudate toward the negative pressure source, through the connecting tube, which may occlude, should the exudate coagulate.

- The need to monitor and control the negative pressure level in conventional systems requires the use of a vacuum transducer, gage or relief valve, which must be connected to the suction tube, which is subject to contamination. Cleaning, disinfecting or isolating the negative pressure monitoring or controlling device are complex, costly and un-reliable.

SUMMARY OF THE INVENTION

It is the purpose of this invention to alleviate all the above listed deficiencies, by providing a wound drainage enclosure and vacuum system, which are impervious to contamination and easy to use.

In accordance with a first aspect of the present invention, there is provided an enclosure for draining an open wound from liquids exuded therefrom. The enclosure is attachable to the wound circumference so as to define a confined volume, and has an outlet, for example formed as a nipple, connectable by means of a tube to an inlet of a vacuum pump so that negative pressure may be created in said confined volume. One or more bleeding holes are provided in the enclosure or adjacent to its outlet such that ambient air can enter the tube and flow together with the exuded liquids when negative pressure is present. Ambient pressure may be restored in the confined volume when the vacuum pump is not operating.

The bleeding hole in the enclosure may be a calibrated orifice or other flow restrictors providing for controlled flow of ambient air into the enclosure or into its

outlet. For instance, a hole plugged with open cell foam or an open pore sintered metal plug, which restrict the flow, but are not susceptible to plugging as is a small orifice.

The bleeding hole renders the wound closure vented or non-airtight, as distinguishable from conventional wound closures. The flow of air from the bleeding hole in the wound closure, in response to the negative pressure created by the vacuum pump, facilitates the removal of exudate, which might otherwise coagulate, dry-up and occlude the tubing.

According to another aspect of the present invention, there is provided a method for draining an open wound from liquids exuded therefrom. The method includes:

- providing an enclosure and sealing it to the wound circumference so as to define a confined volume,

- connecting the confined volume to a vacuum pump,

- connecting a waste container for collection of drained liquids to the vacuum pump, and

- operating said vacuum pump to draw the exuded liquids from the wound.

The method is characterized in that the confined volume is connected to an inlet of the vacuum pump and the waste container is connected to an outlet of the vacuum pump such that the drained liquids flow through said vacuum pump.

The method may include employment of an enclosure with bleeding orifices so that ambient air is allowed to enter the tube and flow together with the drained exuded liquids.

Preferably, gases are separated and released from the drained exuded liquids.

According to a further aspect of the present invention, there is provided a vacuum system for practicing the above method. The vacuum system may use a totally disposable vacuum pump, together with a waste collection bag, as disclosed in WO03016719. The vacuum pump is a two-chambered diaphragm pump adapted for pumping gases and liquids and/or any combination thereof. The vacuum pump is capable of pumping air and fluid which enter its inlet port, to a waste bag attached to its outlet port. The waste bag is vented to the atmosphere, such that it collects only the fluids which enter it.

The vacuum system may be adapted to be carried by an ambulatory patient.

According with a next aspect of the present invention, there is provided a disposable assembly for draining an open wound from liquids exuded therefrom. The

assembly comprises an enclosure attachable to the wound circumference so as to define a confined volume, a vacuum pump unit connected to the enclosure so that negative pressure may be created in the confined volume, and a waste container connected to the vacuum pump unit. The vacuum pump unit has means for detachably attaching to a drive unit for operating the pump unit. The enclosure is connected to an inlet of the vacuum pump unit and the waste container is connected to an outlet of the vacuum pump unit, such that when the vacuum pump unit is operated the drained liquids flow therethrough.

Preferably, the pump unit and the drive unit are adapted for attaching and detaching by simple hand manipulations.

The enclosure may have bleeding holes as described above.

The vacuum pump unit is preferably a two-chambered diaphragm pump adapted for pumping gases and liquids and/or any combination thereof.

The waste container may contain a porous media adapted to soak up the drained liquids and may be in the form of a collapsible or foldable bag.

The drained liquids and air contact only the parts of the disposable assembly. The drained exuded liquids may then be disposed of together with the disposable assembly. More specifically, the pump unit is disposed of after use, together with the tubing connected to it, as well as the waste bag connected, with its content, and with the wound closure which may be connected to the pump unit via the tube.

In accordance with yet another aspect of the present invention, there is provided a vacuum system as described above where the vacuum pump has a drive unit and a control block adapted to power the drive unit so that a predetermined level of negative pressure is maintained in the confined volume. The control block has a sensor for sensing working parameters of the drive unit and means for deriving the level of negative pressure in the confined volume from these working parameters, in order to maintain said predetermined level. The sensor has no fluid connection with the confined volume.

For example, the drive unit may comprise a direct current electric motor and the sensor may sense the electric current driving the motor. The same function of negative pressure control may be accomplished by an adjustable torque limiting clutch, placed between the motor output shaft and the pump.

The control block may be provided with alarm means to warn the user if the predetermined level of negative pressure is not maintained.

If the vacuum pump comprises a disposable pump unit and the drive unit is detachably attachable to the pump unit, the control block with monitoring means is preferably associated with the drive unit which is non-disposable.

Thus, indirect means are provided for controlling or monitoring the level of negative pressure applied to the wound, without making any direct connection to a vacuum sensor, transducer or gage to any portion of the system, which has the negative pressure applied to it. The indirect negative pressure monitoring and control result from the need to dispose of any portion of the system, which may come in contact with the pumped media, which is likely to be contaminated or infectious. Accordingly, all the disposable components in the system may be relatively low in cost, to promote discarding them after use. Pressure transducers, vacuum gages or sensors, are relatively costly, and thus not considered disposable.

BRIEF DESCRIPTION OF THE DRAWINGS

In order to understand the invention and to see how it may be applied, a preferred embodiment will now be described, by way of non-limiting example only, with reference to the accompanying drawings, in which:

Fig. 1 is a schematic sectional view of the vacuum system of the present invention applied on a wound.

Fig. 2 shows the disposable portion of the system of Fig. 1.

DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

The present invention provides a system and a method of treating and healing of a body wound, by applying a negative pressure to the wound, over an area sufficient to promote migration of epithelial and subcutaneous tissue toward the wound.

It is appreciated that the detailed description that follows is intended only to illustrate certain preferred embodiments of the present invention. It is in no way intended to limit the scope of the invention, as set out in the claims.

With reference to Fig. 1, in accordance with the present invention, a vacuum system 10 for draining an open wound from liquids exuded therefrom comprises a wound enclosure 12, a vacuum pump 14, and waste collection bag 31. The wound

enclosure 12 is connected by a suction tube 16 to an inlet 11 of the vacuum pump. The waste collection bag 31 is connected to an outlet 22 of the vacuum pump. Thereby, when the vacuum pump 14 is operated, the drained liquids flow through the pump into the waste bag 31.

Suction tube 16 is connected to nipple 38 of the enclosure 12 which covers wound area of the body 34 such that suction of air through tube 16 creates negative pressure in the volume above the wound area of the body 34. A bleeding orifice 35 is provided within the enclosure 12, or adjacent to it as a tube orifice 37, allowing ambient air to flow into and through suction tube 16, rendering enclosure 12 non-air tight, or vented. This feature, unlike conventional sealed closures, provides for quick movement of exudate entering suction tube 16, toward the vacuum pump 14, and into the waste bag 31, before it dries up or coagulates and occludes the tube. This feature also provides for introduction of ambient pressure to the wound area of the body 34 whenever the vacuum pump stops pumping, allowing cyclic negative pressure application to the wound, by cycling the vacuum pump on and off alternately.

Instead of the bleeding orifice 35 in the enclosure, other flow restrictors may be used to provide for controlled flow of ambient air into the enclosure or into the outlet. For instance, a hole plugged with open cell foam or an open pore sintered metal plug, which restrict the flow, but are not susceptible to plugging as is a small orifice.

The vacuum pump 14 comprises a pump unit 18 and a drive unit 40 which are detachably attachable to each other, as explained below. The pump unit 18 includes a two-chambered housing 17 and a diaphragm 24 secured to the underside of the two-chambered housing 17 so as to form a working chamber 29.

The two-chambered housing 17 has a first chamber 13 with the inlet 11 and a second chamber 21 with an outlet 22. The suction tube 16 is connected to the inlet 11. Two one-way valves 19 and 20 are present at the bottom of the first chamber 13 and the second chamber 21, respectively. To the bottom of the two-chambered housing 17 there is attached a mounting base 23, used to mount the housing 17 to the drive unit 40 by means of a bayonet lock.

The diaphragm 24 has an integral rod-shaped drive member 25, which is used for engagement with the drive unit 40.

The drive unit 40 includes an electric motor 39, batteries 41 and a control block 50 described below. The shaft of the motor 39 has a crank 27 coupled to a reciprocating

rod 26. The rod 26 has a receptacle with a cavity adapted to receive and lock therein the drive member 25.

When the pump unit 18 is attached to the drive unit 40 by means of the bayonet lock in the base 23, the drive member 25 is received in the receptacle cavity of the reciprocating rod 26 and then locked therein.

Upon activation of the motor 39, the crank 27 is rotated and reciprocates the receptacle rod 26, causing the diaphragm 24 to expand and contract the working chamber 29. Thus the pump unit 18 pumps air or liquid that passes through the one-way valves 19 and 20.

Air and liquids enter the two-chambered housing 17 through the inlet 11 and suction tube 16 which is connected to the patient's wound enclosure 12, for the removal of exudate. Liquids and air enter the first chamber 13, which is under negative pressure when diaphragm 24 reciprocates, driving them past one-way valve 20, into the second chamber 21. The air and liquid which are pumped through outlet 22, enter waste bag 31.

The pump's ability to pump air and liquid, unlike conventional pumps, which are efficient in pumping only one type of matter, is enhanced by the flexibility of the diaphragm 24 which allows the diaphragm to yield when encountering heavy loads, such as those present when pumping liquid. This diaphragm flexibility also provides an additional substantial advantage: when the negative pressure in working chamber 29 is high, the diaphragm 24 stretches to allow the reciprocation of the receptacle rod 26 to occur, at minimal burden to the electric motor 39.

The waste bag 31 has a vent 15, through which air and gas are discharged to the atmosphere. Accordingly, waste bag 31 will retain only the waste fluids which are pumped into it. The waste bag may contain a porous media 47 adapted to soak up the drained liquids.

It is important to note that waste bag 31 is made of thin plastic sheet, which allow it to be folded or collapsed when not full, providing the convenience of having minimal bulk and minimal inconvenience to the patient using or carrying it.

The drive unit 40 also includes a control block 50 with control circuits such as cycle control 42, which turns the motor pump on and off alternately, motor voltage and current monitoring and control 43, which controls the negative pressure level produced by the pump unit 18, by controlling the voltage and current which drive motor 39. At any given voltage which drives motor 39, the current draw of the motor is directly

related to the negative pressure generated by the pump 18. Accordingly, monitoring of the current which the motor 39 draws allows for indirect monitoring of the negative pressure attained by pump 18. The ability to monitor the negative pressure developed by pump 18, indirectly, precludes the need of making an infectious negative pressure line connection to a pressure transducer or vacuum gage.

For example, if the motor 39 is a direct current electric motor, a sensor may sense the electric current driving the motor. Since the direct current motor output torque is directly related to the current driving the motor, and since the motor output torque is directly related to the negative pressure the pump 18 produces, monitoring the motor current or controlling it, provide for monitoring and controlling the negative pressure produced by the vacuum pump. Motor current monitoring is only one of the available methods of indirect negative pressure monitoring and controlling. The same function of negative pressure control may be accomplished by an adjustable torque limiting clutch placed between the motor output shaft and the crank 27.

The control block 50 also has a negative pressure comparator 44, which compares the desired set negative pressure level obtained by pump 18, and the actual monitored negative pressure level as obtained indirectly from motor voltage and current monitoring and control 43. Comparator 44 will activate audible alarm 45, whenever pump 18 fails to reach the desired pre-set negative pressure level.

Fig. 2 shows the disposable portion of the system as an assembly 60, which includes the pump unit 18, the waste bag 31, the connecting tube 16 and the wound enclosure 12, all separated from the drive unit and from the wound area of the body 34. The assembly 60 may be disposed of in its totality after use, and replaced by a new assembly, thus keeping the costly drive unit 40 free from any contamination. It would be obvious to those skilled in the art, that the present invention alleviates the need for cleaning or disinfecting any portion of drive unit 40 after use, or providing protective means, such as filters, to keep contaminants from reaching the costly drive 40.

CLAIMS:

1. A vacuum system for draining an open wound from liquids exuded therefrom, comprising an enclosure sealable to the wound circumference so as to define a confined volume, a vacuum pump in fluid communication with said confined volume, and a waste container for collection of drained liquids in fluid communication with said vacuum pump,

wherein said confined volume is connected to an inlet of said vacuum pump and said waste container is connected to an outlet of said vacuum pump, such that when said vacuum pump is operated the drained liquids flow through said vacuum pump.

2. The vacuum system of Claim 1, wherein said enclosure has an outlet connected by means of a tube to said inlet of the vacuum pump, and one or more bleeding holes are provided through said enclosure or adjacent to its outlet so that ambient air may enter said tube and flow together with the drained liquids.

3. The vacuum system of Claim 1, wherein said vacuum pump includes a disposable pump unit detachably attachable to a non-disposable drive unit, said enclosure and said waste container being disposable so that the drained liquids, as well as air coming in contact with them, contact only the disposable elements and said drained liquids may be disposed of together with said disposable elements.

4. The vacuum system of Claim 3, wherein said pump unit and said drive unit are adapted for attaching and detaching by simple hand manipulations.

5. The vacuum system of Claim 1, wherein said vacuum pump includes a drive unit and a control block adapted to power said drive unit so that a predetermined level of negative pressure is maintained in said confined volume,

wherein said control block has a sensor for sensing working parameters of said drive unit and means for deriving the level of negative pressure in said confined volume from said working parameters, in order to maintain said predetermined level, said sensor having no fluid communication with said confined volume.

6. The vacuum system of Claim 5, wherein said drive unit comprises an electric motor and said working parameters include the electric current and/or voltage of said motor.

7. The vacuum system of Claim 1, wherein said waste container is vented so as to release gases mixed with said drained liquids.

8. The vacuum system of Claim 1, wherein said waste container is a collapsible bag.

9. The vacuum system of Claim 1, wherein said vacuum pump is a two-chambered diaphragm pump adapted for pumping gases and liquids and/or any combination thereof.

10. The vacuum system of Claim 1, adapted to be worn by an ambulatory patient.

11. An enclosure for draining an open wound from liquids exuded therefrom, the enclosure being attachable to the wound circumference so as to define a confined volume, and having an outlet connectable by means of a tube to an inlet of a vacuum pump so that negative pressure may be created in said volume,

wherein one or more bleeding holes are provided in the enclosure or adjacent to its outlet such that ambient air can enter said tube and flow together with the exuded liquids under the action of the negative pressure, and the ambient pressure may be restored in said confined volume when said vacuum pump is not operating.

12. The enclosure of Claim 11, having a nipple for connecting to said tube.

13. The enclosure of Claim 11, wherein a plurality of bleeding holes is provided in the form of a porous body mounted in said enclosure.

14. The enclosure of Claim 11, completed with a tube connected to said outlet, for connection to said vacuum pump inlet, wherein said one or more bleeding holes are provided in the tube, adjacent to said outlet.

15. A method for draining an open wound from liquids exuded therefrom, including:

- providing an enclosure and sealing it to the wound circumference so as to define a confined volume,
- connecting said confined volume to a vacuum pump,
- connecting a waste container for collection of drained liquids to said vacuum pump,
- operating said vacuum pump to drain the exuded liquids,

wherein

said confined volume is connected to an inlet of said vacuum pump and said waste container is connected to an outlet of said vacuum pump such that the drained liquids and air flow through said vacuum pump.

16. The method of Claim 15, wherein said enclosure has an outlet connected by means of a tube to said inlet of the vacuum pump, and ambient air is allowed to enter into said tube via one or more bleeding holes provided through said enclosure or adjacent to its outlet so that said air flows together with the drained exuded liquids.

17. The method of Claim 15, comprising separating and releasing of gases from the drained exuded liquids.

18. The method of Claim 17, wherein said gases are released through a vent in the waste container.

19. The method of Claim 15, wherein said vacuum pump is a two-chambered diaphragm pump adapted for pumping gases and liquids and/or any combination thereof.

20. The method of Claim 15, wherein said enclosure, said waste container, and at least a part of said vacuum pump which contacts said drained liquids, are disposable, and the method comprises disposing of the disposable elements together with the drained exuded liquids.

21. The method of Claim 20, wherein the disposable part of said vacuum pump is a pump unit detachably attachable to a non-disposable drive unit, the method including attaching the pump unit to the drive unit before draining, and detaching the pump unit before said disposing.

22. The method of Claim 21, wherein said attaching and detaching include only simple hand manipulations.

23. The method of Claim 15, applied to a wound of an ambulatory patient.

24. A disposable assembly for draining an open wound from liquids exuded therefrom, the assembly comprising an enclosure attachable to the wound circumference so as to define a confined volume, a vacuum pump unit connected to said enclosure so that negative pressure may be created in said volume, said vacuum pump unit having means for detachably attaching to a drive unit for operating the pump unit, and a waste container connected to said vacuum pump unit;

wherein said enclosure is connected to an inlet of said vacuum pump unit and said waste container is connected to an outlet of said vacuum pump unit, such that when said vacuum pump unit is operated the drained liquids flow therethrough.

25. The disposable assembly of Claim 24, wherein said enclosure has an outlet connected by means of a tube to said inlet of the vacuum pump unit, and one or more

bleeding holes are provided through said enclosure or adjacent to its outlet so that ambient air may flow through said tube together with the drained exuded liquids.

26. The disposable assembly of Claim 24, wherein said vacuum pump unit is a two-chambered diaphragm pump adapted for pumping gases and liquids and/or any combination thereof.

27. The disposable assembly of Claim 24, wherein said waste container contains a porous media adapted to soak up said drained liquids.

28. The disposable assembly of Claim 24, wherein said waste container is a collapsible bag.

29. A vacuum system for draining an open wound from liquids exuded therefrom, comprising an enclosure sealable to the wound circumference so as to define a confined volume, a vacuum pump in fluid communication with said confined volume, said vacuum pump having a drive unit, and a control block adapted to power said drive unit so that a predetermined level of negative pressure is maintained in said confined volume,

wherein

said control block has a sensor for sensing working parameters of said drive unit and means for deriving the level of negative pressure in said confined volume from said working parameters, in order to maintain said predetermined level, said sensor having no fluid communication with said confined volume.

30. The vacuum system of Claim 29, wherein said drive unit comprises an electric motor and said working parameters include the electric current and/or voltage of said motor.

31. The vacuum system of Claim 29, wherein said control block has alarm means to warn the user if said predetermined level of negative pressure is not maintained.

32. The vacuum system of Claim 29, further comprising a waste container for collection of drained liquids, where said confined volume is in fluid communication with an inlet of said vacuum pump, and said waste container is in fluid communication with an outlet of said vacuum pump such that when said vacuum pump is operated the drained liquids flow therethrough.

33. The vacuum system of Claim 29, wherein said vacuum pump comprises a disposable pump unit including said inlet and said outlet, and said pump unit is

detachably attachable to said drive unit, said control block with said sensor being associated with the drive unit,

and wherein said enclosure and said waste container are disposable, so that said exuded liquids may contact only the disposable elements of the vacuum system and may be disposed of together with said disposable elements after detaching said drive unit.

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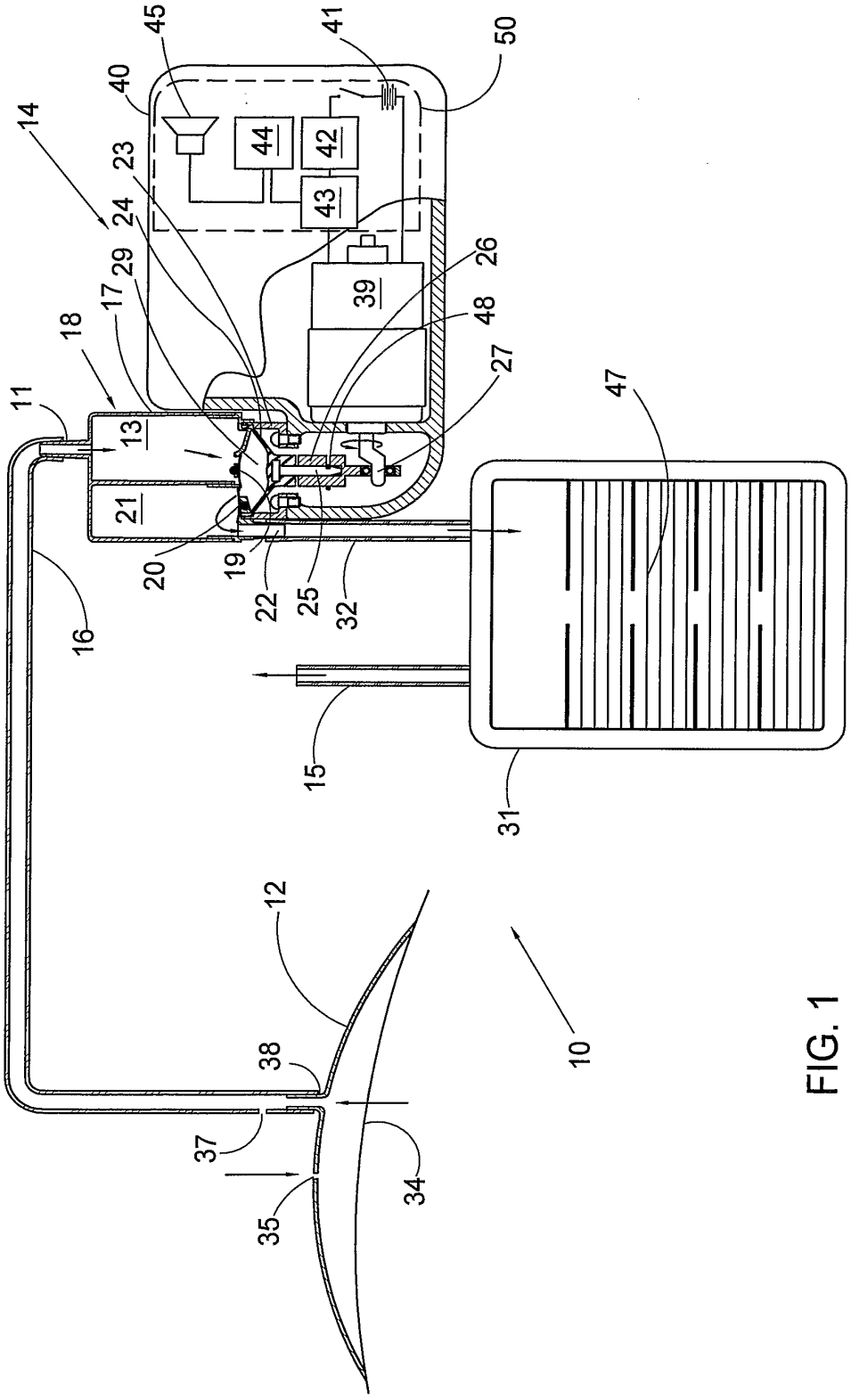

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FIG. 1

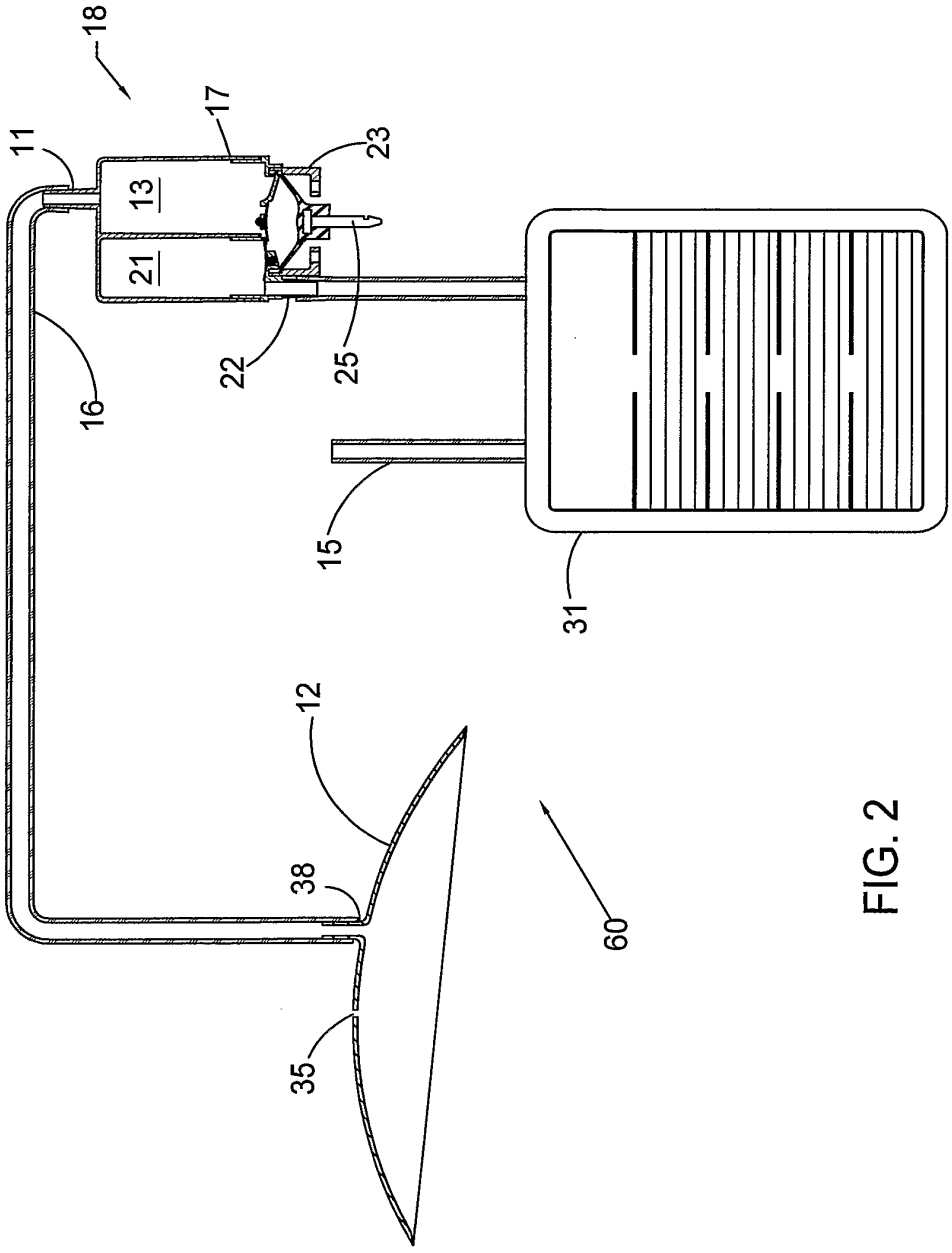


FIG. 2

UNITED STATES NATIONAL STAGE SHEET (DO/EO)
Karen Williams, Paralegal

PUBLICATION NO. WO 07/013049

PUBLICATION DATE 01 FEB 07

U. S. APPL. NO. 11/989297

INTERNATIONAL APPL. IL05/00784

Application Filed By: 30 MOS

International Application ✓ Translation ___ Defective ___ Reason ___

WIPO Designated EP Elected ___ IA Language ENGLISH

Copy of Search Report (ISR) ✓ Article 33 ___ Article 19 ___

371 Filing fees ✓ paid ___ partial ___ none Pages ✓

Total Claims 33 Chargeable 33 Independent 5 Multiple N

Total Drawing Sheets 2 Defective ___ Reason ___

Oath/Declaration needed ___ signed ✓ defective ___ Reason ___

Small entity ✓ Large entity ___ Small entity statement/request ___

Biochemical Seq. Diskette ___ needed ___ damaged ___ entered ___ not entered ___

Biochemical Sequence listing ___ needed ___ statement ___ no statement ___

Copy of References Cited in ISR ___ Statement 37 CFR 3.73(b) ___

Copy of IPER ___ Annexes ___ entered ___ not entered ___ Reason ___

Preliminary Amendment entered ___ not entered ___ Reason ___

Information Disclosure Statement 05 JUN 08 Request for Immediate Examination ✓

Substitute Specification ___ Assignment ___ Priority document ___

Power of Attorney ___ Data Sheet ___ RO/101 ___ PCT Easy ___

Other papers ___

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35 USC Receipt of Request 24 JAN 08
Date completion USC 371 Requirements 24 JAN 08
Notice of Missing Requirements ___
Notice of Defective ___ Translation ___ Declaration ___ Disk ___
Notice of Acceptance 08 JUL 09
Notice of Abandonment ___
Notice of Missing Sequence ___

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Exhibit 1008
Page #1109

PATENT APPLICATION FEE DETERMINATION RECORD
Effective September 30, 2007

Application or Docket Number: 11/989297

CLAIMS AS FILED - PART I

	(Column 1)	(Column 2)	SMALL ENTITY TYPE ☐		OR	OTHER THAN SMALL ENTITY	
			RATE	FEE		RATE	FEE
U.S. NATIONAL STAGE FEES							
BASIC FEE	SMALL ENT. = $ 155	LARGE ENT. = $ 310	BASIC FEE	155	OR	BASIC FEE	
EXAMINATION FEE	Satisfies PCT Article 33(1)-(4) = $ 50 / $ 100	All other situations = $ 105 / $ 210	EXAM. FEE	105		EXAM. FEE	
SEARCH FEE	U.S. is ISA = $ 50 / $ 100 ALL other countries = $ 205 / $ 410	ALL other situations = $ 255 / $ 510	SEARCH FEE	205		SEARCH FEE	
FEE FOR EXTRA SPEC. PGS.	minus 100 =	/ 50 =	X $ 130 =			X $ 260 =	
TOTAL CHARGEABLE CLAIMS	33 minus 20 =	* 13	X $ 25 =	325	OR	X $ 50 =	
INDEPENDENT CLAIMS	5 minus 3 =	* 2	X $ 105 =	210	OR	X $ 210 =	
MULTIPLE DEPENDENT CLAIM PRESENT	N ☐		+ $ 185 =		OR	+ $ 370 =	
			TOTAL	1000	OR	TOTAL	

* If the difference in column 1 is less than zero, enter "0" in column 2

CLAIMS AS AMENDED - PART II

AMENDMENT A	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM ☐				

SMALL ENTITY RATE	ADDITIONAL FEE	OR	OTHER THAN SMALL ENTITY RATE	ADDITIONAL FEE
X $ 25 =		OR	X $ 50 =	
X $ 105 =		OR	X $ 210 =	
+ $ 185 =		OR	+ $ 370 =	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

AMENDMENT B	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM ☐				

SMALL ENTITY RATE	ADDITIONAL FEE	OR	OTHER THAN SMALL ENTITY RATE	ADDITIONAL FEE
X $ 25 =		OR	X $ 50 =	
X $ 105 =		OR	X $ 210 =	
+ $ 185 =		OR	+ $ 370 =	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

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

Medela LLC and Medela AG
Exhibit 1008
Page #1110

MULTIPLE DEPENDENT CLAIM FEE CALCULATION SHEET
(FOR USE WITH FORM PTO-875)

SERIAL NO. 11/989297 | FILING DATE

APPLICANT(S)

CLAIMS

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	IND.	DEP.	IND.	DEP.	IND.	DEP.
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TOTAL IND.	5	⬇		⬇		⬇
TOTAL DEP.	28	⬅		⬅		⬅
TOTAL CLAIMS	33					

	AS FILED		AFTER 1st AMENDMENT		AFTER 2nd AMENDMENT	
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TOTAL DEP.		⬅		⬅		⬅
TOTAL CLAIMS						

PTO - 1360 (REV. 11/04)

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Patent and Trademark Office