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APPLICATION NUMBER: ***11/989,297***
FILING DATE: ***January 24, 2008***
PATENT NUMBER: ***8506554***
ISSUE DATE: ***August 13, 2013***

Certified by

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IAP12 Rec'd PCT/PTO 24 JAN 2008

PTO-1390 (Rev. 09-2007)
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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

U.S. 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.

Solventum-Exhibit 1013-0002

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
Not Yet Assigned 11/989297	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	
22. ☑ Examination fee (37 CFR 1.492(c)) If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) ..... $0 All other situations $210	$ 210.00	
23. ☑ Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the International preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) ..... $0 Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority ..... $100 International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB ..... $410 All other situations $510	$ 410.00	
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	
16 - 100 =	/50 =		x $260	$

Surcharge of **$130.00** for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)). $

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:	$	
			Amount to be charged	$	

Solventum-Exhibit 1013-0003

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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

SIGNATURE

Jerald L. Meyer
NAME

41,194
REGISTRATION NUMBER

Solventum-Exhibit 1013-0004

11/989297
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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

Gary M. Nath, Reg. No. 26,965
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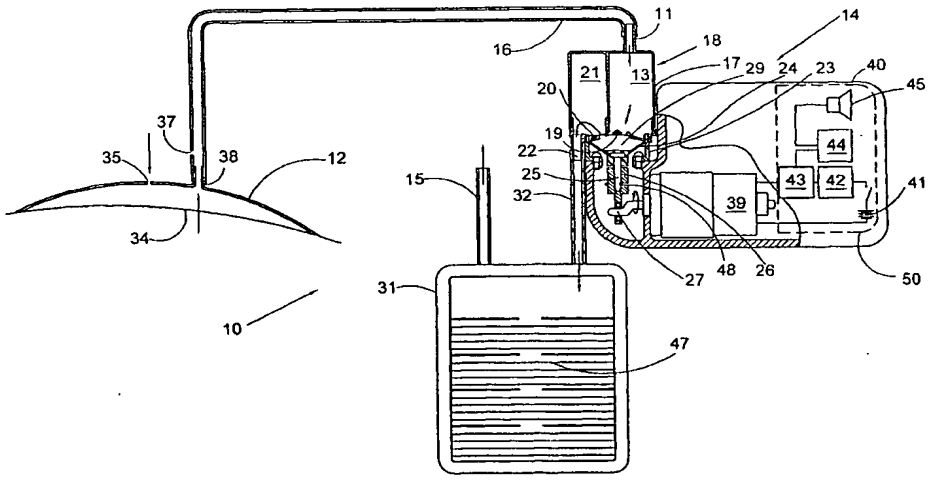
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Published:
— *with international search report*

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

Solventum-Exhibit 1013-0006

11/989297
IAP05Rec'd PCT 24 JAN 2006

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.

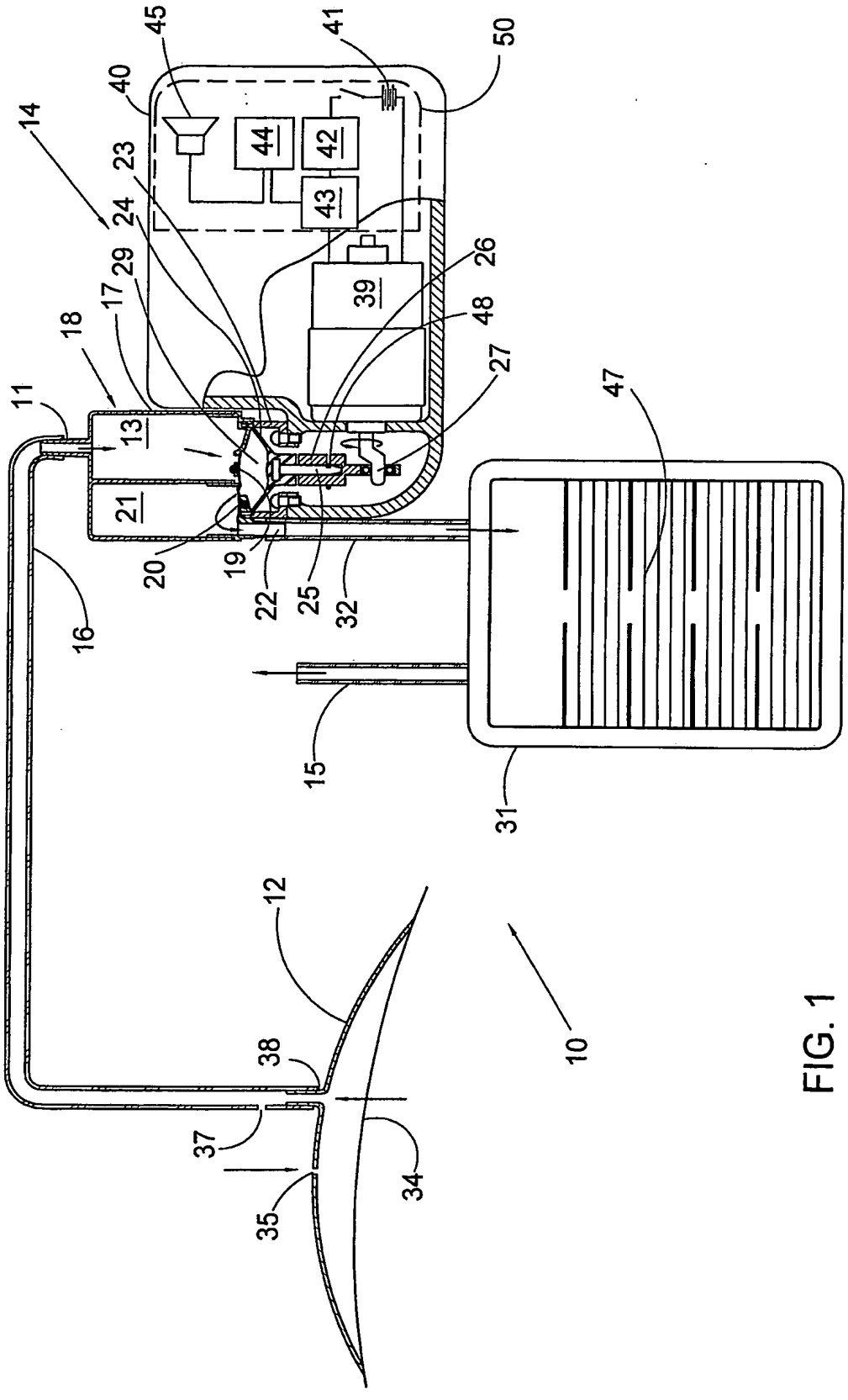


FIG. 1

Solventum-Exhibit 1013-0020

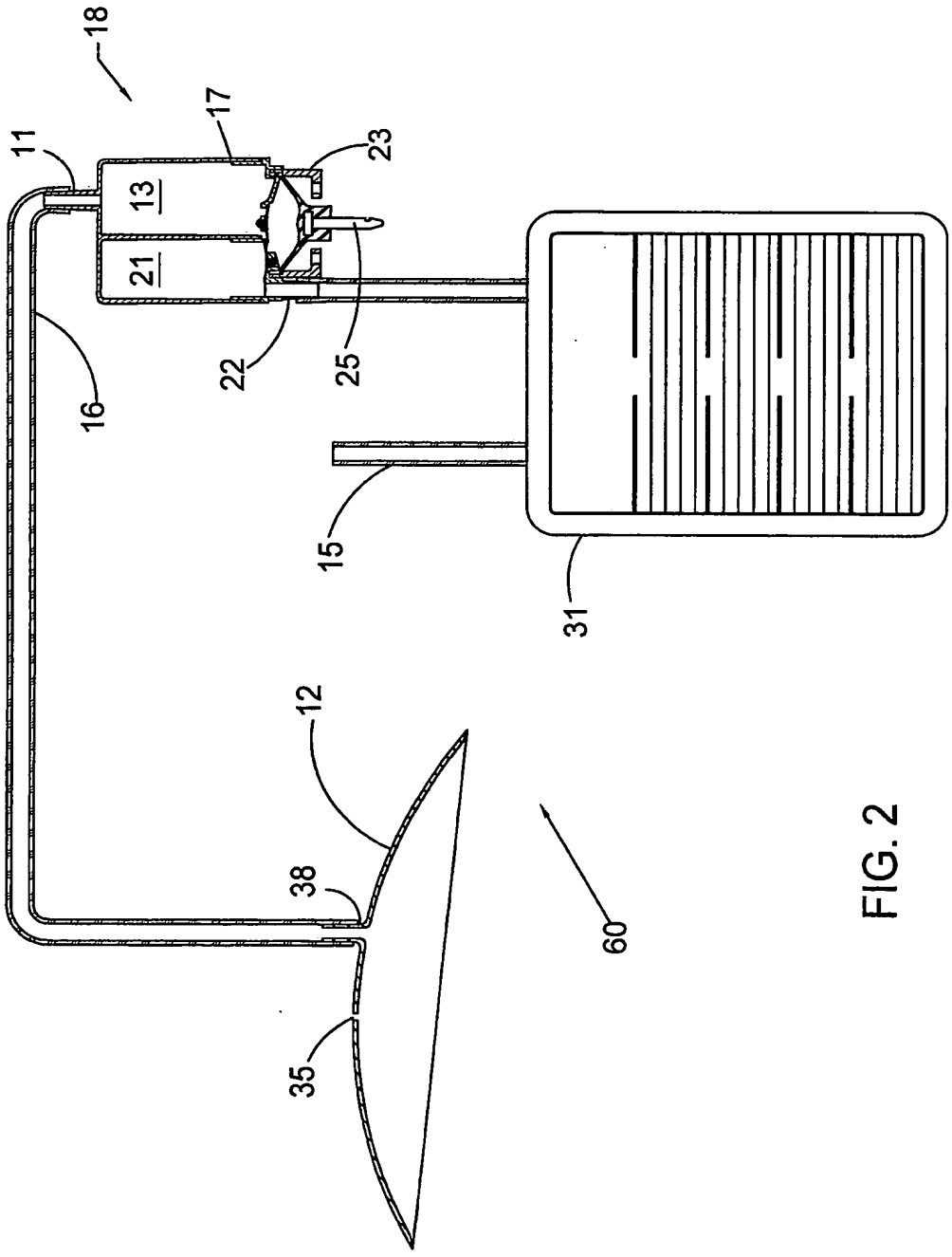


FIG. 2

IT/989297
IAP05Rec'd PCT 24 JAN 2008

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
Ramot
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

-/--

[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)

Solventum-Exhibit 1013-0024

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

Solventum-Exhibit 1013-0025

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.

Solventum-Exhibit 1013-0026

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

---

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
US 2004064132 A1	01-04-2004	NONE	
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		JP 2006500175 T	05-01-2006
		WO 2004028592 A1	08-04-2004

Solventum-Exhibit 1013-0029

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

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

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112 S. West Street
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OIPE TAP97 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.:	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,

Solventum-Exhibit 1013-0032

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
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Derek Richmond
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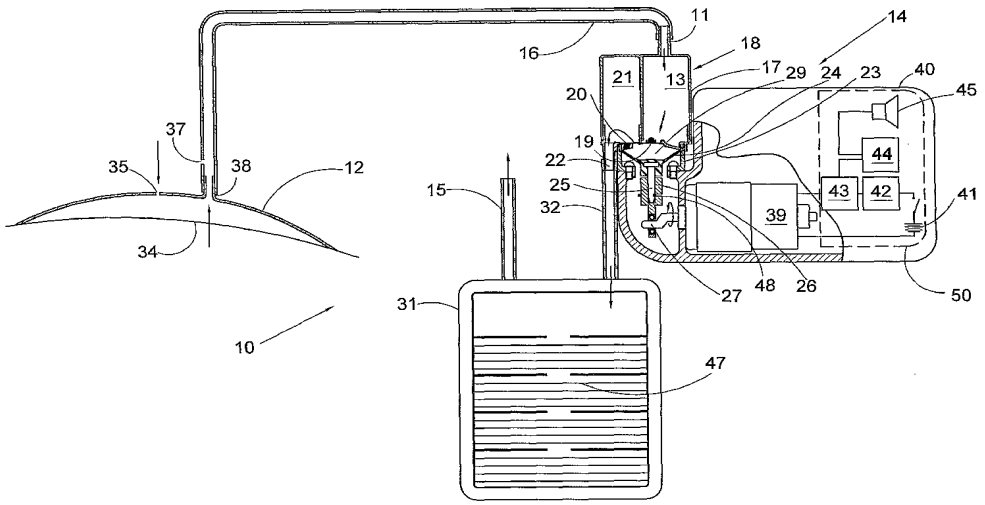
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(54) **Title:** WOUND CLOSURE AND DRAINAGE SYSTEM



(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.

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Solventum-Exhibit 1013-0034

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

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.

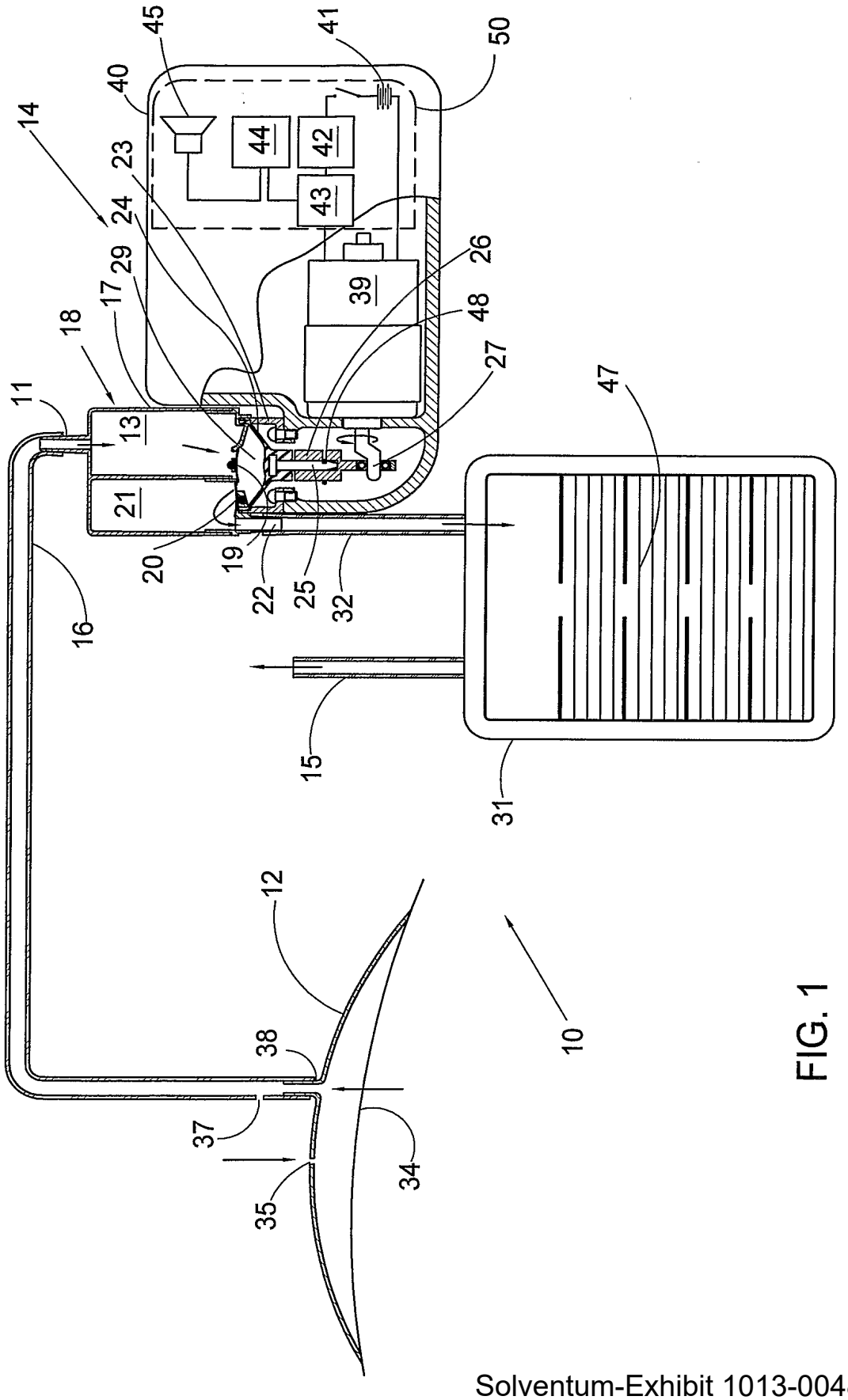


FIG. 1

Solventum-Exhibit 1013-0048

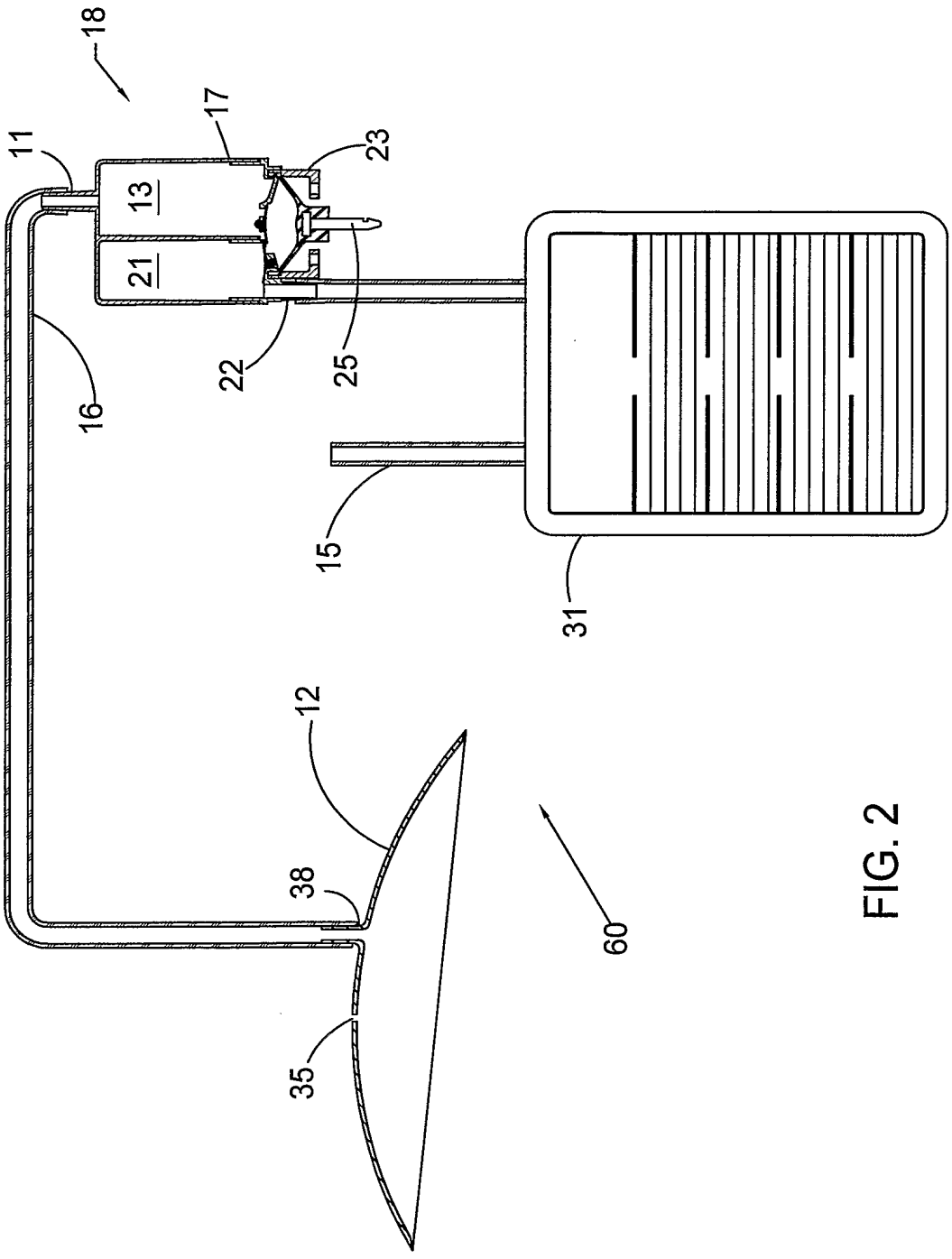


FIG. 2

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

-/--

[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)

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

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.

Solventum-Exhibit 1013-0052

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

---

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
US 2004064132 A1	01-04-2004	NONE	
US 4930997 A	05-06-1990	NONE	
US 4661093 A	28-04-1987	DE 3321151 A1	13-12-1984
		EP 0128388 A2	19-12-1984
		JP 1709724 C	11-11-1992
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WO 03016719 A	27-02-2003	CA 2457658 A1	27-02-2003
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		EP 1427939 A1	16-06-2004
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		JP 2005500455 T	06-01-2005
		US 2004208756 A1	21-10-2004
US 5645081 A	08-07-1997	AT 164055 T	15-04-1998
		AU 674837 B2	16-01-1997
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		DE 69224847 D1	23-04-1998
		DE 69224847 T2	20-08-1998
		DK 620720 T3	28-09-1998
		EP 0620720 A1	26-10-1994
		ES 2114956 T3	16-06-1998
		JP 7501958 T	02-03-1995
		JP 3766934 B2	19-04-2006
		US 5636643 A	10-06-1997
		WO 9309727 A1	27-05-1993
US 2002151826 A1	17-10-2002	NONE	
US 5776119 A	07-07-1998	NONE	
US 2004059284 A1	25-03-2004	AU 2003275165 A1	19-04-2004
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		EP 1545648 A1	29-06-2005
		JP 2006500175 T	05-01-2006
		WO 2004028592 A1	08-04-2004

Solventum-Exhibit 1013-0055

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)

Solventum-Exhibit 1013-0056

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** **

Solventum-Exhibit 1013-0057

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

Solventum-Exhibit 1013-0058

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).

Solventum-Exhibit 1013-0059

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

OIPE
JUL 10 2009
PATENT & TRADEMARK OFFICE

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
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SMH/le

OIPE
JUL 10 2009
PATENT & TRADEMARK OFFICE

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::	

Solventum-Exhibit 1013-0062

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

Solventum-Exhibit 1013-0063

Correspondence Information

Correspondence Customer Number::	20529
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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::

Solventum-Exhibit 1013-0064

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

Solventum-Exhibit 1013-0065

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 ___

---

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 ___

Solventum-Exhibit 1013-0066

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

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
AMENDMENT A	Total	*	Minus	**	=
	Independent	*	Minus	***	=
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM ☐				

SMALL ENTITY RATE	SMALL ENTITY ADDITIONAL FEE	OR	OTHER THAN SMALL ENTITY RATE	OTHER THAN SMALL ENTITY ADDITIONAL FEE
X $ 25 =		OR	X $ 50 =	
X $ 105 =		OR	X $ 210 =	
+ $ 185 =		OR	+ $ 370 =	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
AMENDMENT B	Total	*	Minus	**	=
	Independent	*	Minus	***	=
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM ☐				

SMALL ENTITY RATE	SMALL ENTITY ADDITIONAL FEE	OR	OTHER THAN SMALL ENTITY RATE	OTHER THAN SMALL ENTITY 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.

Solventum-Exhibit 1013-0067

MULTIPLE DEPENDENT CLAIM FEE CALCULATION SHEET

(FOR USE WITH FORM PTO-875)

SERIAL NO. 11/ 989297

FILING DATE

APPLICANT(S)

CLAIMS

	AS FILED		AFTER 1st AMENDMENT		AFTER 2nd AMENDMENT	
	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	
	IND.	DEP.	IND.	DEP.	IND.	DEP.
51						
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TOTAL IND.		⬇		⬇		⬇
TOTAL DEP.		⬅		⬅		⬅
TOTAL CLAIMS						

Solventum-Exhibit 1013-0068

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

OC00000038412023

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

Solventum-Exhibit 1013-0069

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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 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.

Solventum-Exhibit 1013-0070

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: _____.

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

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UNITED STATES DEPARTMENT OF COMMERCE
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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

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
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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	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
	1					

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

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		☐

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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	Carmeli ADAHAN
Art Unit	3761
Examiner Name	ILYA Y. 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.

☐ 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	/Derek Richmond/	Date (YYYY-MM-DD)	2010-08-27
Name/Print	Derek Richmond	Registration Number	45771

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.**

Solventum-Exhibit 1013-0079

Privacy Act Statement

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

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

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

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

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

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

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

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

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

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

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

Electronic Acknowledgement Receipt

EFS ID:	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
Attorney Docket Number:	29068U
Receipt Date:	27-AUG-2010
Filing Date:	24-JAN-2008
Time Stamp:	16:13:10
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	Foreign Reference	EP0865304B1.pdf	566348 77c2e8ed3b7afb47b84786082ec1d975e9bf72f7	no	11

Warnings:	
Information:	

Solventum-Exhibit 1013-0081

2	Foreign Reference	WO8401904.pdf	579866 531d2a02769986c6735a3995c8fcb6512c5cf56b	no	16
Warnings:					
Information:					
3	Foreign Reference	WO0064394.pdf	335605 ec7cee215e795199f3bc54c0ccdcecb890bc0823	no	16
Warnings:					
Information:					
4	Foreign Reference	JP2002541978A.pdf	222510 c9d680e1d3a7871fda553c603ea7eb54bd42659d	no	15
Warnings:					
Information:					
5	Information Disclosure Statement (IDS) Filed (SB/08)	updated_IDS.pdf	611806 303105164132222a920f4f199c2e923169d4a0879	no	4
Warnings:					
Information:					
			Total Files Size (in bytes):	2316135	

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.

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

(11) EP 0 865 304 B1

(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention of the grant of the patent:
18.07.2001 Bulletin 2001/29

(21) Application number: **96938357.9**

(22) Date of filing: **14.11.1996**

(51) Int Cl.[7]: **A61M 27/00**, A61M 1/00

(86) International application number:
PCT/GB96/02802

(87) International publication number:
WO 97/18007 (22.05.1997 Gazette 1997/22)

(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**

(43) Date of publication of application:
23.09.1998 Bulletin 1998/39

(60) Divisional application:
01200016.2 / 1 088 569

(73) Proprietor: **KCI Medical Ltd.**
Witney, Oxfordshire OX8 6BH (GB)

(72) Inventors:
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- **HEATON, Keith, Patrick**
  Poole, Dorset BH14 0QG (GB)

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London EC1M 5SA (GB)

(56) References cited:
WO-A-80/02182
WO-A-94/20041
DE-A- 4 306 478
DE-U- 29 504 378
GB-A- 2 220 357
GB-A- 2 235 877
US-A- 3 066 672
US-A- 4 710 165
US-A- 5 134 994

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

EP 0 865 304 B1

Solventum-Exhibit 1013-0083

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-

Solventum-Exhibit 1013-0084

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

Solventum-Exhibit 1013-0085

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

Solventum-Exhibit 1013-0086

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.

Solventum-Exhibit 1013-0087

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.

Solventum-Exhibit 1013-0088

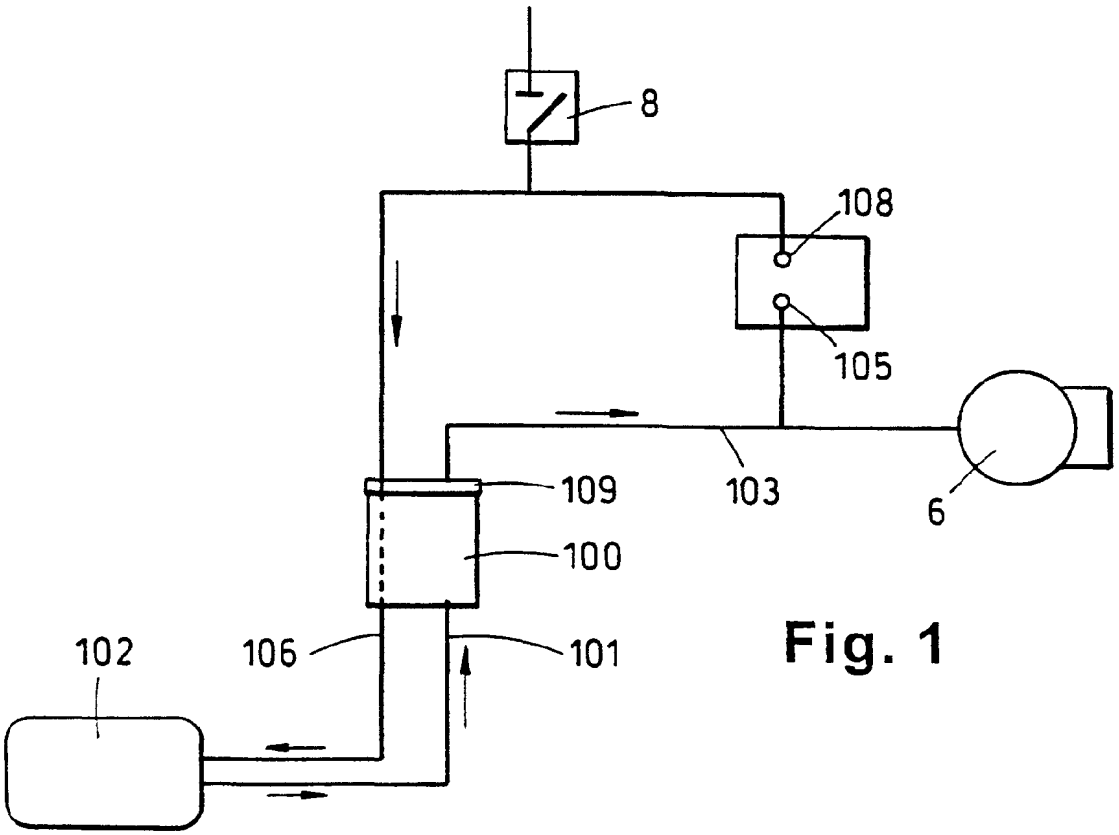


Fig. 1

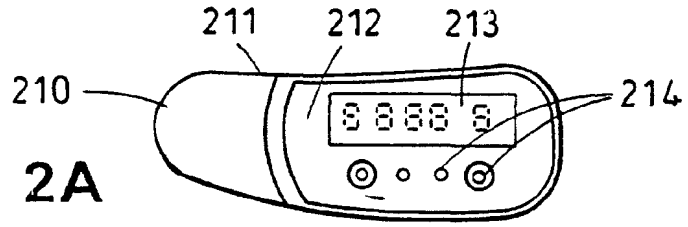


Fig. 2A

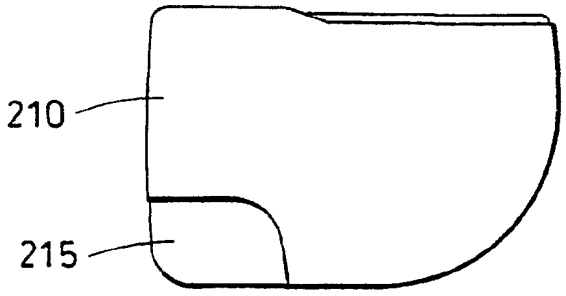


Fig. 2B

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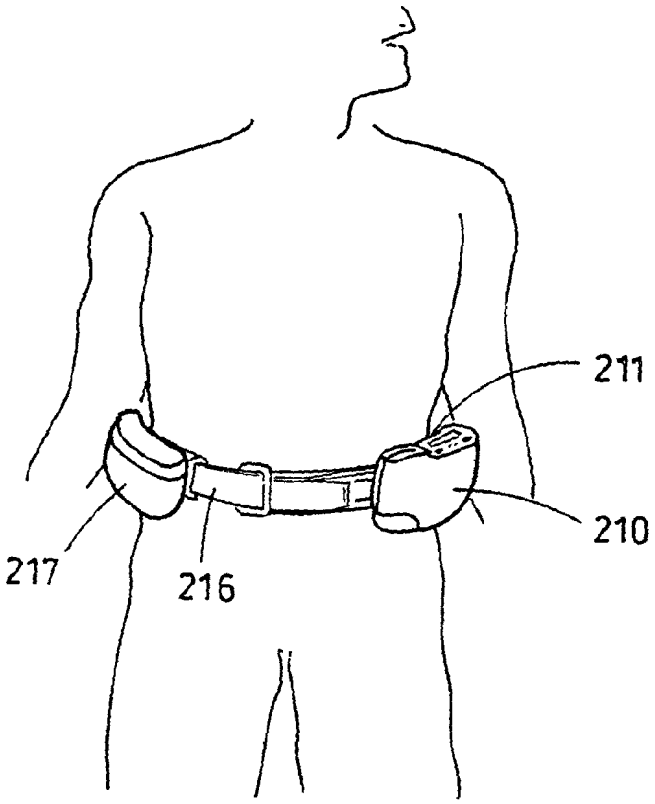


Fig. 3A

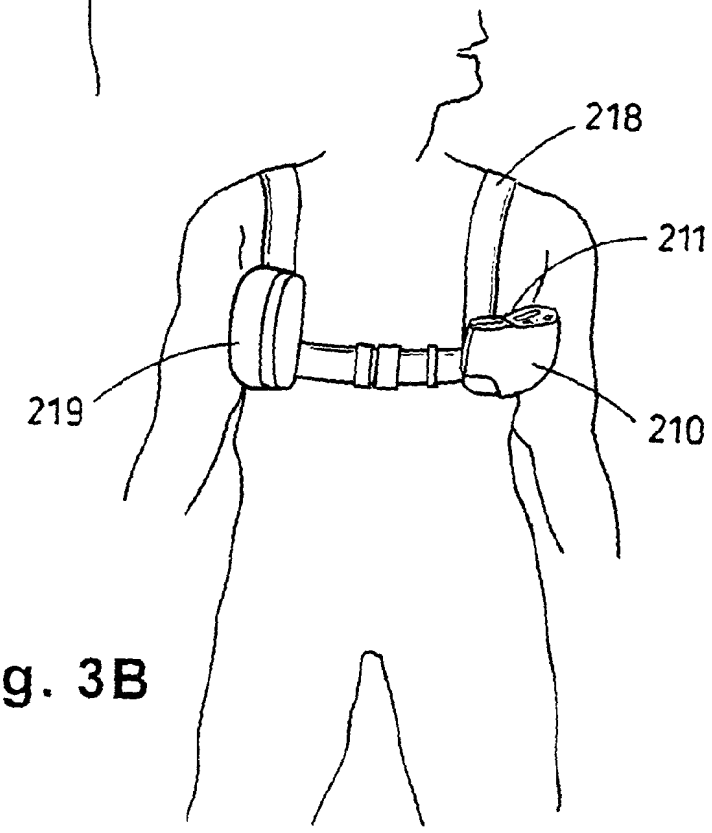


Fig. 3B

Solventum-Exhibit 1013-0090

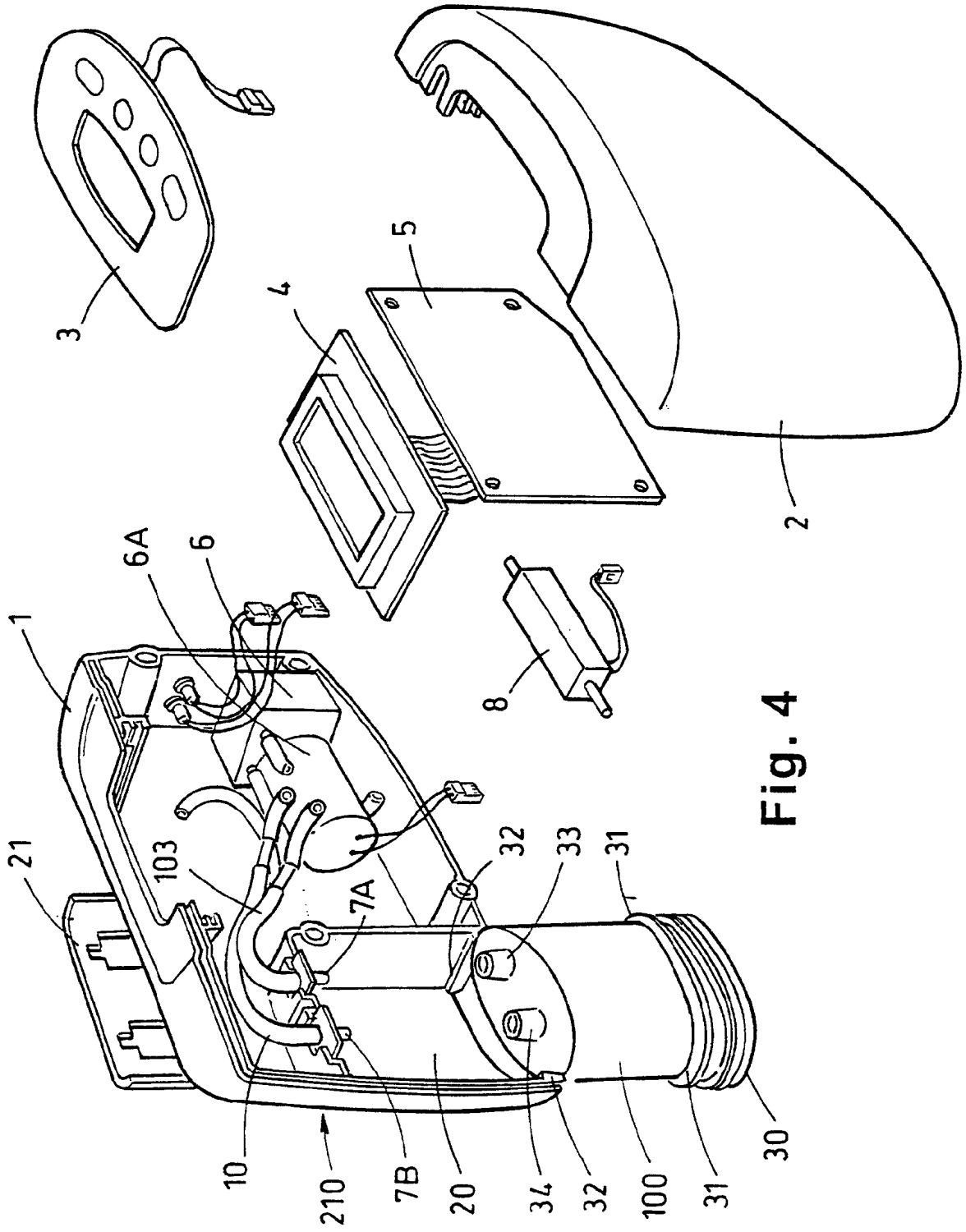


Fig. 4

Solventum-Exhibit 1013-0091

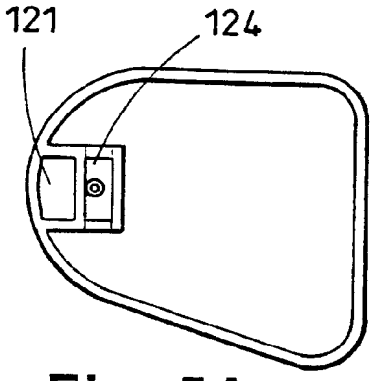


Fig. 5A

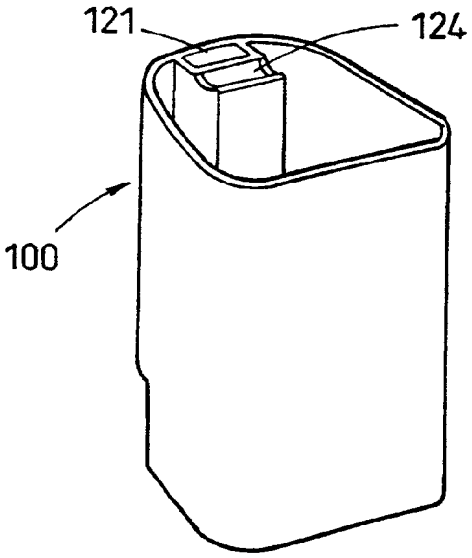


Fig. 5D

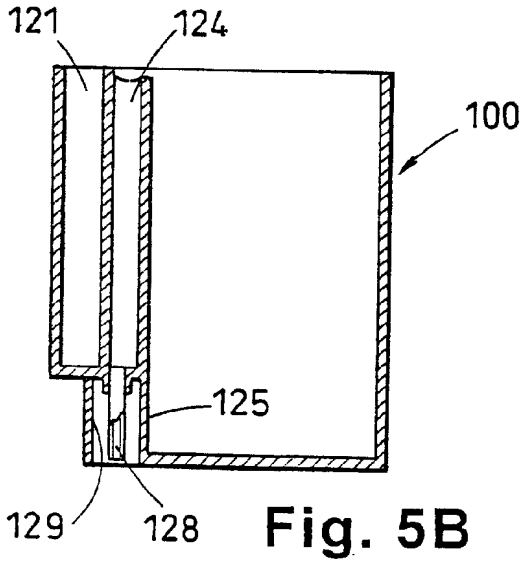


Fig. 5B

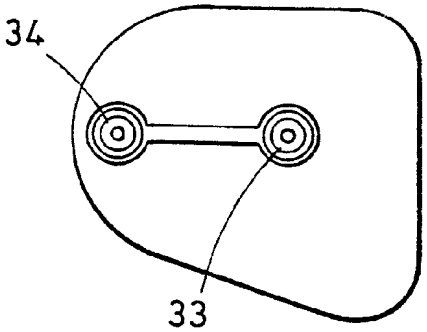


Fig. 5E

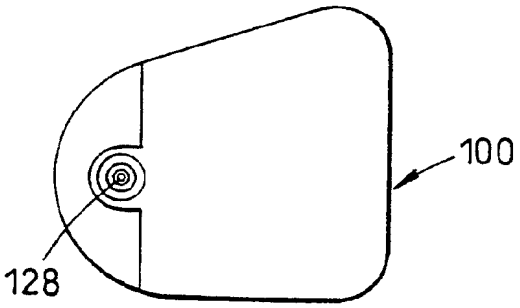


Fig. 5C

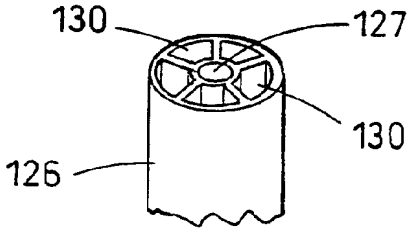


Fig. 5F

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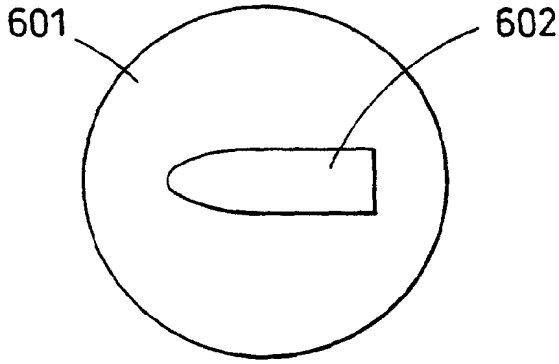


Fig. 6A

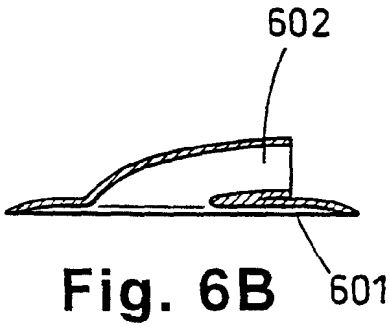


Fig. 6B

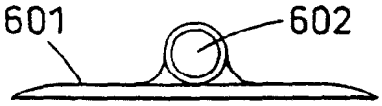


Fig. 6C

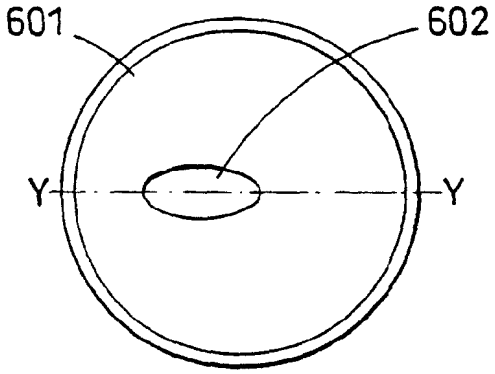


Fig. 6D

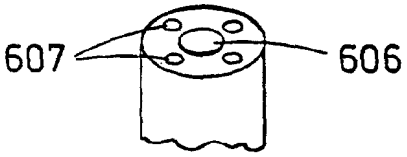


Fig. 6E

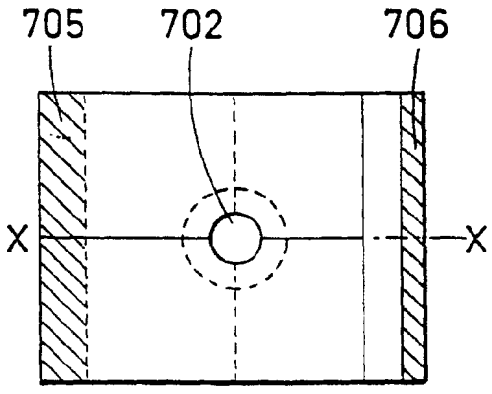


Fig. 7A

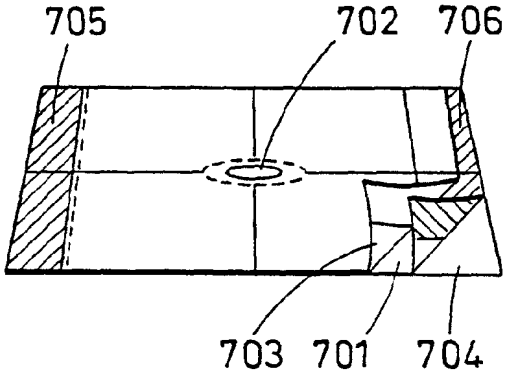


Fig. 7B

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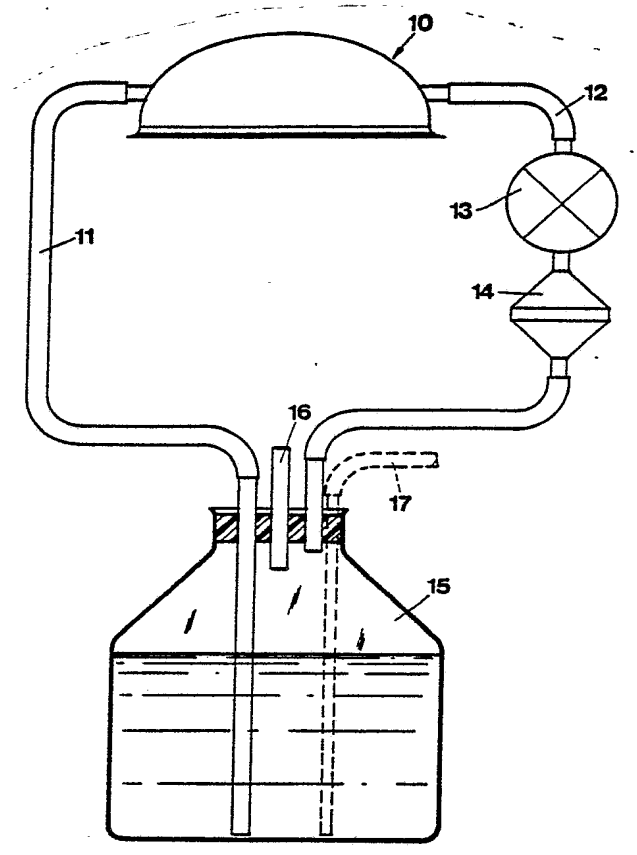
(81) Designated States: AT (European patent), AU, BE (European patent), CH (European patent), DE (European patent), DK, FI, FR (European patent), GB (European patent), JP, LU (European patent), NL (European patent), NO, SE (European patent), US.

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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]

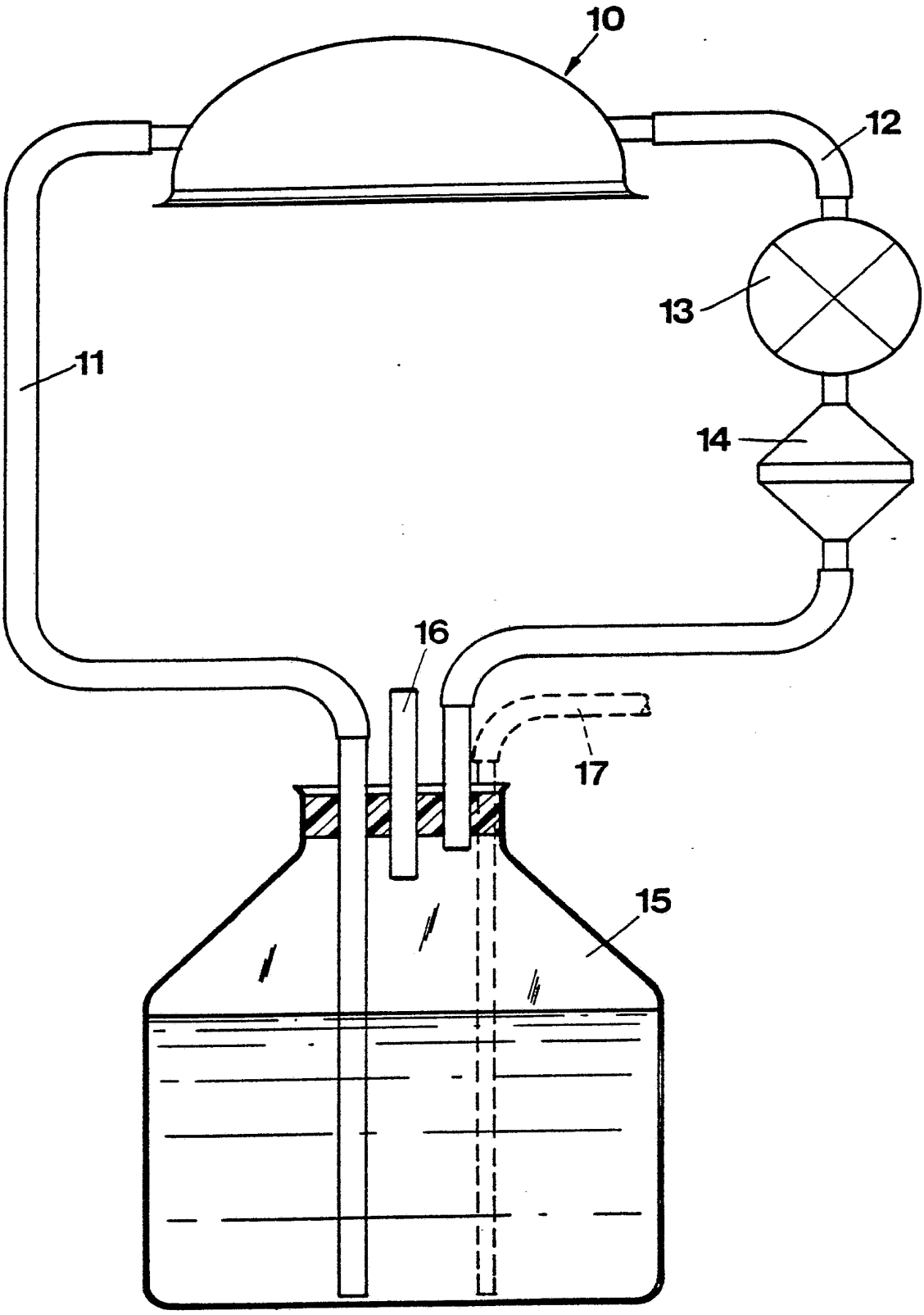
1. A device for rinsing and treating wounds and infected skin portions and comprising a cup-shaped member (10) covering the area to be treated and having its opening towards this and said member having inlet- and outlet openings, said device further comprising a vessel (15) for a treatment solution intended 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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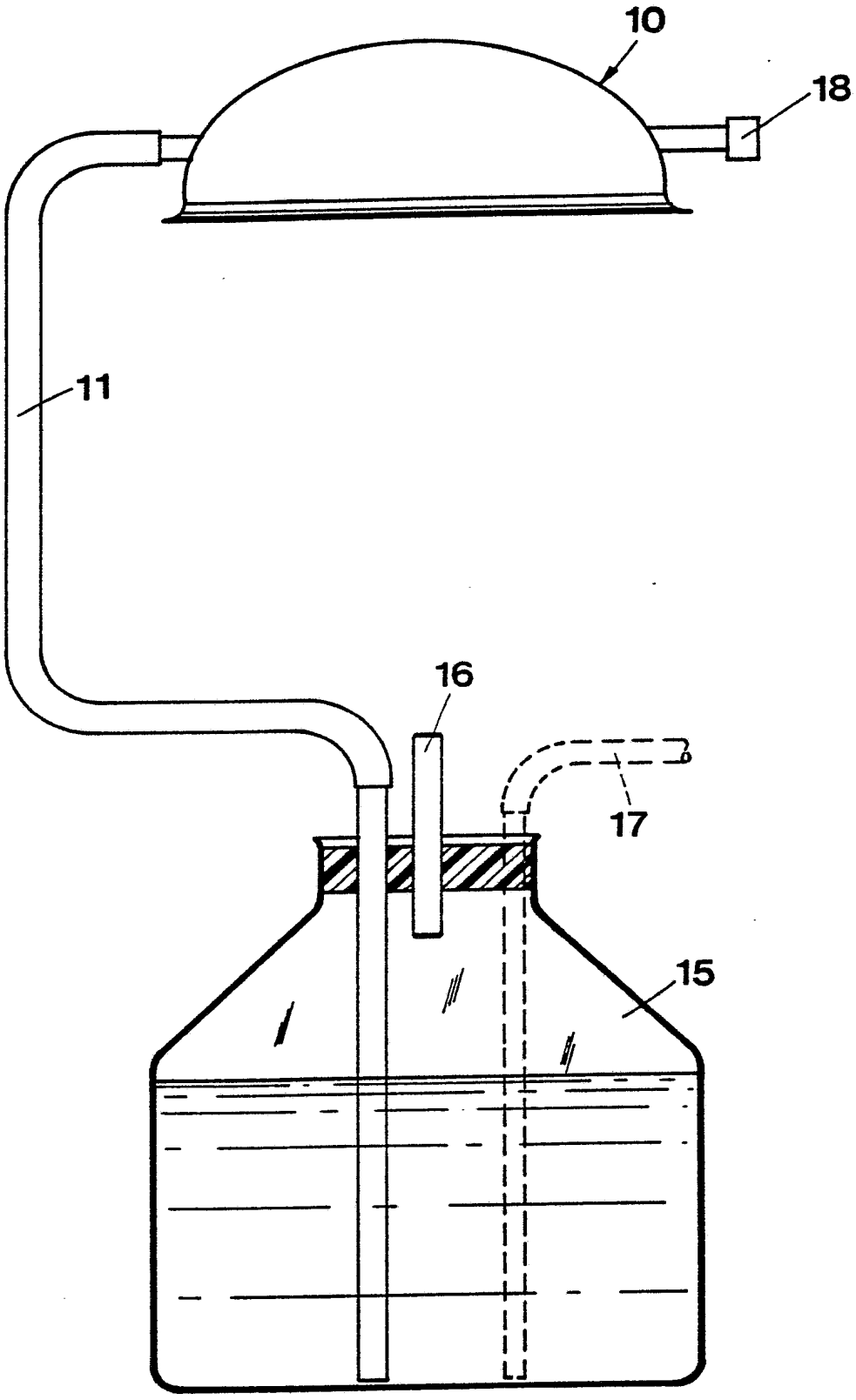
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FIG 1



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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

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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

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IV. CERTIFICATION

Date of the Actual Completion of the International Search [2]	Date of Mailing of this International Search Report [2]
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International Searching Authority [1]	**Signature of Authorized Officer [20]**
Swedish Patent Office	Leif Vingård

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(71) Applicant *(for all designated States except US)*: KCI MEDICAL LIMITED [GB/GB]; Two Rivers, Station Lane, Witney, Oxfordshire OX8 6BH (GB).

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(75) Inventors/Applicants *(for US only)*: HEATON, Keith, Patrick [GB/GB]; 33 Hermitage Road, Poole, Dorset BH13 0QG (GB). HUNT, Kenneth, William [GB/GB]; 18 Egdon Drive, Merley, Wimborne, Dorset BH21 1TY (GB).

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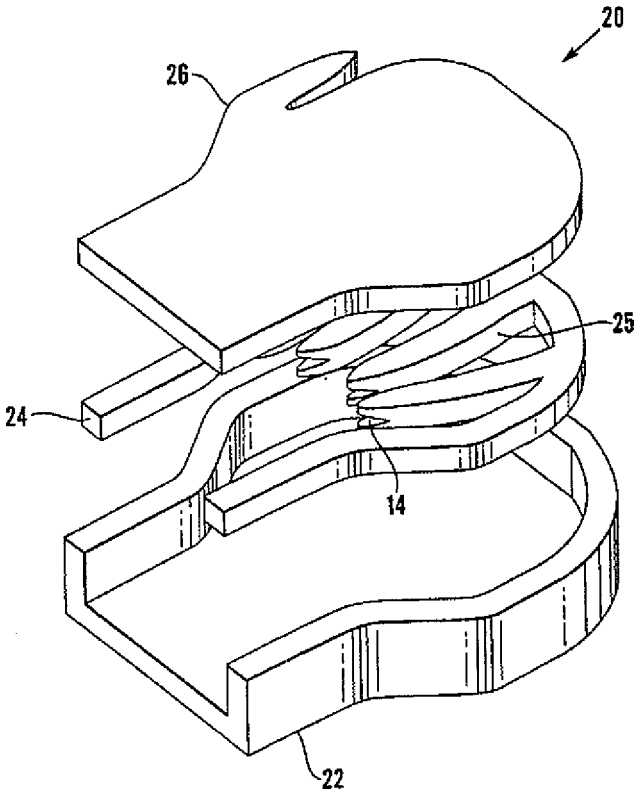
(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

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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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CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	NZ	New Zealand		
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CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
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Solventum-Exhibit 1013-0111

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.

Solventum-Exhibit 1013-0112

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:-

Solventum-Exhibit 1013-0113

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

Solventum-Exhibit 1013-0114

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

Solventum-Exhibit 1013-0115

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.

Solventum-Exhibit 1013-0116

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

Solventum-Exhibit 1013-0117

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.

Solventum-Exhibit 1013-0118

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.

Solventum-Exhibit 1013-0119

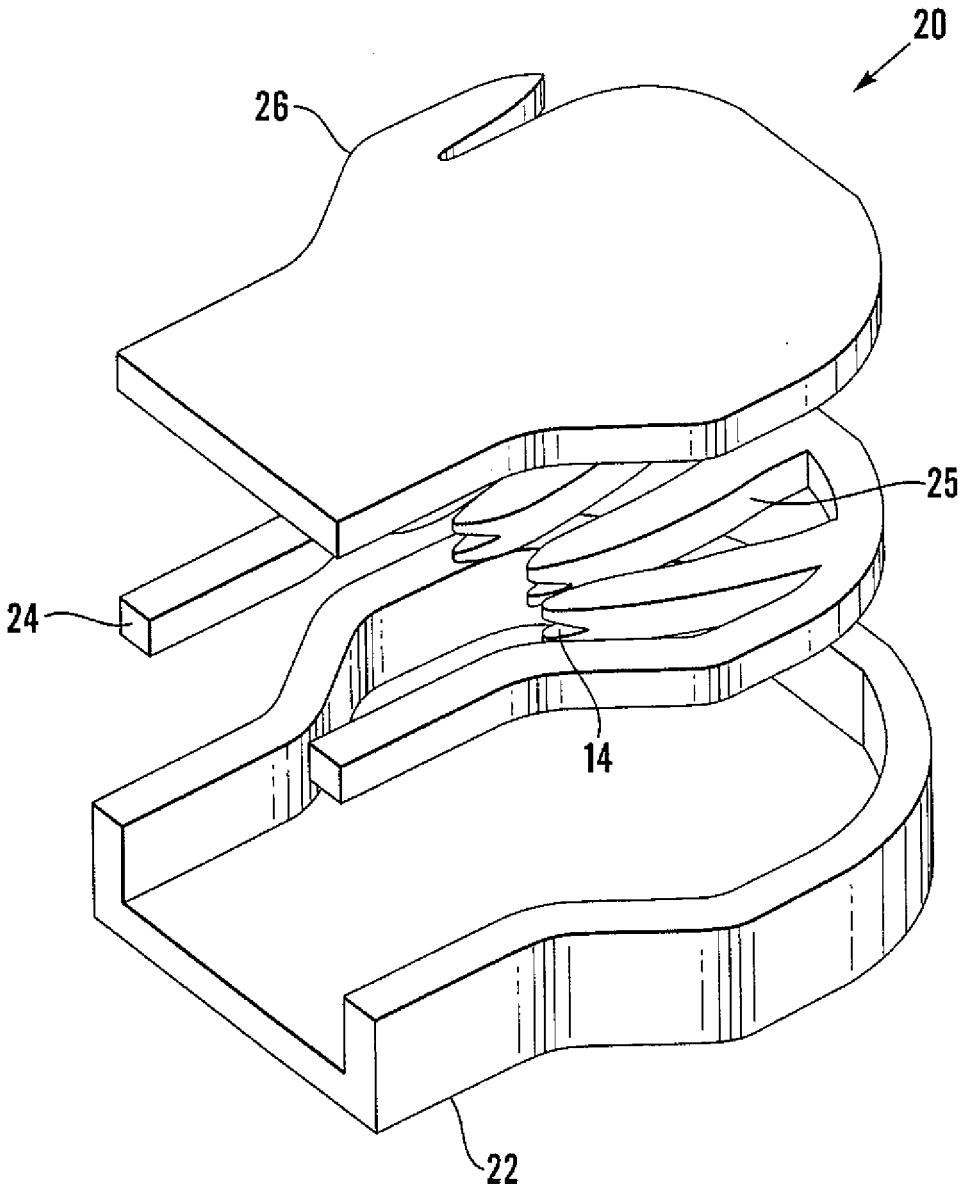


Fig. 1

Solventum-Exhibit 1013-0120

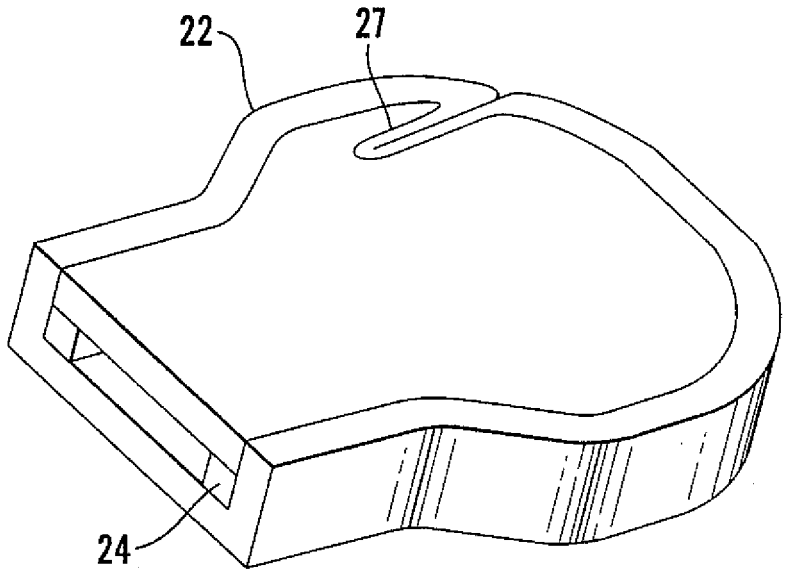


Fig.2

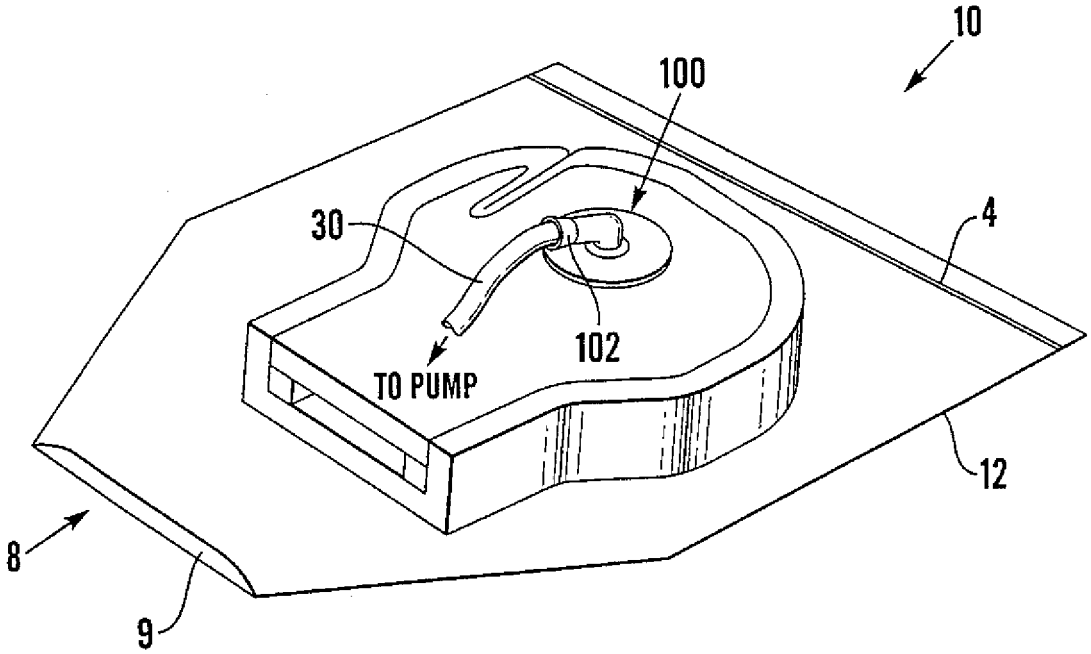


Fig.3

Solventum-Exhibit 1013-0121

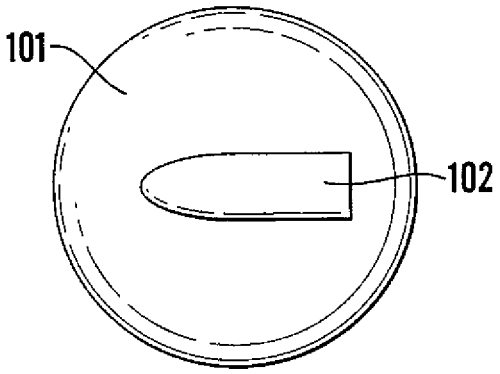


Fig.4A

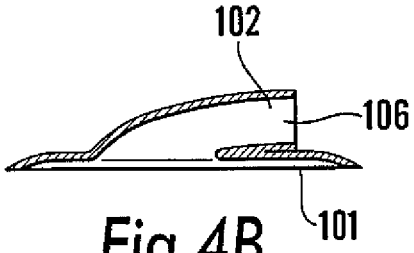


Fig.4B

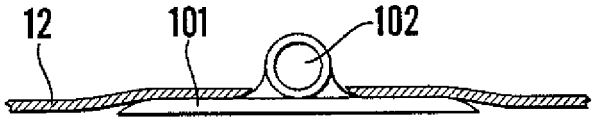


Fig.4C

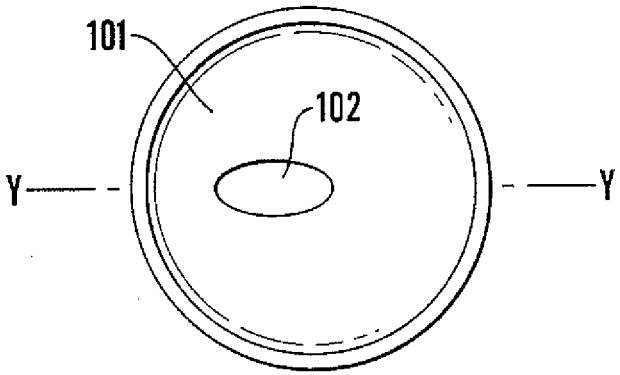


Fig.4D

Solventum-Exhibit 1013-0122

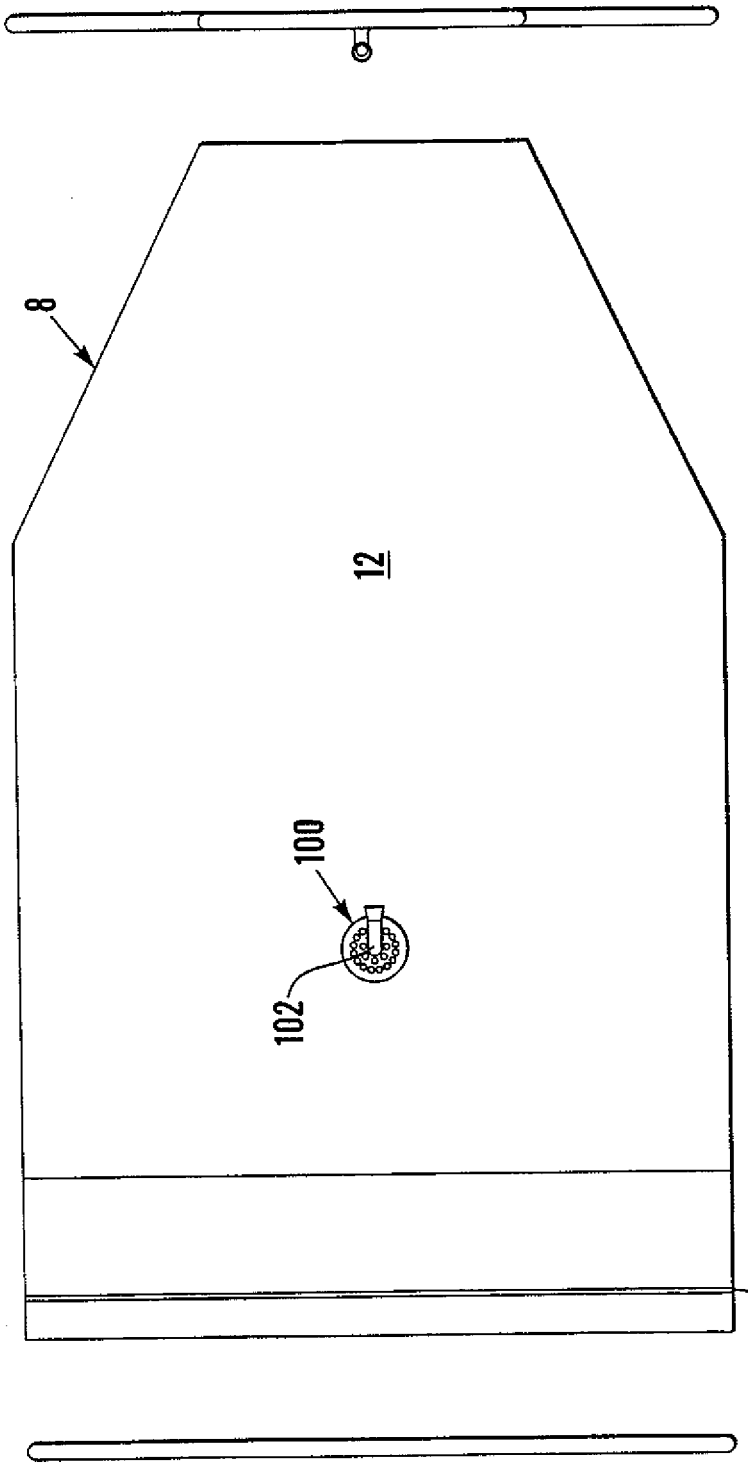


Fig.5

Solventum-Exhibit 1013-0123

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 :

"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

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

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

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

"&" 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

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

Solventum-Exhibit 1013-0124

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int. tional Application No
PCT/GB 00/01566

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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Solventum-Exhibit 1013-0125

(19)日本国特許庁（ＪＰ）　(12) 公表特許公報（Ａ）　(11)特許出願公表番号
特表2002－541978
（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	テーマコード（参考）
Ａ６１Ｆ　13/00	３０１	Ａ６１Ｆ　13/00	３０１Ｃ

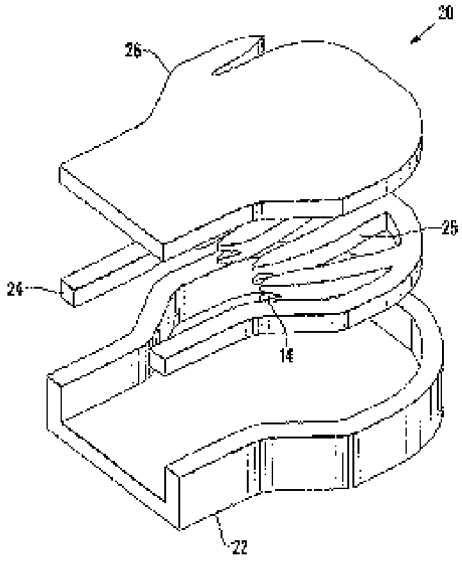
審査請求　未請求　予備審査請求　有　（全 15 頁）

(21)出願番号　特願2000－613396(P2000－613396)
(86)（22)出願日　平成12年４月20日(2000.4.20)
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(86)国際出願番号　ＰＣＴ／ＧＢ００／０１５６６
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(32)優先日　平成11年４月22日(1999.4.22)
(33)優先権主張国　イギリス（ＧＢ）

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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。



Solventum-Exhibit 1013-0126

【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。

Solventum-Exhibit 1013-0127

【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

Solventum-Exhibit 1013-0128

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

Solventum-Exhibit 1013-0129

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適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

Solventum-Exhibit 1013-0130

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、

Solventum-Exhibit 1013-0131

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、発泡体を縫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

Solventum-Exhibit 1013-0132

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。

Solventum-Exhibit 1013-0133

【図１】

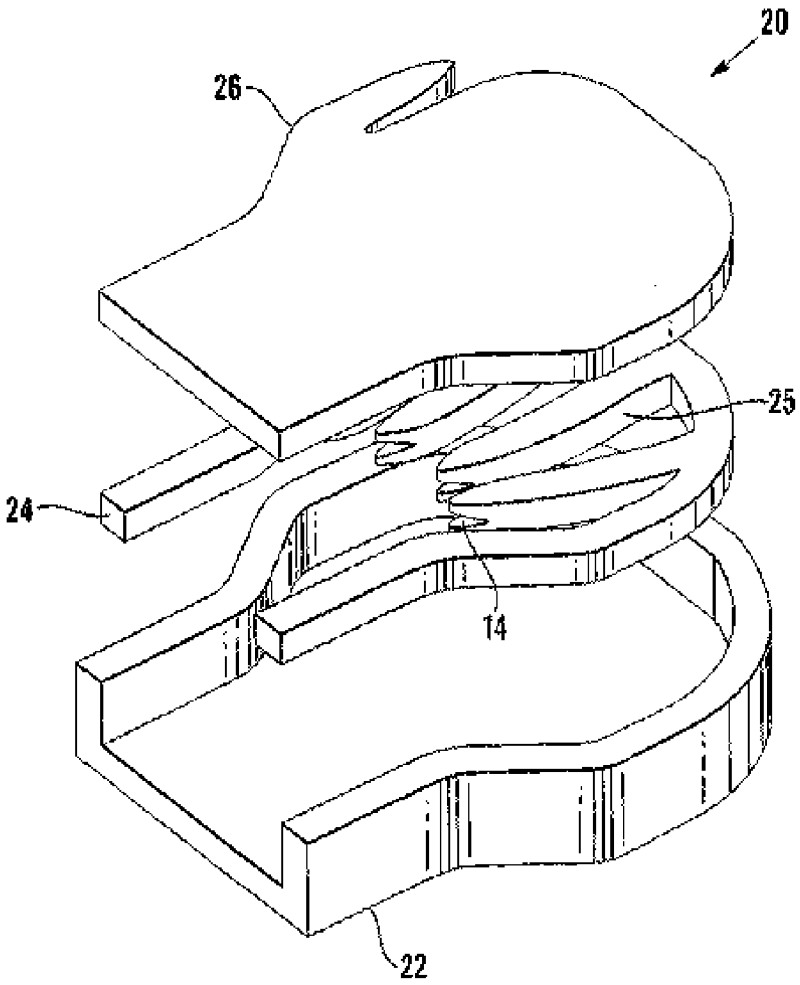


Fig. 1

【図２】

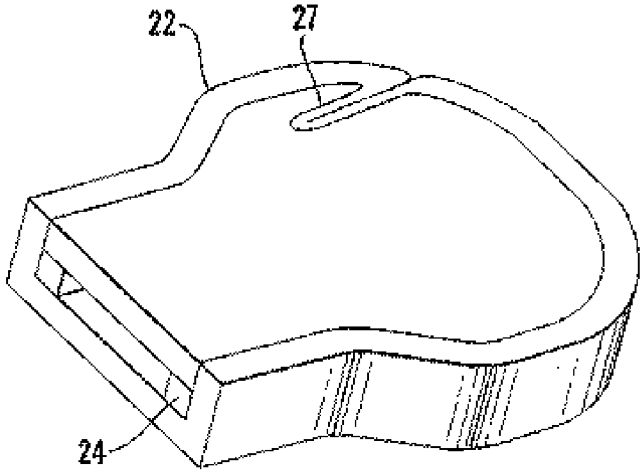
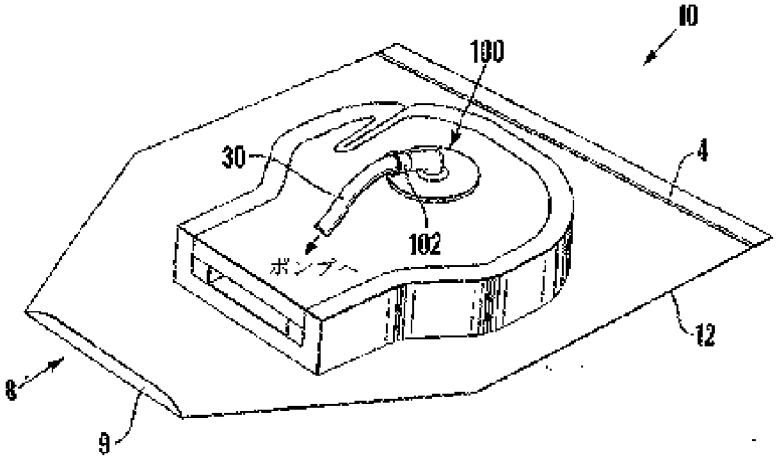


Fig.2

【図３】



【図４Ａ】

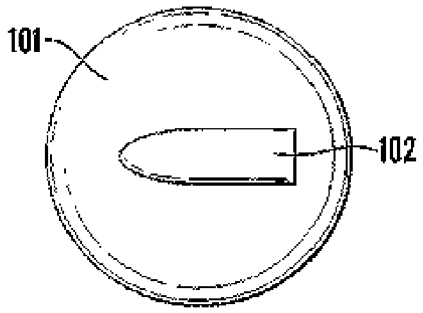


Fig.4A

【図４Ｂ】

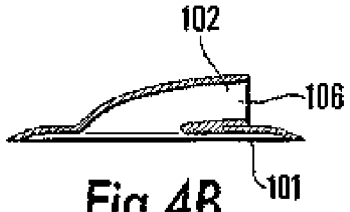


Fig.4B

【図４Ｃ】



Fig.4C

【図４Ｄ】

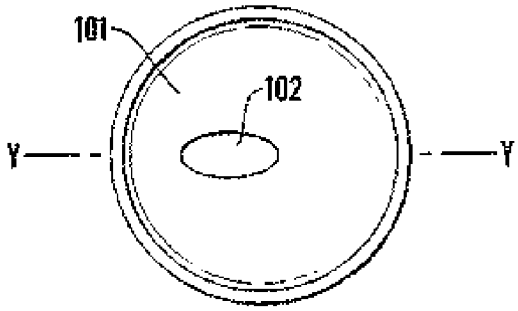


Fig.4D

【図５】

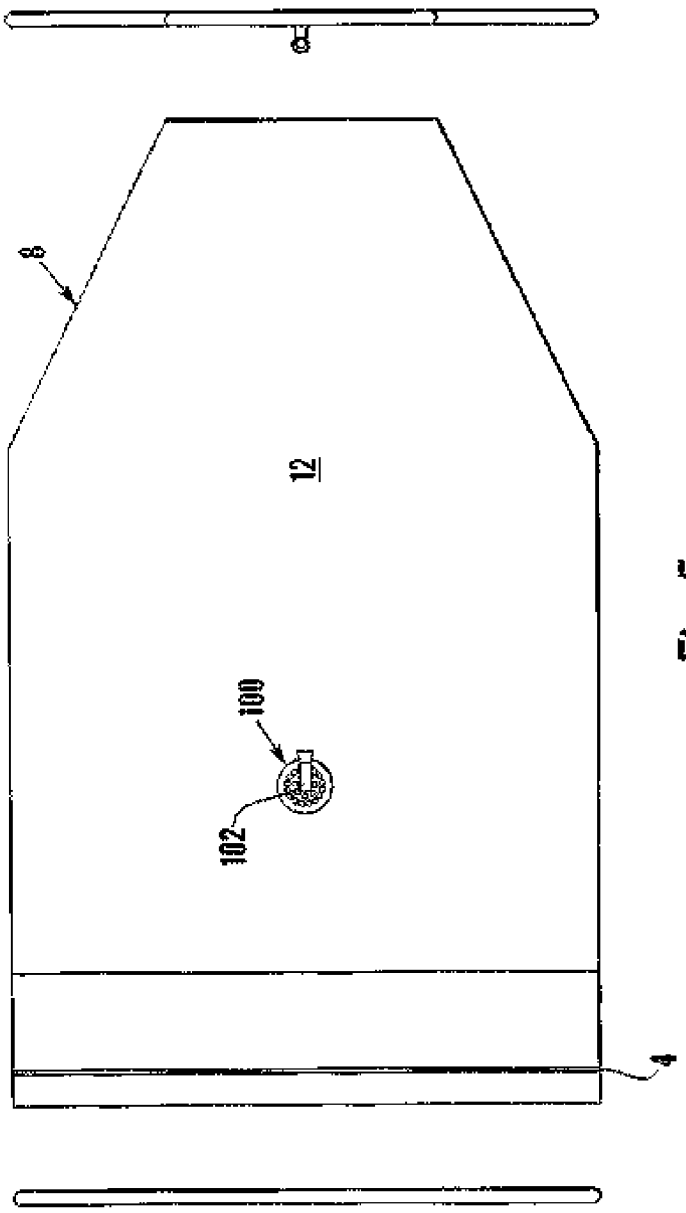


Fig.5

【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 5 527 293 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:

"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	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, M

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

Solventum-Exhibit 1013-0138

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int. 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 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
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		US 5100396 A	31-03-1992
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		US 5100396 A	31-03-1992
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		AU 2029592 A	30-12-1992
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		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)

Solventum-Exhibit 1013-0139

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

Solventum-Exhibit 1013-0140

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
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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:	

Solventum-Exhibit 1013-0144

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
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Susanne M. Hopkins
Registration No. 33,247
Derek Richmond
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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

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY ☒ RATE ($)	SMALL ENTITY ☒ FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			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	09/13/2010	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
	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	

AMENDMENT		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)	OR	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:
/Mamye Wagstaff/

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
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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.

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: _____.

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).

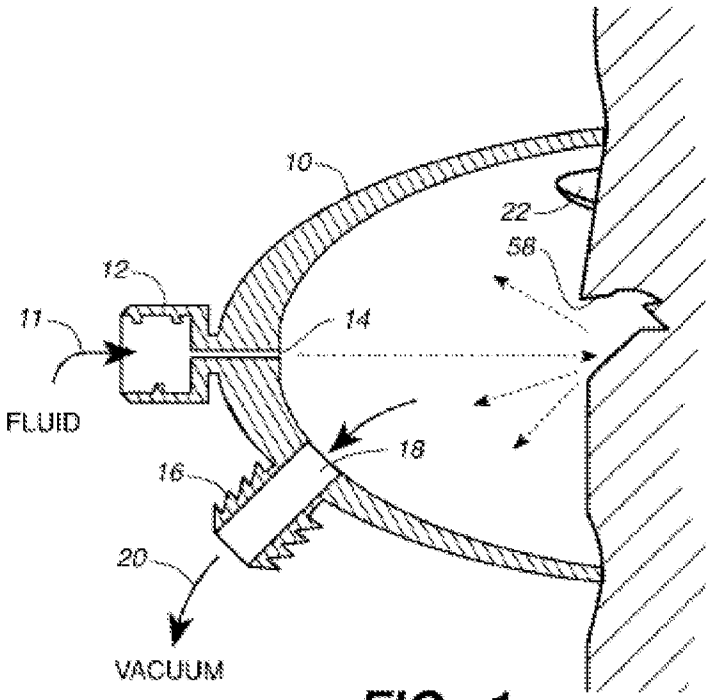


FIG._1

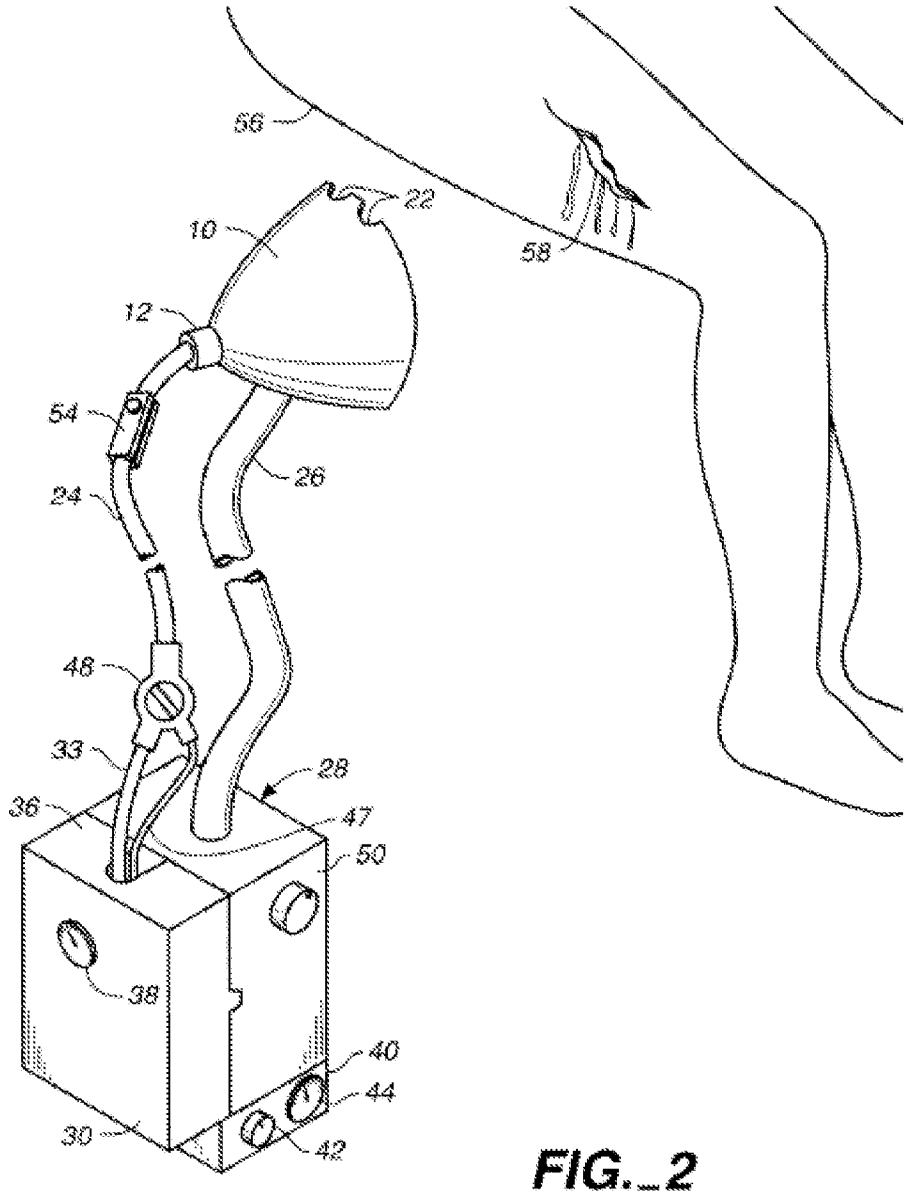


FIG._2

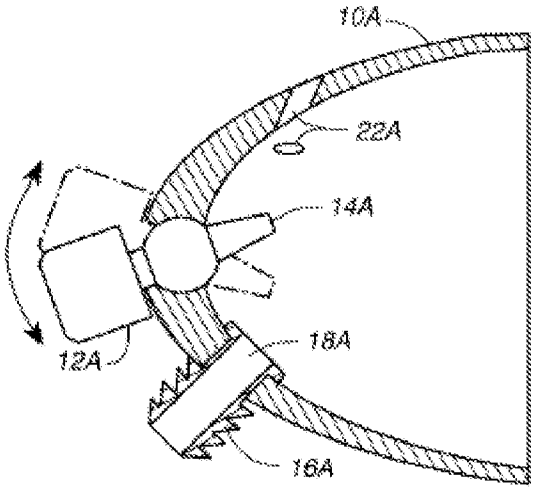


FIG._4

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.

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United States Patent and Trademark Office
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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	35 USC 119(a-d) conditions met	Verified and Acknowledged	Met after Allowance	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
☑ Yes ☐ No	☐ Yes ☐ No	/ILYA Y TREYGER/ Examiner's Signature	☐ Initials	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	-								
	5	-								
	6	-								
	7	-								
	8	-								
	9	-								
	10	-								
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	33	-								

Solventum-Exhibit 1013-0158

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

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

L13	117	2 and 6	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/10/05 16:50
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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		"5261893"				
		"5298015"				
		"5344415"				
		"5358494"				
		"5556375"				
		"5607388"				
		"5636643"				
		"5645081").PN.				
		OR ("6071267").				
		URPN.				

EAST Search History (Interference)

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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	Carmeli ADAHAN
Art Unit	3761
Examiner Name	ILYA Y. 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	7229422	B2	2007-06-12	Klobe	

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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	☒

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

Solventum Exhibit 1013-0164

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		☐

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(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	5370610	A	1994-12-06	REYNOLDS	
	2	5662599	A	1997-09-02	REICH, et al.	
	3	6471982	B1	2002-10-29	LYDON, et al.	
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	8	4447226		1984-05-08	MAYORAL	

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

	9	4611627		1986-09-16	EIDSVOOG, et al.	
	10	1599899		1926-09-14	KETTERING, et al.	
	11	6071267	A	2000-06-06	ZAMICROWSKI	
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	18	4930997		1990-06-05	BENNETT	
	19	4661093		1987-04-28	BECK, et al.	

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	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.	
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	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.	
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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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	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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	Filing Date	2008-01-24
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	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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☐ 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).

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☐ 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.

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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	/Susanne M. Hopkins/	Date (YYYY-MM-DD)	2010-11-16
Name/Print	Susanne M. Hopkins	Registration Number	33247

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(19) World Intellectual Property Organization
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(43) International Publication Date
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PCT

(10) International Publication Number
WO 03/030966 A1

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(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/328,542 11 October 2001 (11.10.2001) US

(71) Applicant *(for all designated States except US)*: **HILL-ROM SERVICES, INC.** [US/US]; 1069 State Route 46 East, Batesville, IN 47006-9167 (US).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **BITEL, Alexander, Bencion** [US/US]; 6763 Verde Ridge Drive, Cincinnati, OH 45247 (US). **LOCKWOOD, Jeffrey, S.** [US/US]; 500 North Walnut, Batesville, IN 47006 (US). **PETROSENKO, Robert** [US/US]; 30 Belmont Place West, Batesville, IN 47006 (US). **RISK, James, Robert, Jr.** [US/US]; 10861 N. Private Road 23 W., Fountaintown, IN 46130 (US).

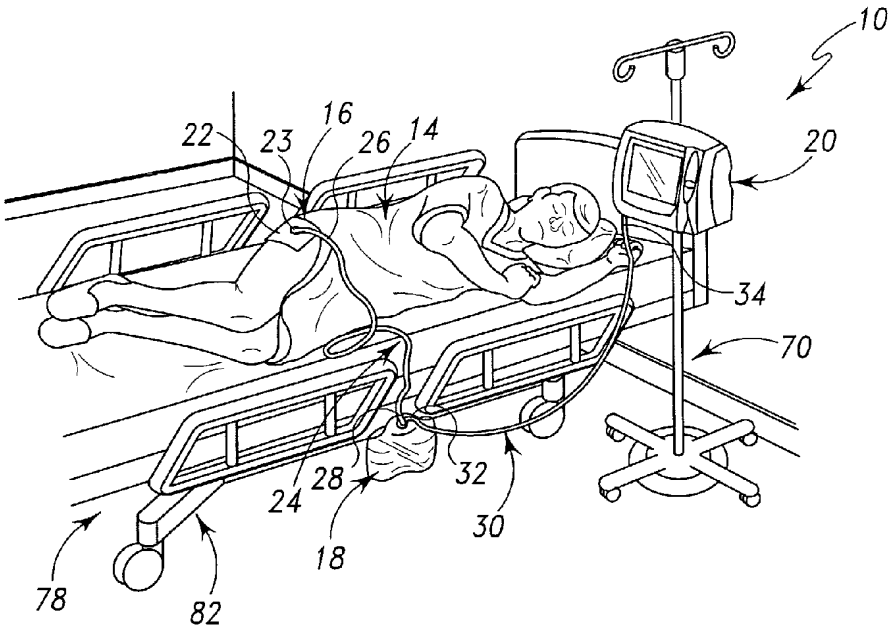
(74) Agent: **CONARD, Richard, D.**; Barnes & Thornburg, 11 South Meridian Street, Indianapolis, IN 46204 (US).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),

[Continued on next page]

(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.

WO 03/030966 A1

Solventum-Exhibit 1013-0174

European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) 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, SD, SE, SG, SI, 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, 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, SD, SE, SG, SI, 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, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)*

Published:

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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.

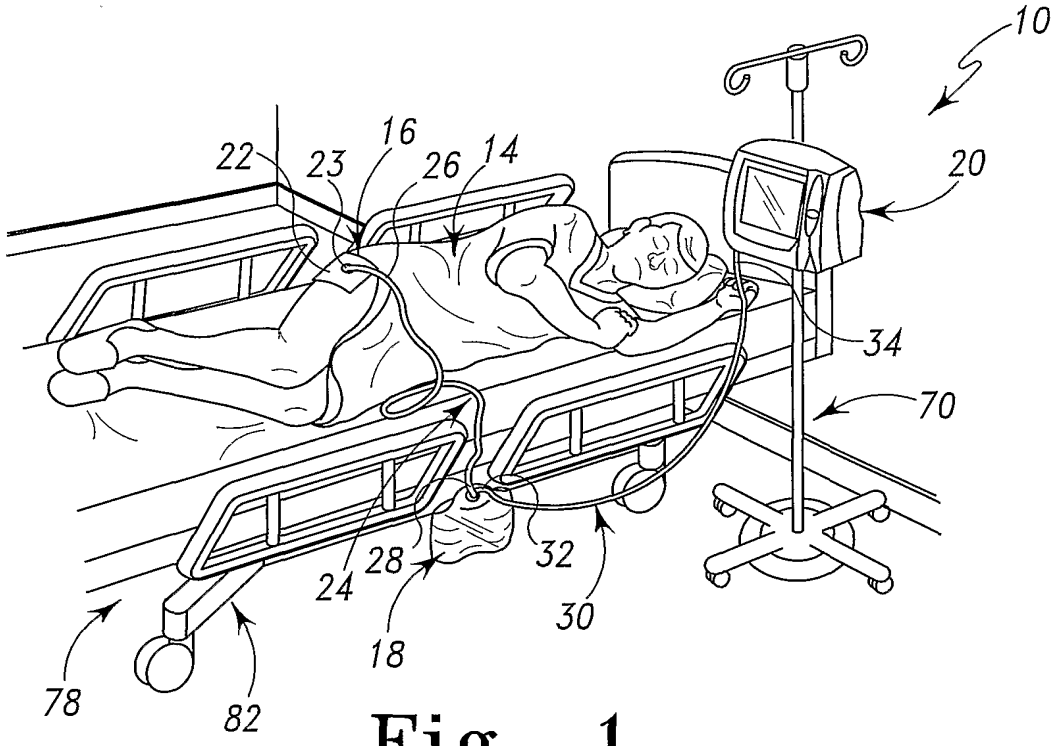

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Fig. 1

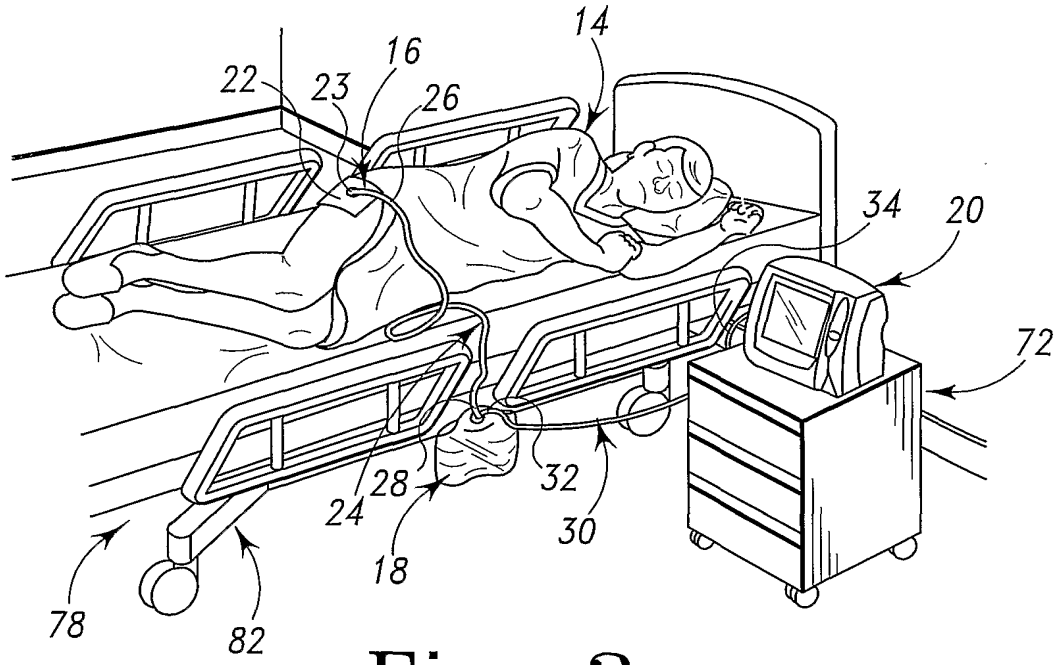

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Fig. 2

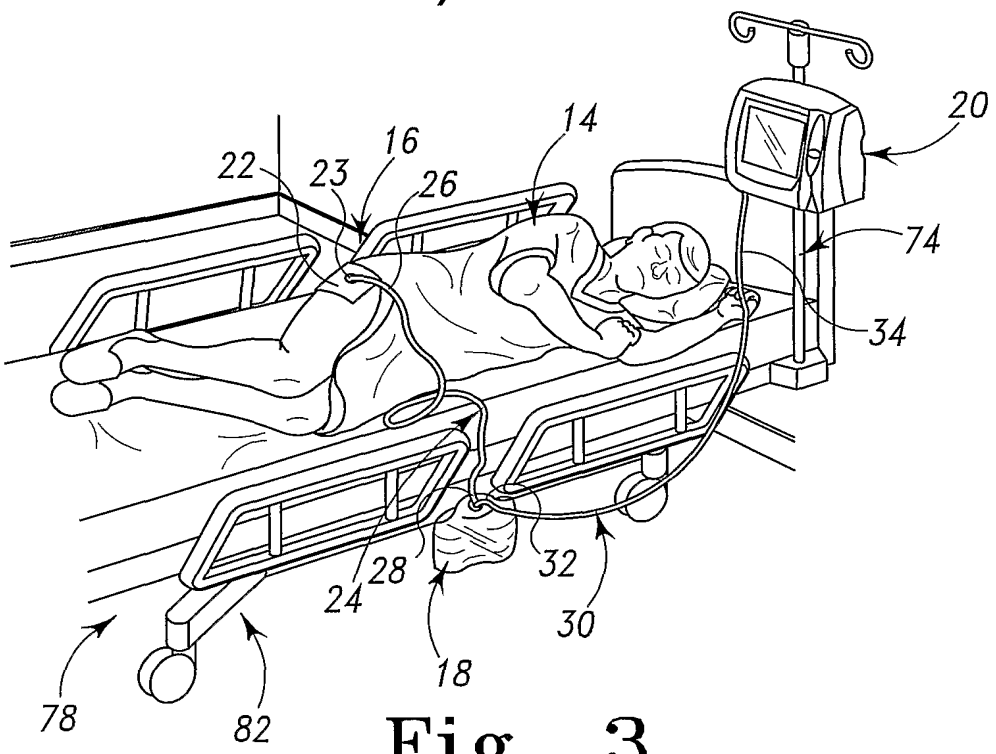

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Fig. 3

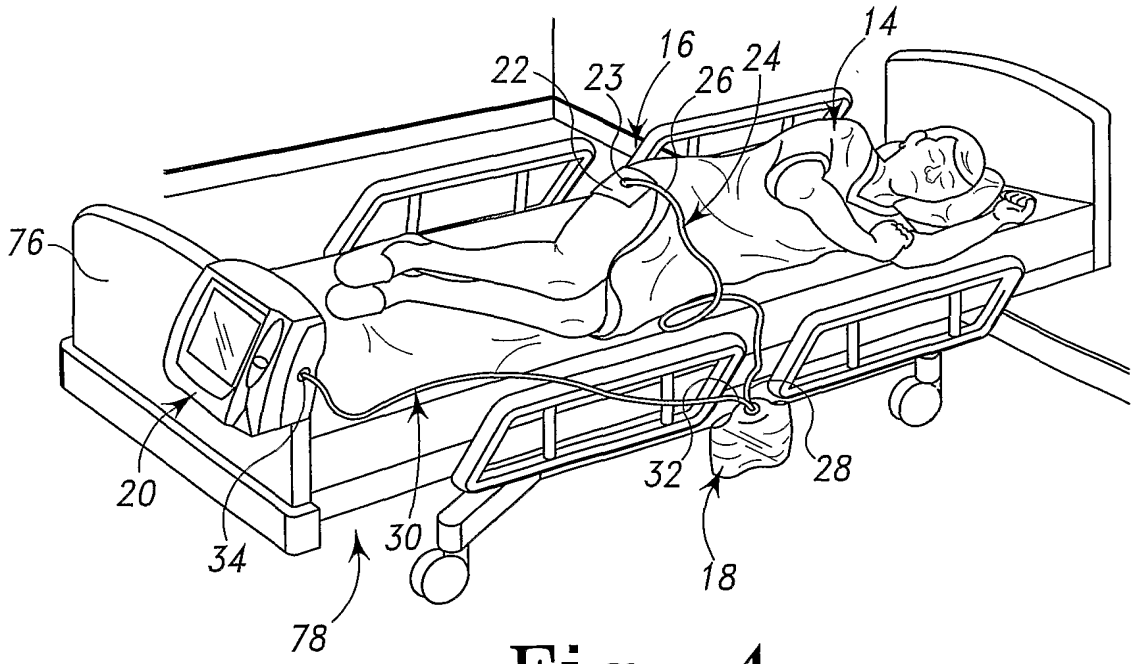

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Fig. 4

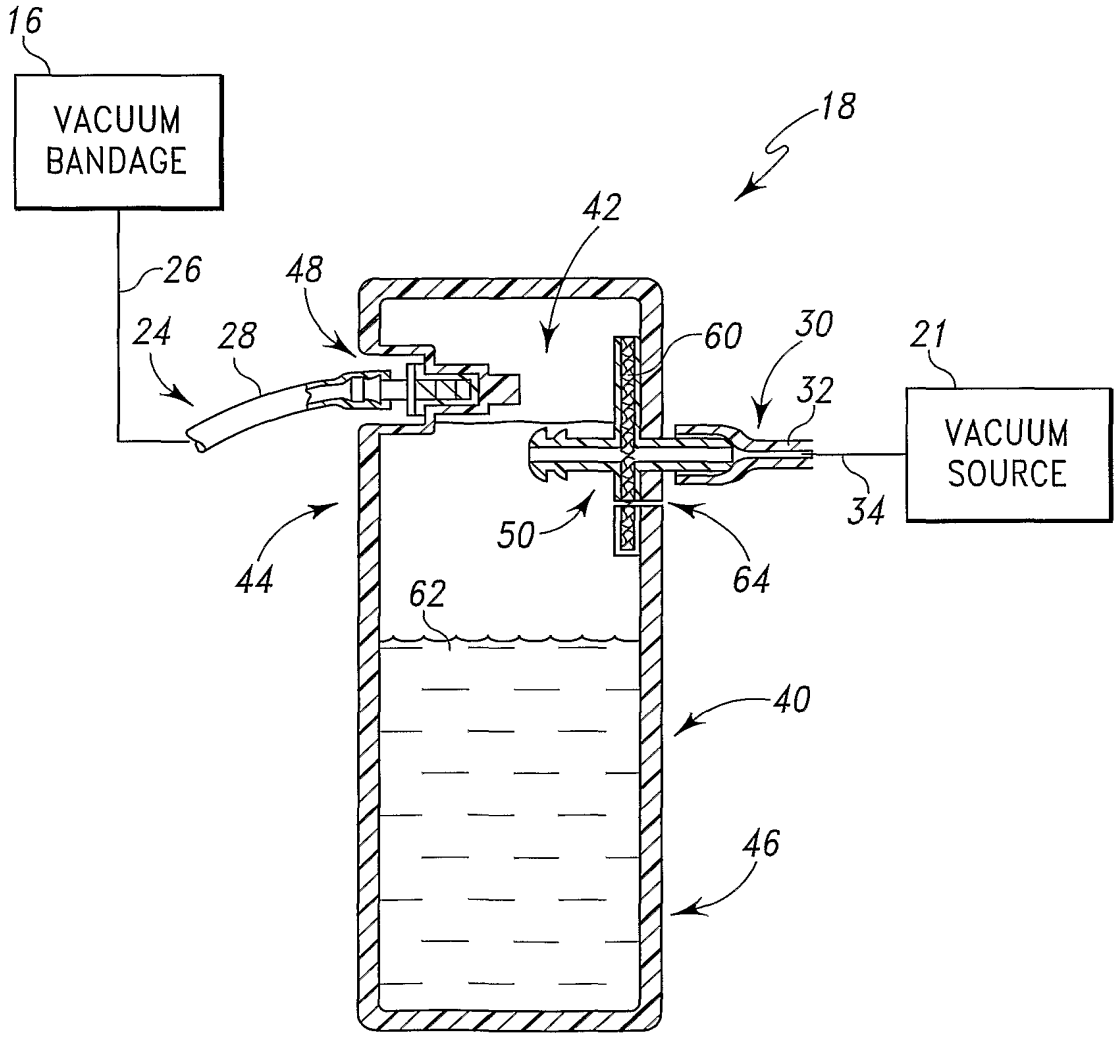

16
VACUUM BANDAGE
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VACUUM SOURCE
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Fig. 5

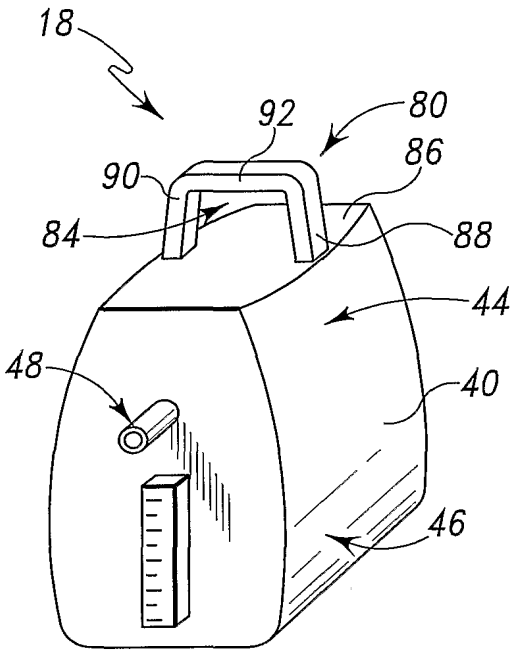


Fig. 6

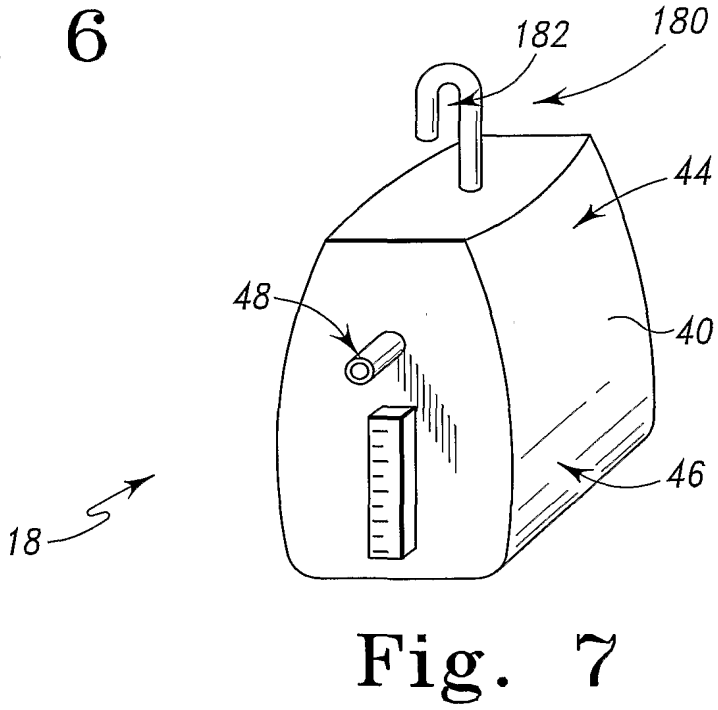


Fig. 7

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

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

[X] Patent family members are listed in annex.

° Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
29 January 2003	05/02/2003

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) (July 1992)

Solventum-Exhibit 1013-0192

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
A	EP 1 088 569 A (KCI MEDICAL LTD) 4 April 2001 (2001-04-04) paragraphs '0011!,'0018!-'0020!; figures 1,3	1-8, 10-14, 16-22
A	GB 1 584 772 A (WALLACE LTD H G) 18 February 1981 (1981-02-18) abstract; figures	7,9,11, 14,21
A	WO 00 21586 A (KCI MEDICAL LTD ;HEATON KEITH PATRICK (GB); HUNT KENNETH WILLIAM () 20 April 2000 (2000-04-20) page 5, line 10 - line 12 page 7, paragraph 3 - paragraph 4 figures	20

Solventum-Exhibit 1013-0193

INTERNATIONAL SEARCH REPORT

Intern[redacted]al 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.

Solventum-Exhibit 1013-0194

INTERNATIONAL SEARCH REPORT

Inf[illegible] on on patent family members

International Application No
PCT/US [illegible]02/32221

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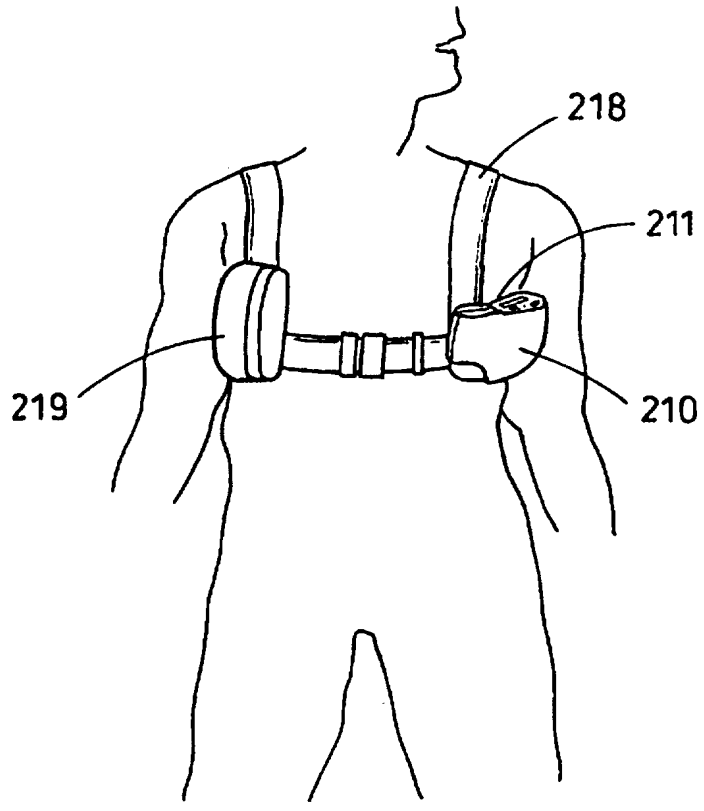
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(57) Abstract

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.



Solventum-Exhibit 1013-0197

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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

Solventum-Exhibit 1013-0199

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

Solventum-Exhibit 1013-0201

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

Solventum-Exhibit 1013-0202

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

Solventum-Exhibit 1013-0203

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

Solventum-Exhibit 1013-0204

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

Solventum-Exhibit 1013-0205

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

Solventum-Exhibit 1013-0206

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.

Solventum-Exhibit 1013-0207

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.

Solventum-Exhibit 1013-0208

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.

Solventum-Exhibit 1013-0209

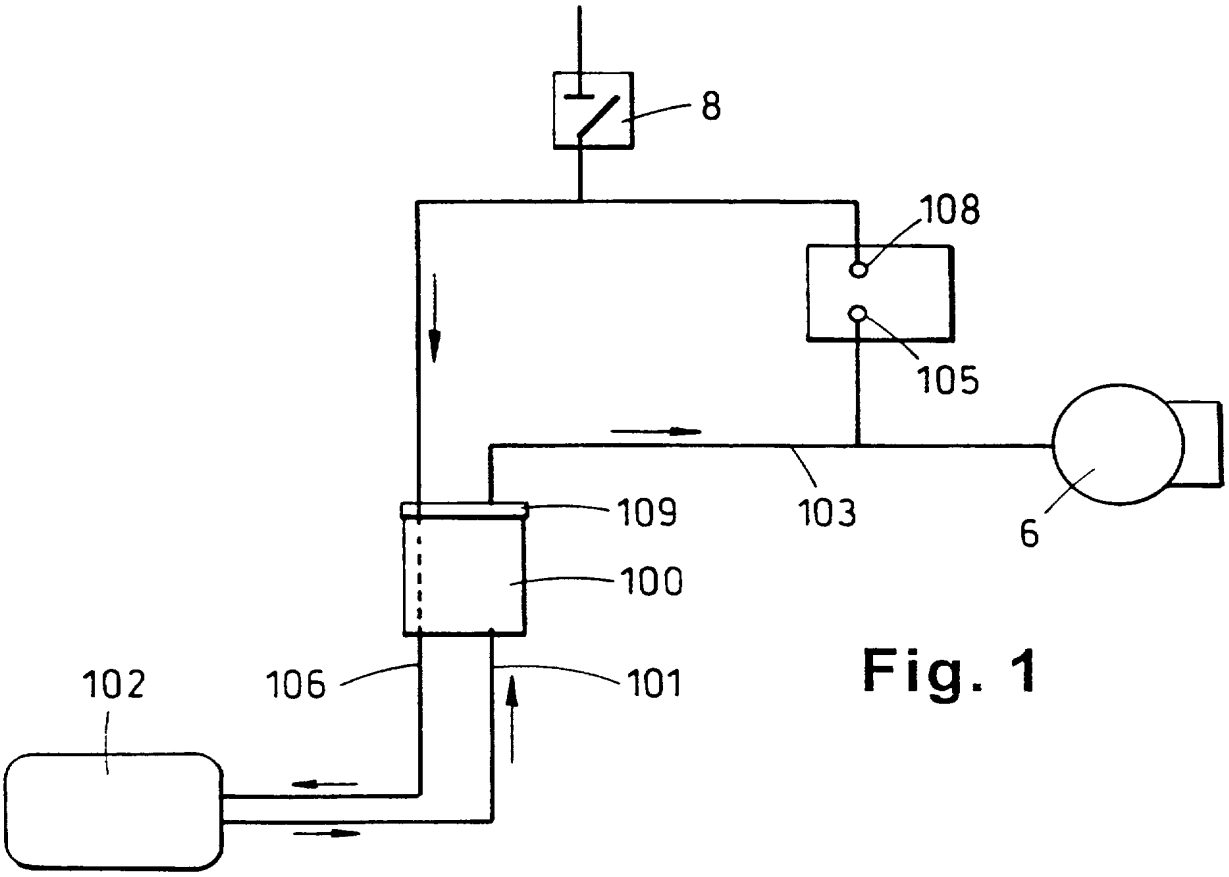


Fig. 1

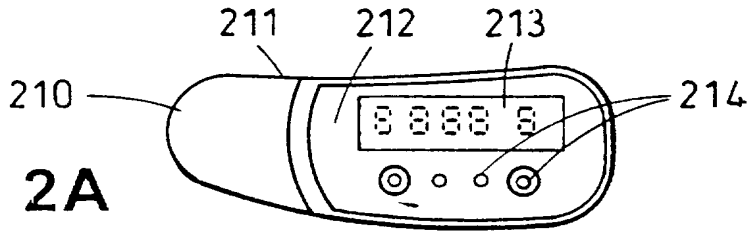


Fig. 2A

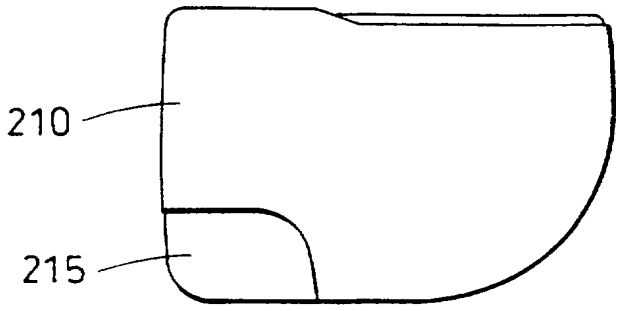


Fig. 2B

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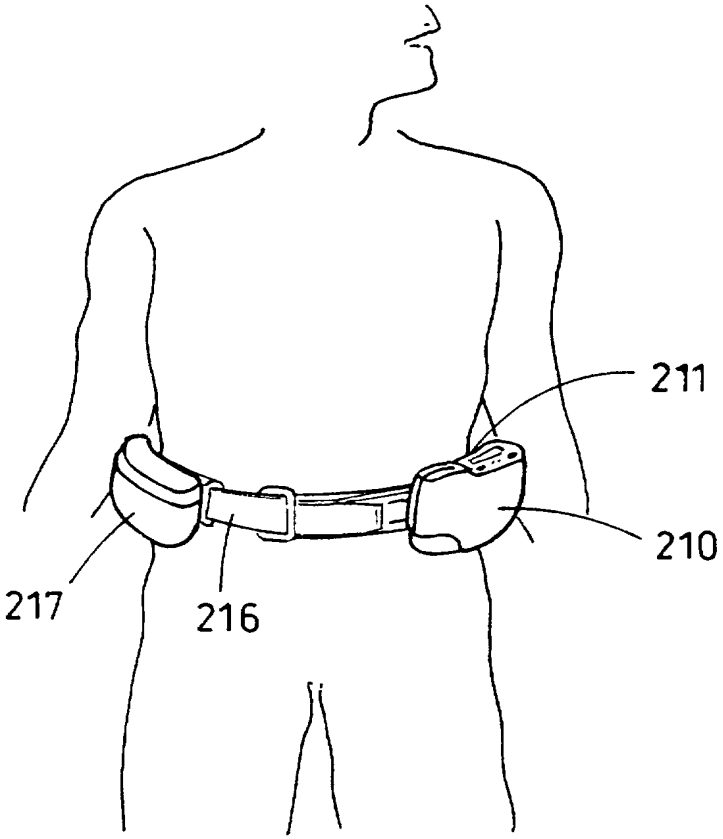


Fig. 3A

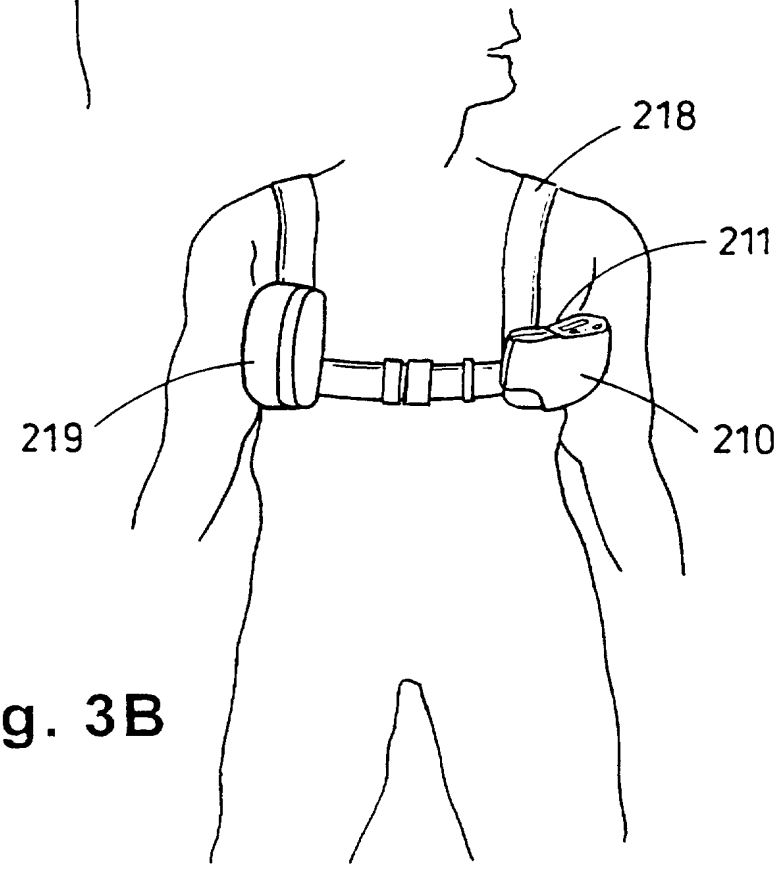


Fig. 3B

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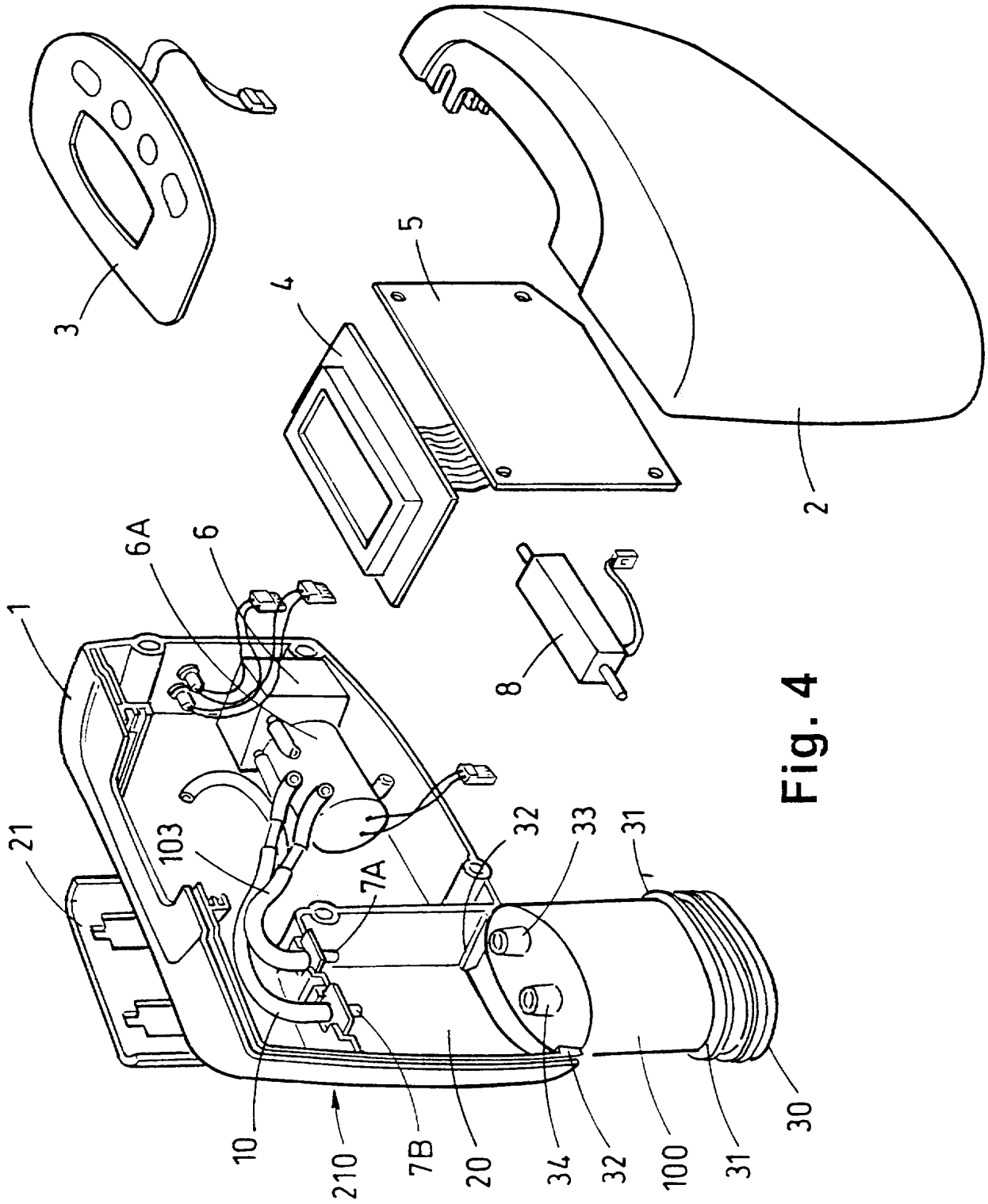


Fig. 4

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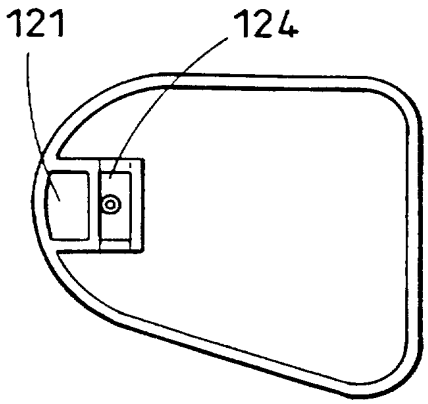


Fig. 5A

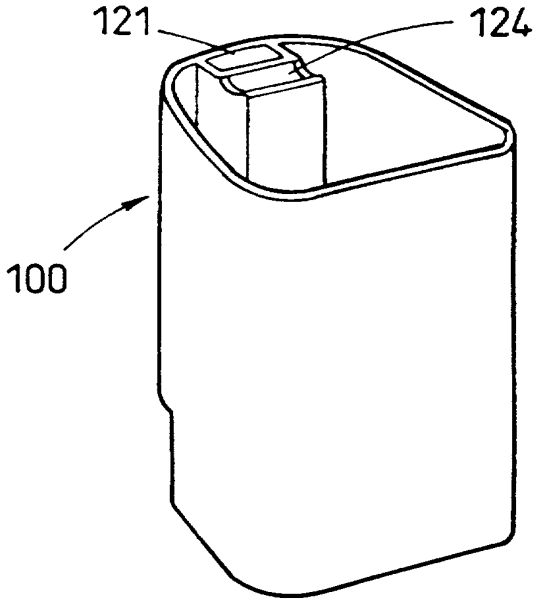


Fig. 5D

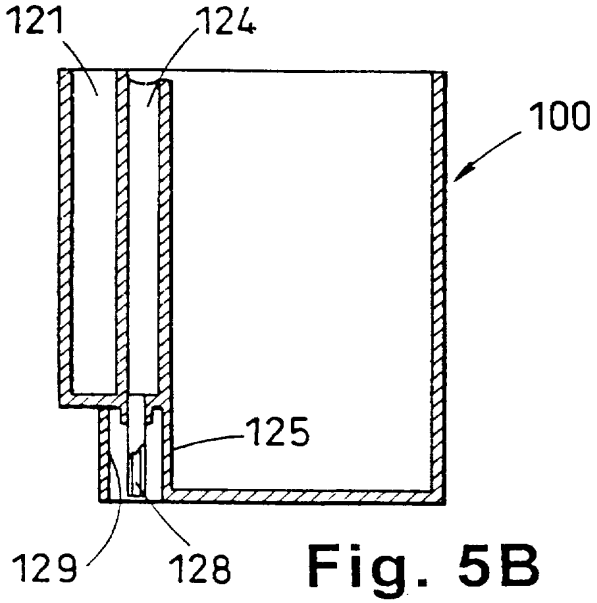


Fig. 5B

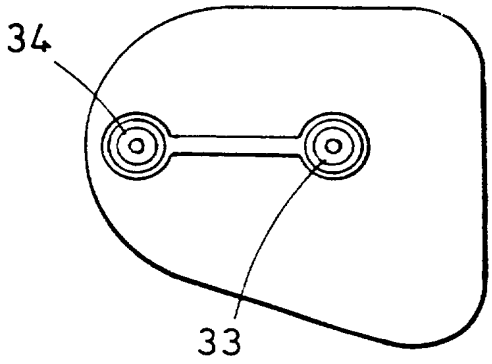


Fig. 5E

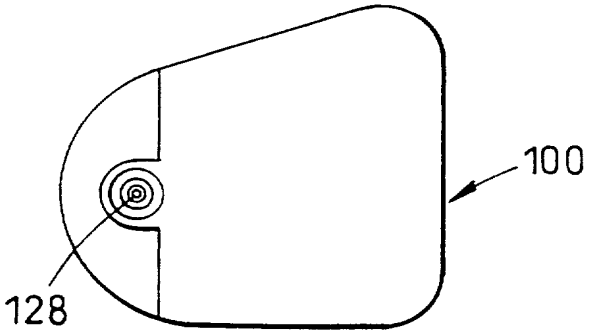


Fig. 5C

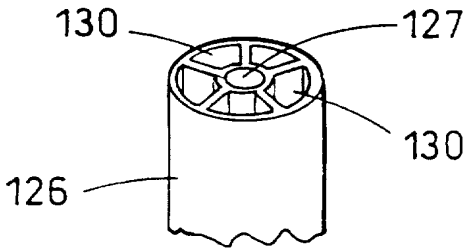


Fig. 5F

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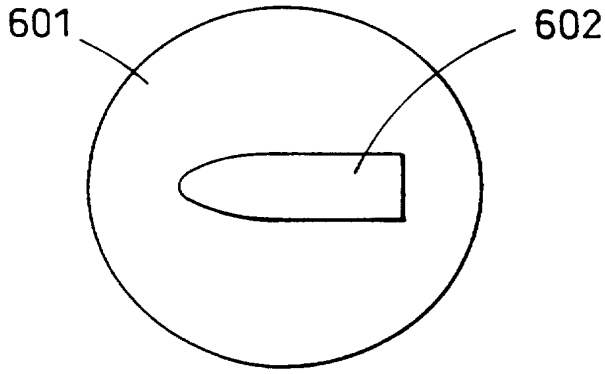


Fig. 6A

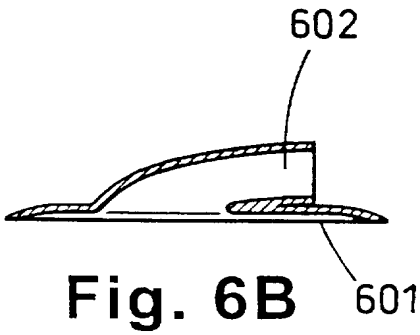


Fig. 6B

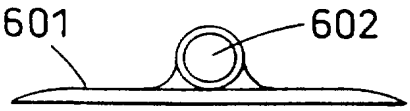


Fig. 6C

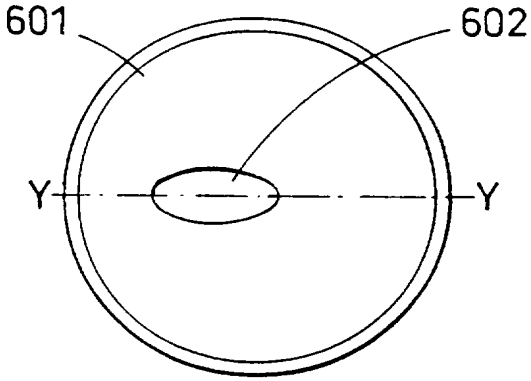


Fig. 6D

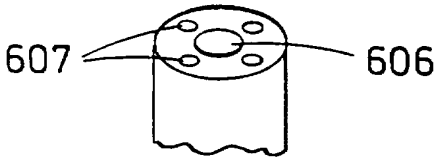


Fig. 6E

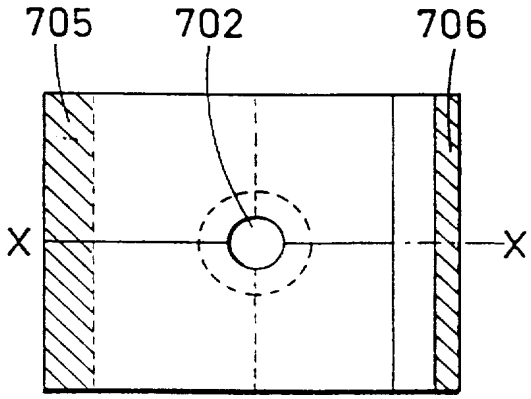


Fig. 7A

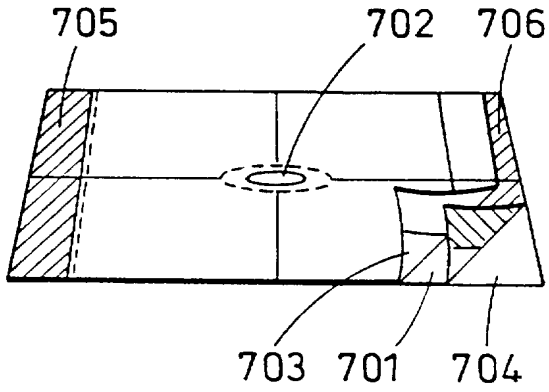


Fig. 7B

Solventum-Exhibit 1013-0214

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	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	Schönleben, J

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

Solventum-Exhibit 1013-0215

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

Solventum-Exhibit 1013-0216

INTERNATIONAL SEARCH REPORT

International application 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 Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box 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.

Solventum-Exhibit 1013-0217

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
		JP 56500360 T	26-03-81
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	

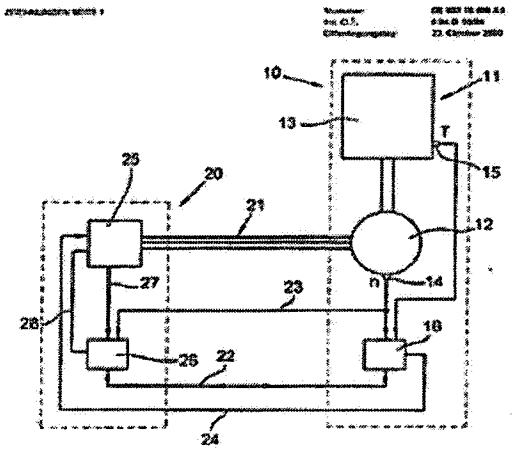
Solventum-Exhibit 1013-0218

© 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

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(74) Vertreter:
Patentanwälte von Kreisler, Selting, Werner et col., 50667 Köln

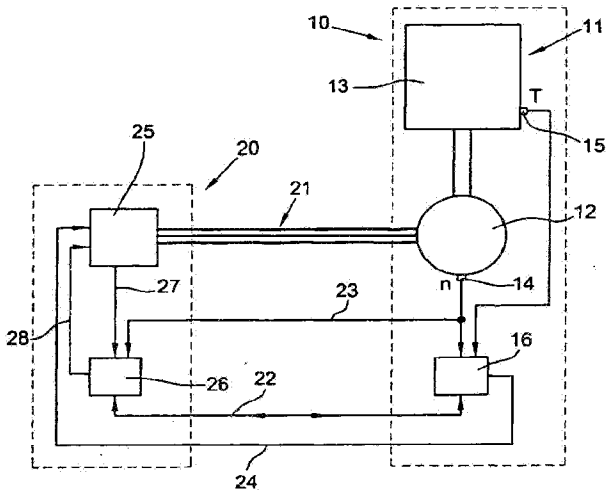
(72) Erfinder:
Harig, Christian, 51105 Köln, DE; Kieffer, Manfred, 50389 Wesseling, DE

(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.



DE 102 15 896 A 1

Solventum-Exhibit 1013-0220

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**.

Solventum-Exhibit 1013-0221

[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.

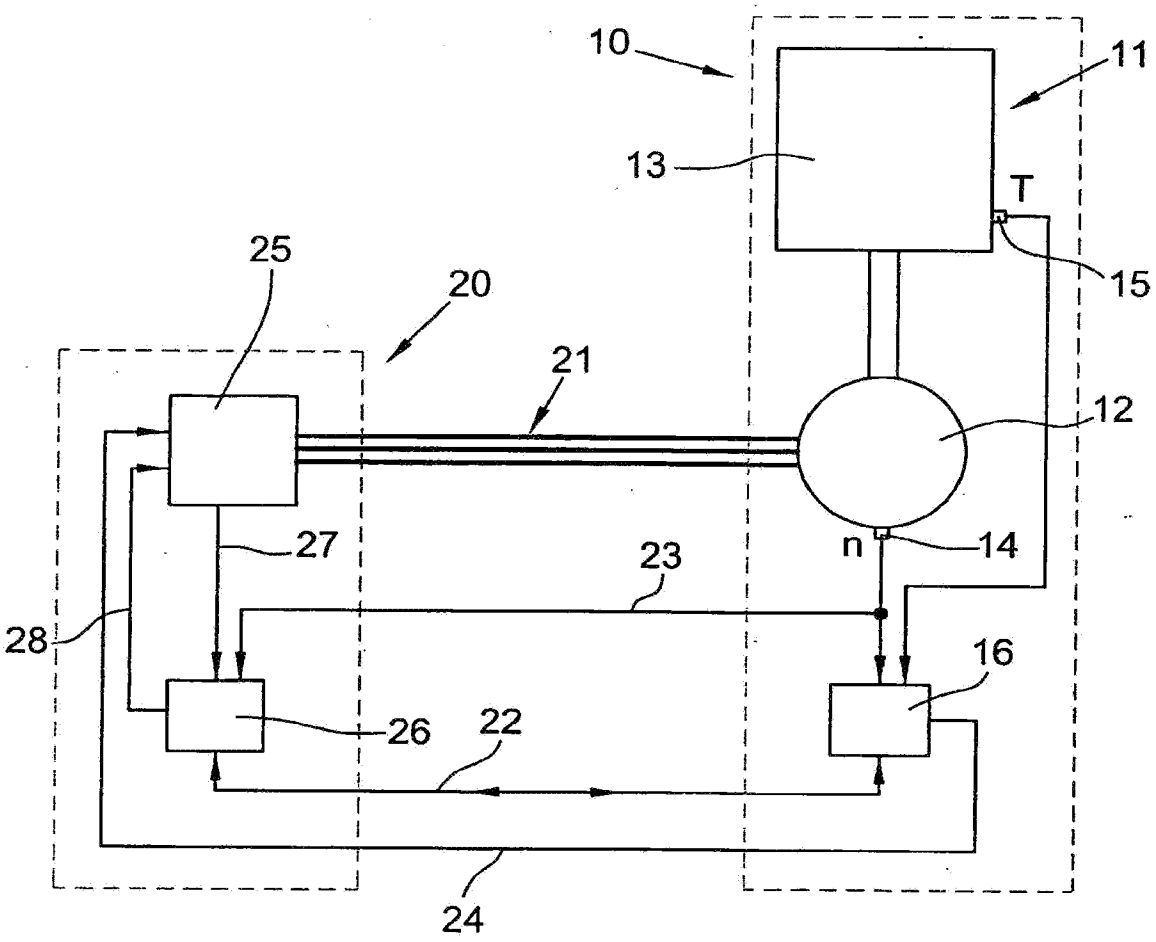
Patentansprüche

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

Solventum-Exhibit 1013-0222

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Int. Cl.[7]: F 04 D 19/04
Offenlegungstag: 23. Oktober 2003



Solventum-Exhibit 1013-0223

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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
27 February 2003 (27.02.2003)

PCT

(10) International Publication Number
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(25) Filing Language: English

(26) Publication Language: English

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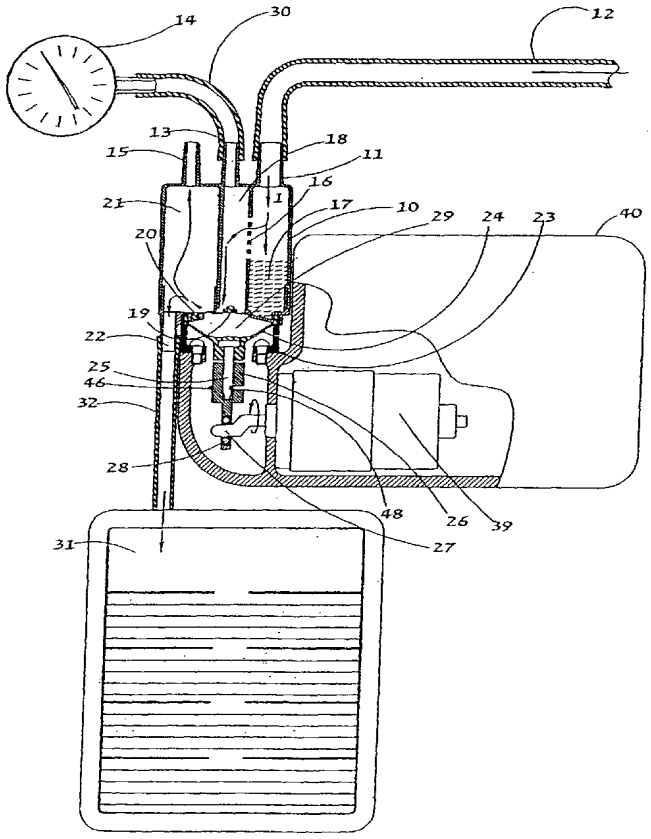
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(54) Title: A COMPACT VACUUM PUMP



(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.

Solventum-Exhibit 1013-0226

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:

Solventum-Exhibit 1013-0227

(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.

Solventum-Exhibit 1013-0228

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.

Solventum-Exhibit 1013-0229

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.

Solventum-Exhibit 1013-0230

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

Solventum-Exhibit 1013-0231

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.

Solventum-Exhibit 1013-0232

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

Solventum-Exhibit 1013-0233

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.

Solventum-Exhibit 1013-0234

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

Solventum-Exhibit 1013-0235

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:

Solventum-Exhibit 1013-0236

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.

Solventum-Exhibit 1013-0237

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.

Solventum-Exhibit 1013-0238

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

Solventum-Exhibit 1013-0239

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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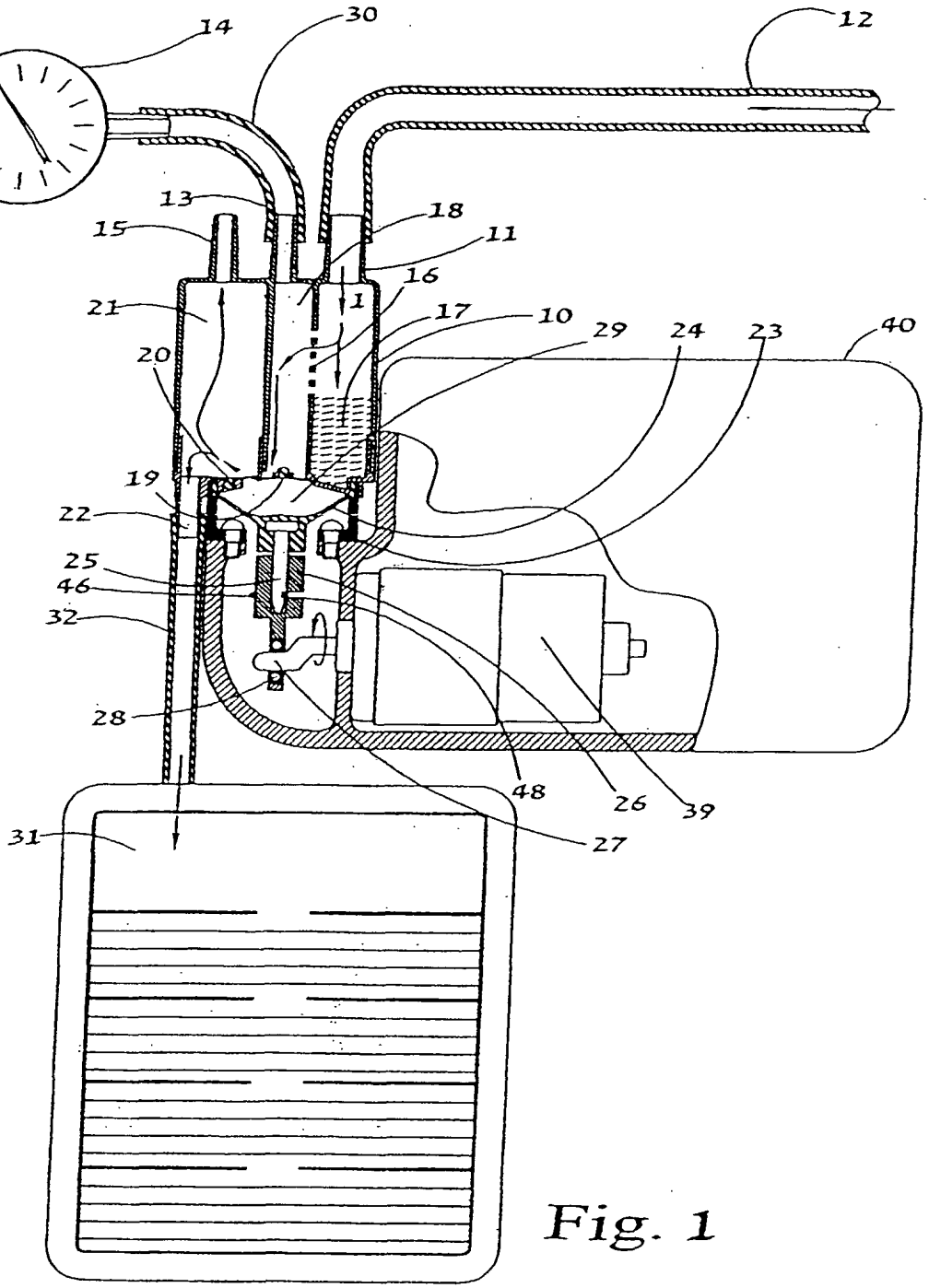


Fig. 1

Solventum-Exhibit 1013-0241

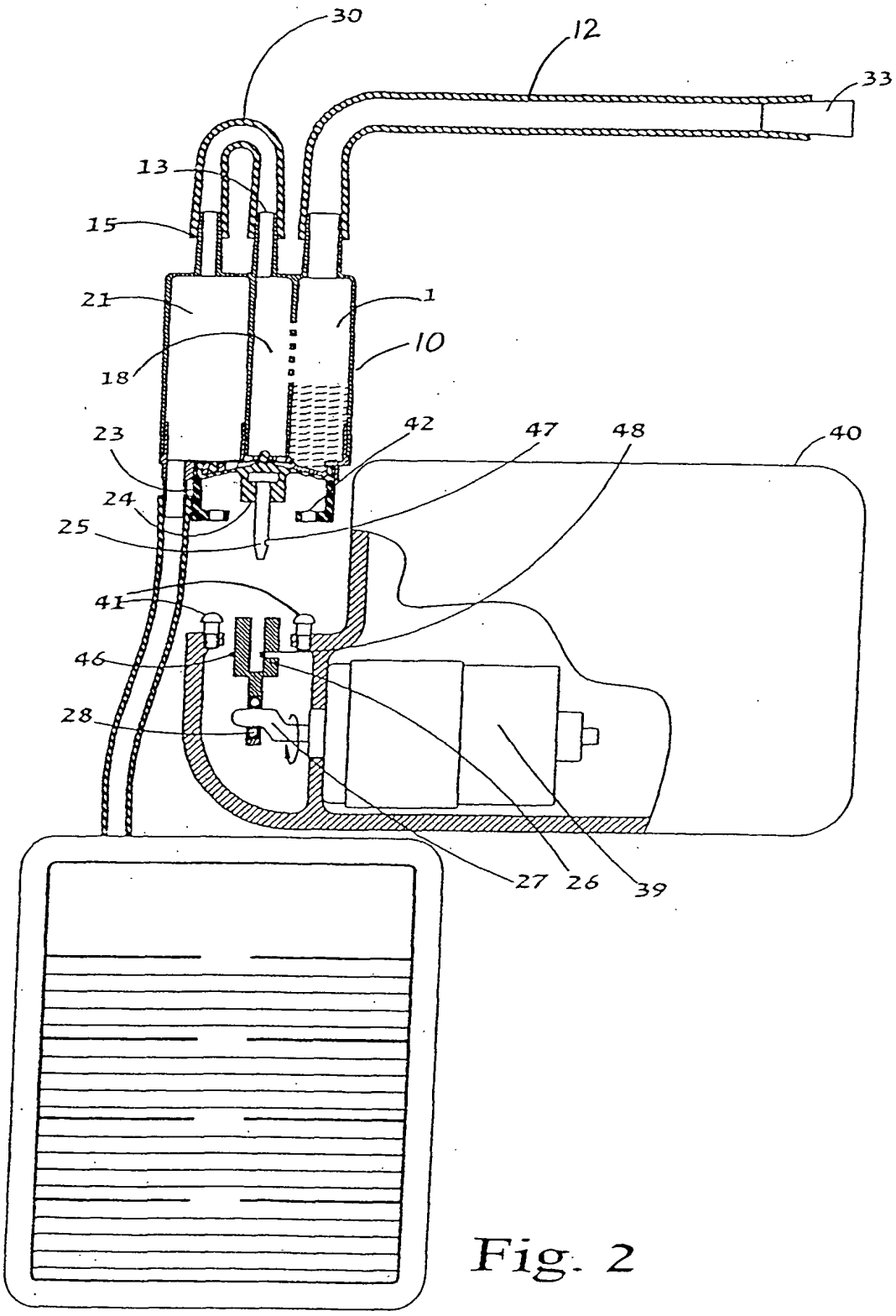


Fig. 2

Solventum-Exhibit 1013-0242

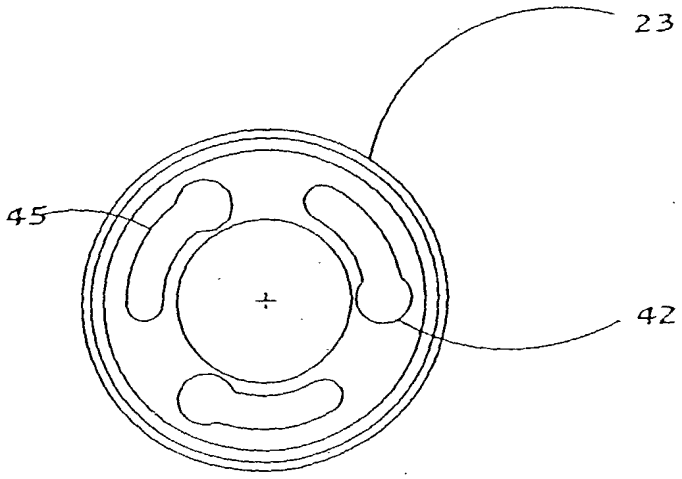


Fig.3

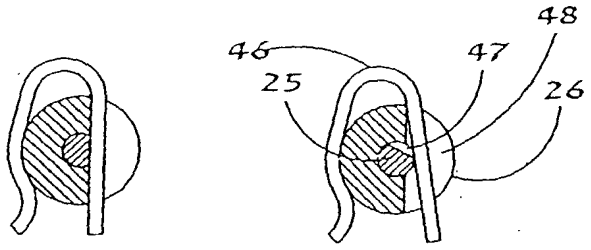


Fig.4

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
10 December 2002 (10.12.2002)

Date of mailing of the international search report
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
Telephone No. 703-308-0861

Form PCT/ISA/210 (second sheet) (July 1998)

Solventum-Exhibit 1013-0244

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.

Solventum-Exhibit 1013-0245

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

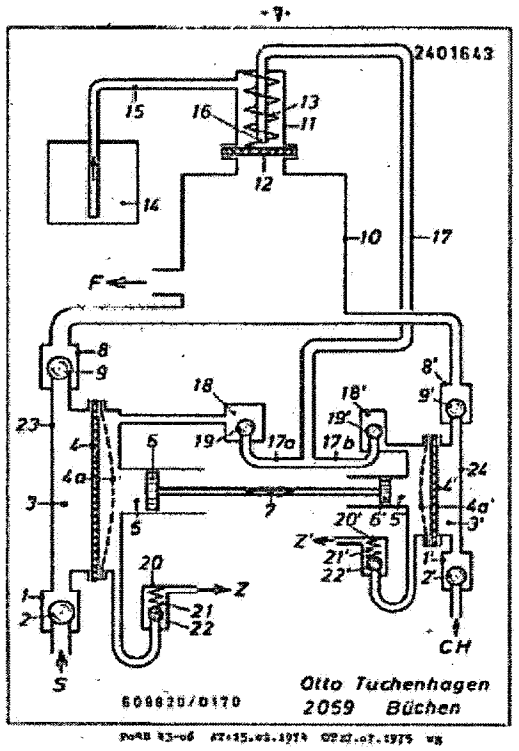
Solventum-Exhibit 1013-0246

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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

(11) Offenlegungsschrift 24 01 643

(21) Aktenzeichen: P 24 01 643.1

(22) Anmeldetag: 15. 1. 74

(43) Offenlegungstag: 17. 7. 75

(30) Unionspriorität:

(32) (33) (31) —

(54) Bezeichnung: Verfahren zur proportionalen Zudosierung in Schlammpumpen, die auf Filterpressen arbeiten

(71) Anmelder: Tuchenhagen, Otto, 2059 Büchen

(72) Erfinder: Stahlkopf, Friedrich, 2059 Büchen

DT 24 01 643 A1

© 7.75 509 829/170 4/60

Solventum-Exhibit 1013-0248

Otto Tuchenhagen
Ingenieur
2059 Büchen, Bez. Hamburg

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.

509829/0170

Solventum-Exhibit 1013-0249

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

Solventum-Exhibit 1013-0250

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-

Solventum-Exhibit 1013-0251

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.

Solventum-Exhibit 1013-0252

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.

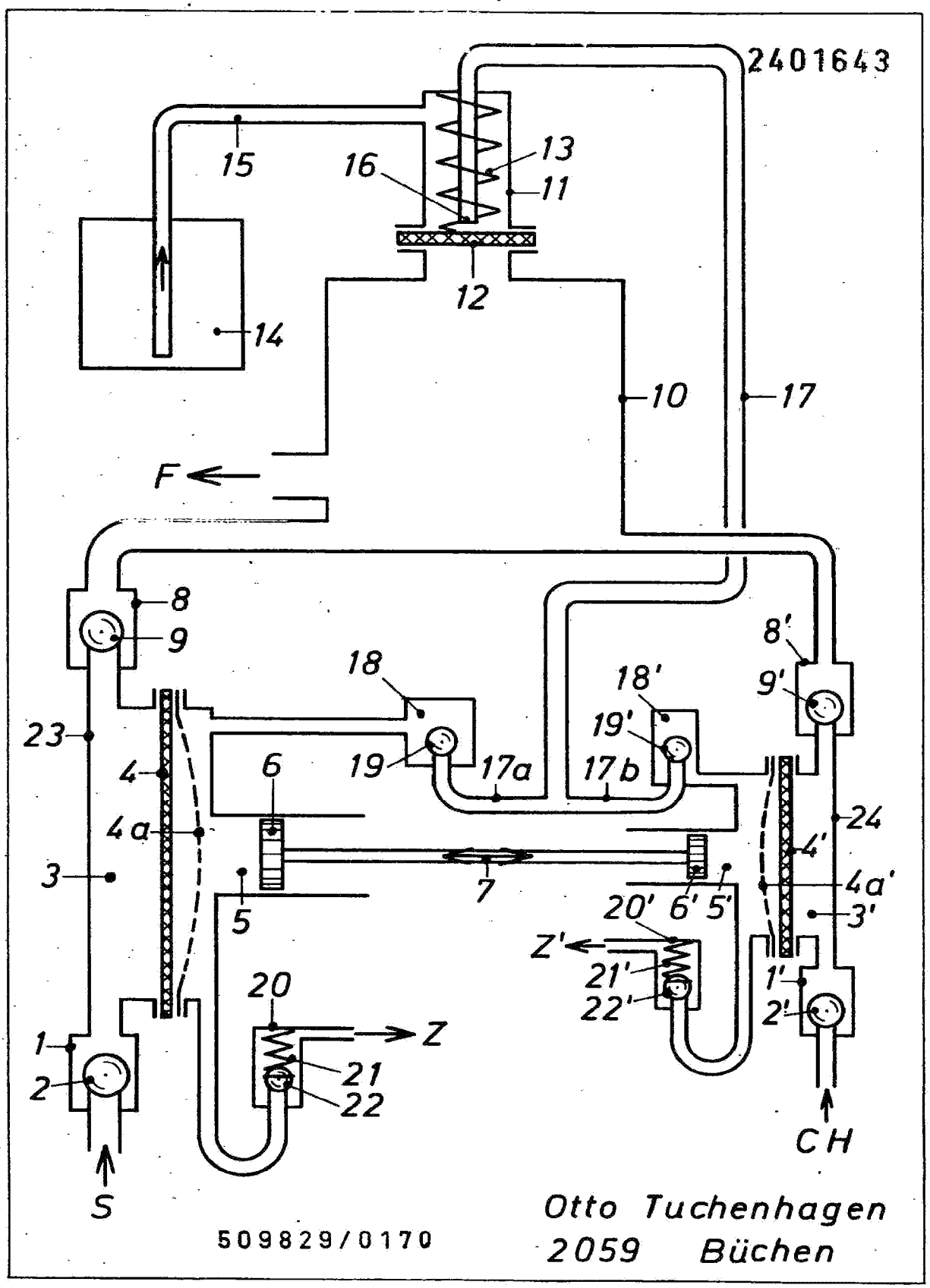
Solventum-Exhibit 1013-0253

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.

Solventum-Exhibit 1013-0254



Fo4B 43-06 AT:15.01.1974 OT:17.07.1975 wg

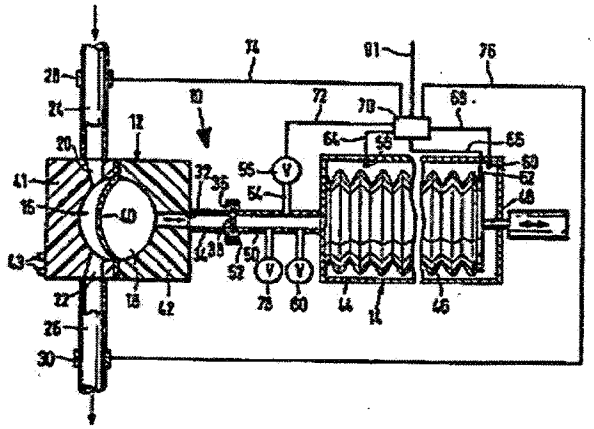
Solventum-Exhibit 1013-0255

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

Family:

Publication number	Publication date	Application number	Application date
DE3408331 A1	19850912	DE19843408331	19840307
DE3408331 C2	19860612	DE19843408331	19840307
DE3582897 D1	19910627	DE19853582897	19850306
EP0156211 A2	19851002	EP19850102535	19850306
EP0156211 A3	19871007	EP19850102535	19850306
EP0156211 B1	19910522	EP19850102535	19850306
JP2050636 C3	19960510	JP19850045724	19850307
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JP7078389 B4	19950823	JP19850045724	19850307
US4634430 A	19870106	US19850709167	19850307

Priority: DE19843408331 19840307 DE19853582897 19850306

Cited documents: US4552552, US4303376, US4265600, US3568214, US3449767, US3213804, US2855144, US2311229, GB716399, FR2304357, EP0088900, DE3205449,

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

(11) Veröffentlichungsnummer: **0 156 211**
A2

(12) EUROPÄISCHE PATENTANMELDUNG

(21) Anmeldenummer: 85102535.3

(22) Anmeldetag: 06.03.85

(51) Int. Cl.⁴: A 61 M 1/00
A 61 M 1/10, F 04 B 43/06

(30) Priorität: 07.03.84 DE 3408331

(43) Veröffentlichungstag der Anmeldung:
02.10.85 Patentblatt 85/40

(84) Benannte Vertragsstaaten:
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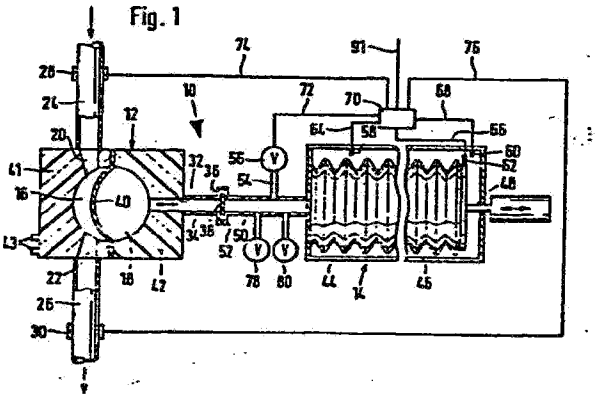
(74) Vertreter: KUHNEN & WACKER Patentanwaltsbüro
Schneggstrasse 3-5 Postfach 1729
D-8050 Freising(DE)

(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 Pumpkammem (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

Croydon Printing Company Ltd.

Solventum-Exhibit 1013-0257

FRESENIUS AG
6380 Bad Homburg vdH

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

Solventum-Exhibit 1013-0258

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.

Solventum-Exhibit 1013-0259

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 $P \times V = \text{constant}$ 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 Bälgvolumen)

$V_T = 80\ cm^3$

d.h. im Grenzfall kann zwar gerade der Ansaugunterdruck

Solventum-Exhibit 1013-0260

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.

Solventum-Exhibit 1013-0261

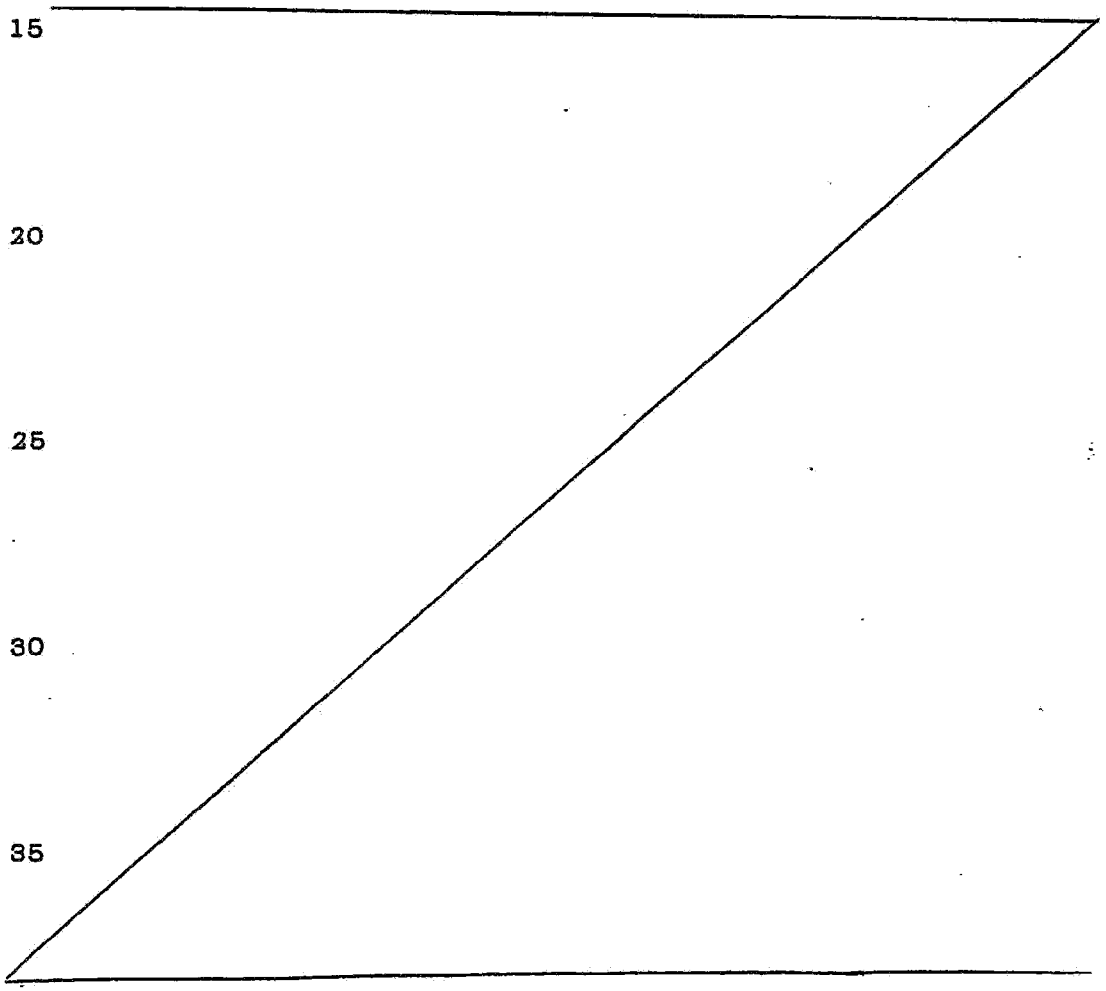
Demzufolge wird bei den eingangs erwähnten Maßnahmen (V_1 = 50, V_2 = 30, p_{min} = -400 mbar und p_{max} = 600 mbar) folgendes Pumpergebnis erzielt:

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

$p\ 30 \times 1000 = 50 \times p_E$

p_E = 600 mbar abs. = -400 mbar rel.



Solventum-Exhibit 1013-0262

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

Solventum-Exhibit 1013-0263

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

Solventum-Exhibit 1013-0264

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

Solventum-Exhibit 1013-0265

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

Solventum-Exhibit 1013-0266

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.

Solventum-Exhibit 1013-0267

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-

Solventum-Exhibit 1013-0268

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.

Solventum-Exhibit 1013-0269

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.

Solventum-Exhibit 1013-0270

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

Solventum-Exhibit 1013-0271

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

Solventum-Exhibit 1013-0272

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

Solventum-Exhibit 1013-0273

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

Solventum-Exhibit 1013-0274

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

Solventum-Exhibit 1013-0275

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.

Solventum-Exhibit 1013-0276

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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.

Solventum-Exhibit 1013-0277

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.

Solventum-Exhibit 1013-0278

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

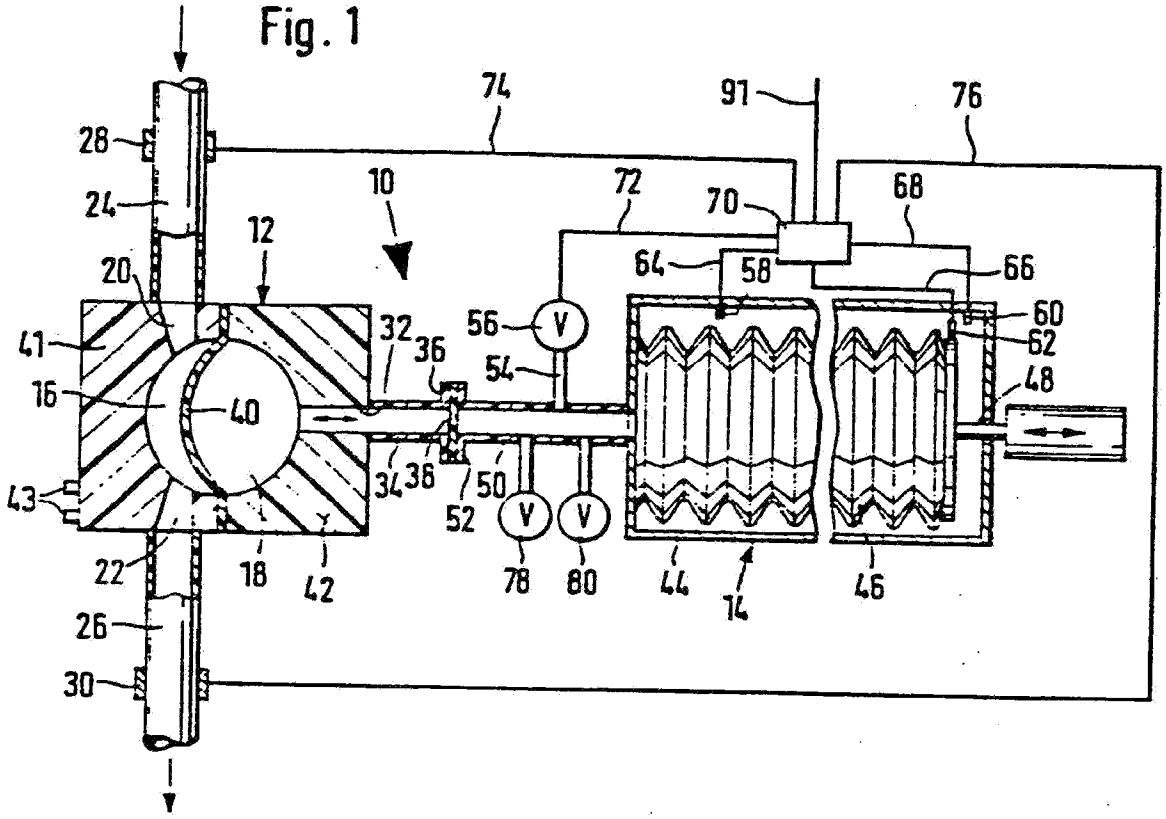
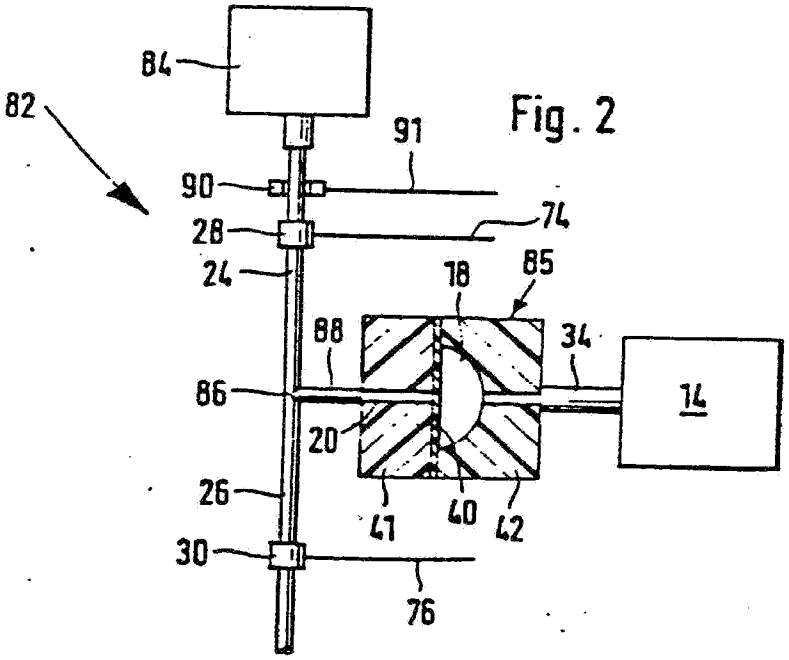
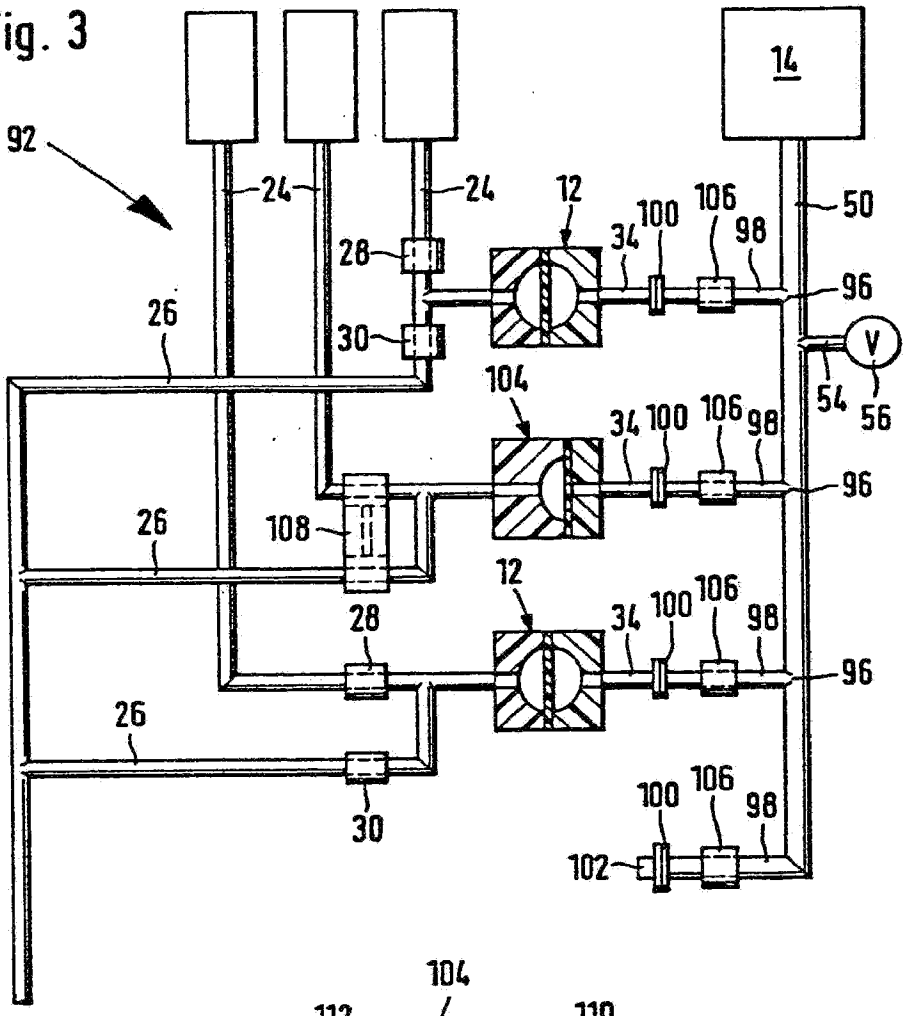


Fig. 2



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Fig. 3



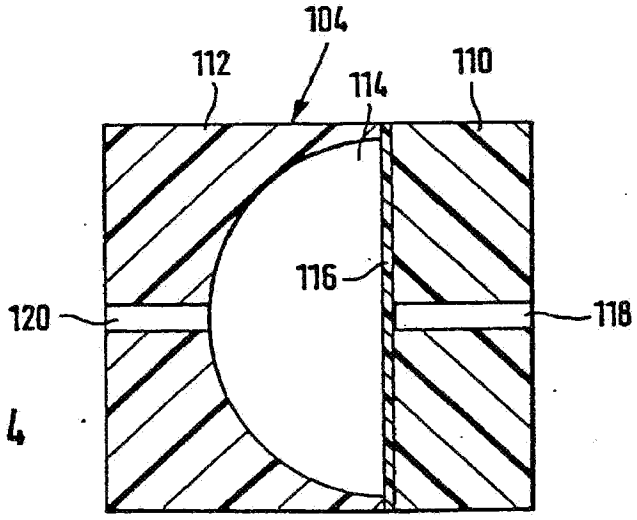


Fig. 4

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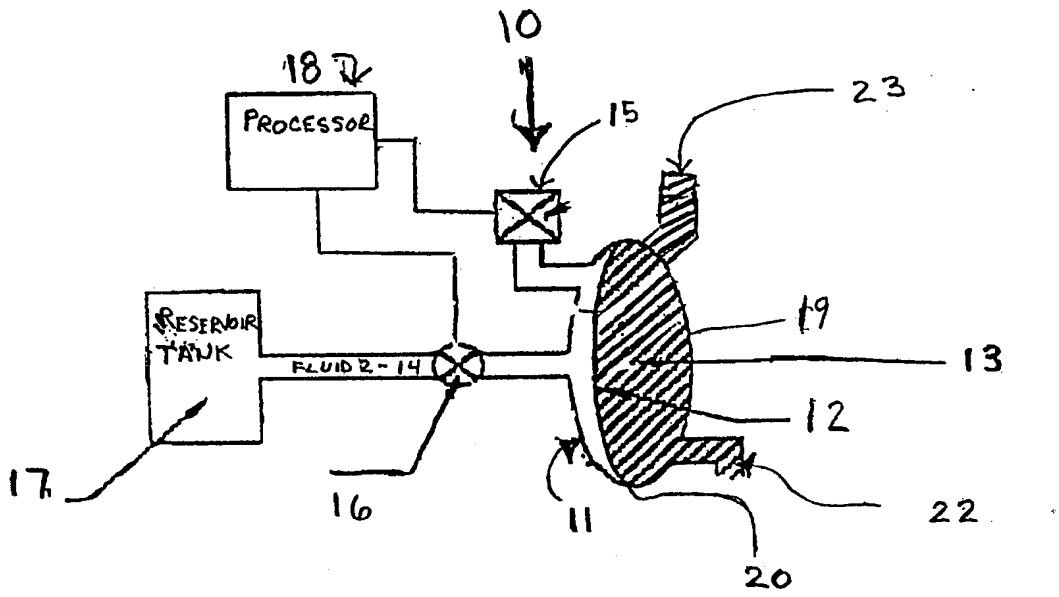
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(57) Abstract

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.

Solventum-Exhibit 1013-0282

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Solventum-Exhibit 1013-0283

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;

Solventum-Exhibit 1013-0284

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

Solventum-Exhibit 1013-0285

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.

Solventum-Exhibit 1013-0286

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

Solventum-Exhibit 1013-0287

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

Solventum-Exhibit 1013-0288

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**

Solventum-Exhibit 1013-0289

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.

Solventum-Exhibit 1013-0290

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

Solventum-Exhibit 1013-0291

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

Solventum-Exhibit 1013-0292

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.

Solventum-Exhibit 1013-0293

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

Solventum-Exhibit 1013-0294

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,

Solventum-Exhibit 1013-0295

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;

Solventum-Exhibit 1013-0296

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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Solventum-Exhibit 1013-0297

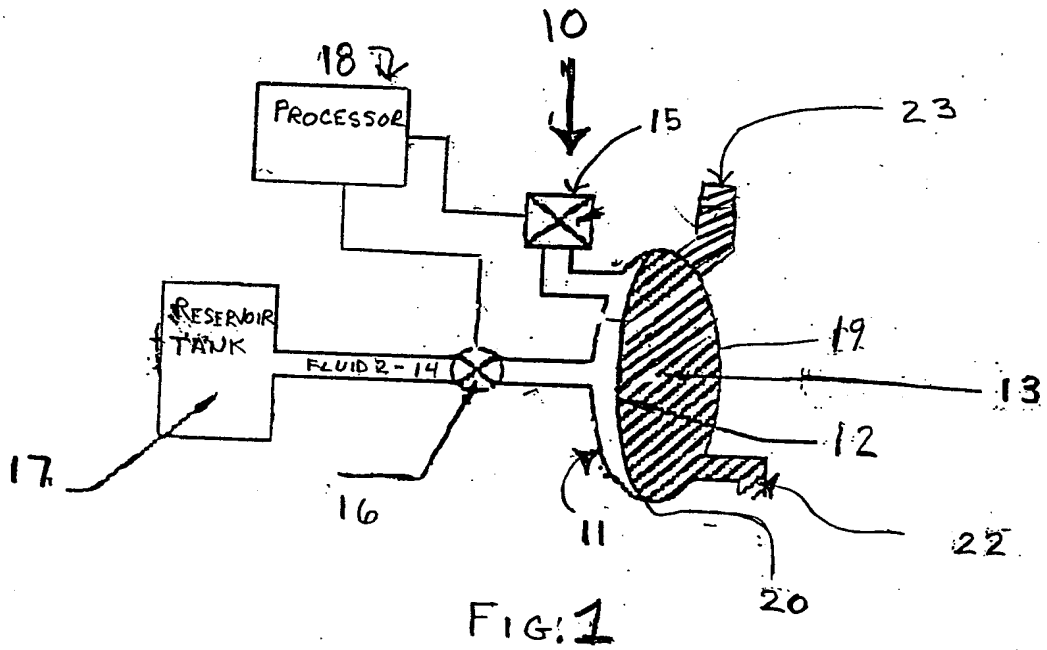
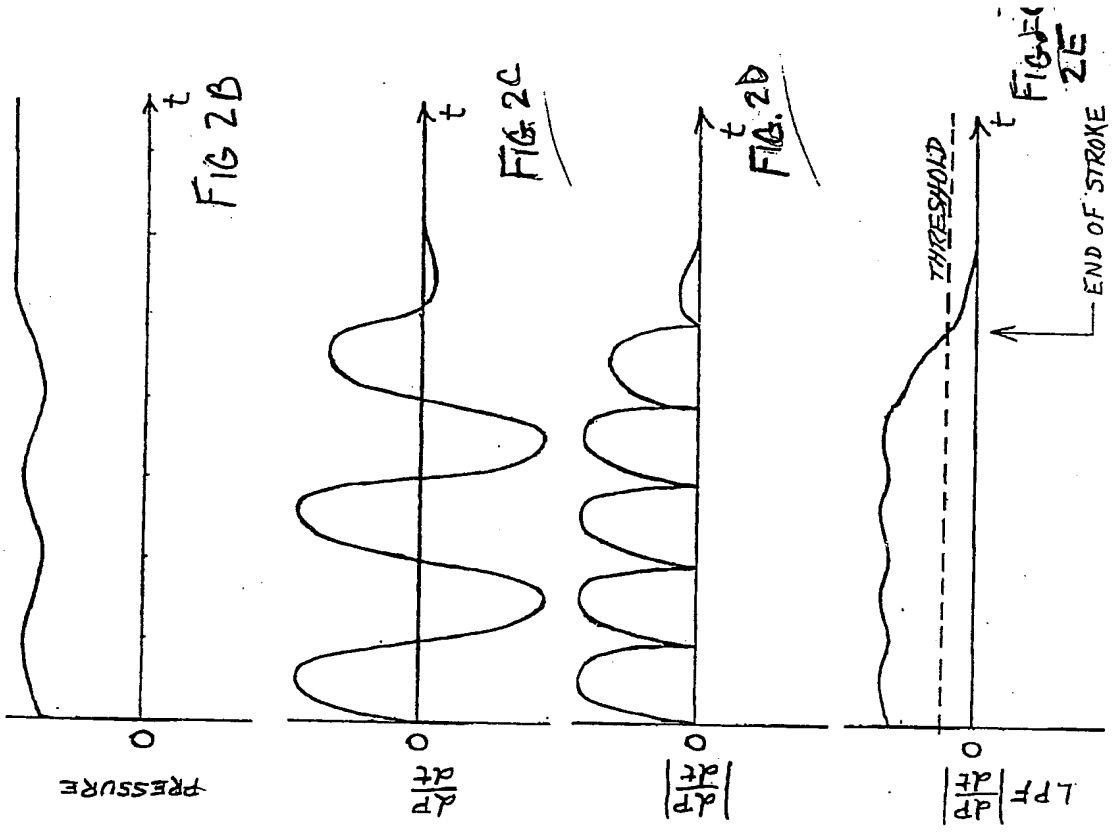


FIG. 1

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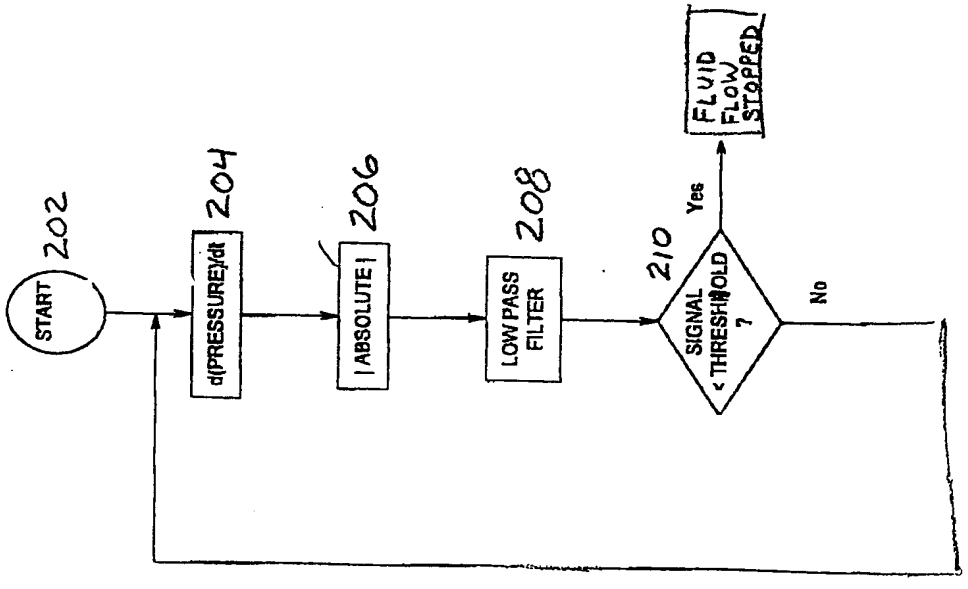


FIG. 2A

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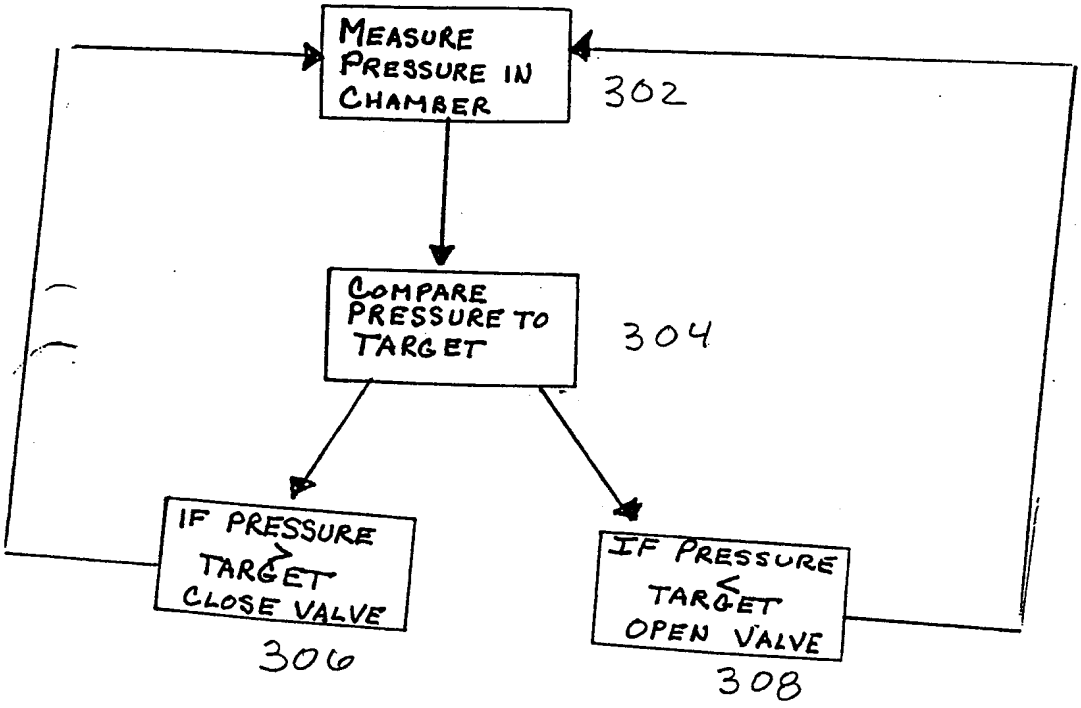


FIG. 3

Solventum-Exhibit 1013-0300

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
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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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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

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Solventum-Exhibit 1013-0301

INTERNATIONAL SEARCH REPORT

Information on patent family members

Interr nal Application No
PCT/US 99/14513

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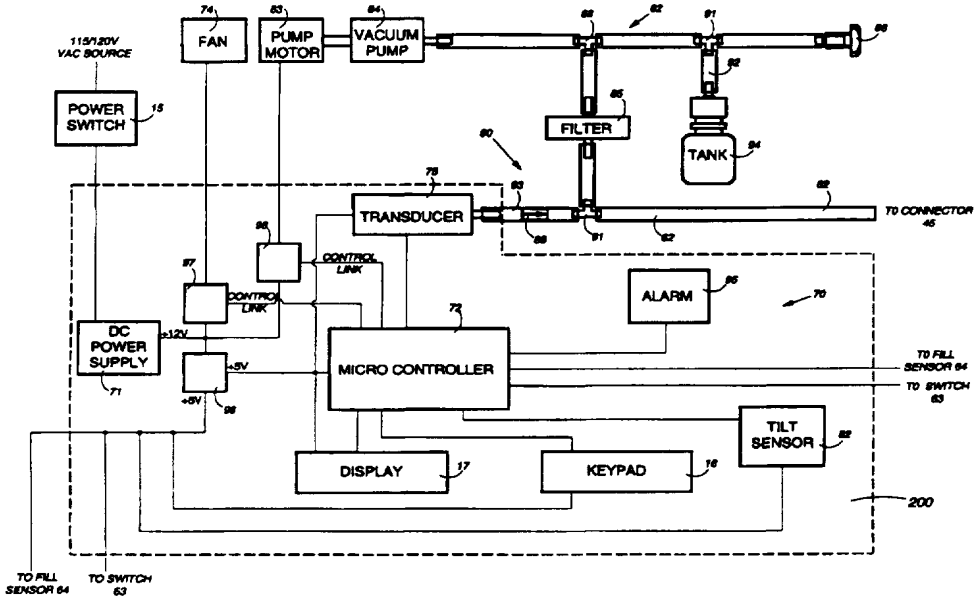
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Published
With international search report.

(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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Solventum-Exhibit 1013-0304

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,

Solventum-Exhibit 1013-0305

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.

Solventum-Exhibit 1013-0306

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.

Solventum-Exhibit 1013-0307

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

Solventum-Exhibit 1013-0308

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.

Solventum-Exhibit 1013-0309

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,

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

Solventum-Exhibit 1013-0311

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.

Solventum-Exhibit 1013-0312

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

Solventum-Exhibit 1013-0313

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

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

Solventum-Exhibit 1013-0315

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

Solventum-Exhibit 1013-0316

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

Solventum-Exhibit 1013-0317

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.

Solventum-Exhibit 1013-0318

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

Solventum-Exhibit 1013-0319

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

Solventum-Exhibit 1013-0321

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.

Solventum-Exhibit 1013-0323

When the unit is returned to the vertical, therapy will be automatically reinstated after a time delay (e.g. about 30 seconds) has elapsed..

Solventum-Exhibit 1013-0324

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.

Solventum-Exhibit 1013-0325

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.

Solventum-Exhibit 1013-0326

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.

Solventum-Exhibit 1013-0327

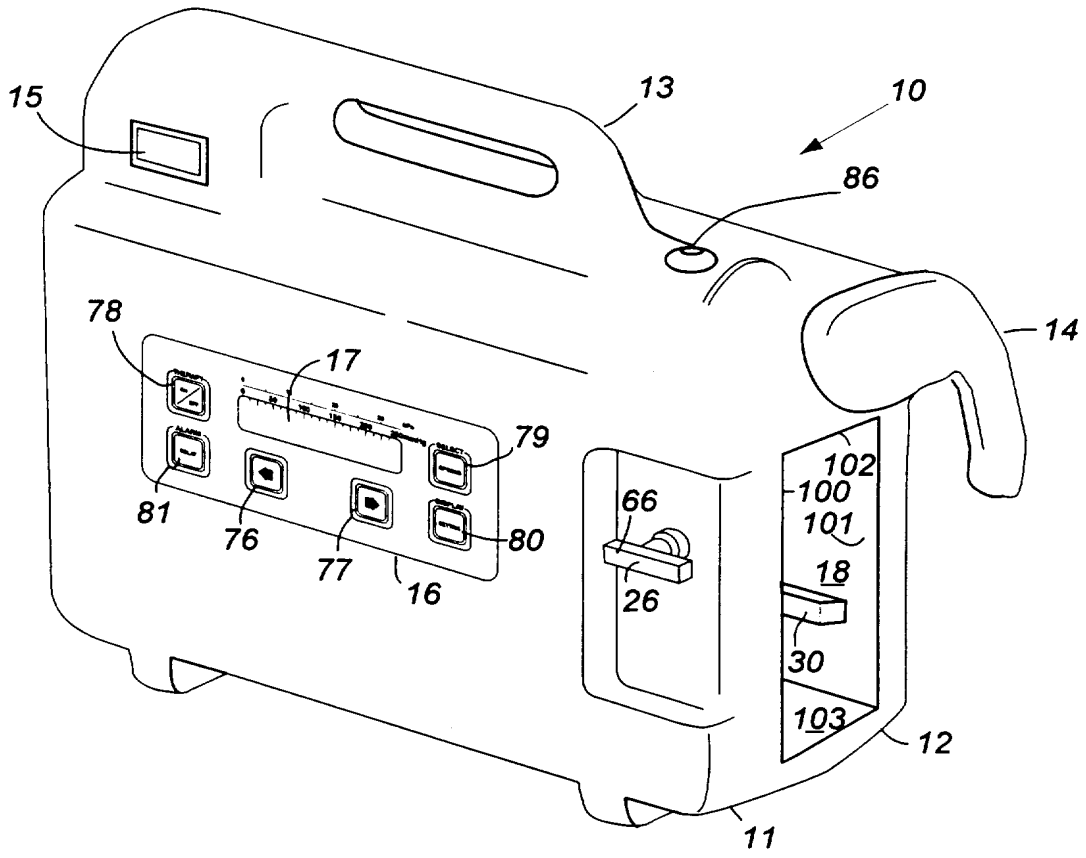


FIG.1

Solventum-Exhibit 1013-0328

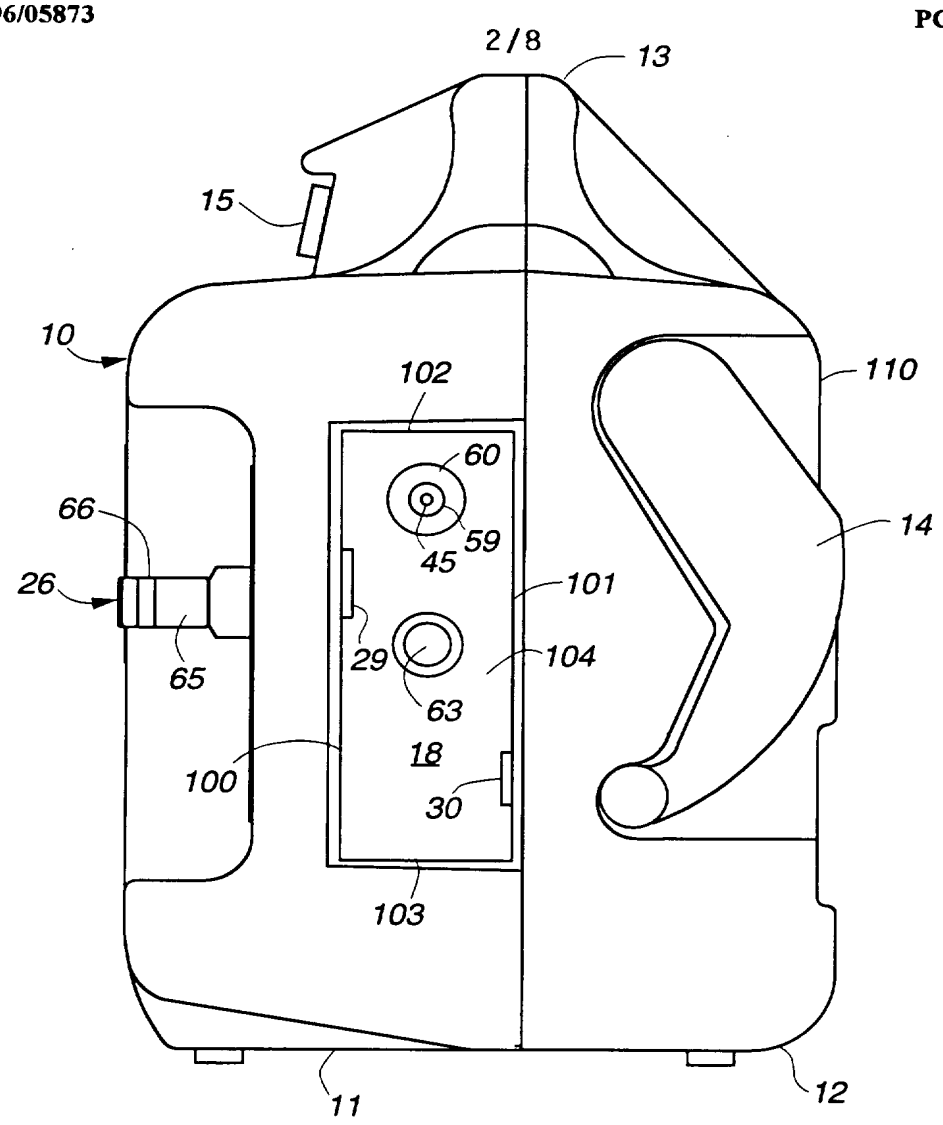


FIG.2

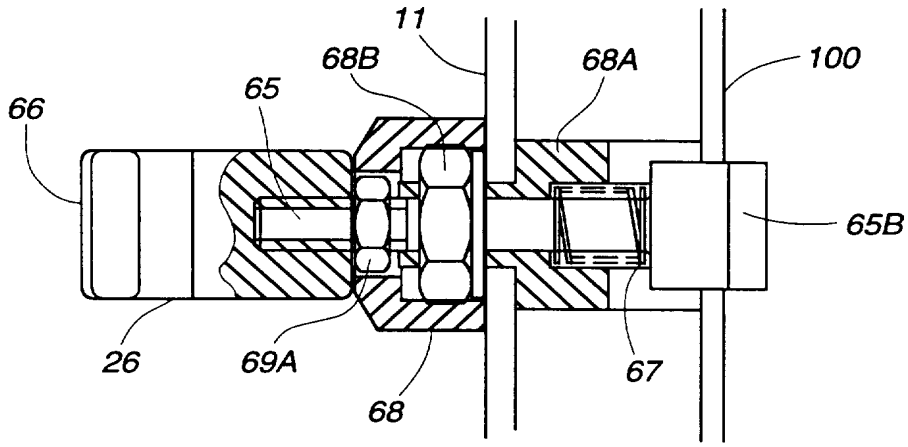


FIG.2A

Solventum-Exhibit 1013-0329

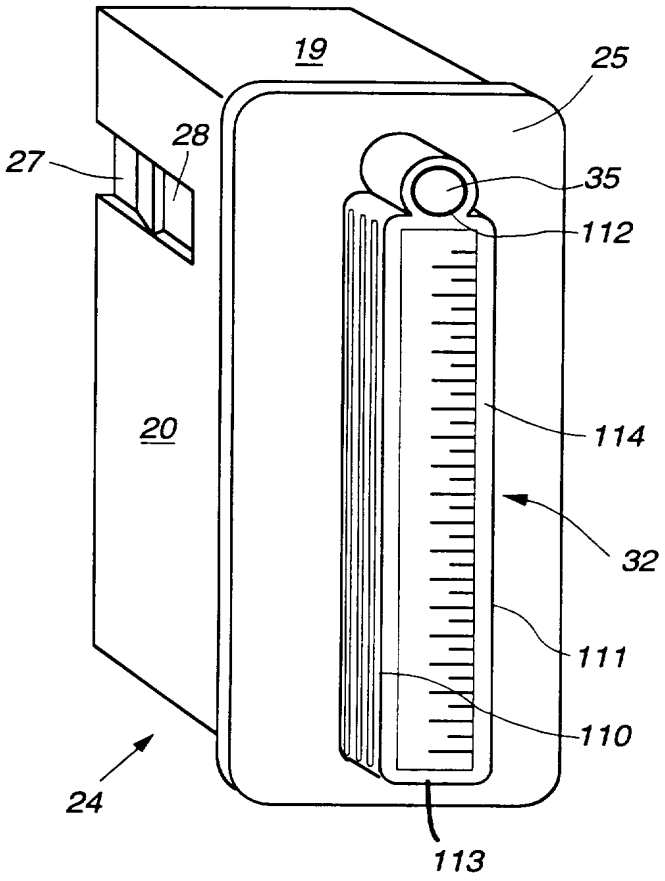


FIG.3

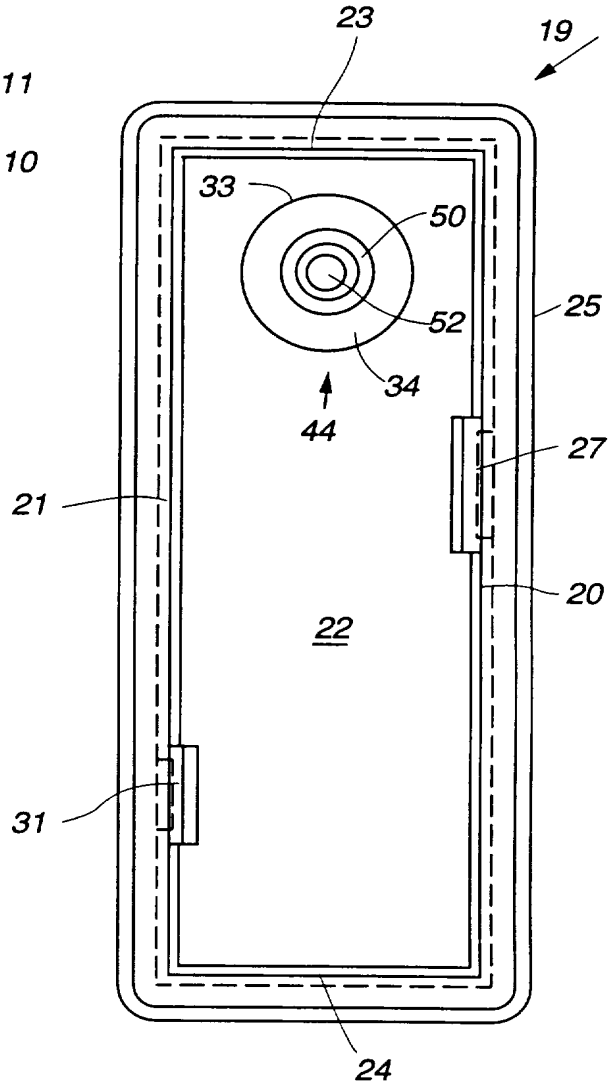


FIG.4

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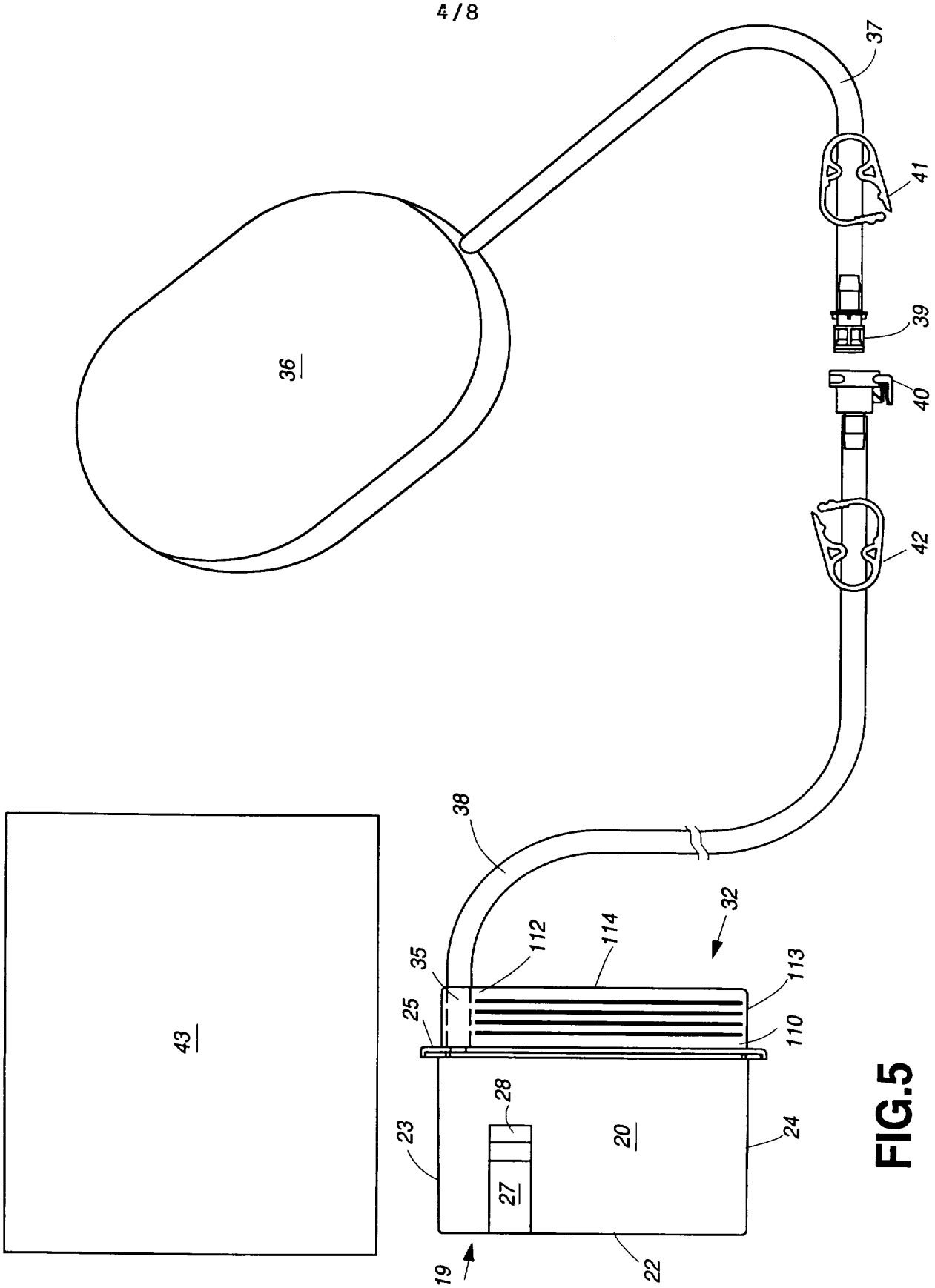


FIG.5

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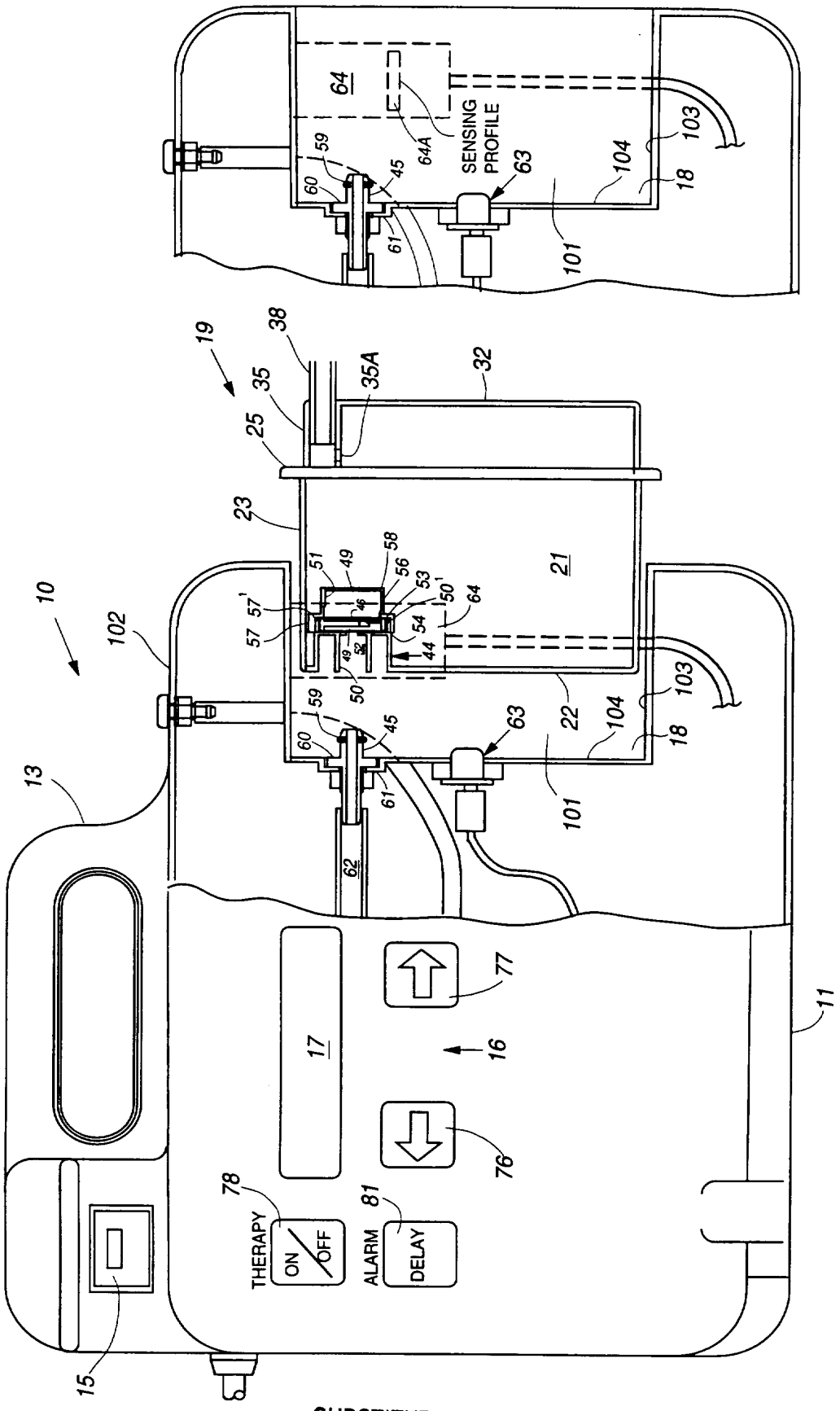


FIG.6A

FIG.6

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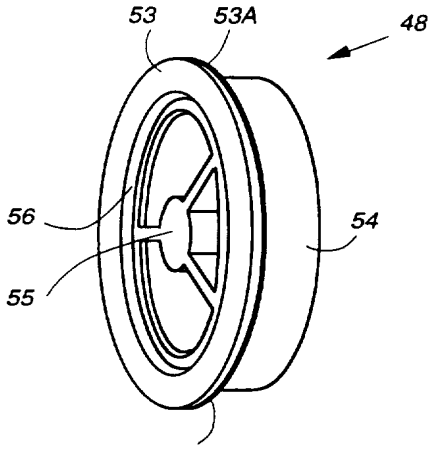


FIG.7

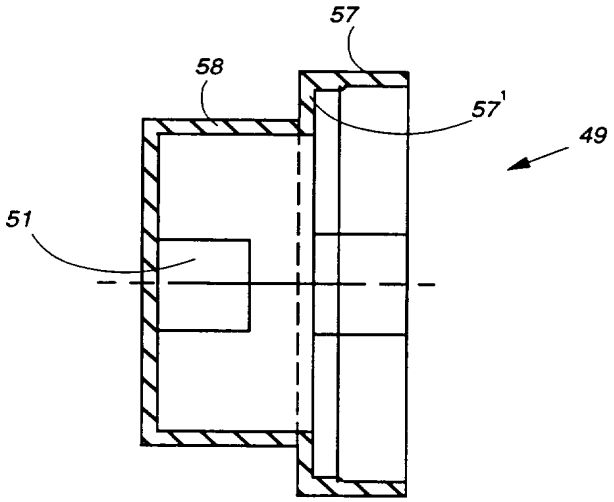


FIG.8

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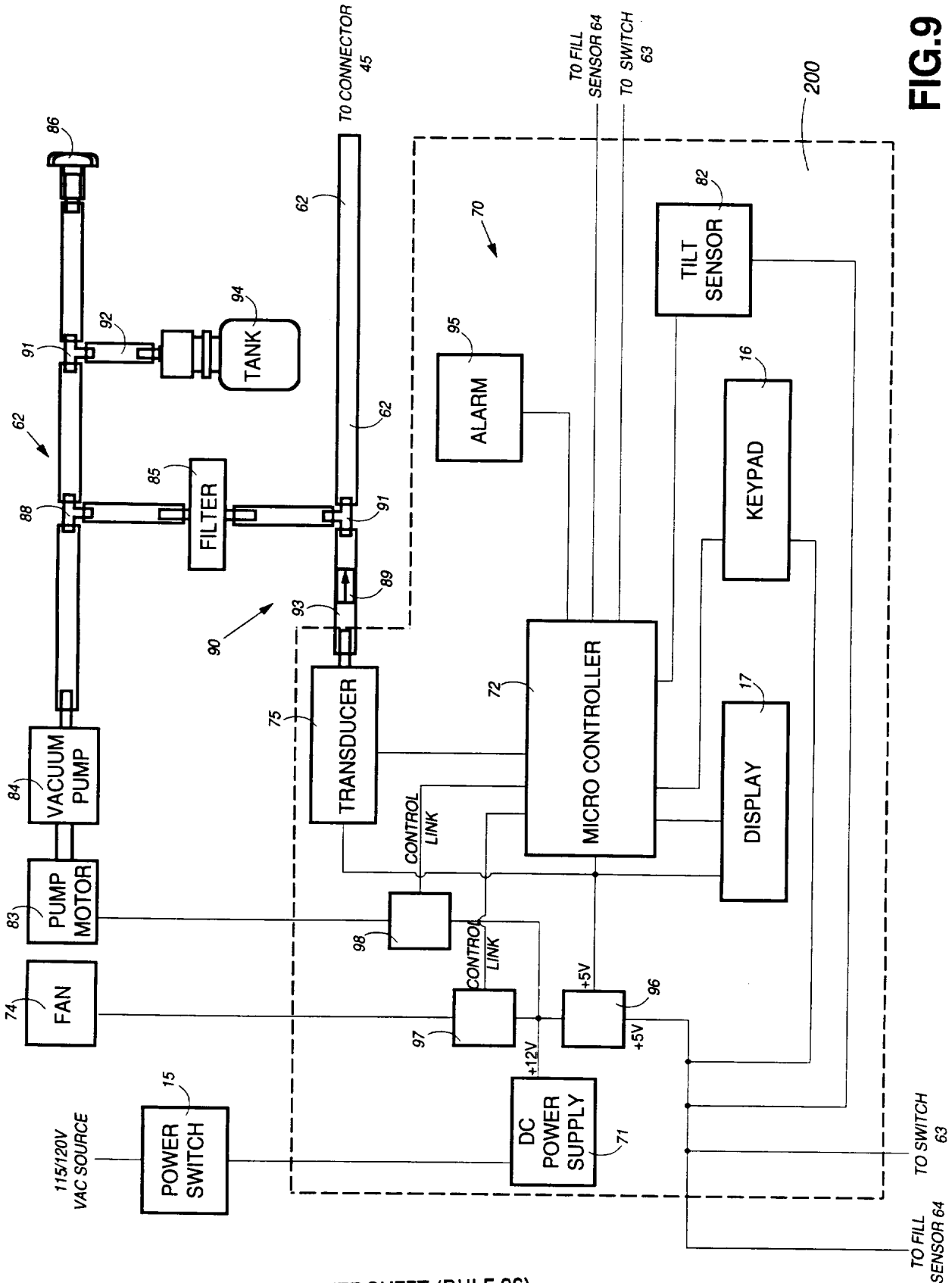


FIG.9

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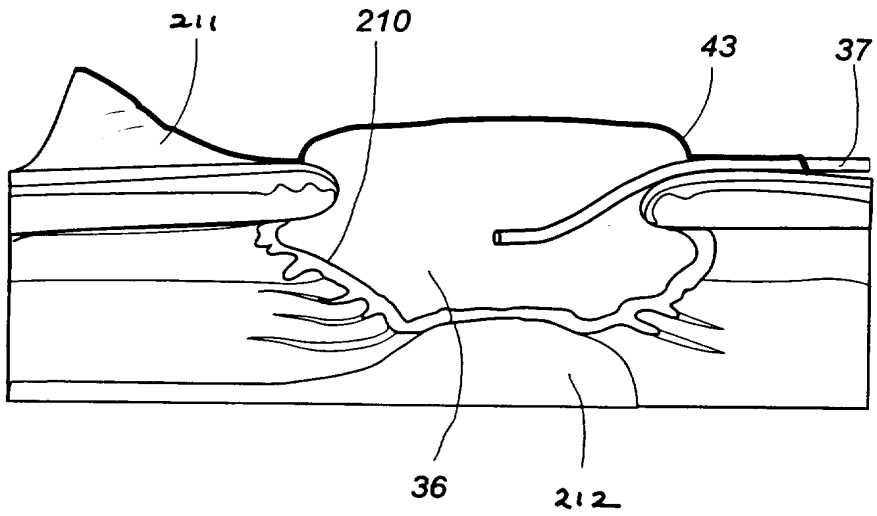


FIG.10

Solventum-Exhibit 1013-0335

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.

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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

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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	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	Zeinstra, H

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

Solventum-Exhibit 1013-0336

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
A	WO,A,93 09727 (WAKE FOREST UNIVERSITY) 27 May 1993 cited in the application	

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Solventum Exhibit 1013-0337

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int. ..onal Application No
PCT/GB 95/01983

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
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		GB-A-	1574066	03-09-80
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		JP-T-	7501958	02-03-95

Solventum-Exhibit 1013-0338

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(43) Date of A Publication 19.02.2003

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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.

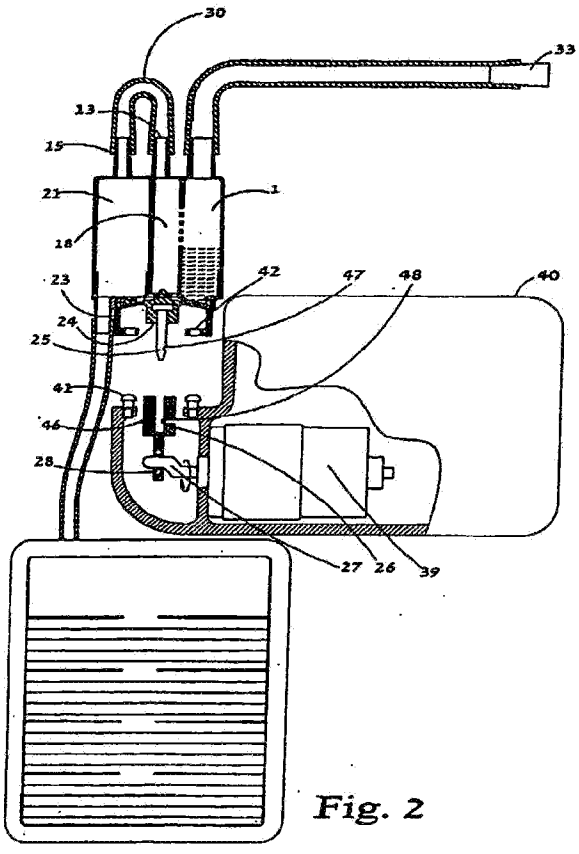


Fig. 2

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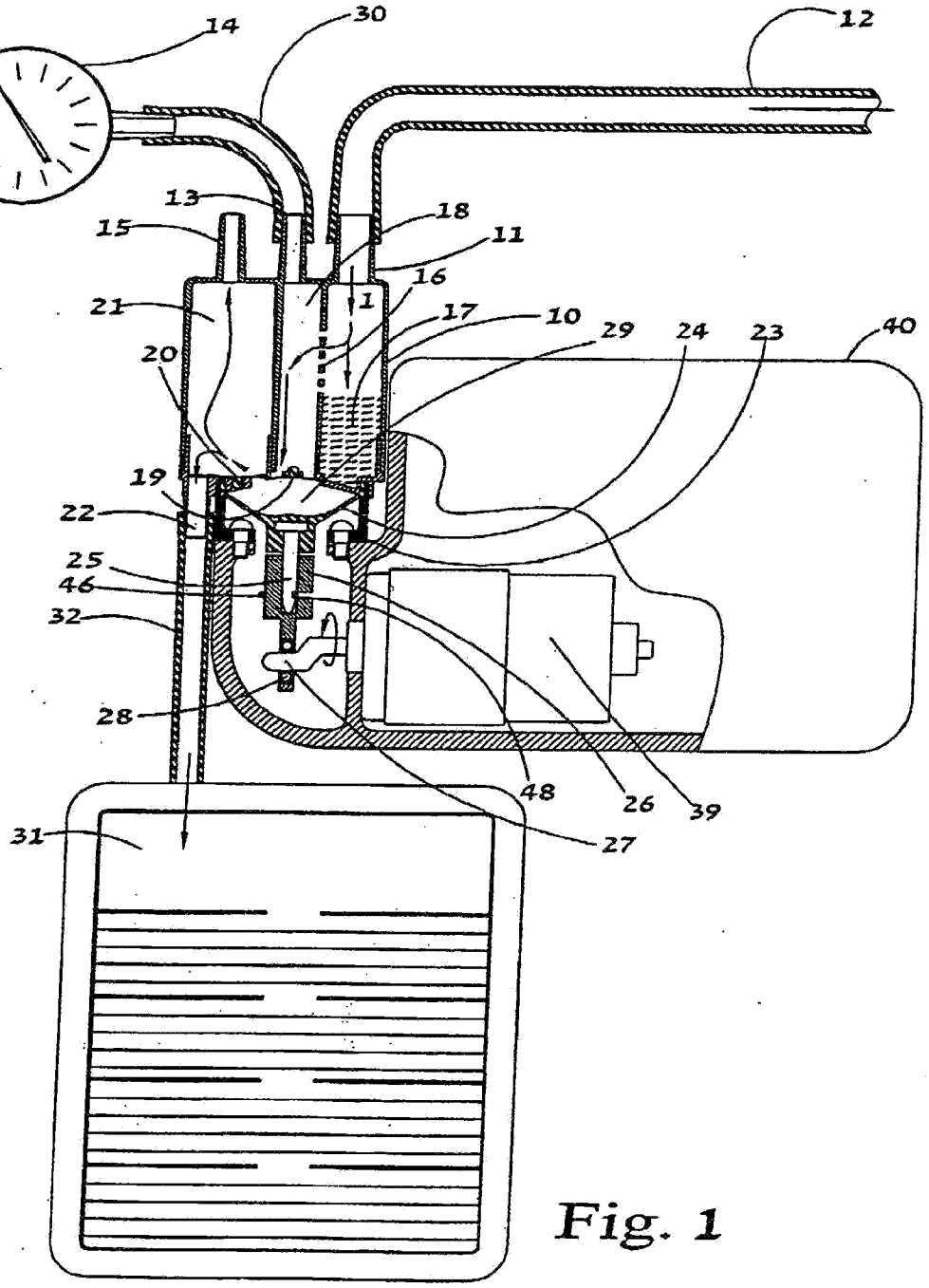

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Fig. 1

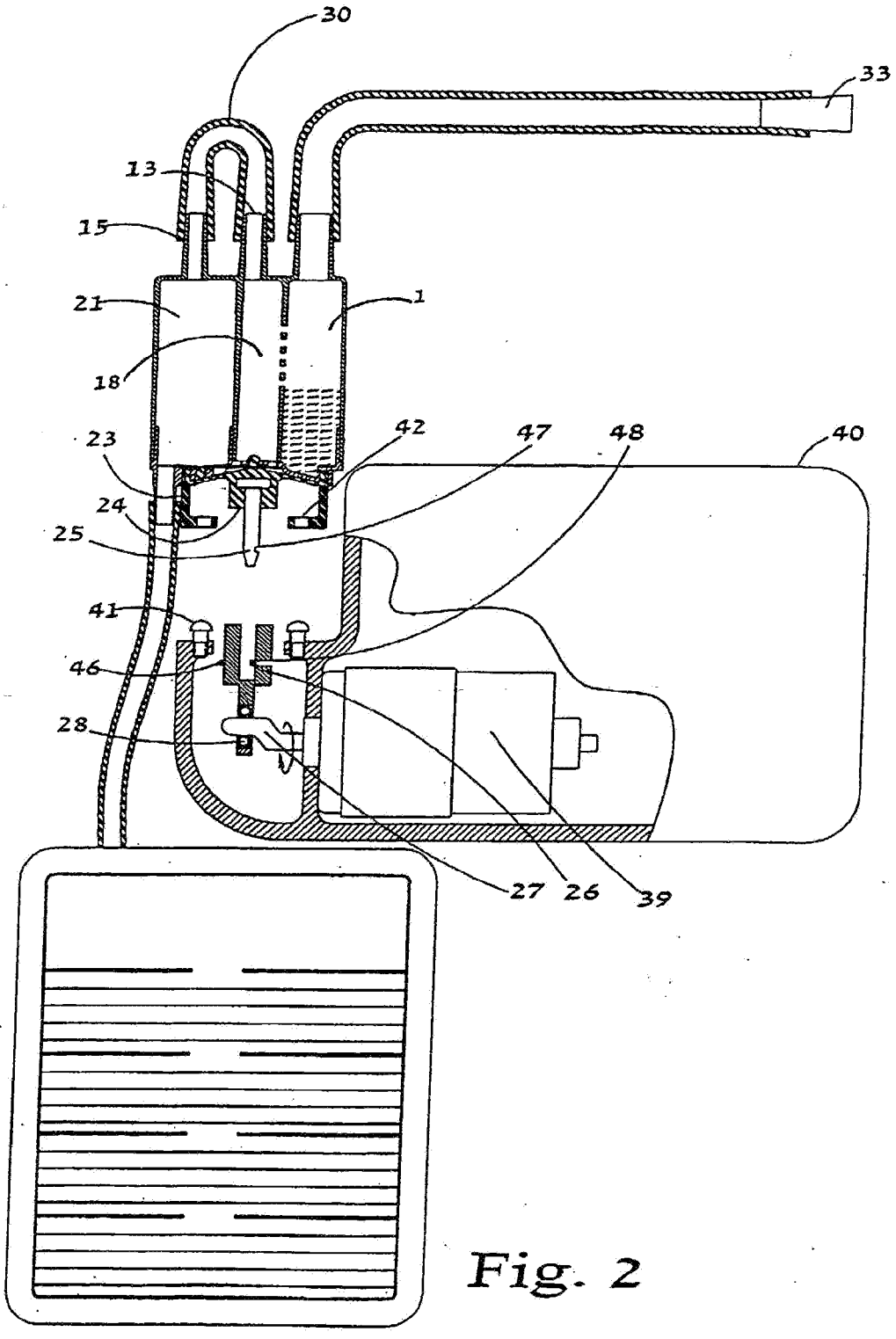


Fig. 2

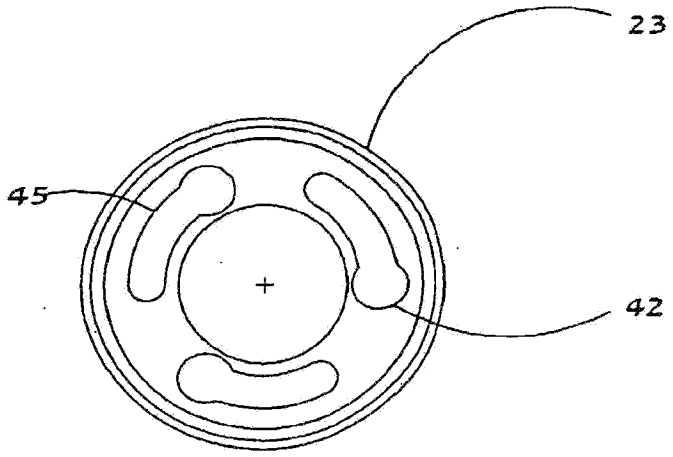


Fig. 3

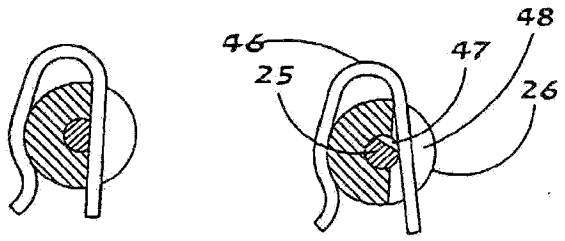


Fig.4

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

Solventum-Exhibit 1013-0351

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

Solventum-Exhibit 1013-0353

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

Solventum-Exhibit 1013-0355

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

Solventum-Exhibit 1013-0359

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.

Solventum-Exhibit 1013-0365

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.

Solventum-Exhibit 1013-0366

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.

Solventum-Exhibit 1013-0367

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.

Solventum-Exhibit 1013-0369

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(30) Priority Data
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A61M 1/00

(52) UK CL (Edition O)
A5R RCEB

(56) Documents Cited
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(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.

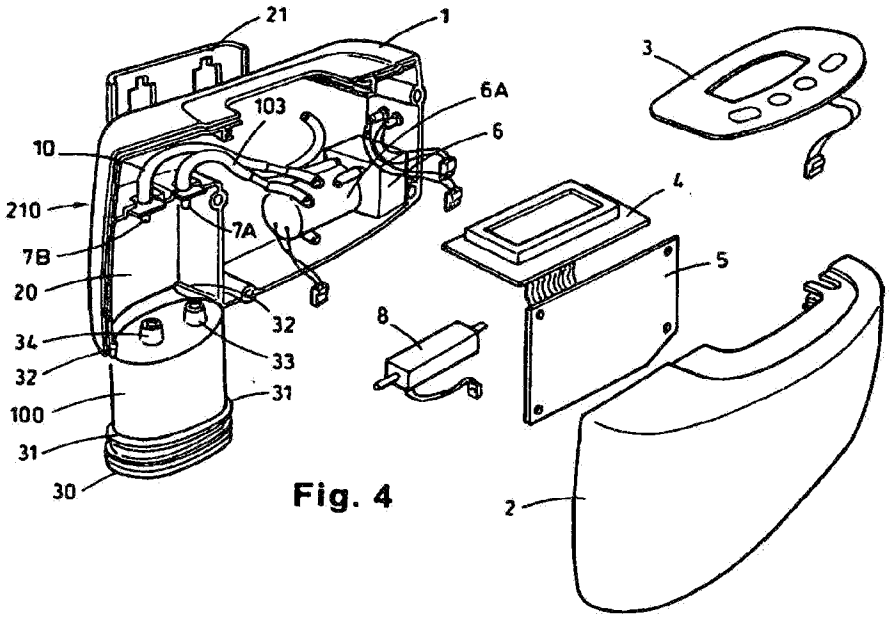


Fig. 4

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.

Solventum-Exhibit 1013-0370

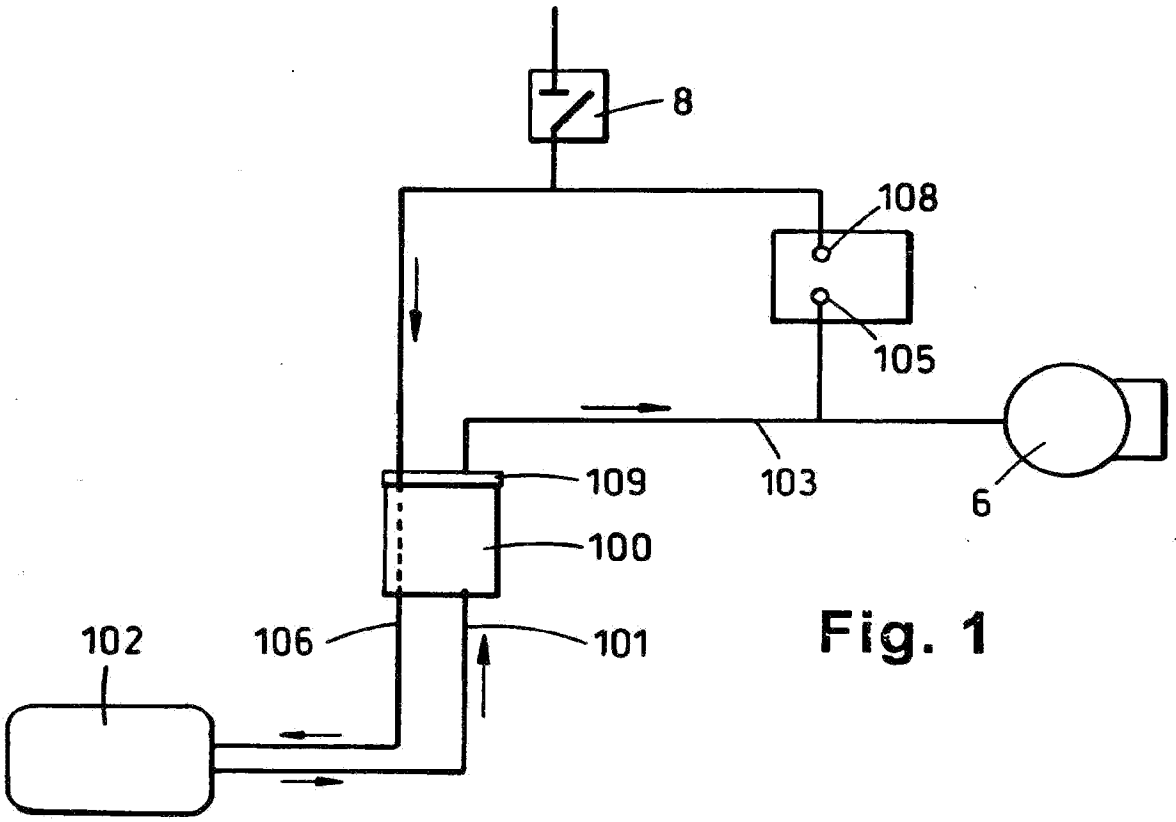


Fig. 1

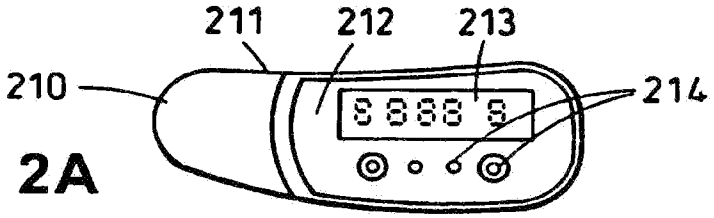


Fig. 2A

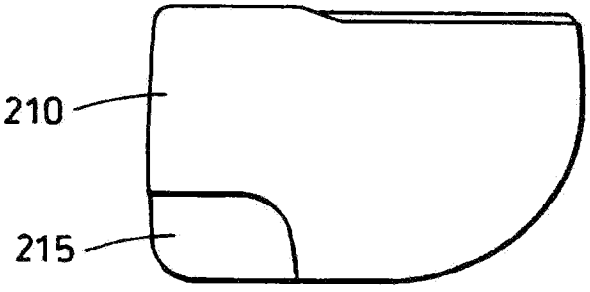


Fig. 2B

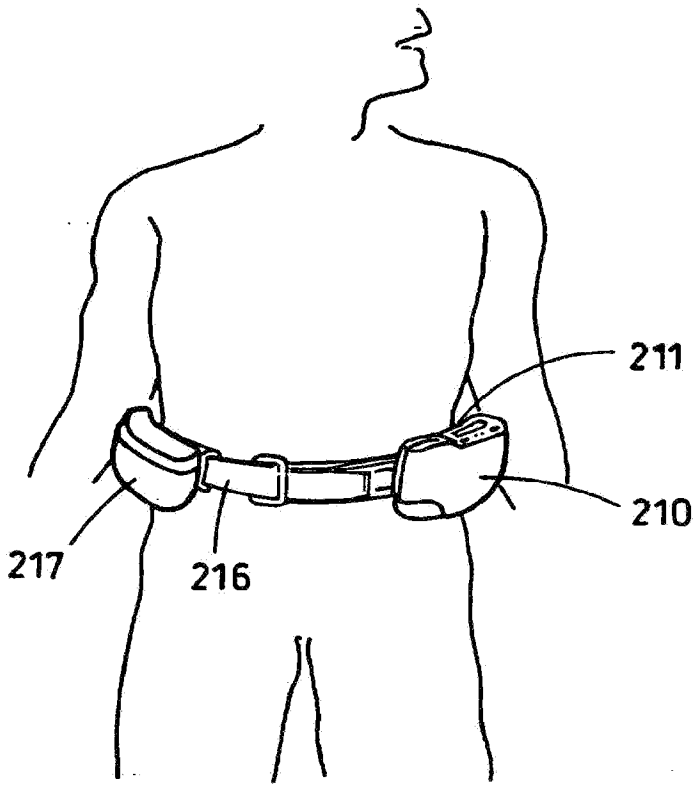


Fig. 3A

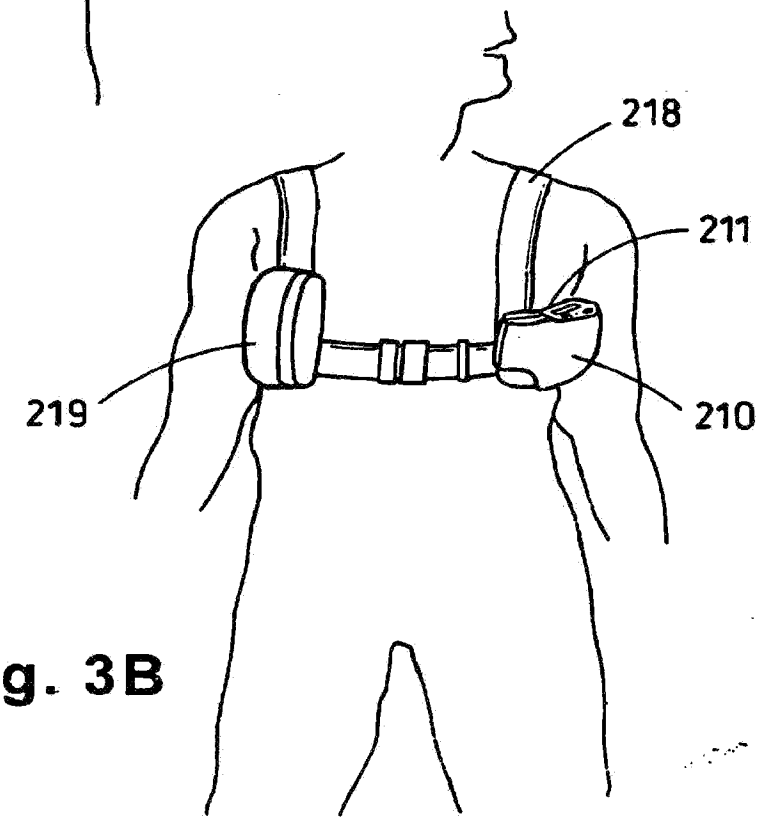


Fig. 3B

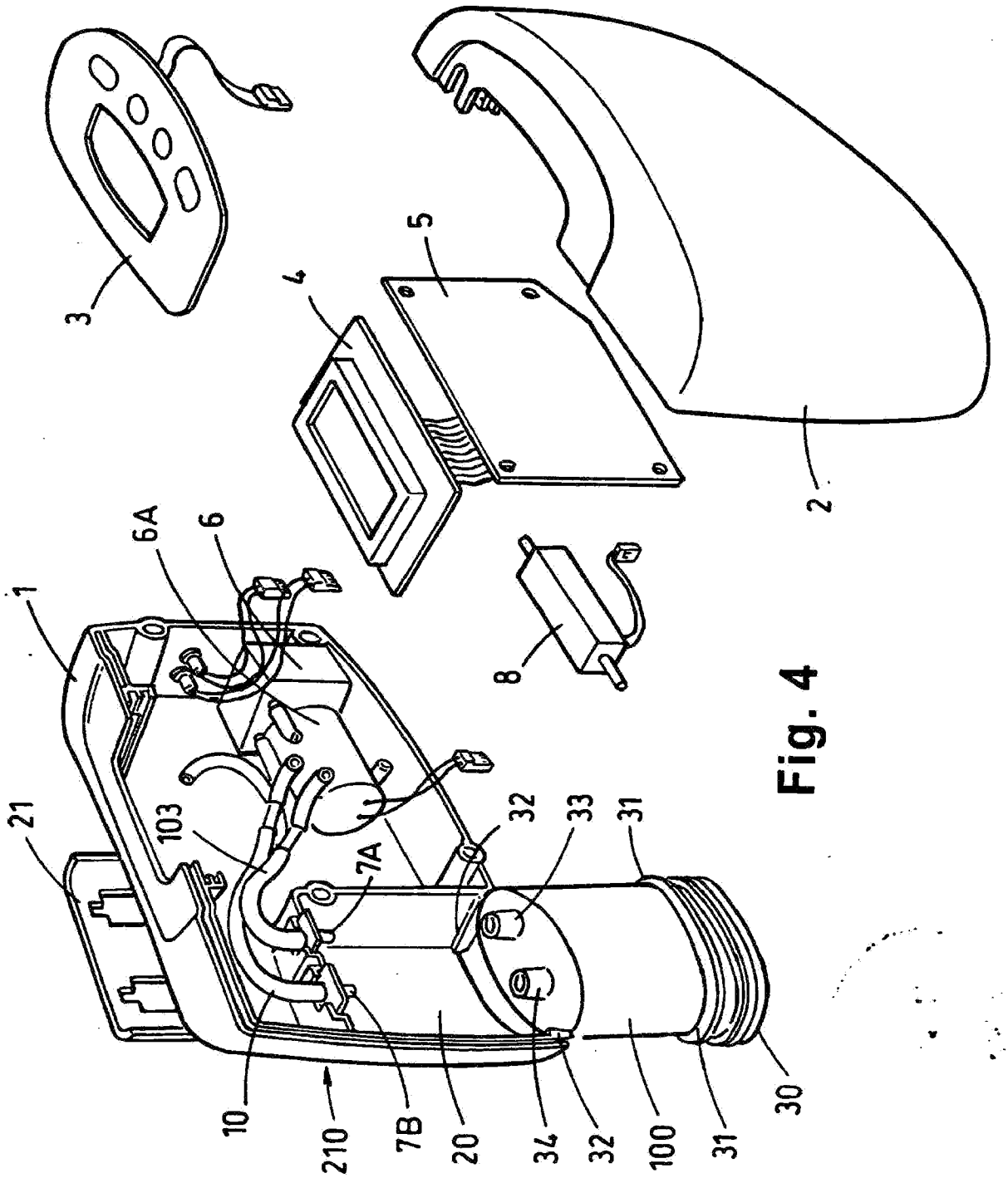


Fig. 4

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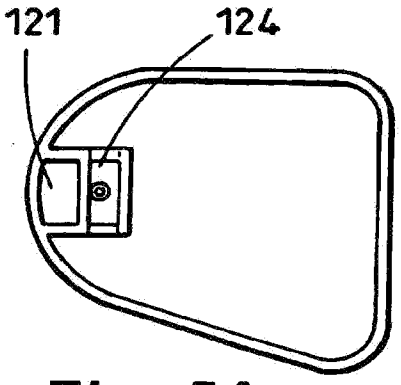


Fig. 5A

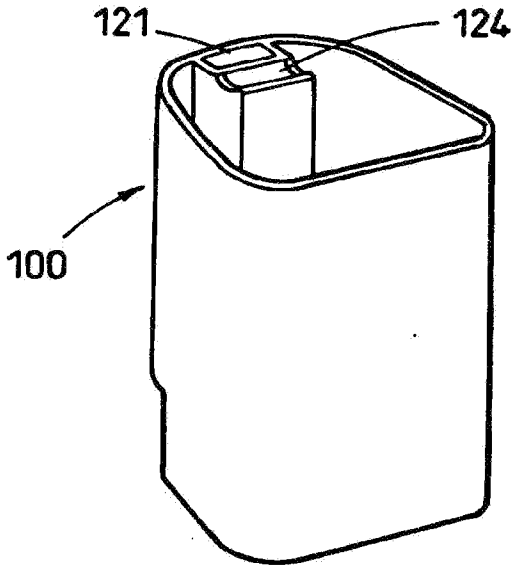


Fig. 5D

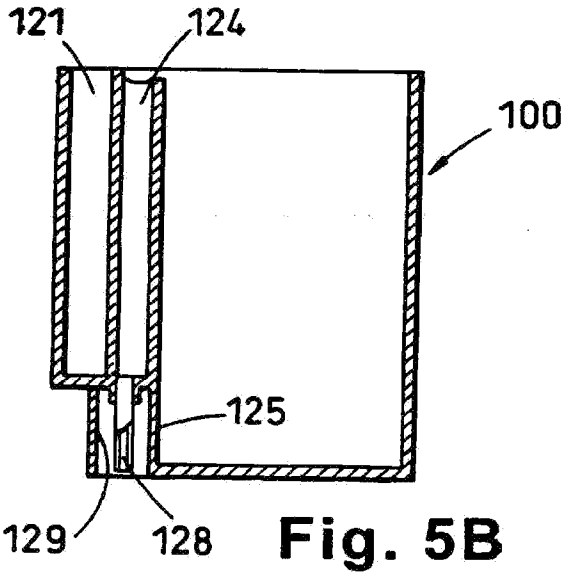


Fig. 5B

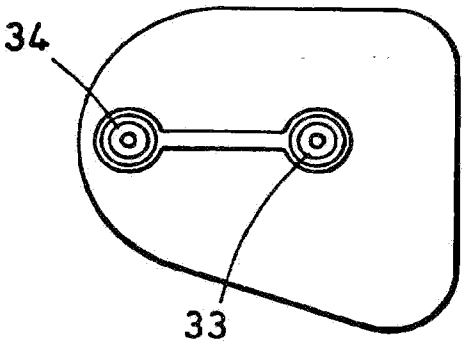


Fig. 5E

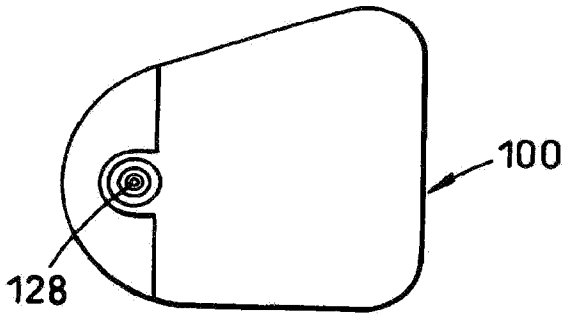


Fig. 5C

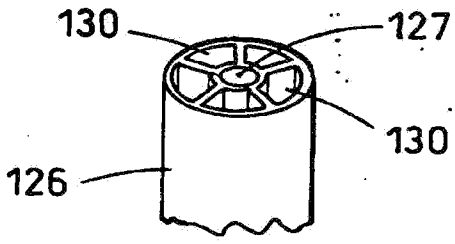


Fig. 5F

Solventum-Exhibit 1013-0374

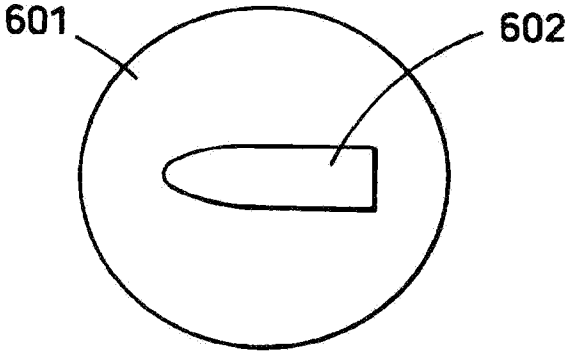


Fig. 6A

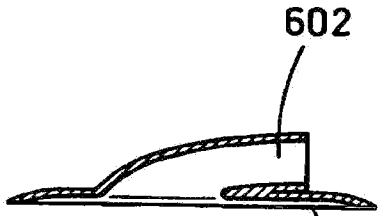


Fig. 6B



Fig. 6C

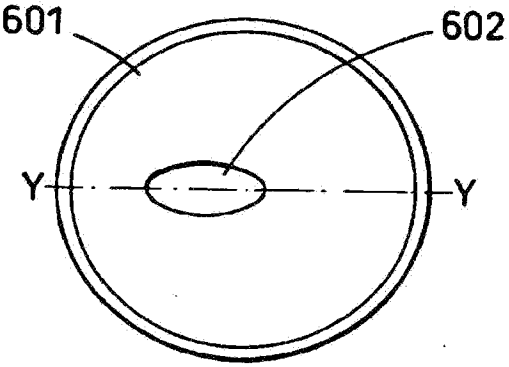


Fig. 6D

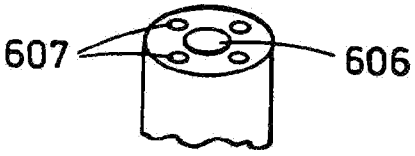


Fig. 6E

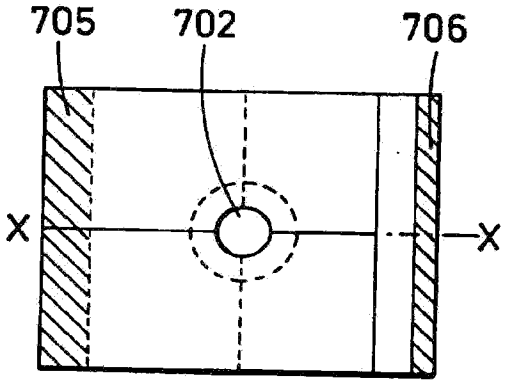


Fig. 7A

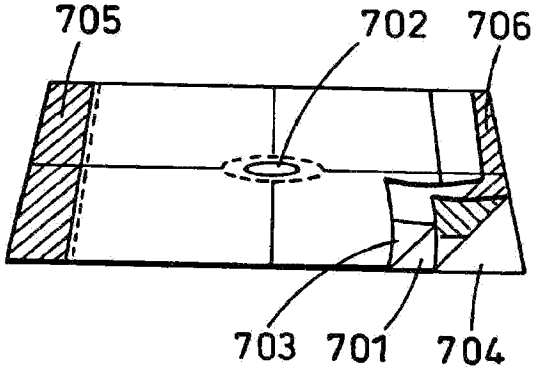


Fig. 7B

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

Solventum-Exhibit 1013-0376

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

Solventum-Exhibit 1013-0377

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

Solventum-Exhibit 1013-0378

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

Solventum-Exhibit 1013-0379

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

Solventum-Exhibit 1013-0380

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

Solventum-Exhibit 1013-0381

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

Solventum-Exhibit 1013-0382

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

Solventum-Exhibit 1013-0383

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.

Solventum-Exhibit 1013-0384

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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Application No: GB 9623743.3 **Examiner:** Mr S J Pilling
Claims searched: 1 and 2 **Date of search:** 11 February 1997

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.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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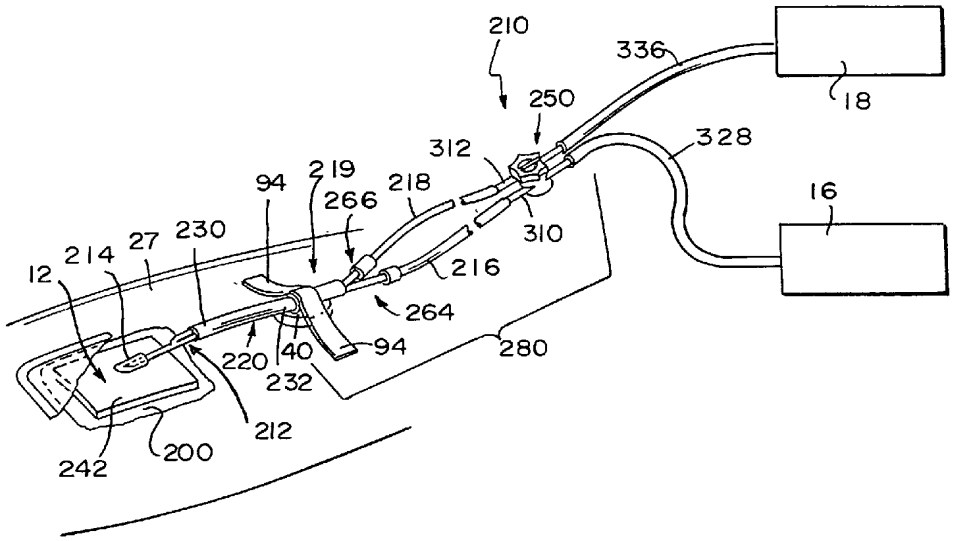
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[Continued on next page]

(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).

WO 03/057070 A2

Solventum-Exhibit 1013-0388

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