

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
23 December 2004 (23.12.2004)

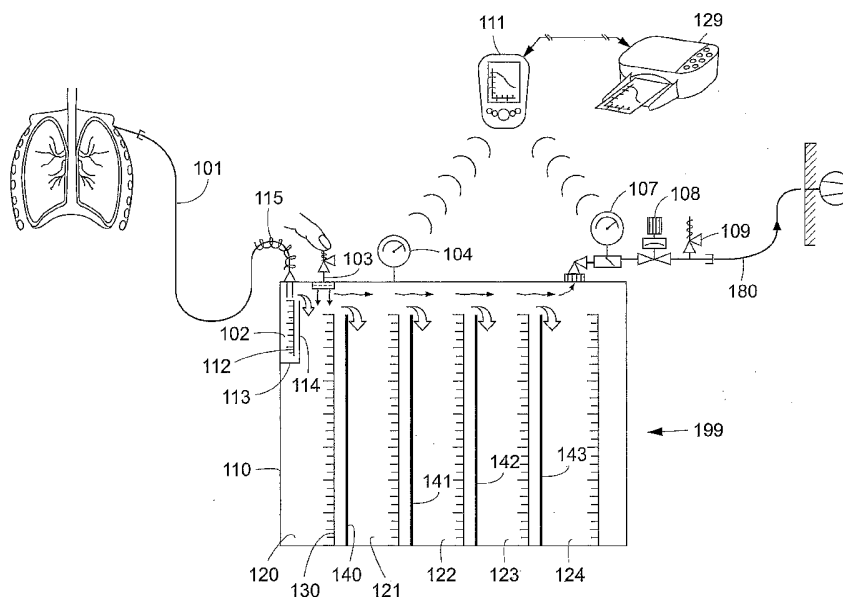
PCT

(10) International Publication Number
WO 2004/110523 A1

- (51) International Patent Classification⁷: **A61M 1/00**, 60 Mölndal (SE). **PETTERSSON, Torbjörn** [SE/SE]; G01F 1/68 Guldhedstorget 1, S-413 21 Göteborg (SE).
- (21) International Application Number: PCT/SE2004/000637 (74) Agents: **LINDAHL, Dan** et al.; Albihns Malmö AB, P O Box 4289, S-203 14 Malmö (SE).
- (22) International Filing Date: 26 April 2004 (26.04.2004) (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
0301817-3 19 June 2003 (19.06.2003) SE
0302434-6 11 September 2003 (11.09.2003) SE
60/481,377 15 September 2003 (15.09.2003) US
- (71) Applicant (for all designated States except US): **MIL-LICORE AB** [SE/SE]; Bredgränd 4, S-111 30 Stockholm (SE).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): **CHARLEZ, Jarl** [SE/SE]; Vårslevägen 9, S-436 42 Askim (SE). **LÖFGREN, Mikael** [SE/SE]; Knarrhögsgatan 8A, S-431
- (84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

[Continued on next page]

(54) Title: CHEST DRAINAGE DEVICE



(57) Abstract: A drainage apparatus (199) useable for collecting fluid from a body cavity of a patient by suction, comprising means (108, 180) for generating a negative pressure in the body cavity, and a collection chamber (110) for said fluid, where said chamber comprises connection means for connecting a drainage tube (101) having a first end connectable to the patient, and a second end connectable to the collection chamber (110), where the evacuated air is made to pass through a flow structure that comprises a microelectronic air flow sensor having a number of bridge coupled sensor resistors and a heating resistor for measuring a flow of air during suction, and a flow display organ (107) showing a value corresponding to the said flow of air.

WO 2004/110523 A1



Declaration under Rule 4.17:

— *of inventorship (Rule 4.17(iv)) for US only*

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.

CHEST DRAINAGE DEVICE

Field of the invention

5 This invention is concerned with a drainage apparatus for extracting fluids from a body, particularly from the pleural cavity in the human body. Even more specifically it concerns such an apparatus working according to a so called “dry” method, i.e., working without a water-seal and also providing suction pressure control without the need of some kind of water column.

10

Background of the invention

Artificial drainage of excessive fluids from the body is necessary for the well being of the patient in variety of medical procedures during and after operations and when
15 the body cannot dispose of such fluids naturally. Fluids to be drained include blood, water and air. A wide range of drainage devices has been developed to drain wounds and larger body cavities. These devices comprise, in general, a chamber for collection of the fluids and an inlet tube for connection between the patient and the chamber. In use, the fluids are drained from the patient via the inlet tube into the
20 collection chamber, which is placed well below the patient to avoid siphoning the fluids back to the patient. Drainage may be caused by gravity, since the chamber is below the patient, or more efficiently, by applying suction to an outlet from the collection chamber to draw the fluid into to chamber.

25 Various thoracic or cardiac surgical procedures as well as trauma wounds, such as bullet or stab wounds accumulate fluids, such as blood, water or air, in the pleural cavity, between the lungs and surrounding chest wall, this accumulation can interfere with breathing and can cause death by inhibiting the normal pressure changes in the pleural cavity which support normal lung function. In the thoracic
30 cavity, accumulation of fluid such as blood can inhibit healing and patient recovery. In these cases of a persistent leakage of air into the pleural cavity, such as from ruptured bleb – a blister on the lung – the pressure builds up in the cavity until a tension pneumothorax is caused. Then the affected lung; or even both lungs, collapse and the patient can suffocate unless the air is drained from the pleural
35 cavity.

The design of a drainage apparatus for the pleural or thoracic cavities presents special problems. To be effective, the drainage apparatus must remove the fluids promptly and efficiently and prevent their return. It is essential to have one way

flow not only to isolate the patient from the atmosphere, so as to avoid infection, but also to prevent fluid, particularly air, from collecting in the pleural cavity and allowing the lung to collapse. The apparatus should also allow relief of over positive pressure caused, for example, by the patient coughing or fluid displacement
5 in the collection chamber when used for gravity drainage and also allow relief of over-negative pressure caused by the application of too much suction to the chamber.

The source of suction, when used can fail and therefore the apparatus should be
10 constructed to function as gravity drainage apparatus as a precaution against this eventuality so that fluid can still be drained from the patient. Display of an accurate suction level reading is also needed so that the physician can readily monitor or easily re-adjust the level of suction during the course of treatment to the patient. Moreover when there is substantial quantity of air leaking from the lungs into the
15 pleural cavity, this air must be withdrawn by the apparatus, which should be constructed to accommodate such air leaks and sudden changes in the rate of leakage while indicating the leak to the users.

The prior art typically uses a water seal in the drainage apparatus between the
20 collection chamber and the source of suction, or between the chamber and the atmosphere in the case of gravity drainage, to isolate the patient from the atmosphere and keep air from getting back into the chest. The water seal also serves as an indicator of air leakage from the patient when air bubbles through the water, the amount of bubbling serving as a guide to the physician of the degree of air
25 leakage. Also motion of the water level indicates the patency and sampling of the patient. Unfortunately, such seals have not been reliable in preventing contamination of the patient and have been inconvenient and unreliable in use, as described below. The simplest form of such a drainage apparatus comprises a single bottle partially filled with water and serving as a water seal chamber. The bottle has
30 an inlet tube from the patient extending below the water and an outlet tube communicating with the air space above the water. This is a rudimentary arrangement, which provides no control over, or indication of, the pressure in the collection chamber. As the drained material gradually fills the bottle, the resistance to drainage increases.

35 To improve on this design, a plurality of bottles has been used, connected in series between the patient and a source of suction. Normally three bottles are used: the first, connected to the patient as a trap, collects the fluids; the second, partially filled with water, forms the seal; and a the third acts as a pressure regulator by having a

tube open to the atmosphere and extending below water in the bottle. The dept of this tube below the water determines the maximum amount of suction that can be drawn through the system because once sufficient suction is reached to drain air down the tube from the atmosphere and bubble through the water, increasing the level of suction only increases the rate of bubbling and consequently the level of suction in the apparatus is limited. However, the separate bottle arrangement is cumbersome and awkward to use and is very difficult to clean for re-use. This has lead to design of a variety unitary, sterilizable and disposable drainage apparatus. U.S. Patents No. 3,363,626, 3,363,827, 3559,647, 3,683,913 and 3,853,128 show the development of rigid, disposable, plastic drainage apparatus, which has adapted the three-bottle arrangement into a unitary structure. A drainage apparatus which includes a water seal, requires a relatively long time to set up because the apparatus must be primed with a certain volume of sterile water to generate the and to fill the U shaped manometer chamber. This volume of water is relatively large and usually more than one chamber has to be filled. U.S. 3,363,627 attempted to overcome this problem by making the connections between the chambers external to the apparatus and above the chambers so that the apparatus could be supplied pre-filled. However the water seal systems suffers from a number of disadvantages, such as evaporation, nuisance, overflow and contamination which all can effect the safety aspects of one-way-valve mechanisms. Lately there have been modifications done by companies like Genzyme (Deknatel) and Atrium and they have overcome the above-described problems of water seal aspects by launching a dry one-way-valve mechanism.

The depth of water in the pressure regulator chamber, as mentioned above limits the amount of suction that can be applied to a water seal system. The maximum suction that can be applied to commercial water seal reservoirs are about 30 cm water, since a much longer pressure control chamber is very cumbersome and expensive to manufacture. This is inadequate since suction up to about 60 cm water is sometimes required. Further, a water seal drainage apparatus is normally relatively heavy and large which is a disadvantage both for hospital staff and for the patient who often holds the apparatus when he is moved. Another serious drawback is the relatively complex instructions required for; it's use, which can lead to mistakes and wasted time. In attempts to overcome these deficiencies, a few waterless devices have been developed. U.S. Patent No. 3,830,238 discloses a simple arrangement which is a waterless, one-chamber device containing an inlet tube having a one-way-valve to prevent flow of fluid back to the patient and a bellows arrangement coarsely measure the pressure in the pleural cavity. But this device does not control or accommodate pressure fluctuations or indicate the actual pressure in the chamber.

Davol, Inc. has also produced a device without a water seal under the trademark Thoraklex and so has Atrium and genzyme (Deknatel). The outlet of these three products and trademarks (Deknatel, Atrium and Thoraklex) is connected to a negative pressure control consisting of a screw or a button for adjustable occluding the outlet passage to regulate the degree of suction,. The outlet also includes a float ball gauge calibrated to indicate the suction applied to the patient and connected to the atmosphere and the outlet. However the real pressure in the pleural cavity is not visualized in these systems, but to overcome that too high negative pressure are build up, these apparatus incorporates an over-negative-pressure relief valve, which vents to atmosphere at a pre-set negative pressure to prevent the vacuum reaching too high a level (60 cm water). This valve is set in a passage between the atmosphere and the collection chamber and comprises a one-way spring-loaded valve. Since actuation of the valve allows air from the atmosphere into the collection chamber, which is open to the patient, it is necessary to provide a filter in the passage. This arrangement suffers from disadvantages that the suction level can build up rapidly in the collection chamber while the valve is opening and although the filter is intended to prevent bacteria entering the chamber, placement of the valve opening directly to the chamber still exposes the patient to risk of infection and also increases manufacturing costs of the apparatus.

20

US 4,654,029 discloses a system for electronically monitoring and controlling the drainage of fluids from a body cavity, including transducers for measuring suction air flow, patient air flow, patient negativity and the like, and displays for rendering measured values in legible form.

25

US 4,889,531 discloses a pressure regulator including high and low pressure chambers separated by a divider having an opening, a closing member biased to a closing position for closing the opening with a biasing force according to a desired pressure differential between the chambers.

30

WO 01/98735 discloses a hot wire flow rate sensor having a bridge circuit with a sensing resistor which avoids saturation of the signal processing circuitry at high gas flows rates by increasing a bias signal to a differential amplifier in the signal processing circuitry in a step-like manner as the flow rate responsive signal to the differential amplifier from the sensing resistor increases.

35

GB 2 077 397 discloses a vacuum regulator comprising a body having parallel passages and a cap attached by a screw thread over one end of the body defining

with the body a chamber containing a diaphragm arranged to co-operate with a seating at the end of a passage.

FR 2 560 770 discloses a vacuum regulator similar to the one in GB 2 077 397.

5

US 4,710,165 discloses a wearable, variable rate suction/collection device.

Therefore, there exists a need for a drainage apparatus, which avoids the disadvantages of the water seal, water U-shaped manometers, pre-set suction levels and lack of visualization of healing control

10 Further, a such apparatus must be able to function under conditions of gravity drainage or vacuum drainage and, in the latter case, apply stable and acceptable levels of suction to the patient. There is also a need for a simple, reliable sensor in the drainage apparatus, to indicate accurately the pressure conditions in the
15 collection chamber over a range of negative pressures. Furthermore there is also vital to measure quantity of air that is evacuated over time, which in it self indicates the progress of healing.

In addition, it's desirable that the apparatus is not too expensive to manufacture and
20 that it could be constructed to reduce the need for guessing the intra pleural pressures and volume of air leakage, and that it will be convenient for the patient and medical staff to use. Many forms of drainage apparatus currently available are not only insufficient to monitor due to their pre-set pressure levels and automatic relief valve, opening first at a negative pressure exceeding 60 cm water. The lack of
25 suitable surveillance means, increased use of X-ray examinations and hasn't really improved the management of treatment with drainage apparatus in aspects of making healing processes more objective or visualized.

A future scenario for standard of care (SOC) should include the possibility to
30 collect and transfer data for patient documentation. This is done in most other surveillance applications in the medical field today.

Summary of the invention

35 An objective of the present invention is to provide an apparatus, which overcomes the disadvantages of prior art and which is reliable and convenient to use under a variety of operating conditions and locations. It is thus an objective to provide an apparatus for draining fluid from a patients pleural cavity while maintaining an amount of suction pressure in said cavity where said apparatus do not need priming

with a certain amount of water. It is a further objective to measure and display important treatment parameters such as present interpleural or pericardial pressure, present air flow, and accumulated amount of drained liquid. Further objectives include also to provide an apparatus that is resistant to position changes and
5 dropping, and that will function without any external electrical power source or batteries. The apparatus should also include safety means to eliminate the risk of too high suction pressure and the risk of causing a non-suction pressure. The apparatus is also preferably provided with means for transferring the above mentioned treatment parameters to an external electronic device e.g. a personal computer (PC)
10 or a personal digital assistant (PDA)

A preferred embodiment of a drainage apparatus according to the present invention comprises an airtight collection chamber having an inlet port for liquid and air from a patient, and an outlet port for evacuated air. The outlet port is connected to a
15 regulator unit. Said regulator unit comprises a capillary breaker unit, a one way valve, flow measuring means, a suction pressure regulator, a high pressure valve and connection means for connecting the apparatus to a source of suction pressure. Said source could comprise e.g. such suction pressure sources provided as wall outlets in most modern hospital wards. The collection chamber is also provided
20 with pressure measuring means for measuring the pressure in said collection chamber, and a vacuum reducing valve for enabling reduction of suction pressure by opening a small temporary connection between the chamber and the ambient air.

The tubing connecting the patient to the apparatus is preferably of a kink-resistant
25 type that is designed to prevent obstruction to flow of fluid and air from the patient. Such obstruction may otherwise cause development of a tension pneumothorax.

The pressure measuring means preferably comprises a piezo electric pressure sensor provided in the lid of the chamber, which directly measure the working pressure in
30 the chamber. In use the piezoelectricity is becoming electrically polarized when stress is applied to it and this electrically polarization is translated to a display device to indicate the pressure in the chamber. Embodiments include MEMS and silicon sensor technology.

35 The flow measuring means comprises a sensor for estimating current flow of air evacuated from the body cavity. Said means will be further described below.

The apparatus of this invention has means for indicating directly the pressure in the collection chamber and displaying the true level of suction applied to the patient,

irrespective of whether an air leak from the patient is passing through the equipment. This pressure measuring means comprises preferably a liquid crystal display making a reading easy to accomplish, accurate and reliable, even at high levels of suction.

5

The flow measuring means is provided to quantify the volume of evacuated air from the patient during use.

All data from the flow measuring means and the pressure measuring means is preferably collectible and transferable to a PC/PDA via an infrared (IR) port. In other embodiments of this invention the collection chamber is provided with features, which make placement, collection and transportation of the device more convenient. The collection chamber is provided with suspension means, which serve both to suspend the collection chamber and to carry it, and yet which may also be stored flush against the chamber when not in use. Said suspension means preferably comprises VELCRO straps making the suspension adjustable.

Thus, according to an embodiment of the invention there is provided a surgical apparatus for draining fluids from the body, especially from the pleural cavity, which comprises a rigid chamber for receiving the fluid. The chamber has an inlet for communication with the body, an outlet for connection to a source of suction when desired and a sensor for indicating the pressure in the chamber during use. This sensor comprises a piezoelectric sensor or a silicon sensor which is impervious to drained liquids and to air and which is mounted in the chamber lid standing in pressure communication with the inside of the chamber. The sensor is connected to means for indicating the pressure. Pressure differentials inside the collection chamber cause the sensor in use to be electrically polarized when stress is applied to it and this electrically polarization is translated to a display device to indicate the pressure in the chamber. Increasing positive or decreasing negative pressure causing the piezoelectric crystals to be polarized and this polarization is translated to the indicating means via a microprocessor to directly display the working pressure in the chamber which is usually less than atmospheric since the apparatus is primarily intended for connection to a source of suction. Preferably the indication is achieved by a LCD-display mounted on the lid of the collection chamber.

35

Thus, according to another embodiment of the invention comprises a flowmeter, which comprises a sensor by means of a thermistor, which is mounted in an air channel for measuring the volume of air passing through the system over time. The channel has an inlet for directing the flow of gases from the collection chamber, and

an outlet for letting the airflow from the apparatus. The sensor comprises in one embodiment a thermistor sensor, which is first heated up and then cooled off by the airflow in the channel. Heat differentials cause the sensor in use to be electrically polarized. In a preferred embodiment four thermal resistors of the same nominal
5 resistance is arranged in a row in said channel along a direction parallel to the air flow and with a heating resistance arranged between resistor number two and three. Said resistors are electrically coupled in a Wheatstone-like bridge such that the voltages of two voltage dividers are compared i.e., the voltage over resistor number four is compared with the voltage over resistor number 2 and where one current is
10 flowing through resistors one and four, and another current is flowing through resistors three and four. The so formed differential voltage is measured under two conditions, i.e, heated with the heating resistor and unheated. The difference between the voltages obtained under heated and unheated conditions are subtracted from each other and the resulting difference is used as representative of the value of
15 the air flow rate.

In another embodiment a so called "moving vain" sensor is used, where a membrane is influenced by the air stream and this influence is translated to an electrical polarization. The electrical polarization is subsequently translated to a display device to indicate the airflow through the apparatus. Increasing flow or
20 decreasing flow causes the sensor to be polarized and this polarization is translated to the indicating means via a microprocessor to directly display the airflow in the channel. Preferably the indication is achieved by a LCD-display mounted in the lid of the collection chamber.

25 The flow meter could also be using a cavity method, in which method a channel with a design of a flout causes different varies of sound frequencies by differences in air flow. These sound frequencies are translated into electrically polarization to the indication means via a microprocessor to directly display the airflow in the channel.

30

The flow meter could also be using a method comprising a silicon sensor.

To accommodate substantial over-negative pressure and to limit the negative working pressure applied to the apparatus, a pressure relief valve is provided on the
35 lid of the chamber. This valve is activated manually to relive the negative pressure in the collection chamber. In one embodiment this pressure relief valve may comprise a spring-loaded or silicone or rubber seal over an opening between the outlet line and the atmosphere. In another embodiment the valve may comprise a rubber or silicone body having resilient properties eliminating the need for a

conventional spring. A particular level of manual pressure will be sufficient to overcome the force of the spring and the seal will open to admit the atmosphere to the collection chamber and thereby relieve the pressure in the collection chamber. To avoid contamination of the chamber and the patient when this valve is activated, the atmospheric air is filtered before entering the chamber by means of a filter, which allows air filtration, and hindering contaminated particles from entering the chamber.

To accommodate substantial over-negative pressure and to limit the amount of suction applied to the apparatus, an adjustable compensating suction regulator is provided on the outlet from the chamber. This regulator is activated when suction is applied to it. This regulator comprises a knob with an interior membrane over a suction shaft and manually turning the knob clockwise or anti clockwise the distance between the membrane and the suction shaft varies and it also varies the force of the suction applied to the apparatus. To increase suction the knob is turned clockwise, which causes an increase of distance and to decrease the suction the knob is turned anti clockwise causing a decrease of distance between membrane and suction shaft.

To allow a one-way communication between the apparatus and the source of suction is by means of a one-way valve, which allow air to pass out, and not into the chamber. This one-way valve comprises a membrane that during a particular level of positive pressure will be sufficient to overcome the force of the valve and the seal will open to let air out from the apparatus. A negative pressure in the collection chamber will close the valve preventing air to flow back to the apparatus.

To limit blood and fluids from immediately enter the one-way valve and suction regulator a capillary breakpoint with increasing area of the capillaries is mounted just before the one-way valve. The capillary breakpoint comprises a membrane with large volume of small holes and their circular are is increasing in area, which allows fluids and blood to pass out from the membrane if they have entered the capillary breakpoint.

Features of the invention also assist in stabilization of the apparatus in use. To limit and prevent blood or fluid from entering the one-way valve and suction regulator of the apparatus in use, means are provided to limit liquid transformation from one part of the system to another. The ergonomic kidney shaped design and labyrinth sectional walls that are designed in such a manner allows this function that they will not only limit the contamination of one-way valve and suction regulator but also

allow good ergonomics when carried by the patient or managed by the hospital staff. Due to the kidney shape, the front and back surfaces of the collection chamber is arched, providing a more rigid and strong structure than would be the case e.g. with a plan surface.

5

Other features of the invention also assist in stabilization of the apparatus in use. Means are provided to suspend the chamber, such as by Velcro® from a bed or rail. The suspension means are mounted on the external surface of the chamber in such a manner that they will not only suspend the chamber but also be nested on the

10

external surface for storage and interlocked to form a carrying handles.

Portable drainage unit

Another embodiment of the invention include a portable drainage unit in the size of approximately 10 times 8 times 2.5 centimetres or less provided with a one way

15

valve, connection to the patients body cavity, an electronics measuring and display organ for measuring and displaying drainage air flow and suction pressure. Said portable drainage unit utilises the body's own ability to provide pressure for pushing out air from a body cavity, i.e., by utilising the flow of air that results from breathing movements and other movements and muscle contractions. The unit is

20

provided with a small collection chamber having an absorbent material inside taking care of possible fluid. This type of apparatus is intended for treatment and monitoring of patients with partly healed and less wet pneumothorax.

Measuring and display means

25

A drainage apparatus according to a preferred embodiment of the invention is provided with measuring and display means providing for high accuracy measurement of the pressure in a body cavity, and the flow from said cavity as mentioned above. The embodiment achieve high accuracy combined with low power consumption so that a single solar cell of an area of approximately 2 times 3

30

centimetres or less is sufficient to provide the needed power. This will allow for almost indefinite shell life. Alternatively a small battery e.g. of button cell type can be used.

35 BRIEF DESCRIPTION OF THE DRAWINGS

The invention is described with reference to the accompanying drawings, in which:

Figure 1 is an explanatory sketch showing the working principle of an embodiment of the present invention.

Figure 2a shows a suction pressure regulator, partly in cross section, for a drainage
5 device according to an embodiment of the present invention

Figure 2b shows, in cross section, a suction pressure regulator according to another embodiment of the present invention.

10 Figure 3 shows a an overview of an embodiment of an apparatus according to the present invention

Figure 4 shows a collection chamber, with the lid removed for clarity, for a drainage device according to an embodiment of the present invention.

15

Figure 5a shows, in cross section, a non return valve unit according to an embodiment of the present invention.

Figure 5b shows, partly in cross section, a detail of the non return valve unit in fig
20 5a.

Figure 6 shows a block diagram of a measuring and display unit for use in a drainage device according to an embodiment of the present invention.

25 Fig. 7a shows a photograph of a MEMS flow sensor according to an embodiment of the invention.

Fig. 7b shows an enlargement view of a part of the sensor in fig. 7a showing four serpentine like sensor resistors

30

Fig. 7c shows a bridge circuit of a preferred way of coupling the sensor resistors.

Fig . 8a shows a circuit diagram of a sensor circuit board for a drainage device according to an embodiment of the present invention

35

Fig. 8b is a circuit diagram showing miscellaneous components of the sensor circuit board

Fig. 9a shows a circuit diagram of a controller circuit board for a drainage device according to an embodiment of the present invention

Fig. 9b shows a connectors overview.

5

Fig. 10 shows a flow chart of a method of obtaining a value representative of an air flow in an apparatus according to one embodiment of the invention.

10 DETAILED DESCRIPTION

Figure 1 is an explanatory sketch showing the working principle of a drainage apparatus 199 according to an embodiment of the present invention. The figure shows a drainage tube 101, preferably of a kink resistant type, having a first and a
15 second end. Said first end is intended to be connected to a patients body to drain fluid from typically a pleural or a pericardial cavity. Said second end is connected to a drainage apparatus 199 having an airtight collection chamber 110. The drainage tube 101 is provided with a reinforced part 105 near its second end close to an inlet opening of the collection chamber 110. Fluids that are extracted from the body
20 include blood, pus and protein containing fluids with a high water content. The collection chamber is intended to be used in an upright position. Fluids entering the collection chamber 110 do, owing to gravity, first enter a first compartment 102, a paediatrics measuring chamber 102 having defining walls 113,114. Said chamber 102 is provided to enable a physician, a nurse or other health care
25 personnel to make an optical reading on a first scale 112. The material of the collection chamber 110 is of an optically transparent type, e.g polycarbonate plastic or the like, allowing for easy and convenient readout of the fluid level inside the collection chamber 110. The paediatrics measuring chamber 102 has a relatively small transverse cross section so that when fluid are filling the chamber the level is
30 increasing relatively much for a certain amount of fluid, making it easy to detect small variations in the fluid level. This is of course of most use when treating small children, whose bodies, heart and lungs are small, and therefore also the amount of fluid that will be drained is small. In an alternative embodiment the paediatrics measuring chamber 102 is having its own set of defining walls making assembly
35 easy by allowing for easy sliding the paediatrics chamber 102 into place in e.g. a dovetail slot.

When treating an adult patient producing a large amount of excess fluid in his pleural or pericardiac cavity, fluid will fill the paediatrics measuring chamber 102

and enter a second compartment 120, having a corresponding measuring scale 130. As fluid levels increase further the second compartment becomes full and the fluid flows over a first dividing wall 140 to a third compartment 121. Preferably the collection chamber comprises a number of such compartments 121-124 divided by
5 dividing walls 140-143, preferably five to six compartments, allowing for easy readout of up to for example 2500 millilitres of fluid.

The collection chamber is provided with a vacuum reducer valve 103. The collection chamber is also provided with a pressure measuring means 104.

10

Air evacuated from the patient passes over the dividing walls 140-143 and is sucked away via an outlet of the collection chamber 110, via protective means 105, comprising a capillary breaker 105, further via a non return valve 106, still further via a flow measuring means 107, a suction regulator 108, a high pressure valve 109,
15 and finally via a suction supply tube 180 to an external source of suction pressure.

In another preferred embodiment the pressure measuring means 104 and/or the flow measuring means 107 is of a type connectable to an electronic measuring unit capable of wireless communication, e.g. infrared communication, with a computer
20 111 for further processing of information. A printer 129 can be connected to the computer 111 for the printing of parameters, trend diagrams on the like. The apparatus can also be provided with display means, connected to the electronic measuring unit, for displaying actual parameter values, such as collection chamber pressure, and current flow.

25

Figure 2a is a view of a suction pressure regulator, partly in cross section, for a drainage device according to an embodiment of the present invention. The regulator preferably comprises two main parts, a house 201, and a turnable cap 202. The cap 202 has preferably a cylindrical shape so it can be screwed onto the house 201. For
30 this purpose the cap is provided on its inner cylindrical surface with threads 205, and the house is correspondingly on its outer cylindrical surface provided with corresponding threads. The threads are airtight in themselves or, in another embodiment, means such as O-ring are provided to provide an airtight connection between the house 201 and the cap 202. The cap 202 is provided with a diaphragm
35 211 attached inside the cap 202 near an inner surface 217 of a top part 220. The inner surface 217 is preferably provided with a rough surface or pimple-like protrusions preventing the diaphragm 211 from adhering to the top inner surface 217. The diaphragm 211 is attached to the inner cylindrical walls in an air tight

manner. The top part 220 is provided with a hole 222 for letting air of atmospheric pressure to enter and leave a small space 230 above the diaphragm 211.

The house 201 comprises connections 231, 232 for supply suction pressure, and
5 regulated suction pressure respectively. The supply connection 231 has a fluid connection through a bottom plate 240 of the house 201 to a prolonged nozzle 241 inside the house 201. Said nozzle part having a top orifice 242 facing the diaphragm 211 so that an airtight contact can be achieved between the diaphragm 211 and the orifice 242. The nozzle part is preferably arranged in the centre of the bottom plate
10 240. Also the regulated pressure connection 232 preferably comprises a prolonged nozzle part 250 inside the house 201, having an orifice 251.

The regulator functions as described below. In some point in the regulatory process the diaphragm is in air tight close contact to the orifice 242 of the supply nozzle
15 241. If the pressure inside the house 201 raises, i.e., the suction pressure becomes less, the diaphragm 211 will bend away from the supply orifice 242, thereby open for a supply suction pressure supplied via the nozzle 241, causing the pressure to fall. As the pressure falls, the diaphragm will bend towards the supply orifice 242 again and eventually make close contact to said orifice 242, thereby closing off
20 suction pressure supply. This process is repeated and the pressure is regulated.

To adjust the pressure the cap 202 is turned clockwise or anticlockwise like a knob so that a distance between the diaphragm 211 and the supply pressure nozzle orifice
25 242 becomes less or more.

Another feature of the regulator is the feature of handling the problem of temporary formation of condensation water. Air coming from the human body normally contains 100% humidity at 37 degrees Celsius. As the temperature falls this humidity will fall out as water. To lower the risk of influence of such water in the
30 regulator the height H2 of the regulated pressure prolonged nozzle 250 is approximately half the height H1 of the supply pressure nozzle 241. Water formed inside the regulator house 201 will stay at the bottom of the house, or leaving towards a collection chamber via the regulated pressure inlet 232, without affecting the diaphragm.

35 Figure 2b shows, in cross section, a pressure regulator according to another embodiment of the invention. Those parts having a corresponding part in fig. 2a have the corresponding reference numerals with the addition of "prim" ('). The embodiment in fig. 2b is based on the same principle as the embodiment in fig. 2a

i.e., the pressure is adjusted by moving a membrane (211, 211') closer to or further away from a suction pressure supply nozzle (241, 241'). The regulator 200 comprises a regulator house 201' and an adjustable cap 202', where said cap is provided with a membrane 211' arranged close to its closed end 220'. The
5 membrane is provided with a bellow 212 allowing the membrane to move in a downward-upward direction following the orifice of the prolonged nozzle 241' when the cap 202' is turned, and the pressure is adjusted is described above. The membrane 211' is also provided with a rim 213 providing structural stability and a means for being able to be kept on place. The membrane 211' is clamped between
10 the upper part 220' of the cap 202' and a slide ring 215, which is kept in position by means of a conical spring 214.

Said conical spring 214 serves the double purpose of on the one hand to provide means of keeping the membrane 211' in position, and on the other hand to provide
15 means for keeping the cap 202' and the house 201' in a firm relationship avoiding loose or play between said cap 202' and house 201' that may otherwise adversely affect the pressure regulatory functioning. The conical spring has a large and a small end, the large end abuts the slide ring, while the small end abuts a shoulder 243 on the prolonged nozzle 241'.

20 The spring 214 is designed to function in the following way: starting with an unloaded spring; when the axial load increases, the turns having the greatest radii are the most active. Said turns undergo deformations successively, one turn after the other, and the smaller turns become more active. By using a conical spring instead of an ordinary spring with constant diameter, wear in threads of the regulator is
25 decreased and jarring is avoided. A wire diameter of 1.4 millimetres has proved to be appropriate. The conical shape allows for low build and do not expand outwards which prevents the origin of sounds when adjusting the suction pressure. Due to the progressive spring forces, a more distinct and controlled fine adjustment of the pressure at low flows is achieved.

30

Figure 3 shows an overview of an embodiment of a drainage apparatus 300 according to the present invention. A collection chamber 310 is provided with an airtight lid 384 having an inlet connection 380 connectable to a drainage tube from the patient, and an suction pressure supply connection 381. The suction pressure
35 supply connection 381 is connected via internal channels in the lid 384 to a suction pressure regulator 387. Regulated suction pressure is connected to the internal of the collection chamber 310 via a non-return valve and a capillary breaker (not shown in fig. 3) A electronics unit 385 is provided in the lid having a pressure display, a air flow display and one or more solar cells for supplying all the power needed to

power the electronics unit 385. The unit 385 is made easy removable allowing environmentally correct disposal of different kind of waste when the apparatus is to be disposed.

- 5 Figure 4 shows a collection chamber 400, with a lid removed for clarity, for a drainage device according to an embodiment of the present invention. The chamber 400 has a cross section providing an indentation running from a bottom part 402, not visible, to the lid, preferably giving the chamber 400 a kidney shaped cross section adding to the stability and rigidity of the chamber 400. Said chamber 400
- 10 is divided into compartments by a number of separating walls 405, 410, 415, 420.. The separating walls are provided with fluid passing cuts near the lid to allow fluid to flow from a full compartment to a not yet full compartment. These separating walls and cuts are arranged in a labyrinth manner preventing or reducing the risk of fluids from entering further compartments if the chamber accidentally falls on the
- 15 side or otherwise is tilted in a non upright position. Two nearby separating walls have their fluid passing cuts formed at opposing sides i.e. near the indented side or near the non indented side. Some of the walls are also provided with cuts to give room for the lid and the electronics in the lid The two outermost dividing walls 405, 420 are provided with longitudinal running bends 406, 421 to further add to
- 20 rigidity and stability. The lid is air tightly sealed to the collection chamber by means of silicone seal, plastic welding or other suitable method. The chamber 400 is provided with fastening means for a strap with VELCRO adjustment means or the like for easy suspension and carrying of the drainage device.
- 25 Figure 5a and 5b shows, in cross section, a non return valve unit according to an embodiment of the present invention. The evacuated air enters an atrium 501 having a floor 502 and vertical walls 503. The atrium 501 is upwardly defined by a capillary breaker 510 in the form of a horizontal wall 510 having a number of conical holes 505 in it. The holes 505 have a smaller and a wider end, and the
- 30 smaller end is directed downwards in fig. 5a and 5b such that air streaming through the atrium 501 and the capillary breaker 510 will have a less water content after the breaker than before said breaker 510. The wall 503 is preferably continued upwards and a central column 512 is formed that holds a horizontal membrane 514 preferably of rubber or another flexible material. A non return valve is formed as
- 35 the membrane forms an air tight seal with an upper part 516 of the vertical wall 503, as long as the pressure is lower on the side of the membrane 514 that is facing the capillary breaker than on the other side. The evacuated air then enters a measuring channel inlet 520 having vertical wall 522 of a height h that together with an airtight

cover 530 forms a condense trap 524 further reducing the possible water content of the evacuated air.

Figure 6 shows a block diagram of a measuring and display organ 600 for use in a drainage device according to an embodiment of the present invention. Said measuring and display organ 600 include a pressure sensor 605 for measuring the pressure in a pressure measuring part of the drainage device that is in pressure connection with the body cavity. Said measuring and display organ 600 also include an airflow sensor 615 for measuring the airflow in an airflow measuring part of the drainage device, representative of the airflow from said body cavity. The sensors 605, 615 are connected to a processor 630 and send signals representative of said pressure and flow to said processor 630. Said processor processes the signals from the sensors 605, 615. Such processing may include analogue to digital conversion of signal values, compensations for nonlinearities etc. The processor 630 also transforms pressure and flow values to signals suitable to drive a display unit 670. The processor is connected to a display unit 670. Said display unit 670 receives signals from the processor 630 representing the pressure and flow values. The display unit 670 displays said values preferably in both a digital and in an analogue format making the values clearly readable for medical personnel handling the nursing and treatment of the patient, making parameters of progress as well as deterioration in the recovery process easily quantifiable. In a preferred embodiment a button is arranged, so that when pressed, the cumulative airflow, representative of the last hours cumulative air leakage is shown on the display 670.

The processor 630 is preferably of the flash type, i.e., it has an internal flash memory which contributes to low power consumption. The measuring and display organ 600 is powered from a solar panel 650 provided with a power regulator 655. In an alternative embodiment the organ 600 is powered from a battery 665. The processor 630 is preferably connected to an IR port 640 for transferring information to an external device such as a personal computer or personal digital assistant. In another embodiment the data transferring is accomplished by wireless BLUETOOTH-means.

The display unit 670 is preferably of a liquid crystal display (LCD) type or another low power consumption type and may be connected to the processor over a latch 675. The pressure value is preferable displayed as a two-digit number representative of the pressure in centimetres water column. The air flow is preferably displayed as a two digit number expressed in litres per minute.

Pressure sensor

The pressure sensor 605 is preferably of a micro electromechanical system (MEMS) type. A suitable sensor is for example the MS761D from Intersema Sensoric SA, BEVAIX, SWITZERLAND (<http://www.intersema.ch>). In a preferred embodiment
5 the pressure sensor 605 include a small rectangular area provided with a measuring resistance along each of the four sides. Electrical connections may be provided at all four corners. The pressure sensor is provided with means to withstand liquids such as water with ions, e.g. salt.

10 *Pressure alarm*

In one embodiment the measuring and display organ 600 comprises pressure-alarm means. Said alarm-means comprises means for setting user-defined, low and high alarm limits. Said alarm-means also comprises a sound-unit 677 or other audio or visual means to indicate that a limit is reached. The processor 630 is provided with
15 the necessary functionality to compare set limits with actual pressure values and to initiate proper indication if a limit is reached. Said functionality is preferably implemented as computer program code in the processor 630.

Air flow sensor

20 In a preferred embodiment the air flow sensor 615 include a micro-electro-mechanical system (MEMS) sensor chip of approximate size 5x5mm or less. The sensor includes a heater element with 2 measuring resistances on each side of it, and a membrane upon which the heater element and other resistors are applied. Said membrane has a size of roughly 125x 250 um. Tables show that the power
25 requirement for keeping the heater element at 200 degrees Celcius should be in the 10mW magnitude. The heater element includes a conductor or "wire" of a size of approximately 3um diameter (cross section) x 100um length. It is calculated that it will be necessary to drive 10mW into the heater element from a 2 Volt voltage source, equivalent to a solar cell under load, and therefore the conductor should
30 have a resistance of roughly 400 ohms. The chosen heater is approximately 24um long and have a diameter or cross section of 6um. A preferred resistance for the measuring resistances will be 2k-20k because of the desire to keep power consumption together with heating down. In one embodiment said measuring resistances comprise 4 identical 3um diameter 100um long serpentine over said
35 membrane. Two extra temperature reference resistors may be designed in as well to increase accuracy. The expected signal at full airflow (specifically at zero flow, because the signal will be inverse proportional to the flow) will be 0,5-2%. The output from the sensor is preferably resistance. At zero airflow the processor will recognize a nominal electrical resistance. At high airflows the processor will

recognize an electrical resistance differing from the nominal with typically 2 percent. The sensor provides preferably a real resolution of 10bits within a measuring range of 5ml – 5l per minute, the least detectable signal being 2ppm with a margin factor of 4. The measuring response is preferably logarithmic giving a
5 sensor more sensitive at low air flows.

The heater wire is designed to withstand high temperatures, but relatively low powers can still break the device. Therefore driver electronics means is provided that drive the heater within acceptable power and temperature. To reduce power
10 consumption the heating is pulsed, i.e., current is applied to the heater element in pulses.

The air flow sensor 615 is preferably arranged in a channel of approximately 5 millimeters cross section that is provided with a narrowing giving rise to a narrow
15 channel of approximately 2 quadratic millimeters in cross section where the airflow sensor 615 is provided. Because of this narrowing the flow speed will become higher making it easier to measure small flows. The sensor is preferably arranged at the uppermost portion of said narrow channel making it less sensitive to condensed
water.

20

The resistors is in a preferred embodiment made of polycrystalline silicon (poly-Si) and conductors on the sensor board is made of metal Al (Cu/Si). A thermal oxide is arranged between said resistors and conductors and a silicon substrate of
approximately 380 microns of thickness.

25

Air flow sensor circuitry

Fig. 7a shows a photograph of a MEMS flow sensor according to an embodiment of the invention. Fig. 7b shows an enlargement view of a part of fig. 7a showing four
30 serpentine like sensor resistors denoted first R1, second R2, third R3 and fourth R4 resistors and a heating resistor Rh. In the fig. 7b a reference direction Ref is shown as arrows pointing from left to right. In the assembled drainage apparatus this direction is preferably the same as the direction of the air flow to be measured. The resistors R1-R4 is arranged from left to right, R2 to the right of R1, R3 to the right of R2 and so on. The heating resistor Rh is placed between R2 and R3, such that the
35 distance from the heating resistance to the second resistance R2 is the same as the distance from the heating resistance Rh to the third resistance R3.

Fig. 7c shows a bridge circuit of a preferred way of coupling the sensor resistors R1-R4. The bridge is defined by four imaginary connection points denoted a first

P1, a second P2, a third P3 and a fourth P4 connection point. The first sensor resistance R1 is connected between the first P1 and the fourth P4 connection points. The second sensor resistance R2 is connected between the second P2 and the third P3 connection points. The third sensor resistance R3 is connected between the first P1 and the second P2 connection points. The fourth sensor resistance R4 is connected between the third P3 and the fourth P4 connection points.

The described way of connecting the four sensor resistances in a bridge has been shown by simulation to give better characteristics compared to using only the second R2 and third R3 sensor resistors together with a pair of dummy resistors in the bridge, and similarly, has also been shown to give better characteristics compared to using only the first R1 and fourth R4 sensor resistors together with a pair of dummy resistors in the bridge. Here, a dummy resistor is a resistor not being exposed to flow of air.

15

Boards and circuitry

Fig . 8a shows a circuit diagram of a sensor circuit board for a drainage device according to an embodiment of the present invention. The J2 in the upper left corner connects the sensor circuit board to a small chip comprising the air flow sensor of fig. 7a. A voltage measured over the second P2 and fourth connection points is fed to an amplifier circuit comprising operational amplifiers U101-A and U101-B. The resulting signal is then fed to a flow offset compensation circuit comprising an operational amplifier U102-A making it possible to adjust for individual sensor differences. An adjusted flow signal output from said offset compensation circuit is fed to the microcontroller U101 which can be a ATMEGA48V. Further, a pressure sensor S101, which can be a MS761D is connected to an amplifier circuit comprising operational amplifiers U101-C and U101-D. The resulting signal is then fed to a pressure offset compensation circuit comprising an operational amplifier U102-C making it possible to adjust for individual sensor differences. The current feeding the pressure sensor S101 flows through the resistor R133. A voltage over the resistor R133 is fed to a conditioning circuit comprising a operational amplifier U102-D. The voltage from said conditioning circuit is then fed to the microcontroller U101. Said voltage from said conditioning circuit is representative of the temperature of the pressure sensor S101 and can be used by the microcontroller U101 to compensate for temperature variations.

Fig. 8b is a circuit diagram showing miscellaneous components of the sensor circuit board. A drain pin of a power transistor Q201 is connected to the heating resistor

Rh, and a gate pin of the same transistor Q201 is connected to and controlled from the microcontroller U101.

A calibration memory circuit comprising a memory circuit U201 is connected to the
5 microcontroller U101

Fig. 9a shows a circuit diagram of a controller circuit board for a drainage device according to an embodiment of the present invention. The microcontroller U101 mentioned above is also connected to two control button switches S101, denoted
10 "DEL" and S102 denoted "ACC" making it possible for the operator to instruct the microcontroller to initiate different functions, such as e.g. displaying the accumulated flow during the last 1, 3 or 6 hours. The microcontroller is also connected to a light emitting diode D1 and a speaker SP101, and a display organ (not shown)

15

Fig. 9b shows a connectors overview.

Other embodiments of air flow sensors useable in a drainage devices according to the invention is listed below.

20

1. Thermistor

A very small thermistor is heated and its resistance measured. For lowest cost, the thermistor will be unheated/heated in periods to also measure the ambient temperature.

25

2. Vortex

A laminar flow is disturbed with a small edge, and the turbulence caused is analyzed. Said turbulence is analysed according to parameters such as the sound frequency and sound volume which is created and that corresponds to the air speed.

30 Such sound parameters is measured with a small microphone and processed by a processor.

3. Moving vane

A flexible vane is introduced in the air stream, and said vanes deflection is
35 measured. Measuring can be accomplished by an optic measuring device.

4. Hot wire

A very thin wire is heated with constant power or held at constant temperature. The power or the temperature is measured.

5. Rotating vane

- 5 A propeller covers the entire air duct and its rotation is measured.

6. Pitot tube

A pitot tube is connected to a pressure sensor and the pressure corresponds to the square root of the air speed

10

7. Differential pressure

Pressure is measured at two locations, and the difference between the points shall correspond to the air speed

15 8. Doppler

Sound is sent through the moving air, and the time taken for the sound to travel from the transmitter to a receiver is affected by the air speed.

9. Cavity resonance

- 20 A tuned cavity is introduced in the air stream, and the volume of the resonant tone is measured

Software controlled functionality

- 25 Airflow and suction pressure measurement functions of a system according to an embodiment of the present invention can be implemented in software.

Airflow measurement processing

Fig. 10 shows a flow chart of a method of obtaining a value representative of an air flow in an apparatus according to one embodiment of the invention.

- 30 A first voltage corresponding to a first difference in temperature between a first and a second resistor in a MEMS airflow sensor device as described above is read 1010 into the memory of a microcontroller unit. Subsequently, the microcontroller unit initiates heating 1020 of the sensor heating resistor. After a short period, a second voltage corresponding to a second difference in temperature between said first and
35 second resistors, is read 1030 into the memory of the microcontroller unit. The microcontroller unit subsequently shut off heating 1040. The microcontroller unit then calculates a difference 1050 between said first and second voltage value. Said difference is representative of the flow passing the sensor and is translated to a flow

value by means of a translation function which can be implemented as a table. The procedure is then repeated.

Pressure

- 5 A voltage value representative of the suction pressure in the drainage device is read into the memory of the microcontroller unit. A current value representative of the temperature of the pressure sensor is read into the memory of the microcontroller unit.

10 *Signal processing*

The electronics provide sensor signal conditioning and compensation, data storage and data display. The electronics is battery powered and is intended for one-time use. An LCD display is used to present measurement data. The electronics is partitioned into two boards because of environmental considerations. The sensors
15 need to be disposed as medical waste, while it is desirable that as large as possible portion of the electronics can be recycled. This is especially important for the battery. The boards are denoted sensor board and controller board. For the case when using the product as a single use model each sensor board will have a unique serial number. Once a controller board has been connected to a sensor board it shall
20 not accept any other sensor board. This is accomplished by software functionality reading identification numbers and then storing said numbers. The next time one of the boards is connected to the same, or another corresponding board these numbers will be checked, and if a mismatch occurs, the boards will be set in an error state.

- 25 Signal processing is performed in the microcontroller unit. The drainage device is adapted to measure, store and display pressure variations and air leakage during the breathing cycle for example postoperatively or the like. The outputs include a display of intrathoracic pressure during breathing, and also a presentation of the present air leakage. The data is saved and could later be retrieved bedside or via a
30 computer.

Display of collected data

- The micro-controller is programmed such that when an operator presses the ACC button once, the accumulated value of the last hour will be displayed on the LCD.
35 One horizontal line will be highlighted on the leftmost position on the LCD to indicate the chosen time range. When pressing the ACC button twice within two seconds, the mean value of the accumulated values of the last 3 hours will be displayed on the LCD. Two horizontal lines on the leftmost position on the LCD will be highlighted. When pressing the ACC button three times within two seconds,

the mean value of the accumulated values of the last 6 hours will be displayed on the LCD. Three horizontal lines on the leftmost position on the LCD will be highlighted

- 5 The micro-controller is programmed such that when the operator presses the DEL button for 5 seconds the pressure and flow data stored in the memory, but not the sensor/controller ID, will be erased.

The data memory is placed on the controller board. The controller board is adapted
10 to be detachable and it is devised to be able to be put in a reader connected to a computer such that said computer can retrieve the data. The controller board is provided with a connector through which the contents of the data memory can be read via a special reader. This will allow receiving the total data collected and displaying it as a graph function or the like.

15

Display pressure segment

In a preferred embodiment display pressure segments (analog scale) shows zero at the six o'clock position. Positive pressure values is presented clockwise and negative pressures counterclockwise. Zero pressure is represented by no segments
20 highlighted.

Alarm management

In a preferred embodiment an alarm LED D1 is adapted to flash when pressure is outside the preferably -40 mbar to +5 mbar region. When pressure is back in the
25 region, the LED D1 is turned off.

CLAIMS

1. A drainage apparatus (199) useable for collecting fluid from a body cavity of a patient by suction, comprising means (108, 180) for generating a negative pressure in the body cavity, and a collection chamber (110) for said fluid, where
5 said chamber comprises connection means for connecting a drainage tube (101) having a first end connectable to the patient, and a second end connectable to the collection chamber (110), **characterised** in that the evacuated air is made to pass through a flow structure that comprises flow measuring means (107) measuring a flow of air during suction, and a flow display organ (107) showing
10 a value corresponding to the said flow of air.
2. A drainage apparatus (199) according to claim 1 **characterised** in that said flow measuring means produces an electrical representation of a flow value.
- 15 3. A drainage apparatus according to claim 2 **characterised** in that said flow measuring means comprises a conductor provided in said flow structure so that the flowing air is directly or indirectly cooling said conductor.
4. A drainage apparatus according to claim 3 **characterised** in that the conductor is
20 electrically heated, and in that an electrical parameter of the conductor, corresponding to the air flow, is measured as said conductor becomes more or less cooled down by the passing air flow.
5. A drainage apparatus according to claim 4 **characterised** in that said electrical
25 parameter is equivalent or corresponding to the electrical representation of the flow value.
6. A drainage apparatus according to claim 2 **characterised** in that said electrical representation is fed to a display control unit or the like for processing.
30
7. A drainage apparatus according to claim 2 **characterised** in that said flow value is presented on a digital display.
8. A drainage apparatus according to claim 1 **characterised** in that said apparatus
35 comprises pressure-measuring means (104) for measuring an air pressure in the collection chamber.

- 9 A drainage apparatus according to claim 2 **characterised** in that said apparatus comprises a pressure display organ (104) for displaying the current air pressure in the collection chamber (110)
- 5 10. A pressure regulator (201, 202) useable for controlling suction pressure in a draining apparatus for draining fluid from a body cavity of a patient, said regulator having a suction supply connection (231), a regulated suction pressure connection (232), a diaphragm (211) capable of closing a connection between the suction supply connection (231) and the regulated suction pressure
10 connection (232), and means (202) for adjustable setting a pressure, **characterised** in that said means for setting comprises a moveable structure (202) with the diaphragm (211) attached to said structure.
11. A pressure regulator according to claim 10 **characterised** in that said moveable
15 structure (202) comprises a cylindrical cap (202) having the diaphragm (211) attached near a top inner surface (217).
12. A pressure regulator according to claim 11 **characterised** in that said top inner
20 surface (217) is provided with a rough structure preventing the diaphragm (211) from adhering to said top inner surface (217).
13. A pressure regulator according to claim 11 **characterised** in that said regulator
25 comprises a cylindrical house (201) having a bottom plate (240) and cylindrical walls provided with threads (207) on a part of their outer side making it possible to screw the cap (202) up and down on the house, thereby adjusting the pressure.
- 14- pressure regulator according to claim 13 **characterised** in that said bottom plate
30 (240) provides wall entrances for the suction supply connection (231) and the regulated pressure connection (232). The wall entrance (231) for the suction supply is further formed inside the house as a prolonged nozzle (241) having a top orifice (242) faced towards the diaphragm (211).
15. A pressure regulator according to claim 14 **characterised** in that said regulated
35 pressure connection wall entrance (232) is further formed inside the house as a prolonged nozzle (250) of a height H2 which is less than a height H1 of the prolonged nozzle (241) of the suction pressure supply.
16. A pressure regulator according to claim 15 **characterised** in that said prolonged
nozzle (250) of the regulated pressure wall entrance have a height H2 which is

approximately half of the height H1 of the prolonged nozzle (241) of the suction pressure supply wall entrance.

17. A pressure regulator according to claim 16 **characterised** in that said supply
5 pressure prolonged nozzle (241) is formed approximately in the centre of the
bottom plate, providing for easy contact with the diaphragm (211) at its centre
where it bend most.
18. A pressure regulator according to claim 14 **characterised** in that the cap (202,
10 202') and the house (201, 201') is loaded away from each other by means of a
spring (214) of conical shape, where said spring's small end abuts a shoulder
(243) on the prolonged nozzle (241, 241')
19. A pressure regulator according to claim 18 **characterised** in that said diaphragm
15 (211') comprises a bellow (212) near its periphery letting the diaphragm (211')
move in a up-down direction during adjustment, where said bellow (212) is
adapted not to interfere with the spring (214) during use of said regulator (200)
20. A non return valve unit (500) useable in the drainage device according to claim
20 1 having a flexible membrane (514), **characterised** by a capillary breaker (510).
21. The non return valve unit (500) according to claim 20 **characterised** in that the
capillary breaker (510) is arranged so that air is made to pass from a lower level
upwards to a higher level when passing said breaker.
25
22. The non return valve unit (500) according to claim 20 **characterised** in that said
capillary breaker (510) comprises a plate (510) with a number of conical bores
(505).
- 30 23. The non return valve unit (500) according to claim 22 **characterised** in that each
of said conical bores (505) have a smaller orifice and a larger orifice where the
bore is arranged so that the small orifice is the first to meet the flow of air.
24. The non return valve unit (500) according to claim 23 **characterised** in that a
35 condensation trap (524) is arranged under an airtight cover 530 for further
reducing the water content of the evacuated air.

25. A collection chamber (400) useable for a drainage device according to claim 1 **characterised** by a kidney shaped cross section adding to both the stability, rigidness and ergonomic usage of said chamber 400
- 5 26. A collection chamber (400) according to claim 25 **characterised** in that said chamber divided into compartments by a number of separating walls 405,410,415, 420 and provided with fluid passing cuts to allow fluid to flow from a full compartment to a not yet full compartment .
- 10 27. A collection chamber (400) according to claim 26 **characterised** in that two adjacent separating walls have said fluid passing cuts provided near the lid, on opposite sides, preventing fluid from entering into an unused chamber prematurely if the chamber falls on the side.
- 15 28. A collection chamber (400) according to claim 27 **characterised** in that the two outermost dividing walls 405, 420 are provided with longitudinal running bends 406, 421 to further add to rigidness and stability.
- 20 29. A collection chamber (400) according to claim 28 **characterised** in that the lid is airtightly sealed to the collection chamber (400) by means of silicone seal, plastic welding or other suitable method.
- 25 30. A collection chamber (400) according to claim 29 **characterised** in that the chamber 400 is provided with fastening means for a strap with VELCRO adjustment means or the like for easy suspension and carrying of the drainage device.
- 30 31. A measuring and display organ (600) for use in a drainage device according to claim 1 **characterised** in that it comprises a pressure sensor 605 for measuring the pressure in a pressure measuring part of the drainage device that is in pressure connection with the body cavity.
- 35 32. A measuring and display organ (600) according to claim 31 **characterised** in that it comprises an airflow sensor 615 for measuring the airflow in an airflow measuring part of the drainage device, representative of the airflow from said body cavity.
33. A measuring and display organ (600) according to claim 32 **characterised** in that the sensors 605, 615 are connected to a processor 630 and send signals

representative of said pressure and flow to said processor 630 which processor processes the signals from the sensors 605, 615.

- 5 34. A measuring and display organ (600) according to claim 33 **characterised** in that such processing include compensations for nonlinearities.
- 10 35. A measuring and display organ (600) according to claim 34 **characterised** in that said organ comprises a display unit 670 that receives pressure and flow values from the processor 630
- 15 36. A measuring and display organ (600) according to claim 35 **characterised** in that the display unit 670 displays said values preferably in both a digital and in an analog format.
- 20 37. A measuring and display organ (600) according to claim 36 **characterised** in that the display unit 670 is of LCD type.
- 25 38. A measuring and display organ (600) according to claim 37 **characterised** in that the processor 630 is of flash type, i.e., it has an internal flash memory which contributes to low power consumption.
- 30 39. A measuring and display organ (600) according to claim 38 **characterised** in that it is powered from a solar cell panel.
- 35 40. A measuring and display organ (600) according to claim 39 **characterised** in that it is powered from a battery 665.
41. A measuring and display organ (600) according to claim 40 **characterised** in that the processor 630 is connected to an IR port 640 for transferring information to an external device such as a personal computer or personal digital assistant.
42. A measuring and display organ (600) according to claim 41 **characterised** in that the display unit 670 displays the pressure value as a two-digit number representative of the pressure in centimetres water column
43. A measuring and display organ (600) according to claim 42 **characterised** in that the display unit 670 displays the air flow as a two digit number in litres per minute.

44. A measuring and display organ (600) according to claim 43 **characterised** in that said organ comprises a pressure alarm function capable of indicating when the pressure exceeds or falls below set limits.
- 5 45. A measuring and display organ (600) according to claim 31 **characterised** in that said organ comprises a cumulative-airflow function for displaying on the display (670) the cumulative airflow, representative of the last hours cumulative air leakage.
- 10 46. A measuring and display organ (600) according to claim 45 **characterised** in that said cumulative-airflow function is implemented using computer program code.
- 15 47. A measuring and display organ (600) according to claim 32 **characterised** in that said organ comprises means for separation of components onto two separate boards, and said means comprises a first connector on a first board and a second connector on a second board and cabling between said connectors.
- 20 48. An organ according to claim 47 where said organ comprises means for keeping a unitary board in a powered off state, and means for powering on of both boards when said boards are connected together.
- 25 49. An organ according to claim 48 where said organ comprises tie means for establishing a tie between said first board and said second board, such that any of said boards will be set in an error state if it is connected to a board not being the same as the one to which it was connected the first time.
- 30 50. An organ according to claim 49 where said tie means comprises computer program code checking a unique control number given to each board at manufacturing.
- 35 51. An air flow sensor useable in the drainage apparatus of claim 1, **characterised** in that said sensor is of a micro-electro-mechanical system (MEMS) type and adapted to sense the cooling effect of an airflow passing a number of measurement resistors and as an output provide a signal representative of a value of said airflow, and in that the resistors is physically arranged on on a chip such that when in use the air flow to be measured is flowing over and cooling the resistors, and in that a heating resistor is arranged such that air of the air flow to

be measured passes at least one measurement resistor before it passes the heater resistor and subsequently at least one other resistor.

52. The sensor of claim 51 **characterised** in that it comprises four measurement resistors physically arranged along a reference line parallel to a flow direction of the flow which flow rate is to be measured and where said four measurement resistors comprise a first resistor (R1) being arranged leftmost with reference to said line, a second resistor (R2) being arranged to the right of said first resistor with reference to said line, a third resistor (R3) being arranged to the right of said third resistor with reference to said line and a fourth resistor (R4) being arranged to the right of said third resistor with reference to said line.
53. The sensor of claim 52 **characterised** in that said sensor comprises an electrical bridge circuit comprising said resistors and a first, a second, a third, and a fourth connection point (P1-P4) , and where said resistors is connected in said bridge in a certain way, and where said certain way comprise that said third resistor (R3) is connected between the first (P1) and the second (P2) connection points, the second resistor (R2) is connected between the second (P2) and the third (P3) connection points, and the fourth resistor (R4) is connected between the third (P3) and fourth (P4) connection points, and the first resistor (R1) is connected between the fourth (P4) and the first (P1) connection points.
54. The sensor of claim 53 **characterised** in that said bridge is fed with a voltage over the first (P1) and the third (P3) connection points, and a voltage (Vout) representative of said flow is measured over the second (P2) and fourth (P4) connection points
55. The sensor of claim 54 **characterised** in that a heating resistor (Rh) is physically arranged between the second (R2) and the third (R3) resistors with reference to the reference line
56. A sensor system **characterised** by the sensor of claim- 54 and further comprising means for alternately energising and not energising the heating resistor (Rh), and also comprising means to form a difference value (Vdiff) between a first voltage value (Vout1) measured when the heating resistor is in a non heated state, and a second voltage value (Vout2) measured when the heating resistor is in a heated state.

57. A sensor system according to claim 56 **characterised** in that said difference value (V_{diff}) is further used as being representative of the flow and being relatively insensitive to offset.
- 5 58. A sensor system according to claim 57 **characterised** in that it also comprises means for compensating the flow measurement for offset caused by temperature shift.
- 10 59. A sensor system according to claim 58 **characterised** in that said means for compensating makes use of the fact that the current flowing through a bridge circuit exposed to the air which temperature is to be compensated for, is representative of said temperature.
- 15 60. A sensor system according to claim 59 **characterised** in that it comprises a pressure sensor bridge circuit, and a value representative of the current through said bridge is used to compensate the flow sensor for temperature variations.
- 20 61. A method for obtaining an air flow rate value from a number of sensor resistances arranged in the air flow which rate is to be obtained, and coupled in a bridge configuration, comprising the following steps
- obtaining a first voltage value representative of a first imbalance of said bridge
 - providing a control signal useable for gating a transistor for heating said resistors
 - obtaining a second voltage value representative of a second imbalance of said
 - 25 bridge
 - forming a difference between the first and second voltage values
 - holding said difference as representative of said air flow rate.
- 30 62. A computer program element comprising: computer program code means to carry out the method steps of claim 61.
63. A computer program element as claimed in claim 62 embodied on a computer readable medium.

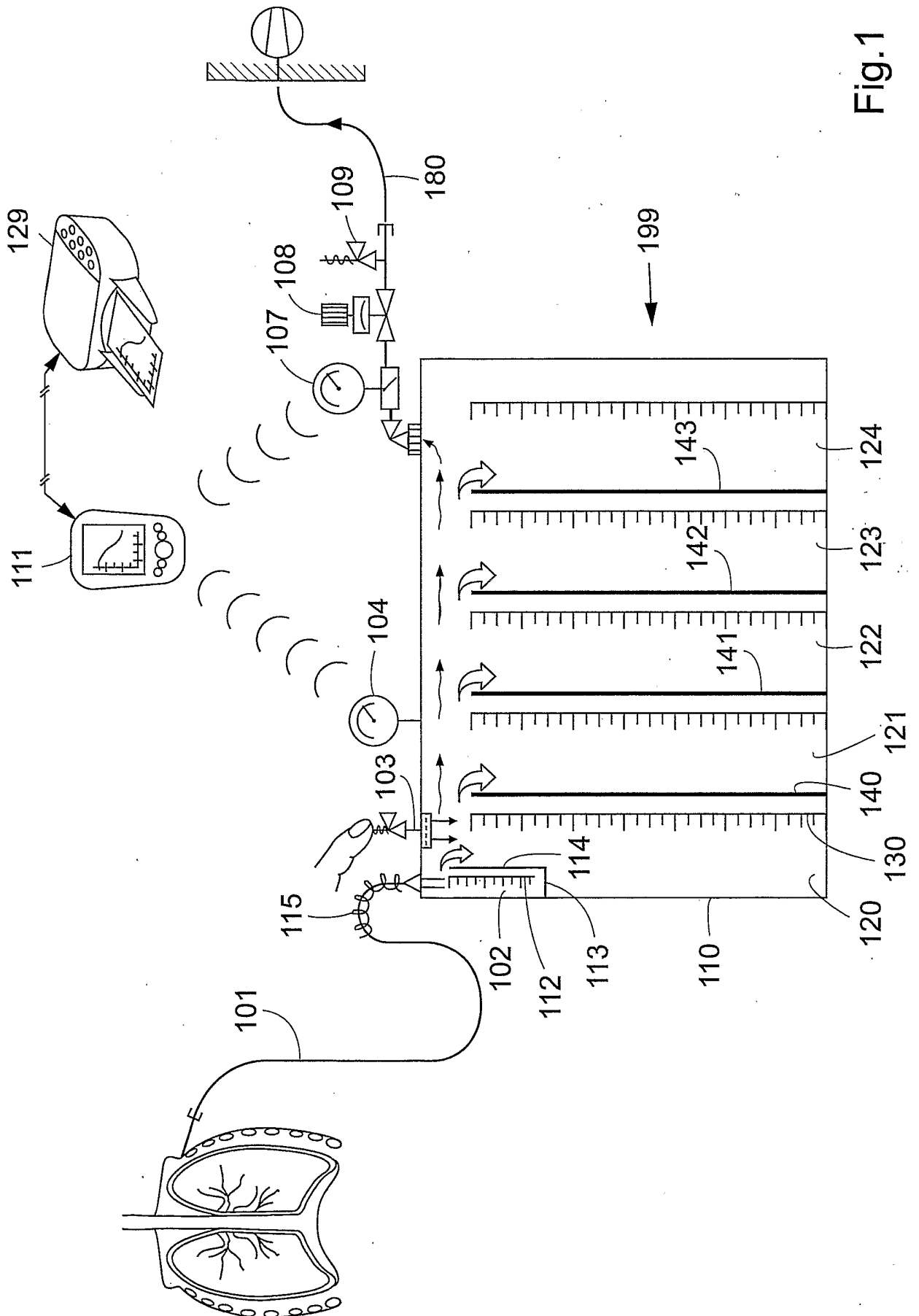


Fig.1

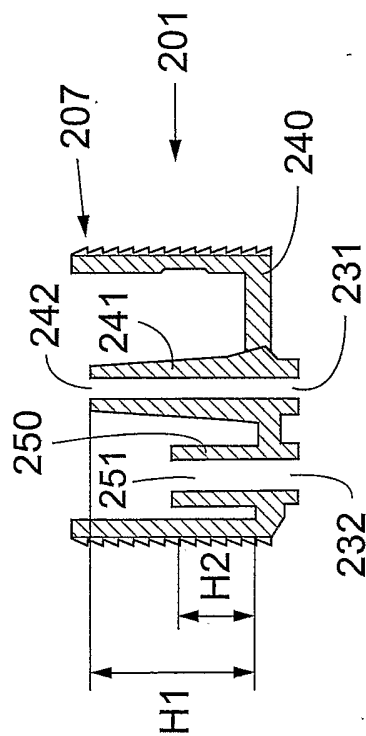
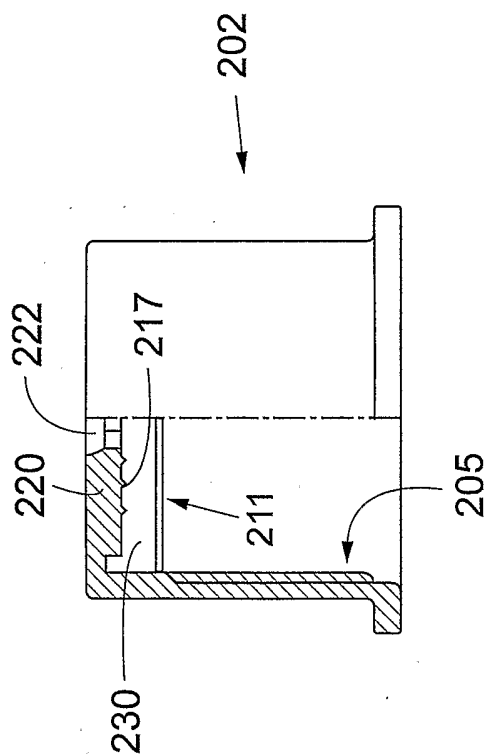


Fig.2a

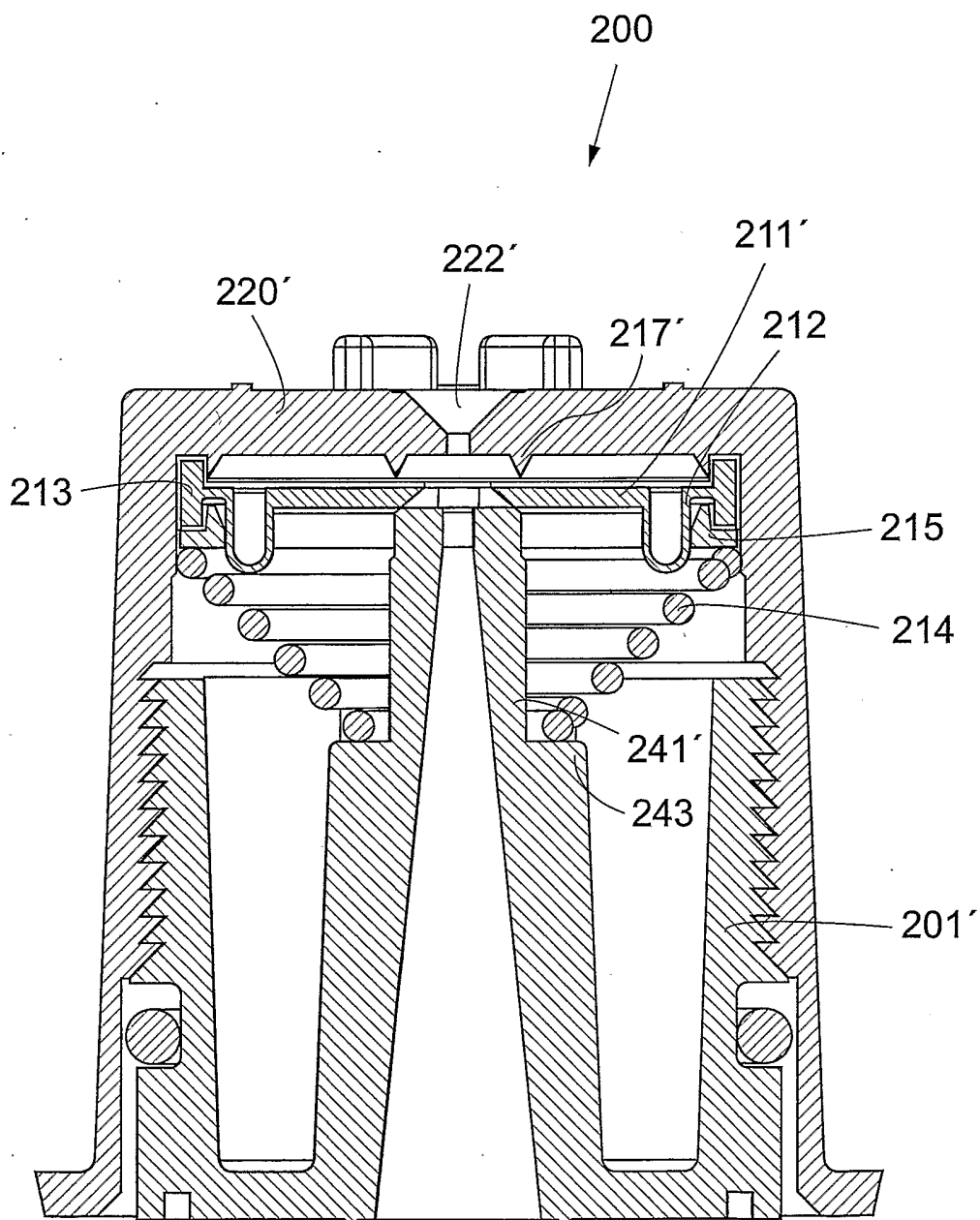


Fig. 2b

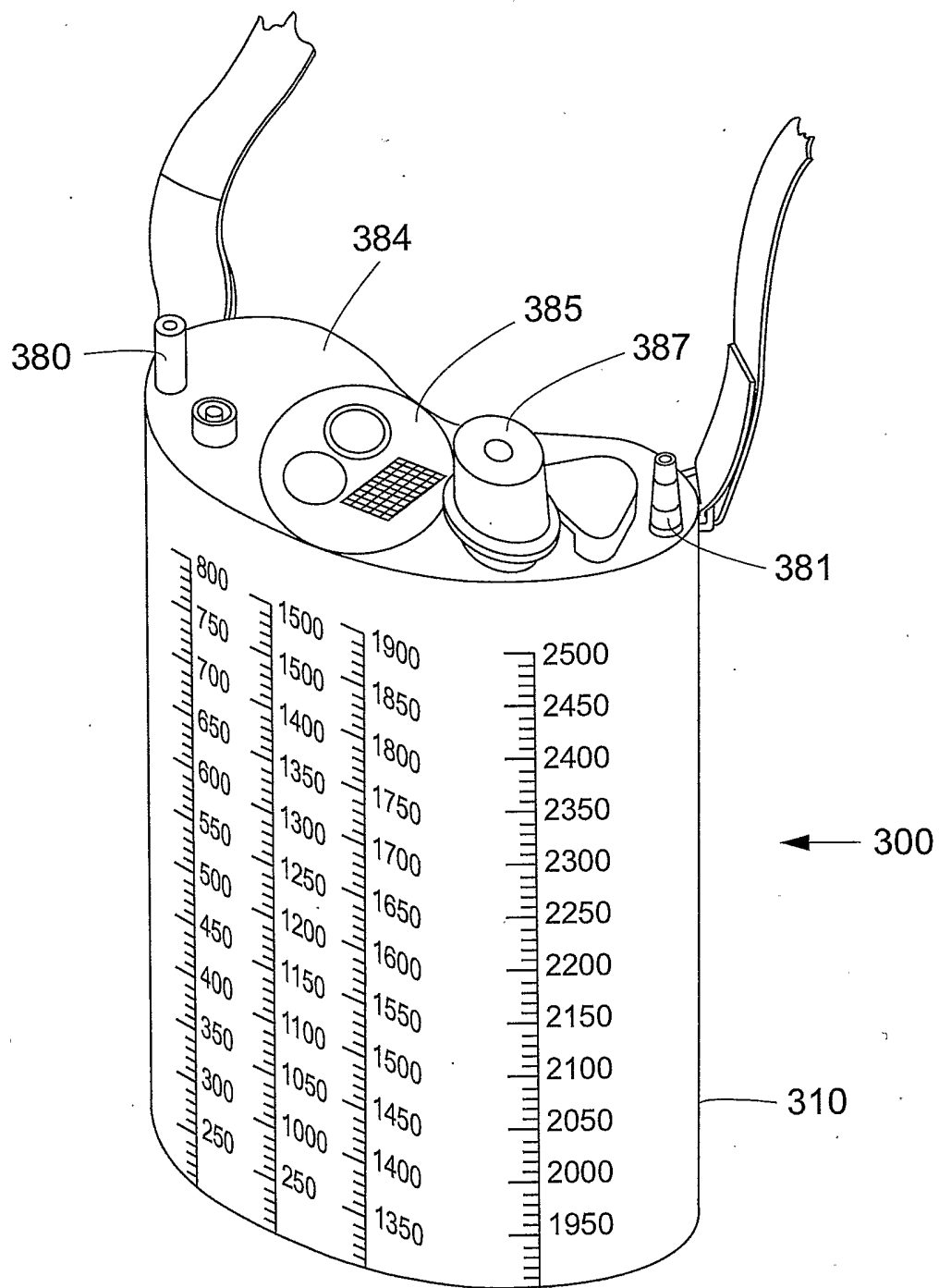


Fig.3

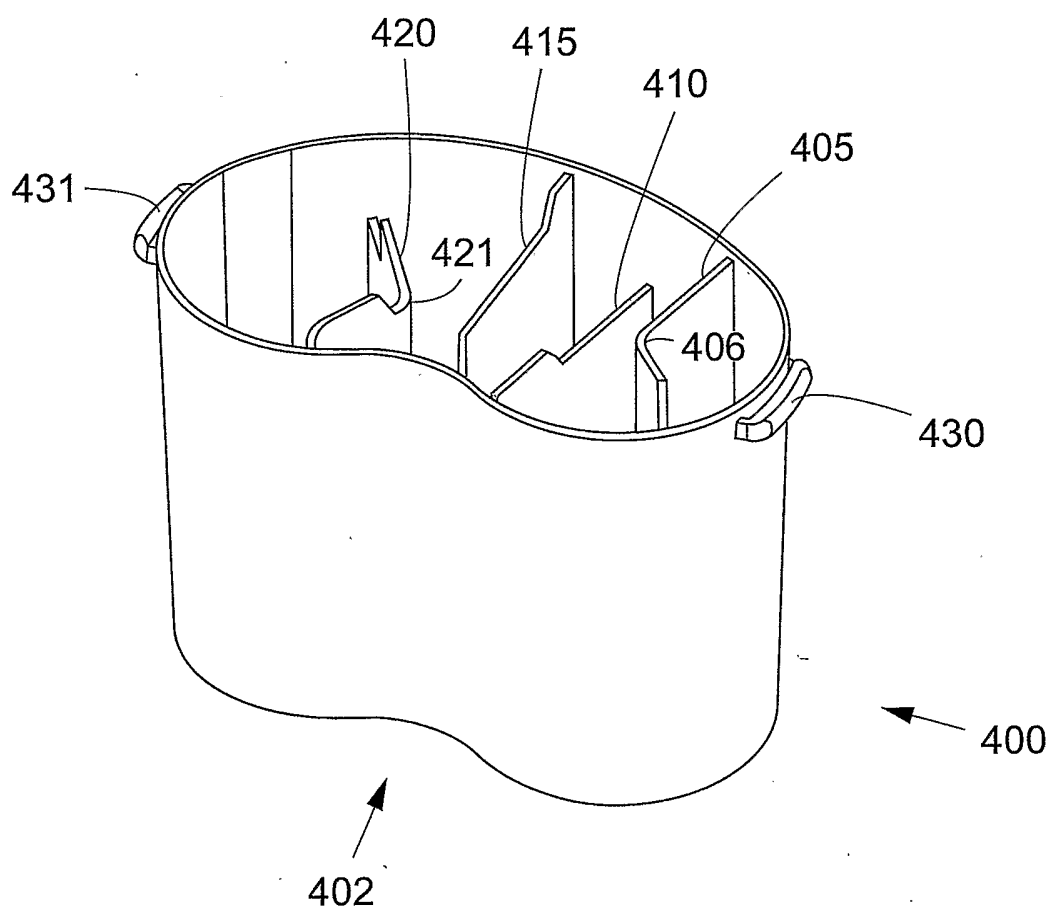


Fig.4

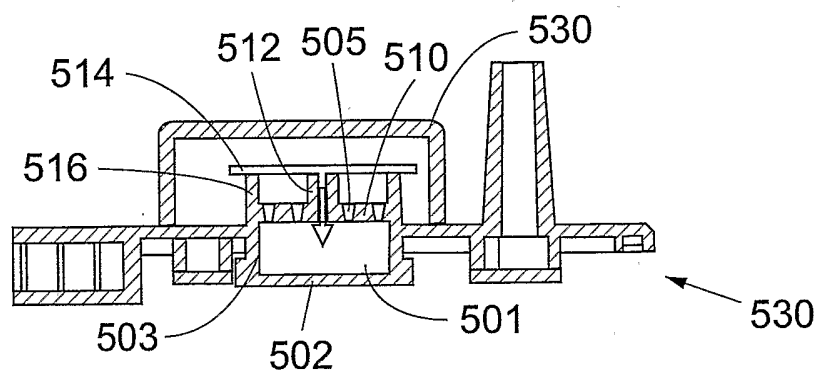


Fig.5a

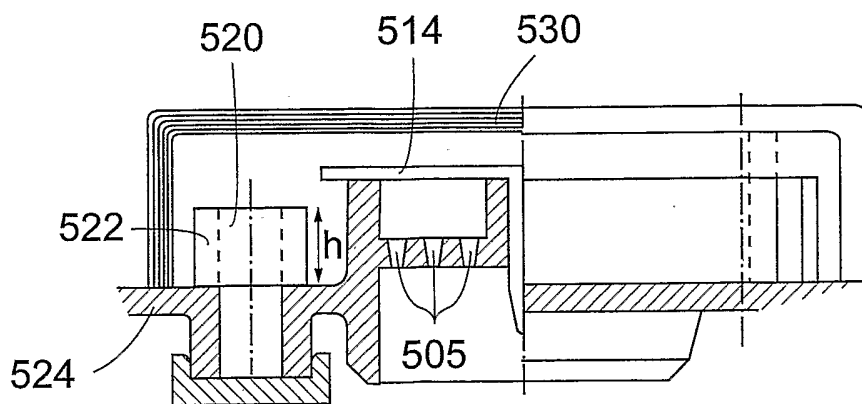


Fig.5b

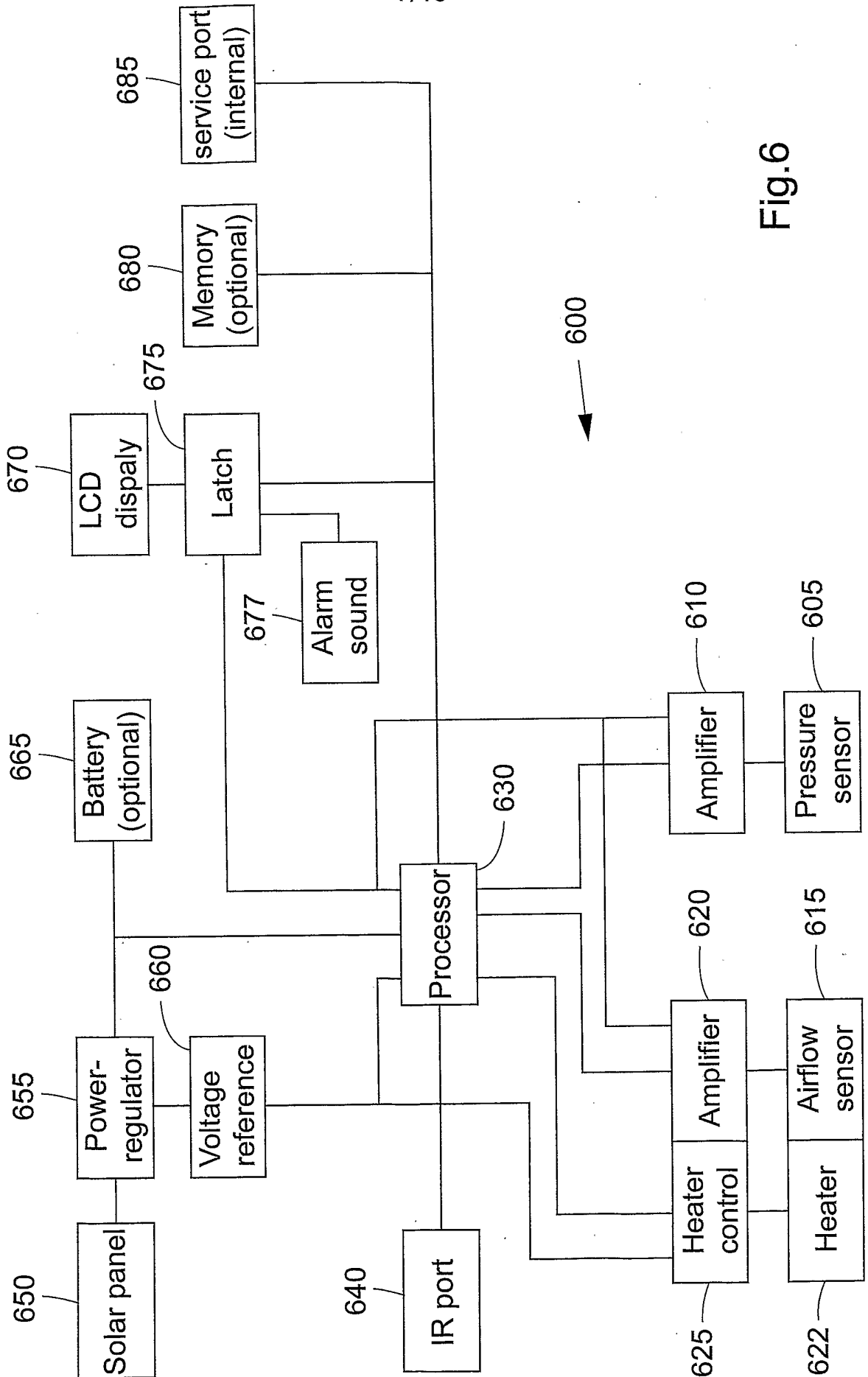


Fig.6

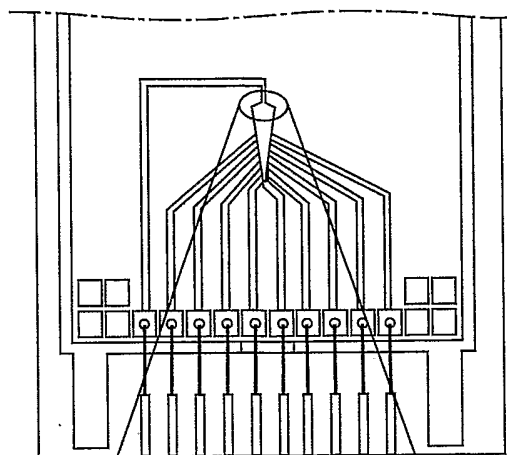


Fig. 7 a

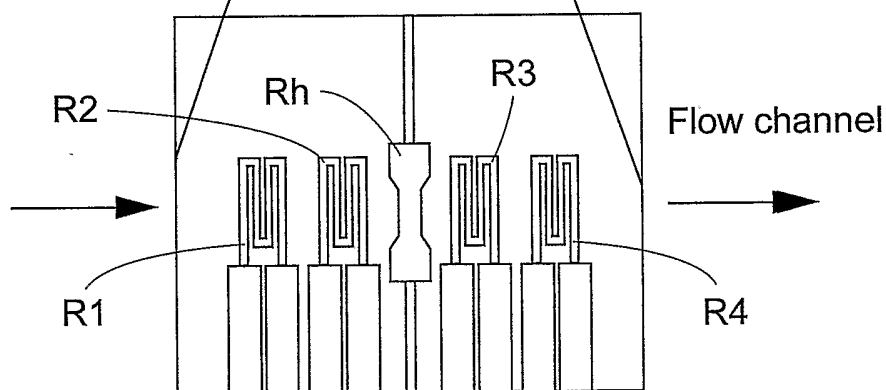


Fig. 7 b

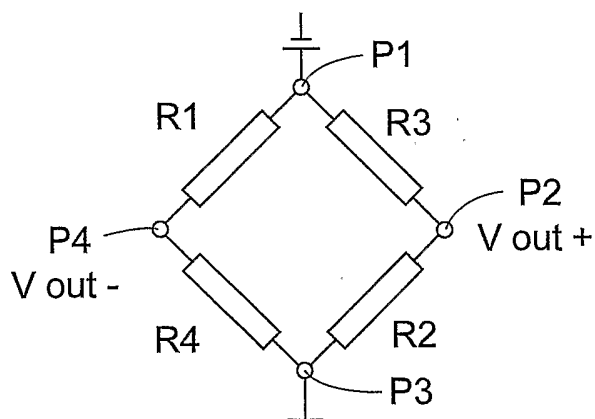


Fig. 7 c

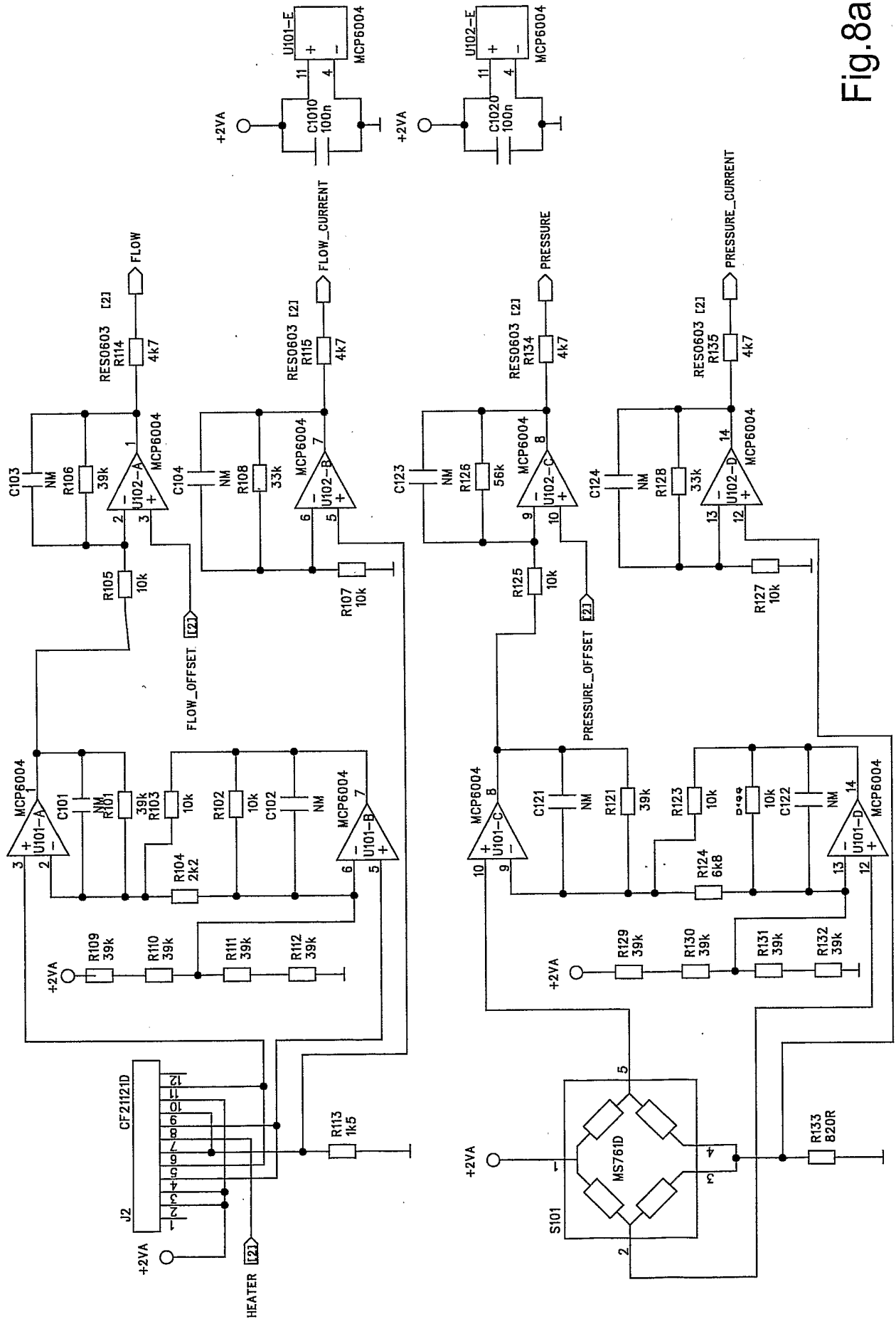


Fig. 8a

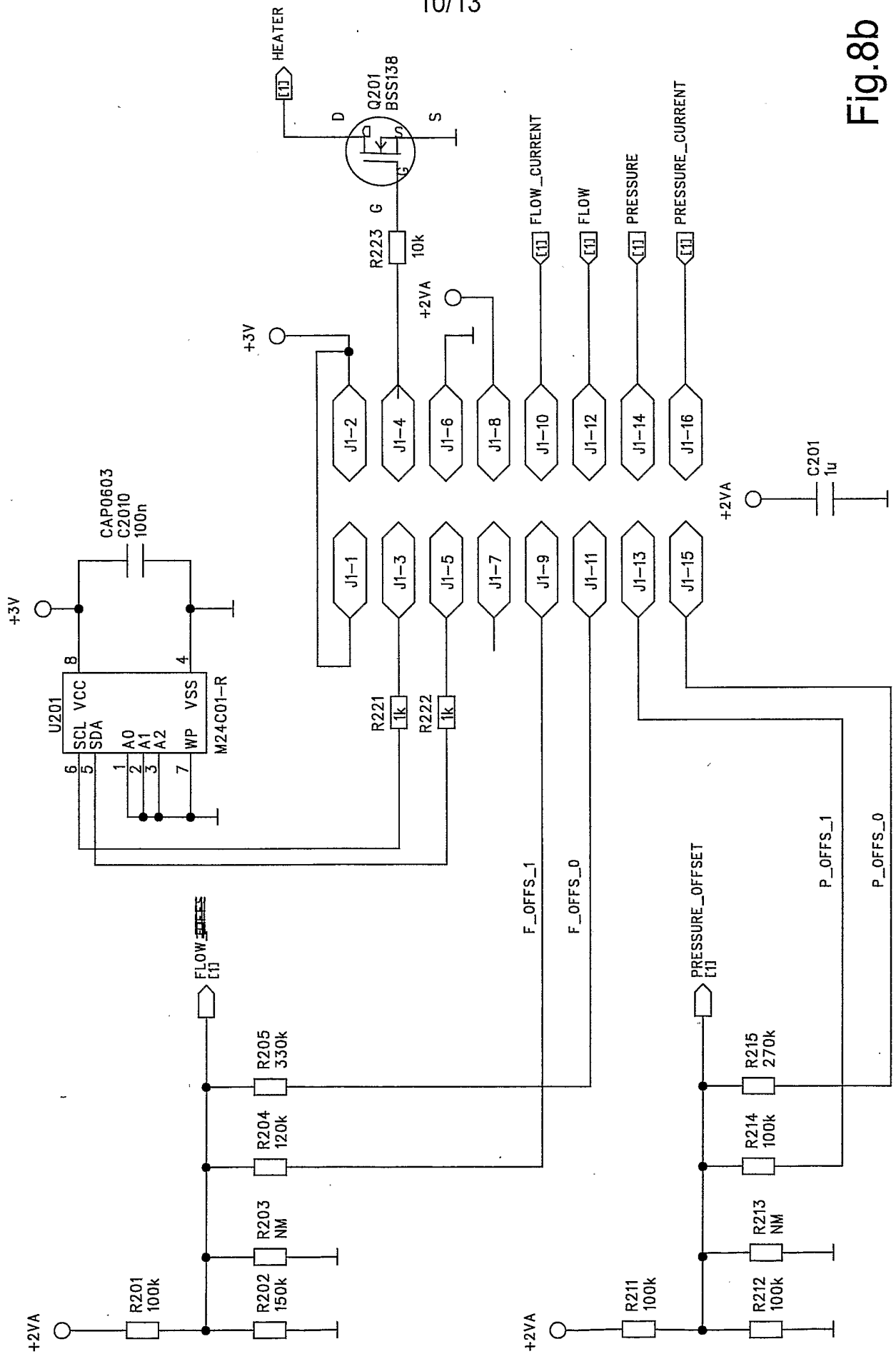


Fig.8b

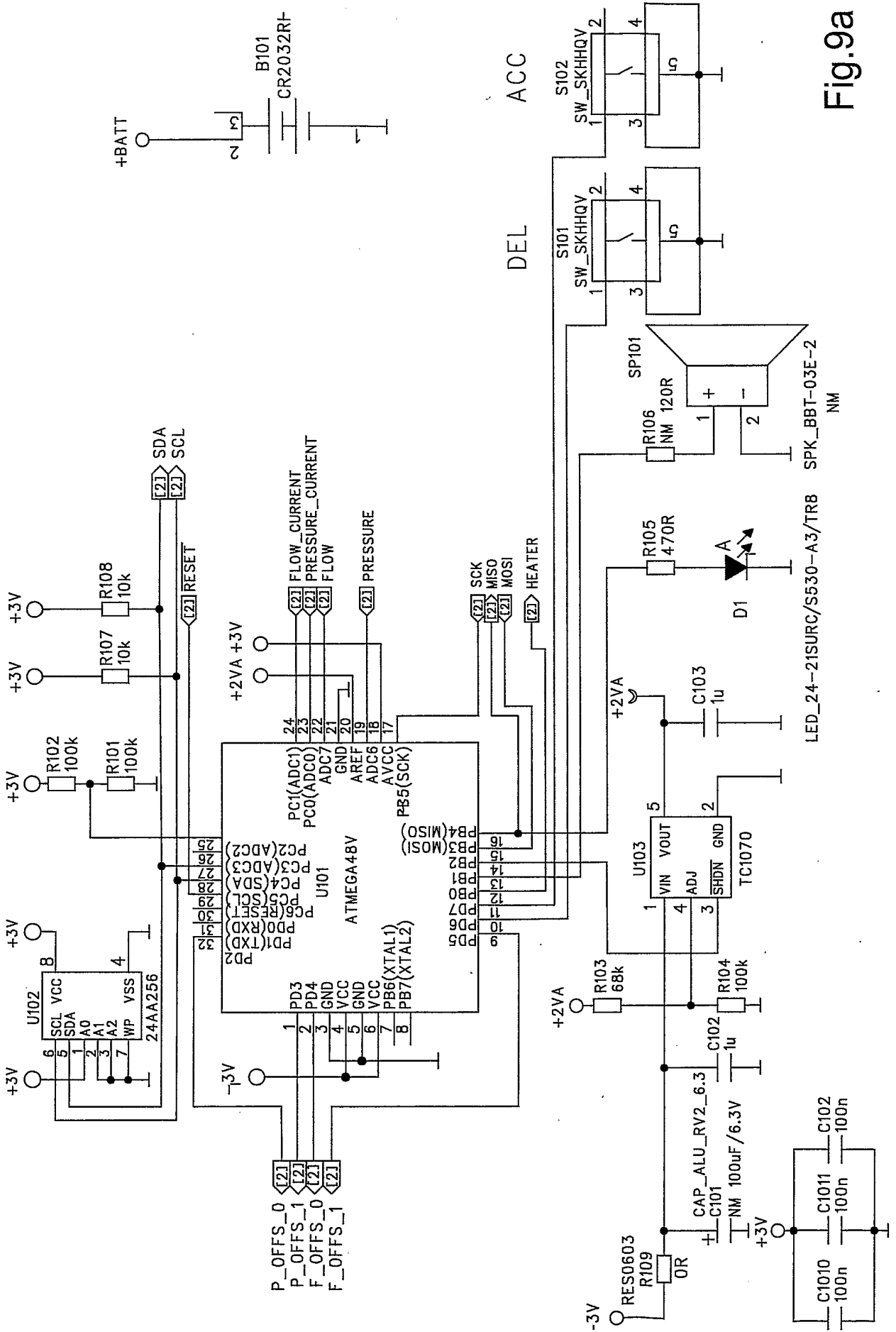


Fig.9a

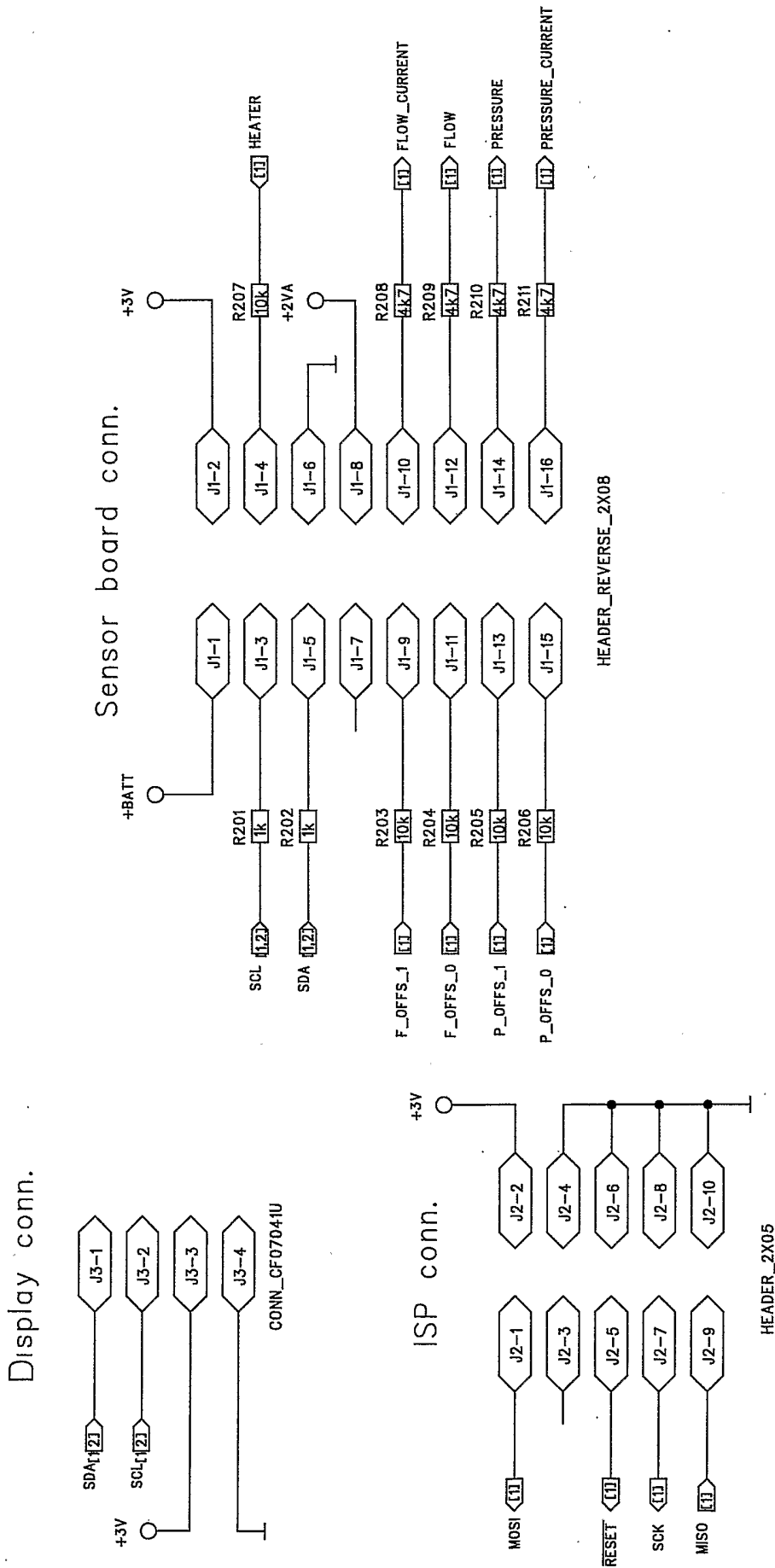


Fig.9b

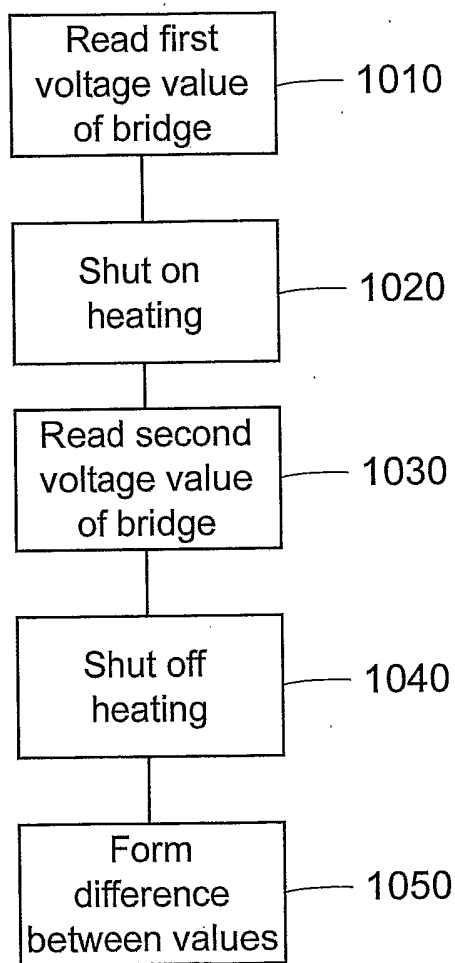


Fig.10

INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 2004/000637

A. CLASSIFICATION OF SUBJECT MATTER		
IPC7: A61M 1/00, G01F 1/68 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)		
IPC7: A61M, G01F		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
SE,DK,FI,NO classes as above		
Electronic data base consulted during the international search (name of data base and, where practicable, 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 4654029 A (D'ANTONIO, N F), 31 March 1987 (31.03.1987), column 3, line 58 - column 5, line 63; column 10, line 12 - line 47	1-7,31-37
Y		51
A		42,44
	--	
X	US 4889531 A (D'ANTONIO, N F ET AL), 26 December 1989 (26.12.1989), column 4, line 25 - column 6, line 9	1,8,9,31,32
Y		25
A		10
	--	
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C. <input checked="" type="checkbox"/> See patent family annex.		
* Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed		"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family
Date of the actual completion of the international search		Date of mailing of the international search report
30 August 2004		
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86		Authorized officer Bo Gustavsson /OGU Telephone No. +46 8 782 25 00

INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 2004/000637

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4710165 A (MCNEIL, C B ET AL), 1 December 1987 (01.12.1987), column 6, line 32 - line 52 --	1,31,40,44
X	GB 2077397 A (THE MEDISHIELD CORP LTD), 16 December 1981 (16.12.1981), whole document	10,11,13,14
A	--	17
A	FR 2560770 A1 (CHEVAL, M), 13 Sept 1985 (13.09.1985), whole document --	10,11,13,14, 17
Y	WO 9910024 A1 (ROCKET MEDICAL PLC), 4 March 1999 (04.03.1999), see the whole document	25
A	--	26-30
A	EP 1184043 A1 (MEDELA AG), 6 March 2002 (06.03.2002), see the whole document --	25-30
A	US 4372336 A (CORNELL, W.D. ET AL), 8 February 1983 (08.02.1983), see the whole document --	10,11,13,14, 25-30
Y	US 6139758 A (TU, X.), 31 October 2000 (31.10.2000), column 1, line 24 - column 3, line 51; column 4, line 25, figure 4A	51
A	--	2-5,52-61
A	WO 0198735 A2 (INSTRUMENTARIUM CORPORATION), 27 December 2001 (27.12.2001), page 1, line 5 - page 2, line 5, abstract -- -----	2-5,51-61

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 2004/000637

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

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

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

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

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see extra sheet

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying 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.: **1-19, 25-63**

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.

The present claims are considered to represent 5 different inventions as indicated below:

I. A first invention according to claims 1-9 and 31-50 relating to a drainage apparatus for collecting fluids from a body cavity comprising flow and pressure measuring means and means for presentation of measured data.

II. A second invention according to claims 10-19 relating to a pressure regulator for controlling the suction pressure in a drainage apparatus.

III. A third invention according to claims 20-24 relating to a non-return valve for use in a drainage apparatus.

IV. A fourth invention according to claims 25-30 relating to a collection chamber useable for a drainage apparatus.

V. A fifth invention according to claims 51-63 relating to an airflow sensor useable in a drainage apparatus, a method for obtaining an airflow rate and a computer program element for performing the method.

A partial search was carried out which related to the first invention mentioned above.

The reason for which the present application has been deemed to contain 5 inventions which are not linked such that they form a single general inventive concept, as required by Rules 13.1, 13.2 and 13.3 PCT are as follows:

The most relevant prior-art has been identified as US 4 654 029 A.

The document shows a drainage apparatus for collecting fluids from a body cavity comprising a collection chamber, catheters for connection between the body cavity and the collection chamber and between the chamber and a vacuum source providing a negative pressure. The apparatus also comprises means for measuring and presenting the flow of gas during the drainage and to measure the negative pressure in the drainage apparatus.

Invention I:

The special technical features contributed by the first invention over prior-art relate to details of the measure and presentation means.

.../...

These technical features tries to solve several different problem relating to signal processing, signal transmission and data presentation.

Invention II:

The special technical features contributed by the second invention over prior-art is to provide a safe and simple pressure regulator.

From these technical features the objective problem to be solved by the second invention can be construed as a simple way of regulating the negative pressure in a drainage apparatus.

Invention III:

The special technical features contributed by the third invention over prior-art is a non-return valve with a "capillary breaker".

From these technical features the objective problem to be solved by the third invention can be construed as the prevention of a backflow of air/gas in a drainage apparatus and deposition of fluids into the collection chamber.

Invention IV:

The special technical features contributed by the fourth invention over prior-art is a collection chamber for a drainage device, where the collection chamber has a specific design.

From these technical features the objective problem to be solved by the fourth invention can be construed as achieving a stable and spill-over secured chamber which also is wearable.

Invention V:

The special technical features contributed by the fifth invention over prior-art is a MEMS airflow sensor sensing the cooling effect of a passing airflow. From these technical features the objective problem to be solved by the fifth invention can be construed as providing an accurate airflow sensor.

The above analysis shows that the special technical features of invention I (claims 1-9 and 31-50) are neither the same as nor corresponding to those of invention II (claims 10-19), nor the same as or corresponding to those of invention III (claims 20-24), nor the same as or corresponding to those of invention IV (claims 25-30), nor the same as or corresponding to those of invention V (claims 51-62).

.../...

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 2004/000637

In conclusion, therefore, the 5 groups of claims are not linked by common or corresponding special technical features and define 5 different inventions not linked by a single general inventive concept.

The application, hence does not meet the requirements of Unity of Invention as defined in Rule 13(1)&(2) PCT.

As additional fees were timely paid for the fourth and fifth inventions, the search also covers these inventions.

A search was also carried out for the second invention according to claims 10-19, as the additional effort involved was negligible.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

31/07/2004

PCT/SE 2004/000637

US	4654029	A	31/03/1987	AT	32431 T	15/02/1988
				AT	60907 T	15/03/1991
				AT	72064 T	15/02/1992
				AU	2231283 A	21/06/1984
				BR	8306830 A	17/07/1984
				CA	1220538 A	14/04/1987
				DE	3375641 D	00/00/0000
				DE	3382168 D	00/00/0000
				DE	3382500 A	05/03/1992
				DK	570383 A	14/06/1984
				EP	0113541 A,B	18/07/1984
				SE	0113541 T3	
				EP	0200004 A,B	05/11/1986
				SE	0200004 T3	
				EP	0200005 A,B	05/11/1986
				SE	0200005 T3	
				ES	282426 U,Y	16/12/1985
				ES	527968 A	16/02/1985
				ES	8503250 A	01/06/1985
				FI	834548 A	14/06/1984
				IE	57881 B	05/05/1993
				IE	58296 B	25/08/1993
				IE	58297 B,L	25/08/1993
				IE	832917 L	13/06/1984
				IE	881719 L	14/06/1984
				IL	70427 D	00/00/0000
				JP	59120161 A	11/07/1984
				NO	834521 A	14/06/1984

US	4889531	A	26/12/1989	AT	158508 T	15/10/1997
				CA	1255988 A	20/06/1989
				DE	3588165 D,T	16/04/1998
				EP	0189478 A	06/08/1986
				EP	0497382 A,B	05/08/1992
				JP	2089508 C	02/09/1996
				JP	6085799 B	02/11/1994
				JP	6285154 A	11/10/1994
				JP	7108314 B	22/11/1995
				JP	61503012 T	25/12/1986
				US	4715855 A	29/12/1987
				US	4902284 A	20/02/1990
				WO	8601091 A	27/02/1986

US	4710165	A	01/12/1987	NONE		

GB	2077397	A	16/12/1981	AU	539461 B	27/09/1984
				AU	7138381 A	10/12/1981
				NZ	193953 A	20/03/1985

FR	2560770	A1	13/09/1985	NONE		

WO	9910024	A1	04/03/1999	AU	8740298 A	16/03/1999
				EP	1003572 A	31/05/2000
				GB	9717623 D	00/00/0000

EP	1184043	A1	06/03/2002	NONE		

INTERNATIONAL SEARCH REPORT
Information on patent family members

31/07/2004

International application No.
PCT/SE 2004/000637

US	4372336	A	08/02/1983	BE	889250	A	16/10/1981
				CA	1168540	A	05/06/1984
				DE	3123787	A,C	16/06/1982
				ES	503100	A	01/04/1982
				ES	8203615	A	16/07/1982
				FR	2484261	A,B	18/12/1981
				GB	2077600	A,B	23/12/1981
				HK	26585	A	12/04/1985
				JP	1433057	C	07/04/1988
				JP	57112874	A	14/07/1982
				JP	62038986	B	20/08/1987
				MX	160239	A	12/01/1990
				NL	189749	B,C	16/02/1993
				NL	8102927	A	18/01/1982
				SG	1485	G	14/06/1985

US	6139758	A	31/10/2000	CN	1077283	B	02/01/2002
				CN	1174984	A	04/03/1998
				US	6378365	B	30/04/2002

WO	0198735	A2	27/12/2001	AU	5658001	A	02/01/2002
				US	6470741	B	29/10/2002
