Abstract: A pressurised medical device comprising an inflatable element arranged to contact a part of a patient; a fluid connector attached to the element and arranged to deliver fluid to the element; a control system arranged to control flow of fluid in the device; a first element pressure sensor arranged to measure the pressure exerted by the element on the part of the patient; and a detection means arranged to detect malfunctioning of the first element pressure sensor.
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.
This invention relates to pressurised medical devices. For example, the invention relates to a compression device for the limb and particularly to a device for use on the leg. For example, the device may be used for compression therapy used in the treatment of venous leg ulcers.

Various compression devices are known for applying compressive pressure to a patient's limb. These types of devices are used to assist mainly in the prevention of deep vein thrombosis (DVT), vascular disorders and the reduction of oedema. US 2004/0111 048 (Jensen et al) and US 6786879 (KCI Licensing Inc) disclose such devices.

Compression therapy is used in the treatment of venous leg ulcers. The treatment relies on the compression achieving a reduction in oedema and improved return of blood via the venous system. This in turn reduces the residence time for blood supplied to the lower limb and the severity of ischaemic episodes within the limb that can result in tissue breakdown.

Composition of the limb in the treatment of venous leg ulcers is most usually achieved by the use of elastic bandages. Elastic bandages have the advantages that the patient can be mobile, can be treated at home and that once applied by a health care professional any removal or interference may be possible to detect. Elastic bandages do however have many disadvantages. They can work loose, the pressure generated by the bandage on the limb is not measured and depends on the level of skill of the health care professional applying the bandage, the level of compression is also affected by the circumference of the limb, the bandage cannot be removed and reapplied by the patient, for instance for bathing, and many patients find them unsightly, uncomfortable, hot or painful.
Compression of the limb in the treatment of venous leg ulcers can also be achieved by the use of compression stockings, although they are most often used in the prevention of leg ulcers for instance in the prevention of recurrence after an active leg ulcer has healed. Compression stockings have many of the advantages of elastic bandages, they can be used at home and the patient can be mobile. They however have some disadvantages. They are difficult to apply as the narrow ankle part has to be pulled over the heel, compliance with treatment is difficult to monitor as the patient may be able to remove and replace the stocking themselves and patients can find them uncomfortable.

Compression of the limb can also be achieved by a pneumatic compression device. As venous leg ulcers are most usually treated at home or in the community and the known compression devices are large, heavy and require professional supervision, their adoption for such treatment has not been widespread. The known devices used previously apply pressure to the limb through a thick cuff or cuffs which affect patient mobility and are aesthetically unacceptable to many patients. The pump which produces the compression is large and heavy and can supply fluid to the cuffs through many pipes. These characteristics make the known devices unsuitable for domestic use.

Pneumatic compression devices have the following advantages: They provide an effective treatment; while deflated, the inflatable cuff or cuffs are easy to apply to the patient's leg; and the pressure is more readily controlled and monitored.

Compression devices typically have inflatable sleeves and can have an associated pressure sensor which measures pressure exerted by the sleeve when in use upon the limb of a patient. The measured pressure can be
used for a variety of reasons. For example it can be used by a healthcare professional, e.g. a doctor, in order to obtain information about use of the product. This can be useful when the doctor is not in attendance whilst the compression device is being used. Data relating to the pressure exerted by the sleeve on the patient's limb can be stored for later analysis by the healthcare professional. Another example of how measured pressure readings can be used is when a control system of the compression device uses such readings to subsequently calculate a pressure to be applied to a patient's limb. Other uses for measured pressure readings will also be apparent to the skilled person. It is important that the measured pressure reading is accurate.

According to a first aspect of the invention there is provided a pressurised medical device comprising: an inflatable element arranged to contact a part of a patient; a fluid connector attached to the element and arranged to deliver fluid to the element, a control system arranged to control flow of fluid in the device, a first element pressure sensor arranged to measure the pressure exerted by the element on the part of the patient; and detection means arranged to detect malfunctioning of the first element pressure sensor.

Preferably the detection means is arranged to detect whether the first element pressure sensor is malfunctioning by detecting whether it is functioning accurately to within a predetermined degree of accuracy.

Preferably the detection means comprises a reference pressure sensor arranged to independently measure the pressure exerted by the element on the part of the patient. Preferably the first element pressure sensor measures pressure in a fluid line comprising the first connector and the reference pressure sensor measures pressure independently in the same fluid line.
Preferably the detection means is arranged to detect malfunctioning by measuring pressure difference between values read by the first element and reference pressure sensors and comparing them to a known relative pressure difference value for a non-malfunctioning first element pressure sensor. The relative pressure difference is preferably substantially zero and is shown as a difference in readings of around 15mmHg or less.

Preferably the control system is arranged to control fluid flow dependent on the pressure measured by the first element pressure sensor. The system is preferably arranged to control the fluid flow to reduce pressure if the detection means detects that the first element pressure sensor is malfunctioning and most preferably is arranged to reduce pressure to substantially zero.

Preferably the control system comprises a pump and a controller unit. Preferably the pressurised medical device comprises a compression device for a limb of a patient, the inflatable element comprises an inflatable sleeve arranged to surround the limb and exert a pressure on the limb, the fluid connector comprises a conduit attached to the sleeve arranged to deliver fluid to the sleeve, and the first element pressure sensor comprises a first sleeve pressure sensor arranged to measure the pressure exerted by the sleeve on the limb. Preferably the inflatable element comprises one or more individually inflatable cells. Each cell preferably has an associated element pressure sensor arranged to determine the pressure exerted by the cell. Separate fluid connectors are attached to each cell and are arranged to deliver fluid to each cell and each associated element pressure sensor is located in each fluid connector. The control system is preferably arranged to control fluid flow to reduce pressure only in cells which have associated element pressure sensors which have been determined as malfunctioning. Preferably a valve arrangement is arranged so as to selectively allow or prevent fluid flow through each
fluid connector and the control system is arranged to control the valve arrangement such that more than one cell cannot be inflated or deflated simultaneously. Alternatively, a valve arrangement is arranged to selectively allow or prevent fluid flow through each fluid connector and the control system is arranged to control the valve arrangement such that more than one cell can be inflated or deflated simultaneously. For example, a single fluid connector could be used to supply fluid to more than one cell. In such examples, the cells connected to the same fluid connector may exert the same pressure as each other.

The or each pressure sensor may comprise a fluid pressure sensor arranged to measure fluid pressure. Alternatively, the or each pressure sensor may comprise a contact pressure sensor arranged to measure contact pressure.

Preferably the pressured device is for the limb of a mobile patient.

The detection means is preferably arranged to check for malfunctioning of the or each element pressure sensor periodically, continuously, from time to time at preset or random intervals, every time the device is used or at any other suitable time when the device is used.

The control system is preferably arranged to control the fluid flow to reduce the exerted pressure to substantially zero if the or each element pressure sensor detects a pressure exceeding a first predefined amount. Preferably the control system is arranged to control the fluid flow to reduce the exerted pressure to substantially zero if the reference pressure sensor detects a pressure exceeding a second predefined amount. Preferably the second predefined amount is greater than the first predefined amount. The control system preferably comprises a first processor arranged to determine whether the pressure exceeds a first
predefined amount and a second processor, distinct from the control system, arranged to determine whether the pressure exceeds the second predefined amount. Alternatively, the control system comprises a first processor arranged to determine whether the pressure exceeds the first pre-defined amount and a hardware unit, distinct from the control system, arranged to determine whether the pressure exceeds the second pre-defined amount.

Preferred embodiments of the invention will now be described with reference to the accompanying drawings in which:

**Figure 1** is a perspective view of the sleeve of a first embodiment of the device on the limb and the controller,

**Figure 2** is a perspective view of the sleeve of the device off the limb and opened up,

**Figure 3** is a schematic diagram of the functional units of the control system of the device,

**Figure 4** shows two perspective views of the sleeve of a second embodiment of the device on the limb,

**Figure 5** is a schematic diagram of the functional units of the control system of the device of Figure 4,

**Figure 6** is a schematic air flow logic diagram of the functional units of the device of Figure 4,

**Figure 7** is a schematic sectional view of a manifold of the device of Figure 4; and
Figure 8 is a perspective view of a sleeve and controller according to a further embodiment of the device on the limb.

In Figure 1 a compression device according to a first embodiment of the invention is shown on the leg of a patient in a standing position. The device comprises a sleeve 2 having a leg cuff 4 connected to a foot cuff 6. The device also comprises a control system housed within a controller unit 8. The sleeve 2 is connected to the controller unit 8 by a fluid connector in the form of a conduit 10. The controller unit 8 is a small, hand held unit that may be clipped to the sleeve or to the waistband of the patient's trousers or skirt. The controller unit 8 is battery powered, by a Lithium battery, and rechargeable so that it can be recharged. The device also comprises an understocking 14 worn between the patient's leg and the sleeve 2. The understocking is present to absorb any moisture from the patient's leg but does not apply compression. The sleeve 2 has an inner 16 and an outer 18 surface composed of a durable flexible material that can be sponged clean and is divided into a plurality of minicells 20 best seen in Figure 2.

The controller unit 8 comprises a display 21 in the form of an LCD panel. Additionally, the controller unit 8 comprises a user input in the form of a row of buttons 26. Referring to Figure 3, the controller unit 8 comprises a microprocessor 28, and a memory 30. The control system also comprises a pump and valve arrangement 32. A sleeve pressure sensor 34 is attached to the sleeve and located between the sleeve and the limb and provides readings of the pressure experienced by the limb due to inflation of the sleeve by the control system. In this embodiment the sleeve pressure sensor 34 is a contact pressure sensor. The microprocessor 28 is able to read data from and write data to the memory. Operation of the control system by a user is achieved via the user input 26.
In use, the sleeve pressure sensor 34 provides information relating to the pressure exerted by the sleeve 2 on the limb. The microprocessor 28 is able to determine the length of time for which the sleeve 2 is inflated and in place surrounding the limb. This data is stored in the memory 30. The compression device operates in a continuous pressure mode. In this continuous pressure mode a patient or healthcare professional uses the buttons 26 to input a desired constant pressure which is required to be applied to the limb via the sleeve 2. The microprocessor 28安排s for inflation of the sleeve 2 to the required pressure. The sleeve pressure sensor 34 is used to determine when the required pressure has been reached. If, during the course of time, the pressure being exerted by the sleeve 2 on the limb falls below a required level it is detected by the sleeve pressure sensor 34 and the microprocessor 28 communicates with the pump and valve 32 in order to inflate the sleeve 2 back up to the required level of pressure.

The microprocessor 28 runs a timer programme to measure the length of time for which the pressure being applied by the sleeve is at a particular level. This data is stored in the memory 30. Using the user input buttons 26, the user can specify the length of time for which the sleeve should remain inflated. After this length of time has expired the microprocessor 28 arranges for deflation of the sleeve 2.

In other embodiments the pressure to be exerted on the limb and the amount of time for which the pressure is to be exerted is pre-programmed on the microprocessor 28. In such embodiments, when the controller unit 8 is turned on the pre-programmed treatment begins. There is no need for a user to input details of the required pressure or duration.
Using the user input buttons 26, the healthcare professional can request details of use of the device to be displayed on the LCD display screen 21, by, for example inputting a PIN number.

In other embodiments there is no need to enter a PIN number and the display may automatically default to a display which shows details of use of the device. For example, in another embodiment, the control unit does not have a conduit which is in the form of an umbilical type cord. In such embodiments the control unit may be fitted, e.g. snap-fitted, onto the sleeve in use. When the control unit is removed from the sleeve its display defaults automatically to showing details of use of the device.

The compression device also comprises detection means which is arranged to detect malfunctioning of the sleeve pressure sensor 34. In this embodiment the detection means comprises a reference fluid pressure sensor 50. The reference fluid pressure sensor 50 is located in the conduit 10 between the controller unit 8 and the sleeve 2 in order to measure the pressure in the conduit 10, i.e. it is located in the same fluid line as the sleeve pressure sensor 34 and is arranged to independently measure pressure in the fluid line.

The microprocessor 28 is arranged to compare measurements obtained from the sleeve pressure sensor 34 and the fluid pressure sensor 50 in order to determine whether or not the sleeve pressure sensor 34 is malfunctioning. In this embodiment the sleeve is typically inflated up to pressures of about 50mmHg (6.7kPa). In this embodiment, for such pressures, the microprocessor 28 is arranged to determine that the sleeve pressure sensor is malfunctioning if the pressures measured by the two sensors 34, 50 are not within 13mmHg of each other. Also, in this embodiment in order to provide more reliable determinations, ten consecutive pressure measurements are taken by each sensor and the
average difference between them is analysed. The measurements are made within one second of each other in this embodiment. If the average difference between the measured pressures is not more than 13mmHg then the microprocessor 28 determines that the sleeve pressure sensor is not malfunctioning i.e. it is functioning correctly. If the average difference between the pressures measured by the sensors 34, 50 is greater than 13mmHg then the microprocessor 28 determines that the sleeve pressure sensor 34 is malfunctioning i.e. it is not functioning accurately enough. This is undesirable since it can be important to accurately know the pressure exerted by the sleeve on the limb. For example it can be dangerous if the compression device is exerting a pressure greater than required on the limb of a patient. Also, if usage data relating to the pressure being exerted on the limb at a particular time is being stored in the memory 30 for later analysis by a healthcare professional then inaccurate stored data can lead to an incorrect determination of the correct subsequent medical treatment required by a patient. Therefore if the microprocessor 28 determines that the sleeve pressure sensor 34 is malfunctioning then it is arranged to instruct the pumping valves 32 to control fluid flow to the sleeve such that the pressure exerted by the sleeve is reduced to substantially zero. In other embodiments the fluid flow may be controlled such that the pressure is significantly reduced. However in this embodiment the pressure is reduced to zero since advantageously, this cannot lead to a situation where a limb is put under more pressure than it should be during the course of a prescribed treatment.

In other embodiments more or less than ten readings may be taken and their average used as an indication of the pressure exerted by the sleeve upon the limb. Also, in this embodiment, pressures measured by the two sensors 34, 50 are required to be within 13mmHg of each other - this amounts to about 15% of the typical inflation pressure of the sleeve. In
other embodiments, if more accuracy is required then a smaller percentage error may be provided. If less accuracy is needed then a greater percentage error may be allowable.

In a further embodiment of the invention, the microprocessor 28 is arranged to run software which causes it to monitor the pressure measured by the sleeve pressure sensor 34. If this measured pressure exceeds 70mmHg (9.3kPa) for a duration of more than five seconds then the microprocessor 28 is arranged to instruct the pump and valve arrangement 32 to reset the pressure being applied back down to a safe pressure level. In this embodiment, the safe pressure level is 65mmHg (8.7kPa). In other embodiments the safe pressure level may be defined as a different value of pressure. Also in other embodiments, the pressure may be monitored over a greater or smaller duration. In addition, a distinct monitoring hardware unit 52 is arranged to monitor the pressure measured by the reference sensor 50. The hardware unit 52 is represented in Figure 3 but is not an essential feature of the previously described embodiment. The hardware unit 52 provides an independent measure of the pressure exerted on the limb by the inflatable sleeve. In this embodiment if a pressure greater than 80mmHg (10.7kPa) is observed for a duration of more than ten seconds then the hardware unit 52 will automatically reset the pressure back down to the safe pressure level. In some embodiments the hardware unit will shut down the fluid flow in the device altogether. Both of these cut off mechanisms operate continuously and data from the previous five or ten second periods is used to determine whether or not the compression device is operating at a safe level. In other embodiments different time periods can be used. Advantageously, the hardware unit 52 determination provides a back up for the determination made by the microprocessor 28 of the control system. Therefore if the microprocessor 28 and control system fail then the
hardware unit 52 should be able to identify this failure and safely reduce the pressure in the compression device.

Figure 4 shows a device according to a further embodiment of the invention where the leg cuff and foot cuff comprise cells with an anatomical shape 22.

Four cells are provided in this embodiment - a foot cell C1, a lower cell C2, a middle cell C3 and an upper cell C4 (see Figure 4). Each cell C1, C2, C3 and C4 has an associated fluid pressure sensor S1, S2, S3, S4 respectively and the sensor is arranged to provide an indication of the pressure exerted by each cell upon the leg. The location of each sensor will be described in more detail below.

In this embodiment, the control system associated with the device is similar to the control system of the device according to the first described embodiment except that there are four fluid sleeve pressure sensors S1, S2, S3, S4 instead of only one contact sleeve pressure sensor 34.

Referring to Figure 5, a control system in this embodiment includes a microprocessor 128 in communication with a memory 130 and a pump and valve arrangement 132. In this embodiment there is no display or user input and it should be understood that these are not essential for the invention. The processor 128 is able to communicate with the sensors S1, S2, S3, S4. The processor 128 is also in communication with a reference sensor S5 which is arranged to provide an indication of the pressure within the fluid flow system of the compression device (described in more detail below).

Referring to Figures 6 and 7, a manifold 100 has fluid flow conduits 40, 42, 44, 46, 48 which lead to the cells C1, C2, C3, C4 and an air
inlet/outlet C5 respectively. Referring to Figure 6, when a cell is required to be inflated, air is taken in via the conduit 48 by operation of the pump and valves V4, V5 under instruction from the processor 128. The processor 128 instructs valves V1, V2, V3 which are arranged between the air inlet C5 and the conduits 40, 42, 44, 46 such that only one of these conduits is operable, i.e. open to fluid flow, at any one time. From Figure 6 it can be seen that valve V3 directs fluid from/to the air inlet/outlet C5 to/from either valve V1 or V2, which in turn selectively open or close fluid paths to either cell C1 or C2 or either cell C3 or cell C4 respectively. A sensor Sl is located in conduit 40 between cell C1 and valve V1 in the controller unit 100. Similarly, sensors S2, S3 and S4 are located in conduits 42, 44 and 46 respectively. Sensors Sl, S2, S3 and S4 are all fluid pressure sensors controlled by the processor 128 and arranged to provide an indication of pressure exerted by their respective cells C1, C2, C3, C4 on the leg. Reference sensor, S5 independently monitors the pressure in the fluid flow system of the pressure device and since only one fluid path 40, 42, 44, 46 is able to be open at any one time, the sensor S5 is always in the same fluid path as whichever sleeve sensor is in the open fluid path. The processor 128 is able to compare measured pressure values from S5 and whichever of Sl, S2, S3, S4 corresponds to the open fluid path in order to check whether the relevant sleeve pressure sensor Sl, S2, S3, S4 is functioning correctly or malfunctioning. The measurements used to make this determination are similar to those in the previously described embodiment.

In other embodiments, it may be possible to have more than one fluid path open at any one time using a different pump and valve arrangement. Also similarly to the first described embodiment, the processor 128 continuously checks whether the pressure measured by Sl, S2, S3, S4 exceeds a desired maximum safe pressure. If so, the pressure in the
system can be reduced or cut off altogether as with the first described embodiment.

Also there is a hardware unit 152 which is able to interrogate the reference fluid pressure sensor S5 in order to determine whether the pressure in the fluid flow system has exceeded a safe level. If it has, the pressure can be reduced or preferably cut off altogether as previously described.

Referring to Figure 8, a compression device according to a further embodiment of the invention is shown on the leg of the patient. The device is functionally similar to the device of the previous embodiment but includes a controller unit 210 which is able to be placed within a pouch provided on the inflatable sleeve 202. The inflatable sleeve 202 comprises cells similarly to the device shown in Figure 4. The controller unit 210 does not have an umbilical cord running from it in order to communicate within the inflatable sleeve. Instead when the controller 210 is correctly in place inside the pouch, it is arranged to be aligned with a fluid connector which allows correct inflation/deflation of the sleeve. The controller 210 is arranged to be snap-fitted into place in order to obtain correct alignment with the fluid connector. In other embodiments, different alignment means may be provided.

Various modifications may be made to the present invention without departing from its scope. For example the controller unit may not have a user input. Instead, for example, the system can receive inputs from e.g. a keyboard of a PC or other processing device when it is in communication (e.g. infrared).

Also it is not necessary for the compression device to be arranged to provide a constant pressure to each cell or to the sleeve (if there is only
one cell). Instead it may operate in a different type of mode which requires a variation in pressure at different times for example.

The pressured medical device may not be a compression device for the limb. For example, it may be an inflatable mattress such as a pressure offloading mattress.
CLAIMS

1. A pressurised medical device comprising:
   - an inflatable element arranged to contact a part of a patient;
   - a fluid connector attached to the element and arranged to deliver fluid to the element,
   - a control system arranged to control flow of fluid in the device,
   - a first element pressure sensor arranged to measure the pressure exerted by the element on the part of the patient; and
   - detection means arranged to detect malfunctioning of the first element pressure sensor.

2. A pressurised medical device as claimed in Claim 1, wherein the detection means is arranged to detect whether the first element pressure sensor is malfunctioning by detecting whether it is functioning accurately to within a predetermined degree of accuracy.

3. A pressurised medical device as claimed in Claim 1 or Claim 2, wherein the detection means comprises a reference pressure sensor arranged to independently measure the pressure exerted by the element on the part of the patient.

4. A pressurised medical device as claimed in Claim 3, wherein the first element pressure sensor is arranged to measure pressure in a fluid line comprising the fluid connector and the reference pressure sensor measures pressure independently in the same fluid line.

5. A pressurised medical device as claimed in Claim 3 or Claim 4, wherein detection means is arranged to detect malfunctioning by
measuring pressure difference between values read by the first element and reference pressure sensors and comparing them to a known relative pressure difference value for a non-malfunctioning first element pressure sensor.

6. A pressurised medical device as claimed in Claim 5, wherein the relative pressure difference is substantially zero.

7. A pressurised medical device as claimed in any preceding claim, wherein the control system is arranged to control fluid flow dependent upon the pressure measured by the first element pressure sensor.

8. A pressurised medical device as claimed in Claim 7, wherein the control system is arranged to control the fluid flow to reduce pressure if the detection means detects that the first element pressure sensor is malfunctioning.

9. A pressurised medical device as claimed in Claim 8, wherein the control system is arranged to reduce pressure to substantially zero if the detection means detects that the first element pressure sensor is malfunctioning.

10. A pressurised medical device as claimed in any preceding claim, wherein the control system comprises a pump and a controller unit.

11. A pressurised medical device as claimed in any preceding claim comprising a compression device for a limb of a patient wherein the inflatable element comprises an inflatable sleeve arranged to surround the limb and exert a pressure on the limb, the fluid connector comprises a conduit attached to the sleeve and arranged to deliver fluid to the sleeve and the first element pressure sensor comprises a first sleeve pressure
sensor arranged to measure the pressure exerted by the sleeve on the limb.

12. A pressurised medical device as claimed in any preceding claim wherein the inflatable element comprises one or more individually inflatable cells.

13. A pressurised medical device as claimed in Claim 12 wherein each cell has an associated element pressure sensor arranged to determine the pressure exerted by the cell.

14. A pressurised medical device as claimed in Claim 13 wherein separate fluid connectors are attached to each cell and are arranged to deliver fluid to each cell and each associated element pressure sensor is located in each fluid connector.

15. A pressurised medical device as claimed in Claim 14, wherein the control system is arranged to control fluid flow to reduce pressure only in cells which have associated element pressure sensors which have been determined as malfunctioning.

16. A pressurised medical device as claimed in Claim 14 or Claim 15, wherein a valve arrangement is arranged to selectively allow or prevent fluid flow through each fluid connector and the control system is arranged to control the valve arrangement such that more than one cell can not be inflated or deflated simultaneously.

17. A pressurised medical device as claimed in Claim 14 or Claim 15, wherein a valve arrangement is arranged to selectively allow or prevent fluid flow through each conduit and the control system is arranged to
control the valve arrangement such that more than one cell can be inflated or deflated simultaneously.

18. A pressurised medical device as claimed in any preceding claim wherein the or each pressure sensor comprises a fluid pressure sensor arranged to measure fluid pressure.

19. A pressurised medical device as claimed in any preceding claim wherein the or each pressure sensor comprises a contact pressure sensor arranged to measure contact pressure.

20. A pressurised medical device as claimed in any of Claims 11 to 19 for the limb of a mobile patient.

21. A pressurised medical device as claimed in any preceding claim, wherein the detection means is arranged to check for malfunctioning of the or each element pressure sensor periodically, continuously, from time to time at preset or random intervals, every time the device is used or at any other suitable time when the device is used.

22. A pressurised medical device as claimed in any preceding claim, wherein the control system is arranged to control the fluid flow to reduce the exerted pressure to substantially zero if the or each element pressure sensor detects a pressure exceeding a first predefined amount.

23. A pressurised medical device as claimed in any of Claims 3 to 22, wherein the control system is arranged to control the fluid flow to reduce the exerted pressure to substantially zero if the reference pressure sensor detects a pressure exceeding a second predefined amount.
24. A pressurised medical device as claimed in Claim 23 when dependent on Claim 22, wherein the second predefined amount is greater than the first predefined amount.

25. A pressurised medical device according to Claim 23 or Claim 24, wherein the control system comprises a first processor arranged to determine whether the pressure exceeds the first predefined amount and a second processor, distinct from the control system, arranged to determine whether the pressure exceeds the second predefined amount.

26. A pressurised medical device according to Claim 23 or Claim 24, wherein the control system comprises a first processor arranged to determine whether the pressure exceeds the first pre-defined amount and a hardware unit, distinct from the control system, is arranged to determine whether the pressure exceeds the second pre-defined amount.

27. A pressurised medical device substantially as herein described with reference to any one or more of the accompanying drawings.
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61H23/04

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)
A61H

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Y</td>
<td>paragraphs [0130], [0175], [0176]</td>
<td>1-6,8,9, 15,19, 22,23</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Y</td>
<td>EP 0 813 047 A (MOORE PRODUCTS CO [US] MOORE PRODUCTS CO) 17 December 1997 (1997-12-17) the whole document</td>
<td>1-6,8,9, 22,23</td>
</tr>
</tbody>
</table>

Further documents are listed in the continuation of Box C

See patent family annex

* Special categories of cited documents
* A - document defining the general state of the art which is not considered to be of particular relevance
* E - earlier document but published on or after the international filing date
* L - document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
* O - document referring to an oral disclosure, use, exhibition or other means
* P - document published prior to the international filing date but later than the priority date claimed

Date of the actual completion of the international search: 2 April 2007

Date of mailing of the international search report: 12/04/2007

Name and mailing address of the ISA/Authorized officer

European Patent Office, P B 5818 Patentlaan 2 NL- 2280 HV Rijswijk
Tel (+31-70) 340-2040 Tx 31651 epo nl,
Fax (+31-70) 340-3016

Schut, Timen
INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2007/000231

(*Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>DE 41 00 501 A1 (BODENSEEWERK GERAETETECH [DE]) 16 July 1992 (1992-07-16) column 1, line 58 - column 2, line 18</td>
<td>19</td>
</tr>
<tr>
<td>Patent document cited in search report</td>
<td>Publication date</td>
<td>Patent family member(s)</td>
</tr>
<tr>
<td>----------------------------------------</td>
<td>-----------------</td>
<td>--------------------------</td>
</tr>
<tr>
<td>US 2005159690 A1</td>
<td>21-07-2005</td>
<td>NONE</td>
</tr>
<tr>
<td></td>
<td></td>
<td>US 5672808 A</td>
</tr>
<tr>
<td></td>
<td></td>
<td>US 5804736 A</td>
</tr>
<tr>
<td></td>
<td></td>
<td>US 6029524 A</td>
</tr>
<tr>
<td></td>
<td></td>
<td>DE 10229702 A1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>US 2006162419 A1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>DE 60101080 D1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>DE 60101080 T2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ES 2208513 T3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>US 6558338 B1</td>
</tr>
<tr>
<td>US 5443440 A</td>
<td>22-08-1995</td>
<td>CA 2127329 A1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 0698387 A1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>JP 8038563 A</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ZA 9404824 A</td>
</tr>
<tr>
<td>DE 4100501 A1</td>
<td>16-07-1992</td>
<td>NONE</td>
</tr>
</tbody>
</table>