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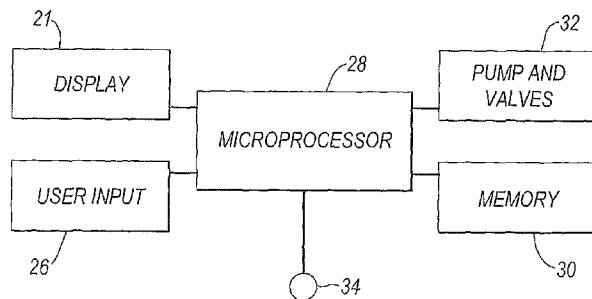
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(54) Title: COMPRESSION DEVICE FOR A LIMB



(57) Abstract: A compression device for a limb of a patient comprises an inflatable sleeve (2) arranged to surround the limb and a conduit (10) attached to the sleeve (2) arranged to deliver fluid to the sleeve (2). The device also comprises a control system arranged to control fluid flow in the device and a memory (30) arranged to store gathered data relating to use of the device.

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COMPRESSION DEVICE FOR A LIMB

This invention relates to a compression device for the limb and particularly to a device for use on the leg. For example, the device may 5 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 10 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 15 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.

20 Compression 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 25 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 30 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 5 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 10 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 15 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 20 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.

We have developed a pneumatic compression device more suitable for 25 home 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 30 controlled and monitored.

However, with all of the previously referenced devices compliance with treatment can be a problem as a patient treated at home or in the community may remove the device for any of the reasons mentioned which can result in insufficient usage of the device and failure to follow a compression therapy schedule prescribed by a healthcare professional. This can lead to a longer healing time for the patient.

According to a first aspect of the present invention there is provided a compression device for a limb of a patient comprising: an inflatable sleeve arranged to surround the limb, a conduit attached to the sleeve arranged to deliver fluid to the sleeve, a control system arranged to control flow of fluid in the device and a memory arranged to store gathered data relating to use of the device.

Advantageously such a compression device allows direct monitoring of use of the device by, for example, a healthcare professional. A patient may only see a healthcare professional once or twice a week and this device provides the healthcare professional with independent knowledge of the usage details which the patient may otherwise be reluctant to provide or may not be able to provide accurately. Problems associated with cases of poor usage of the compression device can thus be more easily identified.

Preferably the control system comprises a pump and a controller unit. The device preferably further comprises a display device arranged to provide a display dependent upon the gathered data. Preferably the controller unit is portable and wearable and most preferably it is attached to the conduit. The controller unit preferably includes the display which may be in the form of an LCD screen. Alternatively, the display may be part of a remote device such as a personal computer with which the

controller can communicate e.g. by cable connection or radio frequency or infrared communication.

The device may comprise at least one pressure sensor arranged to
5 measure the pressure exerted by the device. The sensors may be attached to the sleeve and located between the sleeve and the limb, the sensor(s) providing readings of the pressure experienced by the limb due to the inflation of the sleeve by the controller. The pressure sensor may be a contact pressure sensor.

10

We have found that monitoring the actual pressure experienced by the limb due to the device enables the device to provide a predetermined compression profile to the limb. The predetermined compression profile may be selected by the health care professional to cater for the patient's
15 condition. For example, a patient with lymphodema may require a different level of compression than a patient with a healed leg ulcer. The sensor also allows the device to increase or decrease the pressure on a particular part of the limb to give the predetermined compression profile while the device is in use. This alleviates the problem of pressure
20 difference experienced with the use of elastic bandages where the pressure depends on the tension in the bandage, the amount of overlap and the shape of the leg of the patient.

The pressure sensor may be used to measure the fluid pressure inside the
25 sleeve thus providing a measure of the pressure exerted by the sleeve. The sleeve may have a valve associated with it and the control system be arranged to control operation of the valve and thereby inflation/deflation of the sleeve. The pressure sensors associated with the sleeve are preferably located between the valve and the sleeve. The pressure sensor
30 is preferably a fluid pressure sensor arranged to measure fluid pressure preferably in the line between the valve and sleeve.

Preferably the sleeve comprises one or more individually inflatable cells. More preferably a sensor is associated with each cell to monitor the pressure experienced by the limb due to pressure from that cell. For 5 example, each sleeve may have a valve associated with it and the controller is arranged to control operation of the valve and therefore inflation/deflation of each cell. The pressure sensors associated with each cell are preferably located between the valve and the cell. This allows the device to precisely control the pressure in each cell and thus comply 10 with the predetermined compression profile. It also allows the device to operate an intermittent pneumatic compression.

Preferably the memory is arranged to store data relating to any one or more of; the duration of use of the device, the pressure exerted by the 15 sleeve on the limb and the mode of operation of the device. Preferably, the memory is also arranged to store data relating to the use of the device while it is in place surrounding the limb. In order to do this, the control system must first determine whether or not the device is in place surrounding the limb. This may be achieved by having expected data 20 values relating to use of the device stored in the memory for comparison by the control system with gathered data values. For example, when the sleeve is in place on the limb it will have a different inflation profile compared to when it is not in place surrounding the limb. The control system may monitor a change in pressure exerted by the sleeve as it is 25 inflated, e.g. by monitoring the time taken to inflate the sleeve to a predetermined pressure, and this will vary depending upon whether or not the device is in place surrounding a limb. Therefore by comparing gathered data with expected time and pressure data values the controller can determine whether or not the sleeve is in place surrounding the limb.

Advantageously the control system may be arranged to disregard any data gathered when the sleeve is not in place around the limb and this provides more accurate, useful gathered data for analysis.

5 Preferably, if it is determined that the sleeve is not in place surrounding the limb the control system is arranged to shut off delivery of fluid through the sleeve and preferably deflate the sleeve. Advantageously, this provides a safety mechanism against unnecessary inflation or over - inflation of the inflatable sleeve when it is not in place surrounding the
10 limb.

Due to the sensors and monitoring capacity of the device and the microprocessor present in the control system, it is possible to monitor the usage of the device by the patient. This is not possible with elastic
15 compression devices. Knowledge of the extent of usage will enable the health care professional to prescribe the most suitable treatment for the next stage of healing or prevention.

The capability of the controller to deliver predetermined compression
20 profiles to the limb also enables the health care professional to give the patient some control over their treatment. For a chosen treatment regime the patient can select a high compression or low compression setting. This alleviates the problem of non-compliance in some patients who cannot tolerate the pain of compression bandages or stockings that only
25 provide one compression level. The use of the device on a low setting is preferable to rejection of the treatment altogether.

The compression device may be for the limb of a mobile patient.

30 Preferably the sleeve is low profile and discrete. This allows the patient to use the device wearing ordinary clothes and shoes.

Preferably the sleeve comprises a leg cuff and a foot cuff both of which are low profile and discrete. More preferably the leg and foot cuffs are anatomically shaped to provide compression on those parts of the leg or 5 foot which have the greatest effect on blood flow. This gives the advantage of reducing the overall size of the device and thus the profile of the cuff and size and power of the pump. Depending on the shape of the cuffs it can also reduce discomfort from pressure on bony areas of the limb.

10

According to a second aspect of the present invention there is provided a method of monitoring use of a compression device for a limb of a patient having an inflatable sleeve arranged to surround the limb, a conduit attached to the sleeve arranged to deliver fluid to the sleeve and a control 15 system arranged to control flow of fluid in the device including the step of storing gathered data relating to use of the device.

According to a third aspect of the invention there is provided a data carrier carrying software which when run on a processor of a control 20 system of a compression device is arranged to monitor use of the device according to the method of the second aspect of the invention.

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

25

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 30 opened up and

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

5 **Figure 4** is a perspective view of the sleeve and controller of a second embodiment of the device on the limb,

Figures 5a to 5c are schematic diagrams of a pump and valve arrangement of the device of Figure 4.

10 In Figure 1 the compression device 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 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 on the base unit 12. The device also comprises an understocking 14 worn between the patient's leg and the sleeve 2. The 15 understocking is present to absorb any moisture from the patient's leg but is not intended to 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 cells 20 best seen in Figure 2.

20

25 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 30 comprises a pump and valve arrangement 32. A 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 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 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 10 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 arranges for 15 inflation of the sleeve 2 to the required pressure. The 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 pressure sensor 34 and the microprocessor 28 communicates with the pump and valve 32 20 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 25 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.

Using the user input buttons 26, the healthcare professional can request 30 details of use of the device to be displayed on the LCD display screen 21, by, for example inputting a PIN number.

Figure 4 shows a device according to a second 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. Each 5 cell is provided with a sensor 34 located centrally in each cell but on the inside of the sleeve between the sleeve and the leg. In Figure 4 the sleeve is marked on the outside at a position corresponding to the position of the sensor 34 in the inside of the sleeve at 24. The foot cuff in either embodiment may have a sensor located in a position corresponding to the 10 instep of the foot.

Referring to Figure 4, the control system associated with the device according to the second embodiment is similar to the control system of the device according to the first embodiment except that there are four 15 contact pressure sensors 34 instead of only one contact pressure sensor. There is one pressure sensor 34 associated with each cell of the sleeve. Referring to Figures 5a to 5c, the pump and valve arrangement 32 of the device of this embodiment includes six valves 36 and a pump 38 controlled by the microprocessor 28. The pump 38 has an inlet I and an 20 outlet O and, together with an inlet valve 36P1 and an outlet valve 36P2, controls the air pressure in a fluid feedline F. The other valves are cell valves 36C associated with each cell and arranged to control the flow of air between the cell and the fluid feedline F. The pump valves 36P1, 36P2 each have a port connected to atmosphere and a port connected to 25 the feedline F in addition to a port connected to the pump inlet or outlet. The pump valve 36P1 is able to connect the pump inlet I to the feedline F or to atmosphere. The pump valve 36P2 is able to connect the pump outlet O to the feedline F or to the atmosphere. The microprocessor 28 is able to provide instructions to the pump and valves such that the pump 30 can be used to selectively inflate or deflate any one or more of the cells. This is achieved by selectively operating the pump valves 36P1, 36P2 to

control direction of air flow to or from the fluid feedline F and controlling the cell valves 36C which are selectively opened or closed to allow flow of air to and from the individual cells. For each cell, the pressure sensors 34 are contact pressure sensors located on the surface of
5 the sleeve.

The pump 38 is non-reversible and operates to pump air in a direction from its inlet I to its outlet O. Referring to Figure 5a, when it is desired to draw air from the cells, the pump inlet valve 36P1 is arranged to
10 connect the pump inlet I to the fluid line F by the microprocessor 28 and the pump outlet valve 36P2 is arranged to connect the pump outlet to atmosphere. This operation of the valves 36P1, 36P2 causes the air within the pump and valve arrangement to flow in the direction indicated by the arrows of Figure 5a. Therefore air is pumped away from the cells.
15 Each one of the cell valves 36C can be operated individually under instruction from the microprocessor 28 so that air may be drawn from one or more cells without being drawn from the other cells.

Referring to Figure 5b, when it is desired to pump air to the cells, the
20 first pump valve 36P1 is arranged to connect the pump inlet I to atmosphere and the second pump valve 36P2 is arranged to connect the pump outlet O to the feed line F. Operation of the pump then causes air to flow in the direction of the arrows shown in Figure 5b i.e. air is pumped towards the cells 22. Once again, the cell valves 36C can be
25 individually operated by the microprocessor 28 so that any one or more cells may be pumped up selectively.

Referring to Figure 5c, when the cells are at a desired pressure e.g. after they have been pumped up sufficiently for use in the continuous pressure
30 mode, both pump valves 36P1 and 36P2 are arranged to connect the pump to atmosphere so that the fluid in the feedline F is at atmospheric

pressure. The pump does not operate and the air pressure inside the cells remains unchanged.

The device of the second embodiment is able to be selectively operated in a different mode to that previously described for the first embodiment. The device can also be operated in the same mode as previously described. In its different mode, the device can be used to provide intermittent pneumatic compression in which each of the cells is inflated in sequence e.g. from the bottom of the leg upwards. Compliance data, i.e. data relating to use of the device, can be gathered by the processor 28 and stored in the memory 30. Using the user input 26, the healthcare professional can request that the gathered data stored in the memory 30 is displayed upon the display 21. In this embodiment the display 21 is not part of the controller. Instead, the controller unit can communicate via infrared communication with a remote display screen (not shown). The displayed data includes data relating to the length of time for which each cell has been inflated while surrounding the limb at a particular pressure and in a particular mode e.g. continuous constant pressure mode or intermittent pneumatic compression mode. The displayed data can also include data relating to the number of times which a patient has used the compression device within a set period e.g. within the last week, two weeks, since the last visit by the healthcare professional. The data can also include data relating to the actual time of day at which the compression device is used by a patient. The display data can also be analysed and a display provided to indicate whether or not the compliance by the patient is good or bad. There may be a set threshold of use above which the compliance is good and below which it is bad. The displayed data which is available to the patient may be different to the displayed data which is available to the healthcare professional – the healthcare professional may have access to more information upon entry of a password using the user input.

Using the user input 26, it is possible for the healthcare professional to reset some or all of the data stored in the memory. This can be desirable between the visits of a healthcare professional to a patient for example.

5 The healthcare professional may be required to enter a password using the user input 26 before data stored in the memory 30 can be erased. The memory 30 can also store data on the date of the last reset. Thus for instance if the patient resets the memory the date is recorded and at next visit the healthcare professional is presented with the reset date and the

10 data collected since the reset.

A range of standard or expected inflation times are stored on the memory 30. Therefore if the sleeve 2 is inflated while not in place on the limb then the microprocessor 28 will recognise this by comparing data 15 gathered from the pressure sensors 34 with data stored in the memory 30. For example, the time taken to reach a predetermined pressure value can be measured and if it does not fall within an expected range then the microprocessor 28 recognises that the sleeve is not in place on the limb and causes the pump and valve arrangement 32 to cease inflating the 20 sleeve and to deflate it instead. Data gathered by the sensors 34 whilst the sleeve 2 is not in place on the limb can also be discarded. The microprocessor can therefore determine, when the sleeve is inflated, whether it is in place on the patient's limb or not. This ensures that data collected and stored relating to use of the device can accurately reflect 25 correct use of the device when it is in place, and not be affected by inflation of the sleeve when the device is not in place on the patient.

Similarly a microprocessor 28 can recognise if the pump and valve arrangement is attempting to inflate the sleeve 2 but the pressure 30 measured by one or more of the pressure sensors 34 is not increasing correspondingly. In this situation the microprocessor 28 recognises that

the sleeve 2 has a puncture and a suitable error message can be displayed on the display 21 to inform the user that there is a puncture in said one or more of the cells 22.

5 Although the present invention has been shown and described with respect to several preferred embodiments thereof, various changes, omissions and additions to the form and detail thereof, may be made therein, without departing from the scope of the invention. For example, the data relating to use may be available to any user without requiring entry of a PIN 10 code. However, it may still be necessary to input a PIN code before erasing information.

The intermittent pneumatic compression mode may be selectively available with a device substantially identical to the device of the first 15 embodiment. Also the, or each, sensor may be a contact sensor, a pressure sensor or any other suitable type of sensor. Where more than one sensor is provided, combinations of different types of sensor may be used. For example, the contact pressure sensors of the second embodiment may be replaced by air pressure sensors located in the line 20 between the cell and its associated valve 36. The sensor may be situated in the controller unit 8.

The controller unit 8 may not have a user input 26. Instead, for example, the system may receive inputs from e.g. a keyboard of a PC or other 25 processing device when it is in communication (e.g. infra-red) with it.

CLAIMS

1. A compression device for a limb of a patient comprising:
 - 5 an inflatable sleeve arranged to surround the limb,
 - a conduit attached to the sleeve arranged to deliver fluid to the sleeve,
 - 10 a control system arranged to control flow of fluid in the device, and
 - a memory arranged to store gathered data relating to use of the device.
2. A compression device as claimed in Claim 1, wherein the control system comprises a pump and a controller unit.
- 15 3. A compression device as claimed in Claim 1 or Claim 2 further comprising a display device arranged to provide a display dependent on the gathered data.
- 20 4. A compression device as claimed in any preceding claim wherein the memory is arranged to store data relating to the duration of use of the device.
- 25 5. A compression device as claimed in any preceding claim wherein the memory is arranged to store data relating to pressure exerted by the sleeve on the limb.
6. A compression device as claimed in any preceding claim wherein the memory is arranged to store data relating to a mode of operation of the device.

7. A compression device as claimed in any preceding claim wherein the mode of operation of the device selects a predetermined pressure profile for the sleeve.

5 8. A compression device as claimed in any preceding claim comprising one or more pressure sensors arranged to determine when the pressure exerted by the sleeve on the limb has reached a predetermined value.

10 9. A compression device as claimed in claim 8 when dependent on Claim 7, wherein each cell has an associated pressure sensor arranged to determine the pressure exerted by the cell.

15 10. A compression device as claimed in claim 8 or claim 9 wherein the or each pressure sensor comprises a fluid pressure sensor arranged to measure fluid pressure.

11. A compression device as claimed in claim 8 or claim 9, wherein the or each pressure sensor comprises an air pressure sensor arranged to 20 measure the contact pressure between the sleeve and the limb.

12. A compression device according to any foregoing claim arranged to detect whether the sleeve is in place surrounding the limb.

25 13. A compression device according to claim 12 wherein the gathered data is dependent upon detection of whether the sleeve is in place surrounding the limb.

30 14. A compression device as claimed in any preceding claim wherein expected data values relating to use of the device are stored in the memory.

15. A compression device as claimed in claim 14 wherein the control system is arranged to compare gathered data with expected data and thereby detect an error if the sleeve is not in place surrounding the limb,
5 if there is an error in the device or if there is a puncture in the sleeve.

16. A compression device as claimed in claim 15, wherein the control system is arranged to determine whether the sleeve surrounds the limb by monitoring a change in pressure exerted by the sleeve as it is inflated.

10

17. A compression device as claimed in claim 15 or Claim 16, wherein the control system is arranged to shut off delivery of fluid to the sleeve if it is determined that the sleeve is not in place surrounding the limb.

15 18. A compression device as claimed in any of claims 3 to 17 comprising user input means arranged to receive a user input to cause the display dependent upon the gathered data to be displayed.

19. A compression device as claimed in any preceding claim for the
20 limb of a mobile patient.

20. A method of monitoring use of a compression device for a limb of a patient having an inflatable sleeve arranged to surround the limb, a conduit attached to the sleeve arranged to deliver fluid to the sleeve and a
25 control system arranged to control flow of fluid in the device including the step of storing gathered data relating to use of the device.

21. The method of claim 20 including the further step of displaying information relating to the gathered data.

30

22. The method of claim 20 or claim 21, for a limb of a mobile patient.

23. A data carrier carrying software which when run on a processor of 5 a control system of a compression device is arranged to monitor use of the device according to the method claimed in any of claims 20 to 22.

24. Use of a compression device for a limb of a patient having an inflatable sleeve arranged to surround the limb, a conduit attached to the 10 sleeve arranged to deliver fluid to the sleeve and a control system arranged to control the flow of fluid in the device, in the gathering of data relating to use of the device, the data to be stored in the device for use of the device in the treatment of venous leg ulcers, venous insufficiency or deep vein thrombosis.

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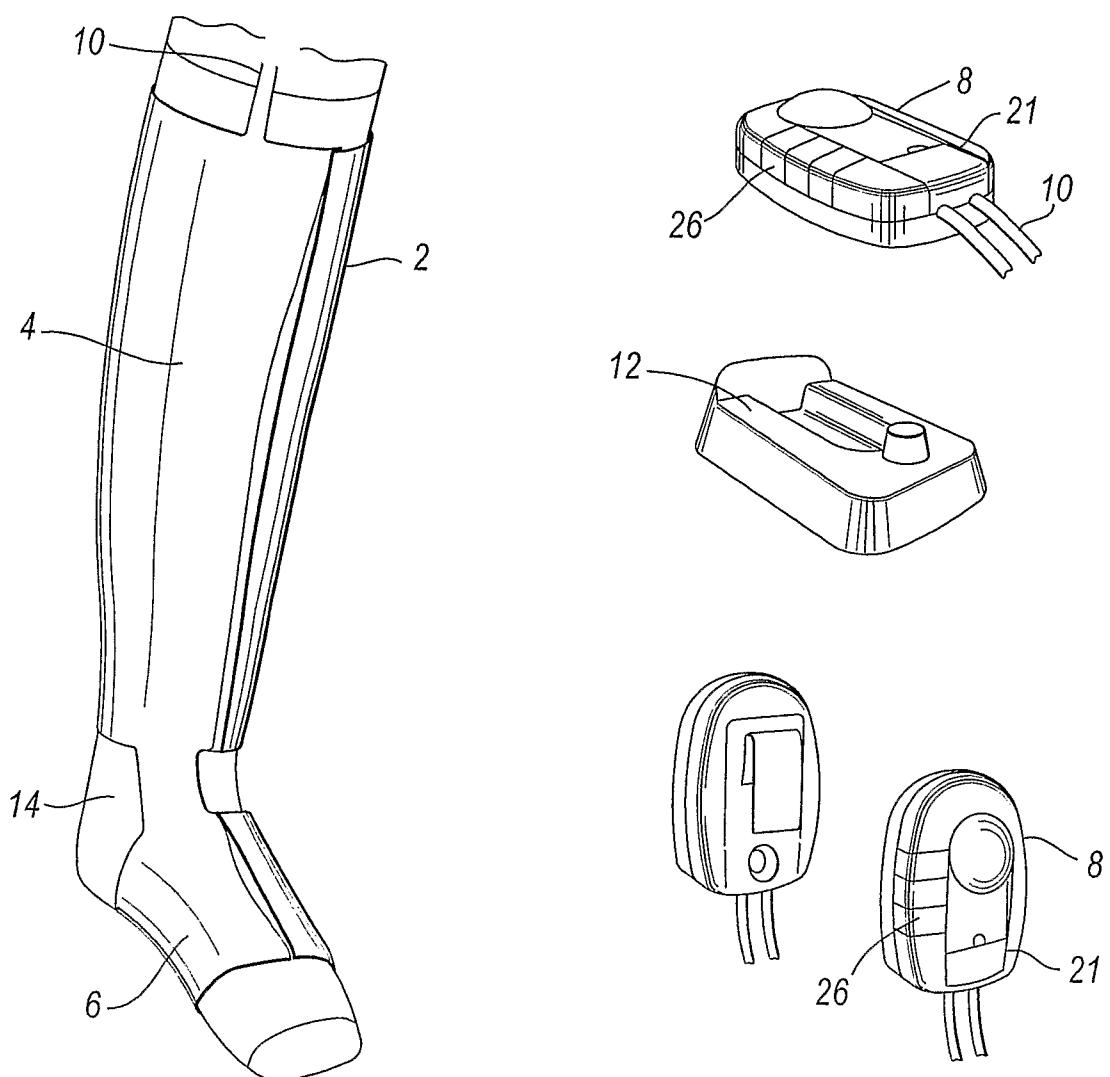


Fig. 1

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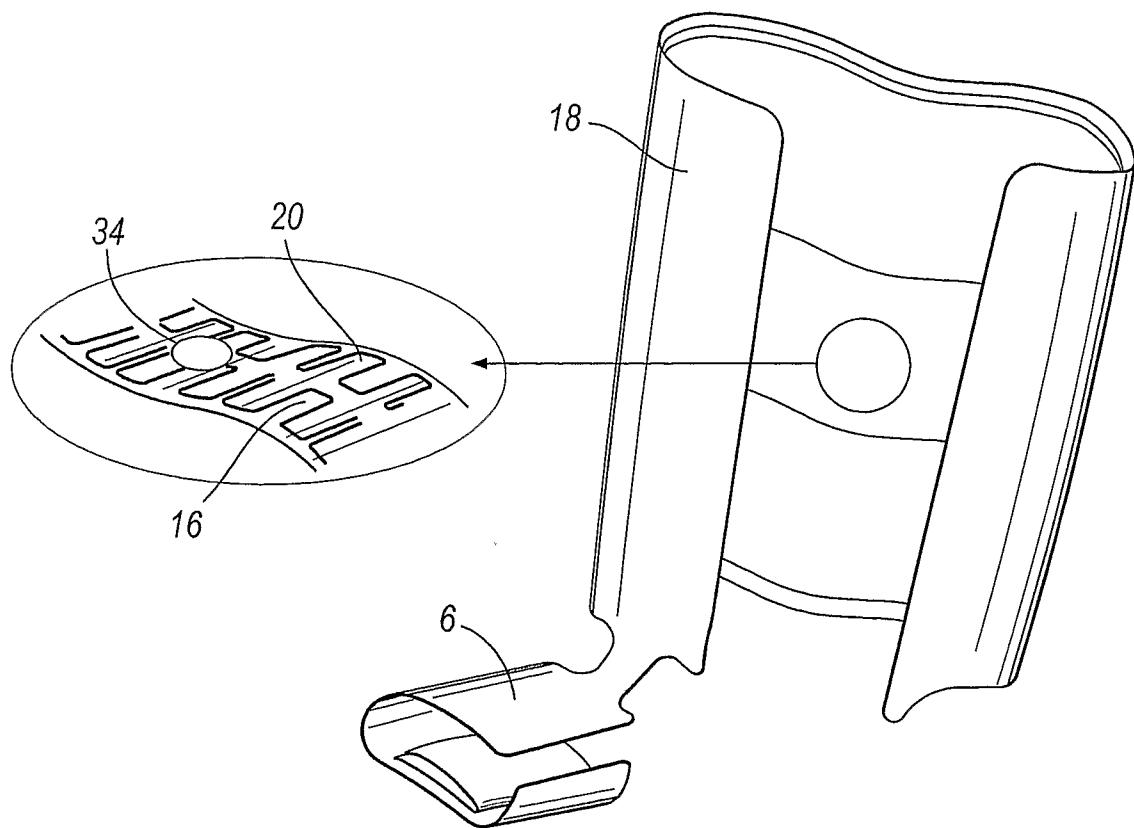


Fig.2

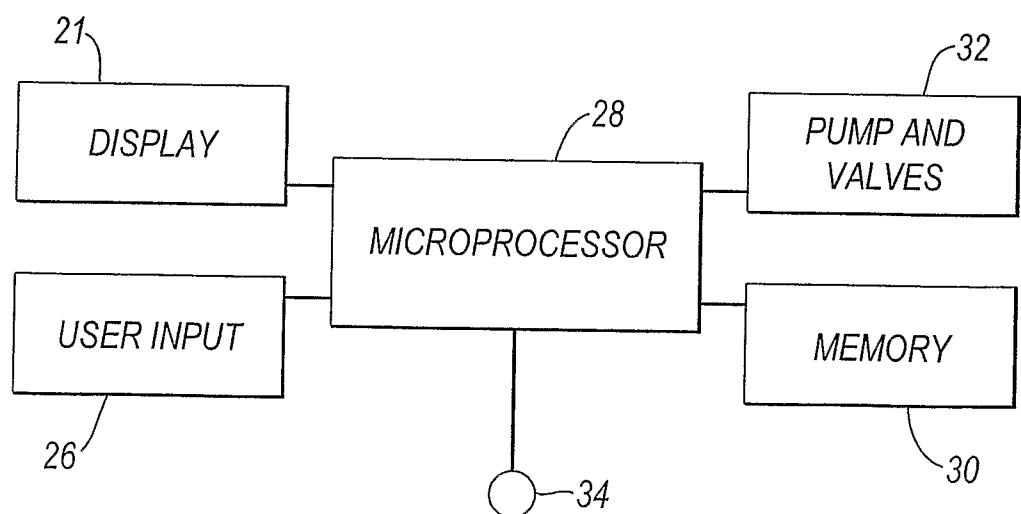


Fig.3

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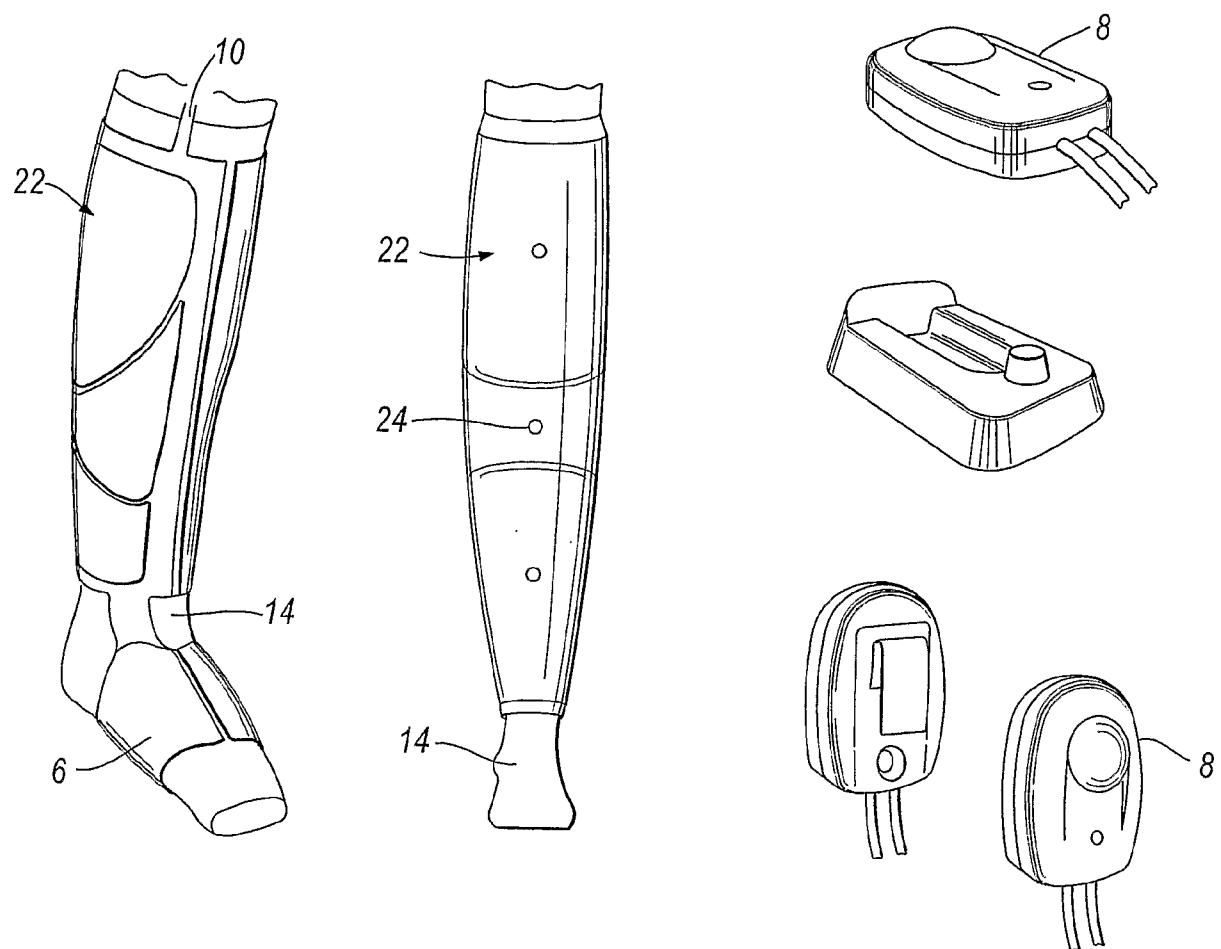


Fig.4

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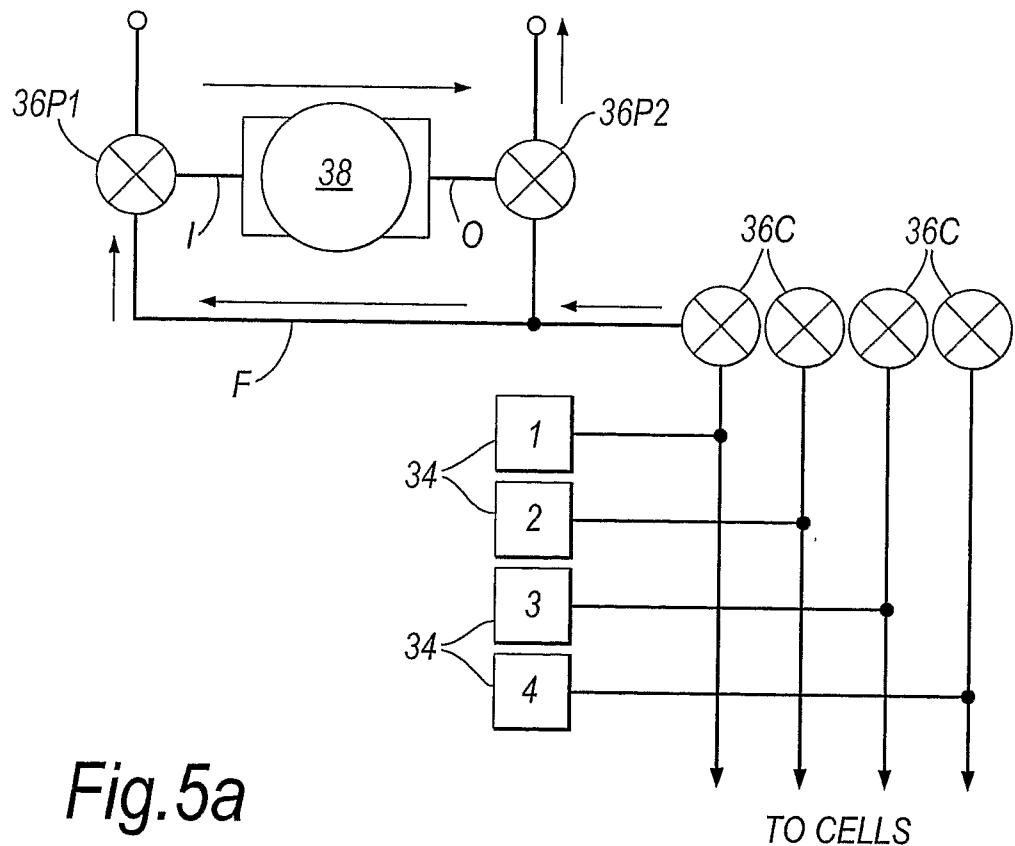


Fig. 5a

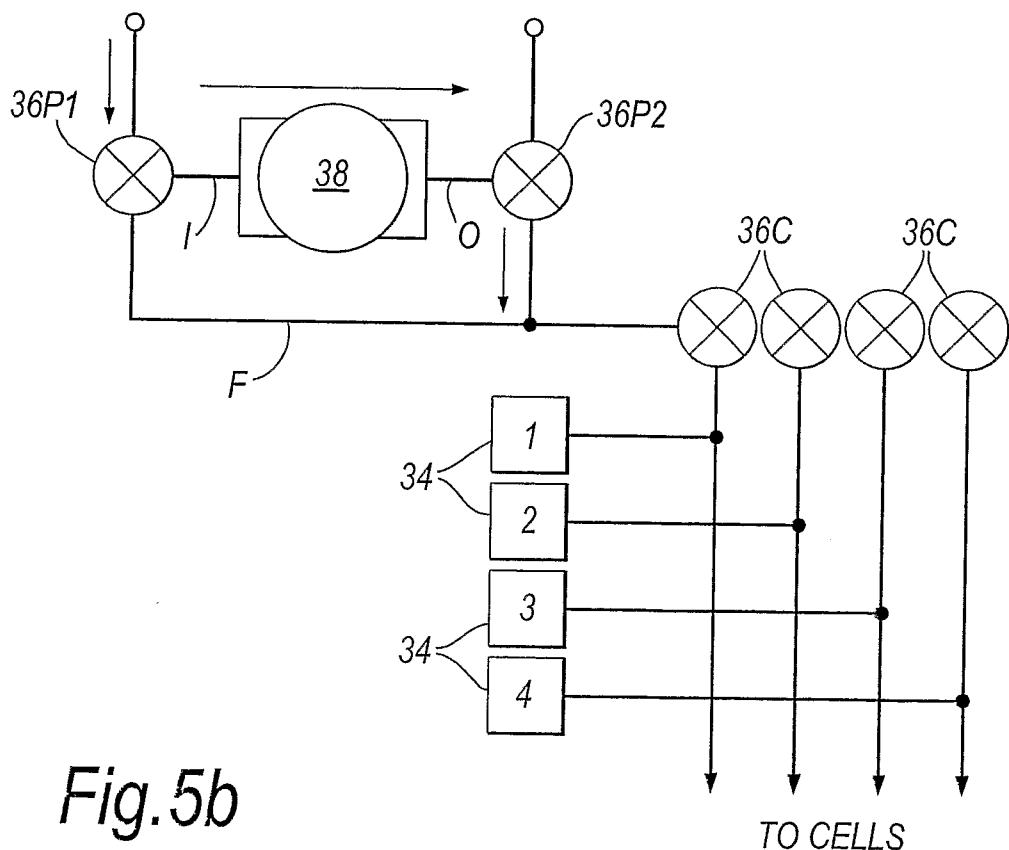


Fig. 5b

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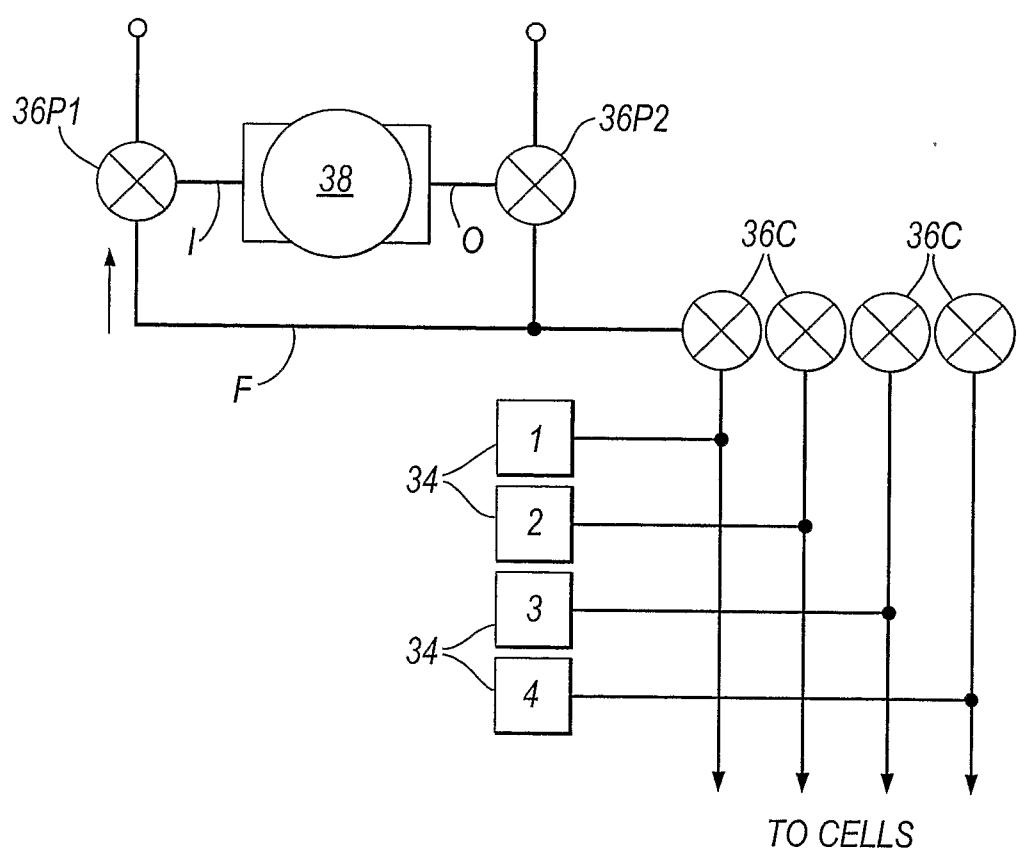


Fig.5c

INTERNATIONAL SEARCH REPORT

International application No

PCT/GB2006/002738

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61H23/00

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61F 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

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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