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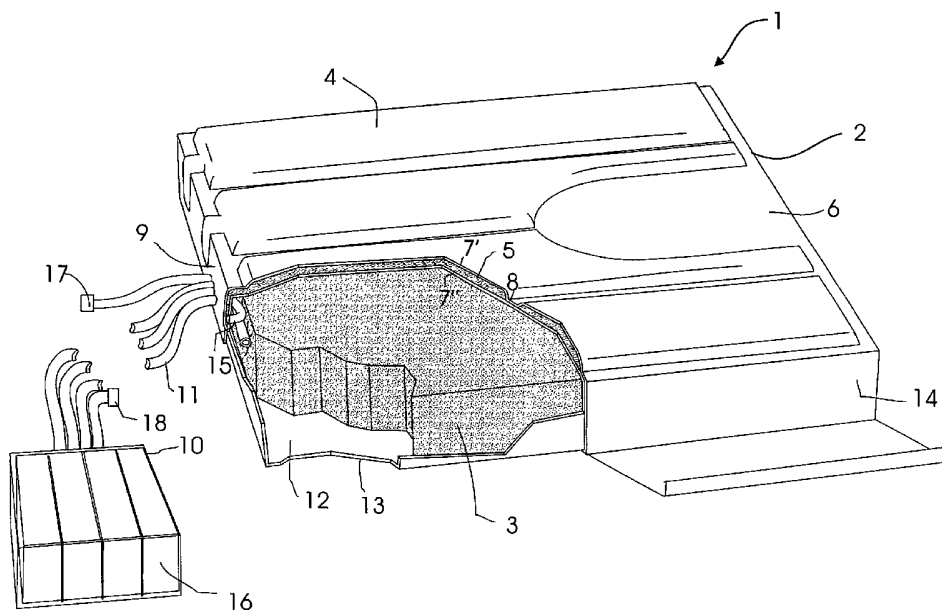
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[Continued on next page]

(54) Title: A DEVICE FOR RELIEF OR PALLIATION OF DECUBITUS ULCERS



(57) Abstract: A device (1) serving for preventing and/or treating decubitus on a user of the device by means of pressure impulses in a fluid (5) in the device. Its main components are a ticking (2) containing the fluid (5) and a pump (10) for generating the pressure impulses in this fluid. The ticking (2) is divided into a number of channels (4a, 4b, 4c, 4d) each having an associated pump (10a, 10b, 10c, 10d) arranged to adjust the pressure in the fluid (5) quickly and selectively. Thereby a structure is obtained that generates pressure impulses in a thin fluid layer immediately against the patient's skin which gives a surprisingly good effect even with relatively weak pressure impulses.



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A device for relief or palliation of decubitus ulcers

The invention relates to a device of the kind that serves to prevent and/or treat decubitus on a user of the device by means of pressure impulses in a fluid in the device and that comprises a ticking containing the fluid and a pump for generating the pressure impulses in this.

Decubitus has been a medical problem for thousands of years and still is a problem to both the patients suffering from decubitus and to the nursing staff.

Decubitus is typically defined as a degenerative change in biological tissue arisen because of compression or dislocation forces (Schut GL. Diagnosis and treatment of decubitus. I: Harting K ed. Theory. Advanced wound healing resource. Denmark: Nofo print/graphic solutions XIII, 1991: 1-35).

Under normal circumstances decubitus will not develop. This is due to the natural reaction to the pain which is caused in tissue that is compressed for a long time resulting in lack of oxygen and consequently provoked pain. The person in question feels the pain and reacts often quite unconsciously by moving a little. Medicine exposure, unconsciousness, anaesthesia, paralyses, and similar condition increase the risk of developing decubitus as the person in these cases is not able to react to the pain.

Thus it is primarily the pressure which reduces or pinch off the blood supply to the tissue with resulting lack of oxygen which ultimately can lead to destruction of tissue. Therefore decubitus is primarily localized to the locations that are subject to pressure and tissue dislocation between bone and support.

Besides pressure there are other factors contributing to the development of decubitus. Examples of these are moist skin, reduced resistance to pressure, friction injuries, and bacterium contamination.

5

Therefore it is important to use aids that can either minimize the pressure on the exposed locations or increase the pressure-distributing surface.

- 10 A number of known products try to combine these two principles to a correlation between the material properties of the product and the physical design of the product. It can be reducing the maximum pressure by using cushions of a certain thickness or cushions resembling the anatomically correct
15 shape or giving pressure distribution or stabilization by adjusting e.g. contractions.

- Other known aids for relieving decubitus are based on e.g. foam, gel, fibres, and air. An example is an air mattress from
20 Völkner® in which each side is inflated by turns and thereby creates an automatic turn-over function. The risk of using such an air mattress is that leaks easily arise that are not discovered so that the air leaks out and the patient therefore is not relieved.

25

- Another commonly used aid is an air mattress filled with water. The degree of filling can and must be varied according to the load on the mattress. To obtain the pressure relieving effect, the patients must either turn over by themselves or be
30 turned over by one or more assistants, which partly can be unpleasant to the patient, partly troublesome and hard to the assistant.

- This problem is sought solved by generating mattresses in
35 which pressure impulses are created, that is fluctuations in the pressure in the fluid.

An example of such a mattress is described in the German patent document DE 199 24 976 A1. The mattress is divided into a row of cells containing water or air. The pressure can be adjusted in groups via a central pump with valves for the individual cell groups. However, this structure will result in energy loss in the valves, unstable pressure regulation and unwanted prolongation of the duration of the pressure impulses.

10 In the mattress known from the German patent document, the pressure impulses are generated in deeper-lying layers and through foam rubber or - plastic, whereby the impulses are cushioned substantially before they, in the thereby created weakened state, reach the patient. In addition, the mattress
15 in the German patent document is arranged to function both with air and fluid. As air and fluid behave differently under pressure, it will thus not be possible to construct a mattress by means of this known technique wherein it is possible to very accurately adjust the pressure and generate very small
20 pressure changes.

The object of the invention is to provide a device of the kind mentioned in the opening paragraph, wherein the pressure impulse pattern in the fluid can be modulated better and more
25 reliably than hitherto known.

A second object of the invention is to provide a device that has a simple, inexpensive design without components that could become ineffective and unhygienic upon wear.

30

A third object of the invention is to provide a device that has a great relieving and healing effect with little input of energy and that is easy to handle and use.

35 The novel and unique feature according to the invention, whereby this is achieved, is the fact that the ticking is

divided into a number of chambers and that each channel has a pump.

By means of this structure it is possible to adjust the
5 pressure in the fluid quickly and selectively because the
pressure is transmitted directly to the fluid in the channels
and adjusted directly by means of the pumps. As each channel
has its own pump, there are no distributing valves in which
energy loss could occur, which means that the structure is
10 very economic in use.

Advantageously the device can comprise a computer with a
programme to control the pumps independently of each other.
The operator can adjust the pumps by means of the computer and
15 its programme to work in such a way that the patient is given
the best possible care to prevent and/or treat decubitus.

This computer can furthermore communicate with a receiver
which receives signals from the computer. Such signals can
20 e.g. be information about the impulse pattern in the
individual device or about deviations in the determined
pattern. Such a structure can save time for the staff in e.g.
a rest home where it can be time-consuming to check the
working of many individual devices. Furthermore it can be
25 possible via the server to signal the device about change in
impulse pattern and the like.

The pressure impulses can follow in immediate continuation of
each other or at greater or smaller intervals. Furthermore the
30 amplitude of the impulses can change for each pressure change
or according to a specific pattern.

It has proven that the best results are obtained in the vast
majority of cases if the computer is arranged to active each
35 pump at a frequency of between 30 seconds and 5 minutes with
intermediate intervals of between 30 seconds and 5 minutes

between a number of activations. However, it will always be individual how the impulse pressure pattern of a patient has to be.

5 In a preferred embodiment the programme is arranged to control each pump in such a way that the fluid volume in respective channel varies between 2% and 20%, preferably between 5% and 15%, and especially between 8% and 10% of the fluid volume in unpressurized state each time the pump is activated.

10

In this way the wanted effect is obtained by means of a relatively small change in fluid for each impulse. Therefore it can be advantageous to use small, inexpensive pumps.

15 To obtain a configuration of the device that is inexpensive and easy to manufacture, each channel can advantageously be made of two layers of e.g. plastic that are joined along the edges of the channel and can, at one end, be connected to the associate pump via a hose. The channels can furthermore be
20 joined in pairs along their longitudinal edges.

If the spacing between the two layers of each channel is between 4-15 mm, preferably between 6 and 11 mm, and especially between 8 and 10 when the channel is filled with
25 fluid in unpressurized state, a structure is obtained that in tests has proven optimal by using a very small fluid volume which means that the device becomes easy and simple to handle to a user or possible nursing staff.

30 To in an appropriate manner be able to distribute the weight of the patient, the device can comprise a support of an elastic material for example foam rubber or foamed plastic of an adequate thickness. This support contributes to the effect of the fluid-filled thin ticking while the support
35 simultaneously distributes the weight of the patient over a large area. As the relieving and healing pressure impulses are

generated in the thin fluid layer immediately against the patient's skin, a surprisingly good effect is obtained with even relatively weak pressure impulses. This feels pleasant to the patient. Furthermore energy is saved whereby the investment in pumps among other things can be kept within modest limits.

For the device to appear as an integrated unit, it can comprise a chamber which is defined by the ticking and a layer of preferably the same material as the ticking.

To in an appropriate manner be able to distribute and absorb the weight of the patient, a support of an elastic material, e.g. foam rubber or foamed plastic of an adequate thickness for that purpose, can be located in this chamber. This support contributes to the effect of the thin ticking, as the pressure impulses are transmitted via the thin fluid layer in the ticking while the support simultaneously distributes the patient's weight over a large area. As the relieving and healing pressure impulses are generated in the thin fluid layer immediately against the patient's skin, a surprisingly good effect is obtained with even relatively weak pressure impulses. This partly feels pleasant to the patient partly prevents development of the damaging dislocation forces. In addition, energy is saved whereby the investment in, among other things, pumps can be kept within modest limits.

In an advantageous embodiment, the hose of each pump is connected to the respective channel in an area adjoining the chamber so that the joints between the hoses and the ticking is hidden in the chamber where they cannot inconvenience the patient.

To ensure that the device is easy to clean and thereby is able to meet the demands on the necessary hygiene, an opening can be made along one of the lateral edges of the chamber, said

opening being arranged so that the support can be removed easily and quickly when the device is to be cleaned and then be returned after cleaning.

5 In an especially advantageous embodiment the pump can in operation be a reciprocating diaphragm pump driven by an electric motor or electromagnet. Such a pump is inexpensive and can easily be adjusted with great accuracy merely by adjusting the current supply to the motor or electromagnet.

10

The invention will be explained in greater details below, describing only an exemplary embodiment with reference to the drawing, in which

15 Fig. 1 is a fractional view of a device according to the invention.

Fig. 2 is a diagrammatic view of how the device according to the invention is used.

20

Fig. 3 shows the changes in volume of each channel according to the invention over time.

25 In the following it is assumed that the device is a seating cushion for use in a wheelchair but it could just as well be e.g. a mattress or cushion within the scope of the invention.

Fig. 1 shows the device according to the invention designated generally by the reference numeral 1.

30

The main components of the device are a ticking 2 and a support 3. The ticking has here four channels 4 each filled with a fluid 5. As the device is to be used for a wheelchair an area 6 is arranged without channels in the ticking so that
35 the user is not inconvenienced by excess material. Each channel is composed of two layers 7', 7'' of e.g. plastic that

are joined along the edges 8 of the channel. Each channel is connected to an associate pump 10 at one end 9 via a hose 11.

In this way it is possible by means of the pumps 10 to adjust the pressure in the fluid in each channel 4, the pressure being transmitted directly to the fluid 5 so that no appreciable energy loss occur, which means that the structure is economic in use.

As the ticking 2 is relatively thin, the ticking is, in the present embodiment, arranged with a chamber 12 arranged to accommodate the support 3. The chamber 12 is defined by the ticking 2 and a lower layer 13 of the same material as the ticking.

Along one lateral edge 13 of the chamber 12, an opening 14 is made that is arranged so that the support 3 can be removed easily and quickly when the device is to be cleaned and then be returned after cleaning.

The support can advantageously be of a viscoelastic material such as foam rubber or plastic foam of an adequate thickness. This support 3 contributes to the effect of the fluid-filled thin ticking 2, as the pressure impulses are transmitted via the thin fluid layer 5 in the ticking while the support 3 at the same time distributes the patient's weight over a large area.

The hose 11 for each pump 10 is connected to the respective channel 4 in an area adjoining the chamber 12 so that the joints 15 between the hoses 11 and the ticking 2 are hidden in the chamber 12 where they cannot inconvenience the patient.

In the case shown, the pump 10 is a, during operation, reciprocating diaphragm pump 16 driven by an electric motor or electromagnet (not shown).

When a user is to use the device shown in fig. 1, the ticking first has to be filled with a fluid. Here the user can use a full disposable syringe which is connected to each hose 11 at a first coupling 17 and thereby transfer the fluid to a channel in the ticking. The channel is then emptied of excess air. This procedure is repeated for each channel.

Then the pump is filled with fluid in the same way via a second coupling 18. Subsequently the pump and the ticking are connected to each other via the two couplings. Said two couplings can advantageously be check valves that ensure that the fluid does not run out when the pumps and the channels are full of fluid.

The pump and the ticking are now connected to each other easily and quickly via the couplings 17 and 18, after which the device is ready for use.

Fig. 2 diagrammatically shows how the device according to the invention is used. An operator can submit input via a control panel 19 to a micro controller 20 which then controls the device. This control panel 19 also comprises a display 21 which e.g. displays changes in fluid volume, the frequency of pressure impulses, and the pressure impulse amplitude. Therefore the operator can quickly and easily assess whether the selected parameters are correct just as the parameters quickly can be changed.

The required change in the fluid volume of each channel 4 is calculated in the micro controller 20 via associated software algorithm. This micro controller then signals a first pump 10a arranged to adjust the fluid volume and thereby the pressure in the first channel 4a either by supplying or removing fluid from the channel via the hose 11a. The pump can advantageously be arranged as a reciprocating diaphragm pump which ensures a light and inexpensive structure.

The micro controller can adjust the pressure in the remaining channels 4b, 4c, 4d in a similar way via the pumps 10b, 10c, 10d and the hoses 11b, 11c, 11d.

5 As the pressure impulses in each channel 4a, 4b, 4c, 4d are controlled and adjusted separately, an effect is obtained that corresponds to the unconscious reaction to pains occurring in tissue which is compressed for a long period of time which is due to the fact that the pressure on the body is changed
10 concurrently with the changes in the pressure impulses in the channels.

Furthermore because of the relatively thin fluid layer in the ticking directly adjoining the skin, a surprisingly good
15 effect is obtained even with weak pressure impulses which eliminates development of the dislocation forces which contribute to occurrence of decubitus. Furthermore the weak impulses are pleasant to the patient, as this patient does not consciously notice the pressure changes.

20

To ensure sufficient blood flow in the outer capillaries, the system can be static for a period, after which the pressure is adjusted again.

25 During use, the device is connected to an energy source which advantageously can be rechargeable battery 21. In this way the user completely preserves his/her freedom of movement, as the device can be recharged at times when the users are at another place.

30

The device can advantageously be covered with a layer of comfortable fabric which easily can be taken off and washed but after a long period of use the device itself may need cleaning. The support can therefore be removed quickly just as
35 the fluid in the channels can be drained, which enable

cleaning of the device itself which often is made of a plastic material exactly for cleaning purposes.

After cleaning the support can be reinserted and the device
5 can be used again.

Example 1:

100 ml water is filled in each channel in the device according
10 to the invention. The device which has 4 channels each 420 mm long and 11 mm wide is to be used as a cushion for relieving decubitus when staying in a wheelchair.

Each pump is filled with 400 ml water, and the cushion is
15 connected to the pumps which is a reciprocating diaphragm pump driven by an electric motor or electromagnet.

The individual strokes of the pumps are 18 mm, 30 mm, 26 mm, and 38 mm, which give a maximum fluid volume displacement in
20 the individual channels of 29,8 ml, 43,0 ml, 49,6 ml, and 62,8 ml respectively.

This corresponds to a height motion of each channel of about 1 mm which is not felt by the user.
25

Fig. 3 illustrates how this volume displacement varies over time.

In the present example the maximum fluid volume displacement
30 for all four channels varies but this displacement could just as well be the same for one or more channels just as the impulses in one or more channels can be static for a period of time.

35

Patent claims

1. A device of the kind that serves for preventing and/or treating bedsores on a user of the device by means of pressure impulses in a fluid in the mattress and that comprises a ticking containing the fluid and a pump for generating the pressure impulses in this fluid, **characterized** in that the ticking is divided into a number of channels and that each channel has a pump.
2. A device according to claim 1, **characterized** in that the mattress comprises a computer with a programme for controlling the pumps independently of each other.
3. A device according to claim 2, **characterized** in that the computer is arranged to activate each pump at a frequency of between 30 seconds and 5 minutes with intermediate intervals of between 30 seconds and 5 minutes between a number of activations.
4. A device according to claim 2 or 3, **characterized** in that the programme is arranged to control each pump in such a way that the fluid volume in the respective channel varies between 2% and 20%, preferably between 5% and 15%, and especially between 8% and 10% of the fluid volume in unpressurized state each time the pump is activated.
5. A device according to claims 1 - 4, **characterized** in that each channel is composed of two layers of e.g. plastic which is joined along the edges of the channel and connected at one end to the associated pump via a hose.
6. A device according to claims 1 - 5, **characterized** in that the channels are joined in pairs along their longitudinal edges.

7. A device according to claims 1 - 6, **characterized** in that the spacing between the two layers of each channel is between 4-15 mm, preferably between 6 and 11 mm, and especially between 8 and 10 mm when the channel is full of fluid in unpressurized state.
8. A device according to claims 1 - 7, **characterized** in that the hose of each pump is connected to the respective area in an area adjoining the chamber.
9. A device according to claims 1 - 7, **characterized** in that the device comprises a chamber defined by the ticking and a layer of preferably the same material as the ticking, that the support is located in this chamber, and that the chamber is made with an opening along at least one lateral edge, said opening being arranged to allow the support to pass and to be detachably closed.
10. A device according to claims 1 - 9, **characterized** in that the pump is a, during operation, reciprocating diaphragm pump driven by an electric motor or electromagnet.

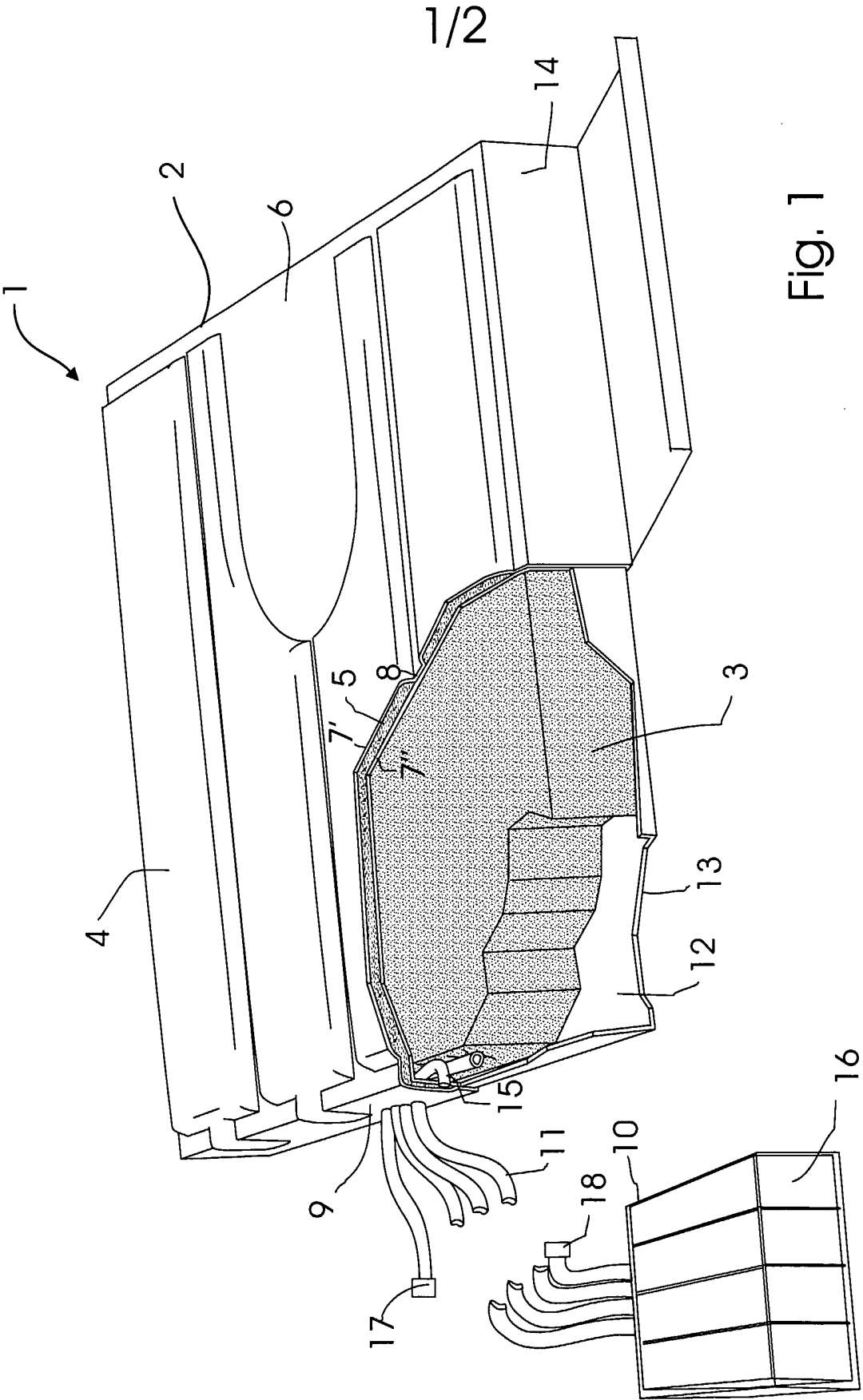


Fig. 1

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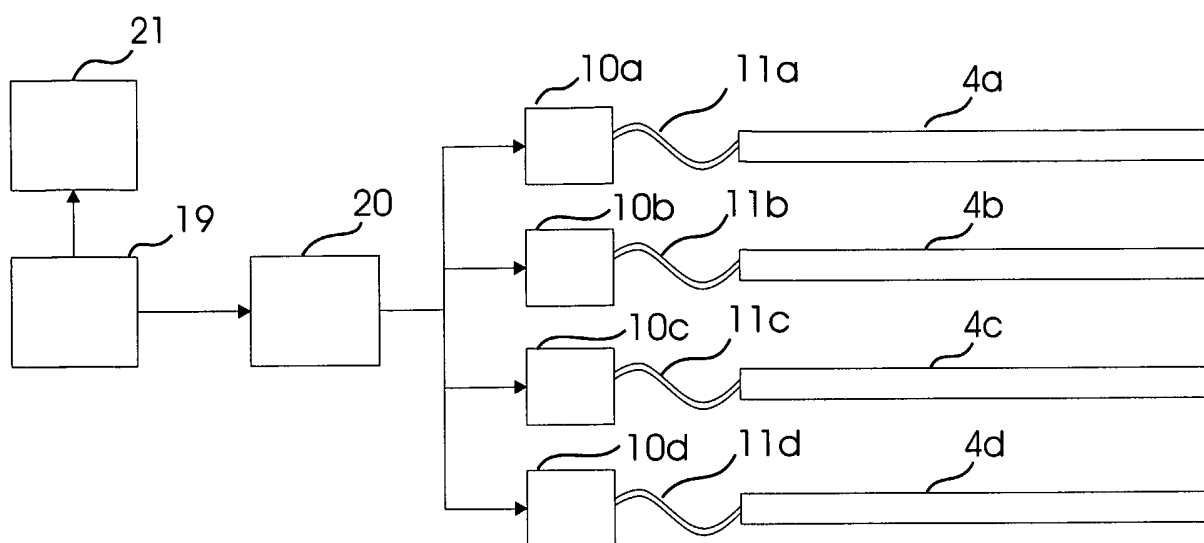


Fig. 2

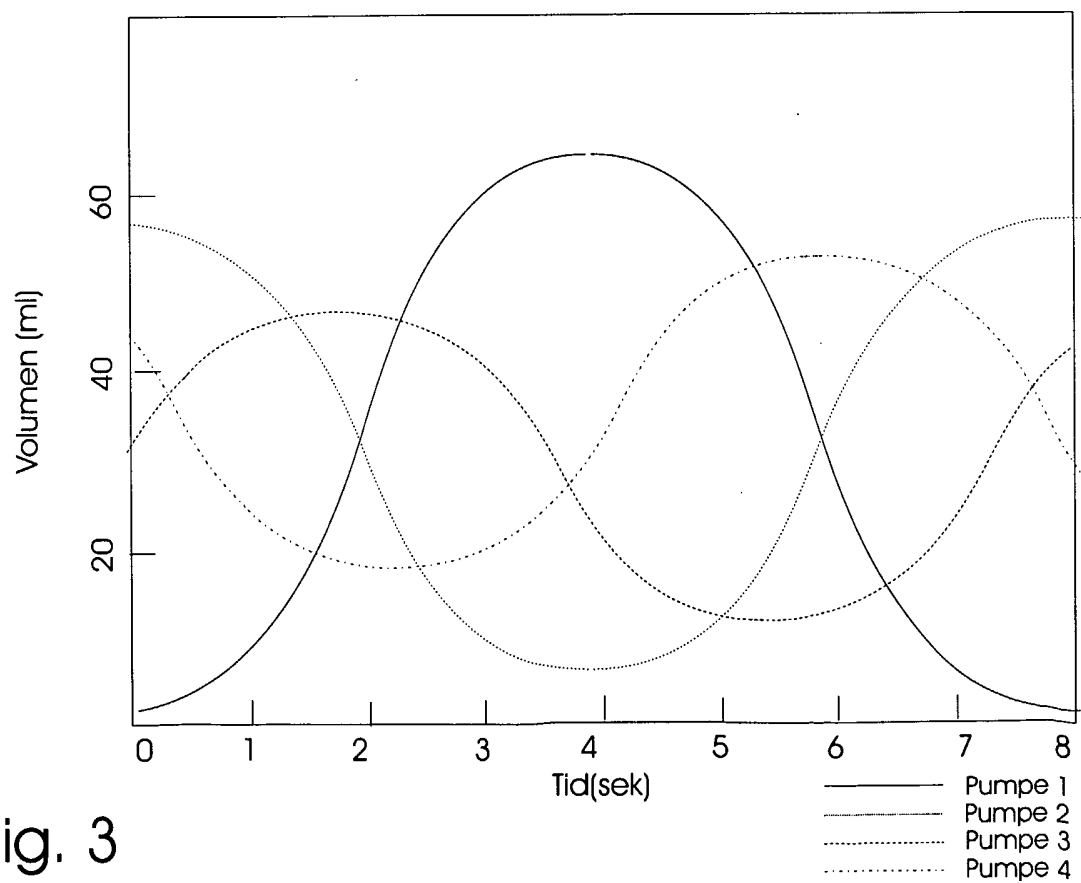


Fig. 3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/DK 2003/000708

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61G 7/057, A61H 23/04 // A47C 27/10, A47C 27/18
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: A61G, A61H

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	NL 9200860 A (JACOBUS LAMBERTUS VAN MERKSTEIJN TE DELDEN), 1 December 1993 (01.12.1993), figures 1,2, abstract	1-10
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A	WO 02074222 A2 (HUNTLEIGH TECHNOLOGY PLC), 26 Sept 2002 (26.09.2002)	2
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Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:

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- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "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
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INTERNATIONAL SEARCH REPORT

Information on patent family members

24/12/2003

International application No.

PCT/DK 2003/000708

NL 9200860 A 01/12/1993 NONE

WO	02074222	A2	26/09/2002	CN	1458838	T	26/11/2003
				EP	1289469	A	12/03/2003
				GB	0106340	D	00/00/0000
				GB	0202235	D	00/00/0000
				GB	0206221	D	00/00/0000
				GB	0320791	D	00/00/0000
				GB	2373189	A	18/09/2002
				GB	2389798	A	24/12/2003
				TW	526056	B	00/00/0000
				US	2003182728	A	02/10/2003
