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(54) Title: MEDICAL THERAPY ARRANGEMENT

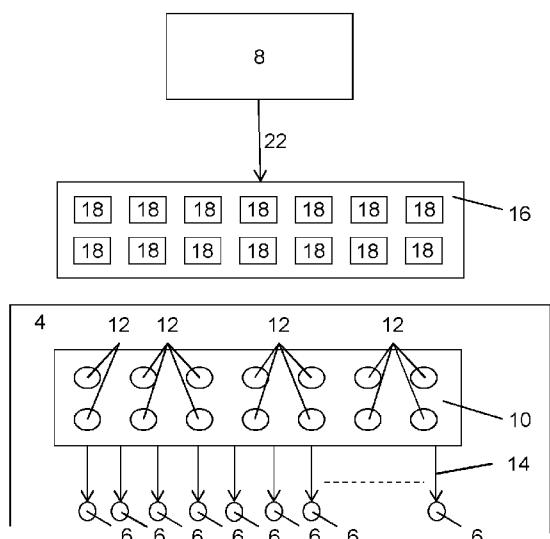


FIG. 1

(57) Abstract: A medical therapy arrangement2, for applying electrical stimulation to a human or animal subject, comprising a garment 4 adapted to be tightly arranged at said subject, and provided with a plurality of electrodes 6 at an inner surface of the garment and which are adapted to be in electrical contact to the skin of the subject. The arrangement further comprises a control unit 8 adapted to provide each electrode 6 to work as one or many of anode, cathode or being disconnected, in accordance with a pre-determined therapy stimulation program. Furthermore, the arrangement comprises -at least one connection unit 10 provided with a predetermined number of connection elements 12 being respectively electrically connected to said electrodes 6 via separate connection lines14 being flexible and elastic and being integrated into the garment, -at least one connection board 16 provided with a predetermined number of connection pads 18 being electrically connected to the control unit8, and that said connection unit 10 is an integrated part of said garment4, wherein said connection board 16 is detachably attachable to said connection unit 10 by a fastening means 20, such that said connection unit 10 and said connection board16, when attached to each other, are positioned in relation to each other in order to electrically connect the connection pads 18 to mating connection elements 12.

Title

Medical therapy arrangement

Field of the invention

5 The present invention relates to a medical therapy arrangement according to the preamble of the independent claim.

Background of the invention

10 The present invention relates in general to muscle relaxation, and more particular to muscle relaxation for spastic muscles in patients having injuries to the central nervous system (CNS) at least by using muscle stimulation.

Injuries to the central nervous system (CNS) are difficult to treat and cure. Spastic paresis, which is a pathologically increased muscle tonus caused by an injury to the central 15 nervous system (CNS) is a significant obstacle for prevention of posturing and loss of mobility.

Today, therapeutic alternatives for the reversal of CNS injury symptoms, such as spasticity, are very limited. Therapies are constructed to prevent further loss of function, rather than alleviating the symptoms. No treatment has been found to truly give back 20 function and, in the long run, reversing the injury through muscle relaxation of spastic muscles.

In addition to the spasms themselves, musculoskeletal pain is a common related 25 complaint. Pain originating from dysfunction in the musculoskeletal system is in most cases caused by muscle spasms due to muscular imbalance. If the pain is not treated properly, patients risk developing chronic pain syndromes, conditions that are difficult to cure.

There are several techniques available to affect muscles in the human body. Electrical muscle stimulation (EMS), also known as neuromuscular electrical stimulation or electromyostimulation is a commonly known method for increasing muscle mass in 30 specific areas, by providing an electric current into the muscle causing contraction, which gradually leads to increased mass in the treated muscle.

Trancutaneous Electrical Nerve Stimulation (TENS) is closely related to EMS, but instead of stimulating muscles to contract, electric stimulation is used to indirectly treat pain, by distracting the brain through the stimulation of other body parts. In US-4,580,572, a garment for electrical monitoring of sites or electrical stimulation, such as EMS is

5 disclosed.

However, none of the currently known muscle stimulation techniques is suited to provide for targeted muscle relaxation. Hence, a new arrangement including a garment allowing for increased muscle relaxation would be advantageous.

10 In general, the parameters of the EMS current signal may be chosen which resemble the physiology of the body. The signals in the nervous system may be compared to current impulses (stimuli) to the synapses. When a certain amount of stimuli has occurred, signal substances are excreted.

15 Generally, a phasic EMS-stimulus is given with a frequency ranging between 2 and 50 Hz, and having a duration between 5 to 300 microseconds.

Muscle relaxation in spastic muscles gives the possibility to induce controlled functional muscle contraction in chosen relaxed muscles. The frequency needed to induce muscle contraction is higher than the frequency used for optimal antagonist muscle relaxation (20Hz/30 μ s). Stimulation frequencies for functional muscle contraction are ranging from

20 25 to 50 Hz and the duration needed is between 50-300 μ s.

The pulsed EMS current signal is controlled by at least the following parameters; pulse frequency, pulse duration, pulse strength.

Experiments have shown that muscles start to contract at a pulse frequency of approximately 15 Hz to approximately 35 Hz, at which frequency range the central nervous system feels the presence of the current signal. The present inventor has realized that by choosing a frequency as low as possible, but still detectable by the central nervous system, the discomfort for the patient is reduced, while the automatic relaxation of the spastic antagonist muscle is taken care of by the central nervous system. A higher frequency than approximately 35 Hz would lead to shortening of the stimulated agonist muscle and therefore activation of the stretch reflex in the antagonist muscle which is not desired, since this would lead to a reciprocal spasm of the agonist muscle.

30 The pulse duration of the current signal is selected such that it resembles the pulse

duration of nervous signals. For example, a pulse duration of approximately 5 to 60 microseconds, such as 30 μ s, has been found to be suitable. However, even shorter pulse duration could be advantageous. Too long pulse duration of the EMS current signal does not correspond to the neurophysiologic parameters of the body.

5 Furthermore, longer pulse duration may also increase the risk of muscle shortage, which is not desired.

Since the spastic muscle behavior in CNS injured patients differs greatly, the professional skills of a neuromuscular system specialist is required for calibrating the system before 10 use, such that the correct agonist muscles are provided with EMS electrodes and joints corresponding thereto are provided with vibrator devices. Every chosen muscle stimulation is paired with an anatomically relevant joint stimulation in order to strengthen the desired relaxation effect. Furthermore, the parameters of the pulsed EMS current signal need to be selected, which parameters may differ between patients.

15

The above-described stimulation and calibration techniques are further disclosed in WO-2011/067327, which relates to a system and garment for muscle relaxation of a spastic muscle, and is assigned to the applicant of the present application. In particular the system is adapted to cause muscle relaxation by reducing muscular spasticity through stimulation 20 of joints and muscles. The system consists of a garment with electrodes, a hardware unit and software controlling the stimulation.

25

WO-03/006106 relates to a method and apparatus for electrical stimulation to selected tissues via an array of electrodes positioned on and/or in the body. Each electrode may be connected either as anode, cathode or neither to provide discrimination between stimulated and non-stimulated regions of tissues of the body.

WO-2011/079866 relates to an apparatus for external activation of paralyzed body parts by stimulation of peripheral nerves.

30

US-2011/0152968 relates to an orthosis for a gait modulation system, and finally, US-7072721, that relates to an electrode vest for electrical stimulation of the abdomen and back

5 Today, when performing external electrical stimulation therapy, it is common to use electrode patches provided with an adhesive for attaching the electrodes to the patient's skin. These electrode patches are disposable, and it is often very time-consuming to attach the electrodes and to connect the electrical cables to each of the electrode patches.

10 The object of the present invention is to achieve an improved stimulation therapy arrangement, which is more user-friendly and less time-consuming to use, than the presently used adhesive electrodes.

As an electrical stimulation therapy preferably must be applied at least 30 minutes in order 15 to give prolonged effect, one further and important aspect of the stimulation therapy arrangement is that it is comfortable and easy to use for the wearer.

Summary of the invention

The above-mentioned object is achieved by the present invention according to the

20 independent claim.

Preferred embodiments are set forth in the dependent claims.

One great advantage of the arrangement according to the present invention is that it is easy 25 to use. This is, among other things, related to that the control unit that includes the pulse generating circuitry, is easily attached to the garment by some few manual steps by attaching the connection board to a connection unit which is integrated into the garment.

The garment is elastic and is intended to be tightly worn by the patient. The garment is 30 ready for use in a user-friendly way for external electrical stimulation therapy of muscles. Electrodes, e.g. silicone-electrodes, are arranged at the inner surface of the garment, the

surface facing the patient's skin and in contact to the patient's skin. The electrical connections connecting the electrodes to connection units are flexible and elastic.

5 The garment is made from materials chosen such that the garment may be washed in

conventional laundry machines.

In particular the garment includes electrical connections adapted to connect the electrodes to one or several connection units, which do not influence the overall flexibility/elasticity of the garment. This is achieved, according to one embodiment, by integrating, e.g. by

10 weaving silver threads into elastic bands or ribbons or into a piece of elastic.

In another embodiment instead an insulated conductor is integrated (e.g. weaved) into a piece of elastic.

The connection units are integrated into the garment, they have e.g. a flat extension, and

15 they are flexible. Preferably, they are made from a rubber material and are provided with a magnetic material. In particular each connection element of the connection unit is provided with a magnet beneath the rubber material and arranged such that a connection pad may be attached at the upper surface and held in place by the magnet. The connection pad is naturally also provided with a magnetic material enabling the attachment.

20 The connection pads are arranged at a flexible flat board having the magnetic material

arranged at predefined positions in order to exactly connect each of the connection pads to a mating connection element of the connection unit. The connection board and the connection unit are held together by the magnetic forces created by the magnetic material at the respective parts.

25

According to one embodiment both the connection unit(s) at the garment and the connection board(s) are made of a flexible material, which is an important aspect making the garment more comfortable to wear.

30 According to the invention the control unit is adapted to control connection of each of the electrodes to be in the state of acting as anode, cathode, or being disconnected.

By this arrangement it is e.g. possible to stimulate two muscles by three electrodes if the applied stimulation pulses are separated in time, i.e. one of the electrodes are used for both muscles. Thus, the control unit enables a very flexible control of the application of the stimulation pulses and by using short simulation pulse durations very complex stimulation 5 programs may be used in that many muscles and muscle groups may be covered during the therapy.

The control unit preferably applies a so-called open-loop control, i.e. no feedback is used to control the applied current/voltage. The advantage of not using feedback is that in case an electrode temporarily loses contact to the skin, or the contact area between electrode 10 surface and skin decreases, the current density of the remaining contact surface not should incur pain.

The amount of energy supplied to the patient via the electrodes is much lower than the energy levels used for by devices for pain relief. One risk, or drawback, with such devices 15 is that the applied energy might stimulate the muscle to contract.

The level of the stimulation energy used in connection with the present invention is much lower than used for example in the device described in WO-03/006106.

Short description of the appended drawings

20 Figure 1 is a schematic block diagram illustrating the medical therapy arrangement according to the present invention.
Figure 2 is a schematic cross-sectional view of a part of the connector board and connector unit according to an embodiment of the present invention.
Figure 3 is a schematic block diagram illustrating another embodiment of the medical 25 therapy arrangement according to the present invention.

Detailed description of preferred embodiments of the invention

The present invention will now be described with references to the appended drawings.

30 With references to figure 1, the present invention relates to a medical therapy arrangement 2, for applying electrical stimulation to a human or animal subject, comprising a garment 4

adapted to be tightly arranged at said subject, and provided with a plurality of electrodes 6 at the inner surface which are adapted to be in electrical contact to the skin of the subject.

The arrangement further comprises a control unit 8 which is adapted to provide each

5 electrode 6 to work as one or many of anode, cathode or being disconnected, in accordance with a predetermined therapy stimulation program.

At least one connection unit 10 is provided which comprises a predetermined number of connection elements 12 being respectively electrically connected to the electrodes 6 via

10 separate connection lines 14, which are flexible and elastic. And, at least one connection board 16 is provided which comprises a predetermined number of connection pads 18 being electrically connected to the control unit 8.

The connection unit 10 is an integrated part of the garment 4 and preferably arranged such that the connection elements 12 are accessible to establish electrical connections to the

15 connection pads 18 of said connection board 16. In that regard the connection board 16 is detachably attachable to the connection unit 10 by a fastening means 20, such that the connection unit 10 and the connection board 16, when attached to each other, are positioned in relation to each other in order to electrically connect the connection pads 18 to mating connection elements 12.

20

According to one embodiment the fastening means 20 is adapted to detachably attach the connection board 16 to the connection unit 10 by magnetic forces. Figure 2 is a schematic cross-sectional view of a part of the connector board 16 and the connector unit 10. In the figure it is shown that the magnetic forces are created by magnetic material, in the figure indicated as separate magnets, arranged at predefined positions of the connection board 16

25 and the connection unit 10, respectively. In the figure the magnets are arranged behind each of the pads 18 and elements 12 in order to secure the electrical connection. As an alternative, the magnets may be arranged e.g. behind every second pad and element or at positions close to the pads and elements.

30 The positions of the magnets at the connection board 16 and at the connection unit 10 ensure that these are correctly positioned in relation to each other. In order to further

improve the positioning, one or many protuberances and mating indentations (not shown in the figure) may be arranged at the connection board and connection unit, respectively.

As an alternative the fastening means 20 comprises mechanical means which is adapted to
5 detachably attach the connection board to the connection unit. These mechanical means may e.g. comprise one or many Velcro straps arranged to provide for the necessary pressure between the connection board and connection unit in order to establish electrical connection between the pads and elements. The mechanical means may also be embodied by some kind of snap connection.

10

Preferably, the connection unit 10 has an essentially planar extension and is made from a flexible material, e.g. a flexible rubber material.

15

Also, in accordance with one embodiment, the connection board 16 has an essentially planar extension and is made from a flexible material, e.g. a flexible rubber material.

20

However, it is advantageous that, in particular the connection unit 10, is made from a flexible material, in order to make the garment comfortable to wear, but it is also possible, within the scope of the present invention, that the connection board 16 and/or the connection unit 10 is made from a rigid material. According to one embodiment the connection unit is made from a flexible material but the connection board is made from a more rigid material, e.g. from a suitable plastic material.

25

The connection board 16 and the connection unit 10 have essentially the same size. In one exemplary embodiment the shape is approximately rectangular having a length in the interval of 8-12 cm, a width of 1.5-3 cm and a thickness of 0.25-1.5 cm.

Naturally, other sizes and shapes are possible, e.g. circular and elliptical, within the scope of the invention as defined by the appended claims.

30

The connection lines 14, that connect each electrode 6 to a respective connection element 12, are flexible and elastic such the wearer of the garment may move unimpededly.

According to one embodiment the connection line 14 is included into a piece of elastic into which an electrical conductor is integrated. This is achieved e.g. by weaving conducting threads, e.g. made from silver, into the piece of elastic.

5 As an alternative the connection line 14 is an insulated conductor being directly integrated, e.g. by weaving, into the material of the garment.

The control unit 8 is preferably a separate unit in relation to the connection board 16, and that the connection pads 18 are connected to the control unit 8 via an electrical cable 22.

10 According to one embodiment the control unit 8 comprises a stimulation pulse generator, an energy source, a storage means, an input/output unit and a coupling unit. The energy source, typically being a battery, e.g. a rechargeable battery, is adapted to energize the circuitry of the control unit, e.g. the stimulation pulse generator. The predetermined therapy stimulation program is stored in the storage means and specific instructions related 15 to the specific patient to be treated is input by the physician via the interface. The input/output unit may include one or many buttons and a display, e.g. a touchscreen. The control unit is preferably attached to the garment wearer by some kind of strap in a position where it is easily accessed but not prevents movements.

20 In accordance with another embodiment the control unit instead is an integral part of the connection board, and then the connecting electrical cable is obviated.

25 The control unit is preferably adapted to apply an open-loop control when controlling the application of stimulation pulses. I.e. no feed-back is used which is advantageous in order to avoid that higher stimulation current is applied in the situation where an electrode loses, or has less, contact to the skin.

The garment is preferably made from a predetermined number of interconnectable parts. The reason is that the garment then is easier to put on. Each part is then provided with a connection unit that in turn is connected to the electrodes.

30 For some patients only a part of the body has to be subjected to stimulation, e.g. an arm or a leg. In that case a garment is used that is adapted to enclose that part. And, for other

patients, the entire body has to be enclosed by the garment in order to gain full effect of the therapy.

An overall requirement of the garment is that it may be tightly arranged at the body to

5 secure that the electrodes are in contact to the skin of the patient. The garment must be able to be washed in a normal laundry machine. Preferably the garment comprises a synthetic fiber made from a polyurethane-polyurea copolymer, e.g. spandex or elastene. According to an embodiment, the garment comprises five major textile and support materials. Elastic spandex for areas covering muscles and, embedded in this spandex, 10 muscle electrodes for skin contact; firm elastic spandex textile in joint areas to induce joint stability and specific skin contact of embedded muscle and vibration (if included) electrodes; and Velcro to interlock the garment parts and also induce joint stability and electrode skin contact. Zippers are placed in the different garment parts to enable simple dressing and use of the garment. Padding and other supportive materials are placed 15 between the textile layers to enhance stability and electrode skin contact.

In order to provide for a perfect garment fit for each patient, each garment may be tailor made for each patient. Hence, each patient may be individually measured. Based on the calibration made by the specialist, the therapist chooses which muscles to stimulate and therefore induce muscle relaxation of corresponding spastic muscles. The tailor made

20 garment is produced and the control unit is programmed with the necessary parameters such as to perform a vibrator (if included) and EMS stimulation in the prescribed manner.

The electrodes are arranged at the inner surface of the garment and must therefore be flexible to adapt to the skin surface. According to one embodiment the electrodes are

25 silicone-electrodes. The number of electrodes is naturally dependent upon the therapy to be applied, but preferably at least ten electrodes are included, often much more.

According to another embodiment the control unit comprises a sensing unit adapted to receive electrical signals, e.g. EMG-signals, sensed by one or many of said electrodes. The 30 received signals may then be analyzed and used to improve the therapy. According to one aspect the sensed electrical signals are used to decide which therapy to be used and then apply that therapy in accordance with an open-loop controlled stimulation therapy.

According to another aspect, it would also be possible to apply the arrangement in a closed-loop controlled simulation therapy where the applied stimulation energy is adapted in dependence of sensed electrical signals.

5 In a further embodiment the arrangement also provides for combined electrical and vibration therapy. This embodiment is schematically illustrated in figure 3. The same references used in figure 1 and 2 apply here as well. To use a combined electrical and vibration therapy has proven an advantageous therapy and in accordance to this embodiment a plurality of vibration units 7 are arranged at the garment, e.g. at the inner 10 surface of the garment, and wherein each vibration unit being connected to the connection unit via a flexible and elastic vibration unit connection line 15. The vibration units may also be arranged at the outer surface of the garment and apply the vibrations through the garment material.

Different types of vibration units may be used, e.g. based upon piezo-technology, a so-

15 called DC-motor, or a solenoid based unit.

Preferably the relation between the number of electrical stimulation electrodes and vibration units is 2:1. However, even fewer vibration units may be used.

The present invention is not limited to the above-described preferred embodiments.

20 Various alternatives, modifications and equivalents may be used. Therefore, the above embodiments should not be taken as limiting the scope of the invention, which is defined by the appending claims.

Claims

1. A medical therapy arrangement (2), for applying electrical stimulation to a human or animal subject, comprising

5 - a garment (4) adapted to be tightly arranged at said subject, and provided with a plurality of electrodes (6) at an inner surface of the garment (4) and which are adapted to be in electrical contact to the skin of the subject,

- a control unit (8) adapted to provide each electrode (6) to work as one or many of anode, cathode or being disconnected, in accordance with a predetermined therapy stimulation program,

10 characterized in that said arrangement further comprises

- at least one connection unit (10) provided with a predetermined number of connection elements (12) being respectively electrically connected to said electrodes via separate connection lines (14) being flexible and elastic and being integrated into the garment,

- at least one connection board (16) provided with a predetermined number of connection 15 pads (18) being electrically connected to the control unit (8),

and that said connection unit (18) is an integrated part of said garment (4), wherein said connection board (16) is detachably attachable to said connection unit (10) by a fastening means (20), such that said connection unit (10) and said connection board (16), when attached to each other, are positioned in relation to each other in order to electrically

20 connect the connection pads (18) to mating connection elements (12).

2. The medical arrangement according to claim 1, wherein said fastening means (20) is adapted to detachably attach said connection board (16) to said connection unit (10) by magnetic forces.

25

3. The medical arrangement according to claim 2, wherein said magnetic forces are created by magnetic material arranged at predefined positions of the connection board (16) and the connection unit (10), respectively.

30 4. The medical arrangement according to claim 1, wherein said fastening means (20) comprises mechanical means which is adapted to detachably attach said connection board (16) to said connection unit (10).

5. The medical arrangement according to any preceding claim, wherein said connection unit (10) has an essentially planar extension and is made from a flexible material.

5

6. The medical arrangement according to any preceding claim, wherein said connection unit (10) is made from a flexible rubber material.

7. The medical arrangement according to any preceding claim, wherein said 10 connection board (16) has an essentially planar extension and is made from a flexible material.

8. The medical arrangement according to any preceding claim, wherein said connection board (16) is made from a flexible rubber material.

15

9. The medical arrangement according to any preceding claim, wherein said connection line (14) is included into a piece of elastic into which an electrical conductor is integrated.

20 10. The medical arrangement according to claim 9, wherein said conductor is integrated by weaving conducting threads, e.g. made from silver, into said piece of elastic.

25 11. The medical arrangement according to any of claims 1-8, wherein said connection line (14) is an insulated conductor being directly integrated into the garment's material or into a piece of elastic.

12. The medical arrangement according to any of preceding claim, wherein said control unit (8) is a separate unit in relation to said connection board (16).

30 13. The medical arrangement according to any of claim, wherein said connection board (16) is connected to the control unit (8) via an electrical cable (22).

14. The medical arrangement according to any of claims 1-11, wherein said control unit (8) is an integral part of said connection board (16).

15. The medical arrangement according to any preceding claim, wherein said 5 garment (4) is adapted to enclose a part of or the entire body of the subject.

16. The medical arrangement according to any preceding claim, wherein said garment (4) comprises a synthetic fiber made from a polyurethane-polyurea copolymer, e.g. spandex or elastene.

10

17. The medical arrangement according to any preceding claim, wherein said electrodes (6) are silicone rubber electrodes.

18. The medical arrangement according to any preceding claim, wherein said 15 control unit (8) is adapted to apply an open-loop control when controlling the application of stimulation pulses.

19. The medical arrangement according to any preceding claim, wherein said control unit (8) comprises one or many of a stimulation pulse generator, an energy source, 20 a storage means, an input/output unit and a coupling unit.

20. The medical arrangement according to claim 19, wherein said control unit comprises a sensing unit adapted to receive electrical signals sensed by one or many of said electrodes (6).

25

21. The medical arrangement according to any preceding claim, wherein said arrangement comprises a plurality of vibration units (7) arranged at said garment (4), and wherein each vibration unit (7) being connected to said connection unit via a flexible and elastic vibration unit connection line (15).

30

1/2

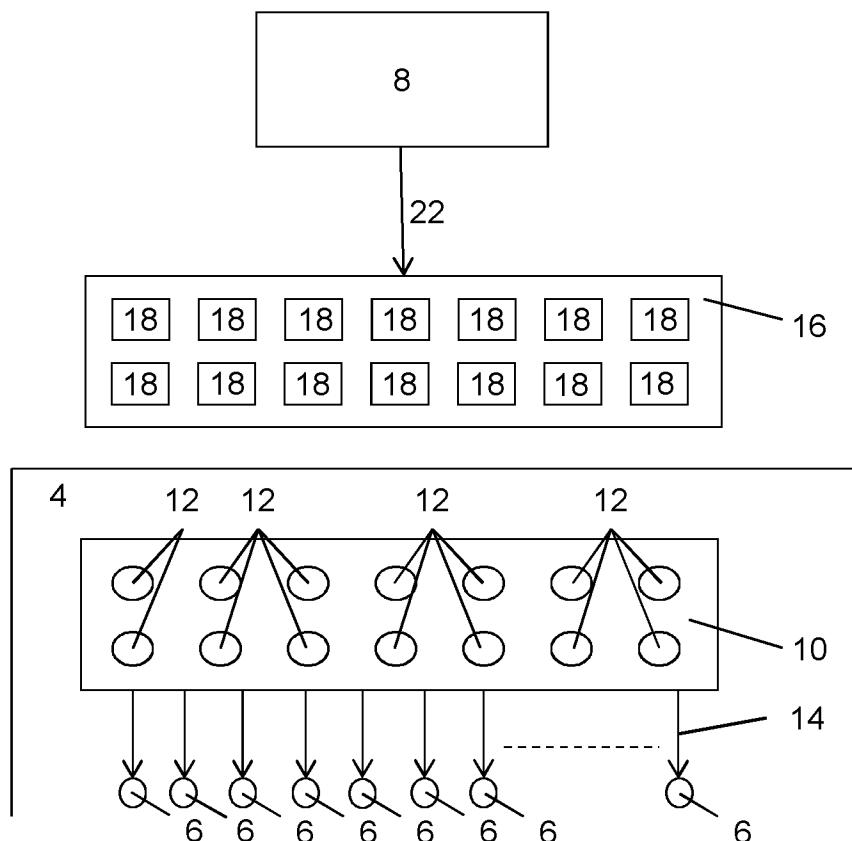
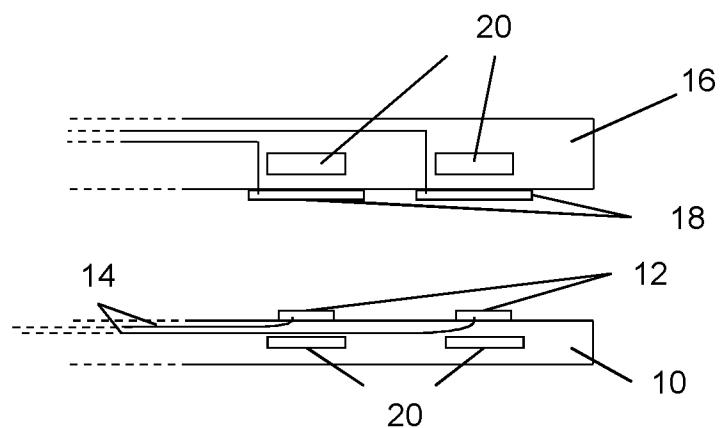


FIG. 1



2/2

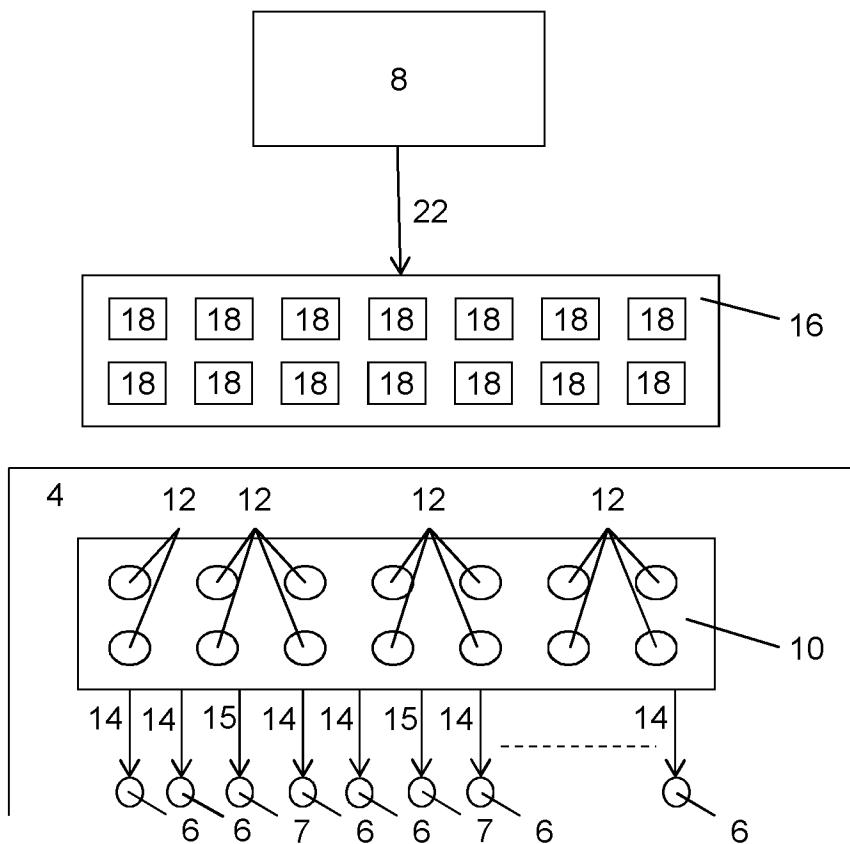


FIG. 3

INTERNATIONAL SEARCH REPORT

International application No
PCT/SE2013/050700

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61N1/04 A61N1/36
ADD.

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)

A61N

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2011/288604 A1 (KAIB THOMAS E [US] ET AL) 24 November 2011 (2011-11-24) abstract; figures 1-5, 13-19 paragraphs [0040] - [0048], [0076] - [0078] ----- US 2004/173220 A1 (HARRY JASON D [US] ET AL) 9 September 2004 (2004-09-09) abstract; figures 1c, 2a, 8a-e paragraphs [0083] - [0089], [0115] - [0122] ----- US 2008/077192 A1 (HARRY JASON D [US] ET AL) 27 March 2008 (2008-03-27) abstract; figures 5a-b, 7-10B, 13A-15B sentences 13-14, 92-109 ----- -/-	1-21 1-21 1-21

Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier application or patent but published on or after the international filing date
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Date of the actual completion of the international search	Date of mailing of the international search report
4 October 2013	15/10/2013
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Authorized officer Lahorte, Philippe

INTERNATIONAL SEARCH REPORTInternational application No
PCT/SE2013/050700

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2011/067327 A1 (INERVENTIONS AB [SE]; LUNDQVIST FREDRIK [SE]) 9 June 2011 (2011-06-09) cited in the application the whole document -----	1-21

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/SE2013/050700

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