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(54) Title: THERMAL TREATMENT SYSTEM AND APPARATUS WITH BIOFEEDBACK-DRIVEN PROTOCOL

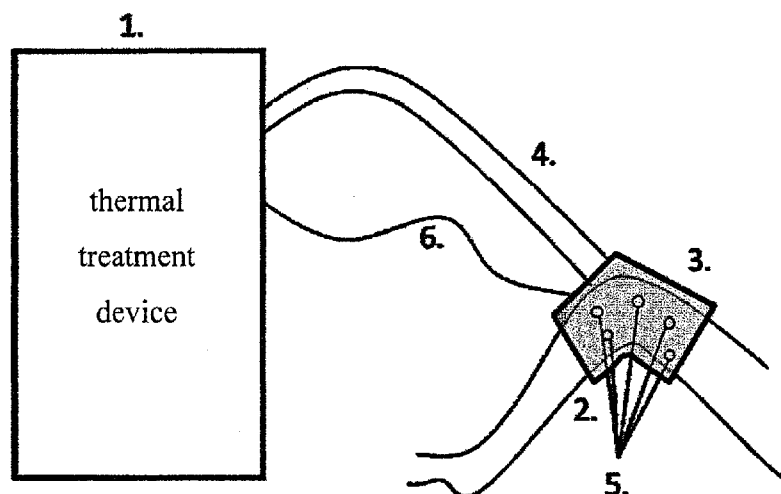


FIG. 1

(57) Abstract: The invention provides for a thermal treatment device for generating a feedback-driven protocol for thermal treatment of a human or animal body part. The device comprises measurement means adapted to acquire data of a thermal treatment from the body part and means for adapting the thermal treatment of the body part on the basis of the data acquired. Further, a method for generating a feedback-driven protocol for thermal treatment of a human or animal body part is provided. Said method comprises the steps of acquiring data of a thermal treatment from the body part and adapting the thermal treatment of the body part on the basis of the data acquired.



Thermal treatment system and apparatus with biofeedback-driven protocol

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The invention relates to a thermal treatment device and method for generating a feedback-driven protocol for thermal treatment of a human or animal body part. In particular, data acquired from a thermal treatment of the body part are analyzed. On the basis of the acquired data, the treatment of the body part is then adapted to optimize the health-
10 beneficial effect.

FIELD OF THE INVENTION

The present invention is in the technical field of thermal treatment of the human body.

15

More particularly, the present invention is in the technical field of thermal treatment of the human or animal body by means of a device providing cooling and/or heating to the body utilizing a biofeedback to select and/or adapt a certain thermal treatment protocol.

20 BACKGROUND OF THE INVENTION

Thermal treatment provides cooling and/or heating to the body in order to reach a beneficial health effect, such as, but not limited to pain reduction, fast swelling reduction and increased mobility.

25

Effective thermal treatment entails exchanging an amount of energy (heat or cold) with the body during a certain span of time and following a particular treatment sequence of treatment cycles. The optimal amount of energy exchanged depends on many factors that

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are difficult to control and will vary from patient to the patient and from disease to disease.

Accordingly, there is a need for an apparatus and system to overcome the problems in the prior art and to optimize the thermal treatment of a patient.

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OBJECTS OF THE INVENTION

The object of the present invention is to provide a thermal treatment apparatus and system optimizing the treatment of a patient.

10

It is a further object of this invention to provide a thermal treatment apparatus and system that automatically determines the optimum treatment protocol for a patient.

Further objects and advantages of the present invention will be disclosed and become
15 apparent from the following description.

SUMMARY OF THE INVENTION

The present invention relates to a thermal treatment device and method for generating a
20 feedback-driven protocol for thermal treatment of a human or animal body part. More specific features for preferred embodiments are set out in the dependent claims.

In one embodiment, the present invention provides an apparatus and system comprising means to measure patient parameters resulting from the on-going thermal treatment and to
25 feedback those parameters to the treatment device to control the on-going treatment. This system of biofeedback-driven protocol adaptation may yield a better and even optimal treatment for the specific patient.

According to the present invention, a thermal treatment device for generating a feedback-
30 driven protocol for thermal treatment of a human or animal body part is provided. The

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device comprises measurement means adapted to acquire data of a thermal treatment from the body part and means for adapting the thermal treatment of the body part on the basis of the data acquired.

- 5 In a particular embodiment, the measurement means is adapted to determine the amount of thermal energy exchanged during the thermal treatment of the body part, on the basis of the acquired data.

10 In a particular embodiment, the means for adapting the thermal treatment is adapted to change the temperature and/or pressure and/or duration and/or duration/frequency of cycles of the thermal treatment and/or treatment content of each cycle of the thermal treatment.

In a particular embodiment, the device further comprises a storage means adapted to store the acquired data and to document the adapting of the thermal treatment.

15

For example, the documentation of the thermal treatment may be realized by generating a protocol and particularly save/store the protocol on a processor unit which may be part of the thermal treatment device. A protocol may contain data and/or commands and/or sequences of commands and may be adapted to control the operation of the thermal
20 treatment.

In a particular embodiment, the measurement means comprises at least one sensor adapted to determine a particular parameter of the body part.

- 25 In a particular embodiment, the particular parameter is at least one of the dimensions of the body part, the skin conductivity, the skin color, the skin temperature, the skin texture, the heart rate, the blood pressure, the blood saturation.

In a particular embodiment, the parameter determined by the sensor of the measurement
30 means of the thermal treatment device is the dimensions of the body part and/or a

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parameter related to the thermal treatment, for example, flow rate, temperature, pressure of the treatment. In this case, for example, a further device, e.g. a thermal exchange device, may comprise at least one sensor adapted to determine the body part related parameter(s), such as the skin conductivity, the skin color, the skin temperature, the skin texture, the heart rate, the blood pressure, the blood saturation.

According to the present invention, a system for generating a feedback-driven protocol for thermal treatment of a human or animal body part is provided. The system comprises a thermal treatment device as discussed above and a thermal exchange device connected to the thermal treatment device and adapted to provide a heating and/or a cooling of the body part.

In a particular embodiment, the system further comprises sensor means adapted to determine particular parameters of the body part.

As discussed above, the sensor may be adapted to determine the body part related parameter(s), such as the skin conductivity, the skin color, the skin temperature, the skin texture, the heart rate, the blood pressure, the blood saturation.

Additionally the system may comprise means for a controlled supply of medication, e.g., a certain pharmaceutical supplied by a drug pump, to the patient, wherein the system determines - via suitable sensors - the patient's response on the medication, namely the change of the body part related parameter(s). The system may provide a certain diagnosis based on the patient's response and/or modify the thermal treatment in a controlled manner in order to optimize the patient's treatment by means of a closed loop (feedback) control.

For example, the combination of treatment by the thermal treatment device in conjunction with other medical treatments, such as, but not limited to antibiotics, anti-inflammatory drugs, and chemotherapy drugs, can cause a positive synergistic treatment effect. In one embodiment, the thermal treatment device may be used to apply cryo-treatment to an area

- 5 -

of the body (e.g. the arm) which is infected with a bacteria which is, for example, normally resistant to antibiotics (e.g. methicillin-resistant *Staphylococcus aureus*). The application of cryo-treatment in this way may cause a reduction in bacterial division and/or spread in the tissue, providing more time for the antibiotics to work effectively in the affected area. This
5 may result in a favorable treatment outcome where amputation may have been the only other viable option.

Further, the invention disclosed herein could operate to monitor the patient's progress with regards to cryo-treatment in combination with other medical treatments and update the
10 treatment protocol accordingly, for example, the choice of medicine and optimal dose rate to maximize pharmaceutical efficacy.

The temperature distribution data may be obtained by an IR (infrared) camera and may be displayed to the physician and/or used for feedback control of the thermal treatment.
15 Furthermore, the time lapsed during the thermal treatment may also be taken into account when controlling the thermal treatment based on the determination of the various body part related parameter(s).

While the present invention discusses the use of biofeedback to adapt a treatment protocol,
20 it is advantageous to disclose the optimal means of obtaining a biofeedback reading, which are preferably non-invasive. For example, the amount of thermal exchange between the thermal pad or Peltier thermal exchange element and skin can be determined by using a temperature sensitive surface between such thermal pad or Peltier thermal exchange element and skin. Alternatively, a measurement of power output to the fluid in the thermal
25 pad or the Peltier thermal exchange element itself can provide an indirect determination of thermal exchange with a body. Alternatively, the amount of thermal exchange between a Peltier thermal exchange element and the skin (such Peltier thermal exchange element preferably being constructed in the manner disclosed in US Patent No. 6017337 by Pira) can be determined indirectly by measuring temperature difference between the cold side
30 and hot side of the Peltier element, and the rate of flow of liquid cooling the heat sink on

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the hot side. Alternatively, a direct measurement of biofeedback (e.g. temperature) from a patient can be obtained by using sensor means to obtain a reading from a drainage catheter, which, for example, has been inserted into the body following knee reconstructive surgery. Although various preferred means of obtaining biofeedback readings have been disclosed
5 herein, other means of obtaining such readings are not excluded.

In a particular embodiment, the thermal exchange device is a hydraulic device and/or a Peltier thermal exchange element.

10 The Pelier effect uses a thermoelectric cooling to create a heat flux between the junction of two different types of materials. A Peltier cooler, heater, or thermoelectric heat pump is a solid-state active heat-pump which transfers heat from one side of the device to the other side against the temperature gradient (from cold to hot), with consumption of electrical energy.

15

According to the present invention, a method for generating a feedback-driven protocol for thermal treatment of a human or animal body part is provided. The method comprising the steps of acquiring data of a thermal treatment from the body part and adapting the thermal treatment of the body part on the basis of the data acquired.

20

In a particular embodiment, the step of adapting the thermal treatment comprises monitoring the amount of thermal energy exchanged during the thermal treatment.

In a particular embodiment, the step of acquiring the data comprises determining a
25 particular parameter of the body part.

In a particular embodiment, the method further comprises the step of documenting the adapting of the thermal treatment by generating a protocol and/or by selecting a known protocol.

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A known protocol may be a protocol which was previously (that means before the present thermal treatment cycle of the body part) generated, for example, during a thermal treatment of a different patient and/or body part and/or during a thermal treatment of the same patient and/or body part but at a different time/date. Further, a known protocol may
5 be a protocol which was generated by computer simulation particularly adapted to the disease of the patient.

For example, a (new) protocol is generated if it is determined that none of the known protocols “fits” with the actual needs of the patient. In particular, a protocol is generated on
10 the basis of a known protocol (e.g. which was used in the cycle before) and then adapted depending on the data acquired from the present cycle.

In a particular embodiment, the adapting of the thermal treatment is an iteration process adapting the thermal treatment on the basis of the data acquired and data previously
15 acquired.

The data previously acquired means data acquired before the present thermal treatment cycle of the body part. In doing so, the next treatment cycle may be further improved and adapted to the actual needs so that the recovery of the patient may be further enhanced.
20

According to the present invention, a computer program product is provided. The computer program product comprises one or more computer readable media having computer executable instructions for actuating and controlling the steps of the method as discussed above.
25

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 schematically shows a thermal treatment device for use with a thermal exchange device;
30

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Fig. 2 schematically shows a thermal treatment device for use with another thermal exchange device;

Fig. 3 is a graphical representation of the reduction in swelling by operation of the invention;

Fig. 4 is a graphical representation of the reduction in pain by operation of the invention; and

Fig. 5 is a graphical representation of the reduction in number of days the patient resides at the hospital or the number of days of inactivity of the patient.

DETAILED DESCRIPTION OF THE INVENTION

Various embodiments of the present invention are described hereinafter with reference to the figures. It should be noted that the figures are not drawn to scale and elements of similar structures or functions are represented by like reference numerals throughout the figures. It should also be noted that the figures are only intended to facilitate the description of specific embodiments of the invention. In addition, an aspect described in conjunction with a particular embodiment of the present invention is not necessarily limited to that embodiment and can be practiced in any other embodiments of the present invention.

In Fig. 1 a thermal treatment device (1) controls the thermo-treatment of a part of a human body (2) by means of a thermal exchange device (3), capable of exchanging heat or cold. The thermal treatment device and the thermal exchange device may be connected by a hydraulic conduit, and electric conduit (providing a Peltier element), both or by other means. The effect of the heat exchange is measured and monitored through a measurement means (5) consisting of at least one sensor, sometimes combined with a signal condition and signal acquisition subsystem. The measurement means can be part of the thermal exchange device or it can be separate from it. The measurement means can be partially

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embedded in the device. The measurement means is adapted to measure the effect of the thermal exchange with the body part and/or measures aspects of the thermal energy exchange itself.

- 5 In Fig. 2 an embodiment is schematically shown, wherein the thermal exchange device (3) encompasses a Peltier thermal exchange element.

The effect of the thermal treatment represents a health benefit to the patient. This can manifest itself as a reduction of swelling, reduction of pain, rapid recovery, fewer days of
10 residence at the hospital as well as other manifestations.

Fig. 3 represents an example where the thermo-treatment results in a reduction of swelling over time. At the leftmost point of Graph (1) an event occurs which causing swelling of a body part. After a certain time, if no thermal treatment is applied, a maximum swelling
15 occurs, represented by the highest point in Graph (1). After that the swelling reduces slowly and eventually fades away completely. When optimal thermal treatment is applied, then the body part reacts differently to the same event. In Graph (2) thermal treatment is applied and results in a lower maximum point and a swelling reduction. In Graph (3) thermal treatment is applied in a suboptimal way: the maximum swelling is lower than in the case without
20 treatment but higher than with optimal treatment. Swelling reduction occurs faster than without thermal treatment but slower than with it.

Fig. 4 depicts the same principle but applied on the health-beneficial effect of pain reduction. It can occur alone or in combination with the effect depicted in Fig. 3.

25

Fig. 5 depicts the same principle but expressed as a reduction in number of days the patient resides at the hospital or the number of days of inactivity of the patient. Bar (1) manifests itself without any thermo-treatment, bar (2) with the optimal thermo-treatment and bar (3) with sub-optimal thermo-treatment.

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- 10 -

The present invention operates for example by enabling the thermal treatment device (1) to attain or approach the optimal treatment by gathering measurement data related to the patient's reaction to the on-going treatment or measurement data related to the thermal exchange with the body part and utilizing such data to adapt or select the optimal treatment protocols for the particular patient, in real-time.

The measurement data related to patient's reaction can be measured directly or indirectly, either using physical reactions to the treatment or psychological relations. Examples of measurements include measuring the dimensions of the body part (e.g. limb circumference), skin conductivity, skin color, skin temperature, skin texture, heart rate, blood pressure, blood saturation, or any other effects that may result from the thermo-treatment.

The measurement data can be measured directly or indirectly by monitoring the amount of energy exchanged by the thermal exchanger.

The measurement data may be relayed/transmitted to the thermal treatment device. The thermal treatment device takes the measurement data into account to optimize the on-going treatment protocol. The optimization entails optimizing (a) the temperature at which the thermal exchange takes place, (b) the pressure at which the thermal exchange takes place, (c) the duration of the thermal cycles, (d) the duration of the total treatment, (e) the temperature and pressure differences at various points in the treatment cycle. The effect of the optimization results in a beneficial effect to the patient, measured as either one or a combination of swelling reduction, pain reduction, fewer days in hospital, decreased inactivity time, better patient well-being, and any other beneficial effect that can be obtained through thermal treatment.

The optimization process combines the measurement data with the statistics gathered through medical research. At regular instances in time during the treatment the effect of the treatment resulting from the actual treatment parameters is correlated with known data. The

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treatment parameters are then adapted in a direction where better effect is expected. Preferably, following this adaptation new measurement data is collected and the above process is repeated until no additional treatment is required (thus providing an iteration process to optimize the thermal treatment).

5

While the invention has been illustrated and described in detail in the foregoing description, such illustration and description are to be considered illustrative or exemplary and non-restrictive; the invention is thus not limited to the disclosed embodiments. Features mentioned in connection with one embodiment described herein may also be advantageous
10 as features of another embodiment described herein without explicitly showing these features. Variations to the disclosed embodiments can be understood and effected by those skilled in the art and practicing the claimed invention, from a study of the disclosure and the appended claims. In the claims, the word “comprising” does not exclude other elements or steps, and the indefinite article “a” or “an” does not exclude a plurality. The mere fact
15 that certain measures are recited in mutually different dependent claims does not indicate that a combination of these measures can not be used to advantage.

CLAIMS

1. Thermal treatment device for generating a feedback-driven protocol for thermal treatment of a human or animal body part, comprising
- 5 measurement means adapted to acquire data of a thermal treatment from the body part;
- means for adapting the thermal treatment of the body part on the basis of the data acquired.
- 10
2. Device of claim 1, wherein the measurement means is adapted to determine the amount of thermal energy exchanged during the thermal treatment of the body part, on the basis of the acquired data.
- 15 3. Device of claim 1 or 2, wherein the means for adapting the thermal treatment is adapted to change the temperature and/or pressure and/or duration and/or duration/frequency of cycles of the thermal treatment and/or treatment content of each cycle of the thermal treatment.
- 20 4. Device of claim 1, 2 or 3, further comprising a storage means adapted to store the acquired data and to document the adapting of the thermal treatment.
5. Device of any one of the preceding claims, wherein the measurement means comprise at least one sensor adapted to determine a particular parameter of the body part.

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6. Device of claim 5, wherein the particular parameter is at least one of the dimensions of the body part, the skin conductivity, the skin color, the skin temperature, the skin texture, the heart rate, the blood pressure, the blood saturation.

5 7. System for generating a feedback-driven protocol for thermal treatment of a human or animal body part, comprising:

a thermal treatment device of one of the preceding claims; and

10 a thermal exchange device connected to the thermal treatment device and adapted to provide a heating and/or a cooling of the body part.

8. System of claim 7, further comprising sensor means adapted to determine particular parameters of the body part.

15

9. System of claim 7 or 8, further comprising means for a controlled supply of medication, and wherein the system is preferably adapted to determine the response of the body part to the medication.

20 10. System of claim 7, 8, or 9, wherein the thermal exchange device is a hydraulic device and/or a Peltier thermal exchange element.

11. Method for generating a feedback-driven protocol for thermal treatment of a human or animal body part, comprising the steps of:

25

acquiring data of a thermal treatment from the body part;

adapting the thermal treatment of the body part on the basis of the data acquired.

12. Method of claim 11, wherein the step of adapting the thermal treatment comprises

5 monitoring the amount of thermal energy exchanged during the thermal treatment.

13. Method of claim ~~10, 11~~, or 12, wherein the step of acquiring the data comprises

determining a particular parameter of the body part.

10

14. Method of claim 10, 11, 12 or 13, further comprising the step of:

documenting the adapting of the thermal treatment by generating a protocol and/or
by selecting a known protocol.

15

15. Method of one of the preceding claims, wherein the adapting of the thermal
treatment is an iteration process adapting the thermal treatment on the basis of the data
acquired and data previously acquired.

20 16. Method of one of the preceding claims, further comprising a step of

updating the feedback-driven protocol by taking a response of the body part to a
medical treatment into consideration.

25 17. Computer program product comprising one or more computer readable media
having computer executable instructions for performing the steps of the method of any one
of claims 10 to 14.

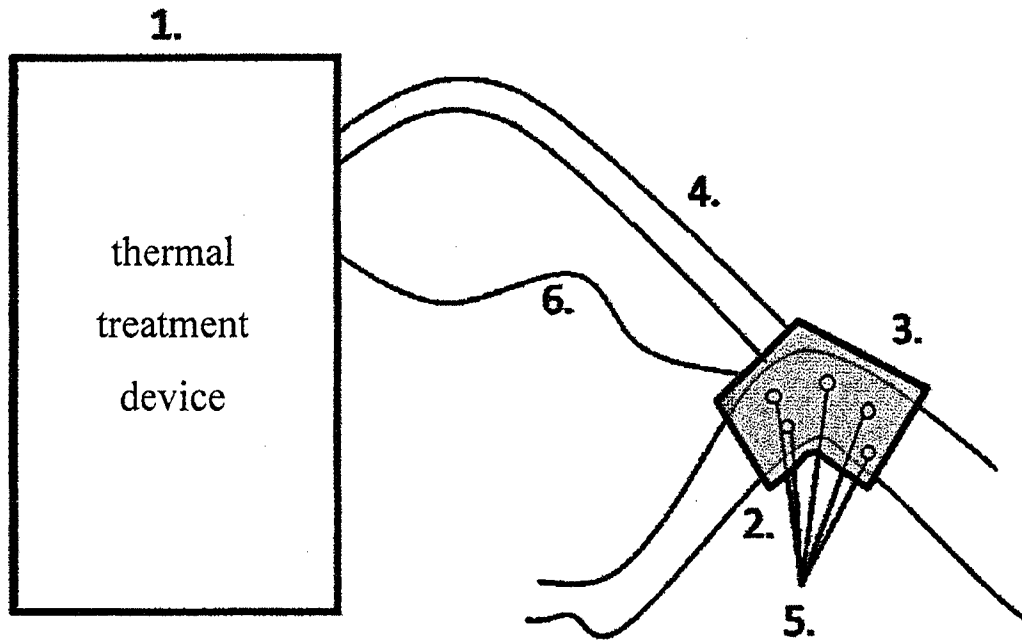


FIG. 1

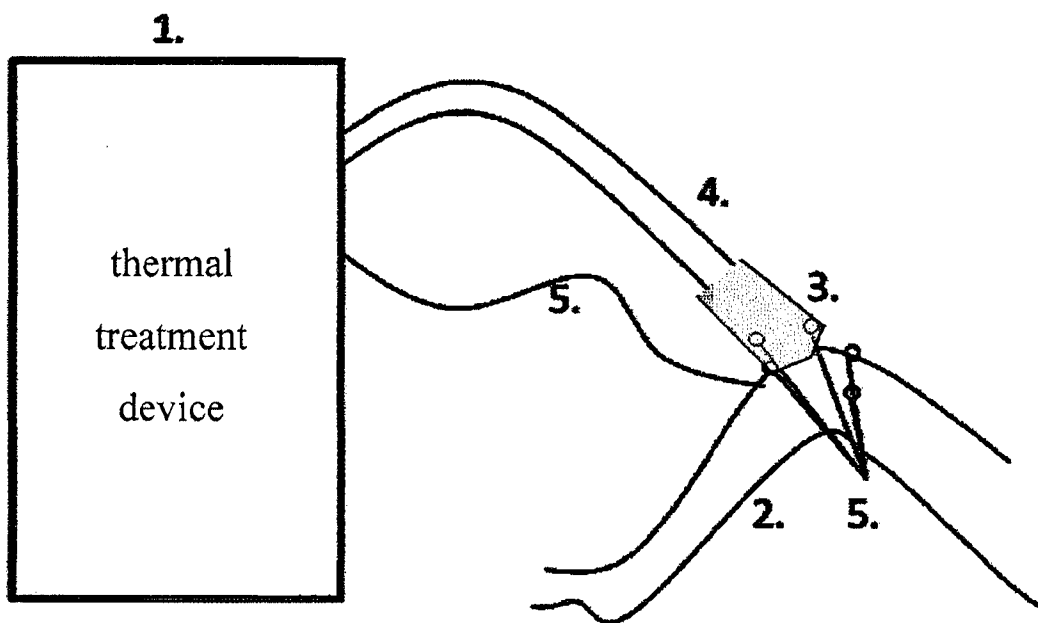


FIG. 2

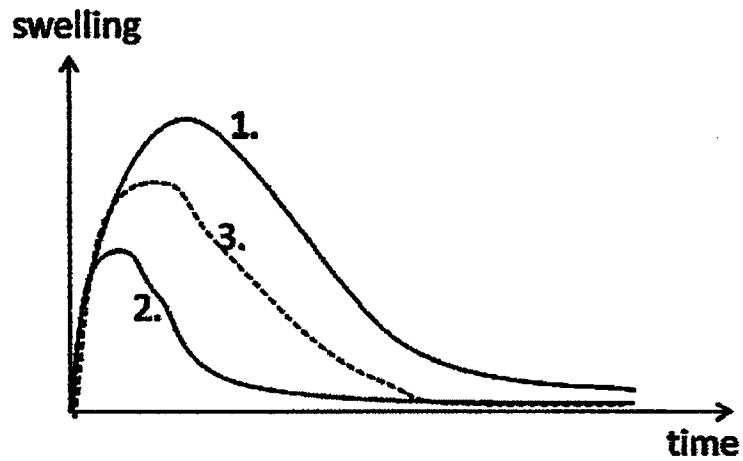


FIG. 3

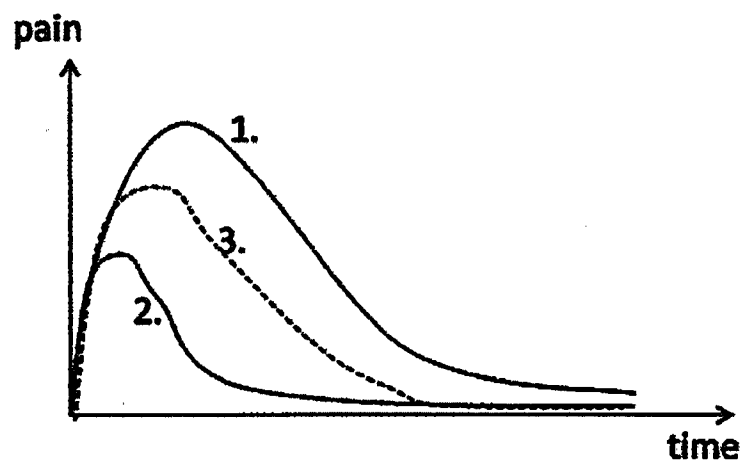


FIG. 4

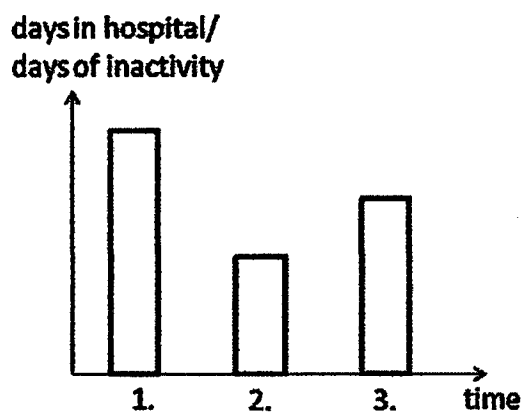


FIG. 5

INTERNATIONAL SEARCH REPORT

International application No

PCT/EP2010/059379

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61F7/00

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)

A61F

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)

EP0-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2002/026226 A1 (EIN ROBERT J [US]) 28 February 2002 (2002-02-28) paragraphs [0004] - [0011], [0015], [0154], [0157]; figure 2 -----	1-10, 17

☐ 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

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

9 September 2010

Date of mailing of the international search report

24/09/2010

Name and mailing address of the ISA/

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2010/059379

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

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

1. ☒ Claims Nos.: 11-16
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/EP2010/059379

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2002026226 A1	28-02-2002	NONE	