



(51) International Patent Classification:

A61B 5/0295 (2006.01)

(21) International Application Number:

PCT/SE2019/050251

(22) International Filing Date:

20 March 2019 (20.03.2019)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

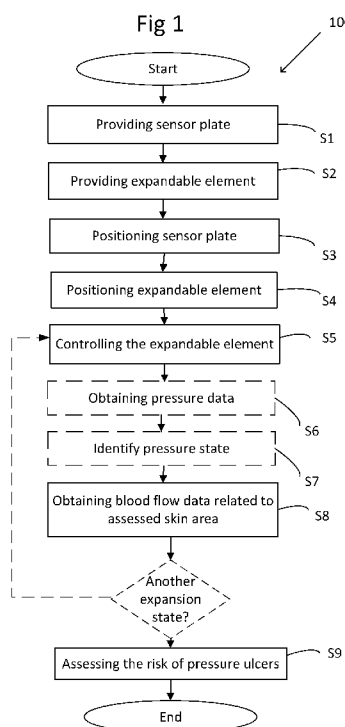
1850354-0 28 March 2018 (28.03.2018) SE

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117N, 114 85 Linköping (SE).(81) Designated States (unless otherwise indicated, for every
kind of national protection available): AE, AG, AL, AM,
AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ,
CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO,DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN,
HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP,
KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME,
MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ,
OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA,
SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN,
TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.(84) Designated States (unless otherwise indicated, for every
kind of regional protection available): ARIPO (BW, GH,
GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ,
UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ,
TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK,
EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV,
MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM,
TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW,
KM, ML, MR, NE, SN, TD, TG).

Published:

— with international search report (Art. 21(3))

(54) Title: A METHOD AND SYSTEM FOR ASSESSMENT OF A BLOOD FLOW



(57) Abstract: The present disclosure relates to a method and system for assessment of a blood flow in an area of the skin and underlying tissue of a patient. The method comprises a step of subjecting the assessed area to at least two different pressure states, wherein the different pressure states are obtained by the patient's weight pressuring against a support on which the patient is placed and an expandable element at least partly circumventing the assessed area and expandable a direction from the support against the patient to substantially eliminate a patient's body from the support in the area at least partly circumventing the assessed area. The method further comprises the steps of obtaining (S8) blood flow data related to the assessed area while subjecting the assessed area to the at least two different pressure states, wherein the blood flow data is obtained by means of photoplethysmography and assessing (S9) the risk of pressure ulcers on the patient based on assessment of the blood flow data obtained for the at least two different pressure states.

A method and system for assessment of a blood flow

TECHNICAL FIELD

The present disclosure relates to a method and system for assessment of a risk of developing pressure ulcers.

5 BACKGROUND ART

Pressure ulcers are injuries to skin and underlying tissue resulting from prolonged pressure on the skin. Those are most often developed on skin that covers bony areas of the body, such as the heels, ankles, hips and sacrum.

10 People most at risk of developing pressure ulcers are those with a medical condition that limits their ability to change positions or those who spend most of their time in a bed or chair. Immobile individuals frequently develop painful pressure ulcers. Moreover, pressure ulcers cause high costs for the health care system.

SUMMARY OF THE INVENTION

15 The present disclosure relates to an improved method for assessment of a risk of developing pressure ulcers.

This has been achieved by means of a method for assessment of a blood flow in an area of the skin and underlying tissue of a patient. The method comprises a step of subjecting the assessed area to at least two different pressure states, wherein the different pressure states
20 are obtained by the patient's weight pressuring against a support on which the patient is placed and an expandable element at least partly circumventing the assessed area and expandable a direction from the support against the patient to substantially eliminate a pressure on the patient's body from the support in the area at least partly circumventing the assessed area. The method further comprises the steps of obtaining (S8) blood flow data
25 related to the assessed area while subjecting the assessed area to the at least two different pressure states, wherein the blood flow data is obtained by means of photoplethysmography and assessing (S9) the risk of pressure ulcers on the patient based on assessment of the blood flow data obtained for the at least two different pressure states.

The method is easy to use and give rise to a decreased discomfort for the patient. The patient may lie down in the same position during the entire measurement.

In different embodiments, in the first pressure state substantially no pressure is provided in the assessed area. Thereby, a measurement of the basal blood flow is obtained and any blood
5 flow measured under pressure can be related to the basal blood flow.

In different embodiments, in the second pressure state, the body weight pressures against the assessed area. Accordingly, a measurement is provided at least more or less reflecting the daily situation when the patient spends most of his/her time in a bed or chair.

Comparing the basal blood flow to the blood flow reflecting the daily situation for the patient
10 provides for a risk assessment with an increased reliability.

The first and the second pressure states may be obtained in the above order to decrease the risk that the measurement of the basal blood flow is disturbed by a previous load to the assessed area.

In different embodiments, the method comprises a step of controlling the expandable
15 element at least between a first expansion state corresponding to the first pressure state and a second expansion state corresponding to the second pressure state.

By this automatization, the requirements on education etc of personnel using the method may be decreased.

In different embodiments, the method comprises a step of obtaining pressure data a step of
20 identifying (S7) the respective pressure states based on the obtained pressure data. The step of assessing the risk of pressure ulcers is then made based on blood flow data obtained for the identified at least two different pressure states.

In practice, the blood flow data may be obtained by: illuminating the skin and underlying tissue with the light from a LED, and measuring the amount of light reflected to a photodiode.

25 The method may further comprise the steps of: providing the expandable element having a controllable expansion state, providing a sensor element for obtaining the blood flow data using photoplethysmography, positioning the expandable element in relation to the patient such that the patient's weight provides the pressure to the assessed area in dependence of

the expansion state of the expandable element, obtaining blood flow data related to the assessed area using the sensor element, and assessing the risk of pressure ulcers on the patient based on assessment of the blood flow data obtained for at least two different expansion states of the expandable element.

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When the sensor element is not integrated with expandable element, the method further comprises a step of attaching the sensor element to the skin of the assessed area.

The present disclosure further relates to a software for performing a method as defined in any of the preceding claims.

- 10 The present disclosure further relates to a system for assessment of a blood flow in an area of the skin and underlying tissue of a patient. The system comprises a sensor plate having at least one blood flow sensor obtained by means of photoplethysmography; and an expandable element (310) having a controllable expansion state. The expandable element is arranged to form a frame at least partly circumventing the sensor plate. The configuration of the
- 15 expandable element secures that the assessed area is subjected to at least two different pressure states obtained by the patient's weight pressuring against a support on which the patient is placed and an expansion of the expandable element in a direction from the support against the patient to substantially eliminate a pressure on the patient's body from the support in the area at least partly circumventing the assessed area. The system further
- 20 comprises a computing system arranged to perform data processing of said blood flow data. The at least one blood flow sensor is arranged to obtain blood flow data while subjecting the assessed area to the at least two different pressure states. The computing system is arranged to assess the risk of pressure ulcers on the patient, based on assessment of the blood flow data for the at least two different pressure states.
- 25 The system may further comprise a Data Acquisition System, DAS, connected to the sensor plate, said Data Acquisition System being arranged for data conditioning and converting of said blood flow data, wherein the computing system is connected to the Data Acquisition System.

The sensor plate may be flexible and arranged to follow the curvature of the skin.

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The sensor plate may be provided with an adhesive for attachment to the patient.

The sensor plate may further comprises a plurality of LED-diodes of at least two different wavelengths and at least one photodetector.

5

The at least one photodetector may be arranged to receive data from a plurality of LEDs and to measure the data from each LED individually.

10

The system may further comprise at least one pressure sensor obtaining pressure data. The computing system is arranged to identify the respective pressure states based on the obtained pressure data and to assess the risk of pressure ulcers on a patient based on blood flow data obtained for the identified at least two different pressure states.

15

The present disclosure further relates to a control element for assessment of a blood flow in an area of the skin and underlying tissue of a patient. The control element comprises an interface arranged to receive blood flow data from at least one sensor obtained by means of photoplethysmography. The blood flow data is obtained from the assessed area subjected to at least two different pressure states obtained by the patient's weight pressuring against a support on which the patient is placed and an expansion of an expandable element in a direction from the support against the patient to at least substantially eliminate a pressure on the patient's body from the support in the area at least partly circumventing the assessed area. The control element further comprises a processor arranged to perform data processing of said blood flow data to assess the risk of pressure ulcers on the patient, based on assessment of the blood flow data for the at least two different pressure states.

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BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a flow chart illustrating an example of a method for assessment of a blood flow.

Figure 2 is flow chart illustrating a step of obtaining blood flow data in a method for assessment of a blood flow for example according to figure 1.

Figure 3 is schematic sketch illustrating an example of a system for assessment of a tissue under pressure.

Figure 4 illustrates schematically an example of a design of a sensor plate.

5 Figures 5a illustrates a view from above of an example of an expandable element for use in assessing a tissue.

Figure 5b illustrates a side view of the expandable element of figure 5a in an expanded state.

Figure 5c illustrates a side view of the expandable element of figure 5a in a non-expanded state.

10 Figure 6 illustrates an example of an application for the method for assessment of a blood flow as disclosed in relation to figure 1.

DETAILED DESCRIPTION

15 Figures 1 and 6 disclose an example of a method for assessment of a blood flow in an area of the skin and underlying tissue of a patient. The method assesses a risk of developing pressure ulcers on the patient based on the blood flow data.

Pressure ulcers are injuries to skin and underlying tissue resulting from prolonged pressure on the skin. Those are most often developed on skin that covers bony areas of the body, such as the heels, ankles, hips and sacrum.

20 The exemplified method for assessment of a blood flow in a skin area to assess a risk of developing pressure ulcers is easy to use and give rise to a decreased discomfort for the patient.

25 The method is based on the concept that the assessed skin area is subjected to at least two different pressure states, wherein the different pressure states are obtained by the patient's weight pressuring against a support on which the patient is placed and an expandable element. The expandable element is at least partly circumventing the assessed area. The expandable element is expandable in a direction from a plane of the support towards the patient to at least substantially eliminate a pressure on the patient's body from the support in

the area at least partly circumventing the assessed skin area. The expansion state of the expandable element controls the body pressure applied to the assessed skin area of the patient.

The at least two different pressure states applied to the assessed skin area may comprise a first pressure state where the assessed skin area is subjected to substantially no pressure. In this first pressure state, the assessed skin area is lifted from the support on which the patient is placed by means of the expandable element. The assessed skin area is in an example lifted from the support no more than enough to substantially eliminate a pressure on the assessed skin area of the patient's body from the support. If lifting the assessed skin area more than necessary above the support, this requires providing a higher pressure than necessary to parts of the skin and underlying tissue around the assessed skin area by means of the expandable element. This may lead to a risk that the blood flow within the assessed area is affected by the pressure subjected to the skin and underlying tissue parts around the assessed area. It is generally desired that the expandable element is designed to effect the blood flow in the assessed skin area as little as possible.

The at least two different pressure states applied to the assessed area may comprise a second pressure state, wherein the body weight provides pressure to the assessed area. Characteristically, the thickness of the expandable element in this state is as thin as possible.

Blood flow data related to the assessed area is obtained while subjecting the assessed area to the at least two different pressure states. The blood flow data is obtained by means of photoplethysmography. The blood flow data may be obtained only by means of photoplethysmography.

The risk of pressure ulcers on the patient is assessed based on assessment of the blood flow data obtained for the at least two different pressure states.

Thus, in accordance with the method, blood flow data is obtained while at least two different pressures are applied to the assessed skin area, wherein the pressure is obtained by using the patient's weight. In one example, one of the pressures under which the blood flow data is obtained corresponds to the patient's weight. Another pressure under which the blood flow data is obtained may correspond to substantially no pressure from the patient's body weight.

The sensor plate is placed on the skin area to be assessed. The design of the sensor plate will be discussed more in detail in relation to figure 4.

In the illustrated examples, the method for assessment of a blood flow in an area of the skin and underlying tissue of a patient comprises a step of providing S1 a sensor element for obtaining blood flow data. As stated above, the sensor plate may comprise a blood flow sensor element arranged to obtain blood flow data based on photoplethysmography.

The method further comprises a step of providing S2 an expandable element having a controllable expansion state. The expandable element may form a rim for the sensor plate. Thus the, sensor element is intended to be partly or entirely surrounded by the expandable element. The expandable element may be fastened to the sensor plate, form a unit integrated with the sensor plate or be a unit physically separated from the sensor plate.

The method further comprises a step of positioning S4 the expandable element in relation to a patient such that the patient's weight provides the pressure to the assessed area in dependence of the expansion of the expandable element In Figure 6 (upper picture) it is illustrated that the expandable element is positioned at the patient's back. The expandable element is in an example positioned at the sacrum of the patient.

Further, the sensor plate is arranged S3 at least partly circumvented by the expandable element to abut against the skin of the patient. This step may comprise of attaching the sensor plate to the skin for example by means of an adhesive. The attachment may for example be provided by means of a double sided tape. The adhesive preferably is substantially transparent to the rays emitted by and reflected to a blood flow sensor element of the sensor plate in order not to disturb the measurements.

The method comprises further a step of controlling S5 expansion of the expandable element. Characteristically, the expandable element is controlled to different expansion states. For example, in a first expansion state substantially no pressure may be applied to the assessed area. A second expansion state may be a non-expanded or deflated state, where the body weight provides pressure to the assessed area.

In figure 6, the lower pictures, the patient is lying on his back. In the lower left picture the expandable element is expanded. The body weight of the patient exercises pressure against the expandable element but not on the assessed area wherein the skin is provided with the sensor plate. Thus, the expanded expandable element protects the sensor element at least partly circumvented by the expansion element from the body weight of the patient. Accordingly, substantially no pressure is applied to the assessed area where the skin is provided with the sensor plate.

In the lower right picture the expandable element is not expanded and the body weight of the patient exercises pressure against the support in the assessed skin area where the skin is provided with the sensor plate.

The method comprises further a step of obtaining S8 blood flow data related to the assessed skin area in the at least two different pressure states. The obtaining of blood flow data may be provided upon determination that the expandable element is in the respective state. In accordance therewith, when it has been determined that the respective expansion state has been reached, the obtaining of blood flow data may be initiated for that expansion state. The obtaining of blood flow data may be performed during a pre-set amount of time. Alternatively, blood flow data may be continuously obtained during the entire procedure.

As stated above, the blood flow data is obtained by means of photoplethysmography (PPG). In detail, a PPG is an optically obtained volumetric measurement of an organ. A PPG may be obtained by illuminating the skin and underlying tissue, and measuring changes in light absorption.

In systole in each cardiac cycle the heart pumps blood to the tissue. Even though this pressure pulse is somewhat damped by the time it reaches the skin, it is enough to distend the arteries and arterioles in the subcutaneous tissue. The change in volume caused by the pressure pulse is detected by illuminating the skin and underlying tissue with the light from a light-emitting diode (LED) and then measuring the amount of light reflected to a photodiode. Each systole cycle appears as a peak. Thus, these pressure pulses are in the present disclosure compared while the skin is subjected to different external pressures caused by the patient's weight, as discussed above.

The method may further comprise a step of obtaining S6 pressure data related to the body pressure applied to the assessed skin area. The pressure data may be provided by measuring the body pressure applied to the assessed skin area. The pressure may for example be measured by means of at least one pressure sensor. The at least one pressure sensor may be
5 formed at the sensor plate which also comprises the blood flow sensor element.

The respective pressure states may be identified based on the obtained pressure data.

The identification of the respective pressure state may then be used for initializing obtaining of blood flow data. Alternatively, the identification of the respective pressure state may then be used for selection of blood flow data for analysis. In accordance with this example, blood
10 flow data corresponding to pre-set pressure intervals may be selected for analysis.

The method further comprises a step of assessing S9 the risk of pressure ulcers on the patient based on blood flow data obtained for at least two different expansion states of the expandable element. The blood flow for the different expansion states is analysed. When the blood flow during the pressure with the body weight against the support in the assessed skin
15 area is greater than the blood flow during no pressure, there is less risk of pressure ulcers. When, on the other hand, the blood flow during the pressure with the body weight against the support in the assessed skin area is lower than the blood flow during no pressure, there is an increased risk of pressure ulcers.

There is generally less risk for pressure ulcers when a blood flow increases with the increased
20 body pressure applied by the patient's weight. On the other hand, there is an increased risk for pressure ulcers when a blood flow decreases with increased body pressure applied by the patient's weight. Thus, the assessment of the risk of pressure ulcers on the patient involves determining whether the blood flow increases or decreases with increased body pressure applied to the assessed skin area by the patient's weight. Preferably, the increase or decrease
25 of the blood flow is related to a basal blood flow, i.e. a blood flow measured unloaded.

As discussed above the assessment may for example be made based on obtained blood flow data obtained at discrete, predetermined pressure states, such as the first pressure state where no pressure is provided in the assessed skin area and the second pressure state where the body weight pressures against the assessed area, or based on continuously obtained blood

flow data. In the first case, the obtained pressure data may be used for identifying S7 the discrete, predetermined pressure states. This identification may in turn be used for initiating blood flow measurements. The obtained pressure data may in the latter case be continuously associated to corresponding continuously obtained blood flow data. The obtained pressure data may then be used for selecting intervals of the blood flow data for the assessment of the risk of pressure ulcers. .

Figure 2 discloses examples of details of the step of obtaining S8 blood flow data related to an assessed skin area. The blood flow data is as discussed in relation to figure 1 obtained by means of photoplethysmography. The obtaining of blood flow data may comprise illuminating S81 the skin with the light from a LED, and measuring S82 the amount of light reflected to a photodiode. The LED and the photodiode form a blood flow sensor element. The blood flow sensor element may be arranged at a sensor plate. The LEDs may emit light having one wavelength. Alternatively, the LEDs may emit light having at least two different wavelengths. In accordance with the latter example, a first set of LEDs emitting at a first wavelength and a second set of LEDs emitting at a second wavelength may be illuminating the skin. The one or a plurality of photodiodes measuring the amount of light reflected thereto may each measure light originating from a plurality of LEDs. The data from each photodiode may be obtained such that that the contribution from each individual LED is identified S83 in the data from the respective photodiode.

The method may further comprise a step of evaluating S84 the data associated to each individual LED. Based on this evaluation it may be identified if any LED or photodiode is faulty. The evaluation may be performed by comparing the blood flow data to expected blood flow data for example defined by an upper and/or lower limit.

A detected faulty LED and/or photodiode may be reported S85.

The evaluation may also be performed so as to identify whether LEDs and/or photodiodes are not positioned correctly, for example not abutting against the skin.

A detected not correctly positioned LED and/or photodiode may be reported S85.

The method may further comprise a step of identifying S86 LED data suitable for use in assessment of the risk of pressure ulcers. The identification may comprise identifying LEDs

giving rise to blood flow data deviating from the blood flow data obtained from other LEDs. The LEDs giving rise to deviating data may for example lack contact with the illuminated skin parts.. The LEDs giving rise to the deviating data may then be removed from use in assessment of the risk of pressure ulcers.

- 5 Figure 3 discloses an example of a system 300 for an assessment of a blood flow an area of the skin and underlying tissue. The system 300 comprises a measurement system 314 including a sensor plate 302. The sensor plate is provided with at least one blood flow sensor element arranged to obtain blood flow data. The blood flow sensor elements may be formed by LEDs emitting light and photodiodes receiving the emitted light and returned from a reflection in
10 the skin and underlying tissue. This has also been discussed in relation to figure 2 and 1.

Further the system 300 may further comprise at least one pressure sensor 315. The pressure sensor 315 is in the illustrated example mounted at the sensor plate 302. The pressure sensor may then be arranged to sense a pressure exerted on the sensor plate. Alternatively, the pressure sensor 315 is separate component physically separated from the sensor plate and/or
15 the blood flow sensor element.

An expansion element 310 having a controllable expansion state forms a frame at least partly bounding the sensor plate 302.

The expansion element may be designed in many different ways. The expansion element may for example be expandable by means of a gas, such as air, or liquid. The expandable element
20 may be expandable by means of a mechanical solution. The expansion element may be expandable by means of a magnetic solution. The expandable element may be expandable by means of a chemical solution. The expandable element may comprise an intelligent textile having the expandable property.

The expandable element may be expanded and retracted over and over again. Alternatively,
25 the expandable element is disposable. The disposable expandable element is characteristically only expandable/retractable once. For example, the expandable element may comprise an ampoule comprising a chemical compound when released being arranged to expand the expandable element.

In the illustrated example, the expandable element is an inflatable element. The inflatable element comprises an inflatable chamber, wherein an amount of air or another gas or the like is controllable. Accordingly, in the illustrated example, the system comprises a compressor 311 in communication with the inflatable element via a pressure regulator 312 and a valve 313.

In different examples, the inflatable element comprises an inflatable chamber, wherein the amount of air in the inflatable chamber is controlled to provide the controllable inflation. The inflatable element may be controlled to at least a first inflation state and a second inflation state by controlling the amount of air in the inflatable chamber.

- 10 The at least one pressure sensor may instead or in addition to measuring the body pressure applied by the patient's bodyweight in the assessed skin area be arranged to sense a pressure in the interior of the inflation element and/or a pressure applied over a pressure line 316 (not disclosed). These pressures may be used to determine the body pressure applied by the patient's bodyweight in the assessed skin area.
- 15 A computing system 305 is arranged to perform data processing of the blood flow data. The computing system 305 is arranged to assess the risk of pressure ulcers on a patient, based on the processed said blood flow data from at least two different inflation states of the inflatable chamber. Examples of this have been discussed in relation to figures 1 and 2. In detail, the strength of the pulse of the body is measured by means of the blood flow data in at least two
- 20 different inflation states. In one example the inflation states comprise a first state where substantially no pressure is applied and a second state where entire body weight pressures on the support in the assessed skin area. The measured pressure may be used for identification that the respective state has been reached.

The computing system may be arranged to control the inflation state. Alternatively, the inflation state is manually controlled. In the illustrated example, the inflation state is controlled by control of the pressure regulator, wherein the pressure regulator is manually controllable and/or controllable by the computing system 305.

The system 300 comprises in the illustrated example further a Data Acquisition System, DAS, 306 connected to the sensor plate 314 and to the computing system 305. The Data Acquisition System is arranged for data conditioning and converting of said blood flow data.

5 The system 300 may comprise a memory 304 for storage of the measured data used by the computing system 305. The memory 304 may further be arranged to store assessments made.

The system 300 comprises further a user interface 303. The user interface may be arranged to display information related to the assessment of the risk for pressure ulcers. For example, the result of the assessment may be presented by means of the user interface. The result may be a YES or NO, i.e. is there a risk of developing pressure ulcers. Alternatively, the risk may be
10 presented as a percentage.

The user interface may further be arranged to present information related to the performance of the assessment. For example, if an individual LED or photodiode has been determined to be defected, this may be presented by means of the user interface. If the evaluation of the data obtained by the photo detectors reveals that the results obtained from measurements at
15 different parts of the sensor plate differs, a warning may be presented. For example, this may indicate that at least some part of the sensor plate is not in abutment to the skin. The warning may then indicate that the measurement should be made again.

In figure 4, an example of a sensor plate is illustrated. The sensor plate may be flexible and arranged to follow the curvature of the skin. The sensor plate may be made of a material mild
20 to the skin. The sensor plate may for example be made of rubber or a rubber based material.

In the illustrated example, the sensor plate is foldable along a plurality of collinear lines in order to be able to follow the curvature of the body. However, many other designs of the sensor plate may be considered enabling the sensor plate to follow the curvature of the body. Measurements may be improved if it can be secured that the sensor plate rest against the skin
25 while making the measurements.

The sensor plate may at its side intended to face the skin be provided with an adhesive for attachment to the skin of the patient.

The sensor plate comprises a blood flow sensor element comprising a plurality of LEDs arranged to emit light at at least two different wavelengths. In one example, the LEDs may be

arranged to emit red and green light. The blood sensor element further comprises at least one photodetector such as a photodiode. In the illustrated example, the blood flow sensor element further comprises a plurality of photodiodes arranged to receive the light emitted from the LEDs and reflected from the skin and underlying tissue. In the illustrated example, the blood flow sensor element comprises a plurality of LEDs emitting light which may be of at least two different wavelengths. Further, in the illustrated example, the blood flow sensor element comprises six photodiodes.

Each at least one photodetector may be arranged to receive data from a plurality of LEDs and to measure the data from each LED individually.

The sensor plate may further comprise at least one pressure sensor (not illustrated) arranged to measure the pressure caused by the body weight of a patient in the assessed skin area.

Figures 5a to 5c illustrate an example of an expansion element in accordance with this disclosure having a controllable expansion state. The expansion element has at least two different expansion states.

As discussed in relation to Figure 3, the expansion element may be designed in many different ways. The expansion element may for example be expandable by means of a gas, such as air, or liquid. The expandable element may be expandable by means of a mechanical solution. The expansion element may be expandable by means of a magnetic solution. The expandable element may be chemically expandable. The expandable element may comprise an intelligent textile having the expandable property.

The expandable element may be expanded and retracted over and over again. Alternatively, the expandable element is disposable. The disposable expandable element is characteristically only expandable/retractable once. For example, a disposable expandable element may comprise an ampoule comprising a chemical compound when released being arranged to expand the expandable element.

The expandable element forms a frame designed to at least partly enclose the sensor plate.

The expansion element may be formed integrally with the sensor plate or being physically separated therefrom.

The expansion element may be formed integrally with the support on which the patient is intended to rest or it may be physically separated from the support. The support may be a bed.

5 In the view seen from above in figure 5a, it is disclosed that the expandable element forms a frame designed to at least partly enclose the sensor plate. Thus, the inflatable element comprises a rim enclosing an area.

10 In the side view of figure 5b it is disclosed that the expandable element when expanded is designed to extend above a sensor plate (dashed in the figure) when arranged in the area at least partly enclosed by the expandable element. Thereby, the rim protects the hollow area in the middle from pressure from a human body pressurizing against the expandable element.

15 In the side view of figure 5c it is disclosed that the expandable element when not expanded is designed to be as thin as possible. It may be desired that the expandable element in this state is essentially aligned with the support on which the expandable element is placed. Further, the upper surface of the expandable element may in this state be in the same plane as the surface of the sensor plate (dashed in the figure) when arranged in the area at least partly enclosed by the expandable element. Thereby, the expandable element does substantially not protect the area at least partly enclosed by the expandable element from the weight of a human body.

CLAIMS

1. A method for assessment of a blood flow in an area of the skin and underlying tissue of a patient, said method comprising the steps of:

5 subjecting the assessed area to at least two different pressure states, wherein the different pressure states are obtained by

 the patient's weight pressuring against a support on which the patient is placed and

 an expandable element at least partly circumventing the assessed area and
10 expandable a direction from the support against the patient to substantially eliminate pressure on a patient's body from the support in the area at least partly circumventing the assessed area,

 obtaining (S8) blood flow data related to the assessed area while subjecting the assessed area to the at least two different pressure states, wherein the blood flow data is
15 obtained by means of photoplethysmography and

 assessing (S9) the risk of pressure ulcers on the patient based on assessment of the blood flow data obtained for the at least two different pressure states.

2. The method according to any of the preceding claims, wherein in the first pressure state substantially no pressure is provided in the assessed area.

20 3. The method according to any of the preceding claims, wherein in the second pressure state, the body weight pressures against the assessed area.

4. The method according to any of the preceding claims, further comprising a step of controlling (S5) the expandable element at least between a first expansion state corresponding to the first pressure state and a second expansion state corresponding to
25 the second pressure state.

5. The method according to any of the preceding claims, further comprising a step of obtaining (S6) pressure data and identifying (S7) the respective pressure states based on the obtained pressure data , wherein the step of assessing (S9) the risk of pressure

ulcers is made based on blood flow data obtained for the identified at least two different pressure states..

6. A method according any of the preceding claims, where the blood flow data is obtained (S8) by:

5 illuminating the skin and underlying tissue with the light from a LED,
measuring the amount of light reflected to a photodiode.

7. The method according to any of the preceding claims, said method comprising the steps of:

providing (S1) the expandable element having a controllable expansion state,

10 providing (S2) a sensor element for obtaining the blood flow data using photoplethysmography,

positioning (S4) the expandable element in relation to the patient such that the patient's weight provides the pressure to the assessed area in dependence of the expansion state of the expandable element

15 obtaining (S8) blood flow data related to the assessed area using the sensor element, and

assessing (S9) the risk of pressure ulcers on the patient based on assessment of the blood flow data obtained for at least two different expansion states of the expandable element.

20 8. The method according to claim 7, further comprising attaching (S3) the sensor element to the skin of the assessed area.

9. Software for performing a method as defined in any of the preceding claims.

10. A system (300) for assessment of a blood flow in an area of the skin and underlying tissue of a patient, said system comprising:

25 a sensor plate (314) having at least one blood flow sensor obtained by means of photoplethysmography;

an expandable element (310) having a controllable expansion state, said expandable element being arranged to form a frame at least partly circumventing the sensor plate (314);

5 wherein the configuration of the expandable element secures that the assessed area is subjected to at least two different pressure states obtained by the patient's weight pressuring against a support on which the patient is placed and an expansion of the expandable element in a direction from the support against the patient to substantially eliminate a pressure on the patient's body from the support in the area at
10 least partly circumventing the assessed area; and

a computing system (305) arranged to perform data processing of said blood flow data, wherein the at least one blood flow sensor is arranged to obtain blood flow data while subjecting the assessed area to the at least two different pressure states, and

15 wherein the computing system (305) is arranged to assess the risk of pressure ulcers on the patient, based on assessment of the blood flow data for the at least two different pressure states.

11. The system according to claim 10, further comprising a Data Acquisition System, DAS, (306) connected to the sensor plate (304), said Data Acquisition System being arranged for data conditioning and converting of said blood flow data, wherein the computing
20 system is connected to the Data Acquisition System.

12. The system according to any of the claims 10 to 11, wherein the sensor plate is flexible and arranged to follow the curvature of the skin.

25 13. The system according to any of the claims 10 to 12, wherein the sensor plate is provided with an adhesive for attachment to the patient.

14. The system according to any of the claims 10 to 13, where the sensor plate (304) further comprises a plurality of LED-diodes of at least two different wavelengths and at least one photodetector.

5 15. The system according to claim 14, wherein the at least one photodetector is arranged to receive data from a plurality of LEDs and to measure the data from each LED individually.

10 16. The system according to any of the claims 10-15, further comprising at least one pressure sensor (315) obtaining pressure data, wherein the computing system (305) is arranged to identify the respective pressure states based on the obtained pressure data and to assess the risk of pressure ulcers on a patient based on blood flow data obtained for the identified at least two different pressure states.

15 17. A control element for assessment of a blood flow in an area of the skin and underlying tissue of a patient, said control element comprising:

an interface arranged to receive blood flow sensor data obtained by means of photoplethysmography, said blood flow sensor data being obtained from the assessed area subjected to at least two different pressure states obtained by the patient's weight pressuring against a support on which the patient is placed and an expansion of an expandable element in a direction from the support against the patient to at least substantially eliminate a pressure on the patient's body from the support in the area at least partly circumventing the assessed area; and

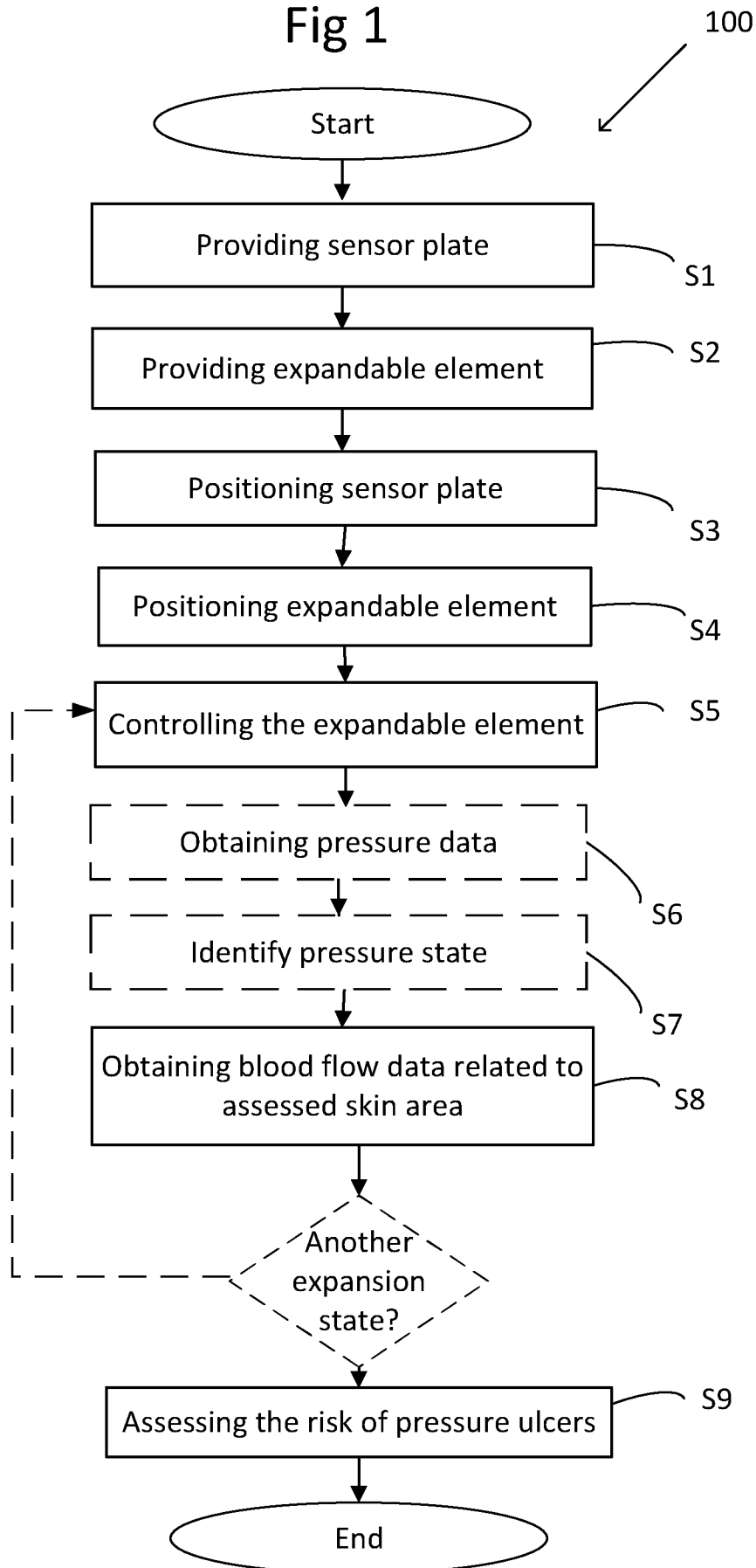
20

a processor arranged to perform data processing of said blood flow data to assess the risk of pressure ulcers on the patient, based on assessment of the blood flow data for the at least two different pressure states.

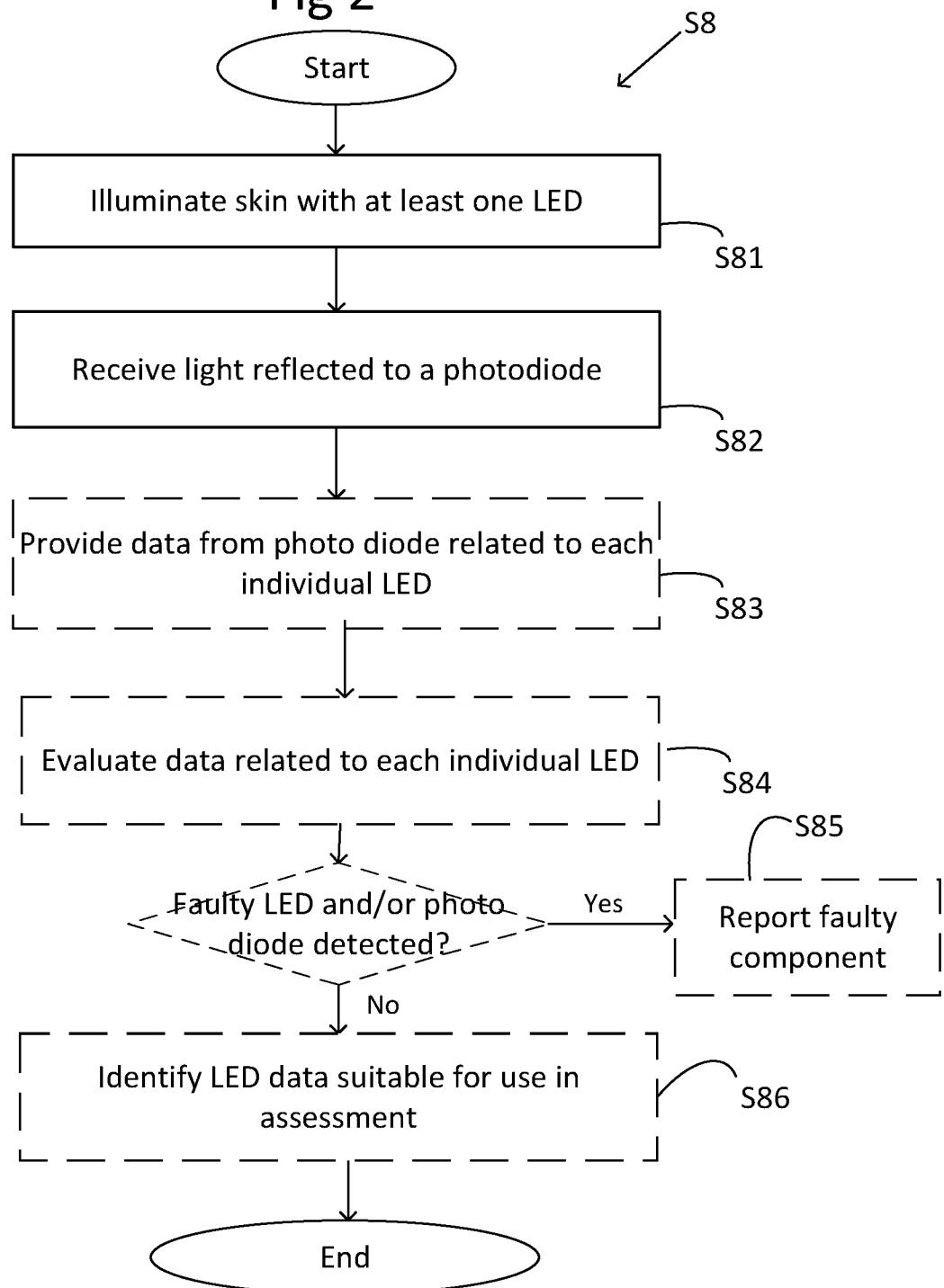
25

$1/4$

Fig 1



2/4
Fig 2



3/4

Fig 3

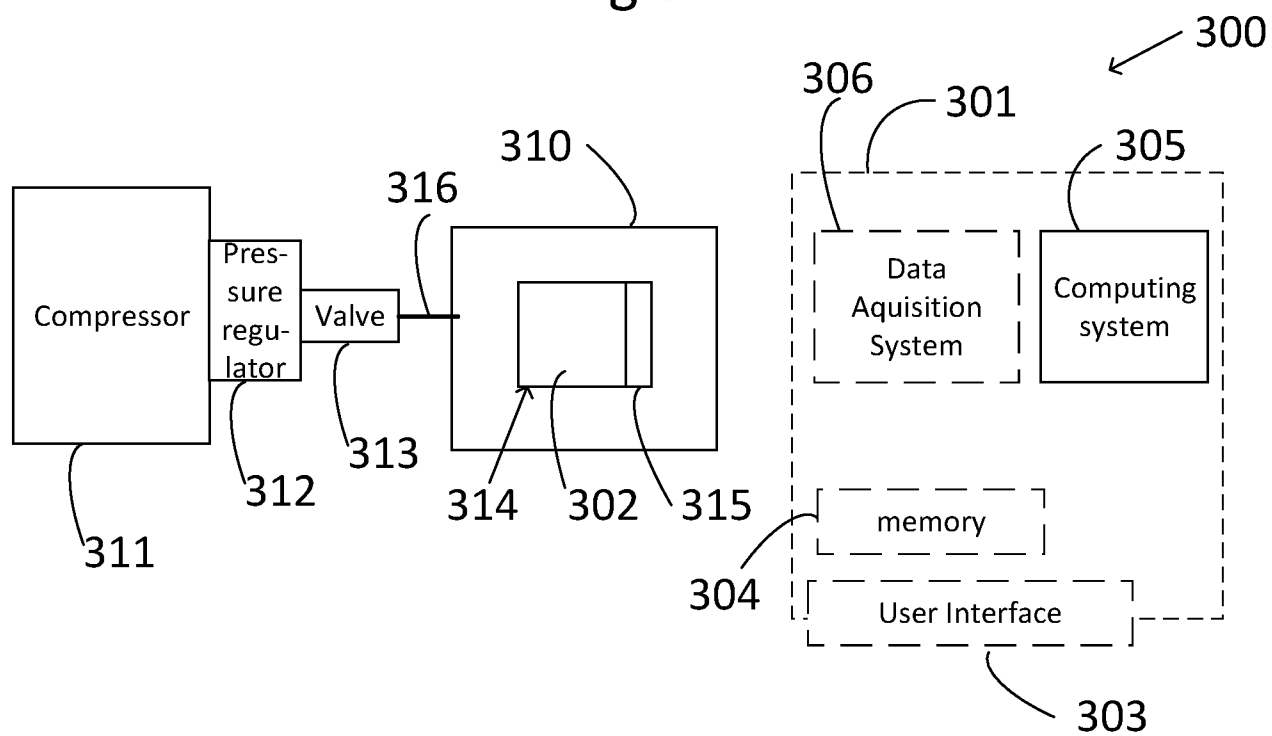
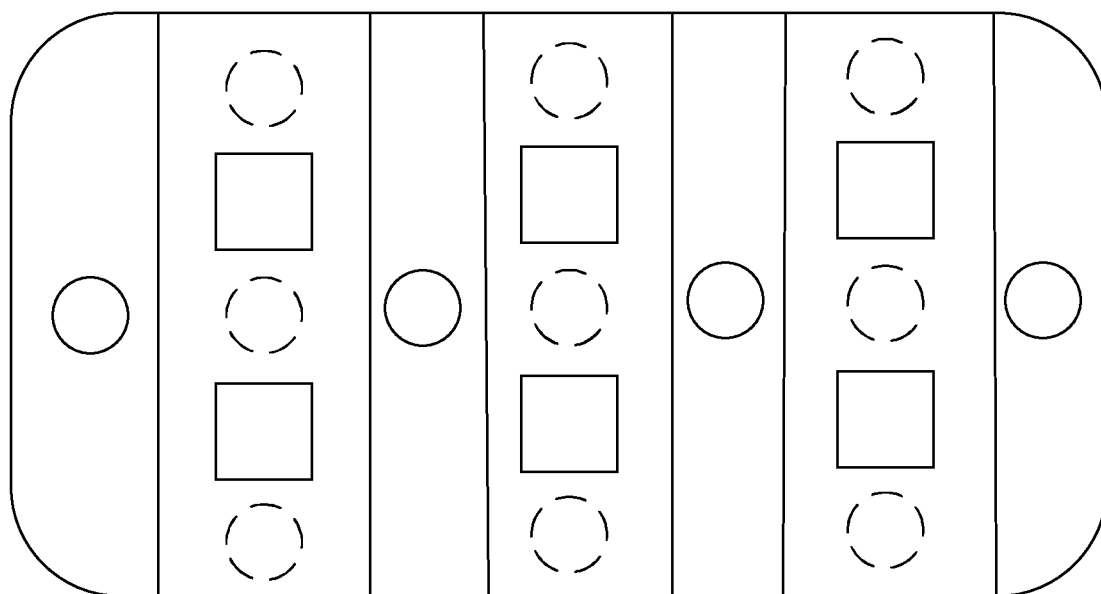


Fig 4



4/4
Fig 5a

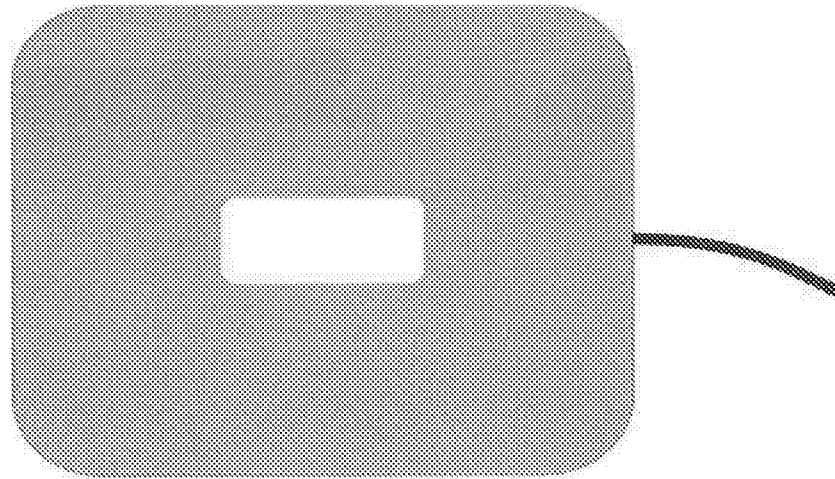


Fig 5b

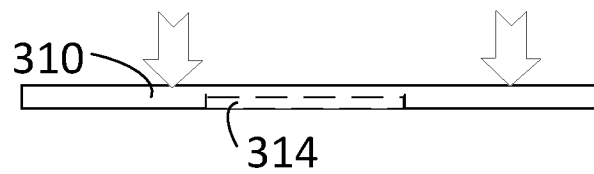


Fig 5c

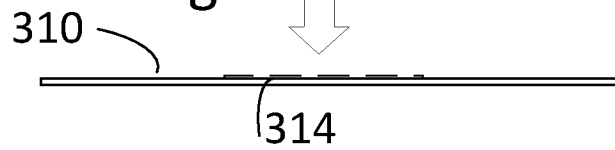
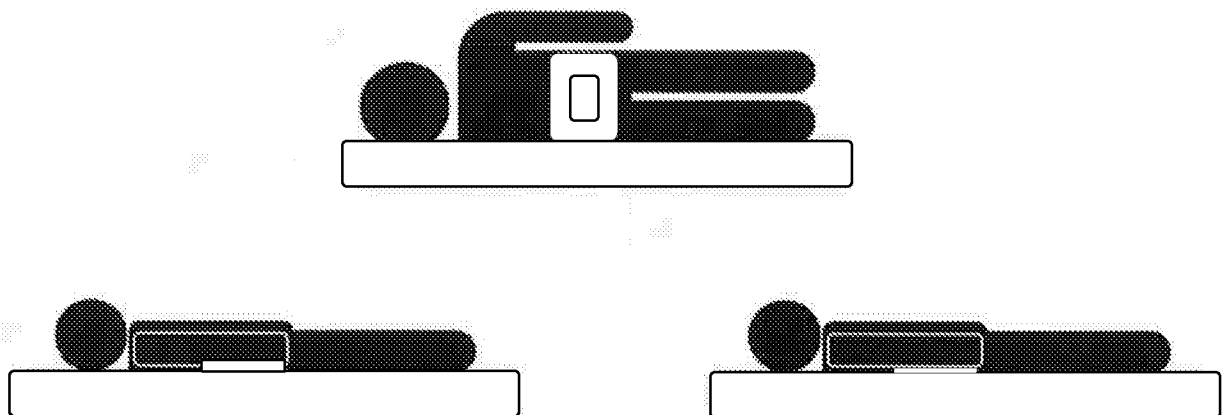


Fig 6



INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE2019/050251

A. CLASSIFICATION OF SUBJECT MATTER

IPC: see extra sheet

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)

IPC: A61B

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, PAJ, WPI data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 8133177 B2 (LAPLANTE PAULITA ET AL), 13 March 2012 (2012-03-13); whole document --	1-17
A	US 20160228050 A1 (SUGLA BINAY ET AL), 11 August 2016 (2016-08-11); whole document --	1-17
A	US 20060287603 A1 (BARTNIK DANIEL J ET AL), 21 December 2006 (2006-12-21); whole document --	1-17
A	US 20180014774 A1 (HOLLOPETER MICHAEL ET AL), 18 January 2018 (2018-01-18); whole document -- -----	1-17

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents:	"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
"A" document defining the general state of the art which is not considered to be of particular relevance	"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
"E" earlier application or patent but published on or after the international filing date	"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
"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)	"&" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search 03-06-2019	Date of mailing of the international search report 04-06-2019
Name and mailing address of the ISA/SE Patent- och registreringsverket Box 5055 S-102 42 STOCKHOLM Facsimile No. + 46 8 666 02 86	Authorized officer Frida Andersson Telephone No. + 46 8 782 28 00

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE2019/050251

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.: **1-9**
because they relate to subject matter not required to be searched by this Authority, namely:

Claims 1-8 relate to a prophylactic therapeutic method for the treatment of the human or animal body, see PCT Rule 43bis.1(b) and PCT Rule 67.1(iv). These claims are marked with * in the table in box V. Nevertheless, an examination has been conducted for these claims. The examination has been made in respect of the technical content of the claims,
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 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.

Continuation of: Box No. II

which is in accordance with the technical content of claims 10-17. Therefore, the opinion for claims 10-17 is valid also for claims 1-8.

Accordingly, the software for performing the method of any of claims 1-8, according to claim 9, falls under the provision of Article 17(2) (a) and Rule 39 PCT, relating to such subject matter for which no search is required.

Continuation of: second sheet
International Patent Classification (IPC)
A61B 5/0295 (2006.01)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/SE2019/050251

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			WO	2018013201 A1	18/01/2018