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DESCRIPTION

The invention relates to the field of prevention of the formation of pressure ulcers, and more particularly to devices making it possible, through an array of movement sensors and a method of analysing these movements, to prevent the formation of pressure ulcers.

The invention finds particular application in beds, especially healthcare beds.

As used herein, the term “pressure ulcers” refers to skin ulcerations or necroses resulting from prolonged compression of the soft tissue on an underlying bony protrusion, at a supporting surface of the body. Pressure ulcers are skin lesions of ischemic origin.

Risk factors for pressure ulcers are conventionally classified as extrinsic or mechanical factors (in particular pressure, friction, shear), and intrinsic or clinical factors (in particular immobility, nutrition, incontinence, skin condition, decreased circulatory flow, neuropathy, age, history of pressure ulcers).

The risk factors for the development of pressure ulcers are multiple, and remain the subject of research, see for example Coleman et al, Patient risk factors for pressure ulcer development: systematic review, International journal of nursing studies (2013), pp.974-1003.

The European Pressure Ulcer Advisory Panel (EPUAP) has developed recommendations regarding the prevention of pressure ulcers in conjunction with the American National Pressure Ulcer Advisory Panel (NPUAP). In their 2014 version, these recommendations comprise a very large number of skin integrity alteration parameters (for example dry skin, excess moisture, erythema, oedema, induration, local heat), nutritional indicators (for example malnutrition, anaemia, haemoglobin, albumin, weight),

factors affecting circulation and oxygenation (for example diabetes, low blood pressure), pressure, friction and shear, repositioning frequency and techniques, advanced age, general state of health, body temperature.

The assessment of the risk of pressure ulcers should therefore take into account a wide range of factors such as tissue oxygenation and vascularization, skin condition, physical activity and mobility, and nutritional status.

Numerous risk assessment scales have been proposed: Norton scale, see Anthony et al, Norton, Waterlow and Braden scores: a review of the literature and a comparison between the scores and clinical judgment, Journal of Clinical Nursing (2008), pp. 646-653; Braden scale, see Chen et al, Braden scale for assessing ulcer risk in hospital patients: a validity and reliability study, Applied Nursing Research (2017), pp. 169-174; Waterloo scale, see Serpa et al, Validity of the Braden and Waterloo subscales in predicting pressure ulcer risk in hospitalized patients, Applied Nursing Research (2011), pp. e23-e28; Cubbin and Jackson scale, see Seongsook et al, Validity of pressure ulcer risk assessment, Cubbin and Jackson, Braden and Douglas scale, International Journal of Nursing Studies (2004), pp. 199-204; Colin and Lemoine French-language scales, Peupliers-Gonesse scale, Angers scale, Geneva scale, see Boisson, *Optimisation de la prévention ambulatoire des ulcères cutanés dus à la pression*, Dissertation, Doctor of Pharmacy (2016).

Pressure ulcer risk assessment scales have limitations. In particular, their use does not result from a continuous assessment of the person, and the observer induces an inevitable subjectivity. It is common for people at high risk, in terms of their assessment by these scales, not to develop pressure ulcers. And it is also common for people at low risk to develop pressure ulcers. A presentation of the limitations of existing scales is provided by Torressan, *Prévalence des escarres dans les établissements pour personnes âgées dépendantes en Aquitaine*, Dissertation, (2015).

Despite their limitations, pressure ulcer risk assessment scales are conventionally taken into account to decide on the setting up and financial coverage of the technical means for preventing pressure ulcers. For example, in France, to determine the threshold of coverage by the health insurance of the cost of mattresses, mattress pads and cushions to help prevent pressure ulcers, the Norton scale is used, a criterion of coverage being a score less than or equal to 14 on the Norton scale or a patient having an equivalent risk, assessed by another validated scale.

The appearance of a pressure ulcer often leads to a significant decrease in the quality and comfort of life, as well as to physical discomfort and suffering, in particular during treatment.

The impact of pressure ulcers in terms of public health is very high. An assessment of the costs of prevention and treatment of pressure ulcers is presented by Démarré et al, The cost of prevention and treatment of pressure ulcers: a systematic review, International journal of nursing studies (2015), pp. 1754-1774.

Pressure ulcers are seen as undesirable events during hospitalization, which can lead to legal action, common in the United States.

The technical means implemented for preventing pressure ulcers are typically gel cushions, memory foam cushions, mono-density foam mattresses in the shape of a waffle iron, mattress pads made of shape memory viscoelastic foam, air mattress pads (constant pressure, dynamic or mixed pressure or air loss), mattresses with inserts in areas at risk of pressure ulcers (water insert).

The preferential risk areas and locations for pressure ulcers are the sacrum and the heels, in particular in patients bedridden in a dorsal position. Other locations are possible, such as the ischium, the trochanter (in patients bedridden in a lateral

position), or the occiput, as all points of support may present a pressure ulcer, for example the elbows or the knees.

The position in which the patient is most often found has an impact on the most likely location of a pressure ulcer. For example, pressure ulcers on the occiput, the sacrum, the heels, the dorsal spine, the shoulder blades and the elbows are associated with a supine position.

To identify areas of high pressure, resistive or capacitive sensor arrays, providing a map with coloured areas of the same pressure area index, are known. The document EP1664712 describes the use of an interface pressure measuring device in an anti-pressure ulcer device, such an interface pressure sensor being proposed for integration in a seat, see Meffre et al Mapi: active interface pressure sensor integrated into a seat, IRBM (2008), pp. 375-379 (see also Meffre, *Conception et réalisation d'une instrumentation dédiée à la prédiction du confort d'assise et à la prévention des escarres*, Dissertation, INSA Lyon, 2007).

The use of data processing algorithms has been proposed in the literature, in order to provide levels of risk of pressure ulcers, these algorithms processing data from continuous and automatic monitoring of patients. A state of the research for such methods can be found in Marchione et al Approaches that use software to support the prevention of pressure ulcer: as systematic review, International Journal of Medical Informatics (2015), pp. 725-736. Of the 36 scientific articles identified by Marchione et al, 26 describe the use of sensors of the pressure exerted on the mattress by the patient's body and 11 propose to deduce the patient's position from the reading of the pressures exerted on the mattress.

The methods proposed in the research identified by Marchione et al have at least one or more of the following disadvantages:

- no alert of a risk of pressure ulcer is delivered;

– the impact of the means of control on the patient's comfort is not taken into account;

– the impact of the means of control on hygiene is not taken into account;

– the efficacy of the method in preventing pressure ulcers is not demonstrated, and no comparison is made with a control group.

The document JPH 11-342161 (Denso) describes a device for recording the postures of a bedridden individual, through pressure sensors placed between a bed's box spring and mattress. The device is connected to a package capable of analysing the individual's positions and displaying the support time on the mattress of each of the individual's limbs. This display is configured to display an alert, when the support time of one of the limbs exceeds a predefined time.

The document JPH 8-238275 (Yokohama Imeeji System) describes a device for measuring the time the individual's body rests on a pressure-sensitive conductive rubber. The device also comprises a package configured to perform an alert, when the support time exceeds a predefined time.

The document *Panfil et al Häufigkeit von Bewegung im Bett zur Einschätzung der Dekubitusgefahrdung - Eine systematisierte Übersichtsarbeit*, International journal of health professions (2014) pp. 61-72 after an in-depth search of the literature, concluded that there is a lack of convincing data about the link between a patient's frequency of movements in bed and the risk of pressure ulcers.

The document EP2508128 relates to the detection of changes in patient position, for example on a bed. A processor is configured to generate alarms based on the patient's detected position, for example an alarm is triggered when the patient leaves the bed, or is sitting at the edge of the bed. Pressure sensors can detect

changes in pressure on the mattress, and the processor can adapt the pressure in the air mattress. The sensors detect minor changes in the patient's position, this detection allowing a mobility score and an activity score to be calculated, and these scores are presented as being related to health risks, including that of the appearance of pressure ulcers. The document EP2508128 indicates that a high risk of pressure ulcers may or may not be associated with a high mobility score, as other factors may be taken into account such as position in bed, mattress firmness, humidity, patient diet, friction.

The document US 2005/172398 describes the use of pressure sensors to increase or decrease the tension of bands forming the support for the patient's weight, on a chair seat or in a bed. One of the objectives is to determine if it is necessary to move the patient, avoiding a movement of the patient back to the position she has just left.

Contrary to the dominant teachings of the state of the art, systematically emphasizing the crucial importance of pressure applied during a long support time, in the appearance of pressure ulcers, the inventors considered a very different paradigm, according to which the risk of pressure ulcers appearance is related to the frequency and amplitude of a person's movements, the frequency of movements of large amplitude being able to prove effective in capillary recirculation.

A first objective is to propose a method for providing an indicator of pressure ulcer risk.

A second objective is to propose such a method, measuring the frequency and amplitude of the movements of a bedridden individual.

A third objective is to propose such a method, analysing the measurements made.

A fourth objective is to propose such a method, delivering an

alert, as a function of the result of the analysis of the measurements.

A fifth objective is to propose a device capable of implementing a method meeting the preceding objectives.

To these ends, firstly, a method is proposed for providing an indicator of risks of pressure ulcers of an individual lying on a support, the method comprising:

a step of measurement of at least one quantity, by means of sensors placed between the support and the individual;

- a step of calculating an indicator of a contact surface of the individual with the support, from said at least one quantity;

- a step of detecting the presence of the individual on the support, as a function of the contact surface of the individual with the support;

- a step of detecting absence of movement made by the individual, as a function of a variation over time of the indicator of the calculated contact surface, if, during the presence detecting step, the presence of an individual is detected on the support;

- a step of detecting the amplitude of movements made by the individual, as a function of the variation over time of the indicator of the calculated contact surface, if, during the step of detecting the absence of movement, an absence of movement is not detected;

- a step of notifying the condition of the individual.

The detection of the amplitude of movements made by the person makes it possible to distinguish between small movements, segmental movements without impact on posture, and movements of large amplitude, in particular turning over.

The detection of the amplitude of movements further makes it possible to measure the time between two movements of large amplitude.

Various additional features can be provided, alone or in combination:

- the step of notifying the condition of the individual comprises:

  o a step of informing about the condition of the individual, transmitting results of the step of detecting the presence of the individual, of the step of detecting the absence of movement and the step of detecting the amplitude of movements, this informing step being regularly transmitted;

  o a step of alerting about the non-presence of the individual on the support, this step of alerting about the non-presence of the individual being transmitted if, in the step of detecting the presence of the individual, no individual is detected for a predetermined time;

  o a step of alerting about the absence of movement of the individual, this step of alerting about the absence of movement being transmitted if, in the step of detecting the absence of movement, no movement is detected for a predetermined time;

  o a step of alerting about the amplitude of movements of the individual, this step of alerting about the amplitude of movements being transmitted if, in the step of detecting the amplitude of movements, a small movement is detected for a predetermined time;

- the notifying step comprises a step of alerting about agitation of the individual, this agitation alerting step being a function of a predetermined number of movements detected for a given time;

– said at least one quantity measured in the measuring step is an electric quantity, and the calculating step comprises:

o a first step of calculating an indicator of a capacitance generated by the sensors;

o a second step of calculating an indicator of an active length of each sensor;

o a third step of calculating an indicator of an area;

o a fourth step of calculating the indicator of the contact surface;

o a fifth step of calculating the variation over time of the indicator of the contact surface.

Secondly, a device is proposed for preventing the formation of pressure ulcers, this device being able to carry out the method as presented above, the device comprising:

– sensors disposed between the support and the individual, the sensors being disposed so as to indicate the presence of an object on the support;

– a package connected to the sensors, the package being provided with:

o a control element, configured to carry out the steps of the method;

o a memory, able to record the steps of the method;

– a tracking terminal, able to display the step of notifying the condition of the individual.

Various additional features can be provided, alone or in

combination:

- the sensors each have the shape of a strip;

- the sensors are substantially perpendicular to a direction along which the individual's body extends;

- the sensors are capacitive sensors;

- the device comprises a beam, connecting the sensors and the package, the beam comprising several independent parts;

- the beam comprises two or three parts.

Other features and advantages of the invention will appear more clearly and concretely upon reading the following description of embodiments, which is made with reference to the appended drawings wherein:

- Figure 1 is a schematic view of a detection, analysis and alert device to prevent the formation of pressure ulcers;

- Figure 2 is a schematic representation, illustrating steps relating to an embodiment of a method of measurement, analysis and alert to prevent the formation of pressure ulcers;

- Figure 3 is a schematic representation of a contact surface of an individual's body lying on the device, in the supine position;

- Figure 4 is a graph representing the capacitance of three beams the sensors of which are respectively controlled by one, two or three controllers.

Figure 1 shows a device **1** for preventing the formation of pressure ulcers, the device **1** comprising a cover **2**, provided with sensors **3** and a protection covering the sensors **3**.

The device **1** can be placed on the mattress of a bed.

The device **1** also comprises a package **4**, connected to the sensors **3** through a beam **5**, capable of measuring and analysing data provided by the sensors **3** and transmitting an alert, as a function of the result of said analysis, in accordance with a procedure **100** shown in Figure 2.

The bed, the mattress and the protection are not shown in the figures, for reasons of simplicity.

The inventors started from the assumption that the prevention of pressure ulcers would be improved by a high frequency and amplitude of movements of an individual lying on the bed.

Three levels of movements are taken into account:

- an absence of movement,

- small movements, corresponding to a flexion of less than 30° of one leg of the individual when the individual is in the lateral decubitus position,

- and large movements, corresponding to a flexion of greater than 30° of one leg of the individual when the individual is in the lateral decubitus position.

In an implementation, a reference surface **R** being the ninety-fifth percentile of the contact surface **S** of an individual lying on the bed for a predetermined time:

- small movements are defined as a variation Δ**S** of the surface **S** less than or equal to 11 percent of a reference surface **R**, for a duration of 400 milliseconds;

- large movements are defined as the variation Δ**S** of the surface **S** greater than 11 percent of the reference surface **R**, for a duration of 400 milliseconds.

The presence of the individual on the bed is defined by a contact surface **S** greater than 20 percent of the reference surface **R**, for a duration greater than 800 milliseconds.

According to an advantageous embodiment, the cover **2** completely envelops the mattress, for example a foam mattress.

Advantageously, the cover **2** is washable. The method and the device according to the invention thus have no impact on hygiene.

According to embodiments, the cover **2** partially envelops the mattress or the cover **2** can be placed on a support different from a bed, thus allowing the monitoring of an individual lying on said support.

The sensors **3** are preferably in the form of strips. Advantageously, the strips are disposed substantially parallel to each other. According to the preferred embodiment, the sensors **3** are at a distance from each other.

The sensors **3** are preferably disposed along a direction substantially perpendicular to a general direction along which the individual's body extends. According to the embodiment illustrated in Figure 1, the sensors **3** are disposed in the width of a mattress.

Advantageously, the cover **2** is sufficiently resistant not to be degraded if a more or less liquid material spreads on it resulting, for example, from incontinence of the individual lying on the cover **2**, or from washing or sterilization of the latter.

Each sensor **3** comprises a connector **6**, allowing a connection between the beam **5** and the sensors **3** and their separations, during movement, washing or sterilization of the cover **2**.

The connectors **6** are preferably disposed at one end of the

sensors **3**, so that the connectors **6** and the beam **5** do not interfere with an individual lying on the cover **2**.

According to an embodiment, the cover **2** comprises eighteen sensors **3** of equal width **l**. The sensors **3** are separated in pairs by the same distance **d**.

According to an embodiment, the width **l** of the sensors **3** is 10 millimetres. The distance **d** separating the sensors **3** is 100 millimetres.

Advantageously, the sensors **3** are made of a flexible material. According to an embodiment, the sensors **3** are made of an electrically conductive fabric.

The sensors **3** are advantageously disposed between the mattress and the protection.

The sensors **3** are advantageously capacitive sensors **3**. Thus, the sensors **3** and the body of the individual disposed on the cover **2** define two separate armatures of an insulating material defined by the protection.

During a measurement, the sensors **3** generate a vacuum capacitance C_v, if no individual is lying on the mattress. The more the individual's body is disposed in front of a sensor **3**, the greater the capacitance **C** generated.

It is thus possible to establish a schematization of the contact surface **S** of the individual's body with the protection, by carrying out a measurement through all the sensors **3**.

The contact surface **S** is calculated as the sum of the areas A_n of trapezoids **7**, the bases of which are defined by an active length **L** of two neighbouring sensors **3**.

The active length **L** of each sensor **3** corresponds to a portion of said sensor **3** in contact with the individual's body.

Figure 3 illustrates an example of such a contact surface **S**, for an individual lying on the mattress in the supine position, the individual's head being positioned on the left side of the figure and the individual's feet positioned on the right side of the figure.

In the embodiment described, the surface **S** does not take into account the area of each sensor in contact with the individual's body.

According to different embodiments, the calculation of the surface **S** takes into account the area of each sensor in contact with the individual's body. The areas A_n are calculated as a function of the shape and the arrangement of the sensors **3**, the areas are not necessarily trapezoidal areas A_n.

The generated capacitance **C** is obtained by adding a capacitance generated by the beam **5** connecting sensors **3** to package 4 to a capacitance generated by the sensors **3**.

The capacitance of the beam **5** can be considered proportional to its length. In order to minimize the risk of errors when measuring the capacitance of each of the sensors **3**, it is therefore advantageous to reduce the length of the beam **5** as much as possible.

It proved, following tests presented in Table **T** below and in Figure **4**, that dividing the beam **5** into several independent parts **8** reduces the total length of the beam **5** and thus the capacitance generated by the beam **5**.

Table **T**, below, shows the length of the beam **5** connecting each sensor **3** to the package **4** and the resulting capacitance for a beam **5** comprising one part **8**, two parts **8** or three parts **8**.

Table **T** also presents the average value of the capacitance generated by the beam, calculated for each of the beams **5**

presented.

Figure 4 is a graph representing the values in Table **T**. The beam **5** comprising a single part **8** is shown in mixed lines, beam **5** comprising two parts **8** is shown in dashed lines and beam **5** comprising three parts **8** is shown in solid lines. The average values of the capacitance generated by beam **5** are shown in bold lines.

Table **T** and Figure 4 clearly illustrate that the more the beam **5** is divided into a large number of parts **8**, the lower the capacitance generated by the beam **5**.

According to the embodiment shown in Figure 1, the beam **5** of the device **1** consists of three parts **8**. According to different embodiments, the beam **5** could be divided into a different number of parts **8**.

The parts **8** are preferably identical.

Each part **8** of the beam **5** is connected to a measuring element **9** belonging to the package **4**.

The measuring elements **9** are configured to periodically perform charging and discharging phases of the sensors **3**. The charging and discharging phases are carried out at a constant current **i**. A voltage **V** is measured, at the terminals of each sensor **3** by their respective measuring element **9**, at the end of the charging phase.

The charging and discharging phases last for a predefined sampling time **T**. The charging and discharging phases preferably have the same duration, i.e., half of the sampling time **T**.

According to the preferred embodiment, the sampling time **T** is 1 millisecond.

The measuring elements **9** carry out the measurement of the voltage

V at the request of a control element **10** belonging to the package **4** according to a measuring step **110** of the method **100** shown in Figure 2.

The control element **10** calculates the capacitance **C** generated by each of the sensors **3**, during a first step **121** of the calculation of the method **100**, with the following formula:

$$C = i \times \frac{T}{V}$$

Test results have shown that, to ensure good measurement quality, the measured voltage **V** must be between a minimum voltage V_{min} and a maximum voltage V_{max} such that:

$$V_{min} = 0.7$$
$$V_{max} = VDD - 0.7$$

the variable **VDD** being the supply voltage of the measuring element **9**.

The supply voltage of the measuring element **9** is, for example, 3.3 volts or 5.0 volts.

The minimum voltage V_{min} and the maximum voltage V_{max} make it possible to define a minimum capacitance C_{min} and a maximum capacitance C_{max} that can be generated by each sensor **3**.

The minimum capacitance C_{min} and the maximum capacitance C_{max} are equal to:

$$C_{min} = i \times \frac{T}{V_{max}} \qquad C_{max} = i \times \frac{T}{V_{min}}$$
$$C_{min} = i \times \frac{T}{VDD-0.7} \qquad C_{max} = i \times \frac{T}{0.7}$$

Advantageously, the control element **10** performs an average of the values of the voltage **V** measured at the conclusion of several consecutive charging phases or an average of the values of the generated capacitance **C**, calculated at the conclusion of several consecutive charging phases.

According to an advantageous embodiment, said average is calculated by taking into account the measured voltage **V** values for six consecutive charging phases.

According to different embodiments, the measurement step **110** is carried out at constant voltage **V**, by measuring the current **i**, at variable voltage **V** or current **i**, by measuring respectively the current **i** or the voltage **V** or by measuring both the voltage **V** and the current **i**.

The measurement step **110** can also be carried out by measuring a pressure or any other quantity provided by the sensors **3**.

Advantageously, in a stopping step **115** of the method **100** illustrated in Figure 2, the control element **10** suspends the measurements made by the measuring element **9** if the measured voltage **V**, i.e., the measured power, drops sharply.

The active length **L** of each sensor **3** is obtained by the following formula, carried out in a second calculation step **122** of the method **100**:

$$L = C - C_V \times struct$$

the variable **struct** being a coefficient, depending on the structure of the device **1**. This coefficient is determined experimentally. According to the embodiment, said coefficient is equal to 13.5 millimetres per picofarad.

The area A_n of one of the trapezoids **7** is equal, according to a third calculation step **123** of the method **100**, to:

$$A_n = d \times \frac{L_n + L_{n+1}}{2}$$

the variable L_n being the active length **L** of one of the sensors **3** numbered **n** and L_{n+1} being the active length **L** of a sensor **3** numbered **n+1** adjacent to said sensor **3** numbered **n**.

The contact surface **S** of the individual's body with the protection is therefore equal, according to a fourth calculation step **124** of the method **100** for a device **1** comprising eighteen sensors **3**, to:

$$S = \sum_{n=1}^{18} A_n S = \sum_{n=1}^{18} d \times \frac{L_n + L_{n+1}}{2}$$

The calculation of the contact surface **S** by the control element **10** in the fourth calculation step **124** of the method **100** allows the presence of an individual on the bed to be verified, and the level of movement of the individual evaluated.

In an implementation, the presence of an individual on the bed is expressed, in a step **130** of detecting the presence of an individual of the method **100**, by the resolution of the following inequation, for a duration greater than 800 milliseconds:

$$S > R \times \frac{20}{100}$$

In order to adapt the sensitivity of the detection to any adult individual, the reference surface **R** is chosen, according to an embodiment, at a value corresponding to an individual whose mass is 45 kilograms. By way of example, the minimum reference surface R_{min}, for an individual whose mass is 45 kilograms, is 155000 square millimetres.

According to different embodiments, the minimum reference surface R_{min} is chosen for an individual with a different mass. Advantageously, the minimum reference surface R_{min} is chosen according to the direct characteristics of the individual lying on the bed.

According to an embodiment, the presence of an individual on the bed is expressed, in step **130** of detecting the presence of an individual, by the resolution of the following inequation, for a duration greater than 800 milliseconds:

$$S > R_{min} \times \frac{20}{100}$$

or

$$S > 155000 \times \frac{20}{100}$$

or

$$S > 31000$$

If the presence of an individual is detected in the presence detection step **130**, a step **140** of detecting the absence of movement is performed by the control element **10**.

The absence of movement of an individual present on the bed is expressed, for sensors **3** having a surface of 3444 square millimetres, by the resolution of the following inequation:

$$\Delta S < 3 \times \frac{3444}{400/1000}$$

or

$$\Delta S < 25830$$

the variable $\Delta S(t)$ being the variation ΔS of the contact surface **S** of the individual's body with the bed for a duration of 400 milliseconds.

In order to verify this inequality, the control element **10** performs a fifth calculation step **125** upstream of the step **140** of detecting the absence of movement.

This fifth calculation step **125** calculates the value $\Delta S(t)$ of the variation ΔS of the contact surface **S** of the individual's body with the bed for a duration of 400 milliseconds.

A variation ΔA_n of the area of one of the trapezoids **7** as a function of time is expressed by the following equation:

$$\Delta A_n(t) = \frac{|A_n(t) - A_n(t - dt)|}{dt}$$

The variable $A_n(t)$ being the area A_n of one of the trapezoids **7** at time **t** and **dt** being the period of time between two measurements.

Thus:

$$\Delta A_n(t) = d \times \frac{|L_n(t) - L_n(t - dt) + L_{n+1}(t) - L_{n+1}(t - dt)|}{2dt}$$

This equation allows us to calculate the value $\Delta S(t)$ of the variation ΔS of the contact surface **S** of the individual's body with the bed during the time between two measurements, in this case 400 milliseconds:

$$\Delta S(t) = \sum_{n=1}^{18} \Delta A_n(t) \Delta S(t) = \frac{d}{2dt} \sum_{n=1}^{18} |L_n(t) - L_n(t - dt) + L_{n+1}(t) - L_{n+1}(t - dt)|$$

According to a different embodiment, the fifth calculation step **125** is carried out at another moment of the method **100**, as long as this fifth calculation step **125** is carried out after the fourth calculation step **124** and before the step **140** of detecting the absence of movement.

If the absence of movement is not detected in the step **140** of detecting the absence of movement, a step **150** of detecting movement amplitude is performed by the control element **10**.

The level of amplitude of movements of an individual present on the bed is expressed by the resolution of the following inequation for a duration of 400 milliseconds:

$$\Delta S > R \times \frac{11}{100}$$

If the inequality is verified, then the individual lying on the bed makes large movements. If not, then the individual on the bed makes small movements.

In order to adapt the sensitivity of the detection to an average individual, the reference surface **R** is chosen, according to the preferred embodiment, as the average reference surface $\mathbf{R_{moy}}$.

By way of example, the average surface reference $\mathbf{R_{moy}}$, for an average individual, is 350000 square millimetres.

According to different embodiments, the average reference surface $\mathbf{R_{moy}}$ is different. Advantageously, the average reference surface $\mathbf{R_{moy}}$ is chosen according to the direct characteristics of the individual lying on the bed.

According to an embodiment, the amplitude of the movements of an individual present on the bed is thus expressed, in the step **150** of detecting the amplitude of movements, by the resolution of the following inequation:

$$\Delta S(t) > R_{moy} \times \frac{11}{100} \times \frac{1}{400/1000}$$

or

$$\Delta S(t) > 350000 \times \frac{11}{100} \times \frac{1}{400/1000}$$

or

$$\Delta S(t) > 96250$$

According to an advantageous embodiment, the control element **10** is able to transmit, in a step **160** of notification of the method **100**, one or more alerts or information taking into account the

results of step **130** of detecting the presence of an individual, step **140** of detecting the absence of movement and step **150** of detecting amplitude of movement.

Thus, the notifying step **160** comprises an informing step **161** transmitting the results of the above detection steps **130, 140, 150.**

The informing step **161** is transmitted regularly, so that the condition of the individual lying on the bed can be monitored.

According to different embodiment, the informing step **161** is transmitted at the request of a person wishing to know the condition of said individual.

The informing step **161** provides information on the individual's current condition and/or past condition, for example during the last 24 hours.

The results of the above detection steps **130, 140, 150** are also transmitted as alerts, targeting the person monitoring on the condition of the individual lying on the bed.

According to an embodiment, the notifying step **160** comprises a step **162** alerting about the non-presence of the individual, alerting the individual if the individual does not lie on the bed for a predetermined time.

If the individual is self-sufficient, the step **162** of alerting about the non-presence of the individual occurs, for example, when an absence from bed is detected, in step **130** of detecting the individual's presence, between 8:00 p.m. and 8:00 a.m. for a period of more than 15 minutes, thus leaving the individual time to go, for example, to the bathroom.

If the individual is not self-sufficient, the step **162** of alerting about the non-presence of the individual occurs, for example, when an absence from the bed is detected, in step **130**

of detecting the presence of an individual, for more than 5 seconds.

The notifying step **160** also comprises a step **163** of alerting about the absence of movement, if a lack of movement of the individual is detected in the step **140** of detecting the absence of movement.

The notifying step **160** comprises a step **164** of alerting about the amplitude of movements, if the step **150** of detecting the amplitude of movements reveals that the individual performs small movements for a predetermined time.

According to a different embodiment, the notifying step **160** also comprises a step of alerting about agitation, if the step **140** of detecting the absence of movement reveals that the individual performs a predetermined number of movements during a given period of time.

According to other embodiments, the step of alerting about agitation is performed if the step **150** of detecting the amplitude of movements reveals that the individual performs a predetermined number of large or small movements for a given time.

According to the preferred embodiment, the transmissions of the informing step **161** and of the alerting steps **162, 163, 164** above are carried out on a tracking terminal **11.**

The tracking terminal **11** is advantageously connected to package **4** via a wireless network.

The tracking terminal **11** is fixed and/or mobile.

According to different embodiments, the transmission is carried out through a wired network and/or the tracking terminal **11** comprises a screen able to display the informing step **161** and the alerting steps **162, 163, 164.**

The package **4** preferably comprises a memory **12** able to store parameters allowing identification of the individual, her physical parameters and/or default parameters, allowing the different steps of the method **100** to be carried out.

The memory **12** is also able to store the results of the detecting steps **130, 140, 150.**

According to a different embodiment, the calculation steps **121, 122, 123, 124, 125** do not calculate physical quantities but indicators of these quantities.

Thus, the first calculation step **121** calculates an indicator of the capacitance **C,** the second calculation step **122** calculates an indicator of the length **L,** the third calculation step **123** calculates an indicator of the area $\mathbf{A_n}$, the fourth calculation step **124** calculates an indicator of the surface **S** and the fifth calculation step **125** calculates a variation $\Delta\mathbf{S}$ of the indicator of the surface **S.** Steps **130, 140, 150** use these indicators.

The method and the device according to the invention have many advantages.

The information provided by the sensor array provides an indicator of the risk of pressure ulcers, this indicator not having any subjectivity related to an observer, the indicator resulting from an automatic, long and continuous observation of the movements of the person.

As a function of the value of this indicator, an alert is generated and communicated for example to the nursing staff.

The information provided by the sensor array also alerts the nursing staff to the risk of falling, wandering, or agitation of a person.

The information provided by the sensor array can be accessible

on fixed or mobile communication terminals, in particular in push mode for alerts. Advantageously, an acknowledgement system ensures that an information broadcast in push mode has been seen by its recipient (for example a family member or nursing staff), an alert being generated in case of no acknowledgement.

The sensor array is advantageously in the form of a standard size mattress cover. The installation of the sensor array is thus facilitated. Advantageously, the cover is washable, the invention having no impact on the hygiene of the bedridden person. Advantageously, the sensor array is disposed between a mattress and a removable protective cover, in particular a coated textile cover.

The presence of the sensor array and the means of processing the information provided by the sensors have no significant impact on patient comfort.

The efficacy of the method in the prevention of pressure ulcers can be easily demonstrated, in particular in comparison with a control group.

The numerical data provided in the above description are applied to the described embodiment and are in no way limiting.

			Sensors located on the side of the head									Sensors located on the side of the feet								
Beam comprising	1 part	*Beam length between each sensor and the package (mm)*	850	750	650	550	450	350	250	150	50	50	150	250	350	450	550	650	750	850
		Capacitance generated by the beam between each sensor and the package (pF)	41,9	38,0	34,0	30,1	26,1	22,2	18,3	14,3	10,4	10,4	14,3	18,3	22,2	26,1	30,1	34,0	38,0	41,9
		Average capacitance generated by the beam between the sensors and the package (pF)	26,1																	
	2 parts	*Beam length between each sensor and the package (mm)*	400	300	200	100	0	100	200	300	400	400	300	200	100	0	100	200	300	400
		Capacitance generated by the beam between each sensor and the package (pF)	24,2	20,2	16,3	12,4	8,4	12,4	16,3	20,2	24,2	24,2	20,2	16,3	12,4	8,4	12,4	16,3	20,2	24,2
		Average capacitance generated by the beam between the sensors and the package (pF)	17,2																	
	3 parts	*Beam length between each sensor and the package (mm)*	250	150	50	50	150	250	250	150	50	50	150	250	250	150	50	50	150	250
		Capacitance generated by the beam between each sensor and the package (pF)	18,3	14,3	10,4	10,4	14,3	18,3	18,3	14,3	10,4	10,4	14,3	18,3	18,3	14,3	10,4	10,4	14,3	18,3
		Average capacitance generated by the beam between the sensors and the package (pF)	14,3																	

Table T

PATENTKRAV

1. Fremgangsmåde (100) til tilvejebringelse af en indikator for risikoen for liggesår hos en person, der hviler på et underlag, hvilken fremgangsmåde (100) omfatter:

– et trin (110) til måling af mindst en størrelse ved hjælp af følere (3) placeret mellem underlaget og personen;

– et trin (121, 122, 123, 124, 125) til beregning af en indikator for en kontaktoverflade (S) mellem personen og underlaget ud fra den mindst ene størrelse;

– et trin (130) til detektion af tilstedeværelsen af personen på underlaget som funktion af indikatoren for kontaktoverfladen (S) mellem personen og underlaget;

– et trin (140) til detektion af fraværet af bevægelse af personen som funktion af en variation (ΔS) med tiden af den beregnede indikator for kontaktoverfladen (S), hvis der i løbet af trinnet (130) til detektion af tilstedeværelsen er detekteret tilstedeværelsen af en person på underlaget;

– et trin (150) til detektion af omfanget af bevægelser af personen som funktion af variationen (ΔS) med tiden af den beregnede indikator for kontaktoverfladen (S), hvis der i løbet af trinnet (140) til detektion af fraværet af bevægelse ikke er detekteret et fravær af bevægelse;

– et trin (160) til meddelelse af personens tilstand.

2. Fremgangsmåde ifølge det foregående krav, kendetegnet ved, at trinnet (160) til meddelelse af personens tilstand omfatter:

– et trin (161) til oplysning om personens tilstand, der udsender resultater fra trinnet (130) til detektion af tilstedeværelsen af personen, fra trinnet (140) til detektion af fraværet af bevægelse og fra trinnet (150) til detektion af omfanget af bevægelser, idet dette informationstrin (161) udsendes jævnligt;

– et trin (162) til alarm for personens manglende tilstedeværelse på underlaget, idet dette trin (162) til alarm for personens manglende tilstedeværelse udsendes, hvis der i trinnet (130) til detektion af personens tilstedeværelse ikke detekteres nogen person inden for et forudbestemt tidsrum;

– et trin (163) til alarm for personens manglende bevægelse, idet dette trin (163) til alarm for manglende bevægelse udsendes, hvis der i trinnet (140) til detektion af fravær af bevægelse ikke detekteres nogen bevægelse inden for et forudbestemt tidsrum;

– et trin (164) til alarm for omfanget af personens bevægelser, idet dette trin (164) til alarm for omfanget af bevægelser udsendes, hvis der i trinnet (150) til detektion af omfanget af bevægelser detekteres en lille bevægelse inden for et forudbestemt tidsrum.

3. Fremgangsmåde ifølge et hvilket som helst af de foregående krav, kendetegnet ved, at meddelelsestrinnet (160) omfatter et trin til alarm for personens urolighed, idet dette trin til alarm for urolighed er funktion af et forudbestemt antal bevægelser detekteret i et givet tidsrum.

4. Fremgangsmåde ifølge et hvilket som helst af de foregående krav, kendetegnet ved, at den mindst ene størrelse, der måles i målingstrinnet (110), er en elektrisk størrelse, og at beregningstrinnet (121, 122, 123, 124, 125) omfatter:

– et første trin (121) til beregning af en indikator for en kapacitet (C) genereret af følerne (3);

– et andet trin (122) til beregning af en indikator for en aktiv længde (L) af hver føler (3);

– et tredje trin (123) til beregning af en indikator for et areal (A_n);

– et fjerde trin (124) til beregning af en indikator for kontaktoverfladen (S);

– et femte trin (125) til beregning af variationen (ΔS) med tiden af indikatoren for kontaktoverfladen (S).

5. Anordning (1) til forebyggelse af liggesår, hvilken anordning (1) er egnet til at iværksætte fremgangsmåden (100) ifølge et hvilket som helst af de foregående krav, idet anordningen (1) omfatter:

– følerne (3) placeret mellem underlaget og personen, idet følerne (3) er således placeret, at de angiver tilstedeværelsen

af en genstand på underlaget;

– en boks (4), der er forbundet til følerne (3), idet boksen (4) er forsynet med:

o et styreelement (10), der er udformet til at iværksætte trinnene i fremgangsmåden (100);

o en hukommelse (12), der er egnet til at registrere trinnene i fremgangsmåden (100);

– en overvågningsterminal (11), der er egnet til at vise trinnet (160) til meddelelse af personens tilstand.

6. Anordning ifølge det foregående krav, kendetegnet ved, at følerne (3) hver har form af et bånd.

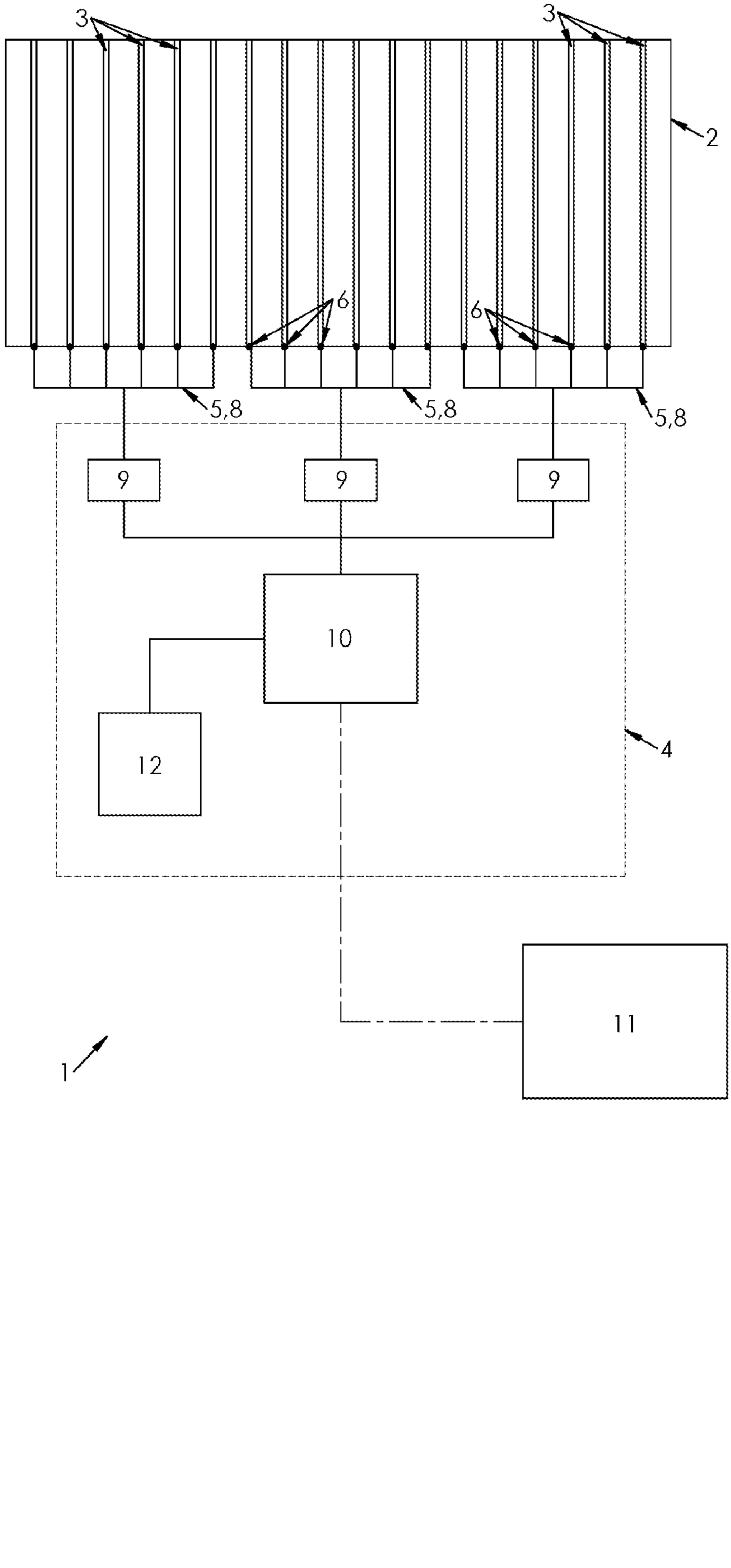
7. Anordning ifølge et hvilket som helst af kravene 5 og 6, kendetegnet ved, at følerne (3) er tilnærmelsesvis vinkelrette på en retning i hvilken personens krop strækker sig.

8. Anordning ifølge et hvilket som helst af kravene 5 til 7, kendetegnet ved, at følerne (3) er kapacitive følere, der genererer kapaciteten (C).

9. Anordning ifølge et hvilket som helst af kravene 5 til 8, kendetegnet ved, at den omfatter et ledningsbundt (5), der forbinder følerne (3) og boksen (4), idet ledningsbundtet (5) omfatter flere uafhængige dele (8).

10. Anordning ifølge ovenstående krav, kendetegnet ved, at ledningsbundtet (5) omfatter to dele (8).

Fig. 1



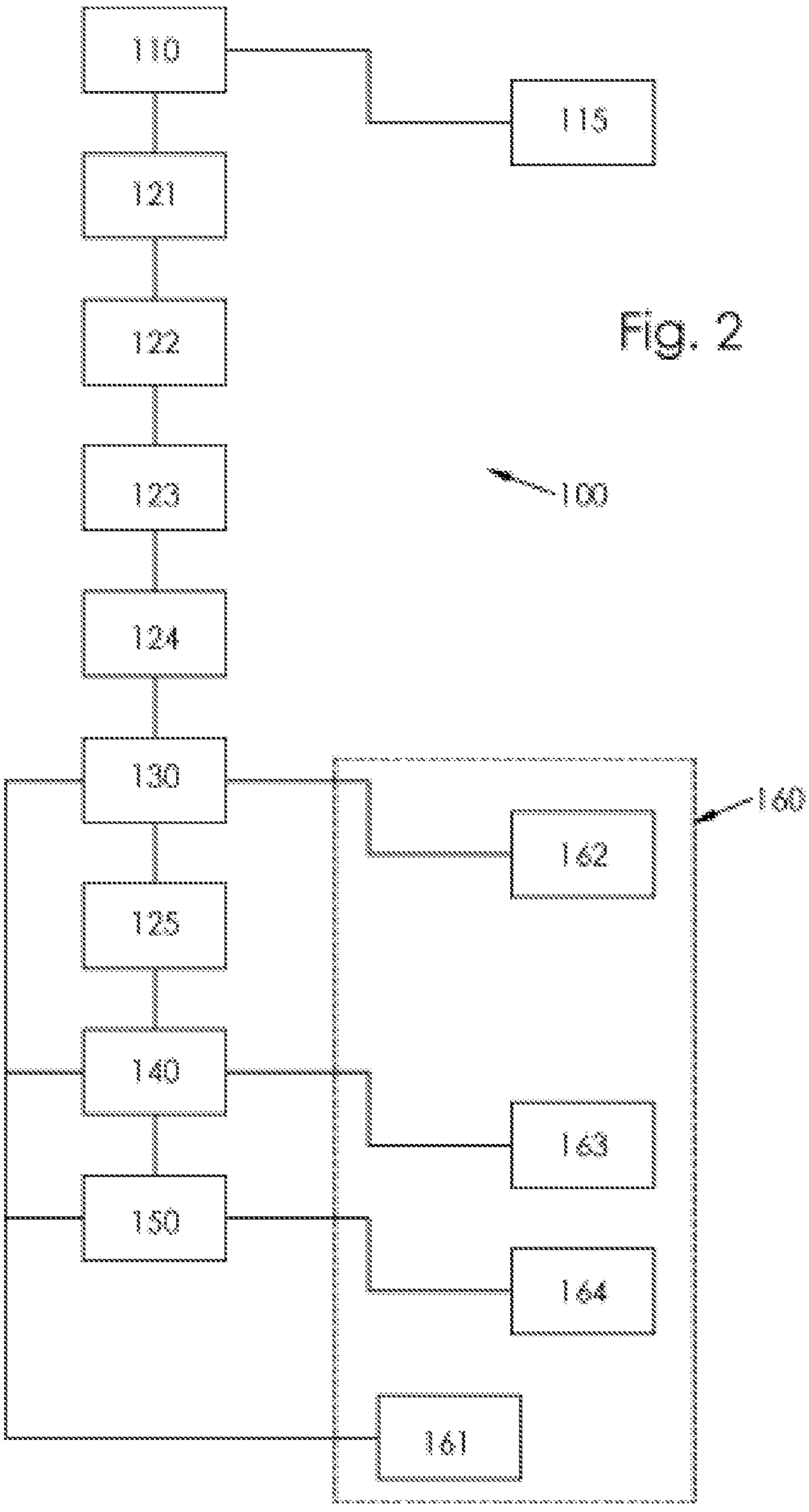


Fig. 2

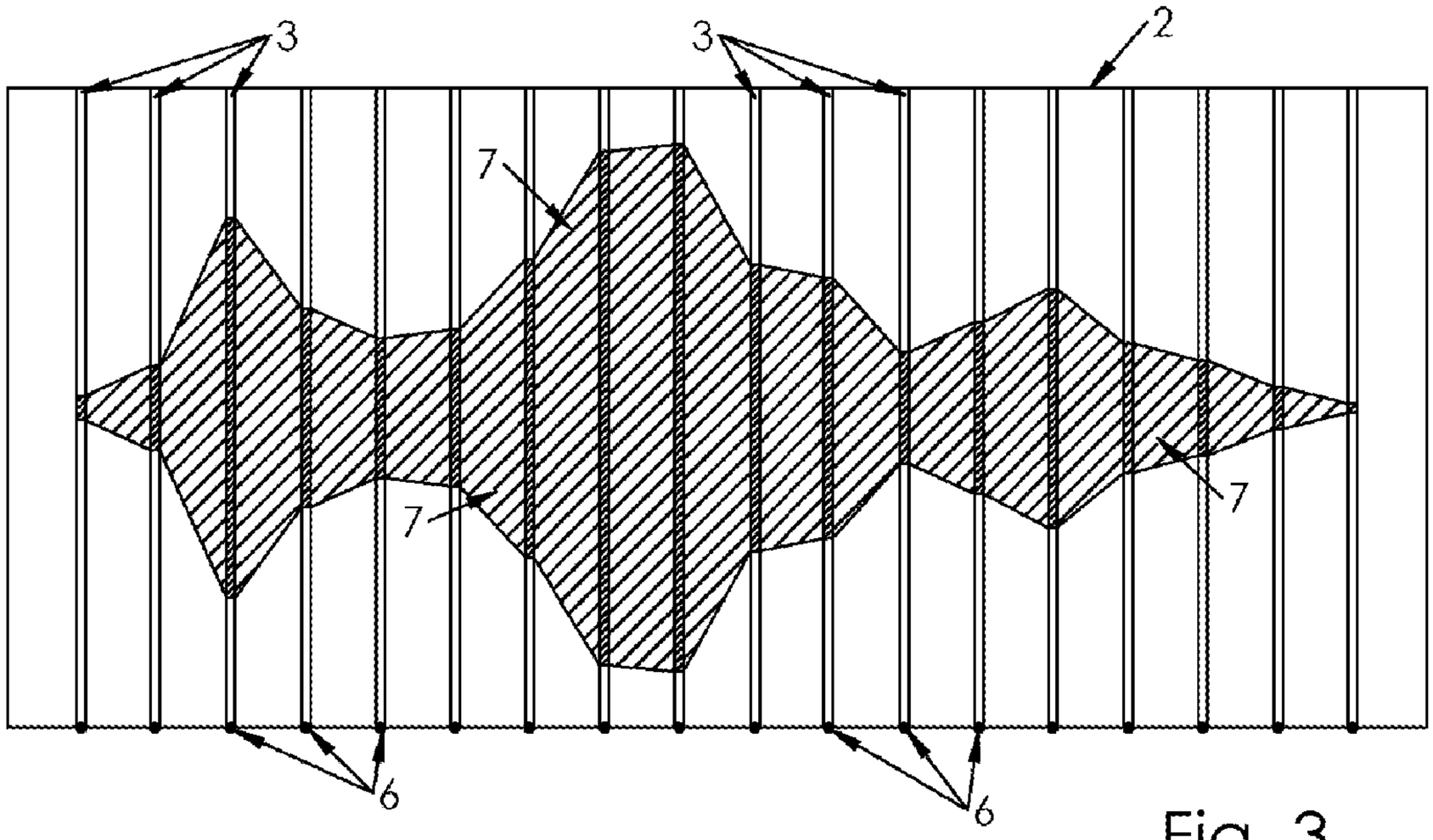


Fig. 3

Fig. 4