

(19) **DANMARK**

(10)

**DK 177485 B1**



(12)

**PATENTSKRIFT**

Patent- og  
Varemærkestyrelsen

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- (51) Int.Cl.: **A 61 G 7/057 (2006.01)** **A 47 C 27/00 (2006.01)** **A 47 C 31/12 (2006.01)**
- (21) Ansøgningsnummer: **PA 2012 70605**
- (22) Indleveringsdato: **2012-10-05**
- (24) Løbedag: **2012-10-05**
- (41) Alm. tilgængelig: **2013-07-15**
- (45) Patentets meddelelse bkg. den: **2013-07-15**
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- (54) Benævnelse: **ANORDNING TIL MENNESKER MED NEDSAT FØLESANS ELLER HANDICAPPEDE MENNESKER**
- (56) Fremdragne publikationer:  
**US A1 2009/0278685**  
**US A1 2008/0186138**  
**WO A1 97/32509**
- (57) Sammendrag:  
**It is the object of the present invention to provide a device for daily personal use which protects via pressure-relief and immediately alerts the user (e.g. private persons or hospital staff) as to undesirable effects of one or more body parts. The invention is a personal assistive device, which enables patients to be subjected to complicated hospital-monitoring in their homes with no external assistance at any time. This is achieved according to the present invention with an appliance for measuring pressure changes wherein the appliance comprises:  
one or more pressure-relieving and shock-absorbing regions which comprise(s) liquid and/or air tight pads, the pads containing liquid, gel, gas or a solid, and where the regions are in communication with each other;  
one or more RFID tags positioned in direct connection with the pressure-relieving and shock-absorbing regions for measuring both static and dynamic pressure changes in the pressure-relieving and shock-absorbing regions.  
The invention further relates to a system comprising the appliance and a user-feedback device.**

Fortsættes ...

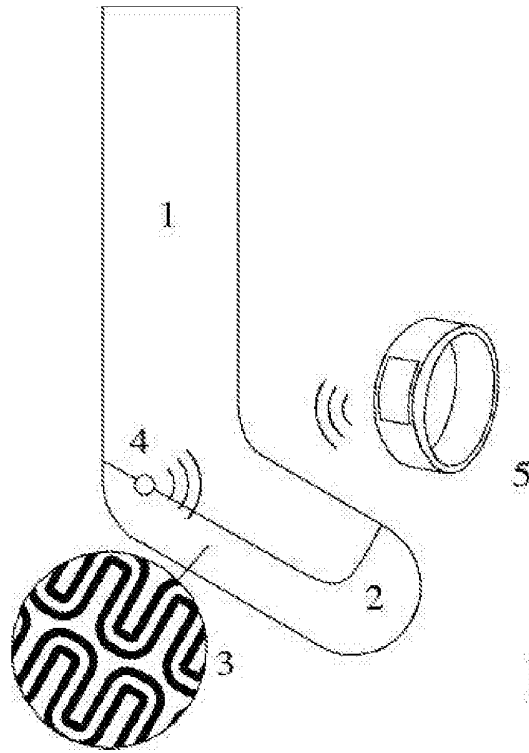


Fig 1

## APPLIANCE FOR PEOPLE WITH REDUCED SENSES OF TOUCH OR DISABLED PEOPLE

The present invention relates to a personal assistive appliance to be incorporated into  
5 e.g. a sheet, a mattress, a seat cover, a shoe sole, a sock or a shoe. The appliance is  
made of a thin, flexible and resilient material such as natural or synthetic fibres, with  
one or more pressure-relieving and shock-absorbing cushion-like pads, the pads  
containing liquid, gel, gas or a solid. Moreover, in direct connection with the cushioning  
10 material, are incorporated or attached one or more Radio Frequency Identification  
(RFID) tags for the measurement of pressure changes. The appliance can also include  
one or more sensors to measure internal and external influences in the pressure-relief  
and shock absorbent materials such as: temperature, acidity and moisture and  
changes thereto. The invention further relates to a system comprising the appliance  
and a user-feedback device.

15

### BACKGROUND

The invention is specifically targeting people with reduced or no sense of feeling  
caused by disease, including bedbound patients. Long-term bed-lying patients in  
hospitals, homes and nursing homes are at high risk of developing pressure sores and  
20 / or pressure damage. Another group of patients who can benefit from the invention are  
for example people with diabetes, since these patients may develop damage to the  
nerves (peripheral sensory neuropathy).

A wound or skin damage, for example on the foot, can occur and for a long time  
25 escape detection, and the condition can progress with devastating consequences such  
as severe infection, slow healing wounds and risk of amputation. Therefore it is  
important that the staff at the hospital / home care constantly keeps an eye on  
vulnerable areas of the body and especially observes pressure related alteration of the  
skin that may be precursors of pressure ulcer.

30

Either the static or the long-term dynamic or punctual load which allows pressure  
marks on the insensitive or passive area on the body can develop into pressure ulcers  
if not taken care of in time. The person with normal sense of feeling and mobility would  
be immediately alerted while the person without sense of feeling - without knowing it -  
35 allows repeated high pressure and / or static load on the same small place on the body.  
This creates sores or precursors thereof.

It is known to perform measurements on humans in order to deduce information on foot pressure distribution during walking. There are several devices, such as patent application (US6155120A), which describe a complex array of piezoresistive pressure sensors incorporated into a sock or sole. Also patent (US5678448A) describes a "stand-alone" pressure measurement system consisting of a thin sole with an integrated sensor array which can be loaded into a shoe. Both devices can provide detailed information about the pressure that affects the foot and also send an alarm when high pressure occurs to the user.

However, the known solutions are vulnerable, mechanical, expensive, locked in performance, and they are non-absorbing. A solution with placing an array of pressure sensors will make it very costly to change such socks every day, as recommended for risk patients. Furthermore, there may be problems with machine washing and / or autoclaving, as the link (a cable) from the sensor to the electronics is not immediately protected adequately. The known technologies have the disadvantage that they will reduce the proportions of the pressure relieving and shock absorbing areas because of the dimensions of these technologies (the arrays) and the minimal space available.

## **SUMMARY OF THE INVENTION**

It is the object of the present invention to provide a device for daily personal use which protects via pressure-relief and immediately alerts the user (e.g. private persons or hospital staff) as to undesirable effects of one or more body parts. The invention is a personal assistive device to be incorporated into e.g. a sheet, a mattress, a seat cover, a shoe sole, a sock or a shoe, which enables patients to be subjected to complicated hospital monitoring in their homes with no external assistance at any time.

This is achieved according to the present invention with an appliance to be incorporated into e.g. a sheet, a mattress, a seat cover, a shoe sole, a sock or a shoe for measuring pressure changes. The appliance may comprise one or more pressure-relieving and shock-absorbing regions which comprise(s) liquid and/or air tight pads, where the pads may contain liquid, gel, gas or a solid, and the regions may be in communication with each other. The appliance may further comprise one or more RFID tags positioned in direct connection with the pressure-relieving and shock-absorbing

regions for measuring both static and dynamic pressure changes in the pressure-relieving and shock-absorbing regions.

5 The appliance aid can be incorporated or embodied into the form of a sheet, a seating surface, a sole, a shoe or a sock.

Accordingly, the invention also comprises a sock comprising the appliance according to the present invention, a sheet comprising the appliance according to the present invention, a sole comprising the appliance according to the present invention, a shoe  
10 comprising the appliance according to the present invention or a seating surface comprising the appliance according to the present invention.

The appliance is made of a thin, flexible, resilient and elastic textile product, preferably of a kind having a suitable permeability for water vapor, is bacteriostatic, and which  
15 takes up and generates as little irritation as possible. The material can be natural or synthetic fibers. On the material is attached a cushioning material creating cushion areas for pressure relief and shock absorption comprising pressure transmitting material. The cushion-like pressure-relieving and the shock-absorbing areas in the device called the appliance are made of a liquid and / or air tight material that can be  
20 secured on parts of the thin, flexible, resilient and elastic textile product or on the entire outer side of the thin, flexible, resilient and elastic textile product by means of thermo-weld, bonding, molding, laminating, sewing or any other suitable manner.

The pressure transmitting material comprised inside the liquid and/or air tight pads in  
25 one or more of the pressure-relieving and shock-absorbing regions can be liquid, gel, gas or a solid. Examples of pressure transmitting material are: foam material such as ethylene vinyl acetate, rubber, silicone rubber, Polyurethane (PUR) rubber, neoprene or air.

30 Moreover, in the appliance, in direct connection with the cushioning material one or more passive or active Radio Frequency Identification (RFID) tags for the measurement of pressure changes may be incorporated or attached. The RFID tag can be embedded or placed where it is most appropriate, e.g. casted into a sole or sewed into a sock. The RFID tag can be placed directly at the measuring area, e.g. in the  
35 middle of the cushioning material as a direct pressure sensor or in the proximity thereof

as an indirect pressure sensor where the pressure signal is being transmitted from one area via one or more other areas to the sensor.

5 The pressure can be measured in Pascal. The force that is transferred to the sensor(s) is dependent on how the weight is distributed over the pressure-relieving and the shock-absorbing areas, e.g. whether the pressure impact is dynamic and/or static.

10 In one embodiment the liquid and/or air pads are made of silicone. In one embodiment the pads create a pattern as shown in the enlarged circles in figure 1 – 4. The pattern can be described as “snake”-like or “hose”-like.

15 The appliance is particular in that the appliance means comprise one or more cushion-like areas (pillows) for pressure relief and shock absorption which is/are in connection/communication with each other, whereby the pressure signals can be transmitted from one area to another area. In one embodiment the cushion-like areas (pillows) for pressure relief and shock absorption form a tree-like structure whereby the areas are in connection/communication with each other via the branches, so that the pressure signals can be transmitted from one area to another area via the branches. The cushion-like areas (pillows) for pressure relief and shock absorption contain a  
20 moveable liquid, gel, gas or a solid rubber-like material, which in addition to transmitting the pressure signals also massages and supports the blood circulation during operation. This provides the advantage that the force which affects the appliance is immediately distributed over a larger area, thus minimizing the deleterious effects. The material in the pressure-relieving and shock-absorbing regions can move,  
25 and can be used to measure the pressure and the change in the pressure-relieving and the shock-absorbing areas that propagate immediately to one or more RFID tags.

30 The cushion-like areas for pressure relief and shock absorption may be a simple silicone “hose”-like shape containing gas or air. The cushion-like areas can be used both as pressure-relieving, shock absorbent and for measuring the internal and external influences, since the changes in the material immediately propagate to one or more sensors.

35 The cushion-like areas for pressure relief and shock absorption act as a closed pressure chamber, where external influences on transporting material change and / or the pressure signal are transported to one or more sensors. Material changes are

measured by using Radio Frequency Identification (RFID) technology. This technology uses wireless radio communications to uniquely identify objects. This is known from e.g. inventory control, theft protection and more relevant for measuring the pressure in the tires of cars. RFID technology consists of Transponder (TAG's) and Readers (reading). The tag is composed of an antenna and a circuit to control a microchip. Both the microchip's and the antennas' changes in conditions can be used for the measurement of pressure. In the present invention, pressure sensors consist of one or more of the passive or active RFID tags that can be embedded in the material (appliance) for radio communication and for measuring both static and dynamic pressure changes. The passive tags have no internal source of energy and need no maintenance. The Passive RFID tag is activated only when sending a specific radio signal. Then the RFID tag "wakes up" and transmits a unique ID number and a characteristic measurable resistance which depends on the pressure of the material to which it is attached. In one embodiment of the present invention, the passive tags are placed directly on the pillow-like material. The antenna of the tag will be stretched by increasing the load on the pillow-like material. Changes in the tag's detectable complex resistance are due to pressure loads on the pillow-like material that in the present invention is used for recording the pressure changes.

In one embodiment the appliance comprises one or more sensors to measure internal and external influences in the pressure-relief and chock absorbent regions such as; temperature, acidity and humidity and changes thereto. These sensors may be commercial available sensors for measuring such influences.

The sensor(s) (including the RFID tags) including optionally signal and power lead for measuring pressure, force, temperature, acidity and humidity can be fixed to the inside of the appliance, outside of the appliance or at the transition between the pressure-relief and chock absorbent regions and the natural or synthetic fibre material by weaving, thermo weld, die cast, gluing, stitching, Velcro and/or elastics.

In one embodiment the sensors for measuring temperature, humidity and the acid value are placed on the inside of the appliance.

The present invention also comprises a system comprising an appliance according to the present invention and a user feedback device.

In one embodiment the user feedback device comprises an external receiver comprising a speaker, vibrator LED and/or a display that can provide immediate and cumulative feedback to the user for exceedings of the standard values from the sensors in the form of sound, light, guidance and/or vibration.

5

The sensors of the appliance send user feedback from all sensors influenced by the material changes in the pressure-relief and chock absorbent materials such as: pressure, temperature, acidity and moisture and changes thereto.

10 The RFID system described can also be combined with the following sensor systems (A-D):

A) Strain gauges. A strain gauge is based on a familiar technology where stretching of the lead wire resistance changes can be measured.

15

B) Resistive piezoelectric sensors are made of a semiconductor material, which is highly sensitive to the deformations and displacements.

20 C) Capacitive sensor. This type works by two conductive plates separated by a non-conductive material constituting a capacitor. The capacity is determined by the area, the distance between the plates and the material separating the plates. This change in the capacity when the plates are pressed against each other can be measured.

25 D) By using a closed pressure chamber, as described above, the sensors can advantageously be a commercially available pressure transducer that can convert the pressure in the chamber into an electrical signal. Generally, it applies to all sensors that can be placed anywhere on the pillow-like pad.

This provides several unique opportunities:

30

(A) Receiver containing electronics and user interface elements as display key(s), audio and / or light can be placed anywhere on the appliance or used in the immediate vicinity of the device and avoids placement of hard materials at vulnerable sites. In addition, this holds the advantage that the signal and the power cable may be  
35 completely avoided by the sensors and electronics to wirelessly transmit data from the



recorded measurement range to the remote receiver, which can be placed somewhere on the device or in the vicinity of the latter.

5 The present invention is further characterized in being able to measure and process pressure signals - static, dynamic and / or the accumulated pressure signals – from several areas on the appliance and can instantaneously warn the user of improper loads. User feedback can take the form of sound, light, graphics and / or messages to the external receiver in a user's phone, bracelet, watch or remote control to tell the user to move the strain/weight from a specific area if static pressure has been put on that  
10 area for a certain time interval, e.g. 1 minute, 5 minutes, 15 minutes, 30 minutes, 1 hour, 2 hours or longer.

In one embodiment of the present invention, the user can use the unique application developed, e.g. on a smart phone to control the recorded data and for receiving the  
15 warnings of unwanted stress.

The invention opens new possibilities for a person to monitor problem areas on the body continuously in his daily life, which in turn opens up new opportunities for long-term monitoring of chronic wounds.  
20

An advantageous embodiment of the device is that the sensors and associated electronics of the appliance may be located visibly or hidden, away from the measurement area, and can be removable. This means that the sensors and associated electronics can be removed to facilitate cleaning, including machine  
25 washing of the device.

#### BRIEF DESCRIPTION OF THE DRAWINGS

The above and other features and advantages of the present invention will become readily apparent to those skilled in the art by the following detailed description of  
30 exemplary embodiments thereof with reference to the attached drawings, in which:

Figure 1 shows one embodiment of the appliance incorporated into a sock.

Figure 2 shows a schematic drawing of what happens if the underside of the foot is subjected to a local compressive load.

Figure 3 shows one embodiment of the appliance incorporated into a sole including the user interface through a smart-phone.

Figure 4 shows one embodiment of the appliance incorporated into a sheet.

Figure 5 shows two examples of display interface messages on the receiver portion or on a smart phone, where the application is embodied as a sheet.

#### DETAILED DESCRIPTION

The figures are schematic and simplified for clarity reasons, and they merely show details which are essential to the understanding of the invention, while other details have been left out.

**Figure 1** shows a view of one embodiment of the appliance incorporated into a sock. Size is adapted to the individual user, so it fits comfortably without pulling. Point (1) in the image shows how the sleeve can be formed as knee stockings. Point (2) shows how the pillow-like region may be designed so that it surrounds the entire underside and the front part of the foot to secure maximum protection of the exposed areas of the foot. Point (3) shows the pressure-relieving and shock-absorbing material that can transmit the changes to the internal and external factors to one or more sensors (e.g. RFID's) placed as shown in Point (4). Point (4) shows a sensor that can wirelessly transfer recorded data from the measurement area to a remote receiver. Point (5) shows the user device, which can be designed as a bracelet, a mobile phone, a remote control or the like. The feedback system can e.g. be embodied with coloured light that indicates which foot is subjected to undesirable stresses.

**Figure 2** shows a schematic drawing of what happens if the underside of the foot is subjected to a local compressive load. Point (1) shows a schematic drawing of the pressure-relieving and shock-absorbing material of the appliance. Point (2) shows what happens if the underside of the foot is subjected to a local compressive load. Point (3) shows how the local compressive load is quickly eliminated by the pressure being dispersed to the entire material. Point (4) shows that the material used to manufacture the pressure-relieving and the shock-absorbing area is resilient and can expand if necessary. Point (5) shows how the pressure changes (both static and dynamic changes) in the material in the pressure-relieving and shock-absorbing areas of the appliance propagate to one or more sensors (RFID's).

35

**Figure 3** shows one embodiment of the appliance incorporated into a sole including the user interface through a smart-phone. Point (1) shows an example of placement of the pillow-like pressure-relieving and shock-absorbing areas that inside the cushioning pads comprise a pressure transmitting material. Point (2) shows an example of placement of the sensors e.g. passive RFID tags. Point (3) shows an example of a user interface for a smart-phone.

**Figure 4** shows (Point (1)) a view of an embodiment of the appliance incorporated into a sheet. Point (2) shows an example of placement of the pillow-like pressure-relieving and shock-absorbing areas comprising the pressure transmitting material, e.g. liquid, gel, gas or a solid incorporated into liquid and/or air tight pads. Point (3) shows an example of placement of the sensors e.g. RFID tags.

**Figure 5** shows two examples of display interface messages on the receiver portion or on a smart phone, where the appliance is embodied as a sheet. Point (1) shows an example where all three measurement zones have been activated recently and therefore are in a proper level and that everything is OK. Point (2) shows an example where the foot zone has not been activated for a defined time interval and can be combined with light and sound warnings to raise awareness of the need for movement in this zone.

**Patentkrav**

1. Anordning til inkorporering i f.eks. et lagen, en madras, et sædebetræk, en skosål, en sok eller en sko til måling af trykændringer, hvor anordningen omfatter:
- 5
- en eller flere trykaflastende og støddæmpende områder omfattende væske og/eller lufttætte puder, hvilke puder indeholder væske, gel, gas eller et faststof, og den ene eller de flere trykaflastende og støddæmpende områder er i forbindelse med hinanden;

10

  - et eller flere RFID-tags (Radio Frequency Identification tags) anbragt i direkte forbindelse med de trykaflastende og støddæmpende områder til måling af både statiske og dynamiske trykændringer i de trykaflastende og støddæmpende områder.
- 15
2. Anordning ifølge krav 1, hvor puderne er lavet af silikone.
3. Anordning ifølge krav 1 eller 2, hvor puderne har en slange-lignende udformning.
- 20
4. Anordning ifølge et hvilket som helst af de foregående krav, hvilken anordning omfatter en eller flere sensorer til måling af indvendige og udvendige påvirkninger i de trykaflastende og støddæmpende områder, såsom temperatur, surhedsgrad og fugtighed samt ændringer deri.
- 25
5. Anordning ifølge krav 4, hvor sensorerne til måling af temperatur, fugtighed og surhedsværdi er anbragt på indersiden af anordningen.
- 30
6. System omfattende en anordning ifølge krav 1 til 5 og en brugerfeedbackindretning, hvor brugerfeedbackindretningen kan være anbragt hvor som helst på anordningen eller anvendes i umiddelbar nærhed af anordningen.
7. System ifølge krav 6, hvor brugerfeedbackindretningen omfatter en ekstern modtager, der omfatter en højttaler, vibrator-LED og/eller et display, som kan tilvejebringe øjeblikkelig og akkumuleret feedback til brugeren om over-

skridelser af standardværdierne fra sensorerne i form af lyd, lys, vejledning og/eller vibration.

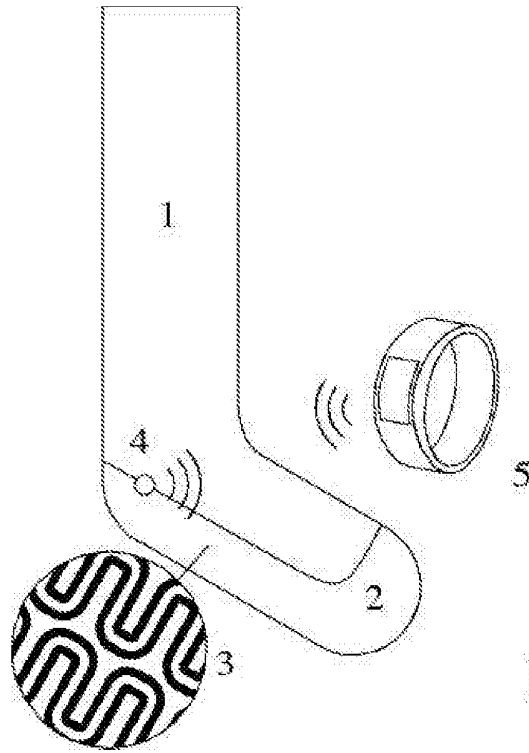


Fig 1

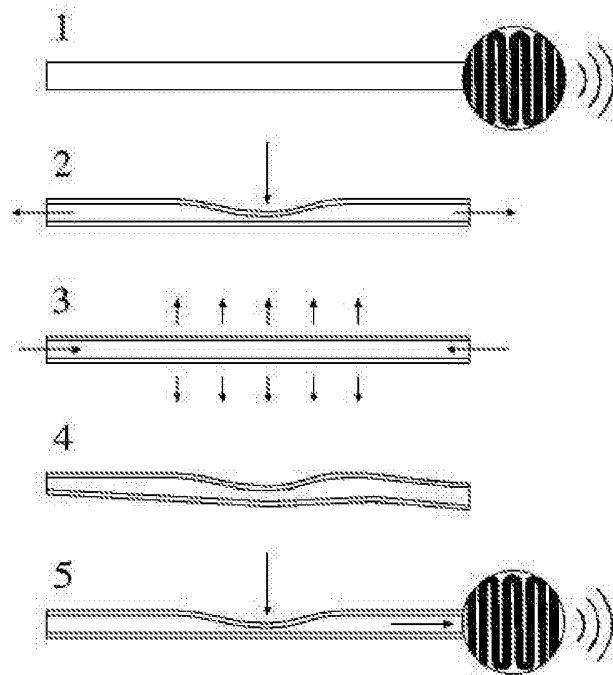


Fig 2

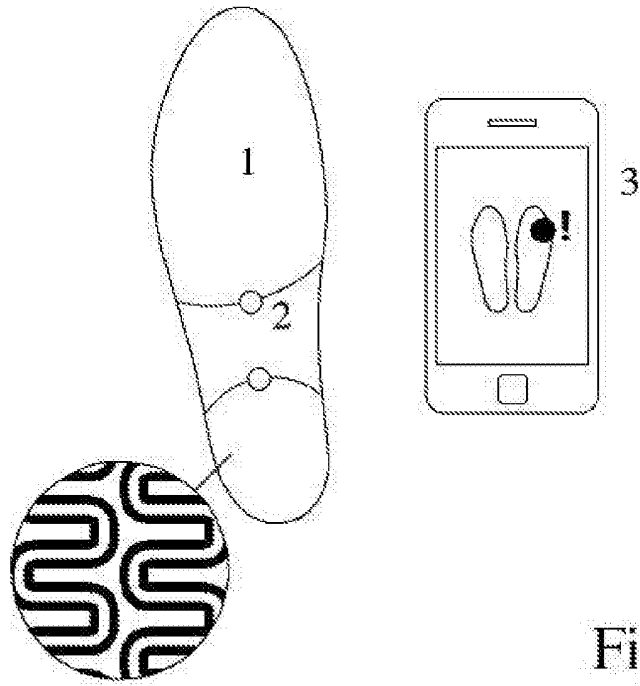


Fig 3



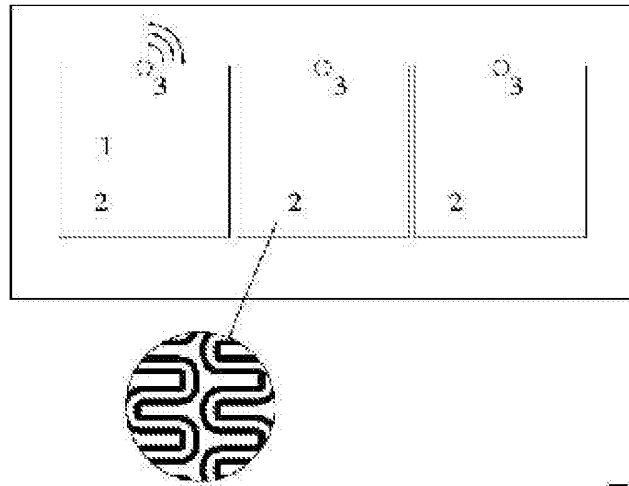


Fig 4

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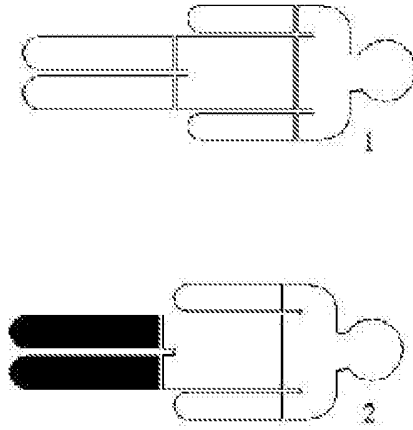


Fig 5