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(54) Benævnelse: **Indretning til påføring af en sensor på et målested, kit af en påføringsindretning og sensor og anvendelse af en påføringsindretning til optiske målinger af fysiologiske parametre**

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DESCRIPTION

[0001] The invention is directed to a device for application of a sensor to a measurement site, a kit of an application device and sensor head and the use of an application device for optical measurements of physiological parameters on or through the skin according to the independent claims.

[0002] Currently, reusable sensor heads for transcutaneous CO_2/O_2 measurements are affixed to the measuring site by adhesive adaptors after applying a contact fluid on either sensor head or patient's skin. Those adaptors have the only purpose to fix the sensor to the measuring site directly on the patient's skin. After use of such adaptors a sensor head has to be elaborately cleaned, which leads to high service needs of the sensor, requires training and consequently leads to high costs. Such adaptors are for example known for electrochemical sensors in medical applications from WO 2008/132205.

[0003] EP1040788A1 discloses a sensor film which comprises a luminescent indicator which reacts to a parameter to be determined by changing at least one optical characteristic. An applicator tube is applied to a measuring surface. The edge of the applicator tube facing the measuring surface lies elastically against the sensor film and is impermeable to radiation.

[0004] US4003707A discloses an arrangement for measuring the concentration of gases in a sample including the generation of a monochromatic light beam. An indicator generates light signals indicative of the concentration of the gases in a sample to be measured and includes a light-transmissive surface positioned to be impinged by the monochromatic light beam, a diffusion membrane adapted to be placed in the proximity of a sample and being permeable to a selected gas component thereof, and an indieating substance positioned to be impinged by the monochromatic light beam penetrating the light-transmissive surface and by the gas component penetrating the diffusion membrane.

[0005] EP0008460A2 discloses an adhesive mounting for measured value pick-ups, comprising an adhesive carrier, which has adhesive surfaces on both sides, for sticking on to the application surface of the pick-up, on the one hand, and for sticking the adhesive carrier to the measuring point, on the other hand. US2003214655 A1 discloses a reflectometer for detecting and measuring subtle changes in colour and shade of colour. A protruding nose portion of the reflectometer can be inserted into a respective opening of a transdermal patch.

[0006] It is an object of the present invention to avoid the drawbacks of the state of the art and in a particular provide a device for application of a sensor to a measuring site, a kit of an application device and a sensor head and a use of an application device for optical measurements of physiological parameters on or through the skin which facilitates the cleaning and handling of a reusable sensor head. Furthermore the shelf-life and life time of the sensor parts should be as long as possible.

[0007] The object is accomplished by a device for application of a sensor to a measurement site according to independent claim.

[0008] The device has at least one application area enabling the application of the device to a patient skin. Furthermore, the device comprises an interface for connecting the device to a sensor head, wherein the device comprises at least a wall arrangement providing an applicator volume above the patient's skin. The wall arrangement comprises a patient's side and a sensor side. At least one gas permeable membrane separates the applicator volume into a first volume being directed to the measuring site at the patient's side of the wall arrangement and a second volume being separated from the patient's skin and directed to the sensor side of the wall arrangement.

[0009] A device for application of a sensor to a measurement site comprising at least one gas permeable membrane enables measurements of gases diffusing from the measurement site and still separates the sensor head from a direct contact to the measurement site. This leads to a lower contamination of the sensor head used.

[0010] The volume of the first and the second volume each does not exceed 10 mm^3 and is preferably smaller than 4 mm^3 for sensor application areas of approx. 80 mm^2.

[0011] Preferably, the application area comprises an adhesive, which is compatible with the human skin.

[0012] The wall arrangement comprises walls that are perpendicular to the measurement site. This way, a volume above the measurement site is created. The wall arrangement can be polyangular, circular or elliptical. The largest extension of the wall arrangement does not exceed 5 cm preferably does not exceed 1.5 cm. Preferably, a sensor head being inserted into the device is still rotatable while being inserted or thereafter. The wall arrangement comprises a patient's side, which is the area of the wall arrangement directly adjacent to the measurement site and a sensor side being the portion of the wall arrangement directed to the sensor. The gas-permeable membrane is arranged substantially in parallel to the measurement site. As a matter of course, the gas permeable membrane can further have other functions or can be combined with additional

[0013] functional layers. Other functions can for example be electrical insulation and/or partial optical transparency.

[0014] At least the wall arrangement and the membrane cannot be disassembled without being destroyed.

[0015] The interface enables the connection of a sensor head to the device. The interface can comprise a sealing function to prevent significant gas leakage and/or to prevent disturbances of optical measurements by ambient light.

[0016] The device does not comprise any electrical or electronical components; as understood herein identification means such as RFID-chips, RFID-antennas, or identification resistors and printable electronical or optical components such as, but not limited to, OFETs, OLEDs(organic light emitting diodes), or OPDs (organic photo diodes) are not electronic or electrical components.

[0017] The membrane can consist of a polymer, like fluoropolymers, such as PTFE, or Polyester, Polyethylenterephtalat (PET), Polymethylpentene or Parylene or Polyethersulfone (PES), acrylic copolymers, cellophane, rubber or silicon elastomer (silastic) films, or of ceramic or semiconductor or metallic films or thin sheets such as alumina, silica, silicon, silicon nitride, titanium nitride, steels, titanium, aluminium, etc. The membrane can be porous or free of pores or contain deliberately introduced pore-like structures, e.g. structured or etched silicon, in particular the membrane can comprise a combination of different porosities such as fine pored and coarse-pored or porous and free of pores.

[0018] The gas-permeable membrane can further be fluid-impermeable. The device can also comprise a second fluid-impermeable membrane, additionally to the first, gas-permeable membrane.

[0019] A further fluid-impermeable functionality of the membrane or a second fluid impermeable membrane prevents fluids from getting into the second volume. Hence, no fluid originating from the measurement site can get into direct contact with sensor head, which is important in particular for optical measurements.

[0020] It is further possible to place a water trap, e.g. a hydrophilic material within the first volume, to intentionally collect the diffusing water from the measurement site.

[0021] The gas-permeable membrane can further be electrically insulating. This leads to a suppression of electrostatic discharge events.

[0022] The application area and/or the wall arrangement on the patient's site is provided with a contact medium (e.g. fluid, gel or paste) as common in sensor application on skin. Preferably, the contact medium seals the first volume from ambient air and/or from ambient radiation.

[0023] Hence, exchange of gas in the first volume with ambient air and/or intrusion of ambient radiation is restricted to an extent such that a significant influence on the measurement result is avoided.

[0024] The contact medium and/or the application layer is covered by a detachable cover layer before use. The contact medium and the adhesive layer on the application area can further be the same layer comprising a medium fulfilling both functions.

[0025] A detachable cover layer on the one hand keeps the application layer clean and functional and on the other hand protects the membrane inside the device from external

influences during transport or storage.

[0026] Such external influences could be mechanical impacts, fluids, gases, or radiation such as ambient light that influence the membrane or other additional layers being arranged within the device, such that the membrane or the additional layers are destroyed or become non-functional.

[0027] The second volume or the gas-permeable membrane can comprise one or several gas sensitive dyes, wherein preferably the sensitive dyes are arranged in a layer, which preferably is protected by a protection layer against environmental gases before use. Preferably, the sensitive dyes are sensitive to CO_2 (e.g. Calmagite, Naphtol Blue Black, Naphtolphtalein or HPTS (1-hydroxypyren-3,6,8-trisulfonate)), O_2(e.g. Ruthenium or Pt and Pd octaethylporphyrins based fluorescent dyes), and/or water vapour (e.g. cobalt(II) chloride, copper(II) chloride, calmagite, etc.). The sensitive dyes can further comprise a pH-indicating dye or a fluorescent dye.

[0028] A sensitive layer comprising a sensitive dye can be disposed together with the device. Generally, sensitive dyes only remain stable during a limited time frame. This time frame is significantly shorter than the product life time of a sensor head, especially in case of an optical sensor head. Since the sensitive dye may also be sensitive to atmospheric gases and ambient light, the sensitive layer is preferably protected by a protection layer before use. In addition or alternatively, the sensitive elements of the device may also be protected by gas and light tight packaging of the whole device.

[0029] The interface comprises a sealing element for sealing the second volume from ambient gases and/or ambient radiation in use.

[0030] To be able to detect the amount of gas diffusing from the measuring site without significant disturbance from ambient gases a further sealing element suppresses the intrusion of ambient air into the second volume. This leads to more accurate measuring results.

[0031] The sealing element can be an elastomer part or some other gastight material.

[0032] The gas-permeable membrane can be an at least partly reflecting layer, having reflecting properties at least in a wavelength range from 400 nm to 1 µm, a white layer, or a metallic layer. Alternatively, an additional at least partly reflecting layer, having reflecting properties at least in a wavelength range from 400 nm to 1 µm, a white layer, or a metallic layer can be provided.

[0033] If for an intended optical measurement light from the sensor head does not have to penetrate any tissue, by means of a reflecting or white layer or metallic layer, the light emitted from the sensor head can be reflected back to a detector within the sensor head and increase the propagation length within the light-affecting element, which can be a gaseous medium or for example some sensitive dye. Alternatively or additionally, ambient light can be reflected

away from the optically sensitive components of device and/or sensor head, which reduces the amount of created but unwanted parasitic signal.

[0034] To be able to fix the device to a measurement site the device may be stuck onto the measurement site by means of an adhesive layer.

[0035] The device is clamped onto the measurement site.

[0036] The clamping solution is especially advantageous for measuring sites on ears, earlobes, fingers, toes or nose.

[0037] The device can comprise means for identification and/or calibration data.

[0038] Advantageously, a sensor head can identify what kind of device is being connected to the sensor head. Hence, the handling is simplified and safety is increased. For example the kind of measurement, the sensitive element used, the wavelength required for measurement, and/or the kind of membranes comprised in the device can be coded within the device. Furthermore, if needed even calibration data can be encoded within the device. Preferably, identification and/or calibration data are encoded in a RFID-chip or a resistor arrangement or mechanical identification means.

[0039] Preferably, the aforementioned device is for measurement of the concentrations of transcutaneous CO_2 and/or transcutaneous O_2 and/or water vapour and/or of spectral properties of haemoglobin and/or myoglobin and/or bilirubin and/or water and/or acetone, ethanol or other alcohols, and/or of pulse oximetric O_2.

[0040] All aforementioned physiological parameters can be determined optically and need a defined measuring site. Some further need a defined measuring volume.

[0041] Hence, all parts having a limited shelf life or life time, in particular a shelf life shorter than 1.5 years are disposable. Furthermore, all parts becoming contaminated during use are disposable.

[0042] The sensor head may comprise detection optics for detection of human status variables, preferably for detection of transcutaneous CO_2 tension and/or transcutaneous O_2 tension and/or water vapour and/or spectral properties of haemoglobin and/or myoglobin and/or bilirubin and/or water and/or acetone, ethanol or other alcohols, and/or for pulse oximetric measurements of O_2. Within the sensor head at least one layer necessary for the sensor's functionality is not provided.

[0043] A layer may comprise complete layers and partial layers.

[0044] The layer or layers not being provided can be easily disposed instead of being cleaned

and by this facilitates the use of the sensor head.

[0045] The layer not being provided, especially in case of an optical, colorimetric or fluorescence measurement sensor head, can be a colorimetric or fluorescent indication layer.

[0046] The indication layer can be a colorimetric, such as CO_2- or pH-sensitive, layer or a fluorescent layer or a combination thereof. Based on a chemical reaction the change of colorimetric or fluorescent indication layer can be detected by the optics and/or electro-optics of the sensor head and the amount of the gaseous medium to be determined can be calculated based on the measuring results.

[0047] The sensor head can comprise all necessary optical and electro-optical parts. Alternatively, some of the necessary parts such as the electro-optical parts can be arranged externally. In this case for example the light for the measurement can be conducted to the sensor head by optical fibres.

[0048] The layer not being provided, in particular in case of an optical measurement sensor head can be a gas-permeable protection layer, which in addition may also be fluid impermeable.

[0049] Since fluid biases measurement results, a fluid-impermeable protection layer leads to more accurate measuring results. The gas permeability is necessary since a gaseous medium has to be able to get into the measuring volume.

[0050] The layer not being provided, in particular in case of optical colorimetric, fluorescence and/or absorption measurements, can be a light reflecting layer, having reflecting properties within a wavelength range from 400 nm to 1 µm.

[0051] Several layers not being provided can be a combination of single layers not being provided. For example, the layers not being provided, in particular in case of optical colorimetric, fluorescence and/or absorption measurements, can be any combination of a gas-permeable and possibly fluid impermeable protection layer, a fluid impermeable protection layer, an at least partially light reflecting layer, and a colorimetric or fluorescent indication layer.

[0052] A light reflecting layer increases the absorption path length in case of absorption measurements. As a matter of course, the reflecting layer does not necessarily have reflecting properties over the complete layer surface. Even a combination of reflecting and non-reflecting areas of the reflecting layer can be useful, for example in case of combined measurements.

[0053] Furthermore, there is provided a kit of a sensor head and a device for application of a sensor to a measurement site according to claim 11, where only the combination of the sensor head and the device for application results in a fully functional measurement sensor.

[0054] The invention as further explained with reference to preferred embodiments and the

following figures which show:

Figure 1
: a schematic view of a device for application of a sensor to a measurement site;

Figure 2
: a schematic view of a device for application of a sensor to a measurement site comprising a membrane with sensitive dye;

Figure 3
: a schematic view of a device for application of a sensor to a measurement site by a clamping arrangement;

Figure 4
: a schematic view of a device for application of a sensor to a measurement site by an adhesive arrangement.

[0055] Figure 1 shows a device 1 for application of a sensor to a measuring site. The device 1 comprises an application area 2 being covered with an adhesive layer. The adhesive layer fixes the device 1 to the skin 3. The device 1 further comprises a wall arrangement 5 which is oriented substantially perpendicular to the application area 2. The wall arrangement 5 can further exhibit different geometrical shapes such as conical elements or grooves. The wall arrangement 5 provides an applicator volume 7 above the skin 3. The wall arrangement can limit the applicator volume in a circular, elliptical or polyangular shape. The wall arrangement 5 is made from plastic material such as ABS or POM or other bio-compatible plastic materials in injection moulding.

[0056] The wall arrangement could further be stamped or blanked. Furthermore, the wall arrangement 5 comprises an interface 4 which enables the connection with the sensor head. The interface 4 is adapted to fit into a groove being arranged on a sensor head.

[0057] Preferably, the interface 4 leads to a Poka Yoke connection of the sensor head and the device 1. Hence, the sensor head either fits into the device 1 in a correct manner so that measurements are possible or it does not fit at all. Alternatively or in addition, the sensor head preferably is rotatable in the device 1 during and/or after fitting them together. A gas permeable membrane 6 separates the applicator volume within the wall arrangement 5 into the first volume 7 being directed to the measuring site at a patients' site of the wall arrangement and a second volume 8 being separate from the patients' skin and directed to the sensor site of the wall arrangement 5. Preferably, the membrane 6 further comprises water-impermeable properties. Of course even further layers are possible. The membrane 6 consists of a fluoropolymer such as PTFE. The membrane 6 is covered with a contact medium 11.

[0058] Figure 2 shows a device 1 as described in figure 1 comprising an application area 2 being stuck onto the skin 3. The device 1 comprises a wall arrangement 5 and a gas permeable membrane 6.

[0059] The wall arrangement further comprises an interface 4 adapted to connect the device 1 to the sensor head. Additionally to the gas permeable membrane 6 the device 1 comprises a sensitive layer 9 being able to react to a gaseous medium diffusing from the skin 3. The sensitive layer 9 comprises a pH-indicator which indicates a change in the pH value based on changing partial pressures of CO_2 by a colour change. Of course further layers within the wall arrangement 5 are possible. A sensitive layer can be a layer as disclosed in EP 1 889 050.

[0060] Figure 3 shows a device 1 in a clamping arrangement. A clamping arrangement is preferably clipped to an ear, ear lobe or ala of the nose. A clamping area 10 resiliently presses against the application area 2, wherein the earlobe is positioned in between the clamping area 10 and the application area 2. Additionally, the application area 2 may be covered with an adhesive layer as well as the clamping area 10. The device 1 further comprises a wall arrangement 5, which is arranged substantially perpendicular to the application area 2 in use. A membrane 6 is arranged substantially perpendicular to the wall arrangement 5 and in parallel to the application area 2 in use. The wall arrangement 5 comprises an interface 4 which enables an optical sensor head to be attached to the device 1. Optionally a contact medium layer 11 can be added to the application area. Preferably, the device 1 is made from POM (polyoxymethylene) or ABS (acrylonitrile butadiene styrene) in injection moulding.

[0061] Figure 4 shows a device 1 in an adhesive arrangement. An adhesive arrangement can basically be stuck to a measuring site anywhere. The adhesive arrangement comprises an application area 2 providing an adhesive layer. The device 1 further comprises a wall arrangement 5 which is arranged substantially perpendicular to the application area 2. A membrane 6 is provided substantially in parallel to the application area 2 in use. The wall arrangement 5 further comprises an interface 4 which enables an optical sensor head to be attached to the device 1. The device is made from plastic material and cannot be dismounted without destroying the device 1. The membrane 6 further comprises a sensitive layer 9 which does not cover the complete membrane 6. The sensitive layer 9 further comprises a reflective layer. This embodiment is preferably used for combined measurements of colorimetric and pulse oximetric measurements or measurements of spectral properties of haemoglobin and/or myoglobin and/or bilirubin and/or water and/or acetone, ethanol or other alcohols.

REFERENCES CITED IN THE DESCRIPTION

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Patentkrav

1. Indretning (1) til påføring af en sensor på et målested, hvilken indretning omfatter mindst et påføringsområde (2), der muliggør påføring af indretningen på en patients hud (3), hvor indretningen er konfigureret som et fastspændingsarrangement med en fastspændingsområde (10), som fjedrende presser mod påføringsområdet (2),
hvor indretningen yderligere har en grænseflade (4) til at forbinde indretningen med et sensorhoved, hvor indretningen i det mindste har et vægarrangement (5) med vægge, der er vinkelret på målestedet og tilvejebringer et applikatorvolumen over patientens hud, hvor vægarrangementet omfatter en patients side og en sensorside, hvor mindst én gasgennemtrængelig membran (6) adskiller applikatorvolumenet i et første volumen (7), der er rettet til målestedet på patientens side af vægarrangementet (5), og et andet volumen (8), der er adskilt fra patientens hud og rettet mod sensorsiden af vægarrangementet (5) og i det mindste vægarrangementet og membranen kan ikke skilles ad uden at blive ødelagt,
hvor grænsefladen (4) omfatter et tætningselement til tætning af det andet volumen mod omgivende gasser og omgivende stråling under brug, og hvor membranen (6) på patientens side er forsynet med en kontaktmedium, som fortrinsvis tætner det første volumen mod omgivende luft og/eller fra omgivende stråling, hvor kontaktmediet er dækket af et aftageligt dæklag før brug.

2. Indretning (1) ifølge krav 1, **kendetegnet ved, at** den gasgennemtrængelige membran (6) er yderligere væskeuigennemtrængelig, eller at indretningen omfatter en anden væskeuigennemtrængelig membran.

3. Indretning (1) ifølge et hvilket som helst af de foregående krav, **kendetegnet ved, at** påføringsområdet eller vægarrangementet (5) på patientens side er forsynet med kontaktmedium (11).

4. Indretning (1) ifølge et hvilket som helst af de foregående krav, **kendetegnet ved, at** påføringsområdet er dækket af et aftageligt dæklag før brug.

5. Indretning (1) ifølge et hvilket som helst af de foregående krav, **kendetegnet ved, at** det andet volumen (8) eller den gasgennemtrængelige membran (6) omfatter et eller flere gasfølsomme farvestoffer, hvor fortrinsvis et følsomt lag (9), der omfatter det følsomme farvestof, er beskyttet af et beskyttelseslag mod miljøpåvirkninger såsom gasser og omgivende lys før brug.

6. Indretning (1) ifølge et hvilket som helst af de foregående krav, **kendetegnet ved, at** den gasgennemtrængelige membran (6) i det mindste delvist er et reflekterende lag, hvidt lag eller metallisk lag, som har reflekterende egenskaber i det mindste i et bølgelængdeområde fra 400 nm til 1 µm, eller der er tilvejebragt et yderligere i det mindste delvist reflekterende lag, hvidt lag eller metallisk lag med reflekterende egenskaber i det mindste i et bølgelængdeområde fra 400 nm til 1 µm.

7. Indretning (1) ifølge et hvilket som helst af de foregående krav, **kendetegnet ved, at** indretningen omfatter midler til identifikation og/eller kalibreringsdata.

8. Indretning (1) ifølge et hvilket som helst af de foregående krav, **kendetegnet ved, at** indretningen (1) er beskyttet af en gas- og lystæt emballage.

9. Indretning (1) ifølge et hvilket som helst af de foregående krav, hvor grænsefladen (4) er indrettet således, at sensorhovedet, der indsættes i indretningen, stadig er roterbart, mens det indsættes eller derefter, især grænsefladen (4) er indrettet til at passe ind i en rille, der er anbragt på et sensorhoved.

10. Anvendelse af en indretning (1) ifølge et hvilket som helst af kravene 1 til 9 til transkutane målinger af CO_2 og/eller O_2 og/eller af hæmoglobins spektrale

egenskaber og/eller til pulsoximetriske målinger af O_2 og/eller vanddamp og/eller af spektrale egenskaber af myoglobin og/eller bilirubin og/eller vand og/eller acetone og/eller alkoholer, såsom ethanol.

11. Kit med et sensorhoved og en indretning til påføring af en sensor på et målested ifølge et hvilket som helst af kravene 1 til 9, hvor kun kombinationen af sensorhovedet og indretningen til påføring resulterer i en fuldt funktionel målesensor.

12. Kit ifølge krav 11, **kendetegnet ved, at** sensorhovedet er indrettet til kolorimetriske eller fluorescerende optiske målinger eller kombinationer deraf, hvor det lag, der ikke er tilvejebragt af sensorhovedet, men af indretningen, er mindst et af et kolorimetrisk og fluorescerende indikationslag.

13. Kit ifølge krav 11 eller krav 12, **kendetegnet ved, at** sensorhovedet er indrettet til optiske kolorimetriske, fluorescerende eller absorptionsmålinger, hvor det lag, der ikke er tilvejebragt af sensorhovedet, men af indretningen, er et lysreflekterende lag med reflekterende egenskaber inden for et bølgelængdeområde fra 400 nm til 1 µm.

14. Kit ifølge et hvilket som helst af kravene 11 til 13, hvor de lag, der ikke er tilvejebragt af sensorhovedet, men af indretningen, er en kombination af et eller flere kolorimetriske eller fluorescerende indikationslag, af et gasgennemtrængeligt og eventuelt også fluid- uigennemtrængeligt lag, der definerer et målevolumen, og af et lysreflekterende lag med reflekterende egenskaber inden for et bølgelængdeområde fra 400 nm til 1 µm.

DRAWINGS

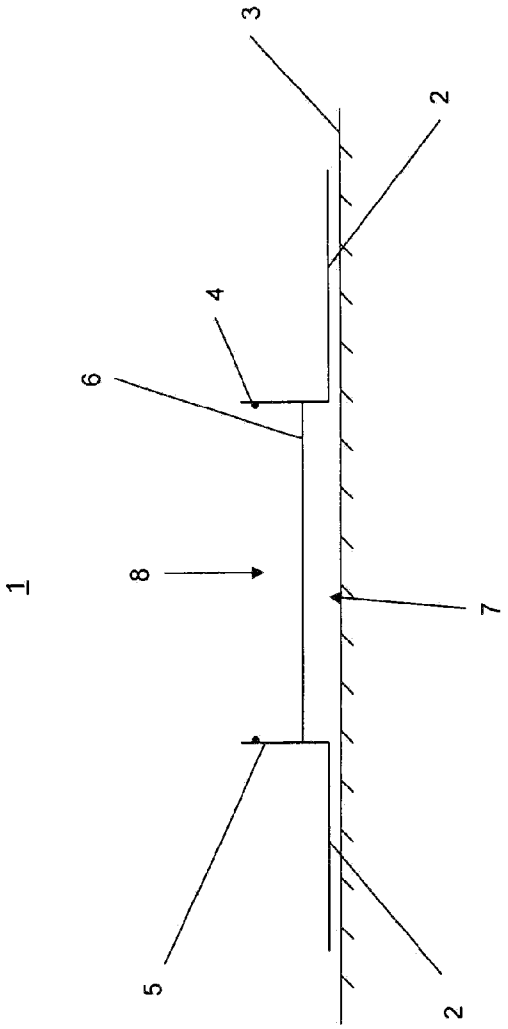

Fig. 1

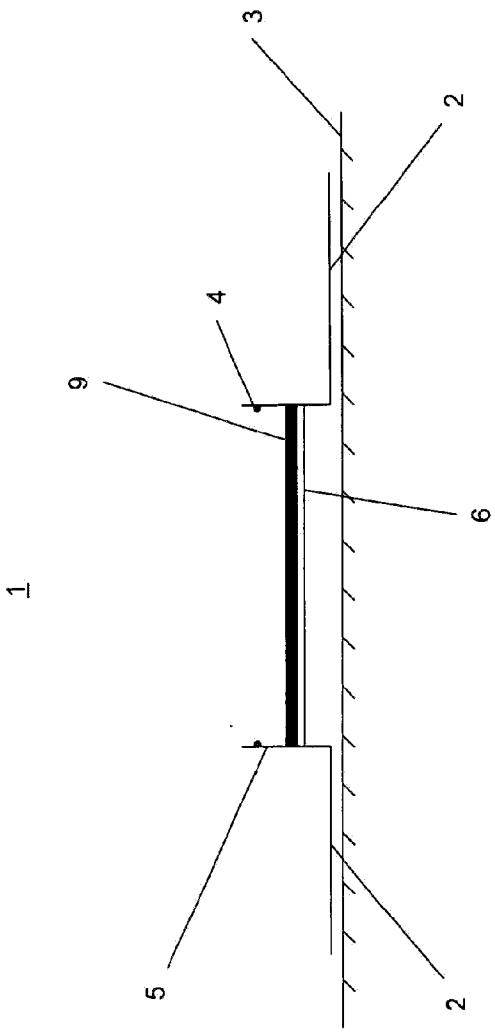

Fig. 2

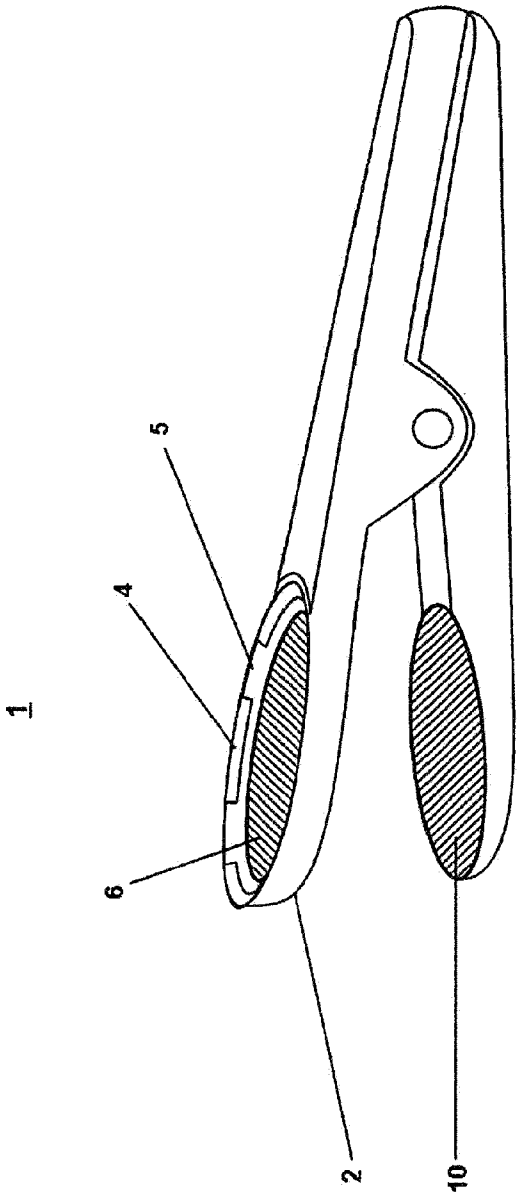

Fig. 3

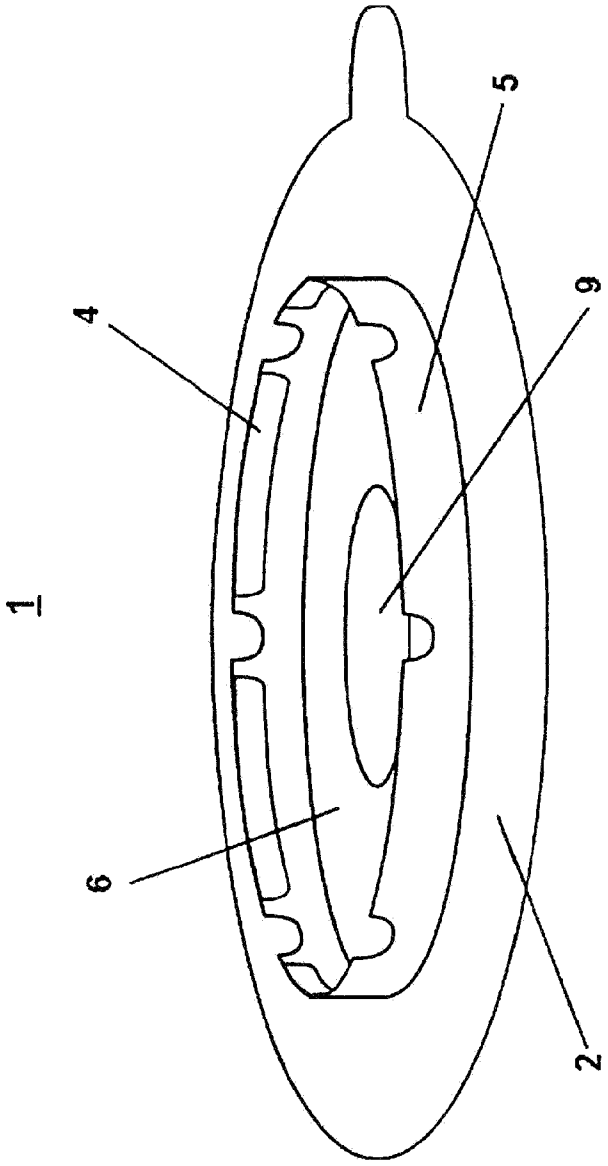

Fig. 4