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(54) **MEDICAL SENSOR ASSEMBLY**

MEDIZINISCHE SENSORANORDNUNG

ENSEMBLE DE CAPTEUR MÉDICAL

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Description

[0001] The invention relates to a medical sensor assembly comprising a flexible plaster adapted for adhesion on the skin of a patient and a sensor configured for transdermal measuring a physiological parameter, wherein the sensor has a measuring part insertable into the skin and a contact part for providing a signal connection to a measuring unit.

[0002] In the area of medical technology in the field of continuous glucose monitoring (CGM), a similar assembly is proposed in EP 2 415 395 A1. This document discloses an implantable sensor device in connection with a rigid base plate, which is part of a disposable or body-mount fixed to the body by means of a plaster. In this connection a wearing period of at least several days is intended. Thus, it should be avoided that the carrier plaster inadvertently detaches from the body.

[0003] Furthermore, documents WO 2013/130711 A1, EP 0 678 308, and EP 2 415 395 A1 disclose medical sensor assemblies according to the preamble of claim 1. WO 2014/099709 A1, WO 97/21459, and EP 1 698 368 A1 disclose dressings which use different types of flaps to secure different medical devices to the skin.

[0004] On this basis the object of the invention is to further improve the known devices and to achieve an improved efficiency for reliable, long-term use and at the same time uncomplicated handling.

[0005] The combination of features stated in claim 1 is proposed to achieve this object. Advantageous embodiments and further developments of the invention are derived from the dependent claims.

[0006] The invention is based on the idea of providing the sensor in fixed connection to the plaster. Correspondingly, it is proposed according to the invention that the plaster has a flap which is adhered to an intermediate section of the sensor between the measuring part and the contact part. These measures guarantee that the sensor is securely and comfortably attached to the patient's skin, specifically in the implantation area where movement could cause erroneous measuring results. Moreover, due to the direct attachment to a flexible structure, a better conformation to the local body shape at the application site is achieved, while a rigid base plate can be avoided. Thus, the possible wearing time is increased, and the risk of detachment due to shearing forces is reduced. Furthermore, the design of the assembly is more simple and less complicated to produce.

[0007] The invention furthermore provides that the flap is formed as a partially cut-out or punched segment of the plaster, such that an opening is provided in the plaster when the flap is folded up for the passage of the intermediate section of the sensor. Thus, a reach-through opening and a connecting element is provided for the sensor with a simple measure at the same time.

[0008] In a specific embodiment, the flap is delimited by a preferably U- or C-shaped cutting line so that a material bridge remains intact to bendably connect the flap to the remaining plaster.

[0009] In order to provide an easy connection it is advantageous when the bottom side of the plaster facing the skin is coated with a pressure-sensitive adhesive coating and the flap is fixedly connected to the intermediate section by means of this adhesive coating. It is also conceivable that the flap is fixed to the sensor by different means, e.g. a structural adhesive which is applied in the joining zone.

[0010] For further use improvement it is advantageous when a hollow inserter cannula is provided in which the sensor at least with its measuring part is located for insertion into the skin, wherein the inserter cannula has a longitudinal slit at least along a distal section for the reach-through of the flap. In this way, it is also possible to prefabricate the combined inserter/sensor assembly while the sensor is already fixedly connected to the plaster.

[0011] Additionally, the invention provides that the measuring part of the sensor is formed by a flexible flat substrate preferably provided with electrode pads or conducting paths thereon. Thus, the sensor can be implanted in the skin for longterm wear without skin irritation due to rigid parts. Moreover, the flap can be easily connected to a flat side of the substrate, thus maintaining a secure connection even with a small adherent area.

[0012] A further improvement provides that the intermediate section of the sensor is formed by a material strip provided with electrically conducting paths, such that the measuring signals can be routed to a body-mounted contact part. In this context, it is also advantageous when the contact part of the sensor is arranged preferably in direct abutment on the upper side of the plaster facing away from the skin. Then, a rigid base with laborious arrangement for sensor fixation can be omitted.

[0013] In another preferred embodiment there is provided a signal transmitter which can be connected to the contact part of the sensor, wherein the signal transmitter is directly fixed to the plaster. Again, this allows for a more flexible design, also in case the transmitter is reused.

[0014] Another improvement also with respect to simplified handling provides that the signal transmitter has a socket to receive the contact part of the sensor by means of transverse pressing against the plaster or by lateral insertion. Another particularly advantageous embodiment provides that the plaster below its upper side defines at least one channel leading from the sensor to the margin of the plaster for conducting blood emerging from a skin wound. In this way, blood can be discharged below the upper surface of the plaster, thus avoiding impairment of the contact part of the sensor.

[0015] Advantageously, he channel is formed by a gap between segments or layers of the plaster preferably as a capillary gap.

[0016] In order to counteract problems due to bleeding from the skin wound, e.g. detachment of the wetted plaster or disturbance of the measurements, it is advanta-

geous when a performance indicator is integrated in the plaster to signalize excessive blood load or wear to the user preferably by a color change.

[0017] For further handling improvement it is advantageous when an inserter for moving the inserter needle into the skin is provided, wherein the plaster affixed to the sensor by means of the flap, and wherein the inserter is supported on the upper side of the plaster preferably by an adherend surface.

[0018] The invention also concerns a preferred use wherein the sensor is a glucose sensor adapted for continuous glucose monitoring.

[0019] The invention is further elucidated in the following on the basis of embodiment examples shown schematically in the drawings, where

Fig. 1 is a sectional view of a medical sensor assembly connected to a partially illustrated inserter provided for transdermal insertion;

Fig. 2 is a perspective view of the implanted sensor assembly with the inserter being removed;

Fig. 3 is a sectional view of the assembly of Fig. 2 when mounting a signal transmitter;

Fig. 4 is a further embodiment in a view similar to Fig. 3;

Fig. 5 is a top view of a plaster of the sensor assembly provided with a blood discharge channel;

Fig. 6 and 7 are sectional views of alternate discharge channel embodiments of the plaster along line 6,7 of Fig. 5.

[0020] Referring to the drawings, a medical sensor assembly 1 worn on the body for long-term diagnostic applications comprises a flexible patch or plaster 10 adapted for adhesion on the skin 12 of a patient and a sensor 14 configured for transdermal measuring a physiological parameter, wherein the plaster 10 has a flap 16 which is permanently adhered to the sensor 14.

[0021] In an initial condition as illustrated in Fig. 1, an inserter 18 is provided in connection with the sensor assembly 1 in order to facilitate the implantation of the sensor 14 into the skin 12. The inserter 18 comprises a support 20 and a hollow cannula 22 received with its proximal section in the support 20. The support 20 has an end face 24 which adheres to an upper surface of the plaster 10. The flexible sensor 14 extends into the distal part of the rigid cannula 22 such that skin penetration is possible. This can be handled manually by means of a stamp (not shown) connected to the support 20.

[0022] The plaster 10 comprises a carrier layer 26 and a pressure-sensitive adhesive coating 28 on its side facing the skin 12. A lateral overlap 30 of the plaster 10 over the support end face 24 allows additional manual fixation on the skin 12 before removal of the inserter 18. The adherency of the end face 24, which can be coated with a transfer adhesive, is less than that of the adhesive coating 28 in order to avoid detaching of the plaster 10 when withdrawing the inserter 18. The inserter 18 can be configured to have an insertion angle between 45° and 90° of the lancing axis 32 with respect to the surface of the skin 12.

[0023] As apparent from Fig. 2, the inserter cannula 22 has a longitudinal slit 34 formed at least along a distal section. This allows a reach-through of the sensor 14 in connection with the flap 16 in the condition as supplied and when retracting the cannula 22.

[0024] As further illustrated in Fig. 2, the sensor 14 consists of a flexible strip which has a distal measuring part 36, a proximal contact part 38 and an intermediate section 40 therebetween. The measuring part 36 is provided with electrode pads 42 for electrochemical detection of a physiological parameter. Specifically, the electrode pads 42 can be configured for continuous glucose measuring in the interstitial fluid of the skin 12. Electrically conducting paths 44 lead from the pads 42 through the intermediate section 40 to leads 46 in the contact part 38.

[0025] The flap 16 is formed as a U-shaped punched segment of the plaster 10, such that an opening 48 is provided in the plaster for the passage of the sensor 14 and a material bridge 50 remains to bendably connect the flap 16 to the remaining area of the plaster 10. At the same time, the flap 16 is fixedly connected to the intermediate section 40 of the sensor 14 by means of the adhesive coating 28.

[0026] Fig. 3 illustrates the sensor arrangement in a further assembly condition comprising a signal transmitter 52 configured to transmit measuring signals from the sensor 14 to a measuring or controller unit (not shown). For this purpose, the transmitter 52 has a socket 54 which can be engaged with the leads 46 of the contact part 40. The signal transmitter 52 is directly fixed to the carrier layer 26 of the plaster 10 by means of a hook-and-loop tape 56 or other quick fasteners. As indicated by arrow 58, the joining movement of the transmitter 52 is transverse to the plaster 10, such that in the connected state the contact 40 of the sensor 14 is arranged in direct abutment on the carrier layer 26 facing away from the skin 12.

[0027] Fig. 4 shows an alternate arrangement of the transmitter 52 wherein the socket 54 is construed for a lateral insertion of the contact part 40 by a joining movement of the transmitter 52 in direction of arrow 60. Then, the electrical contact between the leads 46 and the socket 54 is supported by a pre-loaded spring 62. Again, the transmitter 52 is directly fixed on the plaster 10 e.g. by adhesive connection 64, thus making an additional rigid base plate superfluous.

[0028] Fig. 5 shows an embodiment in which the plaster 10 is provided with radial blood discharge channels

66 leading from the central opening 48 to the outer margin. The channels 66 are provided below the upper surface 68 of the plaster 10 and conduct blood which may emerge from the skin wound created with the cannula 22. Conveniently, the channels 66 are designed as capillary gaps or slits for self-acting fluid transport. In order to facilitate the blood discharge, the channels 66 can be provided with a hydrophilic coating.

[0029] As illustrated in Fig. 6, the plaster 10 can be provided with an additional intermediate layer 70 which is divided in two segments or halves to define the channel 66. In this case, a transfer adhesive 72 provides the connection to the carrier layer 26. Alternatively, the channel 66 can be directly formed in the adhesive coating 28 facing the skin 12, as apparent from Fig. 7. In both cases, the carrier layer 26 can be loaded with an indicator substance 74 to signalize unstopped bleeding or excessive blood load to the user e.g. by a color change.

Claims

1. Medical sensor assembly comprising a flexible plaster (10) adapted for adhesion on the skin (12) of a patient and a sensor (14) configured for transdermal measuring a physiological parameter, wherein the sensor (14) has a measuring part (36) insertable into the skin (12) and a contact part (38) for providing a signal connection to a measuring unit, wherein the measuring part (36) of the sensor (14) is formed by a flexible flat substrate with electrode pads or conducting paths thereon and the plaster (10) is adhered to an intermediate section (40) of the sensor (14) between the measuring part (36) and the contact part (38), **characterized in that** a flap (16) is formed as a partially cut-out or punched segment of the plaster (10), such that an opening (48) is provided in the plaster (10) for the passage of the intermediate section (40) of the sensor (14), and the flap is connected to a flat side of the substrate.

2. Medical sensor assembly according to claim 1, wherein the flap (16) is delimited by a preferably U- or C-shaped cutting line so that a material bridge (50) remains intact to bendably connect the flap (16) to the remaining plaster (10).

3. Medical sensor assembly according to claim 1 or 2, wherein the bottom side of the plaster (10) facing the skin (12) is coated with a pressure-sensitive adhesive coating (28) and the flap (16) is fixedly connected to the intermediate section (40) by means of the adhesive coating (28).

4. Medical sensor assembly according to one of claims 1 to 3, further comprising a hollow inserter cannula (22) in which the sensor (14) at least with its measuring part (36) is located for insertion into the skin (12), wherein the inserter cannula (22) has a longitudinal slit (34) at least along a distal section for the reach-through of the flap (16).

5. Medical sensor assembly according to one of claims 1 to 4, wherein the intermediate section (40) of the sensor (14) is formed by a material strip provided with electrically conducting paths (44).

6. Medical sensor assembly according to one of claims 1 to 5, wherein the contact part (38) of the sensor (14) is arranged preferably in direct abutment on the upper side (68) of the plaster (10) facing away from the skin (12).

7. Medical sensor assembly according to one of claims 1 to 6, further comprising a signal transmitter (52) which can be connected to the contact part (38) of the sensor (14), wherein the signal transmitter (52) is directly fixed to the plaster (10).

8. Medical sensor assembly according to claim 7, wherein the signal transmitter (52) has a socket (54) to receive the contact part (38) of the sensor (14) by means of transverse pressing against the plaster (10) or by lateral insertion.

9. Medical sensor assembly according to one of claims 1 to 8, wherein the plaster (10) below its upper side defines at least one channel (66) leading from the sensor (14) to the margin of the plaster (10) for conducting blood emerging from a skin wound.

10. Medical sensor assembly according to claim 9, wherein the channel (66) is formed by a gap between segments (70) or layers of the plaster (10) preferably as a capillary gap.

11. Medical sensor assembly according to one of claims 1 to 10, further comprising a performance indicator (74) integrated in the plaster (10) to signalize excessive blood load or wear to the user preferably by a color change.

12. Medical sensor assembly according to one of claims 1 to 11, further comprising an inserter (20) for moving the inserter needle into the skin (12), wherein the plaster (10) affixed to the sensor (14) by means of the flap (16), and wherein the inserter (20) is supported on the upper side of the plaster (10) preferably by an adherend surface (24).

13. Medical sensor assembly according to one of claims 1 to 12, wherein the sensor (14) is a glucose sensor adapted for continuous glucose monitoring.

Patentansprüche

1. Medizinische Sensoranordnung mit einem zur Haftung auf der Haut (12) eines Patienten ausgebildeten flexiblen Pflaster (10) und einem zur transdermalen Messung eines physiologischen Parameters konfigurierten Sensor (14), wobei der Sensor (14) einen in die Haut (12) einführbaren Messteil (36) und einen Kontaktteil (38) zum Bereitstellen einer Signalverbindung zu einer Messeinheit aufweist, wobei der Messteil (36) des Sensors (14) durch ein flexibles flaches Substrat mit Elektrodenplatten oder Leiterbahnen darauf gebildet ist und das Pflaster (10) an einem Zwischenabschnitt (40) des Sensors (14) zwischen dem Messteil (36) und dem Kontaktteil (38) angeklebt ist, **dadurch gekennzeichnet, dass** eine Lasche (16) als teilweise ausgeschnittenes oder gestanztes Segment des Pflasters (10) ausgebildet ist, so dass in dem Pflaster (10) eine Öffnung (48) für den Durchgang des Zwischenabschnitts (40) des Sensors (14) gebildet ist, und die Lasche mit einer flachen Seite des Substrats verbunden ist.

2. Medizinische Sensoranordnung nach Anspruch 1, wobei die Lasche (16) durch eine vorzugsweise U- oder C-förmige Schnittlinie begrenzt ist, so dass eine Materialbrücke (50) erhalten bleibt, um die Lasche (16) biegbar mit dem verbleibenden Pflaster (10) zu verbinden.

3. Medizinische Sensoranordnung nach Anspruch 1 oder 2, wobei die der Haut (12) zugewandte Unterseite des Pflasters (10) mit einer Haftklebeschicht (28) beschichtet ist und die Lasche (16) über die Haftklebeschicht (28) fest mit dem Zwischenabschnitt (40) verbunden ist.

4. Medizinische Sensoranordnung nach einem der Ansprüche 1 bis 3, ferner umfassend eine hohle Einführkanüle (22), in der der Sensor (14) zumindest mit seinem Messteil (36) zum Einführen in die Haut (12) angeordnet ist, wobei die Einführkanüle (22) einen Längsschlitz (34) zumindest entlang eines distalen Abschnitts für den Durchgriff der Lasche (16) aufweist.

5. Medizinische Sensoranordnung nach einem der Ansprüche 1 bis 4, wobei der Zwischenabschnitt (40) des Sensors (14) durch einen Materialstreifen gebildet ist, der mit elektrisch leitenden Bahnen (44) versehen ist.

6. Medizinische Sensoranordnung nach einem der Ansprüche 1 bis 5, wobei der Kontaktteil (38) des Sensors (14) vorzugsweise in direkter Anlage auf der von der Haut (12) abgewandten Oberseite (68) des Pflasters (10) angeordnet ist.

7. Medizinische Sensoranordnung nach einem der Ansprüche 1 bis 6, ferner umfassend einen Signalübertrager (52), der mit dem Kontaktteil (38) des Sensors (14) verbindbar ist, wobei der Signalübertrager (52) direkt am Pflaster (10) fixiert ist.

8. Medizinische Sensoranordnung nach Anspruch 7, wobei der Signalübertrager (52) eine Buchse (54) zur Aufnahme des Kontaktteils (38) des Sensors (14) durch Querpressen gegen das Pflaster (10) oder durch seitliches Einsetzen aufweist.

9. Medizinische Sensoranordnung nach einem der Ansprüche 1 bis 8, wobei der Pflaster (10) unterhalb seiner Oberseite mindestens einen Kanal (66) begrenzt, der vom Sensor (14) zum Rand des Pflasters (10) führt, um aus einer Hautwunde austretendes Blut zu leiten.

10. Medizinische Sensoranordnung nach Anspruch 9, wobei der Kanal (66) durch einen Spalt vorzugsweise als Kapillarspalt zwischen Segmenten (70) oder Schichten des Pflasters (10) gebildet ist.

11. Medizinische Sensoranordnung nach einem der Ansprüche 1 bis 10, ferner umfassend einen in das Pflaster (10) integrierten Leistungsindikator (74), um dem Benutzer eine übermäßige Blutbeladung oder Abnutzung vorzugsweise durch einen Farbwechsel zu signalisieren.

12. Medizinische Sensoranordnung nach einem der Ansprüche 1 bis 11, ferner umfassend eine Einführvorrichtung (20) zum Bewegen der Einführnadel in die Haut (12), wobei das Pflaster (10) mittels der Lasche (16) am Sensor (14) befestigt ist, und wobei die Einführvorrichtung (20) auf der Oberseite des Pflasters (10) vorzugsweise durch eine Klebefläche (24) gehalten wird.

13. Medizinische Sensoranordnung nach einem der Ansprüche 1 bis 12, wobei der Sensor (14) ein zur kontinuierlichen Glukoseüberwachung geeigneter Glukosesensor ist.

Revendications

1. Ensemble de capteur médical comprenant un pansement flexible (10) adapté pour une adhérence sur la peau (12) d'un patient et un capteur (14) configuré pour mesurer par voie transdermique un paramètre physiologique, dans lequel le capteur (14) a une partie de mesure (36) pouvant être insérée dans la peau (12) et une partie de contact (38) pour fournir une connexion de signal à une unité de mesure, dans lequel la partie de mesure (36) du capteur (14) est formée par un substrat plat flexible avec des plots

d'électrode ou des pistes conductrices sur celui-ci et le pansement (10) adhère à une section intermédiaire (40) du capteur (14) entre la partie de mesure (36) et la partie de contact (38), **caractérisé en ce qu'**un rabat (16) est formé en tant que segment partiellement découpé ou perforé du pansement (10), de sorte qu'une ouverture (48) soit prévue dans le pansement (10) pour le passage de la section intermédiaire (40) du capteur (14), et le rabat est relié à un côté plat du substrat.

2. Ensemble de capteur médical selon la revendication 1, dans lequel le rabat (16) est délimité par une ligne de coupe, de préférence en forme de U ou de C, de sorte qu'un pont de matière (50) reste intact pour relier par pliage le rabat (16) au pansement (10) restant.

3. Ensemble de capteur médical selon la revendication 1 ou 2, dans lequel le côté inférieur du pansement (10) faisant face à la peau (12) est revêtu d'un revêtement adhésif sensible à la pression (28) et le rabat (16) est relié de manière fixe à la section intermédiaire (40) au moyen du revêtement adhésif (28).

4. Ensemble de capteur médical selon l'une des revendications 1 à 3, comprenant en outre une canule d'insertion creuse (22) dans laquelle se trouve le capteur (14) au moins avec sa partie de mesure (36) pour une insertion dans la peau (12), dans lequel la canule d'insertion (22) a une fente longitudinale (34) au moins le long d'une section distale pour le passage du rabat (16).

5. Ensemble de capteur médical selon l'une des revendications 1 à 4, dans lequel la section intermédiaire (40) du capteur (14) est formée par une bande de matière pourvue de pistes électriquement conductrices (44).

6. Ensemble de capteur médical selon l'une des revendications 1 à 5, dans lequel la partie de contact (38) du capteur (14) est agencée de préférence en butée directe contre le côté supérieur (68) du pansement (10) opposé à la peau (12).

7. Ensemble de capteur médical selon l'une des revendications 1 à 6, comprenant en outre un émetteur de signal (52) qui peut être relié à la partie de contact (38) du capteur (14), dans lequel l'émetteur de signal (52) est directement fixé au pansement (10).

8. Ensemble de capteur médical selon la revendication 7, dans lequel l'émetteur de signal (52) a une prise (54) pour recevoir la partie de contact (38) du capteur (14) au moyen d'une pression transversale contre le pansement (10) ou par insertion latérale.

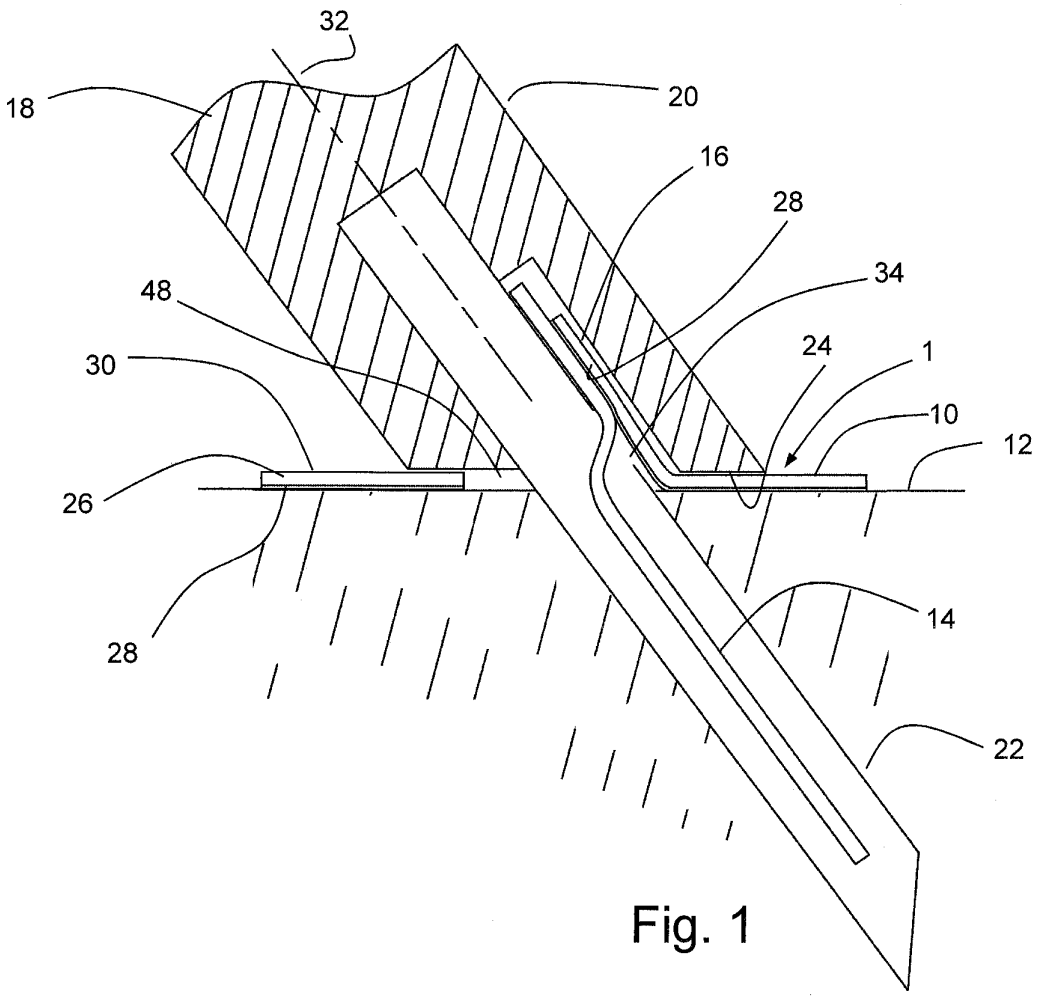
9. Ensemble de capteur médical selon l'une des revendications 1 à 8, dans lequel le pansement (10) en dessous de son côté supérieur définit au moins un canal (66) menant du capteur (14) au bord du pansement (10) pour conduire le sang sortant d'une plaie cutanée.

10. Ensemble de capteur médical selon la revendication 9, dans lequel le canal (66) est formé par un espace entre des segments (70) ou des couches du pansement (10), de préférence en tant qu'espace capillaire.

11. Ensemble de capteur médical selon l'une des revendications 1 à 10, comprenant en outre un indicateur de performance (74) intégré dans le pansement (10) pour signaler une usure ou une charge sanguine excessive à l'utilisateur de préférence par un changement de couleur.

12. Ensemble de capteur médical selon l'une des revendications 1 à 11, comprenant en outre un instrument d'insertion (20) pour déplacer l'aiguille d'insertion dans la peau (12), dans lequel le pansement (10) est fixé au capteur (14) au moyen du rabat (16), et dans lequel l'instrument d'insertion (20) est supporté sur le côté supérieur du pansement (10) de préférence par une surface adhésive (24).

13. Ensemble de capteur médical selon l'une des revendications 1 à 12, dans lequel le capteur (14) est un capteur de glucose adapté pour la surveillance continue du glucose.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24
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30
10
12
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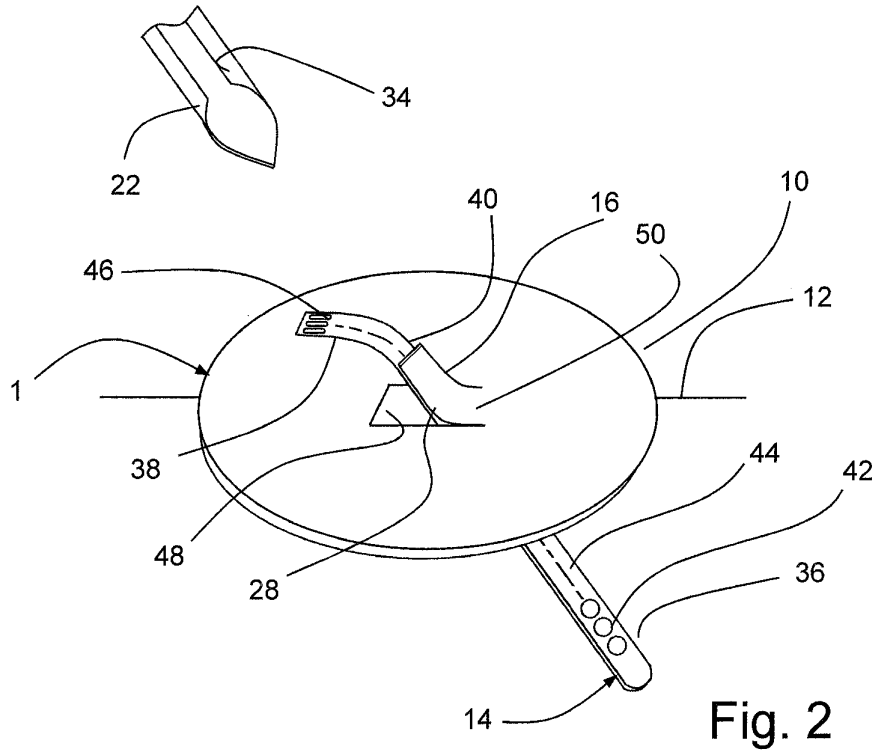
28
14
22

Fig. 1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12
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48
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36
14

Fig. 2

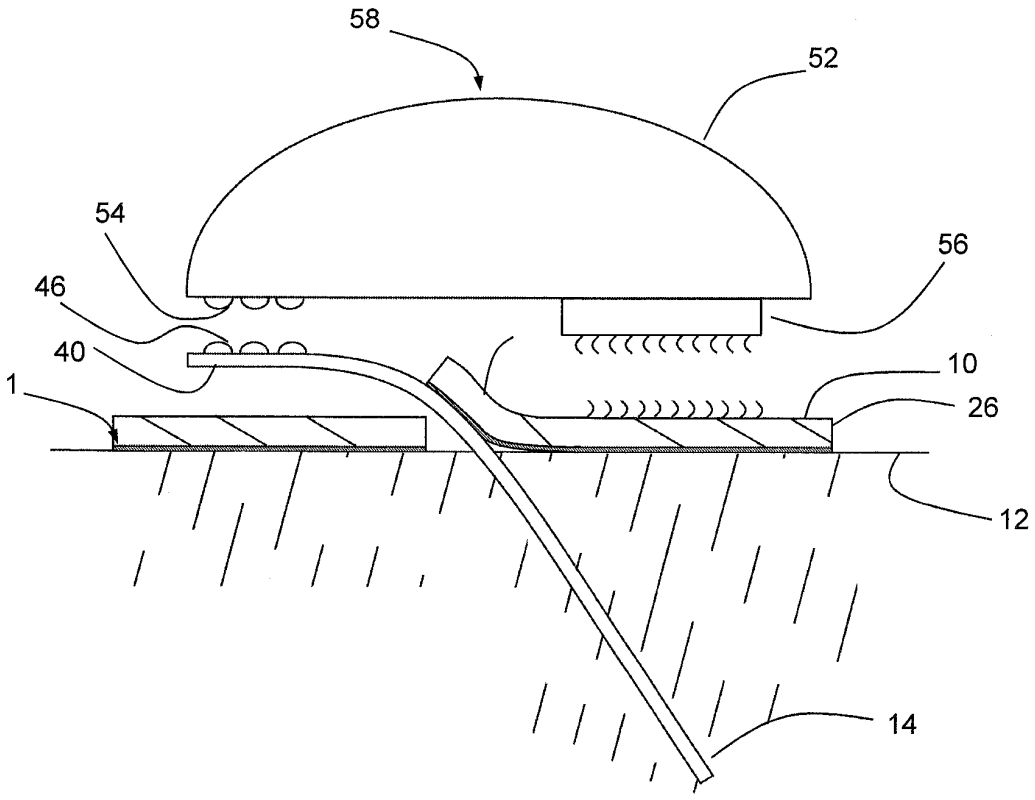

Fig. 3

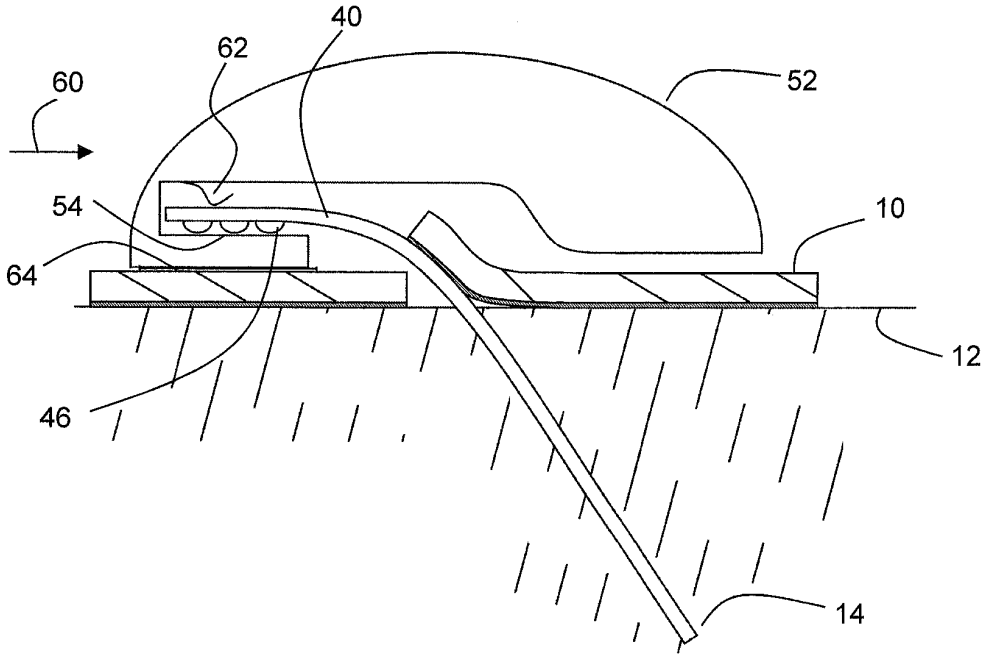

Fig. 4

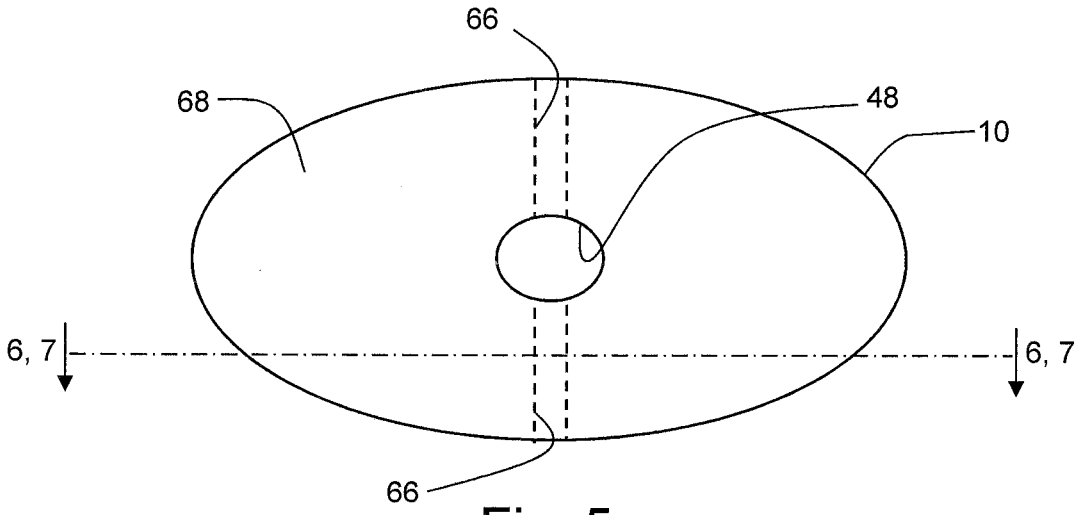

Fig. 5

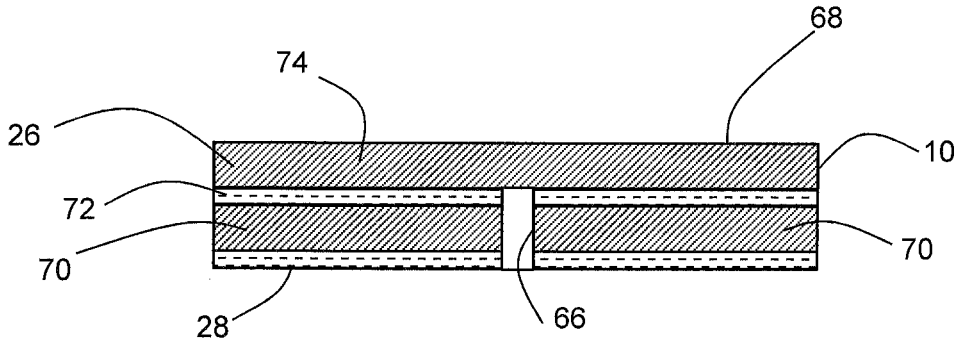

Fig. 6

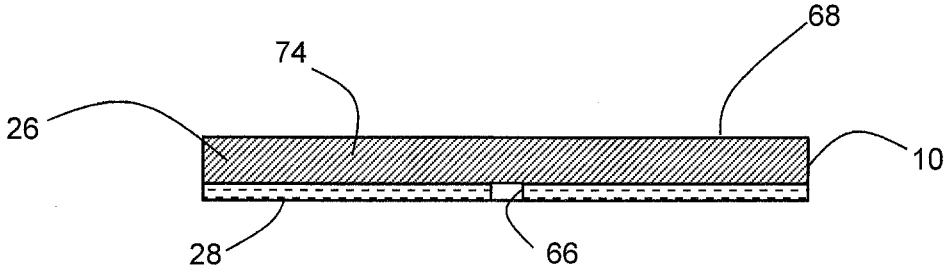

Fig. 7

REFERENCES CITED IN THE DESCRIPTION

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专利名称(译)	医疗传感器组件		
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摘要(译)

本发明涉及一种医疗传感器组件，该医疗传感器组件包括适于粘附在患者的皮肤（12）上的柔性膏药（10）和构造用于经皮测量生理参数的传感器（14），其中传感器（14）具有测量部件 可插入皮肤（12）中的（36）和用于向测量单元提供信号连接的接触部分（38）。 建议的是，灰泥（10）具有翼片（16），该翼片（16）粘附在传感器（14）的在测量部分（36）和接触部分（38）之间的中间部分（40）上。