Innovation, Sciences et Développement économique Canada
Office de la Propriété Intellectuelle du Canada

Innovation, Science and Economic Development Canada
Canadian Intellectual Property Office

CA 2955678 C 2019/05/21

(11)(21) **2 955 678**

(12) BREVET CANADIEN / CANADIAN PATENT

(13) **C**

(86) **Date de dépôt PCT/PCT Filing Date:** 2015/07/28
(87) **Date publication PCT/PCT Publication Date:** 2016/02/04
(45) **Date de délivrance/Issue Date:** 2019/05/21
(85) **Entrée phase nationale/National Entry:** 2017/01/19
(86) **N° demande PCT/PCT Application No.:** EP 2015/067222
(87) **N° publication PCT/PCT Publication No.:** 2016/016217
(30) **Priorité/Priority:** 2014/07/28 (EP14178704.4)

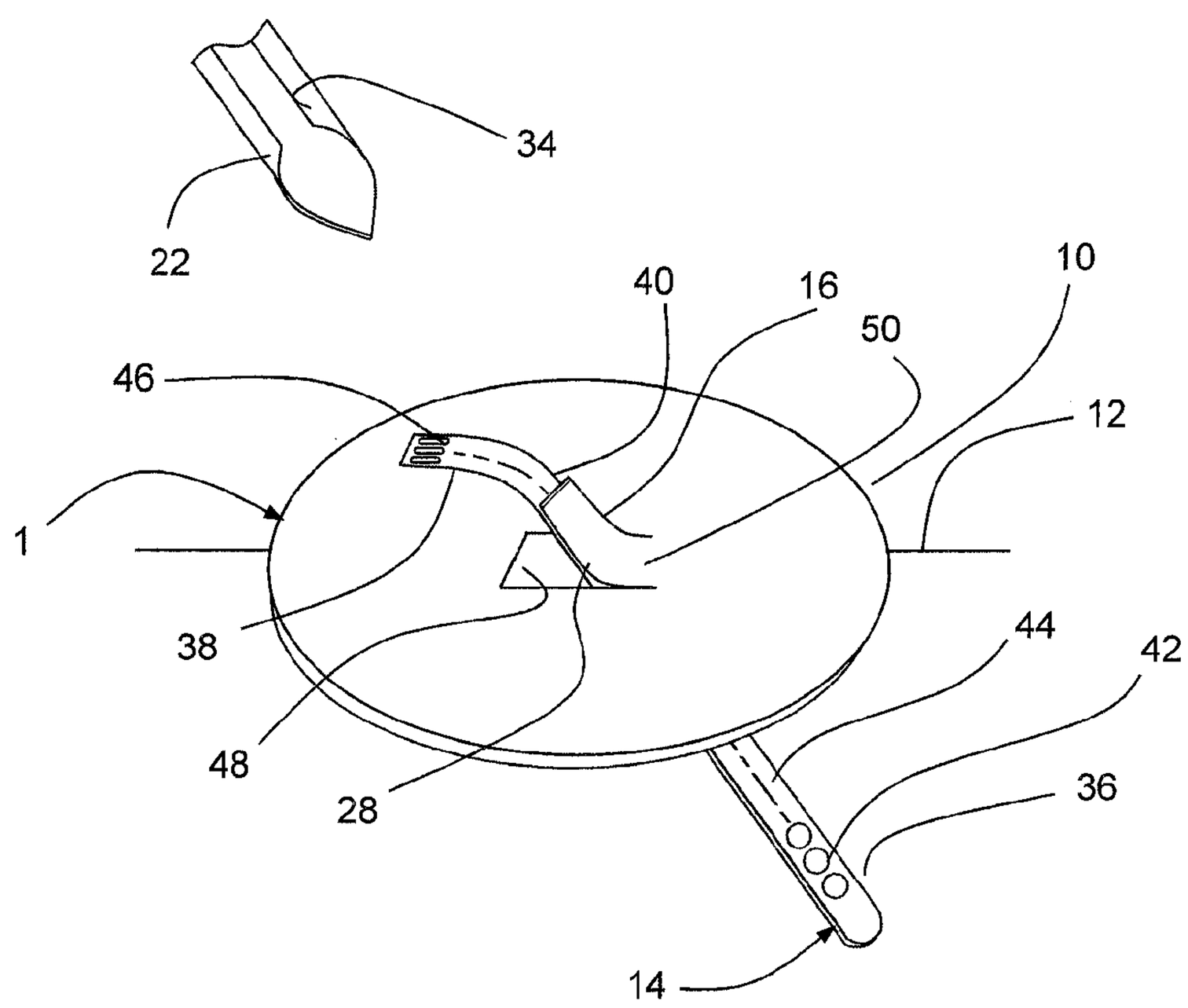
(51) **Cl.Int./Int.Cl.** ***A61B 5/145*** (2006.01), ***A61B 5/1486*** (2006.01), ***A61F 13/02*** (2006.01), ***A61M 39/02*** (2006.01)

(72) **Inventeurs/Inventors:**
FREY, STEPHAN-MICHAEL, DE;
KUBE, OLIVER, DE;
WALTER, HELMUT, DE

(73) **Propriétaire/Owner:**
F. HOFFMANN-LA ROCHE AG, CH

(74) **Agent:** GOWLING WLG (CANADA) LLP

(54) **Titre : ENSEMBLE CAPTEUR MEDICAL**
(54) **Title: MEDICAL SENSOR ASSEMBLY**



(57) **Abrégé/Abstract:**
The invention concerns a 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. It is proposed that the plaster (10) has a flap (16) which is adhered to an intermediate section (40) of the sensor (14) between the measuring part (36) and the contact part (38).

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
4 February 2016 (04.02.2016)

WIPO | PCT

(10) International Publication Number
WO 2016/016217 A1

(51) International Patent Classification:
A61B 5/00 (2006.01) *A61M 25/02* (2006.01)
A61B 5/1486 (2006.01)

(21) International Application Number:
PCT/EP2015/067222

(22) International Filing Date:
28 July 2015 (28.07.2015)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
14178704.4 28 July 2014 (28.07.2014) EP

(71) Applicant *(for DE only)*: **ROCHE DIAGNOSTICS GMBH** [DE/DE]; Sandhofer Strasse 116, 68305 Mannheim (DE).

(71) Applicant *(for all designated States except DE, US)*: **F. HOFFMANN-LA ROCHE AG** [CH/CH]; Grenzacherstrasse 124, CH-4070 Basel (CH).

(71) Applicant *(for US only)*: **ROCHE DIABETES CARE INC.** [US/US]; 9115 Hague Road, Indianapolis, Indiana 46250 (US).

(72) Inventors: **FREY, Stephan-Michael**; Fabrikstrasse 3, 64319 Pfungstadt (DE). **KUBE, Oliver**; Ulrich von Hutten Straße 4, 67549 Worms (DE). **WALTER, Helmut**; Walther Rathenau Straße 23, 64646 Heppenheim (DE).

(74) Agents: **PFIZ, Thomas** et al.; Hauptmannsreute 93, 70193 Stuttgart (DE).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU,

[Continued on next page]

(54) Title: MEDICAL SENSOR ASSEMBLY

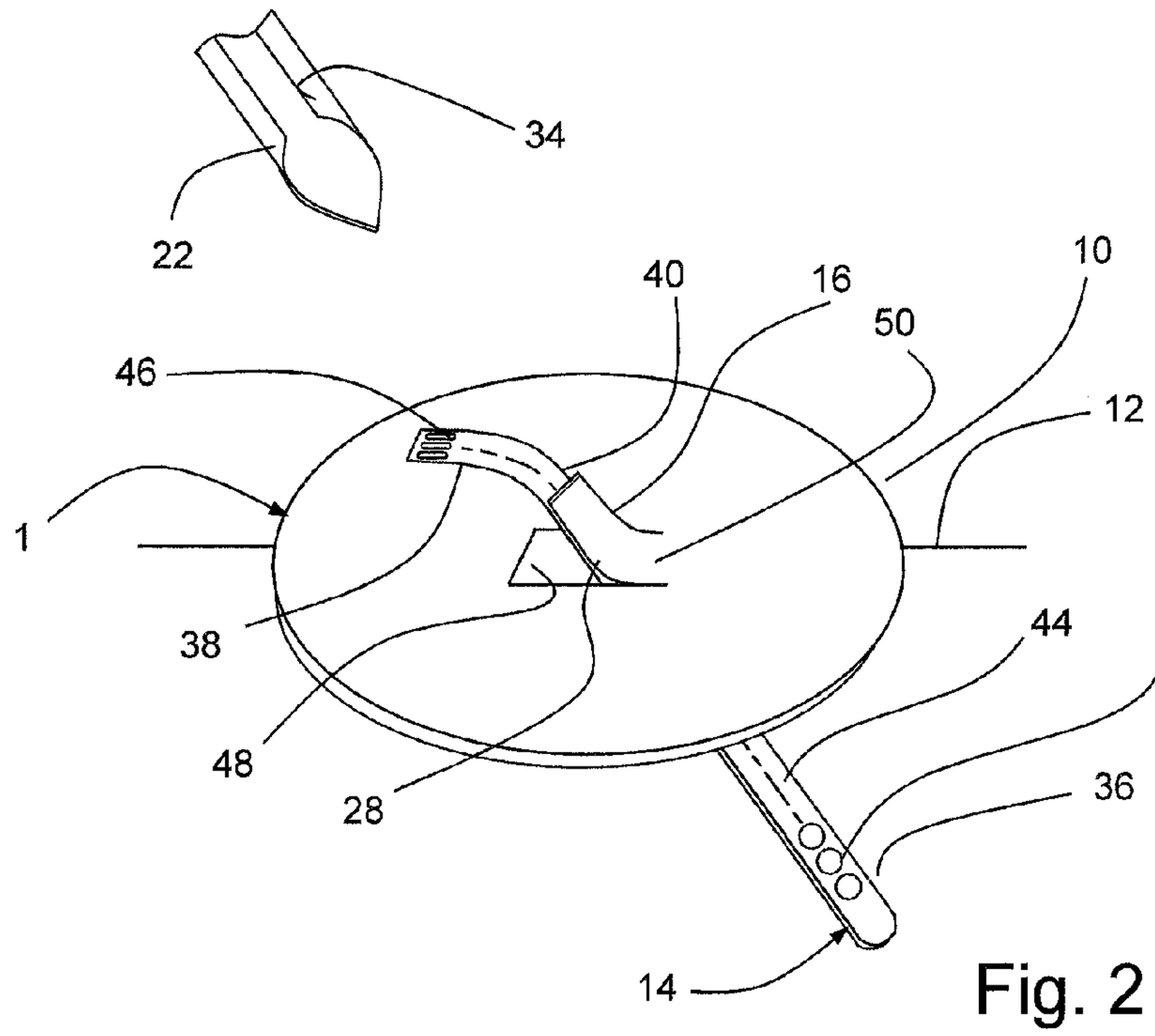


Fig. 2

(57) Abstract: The invention concerns a 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. It is proposed that the plaster (10) has a flap (16) which is adhered to an intermediate section (40) of the sensor (14) between the measuring part (36) and the contact part (38).

WO 2016/016217 A1

WO 2016/016217 A1

LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

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

Medical sensor assembly

Description

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.

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.

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.

In one embodiment, the invention provides for 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, wherein the measuring part of the sensor is formed by a flexible flat substrate with electrode pads or conducting paths thereon and the plaster is adhered to an intermediate section of the sensor between the measuring part and the contact part, wherein a flap is formed as a partially cut-out or punched segment of the plaster, such that an opening is provided in the plaster for the passage of the intermediate section of the sensor, and the flap is connected to a flat side of the substrate.

In a further embodiment of a medical sensor or medical sensors as outlined herein, 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.

In a further embodiment of a medical sensor or medical sensors as outlined herein, 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 the adhesive coating.

In a further embodiment of a medical sensor or medical sensors as outlined herein, the medical sensor or sensors further comprise a hollow inserter cannula 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 a further embodiment of a medical sensor or medical sensors as outlined herein, the intermediate section of the sensor is formed by a material strip provided with electrically conducting paths.

In a further embodiment of a medical sensor or medical sensors as outlined herein, the contact part of the sensor is arranged preferably in direct abutment on the upper side of the plaster facing away from the skin.

In a further embodiment of a medical sensor or medical sensors as outlined herein, the medical sensor or sensors further comprise a signal transmitter which can be connected to the contact part of the sensor, wherein the signal transmitter is directly fixed to the plaster.

In a further embodiment of a medical sensor or medical sensors as outlined herein, 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.

In a further embodiment of a medical sensor or medical sensors as outlined herein, 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 a further embodiment of a medical sensor or medical sensors as outlined herein, the channel is formed by a gap between segments or layers of the plaster preferably as a capillary gap.

In a further embodiment of a medical sensor or medical sensors as outlined herein, the medical sensor or sensors further comprise a performance indicator integrated in the plaster to signalize excessive blood load or wear to a user preferably by a color change.

In a further embodiment of a medical sensor or medical sensors as outlined herein, the medical sensor or sensors further comprise an inserter for moving an inserter needle into the skin, 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.

In a further embodiment of a medical sensor or medical sensors as outlined herein, the sensor is a glucose sensor adapted for continuous glucose monitoring.

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.

A preferred embodiment 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.

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.

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.

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.

A preferred embodiment 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.

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.

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.

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.

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

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

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.

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

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

WE CLAIM:

1. 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, wherein the measuring part of the sensor is formed by a flexible flat substrate with electrode pads or conducting paths thereon and the plaster is adhered to an intermediate section of the sensor between the measuring part and the contact part, wherein a flap is formed as a partially cut-out or punched segment of the plaster, such that an opening is provided in the plaster for the passage of the intermediate section of the sensor, and the flap is connected to a flat side of the substrate.

2. Medical sensor assembly according to claim 1, wherein 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.

3. Medical sensor assembly according to claim 1 or 2, wherein 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 the adhesive coating.

4. Medical sensor assembly according to any one of claims 1 to 3, further comprising a hollow inserter cannula 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.

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

6. Medical sensor assembly according to any one of claims 1 to 5, wherein the contact part of the sensor is arranged preferably in direct abutment on the upper side of the plaster facing away from the skin.

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

8. Medical sensor assembly according to claim 7, wherein 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.

9. Medical sensor assembly according to any one of claims 1 to 8, wherein 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.

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

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

12. Medical sensor assembly according to any one of claims 1 to 11, further comprising an inserter for moving an inserter needle into the skin, 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.

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

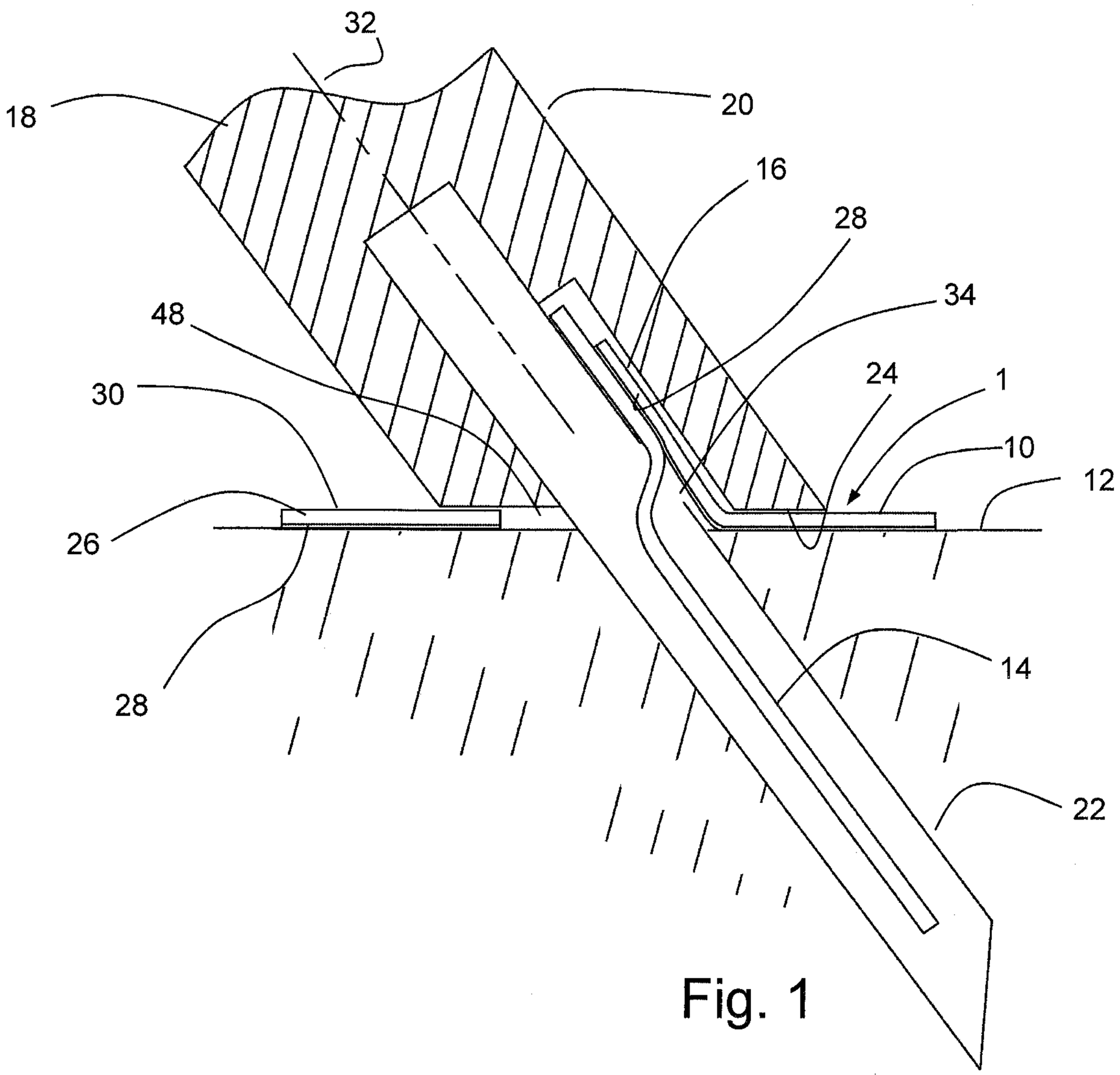

32
18
20
16
28
48
34
30
24
1
10
12
26
14
28
22

Fig. 1

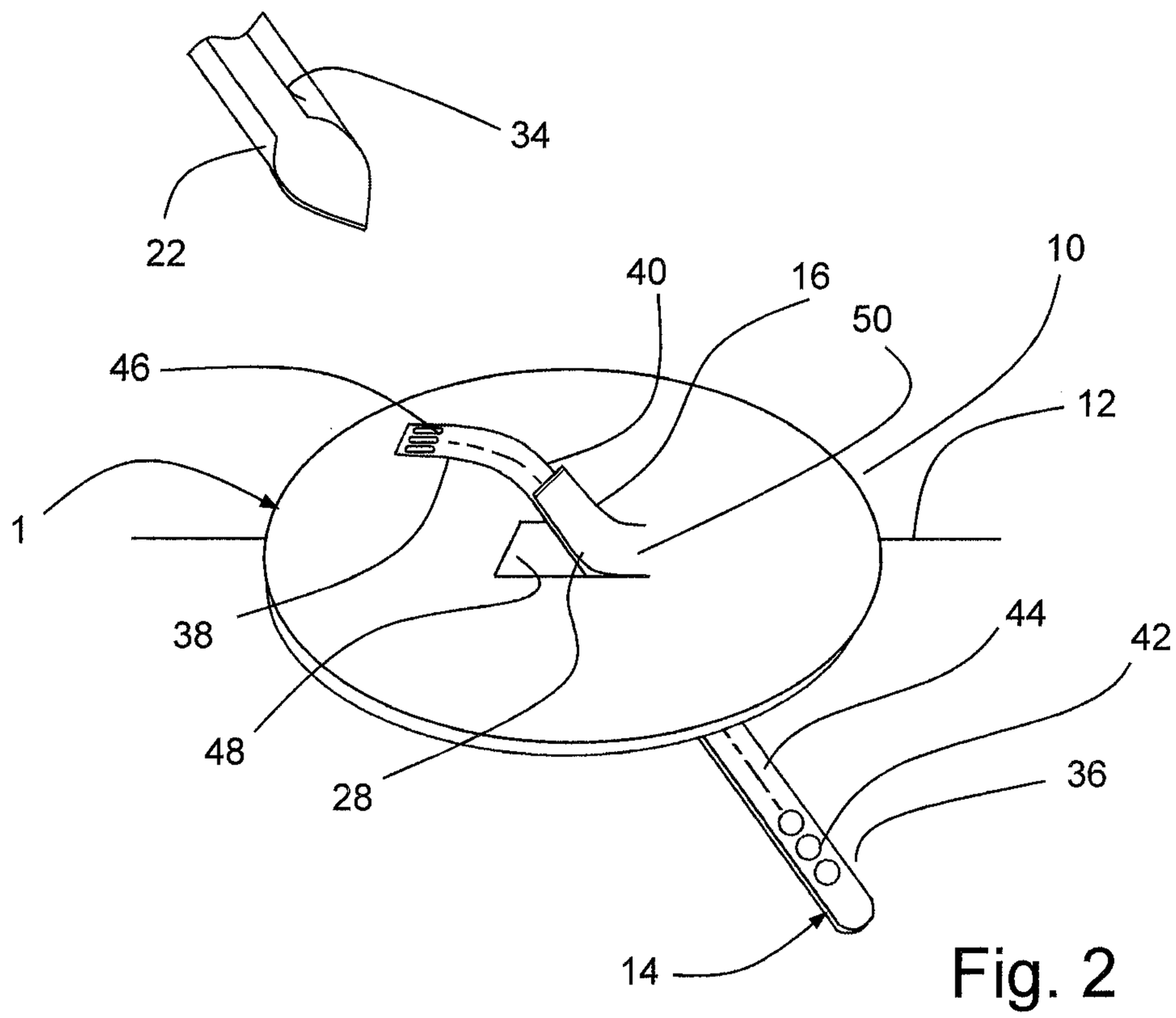

34
22
40
16
10
50
46
12
1
38
48
28
44
42
36
14

Fig. 2

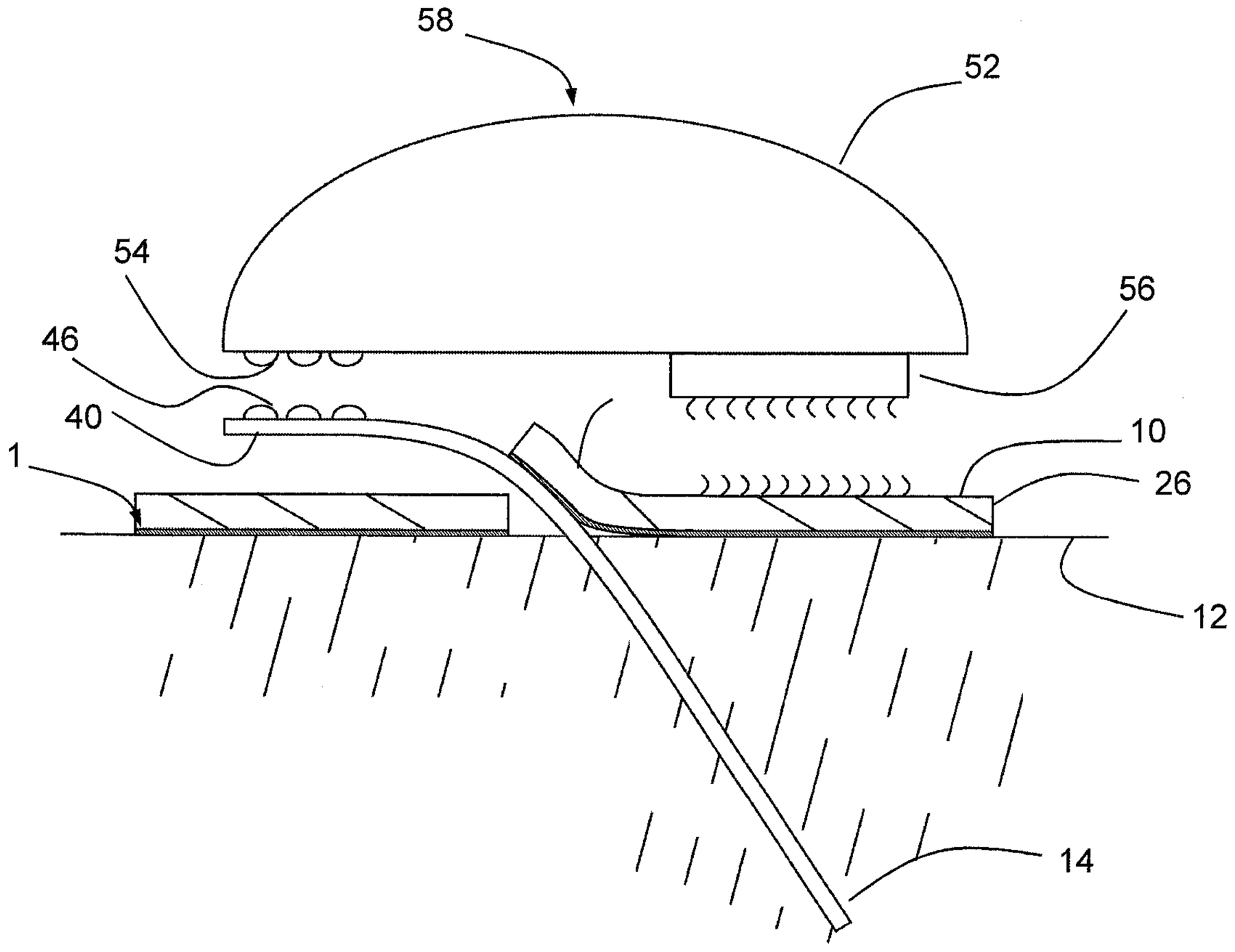


Fig. 3

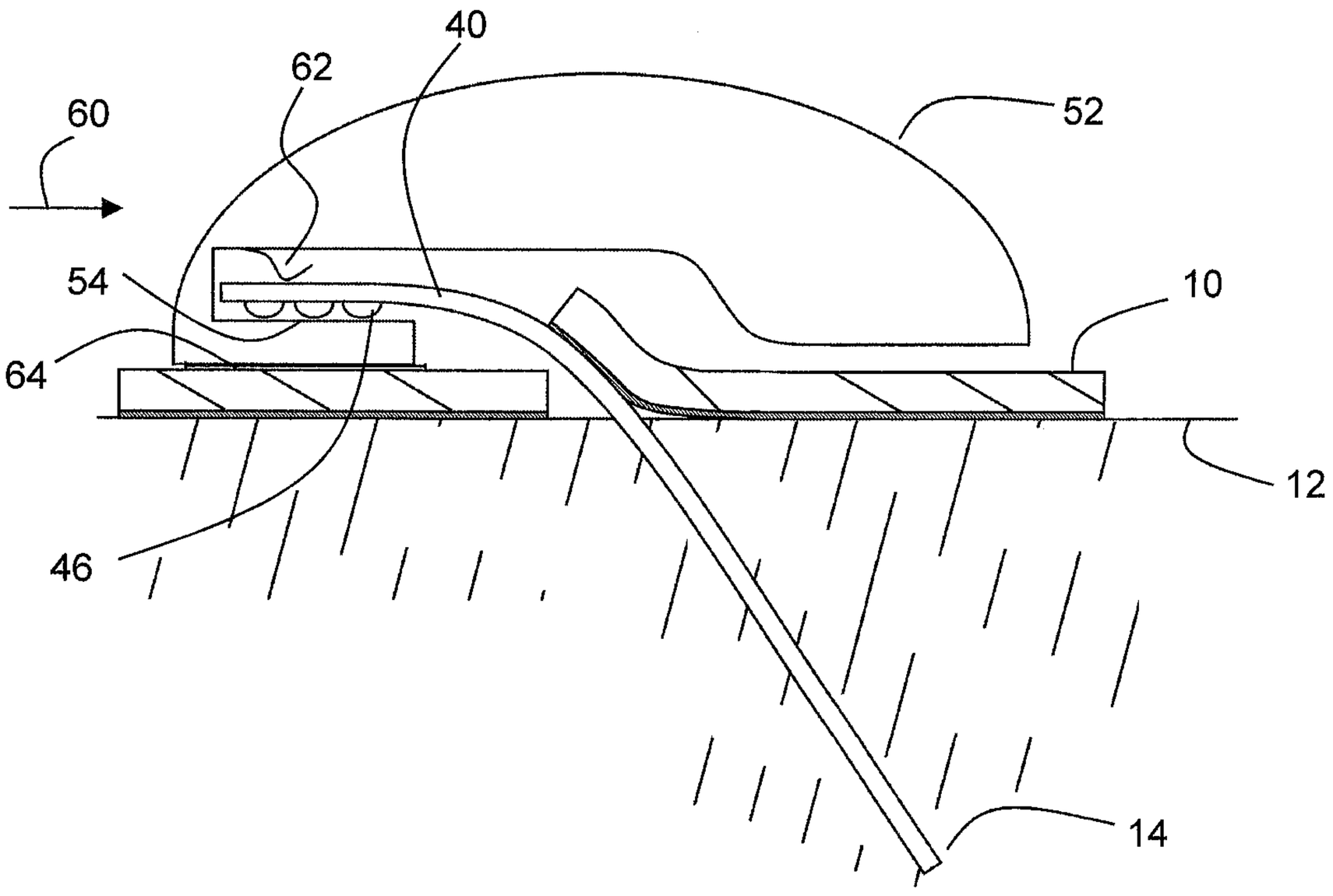


Fig. 4

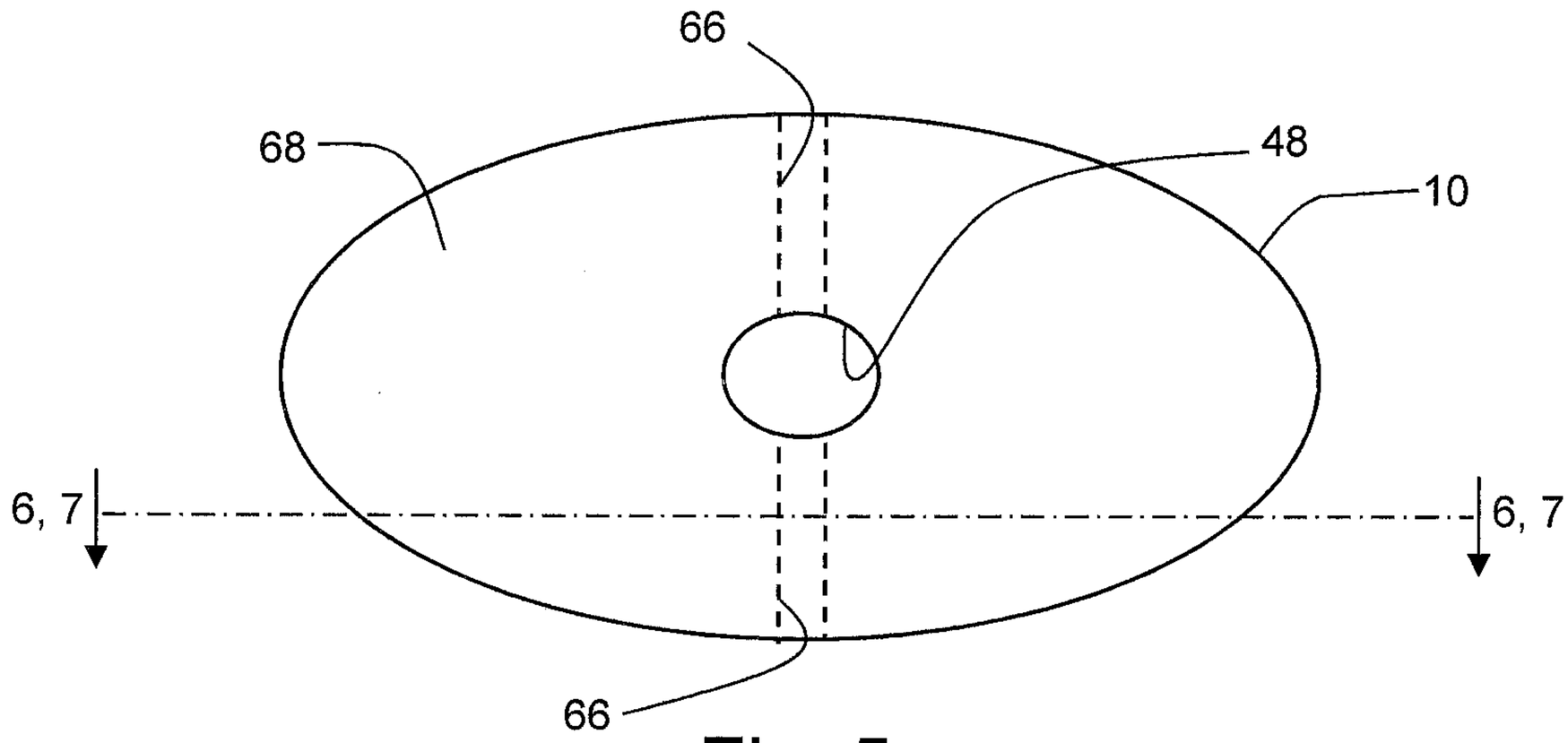


Fig. 5

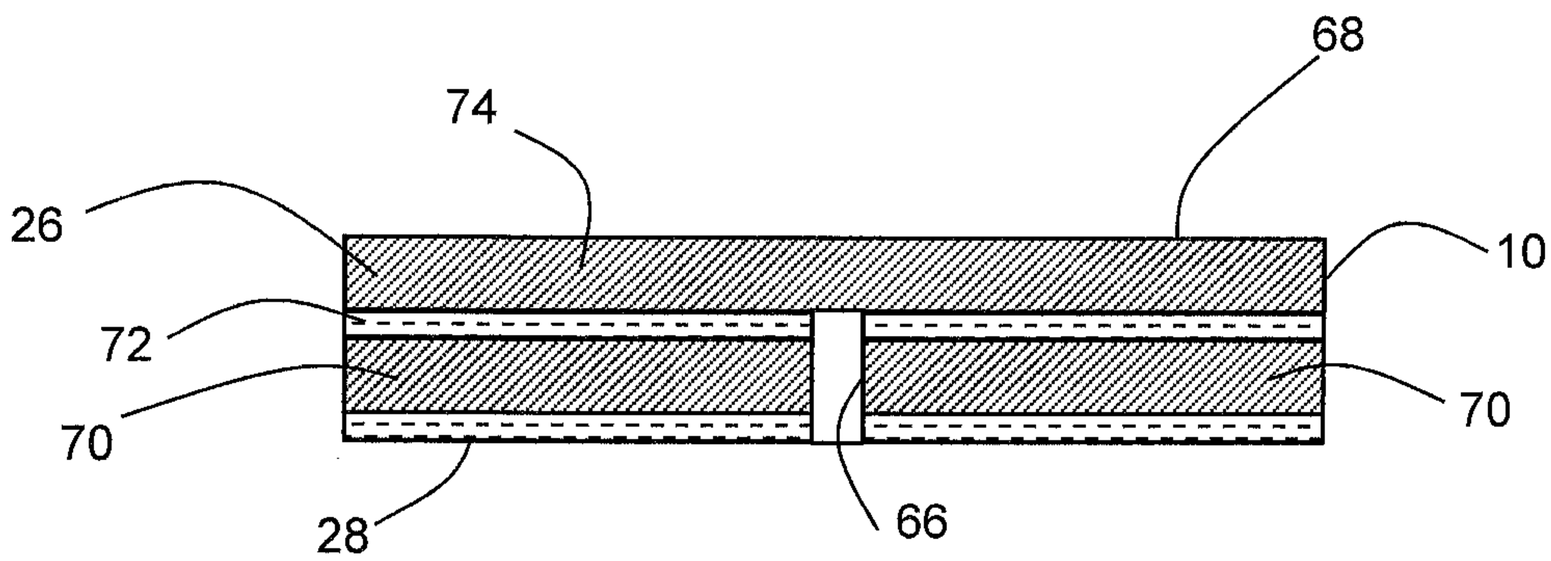


Fig. 6

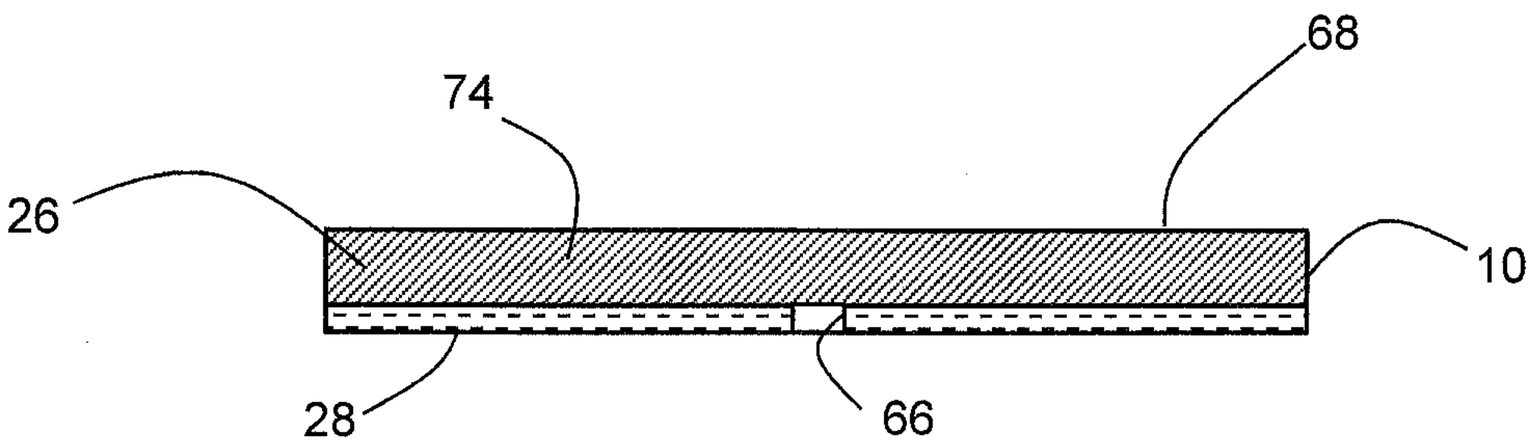
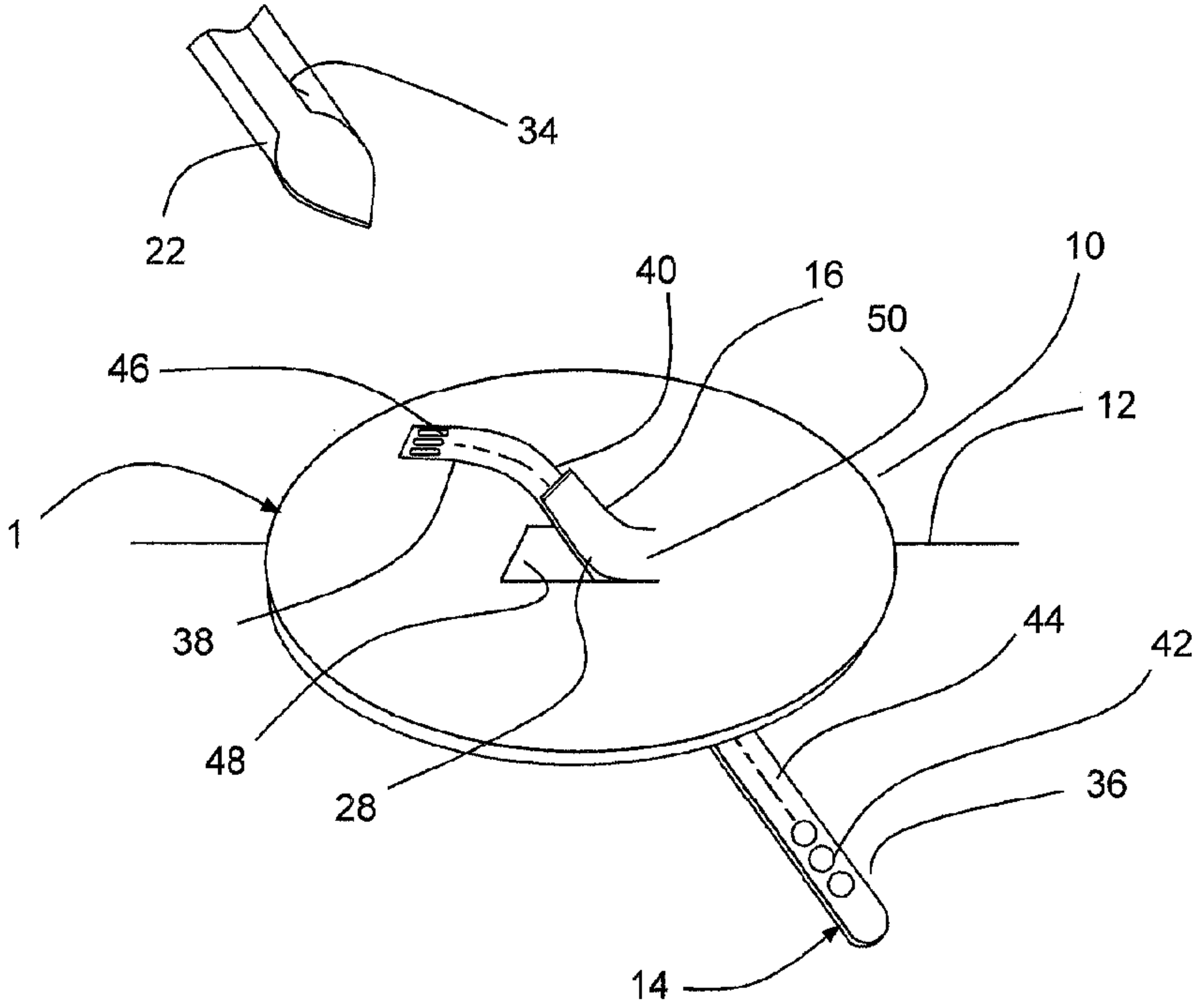


Fig. 7


34
22
40
16
10
50
46
12
1
38
44
42
48
36
28
14