23574/88

606751

FORM 1
REGULATION 9

COMMONWEALTH OF AUSTRALIA

PATENTS ACT 1952-1973

APPLICATION FOR A PATENT

We CRITIKON, INC.

of 4110 George Road, Tampa, FLORIDA 33634, U.S.A.

hereby apply for the grant of a Patent for an invention entitled:

PULSE OXIMETER SENSOR

which is described in the accompanying complete specification. This Application is a Convention Application and is based on the Application(s) numbered: 107,085 for a Patent or similar protection made in U.S.A. on 8 October 1987.

APPLICATION ACCEPTED AND AMENDMENTS ALLOWED 21-11-90

Our address for service is:

GRIFFITH HACK & CO.
71 YORK STREET
SYDNEY N.S.W. 2000
AUSTRALIA

DATED this 7th day of October, 1988.

CRITIKON, INC.
By their Patent Attorneys

GRIFFITH HACK & CO.

TO: THE COMMISSIONER OF PATENTS
COMMONWEALTH OF AUSTRALIA

0889A:rk

CRK102

B — APPLICATION BY ASSIGNEE OF INVENTOR

COMMONWEALTH OF AUSTRALIA
PATENTS ACT 1952

DECLARATION IN SUPPORT OF AN APPLICATION FOR A PATENT

(Name of applicant) In support of an application made by: CRITIKON, INC.

(Title) for a patent for an invention entitled: PULSE OXIMETER SENSOR

(Full name and address of signatory) I, Audley A. Ciamporcero, Jr.
of Critikon, Inc. 4110 George Road, Tampa, FLORIDA 33634 U.S.A.

do solemnly and sincerely declare as follows:

1. I am authorised by the above mentioned applicant for the patent to make this declaration on its behalf.

(Full name and address of inventor(s))

2. The name and address of each actual inventor of the invention is as follows: J.Kie S. Tan; Jeffrey Allan Baker and Daniel A. Jones Of 3208 Rowan Lane, Tampa, FLORIDA 33618 and Route 8, Box 935 Lutz, FLORIDA 33549 and 8008 Dell Drive, Tampa, FLORIDA 33615.

(State whether by assignment or contract of employment)

and the facts upon which the applicant is entitled to make this application are as follows:
"The Applicant is the assignee of the said invention from the actual inventor"

(Delete paragraphs 3 and 4 for non-Convention application)

3. The basic application(s) as defined by Section 141 of the Act was (were) made as follows:
Country USA on October 8, 1987
in the name(s) J.Kie S. Tan; Jeffrey Allan Baker and Daniel A. Jones
and in ..... on .....
in the name(s) .....
and in ..... on .....
in the name(s) .....

4. The basic application(s) referred to in the preceding paragraph was(were) the first application(s) made in a Convention country in respect of the invention the subject of this application.

(Place and date of signing) Declared at New Brunswick this 30th day of September 19 88

Signed: .....
Audley A. Ciamporcero, Jr.
Position: Assistant Secretary

GRIFFITH HASSEL & FRAZER
G.P.O. BOX 4164 SYDNEY, AUSTRALIA

(12) PATENT ABRIDGMENT (11) Document No. AU-B-23574/88
(19) AUSTRALIAN PATENT OFFICE (10) Acceptance No. 606751

(54) Title
PULSE OXIMETER SENSOR

International Patent Classification(s)
(51)[4] A61B 005/02

(21) Application No. : 23574/88 (22) Application Date : 07.10.88

(30) Priority Data

(31) Number (32) Date (33) Country
107085 08.10.87 US UNITED STATES OF AMERICA

(43) Publication Date : 13.04.89

(44) Publication Date of Accepted Application : 14.02.91

(71) Applicant(s)
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(56) Prior Art Documents
AU 542021 72272/81 A61B 5/02
US 4380240
EP 127947

(57) Claim

1. An apparatus for sensing light absorption through transillumination of blood perfused flesh by a light source and reception of light from said light source by a light sensor, the apparatus further comprising a wrap for securing said light source and sensor in optical contact with a patient, wherein said wrap comprises a compliant sheet of metallized material which is capable of reflecting body heat and is highly opaque, and means for securing said sheet of the body to a patient.

11. The apparatus of claim 1, wherein the wrap is arranged for securing said light source and sensor in optical contact with a finger, and is formed from a generally T-shaped complient metallized sheet of material which is capable of reflecting body heat and is highly opaque, the stem of the "T" including means for affixing said light source and sensor to said wrap, and the top of the "T" including first securing means, laterally disposed thereon, for seuring the top of the "T" in a folded

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condition around a finger, wherein electrical connections to said light source and light sensor extend in a direction generally parallel to the longitudinal axis of a finger when the wrap is secured to the finger.

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COMMONWEALTH OF AUSTRALIA

PATENTS ACT 1952 Form 10

COMPLETE SPECIFICATION

FOR OFFICE USE

Short Title:

Int. Cl:

Application Number:
Lodged:

Complete Specification–Lodged:
Accepted:
Lapsed:
Published:

Priority:

Related Art:

This document contains the amendments made under Section 49 and is correct for printing.

TO BE COMPLETED BY APPLICANT

Name of Applicant: CRITIKON, INC.

Address of Applicant: 4110 George Road, Tampa, FLORIDA 33634, U.S.A.

Actual Inventor: J. Kie S. Tan; Jeffrey Allan Baker and Daniel A. Jones

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Complete Specification for the invention entitled:

PULSE OXIMETER SENSOR

The following statement is a full description of this invention, including the best method of performing it known to me/us:–

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PULSE OXIMETER SENSOR

This invention relates to medical sensors for detecting physiological functions and, in particular, to an optical sensor for detecting vascular flow in a pulse oximetry system.

Pulse oximetry is a non-invasive medical technique useful for measuring certain vascular conditions. In practice of the technique, light is passed through a portion of a patient's body which contains arterial blood flow. An optical sensor is used to detect the light which has passed through the body, and variations in the detected light at various wavelengths are then used to determine arterial oxygen saturation and/or pulse rates. Oxygen saturation may be calculated using some form of the classical absorption equation known as Beier's Law.

Accurate measurements of these physiological functions are predicated upon optical sensing in the presence of arterial blood flow. Conveniently a finger may serve this purpose, which allows easy access to a body part through which light will readily pass. Local vascular flow in a finger is dependent upon several factors which affect the supply of blood. Blood flow may be affected by centrally mediated vasoconstriction, which must be alleviated by managing the perceived central causes. Peripheral constriction, however, can be induced by local causes. One such cause of local vasoconstriction is low ambient temperature, which is a particular problem for body extremities such as the finger. Low temperature induced vasoconstriction and the resultant decrease in blood supply can strongly affect the sensor's ability to detect the desired signal.

Conventional attempts to alleviate the problem of low temperature vasoconstriction include the use of an integral heater to the sensor and periodic massaging. Heaters must be well regulated to avoid overheating, increase the complexity of the sensor, and can be costly. Periodic massaging can be effective, but usually requires removal of the sensor while the sensor locality is massaged. After some massaging of the locality to stimulate blood flow to it, the sensor is reapplied and measurement resumed. It would be desirable to employ a less complex, passive means for retaining body heat which does not interrupt the measurement process.

In sensors which detect light transmitted through a portion of the body, ambient light sources may interfere with the signal being observed. Because skin tissue is translucent, outside light is easily scattered and transmitted within the tissue toward the optical detector of the sensor. It is desirable to shield the detector from ambient light for a distance of approximately one-half inch around the detector area. A combination of the use of an opaque material and an effective sensor design will contribute significantly to the prevention of ambient light interference.

Accordingly, the present invention provides an apparatus for sensing light absorption through transillumination of blood perfused flesh by a light source and reception of light from said light source by a light sensor, the apparatus further comprising a wrap for securing said light source and sensor in optical contact with a patient, wherein said wrap comprises a compliant sheet of metallized material which is capable of reflecting body heat and is highly opaque, and means for securing said sheet to the body of a patient.

In accordance with the principles of the present invention, a pulse oximeter sensor may be provided which reduces signal loss due to thermal vasoconstriction and ambient light interference. The sensor may include a light emitting diode

(LED) light source and a photodiode for detecting light from the source. The LED and the photodiode are spaced apart on the body-facing side of a sensor wrap which secures the LED and photodiode on the body. The sensor wrap may comprise a metalized film which is laminated to a backing material. The metallized layer is thermally reflective so that it may reflect body heat back to the body, and is opaque so that it may shield the photodiode from ambient light. The metallized layer may also be grounded to shield the sensor's electrical components from electromagnetic interference. The backing material may comprise insulating material such as foam to provide additional comfort and compliance of the wrap. Means are provided for securing the sensor wrap around a body part such as a finger.

In the drawings:

FIGURES 1a-1c illustrate plan and cross-sectional views of a sensor constructed in accordance with the principles of the present invention;

FIGURES 2a-2c illustrate plan and cross-sectional views of a second embodiment of the present invention;

FIGURES 3-6 illustrate use of the sensor of FIGURES 1a-1c; and

FIGURES 7-11 illustrate use of the sensor of FIGURES 2a-2c.

Referring to FIGURES 1a-1c, an oximeter sensor wrap constructed in accordance with the principles of the present invention is shown. FIGURE 1a is a plan view of the outside of a finger wrap, with the outer surface 12 copmprising a sheet of soft, compliant polyvinylchloride (PVC) film material. The wrap has a length (from top to bottom in the drawing) of approximately 4 1/2 inches, and a width (across the top) which varies from 3 to 3.9 inches, depending upon the finger size for which the wrap is designed. On the right inner surface of the wrap is a

means 14 for securing the wrap about the finger of a patient. This means may be an area of contact adhesive, but in the illustrated embodiment of FIGURE 1a the securing means comprises a patch of tricot loop material which is adhesively laminated to the PVC sheet. A suitable tricot loop material is type SJ3491, available from Minnesota Mining and Manufacturing Company of St. Paul , Minnesota, which is affixed with 3M type Y9485 adhesive laminate.

A second securing means 16 is located along the center of the lower extension of the wrap. This securing means 16 may also be a contact adhesive, but in the illustrated embodiment the means 16 comprises a strip of 3M Scotchmate hook material type SJ 3526 which is adhesively laminated to the wrap. The hook material is designed to mate with the tricot loop material in a secure but releasable engagement as discussed below in conjunction with FIGURES 3-6. The hook and loop securing means is preferred over adhesive securing means because it permits repeated use of the wrap.

The inner, or finger facing side of the wrap is shown in FIGURE 1b. The inner surface 18 of the wrap comprises a sheet of metallized polyester film material, which is described more fully below. Securing means 20 and 22 are located on the inner surface 18 and may comprise contact adhesive. Preferably, the means 20 comprises a patch of the tricot loop material described above, and the means 22 comprises a patch of the hook material. Running along the stem of the T-shaped wrap and extending upward to approximately the center of the top of the "T" is an area 24 of the type Y9485 adhesive. A cross-hatched ink pattern 28 is printed beneath the adhesive and is visible through the adhesive. This pattern indicates to the user

the area in which the LED strip of the sensor is to be placed, as discussed below. To protect the adhesive area 24 from unintended adhesion and contamination prior to use, the adhesive area 24 is covered with a release strip 26 of silicone coated kraft paper.

Referring to FIGURE 1c, a cross-sectional view of the layers comprising the wrap of FIGURES 1a and 1b is shown. The PVC layer 12 which comprises the outer surface of the wrap has a thickness of approximately 13 mils, and the PVC film is reinforced with polyester fibers. This compliant layer 12 is fairly opaque to shade the photodiode in the LED strip from ambient light. The release strip 26 is shown covering the adhesive area 24, which overlies the cross-hatched ink pattern 28. In accordance with the principles of the present invention, the inner surface of the wrap comprises a layer 18 of 1 mil aluminum metallized polyester film. The metallized film is available from Tapemark Co. of W. St. Paul, Minnesota. The resistance of the metallization corresponds directly to the thickness of the metallization on the film and in the illustrated embodiment the metallization has a resistance of less than two ohms per square. This metallization provides the film with an opacity of better than 95%. The metallized surface of the film has a soft matte finish which is non-glaring. The metallized film layer 18 is laminated to the PVC layer 12 with the type Y9485 adhesive as shown by adhesive layer 32. The metallized film provides the sensor with the desired degree of protection from ambient light interference, as well as high thermal protection for the finger. It has been found that approximately 70-80% of body heat loss is through radiation. The metallized inner surface of the wrap is effective for reflecting a substantial portion of this radiated heat back to the finger, thereby aiding in the

reduction of thermal vasoconstriction. The combined opacity and reflective properties of the metallized layer help maintain the conditons needed for good signal reception by the sensor.

If desired, the metallized layer may be electrically grounded to a connection from the LED strip to help shield the electronic components in the LED strip from electromagnetic interference.

In use, the release strip 26 is peeled away to uncover the adhesive area 24 for the LED strip. The LED strip 30 is then affixed to the adhesive area as shown in FIGURE 3. The LED strip 30 is made of a rubber-like material of a medical grade, such as silicone rubber, polyurethane, or PVC. The upper surface of the strip 30 has a window for LED's 34 and a second window for a photodiode 36. Between the two is a shallow depression 38 which allows the LED strip 30 to be folded over the fingertip. Wiring inside the strip 30 connects the LEDs and photodiode to a cable at the end of the strip, either through discrete wires or flexible printed wiring. The rubber-like LED strip may be molded around the electronic components, or may be formed in two halves which are then laminated together. The rubber-like strip is waterproof so that the strip may be washed between uses.

After the fingertip is placed on the photodiode 36 as shown in FIGURE 3, the stem of the T-shaped wrap with the attached LED strip is folded over the top of the finger as shown in FIGURE 4. Then the left side of the wrap is folded over the stem of the "T" so that the tricot loop patch 20 is secured to the hook material 16. This step is shown in FIGURE 5. Finally, the right side of the wrap is folded over the finger so that the patch 22 of hook

material fastens to the tricot loop patch 14, as shown in FIGURE 6. The sensor is thus securely wrapped around the finger, with the finger surrounded by the metallized film layer 18.

After the measurement process is finished, the sensor is unwrapped and the LED strip may be removed from the adhesive area 24 for washing and reuse in another procedure. The hook and loop securing means permit the sensor to be easily unwrapped and resecured if it is desirable to do so during a measurement procedure.

Referring to FIGURES 2a-2c, a disposable wrap for an oximeter sensor is shown. FIGURE 2a shows the outer surface of the wrap, which comprises a layer 40 of 1 mil metallized polyester film. The wrap is approximately 5 inches long and 2 inches wide, and is narrowed in the central region where the wrap folds around the fingertip. Located on the back, or finger-facing side of the wrap is a sheet of release paper 42, shown in the back view of FIGURE 2b. The back of the wrap comprises a sheet 44 of medical grade foam, which is coated with Semex type TT4025 adhesive. The release paper 42 covers the adhesive surface prior to use. A central longitudinal region 46 of the release paper is perforated, allowing this region of the wrap to be uncovered first. The LED strip 30 is then affixed to this initially uncovered adhesive region. Once the LED strip is attached to the wrap, the remaining release paper is peeled away to enable the sensor to be secured to a finger.

A cross-sectional view of the wrap of FIGURES 2a and 2b is shown in FIGURE 2c. The release paper 42 is seen overlying the adhesive coating 49 on the foam layer 44. The preferred foam layer is approximately 30 mils thick,

and is available from Semex Medical Company of Malvern, Pennsylvania as type KM-1422. The foam layer 44 is conformable to the finger of the patient and provides a degree of comfort during use. The matte finished aluminum metallized polyester film layer 40 is laminated to the foam layer by an adhesive 47.

In the FIGURE 2a-2c embodiment, the use of the metallized film as the outer layer provides the same opacity and heat reflective properties as the embodiment of FIGURES 1a-1c. If desired, the foam and metallized film layers could be exchanged so that the metallized film layers directly opposes the finger and the foam is on the outside.

Use of the wrap of FIGURES 2a-2c is depicted in FIGURES 7-11. In FIGURE 7 the LED strip 30 is shown affixed to the central longitudinal region of the wrap after the center strip 46 of the release paper has been removed. The remaining release paper is then peeled away as shown in FIGURE 7. Next, the fingertip is placed over the photodiode 36, as shown in FIGURE 8. The wrap and LED strip are folded over the fingertip as shown in FIGURE 9. The areas of the wrap on either side of the LED strip are folded down about the finger as shown in FIGURE 10. Finally, the lower sides of the wrap are folded up over the outer surface of the wrap, as shown in FIGURE 11, so that the adhesive coating 49 seals the overwrapped sides together. Removal of the sensor will generally impair the adhesive or tear the foam, so the wrap is then removed from the LED strip and disposed of when the measurement procedure is complete.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. An apparatus for sensing light absorption through transillumination of blood perfused flesh by a light source and reception of light from said light source by a light sensor, the apparatus further comprising a wrap for securing said light source and sensor in optical contact with a patient, wherein said wrap comprises a compliant sheet of metallized material which is capable of reflecting body heat and is highly opaque, and means for securing said sheet of the body to a patient.

2. The apparatus of claim 1, further comprising means for securing said light source and said light sensor to said wrap.

3. The apparatus of claim 1, wherein said wrap comprises an inner, body-facing layer of said sheet of metallized material, and an outer layer of fabric.

4. The apparatus of claim 3, wherein said outer fabric layer comprises a layer of polyvinylchloride laminated to said sheet of metallized material.

5. The apparatus of claim 4, wherein said securing means comprises mating pieces of hook material and loop material.

6. The apparatus of claim 1, wherein said wrap comprises an inner, body-facing layer of foam, an an outer layer comprising said sheet of metallized material.

7. The apparatus of claim 6, wherein said foam layer is laminated to said metallized material.

8. The apparatus of claim 7, wherein said securing means comprises pressure sensitive adhesive.

9. The apparatus of claim 8, wherein said pressure sensitive adhesive is covered with release paper prior to use.

10. The apparatus of claim 1, wherein said sheet of metallized material comprises aluminum metalized polyester film.

11. The apparatus of claim 1, wherein the wrap is arranged for securing said light source and sensor in optical contact with a finger, and is formed from a generally T-shaped complient metallized sheet of material which is capable of reflecting body heat and is highly opaque, the stem of the "T" including means for affixing said light source and sensor to said wrap, and the top of the "T" including first securing means, laterally disposed thereon, for seuring the top of the "T" in a folded condition around a finger, wherein electrical connections to said light source and light sensor extend in a direction generally parallel to the longitudinal axis of a finger when the wrap is secured to the finger.

12. The apparatus of claim 11 further comprising second securing means, located on the stem of the "T", for securing the stem of the "T" in a folded condition to the top of the "T".

13. The apparatus of claim 12, wherein said affixing means comprises an adhesive area.

14. The apparatus of claim 13, wherein said first and second securing means comprise mating pieces of hook material and loop material.

15. A pulse oximeter sensor including a wrap substantially as herein described with reference to FIGURES 1a-1c or FIGURES 2a-2c of the accompanying drawings.

DATED this 12th day of November 1990

CRITIKON, INC.
By Their Patent Attorney
GRIFFITH HACK & CO.

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FIG-1a

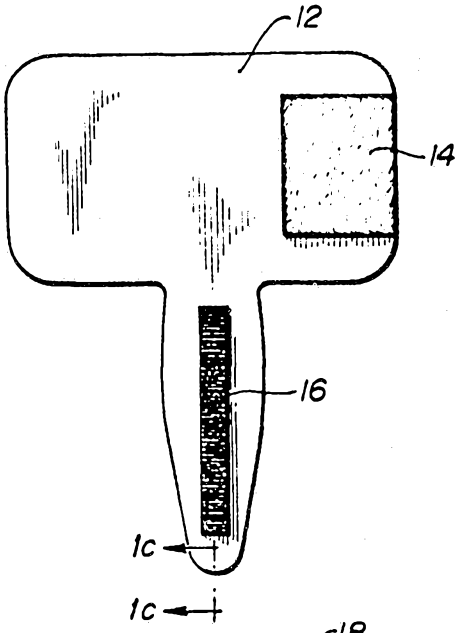

FIG-1b

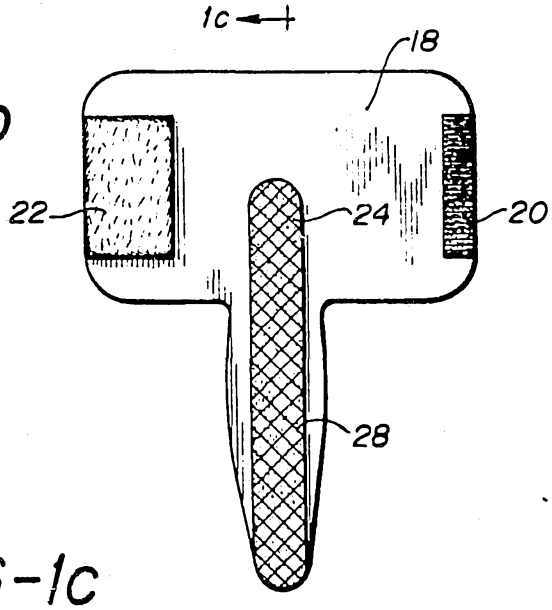

FIG-1c

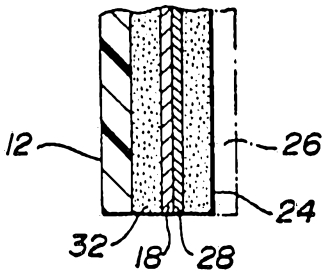

FIG-2a

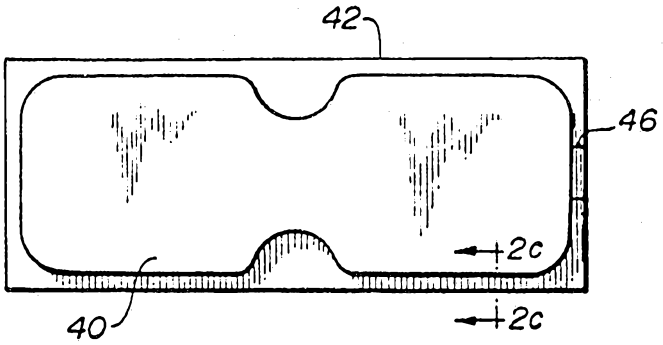

FIG-2b

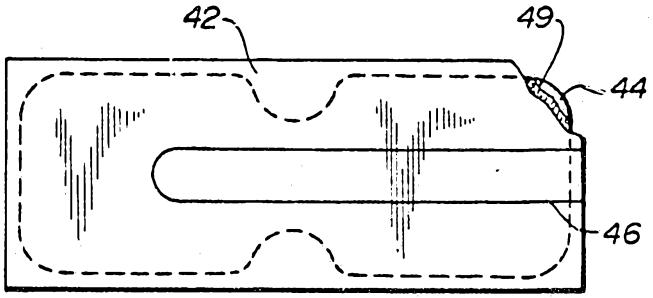

FIG-2c

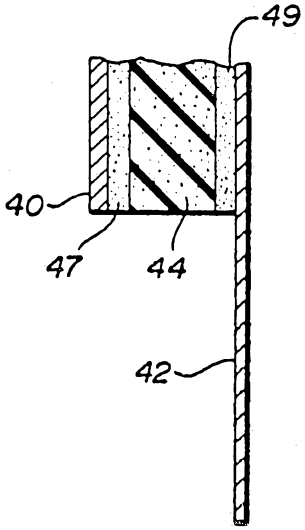

FIG-3

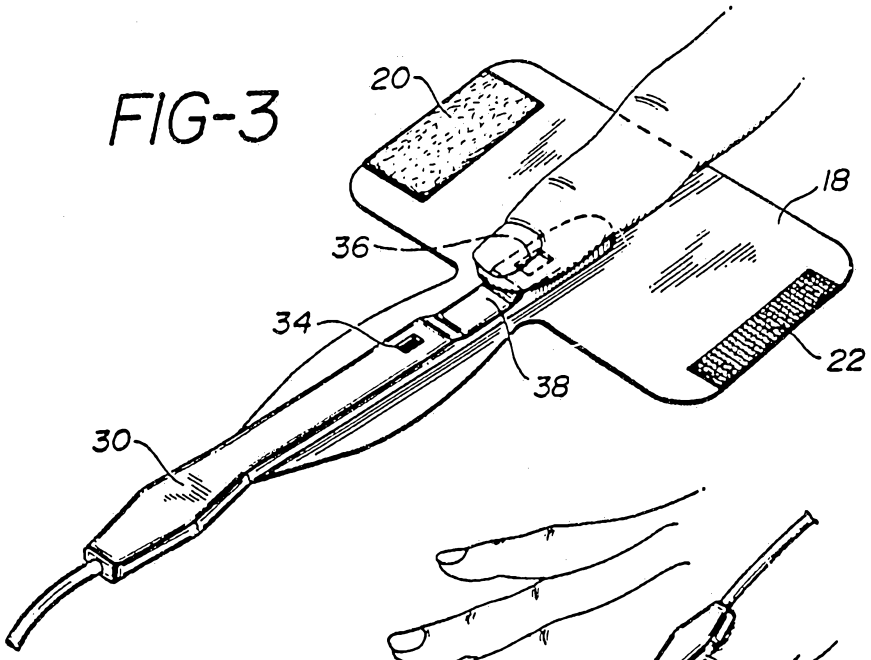

FIG-4

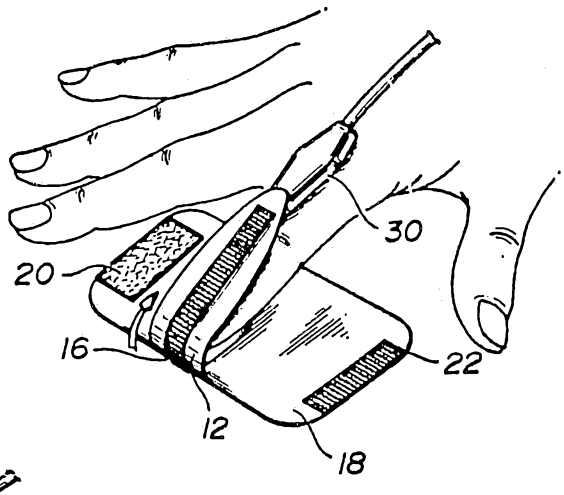

FIG-5

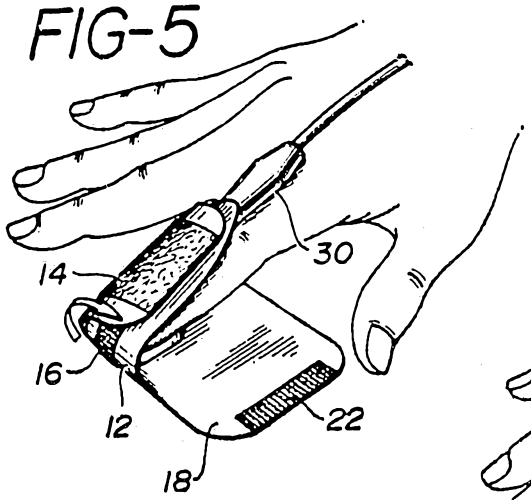

FIG-6

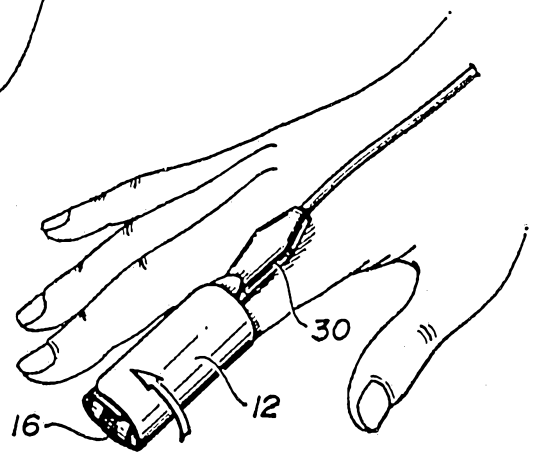

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FIG-7

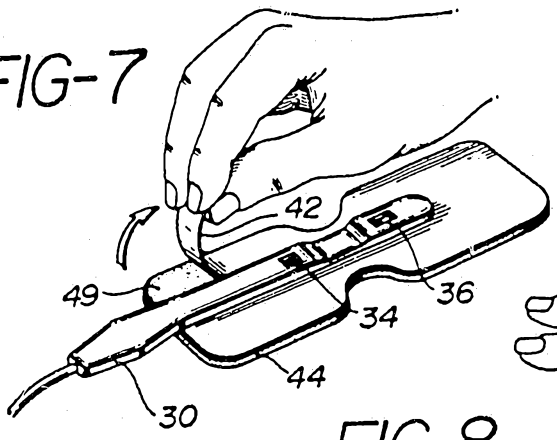

FIG-8

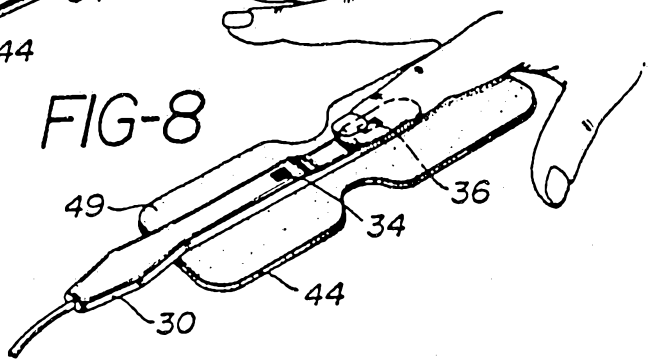

FIG-9

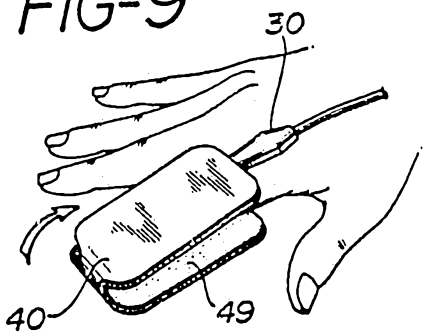

FIG-10

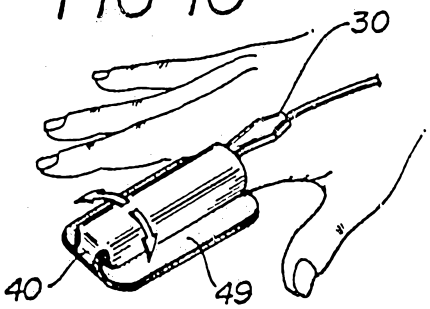

FIG-11