



US00RE41317E

(19) **United States**
(12) **Reissued Patent**
Parker

(10) **Patent Number:** **US RE41,317 E**
(45) **Date of Reissued Patent:** ***May 4, 2010**

(54) **UNIVERSAL MODULAR PULSE OXIMETER
PROBE FOR USE WITH REUSABLE AND
DISPOSABLE PATIENT ATTACHMENT
DEVICES**

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(*) Notice: This patent is subject to a terminal disclaimer.

3,647,299 A	3/1972	Lavallee
3,740,570 A	6/1973	Kaelin et al.
3,799,672 A	3/1974	Vurek
4,086,915 A	5/1978	Kofsky et al.
4,169,976 A	10/1979	Cirri
4,182,977 A	1/1980	Stricklin, Jr.
4,308,456 A	12/1981	van der Gaag et al.
4,346,590 A	8/1982	Brown
4,407,290 A	10/1983	Wilber
4,449,821 A	5/1984	Lee

(Continued)

(21) Appl. No.: **11/404,123**

(22) Filed: **Apr. 13, 2006**

Related U.S. Patent Documents

Reissue of:

(64) Patent No.: **6,721,585**
Issued: **Apr. 13, 2004**
Appl. No.: **09/931,273**
Filed: **Aug. 17, 2001**

U.S. Applications:

(63) Continuation-in-part of application No. 09/417,898, filed on Oct. 14, 1999, now Pat. No. 6,343,224, which is a continuation-in-part of application No. 09/289,647, filed on Apr. 12, 1999, now Pat. No. 6,144,868, said application No. 09/931,273, is a continuation-in-part of application No. 09/758,038, filed on Jan. 11, 2001, now Pat. No. 6,684,091, and a continuation-in-part of application No. 09/679,828, filed on Oct. 5, 2000, now Pat. No. 6,519,487, and a continuation-in-part of application No. 09/352,144, filed on Jul. 13, 1999, now Pat. No. 6,321,100.

(60) Provisional application No. 60/104,332, filed on Oct. 15, 1998.

(51) **Int. Cl.**
A61B 5/1455 (2006.01)

(52) **U.S. Cl.** **600/344; 600/310**

(58) **Field of Classification Search** **600/310,**
600/322, 323, 340, 344
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,463,142 A 8/1969 Harte et al.

FOREIGN PATENT DOCUMENTS

AU	745306	5/2000
CA	2 346 639	4/2000
CA	2 366 493	11/2002
EP	019 478	11/1980
EP	0 745 348	12/1996
EP	1 222 894	7/2002
JP	5275746	10/1993
WO	WO 88/10462	12/1988
WO	WO 99/53831	10/1999
WO	WO 00/21433	4/2000
WO	WO 00/42911	7/2000
WO	WO 01/03574	1/2001

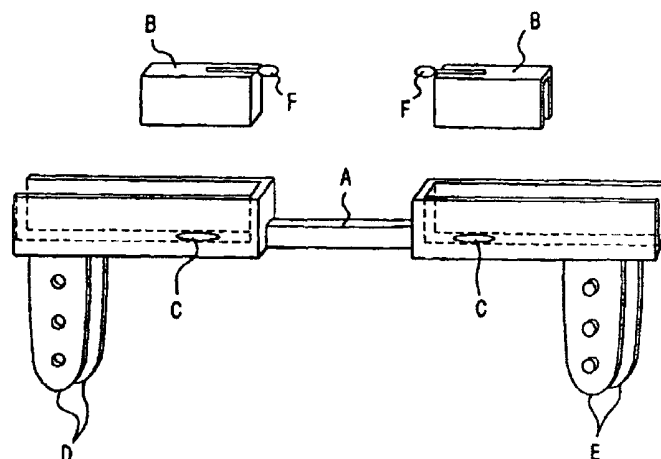
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(57) **ABSTRACT**

[A system and method of standardizing modular probe housings so that the standardized probe housings may be incorporated into probes adapted to work with at least one of a multiplicity of manufacturers' oximeters. The probe housings are adapted to matingly engage at least a disposable bandage apparatus and a reusable finger attachment device.]
A pulse oximeter system comprises a finger attachment device having first and second probe couplers, the first and second probe couplers are configured to be matingly engageable with probe housings of a pulse oximeter probe.

32 Claims, 22 Drawing Sheets



U.S. PATENT DOCUMENTS				
4,480,886 A	11/1984	Bergamin	5,782,757 A	7/1998 Diab et al.
4,580,867 A	4/1986	Wright et al.	5,785,659 A	7/1998 Caro et al.
4,621,643 A	11/1986	New, Jr. et al.	5,786,592 A	7/1998 Hök
4,653,498 A	3/1987	New, Jr. et al.	5,791,347 A	8/1998 Flaherty et al.
4,685,464 A	8/1987	Goldberger et al.	5,810,734 A	9/1998 Caro et al.
4,700,708 A	10/1987	New, Jr. et al.	5,817,008 A	10/1998 Rafert et al.
4,770,179 A	9/1988	New, Jr. et al.	5,817,010 A	10/1998 Hibl
4,830,014 A	5/1989	Goodman et al.	5,823,950 A	10/1998 Diab et al.
4,848,901 A	7/1989	Hood, Jr.	5,830,131 A	11/1998 Caro et al.
4,865,038 A	9/1989	Rich et al.	5,833,618 A	11/1998 Caro et al.
4,877,322 A	10/1989	Hill	RE36,000 E	12/1998 Swedlow et al.
4,913,150 A	4/1990	Cheung et al.	5,860,919 A	1/1999 Kiani-Azarbayjany et al.
4,942,877 A	7/1990	Sakai et al.	5,879,373 A	3/1999 Roper et al.
4,960,128 A	10/1990	Gordon et al.	5,890,929 A	4/1999 Mills et al.
4,964,408 A	10/1990	Hink et al.	5,904,654 A	5/1999 Wohltmann et al.
5,041,187 A	8/1991	Hink et al.	5,910,108 A	6/1999 Solenberger
5,058,588 A	10/1991	Kaestle	5,919,133 A	7/1999 Taylor et al.
5,069,213 A	12/1991	Polczynski	5,919,134 A	7/1999 Diab
5,090,410 A	2/1992	Saper et al.	5,934,925 A	8/1999 Tobler et al.
5,094,240 A	3/1992	Muz	5,940,182 A	8/1999 Lepper, Jr. et al.
5,113,862 A	5/1992	Mortazavi	5,991,648 A	11/1999 Levin
5,140,228 A	8/1992	Biegel	5,995,855 A	11/1999 Kiani et al.
5,158,323 A	10/1992	Yamamoto et al.	5,997,343 A	12/1999 Mills et al.
5,163,438 A	11/1992	Gordon et al.	5,999,834 A	12/1999 Wang et al.
5,170,786 A	12/1992	Thomas et al.	6,002,952 A	12/1999 Diab et al.
5,209,230 A	5/1993	Swedlow et al.	6,011,986 A	1/2000 Diab et al.
5,246,003 A	9/1993	DeLonzor	6,014,576 A	1/2000 Raley
5,249,576 A	10/1993	Goldberger et al.	6,027,452 A	2/2000 Flaherty et al.
5,267,562 A	12/1993	Ukawa et al.	6,036,642 A	3/2000 Diab et al.
5,287,853 A	2/1994	Vester et al.	6,045,509 A	4/2000 Caro et al.
5,308,919 A	5/1994	Minnich	6,061,584 A	5/2000 Lovejoy et al.
5,337,744 A	8/1994	Branigan	6,067,462 A	5/2000 Diab et al.
5,341,805 A	8/1994	Stavridi et al.	6,081,735 A	6/2000 Diab et al.
D353,195 S	12/1994	Savage et al.	6,088,607 A	7/2000 Diab et al.
D353,196 S	12/1994	Savage et al.	6,110,522 A	8/2000 Lepper, Jr. et al.
5,377,676 A	1/1995	Vari et al.	6,124,597 A	9/2000 Shehada
5,387,122 A	2/1995	Goldberger et al.	6,144,868 A	11/2000 Parker
5,397,247 A	3/1995	Aoki et al.	6,151,516 A	11/2000 Kiani-Azarbayjany et al.
D359,546 S	6/1995	Savage et al.	6,152,754 A	11/2000 Gerhardt et al.
5,431,170 A	7/1995	Mathews	6,157,850 A	12/2000 Diab et al.
D361,840 S	8/1995	Savage et al.	6,165,005 A	12/2000 Mills et al.
5,437,275 A	8/1995	Amundsen et al.	6,184,521 B1	2/2001 Coffin, IV et al.
D362,063 S	9/1995	Savage et al.	6,206,830 B1	3/2001 Diab et al.
5,452,717 A	9/1995	Branigan et al.	6,229,856 B1	5/2001 Diab et al.
D363,120 S	10/1995	Savage et al.	6,232,609 B1	5/2001 Snyder et al.
5,456,252 A	10/1995	Vari et al.	6,236,872 B1	5/2001 Diab et al.
5,482,036 A	1/1996	Diab et al.	6,256,523 B1	7/2001 Diab et al.
5,490,505 A	2/1996	Diab et al.	6,263,222 B1	7/2001 Diab et al.
5,494,043 A	2/1996	O'Sullivan et al.	6,278,522 B1	8/2001 Lepper, Jr. et al.
5,507,286 A	4/1996	Solenberger	6,280,213 B1	8/2001 Tobler et al.
5,515,169 A	5/1996	Cargill et al.	6,285,896 B1	9/2001 Tobler et al.
5,533,511 A	7/1996	Kaspari et al.	6,308,089 B1	10/2001 von der Ruhr et al.
5,561,275 A	10/1996	Savage et al.	6,321,000 B1	11/2001 King
5,590,649 A	1/1997	Caro et al.	6,321,100 B1	11/2001 Parker
5,602,924 A	2/1997	Durand et al.	6,334,065 B1	12/2001 Al-Ali et al.
5,619,992 A	4/1997	Guthrie et al.	6,343,224 B1	1/2002 Parker
5,632,272 A	5/1997	Diab et al.	6,349,228 B1	2/2002 Kiani et al.
5,638,816 A	6/1997	Kiani-Azarbayjany et al.	6,360,114 B1	3/2002 Diab et al.
5,638,818 A	6/1997	Diab et al.	6,368,283 B1	4/2002 Xu et al.
5,645,440 A	7/1997	Tobler et al.	6,371,921 B1	4/2002 Caro et al.
5,660,567 A	8/1997	Nierlich et al.	6,377,829 B1	4/2002 Al-Ali
5,664,270 A	9/1997	Bell et al.	6,381,489 B1	4/2002 Ashibe
5,673,693 A	10/1997	Solenberger	6,388,240 B2	5/2002 Schulz et al.
5,678,544 A	10/1997	DeLonzor et al.	6,397,091 B2	5/2002 Diab et al.
5,685,299 A	11/1997	Diab et al.	6,430,525 B1	8/2002 Weber et al.
D393,830 S	4/1998	Tobler et al.	6,463,311 B1	10/2002 Diab
5,743,262 A	4/1998	Lepper, Jr. et al.	6,470,199 B1	10/2002 Kopotic et al.
5,758,644 A	6/1998	Diab et al.	6,501,975 B2	12/2002 Diab et al.
5,760,910 A	6/1998	Lepper, Jr. et al.	6,505,059 B1	1/2003 Kollias et al.
5,769,785 A	6/1998	Diab et al.	6,515,273 B2	2/2003 Al-Ali
			6,519,487 B1	2/2003 Parker

US RE41,317 E

Page 3

6,525,386	B1	2/2003	Mills et al.	6,979,812	B2	12/2005	Al-Ali
6,526,300	B1	2/2003	Kiani et al.	6,985,764	B2	1/2006	Mason et al.
6,541,756	B2	4/2003	Schulz et al.	6,993,371	B2	1/2006	Kiani et al.
6,542,764	B1	4/2003	Al-Ali et al.	6,996,427	B2	2/2006	Ali et al.
6,580,086	B1	6/2003	Schulz et al.	6,999,904	B2	2/2006	Weber et al.
6,584,336	B1	6/2003	Ali et al.	7,003,338	B2	2/2006	Weber et al.
6,595,316	B2	7/2003	Cybulski et al.	7,003,339	B2	2/2006	Diab et al.
6,597,932	B2	7/2003	Tian et al.	7,015,451	B2	3/2006	Dalke et al.
6,597,933	B2	7/2003	Kiani et al.	7,024,233	B2	4/2006	Ali et al.
6,606,511	B1	8/2003	Ali et al.	7,027,849	B2	4/2006	Al-Ali
6,632,181	B2	10/2003	Flaherty et al.	7,030,749	B2	4/2006	Al-Ali
6,639,668	B1	10/2003	Trepagnier	7,039,449	B2	5/2006	Al-Ali
6,640,116	B2	10/2003	Diab	7,041,060	B2	5/2006	Flaherty et al.
6,643,530	B2	11/2003	Diab et al.	7,044,918	B2	5/2006	Diab
6,650,917	B2	11/2003	Diab et al.	7,067,893	B2	6/2006	Mills et al.
6,654,624	B2	11/2003	Diab et al.	7,096,052	B2	8/2006	Mason et al.
6,658,276	B2	12/2003	Kiaul et al.	7,096,054	B2	8/2006	Abdul-Hafiz et al.
6,661,161	B1	12/2003	Lanzo et al.	7,132,641	B2	11/2006	Schulz et al.
6,671,531	B2	12/2003	Al-Ali et al.	7,142,901	B2	11/2006	Kiani et al.
6,678,543	B2	1/2004	Diab et al.	7,149,561	B2	12/2006	Diab
6,684,090	B2	1/2004	Ali et al.	7,186,966	B2	3/2007	Al-Ali
6,684,091	B2	1/2004	Parker	7,190,261	B2	3/2007	Al-Ali
6,697,656	B1	2/2004	Al-Ali	7,215,984	B2	5/2007	Diab
6,697,657	B1	2/2004	Shehada et al.	7,215,986	B2	5/2007	Diab
6,697,658	B2	2/2004	Al-Ali	7,221,971	B2	5/2007	Diab
RE38,476	E	3/2004	Diab et al.	7,225,006	B2	5/2007	Al-Ali et al.
6,699,194	B1	3/2004	Diab et al.	7,225,007	B2	5/2007	Al-Ali
6,714,804	B2	3/2004	Al-Ali et al.	RE39,672	E	6/2007	Shehada et al.
RE38,492	E	4/2004	Diab et al.	7,239,905	B2	7/2007	Kiani-Azarbayjany et al.
6,721,582	B2	4/2004	Trepagnier et al.	7,245,953	B1	7/2007	Parker
6,721,585	B1	4/2004	Parker	7,254,431	B2	8/2007	Al-Ali
6,725,075	B2	4/2004	Al-Ali	7,254,433	B2	8/2007	Diab et al.
6,728,560	B2	4/2004	Kollias et al.	7,254,434	B2	8/2007	Schulz et al.
6,735,459	B2	5/2004	Parker	7,272,425	B2	9/2007	Al-Ali
6,745,060	B2	6/2004	Diab et al.	7,274,955	B2	9/2007	Kiani et al.
6,760,607	B2	7/2004	Al-Ali	D554,263	S	10/2007	Al-Ali
6,770,028	B1	8/2004	Ali et al.	7,280,858	B2	10/2007	Al-Ali et al.
6,771,994	B2	8/2004	Kiani et al.	7,289,835	B2	10/2007	Mansfield et al.
6,792,300	B1	9/2004	Diab et al.	7,292,883	B2	11/2007	De Felice et al.
6,813,511	B2	11/2004	Diab et al.	7,295,866	B2	11/2007	Al-Ali
6,816,741	B2	11/2004	Diab	7,328,053	B1	2/2008	Diab et al.
6,822,564	B2	11/2004	Al-Ali	7,332,784	B2	2/2008	Mills et al.
6,826,419	B2	11/2004	Diab et al.	7,340,287	B2	3/2008	Mason et al.
6,830,711	B2	12/2004	Mills et al.	7,341,559	B2	3/2008	Schulz et al.
6,850,787	B2	2/2005	Weber et al.	7,343,186	B2	3/2008	Lamego et al.
6,850,788	B2	2/2005	Al-Ali	D566,282	S	4/2008	Al-Ali et al.
6,852,083	B2	2/2005	Caro et al.	7,355,512	B1	4/2008	Al-Ali
6,861,639	B2	3/2005	Al-Ali	7,371,981	B2	5/2008	Abdul-Hafiz
6,898,452	B2	5/2005	Al-Ali et al.	7,373,193	B2	5/2008	Al-Ali et al.
6,920,345	B2	7/2005	Al-Ali et al.	7,373,194	B2	5/2008	Weber et al.
6,931,268	B1	8/2005	Kiani-Azarbayjany et al.	7,376,453	B1	5/2008	Diab et al.
6,934,570	B2	8/2005	Kiani et al.	7,377,794	B2	5/2008	Al-Ali et al.
6,939,305	B2	9/2005	Flaherty et al.	7,377,899	B2	5/2008	Weber et al.
6,943,348	B1	9/2005	Coffin, IV	7,383,070	B2	6/2008	Diab et al.
6,950,687	B2	9/2005	Al-Ali	2004/0147824	A1	7/2004	Diab et al.
6,961,598	B2	11/2005	Diab	2005/0245797	A1	11/2005	Al-Ali et al.
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FIGURE 1

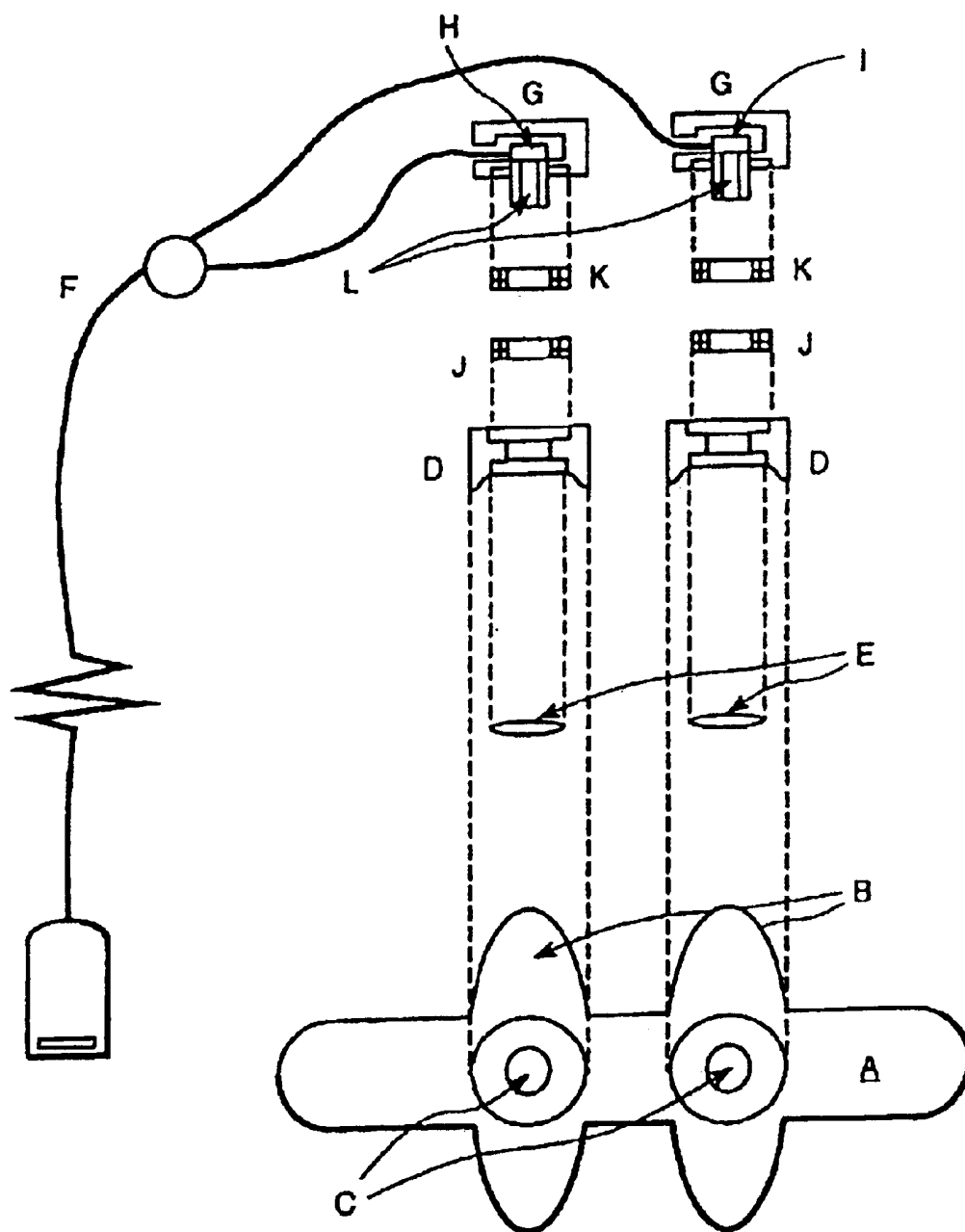


FIGURE 2

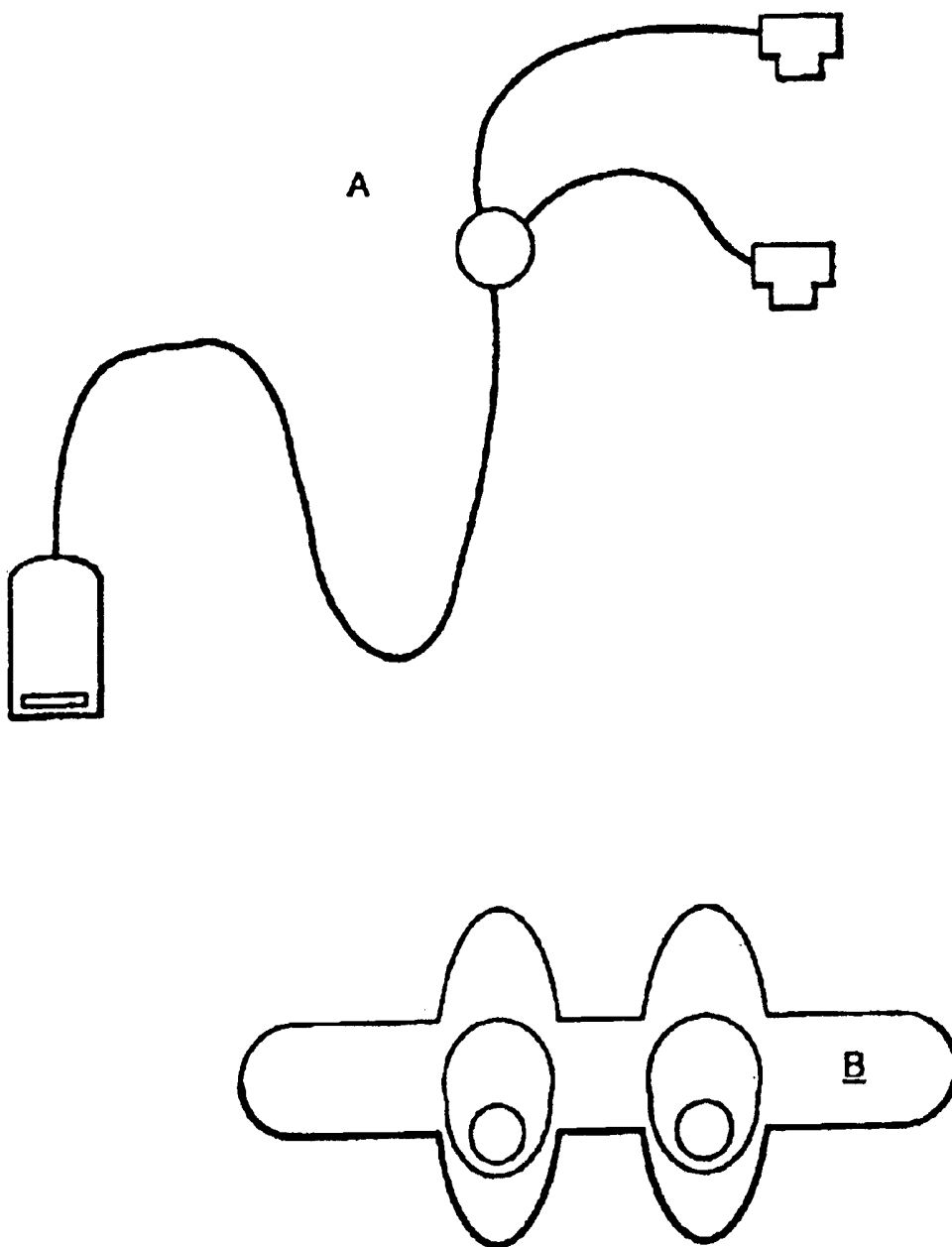


FIGURE 3

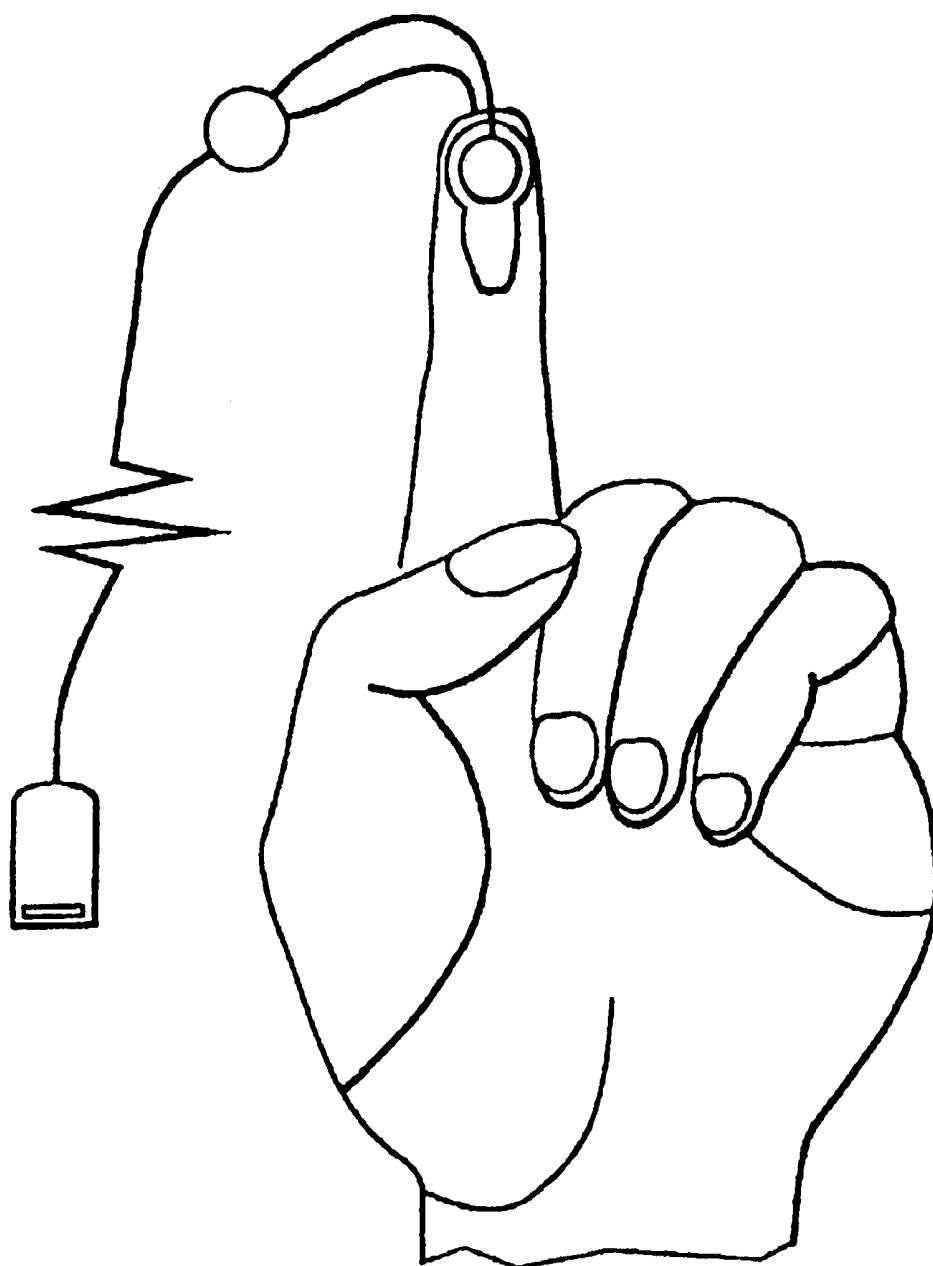


FIGURE 4

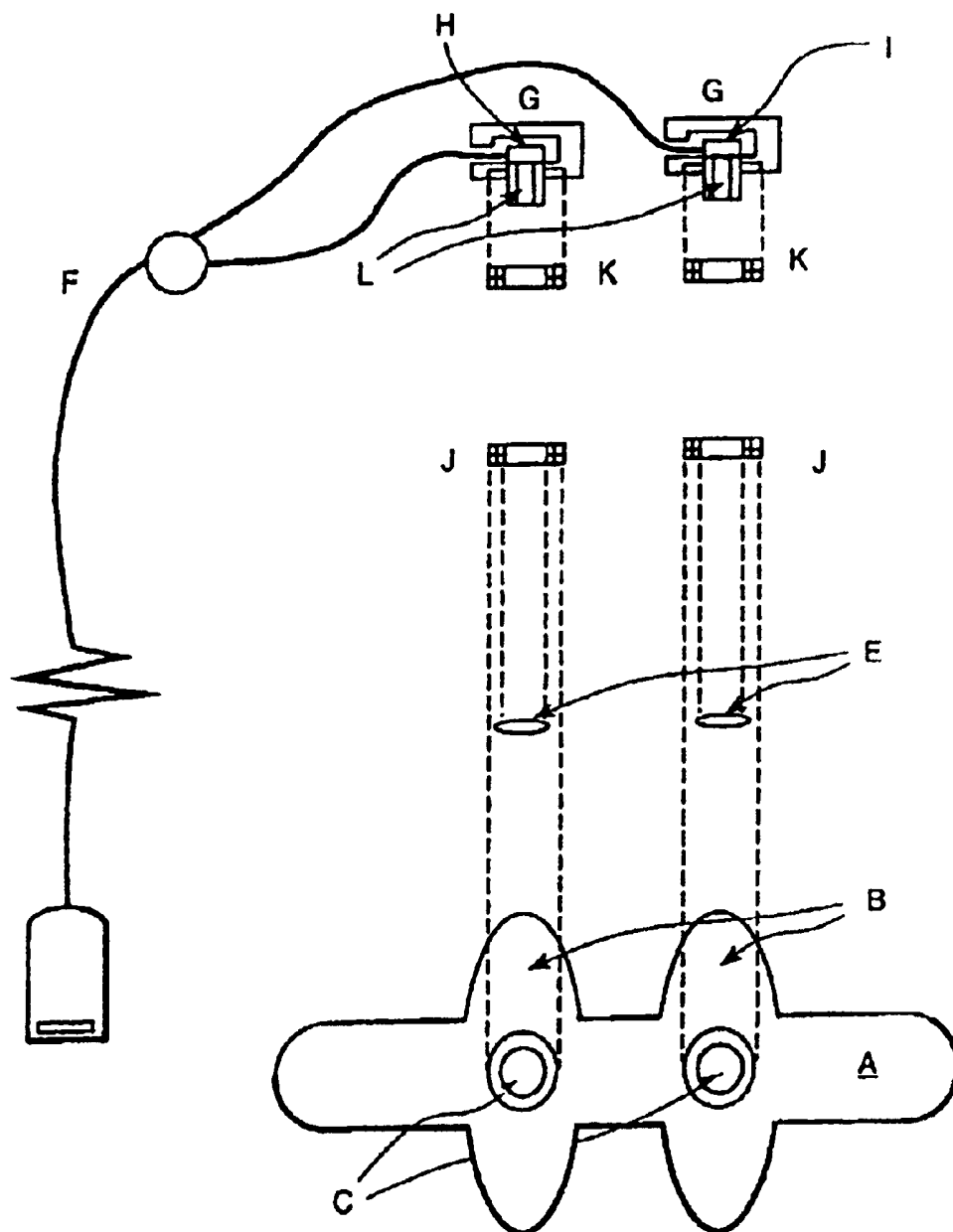


FIGURE 5

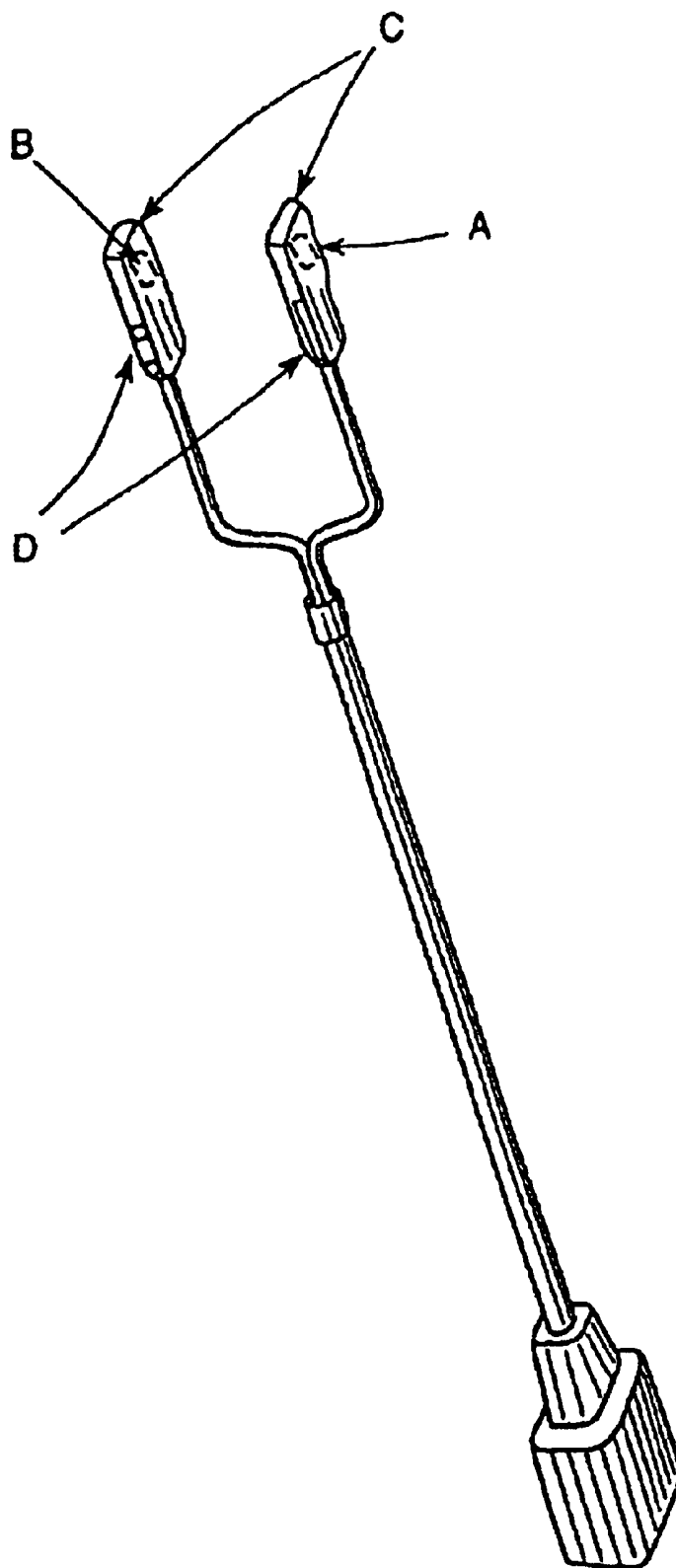


FIGURE 6

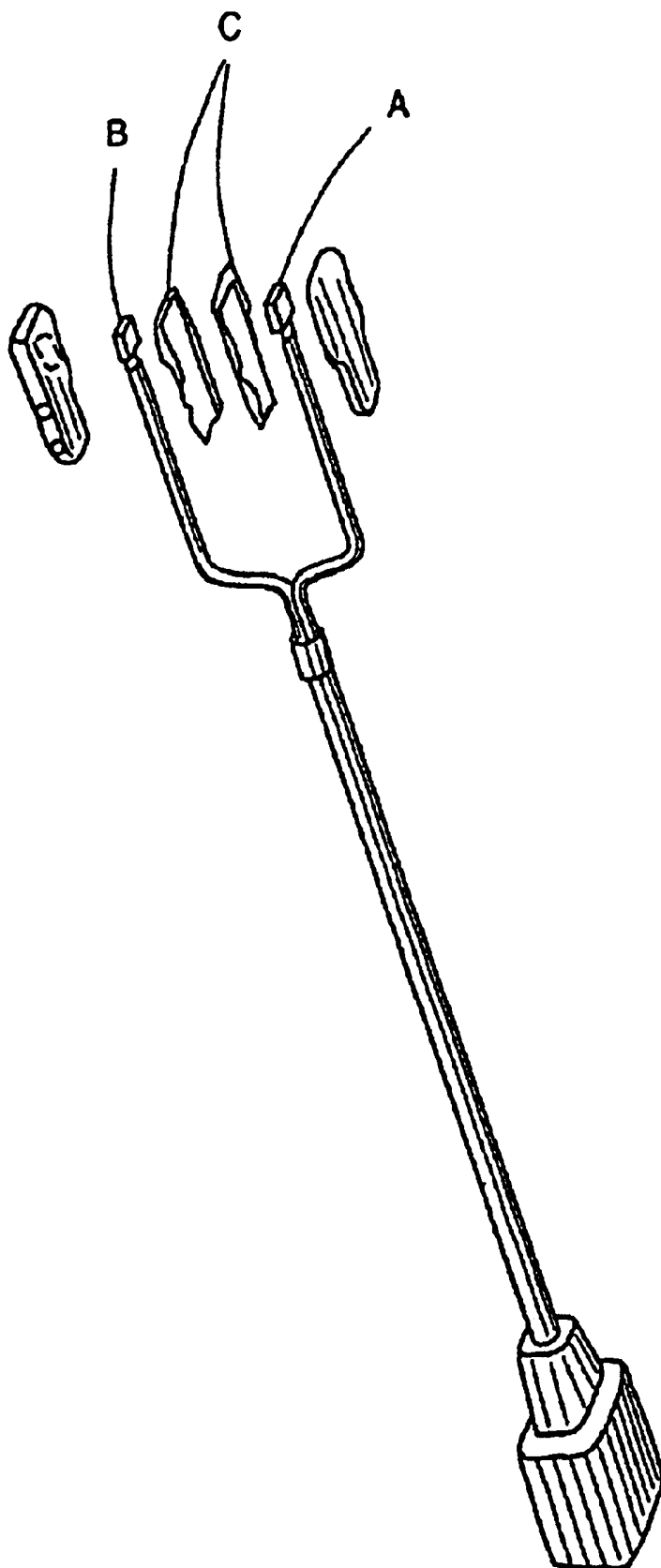


FIGURE 7

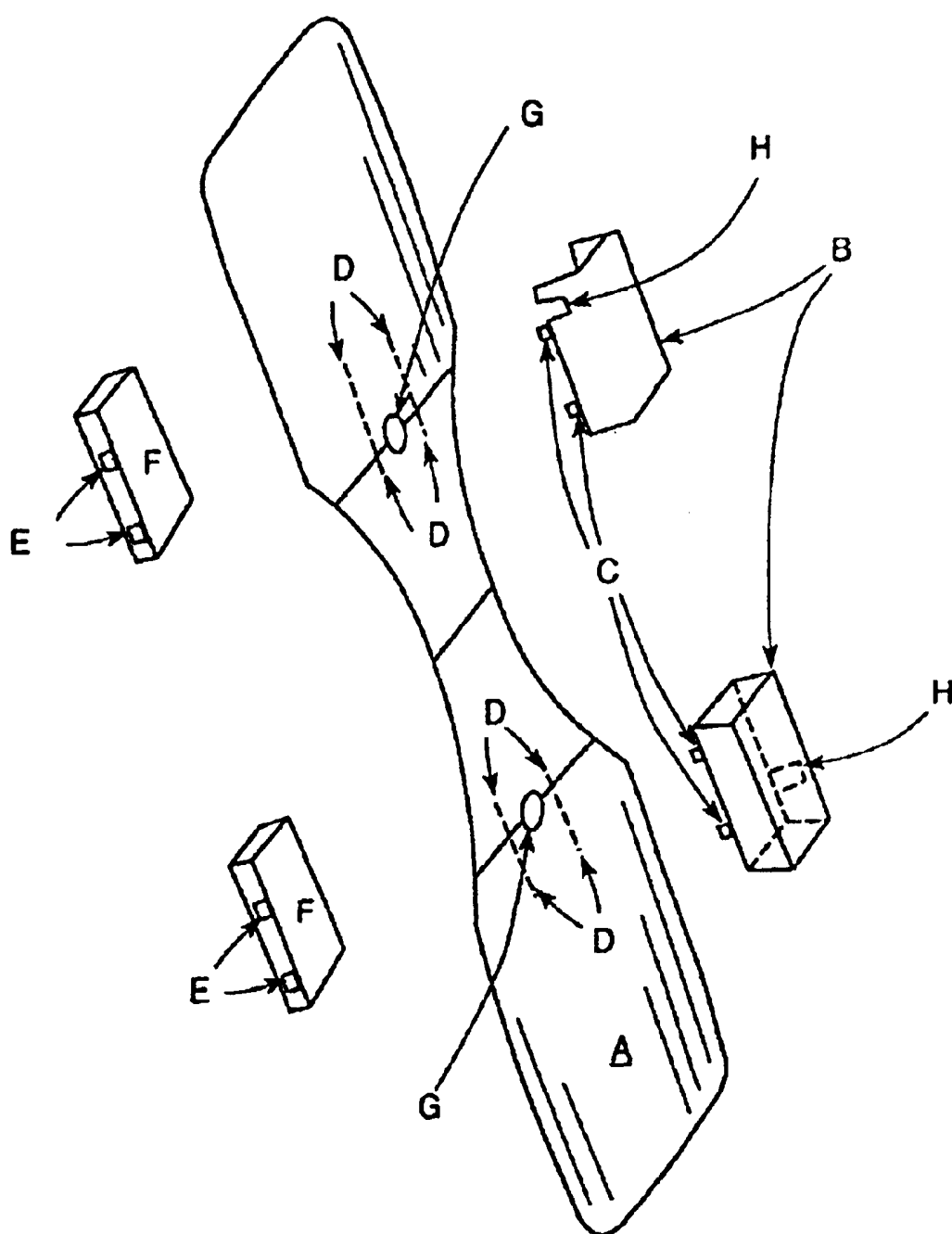
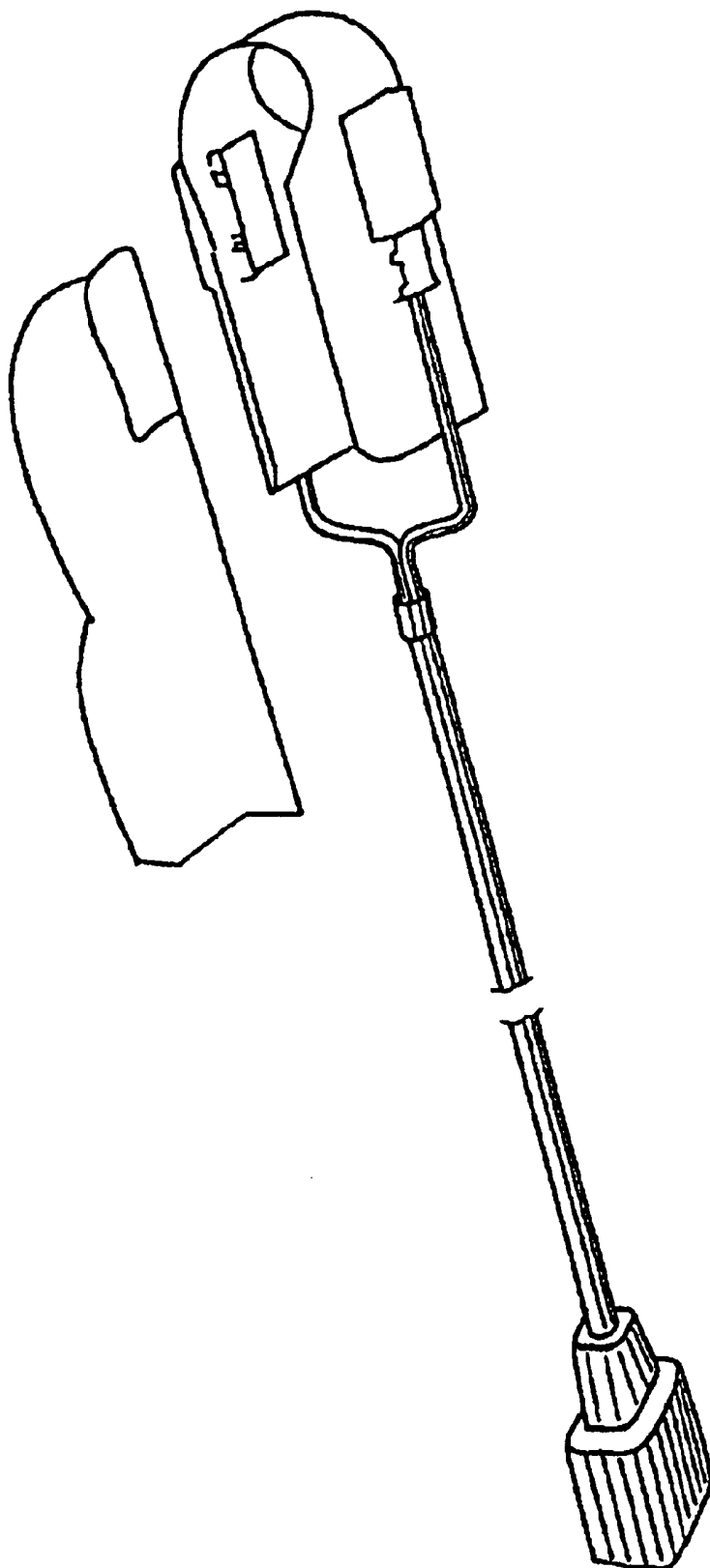


FIGURE 8



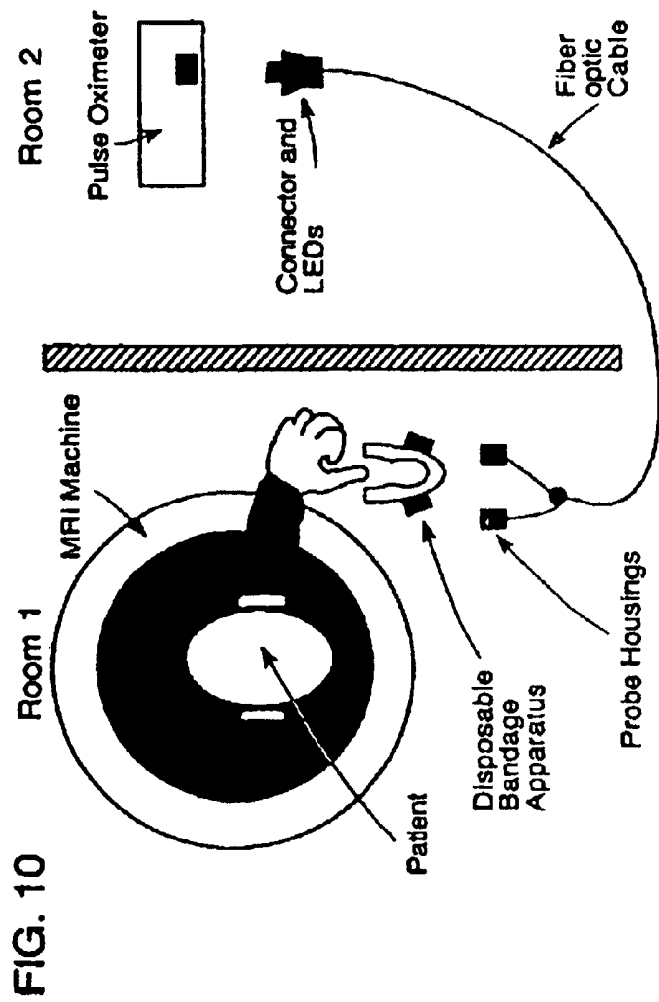
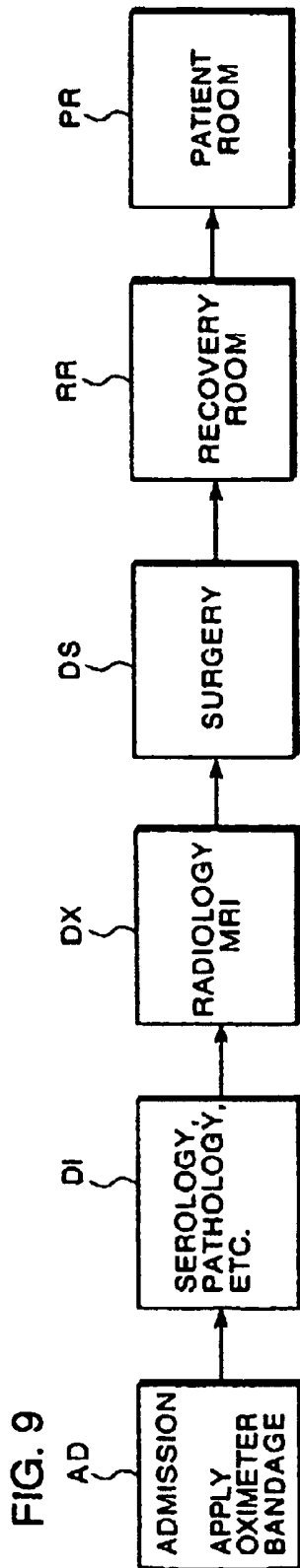
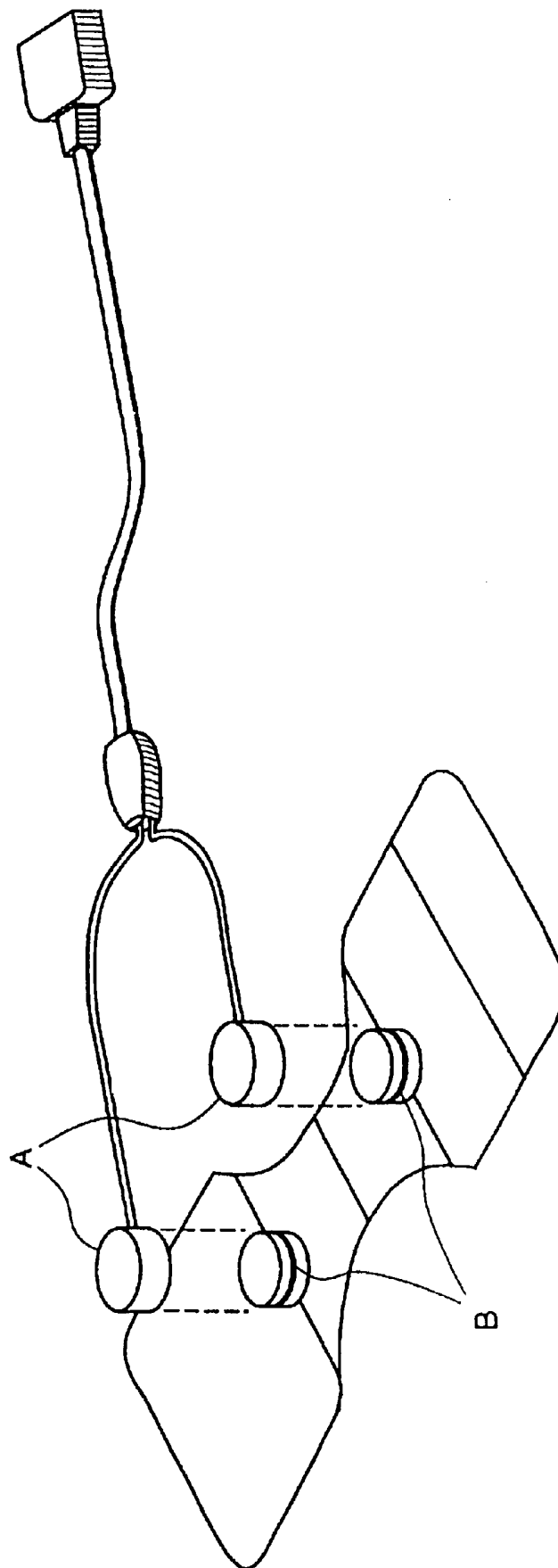


FIG. 11



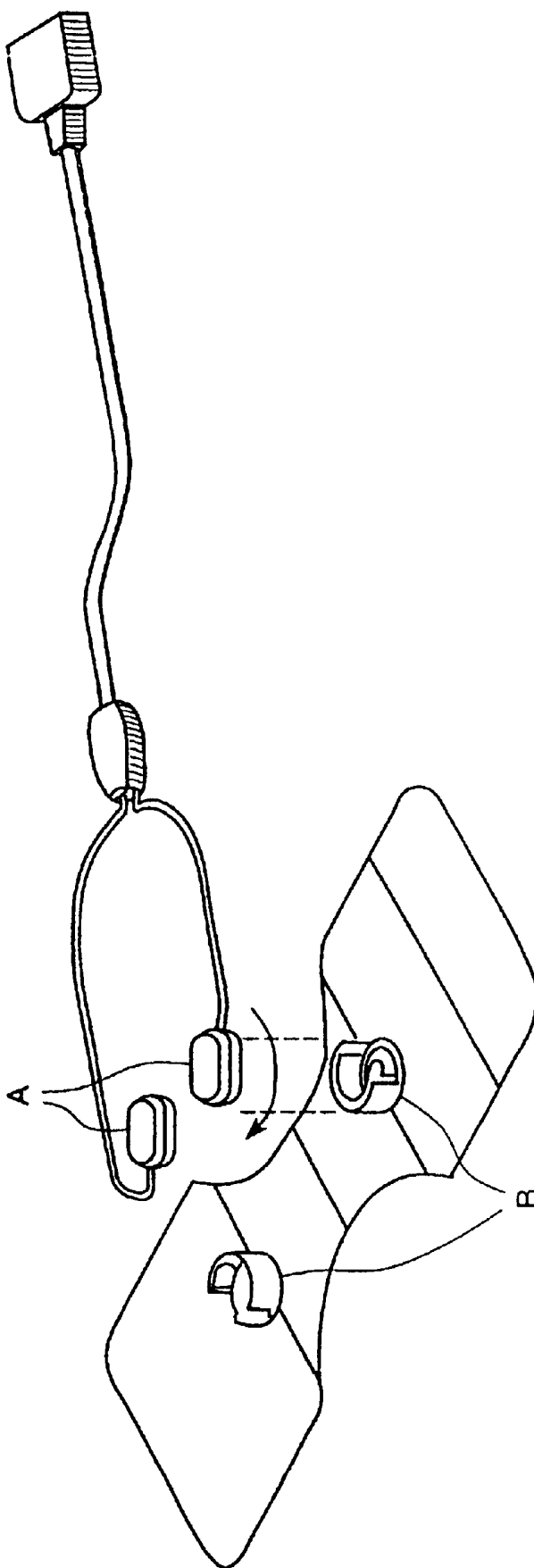


FIG. 12

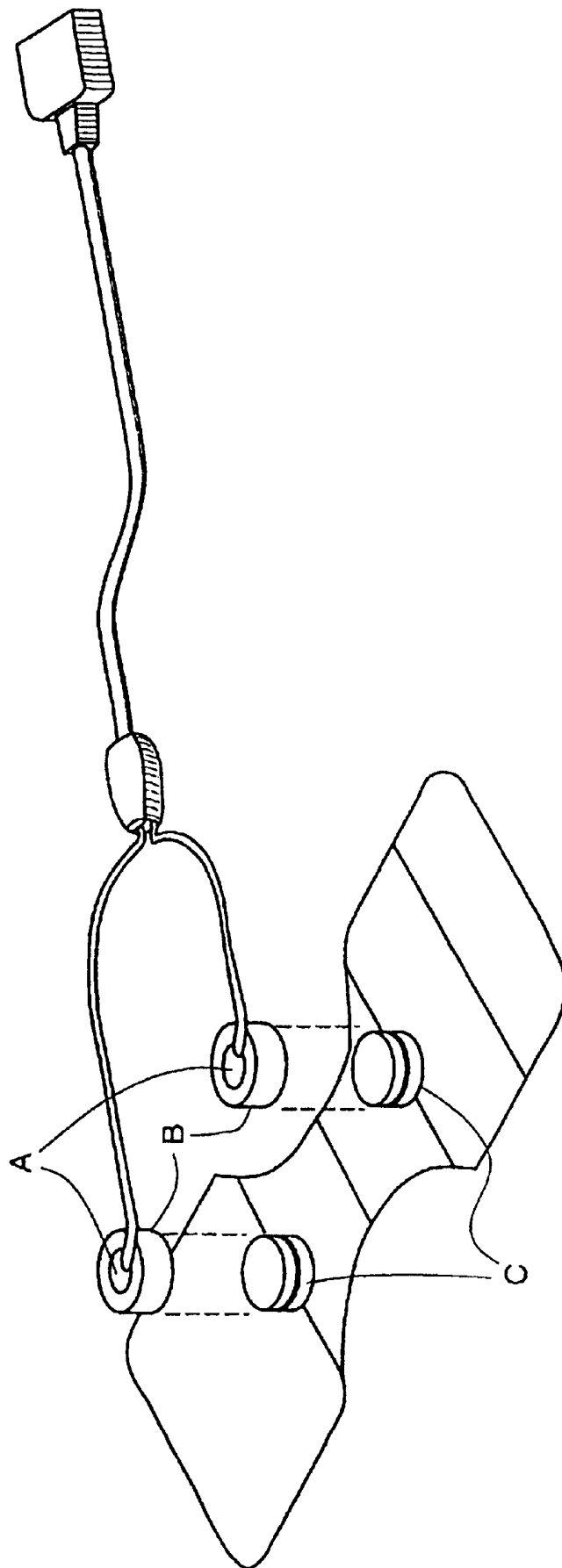


FIG. 13

FIG. 14

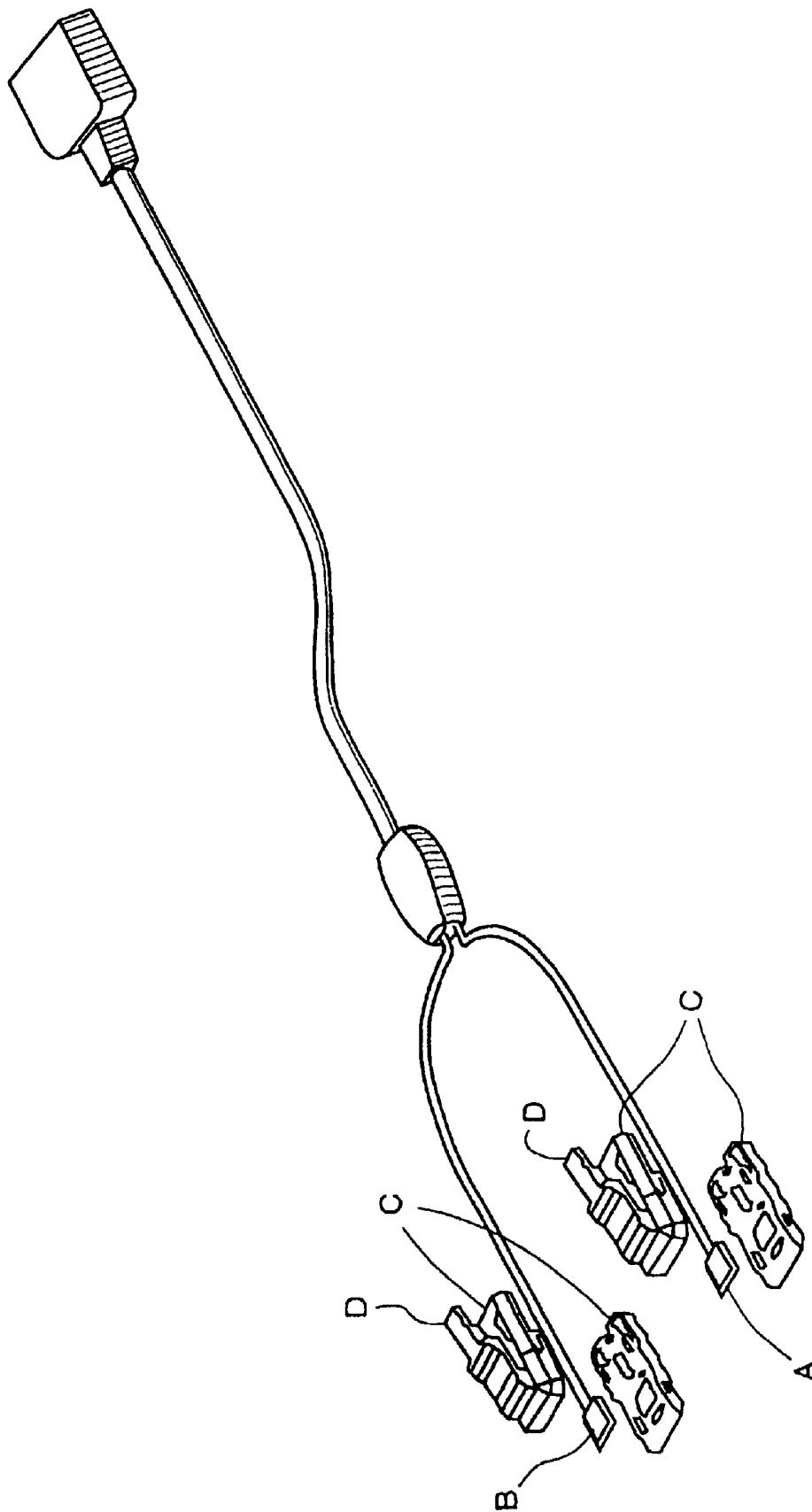


FIG. 15

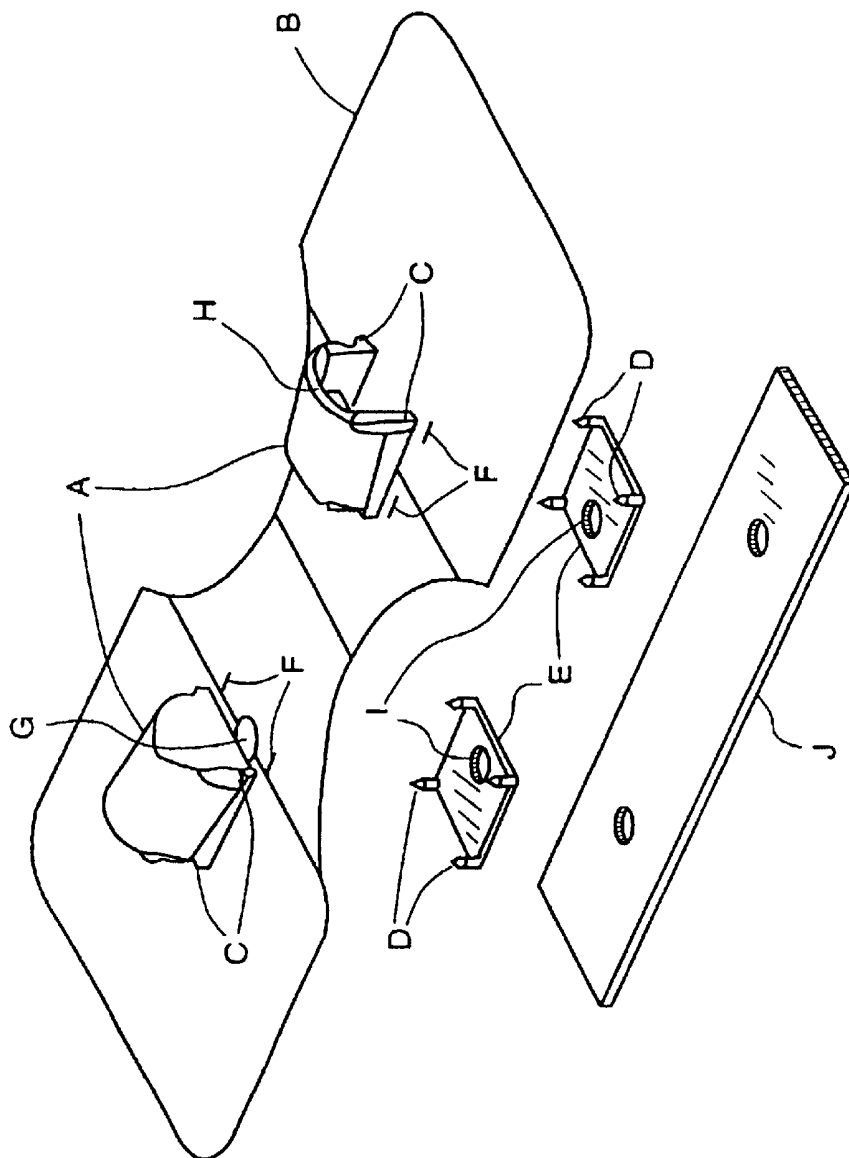


FIG. 16

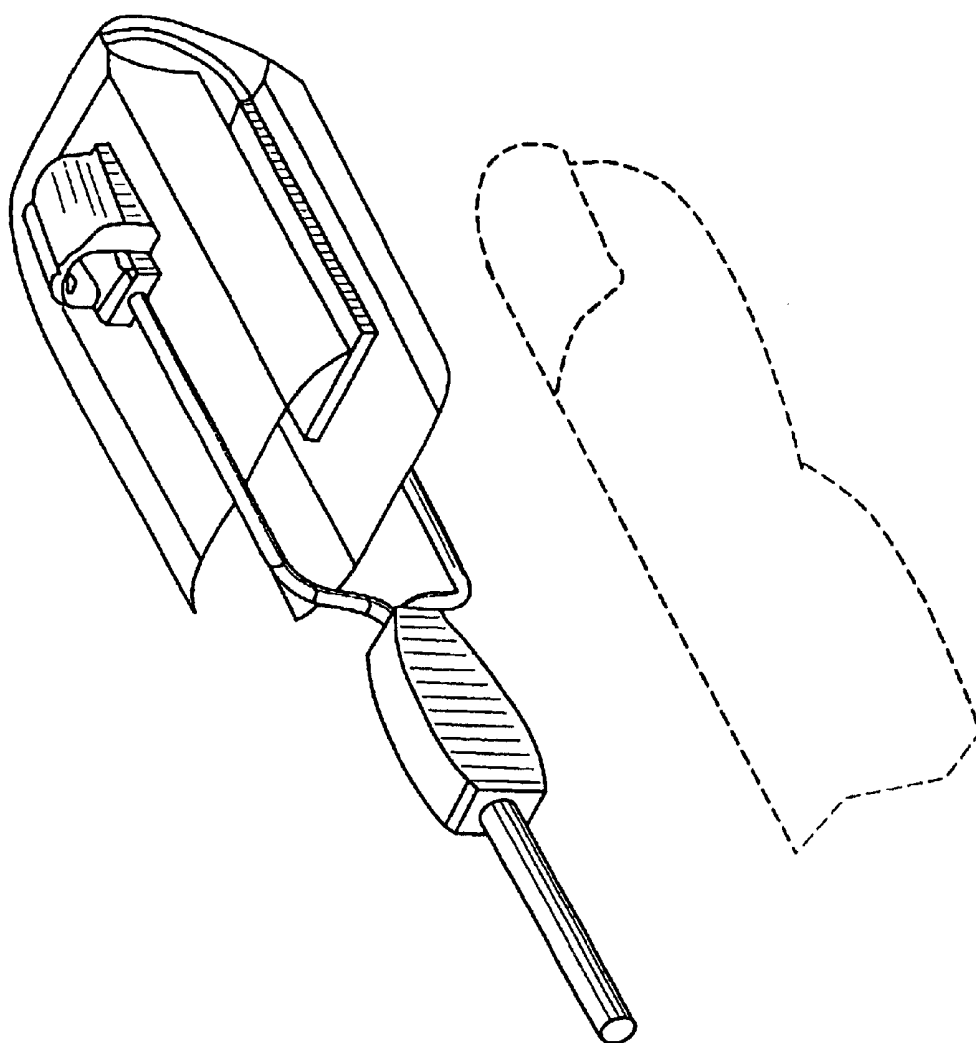


FIG. 17

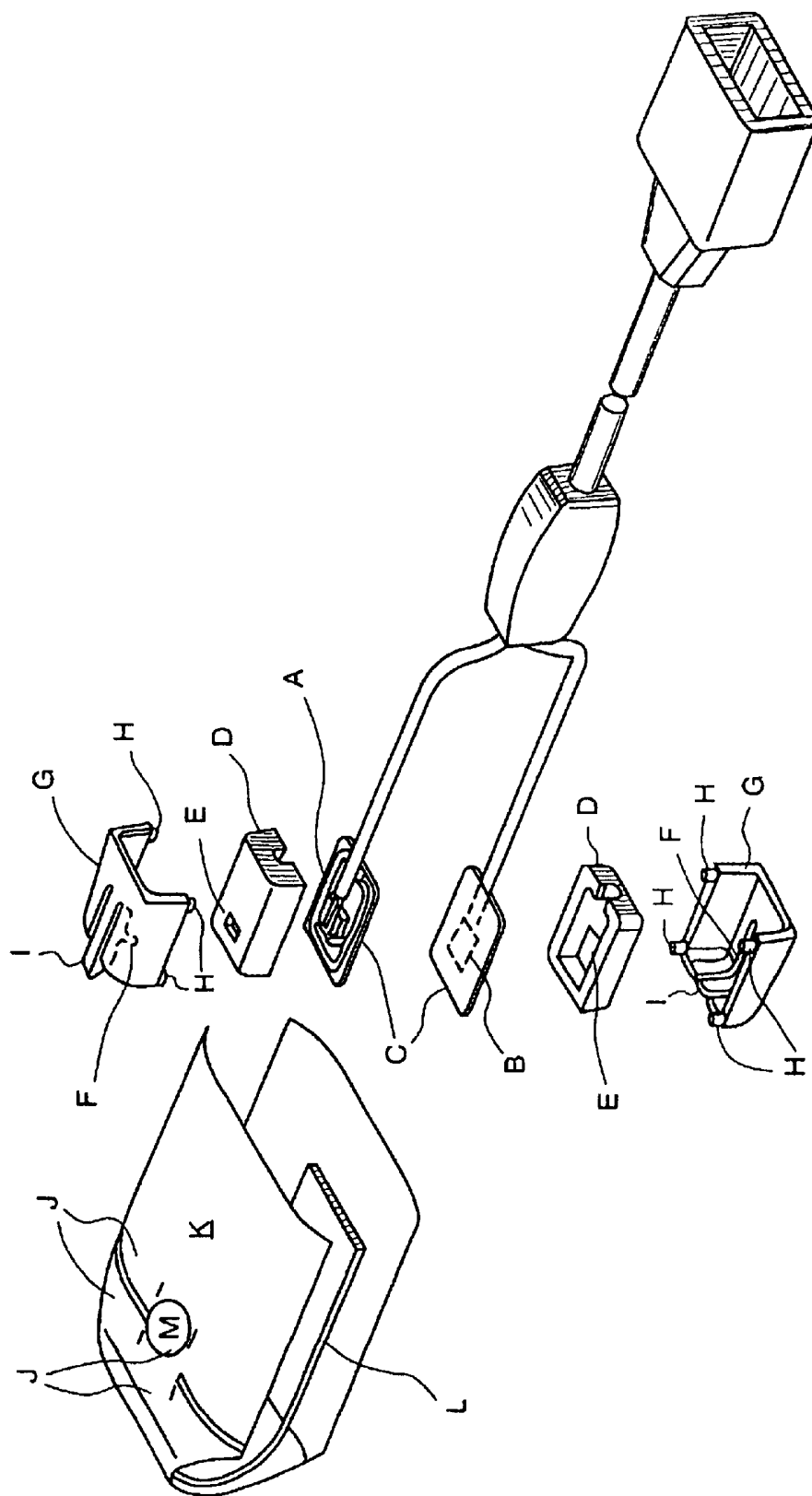
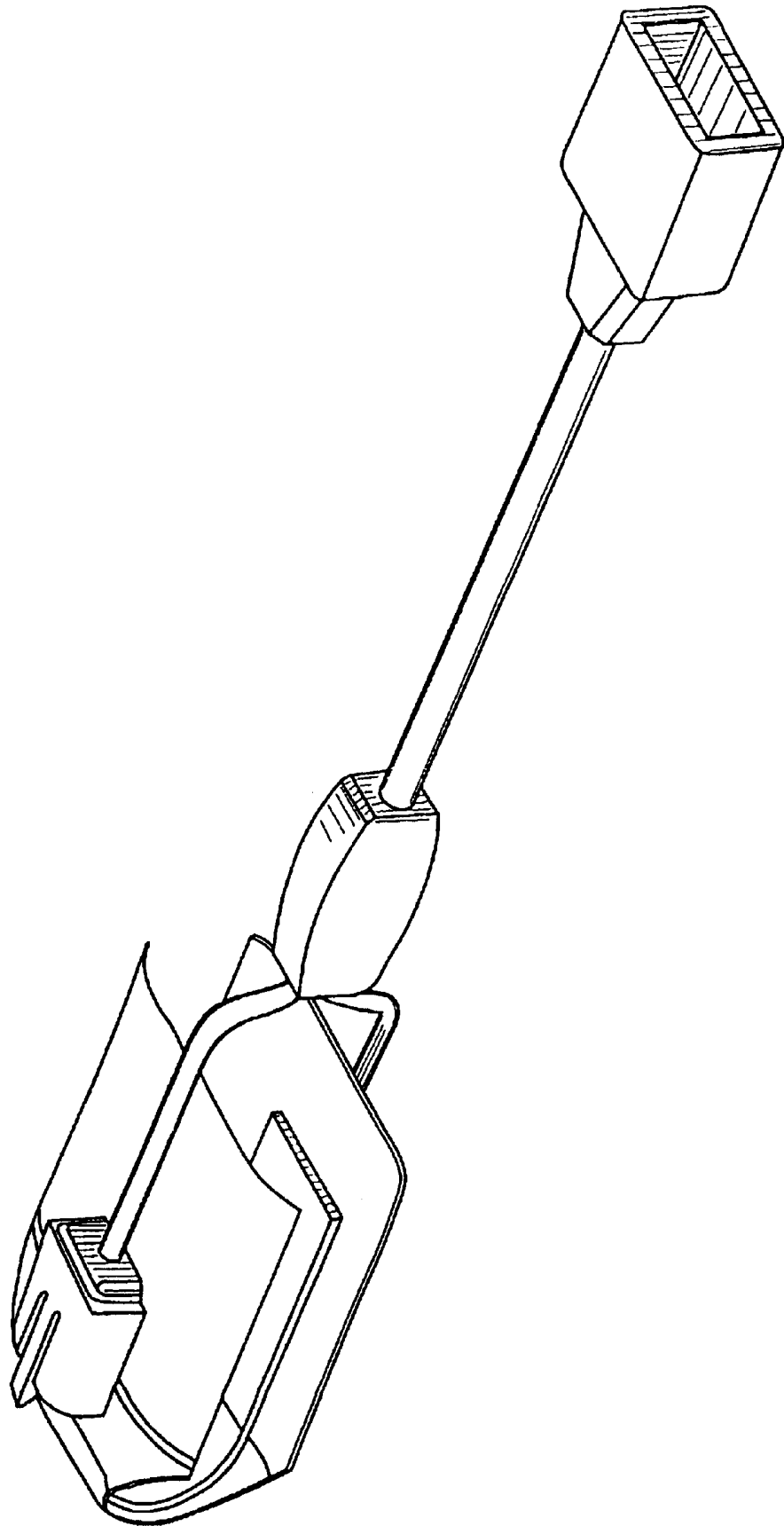


FIG. 18



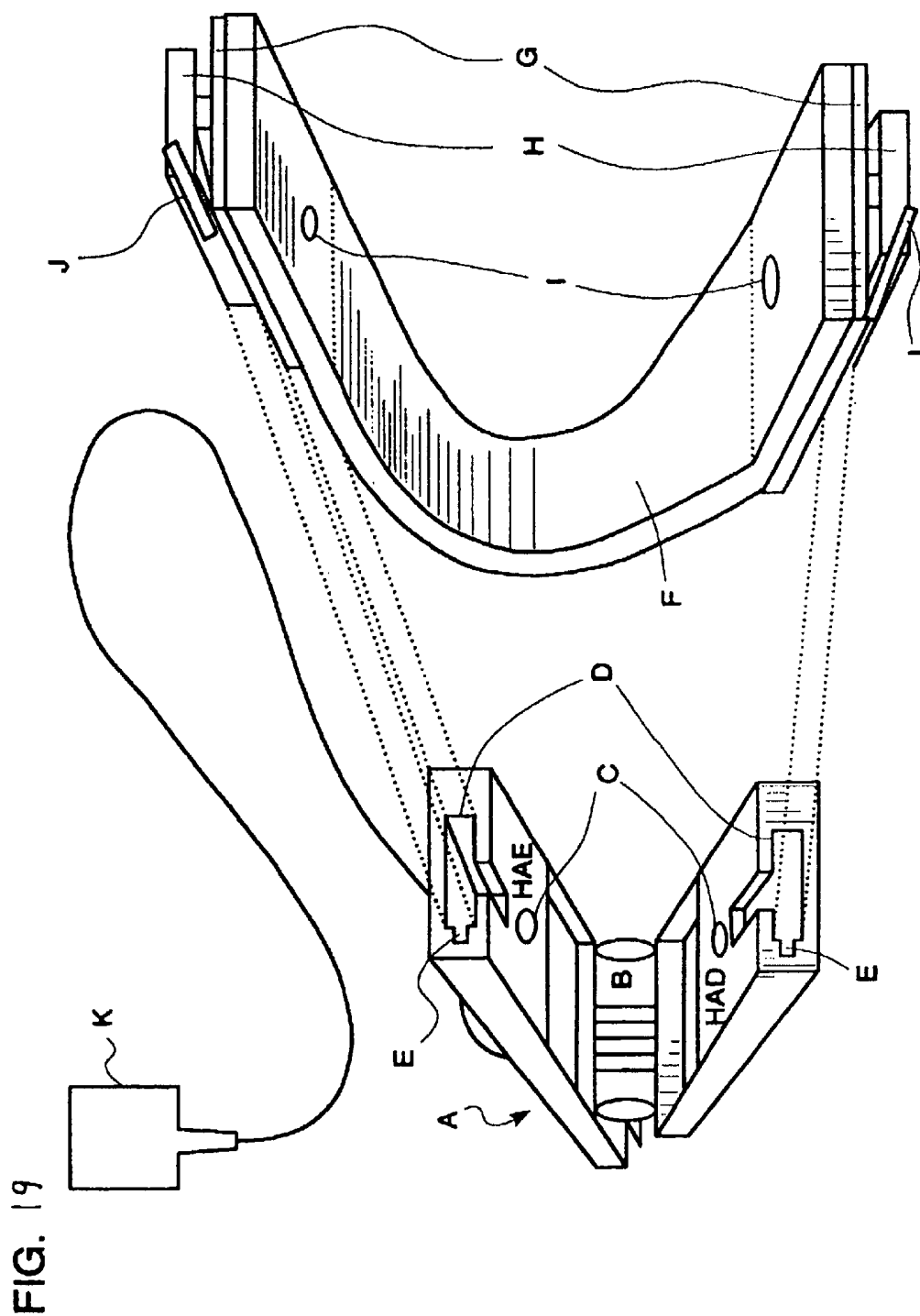
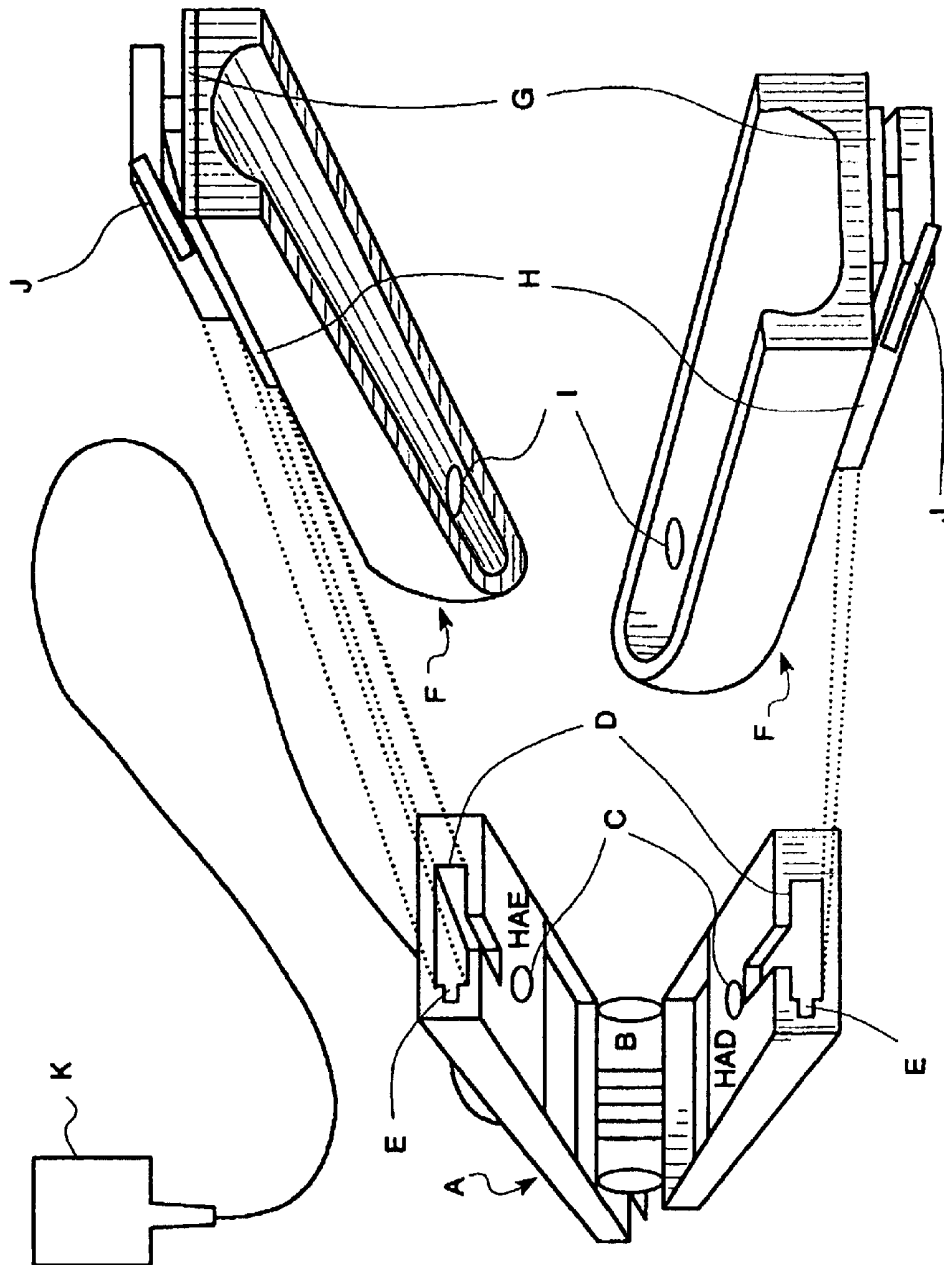


FIG. 20



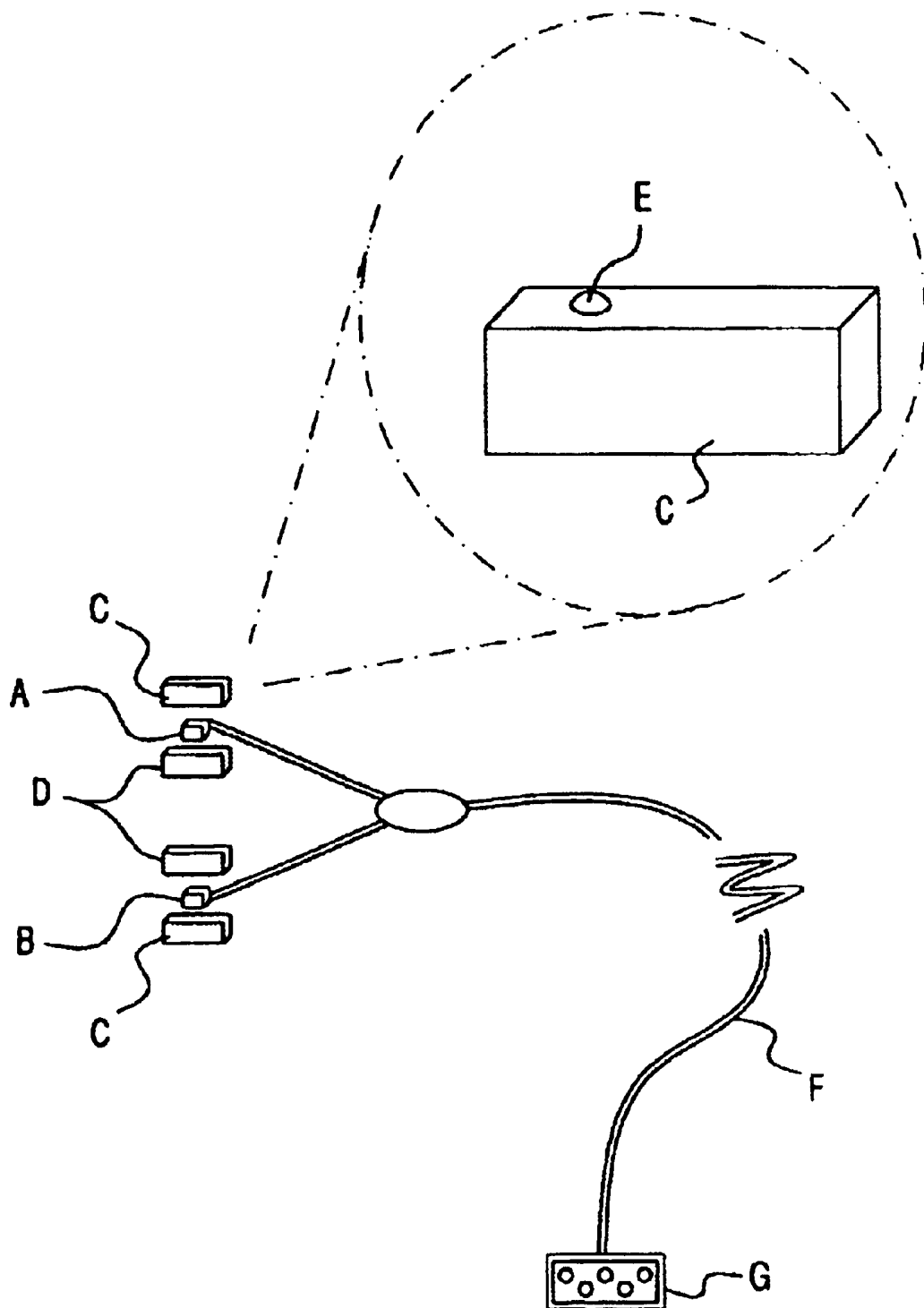


FIG. 21

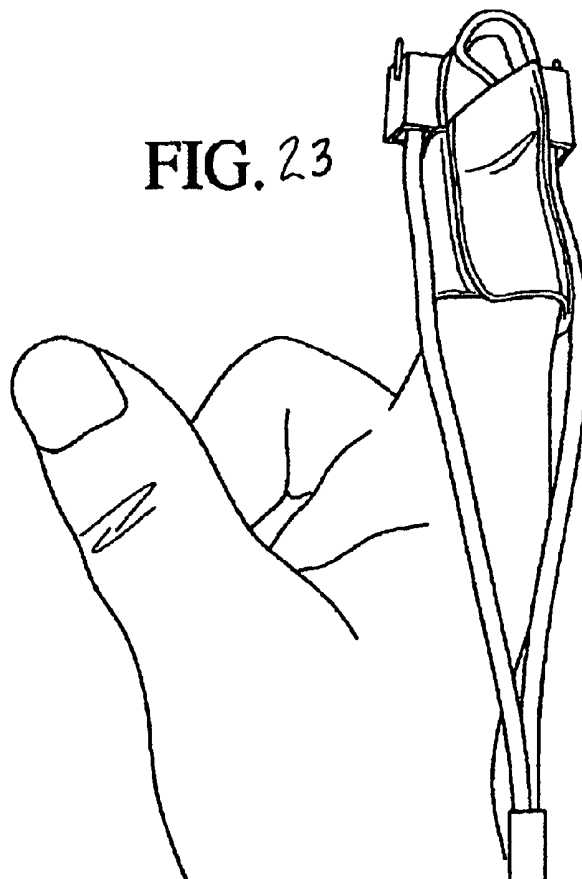
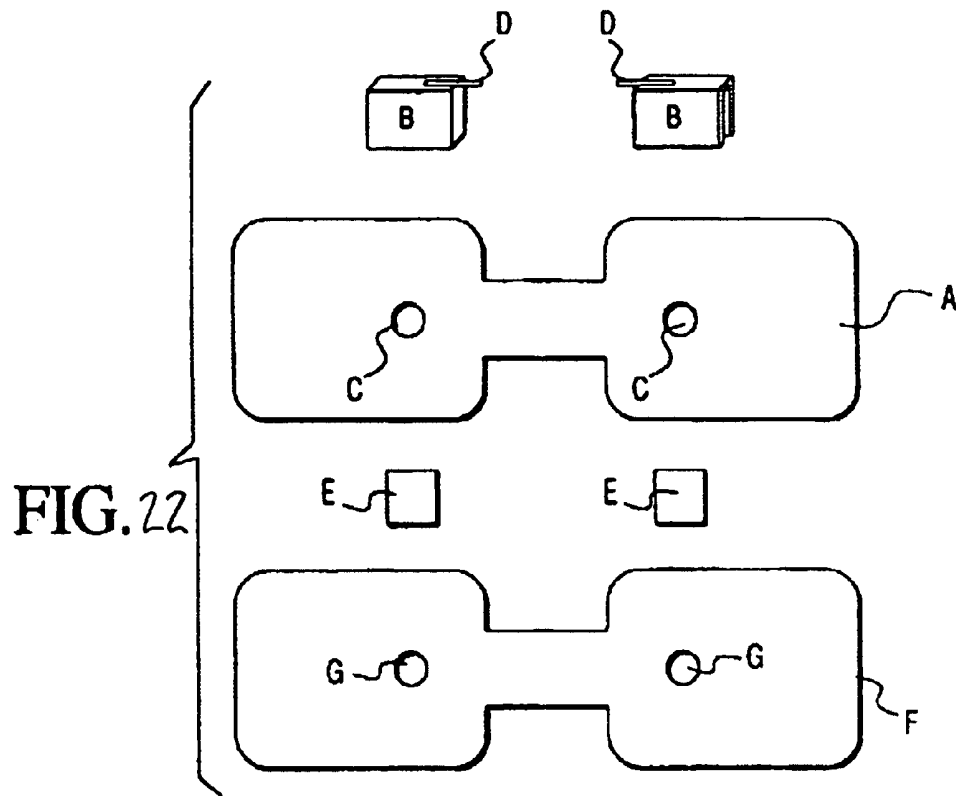


FIG. 24

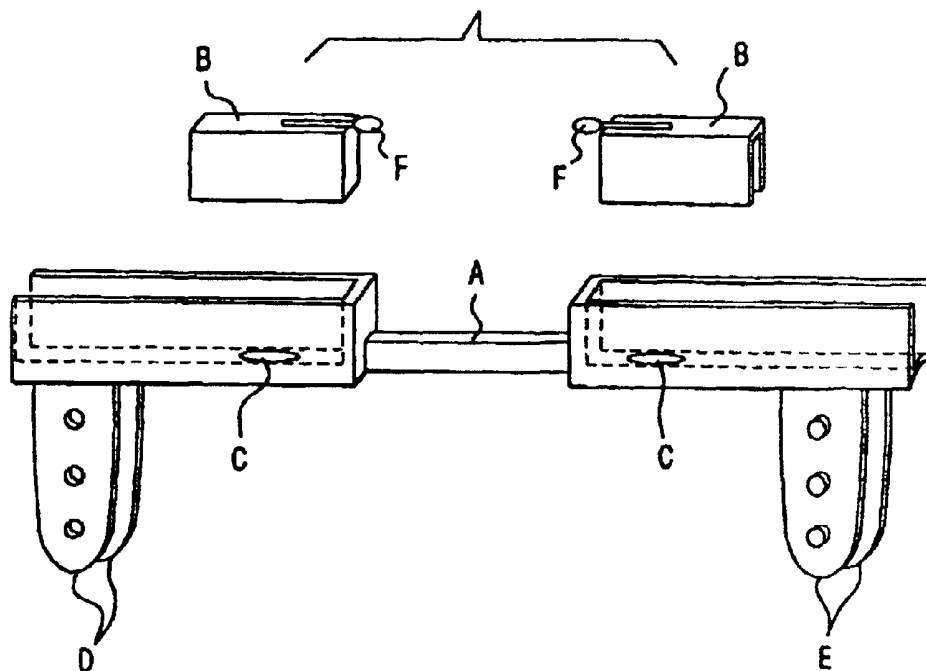
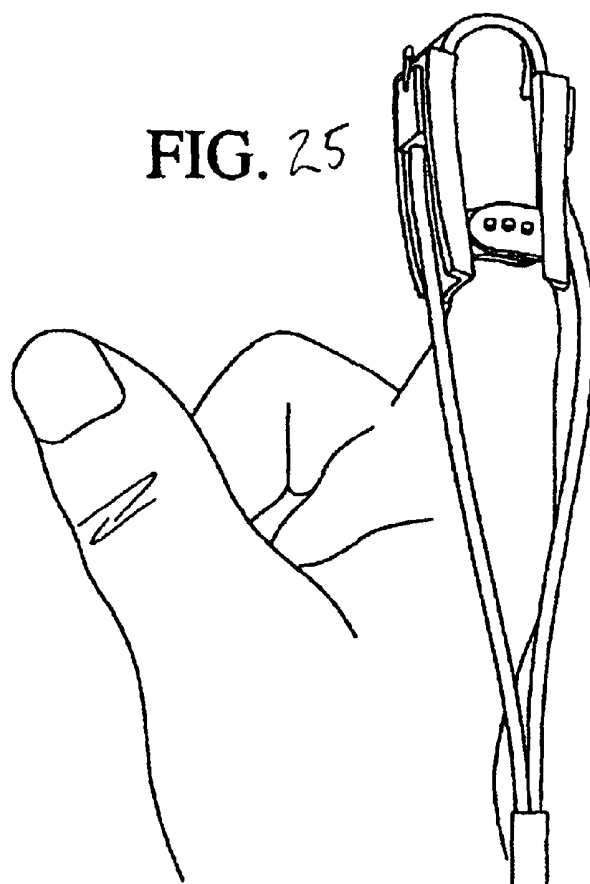


FIG. 25



UNIVERSAL MODULAR PULSE OXIMETER PROBE FOR USE WITH REUSABLE AND DISPOSABLE PATIENT ATTACHMENT DEVICES

Matter enclosed in heavy brackets [] appears in the original patent but forms no part of this reissue specification; matter printed in italics indicates the additions made by reissue.

REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in-part of application Ser. No. 09/417,898, filed Oct. 14, 1999, entitled REUSABLE PULSE[**S**] OXIMETER PROBE AND DISPOSABLE BANDAGE APPARATUS, now U.S. Pat. No. 6,343,224, which in turn is a continuation-in-part of application Ser. No. 09/289,647, filed Apr. 12, 1999, entitled REUSABLE PULSE OXIMETER PROBE AND DISPOSABLE BANDAGE APPARATUS[and], now issued as U.S. Pat. No. 6,144,868[**;**]; and is a continuation-in-part of application [of] Ser. No. 09/679,828, filed Oct. 5, 2000, entitled REUSABLE PULSE OXIMETER PROBE AND DISPOSABLE BANDAGE APPARATUS, now U.S. Pat. No. 6,519,487; and is a [CIP] continuation-in-part of application Ser. No. 09/352,144, filed Jul. 13, 1999[and is CIP of], entitled REUSABLE PULSE OXIMETER PROBE WITH DISPOSABLE LINER, now U.S. Pat. No. 6,321,100; and is a continuation-in-part of application Ser. No. 09/758,038, filed Jan. 11, 2001, entitled REUSABLE PULSE OXIMETER PROBE AND DISPOSABLE BANDAGE METHOD, now U.S. Pat. No. 6,684,091; each of which is incorporated herein by reference. This application claims benefit of U.S. [provisional] provisional application No. 60/104,332, filed Oct. 15, 1998.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to a method of making and affixing a reusable probe to a patient by means of disposable bandage apparatus so that there is no contact between the costly, reusable portion of the probe and the patient. The contaminated bandage apparatus, which is relatively inexpensive, can then be discarded after single patient use and the probe can be re-used with a new bandage apparatus.

2. Description of the Related Art

Heretofore the use of pulse oximeter probes has been limited to the use of a costly, reusable probe, which is contaminated by use on a patient, or cheaper, single-use probes, which, in the aggregate, amount to a considerable expenditure for a healthcare institution.

Others have attempted to convert single-use probes into multi-use probes through a lamination process. In that process, the original adhesive material is removed from the original manufacturer's sensor. The sensor is then laminated in a plastic sheath and the entire sheath is then inserted into a transparent, adhesive-backed sleeve, which is then adhered to a patient. After use, the probe can then be extracted from the sleeve and inserted into a new sleeve for use on another patient.

There are certain disadvantages to this method. Firstly, it is difficult to insert the flexible laminated sensor into a long sleeve. Secondly, the thickness of a laminated sensor inside of a sleeve makes it difficult to bend around, and to stick properly to, a human appendage. Thirdly, transmission and reception of infrared light can be affected by extraneous light entering from the sides of the sleeve. And, fourthly, there is

some dispute as to the affect on infrared light transmission when passing through the sleeve and the adhesive material coupled thereto.

One of the problems with pulse oximetry, and the continuity of monitoring a patient, is the vast array of different monitors used in different hospital departments. Many times a patient will start out in the emergency room (ER) where the hospital utilizes one particular brand of monitor. If a disposable probe is affixed to the patient, and the patient is then admitted to intensive care, the disposable probe that was affixed in the ER will only work if the pulse oximeter used in intensive care is of the same make as the one in the ER. If that same patient is once again taken to radiology, or to have an MRI done, once again these different departments may have different pulse oximeter monitors. What happens many times is that the disposable probes affixed in one department are thrown away and new ones are affixed in other departments. Obviously, this creates additional expense in providing pulse oximetry monitoring.

SUMMARY OF THE INVENTION

The current applicant, in his U.S. Pat. No. 6,144,868, and subsequent continuations-in-part, has described a reusable pulse oximeter probe to be used with a disposable bandage apparatus. With this device, the costly reusable portion of the probe is isolated from the patient by means of an inexpensive bandage apparatus. This allows the caregiver to dispose of the inexpensive bandage apparatus while retaining the more costly, reusable portion of the probe. The reusable probe can then be used in conjunction with another disposable bandage apparatus on another patient.

One embodiment of the present invention is directed to improving the form and affixation method of a reusable pulse oximeter sensor. It comprises a reusable pulse oximeter probe with at least one light emitting diode and one photocell detector wherein said emitter and detector are enclosed in plastic housings, one housing having an aperture or radiation transparent window aligned with said emitter, and the other housing having an aperture or radiation transparent window aligned with said detector. Also included is a disposable bandage apparatus which is at least one bandage strip having adhesive on at least a portion of at least one face thereof and at least two plastic receptacles mounted thereon, each receptacle having at least one aperture or radiation transparent window located therein. The probe housings can matedly engage said bandage receptacles and transmit and receive light through the apertures or radiation transparent windows of said mated housings and receptacles, and through the appendage of a patient. The housings of the reusable pulse oximeter probe may also be made of a material selected from plastic, rubber, metal, wood, or other composite material. The receptacles of the disposable bandage apparatus may also be made of a material selected from plastic, rubber, metal, wood, or other composite material. Additionally, the apertures of said receptacles are large enough to accept the tubular protrusions of the housings for the purpose of concentric location and alignment of the housings to the receptacles and the proper transmission and reception of light therethrough. Sandwiched between the adhesive strip and the receptacles attached thereto, are translucent silicone windows or windows of another radiation transparent material for isolation of the reusable probe assembly from the patient. The bandage apparatus may be discarded after single patient use and the reusable probe may be used again on another patient in conjunction with another bandage apparatus. Additionally, the receptacles of the bandage apparatus may

have a concave surface on one side thereof in order to seat conformably on a human digit, or they may have a flat surface on at least one side thereof in order to attach conformably to a human foot, nose, or ear. The housings and receptacles also contain "mushroom hook" type hook and loop material for the purpose of adhering and detaching said housings to and from said receptacles. Additionally, the housings and receptacles have recessed areas for adhesion of the "mushroom hook" hook and loop material.

In another embodiment of the invention, the receptacle of the disposable bandage apparatus may be the mushroom hook material itself which may be attached directly to the adhesive strip for the selective engagement of the housings of the probe assembly.

In another embodiment of the invention, the housings of the pulse oximeter probe may be affixed to the receptacles of the disposable bandage apparatus by means of a "ring and groove" type snap-on connector.

In yet another embodiment of the invention, the housings of the reusable pulse oximeter probe may be affixed to the receptacles of the disposable bandage apparatus by means of a "twist and lock" type connector.

In a further embodiment of the invention, the housings of the pulse oximeter probe may be affixed to the receptacles of the disposable bandage apparatus by means of a "threaded flange" type of connector.

In a preferred embodiment of the invention, the light emitting diode and photocell detector of the probe assembly may be mounted in modular housings with locking levers which can engage an indentation or slot in the receptacles of the disposable bandage apparatus and securely lock the housings into proper position within the receptacles, thus allowing the transmission and reception of infrared light through the mated housings and receptacles and through the appendage of a patient.

In another variation of this preferred embodiment of the invention, the levers and indentations are reversed, and the light emitting diode and photocell detector of the probe assembly may be mounted in modular housings having indentations therein, and the receptacles of the disposable bandage apparatus may have the locking lever located on them. In such an embodiment, the locking levers of the bandage receptacles lockingly engage the slots or indentations in the probe housings, thus locking them into place within the receptacles and allowing the transmission and reception of infrared light through the mated probe housings and bandage receptacles, and through the appendage of a patient.

In these modular housing and receptacle embodiments, the radiation transparent windows may be of hard plastic and may be mounted against the skin of a patient, thus being used to secure the receptacles on the opposite side of the bandage strip. This is accomplished by the incorporation of locking levers on the radiation transparent windows which are pushed through holes or slots in the bandage and engage holes in the receptacles mounted on the opposite side of the bandage, thus sandwiching the bandage in between. A foam strip with holes in it may also be adhered to said radiation transparent windows in order for them to rest comfortably on a patient's appendage.

In another variation of the above, the bandage receptacles may be secured to the bandage through the use of small plastic protrusions or "heat stakes" mounted on the receptacles themselves. These protrusions can be pushed through slots in the bandage and can be melted on the other side of the bandage strip by means of an ultrasonic welding machine, thus locking the receptacles into position on the

bandage strip. In this embodiment a radiation transparent window may then be adhered to the underside of the bandage strip and the heat stakes and radiation transparent windows may then be overlaid with a foam pad with holes in it, the purpose of which is to allow for the transmission and reception of infrared light through the holes while aiding in patient comfort.

In some embodiments, one object is to provide a method of facilitating the intra-departmental or inter-institutional transport of a patient or patients requiring the pulse oximeter monitoring, and wherein said pulse oximeters used for monitoring said patient may be of different manufacturers. The method comprises affixing to said patient a bandage apparatus having a modular emitter and detector receptacles incorporated thereon, providing each said different manufacturers' pulse oximeter probe with modular housings adapted to matedly engage and/or disengage with receptacles of the disposable bandage apparatus, thus enabling said patient to be monitored by pulse oximeters of different manufacturers without changing the affixed bandage apparatus.

With some embodiments of the present invention, intra-departmental or inter-institutional transport is greatly facilitated by having a bandage device which will accept probes of various manufacturers, as long as those probes contain housings that will matedly engage the receptacles of the disposable bandage apparatus.

Another embodiment of the present invention relates to a method of making and affixing a reusable finger probe to a patient by means of a finger clip apparatus with a disposable liner insert so that there is no contact between the costly, reusable portion of the probe and the patient. The contaminated liner, which is relatively inexpensive, can then be discarded after single patient use and the probe and finger clip can be re-used with a new liner. Additionally, such disposable inserts may be provided of different sizes and would greatly enhance the fit and function of the finger clip on the patient. This is important for several reasons. Firstly, a fitted finger clip would be more comfortable to wear than conventional finger clips. Secondly, a fitted finger clip would allow the transmission and reception of infrared light from the LEDs of the probe without interference from extraneous light sources around the front and edges of the finger, and thirdly, a fitted finger clip would evenly distribute the pressure from the spring of the finger clip and would be much less likely to restrict blood flow to the digit and thereby cause erroneous oxygen saturation readings.

Another embodiment of the present invention comprises a method for improving the reusability, fit, and cleanliness of a reusable pulse oximeter finger sensor. It comprises a reusable pulse oximeter probe with at least one light emitting diode and one photocell detector wherein said emitter and detector are mounted in respective finger clip housing arms having apertures therein, one housing arm having an aperture aligned with said emitter, and the other housing arm having an aperture aligned with said detector. Incorporated into each opposing side of the finger clip is a T-shaped channel or slot with a locking protrusion or detent at the entrance of each of the channels. Also included is a disposable foam liner which is an initially, substantially planar, foam strip, having plastic backing on at least a part thereof and two T-shaped protrusions mounted in the lateral plane of said plastic backing. At opposing ends of the foam strip, and incorporated into the T-shaped protrusions, are notched levers for locking the foam strip into position in the T-shaped channel of the finger clip. In the center of the foam strip, the plastic backing is of a thickness that will allow it to bend into

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a "U" shape for insertion into the finger clip. Alternatively, the plastic backing may be entirely absent and the inherent flexibility of the foam itself will allow it to bend into the desired shape. Additionally, the foam strip contains two apertures located centrally therein containing silicone windows, or windows of another radiation transparent material, that will allow for the transmission and reception of infrared light. Additionally, the foam may also contain an adhesive for helping to adhere the finger clip to the patient.

In another preferred embodiment of the invention, the finger clip may be of scaled down design and would allow for the insertion of different sizes of molded foam that would conform in size to the digit on which the finger clip is to be used. In such an application, the foam itself would be intended to substantially envelop the finger and the finger clip would be a mechanism for pinching or biasing the two foam halves together.

Despite the cost and safety advantages of the reusable probe and disposable bandage apparatus over disposable probes, an increasing number of institutions are beginning to utilize reusable finger clip probes because of the cost savings associated with a completely reusable product. Despite the discomfort of these devices and the risk of spreading infection from patient to patient, the trend toward reusable probes continues to strengthen.

However, in all institutions there is always the need for some disposable probes. Patients who have compromised immune systems, surgical patients, where sterility is important, and neonatal and pediatric patients, where the size of the appendage to be monitored is too small for finger clips, require the use of disposable probes or a disposable bandage apparatus.

Clearly, it would be advantageous to offer a universal, modular, reusable probe that could be used in conjunction with either a reusable finger attachment device or a disposable bandage apparatus, each having receptacles into which the reusable probe could be lockingly engaged and disengaged. In addition, probes from all the different oximeter manufacturers could be standardized so that they could be used in conjunction with these same patient attachment devices.

[THE PRESENT INVENTION]

[The] One embodiment of the present invention is directed to a system and a method of standardization of a pulse oximeter probe wherein the probe comprises at least one light emitting diode and at least one photocell detector wherein said emitter and detector are incorporated into modular plastic housings, at least one housing having an aperture or radiation transparent window aligned with said emitter, and at least said second housing having an aperture or radiation transparent window aligned with said detector; wherein said housings can lockingly engage and disengage receptacles mounted on at least either:

- (a) a reusable finger attachment device, or
- (b) a disposable bandage apparatus,

and transmit and receive light through the appendage of a patient when either of the above devices are attached to a patient and when the housings of said probe are matedly engaged with the receptacles of the attached device.

The receptacles of the disposable bandage apparatus or the reusable finger attachment device may have locking levers for lockingly engaging and disengaging the modular probe housings.

The probe housings may have indentations or detentes for lockingly engaging and disengaging the levers of the recep-

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tacles of the disposable bandage apparatus or reusable finger attachment device.

The disposable bandage apparatus may have radiation transparent windows for the isolation of the probe housings from the patient.

The probe housings may be standardized in size so that probes to fit at least one of a multiplicity of manufacturers' oximeters will incorporate housings that can be matedly engaged with either a reusable finger attachment device or a disposable bandage apparatus.

[What] According to one embodiment, what is disclosed is [the] a method of supplying pulse oximeter probes compatible with at least one of a multiplicity of manufacturers' oximeters, said probe or probes incorporating standardized probe housings, which can be matedly engaged with at least either a reusable finger attachment device or a disposable bandage apparatus.

BRIEF DESCRIPTION OF THE DRAWINGS

The above and other advantages of the invention will become more clear when considered with the following specifications and accompanying drawings wherein:

FIG. 1 is an exploded view of the reusable pulse oximeter probe and disposable bandage apparatus incorporating one embodiment of the invention;

FIG. 2 is a view of the reusable pulse oximeter probe and disposable bandage apparatus shown individually as components of the one embodiment of the invention;

FIG. 3 illustrates one embodiment of the invention in use on a human finger or digit;

FIG. 4 illustrates an exploded view of another embodiment of the invention in which the "mushroom hook" material itself is used as the receptacle of the disposable bandage apparatus;

FIG. 5 illustrates an assembled view of a preferred embodiment of the reusable pulse oximeter sensor in which the light-emitting diode and photocell detector of the reusable probe are mounted in modular housings with locking levers;

FIG. 6 illustrates an exploded view of a preferred embodiment of the reusable pulse oximeter sensor;

FIG. 7 illustrates an exploded view of a preferred embodiment of a bandage apparatus in which the receptacle tops incorporate a slot for engaging the locking levers of modular probe housings, and wherein radiation transparent windows are mounted on the opposite side of the bandage strip, thus sandwiching and securing the bandage in between the two receptacle halves by means of locking levers;

FIG. 8 illustrates a preferred embodiment of the invention as it would appear ready for use on a human digit;

FIG. 9 is a patient flow diagram showing the intra-departmental or inter-institutional transport of a patient;

FIG. 10 is a schematic illustration of how probe housing can utilize fiberoptic cable connecting a light emitter and detector to a disposable bandage according to one embodiment of the invention;

FIG. 11 illustrates an assembled view of another embodiment of the invention in which the housings of the pulse oximeter probe are affixed to the receptacles of the disposable bandage apparatus by means of ring and groove type, snap-on connectors;

FIG. 12 illustrates an assembled view of another embodiment of the invention in which the housings of the pulse oximeter probe are affixed to the receptacles of the disposable bandage apparatus by means of "twist and lock" type connectors;

FIG. 13 illustrates an assembled view of another embodiment of the invention in which the housings of the of the pulse oximeter probe are affixed to the receptacles of the disposable bandage apparatus by means of a "threaded flange" type of connector;

FIG. 14 illustrates an exploded view of a preferred embodiment of the reusable pulse oximeter probe in which the light emitting diode and photocell detector of the probe are encased in housings having a radiation transparent window therein and locking levers for affixing the reusable pulse oximeter probe to the disposable bandage apparatus;

FIG. 15 illustrates an exploded view of a preferred embodiment of the disposable bandage apparatus in which the receptacle tops incorporate a slot for engaging the locking levers of the modular probe housings, and wherein the radiation transparent windows are mounted on the opposite side of the bandage strip, thus sandwiching and securing the bandage in between the two receptacle halves by means of locking tabs or heat stakes that can be ultrasonically welded;

FIG. 16 illustrates a preferred embodiment of the invention as it would appear ready for use on a human digit;

FIG. 17 illustrates an exploded view of another preferred embodiment of the invention in which the probe housings have a slot or indentation incorporated therein and the bandage receptacles have a locking lever for securing the housings to the receptacles;

FIG. 18 illustrates an assembled view of one embodiment of the invention in which the probe housings have a slot or indentation incorporated therein and the bandage receptacles have a locking lever for securing the housings to the receptacles;

FIG. 19 is an exploded view of a standard pulse oximeter probe and finger clip with disposable liner;

FIG. 20 is an exploded view of one preferred embodiment of the invention incorporating two disposable liners having finger conformance;

FIG. [1] 21 is a exploded view of a pulse oximeter probe incorporating modular plastic housings[.];

FIG. [2] 22 is an exploded view of a disposable bandage apparatus incorporating modular plastic receptacles[.];

FIG. [3] 23 is a view of the disposable bandage apparatus with the probe engaged and in use on the appendage of a patient[.];

FIG. [4] 24 is an exploded view of a reusable finger attachment device incorporating modular plastic receptacles[.]; and

FIG. [5] 25 illustrates the reusable finger attachment device, with the probe engaged, and in use on a human appendage.

[DESCRIPTION OF THE MODULAR PULSE OXIMETER PROBE]

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Reusable Pulse Oximeter Probe and Disposable Bandage Apparatuses and Methods

Description of a Reusable Pulse Oximeter Sensor

The reusable pulse oximeter sensor constitutes a "Y" style pulse oximeter probe shown in FIG. 1, Item F. The probe incorporates two plastic housings shown as FIG. 1, Items G. The housings contain apertures or radiation transparent windows L therein. One housing contains the light-emitting

diode of the probe, FIG. 1, Item H, and other contains the photocell detector, FIG. 1, Item I. The emitter and detectors are aligned with the apertures or windows L of the housings in order to transmit and receive light through a human

appendage.

Seated within a recessed area of each housing, and attached permanently thereto, is a "mushroom hook" adhesive-backed pad, FIG. 1, Item K. The purpose of these pads is to selectively engage the "mushroom hook" pads, FIG. 1, Items J, attached permanently to the plastic discs, FIG. 1, Items D, and to attach the reusable probe assembly to the Disposable Bandage Apparatus. The reusable pulse oximeter sensor is shown assembled as FIG. 2, Item A.

In one preferred embodiment of the reusable pulse oximeter sensor, the light-emitting diode (FIG. 5, Item A) and photocell detector (FIG. 5, Item B) of the probe assembly are housed in modular receptacles (FIG. 5, Items C) having locking levers (FIG. 5, Items D) for engaging the receptacles of the disposable bandage apparatus, and locking them into place. In this embodiment, the light-emitting diode (FIG. 6, Item A) and the photocell detector (FIG. 6, Item B) are sandwiched between interlocking receptacle halves, the bottom halves of which (FIG. 6, Items C) are made of a radiation transparent material.

In another embodiment of the invention the light emitting diode and photocell detector of the reusable pulse oximeter sensor are enclosed in housings (FIG. 11, Items A) having a groove on the inner diameter of the housings that is designed to matedly engage rings (FIG. 11, Items B) located on the outer diameter of the disposable bandage apparatus, thus securing and locking the sensor housings to the bandage receptacles.

In another embodiment of the invention the light emitting diode and photocell detector of the reusable pulse oximeter sensor are enclosed in housings (FIG. 12, Items A) which are designed to enter the bandage receptacles (FIG. 12, Items B) and to twist 90 degrees thus locking the sensor housings to the bandage receptacles.

In yet another embodiment of the invention, the light emitting diode and photocell detector of the reusable pulse oximeter sensor are enclosed in housings (FIG. 13, Items A) having a threaded flange (FIG. 13, Items B) that threadedly engages the bandage receptacles, (FIG. 13, Items C) thus securing and locking the sensor housings to the bandage receptacles.

In the one preferred embodiment of the Reusable Pulse Oximeter Sensor, the light emitting diode (FIG. 14, Item A) and photocell detector (FIG. 14, Item B) of the probe assembly are housed in modular receptacles (FIG. 14, Items C) having locking levers, (FIG. 14, Items D) for engaging the receptacles (FIG. 15, Items A) of the disposable bandage apparatus, and locking them into place.

In the another preferred embodiment of the Reusable Pulse Oximeter Sensor, the light emitting diode (FIG. 17, Item A) and the photocell detector (FIG. 17, Item B) are encased in modular housings having a radiation transparent bottom (FIG. 17, Items C) and having opaque housing tops (FIG. 17, Items D). These housing tops and bottoms are ultrasonically welded together thus encapsulating the light emitting diode and photocell detector of the probe assembly. The housing tops incorporate indentations or slots (FIG. 17, Items E) designed to matedly engage a protrusion on the locking levers of the bandage receptacles thus snapping into place and securing the probe housings within the bandage receptacles.

According to one embodiment of the present invention, intra-departmental or inter-institutional transport is greatly

facilitated by having a bandage device which will accept probes of various manufacturers, as long as those probes contain housings that will matedly engage the receptacles of the disposable bandage apparatus.

Description of a Disposable Bandage Apparatus

The components of the apparatus include an adhesive-backed strip, shown as FIG. 1, Item A, the strip A incorporating two oval protrusions B centered thereon and shown as FIG. 1. The strip also incorporates two apertures, centrally located within the oval protrusions, each aperture C having a diameter sufficient in size to accommodate the transmission and reception of light from a light-emitting diode and photocell detector of a pulse oximeter probe.

On top of the apertures C are seated two plastic discs, FIG. 1, Item D, each having a concave base designed to conform to the radius of a human digit, and an aperture of slightly larger diameter than the apertures in the adhesive backed planar strip. The plastic discs are affixed to the adhesive planar strip by means of a permanent adhesive.

Seated in a recessed area on top of each plastic disc is a "mushroom hook", adhesive backed pad shown as FIG. 1, Item J. The purpose of the "mushroom hook" pads is to selectively engage the "mushroom hook" pads attached to the probe, FIG. 1, Items K, and to attach the probe to the disposable bandage apparatus. Sandwiched between the two plastic discs and the planar adhesive strip are two translucent silicone windows, FIG. 1, Item E. The windows are designed to permit the passage of infrared light and yet prevent contact between probe and patient, and consequently, contamination of the reusable probe itself.

The above items constitute the disposable bandage apparatus according to one embodiment of the invention, the apparatus being shown assembled as FIG. 2, Item B.

In another embodiment of the invention, the disposable bandage apparatus may be configured as in FIG. 4 of the drawings. FIG. 4 is an exploded view of the apparatus in which the "mushroom hook" pads of the bandage apparatus, FIG. 4, Items J, are bonded directly to the adhesive planar strip, FIG. 4, Item A, for the selective engagement of the "mushroom hook" pads of the probe, FIG. 4, Items K, the pads being attached permanently to the housings of the probe, FIG. 4, Items G.

In one preferred embodiment of the disposable bandage apparatus, the bandage strip (FIG. 7, Item A) is sandwiched between interlocking receptacle halves. The top halves of the receptacles (FIG. 7, Items B) contain locking levers (FIG. 7, Items C) that are pushed through slots cut in the bandage strip (FIG. 7, Items D) and lockingly engage indentations (FIG. 7, Items E) in the bottom halves of the receptacles (FIG. 7, Items F), thus sandwiching and locking the bandage in between. The bandage strip contains two apertures (FIG. 7, Items G) for the transmission and reception of light from the light-emitting diode and photocell detector of the pulse oximeter sensor which are encased in modular housings having locking levers (FIG. 5, Items D) wherein the levers engage slots in the receptacles (FIG. 7, Items H) thereby locking the housings into place within the receptacles. In addition, the bottom halves of the receptacles (FIG. 7, Items F) are of a radiation transparent material, thus allowing the light-emitting diode and photocell detector contained in the probe housings, when engaged in the bandage receptacles, to transmit and receive light through the apertures of the bandage strip and through the radiation transparent material of the bottom halves of the receptacles, and through the appendage of a patient. The complete reusable pulse oximeter probe and bandage assembly is shown assembled and ready for use on a human digit in FIG. 8.

In other embodiments of the disposable bandage apparatus, the bandage may have mounted thereon receptacles having means of matedly engaging the housings of the reusable pulse oximeter sensor by way of "ring and groove" snap-on type connectors (FIG. 11, Items B); "Twist and Lock" type connectors (FIG. 12, Items B); or "threaded flange" type connectors (FIG. 13, Items C).

In one preferred embodiment of the Disposable Bandage Apparatus, the bandage strip (FIG. 15, Item B) is sandwiched between interlocking receptacle halves. The top halves of the receptacles (FIG. 15, Items A) each contain 4 holes (FIG. 15, Items C) that are designed to matingly engage locking tabs (FIG. 15, Items D) on the bottom half of the receptacles (FIG. 15, Items E) that are pushed through slots cut in the bandage strip (FIG. 15, Items F) thus securing and locking the bandage in between.

The bandage strip contains two apertures or radiation transparent windows (FIG. 15, Items G) allowing for the transmission and reception of light from the light emitting diode and photocell detector of the pulse oximeter sensor which are encased in modular housings having locking levers (FIG. 14, Items D) wherein said levers engage slots in the receptacles (FIG. 15, Items H) thereby locking the housings into place within the receptacles. In addition, the bottom halves of the receptacles (FIG. 15, Items E) can be of a radiation transparent material, or may contain apertures (FIG. 15, Items I) thus allowing the light emitting diode and photocell detector contained in the probe housings, when engaged in the bandage receptacles, to transmit and receive light through the apertures of the bandage strip and through the radiation transparent material, or apertures, of the bottom halves of the receptacles, and through the appendage of a patient. The disposable bandage apparatus may also incorporate a foam strip (FIG. 15, Item J) in order to cushion a patient's appendage from any discomfort caused by the bottom half of the bandage receptacles. The complete Reusable Pulse Oximeter Sensor, engaged in the disposable Bandage Apparatus, and ready for use on a human appendage, is shown in FIG. 16.

In another preferred embodiment of the disposable bandage apparatus, the bandage receptacles (FIG. 17, Items G) are secured to the bandage (FIG. 17, Item K) by means of four protrusions or "heat stakes" (FIG. 17, Items H) which are pushed through slots (FIG. 17, Items J) on the bandage (FIG. 17, Item K) and are ultrasonically welded on the other side, thus securing the receptacles to the bandage. A radiation transparent window (FIG. 17, Item M) is then adhered to the underside of the bandage and the radiation transparent windows and melted heat stakes are then overlaid by a foam pad (FIG. 17, Item L) to aid in patient comfort. This foam pad also incorporates two holes which are in alignment with the two holes on the bandage itself, and when the foam pad is overlaid on the underside of the bandage, the radiation transparent windows are sandwiched in between.

The probe housings are designed to matedly engage the bandage receptacles (FIG. 17, Items G) and are held in place within the receptacles by means of protrusions (FIG. 17, Items F) on the locking levers (FIG. 17, Items I) which snap into place when the probe housings are pushed into the bandage receptacles. When the probe housings are locked into place within the bandage receptacles the light emitting diode and photocell detector are in alignment with the holes in the bandage and the foam overlay, and the probe is then able to transmit and receive light through the mated housings and receptacles, through the holes contained in the bandage and foam overlay, and through the appendage of a patient. The complete assembled Reusable Pulse Oximeter

Sensor engaged within the Disposable Bandage Apparatus, as it would appear ready for use on a patient, is shown in FIG. 18.

Other Fastening Means

As can be appreciated, there are many ways of fabricating the above components of the invention. The above description describes attachment of the reusable pulse oximeter sensor to the disposable bandage apparatus by way of a "mushroom hook" type hook and loop material and by the use of telephone type modular connectors and receptacles. In addition to this means, a number of other methods may be used including standard hook and loop material, "ring and groove" type snap-on connectors, "push and twist" type Luerlock connectors, and threaded flange type connectors. While these means are fairly comprehensive, they should in no way be considered exhaustive.

Method of Use

According to one method for use on an individual patient, the probe is affixed in the following manner:

Firstly, the backing is removed from the adhesive strip of the disposable bandage apparatus. One of the apertures of the apparatus is visually positioned on the center of the nail bed of the patient's appendage and one side of the adhesive strip and the oval protrusions are adhered to the patient's digit. The rest of the strip is then looped over the end of the patient's appendage, and the plastic disc is aligned so as to exactly oppose the plastic disc already attached to the other side of the digit. Once the disposable bandage apparatus has been properly adhered to the patient, the plastic housings of the probe assembly can be easily snapped into place on opposing sides of the digit. The entire assembled probe is shown as it would appear in use on a patient in FIG. 3.

According to one method for use with the "ring and groove" type snap-on connectors, "twist and lock", and "threaded flange" connectors, the backing is firstly removed from the adhesive strip. The strip is then folded in half where indicated on the bandage and the bandage apparatus is adhered to either side of the human digit. Once the bandage apparatus is in place the probe housings are simply snapped, twisted or screwed into place.

According to one method for use with a patient, the modular probe and bandage assembly, which is one preferred embodiment of the invention, would be attached as follows:

Firstly, the backing is removed from the adhesive strip. The strip is then folded where indicated on the bandage and the strip is then adhered to opposing sides of the human digit. Once the bandage apparatus is in place, the housings of the probe are pushed into the receptacles and locked in place by means of the locking levers. When the patient is moved between different service areas of a hospital, the probes can be removed and the patient transported to a new service area where that area's oximeter probes are pushed into the receptacles for further oximeter readings.

As shown in FIG. 9, one embodiment of the invention is easily adaptable to different manufacturers' oximeters being used in different departments or institutions when the patient is to be transported between the departments or institutions. As shown in FIG. 9, at the admissions area AD, where the patient is admitted to the hospital or facility, an oximeter bandage is initially applied. Then the patient may go through another testing area or department DI where various serological, pathological tests may be run. Then the patient is shown as being transported to a radiology area such as where X-ray and magnetic resonance images (MRI) scans are made. Other departments may have the patient transported thereto such as a surgery department DS and a

recovery room RR and the patient's room PR where, in each instance, a different manufacturer or different oximeter probes may be attached where, according to the invention, the receptacles on the bandages are able to receive and retain housings on the emitter and detector elements of the probe.

An example of the flexibility of the system of this invention is illustrated in FIG. 10. In this pictorial embodiment, a magnetic resonance image system or an MRI machine is shown as being positioned in one room with the patient and having applicant's disposable bandage apparatus attached to the finger of a patient. In this case, the patient is in the MRI facility where the patient is just having MRI work done. The probe housings are shown attached at the ends of fiberoptic cable connected to a connector which has the light-emitting diode and the light detector incorporated therein with a connector or plug for plugging into a pulse oximeter PO. The light-emitting and light-receiving ends of the fiberoptic cable are directed or oriented in the modular housings to emit IR light into the finger and receive IR light transmitted through the finger. It will be noted that since in the MRI application no ferrous materials are allowed, the LED's are placed in a room many feet away (up to fifty or more feet away) and (the oximeter device is in optical communication with the applicant's bandage apparatus. Thus, in situations where non-ferrous materials are required, the probe has non-ferrous housings and materials designed to matedly engage with the receptacles of applicant's disposable bandage apparatus. The housings of the probe are in fiberoptic communication with the LED's which would be at the other end of the probe near the pulse oximeter.

As shown above, in case of magnetic resonance imaging (MRI) situations where the presence of any metal in the environment can effect the MRI readings, the probe and emitter elements are situated remotely from the MRI machine and fiberoptic cable conveys light to and from the patient's finger. In this case, the oximeter probe housings are the termination ends of the fiberoptic cable and the modular housings are therefore able to be inserted into the bandage receptacles and the oximeter readings taken in this fashion from a remote area.

In some embodiments of the invention, when the probe is no longer required on the patient, the housings of the reusable probe are simply unsnapped from the disposable bandage apparatus, the bandage apparatus is thrown away, and the probe can then be reused on a new patient in conjunction with a new bandage apparatus.

Advantages of Some Embodiments

Current reusable pulse oximeter probes are either "clam shell" type clamping devices which can restrict circuit or "Y" type probes which are taped directly to the patient. Both types also come in direct contact with the patient's skin and bodily fluids and need sterilization after use. Because of the fact that these devices incorporate many surfaces and at times, porous materials, proper sterilization is very difficult. With some embodiments of the present invention there is no contact between the reusable probe and the skin or bodily fluids of the patient.

Disposable probes are very costly because of the fact that the cable, connectors and photodiodes are all disposed of after use. Some embodiments of the present invention accomplish the same goals as a disposable probe from a cleanliness standpoint, but since only the attachment apparatus is discarded after use, the cost is much less to a health-care institution.

One embodiment of the present invention, with the concave shape of the plastic discs of the bandage apparatus,

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when backed by the adhesive strip, is extremely effective in preventing the entrance of extraneous light from the sides of the patient's digit. Current probes on the market, whether disposable or reusable, because of the nature of their shape and affixation means, have problems in dealing with extraneous light reception.

One embodiment of the present invention utilizes an easy snap-on, snap-off, or modular connector attachment means for attaching the probe to the disposable bandage apparatus. Probe-shield type devices available in the past not only required the modification of the original manufacturer's probe, but required the difficult procedure of inserting a flexible laminated probe into a sheath for each patient.

Probe-shield devices, because of the lamination process involved, raised some concern over the transmission and reception of infrared light through the laminating material. One embodiment of the present invention uses a silicone window for the isolation of the probe from the patient. Infrared light transmission and reception is not affected by passage through translucent silicone.

In these days of environmental consciousness, the annual waste generated from tens of millions of disposable probes is enormous. Some embodiments of the present invention, if used in considerable numbers, would greatly reduce the amount of environmental waste generated by disposable pulse oximeter probes.

In some embodiments, intra-departmental or inter-institutional transport is greatly facilitated by having a bandage device which will accept probes of various manufacturers, as long as those probes contain housings that will matedly engage the receptacles of the disposable bandage apparatus.

Reusable Pulse Oximeter Probe with Disposable Liner

Description of a Reusable Pulse Oximeter Probe

According to one embodiment, the Reusable Pulse Oximeter Sensor constitutes a finger clip style pulse oximeter probe shown as FIG. 19, Item A. The probe incorporates two plastic housing arms, each housing arm containing apertures therein, said apertures shown as FIG. 19, Items C. One housing (HAE) contains the light emitting diode of the probe, and the other (HAD) contains the photocell detector. The emitter and detectors are aligned with the apertures of said housings in order to transmit and receive light through a human appendage. The housings are held together by a pin incorporating a spring, FIG. 19, item B, which inclines the two housings toward each other and clamps the apparatus on a human digit.

Within each housing is a "T" shaped channel, FIG. 19, item D, with a locking notch at the entrance thereof, said notch shown as FIG. 19, items E. The purpose of the channel and notch is to slidably engage the disposable liner of the finger clip and to lock it into its appropriate position within the finger clip. The probe is attached to a pulse oximeter through a connector, FIG. 19, item K. The above description constitutes the Reusable Pulse Oximeter Probe component of the invention.

Description of a Disposable Liner or Shield

According to one embodiment, the components of the disposable liner or shield include an initially planar foam strip shown as FIG. 19, item F, incorporating two apertures, centrally located within the strip, and shown as FIG. 19, Items I. Each aperture has a diameter sufficient in size to accommodate the transmission and reception of light from a light

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emitting diode and photocell detector of the reusable pulse oximeter probe. Each aperture has a silicone window, or window of another material, which will allow for the transmission and reception of infrared light therethrough.

On either end of the foam strip there is a thin plastic backing, FIG. 19, items G, having a "T" shaped protrusion mounted in the lateral plane thereof and shown as FIG. 19, item H. The purpose of the "T" shaped protrusion is to slidably engage the "T" shaped channel of the reusable sensor, FIG. 19, item D, and to lock into place by means of the locking levers, FIG. 19, items J, a releasable detent.

In one preferred embodiment of the invention, there are two disposable foam liners, with finger-shaped indentations therein, said indentations varying in size depending on the size of the patient's digit on which they are intended to be used. In this embodiment, the foam liners, FIG. 20, items F, have a plastic backing, FIG. 20, items G. The plastic backings have "T" shaped protrusions mounted thereon, FIG. 20, items H, which slidably engage the "T" shaped channel of the finger clip, FIG. 20, items D, the locking levers, FIG. 20, items J, engaging the locking notches of the finger clip, FIG. 20, items E, and securing the foam into place.

Other Fastening Means

As can be appreciated there are many ways of attaching the Disposable Liner or Shield to the Reusable Pulse Oximeter Probe. The above description describes attachment of the Disposable Liner to the Reusable Pulse Oximeter Probe by way of a modular type sliding connector. In addition to this means a number of other methods may be used including, hook and loop material, snap-on connectors, and removable adhesive.

[DESCRIPTION OF THE MODULAR PULSE OXIMETER PROBE] Universal Modular Pulse Oximeter Probe for Use with Reusable and Disposable Patient Attachment Devices

Description of a Modular Pulse Oximeter Probe

[The] According to one embodiment, the Modular Pulse Oximeter Probe consists of a "Y" type probe assembly in which the Light Emitting Diode (FIG. [1] 21, Item A) and the Photocell Detector (FIG. [1] 21, Item B) are incorporated into modular plastic housings. Said housings have an aperture or radiation transparent window incorporated therein so that said emitter and detector may be in communication with each other when said windows are in alignment with each other. In this preferred embodiment the modular housings consist of two half shells which encapsulate each the emitter and detector, one side of said shells (FIG. [1] 21, Items C) being fabricated of an opaque plastic material and the other half of said shells (FIG. [1] 21, Items D) being fabricated of a radiation transparent plastic material. The housings are designed in order to accommodate at least one of a possible multiplicity of manufacturers' light emitting diodes and photocell detectors. The housings may also contain an indentation (FIG. [1] 21, Items E) into which a locking lever of the receptacles of the disposable bandage apparatus or reusable finger attachment device may lodge in order to secure the probe housings to the receptacles of the preferred attachment device. The cable (FIG. [1] 21, Item F) and the connector (FIG. [1] 21, Item G) of the probe may also be interchanged in order to be compatible with a multiplicity of different manufacturers' oximeters.

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[DESCRIPTION OF THE DISPOSABLE
BANDAGE APPARATUS]*Description of a Disposable Bandage Apparatus*

[The] According to one embodiment, the disposable bandage apparatus consists of at least one adhesive bandage strip (FIG. [2] 22, Item A) wherein at least two receptacles (FIG. [2] 22, Items B) are mounted on said strip. Said receptacles are mounted over apertures in the strip (FIG. [2] 22, Items C) so that these apertures may diametrically oppose each other when the bandage strip is wrapped over the end of a patient's appendage. The Receptacles of the Disposable Bandage Apparatus may also incorporate locking levers (FIG. [2] 22, Items D) that are intended to engage the indentations in the housings of the probe (FIG. [1] 21, Items E) thus securing the probe housings within the bandage receptacles. The apparatus may also contain a radiation transparent window (FIG. [2] 22, Items E) for isolation of the probe housings from the patient and may also incorporate an additional foam strip (FIG. [2] 22, Item F) with apertures (FIG. [2] 22, Items G) for cushioning the patient's appendage from the radiation transparent windows. FIG. [3] 23 illustrates the disposable bandage apparatus with an engaged probe as it would appear in use on a human appendage.

[DESCRIPTION OF THE REUSABLE FINGER
ATTACHMENT DEVICE]*Description of a Reusable Finger Attachment Device*

[The] One preferred embodiment of the Reusable Finger Attachment Device comprises a flexible plastic or foam strip (FIG. [4] 24, Item A) with two receptacles (FIG. [4] 24, Items B) mounted thereon. Said receptacles are mounted over apertures in the strip (FIG. [4] 24, Items C) so that these apertures may diametrically oppose each other when the bandage strip is wrapped over the end of a patient's appendage. The strip also incorporates two perforated tabs (FIG. [4] 24, Items D) and two additional tabs with molded knobs (FIG. [4] 24, Items E) so that when the strip is looped over a human digit, the tabs with the perforations overlay the tabs with the knobs and these, when pressed together, can adjustably and removably interlock with each other for securing the device to a human digit. The Receptacles of the Reusable Finger Attachment Device may also incorporate locking levers (FIG. [4] 24, Items F) that are intended to engage the indentations in the housings of the probe (FIG. [1] 21, Items E) thus securing the probe housings within the bandage receptacles. FIG. [5] 25 illustrates the device as it would appear in use on a patient with the probe housings engaged in the Reusable Finger Attachment Device.

Other Fastening Means

As can be appreciated there are many means of fabricating [either] the Disposable Bandage Apparatus and the Reusable Finger Attachment Device using modular receptacles into which a universal modular probe housing could be lockingly engaged. While these devices may offer the most efficient method fabrication and/or user friendliness, they are by no means exhaustive.

Method of Use

Whether using the Disposable Bandage Apparatus or the Reusable Finger Attachment Device, the methods of use are essentially the same. With either apparatus, the end of the human appendage is wrapped by the device and, in the case of the Disposable Bandage Apparatus, the adhesive strip simply sticks to the skin of the patient. With the Reusable

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Finger Attachment Device, the tabs containing the perforations and knobs are simply overlaid and pushed together thus securing the device to the digit. With either device the probe housings are pushed into the receptacles of the device and are locked into place by the locking levers that engage the indentations in the probe housings. When the monitoring of the patient is complete, the locking levers of the receptacles of either device are lifted in order to release the probe housings and the probe is removed from the device. In the event that a Disposable Bandage Apparatus is in use, it is then thrown away after the probe has been removed. When a Reusable Finger Attachment Device is in use, it may be removed, washed, and reused on another patient.

[ADVANTAGES OF THE PRESENT INVENTION]

Advantages of Some Embodiments

[1.] The standardization of probes within a hospital whereby a multiplicity of manufacturers' oximeters could utilize probes having housings of the same size for engaging either reusable or disposable attachment devices is very favorable.

[2.] Finger attachment devices on the market today are hard wired to the probes, and when breakage occurs on the finger clip, the entire probe must be repaired or thrown away. With some embodiments of the present invention, when breakage occurs in either the finger attachment device or the probe itself, only the broken component has to be replaced.

[3.] A big problem exists with maintaining the cleanliness of reusable finger clips because the electronics are not removable from the finger clip and the device cannot be immersed or cleaned. With some embodiments of the present invention, the Reusable Finger Attachment Device can be removed from the probe and cleaned or sterilized.

While the invention has been described in relation to preferred embodiments of the invention, it will be appreciated that other embodiments, adaptations and modifications of the invention will be apparent to those skilled in the art.

What is claimed is:

1. A pulse oximeter probe system comprising a probe having at least one light emitting diode and at least one photo-cell detector wherein said emitter and detector are incorporated into modular [plastic] housings, at least one housing having an aperture or radiation transparent window aligned with said diode, and at least a second housing having an aperture or radiation transparent window aligned with said detector; a selected one of:

(a) a reusable finger attachment device having a first modular receptacle pair mounted thereon, or

(b) a disposable bandage device having a second modular receptacle pair mounted thereon;

wherein respective ones of said housings can lockingly engage and disengage respective ones of said modular receptacles and transmit and receive light through the appendage of a patient when the selected one of the above devices (a) or (b) is attached to a patient and when the respective housings of said probe are matedly engaged with the respective receptacles of the attached device; and the receptacles of the disposable bandage device or the reusable finger attachment device have locking levers for lockingly engaging and disengaging said modular probe housings, respectively.

2. The probe system of claim 1 in which said housings have indentations for lockingly engaging and disengaging the levers of receptacles of a disposable bandage apparatus or reusable finger attachment device.

3. The probe system of claim 1 wherein said disposable bandage apparatus incorporates radiation transparent windows for the isolation of the probe housings from the patient.

4. The probe system of claim 1 in which the probe housings of probes to be used on a multiplicity of manufacturers' oximeters are adapted to be matedly engaged with a selected reusable finger attachment device or a disposable bandage apparatus having receptacles designed to mate with said probe housings.

5. A reusable finger attachment device for use with a pulse oximeter probe incorporating modular housings, comprising said attachment device incorporating modular receptacles for matingly engaging said modular probe housings; wherein the receptacles of the reusable finger attachment device have locking levers for lockingly engaging and disengaging said modular probe housings.

6. The reusable finger attachment device of claim 5 which said modular probe housings are adapted to be removed from said reusable finger attachment device in order to clean or sterilize said reusable finger attachment device.

7. A method of standardizing probes comprising designing probe housings to be matingly engageable with modular receptacles of a disposable bandage apparatus and a reusable finger attachment device and further constructing said probe housings to be incorporated into probes adapted to work with at least one of a multiplicity of manufacturers' oximeters.

8. A standardized pulse oximeter probe comprising probe housings designed to be matingly engageable with modular receptacles of a disposable bandage apparatus and a reusable finger attachment device, said probe housings constructed to be incorporated into probes adapted to work with at least one of a multiplicity of manufacturers' oximeters.

9. A disposable finger attachment device for use with a reusable probe sensor assembly for sensing a physiological parameter of a patient comprising a bandage apparatus and first and second probe couplers, the bandage apparatus having adhesive on at least a portion thereof, the first and second probe couplers being operably attached to the bandage apparatus and configured to be matingly engageable with probe housings of a reusable probe sensor assembly, wherein the first and second probe couplers comprise respective first and second locking mechanisms that lockingly engage and disengage probe housings of a reusable probe sensor assembly.

10. The device of claim 9, wherein said first and second probe couplers are receptacles.

11. The device of claim 9, wherein said first and second probe couplers are modular.

12. The device of claim 9, wherein at least one of said first and second locking mechanisms comprise a fastener.

13. The device of claim 9, wherein at least one of said first and second locking mechanisms comprise a hook-and-loop type material.

14. The device of claim 9, wherein at least one of said first and second locking mechanisms comprise a snap-on connector.

15. The device of claim 9, wherein at least one of said first and second locking mechanisms comprise a ring.

16. The device of claim 9, wherein at least one of said first and second locking mechanisms comprise a groove.

17. The device of claim 9, wherein at least one of said first and second locking mechanisms comprise a notch.

18. The device of claim 9, wherein at least one of said first and second locking mechanisms comprise a twistable connector.

19. The device of claim 9, wherein at least one of said first and second locking mechanisms comprise a contoured portion of a receptacle.

20. The device of claim 9, wherein at least one of said first and second locking mechanisms comprise a threaded connector.

21. The device of claim 9, wherein at least one of said first and second locking mechanisms comprise a flange.

22. The device of claim 9, wherein at least one of said first and second locking mechanisms comprise a tab.

23. The device of claim 9, wherein at least one of said first and second locking mechanisms comprise an indentation.

24. The device of claim 9, wherein at least one of said first and second locking mechanisms comprise a slot.

25. A pulse oximeter probe system comprising:

a probe assembly having an emitter, a detector, and first and second modular housings for the emitter and detector, respectively; and

a finger attachment device having first and second modular receptacles mounted thereon, said modular receptacles having locking levers for lockingly engaging and disengaging with said modular housings of said probe;

wherein said probe assembly can transmit and receive light through the appendage of a patient when said finger attachment device is attached to a patient and when said modular housings of said probe assembly are engaged with said modular receptacles of said finger attachment device.

26. The system of claim 25, wherein said finger attachment device is reusable.

27. The system of claim 25, wherein said finger attachment device is disposable.

28. The system of claim 25, wherein said finger attachment device comprises a bandage apparatus.

29. A disposable bandage apparatus for use with a reusable probe sensor assembly having at least one emitter and at least one detector, the emitter being enclosed in a first probe housing having an aperture or radiation transparent window aligned with the emitter, and the detector being enclosed in a second probe housing having an aperture or radiation transparent window aligned with the detector, the disposable bandage apparatus comprising a bandage strip having adhesive on at least a portion of at least one face thereof and first and second modular receptacles mounted thereon, said first and second modular receptacles having respective first and second apertures located therein, said first and second modular receptacles being configured to lockingly engage and disengage with the first and second probe housings such that the emitter can transmit a signal to be received by the detector through the apertures of said modular receptacles when engaged with the first and second probe housings; wherein said first and second modular receptacles comprise locking means for lockingly engaging and disengaging the first and second probe housings.

30. The disposable bandage apparatus of claim 29 wherein at least a portion of at least one of said modular receptacles is plastic.

31. A method for the affixation of a reusable pulse oximeter sensor to the digit of a patient, comprising:

providing a disposable finger attachment device with at least two apertures therein and at least two receptacles operatively attached to an adhesive bandage apparatus of the disposable finger attachment device over said apertures, said at least two receptacles each at least partially defining an aperture aligned with the respective aperture of the finger attachment device, wherein said at least two receptacles comprise respective first and second locking mechanisms that lockingly engage and disengage probe housings of a reusable pulse oximeter probe sensor;

positioning said disposable finger attachment device on the digit of the patient; and

engaging probe housings of the reusable pulse oximeter probe sensor with said at least two receptacles.

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32. A method of sensing a physiological parameter of a patient, comprising:

providing a probe assembly having an emitter, a detector, and first and second modular housings for the emitter and the detector;

providing a disposable finger attachment device having first and second modular receptacles operatively attached to a bandage apparatus of the disposable finger attachment device, the bandage apparatus having an adhesive on at least a portion thereof, said modular receptacles being configured to lockingly engage and disengage with said modular housings of said probe

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assembly, wherein said first and second modular receptacles comprise respective first and second locking mechanisms that lockingly engage and disengage modular housings of the probe assembly; and

transmitting and receiving a signal through the appendage of a patient when said finger attachment device is attached to a patient and when said modular housings of said probe assembly are engaged with said modular receptacles of said finger attachment device.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

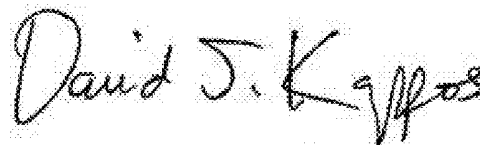
PATENT NO. : RE41,317 E
APPLICATION NO. : 11/404123
DATED : May 4, 2010
INVENTOR(S) : Brent Parker

Page 1 of 1

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 1, line 10, above the heading "REFERENCE TO RELATED APPLICATIONS" insert --Notice: More than one reissue application has been filed for the reissue of patent 6,721,585. The reissue applications are 11/404,123, now U.S. Reissue Patent 41,317 and 12/573,851, which is a continuation reissue application of 11/404,123.--.

Signed and Sealed this
Fourth Day of October, 2011

A handwritten signature in black ink that reads "David J. Kappos". The signature is written in a cursive, flowing style with a large initial "D" and a stylized "K".

David J. Kappos
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE
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-- Notice: More than one reissue application has been filed for the reissue of patent 6,721,585. The reissue applications are application number 11/404,123, filed April 13, 2006, now U.S. Reissued Patent No. 41,317, application number 12/573,851, filed Oct. 5, 2009, which is a continuation reissue application of the 11/404,123 application and claims the benefit thereof, now U.S. Reissued Patent No. 43,169, and application number 13/367,666, filed Feb. 7, 2012, which is a continuation reissue application of the 12/573,851 application and claims the benefit of both of the prior reissue applications. --

This certificate supersedes the Certificate of Correction issued October 4, 2011.

Signed and Sealed this
Twelfth Day of November, 2013



Teresa Stanek Rea
Deputy Director of the United States Patent and Trademark Office

专利名称(译)	通用模块化脉搏血氧仪探头，用于可重复使用和一次性患者连接装置		
公开(公告)号	USR41317	公开(公告)日	2010-05-04
申请号	US11/404123	申请日	2006-04-13
[标]申请(专利权)人(译)	梅西莫股份有限公司		
申请(专利权)人(译)	Masimo公司		
当前申请(专利权)人(译)	Masimo公司		
[标]发明人	PARKER BRENT		
发明人	PARKER, BRENT		
IPC分类号	A61B5/1455 A61B5/00		
CPC分类号	A61B5/14552 A61B5/6838 A61B5/6826 A61B2560/0443		
优先权	60/104332 1998-10-15 US		
外部链接	Espacenet USPTO		

摘要(译)

一种标准化模块化探针外壳的系统和方法，使得标准化的探针外壳可以结合到适于与多个制造商的血氧计中的至少一个一起工作的探针中。探针外壳适于与至少一次性绷带装置和可重复使用的手指附接装置配合地接合。脉冲血氧计系统包括具有第一和第二探针耦合器的手指附接装置，第一和第二探针耦合器被配置成可与之配合地接合。探头脉冲血氧计探头的外壳。

