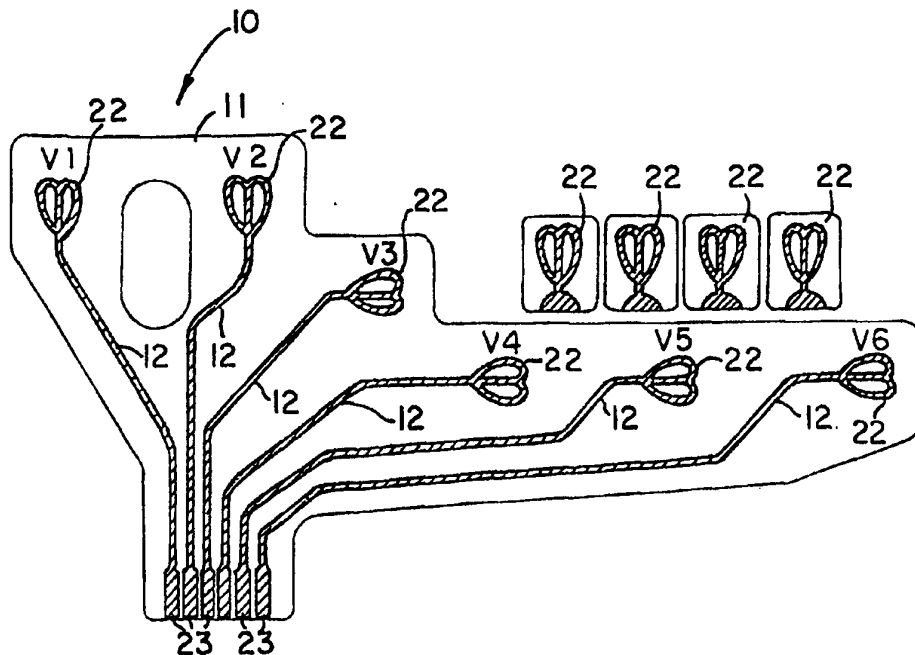




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<p>(51) International Patent Classification ⁶ : A61B 5/0402</p>	<p>A1</p>	<p>(11) International Publication Number: WO 97/04703 (43) International Publication Date: 13 February 1997 (13.02.97)</p>
<p>(21) International Application Number: PCT/US96/12100 (22) International Filing Date: 23 July 1996 (23.07.96) (30) Priority Data: 08/508,928 28 July 1995 (28.07.95) US (71) Applicant: CARDIOTRONICS INTERNATIONAL, INC. [US/US]; 12 El Verano Street, Orinda, CA 94563 (US). (72) Inventors: KELLY, Robert, J.; 1216 Shadybrook Drive, Beverly Hills, CA 90210 (US). LAVINE, Thomas; 672 Calle Del Norte, Camarillo, CA 93010-8441 (US). (74) Agents: KUTZENCO, Allan et al.; John Lezdey & Associates, 701 Haddon Avenue, Collingswood, NJ 08108 (US).</p>		<p>(81) Designated States: AU, CA, JP, KR, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i></p>

(54) Title: DISPOSABLE ELECTRO-DERMAL DEVICE



(57) Abstract

A disposable electro-dermal connector device (10) comprising a flexible non-conductive sheet (11) having a fixed array of electrical strips (12) affixed thereon, and positioned in a specific size configuration normally used for electro-cardia recording, is disclosed. The connector strips (12) have a receptor pad end (22) adapted for electrical connection with the skin for receiving electrical impulses, and a terminal connection end (23) which is adapted for connection with an electrocardiology measuring apparatus. Receptor pads (V₁)(V₂) are attached approximately over the sternum at the fourth intercostal space, and receptor pads (V₃)(V₄) are attached over the ribs, the distance between (V₁)(V₂), (V₂)(V₃)(V₄) is 1.75 inches plus or minus 0.56 inch.

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DISPOSABLE ELECTRO-DERMAL DEVICEField Of The Invention

This invention relates to a disposable medical device employing electrical signals to monitor or stimulate various parts of the body. More particularly the present invention involves a device for establishing electrical connection to a patient's skin containing a fixed array of conductive paths of substantially the same electrical resistance for use with an electrocardiological measuring apparatus.

Description Of The Prior Art

Prior art medical electrodes generally are combination structures including a metallic or otherwise conductive support member to which an electric wire from an assorted apparatus may be attached. Generally electrocardiograms sometimes referred to as an EKG or ECG have ten cable leads which attach to various points on the upper and mid-torso of a patient to measure and analyze cardiac data.

The person responsible for attaching the cable leads of the EKG often has problems in attaching these multiple leads to the patient because the cable leads may tangle with one another or may become detached before they are all connected. Accurately placing and securing a large number of leads can be difficult and time consuming and requires the knowledge of a skilled technician or physician.

Periodic electrocardiograms can provide a cardiographic profile of a patient for early detection and diagnosis of cardiovascular diseases. For purposes of providing an accurate profile, it is important that each electrocardiogram

be taken with sensors affixed at the same location on the patient. The accuracy of the reproducible results is critical so that a series of electrocardiograms can be compared, between testing episodes, to provide a continuing profile of a patient for diagnosis and treatment of heart disease.

Although a full screen, ten electrode electrocardiograph provides the most accurate picture for recognizing ischemic electrocardiographic changes, however, because of the urgent situation electrocardiograms taken during an acute symptomatic episode of a cardiac patient are generally limited to only two to four attached electrodes. Therefore, it would be advantageous and desirable to have a device which enables more leads accurately placed and quickly secured during an acute symptomatic episode.

On the other hand it may be necessary to quickly remove the chest cable leads of the EKG when a patient is experiencing another heart attack in order to administer CPR, to massage the heart, administer drugs or apply electrical defibrillation paddles. Accordingly, valuable seconds are often lost in removing the chest cable leads of the EKG device in order to administer aid to the patient.

Likewise it may be desirable to remove only the electrodes necessary to administer aid so that the remaining electrodes can continuously monitor the electrical activity on the heart during an acute symptomatic episode of the patient.

U.S. Patent No. 4,328,814 to Arkam teach a plurality of electrodes attached to a single junction connector having one cable leading to the EKG device. This device is designed for

an adult patient so that patients having larger or smaller torsos will have difficulty in using the device because the electrodes cannot be easily adjusted to accommodate a smaller or larger torso. Also, in the event of a heart attack, the plurality of electrodes must be disconnected from the EKG device by disconnecting the main connectors and then detaching the plurality of the electrodes. No electrodes remain on the patient to monitor the heart attack.

U.S. Patent No. 4,353,372 to Ager discloses a plurality of electrodes which plug into a junction box connected to an EKG machine. Each of the electrodes includes wires molded into a central cable system which joins the junction box. This device, does not include means for quickly attaching or removing the electrodes. For example, in an emergency situation if the electrodes must be removed quickly, the junction box must be disconnected first and then each of the electrodes must be detached. Although each electrode has a wire lead from the main molded cable, which may permit some adjustment in the placement of the electrodes on the upper portion of a human torso, the device is not entirely adequate for large adults or very small children because of the limited adjustment of each electrode.

U.S. Patent No. 4,608,987 to Mills relates to a vest-like garment having a plurality of apertures adapted for receiving associated electrodes. However, the vest is not tailored for a specific patient and proper fit is provided by adjustable straps which may be secured by VELCRO^R material. Therefore, there is no assurance that the electrodes are placed at the

same anatomical location upon reuse with the same patient.

U.S. Patent No. 3,910,260 describes telephonic units for transmitting ECG signals to ECG receiving equipment which could be at a hospital or a physician's office. The transmission may take place in emergency vehicles where prior medical history may not be readily available. In order to obtain meaningful and reliable data ECG signals are necessary for the care providers. None of the prior art devices have disclosed a low cost solution for obtaining repeatable placement of sensors for accurate and readable ECG signals in the field by unskilled individuals.

Because of the inadequacies of prior art devices there is a need for a system which prevents EKG electrode leads from being entangled; provides quick removal of some of the electrodes while leaving the remaining electrodes in position when it is necessary to administer aid to a patient having a heart attack; provides accurate repeatable placement of electrodes at substantially the same anatomical location; accurately and repeatedly obtains signals from body electrodes by efficient and effective electrical transmission; may be attached by unskilled persons; and may be available in various sizes to accommodate to fit the patient.

Summary Of The Invention

The present invention, in the broadest sense involves a disposable non-conducting flexible sheet incorporating a fixed array of electrical conducting strips emanating from a terminus that can connect to a standard electrocardiographic cable or telemetric unit. The strips are used as both collectors and as transmitters for electrical impulses.

Conventional sensory electrodes are optional since the device can function without them. More particularly, the invention relates to a disposable, electro-dermal connector device comprising: a flexible non-conductive sheet comprising a fixed array of electrical conductor strips affixed thereto having a receptor pad end and a terminal connection end said array positioned in the configuration normally used for electrocardial recording whereby the flexibility of said connector and adhesion of the surface of the flexible sheet to skin are substantially enhanced.

Each strip includes a first end portion or receptor end adapted for electrical connection with the skin for receiving electrical impulses. A second end portion terminates in a common electrical connection or cable junction which is adapted for connection with a standard type of cable junction for connection with the electrocardiograph device.

The conductive strips may be printed on the single layer non-conductive film or sheet by any conventional printing or silk screening type of process. The portion of the strip which need not be exposed can be coated or covered with a non-conductive coating or adhesive material which can be cured. Conductor strips which are less than 10 micrometers in thickness which provide enhanced flexibility without distorting the electrical signal.

More particularly, the invention relates to a disposable electro-dermal connector device comprising: a flexible non-conductive sheet comprising a fixed array of electrical conductor strips affixed thereon and positioned in a specific size configuration normally used for standard electrocardial

recording, said conductor strips having a receptor pad end adapted for electrical connection with the skin for receiving electrical impulses and a terminal connection end which is adapted for connection with an electrocardiological measuring apparatus, wherein receptor pads V_1 and V_2 are attached approximately on either side of the sternum at the fourth intercostal space and receptor pad V_3 is attached over the fifth intercostal space midway between V_2 and V_4 . V_5 is equidistant between V_4 and V_6 . The distance between V_1 and V_2 , V_2 and V_3 and V_4 is about 1.75 inches \pm 0.56 inch.

Brief Description Of The Drawings

FIG. 1 shows a preferred device of the present invention for attachment to the torso of a patient.

FIG. 2 shows a preferred embodiment of the present invention of properly positioning the device on a patient.

FIG. 3 illustrates the first step in the method for determining the size of the device to be used on a patient according to this invention.

FIG. 4 shows the second step in the method for determining the size of the device to be placed on a patient according to this invention.

Description Of The Preferred Embodiments

Referring now to the drawings, FIG. 1 illustrates the electro-dermal connector device 10 of the present invention for placement on the chest of a patient comprising flexible non-conducting sheet 11 incorporating multiple conductor strips 12 for connection to a standard electrocardiographic receiving unit. The non-conducting sheet 11 includes conductor strips 12 which form end sensors or receptor 22

which are positioned on the sheet and spaced relative to each other whereby each receptors **22** is positioned in a specific size configuration normally used for electrocardial recordings.

Each strip **12** includes a first end portion or receptor **22** adapted for electrical connections with the skin for receiving and transmitting electrical impulses generated by the body. A second end of each strip **12** or the terminal connector end **23** to engage a common electrical connection or cable junction (not shown) for connection with the electrocardiograph device (not shown).

When in use an electrically conductive ion containing a biocompatible adhesive gel is applied to the body contacting side of sheet **11** at each receptor **22** of connector **12** for adhesion to the skin of the patient for providing electrical connection between each of the precordial ends and the terminal end **23** connected to the proper receiving devices (not shown).

The adhesive gel coated area of connector device includes at least one release liner in releasable adhesive contact with the gel. Each of the conductor strips **12** are less than 10, preferably less than 5 micrometers in thickness whereby the flexibility of the connector and adhesion of the gel surface to the skin are substantially enhanced.

FIG. 1 shows the connector array (V_1 , V_2 , V_3 , V_4 , V_5 , and V_6) on flexible sheet **11** which is designed to adhere to a human torso so that the terminal ends **22** are located below the sternal notch, over the ribs and at the side of the torso. The flexible sheet **11** can be substantially transparent and

includes an opening in the proximate center which is intended to span the upper portion of the sternum of the patient. The sheet may include indicia adjacent to or on each of the conductor strips to facilitate correct placement of the receptors on the precordial areas of the human torso.

FIG. 2 illustrates the position of the electro-dermal connector device 10 as it is properly positioned upon a patient. The connector device 10 is generally attached by adhering the precordial receptors. The receptors V_1 and V_2 are attached approximately on opposite sides of the sternum at the fourth intercostal space. Pads V_3 and V_4 are attached over the ribs. Pads V_5 and V_6 are placed at the side of the torso so that V_5 is midway between V_4 and V_6 . For small sizes the distance between V_4 and V_6 is on the average 3.5 inches, for medium 5.0 inches and for large 7 inches. The contour of the electro-dermal connector 10 is configured to conform substantially to the shape of a human trunk.

In cross section a preferred laminate of the invention comprises the following layers:

- a) a flexible non-conductive film of polyethylene terephthalate;
- b) a catalyst layer in contact with silver ink;
- c) a connector strip in contact with silver ink;
- d) a dielectric layer in contact with silver ink and silver chloride receptor layer superimposed upon the silver ink layer;
- e) a conductive hydrogel layer superimposed upon the silver chloride receptor layer; and
- f) a flexible release liner as the top layer superimposed

upon the conductive hydrogel.

The flexible non-conductive web or sheet 11 may be formed from any non-conductive flexible natural or synthetic sheet material which is capable of accepting a print. Generally any cellulosic material, polyester, polyolefin, polyvinyl chloride, nylon or mixtures thereof would be suitable. Preferably, cotton, polypropylene, polyethylene can be used because of cost. Polyethylene terphthalate is most preferred. The polymer sheet material may be color coded for specific body areas or may contain an outline and/or color markings to simplify the electro-dermal connector device. As mentioned earlier the device of this invention is designed to include the use by an untrained or trained individual. This device allows an untrained person including the patients themselves to provide highly reliable and repeatable ECG signals.

The receptors 12 can be produced from any electrically conductive material, e.g., metals, conductive polymers, graphite, carbon fibers and the like. Conductive materials such as gold, copper, silver, tin, aluminum, N-vinyl pyrrolidone and alloys or mixtures thereof maybe used. The receptors can be made of metal foil or made from a conductive paste of a metal in particle form in a suitable binder which is printed or silk screened onto the flexibly non-conductive sheet. The connective polymer may be heat pressed or otherwise conventionally adhered to the web or sheet.

Preferably, copper strips are electrolessly deposited on the polymeric sheets in a range from about 0.25 to about 5 microns, more preferably from 0.25 to 1.5 microns and most preferably 0.4 microns in thickness.

If desired, the exposed conductive strips may be partially coated with a dielectric polymeric material so that only selective portions are exposed. Suitable dielectric coatings include polyesters, ethylene-vinyl acetate copolymers, polyvinyl chloride and its copolymers, terpolymers such as acrylonitrile-butadiene styrene (ABS resins) and inter alia.

One form of metallic ink which may be used is a silver ink is commercially available and marketed by Dupont Chemical Corp. of Wilmington, Delaware under the tradename Composition 9793.

The conductive adhesive hydrogel is sold commercially by Lee Tec Corporation of Eden Prairie, MN. Other suitable conductive adhesives are manufactured by 3M Corporation of St. Paul, MN. Although an adhesive hydrogel is preferred any commercial electro-dermal adhesive would be operable. Preferably the area size of the hydrogel is between about 3 and 9 square centimeters.

The flexible release liner may be made from a suitable dielectric film which includes polyesters, olefinic polymers, polyvinyl chloride and its copolymers, acrylic rubbers, ABS resin and the like.

In a preferred embodiment the electro-dermal connector device 10 comprises at least six gel contact areas and is adapted for use in electrocardiography.

The electro-dermal connector device 10 is available in sizes to accommodate any size adult person. It has been found that the distance between pads V_1 to V_4 is constant for all sizes. The separation of 1.75 inches will accommodate all

adults with a tolerance of plus or minus 0.56 inch at each pad. It has also been found that body placement for pads V_5 and V_6 vary depending on individual size. FIG. 4 shows a method of determining the proper size. The measurement from the V_4 position to V_6 position determines the size of the device. As illustrated in FIG. 4 this measurement is the distance determined between the thumb and the middle finger and then matched to a scale provided. The table below corresponds to the illustrated scale.

TABLE

<u>SIZE</u>	<u>$V_4 - V_5$</u>	<u>$V_5 - V_6$</u>
Small	1.75 "	1.75 "
Medium	2.50 "	2.50 "
Large	3.50 "	3.50 "

Generally, the distance between V_4 to V_6 will be determined by the size of the patient, that is, the size of the vest. For a small vest the distance between V_4 and V_6 is about 2.5 to 4.5 inches with the centering of V_5 being at about 1.75 inches, the medium vest has a distance of about 4.0 to 6.0 inches with the centering of V_6 being about 2.5 inches, and the large vest the distance is about 6.0 to 8.0 inches with the centering being about 3.5 inches.

In all sizes of the devices of the invention V_1 , V_2 , V_3 and V_4 are all positioned the same. The center of V_1 is located on a radius of 0.825 inches from a point 1.75 inches \pm 0.56 inches from the center of V_2 on the 270 (90) degree radial from the center of V_2 wherein the radial is measured with zero degrees from the top of the device. The center of V_3 is

located within a radius of 0.825 from a point 1.75 inches ± 0.56 inches from the center V₂ on the top 236 (56) degree radial from the center of V₂. The center of V₄ is located within a radius of 0.825 inches from a point 3.5 inches from the center V₂ on the 236 (56) degree radial from the center of V₂.

A typical dimensional layout for V₅ and V₆ relative to V₄ is as follows:

Table

<u>SIZE</u>	<u>V₄ - V₅</u>	<u>V₅ - V₆</u>
Small Vest	1.75"	1.75"
Medium Vest	2.50"	2.50"
Large Vest	3.50"	3.50"

The distance between V₁ and V₂ is 1.75 inches, the distance between sternum and V₄ along a horizontal line is 3.85 inches with V₃ along a horizontal line being equidistant from V₂ and V₄.

What Is Claimed Is:

1. A disposable electro-dermal connector device comprising:
a flexible non-conductive sheet comprising a fixed array of electrical conductor strips affixed thereon and positioned in a specific size configuration normally used for standard electrocardial recording, said conductor strips having receptor ends V_1 to V_6 adapted for electrical connection with the skin for receiving and transmitting electrical impulses and a terminal connection end which is adapted for connection with an electrocardiological measuring apparatus wherein receptor pads V_1 and V_2 are attachable approximately on either side of the sternum at the fourth intercostal space and receptor pad V_3 is attachable over the fifth intercostal space midway between V_2 and V_4 , the distance between V_1 and V_2 , V_2 and V_3 and V_3 and V_4 is 1.75 inches \pm 0.56 inch, and V_5 is equidistant between V_4 and V_6 .
2. The connector device of claim 1 wherein said sheet material is selected from non-conductive flexible natural or synthetic sheet material.
3. The connector device of claim 2 wherein said non-conductive sheet is selected from cellulosic materials, polyesters, polyolefins, polyvinyl chloride or nylon.
4. The connector device of claim 3 where said cellulosic material is cotton or paper.
5. The connector device of claim 3 wherein said polyester is polyethylene terphthalate.
6. The connector device of claim 1 wherein the conductor strips are selected from metal, polymer, graphite or carbon

fibers.

7. The connector device of claim 6 wherein said metal is selected from gold, copper, silver, tin or aluminum and alloys or mixtures thereof.

8. The connector device of claim 7 wherein said conductor strips are made of metal foil or a metal paste.

9. The connector device of claim 8 wherein said paste is printed or silk screened onto said non-conductive sheet.

10. The connector device of claim 7 wherein said paste is electrolessly deposited on the non-conductive sheet.

11. The connector device of claim 6 wherein the exposed conductive strips are coated with a dielectric polymeric material so that only sensitive portions are exposed.

12. The connector device of claim 11 wherein said dielectric polymeric material is selected from polyesters, copolymers of ethylene-vinyl acetate, homopolymers and copolymers of polyvinylchloride and ABS resins.

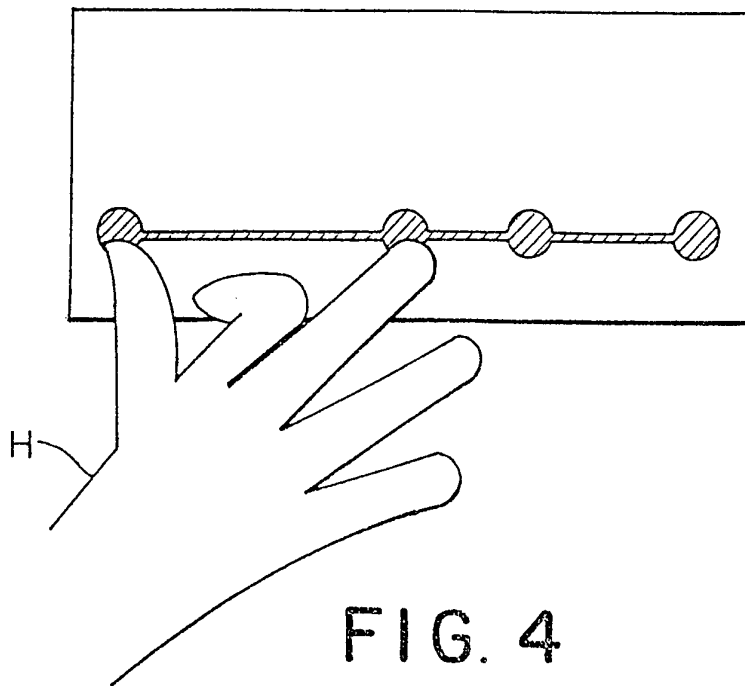
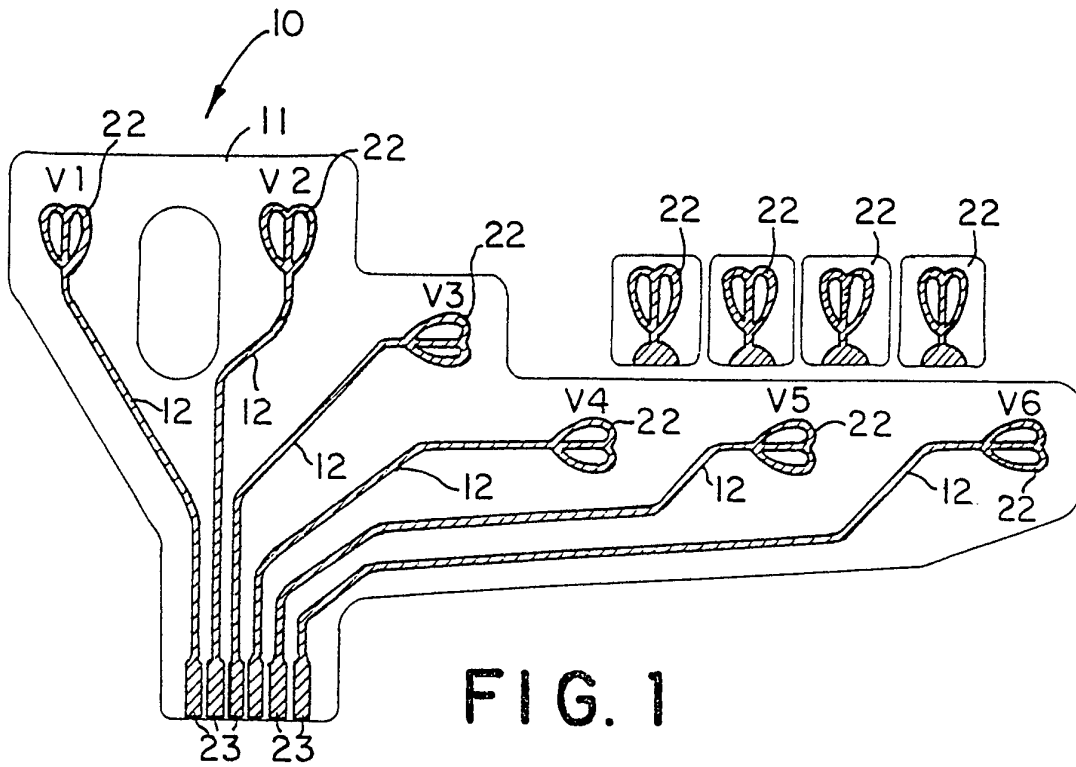
13. The connector device of claim 7 wherein said conductor strips are less than 10 microns in thickness.

14. The connector device of claim 1 wherein the distance between V_4 and V_5 and V_5 and V_6 is about 1.75 inches.

15. The connector device of claim 1 wherein the distance between V_4 and V_5 and V_5 and V_6 is about 2.5 inches.

16. The connector device of claim 1 wherein the distance between V_4 and V_5 and V_5 and V_6 is about 3.5 inches.

17. The connector device of claim 1 wherein V_1 is located 1.75 inches \pm 0.56 inches in radius on the 270 degree radial from the center of V_2 .



2/2

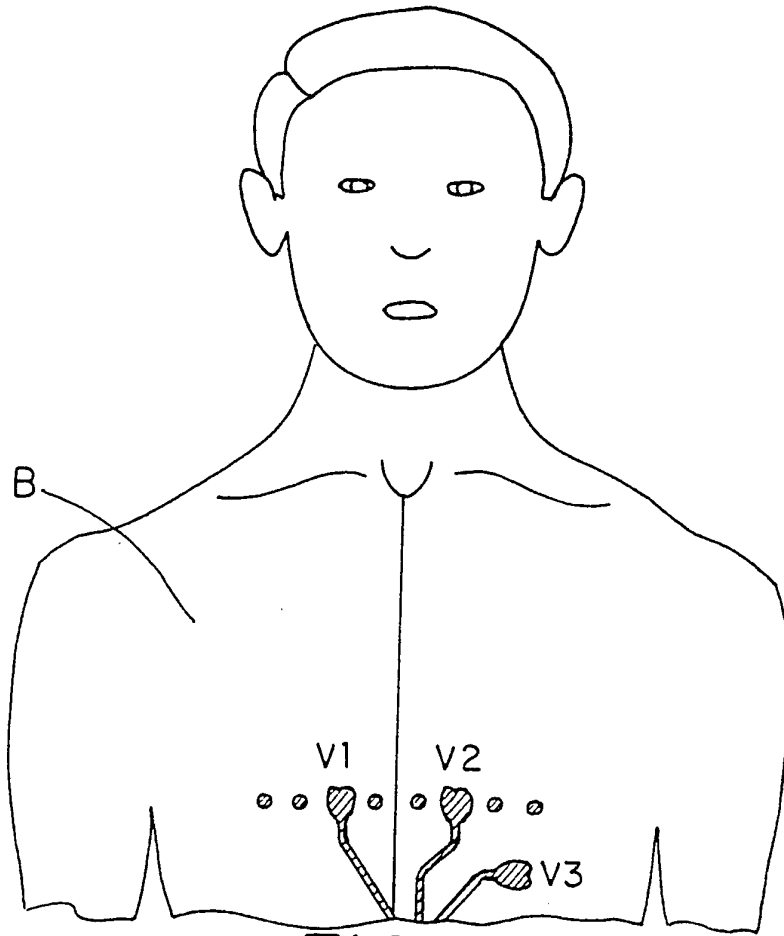


FIG. 2

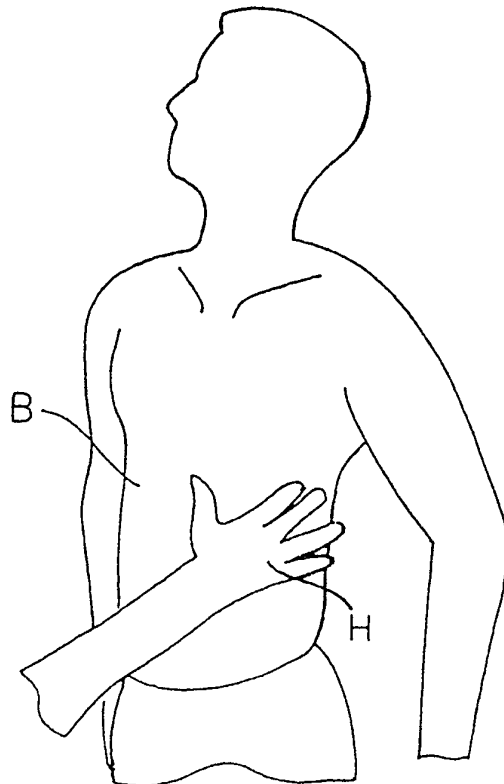


FIG. 3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/12100

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 5/0402
US CL :128/640

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/640, 644

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 5,522,211 (BARE ET AL.) 11 June 1985, see column 7 lines 48-50.	13
Y	US, A, 4,583,549 (MANOLI) 22 April 1986, see entire document.	1-17
Y	US, A, 4,763,660 (KROLL ET AL.) 16 August 1988, see column 5 lines 43-47.	1-17

Further documents are listed in the continuation of Box C. See patent family annex.

* "A"	Special categories of cited documents: document defining the general state of the art which is not considered to be part of particular relevance	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
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"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O"	document referring to an oral disclosure, use, exhibition or other means	"&"	document member of the same patent family
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Date of the actual completion of the international search

11 SEPTEMBER 1996

Date of mailing of the international search report

02 OCT 1996

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