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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 :		(11) International Publication Number:	WO 94/01039
A61B 5/04	A1	(43) International Publication Date:	20 January 1994 (20.01.94)

(21) International Application Number: PCT/US93/06386

(22) International Filing Date: 7 July 1993 (07.07.93)

(30) Priority data:
07/911,561 7 July 1992 (07.07.92) US

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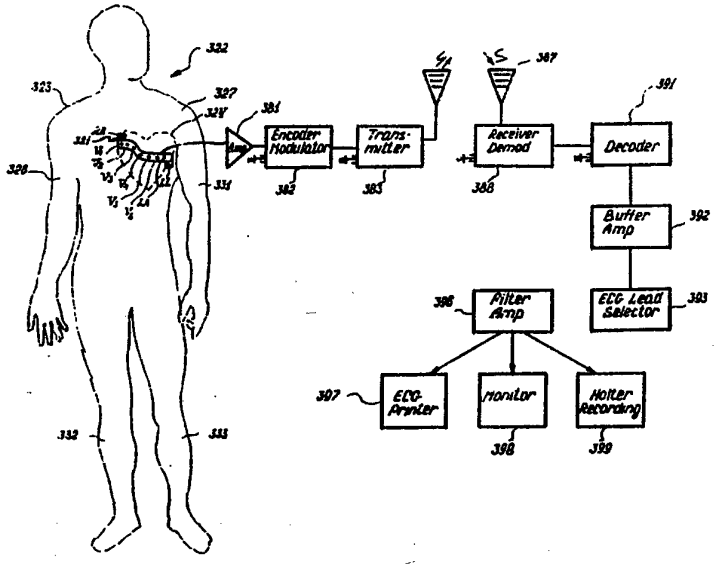
(81) Designated States: JP, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.

(54) Title: WIRELESS ELECTROCARDIOGRAPHIC SYSTEM AND WIRELESS ELECTRODE ASSEMBLIES



(57) Abstract

A precordial system and method having a strip assembly (321) for use on a patient having skin, right and left arms and legs and a heart with a precordium lying thereover comprising an elongate strip (321) having first and second surfaces. Six conductive contact elements identified as V1 through V6 are mounted in space apart positions along the length of the strip (321). The strip (321) is connected to an amplifier (381) which is connected to an encoder modulator (382) which is connected to a transmitter (383) for frequency transmission of signals to receiver (388). Decoded signals are filtered by filter (396) and output to ECG printer (397) or monitor (398) or Holter recorder (399).

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WIRELESS ELECTROCARDIOGRAPHIC SYSTEM AND WIRELESS ELECTRODE ASSEMBLIES

FIELD OF THE INVENTION

This invention relates to medical instrumentation and to a system for the use thereof, as well as to a system and method of monitoring certain physiological parameters, and for the detection and transmission of these without the use of wires to suitable display and/or recording monitoring equipment. This invention is described in detail with reference to electrocardiographic and cardiocirculatory monitoring equipment and method and system relating thereto. According to this invention, other or further physiological data of a patient can be measured and if desired, wirelessly transmitted to suitable equipment for detection, monitoring and evaluation.

In my previous US Patent No. 4,981,141 there is described and claimed, amongst others a wireless electrocardiographic monitoring system for displaying detected heart-signals, said system including:

right arm, left arm, right leg and left leg electrodes for attachment to the indicated limbs of a patient;
right arm heart-signal transmitting means electrically couplable to said right arm electrode for radiating a signal corresponding to the heart-signal at said right arm electrode;
left arm heart-signal transmitting means electrically couplable to said left arm electrode for radiating a signal corresponding to the heart-signal to said left arm electrode;
left leg heart-signal transmitting means electrically couplable for radiating a signal corresponding to the heart-signal at said left leg electrode;

a plurality of signal receiving means, one each for receiving and detecting said radiated heart-signals from said left arm, right arm and left leg electrodes, respectively, to individually produce a received left arm heart-signal, a received right arm heart-signal and a received left leg heart-signal.

means for combining said individually received left arm, right arm and left leg heart-signals to produce a reference potential;

reference potential transmitting means coupled to said combining means for transmitting said reference potential;

right leg signal receiving means electrically couplable to said right leg electrode for receiving said reference potential and applying said reference potential to said right leg electrode;

a set of precordial electrodes for attachment to the chest of a patient;

a set of precordial heart-signal transmitting means each one electrically couplable to different ones of said precordial electrodes in said set for individually radiating signals corresponding to the heart-signal at respective ones of said precordial electrodes;

a set of precordial heart-signal receiving and detecting means, each one associated with a different one of said precordial heart-signal transmitting means for individually reproducing the heart-signals appearing at each of said precordial electrodes in said set;

signal display means;

means for coupling said detected heart-signals from said right arm, left arm and left leg electrodes and from said precordial electrodes to said signal display means; and

means for providing operating power for all of the foregoing.

In my US Patent No. 5,168,874 there is described and claimed amongst others an electrode structure for use in the wireless monitoring system, including:

an electrically non-conductive patch electrode having first and second sides;
first and second conductive elements carried by said patch electrode in spaced relationship to each other and disposed on said first side of said patch electrode;
a battery having at least one voltage terminal and a ground terminal carried on said second side of said patch electrode;
a micro-chip amplifier carried on said second side of said patch electrode and having a signal input terminal coupled to said first conductive element for receiving heart signals therefrom and having an output terminal;
a micro-chip encoder-modulator carried on said second side of said patch electrode and having an input terminal coupled to said output terminal of said amplifier and having an output terminal;
a micro-chip transmitter carried by said patch electrode on said second side thereof and having an input terminal and an output terminal, said input terminal of said transmitter being coupled to said output terminal of said encoder-modulator;
a wireless-signal radiator having an input terminal coupled to said output terminal of said micro-chip transmitter;
means for applying operating potentials from said battery to said micro-chip amplifier, encoder-modulator and transmitter, respectively; and
means for coupling said ground terminal of said battery to said second conductive element;

said first and second conductive elements being concentric.

The content of these two patent is incorporated herein by reference so as to obtain a better understanding of the improvements of the present invention.

Prior Art

Every muscle can perform only one movement, the shortening of its fibers by contraction. This also applies to the heart muscle. Every action of a muscle has associated with it an electrical activity which changes in the course of the contraction. The electrical signal thus associated with the muscle action is transmitted through various tissues and ultimately reaches the surface of the body whereupon such electrical signals can be detected by electrodes applied to the skin. Thus, such signals that are being detected by the electrodes can be recorded with the aid of suitable electrocardiographic equipment or can be observed in or recorded with a monitor/recording unit. The record thus obtained is called an electrocardiogram or a rhythm-monitoring strip.

As early as 1855 action currents from the heart were recorded as measurements were being made of a beating frog heart. The first actual recording of a frog electrocardiogram was made by A.D. Waller in 1887. The first recording of a human heart electrical action signal (hereinafter "heart-signal") was made by A.D. Waller in 1889. Modern electrocardiography, however, started with Einthoven (credited with the bipolar lead triangle setting for recordings of standard limb leads I, II and III), who invented the string galvanometer and applied it to recording small voltages of short duration, which is the category into which heart-signals fall. His recording techniques have not been improved upon very much since they were first published many years ago. Here it should

be noted that the term "lead" as used herein is being used in the medical sense and not in the electronic sense (i.e., "lead" is a spatial position at which the heart-signal is viewed, not a wire).

After Einthoven's work, the entire field of research stagnated for nearly thirty years until the introduction by Wilson of upper and lower extremities' local leads and the zero electrode used in unipolar recordings.

The entire twelve-lead system is fed by unipolar and bipolar signals. Unipolar leads are divided into unipolar extremity or limb leads and unipolar precordial or chest leads.

In the unipolar lead system, the limb leads are:

aVR -- the unipolar right arm lead, (R designating the right arm);

aVL -- unipolar left arm lead, (L designating the left arm); and

aVF -- unipolar left leg lead.

In all of these limb leads, the "a" stands for "augmented". The unipolar chest leads are designated by the letter "V" followed by a subscript numeral which represents the exact location on the chest. In a standard electrocardiographic setting there are six precordial leads, V1-V6.

In the unipolar lead system, in existing conventional electrochardiographic equipment the potential differences are measured between each of the electrodes that are placed on the right arm, left arm, left leg, and precordial points V1-V6 on the chest and a common reference point consisting of an electrode on the right leg. Each of the electrodes

is independently considered as an active point compared to the common reference electrode (point) on the right leg, and is measured in relation to that common reference electrode.

In standard bipolar leads, lead I is the potential difference between the arms, i.e., the left arm potential minus the right arm potential. Lead II is the potential difference between the left leg potential and the right arm potential. Lead III is the potential difference between the left leg and the left arm. If the leads are diagrammed on the body they inscribe, essentially, an equilateral triangle. The polarity of these widely-separated bipoles was arbitrarily determined many years ago in order to record upright electrical deflections in these three limbs leads in most normal objects. The electrocardiograph generates the lead voltages from the potentials applied to it from the electrodes. The term "lead" as used in electrocardiography means view of the heart's electrical impulse. That view varies among leads.

The electrocardiograph is widely used by the medical profession. To obtain complete 12-lead ECG, the standard electrocardiograph requires at least ten wires which are attached to the body of the
patient at one end and to the electrocardiograph at the other end to detect heart-signals and transform them into a twelve-lead electrocardiogram evaluation. This involves attaching six electrodes to the chest or precordial area to obtain recordings of leads V1-V6 as well as attaching four electrodes to the arms and legs of the patient to obtain recordings of leads I, II, III, aVR, aVL and aVF. For heart rhythm monitoring, only three electrodes and three terminal wires are applied to the chest, thus providing single lead detection. After the ten electrodes are

attached to the patient, ten specific wires must be connected between each specific electrocardiograph terminal and the related electrode of the predetermined position on the patient's body.

In electrocardiographic terminology, the terms "dipole", "bipole" and "unipolar" have different meanings and applications. The "single dipole" concept is used to represent the local spread of excitation over cardiac tissue as recorded by a single recording electrode. This local excitation is in the form of a local influx and/or outflux of electrically charged elements, referred to as ions, passing through the cell membrane. The term "equivalent dipole" has been a term used since the days of Einthoven to represent the theoretical "electrical center" of a volume conductor used to describe the progression, magnitude and location of the electrical activity of the human body. This "equivalent dipole" has both direction and magnitude at any instance in the cardiac cycle and is traditionally represented as a vector that points in the direction of the positive pole of a dipole having both positive and negative poles. The vector has a length proportional to the magnitude of the dipoles' potential difference (i.e., the potential difference between its positive and negative poles).

The term "bipolar" has several uses in clinical electrocardiography and electrophysiology. Bipolar endocardial and epicardial recordings refer to recordings made between a cathode and anode of a recording device which are relatively closely spaced (e.g., several millimeters to one centimeter). For example, bipolar cardiac recordings are taken by modern pacemakers having leads that are reasonably closely spaced. In surface electrocardiographic practice, bipolar lead systems, as

discussed above, are defined as limb lead systems that measure the potential differences between the three limb electrodes on the right and left arms and the left leg. The term "unipolar" is used in the practice of surface electrocardiography as described above.

The conventional and currently existing electrocardiographic monitoring systems are limited in their operation and do not provide important clinical information. An early manifestation of acute myocardial ischemia is the development of ST-segment and T-wave changes. Clinical decisions for treatment are based on ST-segment shifts on the surface electrocardiogram. ST-segment depression is believed to represent subendocardial involvement, with less extensive myocardial injury. ST-segment elevation reflects transmural involvement, with greater extent of myocardial injury. Currently existing electrocardiographic monitoring equipment in the coronary intensive care units (CICU) and intensive care units (ICU) provides single-lead arrhythmia monitoring of cardiac events which is unable to detect myocardial ischemia or dynamic coronary insuficiency in real time occurrence.

In the surgical setting, the cardiac catheterization laboratory protocol of percutaneous transluminal coronary angioplasty (PTCA) procedures employs the use of no more than three-lead arrhythmia monitoring which is unable to detect ischemic events during actual performance of percutaneous transluminal coronary angioplasty.

In the ambulatory setting, Holter monitoring provides only arrhythmia recording and detection, which is unable to identify or locate corcnary silent or symptomatic ischemia.

Transtelephonic electrocardiogram transmission currently employs single-lead arrhythmia monitoring which is unable to identify or locate myocardial ischemic events in patients who have undergone percutaneous transluminal coronary angioplasty procedures, coronary artery bypass graft (CABG) surgery, or are currently being treated with antiarrhythmic drugs or are experiencing stable angina pectoris episodes.

In other settings, existing protocols employ single-lead electrocardiographic monitoring in the coronary intensive care mobil unit and emergency room, thereby permitting arrhythmia monitoring only. As can be seen, current coronary care electrocardiographic monitoring techniques are aimed at detection of cardiac arrhythmias rather than myocardial ischemia.

Existing electrocardiographic systems are also limited in diagnosing myocardial ischemia after noncardiac surgery. Patients undergoing noncardiac surgery sometimes have postoperative cardiac events. Adverse cardiac events are a major cause of morbidity and mortality after such surgery. It is necessary to determine the predictors of these cardiac outcomes in order to focus efforts on prevention and treatment. It would be helpful to know which patients are at highest risk. Clinical experience has demonstrated that postoperative myocardial ischemia during the first 48 hours after surgery confers a nearly threefold increase in the odds of having an adverse cardiac outcome and, more importantly, a ninefold increase in the odds of having an myocardial ischemic event (that may lead to cardiac death, nonfatal myocardial infarction or unstable angina) in patients undergoing noncardiac surgery. In some clinical

studies, postoperative myocardial ischemia was prevalent, occurring in more than 40 percent of the patients, and was silent in nearly all cases studied.

In addition, many and frequent difficulties are associated with the practical operation of the conventional and currently existing electrocardiographic monitoring systems due to the following factors:

1. The need to connect predetermined specific wires to predetermined specific electrodes (e.g. defined limb and side to defined wire, as well as specific precordial points to defined precordial wires) is time-consuming. In addition, connection errors are relatively frequent.

2. The wires often need to be untangled, resulting in the loss of precious time.

3. Existing electrocardiographic systems are somewhat impractical for use in coronary intensive care mobile units where speed of operation is critical.

4. Wire defects and damage are difficult to detect.

5. During many surgical procedures, single lead arrhythmia monitoring wires extend beneath the sterile surgical field. These wires often become disconnected from the electrodes and can interrupt the surgical procedure as they have to be reconnected beneath the sterile field. In addition, existing electrocardiographic systems do not permit myocardial ischemia detection during surgery.

6. Patients in intermediate coronary care units sometimes disconnect the signal carrying wires from the electrocardiographic monitor while ambulating. By doing so, cardiac rhythm monitoring is interrupted.

7. Current electrocardiographic monitoring is limited in range and distance by the proximity between the patient and the electrocardiograph or monitor, resulting from wires limited length.

8. Current percutaneous transluminal coronary angioplasty (PTCA), diagnostic heart catheterization and other invasive interventional procedures performed in the cardiac catheterization suite; electrocardiographic monitoring in coronary intensive care units, intensive care unit (ICU) and coronary intensive care mobile units; and thrombolytic therapy monitoring; in each case, employ single lead or three lead electrocardiographic detection which provides only arrhythmia monitoring and is unable to diagnose myocardial ischemic events.

9. Patient compliance with the procedures and equipment and requirements of current electrocardiographic systems is minimal.

Therefore, it is an object of this invention to overcome the problems previously experienced in connection with the application of electrocardiographs in the taking of electrocardiograms and in connection with the limited clinical information obtained from rhythm monitoring of patients.

Another object of this invention is to provide an electrocardiographic and monitoring system in which the physical wires between the patient and the electrocardiograph or monitor are eliminated.

Another object of this invention is to provide an electrocardiographic and monitoring system in which a reduced standard number of wireless electrodes provide a complete standard twelve-lead electrocardiogram.

Another object of the present invention is to provide a precordial strip assembly containing a plurality of conductive elements for placement on the precordium area of a patient.

Another object of the invention is to provide a precordial strip assembly containing a reference conductive elements permitting elimination of the standard right leg reference electrode.

Another object of the invention is to provide a precordial strip assembly having RA and LL conductive elements positionable on the patient in a position remote from or adjacent to the V1 through V6 and LA conductive elements.

Another object of the invention is to provide a self ontained precordial strip assembly having one or more microchips for detecting, elaborating and transmitting heart signals from a patient to a receiving unit interfaced to display or recording monitoring equipment.

Summary of the Invention

In accordance with the preferred embodiments of the resent invention there is disclosed a two-section medical monitoring system. One section includes the strip electrode that is affixed to the patient for detection of and/or array analysis of specific electrical signals and the second section is the receiving equipment to permit analysis the signals. No wires extend between the two sections. The second section interfaces with the electrocardiograph or electrocardiographic monitoring display equipment. The wireless strip or strip-electrode operates independently of other operating strip-electrodes and is a self-contained one or more microchips and self-powered and individually radiates its measured signals to a corresponding individual receiver interfaced to the monitoring equipment section. To ensure that the receivers in the monitoring-receiving section operate on the proper signal from the individual strip electrode, each strip electrode transmits its signal with an encoded pattern that can be decoded only by its corresponding receiver in the properly coupled and interfaced unit placed within or connected to electrocardiographic display or recording equipment.

The present invention presents several different configurations, or groupings, of the ten conductive elements needed to enable a "complete" standard twelve-lead electrocardiogram (ECG) monitoring. By grouping the conductive elements, while maintaining their individual electrophysiological proper function, the number of appliances that have to be affixed to the patient is reduced, thus reducing the amount of time necessary to apply conventional electrodes and further minimizing the chance of error from the placement of the conventional

eletrodes in the wrong locations on the patient and avoid their possibly mistaken predetermined connections.

The electrocardiac activity information detected and transmitted by the system according to this invention conforms to all professional standards and levels of accuracy for vector progression, duration, intensity, and form characteristics specifically with respect to the following features:

1. Rhythm
2. Rate
3. P wave
4. P-R interval
5. QRS interval
6. QRS complex
7. ST segment
8. T wave
9. U wave
10. Q-T duration

The system will function within a nominal range of approximately 50 to 100 meters or less between the strip electrode system and the receiving unit. This configuration is suitable for operation with either a single-channel or a multi-channel electrocardiograph, monitor, or Holter. Each of those hardware units may be fixed or portable, battery or AC powered. The receiving-demodulating-decoding base unit of the system of the present invention can be connected to or interfaced existing stand-alone electrocardiographs or, by reason of its miniature size, can be integrated into new generations of such machines. Interference between multiple systems operating in the same facility is prevented by choosing different center frequencies for each of the transmitters

and corresponding receivers within the corresponding system and all other systems within 100 meters or more of each other.

While reference has been made herein to a radio frequency (RF) system of coupling between body electrodes and the receiving base unit that is interfaced to the monitoring equipment, it should be understood that with only minor changes in the circuitry and the proper operating environment, ultrasonic or semiconductors or transmission techniques as well as other technologies may be used.

The electrode on the right leg has been eliminated to further reduce the number of electrode assemblies that must be placed on the patient. The reduction in electrode assemblies can be made by using a patch or strip on which all of the precordial V1 to V6 contact elements are mounted and the LA, RA, LL contact elements and reference contact element (instead of RL in conventional setting) are mounted on or spaced adjacent to said precordial strip electrode.

The precordial strip assembly of the present invention is for use on a patient having skin, right and left arms and legs and a heart with a precordium lying thereover. The assembly includes an elongate strip with first and second surfaces. Six conductive contact elements identified as V1 through V6 are mounted in spaced apart positions along the length of the strip. In other embodiments, conductive contact elements identified as LA, LL and RA can be mounted on or connected to the strip or patch-electrode. A reference contact element can be carried by or spaced adjacent to the strip for serving as a common reference for each of the conductive contact elements for unipolar lead

detection. The contact elements are exposed on the first surface of the strip and are adapted to contact the patient's skin for detecting heart signals from the patient when the precordial strip assembly is placed on the precordium of the patient. Junction means is carried in a single region by the strip and is electrically connected to the contact elements. One or more microchips can be connected to the contact elements for detection of the heart signals and elaborating the 12-lead ECG output and transmitting a single channeledradio frequency digitally encoded signal which carries the heart signals detected by the contact elements positioned on the strip electrode.

Brief Description of the Drawing

This invention and its advances over the prior art can best be understood by reading the Specification which follows in conjunction with the drawing herein, in which:

Figure 1 is a side elevational view of another embodiment of a dipole electrode structure.

Figure 2 is a top plan view of a portion of the dipole electrode structure shown in Figure 1.

Figure 3 is a side elevational view of a portion of the dipole electrode structure shown in Figure 1.

Figure 4 is a view of another embodiment of a precordial strip assembly for electrocardiographic monitoring placed on the precordium area of a patient, together with a block diagram of a wireless electrocardiographic monitoring system.

Figure 5 is a top plan view of the precordial strip assembly shown in Figure 4.

Figure 6 is a cross-sectional view of the precordial strip assembly shown in Figure 5 taken along the line 19-19 in Figure 5.

Figure 7 is a diagram of a portion of the wireless electrocardiograph system shown in Figure 4.

Figure 8 is a more detailed block diagram of the wireless electrocardiograph system shown in Figure 4.

Figure 9 is a top plan view of another embodiment of a precordial strip assembly, similar to the embodiment shown in Figure 5 incorporating the present invention.

Figure 10 is a top plan view of another embodiment of a precordial strip assembly, similar to the embodiment shown in Figure 5, incorporating the present invention.

Figure 11 is a view of another embodiment of a precordial strip assembly for electrocardiographic monitoring placed on the precordium area of a patient, together with a block diagram of a portion of a wireless electrocardiographic monitoring system.

Figure 12 is a top plan view of another embodiment of a precordial strip incorporating the present invention.

Figure 13 is a top plan view of another embodiment of a precordial strip incorporating the present invention.

Figure 14 is a top plan view of yet another embodiment of a precordial strip incorporating the present invention.

Figure 15 is a block diagram of a wireless electrocardiographic monitoring system which incorporates the present invention.

Detailed Description of the Preferred Embodiments

In this application, the terms "unipolar" and "bipolar" are used in the traditional electrocardiographic sense, that is denoting measurements between electrode pairs relating to the appropriate limbs and having the conventional polarity, thereby yielding conventional electrocardiographic wave-forms during cardiac excitation. The term "dipolar" recording, however, is used in this application in a novel way, and refers to the new method and electrode concept in which the single strip-electrode in the wireless single electrode system configuration, is comprised of both a positive and a negative terminal (pole), thereby obviating the need for a right leg grounding terminal as the reference point (reference electrode as used in conventional existing ECG equipment setting). The above mentioned wireless system and method configurations enable recording of complete standard twelve-lead electrocardiograms. The "dipolar electrode" concept is completely different from the traditional "bipolar recording" obtained from the limb leads of standard electrocardiography machines currently available for clinical use.

Reference to only a wireless ECG has been made. However, the wireless transmission of signals from a patient, regardless of the function being monitored, can be transmitted and received remotely in the same way. Thus, a truly wireless monitoring system that includes in addition to the 12-lead ECG detection also enables detection of

temperature, blood pressure and measurement of oxygen saturation in the blood, etc., can be easily accomplished with the detection and transmitting means and receiving sections of the present invention.

Figure 1 is an embodiment of dipole electrode structure 158 illustrated in Figure 6 of International Application No. PCT/US90/00672 having an interntional filing date of February 12, 1990 and published on August 23, 1990 under International Publication No. WO 90/09143 which includes a detachable microchip 230 to permit reuse thereof. Structure 158 includes a non-conductive layer of plastic material 231 with signal electrode 160, reference electrode 162 and a chip receptacle 232 mounted thereon. Structure 158 further includes connectors 163 and 165 which electrically connect and couple electrodes 160 and 162 to chip receptacle 232. Chip receptacle 232 is provided with a plurality of sockets 233, four of which are represented in Figure 2.

Microchip 230 has electronic components substantially similar to those contained in microchip 164, of International Application No. PCT/US90/00672 having an interntional filing date of February 12, 1990 and published on August 23, 1990 under International Publication No. WO 90/09143 including an amplifier, an encoder-modulator and a transmitter, and can be snapped on and off of structure 158. To facilitate its attachment and removal from structure 158, microchip 230 has a plurality of prongs or pins 234, four of which are represented in Figure 3. Prongs 234 cooperatively mate with sockets 233, as shown in Figure 1, when microchip 230 is attached to chip receptacle 232.

A further embodiment of the invention which permits transmission of a multichannel twelve-lead electrocardiogram on a digitally encoded radio frequency signal by means of a single frequency channel is illustrated in the drawings starting with Figure 4. Precordial strip assembly 321 of the present invention is for use on a patient 322 having a body 323 with a heart 324 and a precordium or precordium area 326 overlying heart 324. Body 323 is covered by an outer layer of skin 327. Patient 322 also has right and left arms 328 and 331 and right and left legs 332 and 333. Strip assembly 321 includes an elongate strip or strip means 336 generally horizontal "S" shaped in conformation.

Strip 336 has a length and a width identified by dimensions 337 and 338 in Figure 5 and a height identified by dimension 339 in Figure 6. Length 337 can range from five to thirty-eight centimeters, width 338 from two to five centimeters, and height 339 from one-third to one and one-half centimeters. Strip 336 can be made in various sizes to fit the desired range of pediatric, male or female patients.

Strip 336 is comprised of a central elongate portion 336a which is generally linear and has first or left and second or right ends 343 and 344. Strip 336 has first and second elastic portions 336b and 336c which commence near first and second ends 343 and 344, respectively, and first and second extendable or stretchable portions 336d and 336e adjacent elastic portions 336b and 336c. Elastic portions 336b and 336c protrude from central portion 336a at approximately right angles, and extendable portions 336d and 336e are substantially colinear with elastic portions 336b and 336c, respectively. Strip 336 further has first and second surfaces 341 and 342.

Strip 336 can be made from a suitable non-conductive, insulating and flexible plastic sheet formed from a layer of material such as polyurethane or polyvinyl chloride (PVC), or a combination thereof. Polyurethane offers flexibility with relative stiffness. Its hardness (e.g., Shore A 21, 41, 81 or 90) can be adjusted by blending materials of various hardness to obtain the desired flexibility and stiffness. Thus, if desired, the hardness of strip 336 can be varied from one portion to another to provide elastic portions 336b and 336c which are stretchable to permit pulling of extendable portions 336d and 336e from positions near central portion 336a to positions remote central portion 336a. Polyvinyl chloride offers higher flexibility by using variations in the thickness of the material. Thus, single or multiple layers can be combined together or stood alone, with the same thicknesses tapered thicknesses that permit variation in elasticity and manipulation of the plastic material.

Strip 336 is provided with a plurality of spaced apart cylindrical receptacle bores 346 commencing in first surface 341 and terminating at inner surface 347 of strip 336, one of which is identified in each of Figures 5 and 6. A thin cylindrical conductive pad 348 is disposed in each receptacle bore 346 and mounted to inner surface 347. Central portion 336a of strip 336 is also provided with an elongate recess 356 terminating at inner surface 357 of strip 336. A conductive pad 358 is embedded in a portion of inner surface 357 as shown in Figure 6.

A plurality of conductive contact elements or conductive elements 361 are mounted in spaced apart positions along the length of strip 336 for detecting heart signals from patient 322. Conductive elements 361 are generally cylindrical in conformation and have a contact surface 362

and dimensions which permit their disposition in receptacle bores 346 such that contact surface 362 is exposed on and generally in the plane formed by first surface 341 of strip 336. Conductive elements 361 are fastened to conductive pads 348 with a suitable conductive adhesive.

Conductive elements 361 include six precordial elements identified as V1 through V6 mounted sequentially across first surface 341 of central portion 336a with the V1 conductive element adjacent second end 344 of central portion 336a. Conductive elements 361 also include a seventh conductive element 361 identified as LA mounted on first surface 341 of central portion 336a adjacent first or left end 343 and the V6 conductive contact element (at the very left side of central portion 336a of strip 336, at midaxillary line position, as viewed by patient 322). Two additional conductive elements 361 identified as LL and RA are mounted in first and second extendable portions 336d and 336e, respectively. Conductive element LL on extendable portion 336d is separated or set apart from adjacent conductive element LA on central portion 336a by first elastic portion 336b, while conductive element RA on second extendable portion 336e is separated or set apart from adjacent conductive element V1 on central portion 336a by second elastic portion 336c.

First and second elastic portions 336b and 336c serve as stretchable means. First elastic portion 336b permits spacing of LL conductive element 361 between a first position in close proximity with V1 through V6 conductive elements 361 and adjacent LA conductive element 361 and a second position or "floating" position remote therefrom as illustrated in Figure 5. Second elastic portion 336c

permits spacing of RA conductive element 361 between a first position in close proximity with V1 through V6 conductive elements 361 and adjacent conductive element V1 and a second position or "floating" position remote therefrom also illustrated in Figure 5. First and second elastic portions 336b and 336c stretch and extend approximately five to fifteen centimeters to permit spacing of LL and RA conductive elements 361 in a second remote position. Elastic portions 336b and 336c of strip 336 contain suitable elastic qualities, such as those discussed above, to urge LL and RA conductive elements 361 towards their first position.

A reference contact element that can be elongated or round or rectangular or reference element 363 having a contact surface 364 and made of a suitable material such as copper or a silver derivative is carried by central portion 336a of strip 336 and serves as a common reference for conductive elements 361. Reference element 363 is mounted in elongate recess 356 such that contact surface 364 is exposed on and generally in the plane formed by first surface 341 of central portion 336a. Reference element 363 is fastened to inner surface 357 in a suitable manner and to conductive pad 358 with a suitable conductive adhesive. It should be appreciated by those skilled in the art that reference element 363 is within the scope of the present invention if it is a single long element, is partially extended and/or consists of several electrically connected segments, regardless of whether the segments are adjoining. In addition, reference element 363 may have a circular, ring shaped or other conformation and/or be located elsewhere on strip 336.

Most desirably, first surface 341 of at least central portion 336a and first and second extendable portions 336d and 336e of strip 336 is adhesive to permit retention of contact elements 361 and 363 and strip 336 in proper position when strip assembly 321 is placed on precordium area 326. Adhesive first surface 341 carries a protective covering 365, as illustrated in Figure 6 with respect to central portion 336a, which is removed therefrom to expose first surface 341 for placement on precordium area 326. Protective covering 365 may be of a one piece or segmented design; a one piece design would permit removal of the protective covering in a single removal action. It should be appreciated by those skilled in the art that first surface 341 may have adhesive characteristics only in the vicinity of contact elements 361 and 363, or contact elements 361 and 363 may be retained in position on the patient by other means, and be within the scope of the present invention.

Chip receptacle 366 serves as junction means carried in a single region by central portion 336a of strip 336, as illustrated in Figures 18 and 19, and has a sufficient number of pin sockets 367 for receiving the heart signals detected by contact elements 361 and 363. Chip receptacle 366 is mounted on second surface 342 of central portion 336a by a suitable adhesive.

Conductive pad 358 and each cylindrical conductive pad 348 on central portion 336a is connected by a thin conductive wire 368 to a pin socket 367, with wires 368 and conductive pad 358 or cylindrical conductive pads 348 serving as means for electrically coupling and connecting reference element 363 and V1 through V6 and LA conductive elements 361, respectively, to chip receptacle 366.

(Several representative pin sockets 367 and wires 368 are identified in Figures 5 and 6.) Wires 371 and cylindrical conductive pads 348 on extendable portions 336d and 336e serve as the means for electrically coupling and connecting LL and RA conductive elements 361 to chip receptacle 366, and have extendable or stretchable portions 371a which are urged towards a first position when extendable portions 336d and 336e are in a first position and capable of extension to a second position when extendable portions 336d and 336e are in a second remote position. By electrically coupling and connecting conductive pads 348 and 358 to chip receptacle 366, wires 368 and 371 serve to electrically couple and connect conductive elements 361 to reference element 363.

A microchip 372 is mounted on second surface 342 of central portion 336a of strip 336 in contact with the junction means for transmitting a radio frequency signal which carries the heart signals detected by contact elements 361 and 363. More specifically, microchip 372 receives the heart signals detected by precordial V1 through V6 conductive elements 361, LA, RA and LL conductive elements 361, and reference element 363 (See Figure 7). Microchip 372 is received by chip receptacle 366 for retention on strip 336 and has a plurality of pins 373 which cooperatively mate with pin sockets 367 (See Figure 6). Microchip 372 may be detachably mounted to chip receptacle 366. For example, microchip 372 can be plugged into and ejected out of chip receptacle 366 mounted on strip 336 of strip assembly 321.

Microchip 372 includes means for transmitting a single encoded radio frequency signal which carries the twelve-lead electrocardiographic multiple heart signals detected

by contact elements 361 and 363, and comprises one or more microchip amplifiers and filters, a multiplexer, a microchip encoder-modulator, a microchip transmitter, a wireless-signal radiator and a battery means. Microchip 372 can transmit a time multiplexed and modulated multichannel twelve-lead electrocardiogram by a digitally encoded radio frequency signal via a single frequency channel.

Some of the components of the wireless electrocardiographic monitoring system contained in microchip 372 are illustrated in Figure 4. Microchip 372 includes amplifiers 381 (shown for simplicity as a single amplifier), encoder-modulator 382 (which includes an analog-to-digital converter and a multiplexer), transmitter 383 and wireless-signal radiator or sending antenna 386. The digitally encoded radio frequency signal containing the time multiplexed and modulated multichannel twelve-lead electrocardiogram is received by receiving antenna 387, after which it passes through receiver-demodulator 388, decoder 391, buffer amplifier 392, electrocardiograph lead selector 393 and filter amplifiers 396 (shown for simplicity as a single amplifier). From filter amplifiers 396, the twelve signals detected by the twelve-lead electrocardiogram can be sent to an electrocardiographic printer 397, a monitor 398 and/or a Holter recording 399.

A more detailed diagram of a wireless electrocardiographic monitoring system is illustrated in Figure 8. Microchip 372 has a separate amplifier for amplifying to a more workable level the relatively weak heart signals detected by V1 through V6, LA, RA and LL conductive elements 361 and reference element 363. Each amplifier 381 can include

a filter for removing or suppressing undesirable portions of the detected signal; this filter may be similar to that contained in differential input amplifier 26'. Each microchip amplifier with filter has a signal input terminal coupled to each pin 373 carrying a heart signal from a conductive element 361 or reference element 363, and an output terminal for sending the amplified and filtered heart signals.

The output of each amplifier 381 is connected to an input to analog multiplexer 401, a time-division multiplexed system, which combines the heart signals for transmission through a common channel. Multiplexer 401 includes an analog-to-digital converter for converting the analog heart signals detected by contact elements 361 and 363 to digital signals, and an encoder-modulator which changes the combined heart signals into an information signal suitable for propagation over a radio frequency. The encoder-modulator may include adjustment means for varying the digital encoding of the encoder-modulator.

Multiplexer 401 is connected to control logic 402 which monitors microchip 372 and the heart signals received thereby. A synchronized signal travels between multiplexer 401 and control logic 402 to permit monitoring of strip assembly 321. For instance, if patient 322 is out of range from the receiving unit or the battery powering microchip 372 is low, a warning may be triggered.

Multiplexer 401 can also be connected to motion electronic stabilizers 403 (which in turn would be connected to control logic 402) for avoiding artifacts which can result in misleading readouts. (Artifacts create additional

background noise which is picked up by contact elements 361 and 363 and reduces the accuracy of the electrocardiographic reading.) Multiplexer 401 has an output for transmission of a modulated output signal, and control logic 402 has an output for transmission of certain control capability information.

The outputs of multiplexer 401 and control logic 402 are connected to inputs to transmitter 383 which generates a high frequency electric current or carrier wave whose characteristics of amplitude, frequency or phase modulation are altered, or modulated, by the output signal from the encoder-modulator within multiplexer 401. Transmitter 383 may include an adjustment means for varying the frequency of operation thereof. The output of transmitter 383 is coupled to the input for the wireless-signal radiator 386 which radiates the signal over a single radio frequency.

Microchip 372 includes battery means, such as a 3 volt lithium coin cell, which serves as an exclusive power supply for strip assembly 321 and microchip 372 and has at least one voltage terminal for supplying power to microchip 372 and a ground terminal carried on first surface 341, possibly by reference element 363. Microchip 372 includes a means for applying operating potentials from the battery means to amplifiers 381, multiplexer 401, control logic 402, motion electronic stabilizers 403 and transmitter 383.

The radio frequency signal is received by antenna 387, which receives signals in quadrature configuration. The radio frequency signal is sent to receiver 411 which has a front end 412 and produces a synchronized output signal

and a time multiplexed output signal. The outputs of receiver 411 are connected to the inputs of decoder and controller 413. Decoder and controller 413 is connected to alarm controller 416. The twelve electrocardiogram leads, detected and generated on patient 322 in accordance with both the unipolar and bipolar lead systems, are removed from the time multiplexed signal by decoder and controller 416 and separately fed through filter amplifiers 396 to interface unit 417. The twelve-lead electrocardiogram can be sent by interface unit 417 to an electrocardiographic printer 397 and/or a monitor 398.

It should also be appreciated by those skilled in the art that strip assembly 321 may have means for transmitting a time multiplexed and modulated multichannel twelve-lead electrocardiogram by a digitally encoded radio frequency signal via a single frequency channel which includes or consists of components other than those described above and/or accomplishes the transmitting of heart signals by means other than as discussed herein and still be within the scope of the present invention.

Strip assembly 321 is sized and configured such that V1 through V6 and the other conductive elements 361 are properly positioned on patient 322 to permit standard twelve-lead (I, II, III, aVR, aVL, aVF, V1 through V6) electrocardiographic monitoring. Contact elements 361 and 363 on strip 336 are adapted to contact skin 327 for detecting the required heart signals from patient 322 when strip assembly 321 is placed on precordium area 326 of patient 322. Placement of strip assembly 321 on patient 322 is relatively simple and quick. After selecting the proper size strip assembly to fit the size of the patient's thorax, protective covering 365 is removed from

first surface 341 of central portion 336a of strip 336 to expose contact elements 361 and 363 thereon, and central portion 336a is then placed on precordium area 326. (If protective covering 365 is of a one piece design, it is removed from all of first surface 341 at this time.) Adhesive first surface 341 of central portion 336a retains it in position on precordium area 326. LA conductive element 361 carried on central portion 336a of strip 336 adjacent V6 conductive element 361 and first end 343 is positioned on strip 336 so as to be near left arm 331 and substitutes for the separate electrode formerly positioned on the left arm of patient 322.

LL and RA conductive elements 361 are positioned on patient 322 by simply pulling extendable portions 336d and 336e from their first position near V1 through V6 and LA conductive elements 361 to their second position remote the V1 through V6 and LA contact elements and near left leg 333 and right arm 328, respectively, of patient 322. More specifically, LL conductive element 361 is placed in a remote position on the lower left thorax and upper left abdomen of patient 322, and RA conductive element 361 is placed in a remote position on the upper right thorax of patient 322. In their remote positions, LL and RA conductive elements 361 constitute "floating" conductive elements.

This pulling of extendable portions 336d and 336e away from central portion 336a to position or place LL conductive element 361 on the lower left thorax and upper left abdomen and RA conductive element 361 on the upper right thorax is permitted by first and second elastic portions 336b and 336c of strip 336 and extendable portions 371a of wires 371. When LL and RA conductive elements 361 are in their remote positions, first and

second extendable portions 336d and 336e are each distanced between five and fifteen centimeters from central portion 336a. There is no need for millimetric accuracy in positioning of LL and RA conductive elements 361 carried by extendable portions 336d and 336e.

If protective covering 365 is segmented and not yet been removed, the balance of the protective covering is removed from extendable portions 336d and 336e of strip 336, to expose LL and RA conductive elements 361 and adhesive first surface 341, before placing first and second extendable portions 336d and 336e on patient 322. LL and RA "floating" conductive elements 361 carried by extendable portions 336d and 336e substitute for the separate electrodes formerly positioned on the left leg and right arm of the patient.

It should be appreciated that elastic portions 336b and 336c may be designed to permit extendable portions 336d and 336e to separate and break off from central portion 336a during placement of LL and RA conductive elements 361 on patient 322 and be within the scope of the present invention. The separation of extendable portions 336d and 336e from central portion 336a by causing elastic portions 336b and 336c to break apart can be accomplished by adjusting the elasticity and flexibility of the polyurethane, polyvinyl chloride or other plastic material from which the elastic portions are made. For example, if elastic portions 336b and 336c are made of polyurethane, it is possible to set its hardness scale to be low enough to permit complete separation.

Elastic portions 336b and 336c designed to completely separate from central portion 336a do not cause wires 371 to break or sever. Accordingly, LL and RA conductive elements 361 remain electrically connected and coupled to microchip 372 by respective wires 371. Stretchable portions 371a of wires 371 permit such electrical coupling when LL and RA conductive elements are in their remote "floating" positions.

The inclusion in strip assembly 321 of common reference element 363 eliminates the need for a separate reference electrode on the right leg of patient 322. In addition, reference element 363 is a common reference for all conductive elements 361. As a result, there is no need to electronically or otherwise calculate the reference point during unipolar monitoring. A conductive gel may be applied between each contact element 361 and 363 to enhance the detection of heart signals thereby. Strip assembly 321 may be provided with a microchip 372 which is removable or nonremovable. A removable microchip 372 can be used in multiple monitorings, reducing the cost of an electrocardiographic testing performance.

Upon commencement of monitoring, the twelve lead electrocardiographic monitoring system carried by strip assembly 321 detects heart signals at each and among the ten contact elements 361 and 363 to permit complete unipolar and bipolar "leads" views of heart 324 electrical activity. The reference heart signal is detected by reference element 363 incorporated within strip assembly 321. Once detected, the signals are carried through wires 368 and 371 to chip receptacle 366, where they are picked up by pins 373 on microchip 372 which cooperatively mate with pin sockets 367 in the chip receptacle. Microchip 372 combines the heart signals detected by contact

elements 361 and 363 into a twelve-lead electrocardiogram configuration. Microchip 372 contains the necessary electronic components for transmitting the multiplexed encoded and modulated twelve-lead electrocardiogram heart signals over a single freqency radio frequency signal. No wires connecting patient 322 to the receiver and decoder portion of the wireless system are needed to permit completion of the electrocardiographic monitoring.

Thus, microchip 372 transmits the twelve-lead electrocardiogram single encoded signal using the information derived from the electrocardiographic twelve-lead "views". The electrocardiogram "lead" is a "view point" from which the electrical activity of the heart is examined. Each view is the result of a combination of two signals at two spaced apart or separated points as measured by two contact elements, such as one conductive element 361 and another conductive element 361 (RA, LA and LL conductive elements 361 which are compared to each other to determine leads I, II and II of the Einthoven triangle bipolar lead system), or a conductive element 361 and common reference element 363 (LA, LL , RA and V1 through V6 conductive elements 361 which are compared to reference element 363 to determine leads aVR, aVL, aVF and V1 through V6 in the unipolar lead system).

Therefore, in this invention, microchip 372 provides the end results of these views or coupled measurements, of which specific combination of contact elements provide a "lead view" while coupling of variable contact elements create, according to electrophysiological principals, the complete "picture" of twelve-lead electrocardiograms. The inclusion by this invention of microchip 372 in strip assembly 321 creates an "active" and "smart" wireless electrode system which permits a "novel" method of

electrocardiographic analysis. Under this method, a complete twelve-lead electrocardiogram is created on the patient side. This twelve-lead electrocardiogram is created not merely by electrocardiographic hardware, as is done by current and existing electrocardiograph systems. The invention provides a new "smart" method of electrocardiographic data analysis also on the pateint's end.

During monitoring, patient 322 can ambulate within the approximate 50 to 100 meter transmission range of microchip 372 without interrupting the detection and transmission of twelve-lead electrocardiographic heart signals for analysis. Motion electronic stabilizers may be incorporated or connected to or within microchip 372 in order to optimize "clean" from noise recording of heart signals. These stabilizers may consist of a combination of various filters and similar digital signal stabilizers to eliminate unwanted noise such as artifacts or surounding noise. Furthermore, the unitary structure of strip assembly 321 eliminates the likelihood of interchanging signals and the inaccuracies in the heart signals from faulty wires and wire connections or disconnections.

In another embodiment, precordial strip assembly 321 includes an elongate strip or strip means 431 generally in the shape of a horizontal inverted "L", and having a length identified by dimension 432 in Figure 9 and a width and height substantially equal to width 338 and height 339 in Figures 5 and 6, respectively. Length 432 can range from five to forty-two centimeters. Strip 431 can be made from the same material as strip 336, and has a central portion 431a, first and second elastic portions 431b and 431c and first and second extendable or stretchable portions 431d and 431e substantially identical

to central portion 336a, first and second elastic portions 336b and 336c and first and second extendable portions 336d and 336e of strip 336. Central portion 431a has first or left and second or right ends 343 and 344.

Like central portion 336a, central portion 431a has V1 through V6 and LA conductive contact elements 361 and a reference contact element 363 mounted thereon, and is also provided with a chip receptacle 366 and a microchip 372 thereon. Wires 368 assist in electrically connecting and coupling V1 through V6 and LA conductive elements 361 and reference element 363 to chip receptacle 366. First and second extendable portions 431d and 431e have LL and RA conductive contact elements 361 mounted thereon in the same manner as those elements are mounted on extendable portions 336d and 336e, respectively. Wires 371, with extendable or stretchable portions 371a, assist in electrically connecting and coupling LL and RA conductive elements 361 to chip receptacle 366.

First elastic and extendable portions 431b and 431d are configured with respect to central portion 431a in the same manner as first elastic and extendable portions 336b and 336d are configured with respect to central portion 336a. Second elastic and extendable portions 431c and 431e protrude in a substantially colinear manner from second end 344 of central portion 431a.

In another related embodiment, precordial strip assembly 321 includes an elongate strip or strip means 441 generally linear and horizontal in conformation, and having a length identified by dimension 442 in Figure 11 and a width and height substantially equal to width 338 and height 339 in Figures 5 and 6, respectively. Length 442 can range from five to fifteen centimeters. Strip

441 can be made from the same material as strip 336, and has a central portion 441a, first and second elastic portions 441b and 441c and first and second extendable or stretchable portions 441d and 441e substantially identical to central portion 336a, first and second elastic portions 336b and 336c and first and second extendable portions 336d and 336e of strip 336. Central portion 441a has first or left and second or right ends 343 and 344.

Like central portion 336a, central portion 441a has V1 through V6 and LA conductive contact elements 361 and a reference contact element 363 mounted thereon, and is also provided with a chip receptacle 366 and a microchip 372 thereon. Wires 368 assist in electrically connecting and coupling V1 through V6 and LA conductive elements 361 and reference element 363 to chip receptacle 366. First and second extendable portions 441d and 441e have LL and RA conductive contact elements 361 mounted thereon in the same manner as those elements are mounted on extendable portions 336d and 336e, respectively. Wires 371, with extendable or stretchable portions 371a, assist in electrically connecting and coupling LL and RA conductive elements 361 to chip receptacle 366.

First elastic and extendable portions 441b and 441d protrude in a substantially colinear manner from first end 343 of central portion 441a. Second elastic and extendable portions 441c and 441e protrude in a substantially colinear manner from second end 344 of central portion 441a.

The operation of strip assembly 321 which includes either strip 431 or strip 441 is similar to the operation discussed above with respect to the strip assembly having strip 336. After selecting the proper size strip assembly

321 and placing central portion 431a or 441a on the precordium area 326 of patient 322, LL and RA conductive elements 361 on strip 431 or 441 are positioned on patient 322 near left leg 333 and right arm 328, respectively, of patient 322. More specifically, LL conductive element 361 is placed on the lower left thorax and upper left abdomen of patient 322, and RA conductive element 361 is placed on the upper right thorax of patient 322.

With respect to strip 431, LL conductive element 361 is so positioned by pulling extendable portion 431d downwardly from its first position near V1 through V6 and LA conductive elements 361 to its second position remote the V1 through V6 and LA conductive elements. With respect to strip 441, LL conductive element 361 is so positioned by pulling extendable portion 441d sidewardly and leftwardly from its first position near V1 through V6 and LA conductive elements 361 to its second position remote the V1 through V6 and LA conductive elements. With respect to both strips 431 and 441, RA conductive element 361 is so positioned by pulling extendable portion 431e or 441e sidewardly or rightwardly from its first position near V1 through V6 and LA conductive elements 361 to its second position remote the V1 through V6 and LA conductive elements. In their remote positions, LL and RA conductive elements 361 constitute "floating" conductive elements.

In each instance, the pulling of extendable portions 431d and 431e or 441d and 441e away from central portion 431a or 441a, respectively, is permitted by first and second elastic portions 431b and 431c or 441b and 441c and extendable portions 371a of wires 371. When LL and RA conductive elements 361 are in their remote positions, the extendable portions are each distanced between five and fifteen centimeters from the central portion.

In another embodiment, precordial strip assembly 321 includes an elongate strip or strip means 451 substantially similar to central portion 336a of strip 336. Like strip 336, strip 451 has V1 through V6 and LA conductive contact elements 361 and a reference contact element 363 mounted thereon, and is also provided with a chip receptacle 366 and a microchip 372 thereon (See Figures 12 and 13). Microchip 372 includes amplifiers 381 (shown for simplicity as a single amplifier), encoder-modulator 382 (which includes an analog-to-digital converter and a multiplexer), transmitter 383 and wireless-signal radiator or sending antenna 386. Wires 368 assist in electrically connecting and coupling V1 through V6 and LA conductive elements 361 and reference element 363 to chip receptacle 366.

In this embodiment, LL and RA conductive elements 361 are mounted on first and second patches 452 and 453 in the same manner that conductive elements 361 are mounted on strips 336 and 451. Patches 452 and 453 are made of a suitable non-conductive and insulating layer of plastic material which is also flexible. The plastic material may include suitable materials such as polyurethane and/or polyvinyl chloride, or a combination thereof, and may be formed through the processes discussed above to vary in flexibility. Patches 452 and 453 have an adhesive on one surface thereof similar to the adhesive contained on first surface 341 of strip 336. Wires 454, which are thin, conductive and flexible, serve as means for electrically coupling and connecting RA and LL conductive elements 361 to chip receptacle 366. Wire 454 relating to LL patch 452 joins strip 451 near left end 343, while 454 relating to patch 453 joins strip 451 near right end 344. Wires 454 extend from three to fifteen centimeters from strip 451.

RA and LL conductive elements 361 are adapted to contact skin 327 near right arm 328 and left leg 333, respectively, for detecting heart signals from patient 322. More specifically, RA conductive element 361 is positioned on the upper right thorax of the patient, and LL conductive element 361 is positioned on the lower thorax and left upper abdomen of the patient.

The operation of strip assembly 321 which includes strip 451 is similar to the operation discussed above with respect to the strip assembly having strip 336. Patches 452 and 453 are placed on patient 322 in close proximity to strip 451, and wires 454 can serve to define the maximum distance between the patches and strip 451.

In another embodiment, precordial strip assembly 321 includes an elongate strip or strip means 471 which is slightly shorter in length but otherwise substantially similar to central portion 336a of strip 336. Strip 471 has V1 through V6 conductive contact elements 361 mounted thereon, like strip 336, but does not have a LA conductive element or a reference contact element mounted thereon (See Figure 14). Strip 471 has first or left and second or right ends 472 and 473, and is also provided with a chip receptacle 366 and a microchip 372 thereon. Wires 368 assist in electrically connecting and coupling V1 through V6 conductive elements 361 to chip receptacle 366.

LL and RA conductive elements 361 are mounted on first and second patches 452 and 453, in the same manner as on strip assembly 321 which includes strip 451 illustrated in Figure 13, and are electrically coupled and connected to chip receptacle 366 by wires 454. In this embodiment, LA conductive element 361 is similarly mounted on a patch 476 and a tenth contact element, reference contact element 477

which is substantially identical in construction to conductive contact elements 361, is also similarly mounted on a patch 478. Patch 478, with conductive element 361 thereon, is sometimes referred to as the RL contact element.

Patches 476 and 478 are made of a suitable non-conductive and insulating layer of plastic material which is also flexible. The plastic material may include suitable materials such as polyurethane and/or polyvinyl chloride, or a combination thereof, and may be formed through the processes discussed above to vary in flexibility. Patches 476 and 478 have an adhesive on one surface thereof similar to the adhesive contained on first surface 341 of strip 336. Wires 481, which are thin, conductive and flexible, serve as means for electrically coupling and connecting LA conductive element 361 and RL reference element 477 to chip receptacle 366. Wire 481 relating to LA patch 476 joins strip 471 near left end 472, while wire 481 relating to patch 478 joins strip 471 near right end 473. Wires 481 extend from three to fifteen centimeters from strip 471.

LA conductive element 361 and RL reference element 477 are adapted to contact skin 327 near left arm 331 and right leg 332, respectively, for detecting heart signals from patient 322. More specifically, LA conductive element 361 is positioned on the upper left thorax of the patient, and RL reference element 477 is positioned on the lower thorax and right upper abdomen of the patient.

The operation of strip assembly 321 which includes strip 471 is similar to the operation discussed above with respect to the strip assembly having strip 336. Patches 452, 453, 476 and 478 are placed on patient 322 in close

proximity to strip 471, and wires 454 and 481 can serve to define the maximum distance between the patches and strip 471.

In another embodiment of strip assembly 321, a strip 488, substantially similar to central portion 336a but without chip receptacle 366 and microchip 372, includes cable means for carrying the heart signals detected by contact elements 361 and 363 to the monitor and related analysis equipment. Strip 488 has first or left and second or right ends 489 and 490. In this embodiment, illustrated in Figure 15, the junction means is comprised of a cable jacket 491 being carried in a single region near first end 489 of strip 488 and having a plug 492 on the end thereof. Strip 488 has wires 493 which, together with cylindrical conductive pads 348 and conductive pad 358, serve as means for electrically coupling and connecting conductive elements 361 and reference element 363, respectively, to cable jacket 491. Cable 494 serves as the cable means and connects to plug 492. Strip assembly 321 of this embodiment could include elastic and extendable portions similar to elastic portions 336b and 336c and extendable portions 336d and 336e or patches similar to patches 452, 453 and 476 for carrying LL, RA and/or LA conductive elements 361 or similar to patch 478 for carrying reference element 477 and be within the scope of the present invention.

According to another embodiment of the invention the strip assembly can be provided with both wireless transmission or signals processing means having also a connecting cable to the monitoring display/recording equipment. Said connecting cable 491 as described in Figure 14, may link to extending cable 494 by means of electrical interface unit 492 connecting between the cable 491 and 494 in Figure 14.

Said interface unit 492 can be placed either along the connecting cable 491/494 or can be placed within the strip electrode structure 490 intergrated on the said second side which is not in contact with the patient's skin. In said configuration, interface unit 492 can provide both connection to electrical cable connection and/or provide embedded contacts housing for microchip interface that can elaborate or transmit the detected heart signals to a receiving unit placed within the display/recording hardware equipment.

Precordial strip assembly 321 utilizes the method and system of electrocardiographic monitoring in which the detection and processing of a twelve-lead electrocardiogram is performed and accomplished on the body of patient 322 (See Figure 16). As more fully discussed above, conductive contact elements 361, together with common reference contact element 363 or 477, detect heart signals which correspond to traditional precordial detection points V1 through V6 and limb detection points LA, LL, RA and RL. These heart signals are analyzed and coupled, by microchip 372, to create the aVR, aVL and aVF limb leads and precordial leads V1 through V6 of the unipolar lead system and leads I, II and III of the bipolar lead system. Microchip 372 can also serve as means for transmitting the electrocardiogram over a radio frequency signal. More specifically, microchip 372 serves to digitize and combine the multichannel twelve-lead electrocardiogram into a time multiplexed signal and send the combined signal over a single transmission freqency.

One of the approaches suggested by the wireless electrocardiographic monitoring system (WEMS) of the invention is to eliminate the physical wires between the patient and the electrocardiograph and/or monitor and

to provide a complete standard twelve-lead electrocardiogram with only one electrode strip. This approach has the potential to greatly enhance the practicality of and simplify the use of electrocardiographic equipment and significantly improve clinical care of patients affected by heart disease. In addition, a wireless electrocardiographic monitoring system would expand the use of complete standard twelve-lead electrocardiograms. This may significantly improve clinical control modalities for the diagnosis and therapy of critically ill cardiac patients that require and benefit from maximal electrophysiological activities detection and evaluation not available with currently existing methods and clinical management protocols which employ only single-lead or three-lead arrhythmia monitoring.

A wireless electrocardiographic monitoring system according to this invention would permit early detection of unrecognized myocardial ischemia while a patient is in a coronary intensive care unit or intensive care unit and, accordingly, expand diagnostic accuracy and specifically determine the urgency and/or the need for other therapeutic modalities such as medication (including anticoagulants and thrombolytic drugs), angiography, percutaneous transluminal coronary angioplasty or coronary artery bypass graft surgery.

A wireless electrocardiographic monitoring system according to this invention would also enable accurate detection of myocardial ischemia during percutaneous transluminal coronary angioplasty. An accurate detection would maximize diagnosis efficacy and improve therapy effectiveness, and possibly result in modification of the percutaneous transluminal coronary angioplasty procedure itself. The system would precisely determine the severity and location

of the ischemic event and be critical for deciding whether to repeat the angioplasty procedure in the coronary artery and/or to modify treatment protocol with adjunctive medications (e.g., vasodilators, anticoagulants or thrombolytic drugs) and/or coronary artery bypass graft surgery. It should also be noted that there is preliminary evidence to suggest that early detection of myocardial ischemia may be an important predictor in the development of restenosis following percutaneous transluminal coronary angioplasty of the coronary arteries.

In addition, complete standard twelve-lead electrocardiographic recordings taken during percutaneous transluminal coronary angioplasty could function as an individualized noninvasive template or "fingerprint", useful in evaluating transient ischemic episodes after the patient leaves the cardiac catheterization laboratory.

Occasionally, an acute myocardial infarction develops spontaneously in the hours after elective percutaneous transluminal coronary angioplasty. Use of continuous complete standard twelve-lead electrocardiograms would facilitate comparisons between the dynamic changes of the "controlled" ischemic period during the percutaneous transluminal coronary angioplasty procedure (as baseline value) and the ischemic period during the evolving MI (rather than observing changes in numbers of millimeters). Such information may provide a more complete understanding of the evolution of the acute ischemic process, which may be critical for therapeutic considerations.

Complete twelve-lead electrocardiograms by a wireless electrocardiographic monitoring system according to this invention would also expand the field of diagnosis and therapy of silent coronary ischemia in the ambulatory

By providing an accurate and complete ambulatory method of detecting silent ischemia, it could direct to early and accurate therapy (medication, invasive intervention and/or surgery), thereby increasing significantly the efficacy of therapy and reducing morbidity and mortality rates of heart disease.

A wireless electrocardiographic monitoring system according to this invention would also be a comprehensive and reliable ambulatory tool for providing accurate detection, 24 hours a day, upon demand and in real time occurrence, of coronary ischemia in high risk cardiac patients who must transmit electrocardiograms transtelephonically.

The complete standard twelve-lead electrocardiogram, detected by the wireless electrocardiographic monitoring system of this invention, would be recorded by a currently available beeper-size twelve-lead electrocardiogram recorder and transmitter carried by the patient and be transmitted by the patient through any telephone line to a cardiac monitoring control center. This system would expand the quality of heart disease control and detection capabilities and, in addition, would direct to better accuracy of treatment, whether it be medication, invasive intervention or urgent surgery. Furthermore, this transtelephonic method would significantly extend the control and improve the follow-up of a significant number of patients affected by hear disease, with both enhanced efficacy and efficiency of treatment. A complete standard twelve-lead electrocardiogram detection in high risk patients, 24 hours a day and upon demand, has the potential of greatly decreasing the heart disease mortality rate.

A wireless electrocardiographic monitoring system according to this invention could provide complete standard twelve-lead electrocardiograms in coronary intensive care mobil units and emergency rooms for early accurate myocardial ischemia detection and diagnosis, and thus improve therapeutic management and the administration of thrombolytic or anticoagulative drugs in the early stages of a coronary ischemic event. In addition, the system could direct to more accurate therapy (e.g., percutaneous transluminal coronary angioplasty or coronary artery bypass graft surgery), if necessary, during hospitalization.

In patients with acute myocardial infarction who undergo thrombolytic reperfusion therapy, monitoring ST-segment deviation could provide an early noninvasive indicator of coronary artery reocclusion not available from current coronary care electrocardiographic monitoring aimed at the detection of cardiac arrhythmias. A complete standard twelve-lead electrocardiogram that can be enabled according to this invention can, therefore, identify patients who may require further pharmacological treatment to prevent reocclusion of the coronary artery, or who may require subsequent invasive investigation before coronary angioplasty or bypass surgery for residual coronary arterial stenosis.

Intraoperative twelve-lead electrocardiograms would diagnose accurately more postoperative myocardial ischemia than any other monitoring modality. It is noninvasive, and would allow preoperative, intraoperative and postoperative electrocardiographic monitoring to proceed without interruption.

In view of the foregoing, the wireless electrocardiographic monitoring system of the present invention overcomes practical difficulties in existing electrocardiographic monitoring systems. It accomplishes this by, for example:

1. Reducing significantly the number of electrodes required to obtain a complete standard twelve-lead electrocardiogram;

2. Eliminating the time spent connecting predetermined multiple wires to predetermined multiple electrodes;

3. Eliminating wire connection errors;

4. Eliminating the time spent untangling wires;

5. Simplifying the method of operation when used by a coronary intensive care mobile unit where speed of operation is critical;

6. Reducing or eliminating wire defects that are often difficult to detect;

7. Reducing or eliminating problems relating to the wire connections to electrodes;

8. Reducing or eliminating problems relating to wire disconnections occurring beneath the sterile field during operating room surgical procedures;

9. Reducing cardiac monitoring interruptions by ambulating patients in the intermediate coronary unit;

10. Improving clinical care management as standard complete twelve-lead electrocardiograms would be available for detection of myocardial ischemia and/or dynamics of coronary inusufficiency during and following percutaneous transluminal coronary angioplasty, percutaneous laser coronary angioplasty procedures, percutaneous coronary retroperfusion, coronary artery bypass graft surgery, and thrombolytic therapy (Currently, only single-lead or three-lead arrhythmia monitoring is performed with these procedures.);

11. Making possible portable transtelephonic wireless twelve-lead electrocardiographic monitoring;

12. Eliminating proximity limitations between the patient and currently operated electrocardiographs or monitors; and

13. Increasing patient's compliance (comfort level) when twelve-lead electrocardiographic testing is required (i.e., when sleeping or already connected to other instrumentation as in a coronary intensive care unit).

Also in view of the foregoing, it can be seen that the new precordial strip assembly of the present invention is a significant improvement over the prior art. The strip assembly contains a plurality of conductive elements for placement on the precordium area of a patient, and includes a reference conductive element permitting elimination of the standard right leg reference electrode. The strip assembly serves as an "active" electrode, as opposed to "passive" electrodes currently used for electro-cardiographic testing. The strip assembly includes RA and LL conductive elements positionable on the patient in a position remote from the V1 through V6 and LA

conductive elements. The invention provides a self contained strip assembly for detecting and transmitting twelve-lead electrocardiogram heart signals.

In further views of the foregoing, the approach of this invention can be applied for detection and transmission also of blood pressure measurements, termperature measurements and measurements of oxygen saturation levels in tissues of a patient, to accomplish this in addition to the 12-lead ECG, the microchip porcessor and transmitter can elaborate the series of detected signals of said blood pressure, temperature and oxygen saturation through parallel channels in the microchip and transmit them digitally to the receiving section. The receiving section can interface all these signals in addition to the 12-lead ECG, to a display monitor or printing hardware equipment.

Furthermore, the wireless 12-lead ECG system according to this invention, can be connected to pacemakers or Automated Implemented Cardioverter Defibrilators (AICD) and can be trigged bywired or wireless means connecting between these devices and the wireless 12-lead ECG system to start the detection and recording and transmission of the 12-lead ECG according to this invention upon activation of the Pacemaker or AICD itself, said function can be automatedly controlled by software within the microchip itself or within the pacemaker or AICS device.

While particular embodiments have been shown and described, it will be apparent to those skilled in the art that variations and modifications may be made in these embodiments without departing from the spirit and scope of this invention. It is the purpose of the appended Claims to cover any and all such variations and modifications.

CLAIMS:

1. A precordial strip assembly for use on a patient having a heart with a precordium lying thereover, skin and right and left arms and legs comprising an elongate strip having first and second surfaces, six conductive contact elements identified as V1 through V6 being mounted in spaced apart positions along the length of said strip, said strip being substantially continuous between said conductive elements and said conductive contact elements being exposed on the first surface of said strip and being adapted to contact said patient's skin for detecting heart signals from said patient when said precordial strip assembly is placed on the precordium of the patient, and junction means being carried in a single region by said strip and being electrically connected to said conductive contact elements.

2. A precordial strip assembly according to Claim 1 wherein said elongate strip includes a reference contact element mounted thereon in close proximity with said V1 through V6 conductive contact elements, said reference contact element serving as a common reference for each of said V1 through V6 and RA, LL, LA conductive contact elements and being electrically connected to said junction means and said reference contact element being exposed on the first surface of said strip and being adapted to contact said patient's skin.

3. A precordial strip assembly according to Claim 1 or 2 where a microchip is mounted on said strip and means carried by said strip for electrically connecting said conductive contact elements to said microchip, said

microchip including means for transmitting a radio frequency signal which carries the heart signals detected by said contact elements.

4. A precordial strip assembly according to any of Claims 1 to 3, wherein said strip carries a reference contact element which serves as a common reference for each of said V through V and RA, LL, LA conductive contact elements and is exposed on the first surface of said strip for contacting said patient's skin and means for electrically connecting said reference contact element to said microchip.

5. A precordial strip assembly according to any of Claims 1 to 4, wherein said microchip is detachably mounted to said strip.

6. A precordial strip assembly according to any of Claims 1 to 5, wherein said strip has first and second ends and wherein said precordial strip assembly further includes an additional conductive contact element identified as LA which is mounted on said strip adjacent said first end and said V conductive contact element and is exposed on the first surface of said strip for contacting said patient's skin and means for electrically connecting said LA conductive contact element to said microchip.

7. A precordial strip assembly according to any of Claims 1 to 6, wherein said strip carries additional conductive contact elements identified as LL and RA which are exposed on the first surface of said strip and means for electrically connecting said LL and RA conductive contact elements to said microchip and wherein said strip includes stretchable means to permit spacing of said LL and RA conductive contact elements between a first position in

close proximity with said V through V conductive contact elements and a second position remote therefrom, said LL and RA conductive contact elements contacting said patient's skin near said right arm and left leg, respectively, when in said second position and when said precordial strip assembly is placed on the precordium of the patient.

8. A self-contained electrode structure for use in a wireless patient monitoring system for receiving signals from the heart in a body of a patient comprising a layer of insulating material having first and second sides, a conductive element carried by said layer of insulating material and disposed on said first side of said layer of insulating material, a battery carried on said second side of said layer of insulating material, microchip processor of detected signals and microchip amplifier and transmitter means carried on said second side of said layer of insulating material and being coupled to said battery and to said conductive element for receiving heart signals from the heart of the patient and for transmitting wireless signals in accordance with heart signals received whereby said electrode structure has its own exclusive power supply and microchip amplifier and transmitter means.

9. A method of electrocardiographic monitoring on a patient having a body with a heart therein and a precordium lying over the heart comprising the steps of placing an electrode assembly on the precordium of said patient, said electrode assembly having six conductive contact elements identified as V through V mounted in spaced apart positions therealong and a microchip mounted thereon in electrical contact with said V through V conductive contact elements, placing conductive contact elements identified as LA, LL and RA and a reference contact element

on the body of said patient in electrical contact with said microchip, detecting heart signals from said patient through said contact elements, processing the heart signals in said microchip to produce twelve-lead electrocardiogram signals and transmitting a radio frequency signal which carries said twelve-lead electrocardiogram signals.

10. A precordial strip assembly according to any of claims 3 to 9, which is provided in addition to the microchip and transmission means, also with electrical wiring making possible a direct connection, having an interface connector between the display or recording monitoring hardware equipment and the strip electrode or the cable connecting to the strip electrode and said interface unit having embedded housing means with electrical contacts to permit injection or placement of microchip or transmission means.

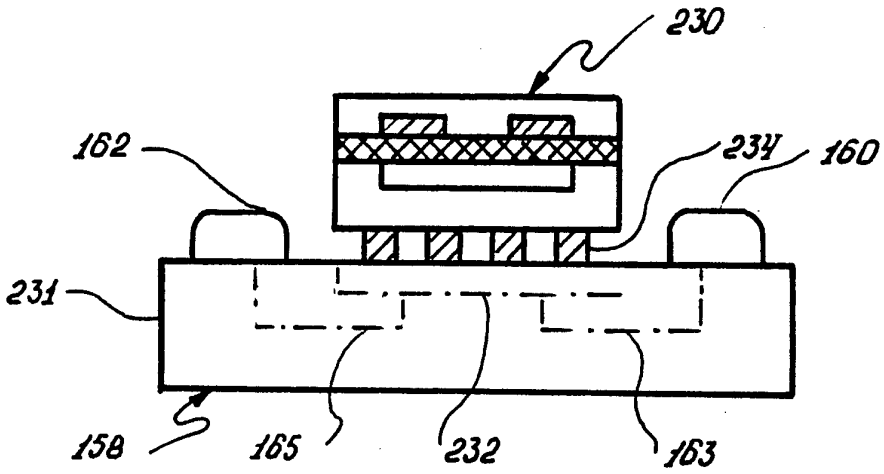


FIG 1

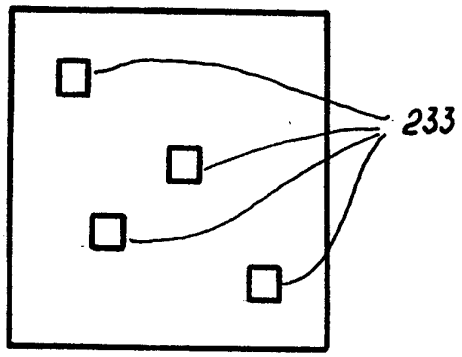


FIG 2

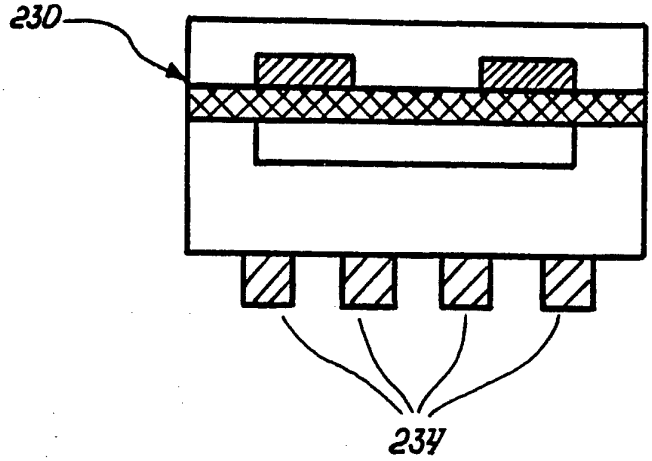


FIG 3

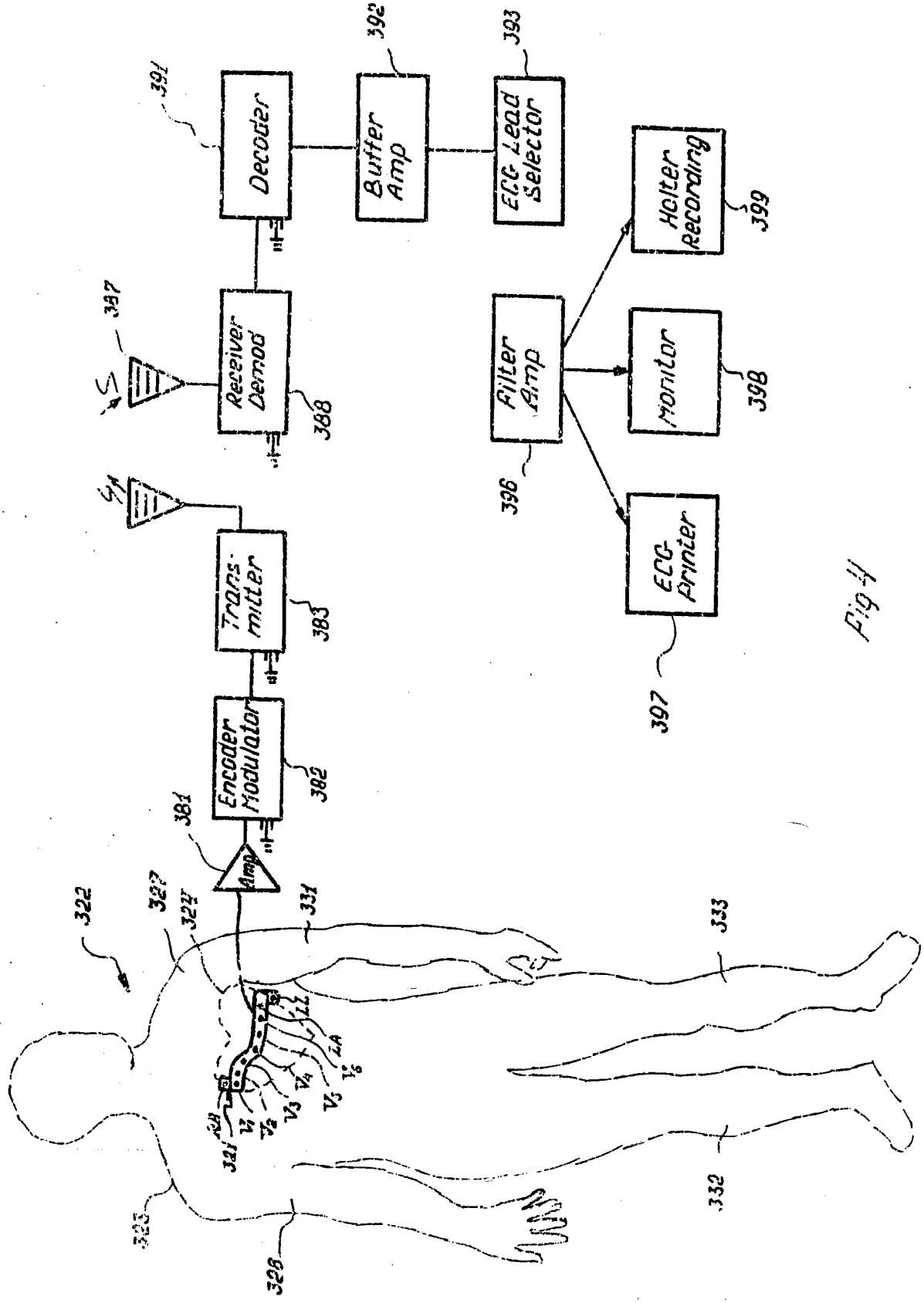
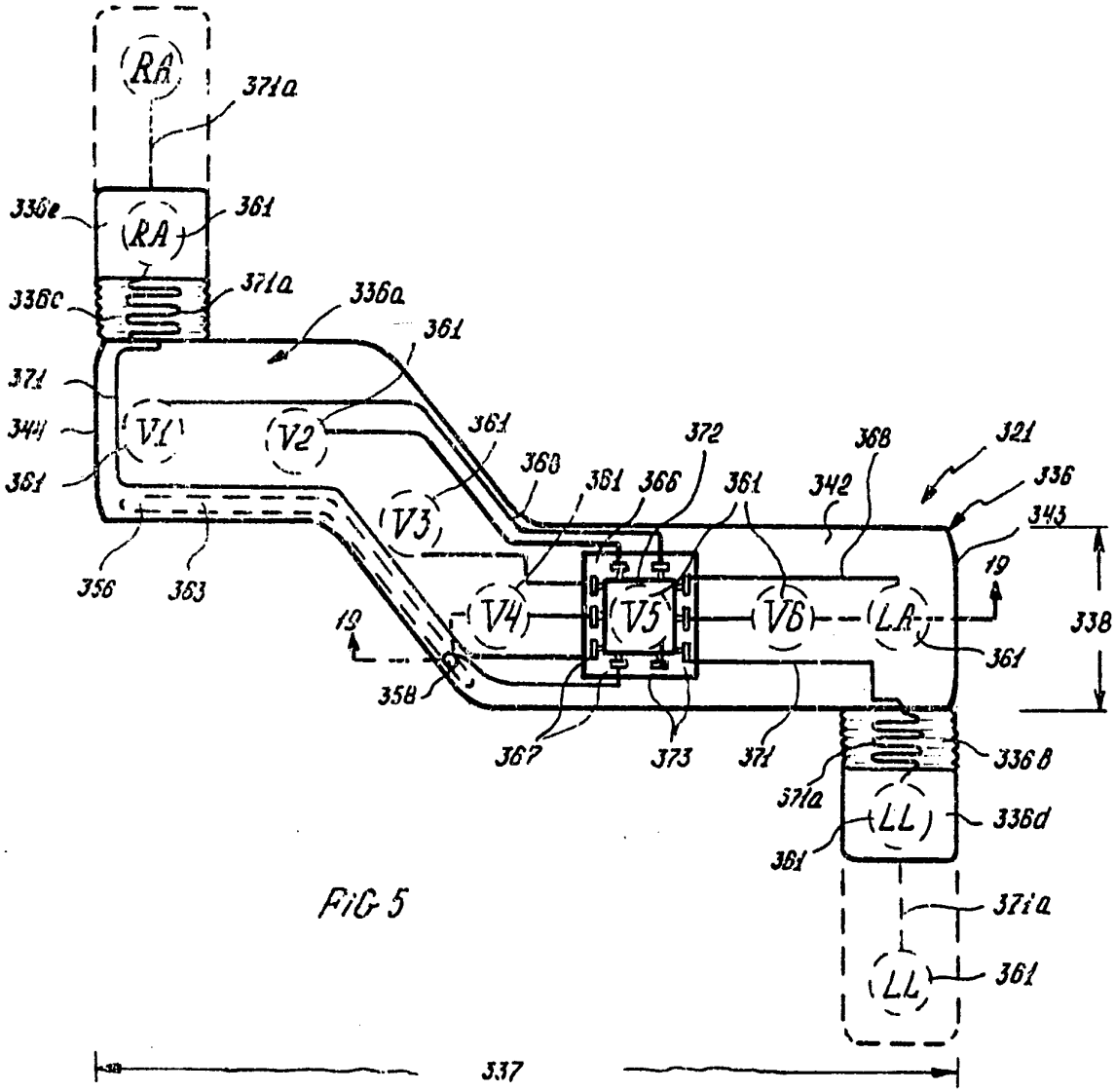

Decoder
391
Buffer Amp
392
ECG Lead Selector
393
Holter Recording
399
Receiver Demod
388
387
Filter Amp
396
Monitor
398
ECG Printer
397
Trans-mitter
383
Encoder Modulator
382
Amp
384
322
327
324
331
333
332
328
325
321
RA
LL
LA
V1
V2
V3
V4
V5
V6

Fig 4


RA
371a
336e
361
336c
336a
371
344
V1
V2
V3
V4
V5
V6
LA
LL
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321
336
343
338
19
336b
336d
337

FIG 5

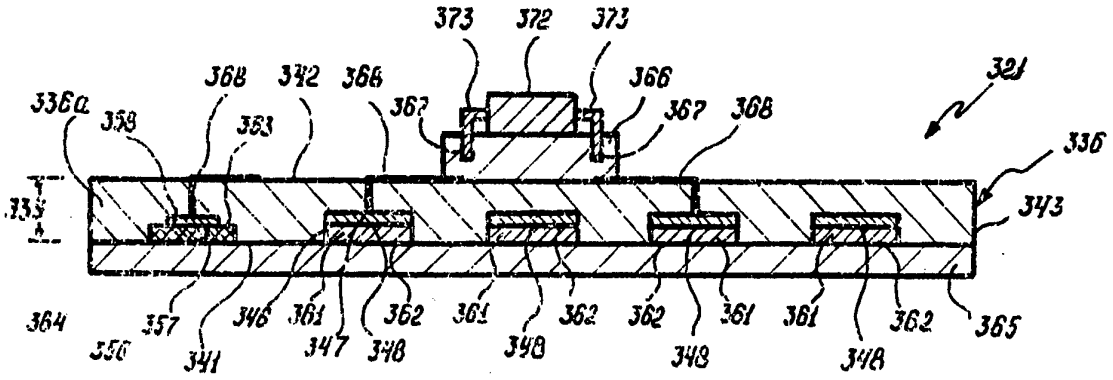
373
372
368
342
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FIG 6

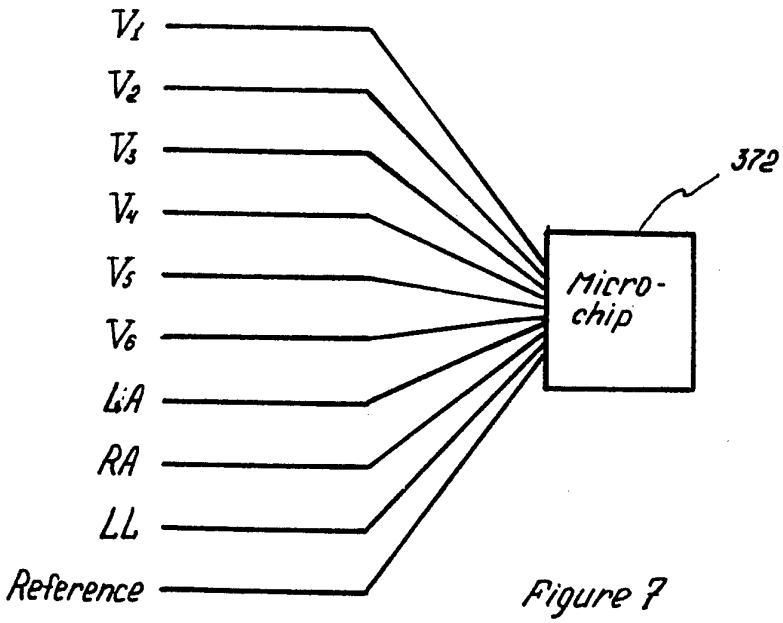


Figure 7

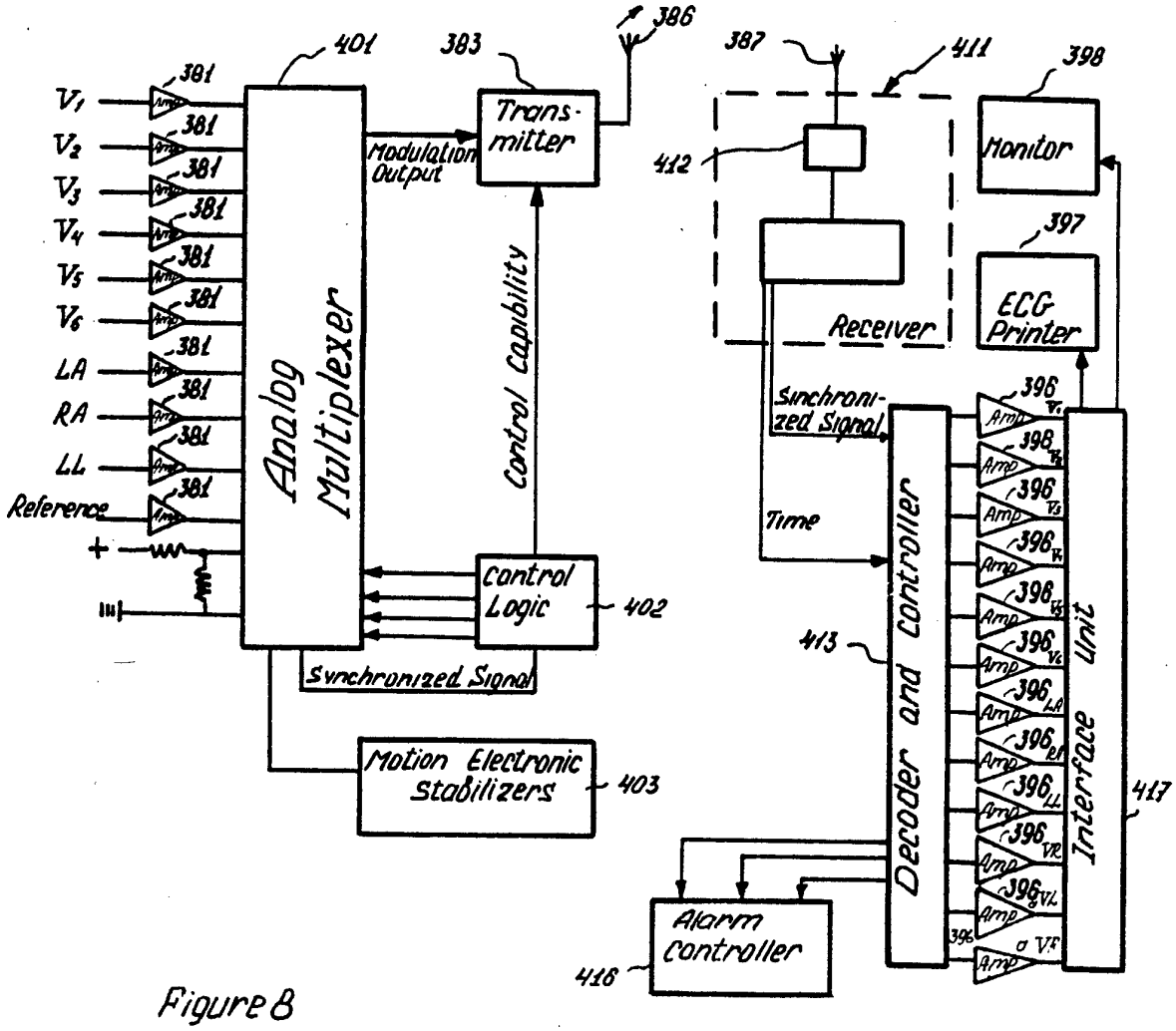


Figure 8

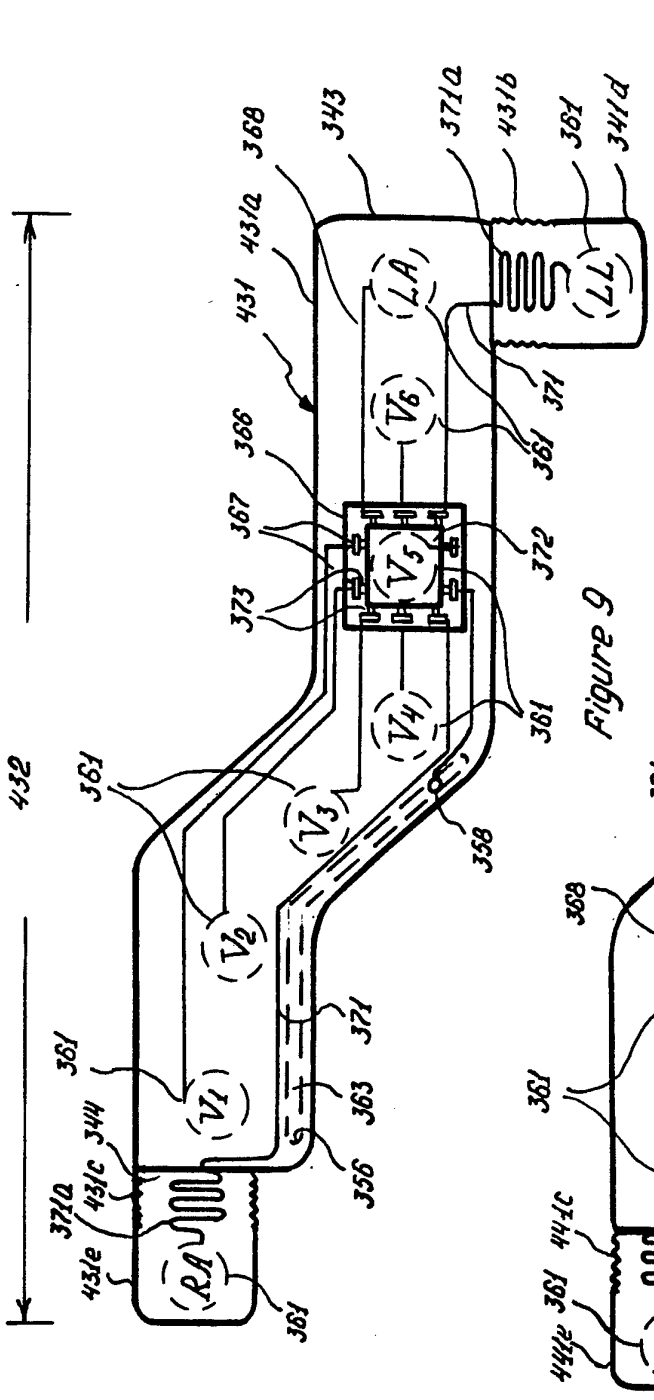


Figure 9

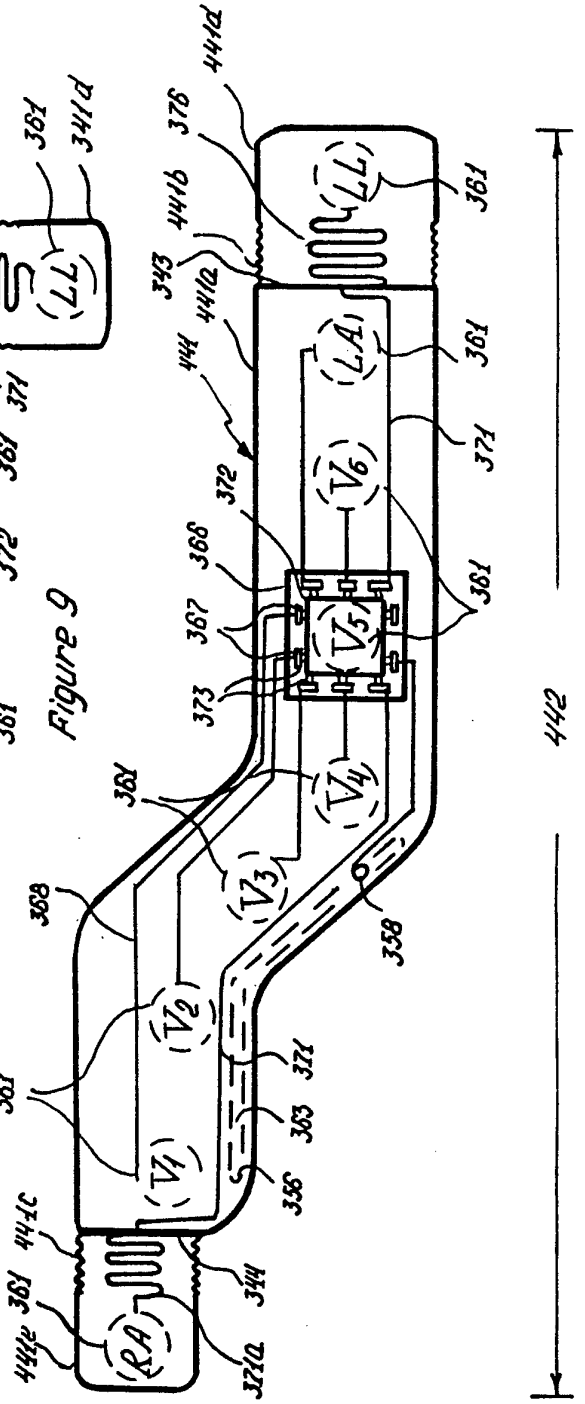


Figure 10

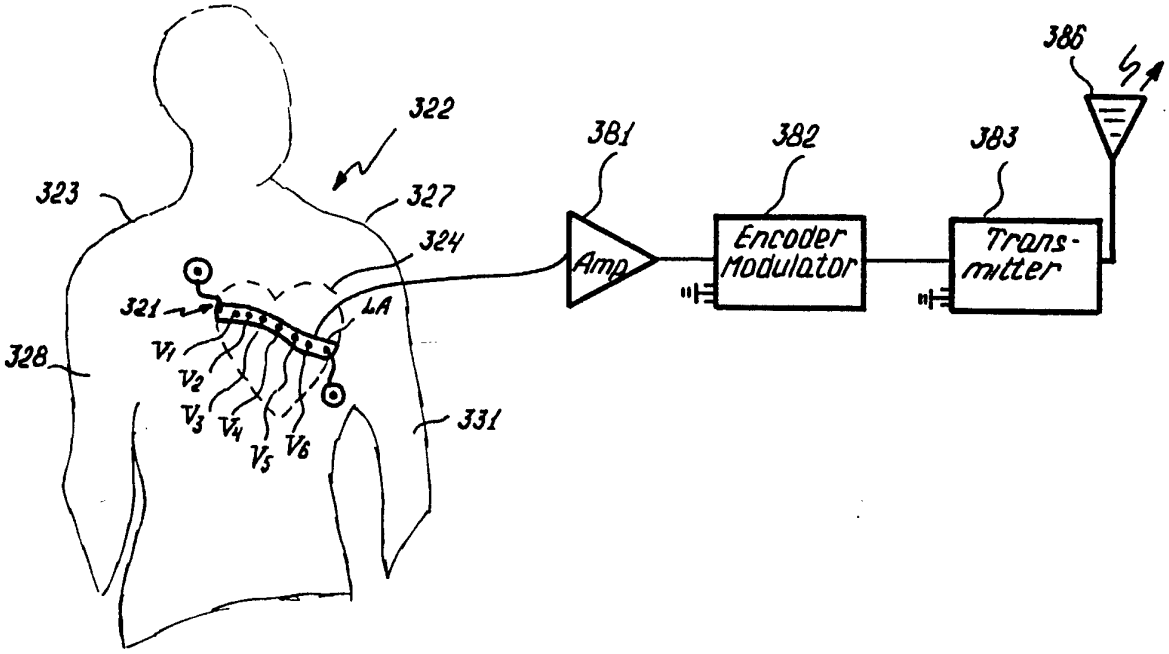


Figure 11

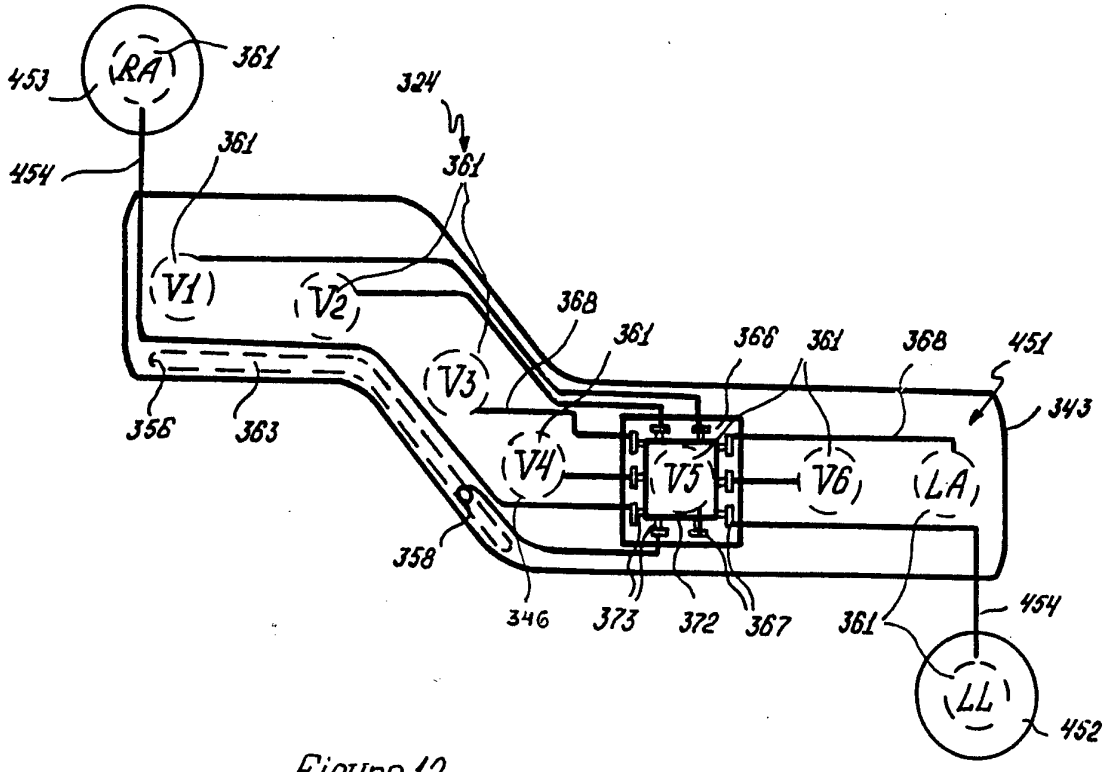


Figure 12

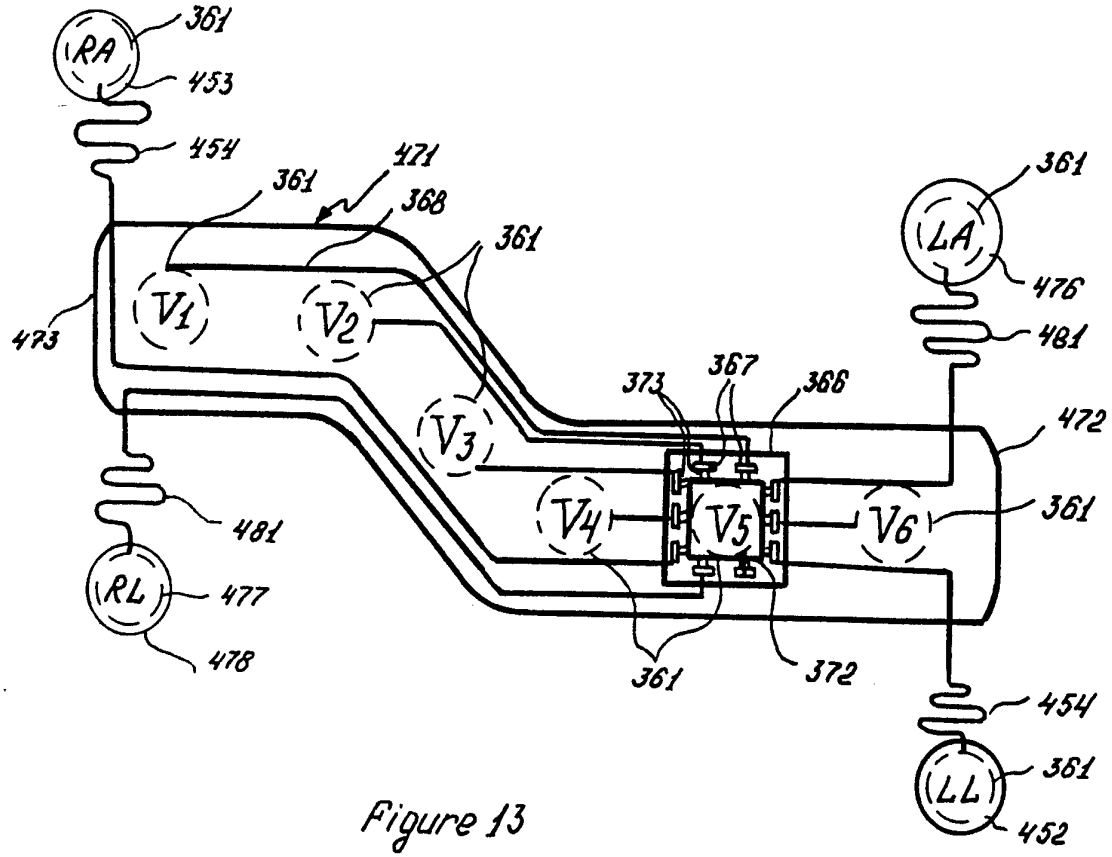


Figure 13

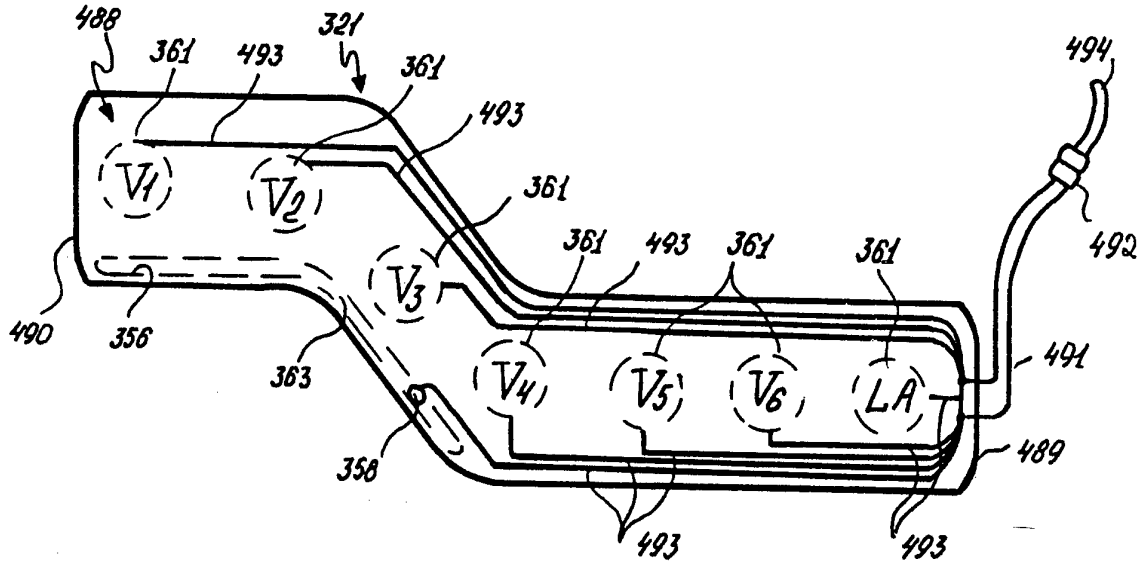


Figure 14

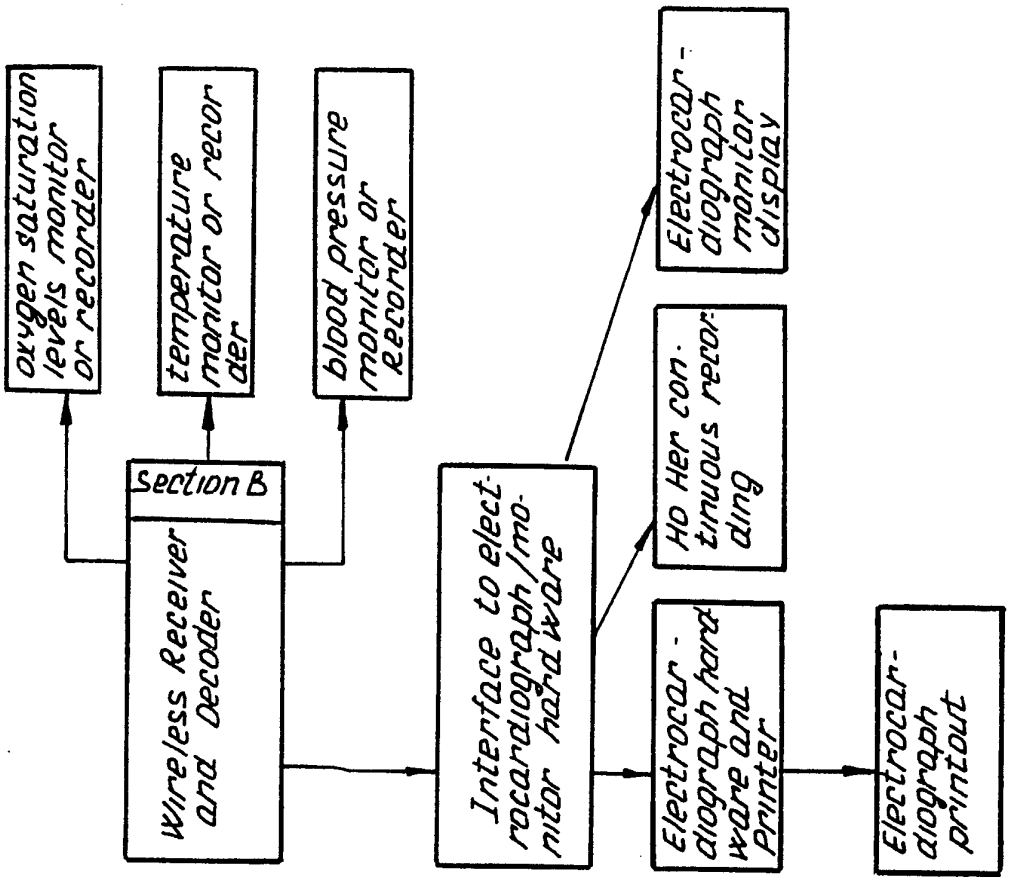
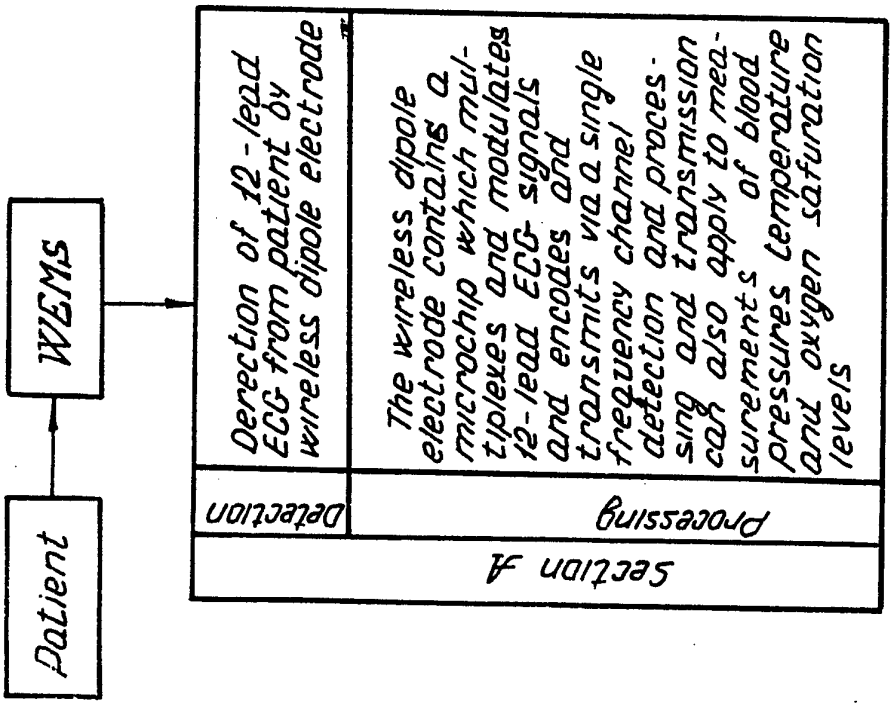

oxygen saturation levels monitor or recorder
temperature monitor or recorder
blood pressure monitor or recorder
Section B
Wire/less Receiver and Decoder
Interface to electrocardiograph/monitor hardware
Electrocardiograph monitor display
Holter continuous recording
Electrocardiograph hardware and Printer
Electrocardiograph printout

Figure 15


Patient
WEMS
Section A
Detection
Processing
Detection of 12-lead ECG from patient by wireless dipole electrode
The wireless dipole electrode contains a microchip which multiplexes and modulates 12-lead ECG signals and encodes and transmits via a single frequency channel detection and processing and transmission can also apply to measurements of blood pressures temperature and oxygen saturation levels

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US93/06386

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :A61B 5/04
US CL :128/696

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. : 128/696, 903, 639, 640, 641, 644; 364/413.06

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

None

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

None

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US, A, 4,583,549 (Manoli) 22 April 1986, see entire document.	1
X,P	US, A, 5,184,620 (Cudahy et al.) 09 Feb. 1993, see entire document.	2, 4, 6
A	US, A, 4,957,109 (Groeger et al.) 18 September 1990, see entire document.	1-10
A,P	US, A, 5,153,584 (Engira) 06 October 1992, see entire document.	1-10
A	US, A, 4,981,141 (Segalowitz) 01 January 1991, see entire document.	1-10

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

*	Special categories of cited documents:	"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
"A"	document defining the general state of the art which is not considered to be part of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"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
"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)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 04 August 1993	Date of mailing of the international search report 25 OCT 1993
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. NOT APPLICABLE	Authorized officer George Manuel Telephone No. (703) 308-0858

Form PCT/ISA/210 (second sheet)(July 1992)*