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(19) **United States**(12) **Patent Application Publication**
Salerno(10) **Pub. No.: US 2016/0249814 A1**(43) **Pub. Date: Sep. 1, 2016**(54) **MEDICAL DEVICE FOR THE DETECTION,
MEASUREMENT, IN AN UNBLOODY AND
NON-INVASIVE MANNER, AND
TRANSMISSION OF VITAL, BIOMEDICAL
PARAMETERS, SUCH AS
CARDIOVASCULAR AND RESPIRATORY
PARAMETERS, OF A HUMAN BODY***A61B 5/026* (2006.01)*A61B 5/024* (2006.01)*A61N 1/39* (2006.01)*A61B 5/0404* (2006.01)*A61B 8/08* (2006.01)(52) **U.S. Cl.**CPC *A61B 5/0205* (2013.01); *A61B 5/0404*
(2013.01); *A61B 5/0022* (2013.01); *A61B**5/6831* (2013.01); *A61B 8/52* (2013.01); *A61B**8/488* (2013.01); *A61B 5/6822* (2013.01);*A61B 5/026* (2013.01); *A61B 5/02438*(2013.01); *A61N 1/3987* (2013.01); *A61N**1/36585* (2013.01); *A61B 8/486* (2013.01)(71) Applicant: **Mario SALERNO**, Catania (IT)(72) Inventor: **Mario Salerno**, Catania (IT)(21) Appl. No.: **15/028,687**(22) PCT Filed: **Oct. 17, 2014**(86) PCT No.: **PCT/IB2014/065414**

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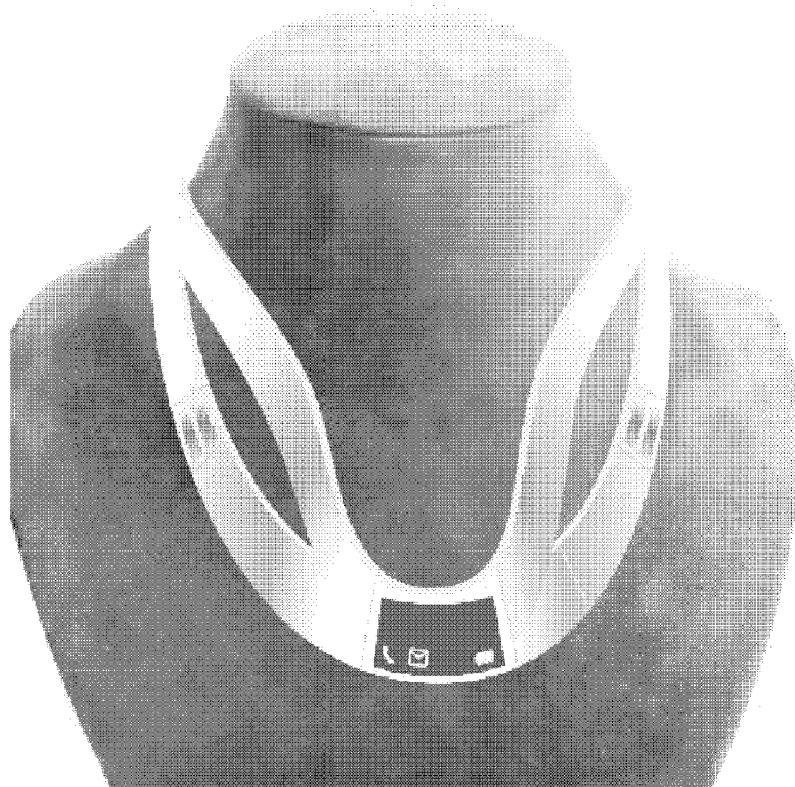
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(57)

ABSTRACT

A medical device for detecting, measuring and transmitting vital parameters and biomedical data such as the continuous or instantaneous recording of an electrocardiography, acquisition of a Doppler ultrasonography of ascending aorta and of an echocardiography, with immediate or remote operations, by means of units inserted in the device, on the human body, in a non-invasive way, comprising: a flexible strip-shaped support adapted to be applied on the human body in the area of the neck; one or more units adapted to detect body parameters; one or more connection interfaces for transmitting and receiving data and the parameters towards external units; hardware and software electronic components integrated inside the flexible support and adapted to receive the body parameters from the one or more units, store them, organize them and transmit them by connection interfaces; a sim card allowing transmission and reception.



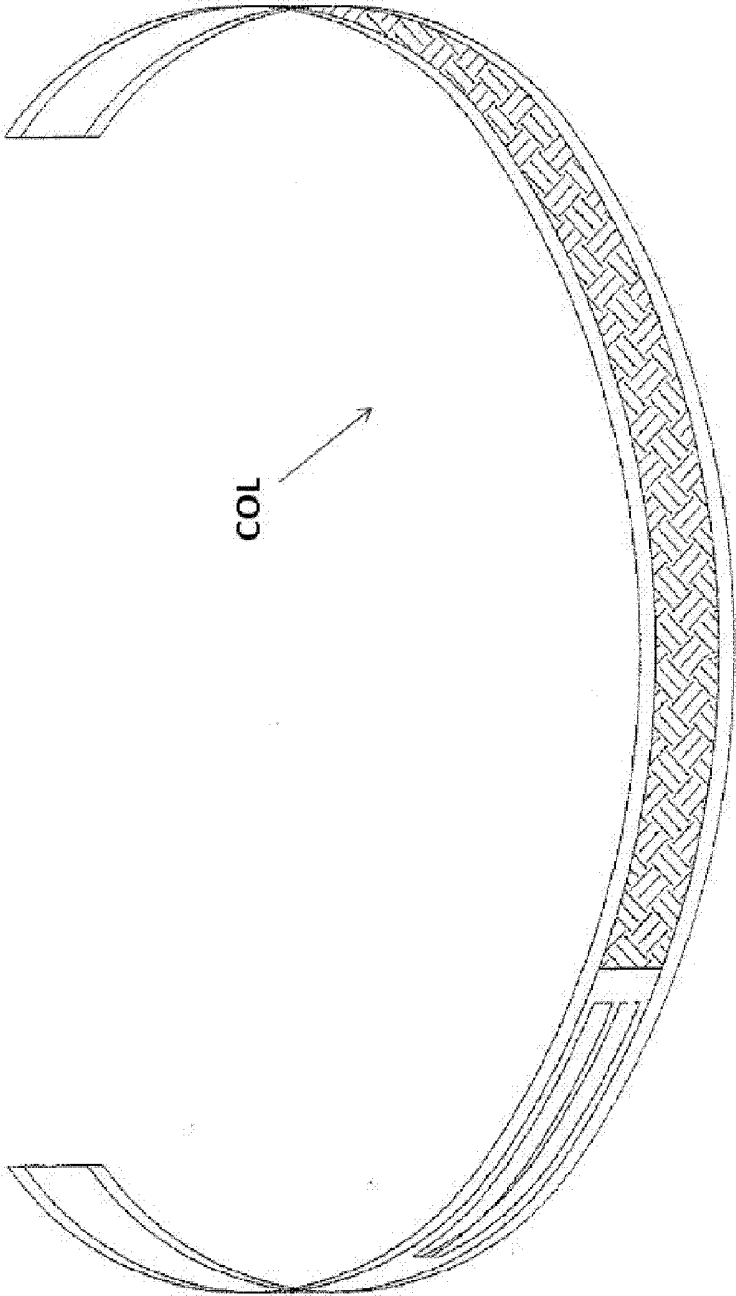


FIG. 1

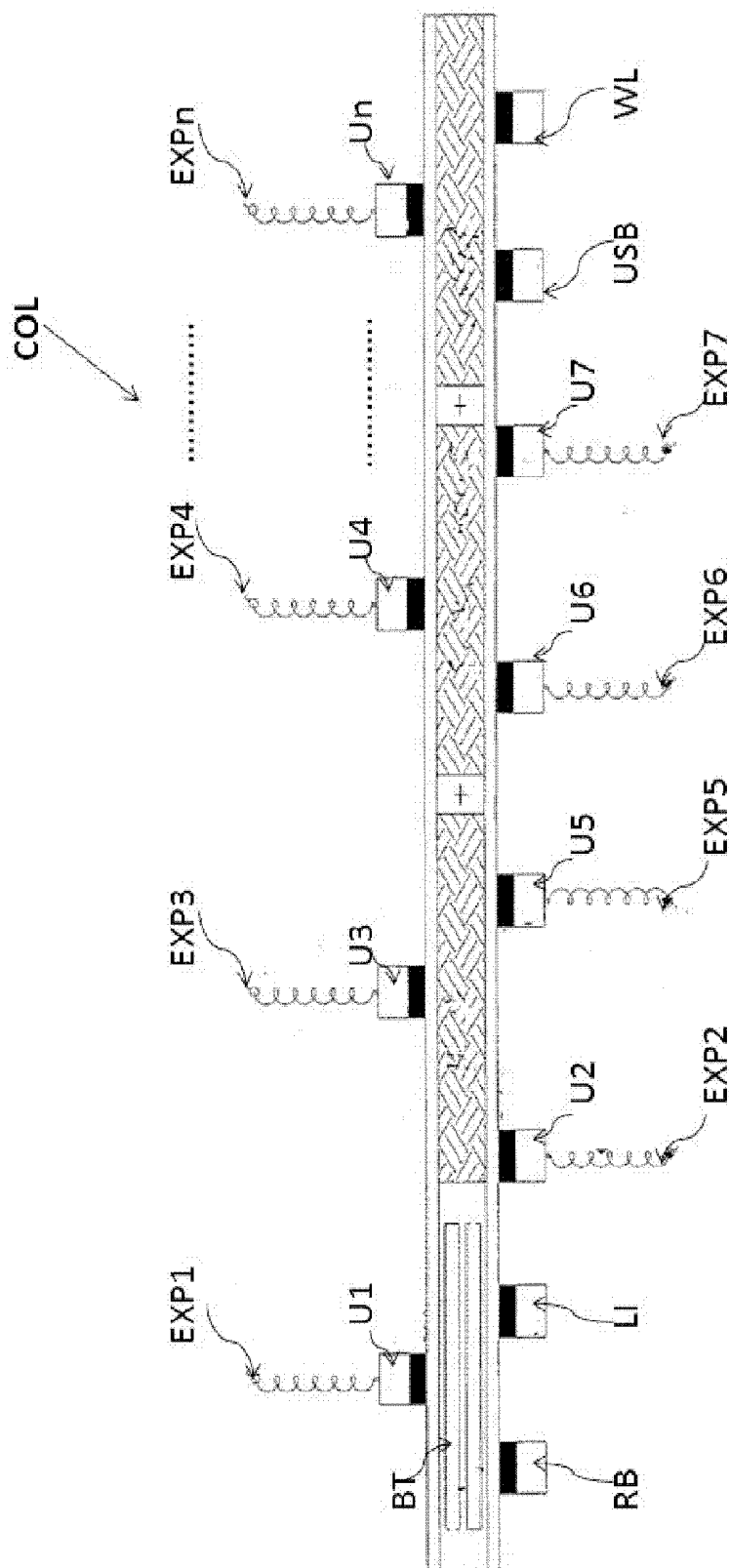


FIG. 2

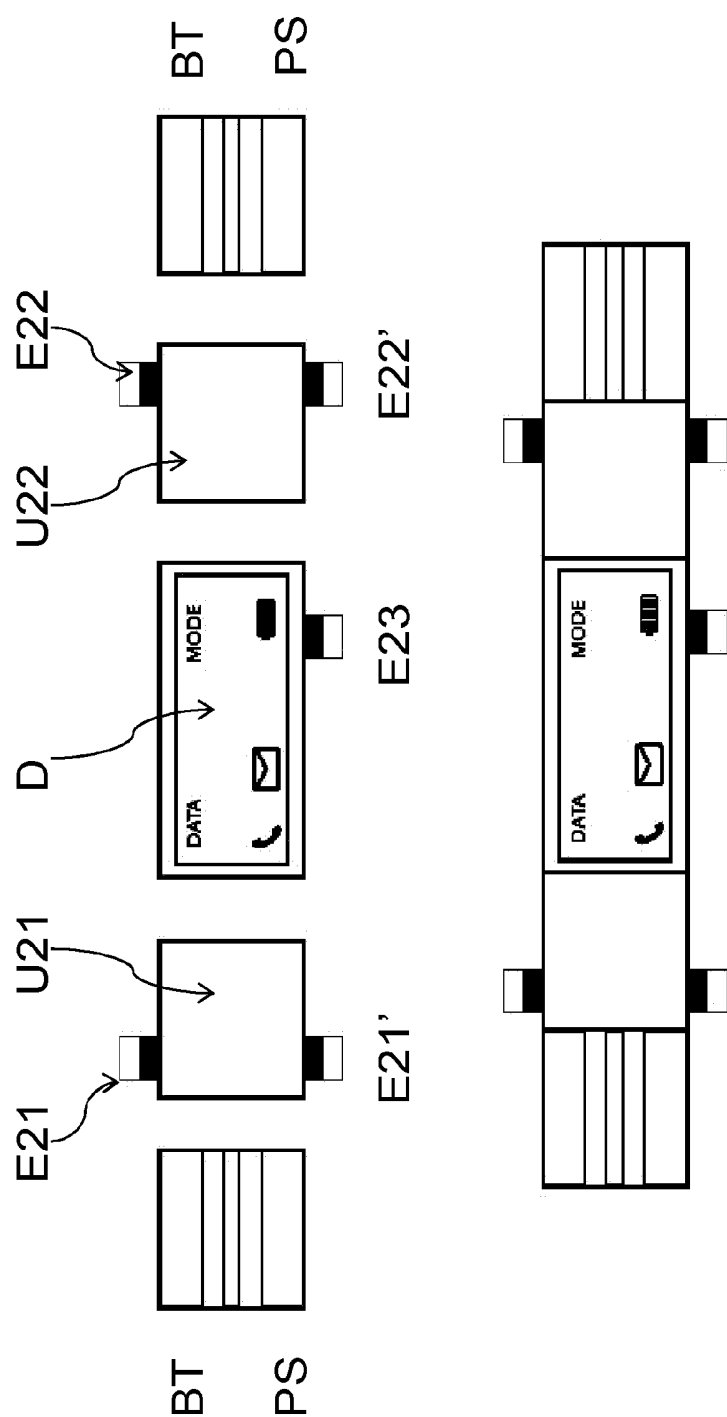


FIG. 3

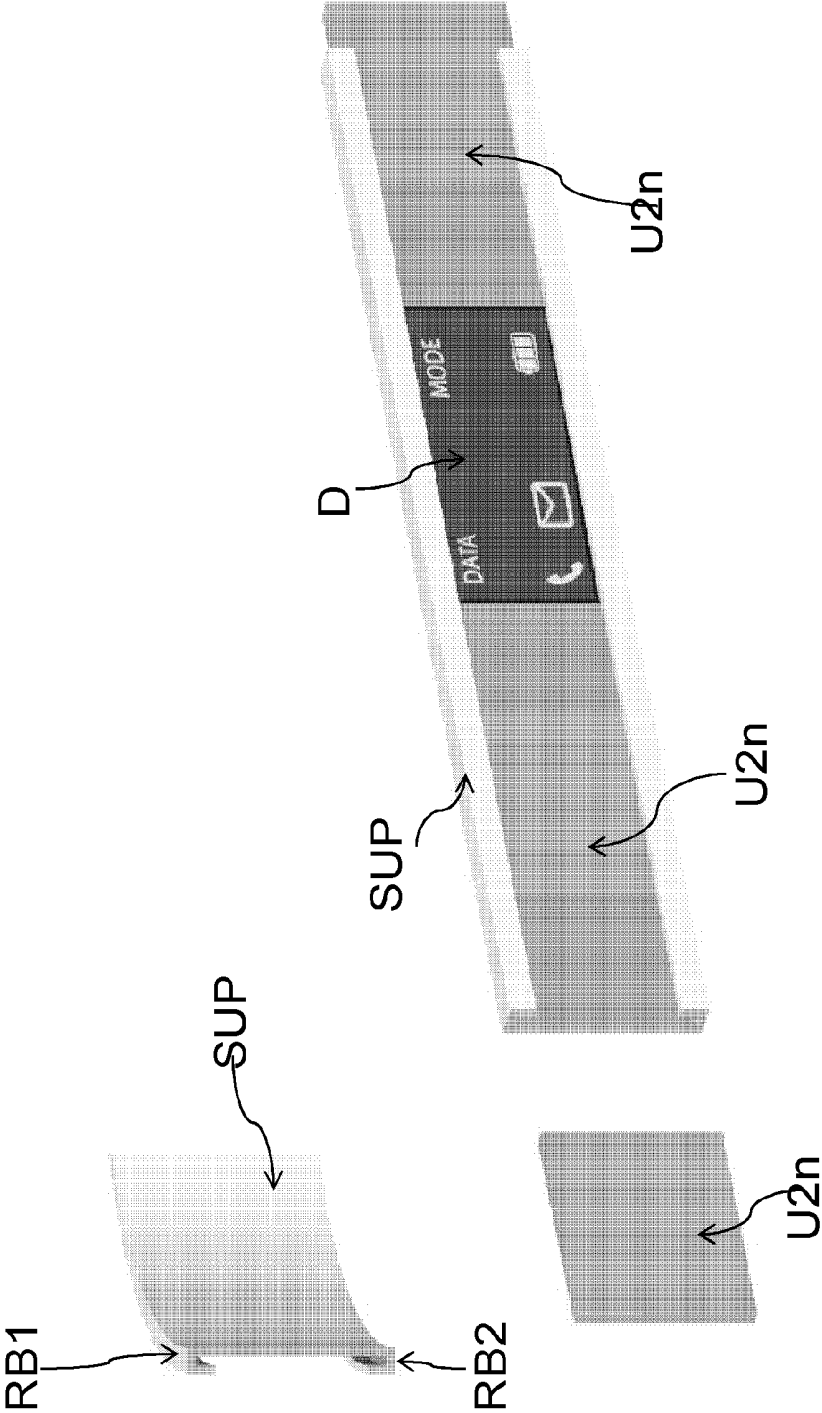


FIG. 4

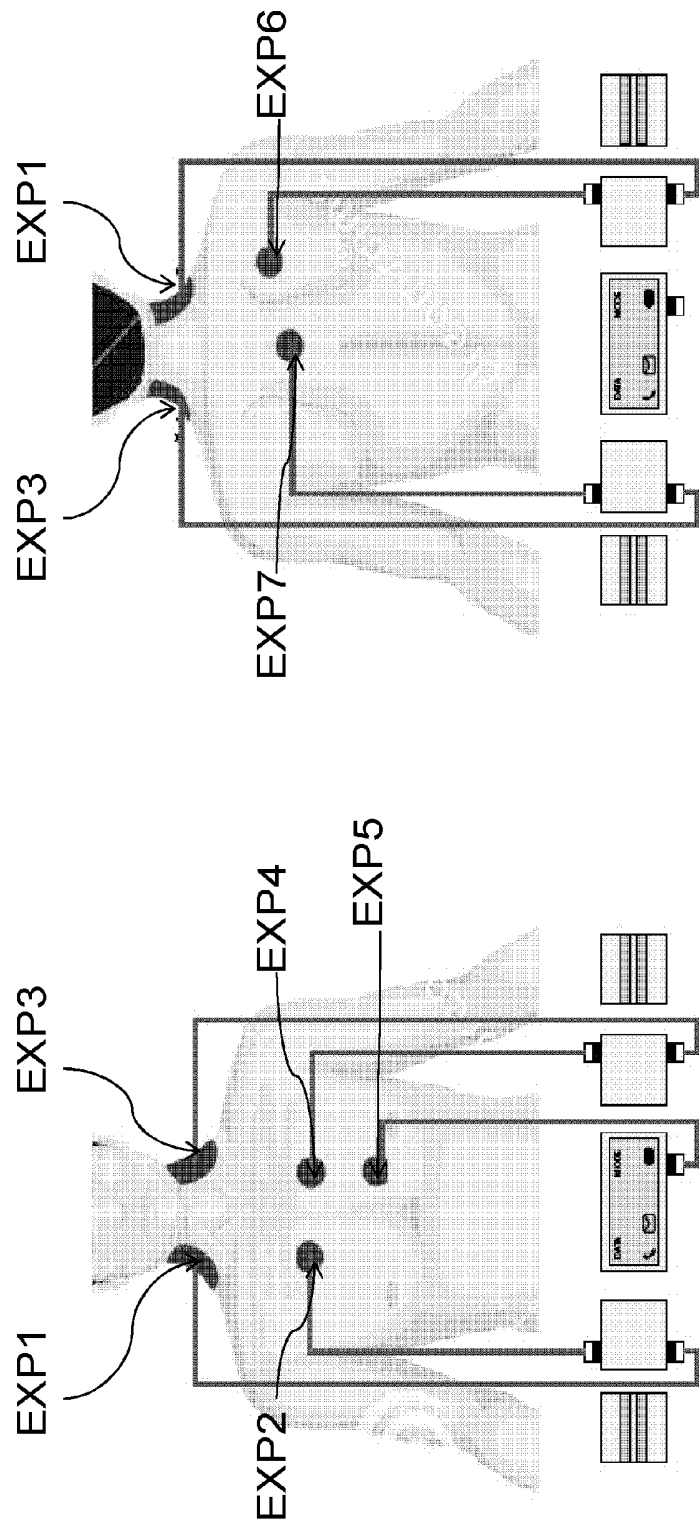


FIG. 5



FIG. 6.1

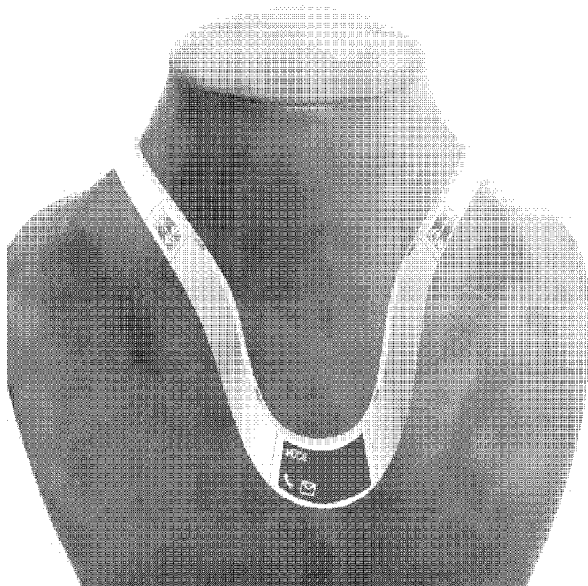


FIG. 6.2

**MEDICAL DEVICE FOR THE DETECTION,
MEASUREMENT, IN AN UNBLOODY AND
NON-INVASIVE MANNER, AND
TRANSMISSION OF VITAL, BIOMEDICAL
PARAMETERS, SUCH AS
CARDIOVASCULAR AND RESPIRATORY
PARAMETERS, OF A HUMAN BODY**

APPLICATION FIELD OF THE INVENTION

[0001] The present invention refers to a medical device for detecting, measuring, and transmitting, in a non-invasive, continuous and instantaneous way, vital parameters of the human body, and other biomedical parameters, and consequent operations, especially for indicating the need of an intervention.

DESCRIPTION OF THE PRIOR ART

[0002] WHO (World Health Organization) defines health as “A state of complete physical, mental and social well-being and not merely the absence of disease or infirmity”.

[0003] Such definition defines the fundamental right to health.

[0004] Therefore a broader and broader demand is increasingly developing, not only for treating the different diseases, but above all for:

[0005] preventing the illnesses due to the increase of the average life expectancy;

[0006] intervening in an early, prompt and adequate way for those acute diseases, above all cardiovascular and respiratory, which are a potential cause of death and which may provoke disabilities;

[0007] controlling and monitoring vital parameters and clinical data in life-threatening chronic illnesses and/or to prevent the development of secondary handicaps.

[0008] In parallel to such a pressing demand, in all domestic economies the need for coherent and documented diagnosis arises, in order to give a justified access to both hospitalization and sophisticated, and therefore expensive, medical examinations and procedures, and thus avoid wasting precious economical resources.

[0009] Currently, by activating the different medical diagnostic devices, both in acute and in chronic diseases, it is not possible to obtain an immediate and general evaluation of those parameters, that in some patients are crucial to define the diagnosis and start a treatment, above all in the most urgent cases.

[0010] It is important to have access, above all, to fundamental detections:

[0011] in patients with chronic cardiovascular, respiratory diseases and in their emergencies due to relapse or complications;

[0012] in healthy subjects which have an acute symptomatology referring to the cardiovascular and/or respiratory apparatus;

[0013] in patients having chronic diseases for which some vital parameters need to be monitored.

[0014] Currently, medical devices that are able to provide and, at the same time, to send data in an instantaneous or continuous non-invasive way, in order to respond to such medical and diagnostic needs, for both acute and chronic cardiovascular and respiratory diseases, are not known in the art.

[0015] The known devices, such as for example the ones described in US2007/142738-A1 or in US2006/184059-A1, allow to record and to send heartbeat, and to record electromyography graphs in a non-invasive way, to evaluation centres.

[0016] In recent times, modern smartphones and tablets, which are actually starting to include pre-installed medical software applications, are also used for both receiving and transmitting analysis and responses to detection centres, also as a support of amateur and agonistic sport activities.

[0017] US2013/014706-A1 describes a collar-type device for veterinary applications to animals, which comprises some sensors adapted to measure the animal's parameters and to transmit them, also remotely. The device comprises an inflatable band adapted to create a tension of the collar against the neck of the animal, so as to keep it still and adherent in order to press the sensors against the neck of the animal itself. In addition to the functional limitations of such device, and to the dangerousness of pressing a collar against the neck of a person, it is not adapted to applications to the human body, as it is not possible to obtain reliable detections for critical parameters, nor for other complex parameters that are useful and necessary in the cardiovascular and respiratory emergencies.

[0018] Currently, medical devices adapted to the use on human body that have all the following requirements are not known in the art:

[0019] ability to detect, record and transmit vital parameters and complex biomedical parameters to the home or to the hospital;

[0020] ability to carry out immediate or remote operations for cardiovascular emergencies, using a single or multiple parameters;

[0021] easy application to patient;

[0022] ability to store the parameters detected, both wired and wireless interactivity on smartphones, PCs and networks;

[0023] ability to localize and identify the device and thus the patient;

[0024] flexibility to implement the connection of detectors of other parameters;

[0025] non-invasiveness;

[0026] simple management.

SUMMARY OF THE INVENTION

[0027] Therefore the aim of the present invention is to provide a medical device adapted to detect, to measure, in a bloodless and non-invasive way, and to transmit vital, biomedical parameters, such as cardiovascular and respiratory ones, of the human body, able to overcome all the aforementioned drawbacks.

[0028] It is an object of the present invention a medical device adapted to detect, to measure, in a bloodless and non-invasive way, and to transmit vital, biomedical parameters, such as cardiovascular and respiratory ones, of the human body, the device being characterized in that it comprises:

[0029] a flexible strip-shaped support (COL, SUP) adapted to be applied on the human body in the area of the neck;

[0030] one or more units (U1, U2, . . . Un) adapted to detect body parameters;

[0031] one or more connection interlaces (USB, WL) for transmitting and receiving data and said parameters towards external units;

[0032] hardware and software electronic components integrated inside the flexible support and adapted to receive said body parameters from said one or more units (U1, U2, . . . Un), to store them, to organize them and to transmit them as encrypted or not encrypted by means of said one or more connection interfaces (USB, WL).

[0033] said device being adapted to record an electrocardiography in a continuous or instantaneous way, to acquire the Doppler ultrasonography of ascending aorta, to acquire m-B mode echocardiography, to immediately or remotely operate on emergency intervention units such as a temporary transcutaneous pacemaker and/or a cardiac defibrillator.

[0034] It is particular object of the present invention a medical device adapted to detect, to measure, in a non-invasive way, and to transmit vital, biomedical parameters, such as cardiovascular and respiratory ones, of the human body, as described more fully in the claims that are considered as an integral part of the present description.

BRIEF DESCRIPTION OF THE FIGURES

[0035] Further aims and advantages of the present invention will become more apparent from the following detailed description of an embodiment thereof (and of its alternative embodiments) and from the annexed drawings, which are supplied by way of non-limiting example, wherein:

[0036] FIG. 1 shows a first embodiment of the device that is object of the present invention;

[0037] FIG. 2 shows the device of FIG. 1 extended in a straight line, with indication of the elements connected to it;

[0038] FIGS. 3 and 4 show a second embodiment of the device that is object of the present invention, with units that can be assembled separately or that are assembled on one single support;

[0039] FIG. 5 shows an example of application of the device for measuring medical parameters in some body areas;

[0040] FIGS. 6.1, 6.2 show two possible embodiments of the device.

DETAILED DESCRIPTION OF EMBODIMENTS

[0041] In a first embodiment, with reference to FIGS. 1 and 2, the device is shaped, by way of example, as a collar COL formed by a strip-shaped flexible support made of suitable material, an appropriate fastening device (not shown), for example a clip or a button, being placed at its ends.

[0042] A number of units U1, U2, . . . made in a way per se known and able to detect body parameters are connected to the device COL. Each unit is adapted to be connected to one or more relating explorers EXP1, EXP2, . . . EXPn either by means of possibly extendable and retractable wires, or in wireless mode.

[0043] In addition, further connection interfaces, such as USB, WL (wireless) are connected to the device COL for transmitting and receiving data and parameters towards suitable external units.

[0044] The device (COL) further comprises connections for battery recharging (RB), by using modern technology for installing batteries that ensures its safety and durability, possibly using micro solar panels to have another energy source.

[0045] For the identification and localization of the patient, to which the device is applied, GPS satellite localizers are

placed on the site LI. Also, in such site, a microchip is positioned for the identification of the patient using a PIN or other identification sequence.

[0046] Furthermore, in such site LI a SIM card is inserted which provides both the patient localization and identification either on WEB or on other detection device, protecting his/her privacy.

[0047] By adding a SIM card, the device acquires an important smartphone function, with all its current and future operating potential. That, in addition to all of its multiple applications (for example a micro-camera), allows the patient to have a normal cell phone available that connects him/her directly (also using speakerphone or earphones) to other apparatuses or to a help centre, providing immediately his/her position, his/her identification and the possibility of talking directly to the operators.

[0048] The device COL, of reduced dimensions, may become a smartphone by just inserting the SIM card, freeing the patient's, or any possible user's, hands and being itself either only a smartphone or a device able to send a help request to help centres.

[0049] What just said about localization and identification of the patient, may and will be improved by new micro-technologies.

[0050] The eccentric, namely peripheral, position of the site LI (Localization, Identification) and KB (battery recharging) on the collar allows to avoid any interference with the normal bioelectric activity of the heart.

[0051] The units U1, U2, . . . Un and the interfaces USB, WL are connected to suitable hardware and software components integrated in the device, and adapted to receive the data detected by the units, store them, organize them and transmit them, in a not encrypted or encrypted way for privacy reasons, immediately or at suitable times, even on demand, to external units such as PC, tablets, smartphones, being them single or organized in a network, placed at the patients' home or in evaluation centres where data can undergo further processing and integration using hardware and software suitable for the detected data. The latter may, in its turn, offer immediate responses or communicate with patients or medical, paramedical personnel at the patients' home or at a hospital.

[0052] The electronic components of the collar COL are battery-powered: the batteries BT can be integrated inside the collar.

[0053] The collar or necklace shape is important as it is anatomical and can be applied in an anatomically suitable area on the human body. Thus the collar or necklace shape is crucial for making its usage easy and effective; this is because it can be worn fast and easily, as it is located in the proximity of most of the organs of cardiovascular and respiratory interest that is object of the detection of biomedical parameters.

[0054] The device COL can be made in a single piece or by articulated meshes, for example of the modular type, each mesh being able to connect a respective unit, so as to combine consecutive units.

[0055] The collar can be made of light, anallergic material, made of carbon fibre with a fastener, e.g. having dimensions 3 cm×80 cm.

[0056] The different units U1, U2, . . . Un can be activated only if needed, not necessarily all together. They can be connected externally to one or both most elongated sides of the collar.

[0057] The different units are expected to communicate with each other by means of the electronic components of the

collar, for example defibrillator and cardiac arrhythmia detector: once the arrhythmia is detected, it is communicated to the defibrillator which is immediately activated.

[0058] A second embodiment of the medical device is shown in FIGS. 3, 4 e 5.

[0059] The device comprises essentially:

[0060] a flexible strip-shaped support SUP, preferably collar or necklace shaped; it comprises folds RB1, RB2 at the edges of the longer sides so as to make a rail on which the different detection or possibly transmission operating units U21 . . . U2n, or a single case containing tile different units U21, . . . U2n, can be inserted in a sliding and removable way. The strip of the flexible support is thus turned towards the inner side of the support towards the body of the person, while its opposite outer side remains open, in order to show most of the surface of the elements accommodated inside the support.

[0061] detection and possibly transmission operating units U21 . . . U2, Un, which can be made by single components which carry out the different functions, or a single case that supports the different operating units.

[0062] exploring probes EXP1, EXP2, . . . EXPn adapted to be connected to said operating units U1 . . . Un by means of connections E21 . . . E23 and possibly extendable and retractable wires or in wireless mode.

[0063] plates placed on the anatomical sites of the person to be analyzed, adapted to connect said explorers and wires to the body. Plates are of a type known in the art, adapted to ensure a long adherence, in an anallergic way, and make the adherence, the data transmission and thus the reading perfect, reducing the recording errors. Said plates may serve as detectors, data integration and transmission in wireless, Bluetooth or other mode, to allow a new type of mobility in the data transmission.

[0064] at least one display D preferably of the touchscreen type. Time presence of the touchscreen display may allow the user or the operator, with respective suitable icons, to use immediately all the functions of the device, including all its operations and data storing.

[0065] at least one SIM card with the functions described above with reference to the first embodiment of the device.

[0066] at least one battery BT compartment, preferably of the rechargeable type.

[0067] miniaturized solar panels PS for battery recharging and for increasing the endurance and the mobility of the device.

[0068] USB ports to connect other devices

[0069] wireless, Bluetooth telecommunication devices

[0070] connection (not shown), also of the wireless type, for a keyboard for the input of data and commands.

[0071] Other general characteristics can be referred to what described above with reference to the first embodiment of the device.

[0072] FIG. 5 shows examples of anatomical sites, where the mentioned detections and operations take place, such as:

[0073] area of the neck, at the base of the neck

[0074] right and left second parasternal intercostal space

[0075] fifth space on the left midclavicular line

[0076] right dorsal scapular and interscapular area.

[0077] FIGS. 6.1, 6.2 show two possible embodiments of the device with flexible collar or necklace shaped support, to allow an easy application on the neck area of the person.

[0078] The flexible support can be made of plastic or carbon fibre with a fastener, e.g. having dimensions 3 cm×80 cm.

[0079] The particular shape of the device allows, for example:

[0080] any easy application on the neck area of the patient;

[0081] an easy access for the detectors to the anatomical sites from which they can

[0082] a—display the vital parameters that are object of the detection, namely: skin temperature, arterial pressure, SpO2%; heartbeat;

[0083] b—acquire the Doppler ultrasonography of ascending aorta;

[0084] c—record the ECG (electrocardiography) in a continuous and instantaneous way;

[0085] d—acquire M-mode and B-m echocardiography (parasternal and apical 5 chamber view)

[0086] e—intervene, from an operation point of view, with PM (temporary transcutaneous pacemaker) and cardiac defibrillator.

[0087] f—localize and identify the patient quickly;

[0088] g—make its shape flexible, which can be modified and lightened;

[0089] h—have pre-programmed cut-offs, which can be visual or acoustic, thus limiting the data transmission and providing immediately an alert warning to the user;

[0090] i—reduce improper or incoherent hospitalization having documented the data of the diseases that are object of the detection;

[0091] l—have fast operating responses with an overall picture documented by the diseases that are object of the data detection;

[0092] m—communicate, also using the smartphone function inserted in the collar, with the patient providing him/her with indications;

[0093] n—let the patient free from the fear to be far from an help centre.

[0094] o—access to the display for setting, desired information and necessary operations.

[0095] Indeed, the clinical data acquired by the device, by using detectors placed in well-defined anatomical areas, are not just relating to vital parameters detected by a generic rescuer, by the so-called “primary exam” (arterial pressure, heartbeat, body temperature, consciousness), but also to more complex cardiovascular and respiratory data (electrocardiography, Doppler ultrasonography of carotid axis, percentage of oxygen saturation), that, in acute emergencies, above all cardio-respiratory ones, may provide documented data adapted to provide operating responses at different levels, namely:

[0096] immediately on the patient;

[0097] by activating a complete information that may remotely command the response units inserted in the device (temporary transcutaneous pacemaker; defibrillator);

[0098] by creating an information flow that allow the highest promptness and effectiveness in the medical intervention (ambulance, emergency room, etc.).

[0099] The device that is object of the patent is a medical device, in the sense that its application, management, and the interventions that are considered appropriate are in charge of specialized medical personnel only. Users may possibly have access to simple detections (skin temperature, arterial pressure, heartbeat), but always under medical supervision.

[0100] It will be apparent to the person skilled in the art that other equivalent embodiments, and their combinations, of the invention can be conceived and reduced to practice without departing from the scope of the invention.

[0101] The elements and the characteristics shown in the different preferred embodiments can be combined with each other without departing from the scope of the present patent.

[0102] From the description set forth above the person skilled in the art is able to realize the object of the invention without introducing further constructive details.

1. A medical device adapted to detect, to measure, in a bloodless and non-invasive way, and to transmit vital, biomedical parameters, such as cardiovascular and respiratory ones, of the human body; the device comprising:

a flexible strip-shaped support adapted to be applied on the human body in the area of the neck;

one or more units adapted to detect body parameters;

one or more connection interfaces for transmitting and receiving data and said parameters towards external units;

hardware and software electronic components integrated inside the flexible support and adapted to receive said body parameters from said one or more units, store them, organize them and transmit them as encrypted or not encrypted way by means of said one or more connection interfaces.

said device being adapted to record an electrocardiography in a continuous or instantaneous way, to acquire the Doppler ultrasound of ascending aorta, to acquire m-B mode echocardiography, to immediately or remotely operate on emergency intervention units such as a temporary transcutaneous pacemaker and/or a cardiac defibrillator.

2. The medical device adapted to detect, to measure, in a non-invasive way, and to transmit vital, biomedical parameters, such as cardiovascular and respiratory ones, of the human body, as in claim 1, comprising one or more exploring probes adapted to be connected to said one or more units by means of possibly extendable and retractable wires, or in a wireless mode.

3. The medical device adapted to detect, to measure, in a non-invasive way, and to transmit vital, biomedical parameters, such as cardiovascular and respiratory ones, of the human body, as in claim 1, wherein said electronic components are powered by batteries integrated in the flexible support, said collar comprising connections to recharge the batteries and means for identifying the patient.

4. The medical device adapted to detect, to measure, in a non-invasive way, and to transmit vital, biomedical parameters, such as cardiovascular and respiratory ones, of the human body, as in claim 3, wherein said means for identifying the patient comprise a GPS satellite localizer and a SIM card, said device being able to serve as a smartphone.

5. The medical device adapted to detect, to measure, in a non-invasive way, and to transmit vital, biomedical parameters, such as cardiovascular and respiratory ones, of the human body, as in claim 1, wherein said flexible strip-shaped support is made in a single piece or is made by modular meshes, each mesh being able to connect a respective unit.

6. The medical device adapted to detect, to measure, in a non-invasive way, and to transmit vital, biomedical parameters, such as cardiovascular and respiratory ones, of the human body, as in claim 5, wherein said one or more units can be activated and are connected externally to one or both most elongated sides of the flexible strip-shaped support.

7. The medical device adapted to detect, to measure, in a non-invasive way, and to transmit vital, biomedical parameters, such as cardiovascular and respiratory ones, of the human body, as in claim 1, wherein said flexible strip-shaped support comprises folds at the edges of the longer sides adapted to make a rail to insert in a sliding and removable way said one or more units, and/or said one or more connection interfaces, and/or said hardware and software electronic components.

8. The medical device adapted to detect, to measure, in a non-invasive way, and to transmit vital, biomedical parameters, such as cardiovascular and respiratory ones, of the human body, as in claim 7, wherein said strip is turned on the inner side of the support towards the body of the person, while the opposite outer side is open.

9. The medical device adapted to detect, to measure, in a non-invasive way, and to transmit vital, biomedical parameters, such as cardiovascular and respiratory ones, of the human body, as in claim 1, wherein said one or more units are adapted to communicate with each other by means of said electronic components.

10. The medical device adapted to detect, to measure, in a non-invasive way, and to transmit vital, biomedical parameters, such as cardiovascular and respiratory ones, of the human body, as claimed in claim 1, wherein said flexible strip-shaped support is collar or necklace shaped.

11. The medical device adapted to detect, to measure, in a non-invasive way, and to transmit vital, biomedical parameters, such as cardiovascular and respiratory ones, of the human body, as claimed in claim 1, made of plastic or carbon fibre, adapted to be positioned on the human body in a position that does not interfere with the cardiac bioelectric activity.

12. The medical device adapted to detect, to measure, in a non-invasive way, and to transmit vital, biomedical parameters, such as cardiovascular and respiratory ones, of the human body, as in claim 1, wherein a fastener is placed at the ends of the flexible support.

13. The medical device adapted to detect, to measure, in a non-invasive way, and to transmit vital, biomedical parameters, such as cardiovascular and respiratory ones, of the human body, as in claim 1, adapted to realize a support for smartphone or other transmission means.

14. The medical device adapted to detect, to measure, in a non-invasive way, and to transmit vital, biomedical parameters, such as cardiovascular and respiratory ones, of the human body, as in claim 2, comprising plates adapted to be placed on anatomical sites and connected to said explorers said plates being adapted to become a seat for data integration and transmission in wireless, Bluetooth mode.

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专利名称(译)	用于检测，测量，非血液和非侵入性方式的医疗设备，以及人体的心血管和呼吸参数等重要生物医学参数的传输		
公开(公告)号	US20160249814A1	公开(公告)日	2016-09-01
申请号	US15/028687	申请日	2014-10-17
[标]申请(专利权)人(译)	SALERNO MARIO		
申请(专利权)人(译)	萨勒诺，MARIO		
当前申请(专利权)人(译)	萨勒诺，MARIO		
[标]发明人	SALERNO MARIO		
发明人	SALERNO, MARIO		
IPC分类号	A61B5/0205 A61B5/00 A61N1/365 A61B5/026 A61B5/024 A61N1/39 A61B5/0404 A61B8/08		
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优先权	102013902200032 2013-10-18 IT		
外部链接	Espacenet USPTO		

摘要(译)

一种用于检测，测量和传输生命参数和生物医学数据的医疗设备，例如心电图的连续或瞬时记录，升主动脉多普勒超声检查和超声心动图检查，通过插入的单元进行即时或远程操作该装置，在人体上，以非侵入性的方式，包括：柔性条形支撑件，适于在颈部区域中施加在人体上；一个或多个适于检测身体参数的单元；一个或多个连接接口，用于向外部单元发送和接收数据和参数；硬件和软件电子组件集成在灵活支撑内部，适于从一个或多个单元接收身体参数，存储它们，组织它们并通过连接接口传输它们；一张允许发送和接收的SIM卡。

