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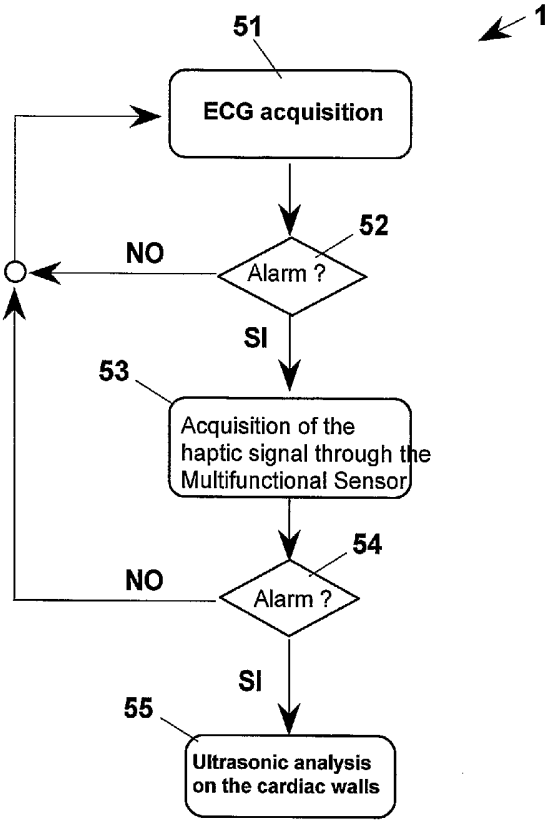
(54) Title: WEARABLE DEVICE FOR MONITORING CARDIOVASCULAR SIGNALS



(57) Abstract: Wearable device for non-invasive monitoring of a patient's heart functionality through the acquisition electrocardiographic (ECG) signal whose graph is acquired and compared with a previously recorded standard graph. The device detects cardiovascular signals and finds out any cardiopathies by means of both of the ECG electrodes and a piezoelectric multifunctional transducer. The latter, through a wide frequency band operativity, can work both at low frequency as a transducer of the heart apical impact, and as microphone for recording cardiac sounds, as well as can operate in ultrasonic echo M mode. In case of substantial differences between the actual graph and the standard, the real conditions of the walls heart are tested through the acquisition of a haptic signal (heart apical impact). If, from the analysis of the heart beat impact signal, an abnormality of the patient's cardiovascular functionality is observed, an ultrasonic analysis is started on the cardiac wall in order to find out any occurrences of akinesia of the patient's heart.

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TITLE

WEARABLE DEVICE FOR MONITORING CARDIOVASCULAR SIGNALS

DESCRIPTION

Field of the invention

The present invention relates to medical outpatient non-invasive monitoring services and in particular it relates to a wearable device by a patient for monitoring cardiovascular signals and detecting possible cardiopathy by means of a multifunctional transducer.

Background of the invention

As known, a variety of types exist of apparatus used in the field of medicine for monitoring heart functionality of risk patients, such as post-infarcted patients, people with various cardiopathies, people that occasionally or regularly carry out operations that risk the heart such as extreme sports, heavy work, etc.

In hospitals heart functionality of patients are usually controlled by the analysis of the electrocardiogram (ECG), which is a graph of the cardiac potential versus time. An electrocardiogram is, in particular, a registration of the electrical activity of the heart whose signals propagate, by electrical conductivity, up to the body surface where they are picked up by suitably arranged electrodes. In particular, possible damages to the cardiac conductive tissue change the electrochemical signals path and the pulse frequency, thus changing also the signals measured on the body surface, i.e. the electrocardiogram morphology. Therefore, by investigating the changes in the shape of the actual electrocardiogram with respect to standard graphs, it is possible to determine many pathologies of the cardiac tissue.

For example, if the examined pathology is a cardiac ischemia, both natural and induced, in particular the so-called "ST" segment of the electrocardiogram is analysed. In fact, a low ST segment with respect to a base line indicates coronary insufficiency.

The electrocardiogram provides, then, data on both the actual pathology and on destructive effects on the heart of past pathologies, and is therefore a very useful tool for preventing a myocardial infarction. Often, cardiopathies that have a short and sudden course are an indication for preventing an evolution, often irreversible, of the pathology. If a coronary insufficiency is diagnosed in advance, an effective therapy can be arranged for preventing a myocardial infarction. An irregular heart beat can warn a doctor about the presence of a pathology that is affecting the conductive tissue of the cardiac impulse.

For detecting such transitory cardiac function abnormalities, usually an electrocardiographic recorder is used, commonly called HOLTER and of minimum encumbrance, capable of picking up and storing the electrocardiogram for very long periods, which can exceed 24 hours. Even if, normally, a simple analysis of an electrocardiogram is not sufficient for readily establishing with high precision the seriousness of a particular pathology, in an advanced stage of an ischemic attack the mechanical damages to the cardiac walls involve a deformation of the ST segment, and this can be seen in an electrocardiogram.

Such a deformation can be exploited as alarm signal for starting a deeper ischemic analysis that can be carried out, for example, with ultrasonic apparatus capable of emitting beams of acoustic waves that are

reflected at the borders of tissues giving rise to response signals or echoes. These signals are then turned into electrical signals that can be treated for displaying the results on a video. This technology allows to determine possible mechanical damages to the heart.

However, the apparatus that use the ultrasonic technology are bulky and require the hospitalization of the patients to be monitored. On the other hand, in case of serious cardiac crisis caused by cardiac ischemia, for example conditions of "akinesia" of the cardiac walls, it is not presently possible to provide to the patient an outpatient instrument for warning readily a doctor.

Summary of the invention

It is a feature of the present invention to provide a non-invasive monitoring device of a patient's heart functionality for readily determining any critical cardiovascular conditions.

It is another feature of the present invention to provide a non-invasive monitoring device of a patient's heart functionality that is wearable and of small encumbrance for being inserted for example in a vest, a jacket, a shirt, etc.

These and other features are accomplished with one exemplary wearable non-invasive monitoring device of a patient's heart functionality comprising:

- means for picking up an electrocardiographic signal;
- means for comparing said electrocardiographic signal with preliminarily recorded data;
- a multifunctional ultrasonic transducer capable of

working both as sender of acoustic waves, suitable for being reflected by the patient's cardiac walls in the form of a response signal, or echo, and as receiver of an impact signal relative to patient's heart functionality;

- means for comparing said impact signal with preliminarily recorded data.

Advantageously, furthermore, means for emitting an alarm signal are provided;

In particular, in standard operative conditions, the means for picking up an electrocardiographic signal detects the relative signals, which are compared to predetermined data by said means for comparing, and the ultrasonic transducer remains switched in a passive receiving condition. If said means for comparing determine the detected electrocardiographic signal as not consistent to the relative recorded data, the multifunctional ultrasonic transducer is switched to a transmission mode and generates a beam of ultrasonic waves. More in detail, the beam of ultrasonic waves is reflected by the examined cardiac region giving rise to a response signal, or echo, which can be detected by the transducer same and which is then compared with predetermined data by said means for comparing, for testing the status of the patient's cardiac walls.

In particular, the ultrasonic transducer allows determining the mechanical changes of the cardiac walls due to transitory occurrences of cardiac ischemia that are critical in case of akinesia of a cardiac wall. More in detail, if the cardiac walls are motionless (akinesia) the ultrasonic transducer receives two successive signals that are identical and this is detected as clear alarm of ongoing crisis.

Advantageously, said multifunctional ultrasonic transducer comprises:

- a support element, or "backing";
- a first and a second electrode;
- a piezoelectric element located between said first and said second electrode suitable to generate a beam of acoustic waves when a voltage is applied at the ends of said electrodes.

Brief description of the drawings

Further characteristics and the advantages of the wearable device for monitoring cardiovascular signals by a multifunctional transducer, according to the invention, will be made clearer with the following description of an exemplary embodiment thereof, exemplifying but not limitative, with reference to the attached drawings, in which like reference characters designate the same or similar parts, throughout the figures of which:

- figure 1 shows a flow-sheet of the operation of a wearable device for monitoring cardiovascular signals by a multifunctional transducer, according to the invention;
- figure 2 shows diagrammatically a cross sectional view of an ultrasonic transducer that can be used in the wearable device for monitoring cardiovascular signals, according to the invention;
- figures 3 to 5 show a top plan view of three possible garments where the device according to the invention can be arranged in order to be worn by a patient.

Description of a preferred exemplary embodiment

With reference to figure 1, a minimum configuration for a wearable device for a non-invasive patient's heart functionality monitoring, according to the present invention, provides a procedure that starts from the

acquisition of an electrocardiographic signal (ECG), for example by a Holter apparatus, block 51. The electrocardiogram is picked up and analysed in real time. More in detail, the graph is compared with a previously recorded standard graph, block 52. If no substantial differences are observed between the actual and the standard, the acquisition of the electrocardiogram is repeated. Alternatively, a procedure is started of checking the real conditions of the patient's cardiac walls through the acquisition of an impact signal, block 53. If, from the analysis of the heart beat impact signal, an abnormality of the patient's cardiovascular functionality is observed, an ultrasonic analysis is started on the cardiac wall in order to find out any occurrences of akinesia of the patient's heart. In this case the nearest emergency assistance will be warned and if necessary the patient is hospitalized.

The acquisition of the impact signal and the possible following ultrasonic analysis on the patient's cardiac wall is effected by an ultrasonic transducer 1 (figure 2). In particular, the ultrasonic transducer 1 is arranged integrally to the acquisition system of the electrocardiogram in a plate located in use at the same level of the patient's thorax 60, whose position is indicated with dotted line 21 (figure 5). It operates in "dual mode", i.e. in standard conditions it works as sensorial element whereas in certain conditions it switches into a spatial emitter of a beam of ultrasonic waves. In the latter case, switching back to the receiving mode, the transducer 1 same detects the echo reflected by the cardiac walls and gives possible data of any cardiopathies, for example an ischemia, for which the involvement of a doctor is necessary.

In the not limitative exemplary embodiment shown in figure 2, the transducer 1 comprises a support element, or "backing" 6, a couple of electrodes 3 and 4 and a piezoelectric element 5 located between them.

In particular, the ultrasonic transducer 1 can comprise a copolymer film 5 of about 100μm thickness, metal coated on one of the two sides using an electrode of gold 3. On the other side of polymer 5, a brass thin sheet 4 can be glued of thickness of about 90μm, having surface larger than the active surface of transducer 1, for example by a layer of bi-component epoxy resin. In particular, the brass thin sheet 4 has both the function of backing for the ultrasonic beam and of electrode as second pole for the voltage. Concerning the electrical contacts a co-axial cable 2 can be used, whereas the contacts can be made with a bi-component conductive glue. One electrode (braiding) of the co-axial cable is connected to brass electrode 4, the other electrode (warm pole) instead is connected to the front gold electrode 3. Finally, the "multilayer structure" above described can be inserted between two Mylar sheets 7a and 7b having function of protection. In particular, this material has impedance similar to that of copolymer 5 that does not create unbalancing with subsequent wave attenuations.

When the ultrasonic transducer 1 operates as sender, the piezoelectric element 5, for example of PVDF, transforms the voltage at the ends of the electrodes 3 and 4 into acoustic waves. When, instead, the transducer 1 operates as receiver it transforms the acoustic echo into electrical signals that are then computed and that can be displayed on a video.

In figures from 3 to 5 some examples are shown of garments 10 in particular, a jacket, a vest and a

waistcoat where plate 11 can be arranged with suitable sensors to provide the wearable device of the invention.

The foregoing description of a specific embodiment will so fully reveal the invention according to the conceptual point of view, so that others, by applying current knowledge, will be able to modify and/or adapt for various applications such an embodiment without further research and without parting from the invention, and it is therefore to be understood that such adaptations and modifications will have to be considered as equivalent to the specific embodiment. The means and the materials to realise the different functions described herein could have a different nature without, for this reason, departing from the field of the invention. It is to be understood that the phraseology or terminology employed herein is for the purpose of description and not of limitation.

CLAIMS

1. Wearable non-invasive monitoring device of the heart functionality **characterised in that** it comprises:

   - means for picking up an electrocardiographic signal;
   - means for comparing said electrocardiographic signal with preliminarily recorded data;
   - a multifunctional ultrasonic transducer capable of working both as sender of acoustic waves, suitable for being reflected by the patient's cardiac walls in the form of a response signal, or echo, and as receiver of a impact signal relative to patient's heart functionality;
   - means for comparing said impact signal with preliminarily recorded data.

2. Device, according to claim 1, wherein the following are also provided:

   - means for emitting an alarm signal.

3. Device, according to claim 1, wherein in standard operative conditions said means for picking up an electrocardiographic signal detect the relative signals that are compared to predetermined data by said means for comparing and said ultrasonic transducer remains switched in a passive receiving condition.

4. Device, according to claim 1, wherein, if during said standard operative conditions said means for comparing verify a not consistent electrocardiographic signal with respect to the relative recorded data, said multifunctional ultrasonic transducer is switched in a mode of transmission of a beam of ultrasonic waves.

5. Device, according to claim 1, wherein said multifunctional ultrasonic transducer comprises:

   - a first and a second thin sheet electrodes connected to respective electric cables;

- a layer of piezoelectric material located between said first and said second electrodes suitable to generate a beam of acoustic waves when a voltage is applied to said electrodes through said cables.

6. Device, according to claim 5, wherein said first and/or second electrodes are metal sheets with function of transducer backing.

Fig. 1

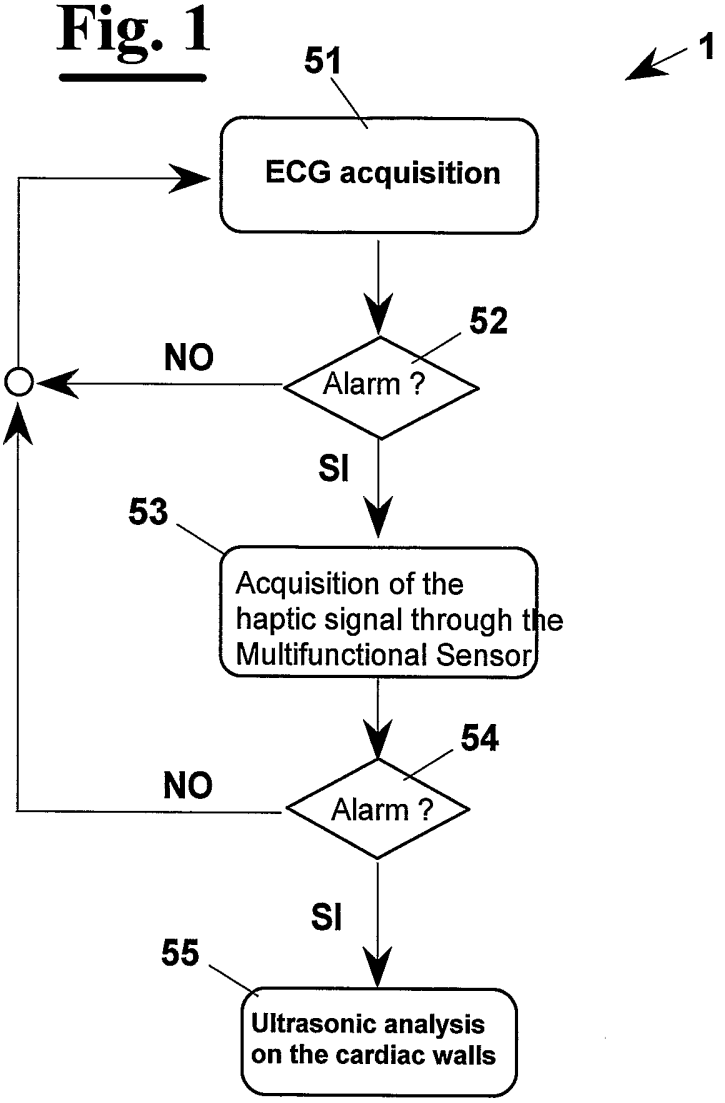

1
51
ECG acquisition
52
NO
Alarm ?
SI
53
Acquisition of the haptic signal through the Multifunctional Sensor
54
NO
Alarm ?
SI
55
Ultrasonic analysis on the cardiac walls

Fig. 2

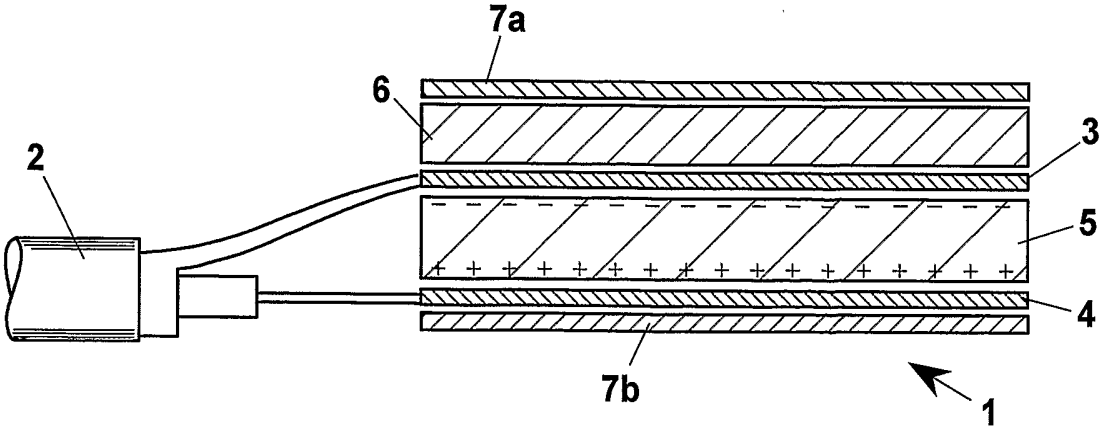

7a
6
3
2
5
4
7b
1

Fig. 3

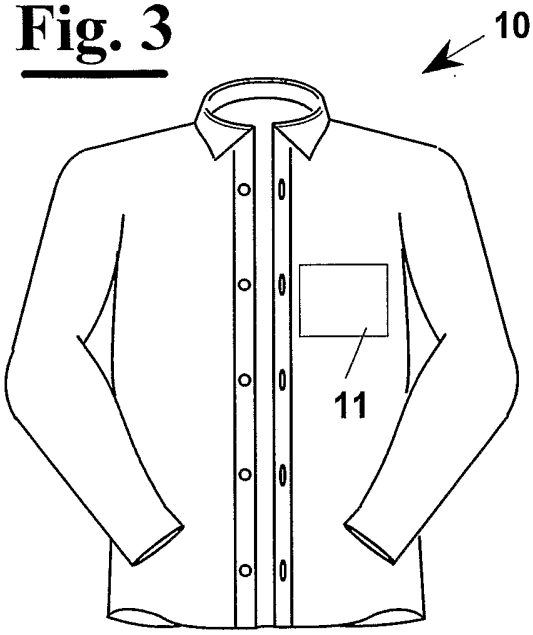


Fig. 4

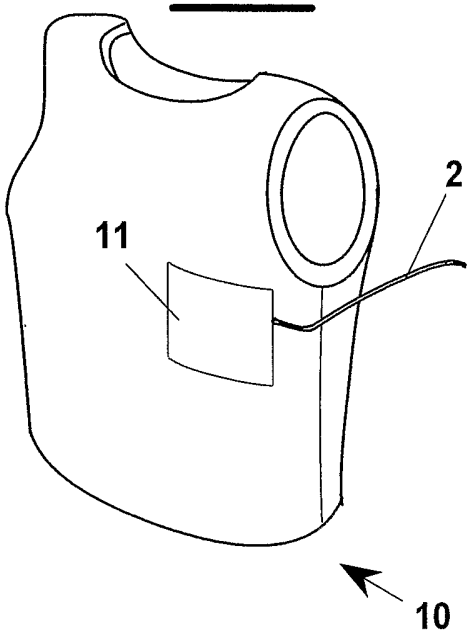
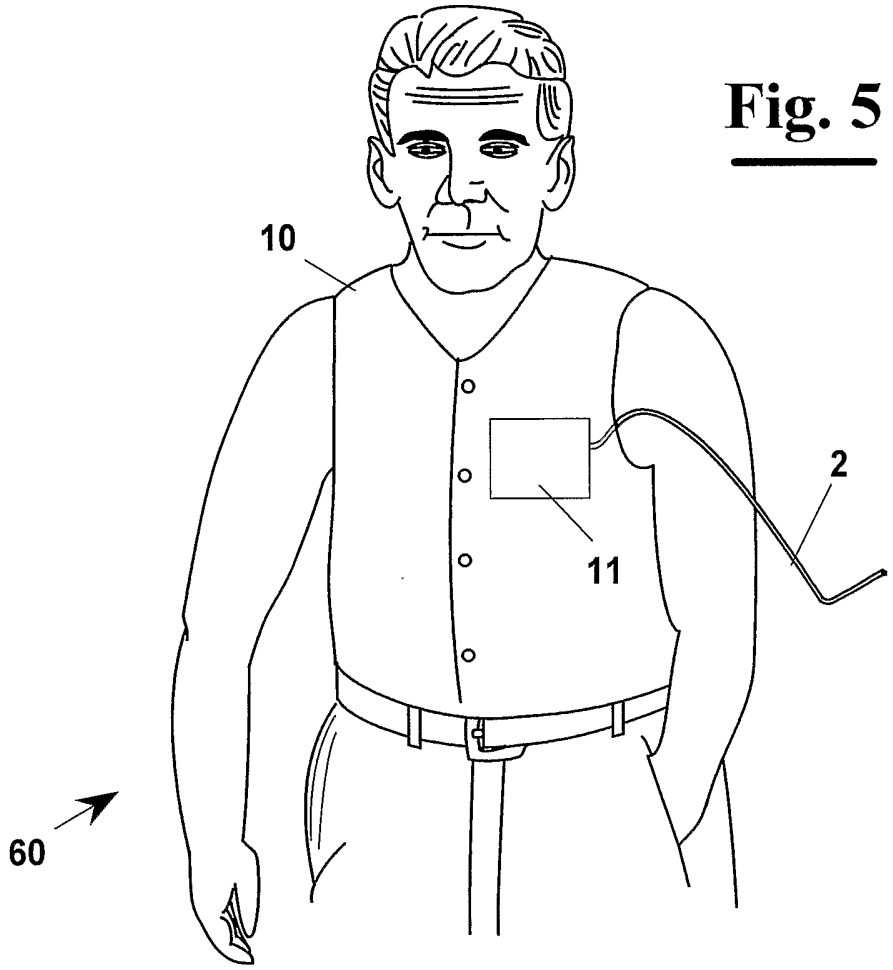


Fig. 5



INTERNATIONAL SEARCH REPORT

Internal Application No
PCT/IB2004/002360

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B5/0468 A61B8/08

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)
IPC 7 A61B G06F

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

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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Y	US 2002/156379 A1 (ANGELSEN BJORN A J ET AL) 24 October 2002 (2002-10-24) paragraph '0067!; figure 1 paragraph '0089!; figure 4 paragraph '0094! - paragraph '0111!; figure 5	5,6

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

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Date of the actual completion of the international search	Date of mailing of the international search report
8 December 2004	17/12/2004

Name and mailing address of the ISA	Authorized officer
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INTERNATIONAL SEARCH REPORT

Intern[redacted]al Application No
PCT/IB2004/002360

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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Information on patent family members

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