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Declarations under Rule 4.17:

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

Published:

— *with international search report (Art. 21(3))*

(54) Title: INTEGRATED PATIENT MONITORING DEVICE

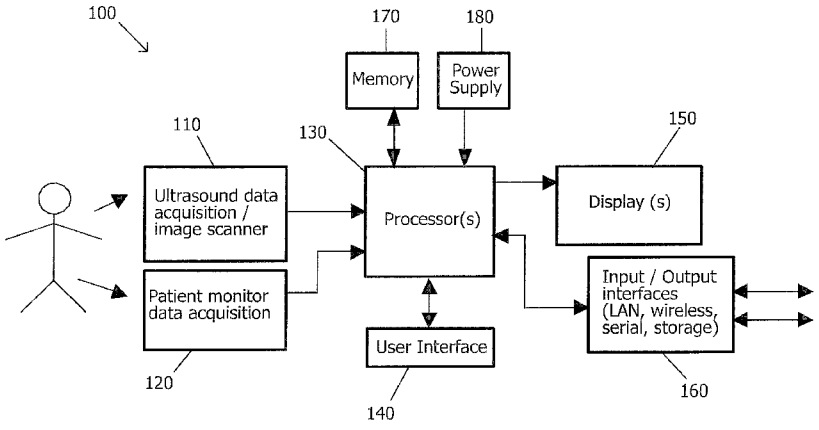

FIG. 2

(57) Abstract: A patient monitoring system for monitoring, diagnosing and treating a patient that receives data from multiple sources. The sources including an ultrasound transducer that acquires ultrasound data of a patient. The sources further including a patient monitor including a sensor acquiring patient parameter data of the patient. The system further includes a processor receiving and processing the ultrasound data and the patient parameter data.

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Integrated patient monitoring device

BACKGROUND OF THE INVENTION

Modern medicine has produced many treatments for various patient ailments. However, in order to provide a patient with the best possible medical care for the particular ailment the patient is suffering from, the treating medical professional (*e.g.*, doctor, nurse, nurse practitioner, etc.) requires data concerning various parameters from the patient. An oral recitation by the patient themselves is not always the best source of data for reasons such as, the patient is unconscious, the patient cannot express the symptoms, the patient cannot know some of the data, etc. Thus, this data needs to be collected in some other manner from the patient. Accordingly, a variety of medical devices have been developed to allow medical professionals to collect data from patients such as stethoscopes, thermometers, sphygmomanometers, etc.

SUMMARY OF THE INVENTION

A system for monitoring a patient. The system having an ultrasound transducer to acquire ultrasound data of the patient. The system also having a patient monitor including a sensor to acquire patient parameter data of the patient. The system also has a processor to receive and process the ultrasound data and the patient parameter data.

A method for monitoring, diagnosing or treating a patient. The method includes acquiring ultrasound data via an ultrasound transducer and acquiring patient parameter data via a sensor of a patient monitor, wherein the ultrasound transducer and the patient monitor are portions of a single physical device. The method further includes processing the acquired ultrasound data and the acquired patient parameter data.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 shows an exemplary embodiment of a patient monitor including an ultrasound transducer.

Fig. 2 shows a schematic block diagram of the exemplary embodiment of the patient monitor including the ultrasound transducer of Fig. 1.

Fig. 3 shows a schematic block diagram of an exemplary embodiment of a patient monitor including an ultrasound transducer and a defibrillator.

Fig. 4 shows a flow diagram of an exemplary method for collecting data using the exemplary devices of Figs. 1-3.

DETAILED DESCRIPTION

The following is a description of exemplary embodiments and the related appended drawings, wherein like elements are provided with the same reference numerals. The exemplary embodiments are related to a system and method for integrating a plurality of medical devices. In the described exemplary embodiments, the system and method relate to the integration of a patient monitor and an ultrasound imaging scanner and/or a defibrillator.

Patient monitors are a class of devices that may be used for general patient monitoring. For example, patient monitors may be used to measure patient parameters such as a blood pressure (non-invasive, invasive), an ECG (electrocardiogram), a (SPO_2) saturation of peripheral oxygen, etc. Those skilled in the art will understand that the above listed patient parameters are only exemplary and that exemplary embodiments of patient monitors may measure other or additional patient parameters such as CO2 measurements, arrhythmia or other cardiac parameters, temperature, etc. It should also be understood that the particular patient parameter(s) that are measured by the patient monitor may vary depending on the implementation of the patient monitor. For example, a patient monitor that is used in a cardiac care unit may measure different patient parameters from a patient monitor implemented in an emergency room or an oncology unit, etc.

The patient parameters measured by the patient monitor may provide information to the medical professional, but may not be enough information to identify, for example, worsening conditions or a developing condition. Additional patient data may be required to more fully diagnose and/or treat the patient. Additional monitoring devices may need to be used to obtain this additional data or provide treatment. For example, it may be beneficial to also use an ultrasound image scanner for advanced monitoring of patients with severe conditions such that deteriorating conditions may be prevented.

For example, in a case of a potential cardiac condition, a cardiac ultrasound may be used to collect additional information from the patient. A cardiac ultrasound, also known as an echocardiogram, is a sonography of the heart that uses standard ultrasound techniques to image the cardiovascular system. An echocardiogram may also be used to assess the velocity of blood and tissue at any point using pulsed or continuous wave Doppler

ultrasound, thereby allowing assessment of cardiac valve areas and function, any abnormal communications between the left and the right side of the heart, any leaking of blood through the valves, and calculation of the cardiac output.

In another example, a vascular ultrasound is able to show the structure and the movement of the body's internal organs as well as blood flowing through the blood vessels. Thus, a vascular ultrasound may be used to evaluate the circulatory system by monitoring blood flow to organs and tissues, identifying abnormalities, and locating and identifying blockages. In a further example, the patient may be a pregnant woman and an ultrasound may be used to monitor the health of the baby in addition to monitoring the mother.

As can be seen from the above examples, situations may arise in which it would be advantageous to utilize a patient monitor/defibrillator and an ultrasound imaging scanner. However, this may not always be possible since there is limited space in treatment areas such as pre-hospital settings (*e.g.*, ambulances, other transport vehicles), hospital rooms, there is a finite number of power connections available and other reasons. Thus, it is very difficult to have all the equipment needed for diagnosis and treatment in the available treatment area. In the exemplary embodiments, it is recognized that patient monitor/defibrillator devices and ultrasound imaging scanners share several of the same components, and therefore it is more cost-effective and convenient for a user to acquire an ultrasound image and patient parameter data using a single system that shares components such as a processor, a display, a user interface and power supplies.

As the exemplary embodiments are described, it is noted that although the exemplary embodiments may be specifically described with reference to the evaluation of cardiac conditions, the systems and methods of the present invention may be used to monitor and analyze a variety of patient conditions in which a patient monitor and a ultrasound imaging scanner would be useful.

Figs. 1-2 show a system 100, according to an exemplary embodiment, comprising an ultrasound transducer 110 and a patient monitor 120. In the view of Fig. 1, the ultrasound transducer 110 is connected via a cable to the patient monitor 120. The schematic block diagram of Fig. 2 shows the components of the system 100 in more detail. In Fig. 2, the ultrasound transducer 110 and the patent monitor 120 are shown in addition to a processor 130, a memory 170, a power supply 180 and a display 150. The system 100 may further comprise a shared user interface 140 and/or an input/output (I/O) interface 160. Referring back to Fig. 1, the other components described above (*e.g.*, the processor 130, the memory 170, the display 150, etc.) may be included fully or partially within the housing of the patient

monitor 120. It is also noted that throughout the description, the patient monitor 120 may be used to refer to either or both of the physical device (*e.g.*, the housing illustrated in Fig. 1 that may include various components) and the functionality being performed by the patient monitor (*e.g.*, if the patient monitor is measuring blood pressure, the reference is to those components of the patient monitor required to perform the blood pressure measurement).

Referring back to Fig. 2, the ultrasound transducer 110 and the patient monitor 120 may be coupled to the processor 130, which receives and processes data acquired by the ultrasound transducer 110 and the patient monitor 120 to be displayed on the display 150 and/or stored in the memory 170. A user may control aspects of the system 100 via the user interface 140. The user may also transmit and/or acquire data through the I/O interface 160. The power supply 180 provides power for the system 100. The power supply may include a connection to an external power source (*e.g.*, a plug that plugs into a wall outlet) and may also include a battery or other power storage mechanism as a back-up power supply.

The ultrasound transducer 110 is capable of sending out high frequency sound waves and listening for a return echo in order to collect data from the patient. Throughout this description, this data may be referred to as "ultrasound data" and it should be understood that this term encompasses any type of data that may be collected using the ultrasound transducer 110. For example, the ultrasound transducer 110 may collect image data to provide an image of a particular body part. However, the data may also include non-image data such as a blood flow rate that may be collected by the ultrasound transducer. Accordingly, the ultrasound data is not limited to image data.

The ultrasound transducer 110 may be housed in a probe, which contains one or more ultrasound transducers 110. It should also be noted that the ultrasound transducer 110 may also include other components that may be used, for example, for implementing gain, filtering, beamforming, detection and transmit functions of the ultrasound function. These additional components (*e.g.*, circuitry) may be housed within the ultrasound transducer probe or they may be included within the housing of the patient monitor 120. In the case where the component(s) are included in the ultrasound transducer probe, the probe may have a simple interface (*e.g.*, USB) to the host processor 130.

In another exemplary embodiment, the ultrasound transducer may be operated in a hands free manner. For example, instead of a user holding the ultrasound transducer 110 probe on the portion of the body from which ultrasound data is to be collected, the ultrasound transducer 110 probe is attached to the patient (*e.g.*, via an adhesive pad or other attachment mechanism).

The patient monitor 120 may be comprised of one or more sensors for acquiring patient parameter data, such as a blood pressure, an ECG, a SPO2, etc. Those skilled in the art will understand that the various sensors may also include additional support circuitry or components to perform their function. This additional circuitry/components may be housed with the sensor or in the main housing of the patient monitor 120.

The data acquired by the ultrasound transducer 110 and the patient monitor 120 are received and processed by the processor 130 to be displayed on the display 150 and/or stored in the memory 170. It will be understood by those skilled in the art that the memory 170 may also store software (such as an operating system and/or application programs) that is executed by the processor 130 to operate the system 100 properly and to process the data collected by the ultrasound transducer 110 and the patient monitor 120.

The ultrasound transducer 110 and the patient monitor 120 may be controlled by the shared user interface 140. The user may indicate whether to power on or off the ultrasound transducer 110 and/or the patient monitor 120 so that they may be activated separately such that the ultrasound transducer 110 may acquire data while the patient monitor 120 is inactive or, in the alternative, the patient monitor 120 may acquire data while the ultrasound transducer 110 is inactive. It will be understood by those skilled in the art, however, that both the ultrasound transducer 110 and the patient monitor 120 may acquire data simultaneously. As the ultrasound transducer 110 and/or the patient monitor 120 acquires ultrasound data and/or patient parameter data, respectively, the processor 130 retrieves and processes the data to be displayed on the display 150. The user interface 140 may also be used to indicate whether the data should be displayed separately or simultaneously. A simultaneous display may allow a user to conduct an analysis of the patient's condition using all relevant and available data.

The user interface 140 may also be used to print or store the processed ultrasound data and patient parameter data. Data may be printed to be stored in a patient file. Stored data may be retrieved at a later time for further analysis. Thus, a printer and/or an external memory (*e.g.*, a flash memory card) may be coupled to the system 100 via the I/O interface 160. The I/O interface 160 may also support connectivity to LAN, wireless networks and wired connections such that data may be transmitted to and from other devices as well as clinical information systems.

As described above, patient monitors and ultrasound imaging scanners share several of the same components such as a processor, a memory, a user interface, a power supply and a display. Thus, the integration of the ultrasound functionality with the patient

monitoring functionality allows these multiple functionalities to be performed by the same physical device, thereby saving space in the treatment area, reducing power consumption of multiple devices, relieving power access constraints, savings costs associated with multiple devices, etc. In addition, it relieves the medical professional from having to learn how to operate different devices having different user interfaces. Moreover, it also allows the data to be easily shared between the different functionalities. For example, if an ultrasound is being performed on the heart, it may be useful to know a heart rate or a blood pressure at the time the ultrasound is being performed so that the processing of the ultrasound data may take these factors into account. Since the processor 130 of the system 100 has access to all this data, the data from the patient monitor 120 may be used in the ultrasound image/data processing algorithm, or vice versa.

In one exemplary embodiment, the ultrasound transducer 110 may be coupled to the patient monitor 120 by plugging in the ultrasound transducer 110 into a port of the I/O interface 160. In another exemplary embodiment, the ultrasound transducer may be permanently or semi-permanently wired into the housing. The processor 130 may be adapted to receive and process both ultrasound data and patient parameter data for displaying on the display 150. As described above, the memory 170 may store software that is executed by the processor 130 to operate the system 100. The user interface 140 may also be adapted to collect and process both types of data. In addition, the display 150 may be adapted to simultaneously display the various data collected and processed by the system 100 so that a user may see the different types of data.

In a further exemplary embodiment, as shown in Fig. 3, a system 200 may also comprise the components described with reference to system 100 of Fig. 2, *e.g.*, an ultrasound transducer 210, a patient monitor 220, a processor 230, a user interface 240, a display 250, an I/O interface 260, a memory 270 and a power supply 280. However, the system 200 further includes a defibrillator 290, which is used to deliver therapeutic doses of electrical energy to the heart. Defibrillation is the definitive treatment for life-threatening cardiac arrhythmias, ventricular fibrillation and pulseless ventricular tachycardia. Thus, defibrillation may be a required treatment for cardiac conditions that are diagnosed using the data acquired from the ultrasound transducer 210 and the patient monitor 220. It should be noted that in this description, the term "defibrillation" encompasses any delivery of therapeutic energy to the heart. Thus, the term "defibrillator" refers to any type of device that is capable of delivering such therapeutic energy including, but not limited to, a traditional cardiac defibrillator, a pacemaker, etc.

A defibrillator shares many of the same components as an ultrasound imaging scanner and a patient monitor such as, for example, a processor, a user interface and a power supply. Thus, it will be understood by those of skill in the art that the defibrillator 290 may be integrated into the system 200 by connecting paddles or pads of the defibrillator 290 to the processor 230. The defibrillator 290 may be used manually or automatically by controlling activation and/or activation settings via the user interface 240. The user interface 240 may also be used to indicate what charge should be delivered to the patient via the paddles of the defibrillator 290. The charge being delivered, and any other relevant information, may be displayed on the display 250.

Fig. 4 shows an exemplary method 300 that may be performed by either or both of the systems 100 and 200. In this description, the reference signs of system 100 will be used to refer to exemplary components that are used to perform some or a portion of the described steps of the method. However, those skilled in the art will understand that the corresponding components of system 200 or other types of components may also be used to perform the described steps. In step 310, the ultrasound transducer 110 and the patient monitor 120 acquire ultrasound data and patient parameter data, respectively. The ultrasound data and the patient parameter data may be acquired separately or simultaneously. Additionally, the patient parameter data and ultrasound data may be acquired over a period of time or acquired only when activated. The activation may be controlled via the user interface 140. As the data, is being acquired, the data is received by the processor 130, in step 320. The received data is then processed such that the data may be displayed on the display 150 and/or stored in memory 170.

In step 330, the processed ultrasound data and the processed patient parameter data may be displayed separately or simultaneously, as desired by the user. These preferences may be indicated by the user via the user interface 140 and are communicated to the processor 130.

In step 340, the processor 130 may receive additional user input via the user interface 140. For example, the user may indicate whether to print the processed data from the display 150 or to store the processed data to the memory 170 such that it may be retrieved at a later time for further analysis. The printer and the external memory may be connected to the system 100 via the I/O interface 160. The user input may also indicate whether to transfer or share the processed data with other devices that may also be connected to the system 100 via the I/O interface 160.

In step 350, the processed data may be analyzed by reviewing the displayed data on the display 150, reviewing the printed data or retrieving previously stored data. In a further embodiment, depending on the diagnosis or analysis of the patient condition, the defibrillator 290 may be used to deliver treatment to the patient.

It will be apparent to those skilled in the art that various modifications and variations can be made in the structure and methodology of the present invention, without departing from the spirit and scope of the invention. Thus, it is intended that the present invention cover the modifications and the variations of this invention provided that they come within the scope of the appended claims and their equivalents.

It is also noted that the claims may include reference signs/numerals in accordance with PCT Rule 6.2(b). However, the present claims should not be considered to be limited to the exemplary embodiments corresponding to the reference signs/numerals.

CLAIMS:

1. A system, comprising:

an ultrasound transducer (110) acquiring ultrasound data of a patient;

a patient monitor (120) including a sensor acquiring patient parameter data of the patient; and

a processor (130) receiving and processing the ultrasound data and the patient parameter data.

2. The system of claim 1, further comprising:

a display (150) simultaneously displaying the processed ultrasound data and the processed patient parameter data.

3. The system of claim 1, further comprising:

a defibrillator (290) delivering electrical therapy to the patient, wherein one of a type and an amount of electrical therapy is controlled by the processor (130) based on at least one of the ultrasound data and the patient parameter data.

4. The system of claim 1, further comprising:

a user interface (140) adapted to receive a user input controlling at least one of i) an acquisition of the ultrasound data and the patient parameter data, and ii) a transmission of the ultrasound data and the patient parameter data.

5. The system of claim 1, further comprising:

an input/output interface (160) connectable to one of a device and a communication network for transmitting the processed ultrasound data and the processed patient parameter data.

6. The system of claim 1, wherein the processor (130) uses the patient parameter data in processing the ultrasound data.

7. The system of claim 1, wherein the processor (130) uses the ultrasound data in processing the patient parameter data.

8. The system of claim 1, wherein the ultrasound transducer is attached to the patient to acquire the ultrasound data.

9. A method, comprising:
acquiring ultrasound data via an ultrasound transducer (110);
acquiring patient parameter data via a sensor of a patient monitor (120); and
processing the acquired ultrasound data and the acquired patient parameter data, wherein the ultrasound transducer (110) and the patient monitor (120) are portions of a single physical device.

10. The method of claim 9, further comprising:
simultaneously displaying the processed ultrasound data and processed patient parameter data on a display (150) of the physical device.

11. The method of claim 9, further comprising:
receiving a user input via a user interface (140) of the physical device, the user input controlling at least one of i) an acquisition of the ultrasound data and the patient parameter data, and ii) a transmission of the ultrasound data and the patient parameter data.

12. The method of claim 9, further comprising:
delivering treatment to a patient based on one of the processed ultrasound data and the processed patient parameter data, wherein the treatment includes delivering an electrical pulse via a defibrillator (290).

13. The method of claim 9, wherein the processing of the acquired ultrasound data is at least partially based on the patient parameter data.

14. The method of claim 9, wherein the processing of the acquired patient parameter data is at least partially based on the ultrasound data.

15. A system, comprising:

means (110) for acquiring ultrasound data;

means (120) for acquiring patient parameter data;

means (130) for processing the acquired ultrasound data and the acquired patient parameter data; and

means (290) for delivering therapeutic energy to a patient.

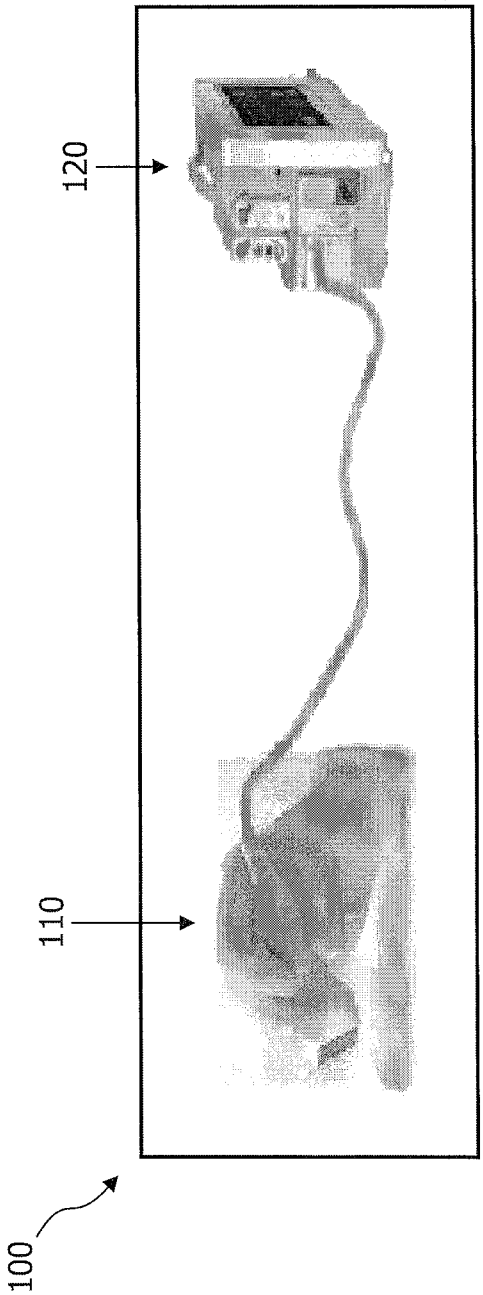

FIG. 1

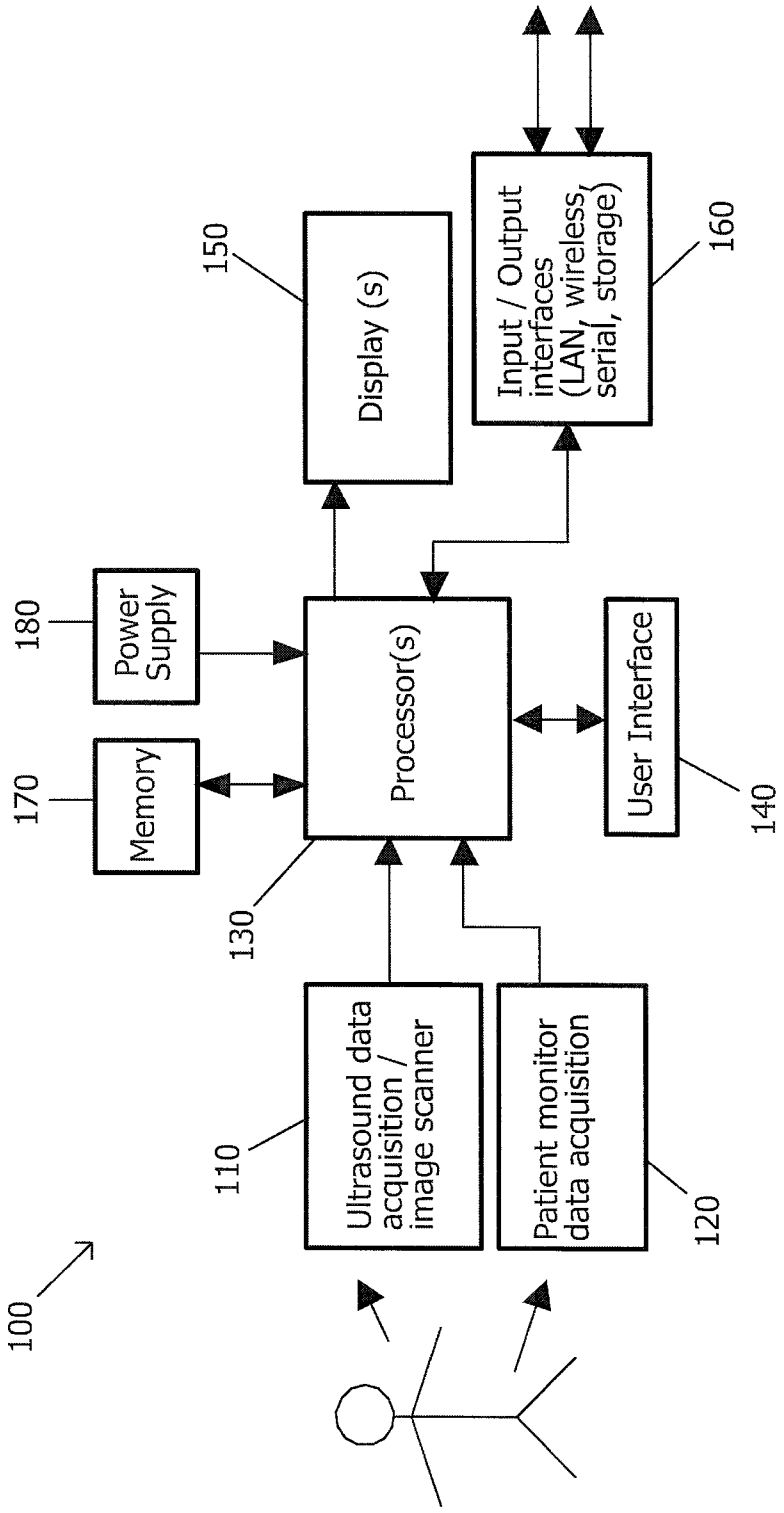
100
Ultrasound data acquisition / image scanner
110
Patient monitor data acquisition
120
130
Processor(s)
User Interface
140
Memory
170
Power Supply
180
Display (s)
150
Input / Output interfaces (LAN, wireless, serial, storage)
160

FIG. 2

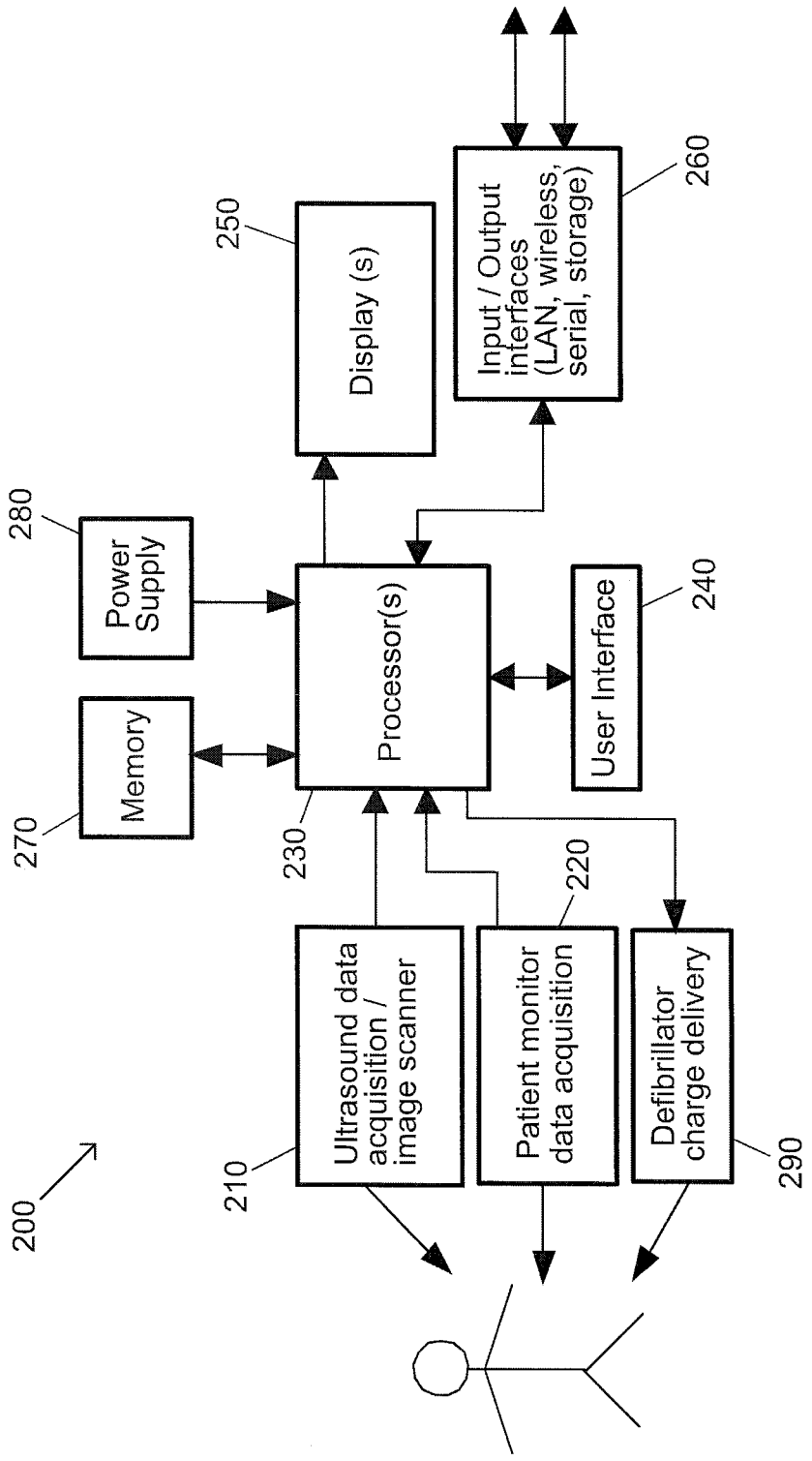
200
210
Ultrasound data acquisition / image scanner
220
Patient monitor data acquisition
290
Defibrillator charge delivery
230
Processor(s)
240
User Interface
270
Memory
280
Power Supply
250
Display (s)
260
Input / Output interfaces (LAN, wireless, serial, storage)

FIG. 3

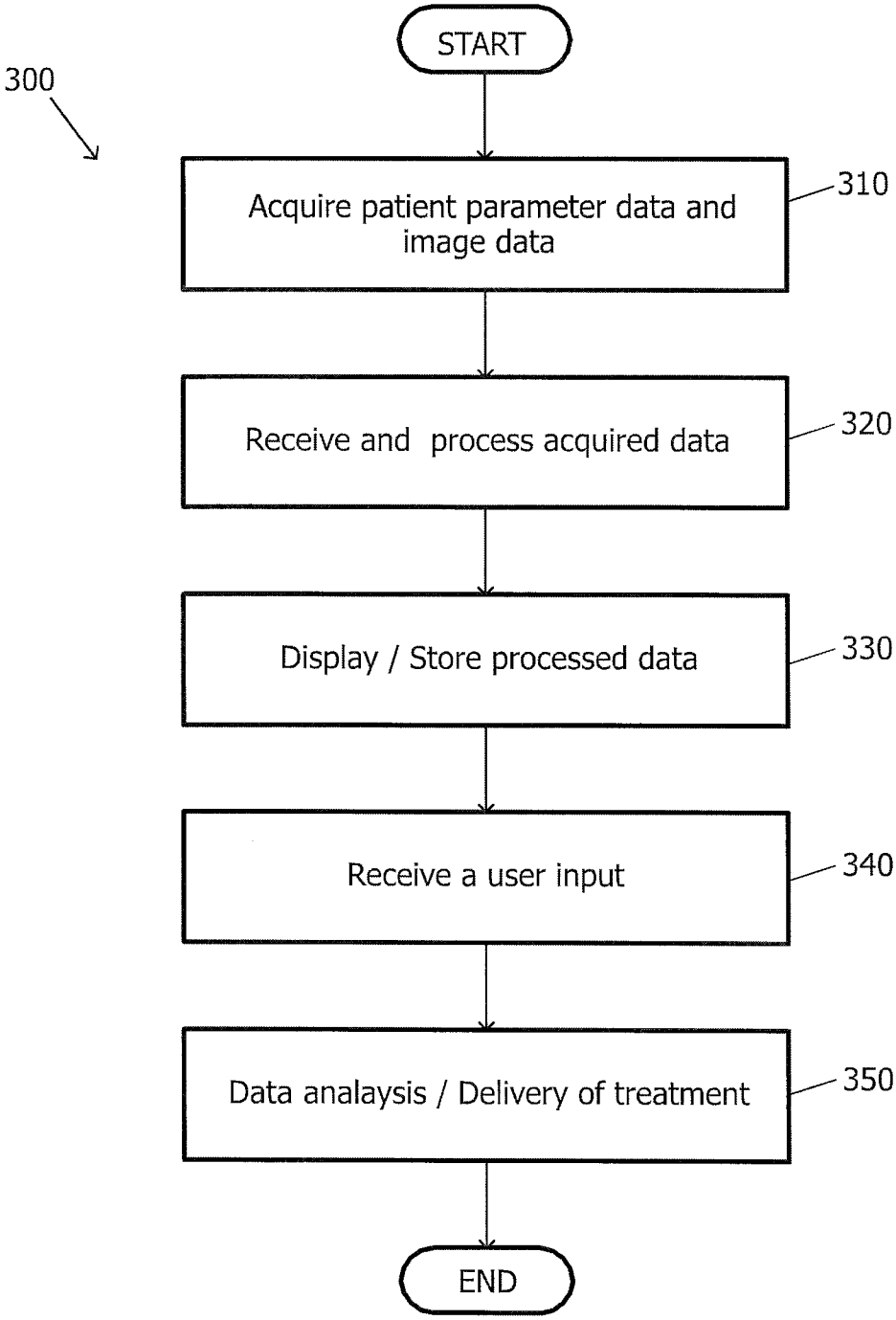
300
START
Acquire patient parameter data and image data
310
Receive and process acquired data
320
Display / Store processed data
330
Receive a user input
340
Data analaysis / Delivery of treatment
350
END

FIG. 4

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2009/051846

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B8/00 A61N1/39

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)
A61B A61N

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.
X	US 2007/038256 A1 (MASCHKE MICHAEL [DE]) 15 February 2007 (2007-02-15) the whole document	1-8,15
X	US 2005/043763 A1 (MARCOVECCHIO ALAN F [US] ET AL) 24 February 2005 (2005-02-24) paragraph [0048] claim 1 figure 1	1,3,6-8, 15
X	US 2002/173725 A1 (ROCK JOSEPH E [US] ET AL) 21 November 2002 (2002-11-21) abstract figures 1,3,7	1,3,6-8, 15

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"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)

"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

"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

"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

"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.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
10 August 2009	19/08/2009

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Willig, Hendrik

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2009/051846

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 9-14
because they relate to subject matter not required to be searched by this Authority, namely:

see FURTHER INFORMATION sheet PCT/ISA/210

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers allsearchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search reportcovers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 9-14

The method of claims 9-14 comprises the step of "delivering treatment to a patient (...), wherein the treatment includes delivering an electrical pulse via a defibrillator" (see claim 12). Such a step is clearly performed for therapeutical purposes. Thus, by means of this step the method of claims 9-14 as a whole is considered to be a method for treatment of the human or animal body by therapy according to Rule 39.1(iv) PCT.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/IB2009/051846

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