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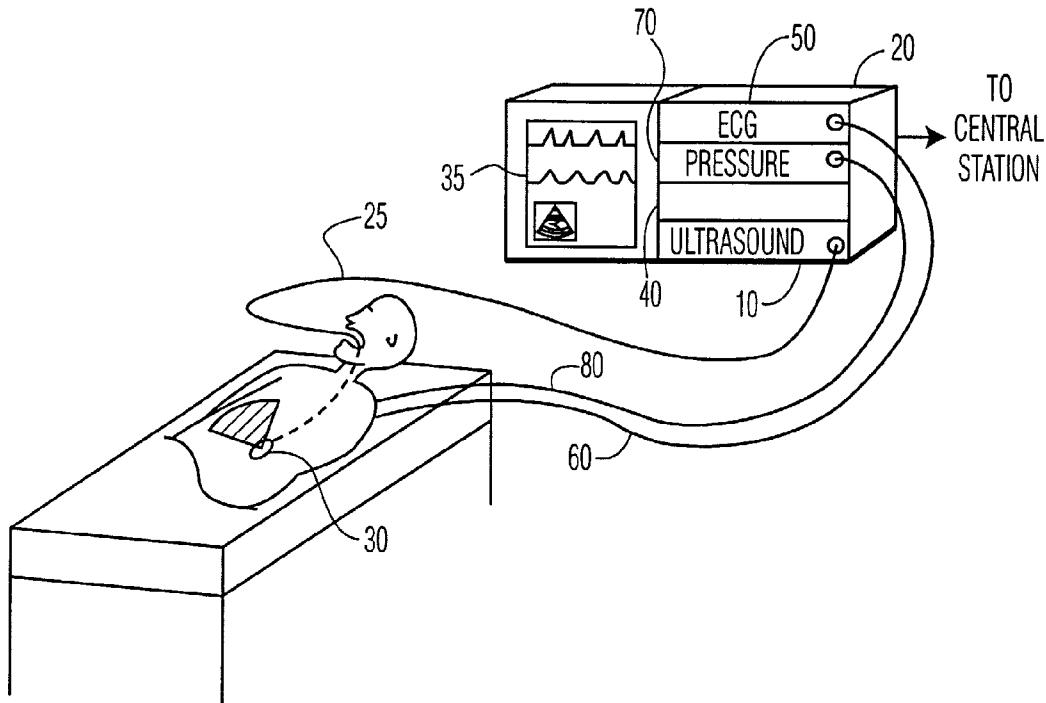
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(54) Title: ULTRASOUND IMAGING ENHANCEMENT TO CLINICAL PATIENT MONITORING FUNCTIONS



WO 03/071951 A1

(57) Abstract: An apparatus includes an ultrasound imaging unit integrated into a patient monitoring system continuously generating ultrasound images from a patient and continuously extracting therefrom diagnostic data.

Ultrasound imaging enhancement to clinical patient monitoring functions

Conventional ultrasound imaging systems used in a clinical setting are presently operated as standalone instruments, typically dedicated to diagnostic image acquisition. In this mode of operation, the ultrasound imaging system is normally used for a short period of time to diagnose a patient. The ultrasound imaging system is also a focused 5 diagnostic system monitoring a particular pathology. An exception to this usage is the use of the transesophageal echocardiogram (TEE) probe in operating room environments for monitoring of cardiac activity during the duration of surgical procedures under active observation by clinical observers. TEE is a test that allows a cardiologist to view images of the internal structures of the heart and the heart's major vessel by inserting an ultrasound 10 probe down the patient's throat or nose. For example, the patient is evaluated for atrial thrombi using the TEE probe.

However, although the TEE test may be four to six hours in duration, the heart is not monitored during the entire duration of the TEE test. Rather, intermittent image snapshots are obtained of the heart and the images are compared, for instance, image 15 snapshots of the heart at pre-surgery are compared to images of the heart at post-surgery. Although, the conventional ultrasound imaging systems may be connected to a hospital's information network, the information network is used primarily for archiving the images and not for doing any diagnostic work or patient management. Further, size and complexity of present ultrasound imaging systems preclude their present use for long term patient 20 monitoring applications.

Modern ultrasound imaging system design is moving towards systems of radically reduced size and complexity. Additionally, increased sophistication of control algorithms in ultrasound imaging systems is rendering the ultrasound imaging systems far more capable of self-adaptation to the imagining environment presented by individual 25 subjects. Further, advancements in the art of information extraction from the ultrasound images allow for improved automatic determination of physiological functionally from the ultrasound image data.

Thus, it is necessary to develop an ultrasound imaging enhancement unit integrated into a patient monitoring system to allow physicians to continuously monitoring

physiological functions of a patient from images generated from the ultrasound imaging unit. Rather than limiting the user of the ultrasound imaging unit to diagnostic situations in an emergency room, the ultrasound imaging unit would allow monitoring of non-acute conditions of a patient, such as in intensive-care recovery situations.

5 In an exemplary embodiment, the present invention provides for an apparatus, including a patient monitoring system; and an ultrasound imaging unit integrated into the patient monitoring system continuously generating ultrasound images from a patient and continuously extracting therefrom diagnostic data.

The present invention also provides an apparatus including an apparatus,
10 including a patient monitoring system; and a compact standalone ultrasound imaging unit connected to the patient monitoring system continuously collecting ultrasound images from a patient and processing the ultrasound images to continuously extract therefrom diagnostic data.

The present invention is also achieved by a method including: integrating an
15 ultrasound imaging unit to a patient monitoring system; connecting the ultrasound imaging unit to a patient; continuously collecting ultrasound imaging data from the patient; processing the ultrasound imaging data to generate therefrom diagnostic data; continuously transmitting the diagnostic data using a communication channel to a person or to a remote diagnostic system at another location; and analyzing the diagnostic data and determining therefrom a
20 medical treatment for the patient.

These together with other objects and advantages, which will be subsequently apparent, reside in the details of construction and operation as more fully hereinafter described and claimed, reference being had to the accompanying drawings forming a part hereof, wherein like numerals refer to like parts throughout.

25

Advantages of the invention will become apparent and more readily appreciated for the following description of the preferred embodiments, taken in conjunction with the accompanying drawings of which:

30 Fig. 1 is a schematic diagram of an embodiment of a system including an ultrasound imaging unit as a plug-in module in accordance with the present invention; and

Fig. 2 is a schematic diagram of an embodiment of a standalone ultrasound imaging unit in accordance with the present invention;

Fig. 3A is a display unit showing a split screen display;

Fig. 3B is a display unit showing a “window-in-window” display; and

Fig. 4 is a flow chart illustrating a method embodiment of the present invention.

5

Reference will be now made in detail to the present exemplary embodiments of the present invention, examples of which are illustrated in the accompanying drawings, wherein like reference numerals refer to the like elements throughout.

Patient monitoring functions are routinely performed on a variety of patients in
10 many different settings of clinical usage, for instance intensive care units, surgical recovery units, individual patient monitoring, etc. Parameters obtained from the patient monitoring functions typically include cardiac functions (i.e., EKG, blood pressure, etc.), temperature, respiration, fetal activity, etc. These parameters are taken in a continuous period of time. In contrast, an ultrasound imaging exam for diagnostic image acquisition is typically conducted
15 at sporadic times. Nevertheless, ultrasound imaging offers a potentially valuable adjunct to the parameters measured during patient monitoring applications, which require continuous periods of monitoring. The parameters that may be extracted from an ultrasound image, such as stroke volume would be useful when monitoring the cardiac condition in the patient.

For instance, in a recovery situation if medication is provided to the patient to
20 correct for wall motion abnormalities in the heart, it is necessary to determine if the medication was effective. Ultrasound imaging may be used to monitor whether the medication is effective in the patient. However, determining whether the medication was effective requires that the heart be monitored for a continuous period of time. Thus, an ultrasound imaging enhancement unit in accordance with the present invention, would
25 execute an ultrasound imaging exam for a continuous period of time, necessary to monitor the effectiveness of medication.

A variety of algorithms could be applied to the ultrasound imaging unit as
applied to patient monitoring applications. Such applications enable much more autonomous
operation of the ultrasound imaging unit than conventional diagnostic imaging situations,
30 which require a sonographer to be present full time with the patient.

The ultrasound imaging unit may implement a conventional automatic gain control to optimize the image gain, contrast, etc. The automatic gain control would be useful in initial setup of the ultrasound imaging unit to acquire an ultrasound image with minimal

manual intervention, to maintain the image quality overtime, and to compensate for patient motion.

Conventional algorithms that may be modified and implemented into the ultrasound imaging unit to continuously extract from the ultrasound image patient monitoring parameters are, for instance, an automatic boundary extraction algorithm and regional wall motion algorithm. The automatic boundary extraction algorithm delineates boundaries of cardiac chambers, allowing derivation a several clinically useful measurements for cardiac monitoring applications. Conventional integrated backscatter methods could be employed for such boundary recognition. Further, kinesis measurements of tissue motion may be employed in the ultrasound imaging unit to continuously obtain contractility measurements, utilizing Doppler techniques, or others. As previously set forth, current ultrasound monitoring systems execute the algorithms in a non-continuous manner. The ultrasound imaging unit of the present invention modifies these algorithms by executing the algorithms in a continuous manner. Accordingly, the present invention provides for an ultrasound imaging unit allowing a physician to continuously extract from ultrasound images physiological data from a patient. This data, collected continuously over a period of hours or days, would allow generation of long-term trend analysis of physiological functions. Such trend data could be correlated against interventional measures to provide feedback information on the intervention's efficacy. Such ultrasound based feedback is very difficult to obtain from the present intermittent imaging methodologies.

In current ultrasound systems, once the user connects the ultrasound system to the patient or a TEE probe is inserted into the patient, the user places cursors or markers on the image of the heart to define what specific region of the heart the algorithm should be confined to analyze. Once the user determines the particular region of the heart that must be monitored, the user then selects a particular algorithm to be executed. During execution, the algorithm extracts required information and outputs a numeric number or a short-term waveform of the response of the heart versus time on a heartbeat by heart beat basis.

In contrast, the ultrasound imaging unit of the present invention would require less user intervention and less user sophistication. Specifically, once the user connects the ultrasound imaging unit to the patient or the TEE probe is inserted into the patient, the ultrasound imaging unit could automatically analyze and determine the region of the heart that needs to be monitored. In a display unit, the user would be able to see the window or region determined by the algorithm in the ultrasound imaging unit that requires attention. The ultrasound imaging unit may incorporate alarms indicating to the user whether the patient's

cardiac functions, such as stroke volume, contractility, etc. have exceeded a predetermined threshold. Accordingly, the ultrasound imaging unit would continuously acquire patient monitoring information and present the information as trend data rather than instantaneous data.

5 The ultrasound imaging unit may be connected to a hospital network for remote monitoring. The ultrasound imaging unit may include a communication channel to download to the hospital network patient monitoring information. Thus, control of the ultrasound imaging unit may be autonomous, contained as "smart" control algorithms in the ultrasound imaging unit, or remotely controlled from a central station in the hospital. Further,
10 the ultrasound imaging unit of the present invention may provide a remote override capability where if a physician at a remote location does not like the information provided from the ultrasound imaging unit, the physician may manually override and control the ultrasound imaging unit remotely. Thus, the ultrasound imaging unit of the present invention is flexible where a physician may monitor multiple patients from the central station and remotely
15 control the patient monitoring unit to continuously optimize an ultrasound image and thereby obtain optimized physiological information from each patient.

 The information downloaded via the communication network may include basic images, monitoring information derived from the images, or other ultrasound information. The ultrasound imaging unit may itself derive the monitoring information, or the
20 ultrasound images would be directly downloaded to the central station and processed by a remote information processor at the central station to derive therefrom the monitoring information.

 Fig. 1 is a schematic diagram of an embodiment of a system including an ultrasound imaging unit as a plug-in module 10, which is plugged into a bedside patient monitor unit 20. A cable 25 is connected from the ultrasound plug-in module 10 to a probe, such as a TEE probe 30 or an endoscope in the patient to monitor cardiac activity. Said probe may be insertable through a mouth or a nose of the patient to monitor the region for a continuous period of time. The TEE probe 30 may be remotely manipulated or monitored from a central station via the communication channel in the ultrasound plug-in module 10 or
25 may be manipulated from the bedside patient monitor unit 20 to obtain different views and direct the transducer in the TEE probe 30 to a particular region of the heart to obtain an optimal view of the heart. The communication channel may include a communication cable, an infrared (IR) port, a telephone modem, a wireless modem, or a business intranet connection. Thus, the output from the patient monitor unit 20 may be connected to a
30

communication network of the central location, such as a clinical institution to allow immediate access to information derived from the ultrasound images for patient monitoring activities.

The patient monitor unit 20 is a modular device including a display 35, which
5 the physician monitors at the bedside. Multiple small modules 40 are provided that plug into various slots within the patient monitor unit 20. For instance, if it is necessary to monitor a patient's ECG, then an ECG module 50 is plugged into the patient monitor unit 20. A cable 60 is connected from the ECG module 50 to electrodes on the patient. Similarly, if the physician is monitoring blood pressure, a blood pressure module 70 is plugged into the
10 patient monitor unit 20 and a cable 80 is connected from the blood pressure module 70 to a pressure transducer (not shown) on the patient. In this instance, the algorithms extracting the patient information from the ultrasound images may be stored and executed by the ultrasound plug-in module 10, by the patient monitor unit 20, or by a remote processor at the remote location. The algorithms would generate the ultrasound displays and may process pressure
15 waveforms, cardiac waveforms, and ultrasound waveforms in a continuous manner. Further, the algorithms would process the image information to provide patient monitoring information. The information received and/or processed at the patient monitor unit 20 may be downloaded to the remote processor at the central station and displayed for observation at that station.

Information gained from the ultrasound imaging unit may be used to generate trend line data for analysis by clinical staff. It could also be integrated with other clinical data obtained from other algorithms that may be implemented into the patient monitoring system. For example, combining stroke volume with pressure data could prove useful in analysis of cardiac workload capability.

An alarm may be triggered at the bedside and/or at the central station if the processor determines from the waveforms that the patient's diagnostics exceed predetermined thresholds. A physician at the central station may send a feedback signal via the network to the patient monitor unit 20 to manipulate the ultrasound image to optimize the image, to manipulate the TEE probe 30, or to command further testing.

Fig. 2 is a schematic diagram of an embodiment of a standalone ultrasound imaging unit 90. The standalone ultrasound imaging unit 90 is connected to the patient monitor unit 20. The control, operation, and exchange of patient information between the patient monitor unit 20, the ultrasound imaging unit 90, and the central station are described in FIG. 1.

The patient monitor unit 20 and the ultrasound imaging unit 90 each may independently or concurrently download patient monitoring information to the central station. The ultrasound imaging unit 90 may process the ultrasound images obtained to generate patient monitoring information or may download the images to the patient monitor unit 20 or 5 the central station for processing. A cable 96 is connected from the ultrasound imaging unit 90 to a trans-nasal TEE probe, entering the patient through a nasal passage, residing in the esophagus.

Fig. 2, the ultrasound imaging unit 90 is illustrated as a dedicated display unit. A separate display unit 92 on the patient monitor unit 20 displays waveforms from the ECG 10 module 50 and the blood pressure module 70. The patient monitor display unit 92 may be used to also display ultrasound derived images or data. The ultrasound imaging unit 90 may include sophisticated image demodulation techniques, such as acoustic quantification or color kinesis or regional wall motion, which is an algorithm to determine abnormal heart wall motions. These sophisticated image demodulation techniques could be applied to the 15 ultrasound image information by either local processing, or remote processing capability.

Either ultrasound imaging unit shown in Figs. 1 and 2 may be incorporated in an ambulatory vehicle, where a user would not be required to have expertise in monitoring cardiac activity, for instance. The user would download the images via an RF connection, for instance, to a hospital network where the physician would be able to read the images and to 20 obtain therefrom continuous diagnostic data from the patient. The physician may then communicate with the user of the system recommending treatment or medication to the patient while continuously monitoring the patient's condition. In the alternative, the physician may remotely control the ultrasound imaging unit.

Fig. 3A is a schematic diagram of a split screen display displaying the 25 patient's physiological parameters including ECG and blood pressure, and related trend lines on one side of the screen. The ultrasound image and related trend lines extracted from the ultrasound image are shown on the other side of the screen. Fig. 3B is a schematic diagram of a display unit showing a "window-in-window" display. Here, the ultrasound image and related trend lines extracted from the ultrasound image are shown as a smaller window within 30 the main patient monitoring window. ECG, blood pressure, and related trend lines are also displayed on the same display.

As illustrated in Fig. 4, a flow chart illustrating a method embodiment of the present invention is shown. At operation 100, the user of the ultrasound imaging unit 10, 90 inserts the TEE probe 30 into the patient. At operation 110, the ultrasound imaging unit 10,

90 continuously collects ultrasound image data. At operation 120, the ultrasound imaging unit 10, 90, the patient monitor unit 20, or a remote processing station, such as the central station, continuously processes the ultrasound image data collected to diagnostic data. At operation 130, the ultrasound imaging unit 10, 90 or the patient monitor unit 20 continuously

5 transmits the diagnostic data to the physician at another location to analyze the diagnostic data. At operation 140, if the diagnostic data is adequate to determine a medical treatment for the patient, then, at operation 150, the physician recommends the medical treatment for the patient to the user. Otherwise, from operation 140, the method returns to operation 110 where the procedure is repeated to continuously obtain the diagnostic data.

10 Accordingly, the present system provides for an ultrasound imaging unit, integrated into a patient monitoring system to generate continuously and in real-time physiological information from an ultrasound image. Further, the ultrasound imaging unit, according to the present invention, provides flexibility to a user by allowing a physician to monitor multiple patients from a central location and remotely control the patient monitoring

15 unit including the ultrasound imaging unit. The system would be able to automatically regulate and control the ultrasound-monitoring module to generate an optimal ultrasound image.

Although a few preferred embodiments of the present invention have been shown and described, it would be appreciated by those skilled in the art that changes may be
20 made in this embodiment without departing from the principles and spirit of the invention, the scope of which is defined in the claims and their equivalents.

CLAIMS:

1. An apparatus, comprising:
 - a patient monitoring system; and
 - an ultrasound imaging unit connected to the patient monitoring system
- 5 continuously collecting ultrasound images from a patient and processing the ultrasound images to continuously extract therefrom diagnostic data.
2. The apparatus as recited in claim 1, wherein the ultrasound imaging unit is a plug-in unit.
- 10
3. The apparatus as recited in claim 1, wherein the ultrasound imaging unit is a compact standalone ultrasound imaging unit.
4. The apparatus as recited in one of the claims 1 to 3, wherein the ultrasound imaging unit continuously executes at least one of an automatic boundary extraction algorithm, regional wall motion algorithm, an automatic gain control algorithm, kinesis measurement, or a physiological measurement.
- 15
5. The apparatus as recited in one of the claims 1 to 3, wherein the ultrasound imaging unit continuously transmits the diagnostic data using a communication channel integrated therein to a person at a remote location.
- 20
6. The apparatus as recited in claim 5, wherein the person at the remote location remotely controls via a communication channel the continuous extraction of the diagnostic data from the ultrasound images.
- 25
7. The apparatus as recited in claim 1, wherein the ultrasound imaging unit automatically determines a region of a heart of the patient that needs to be monitored.

8. The apparatus as recited in claim 7, wherein the ultrasound imaging unit further comprises a remote override capability allowing a person at a remote location to override via a communication channel and manually determine the region of the heart of the patient that needs to be monitored.

5

9. The apparatus as recited in one of the claims 1 to 3, wherein a person at a remote location remotely manipulates a probe coupled to the ultrasound imaging unit via a communication channel in the ultrasound imaging unit.

10 10. The apparatus as recited in one of the claims 1 to 3, wherein the ultrasound imaging unit comprises a communication channel to download to a hospital network at least one of the ultrasound images and the diagnostic data.

15 11. The apparatus as recited in one of the claims 1 to 3, wherein the patient monitoring system comprises slots to plug modules comprising at least one of a blood pressure module and an ECG module to monitor a patient's blood pressure and ECG signals.

12. The apparatus as recited in one of the claims 1 to 3, further comprising a display screen displaying the ultrasound images and the diagnostic data on a screen.

20

13. The apparatus as recited in claim 12, further comprising a split screen display displaying patient monitoring data and related trend lines and the ultrasound images and related trend lines extracted from the ultrasound images.

25 14. The apparatus as recited in claim 12, further comprising a window-in-window display displaying patient monitoring data and related trend lines together with the ultrasound images and related trend lines extracted from the ultrasound images.

30 15. The apparatus as recited in one of the claims 1 to 3, wherein the apparatus comprises an alarm indicating that a patient's physiological parameter has exceeded a predetermined threshold, where the alarm is triggered by the ultrasound images or the diagnostic data comprising stroke volume, heart rate, or blood pressure.

16. A method comprising:

integrating an ultrasound imaging unit to a patient monitoring system;

connecting the ultrasound imaging unit to a patient; and

continuously collecting ultrasound imaging data from the patient.

- 5 17. The method as recited in claim 16, further comprising:
 processing the ultrasound imaging data to generate therefrom diagnostic data.
18. The method as recited in claim 17, further comprising:
 continuously transmitting the diagnostic data using a communication channel
10 to a person at another location.
19. The method as recited in claim 18, further comprising:
 analyzing the diagnostic data and determining therefrom a medical treatment
 for the patient.

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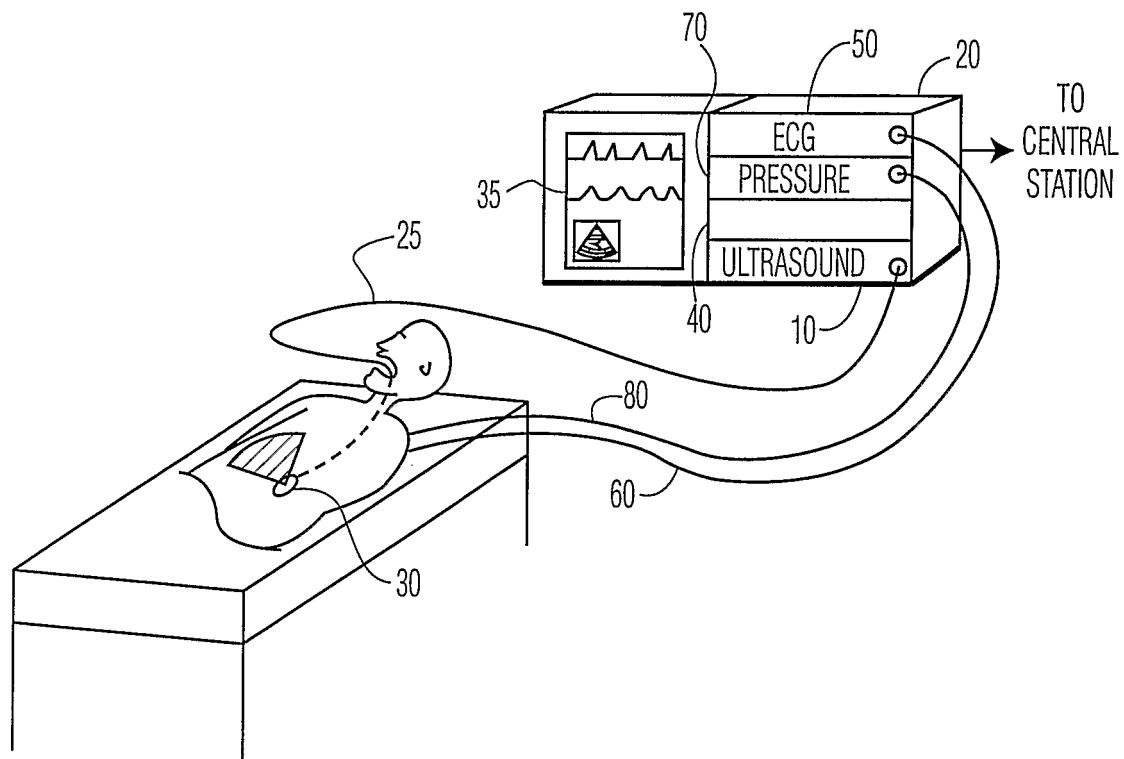


FIG. 1

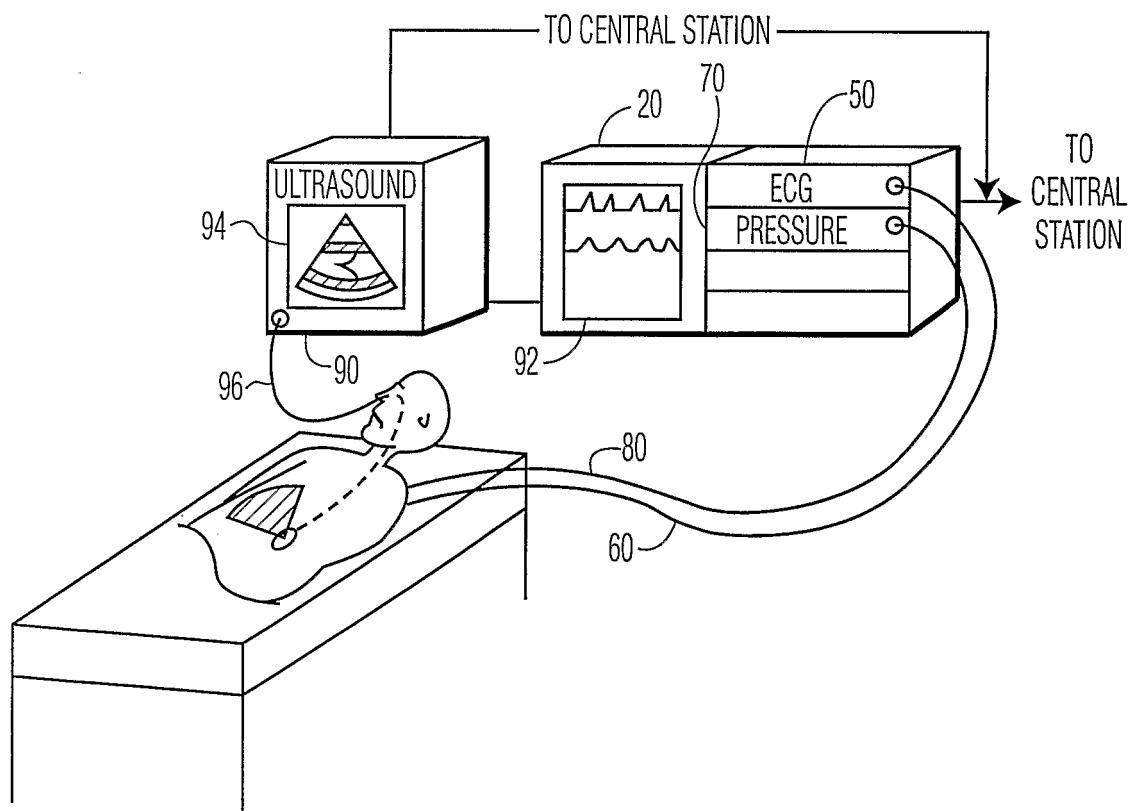


FIG. 2

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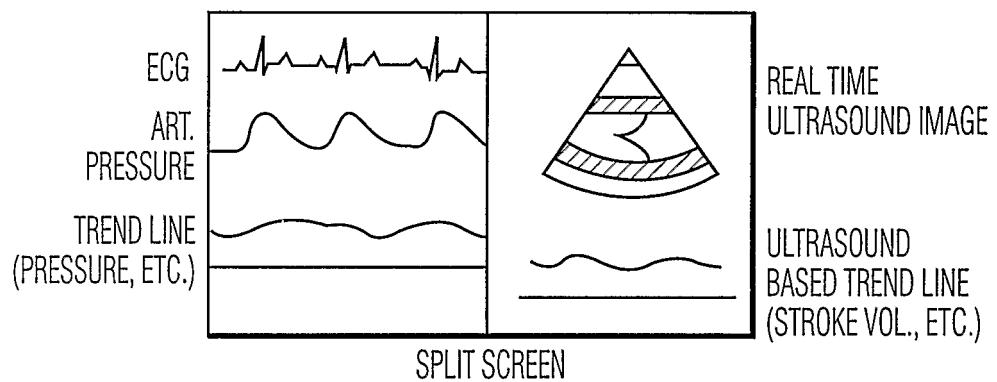


FIG. 3A

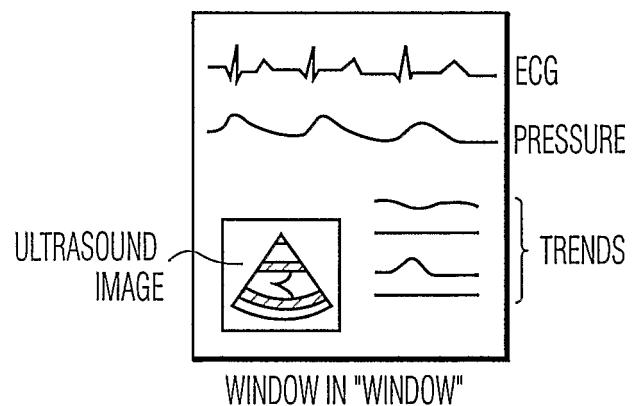


FIG. 3B

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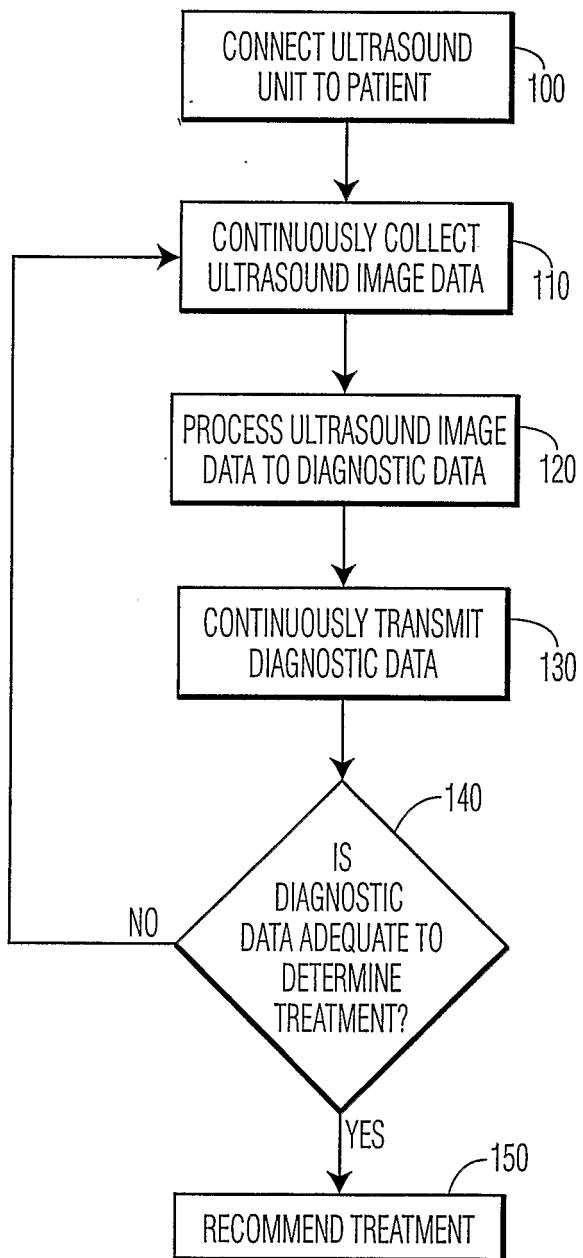


FIG. 4

INTERNATIONAL SEARCH REPORT

International Application No

PCT/IB 03/00693

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61B8/14 A61B5/00 A61B8/12

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

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 5 437 278 A (WILK PETER J) 1 August 1995 (1995-08-01) the whole document ---- | 1,3-5, 10,12,15 |
| P,X | US 6 438 405 B1 (MOONEY MATTHEW ET AL) 20 August 2002 (2002-08-20) column 3, line 48 -column 4, line 64; figures 1,2 ---- | 1,3,4,15 |
| A | US 2001/011969 A1 (POLZ HANS) 9 August 2001 (2001-08-09) page 1, left-hand column, paragraph 10 -page 2, right-hand column, paragraph 27; figure 1 ---- | 1,3-6,9, 10,12 |

 Further documents are listed in the continuation of box C. Patent family members are listed in 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.

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Date of the actual completion of the international search

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Artikis, T

INTERNATIONAL SEARCH REPORTInte
nal application No.
PCT/IB 03/00693**Box I Observations where certain claims were found unsearchable (Continuation of item 1 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. Claims Nos.: 16-19 because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT – Diagnostic method practised on the human or animal body and method for treatment of the human or animal body by surgery
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 II Observations where unity of invention is lacking (Continuation of item 2 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 all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers 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.
- No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IB 03/00693

| Patent document cited in search report | | Publication date | | Patent family member(s) | | Publication date |
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|----------------|--|---------|------------|
| 专利名称(译) | 超声成像增强临床患者监测功能 | | |
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| 申请号 | EP2003742996 | 申请日 | 2003-02-21 |
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| 申请(专利权)人(译) | 皇家飞利浦电子N.V. | | |
| 当前申请(专利权)人(译) | 皇家飞利浦电子N.V. | | |
| [标]发明人 | GATZKE RONALD D | | |
| 发明人 | GATZKE, RONALD, D. | | |
| IPC分类号 | A61B5/00 A61B5/0205 A61B5/0402 A61B8/08 A61B8/12 A61B8/14 | | |
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| 优先权 | 10/086007 2002-02-28 US | | |
| 其他公开文献 | EP1480562B1 | | |
| 外部链接 | Espacenet | | |

摘要(译)

一种装置包括集成到患者监测系统中的超声成像单元，其连续地从患者生成超声图像并连续地从中提取诊断数据。