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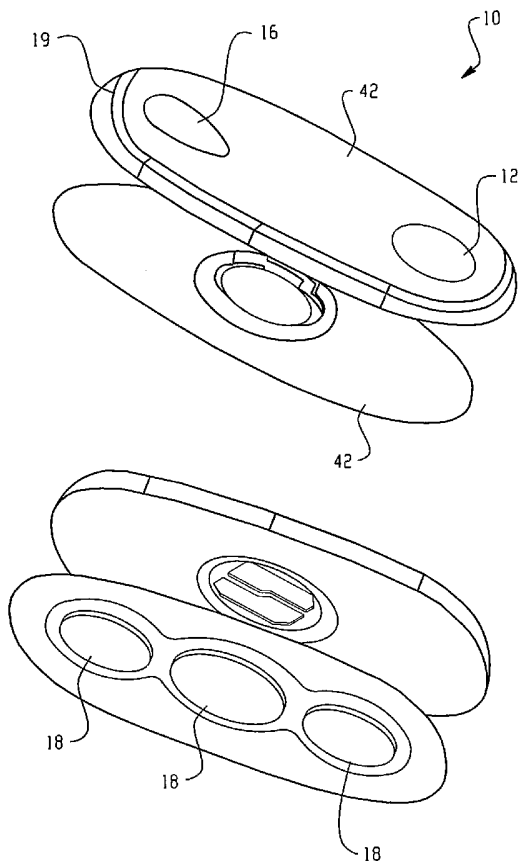
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(54) Title: AMBULATORY MEDICAL TELEMETRY DEVICE HAVING AN AUDIO INDICATOR



(57) Abstract: An ambulatory medical telemetry device (10) is provided. The device includes at least one sensor (18) for detecting at least one physiological parameter of a patient and a housing that is securable to the patient. A circuit (50) is located in the housing for receiving and processing a signal representative of the physiological parameter from the sensor to generate recordable physiological data. An audio transducer (16) is located in the housing and operationally coupled to the circuit for generating an audio signal indicating at least one operational state of the device.

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**AMBULATORY MEDICAL TELEMETRY DEVICE HAVING AN AUDIO
INDICATOR**

DESCRIPTION

The present invention relates generally to ambulatory medical telemetry devices, and more particularly to an ambulatory medical telemetry device that includes an audible indicator for providing audio feedback to individuals in the physical vicinity of the device.

5

Monitoring of human physiological status data has received a high and growing level of interest in a number of medical, industrial, scientific and recreational disciplines. For example, monitoring of electrocardiography (ECG) data is a useful tool in diagnosing the condition of a patient's heart. Conventional medical telemetry devices allow
10 instantaneous values of the physiological parameters to be viewed.

An ambulatory medical telemetry device is a portable electronic device that is secured to a patient for extended periods of time so that the physiological parameter(s) detected by the device can be continuously monitored and analyzed. The monitoring system may or may not include a recording unit for storing the data for subsequent
15 analysis.

Patients may wear an ambulatory medical telemetry device in a variety of different settings, including their residence, a hospital or other medical care or rehabilitation institution. Regardless of the setting, clinical users need to ensure that the system is functioning properly. Since the clinical user is generally not as highly trained as a
20 technician in the operation of the system, the user should ideally receive some assurance that the system has been correctly activated and is operating properly. In addition, when a patient is ambulatory, it can often be difficult to locate the patient. This can be critically important if a life-threatening or other emergency situation has arisen.

Accordingly, it would be desirable to provide means for feedback to the patient or
25 other nearby individuals concerning the operation and status of the medical telemetry device and overall monitoring system.

In accordance with the present invention, an ambulatory medical telemetry device is provided. The device includes at least one sensor for detecting at least one physiological parameter of a patient and a housing that is securable to the patient. A circuit is located in the housing for receiving and processing a signal representative of the physiological parameter from the sensor to generate recordable physiological data. An audio transducer is located in the housing and operationally coupled to the circuit for generating an audio signal indicating at least one operational state of the device.

In accordance with one aspect of the invention, the audio signal generated by the audio transducer further indicates physiological-related information.

In accordance with another aspect of the invention, a wireless receiver is operationally coupled to the circuit and the audio transducer and is located in the housing for receiving a wireless paging signal such that the audio transducer, in response to the wireless signal, generates an audio paging signal.

In accordance with another aspect of the invention, the operational state of the monitor that is indicated is successful completion of a self-test.

In accordance with another aspect of the invention, the operational state of the monitor that is indicated is a failure of a self-test.

In accordance with another aspect of the invention, the operational state of the monitor that is indicated is a successful completion of a test result to obtain the physiological data.

In accordance with another aspect of the invention, the audio transducer generates at least one tone.

In accordance with another aspect of the invention, the audio transducer generates at least one different tone for each operational state of the monitor that is to be indicated.

In accordance with another aspect of the invention, the audio transducer generates a plurality of tones each corresponding to a different operational state of the monitor.

In accordance with another aspect of the invention, each of the plurality of tones differ in at least one characteristic selected from the group consisting of frequency, duration, intervals between tones and intensity.

In accordance with another aspect of the invention, one of the tones represents positive feedback and another of other of the tones represents negative feedback.

In accordance with another aspect of the invention, a wireless transceiver is operationally coupled to the circuit and the audio transducer and is located in the housing for, in a receiving state of operation, receiving a wireless paging signal such that the audio transducer, in response to the wireless signal, generates an audio paging signal.

5 In accordance with another aspect of the invention, the physiological parameter detected by the sensor is selected from the group consisting of electrocardiogram/respiration (ECG/RESP), electrocardiogram (ECG), invasive pressures, temperature, non-invasive blood pressure (NIBP), SpO₂ /Pleth level, carbon dioxide level (CO₂), and cardiac output.

10 In accordance with another aspect of the invention, a method is provided for providing audible feedback from an ambulatory medical telemetry device securable to a patient. The method begins by detecting at least one physiological parameter of the patient and receiving and processing a signal representative of the physiological parameter to generate recordable physiological data. An audio signal is generated indicating at least one
15 operational state of the device.

FIG. 1 shows a perspective view of an ambulatory medical telemetry device in accordance with the present invention.

20 FIG. 2 shows a functional block diagram of one embodiment of the ambulatory medical telemetry device shown in FIG. 1.

The present inventor has recognized that the aforementioned problems can be
25 alleviated by equipping the ambulatory medical telemetry device with a transducer or other mechanism for generating an audible signal. The audible signal can provide feedback ensuring the user that the device and/or overall monitoring system is operating correctly. For example, the feedback may indicate the status of the patient being monitored, the status of the device hardware, or the status of algorithms employed in monitoring the patient. For
30 instance, the audible signal may indicate that a measurement has been completed, that monitoring is inoperable, a self-test failed, that the device is otherwise unable to make a measurement, or that the measured value is outside of a predetermined range. The audible

signal can also serve as a paging signal by which a caregiver can, for example, request that the patient return to their room or to aid in locating the patient after transmitting a wireless signal to the monitor.

The ambulatory device in which the present invention is employed can measure any
5 of a variety of different physiological parameters, including, without limitation,
electrocardiogram/respiration (ECG/RESP), electrocardiogram (ECG), invasive pressures,
temperature, non-invasive blood pressure (NIBP), SpO₂ /Pleth level, carbon dioxide level
(CO₂), and cardiac output.

A perspective view of an ambulatory medical telemetry device 10 in accordance
10 with the present invention is shown in FIG. 1. The elements of the ambulatory device 10
are enclosed within a housing 42. A user interface 12, an audible indicator 16, a patient
connector/sensor 18 and antenna(s) 19 are incorporated in the ambulatory device 10. The
user interface 12, which may comprise a display, buttons and/or other actuators, and the
like, may be used to activate the device, and select from among the different operational
15 states that are available. The patient connector provides a connection between the circuitry
or mechanisms of the ambulatory device 10 and sensors or other transducers affixed to the
patient for monitoring the patient's condition. The antenna(s) 19 is used for wireless
communication as described below. The ambulatory device 10 is carried by an ambulatory
patient during the patient's normal activities, and the patient's physiological parameters of
20 interest may be analyzed, monitored, displayed and recorded while the patient is
ambulatory.

It should be noted that while ambulatory device 10 is typically designed to be
simple and compact, in some embodiments of the invention it may include additional
features such as other wireless link(s) for additional data exchanges or external battery
25 packs to provide additional power for extended use. However, such features are optional
and should not be construed as a limitation on the invention.

A block diagram of one embodiment of the ambulatory medical telemetry device
10 is shown in FIG. 2. The contacts in patient connector/sensor 18 are connected to a
circuit 50 in electronics module 20. As indicated above, sensors attached to the patient are
30 connected through connector 18 to the ambulatory device 10. The circuit 50 processes
physiological signals from the patient sensors. The outputs of circuit 50 are connected to
an acquisition processor 52, which controls a portion of the device operation and converts

physiological signals into useful data formats. The acquisition processor 52 is connected to a memory 54 which includes a program storage area 56 and a data buffer 58. The program storage area 56 is used to store a program for controlling operation of the acquisition processor 52. Data buffer 58 provides temporary storage of physiological data. A clock 62 is connected to acquisition processor 52. Portions of the ambulatory device 10 may be powered down when not in use to save battery power.

A command processor 66 is connected to acquisition processor 52 and to memory 54. The program storage area 56 is used to store programs for controlling operation of the command processor 66. The command processor 66 also controls transmission and reception of information through wireless alert transceiver 28 as described below. In one embodiment of the invention the wireless transceiver 28 is an integrated radio frequency telemetry unit. In some embodiments of the invention the full functionality of a transceiver may not be required, in which case only a wireless receiver or a wireless transmitter may be employed, depending on the requirements of the particular monitor.

An audible indicator 16 is connected to the command processor 66. Audible indicator 16 may be a simple audio transducer that generates one or more tones. Alternatively, audible indicator 16 may be a more complex component that generates a variety of different tones or tunes, or voice. The audible indicator 16 may be able to vary the duration and intensity of the tone or tones.

The audible indicator 16, under control of the command processor 66, generates an audio signal that represents various operational states or conditions, thereby providing audio feedback to the patient or other individual in the vicinity of the patient. The feedback that is provided may be negative feedback (if, for example, the monitor is inoperable or fails a self-test, or if the monitor is otherwise unable to make a measurement, or if the measured value is outside of a predetermined range). On the other hand, the feedback that is provided may be positive feedback, indicating, for example, that a self-test has been successfully completed, that a measurement has been successfully obtained, or the like. The audible indicator 16 may distinguish between positive and negative feedback in a variety of different ways. For example, if a tone is employed, the duration, intensity, and/or the frequency of the tone may be different for each type of feedback. Alternatively, a different tune may be employed for the different types of feedback.

The audible signal can also be used for a variety of other purposes. For instance, the audible signal can serve as a paging signal by which a caregiver can locate the patient after transmitting a wireless signal to the monitor. More specifically, in some embodiments of the invention the audible indicator 16 may be used to provide a paging feature. In this
5 embodiment, wireless transceiver 28 (or wireless receiver) receives a wireless command signal from a central station (e.g., a nurse's station) or other location that activates the audible indicator 16. In this way the sound emanating facilitates the location of the device and/or the patient.

In some cases the paging feature can be used in two different ways. In particular, it
10 can be used to request or page the patient to return to some predetermined location, e.g., his or her room. When used in this manner the audible signal has a distinctive tone or tune recognizable by the patient as a paging signal requesting the patient to return to the predetermined location. For example, such a paging signal could be a periodic tone having a fixed volume. On the other hand, the paging feature can also be used to find the
15 ambulatory device, whether or not it is secured to the patient. In this case the paging signal advantageously may be different from the paging signal used to instruct the patient to return to the predetermined location. For example, the tone or tune may be continuous and at its maximum possible volume so that the device can be readily located.

In those embodiments of the invention providing the functionality of wireless
20 transmission, wireless transceiver 28 can transmit the physiological data to a remote location for analysis. Also, in the event of an emergency as indicated by the physiological parameter being measured, the transceiver 28 can send an alert to a remote location to notify the emergency responder. In some embodiments of the invention the wireless transmitter 28 may send the data to a device that in turn forwards the data to the responder
25 over a telephony or computer network. For example, if the monitor is to be used primarily in the patient's residence, the wireless transmitter 28 may forward the data to a specially enabled telephone that is also located in the residence.

In operation, the acquisition processor 52 acquires signals representing the physiological parameter being measured from circuit 50, converts the signals to data and
30 may store the data in data buffer 58. In some cases the acquisition processor 52 can also check alarm limits (e.g., a life-threatening event) with respect to the physiological data. For example, if physiological data is being measured, the acquisition processor 52 may check

the data for the occurrence of abnormal heartbeats. The alarm limits may be stored in program storage area 56 or any other appropriate location that can be accessed by acquisition processor 52. If the acquisition processor 52 determines that an alarm limit has been exceeded, indicative of an emergency situation, the acquisition processor 52 can
5 activate audible indicator 16 via command processor 66.

Although various embodiments are specifically illustrated and described herein, it will be appreciated that modifications and variations of the present invention are covered by the above teachings and are within the purview of the appended claims without departing from the spirit and intended scope of the invention. For example, while the
10 various components have been depicted as discrete elements, those of ordinary skill in the art will recognize that the functionality of those elements may be embodied in hardware, software, or any combination thereof, and thus are not necessarily embodied in discrete physical components.

CLAIMS

1. An ambulatory medical telemetry device, comprising:
at least one sensor (18) for detecting at least one physiological parameter of a patient;
a housing (42) securable to the patient;
a circuit (50) located in said housing for receiving and processing a signal representative of the physiological parameter from the at least one sensor to generate recordable physiological data; and
an audio transducer (16) located in said housing (42) and operationally coupled to said circuit (50) for generating an audio signal indicating at least one operational state of the device.
2. The device of claim 1 wherein said audio signal generated by the audio transducer (16) further indicates physiological-related information.
3. The device of claim 1 further comprising a wireless receiver (28) operationally coupled to the circuit (50) and the audio transducer (16) and located in said housing (42) for receiving a wireless paging signal such that the audio transducer (16), in response to the wireless signal, generates an audio paging signal.
4. The device of claim 1 herein said at least operational state of the monitor that is indicated is successful completion of a self-test.
5. The device of claim 1 wherein said at least operational state of the monitor that is indicated is a failure of a self-test.
6. The device of claim 1 wherein said at least one operational state of the monitor that is indicated is a successful completion of a test result to obtain the physiological data.

7. The device of claim 1 wherein said audio transducer (16) generates at least one tone.
8. The device of claim 1 wherein said audio transducer (16) generates at least one different tone for each operational state of the monitor that is to be indicated.
9. The device of claim 1 wherein said audio transducer (16) generates a plurality of tones each corresponding to a different operational state of the monitor.
10. The device of claim 9 wherein each of said plurality of tones differ in at least one characteristic selected from the group consisting of frequency, duration, intervals between tones and intensity.
11. The device of claim 9 wherein one of the tones represents positive feedback and another of other of the tones represents negative feedback.
12. The device of claim 1 further comprising a wireless transceiver operationally coupled to the circuit and the audio transducer and located in said housing for, in a receiving state of operation, receiving a wireless paging signal such that the audio transducer, in response to the wireless signal, generates an audio paging signal.
13. The device of claim 1 wherein the physiological parameter detected by the sensor is selected from the group consisting of electrocardiogram/respiration (ECG/RESP), electrocardiogram (ECG), invasive pressures, temperature, non-invasive blood pressure (NIBP), SpO₂ /Pleth level, carbon dioxide level (CO₂), and cardiac output.
14. A method for providing audible feedback from an ambulatory medical telemetry device securable to a patient, said method comprising the steps of:
 - detecting at least one physiological parameter of the patient;
 - receiving and processing a signal representative of the physiological parameter to generate recordable physiological data; and

generating an audio signal indicating at least one operational state of the device.

15. The method of claim 14 wherein said audio further indicates physiological-related information.

16. The method of claim 14 further comprising the steps of receiving a wireless paging signal and, in response to the wireless signal, generating an audio paging signal.

17. The method of claim 14 herein said at least operational state of the monitor that is indicated is successful completion of a self-test.

18. The method of claim 14 wherein said at least operational state of the monitor that is indicated is a failure of a self-test.

19. The method of claim 14 wherein said at least one operational state of the monitor that is indicated is a successful completion of a test result to obtain the physiological data.

20. The method of claim 14 wherein said audio signal comprises at least one tone.

21. The method of claim 14 wherein said audio signal comprises at least one different tone for each operational state of the monitor that is to be indicated.

22. The method of claim 14 wherein said audio signal comprises a plurality of tones each corresponding to a different operational state of the device.

23. The method of claim 22 wherein each of said plurality of tones differ in at least one characteristic selected from the group consisting of frequency, duration, intervals between tones and intensity.

24. The method of claim 22 wherein one of the tones represents positive feedback and another of other of the tones represents negative feedback.

25. The method of claim 14 wherein the physiological parameter that is detected is selected from the group consisting of, without limitation, electrocardiogram/respiration (ECG/RESP), electrocardiogram (ECG), invasive pressures, temperature, non-invasive blood pressure (NIBP), SpO₂ /Pleth level, carbon dioxide level (CO₂), and cardiac output.

26. The method of claim 14 further comprising the steps of receiving a first or second wireless paging signal and, in response, generating a first or second audio paging signal, respectively, wherein the first and second audio paging signals are audibly distinctive from one another.

27. The method of claim 26 wherein the first audio paging signal requests the patient to return to a predetermined location.

28. The method of claim 27 wherein the second audio paging signal is used to locate the ambulatory medical telemetry device.

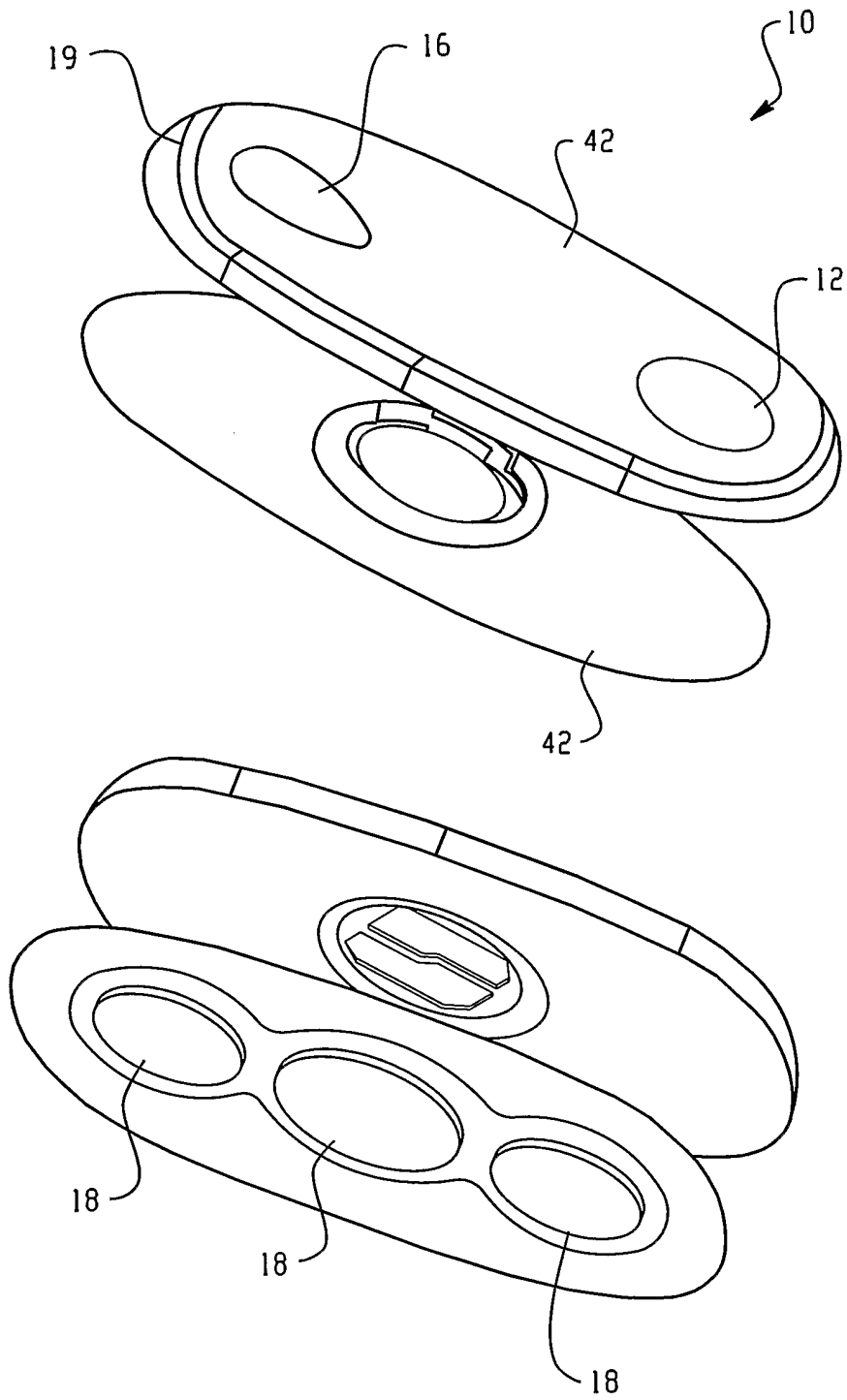


Fig. 1

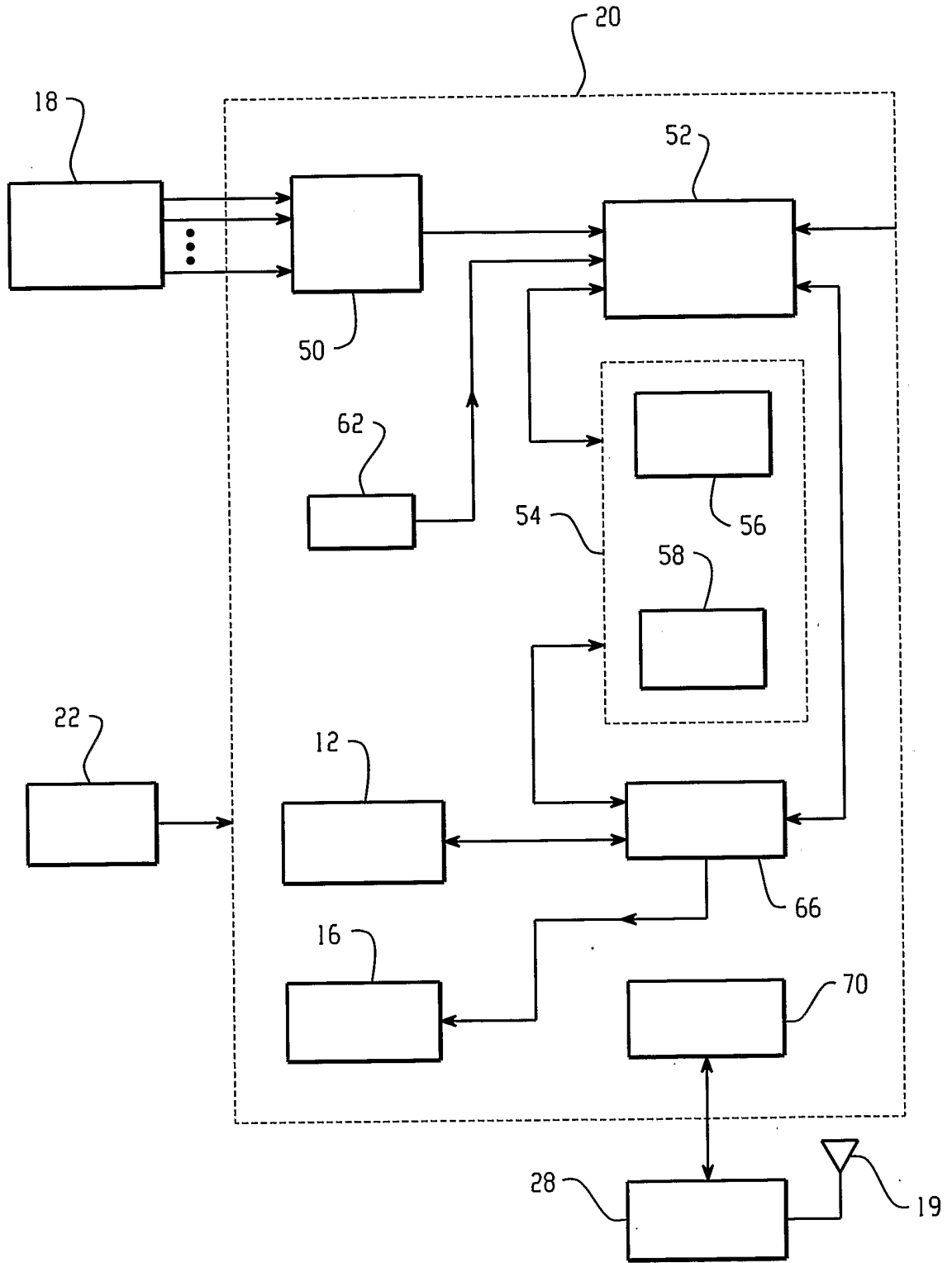


Fig. 2

INTERNATIONAL SEARCH REPORT

International Application No
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A. CLASSIFICATION OF SUBJECT MATTER
A61B5/00 G08B21/18

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 G06F G08B

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	WO 02/067122 A (I-MEDIK, INC) 29 August 2002 (2002-08-29)	1, 2, 5-9, 12-15, 18-22, 25 3, 4, 10, 11, 16, 17, 23, 24, 26-28
Y	page 4, line 17 - line 24 page 8, line 18 - line 29 page 13, line 27 page 14, line 28 - page 15, line 31 page 21, line 22 - line 30 page 24, line 5 - page 25, line 26 page 35, line 8 figures 1A, 2, 5	
Y	US 5 465 082 A (CHACO ET AL) 7 November 1995 (1995-11-07) column 2, line 42 - column 3, line 55	3, 16, 26-28
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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
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INTERNATIONAL SEARCH REPORT

International Application No

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 204 657 A (PROSSER ET AL) 20 April 1993 (1993-04-20) column 1, line 1 - column 2, line 23 -----	3,28
Y	US 6 278 890 B1 (CHASSAING CHARLES E ET AL) 21 August 2001 (2001-08-21) column 13, line 56 - line 60 -----	4,11,17, 24
Y	US 2004/193026 A1 (SCHARF TOM D) 30 September 2004 (2004-09-30) paragraphs '0002!, '0010!, '0012!, '0037! - '0039! -----	10,23
X	US 2003/130590 A1 (BUI TUAN ET AL) 10 July 2003 (2003-07-10) paragraphs '0053!, '0062!, '0065!, '0068!, '0075!, '0076!, '0134!, '0135!, '0160!; figures 2,3 -----	1,2,5,6, 8,9,13
X	US 5 027 824 A (DOUGHERTY ET AL) 2 July 1991 (1991-07-02) column 4, line 6 - line 9 column 4, line 35 - line 37 column 6, line 37 - line 42 column 18, line 49 - line 54 column 23, line 39 - line 53 figures 2,11 -----	1,2,8,9
X	US 2003/126593 A1 (MAULT JAMES R) 3 July 2003 (2003-07-03) paragraphs '0026! - '0029!, '0065! figures 1,3 -----	1,2

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IB2005/053620

Patent document cited in search report		Publication date		Patent family member(s)	Publication date
WO 02067122	A	29-08-2002	AU EP	2002255545 A1 1410206 A1	04-09-2002 21-04-2004
US 5465082	A	07-11-1995	US	5291399 A	01-03-1994
US 5204657	A	20-04-1993	NONE		
US 6278890	B1	21-08-2001	NONE		
US 2004193026	A1	30-09-2004	NONE		
US 2003130590	A1	10-07-2003	NONE		
US 5027824	A	02-07-1991	NONE		
US 2003126593	A1	03-07-2003	NONE		