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- (71) Applicant (for all designated States except US): **DATASCOPE INVESTMENT CORP.** [US/US]; 14 Philips Parkway, Montvale, NJ 07645 (US).

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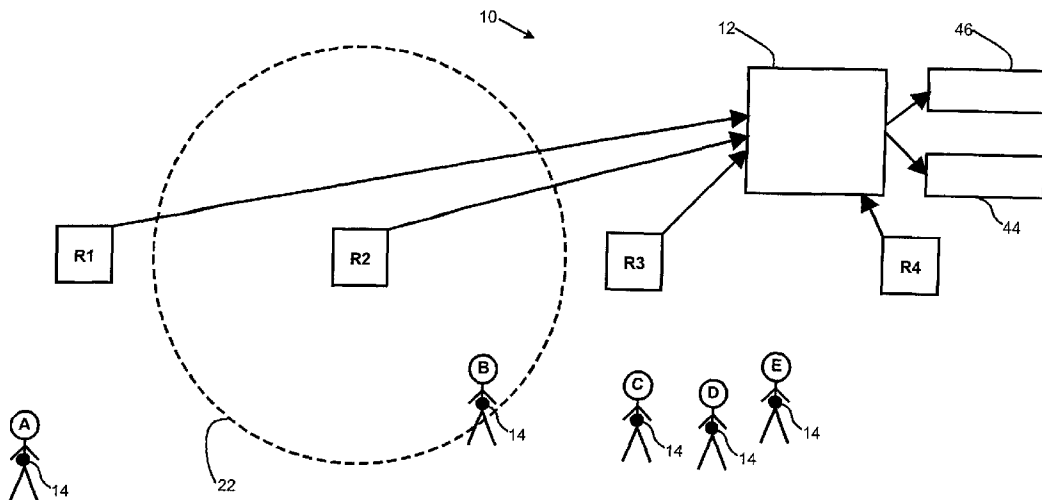
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- (72) Inventors; and
- (75) Inventors/Applicants (for US only): **SAPER, Lawrence** [US/US]; 14 Philips Parkway, Montvale, NJ 07645 (US). **KINAST, Eric** [US/US]; 2409 North Helioprobe Drive, Santa Ana, CA 92706 (US).
- (74) Agent: **RONAI, Abraham**; Datascope Corp., 14 Philips Parkway, Montvale, NJ 07645 (US).

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(54) Title: MOBILE PATIENT MONITOR



(57) Abstract: A one-way communication mobile patient monitoring system (10) comprising patient transmitters (14), receivers (R1-R4), and a central monitoring station (12). The transmitters (14) analyse a patient's ECG signal and transmit heart rate and rhythm data to the central station (12) via the receivers (R1-R4). The central station (12) alerts hospital staff when vital signs fall outside a preset range.



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RELATED APPLICATIONS

{0001} This application herein incorporates by reference and claims priority to United States Provisional Patent Application No. 60/308,070, filed on July 26, 2001.

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BACKGROUND OF THE INVENTION

Field of the Invention:

{0002} The invention relates to a medical monitoring system. More particularly, the invention relates to a system for monitoring the condition and location of a subject or patient.

Description of the Prior Art:

{0003} The prior art is replete with various systems to monitor hospitalized patients and provide patient data to a central location. One type of system, employed in the intensive care units (ICU) of hospitals where vital signs of a patient are monitored, is a bedside system. In such a system the patient is confined to a bed and is suitably connected to sensors so as to allow for physiological medical information to be transmitted to a central location via cables or other means.

{0004} More modern systems generally equip a patient with a transmitter and receiver and utilize wireless transmission, such as telemetry systems, to communicate the patient's physiological medical information. Sensors placed on the patient monitor electrical signals produced by the patient to

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5 provide, for example, electrocardiogram (EKG) signals. These
subject or physiological signals are then transmitted by
antennas, conventional radio links or by other radio frequency
(RF) techniques. Existing ambulatory systems can provide
various signals relating to the monitoring, for example, the
10 patient's temperature, heart rate and so on. Essentially, the
type of signal which can be transmitted by such systems
includes any type of signal which can be measured by
conventional sensors which are applied to the skin or
otherwise implanted in the patient.

15 ^[0005] Prior art monitoring systems also exist which give an
indication of the location of the patient. A typical prior art
system is described in U.S. Pat. No. 4,958,645 entitled Multi-
Channel Digital Medical Telemetry System, which issued on Sep.
25, 1990 to Cadell et al. The medical radio telemetry system
20 described therein utilizes a plurality of antennas, which are
distributed throughout a hospital or other premises. The
patient is outfitted with a radio receiver and transmitter to
collect a patient physiological signal, including, for
example, the patient's temperature, heart rate, pacer rate,
25 respiration rate, brain activity level and blood pressure
level. The transmitter and receiver associated with the
patient operate in conjunction with one or more room locator
transmitters spaced in rooms where the patient is being
monitored. The room locator transmitters emit signals
30 indicative of the room they are emanating from. Signals from
the room locator transmitters are combined with the patient
signals so as to enable hospital staff to monitor the location
of patients.

^[0006] U.S. Pat. No. 4,981,141, entitled Wireless
35 Electrocardiogram Monitoring System, issued on Jan. 1, 1991 to

5 Segalowitz, discloses an electrocardiographic monitoring system where the patient's heart-signaling sensing electrodes are each coupled to the heart-signal monitor/recorder by respective wireless transmitters and corresponding respective wireless receivers in a base unit. Each transmitter/receiver
10 combination operates at a separate radio frequency to provide a zero or reference signal at a base unit and which is used to modulate a signal transmitter at the base unit. Each modulated signal, when received and demodulated provides information concerning signal sensed by a respective electrode carried by
15 the patient, as for example, the right-leg electrode, etc.

[0007] It is clear from the above that it is extremely desirable to monitor various vital signs of an ambulatory patient. This is even more important due to the recent trend to get patients ambulating as soon as possible. It is also important to
20 determine the location of a monitored patient within, for example, the confines of a hospital or other area so as to ensure expedient care in the case of an emergency, for example.

[0008] The disadvantage to the prior art bedside system is clear:
25 the system does not allow for patient mobilization. The more modern telemetry monitoring systems, although superior to the bedside systems, also have a number of significant drawbacks.

[0009] One-way communication systems are designed such that they use a different channel for each patient in order to avoid
30 interference between patient signals, i.e. patient signals arriving at a receiver at the same. When the number of patients becomes large these systems become expensive, complex and unwieldy, requiring many channels and complex receivers. Often, in order to avoid this problem, as well as to assist in
35 patient location, as in U.S. Patent No. 4,958,645, designers

5 revert to a two-way communication system. However, as
detailed below, two-communication adds considerable complexity
to the system and precludes a patient-worn device from being
small, light, and low-power.

[00010] The more modern telemetry systems often employ two-way
10 communications for system management purposes to better
coordinate the actions of the individual patient transmitters,
such that patient signal transmissions are scheduled in an
orderly and efficient manner to avoid interference and make
full use of the available bandwidth. Each transmitter is
15 assigned a time slot, during which it has exclusive use of the
channel to transmit a burst of data. In order to keep each
transmitter operating in its assigned time slot, the
transmitters must be coordinated via, for example, a
transmitter broadcasted beacon, thus rendering the system two-
20 way; the first link for transmission of the patient signal to
the transmitter and the second link for transmission of the
coordinating beacon back to the patient. Because the time
slots can be precisely assigned, this two-communication system
makes very efficient use of the bandwidth, but at the expense
25 of requiring a two-way link.

[00011] The two-way communication capability, which requires a
receiver as well as a transmitter, adds considerable
complexity to the system and precludes a patient-worn device
from being small, light, and low-power. If the need to manage
30 the transmitters can be avoided, then one-way communications
can be used and the monitor could be small, light and use low
power.

SUMMARY OF THE INVENTION

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5 (00012) Accordingly, it is an object of the invention to produce a one-way communication, small, light and low power telemetry system for monitoring the health and location of a subject or patient.

10 (00013) Currently, unmonitored patients may succumb to sudden cardiac arrest without knowledge of hospital staff. The present system attempts to correct this problem by providing continuous vigilance over those patients that might not otherwise be monitored.

15 (00014) The device comprises one or more transmission means for acquiring and analyzing a subject signal and for transmitting data resulting from the analysis to one or more receiving means. Said receiving means receive the data from the transmission means and communicate the data to a central station means. Said central station means receives and
20 analyzes the data from the receiving means, optionally including data related to the location of the patient, and notifies a user, i.e. hospital staff, of an alert or other predetermined patient condition.

25 (00015) The device size and power consumption are minimized by (i) analyzing the patient signal at the transmission means end, the patient side of the system, and only transmitting vital sign or other important physiological patient information to the central station and (ii) limiting the range of transmission means. Limiting the range of the transmission
30 means also facilitates patient location. Given the shortened range only a few patients should be within range of any given receiving means at any one time.

(00016) Note that the present invention is not limited to a hospital setting to monitor patients. Rather, the present
35 invention may be employed whenever there is a need to track

5 the condition and/or location of a subject, which may include inanimate objects, animal or humans, in a defined area.

[00017] To the accomplishment of the above and related objects the invention may be embodied in the form illustrated in the accompanying drawings. Attention is called to the fact,
10 however, that the drawings are illustrative only. Variations are contemplated as being part of the invention, limited only by the scope of the claims.

[00018]

BRIEF DESCRIPTION OF THE DRAWINGS

15

[00019] In the drawings, like elements are depicted by like reference numerals. The drawings are briefly described as follows.

20 [00020] Figure 1 is a block diagram of the mobile monitoring system of the present invention, showing the relationship of several patients to multiple receiving means.

[00021] Figure 2 is a perspective view of the patient transmission means.

25 [00022] Figure 3 is an electronic block diagram of the patient transmission means of Figure 2.

5 [00023]

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[00024] An overview of the preferred embodiment of the system 10 is shown in Figure 1. System 10 consists of a central station means 12 linked to a series of receiving means, labeled R1-R4, distributed throughout a defined area, such as the patient areas of a hospital. Each of five patients, labeled A-E, have an associated transmission means 14 for acquiring his or her physiologic signal, processing it to obtain medical condition data and then transmitting this medical condition data to one or more of the receiving means, R1-R4, for transmittal to central station means 12. In the present example the physiologic signal acquired is the patient's ECG waveform and the medical condition data consists of heart rate and rhythm.

20 [00025] Note that transmission means 14 will vary depending on the type of subject and range of conditions being monitored. The present invention is not limited to monitoring cardiac health of a patient in a hospital setting. One may want to track the movements of a turtle in a defined area, for example, and monitor the water content of its shell.

[00026] In the preferred embodiment, however, transmission means 14 is adhered to a patient's chest and comprises a device capable of measuring a patient's physiological signal, preferably the ECG signal, and analyzing this signal for patient medical condition data, such as heart rate and rhythm. More specifically, one transmission means 14 is connected to each patient, A through E.

[00027] In general, transmission means 14 comprises a signal sensing means 16, a computing means 18, and a transmitter 20 (see Figures 2 and 3). Signal sensing means 16 may comprise

5 one or more electrodes (as illustrated in Figures 2 and 3), a plethysmograph sensor, or other heart beat detection means. Computing means 18 analyzes a subject signal and produces patient condition data based on the subject signal. Computing means 18 may comprise a microprocessor, microcontroller, ASIC, or other programmable logic. Transmitter 20 transmits the patient condition data to central station means 12. Transmitter 20 may comprise a radio frequency, infrared, or ultrasonic device, or other device known in the art capable of transmitting bursts of data. The preferred embodiment of transmission means 14 is detailed below.

10 [00028] Receiver means R1-R4 comprise any device known in the art capable of receiving bursts or a stream of data and communicating this data to central station means 12. In this example, receiver means R1-R4 comprise a radio frequency receiver, means for communicating with central station means 12, and computing means (all not shown). Computing means may comprise a microprocessor, microcontroller, ASIC, or other programmable logic. Means for communicating with central station means 12 may comprise any of various computer data network communication devices, such as a wireless network, or wired network having either star, multidrop, or ring topology.

25 [00029] Central station means 12 may comprise any device capable of receiving and analyzing bursts or streams of data. Central station means 12 monitors each patient's medical condition data for predetermined rate and rhythm alarms. When an alarm condition is detected an alert is sounded or displayed on an associated display (not shown). Central station means 12 may also be configured to directly summon a response team, by means such as an interface to a telephone or pager system. By identifying the particular receiving means, R1-R4, picking up

5 a given patient's signal the patient's location is known.
Central station means 12 may comprise custom software running
on a PC, equipped with suitable commercial wired or wireless
network connectivity, or other computing platform.

10 ^[00030] Note that despite the system 10's optimization to work for
short bursts of data, as opposed to extended or continuous
signals, due to interference concerns, central station means
12 may receive and analyze physiological signals.

15 ^[00031] As indicated above, Figure 1 illustrates a schematic
representation of system 10 of the present invention. Five
patients, labeled A through E, are being monitored by four
receiving means, designated R1 through R4. Note that the
number of patients and receiving means may vary and that the
numbers used in this example are for illustration purposes
only. Each receiving means has a coverage radius overlapping
20 that of at least an adjacent receiving means, as is
illustrated by the dotted circle, labeled 22, surrounding
receiving means R2. In the example illustrated in Figure 1,
patient A is in range of only receiving means, namely, R1.
However, patient B is in range of both receiving means R2 and
25 R3. Further, receiving means R3 is also receiving signals
from patients C, D, and E. Patient E is also in range of
receiving means R4. As a patient moves, his signal will pass
out of range of his original receiving means, and into range
of an adjacent receiving means, with some overlap.

30 ^[00032] System 10 of the present invention is designed so as to
handle patients within range of two or more receiving means at
one point and designed such that patient condition data from
multiple patients arriving at a single receiving means will
not interference with each other. The system is also designed
35 such that there is no loss of data or manual intervention as a

5 patient moves from one receiving means to the next.
Furthermore, transmission means 14 includes in the patient
condition data information relating to the patient identity,
since it is not known in advance where each patient's signal
will be received.

10 [00033] Some known telemetry systems, as heretofore discussed,
require bidirectional communication to manage the
communication process itself. For example, in some known
systems a central point sends a polling request to interrogate
each remote unit, which then responds with data, as a means of
15 allowing multiple devices to share a single channel. In order
to minimize power and complexity, the present system uses
unidirectional communications only, but at the expense of
losing some ability to manage the communication process.

[00034] The inventor of the present invention has successfully
20 designed a mobile patient monitoring system 10, employing a
uni-directional system, with minimal interference issues.
Interference is minimized by transmitting to central station
means 12 patient condition data, i.e. vital signs, rather than
the patient's physiological signal, i.e. ECG waveform.

25 Information is transmitted in short bursts, at low duty cycle,
to minimize interference, i.e. the chance that information
from different patients arrive at a single receiving means at
the same time. In contrast to ECG waveforms, the amount of
data associated with vital signs is small and changes slowly,
30 and thus, is amenable to short burst transmissions. Further,
given that vital signs, such as heart rate and rhythm, are
based on averaging information from several heart beats, and
thus do not change instantaneously, it is adequate to update
the data every second or two. This is in contrast to ECG
35 waveforms which need to be updated much more frequently to

5 maintain a smooth waveform. Note that occasional interference
of patient data does not significantly affect the monitoring
value of the present system because data updating is quite
redundant; that is, the loss of an occasional update does not
10 severely limit the value of the data, and adequate information
can be obtained by simply waiting for the next update. Given
this, it is not necessary to request that the lost data be
retransmitted.

[00035] In accordance with the above, present system 10 uses
multiple transmission means 14, which use the same channel but
15 without any coordination, i.e. they are variable in timing and
asynchronous. In other words, one patient transmission means
transmits bursts of data to receiving means without any
attempt to make sure that another transmission means is not
transmitting at the same time. While this may result in
20 occasional interference between competing transmission means
14, and therefore occasional loss of data, if the interference
is made sufficiently rare it is not objectionable.

[00036] Each cycle has an active phase in which energy modulated
with the patient condition data is emitted and a longer
25 inactive phase in which no energy is emitted. To avoid
overlap of the active periods, the duration of the active
phase should be less, and preferably much less, than the
period of a complete cycle divided by a predetermined maximum
number of transmission means anticipated to be within range of
30 any one receiving point at any one time. The shorter the
active phase is made, the less the probability of overlaps and
associated interference.

[00037] As indicated above, in order to minimize interference,
transmission means 14 sends updates as short bursts of data,
35 preferably lasting approximately 5 milliseconds with burst of

5 data at intervals averaging one second, with a random
variation. Thus, transmitter 20 is in an active phase only
about 0.5% of the time. If two such transmission means,
without any synchronization between them, are sharing a single
receiving means, there is a small probability that they will
10 occasionally interfere, with the result that they both lose
one update. However, because of the randomness of the time to
the next update, it is highly unlikely that they will lose the
next update as well. In the very unlikely event that this
happens, there is an even smaller, essentially negligible,
15 probability that this would happen a third time. Therefore,
the worst that could happen as a result of the mutual
interference of these unmanaged transmitters 20 is a rare
delay in the data update by a second or two at most. As more
similar transmission means are brought into range of this one
20 receiving means, the probability of interference increases,
but since the patient transmission means is designed with a
short range, it limits the number of transmission means 14
that can be within range of each receiving means, R1-R4, while
at the same time reducing power consumption.

25 (00038) Transmission means 14 operate on a duty cycle which is
determined by taking into consideration and optimizing the
following variables: (a) the amount of patient condition data
that must be transmitted; (b) the speed of the transmission;
(c) how often the patient condition data must be sent; (d) the
30 allowable number of transmission means that can be in range of
a receiving means at once; (e) the spacing of the receiving
means; (f) the acceptable rate of patient condition data loss;
(g) overhead associated with transmission of the burst of
patient condition data; and (h) the average depletion rate of
35 the data bursts.

5 (00039) The data to be transmitted preferably includes the
patient's rate and rhythm information, as well as a patient
identification, the technical status of the transmitter, and
error-checking information. The heart rate is a number in the
range of 0 to perhaps 300, and therefore can be represented in
10 9 bits of information. In addition to this, a few flags or
codes are desirable to indicate rhythm alarms. Therefore, the
patient heart rate and rhythm information will fit in two
bytes, or 16 bits. Allowing 3 bytes for the patient
identification provides over 16 million unique identifications
15 possible. The technical status needs only a few indicators
such as low battery or electrode faults, so one byte is
adequate. Finally, one byte can be used for error checking.
Therefore, a total of 7 bytes is transmitted by transmission
means 14.

20 (00040) A certain amount of time is required to power up and
stabilize transmission means RF transmitter 20, as well as to
shut it down. The above described data is framed in such a
way that receiving means, R1-R4, can synchronize to the burst
of data from transmission means 14 and extract individual data
25 fields. The data framing consist of two parts. The first is
the preamble, which contains some void data bytes during which
time receiving means, R1-R4, stabilize and synchronize on the
incoming data. This is followed by a header, which contains
an unambiguous marker of the start of the data. The header
30 function can be achieved in two bytes, and 4 bytes is a
reasonable length for the preamble, although this is strongly
dependent on the receiver technology adopted. Therefore, an
additional 6 bytes, plus the power up and power down time of
transmitter 20 are required.

5 [00041] Based upon the above, it is preferred that 13 bytes be
transmitted by transmission means 14. Although each byte
contains 8 bits of data, it actually requires 10 bits to
transmit in asynchronous format. The time this takes depends
10 on the data rate, and thus, on the transmission means
transmitter 20. One available commercial miniature
transmitter module has a maximum data rate of 115,200 bits per
second, and could send this data in 1.13 ms. However, higher
link reliability in the face of noise and interference can be
achieved by using less than the maximum data rate. Therefore,
15 as an example, if the data is sent at one quarter of this
rate, 4.51 ms is required. This same transmitter module takes
less than 50 μ s each to power up and down, making the total
transmitter "on" time 4.61 ms.

[00042] An interval of one update per second appears more than
20 adequate. For example, most bedside monitors only update
their numeric displays at 2-second intervals. Therefore, the
transmitter would operate at a duty cycle of 4.61 ms out of
every second, or about 0.5%. This duty cycle is low enough
that the other aspects of the compromise, relating to
25 interference, discussed above are not difficult to maintain.
Further, this very low duty cycle is promising from the
standpoint of battery life, since it means that very little
average power is required for the transmission means
transmitter 20. If more data were to be sent in each burst,
30 such as a rudimentary waveform, the duty cycle would become
greatly increased. For example, if an ECG waveform sampled at
100 points/second (corresponding to a poor recording) were to
be continuously sent, the duty cycle would increase to almost
4%. This would greatly increase the probability of
35 interference between transmitters 20, and lost data. However,

5 because the waveform is not as redundant as the simple
numerical data, the impact of occasional lost data is much
greater. Given the problems with transmitting full waveforms,
representative samples of waveform may be transmitted at
certain times. In particular, such a sample can be taken at
10 the time an alarm condition is detected.

[00043] Figure 2 illustrates a perspective view of the preferred
embodiment of the patient transmission means 14 which
comprises a subject portion 24 and a transmitter portion 26,
both of which are circumscribed by broken line boxes.

15 [00044] Subject portion 24 of transmission means 14 comprises
signal sensing means, such as ECG electrodes 16, a power
supply 28, patient identifier means 30 and a support 32
(Figure 2), which is preferably adhesive and disposable.

[00045] Power supply 28 may comprise a battery, for example,
20 lithium coin cells. These cells take the form of a flat disk,
similar in size to a stack of one or two quarters. Patient
identifier means 30 may comprise a device containing a
numerical identifier, or serial number, such as a memory
device, for example, a serial PROM. Since power supply 28 is
25 part of subject portion 24, a fresh power supply 28,
preferably a battery, is automatically provided for each
patient. The device is activated when transmitter portion 26
is attached to subject portion 24.

[00046] Figure 3 is a block diagram of transmission means 14
30 showing the internal parts of transmitter portion 26 and
subject portion 24.

[00047] Transmitter portion 26 is removably connected to subject
portion 24. The patient's ECG is picked up by electrodes 16,
passed through an amplifier 34 and into a computing means 18
35 and an analog-to-digital converter 36. Computing means 18 may

5 comprise a microprocessor, microcontroller, ASIC, or other
programmable logic. A number of electrical contacts 40 are
provided as part of subject portion 24 so that the reusable
transmitter portion 26 can be attached, mechanically as well
as electrically. Patient identifier means 30 is also
10 connected to computing means 18. Computing means 18 performs
an analysis and outputs patient condition data to RF
transmitter 20 which has an associated antenna 42 for
broadcasting the patient condition data, according to the
telemetry scheme outlined above.

15 [00048] ECG electrodes 16 are just a few inches apart on support
32. While this does not provide a conventional ECG vector
(for example, lead II), it does provide a signal that is
useful for basic rate and rhythm measurement. However, should
this signal be inadequate, there are modifications to the
20 structure that will allow a conventional electrode placement
to be used. For example, the second electrode could be
located remotely and connected by a wire to support 32.
However, the use of closely spaced electrodes on a single
support provides a desirable simplicity and a clean design.

25 [00049] Alternatively, subject portion 24 may be configured as a
belt wrapped around the chest. In this case, wider electrode
spacing, approximating a conventional Lead I ECG, is possible.

30 [00050] Patient identifier means 30 may comprise a tiny inexpensive
integrated circuit encoding a unique serial number and patient
ID for each support. Such devices are available commercially
with unique serial numbers already installed by the
manufacturer, such as the "Silicon Serial Number" made by
Dallas Semiconductor (Dallas, Texas). When the adhesive
support 32 is manufactured, the imbedded serial number
35 integrated circuit is interrogated, and a matching number is

5 printed on bar code label 33 attached to support 32 to
facilitate patient admission.

[00051] Off-the-shelf technology is available for RF transmitter
20. For example, RF Monolithics (Dallas, Texas) manufactures
very small RF transmitters that require only a few tiny
10 support components. Their TX6000 series measures nominally
7mm by 10mm by 2 mm, and incorporates the entire RF function
except for the antenna. Other manufacturers offer similar
products.

[00052] As indicated above, a microcontroller chip may be used for
15 transmitter portion computing means 18. These chips often
include an internal analog to digital converter of suitable
quality for acquiring the ECG signal. The chip should be
computationally powerful enough to analyze the rhythm of the
acquired patient ECG signal. While rhythm analysis is a
20 complex subject, in this case the primary goal is to reliably
identify lethal arrhythmias, in particular, those rhythms that
would be considered "shockable" by an automatic external
defibrillator (AED). Poor specificity between different
types of lethal arrhythmias is not of great concern, since the
25 response to any such arrhythmia is likely to be the same, the
dispatch of an intervention team. Algorithms far simpler than
those used for complete rhythm analysis can be used to
identify shockable rhythms, such that satisfactory rhythm
identification can be performed with a fairly simple and low
30 power microprocessor. In general, such simplified algorithms
concentrate on the timing of the heart beats, rather than the
details of their morphology. For example, the arrhythmias of
ventricular tachycardia and ventricular fibrillation may be
identified on the basis of high apparent heart rate, without
35 making an effort to distinguish between them on the basis of

5 waveform shape, as in both cases an alarm condition would be declared. Potential devices include various members of the PIC family made by Microchip (Chandler, Arizona), AVR devices made by Atmel (San Jose, California), and 430 series microcontrollers by Texas Instruments (Dallas, Texas).

10 (000531) Amplifier 34 used to receive the signal from electrodes 16 is much simpler than the circuits found in conventional monitors. Because the device is body-worn and has no interconnecting lead wires or cables, the 60Hz common mode rejection problems that challenge conventional monitors are

15 nonexistent. Much of the dynamic range of conventional ECG circuits is occupied by the need to accept, and later filter out, low frequency phenomenon, such as the DC offset voltage present at the electrodes and baseline wander. However, the ECG signal in the present system 10 is used primarily for rate

20 and rhythm analysis. The first operation performed in such analysis is often to severely high pass filter the ECG signal. For example, the rate-meter in many monitors utilizes an approximately 10 Hz high pass filter. If the amplifier is coupled to the ECG electrodes through capacitors, rather than

25 directly, this high pass filtering can be performed before the signal even enters the amplifier. In this way, none of the dynamic range of the amplifier is wasted on DC offsets and other low-frequency artifacts. Therefore, a very modest circuit is used for amplifier 34. Further, this arrangement

30 relieves the computing means 18 of the need to perform such filtering in software. Such a simplified amplifier can be constructed very compactly, using the highly miniaturized components available today. However, consideration is given to compatibility with patients having implanted pacemakers.

35 Additional electronics and signal processing is required to

5 identify and reject the pacemaker spikes, so that they do not interfere with the beat triggering.

[00054] In addition to the circuits shown on the block diagram, it is necessary to perform self-testing. In particular, the battery level must be monitored, the quality of the electrode contact verified, and all of the internal signal acquisition and processing functions checked. Analog to digital converter 36 embedded in computing means 18 has an input multiplexer (not shown) that allows it to also check the battery voltage. Computing means 18 can inject test currents into electrodes 16 to verify their impedance. Similarly, a test pulse can be injected into amplifier 34 to verify its gain. Various software checks can be used to verify the internal operation of computing means 18.

[00055] The average current consumption of each component is the product of its operating current and duty cycle. The following estimates assume a 3 volt lithium battery as the power source. RF transmitter 20 consumes $5\mu\text{A}$ on standby, and 12mA when active. The average active current is therefore 12mA times the 0.5% active duty cycle, or $60\mu\text{A}$. The average standby current is then $5\mu\text{A}$ times the 99.5% standby duty cycle, or nearly $5\mu\text{A}$. Amplifier 34 operates on a 100% duty cycle, with $250\mu\text{A}$ of current. Computing means 18, including internal analog to digital converter 36, consumes an average current of $600\mu\text{A}$. Patient identifier means 30 is disabled after it is initially interrogated, and therefore contributes nil to the average current consumption. The total average current consumption is the sum of these average figures, or $915\mu\text{A}$.

5 [00056] The power consumption estimate can be evaluated with
respect to the capacities of some typical batteries.
Inexpensive lithium coin cells are available with diameters in
the range of 20 to 23 mm, and thickness varying from 1.6 to
3.2 mm, according to capacity. All of these cells cost under
10 one dollar in quantity, with the least expensive being under
30 cents. Capacities range from 100 to 255 mA hours. Since
the estimated current of the device is just under 1 mA, run
times of 100 to 250 hours, or 4 to 10 days, are achievable
with these inexpensive batteries.

15 [00057] The range of patient transmission means 14 is on the order
of the size of a patient room or ward. Due to the short range
of patient transmission means 14, receiving means must be
placed at frequent intervals, such as in each room. The
function of the receiving means, R1-R4, is to collect the
20 patient condition data from any patient transmission means 14
within its range. This data is then merged with an identifier
of the receiving means location, and transmitted to central
station means 12.

[00058] The manufacturers of RF transmitter 20 also produce
25 complementary receiver modules, which may be used in the
receiving means. However, in the interests of achieving
higher performance, it is desirable to use a somewhat more
sophisticated receiver. In particular, it is desirable that
the receiver comprise a means for quantify the signal strength
30 of the received patient condition data, as this is helpful in
refining patient location when patient condition data is being
received by more than one receiving means. In addition to
considering signal strength, the phase or time of arrival of
the received patient condition data at multiple receiving
35 means can be used to refine the estimate of the transmission

5 means location, by well-known triangulation means.
Accordingly, it is preferred that the receiving means, R1-R4,
comprise a means for keeping track of the phase and/or time of
arrival of the received patient condition data.

10 (00059) Once the patient condition data has been received and
merged, it must be communicated to central station means 12.
Since many receiving means may be connected to a single
central station means 12, some type of networked link to
central station means 12 is desirable. This could be a wired
connection, such as Ethernet. However, due to the large
15 number of receiving means in some installations, the use of
wired connections may be costly, due to the expense of
installation of the wiring. In these cases, a second wireless
link, from the receiving means to the central station means,
is preferable. Wireless computer networking products are
20 commercially available and therefore satisfactory technology
is available off the shelf. These devices typically duplicate
the functionality of wired Ethernet via their wireless links.
An example is a 2.4 GHz network operating with IEEE 802.11
protocol, available as standard product from several
25 manufacturers. Since the receiving means can be operated from
the AC line, there are no special constraints regarding power
consumption.

30 (00060) The wireless network products are available as small
modules or cards that can be embedded into a product. In
addition to means for communicating with central station means
12, the receiving means R1-R4 may optionally also contain a
computing means, such as a microprocessor, which performs
error checking of the received data, appends the identifier of
the receiving means location and received signal strength
35 indicator, and controls the communication of this merged data

5 over the networked link to the central station. However, this
too is a physically small device, allowing the entire
receiving means to be made in a small enclosure self-supported
by prongs that fit into an AC outlet, similar to common power
adapter units. Therefore, installation is as simple as
10 plugging the receiving means into an outlet in each room.

[00061] Central station means 12 receives the patient condition
data from receiving means R1-R4, either by wire or wireless
network. Central station means 12 may consist of custom
software running on a PC, equipped with suitable commercial
15 wired or wireless network connectivity. Central station means
12 performs a first task of sorting the received patient
condition data, as data may have been acquired by more than
one receiving means. The incoming data is then analyzed in
two ways. The content of the data is analyzed for alarm
20 conditions. High and low rate alarms could be provided at the
central station means, although the detection of fatal
arrhythmias is preferably performed in the transmission means.
Second, the location of the receiving means receiving the
strongest patient condition data signal strength is noted,
25 providing the patient locator function. Associated with this
is an evaluation of the patient condition data signal quality
and monitoring of technical alarms, such as low battery, bad
electrode, etc. Central station 12 means also contains the
database that associates each patient's name with the
30 numerical identifier obtained from the support serial number
33.

[00062] If desired, central station means 12 may further comprise a
display for displaying the real time data for all patients,
and even log this to a patient trend database. Obviously, it
35 is possible to sound a local alarm, and indicate the patient

5 alarm condition and location on the unit's display. However,
the system may be more valuable if it also directly notifies a
response team. This can be done by an interface to a paging
system 44 (Figure 1). In the case of a paging system with
alphanumeric capability, patient location can be transmitted.
10 However, an interface to a voice pager or telephone system 46
(Figure 1) is also possible using speech synthesis or voice
messaging technology.

100063] Note again that the present invention is not limited to use
in monitoring patients in a hospital setting. Rather the
15 invention may be used to monitor conditions of any subject,
including animate and inanimate objects, in a defined area.
When monitoring the cardiac health of patients, the preferred
embodiment uses an ECG waveform as a subject or patient
signal; however, other signals indicative of the heart rate
and rhythm can be used. The ECG is a convenient signal that
20 may be acquired with high reliability and a minimum
expenditure of power. Similar information, however, can be
obtained from a plethysmographic signal. For example, a
photoplethysmograph sensor could be arranged to operate in the
25 reflectance mode, such that a plethysmographic signal is
obtained from the tissue beneath the device. This signal
would take the place of the ECG for rate and rhythm
monitoring. In this case, the device need not be applied over
the chest; it could be attached to any suitably perfused
30 tissue. Alternatively, the device could be configured to use
a more conventional transmission mode photoplethysmographic
sensor, which could be applied to a suitable appendage such as
the earlobe or finger. Similarly, the plethysmographic signal
could be obtained by known impedance methods, such as by

5 measuring the impedance of the tissue beneath the device by
 means of suitable electrodes.

[00064] Thus, it is understood, that while particular examples have
 been described it should be apparent to those skilled in the
 art that many modifications can be made without departing from
10 the scope and intent of the invention. Accordingly, the
 invention is not limited to the specific embodiments thereof
 except as defined in the appended claims.

5

CLAIMS

What is claimed is:

1. A monitoring system for monitoring each of a plurality of subjects, comprising:
one or more transmission means for acquiring and analyzing a
10 subject signal for subject condition and for transmitting
subject condition data resulting from the analysis, one or more
receiving means for receiving the subject condition data from
the transmission means and for communicating the subject
condition data to a central station means, said central station
15 means receiving and analyzing the subject condition data from
the receiving means.
2. The monitoring system as claimed in claim 1 wherein the
central station means alerts a user when content of the subject
condition data indicates a predetermined alert condition.
- 20 3. The monitoring system as claimed in claim 1 wherein a
plurality of transmission means operate on the same transmission
channel.
4. The monitoring system as claimed in claim 1 wherein a
plurality of the transmission means operate on an identical
25 transmission channel and wherein transmission from each
transmission means is comprised of cycles, each cycle having an
active phase in which energy modulated with the data is emitted
and a longer inactive phase in which no energy is emitted, the
duration of the active phase being less than the period of a
30 complete cycle divided by a predetermined maximum number of
transmission means.
5. The monitoring system as claimed in claim 4 wherein the
cycles are asynchronous.
6. The monitoring system as claimed in claim 4 wherein the
35 period of the cycles is variable.

- 5 7. The monitoring system as claimed in claim 1 wherein the subject is a patient and the subject signal comprises a physiological signal.
8. The monitoring system as claimed in claim 1 wherein the subject is a patient and the subject signal comprises an
10 electrocardiogram signal.
9. The monitoring system as claimed in claim 1 wherein the subject is a patient and the subject signal comprises an electrocardiogram signal and wherein at least a portion of the subject condition data resulting from the transmission means
15 analysis of the electrocardiogram signal comprises at least one patient vital sign.
10. The monitoring system as claimed in claim 9 wherein at least a portion of the transmission means analysis results comprise patient heart rate and rhythm.
- 20 11. The monitoring system as claimed in claim 1 wherein the transmission means comprises a subject portion and a transmitter portion, said subject portion receiving the subject signal from the subject, said transmitter portion releasably connected to the subject portion and communicating with the receiving means.
- 25 12. The monitoring system as claimed in claim 11 wherein the subject portion comprises a patient identifier means.
13. The monitoring system as claimed in claim 11 wherein the subject portion comprises a battery.
14. The monitoring system as claimed in claim 11 wherein the
30 subject portion comprises physiological signal sensing means.
15. The monitoring system as claimed in claim 11 wherein the subject portion comprises electrocardiogram electrodes.
16. The monitoring system as claimed in claim 11 wherein the transmitter portion comprises a computing means for analyzing
35 the subject signal and a transmitter.

5 17. The monitoring system as claimed in claim 1 wherein data communicated to the central station means from each receiving means includes receiver identification information.

18. The monitoring system as claimed in claim 1 wherein the subject condition data communicated to the central station means
10 from each receiving means includes receiver identification information, the central station means utilizing this receiver identification information to locate the subject.

19. The monitoring system as claimed in claim 1 wherein receiving means comprises means for measuring signal strength of
15 the subject condition data received from the transmission means and wherein the subject condition data communicated to the central station means from each receiving means includes receiver identification information and receiving means incoming signal strength, the central station means utilizing the
20 receiver identification information and the incoming signal strength to locate the subject.

20. The monitoring system as claimed in claim 1 wherein receiving means comprises means for measuring the time of arrival of the subject condition data received from the
25 transmission means and wherein the subject condition data communicated to the central station means from each receiving means includes receiver identification information time of arrival, the central station means utilizing the receiver identification information and time of arrival to locate the
30 subject.

21. The monitoring system as claimed in claim 1 wherein the central station means further comprises an interface to a phone or paging system.

22. The system as claimed in claim 4 wherein each receiving
35 means has a coverage area in which it is capable of receiving

5 subject condition data from transmitting means located within
said coverage area, the coverage area of each receiving means
overlaps that of immediately adjacent receiving means but does
not overlap the coverage area of less proximate receiving means.

23. A method for monitoring each of a plurality of subjects,
10 comprising the steps of:
acquiring a subject signal from each subject;
analyzing said subject signals for subject condition data;
transmitting subject condition data resulting from the analysis
to one or more receiving means;
15 transmitting the data from the receiving means to a central
station means;
analyzing the data from the receiving means at the central
station means; and
alerting a user when a subject is experiencing a predetermined
20 subject condition.

24. The method as claimed in claim 23 wherein the subject
condition data from each subject is transmitted on the same
transmission channel.

25. The method as claimed in claim 23 wherein the subject
25 condition data from each subject is transmitted on the same
transmission channel and is transmitted in cycles, each cycle
having an active phase in which energy modulated with the
subject condition data is emitted and a longer inactive phase in
which no energy is emitted, the duration of the active phase
30 being less than the period of a complete cycle divided by a
predetermined maximum number of subjects.

26. The method as claimed in claim 25 wherein the cycles are
asynchronous.

27. The method as claimed in claim 25 wherein the period of the
35 cycles is variable.

- 5 28. The method as claimed in claim 25 wherein the subject is a patient and the subject signal comprises a physiological signal.
29. The method as claimed in claim 25 wherein the subject is a patient and the subject signal comprises an electrocardiogram signal.
- 10 30. The method as claimed in claim 25 wherein the subject is a patient and the subject signal comprises an electrocardiogram signal and wherein at least a portion of the patient condition data resulting from the analysis of the electrocardiogram signal comprises at least one patient vital sign.
- 15 31. The method as claimed in claim 30 wherein at least a portion of the subject signal analysis results comprise patient heart rate and rhythm.
32. The method as claimed in claim 23 wherein each subject has a subject identifier and wherein said subject identifier is
- 20 transmitted to the receiving means and from the receiving means to the central station means.
33. The method as claimed in claim 23 wherein the transmission from the receiving means to the central station means includes receiver identification information and further comprising the
- 25 step of utilizing the receiver identification information to locate a subject.
34. The method as claimed in claim 23 further comprising the step of measuring time of arrival of the subject condition data received by each receiving means and utilizing the receiver
- 30 identification information and time of arrival to locate the subject.

FIGURE 1

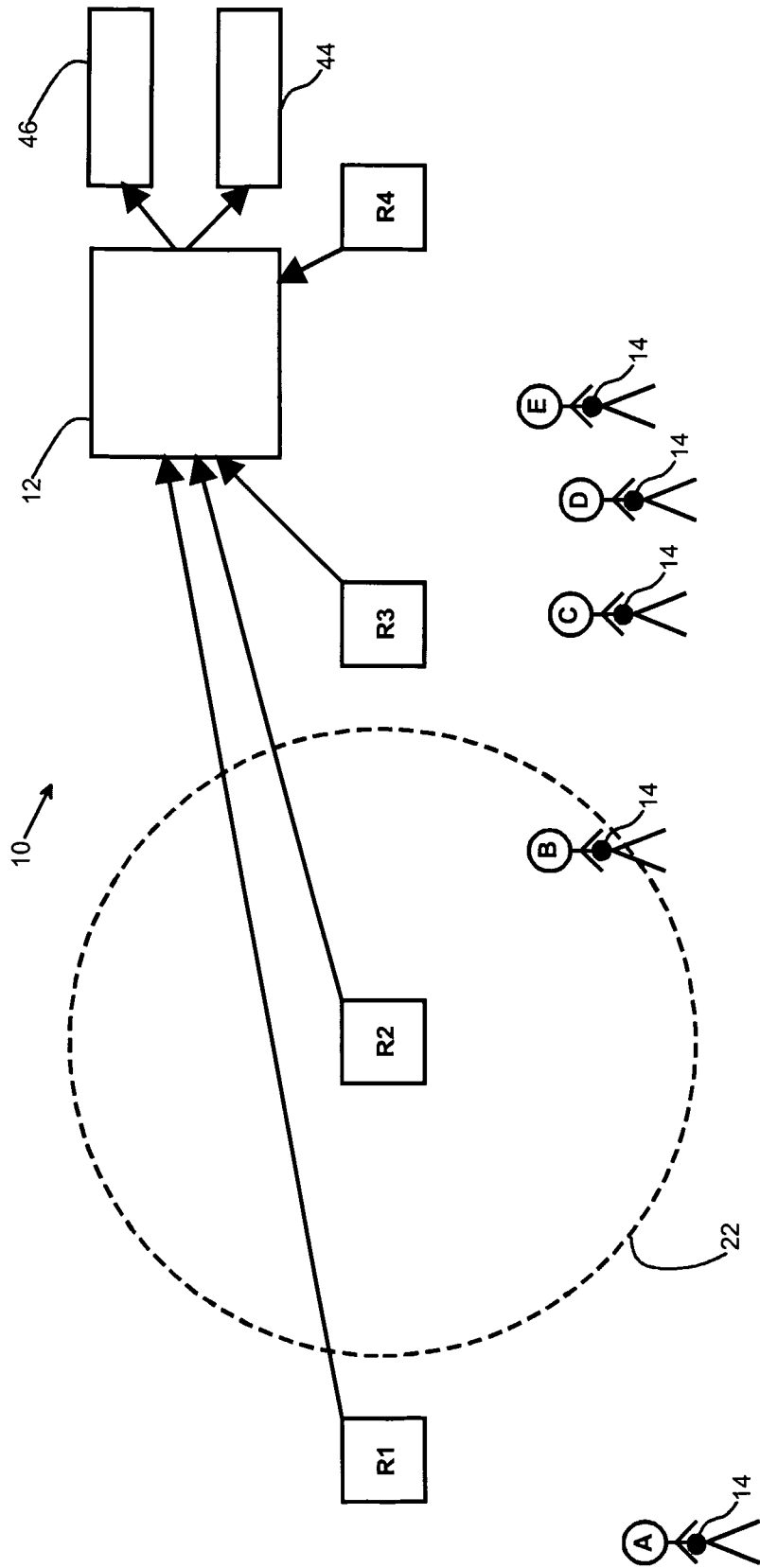


FIGURE 2

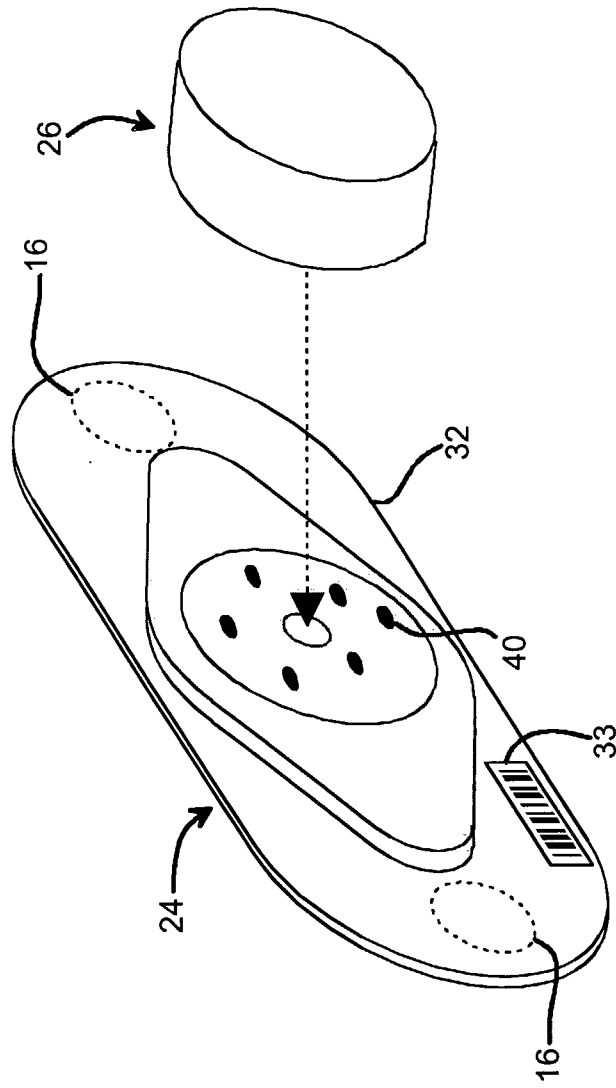
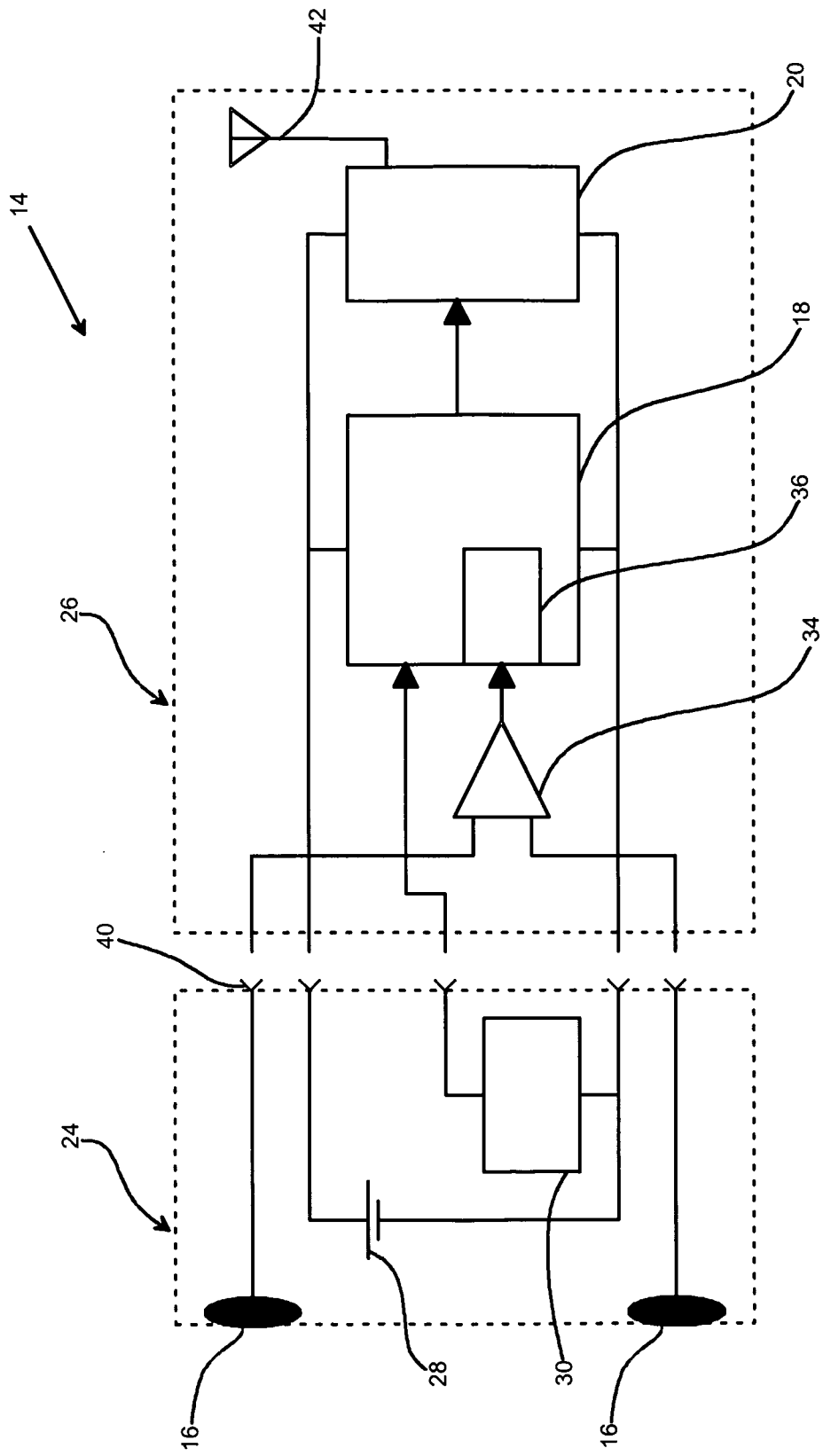


FIGURE 3



INTERNATIONAL SEARCH REPORT

International application No.

PCT/US02/23434

A. CLASSIFICATION OF SUBJECT MATTER		
IPC(7) : A61B 5/00 US CL : 600/300		
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) U.S. : 600/300-301, 509; 128/903-904, 920; 607/5, 32, 60		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched NONE		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) WEST 2.1		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X, P	US 6,405,083 B1 (ROCKWELL et al.) 11 JUNE 2002, see entire document	1-34
A, E	6,440,067 B1 (DELUCA et al.) 27 AUGUST 2002, see entire document	1, 23
A, P	6,289,238 B1 (BESSON et al.) 11 SEPTEMBER 2001, see entire document	1, 23
A	6,090,056 A (BYSTROM et al.) 18 JULY 2000, see entire document	1, 23
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> 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	"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	
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Date of the actual completion of the international search	Date of mailing of the international search report	
18 September 2002 (18.09.2002)	19 DEC 2002	
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摘要(译)

一种单向通信移动患者监测系统 (10) , 包括患者发射器 (14) , 接收器 (R1-R4) 和中央监测站 (12) 。发射器 (14) 分析患者的ECG信号并通过接收器 (R1-R4) 将心率和节律数据发送到中心站 (12) 。当生命体征超出预设范围时 , 中心站 (12) 向医院工作人员发出警报。