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(54) Title: ENHANCED WIRELESS COMMUNICATION FOR MEDICAL DEVICES

(57) Abstract: Methods and apparatuses for wireless communication between med-
ical devices (100, 120) are provided. In some embodiments, commodity low power,
low bandwidth communication protocols may be utilized to simultaneously convey
multiple signals with high fidelity and reliability. For example, cardiac sound data
and ECG data may be compressed using a common ADPCM component (330) and
inserted into a common BLE packet structure (200). Command-control data (220)
may also be inserted. Where required command-control data reporting frequency is
less than the packet frequency, header bits may be utilized to convey multiple types
of command-control data in a given packet byte position. Rolling packet sequence
values may be inserted into the common packet structure, for use by receiving de-
vices to identify link integrity failures.

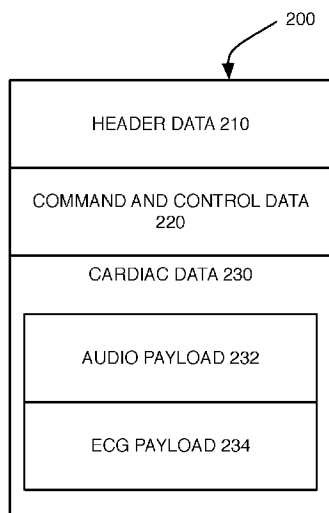


FIG. 2

Declarations under Rule 4.17:

- *as to the identity of the inventor (Rule 4.17(i))*
- *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*
- *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

Published:

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TITLE OF THE INVENTION

ENHANCED WIRELESS COMMUNICATION FOR MEDICAL DEVICES

TECHNICAL FIELD

5 **[0001]** The present disclosure relates to medical devices utilizing wireless electronic communications. More specifically, this disclosure relates to methods and apparatuses for enhancing wireless communications in medical device applications, such as wireless cardiac sensors.

BACKGROUND

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[0002] Use of wireless communications techniques for electronic devices is becoming increasingly popular. Wireless devices provide convenience and ease of use. Bluetooth has become particularly prevalent as a wireless communications protocol. It provides versatile mechanisms for transmitting digital signals over short distances with
15 very low power consumption. Bluetooth has become a ubiquitous standard amongst mobile phones, tablet computers, personal computers, wireless headphones, automobiles, and a wide variety of other device types. As a result, Bluetooth devices are readily interoperable with other electronic devices. Meanwhile, high production volumes result in ready availability and relatively low cost for transceiver chipsets and circuit
20 boards, further reinforcing the widespread adoption of the standard.

[0003] Bluetooth Low Energy ("BLE") is a subprotocol defined within the Bluetooth 4.0 protocol, that enables highly energy-efficient transfer of data between a client device (e.g. a sensor) and a server device (e.g. a mobile phone or personal computer). BLE can be particularly valuable for battery-operated devices, for which minimizing power
25 consumption may be critical.

[0004] While the prevalence of Bluetooth and power-efficiency of BLE provide many advantages, some device types, particularly in the context of medical instrumentation, give rise to communication requirements that may not be well-satisfied by standard Bluetooth implementations. For example, many types of instrumentation may require transmission of multiple signal types, which would traditionally be conveyed by multiple wires or multiple wireless radios. However, consumer electronic devices may be limited in the number of radios provided, while sensors with multiple radios may require greater power consumption, resulting in larger batteries and/or worse battery life. Meanwhile, BLE bandwidth limitations may impact sensor performance. For example, while humans can typically perceive sounds ranging from about 20 Hz to about 20 kHz, BLE as a protocol does not have enough bandwidth to transmit the entirety of the human audio spectrum, due to small packet size and slow packet speed. Traditional Bluetooth and BLE implementations may be particularly disadvantageous or limiting for medical devices such as wireless cardiac devices.

SUMMARY

[0005] Improved implementations of BLE-based wireless communication protocols can provide high levels of performance in wireless medical device applications, while still enabling use of commodity Bluetooth transceiver hardware and commodity host electronic devices.

[0006] In some embodiments, a method is provided for transmitting cardiac data from a wireless sensor to a host device. Cardiac sound data and ECG data are received at a wireless sensor, such as via onboard transducers digitizing audio and electrical signals sensed on a patient. The cardiac sound and ECG data can be filtered, such as via application of a digital lowpass filter to cardiac sound data to attenuate frequency components above approximately 2 kHz. The cardiac sound data and ECG data are compressed, such as through application of the data to an adaptive differential

compression component. In some embodiments, a common adaptive differential compression component can be applied to both the cardiac sound data and the ECG data. The compressed cardiac sound data and compressed ECG data can be combined into a common packet structure, and transmitted from the wireless sensor to the host device.

[0007] The common packet structure may also include command-control data. In embodiments where the packet frequency is greater than the required frequency of command-control data reporting, command-control data may include a header bit indicating one of multiple command-control data content types with which an associated command-control value is associated – thereby reducing the number of bits that must be allocated to command-control data within the packet structure.

[0008] The common packet structure may also include mechanisms to identify wireless communication link integrity problems. A packet sequence value, such as a rolling four-bit value, can be inserted into each packet by the transmitting device, such as a cardiac sensor. The receiving device, e.g. the host device, can decode the packet sequence value towards ensuring that sequentially-received packets have sequential packet sequence values. In the event that the receiving device identifies a gap in rolling packet sequence values, the receiving device may determine the existence of a failure of the wireless communication link integrity. Such a failure may then be conveyed to a user via, e.g., displaying a warning indicia on a host device user interface.

BRIEF DESCRIPTION OF THE FIGURES

[0009] Figure 1 is a schematic block diagram of a medical instrumentation environment including a wireless cardiac sensor and host device.

[0010] Figure 2 is a schematic block diagram of a wireless packet structure.

5 **[0011]** Figure 3 is a schematic block diagram of a cardiac signal processing chain.

DETAILED DESCRIPTION OF THE DRAWINGS

[0013] While this invention is susceptible to embodiment in many different forms, there are shown in the drawings and will be described in detail herein several specific embodiments, with the understanding that the present disclosure is to be considered as
5 an exemplification of the principles of the invention to enable any person skilled in the art to make and use the invention, and is not intended to limit the invention to the embodiments illustrated.

[0014] Techniques are described that can be used to effectively transmit medical device data, particularly heart diagnostic data, via a low-power, low-bandwidth wireless
10 communications protocol such as Bluetooth Low Energy. Several techniques described hereinbelow can be applied individually or in combination.

[0015] Figure 1 illustrates a typical operating environment in which embodiments can be employed. Cardiac sensor 100 is a wireless heart monitor capable of detecting multiple types of diagnostic data, including heart sounds and ECG electrical recordings.

15 Sensor 100 includes microprocessor 102 for processing and storing data from transducers 103 into memory 104. Sensor transducers 103 can include audio transducer 103A, for auscultation such as recording of heart sounds, and ECG transducer 103B, for monitoring of cardiac electrical activity. Bluetooth transceiver 105 is in operable communication with processor 102 in order to convey data to and from
20 remote electronic devices, such as host device 120. Battery 106 is a rechargeable battery supplying power to sensor 100. In order to maximize the duration between required charges, and minimize the size, weight and expense of sensor 100, sensor 100 is designed for low power consumption during operation.

[0016] Sensor 100 communicates via wireless data connection 110 with host device
25 120. Host device 120 may preferably be a standard, commodity mobile wireless computing device, such as a smartphone (e.g. Apple iPhone™), tablet computer (e.g.

Apple iPad™), or laptop computer. Host device 120 includes microprocessor 122 for processing and storing data. Bluetooth transceiver 123 enables wireless communication between processor 122 and external devices, such as sensor 100. Host device 120 further includes user interface components 124 (such as a touchscreen), memory 125
5 for data storage, and battery 126. While illustrated as a mobile device in the embodiment of Figure 1, in other embodiments, host device 120 could alternatively be selected from amongst other types of computing devices having a Bluetooth transceiver, such as a personal computer or a central sensor monitoring station.

[0017] The BLE protocol may be desirable for implementation of wireless

10 communications link 110, in order to minimize energy consumption during operation and therefore extend the battery life of sensor 100 and host device 120. However, BLE, as commonly implemented, presents significant limitations in a wireless cardiac sensor environment. One such limitation is bandwidth. Common mobile devices 120 have limitations in packet rate utilizing the BLE protocol for communications link 110. For
15 example, some mobile phones may have a theoretical minimum packet interval at which one BLE packet can be accepted every 5 milliseconds. Exacerbating this limitation is a need in medical applications for high data integrity and reliability. In such embodiments, it may not be desirable to potentially sacrifice data integrity and link reliability by requiring data transmission at or near theoretical maximum packet rates. While
20 decreasing packet rate may provide better packet interval operating margin, bandwidth constraints are even more limiting. With some common consumer mobile devices, it has been found that reliable BLE communications can be maintained sending packets at 8 ms intervals.

[0018] BLE also imposes packet size constraints. Moreover, regardless of protocol
25 constraints on packet size, it may be further desirable to reduce packet size in order to reduce power consumption. Meanwhile, in order to implement an effective wireless

cardiac sensor providing both auscultation and ECG data, packets will preferably accommodate multiple data streams, such as heart sound audio data from audio transducer 103A, ECG data from transducer 103B, and command-and-control data associated with the operation of cardiac sensor 100 and its interaction with host device

5 120. Packet efficiency may be critical to use of BLE in such environments.

[0019] Figure 2 illustrates an optimized BLE packet structure that may be utilized in communications from cardiac sensor 100 to host device 120. The packet structure of Figure 2 is optimized to convey multiple types of medical instrument and control data via a relatively low-bandwidth and low-power BLE communication link that can be reliably
10 received by standard smartphones, tablets or other consumer electronic devices. Specifically, the packet structure of Figure 2 conveys heart sounds, ECG data and command/control data simultaneously, with clinical fidelity, within a single BLE packet, using one standard BLE radio set.

[0020] Each packet 200 in Figure 2 is preferably formed having a byte length
15 provided for by BLE standards, and packet intervals preferably compatible with commodity BLE chipsets and computing devices. Such a data structure may provide an effective bitrate of approximately 20 kbps.

[0021] Packet 200 includes header bytes 210, command and control bytes 220, and cardiac data 230. In the illustrated embodiment, cardiac data 230 includes audio
20 payload 232 and ECG payload 234. Audio payload 232 is utilized for transmitting heart sound data recorded by audio transducer 103A. Figure 3 illustrates a schematic representation of cardiac signal processing components within cardiac sensor 100, which operate to generate data conveyed in the BLE packet structure of Figure 2. Audio sensor 300 converts an audio signal, such as cardiac auscultation, into an analog
25 electronic signal. Analog-to-digital converter (ADC) 310 samples the output of sensor 300 and generates a digital data stream 311. ADC 310 initially samples acoustic heart

sound signals at an approximately 4 kHz sample rate, with 16-bit samples, yielding a 64 kbps audio stream. Audio compression is applied by adaptive differential pulse-code modulation (ADPCM) encoder 330 to yield a 4-bit audio stream 332 at a 4 kHz rate (i.e. one 4-bit sample each .25 ms). Therefore, with an 8 ms packet interval, each packet
5 200 includes audio payload 232 having 32 4-bit audio samples.

[0022] Digital filters 320 can be applied to the output 311 of ADC 310 prior to ADPCM encoder 330 in order to reduce artifacts and distortion during the ADPCM compression process. In particular, filters 320 will include strong low-pass filters to eliminate or drastically attenuate high frequency components above the 2 kHz range. It
10 has been determined that frequency range limitations imposed by aggressive pre-filtering of cardiac auscultation sounds before ADPCM compression is preferable for purposes of human medical diagnostics, as compared to less aggressive filtering accompanied by potential introduction of compression noise and artifacts by ADPCM encoder 330.

[0023] Another advantage of the packet structure of Figure 2, particularly given limitations on packet interval in common smartphones and other mobile devices that may be utilized as host device 120, is that it combines heart sound and ECG data within a single BLE packet. Figure 3 further illustrates a schematic representation of an ECG data pipeline that may be implemented on cardiac sensor 100. In use, ECG sensors
20 340 are connected to a patient, and output electrical signals 341 indicative of a patient's cardiac electrical activity.

[0024] Cardiac electrical signals 341 are sampled by analog-to-digital converter 350. In an exemplary embodiment, ADC 350 may generate 16-bit samples at a 500 Hz sampling rate. This yields a digital ECG data stream 351 having a data rate of 8 kbps, to
25 which filter 360 may be applied. Utilizing an 8 ms BLE packet interval, ECG data stream 351 would therefore require 8 bytes within each BLE packet. However, given the

amount of packet 200 allocated to cardiac audio data, as described above, it may be desirable to compress the ECG data stream, provided the compression can be achieved without material negative impact on the ECG data fidelity.

[0025] It has been determined that the same ADPCM encoder 330 used to encode cardiac audio data, can also be effectively utilized to reduce ECG data bandwidth without significant negative impact on the ECG signal fidelity via strategic specification of sample rate. By selecting a 500 Hz sample rate, measurement differentials between adjacent samples in a typical digitized ECG signal are such that the ECG data stream may be effectively encoded by ADPCM encoder 330 to yield an encoded ECG data stream 334 that reduces the size of ECG payload 234. ~~This signal characteristic enables use of a 4-bit ADPCM encoder, generating four 4-bit samples per 8 ms. Therefore, ECG data may be conveyed in 2 bytes (i.e. byte positions 2 and 3) of the packet structure of Figure 2.~~

[0026] In some embodiments, audio sensor 300 and ADC 310 can be implemented within audio transducer 103A, ECG sensors 340 and ADC 350 can be implemented within ECG transducer 103B, with filter 320, filter 360 and encoder 330 being implemented by processor 102. In other embodiments, the elements of Figure 3 can be distributed differently amongst components such as audio transducer 103A, ECG transducer 103B, processor 102, custom ASICs, GPUs, or other components.

[0027] Bandwidth-efficient conveyance of command and/or control data (sometimes referred to as command-control data) may also be important in wireless cardiac sensor and other medical device applications. For command-control data of a nature that the acceptable reporting frequency is less than the packet frequency, it may be desirable for sequential packets to transmit different command-control data content types within the same packet bit positions. A header bit or bits may be utilized to indicate which of

multiple types of command-control data is conveyed within associated packet bit positions.

[0028] For example, in the context of a wireless cardiac sensor transmitting at an 8 ms packet interval, it may not be necessary to transmit certain command-control data, such as volume level or battery level, at 8 ms intervals. Longer intervals may be sufficient, while still ensuring users perceive a high level of responsiveness. Thus, in the packet structure of Figure 2, bits within header 210 can be utilized to convey one of multiple content types of command-control data. For example, a header bit may be utilized to indicate whether the data within command and control data 220 reflects a volume level or battery level. Depending on the number of bits required for sufficient command-control data value granularity, and the desired frequency of command-control data conveyance, in other embodiments, multiple header bits can be utilized to enable greater numbers of command-control data content types to be conveyed within a given packet byte position. For example, in another embodiment, two bits may be used to specify one of four different command-control data content types, with associated bit positions conveying an associated value. In some embodiments, header bits may be conveyed in different byte positions from associated command and control values within packet 200; in other embodiments, header bits and associated command and control values may be conveyed within the same byte position of packet 200, thereby intermixing header data 210 and command and control data 220.

[0029] Another important aspect of wireless communications in some medical applications is verifying link integrity. For high risk data such as heart sound and ECG data, it may be desirable for devices to rapidly and reliably alert the user when a data transmission quality problem arises. By effectively identifying data transmission issues, a user can promptly remedy equipment problems and ensure that anomalous results are attributed to instrumentation error rather than the patient being monitored. However,

traditional BLE protocols do not provide mechanisms to determine when packets are dropped.

[0030] Therefore, the packet of Figure 2 preferably includes a link integrity verification mechanism integrated within the packet structure. Predetermined bits within header 210 can be allocated to a rolling packet sequence indicator. When transmitted by cardiac sensor 100, processor 102 constructs consecutive packets to increment through a rolling multi-bit packet sequence value. The receiving device 120 can then decode the packet sequence value to verify that consecutive packets are received with sequentially incrementing packet sequence values. In the event that packet sequence values are not sequential in adjacent packets, receiving device 120 can determine that the integrity of link 110 has been compromised, and alert a user to the issue by, e.g., displaying an appropriate warning indicia on user interface 124. The embodiment of Figure 2 utilizes a rolling packet sequence value that is four bits in length, which in some embodiments may be an optimal tradeoff between minimizing failures to identify link integrity problems (for which longer sequence values are better), and minimizing power consumption and bandwidth attributed to the link integrity verification function (for which shorter sequence values are better).

[0031] The previous description of the disclosed embodiments is provided to enable any person skilled in the art to make or use the invention disclosed herein.

Various modifications to these embodiments will be readily apparent to those skilled in the art, and the generic principles defined herein may be applied to other embodiments without departing from the spirit or scope of the disclosure. Thus, the present disclosure is not intended to be limited to the embodiments shown herein but is to be accorded the widest scope consistent with the principles and novel features disclosed herein. All references cited herein are expressly incorporated by reference.

CLAIMS

What is claimed is:

1. A method for transmitting cardiac data from a wireless sensor to a host device, the method comprising:

5 digitizing cardiac sound data and ECG data received at the wireless sensor;
filtering the digitized cardiac sound data and ECG data;
compressing the cardiac sound data and the ECG data using an adaptive
differential compression component;
combining the compressed cardiac sound data and compressed ECG data into a
10 common packet structure; and
transmitting the common packet structure from the wireless sensor to the host
device via a Bluetooth Low Energy communications link.

2. The method of claim 1, in which the step of compressing the cardiac sound data
15 and ECG data comprises applying both the cardiac sound data and the ECG data to a
common adaptive differential pulse code modulation encoder.

3. The method of claim 2, in which the ECG data has a sample rate of
approximately 500 Hz.

20 4. The method of claim 3, in which the cardiac sound data has a sample rate of
approximately 4 kHz.

5. The method of claim 4, in which the step of filtering the digitized cardiac sound
25 data comprises applying a digital lowpass filter to attenuate frequency components
above 2 kHz.

6. The method of claim 1, in which the step of combining the compressed cardiac sound data and compressed ECG data into a common packet structure further comprises inserting command-control data into the common packet structure.

5

7. The method of claim 6, in which the command-control data has a reporting frequency lower than the packet frequency, wherein the step of inserting command-control data into the common packet structure comprises inserting a command-control comprising a command-control value and a header value, the header value indicative of
10 a content type with which the command-control value is associated.

8. The method of claim 1, in which the step of combining the compressed cardiac sound data and compressed ECG data into a common packet structure further comprises inserting a rolling packet sequence value into the common packet structure.

15

9. The method of claim 8, in which the rolling packet sequence value is four bits in length.

10. The method of claim 8, further comprising:

20 receiving by the host device sequential data packets having non-sequential rolling packet sequence values; and
displaying a warning indicia on a host device user interface.

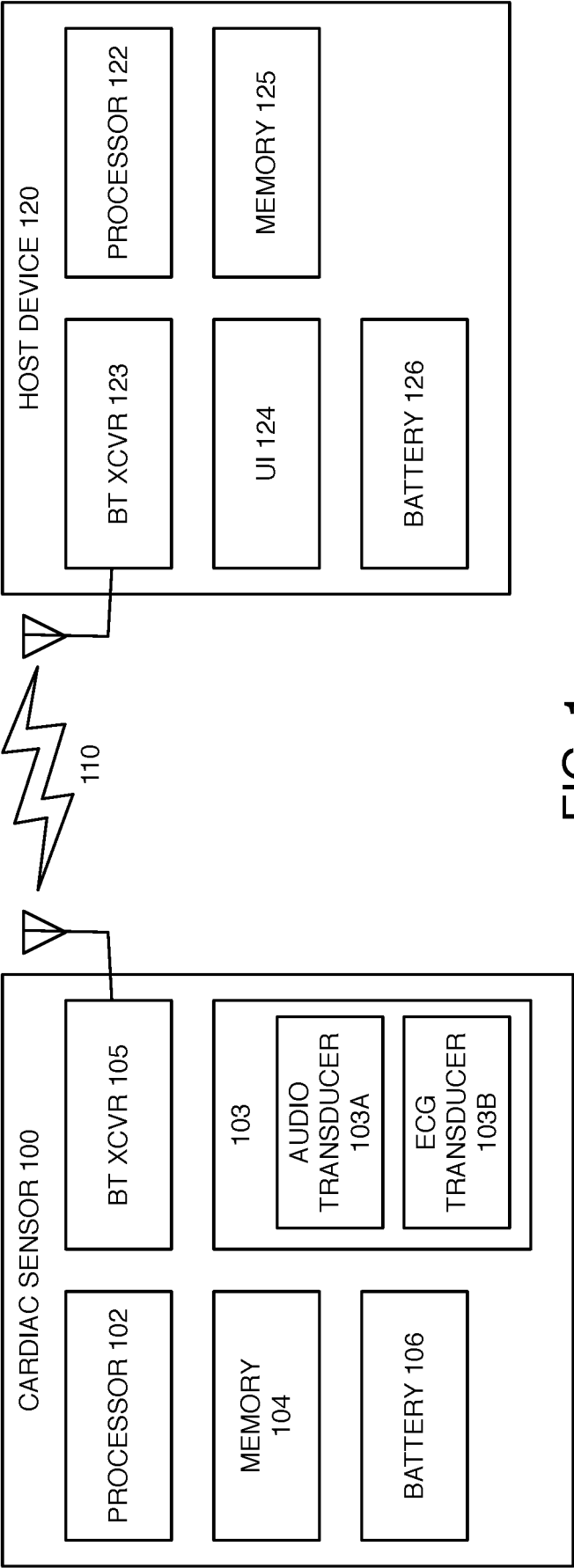


FIG. 1

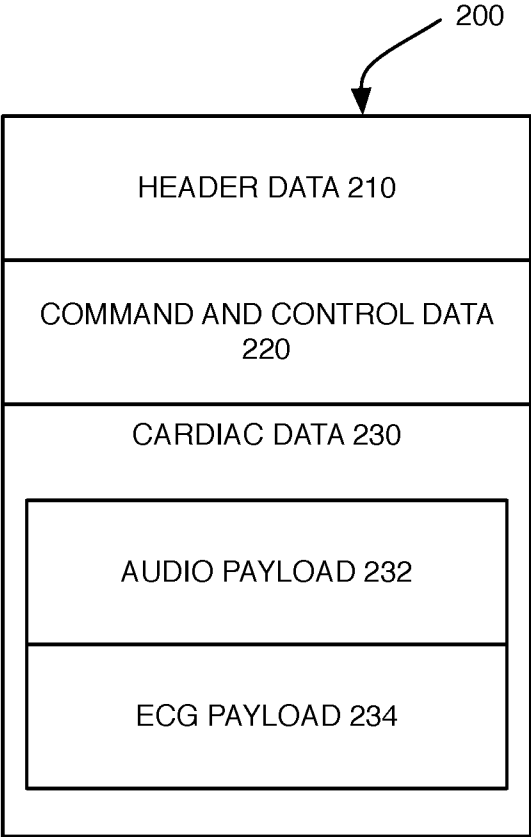


FIG. 2

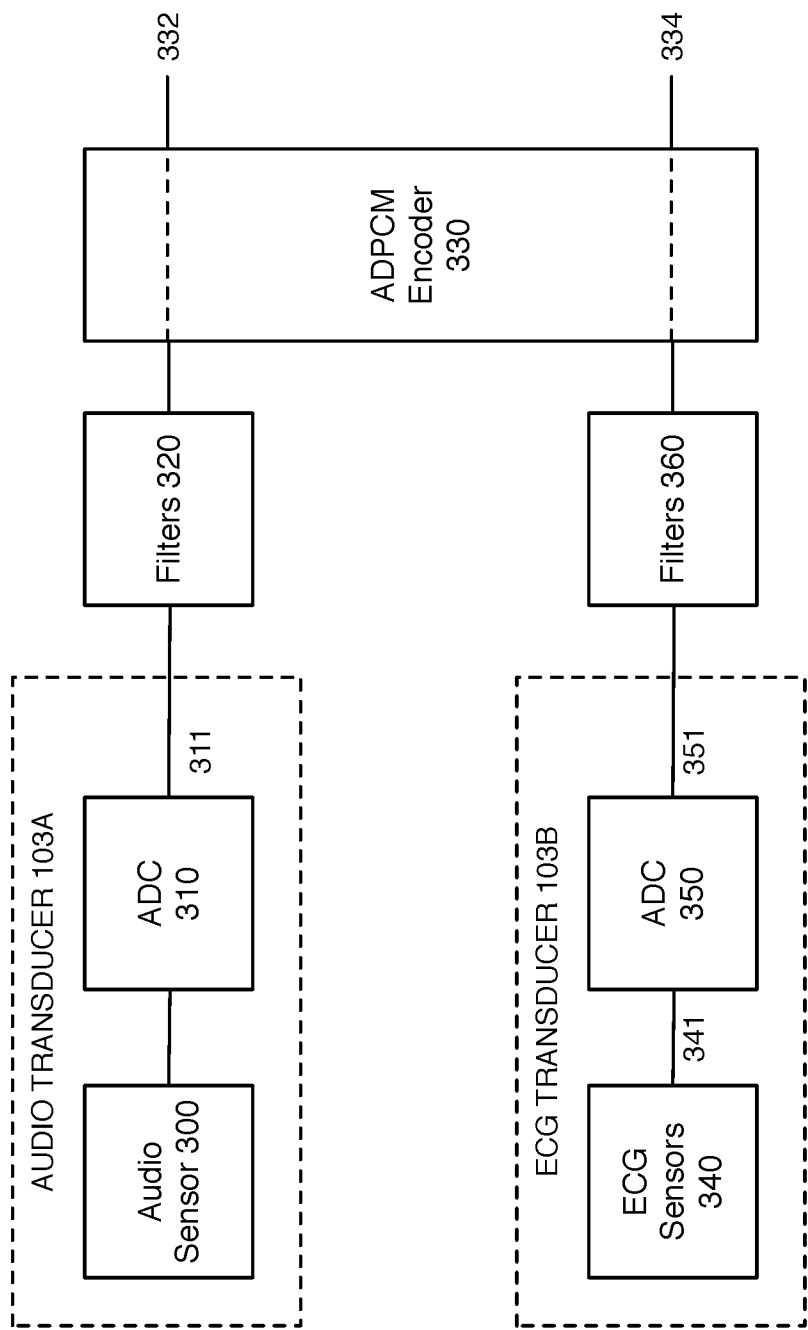


FIG. 3

INTERNATIONAL SEARCH REPORT		International application No. PCT/US17/67337		
A. CLASSIFICATION OF SUBJECT MATTER IPC: H04W 4/00 (2009.01); A61B 5/00 (2006.01), 5/04 (2006.01), 5/0402 (2006.01) CPC: H04W 1/7253, 84/18, 88/06, 2250/02, 76/02 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) CPC. : H04W 1/7253, 84/18, 88/06, 2250/02, 76/02				
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 practicable, search terms used)				
C. DOCUMENTS CONSIDERED TO BE RELEVANT				
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.		
A	US 2016/0144192 A1 (Sanghera et al.) 26+ May 2016, see entire document.	1-10		
A	US 2014/0328210 A1 (Knaappila) 06 November 2014, see entire document.	1-10		
A	US 2016/0014550 A1(CHIDDARWAR et al.) 14 January 2016, see entire document.	1-10		
A	US 2007/0208233 A1 (Kovacs) 06 September 2007, see entire document.	1-10		
☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.				
<table style="width: 100%; border: none;"> <tr> <td style="width: 50%; vertical-align: top;"> * 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 application or patent 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 </td> <td style="width: 50%; vertical-align: top;"> "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family </td> </tr> </table>			* 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 application or patent published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family
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Date of the actual completion of the international search 24 January 2018 (24.01.2018)		Date of mailing of the international search report 30 JAN 2018		
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-8300		Authorized officer Michael Horabik Telephone No. 571-272-4300		

专利名称(译)	用于医疗设备的增强型无线通信		
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申请号	EP2017884995	申请日	2017-12-19
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[标]发明人	LANDGRAF CONNOR GERSHTEIN EUGENE CROUCH TYLER		
发明人	LANDGRAF, CONNOR GERSHTEIN, EUGENE CROUCH, TYLER		
IPC分类号	H04W4/00 A61B5/00 A61B5/04 A61B5/0402		
CPC分类号	A61B5/0006 A61B7/00 G16H40/63 G16H40/67 H04W4/38 H04W4/80 Y02D70/144 A61B5/002 A61B5/04017 A61B5/0402 H04W4/70		
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其他公开文献	EP3560219A4		
外部链接	Espacenet		

摘要(译)

提供了用于医疗设备 (100,120) 之间的无线通信的方法和装置。在一些实施例中, 可以利用商品低功率, 低带宽通信协议来以高保真度和可靠性同时传送多个信号。例如, 心脏声音数据和ECG数据可以使用公共ADPCM组件 (330) 压缩并插入到公共BLE分组结构 (200) 中。还可以插入命令控制数据 (220)。在所需的命令控制数据报告频率小于分组频率的情况下, 可以利用报头比特在给定的分组字节位置中传送多种类型的命令控制数据。可以将滚动分组序列值插入到公共分组结构中, 以供接收设备使用以识别链路完整性故障。