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Landgraf et al.(10) **Pub. No.: US 2018/0324568 A1**(43) **Pub. Date: Nov. 8, 2018**(54) **ENHANCED WIRELESS COMMUNICATION
FOR MEDICAL DEVICES**(71) Applicant: **Eko Devices, Inc.**, Berkeley, CA (US)(72) Inventors: **Connor Landgraf**, San Francisco, CA
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Francisco, CA (US)(73) Assignee: **Eko Devices, Inc.**(21) Appl. No.: **16/020,054**(22) Filed: **Jun. 27, 2018****Related U.S. Application Data**(63) Continuation of application No. PCT/US2017/
067337, filed on Dec. 19, 2017, which is a continu-
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A61B 5/04 (2006.01)**A61B 5/00** (2006.01)**H04W 4/38** (2018.01)**H04W 4/70** (2018.01)**G16H 40/63** (2018.01)(52) **U.S. Cl.**CPC **H04W 4/80** (2018.02); **A61B 7/00**
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(2018.01); **A61B 5/002** (2013.01)(57) **ABSTRACT**

Methods and apparatuses for wireless communication between medical devices 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 and inserted into a common BLE packet structure. Command-control data 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 devices to identify link integrity failures.

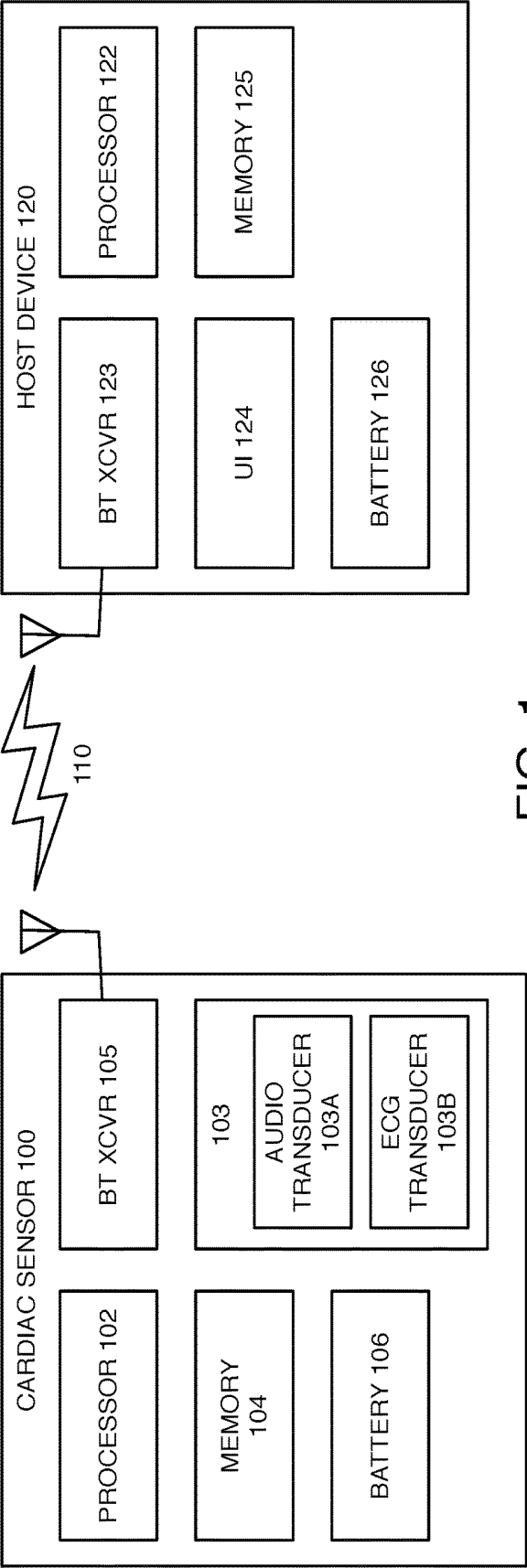


FIG. 1

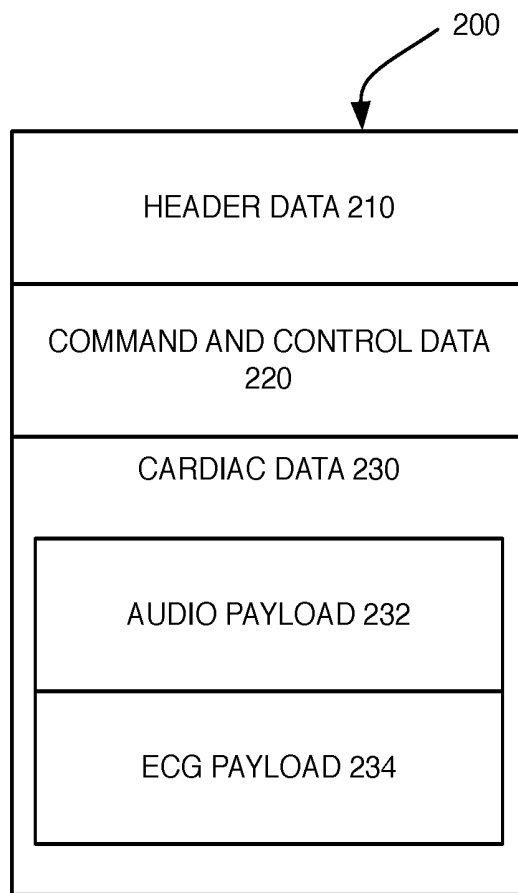


FIG. 2

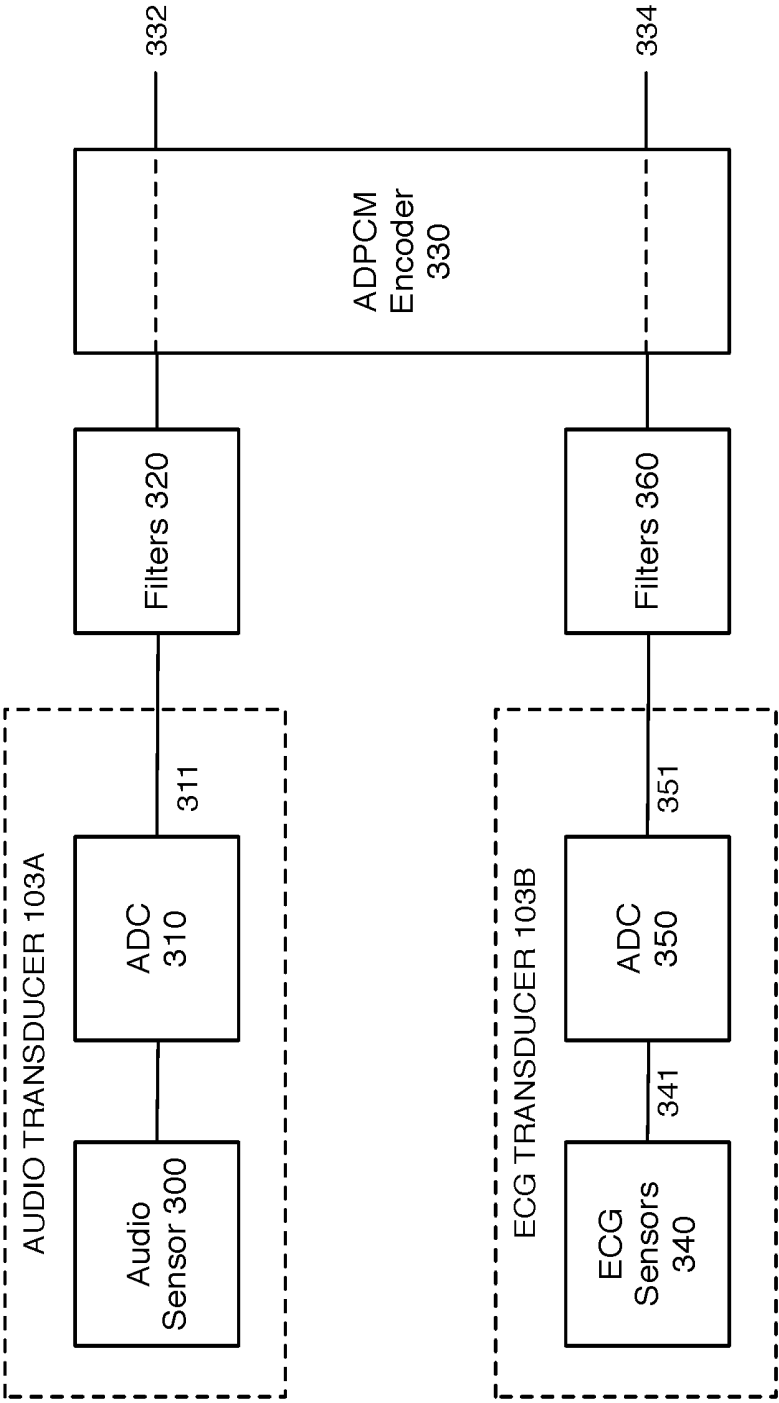


FIG. 3

ENHANCED WIRELESS COMMUNICATION FOR MEDICAL DEVICES

TECHNICAL FIELD

[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

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

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

[0011] FIG. 3 is a schematic block diagram of a cardiac signal processing chain.

DETAILED DESCRIPTION OF THE DRAWINGS

[0012] 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 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.

[0013] Techniques are described that can be used to effectively transmit medical device data, particularly heart diagnostic data, via a low-power, low-bandwidth wireless communications protocol such as Bluetooth Low Energy. Several techniques described hereinbelow can be applied individually or in combination.

[0014] FIG. 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. 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 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.

[0015] Sensor **100** communicates via wireless data connection **110** with host device **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** for data storage, and battery **126**. While illustrated as a mobile device in the embodiment of FIG. 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.

[0016] The BLE protocol may be desirable for implementation of wireless 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 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 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.

[0017] BLE also imposes packet size constraints. Moreover, regardless of protocol 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 **120**. Packet efficiency may be critical to use of BLE in such environments.

[0018] FIG. 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 FIG. 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 received by standard smartphones, tablets or other consumer electronic devices. Specifically, the packet structure of FIG. 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.

[0019] Each packet **200** in FIG. 2 is preferably formed having a byte length 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.

[0020] Packet **200** includes header bytes **210**, command and control bytes **220**, and cardiac data **230**. In the illustrated embodiment, cardiac data **230** includes audio payload **232** and ECG payload **234**. Audio payload **232** is utilized for transmitting heart sound data recorded by audio transducer **103A**. FIG. 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 FIG. 2. Audio sensor **300** converts an audio signal, such as cardiac auscultation, into an analog 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 0.25 ms). Therefore, with an 8 ms packet interval, each packet **200** includes audio payload **232** having 32 4-bit audio samples.

[0021] 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 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**.

[0022] Another advantage of the packet structure of FIG. 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. FIG. 3 further illustrates a schematic representation of an ECG data pipeline that may be implemented on cardiac sensor **100**. In use, ECG sensors **340** are connected to a patient, and output electrical signals **341** indicative of a patient's cardiac electrical activity.

[0023] 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 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.

[0024] 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.

[0025] 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 FIG. 3 can be distributed differently amongst components such as audio transducer 103A, ECG transducer 103B, processor 102, custom ASICs, GPUs, or other components.

[0026] 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.

[0027] 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 FIG. 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.

[0028] 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.

[0029] Therefore, the packet of FIG. 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 FIG. 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).

[0030] 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.

1. A method for collecting diagnostic data from a heart of a subject, comprising:

- (a) using a monitoring device comprising an ECG sensor and an audio sensor to measure ECG data and audio data from said heart of said subject;
- (b) transmitting said ECG data and audio data wirelessly to a computing device separate from said monitoring device; and
- (c) using said computing device to process said ECG data and audio data to provide an output indicative of said state or condition of said heart of said subject.

2. The method of claim 1, further comprising, prior to (b), compressing said ECG data and said audio data.

3. The method of claim 1, further comprising, prior to (b), filtering said ECG data and said audio data.

4. The method of claim 3, wherein said filtering comprises attenuating frequency components above 2 kHz.

5. The method of claim 1, further comprising (i) determining that a wireless communication link between said computing device and said monitoring device has been compromised, and (ii) displaying a warning on a user interface of said computing device, which warning is indicative of a compromise in said wireless communication link.

6. The method of claim 1, further comprising, prior to (b), using said ECG data and said audio data to generate a common packet structure.

7. The method of claim 6, further comprising inserting a rolling packet sequence into said common packet structure.

8. The method of claim 7, further comprising (i) receiving at said computing device a sequential data packet having a non-sequential rolling packet sequence, and (ii) displaying a warning on a user interface of said computing device, which warning is indicative of a compromise in a wireless communication link between said monitoring device and said computing device.

9. The method of claim 6, wherein said common packet structure comprises command-control data.

10. The method of claim 9, wherein said command-control data is present at a reporting frequency that is lower than a data packet frequency corresponding to said ECG data and/or said audio data.

11. The method of claim 9, wherein said command-control data comprises a header value indicative of a content type of said command-control data.

12. The method of claim 1, wherein said ECG data and said audio data are transmitted from said monitoring device to said computing device via radio frequency communication.

13. The method of claim 1, wherein said ECG data and said audio data are transmitted from said monitoring device to said computing device via a Bluetooth Low Energy communications link.

14. The method of claim 1, further comprising storing said ECG data and said audio data on said monitoring device.

15. The method of claim 1, further comprising identifying a data transmission issue with transmitting said ECG data and said audio data to said computing device.

16. The method of claim 1, wherein said computing device is a mobile computing device.

* * * * *

专利名称(译)	增强医疗设备的无线通信		
公开(公告)号	US20180324568A1	公开(公告)日	2018-11-08
申请号	US16/020054	申请日	2018-06-27
[标]申请(专利权)人(译)	EKO DEVICES		
申请(专利权)人(译)	EKO DEVICES , INC.		
当前申请(专利权)人(译)	EKO DEVICES , INC.		
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发明人	LANDGRAF, CONNOR GERSHTEIN, EUGENE CROUCH, TYLER		
IPC分类号	H04W4/80 A61B7/00 A61B5/0402 A61B5/04 A61B5/00 H04W4/38 H04W4/70 G16H40/63		
CPC分类号	H04W4/70 A61B7/00 A61B5/0402 A61B5/002 A61B5/04017 A61B5/0006 H04W4/38 Y02D70/144 H04W4/80 G16H40/63 G16H40/67		
其他公开文献	US10362467		
外部链接	Espacenet USPTO		

摘要(译)

提供了用于医疗设备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，可以使用公共ADPCM组件来压缩心脏声音数据和ECG数据，并将其插入到公共BLE分组结构中。还可以插入命令控制数据。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。

