(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
5 October 2017 (05.10.2017)

WIPO | PCT

(10) International Publication Number
WO 2017/170177 A1

(51) International Patent Classification:
A61B 5/00 (2006.01) *A61B 5/0452* (2006.01)
A61B 5/0432 (2006.01) *A61B 5/0404* (2006.01)

(21) International Application Number:
PCT/JP2017/011865

(22) International Filing Date:
23 March 2017 (23.03.2017)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
2016-065565 29 March 2016 (29.03.2016) JP

(71) Applicant: **NIHON KOHDEN CORPORATION** [JP/JP]; 31-4, Nishiochiai 1-chome, Shinjuku-ku, Tokyo, 1618560 (JP).

(72) Inventors: **ONO Yoshinobu**; c/o NIHON KOHDEN CORPORATION, 31-4, Nishiochiai 1-chome, Shinjuku-ku, Tokyo, 1618560 (JP). **TAKAYANAGI Tsuneo**; c/o NIHON KOHDEN CORPORATION, 31-4, Nishiochiai 1-chome, Shinjuku-ku, Tokyo, 1618560 (JP).

(74) Agent: **SHIN-EI PATENT FIRM, P.C.**; Toranomon East Bldg. 8F, 7-13, Nishi-Shimbashi 1-chome, Minato-ku, Tokyo, 1050003 (JP).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

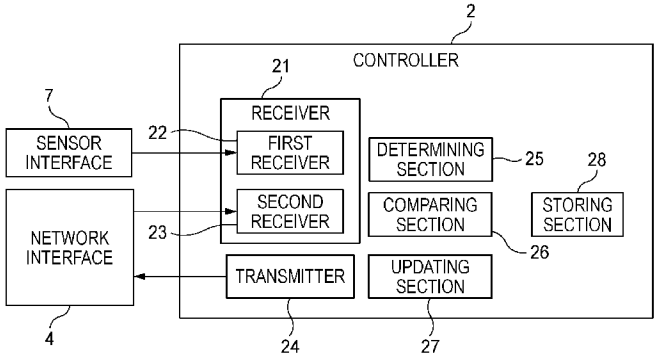
(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

(54) Title: ELECTROCARDIOGRAM RECORDING DEVICE AND ELECTROCARDIOGRAM ANALYSIS METHOD

FIG.2



(57) Abstract: An electrocardiogram recording device, includes: a first receiver (21) configured to receive in real time electrocardiogram waveform data from an electrode attached to a patient, a transmitter (24) configured to transmit a portion of the received electrocardiogram waveform data to an external apparatus; a second receiver (22) configured to receive electrocardiogram analysis information from the external apparatus; a storing section (28) configured to store the electrocardiogram waveform data and the electrocardiogram analysis information; a comparing section (26) configured to compare each of the plurality of electrocardiogram waveforms indicated by the electrocardiogram waveform data, with the electrocardiogram analysis information; and an updating section (27) configured to update the electrocardiogram analysis information stored in the storing section, based on new electrocardiogram analysis information received by the second receiver, in a state where the electrode remains to be attached to the patient.

WO 2017/170177 A1

Description

Title of Invention: ELECTROCARDIOGRAM RECORDING DEVICE AND ELECTROCARDIOGRAM ANALYSIS METHOD

Technical Field

[0001] The present disclosure relates to an electrocardiogram recording device and an electrocardiogram analysis method. The present disclosure also relates to an electrocardiogram analysis program and a computer readable medium storing the electrocardiogram analysis program. The present disclosure further relates to an electrocardiogram analysis system which includes an electrocardiogram recording device and an external apparatus.

Background

[0002] A portable electrocardiogram (hereinafter, "electrocardiogram" is often abbreviated as ECG) recorder such as an ECG event recorder or an ECG Holter recorder not only acquires in real time ECG waveform data of a patient to whom the portable ECG recording device is attached, but also has a function of analyzing the ECG waveform data. By contrast, such a portable ECG recording device has a restriction that a sophisticated computer (such as a sophisticated microcomputer) which can perform a complicated calculation process cannot be mounted on the recorder from viewpoints of the production cost, the size of the recorder, the lifetime of a battery, and the like.

[0003] On the other hand, in order to determine a reference ECG waveform (reference heartbeat waveform) of one cycle (one beat) which is obtained by performing a calculation process on a plurality of ECG waveforms (heartbeat waveforms) that continuously appear on the time axis, the calculation process must be performed in a very complicated manner. Because of the above-described restriction and the like, therefore, it is very difficult to, in the portable ECG recording device, determine a reference ECG waveform from ECG waveform data.

[0004] According to disclosure of JP-A-2014-54391, a reference ECG waveform is determined by an electrocardiograph and a work station (WS), and the determined reference ECG waveform is stored in a Holter electrocardiograph which can be taken out. Thereafter, ECG waveforms acquired by the Holter electrocardiograph are compared with the reference ECG waveform, whereby an abnormality (for example, detection of arrhythmia) of the heart of a patient to whom the Holter electrocardiograph is attached can be detected.

Summary

[0005] In the technique disclosed in JP-A-2014-54391, however, positions at which electrodes connected to the electrocardiograph are respectively attached cannot be

made strictly coincident with those at which electrodes connected to the Holter electrocardiograph are respectively attached. Usually, the electrocardiograph and the Holter electrocardiograph are not configured by identical apparatuses. Moreover, timings when the plurality of ECG waveforms are acquired by the electrocardiograph are different from those when the plurality of ECG waveforms are acquired by the Holter electrocardiograph.

[0006] In view of the above-mentioned points, the reference ECG waveform which is determined by the work station is different from that which would be obtained by performing a calculation process on the plurality of ECG waveforms acquired by the Holter electrocardiograph. Therefore, the reliability of the reference ECG waveform which is determined by the work station is reduced, and hence the accuracy of analysis of a plurality of ECG waveforms acquired by the Holter electrocardiograph is lowered.

[0007] Furthermore, ECG waveforms which are acquired in real time vary with time. Therefore, the accuracy of analysis of ECG waveform data by using the reference ECG waveform which is determined by the work station is lowered with time.

[0008] An aspect of the present disclosure provides an electrocardiogram recording device, an electrocardiogram analysis method, and an electrocardiogram analysis program, in which the accuracy of analysis of ECG waveform data can be improved even when a sophisticated computer or the like is not used. Another aspect of the present disclosure provides a computer-readable medium causing a computer to perform the electrocardiogram analysis method. Another object of the invention provides an electrocardiogram analysis system which includes the electrocardiogram recording device and an external apparatus.

[0009] According to a first aspect of the present disclosure, there is provided an electrocardiogram recording device, comprising:

a first receiver configured to receive in real time electrocardiogram waveform data from an electrode attached to a patient, wherein the electrocardiogram waveform data indicates a plurality of electrocardiogram waveforms which are continuously generated on a time axis;

a transmitter configured to transmit a portion of the received electrocardiogram waveform data to an external apparatus;

a second receiver configured to receive electrocardiogram analysis information from the external apparatus;

a storing section configured to store the electrocardiogram waveform data and the electrocardiogram analysis information;

a comparing section configured to compare each of the plurality of electrocardiogram waveforms indicated by the electrocardiogram waveform data, with the electrocardiogram analysis information; and

an updating section configured to update the electrocardiogram analysis information stored in the storing section, based on new electrocardiogram analysis information received by the second receiver, in a state where the electrode remains to be attached to the patient.

[0010] According to a second aspect of the present disclosure, there is provided a method performed by a computer, comprising:

a) receiving in real time electrocardiogram waveform data from an electrode attached to a patient, wherein the electrocardiogram waveform data indicates a plurality of electrocardiogram waveforms which are continuously generated on a time axis;

b) transmitting a portion of the received electrocardiogram waveform data to an external apparatus;

c) receiving electrocardiogram analysis information from the external apparatus;

d) storing the electrocardiogram waveform data and the electrocardiogram analysis information;

e) comparing each of the plurality of electrocardiogram waveforms indicated by the electrocardiogram waveform data, with the electrocardiogram analysis information; and

f) updating the stored electrocardiogram analysis information, based on new electrocardiogram analysis information, in a state where the electrode remains to be attached to the patient.

[0011] According to a third aspect of the present disclosure, there is provided a program causing a computer to perform the method.

[0012] According to a fourth aspect of the present disclosure, there is provided a computer-readable medium storing the program.

[0013] According to a fifth aspect of the present disclosure, there is provided a system comprising: the electrocardiogram recording device; and an external apparatus configured to generate electrocardiogram analysis information by analyzing a portion of the electrocardiogram waveform data received from the electrocardiogram recording device.

Brief Description of Drawings

[0014] [fig.1]Fig. 1 illustrates an ECG analysis system including an ECG recording device of an embodiment of the invention.

[fig.2]Fig. 2 illustrates functional blocks of a controller of the ECG recording device.

[fig.3]Fig. 3 is a sequence diagram illustrating an ECG analysis method using the ECG recording device.

Description of Embodiments

[0015] Hereinafter, an embodiment of the invention will be described with reference to the

drawings. The description of components denoted by the same reference numerals which are identical with those designating components that have been described in the embodiment will be omitted for the sake of convenience of description.

[0016] Fig. 1 illustrates an ECG analysis system 100 including an ECG recording device 1 of the embodiment of the invention (hereinafter, referred to merely as "the embodiment"), an external apparatus 10, and an external server 30. As shown in Fig. 1, the ECG recording device 1 (hereinafter, referred to merely as "recording device 1") is a portable ECG recording device which is to be carried by a patient P, such as an ECG event recorder or an ECG Holter recorder. It should be noted that, in Fig. 1, the recording device 1 is illustrated in an enlarged manner relative to the patient P for the sake of convenience of description, and the recording device 1 is carried by the patient P. The recording device 1 includes a controller 2, a storage device 3, a network interface 4, a displaying section 5, an input operating section 6, and a sensor interface 7. The components are communicably connected to one another through a bus 8.

[0017] The controller 2 includes a memory and a processor. The memory is configured by, for example, a read only memory (ROM) which stores various programs and the like, and a random access memory (RAM) having a plurality of work areas in which programs to be executed by the processor are to be stored. For example, the processor is a central processing unit (CPU), and configured to develop designated one of the various programs stored in the ROM, on the RAM, and cooperate with the RAM to execute various processes.

[0018] Particularly, the processor may develop an ECG analysis program which will be described later, on the RAM, and cooperate with the RAM to execute the program, thereby causing the controller 2 to control various operations of the recording device 1. The controller 2 and the ECG analysis program will be described later in detail.

[0019] The storage device 3 is a storage device such as a USB flash memory or an SD card, and configured to store programs and various data. The ECG analysis program may be installed in the storage device 3. Furthermore, comparison result data (comparison result) which are obtained by a comparing section 26 that will be described later, and reference ECG waveform data (reference electrocardiograph waveform) which is acquired from the external apparatus 10 may be stored in the storage device 3.

[0020] The network interface 4 is configured to connect the recording device 1 to a communication network (not shown). The communication network is a local area network (LAN), a wide area network (WAN), the Internet, or the like. For example, the ECG analysis program may be acquired from a computer located on the communication network through the network interface 4. Data stored in the recording device 1 may be wirelessly transmitted to the external server 30 which is located on the communication network, through the network interface 4.

[0021] The displaying section 5 is a display device such as a liquid crystal display (LCD) or an organic EL display (OELD), and configured to display (visualize) in real time a plurality of ECG waveforms (heartbeat waveforms) which are continuously generated on the time axis, based on ECG waveform data that are acquired in real time through the sensor interface 7. The displaying section 5 may not be disposed in the recording device 1.

[0022] The input operating section 6 is configured to receive an input operation performed by the operator who operates the recording device 1, and generate an instruction signal corresponding to the input operation. For example, the input operating section 6 is a touch panel which is overlaid on the displaying section 5, operation buttons which are attached to a housing, event switches, or the like. The input operating section 6 receives an input operation such as that for starting acquisition of ECG waveform data or that for switching displayed waveforms, and generates an instruction signal corresponding to the input operation. The generated instruction signal is transmitted to the controller 2 through the bus 8. The controller 2 is configured to control the operation of the recording device 1 based on the instruction signal.

[0023] The sensor interface 7 is connected to electrodes 40, 42 attached to the patient P, and an indifferent electrode (not shown). The electrodes 40, 42 are contacted with measurement portions of the patient P, and function as sensors for delivering potential changes of the measurement portions. The electrodes 40, 42 are configured to derive the potential difference of the measurement portions, and the indifferent electrode is configured to eliminate external noises which are induced in phase in the electrodes 40, 42.

[0024] The sensor interface 7 receives: an electrical signal which is output from the electrode 40, and which indicates a potential change (potential); another electrical signal which is output from the electrode 42, and which indicates a potential change (potential); and a further electrical signal which is output from the indifferent electrode, and which indicates a potential change (potential). The sensor interface 7 differentially amplifies the potential delivered from the electrode 40, and the potential derived from the electrode 42, eliminates external noises by the potential derived from the indifferent electrode, and generates an amplified ECG signal. Moreover, the sensor interface 7 analog-digital converts (AD converts) the amplified ECG signal to generate ECG waveform data. The generated ECG waveform data are supplied to the memory of the controller 2 through the bus 8. Here, the ECG waveform data indicate a plurality of ECG waveforms (waveforms generated in one beat, that is, heartbeat waveforms) which are continuously generated on the time axis.

[0025] The recording device 1 further includes a power supply (not shown). The power supply is configured by, for example, a battery. In the embodiment, from the

viewpoints of the production cost of the recording device 1, the size of the recording device 1, the life time of the battery, and the like, the controller 2 cannot execute a complicated calculation process (in other words, the controller 2 does not include a high-performance processor). In the embodiment, therefore, a complicated calculation process is executed by a controller 14 of the external apparatus 10 as described later.

[0026] For example, the external apparatus 10 may be an apparatus dedicated to analysis of ECG waveform data, a personal computer, a smart phone, a tablet, or a wearable device (such as Apple Watch (registered trademark)) which is to be attached to the body (e.g., the arm or the head) of the operator (medical person). The external apparatus 10 includes the controller 14, a network interface 12, and a storage device 13. These components are communicably connected to one another through a bus 15.

[0027] The controller 14 includes a memory and a processor. The memory is configured by, for example, a ROM which stores various programs and the like, and a RAM having a plurality of work areas in which programs to be executed by the processor are to be stored. For example, the processor is a CPU, and configured to develop designated one of the various programs stored in the ROM, on the RAM, and cooperate with the RAM to execute various processes. As described above, the controller 14 includes a high-performance processor which can execute a complicated calculation process.

[0028] The network interface 12 is configured to connect the external apparatus 10 to the communication network. In response to a request from the recording device 1, for example, the controller 14 of the external apparatus 10 analyzes a portion of the ECG waveform data to generate the reference ECG waveform which will be described later, and wirelessly transmits the generated reference ECG waveform to the recording device 1 through the network interface 12 and the communication network. The recording device 1 and the external apparatus 10 may wirelessly communicate with each other through an access point, or in Adhoc mode.

[0029] The storage device 13 is a storage device such as a hard disk drive (HDD) or a solid state drive (SSD), and configured to store various programs and data.

[0030] The external server 30 is connected to the communication network. For example, the external server 30 is configured to receive data of results of comparisons between a plurality of ECG waveforms and the reference ECG waveform from the recording device 1 through the communication network, and analyze the received comparison result data, thereby correctly determining the presence or absence of an abnormality of the heart (for example, the presence or absence of arrhythmia) of the patient P. Alternatively, the above-described determination of the presence or absence of an abnormality of the heart may be performed by the recording device 1.

[0031] Next, the functional blocks of the controller 2 of the recording device 1 will be described with reference to Fig. 2. Fig. 2 illustrates the functional blocks of the

controller 2 of the recording device 1. As shown in Fig. 2, the controller 2 includes a receiver 21, a transmitter 24, a determining section 25, the comparing section 26, an updating section 27, and a storing section 28. The receiver 21 includes a first receiver 22 and a second receiver 23. The first receiver 22 is configured to receive in real time the ECG waveform data from the electrodes 40, 42 attached to the patient P, through the sensor interface 7. The second receiver 23 is configured to receive the reference ECG waveform (an example of the electrocardiogram analysis information) from the external apparatus 10 through the network interface 4. The transmitter 24 is configured to transmit a portion of the ECG waveform data which are received by the first receiver 22, to the external apparatus 10 through the network interface 4. The storing section 28 is configured to store the ECG waveform data which are received by the first receiver 22, and the reference ECG waveform which is received by the second receiver 23. The storing section 28 may be configured by a memory such as a RAM, or by the storage device 3 such as an SD card.

[0032] The determining section 25 is configured to determine whether or not a predetermined period of time (for example, 24 hours) has elapsed since the reference ECG waveform is stored in the storing section 28. The comparing section 26 is configured to compare each of the ECG waveforms (waveforms generated in one beat) indicated by the ECG waveform data, with the reference ECG waveform. The updating section 27 is configured to update the reference ECG waveform stored in the storing section 28, to a new reference ECG waveform. Although, in the embodiment, the reference ECG waveform is updated under conditions that the predetermined period of time has elapsed since the reference ECG waveform is stored in the storing section 28, the reference ECG waveform may be updated under the following conditions:

- a condition in which the operator operates the touch portion, wherein the input operating section 6 includes a touch portion or the like for updating the reference ECG waveform;
- a condition in which the comparing section 26 does not detect an ECG waveform which is coincident with the reference ECG waveform, for a certain period of time, or
- a condition in which a change of the body posture of the patient P is detected by the sensor, wherein the recording device 1 includes a sensor (such as an acceleration sensor) for detecting the body posture of the patient P.

[0033] Next, an ECG analysis method in which the recording device 1 is employed will be described with reference to Fig. 3. Fig. 3 is a sequence diagram illustrating the ECG analysis method in which the recording device 1 is employed. In step S1, as shown in Fig. 3, the medical person such as the doctor attaches the electrodes 40, 42 and the indifferent electrode (not shown), to the patient P, and then turns ON the power supply of the recording device 1. In step S2, then, the recording device 1 (specifically, the first

receiver 22) starts acquisition of ECG waveform data from the electrodes 40, 42 attached to the patient P, through the sensor interface 7. In step S3, then, the transmitter 24 transmits a part (for example, ECG waveform data in a predetermined period of time) of the ECG waveform data which are received by the first receiver 22, to the external apparatus 10 through the network interface 4 and the communication network. Here, an example of the predetermined period of time is 10 seconds. Next, the controller 14 of the external apparatus 10 acquires the portion of the ECG waveform data through the network interface 12, and analyzes the acquired portion of the ECG waveform data to generate the reference ECG waveform (step S4). Then, the external apparatus 10 transmits the reference ECG waveform to the recording device 1 through the communication network (step S5). Here, the reference ECG waveform is a typical waveform which is extracted from a plurality of ECG waveforms indicated by the acquired portion of the ECG waveform data based on a predetermined criterion, or a calculated waveform which is obtained by performing a calculation process on the plurality of ECG waveforms.

[0034] An example of a technique for extracting a typical waveform from a plurality of ECG waveforms will be described below. For example, each of the plurality of ECG waveforms is subjected to measurements of the following items.

<Items>

- Noise mixing degree,
- Shape of QRS waveform (classified into R type, QR type, RS type, etc.),
- R amplitude,
- S amplitude, and
- T amplitude

[0035] With respect to the noise mixing degree, the smaller the degree, the higher the point is given. With respect to the other items (the shape of QRS waveform, the R amplitude, the S amplitude, and the T amplitude), the closer the value to the average, the higher the point is given. After the point which is to be given to each ECG waveform is determined in this way, the ECG waveform in which the point is highest is extracted as the typical waveform.

[0036] Examples of a technique for performing a calculation process on a plurality of ECG waveforms to obtain a calculated waveform are as follows:

1) Arithmetic averaging is simply performed on all ECG waveforms to calculate the calculated waveform;

2) Shapes of ECG waveforms are compared with one another, ECG waveforms which are clearly different in shape from other ECG waveforms are eliminated, and then arithmetic averaging is performed on the remaining ECG waveforms to calculate the calculated waveform; and

3) ECG waveforms are arranged by taking the QRS position as the reference, and the median value (or the average value) at each time is determined as the typical value. A waveform configured by the typical values at respective times is set as a calculated waveform.

[0037] In the embodiment, the generation of the reference ECG waveform requires a complicated calculation process as described above, and therefore the external apparatus 10 including the high-performance processor generates the reference ECG waveform, in place of the recording device 1.

[0038] In step S6, then, the second receiver 23 receives the reference ECG waveform from the external apparatus 10, through the communication network and the network interface 4. Thereafter, the received reference ECG waveform is stored in the storing section 28 (for example, the RAM) (step S6).

[0039] In step S7, then, the comparing section 26 compares each of the ECG waveforms indicated by the ECG waveform data which are acquired in real time from the electrodes 40, 42, with the reference ECG waveform, and generates the comparison result data. For example, the comparing section 26 may determine the presence or absence of an abnormality of each of the ECG waveforms by comparing the ECG waveform with the reference ECG waveform. Alternatively, the comparing section 26 may determine the presence or absence of arrhythmia by comparing the ECG waveforms with the reference ECG waveform.

[0040] In step S8, then, the determining section 25 determines whether the acquisition of ECG waveform data is to be ended or not. In the case where the time period of acquisition of ECG waveform data is set to one month, for example, the determining section 25 determines whether one month has elapsed after the start of the acquisition of ECG waveform data or not. If YES in step S8, the transmitter 24 wirelessly transmits the comparison result (comparison result data) to the external server 30 through the communication network (step S9). The external server 30 analyzes the transmitted comparison result data to correctly determine the presence or absence of an abnormality of the heart (for example, the presence or absence of arrhythmia) of the patient P.

[0041] If NO in step S8, by contrast, the determining section 25 determines whether or not a predetermined period of time (for example, 24 hours) has elapsed since the reference ECG waveform is stored in the storing section 28 (step S10).

[0042] If YES in step S10 (namely, for example, in the case where the determining section 25 determines that the predetermined period of time has elapsed after the reference ECG waveform is stored in the storing section 28), the transmitter 24 transmits another portion (for example, ECG waveform data in 10 seconds) of the ECG waveform data which are acquired in real time, to the external apparatus 10 through the network

interface 4 and the communication network (step S3). Thereafter, the external apparatus 10 analyzes the other portion of the ECG waveform data to generate a new reference ECG waveform, and transmits the new reference ECG waveform to the recording device 1 (steps S4 and S5). After the second receiver 23 then receives the new reference ECG waveform from the external apparatus 10, the updating section 27 updates the reference ECG waveform stored in the storing section 28, to the new reference ECG waveform (step S6). In a state where the electrodes 40, 42 and the indifferent electrode remain to be attached to the patient P, particularly, the updating section 27 updates the reference ECG waveform stored in the storing section 28, based on the new reference ECG waveform which is received by the second receiver 23. Thereafter, the comparing section 26 compares each of the ECG waveforms indicated by the ECG waveform data which are acquired in real time, with the new reference ECG waveform (step S7). In this way, the latest ECG waveform data are transmitted to the external apparatus 10 each time when the predetermined period of time has elapsed after the reference ECG waveform is stored in the storing section 28, and the latest reference ECG waveform which is based on the latest ECG waveform data is generated by the external apparatus 10. Moreover, the reference ECG waveform stored in the storing section 28 is updated to the latest reference ECG waveform, and the ECG waveforms are compared with the latest reference ECG waveform. Therefore, the reference ECG waveform is updated each time when the predetermined period of time has elapsed, and consequently the reliability of the reference ECG waveform can be enhanced.

[0043] If NO in step S10, by contrast, steps S7 and S8 are repeatedly executed until the predetermined period of time has elapsed.

[0044] According to the embodiment, the reference ECG waveform is received from the external apparatus 10, and each of the ECG waveforms indicated by the ECG waveform data is compared with the reference ECG waveform. Moreover, the reference ECG waveform stored in the storing section 28 is updated in the state where the electrodes 40, 42 and the indifferent electrode remain to be attached to the patient P. Even when the recording device 1 does not include a sophisticated calculation function, in this way, the reference ECG waveform can be acquired from the external apparatus 10. Moreover, the attachment positions of the electrodes 40, 42 and the indifferent electrode can be maintained during at least a period from when the portion of the ECG waveform data is transmitted to the external apparatus 10, to when each of the ECG waveforms is compared with the reference ECG waveform. Moreover, the reference ECG waveform can be updated. Therefore, comparison analysis can be performed by using the reference ECG waveform which is adapted to ECG waveform data that are acquired in real time. In this way, the reliability of the reference ECG

waveform can be enhanced.

Therefore, it is possible to provide the recording device 1 in which, even when a sophisticated computer or the like is not used, the accuracy of analysis of ECG waveform data can be improved.

Moreover, the transmitter 24 is configured to wirelessly transmit the comparison result data which are obtained by the comparing section 26, to the external server 30, and therefore an abnormality of the heart of the patient P can be rapidly diagnosed.

According to the embodiment, furthermore, it is possible to provide the ECG analysis system 100 in which the accuracy of analysis of ECG waveform data can be improved.

[0045] In order to realize the recording device 1 of the embodiment by using software, the electrocardiogram analysis program may be pre-installed in the storage device 3 or the ROM. Alternatively, the electrocardiogram analysis program may be stored on a computer readable storage medium such as a magnetic disk (an HDD or a floppy disk), an optical disk (a CD-ROM, a DVD-ROM, a Blu-ray disk (registered trademark), or the like), a magneto-optical disk (an MO or the like), or a flash memory (an SD card, a USB memory, an SSD, or the like). In this case, when the storage medium is connected to the recording device 1, programs which are stored on the storage medium are installed into the storage device 3. Then, the electrocardiogram analysis program installed in the storage device 3 is loaded into the RAM, the processor executes the loaded program, and as a result the controller 2 executes the various processes illustrated in Fig. 2.

[0046] Alternatively, the electrocardiogram analysis program may be downloaded from a computer on the communication network, through the network interface 4. Also in this case, the downloaded program is installed into the storage device 3.

[0047] Although the embodiment of the invention has been described, the technical scope of the invention should not be interpreted in a limited manner based on the description of the embodiment. It should be understood by those skilled in the art that the embodiment is a mere example, and may be variously changed within the scope of the invention as defined in the claims. The technical scope of the invention should be determined based on the scope of the invention (claimed invention) as defined in the claims, and the scope of equivalence thereof.

[0048] Although, in the embodiment, a reference ECG waveform has been described as an example of the electrocardiogram analysis information, the electrocardiogram analysis information is not limited to a reference ECG waveform. For example, the information may be the reference RR interval or the reference QT interval. In the case where the electrocardiogram analysis information is the reference RR interval, the external apparatus 10 analyzes the ECG waveform data transmitted from the recording device 1, to generate the reference RR interval (for example, the typical, average, or median

value of the RR interval), and transmits the generated reference RR interval to the recording device 1. Thereafter, the storing section 28 stores the reference RR interval, and the comparing section 26 then compares the RR interval of each of ECG waveforms with the reference RR interval to generate the comparison result. As described above, the electrocardiogram analysis information as defined in the claimed invention is not limited to the reference ECG waveform that has been described in the embodiment, and various reference indexes may be applied as the electrocardiogram analysis information.

[0049] Although, in the description of the embodiment, an ECG event recorder and an ECG Holter recorder are exemplified as the ECG recording device, the embodiment is not limited to such a recorder. For example, the ECG recording device may be a patient monitor having a function of recording a measured ECG, a defibrillator, a medical transmitter, or the like.

[0050] The outline of the embodiment will be summarized as follows.

[0051] An electrocardiogram recording device comprises:

a first receiver configured to receive in real time electrocardiogram waveform data from an electrode attached to a patient, wherein the electrocardiogram waveform data indicates a plurality of electrocardiogram waveforms which are continuously generated on a time axis;

a transmitter configured to transmit a portion of the received electrocardiogram waveform data to an external apparatus;

a second receiver configured to receive electrocardiogram analysis information from the external apparatus;

a storing section configured to store the electrocardiogram waveform data and the electrocardiogram analysis information;

a comparing section configured to compare each of the plurality of electrocardiogram waveforms indicated by the electrocardiogram waveform data, with the electrocardiogram analysis information; and

an updating section configured to update the electrocardiogram analysis information stored in the storing section, based on new electrocardiogram analysis information received by the second receiver, in a state where the electrode remains to be attached to the patient.

[0052] According to the above configuration, electrocardiogram analysis information is received from the external apparatus, and each of the plurality of electrocardiogram waveforms indicated by the electrocardiogram waveform data is compared with the received electrocardiogram analysis information. In the state where the electrodes remain to be attached to the patient, furthermore, the electrocardiogram analysis information stored in the storing section is updated. Thus, even when the electro-

cardiogram recording device does not have a sophisticated calculation function, in this way, electrocardiogram analysis information can be acquired from the external apparatus.

[0053] The attachment positions of the electrodes can be maintained during at least the period from the transmission of the portion of the electrocardiogram waveform data to the external apparatus, to the comparison of each of the electrocardiogram waveforms with the electrocardiogram analysis information. Moreover, the electrocardiogram analysis information can be updated, and therefore comparison analysis can be performed using the electrocardiogram analysis information which is adapted to electrocardiogram waveform data that are received in real time. In this way, the reliability of the electrocardiogram analysis information can be enhanced.

[0054] Therefore, it is possible to provide the electrocardiogram recording device in which, even when a sophisticated computer or the like is not used, the accuracy of analysis of electrocardiogram waveform data can be improved.

[0055] The electrocardiogram analysis information may be a reference electrocardiogram waveform. The reference electrocardiogram waveform may be a typical waveform which is extracted from a plurality of electrocardiogram waveforms indicated by a portion of the electrocardiogram waveform data based on a predetermined criterion, or a calculated waveform which is obtained by performing a calculation process on the plurality of electrocardiogram waveforms.

[0056] According to the above configuration, the reference electrocardiogram waveform is received from the external apparatus, and each of the plurality of electrocardiogram waveforms indicated by the electrocardiogram waveform data is compared with the received reference electrocardiogram waveform. Even when the electrocardiogram recording device does not include a sophisticated computer or the like, in this way, the reference electrocardiogram waveform can be compared with the electrocardiogram waveforms with high accuracy.

[0057] The transmitter may be configured to wirelessly transmit a comparison result which is obtained by the comparing section.

[0058] According to the above configuration, the comparison result which is obtained by the comparing section is wirelessly transmitted, and therefore an abnormality of the heart of the patient can be rapidly diagnosed.

[0059] The electrocardiogram recording device may further comprise:

a determining section configured to determine whether or not a predetermined period of time has elapsed since the electrocardiogram analysis information is stored in the storing section.

If the determining section determines that the predetermined period of time has elapsed since the electrocardiogram analysis information is stored in the storing

section,

the transmitter transmits another portion of the received electrocardiogram waveform data to the external apparatus,

the second receiver receives new electrocardiogram analysis information from the external apparatus,

the updating section updates the electrocardiogram analysis information stored in the storing section, with the new electrocardiogram analysis information,

and

the comparing section compares each of the plurality of electrocardiogram waveforms indicated by the electrocardiogram waveform data, with the new electrocardiogram analysis information.

[0060] According to the above configuration, it is determined whether the predetermined period of time has elapsed from the storage of the electrocardiogram analysis information in the storing section or not, and, if it is determined that the predetermined period of time has elapsed from the storage of the electrocardiogram analysis information in the storing section, the electrocardiogram analysis information which has been stored in the storing section is updated to the new electrocardiogram analysis information. In this way, the electrocardiogram analysis information is updated every predetermined period of time, and therefore the reliability of the electrocardiogram analysis information can be enhanced.

[0061] A method performed by a computer, comprises:

a) receiving in real time electrocardiogram waveform data from an electrode attached to a patient, wherein the electrocardiogram waveform data indicates a plurality of electrocardiogram waveforms which are continuously generated on a time axis;

b) transmitting a portion of the received electrocardiogram waveform data to an external apparatus;

c) receiving electrocardiogram analysis information from the external apparatus;

d) storing the electrocardiogram waveform data and the electrocardiogram analysis information;

e) comparing each of the plurality of electrocardiogram waveforms indicated by the electrocardiogram waveform data, with the electrocardiogram analysis information; and

f) updating the stored electrocardiogram analysis information, based on new electrocardiogram analysis information, in a state where the electrode remains to be attached to the patient.

[0062] The electrocardiogram analysis information may be a reference electrocardiogram waveform. The reference electrocardiogram waveform may be a typical waveform which is extracted from a plurality of electrocardiogram waveforms indicated by the

portion of the electrocardiogram waveform data based on a predetermined criterion, or a calculated waveform which is obtained by performing a calculation process on the plurality of electrocardiogram waveforms.

[0063] The method may further comprise:

g) wirelessly transmitting a comparison result which is obtained by comparing each of the plurality of electrocardiogram waveforms indicated by the electrocardiogram waveform data, with the electrocardiogram analysis information.

[0064] The method may further comprise:

h) determining whether or not a predetermined period of time has elapsed since the electrocardiogram analysis information is stored,

i) if determining that the predetermined period of time has elapsed since the electrocardiogram analysis information is stored,

i1) transmitting another portion of the received electrocardiogram waveform data to the external apparatus;

i2) receiving new electrocardiogram analysis information from the external apparatus;

i3) updating the stored electrocardiogram analysis information with the new electrocardiogram analysis information; and

i4) comparing each of the plurality of electrocardiogram waveforms indicated by the electrocardiogram waveform data with the new electrocardiogram analysis information.

[0065] There may be provided a program causing a computer to perform the above method.

[0066] There may be provided a computer-readable medium storing the program.

[0067] A system comprises:

the electrocardiogram recording device; and

an external apparatus configured to generate electrocardiogram analysis information by analyzing a portion of the electrocardiogram waveform data received from the electrocardiogram recording device.

[0068] This application is based on Japanese Patent Application No. 2016-065565 filed on March 29, 2016, the entire contents of which are incorporated herein by reference.

Claims

[Claim 1] An electrocardiogram recording device, comprising:
a first receiver configured to receive in real time electrocardiogram waveform data from an electrode attached to a patient, wherein the electrocardiogram waveform data indicates a plurality of electrocardiogram waveforms which are continuously generated on a time axis;
a transmitter configured to transmit a portion of the received electrocardiogram waveform data to an external apparatus;
a second receiver configured to receive electrocardiogram analysis information from the external apparatus;
a storing section configured to store the electrocardiogram waveform data and the electrocardiogram analysis information;
a comparing section configured to compare each of the plurality of electrocardiogram waveforms indicated by the electrocardiogram waveform data, with the electrocardiogram analysis information; and
an updating section configured to update the electrocardiogram analysis information stored in the storing section, based on new electrocardiogram analysis information received by the second receiver, in a state where the electrode remains to be attached to the patient.

[Claim 2] The electrocardiogram recording device of claim 1, wherein
the electrocardiogram analysis information is a reference electrocardiogram waveform, and
the reference electrocardiogram waveform is a typical waveform which is extracted from a plurality of electrocardiogram waveforms indicated by the portion of the electrocardiogram waveform data based on a predetermined criterion, or a calculated waveform which is obtained by performing a calculation process on the plurality of electrocardiogram waveforms.

[Claim 3] The electrocardiogram recording device of claim 1 or 2, wherein
the transmitter is configured to wirelessly transmit a comparison result which is obtained by the comparing section.

[Claim 4] The electrocardiogram recording device of any one of claims 1 to 3, further comprising:
a determining section configured to determine whether or not a predetermined period of time has elapsed since the electrocardiogram analysis information is stored in the storing section,

wherein
if the determining section determines that the predetermined period of time has elapsed since the electrocardiogram analysis information is stored in the storing section,
the transmitter transmits another portion of the received electrocardiogram waveform data to the external apparatus,
the second receiver receives new electrocardiogram analysis information from the external apparatus,
the updating section updates the electrocardiogram analysis information stored in the storing section, with the new electrocardiogram analysis information,
and
the comparing section compares each of the plurality of electrocardiogram waveforms indicated by the electrocardiogram waveform data, with the new electrocardiogram analysis information.

[Claim 5] A method performed by a computer, comprising:
a) receiving in real time electrocardiogram waveform data from an electrode attached to a patient, wherein the electrocardiogram waveform data indicates a plurality of electrocardiogram waveforms which are continuously generated on a time axis;
b) transmitting a portion of the received electrocardiogram waveform data to an external apparatus;
c) receiving electrocardiogram analysis information from the external apparatus;
d) storing the electrocardiogram waveform data and the electrocardiogram analysis information;
e) comparing each of the plurality of electrocardiogram waveforms indicated by the electrocardiogram waveform data, with the electrocardiogram analysis information; and
f) updating the stored electrocardiogram analysis information, based on new electrocardiogram analysis information, in a state where the electrode remains to be attached to the patient.

[Claim 6] The method of claim 5, wherein
the electrocardiogram analysis information is a reference electrocardiogram waveform, and
the reference electrocardiogram waveform is a typical waveform which is extracted from a plurality of electrocardiogram waveforms indicated by the portion of the electrocardiogram waveform data based on a pre-

determined criterion, or a calculated waveform which is obtained by performing a calculation process on the plurality of electrocardiogram waveforms.

[Claim 7] The method of claim 5 or 6, further comprising:
g) wirelessly transmitting a comparison result which is obtained by comparing each of the plurality of electrocardiogram waveforms indicated by the electrocardiogram waveform data, with the electrocardiogram analysis information.

[Claim 8] The method of any one of claims 5 to 7, further comprising:
h) determining whether or not a predetermined period of time has elapsed since the electrocardiogram analysis information is stored,
i) if determining that the predetermined period of time has elapsed since the electrocardiogram analysis information is stored,
i1) transmitting another portion of the received electrocardiogram waveform data to the external apparatus;
i2) receiving new electrocardiogram analysis information from the external apparatus;
i3) updating the stored electrocardiogram analysis information with the new electrocardiogram analysis information; and
i4) comparing each of the plurality of electrocardiogram waveforms indicated by the electrocardiogram waveform data with the new electrocardiogram analysis information.

[Claim 9] A program causing a computer to perform the method of any one of claims 5 to 8.

[Claim 10] A computer-readable medium storing the program of claim 9.

[Claim 11] A system comprising:
the electrocardiogram recording device of any one of claims 1 to 4; and
an external apparatus configured to generate electrocardiogram analysis information by analyzing a portion of the electrocardiogram waveform data received from the electrocardiogram recording device.

[Fig. 1]

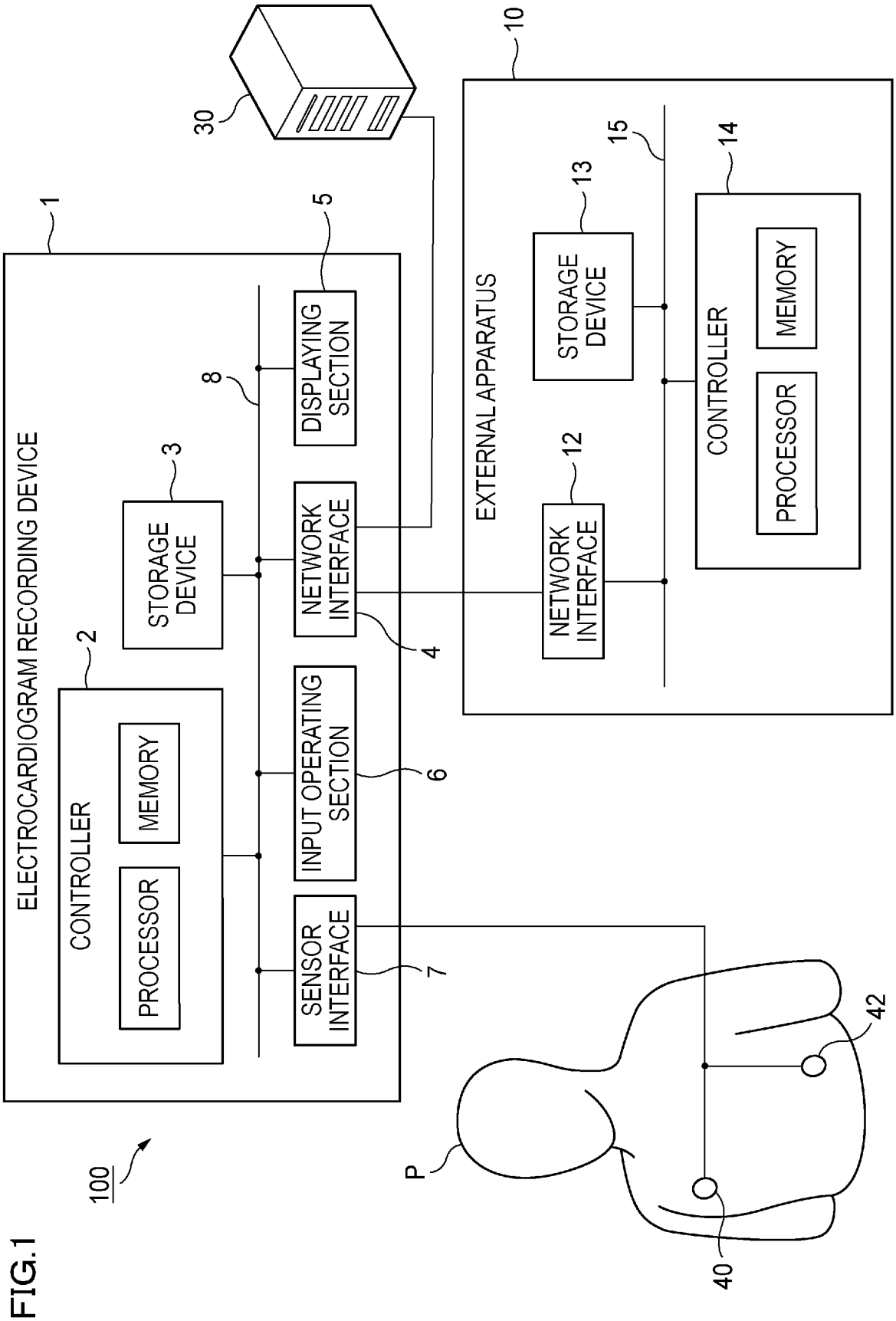

100
ELECTROCARDIOGRAM RECORDING DEVICE
1
CONTROLLER
2
PROCESSOR
MEMORY
STORAGE DEVICE
3
NETWORK INTERFACE
4
DISPLAYING SECTION
5
INPUT OPERATING SECTION
6
SENSOR INTERFACE
7
8
30
EXTERNAL APPARATUS
10
NETWORK INTERFACE
12
STORAGE DEVICE
13
CONTROLLER
14
PROCESSOR
MEMORY
15
P
40
42

FIG.1

[Fig. 2]

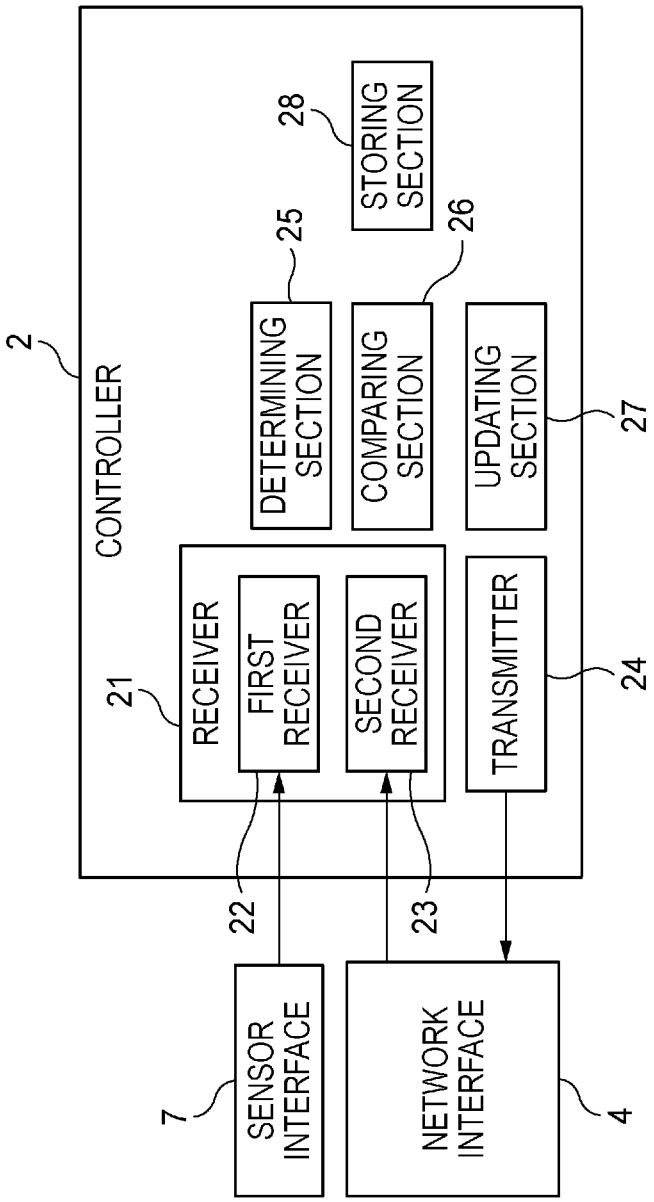
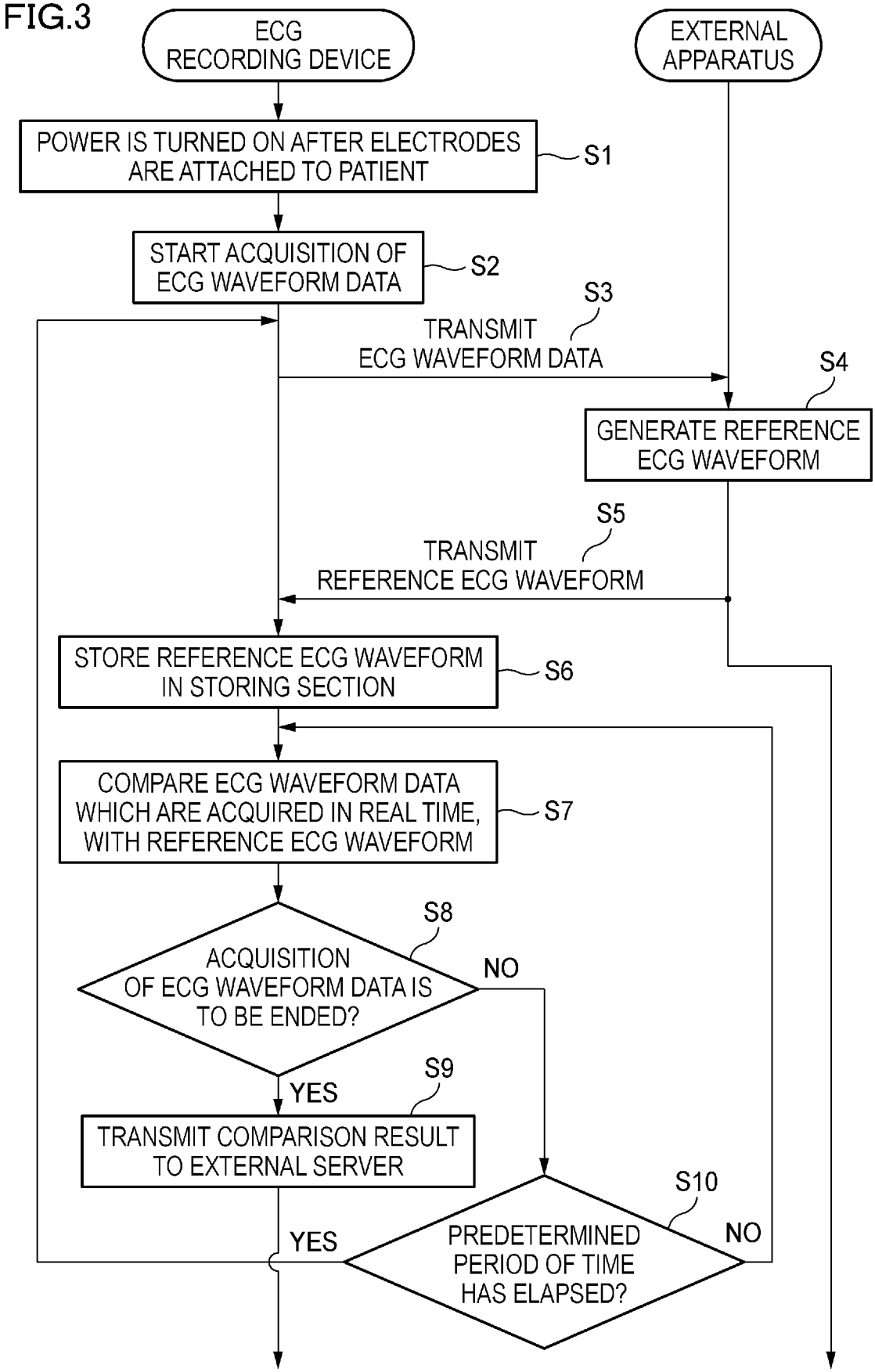

2
CONTROLLER
28
STORING SECTION
25
DETERMINING SECTION
26
COMPARING SECTION
UPDATING SECTION
27
21
RECEIVER
FIRST RECEIVER
SECOND RECEIVER
TRANSMITTER
24
22
23
7
SENSOR INTERFACE
NETWORK INTERFACE
4

FIG.2

[Fig. 3]

FIG.3


ECG RECORDING DEVICE
EXTERNAL APPARATUS
POWER IS TURNED ON AFTER ELECTRODES ARE ATTACHED TO PATIENT
S1
START ACQUISITION OF ECG WAVEFORM DATA
S2
S3
TRANSMIT ECG WAVEFORM DATA
S4
GENERATE REFERENCE ECG WAVEFORM
S5
TRANSMIT REFERENCE ECG WAVEFORM
STORE REFERENCE ECG WAVEFORM IN STORING SECTION
S6
COMPARE ECG WAVEFORM DATA WHICH ARE ACQUIRED IN REAL TIME, WITH REFERENCE ECG WAVEFORM
S7
S8
ACQUISITION OF ECG WAVEFORM DATA IS TO BE ENDED?
NO
YES
S9
TRANSMIT COMPARISON RESULT TO EXTERNAL SERVER
S10
PREDETERMINED PERIOD OF TIME HAS ELAPSED?
NO
YES

INTERNATIONAL SEARCH REPORT

International application No
PCT/JP2017/011865

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/00 A61B5/0432 A61B5/0452
ADD. A61B5/0404

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

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)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 1 928 311 A2 (TOUMAZ TECHNOLOGY LTD [GB]) 11 June 2008 (2008-06-11) paragraphs [0019], [0023] - [0031] paragraphs [0041], [0042], [0047] paragraphs [0055] - [0060] figures -----	1-11
X	WO 2005/117467 A2 (UNITED THERAPEUTICS CORP [US]; KURZWEIL RAYMOND C [US]; ALBRECHT PAUL) 8 December 2005 (2005-12-08) page 7, line 14 - page 20, line 21 page 32, line 7 - page 33, line 12 figures -----	1-11

-/--

[X] Further documents are listed in the continuation of Box C.

[X] 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

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
22 May 2017	31/05/2017

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Bataille, Frédéric

1

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/JP2017/011865

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 092 340 A (YAMAGUCHI KEIJI [JP] ET AL) 3 March 1992 (1992-03-03) column 8, line 8 - column 10, line 36 column 11, line 64 - column 13, line 17 figures -----	1,5,9-11

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/JP2017/011865

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 1928311 A2	11-06-2008	AT 476914 T	15-08-2010
		CN 101272733 A	24-09-2008
		EP 1928311 A2	11-06-2008
		GB 2420628 A	31-05-2006
		JP 5244600 B2	24-07-2013
		JP 2009509607 A	12-03-2009
		US 2008214946 A1	04-09-2008
		WO 2007036748 A2	05-04-2007
WO 2005117467 A2	08-12-2005	NONE	
US 5092340 A	03-03-1992	DE 3789060 D1	24-03-1994
		DE 3789060 T2	19-05-1994
		EP 0327646 A1	16-08-1989
		JP H0347094 B2	18-07-1991
		JP S6399840 A	02-05-1988
		US 5092340 A	03-03-1992
		WO 8802617 A1	21-04-1988

专利名称(译)	心电图记录装置和心电图分析方法		
公开(公告)号	EP3435845A1	公开(公告)日	2019-02-06
申请号	EP2017716018	申请日	2017-03-23
[标]申请(专利权)人(译)	日本光电工业株式会社		
申请(专利权)人(译)	日本光电公司		
当前申请(专利权)人(译)	日本光电公司		
[标]发明人	ONO YOSHINOBU TAKAYANAGI TSUNEO		
发明人	ONO YOSHINOBU TAKAYANAGI TSUNEO		
IPC分类号	A61B5/00 A61B5/0432 A61B5/0452 A61B5/0404		
CPC分类号	A61B5/0006 A61B5/0404 A61B5/0432 A61B5/04525		
优先权	2016065565 2016-03-29 JP		
外部链接	Espacenet		

摘要(译)

一种心电图记录装置，包括：第一接收器（21），被配置为从附接到患者的电极实时接收心电图波形数据;发送器（24），被配置为将所接收的心电图波形数据的一部分发送到外部装置;第二接收器（22），用于从外部设备接收心电图分析信息;存储部分（28），用于存储心电图波形数据和心电图分析信息;比较部（26），用于将由心电图波形数据表示的多个心电图波形中的每一个与心电图分析信息进行比较;更新部分（27），被配置为在电极保持附着于患者的状态下，基于由第二接收器接收的新的心电图分析信息，更新存储在存储部分中的心电图分析信息。