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Samejima et al.

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(54) **ELECTROCARDIOGRAPHIC WAVEFORM MEASUREMENT DEVICE, INFORMATION MANAGEMENT SYSTEM, ELECTROCARDIOGRAPHIC WAVEFORM MEASUREMENT DEVICE CONTROL METHOD, AND NON-TRANSITORY RECORDING MEDIUM INCLUDING PROGRAM RECORDED THEREIN**

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A61B 5/00 (2006.01)
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CPC *A61B 5/7264* (2013.01); *A61B 5/282* (2021.01); *A61B 5/332* (2021.01); *A61B 5/6823* (2013.01)

(58) **Field of Classification Search**
CPC A61B 5/7264; A61B 5/332; A61B 5/282; A61B 5/6823
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,283,181 A * 11/1966 Johanson H04R 17/02 600/407
8,738,118 B2 * 5/2014 Moon A61B 5/33 600/513
(Continued)

FOREIGN PATENT DOCUMENTS

CN 107530004 A 1/2019
CN 109893122 A 6/2019
(Continued)

OTHER PUBLICATIONS

International Search Report for International Application No. PCT/JP2020/045630, Dated Feb. 16, 2021.
(Continued)

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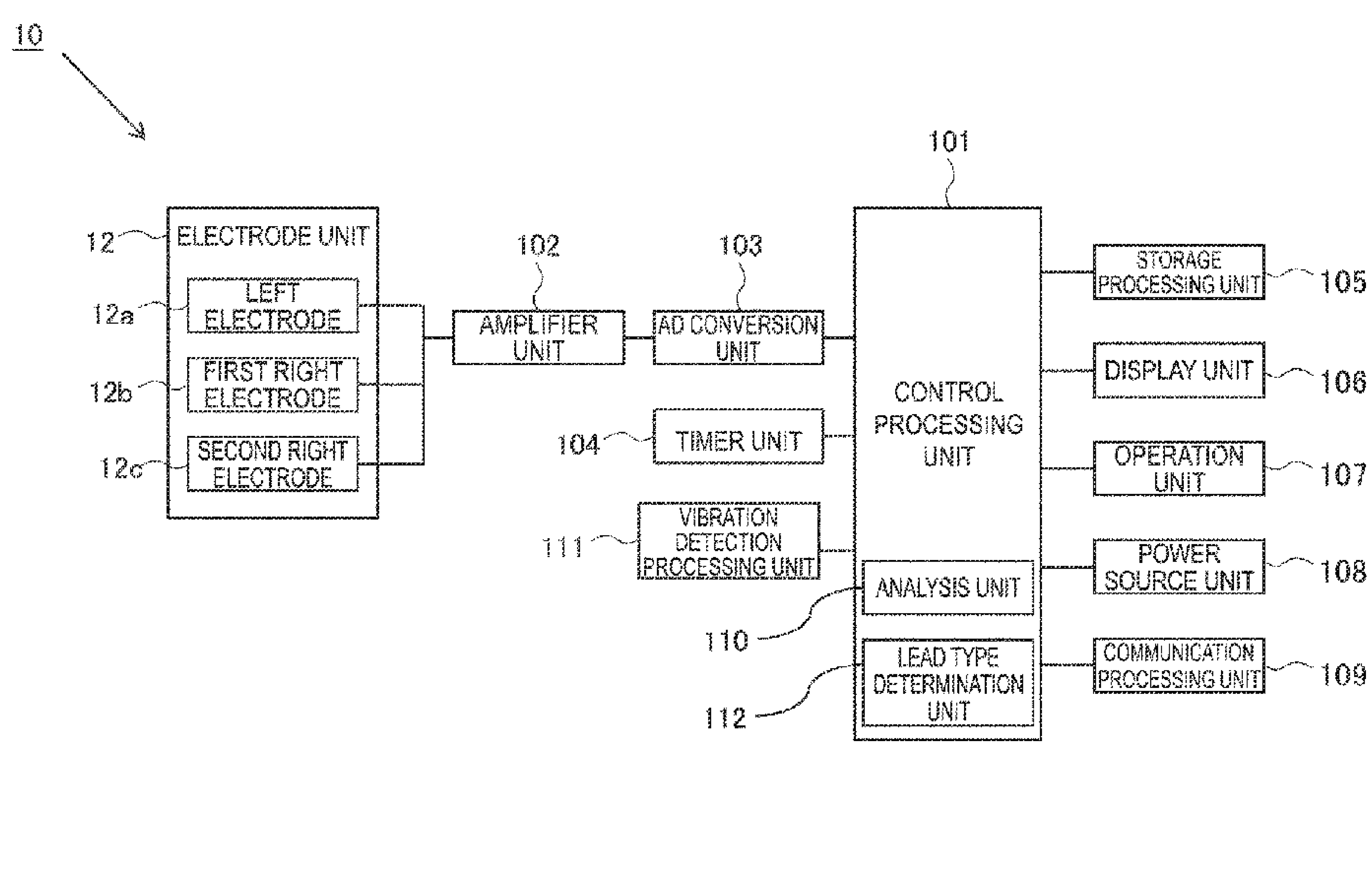
(57) **ABSTRACT**

An electrocardiographic waveform measurement device includes a plurality of electrodes configured to measure an electrocardiographic waveform of a measurement target, a vibration detection unit configured to approach a chest region of the measurement target to detect vibration based on a beat of a heart of the measurement target, and a control unit configured to execute measurement processing for the electrocardiographic waveform. The control unit further executes lead type determination processing for determin-
(Continued)



ing, based on a detection result from the vibration detection unit, at least whether the electrocardiographic waveform measured by the measurement processing is an electrocardiographic waveform obtained by chest lead measurement.

7 Claims, 10 Drawing Sheets

(51) **Int. Cl.**
A61B 5/282 (2021.01)
A61B 5/332 (2021.01)

(56) **References Cited**

U.S. PATENT DOCUMENTS

2015/0265217	A1*	9/2015	Penders	A61B 5/33 600/300
2017/0273584	A1*	9/2017	Huang	A61B 5/259
2018/0042502	A1*	2/2018	Wang	A61B 5/6823

FOREIGN PATENT DOCUMENTS

JP	2002-51997	A	2/2002
JP	2005-000468	A	1/2005
JP	2014-128455	A	7/2014
JP	2014-223184	A	12/2014

OTHER PUBLICATIONS

Office Action issued on Sep. 11, 2024 in corresponding CN patent application No. 202080078132.X.

* cited by examiner

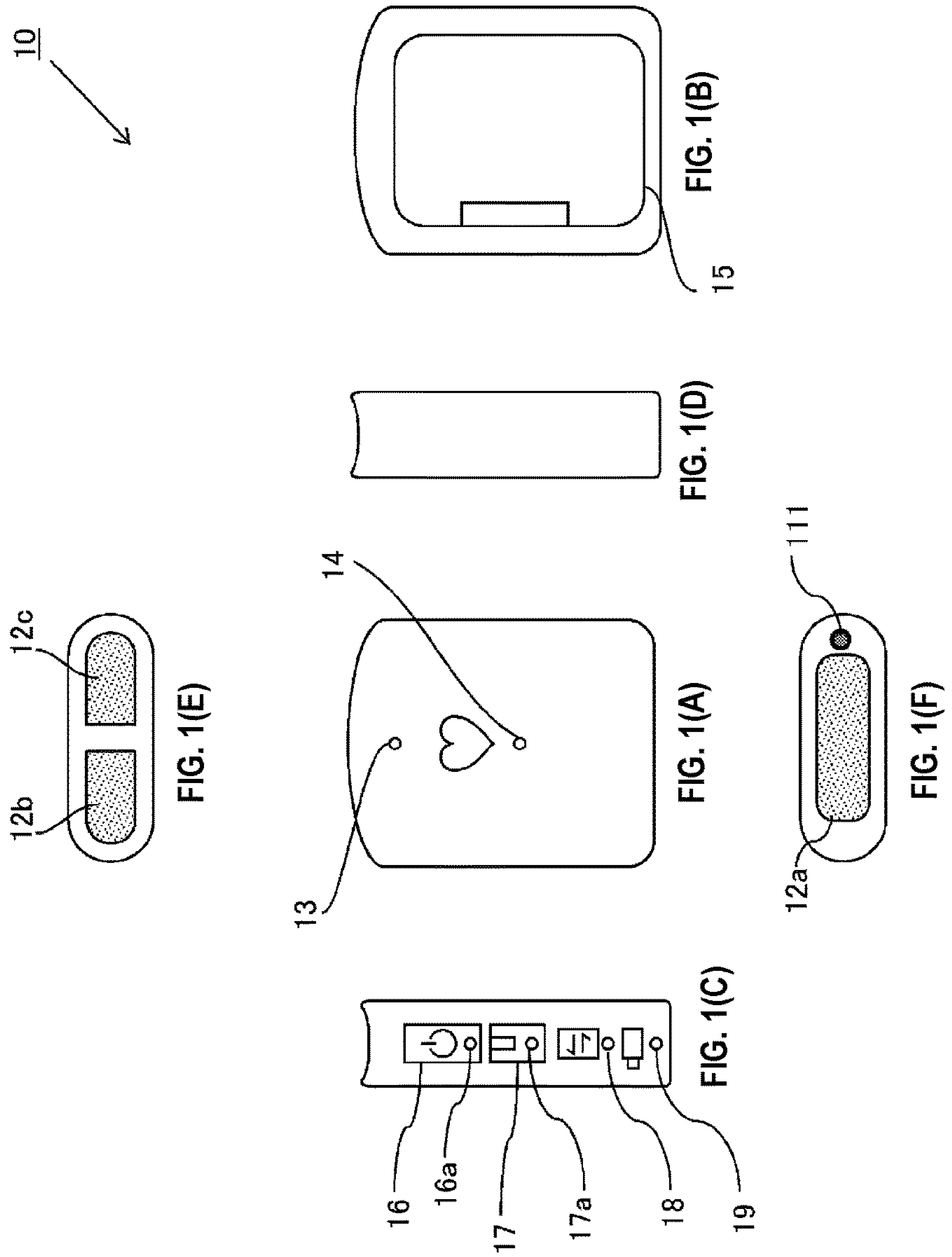


FIG. 1(A)
FIG. 1(B)
FIG. 1(C)
FIG. 1(D)
FIG. 1(E)
FIG. 1(F)

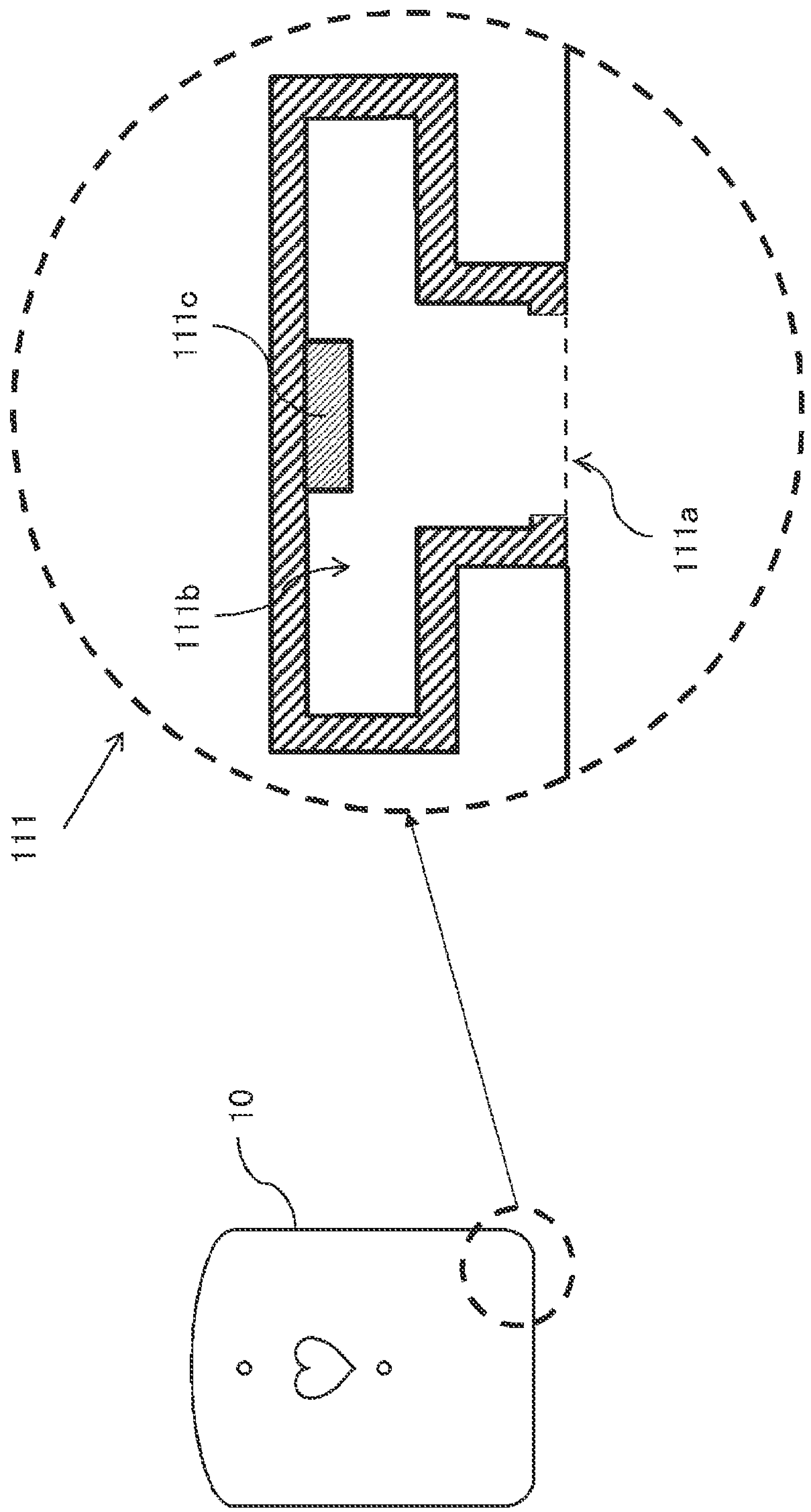


FIG. 2

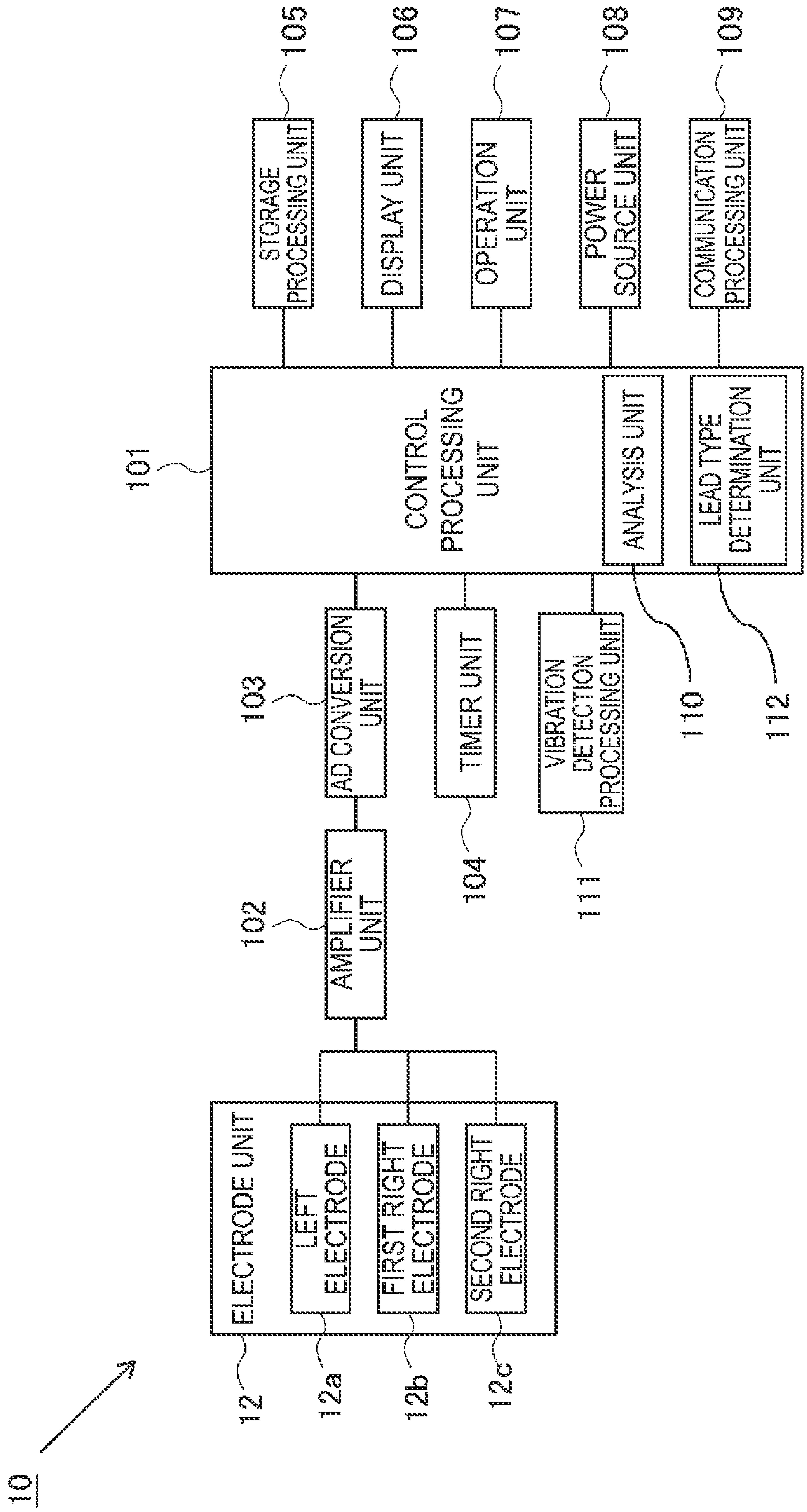
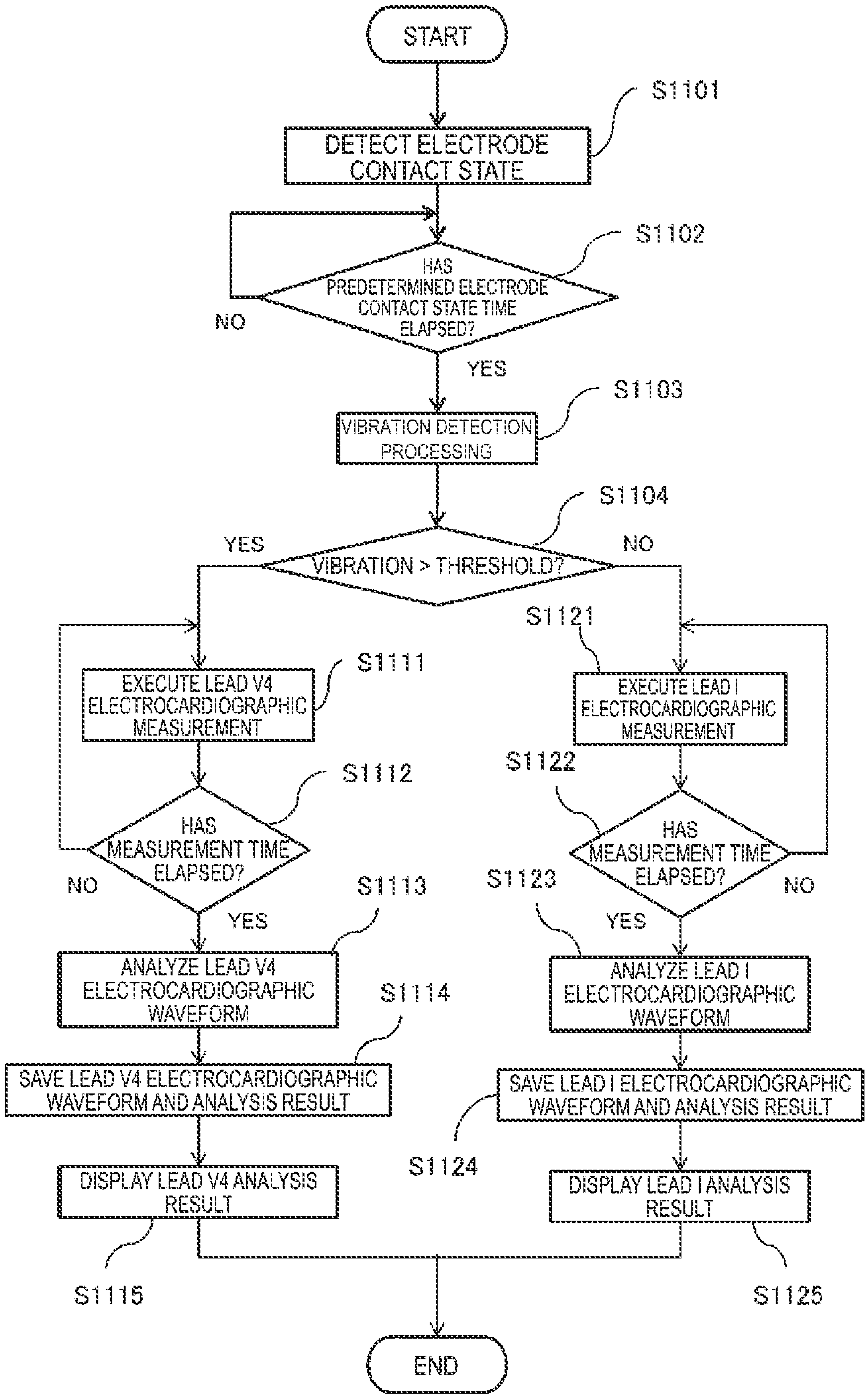

10
ELECTRODE UNIT
LEFT ELECTRODE
FIRST RIGHT ELECTRODE
SECOND RIGHT ELECTRODE
12
12a
12b
12c
AMPLIFIER UNIT
102
AD CONVERSION UNIT
103
TIMER UNIT
104
VIBRATION DETECTION PROCESSING UNIT
111
CONTROL PROCESSING UNIT
101
ANALYSIS UNIT
110
LEAD TYPE DETERMINATION UNIT
112
STORAGE PROCESSING UNIT
105
DISPLAY UNIT
106
OPERATION UNIT
107
POWER SOURCE UNIT
108
COMMUNICATION PROCESSING UNIT
109

FIG. 3

FIG. 4


START
S1101
DETECT ELECTRODE CONTACT STATE
S1102
HAS PREDETERMINED ELECTRODE CONTACT STATE TIME ELAPSED?
NO
YES
S1103
VIBRATION DETECTION PROCESSING
S1104
VIBRATION > THRESHOLD?
YES
NO
S1111
EXECUTE LEAD V4 ELECTROCARDIOGRAPHIC MEASUREMENT
S1112
HAS MEASUREMENT TIME ELAPSED?
NO
YES
S1113
ANALYZE LEAD V4 ELECTROCARDIOGRAPHIC WAVEFORM
S1114
SAVE LEAD V4 ELECTROCARDIOGRAPHIC WAVEFORM AND ANALYSIS RESULT
DISPLAY LEAD V4 ANALYSIS RESULT
S1115
S1121
EXECUTE LEAD I ELECTROCARDIOGRAPHIC MEASUREMENT
S1122
HAS MEASUREMENT TIME ELAPSED?
NO
YES
S1123
ANALYZE LEAD I ELECTROCARDIOGRAPHIC WAVEFORM
SAVE LEAD I ELECTROCARDIOGRAPHIC WAVEFORM AND ANALYSIS RESULT
S1124
DISPLAY LEAD I ANALYSIS RESULT
S1125
END

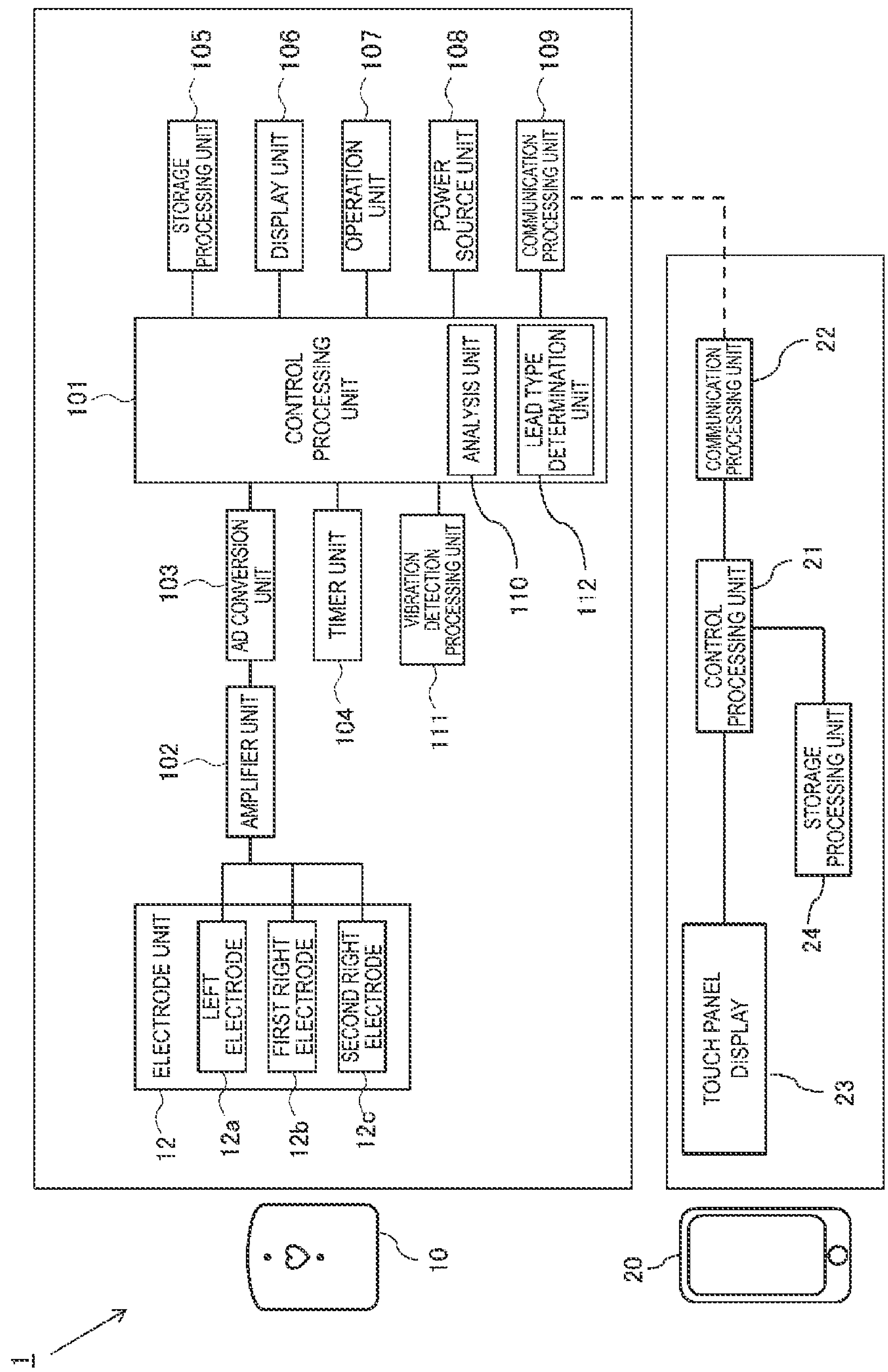

STORAGE PROCESSING UNIT
DISPLAY UNIT
OPERATION UNIT
POWER SOURCE UNIT
COMMUNICATION PROCESSING UNIT
105
106
107
108
109
101
CONTROL PROCESSING UNIT
ANALYSIS UNIT
LEAD TYPE DETERMINATION UNIT
103
AD CONVERSION UNIT
TIMER UNIT
VIBRATION DETECTION PROCESSING UNIT
110
112
102
AMPLIFIER UNIT
104
111
ELECTRODE UNIT
LEFT ELECTRODE
FIRST RIGHT ELECTRODE
SECOND RIGHT ELECTRODE
12
12a
12b
12c
10
1
COMMUNICATION PROCESSING UNIT
22
CONTROL PROCESSING UNIT
21
STORAGE PROCESSING UNIT
24
TOUCH PANEL DISPLAY
23
20

FIG. 5

FIG. 6

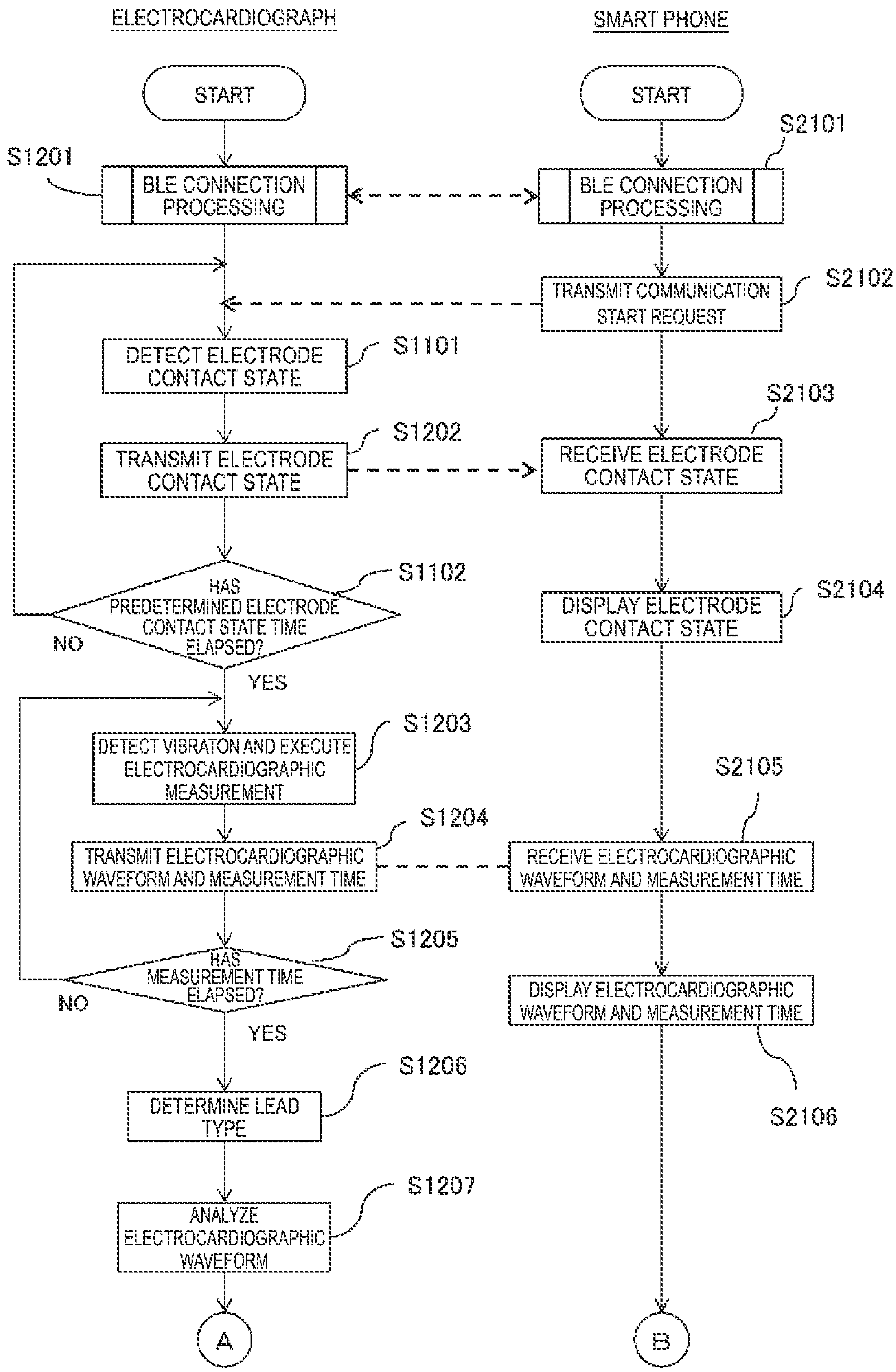

ELECTROCARDIOGRAPH
SMART PHONE
START
START
S1201
BLE CONNECTION PROCESSING
BLE CONNECTION PROCESSING
S2101
TRANSMIT COMMUNICATION START REQUEST
S2102
DETECT ELECTRODE CONTACT STATE
S1101
TRANSMIT ELECTRODE CONTACT STATE
S1202
RECEIVE ELECTRODE CONTACT STATE
S2103
HAS PREDETERMINED ELECTRODE CONTACT STATE TIME ELAPSED?
S1102
NO
YES
DISPLAY ELECTRODE CONTACT STATE
S2104
DETECT VIBRATON AND EXECUTE ELECTROCARDIOGRAPHIC MEASUREMENT
S1203
TRANSMIT ELECTROCARDIOGRAPHIC WAVEFORM AND MEASUREMENT TIME
S1204
RECEIVE ELECTROCARDIOGRAPHIC WAVEFORM AND MEASUREMENT TIME
S2105
HAS MEASUREMENT TIME ELAPSED?
S1205
NO
YES
DISPLAY ELECTROCARDIOGRAPHIC WAVEFORM AND MEASUREMENT TIME
S2106
DETERMINE LEAD TYPE
S1206
ANALYZE ELECTROCARDIOGRAPHIC WAVEFORM
S1207
A
B

FIG. 7

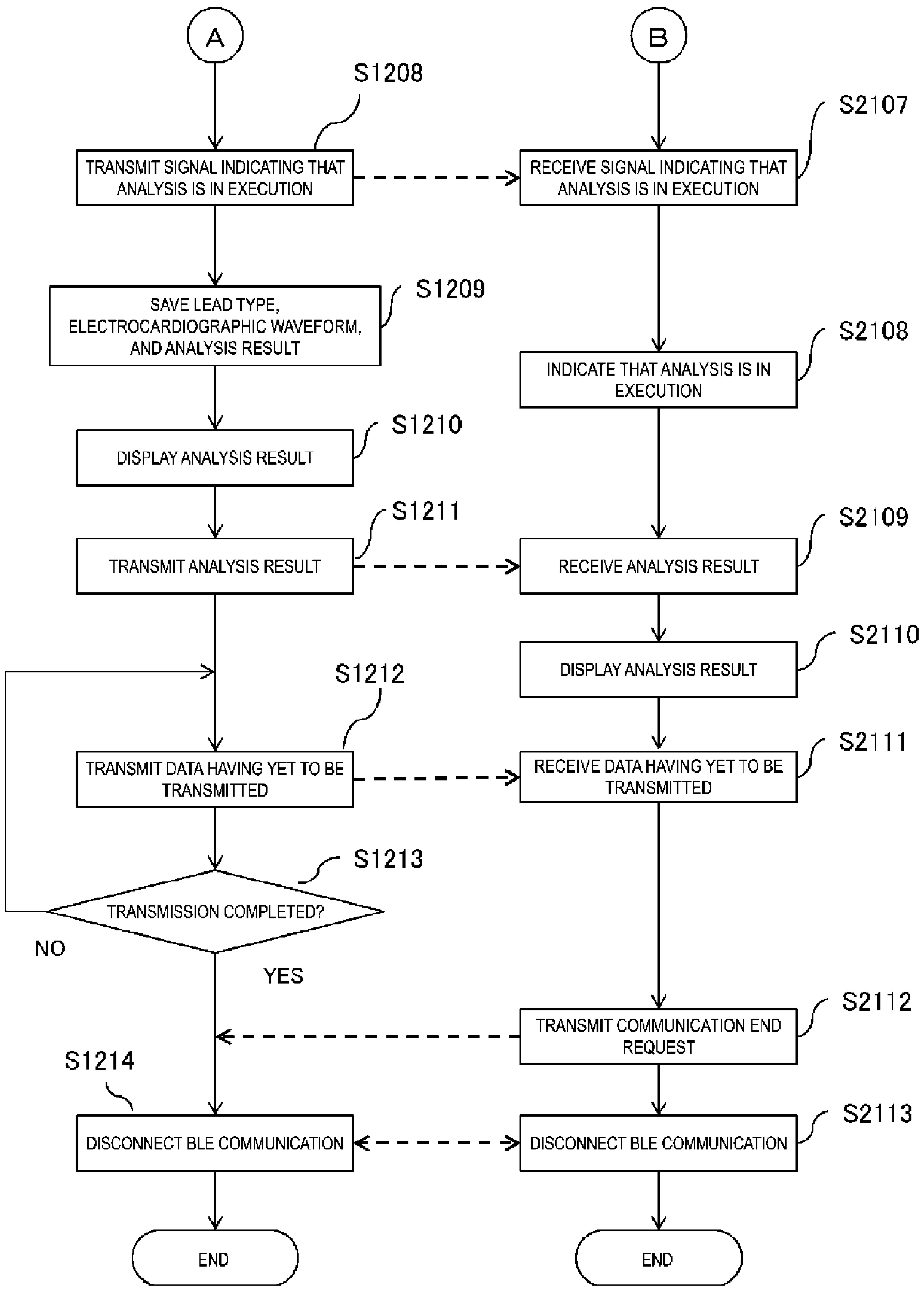

A
B
S1208
TRANSMIT SIGNAL INDICATING THAT ANALYSIS IS IN EXECUTION
S2107
RECEIVE SIGNAL INDICATING THAT ANALYSIS IS IN EXECUTION
S1209
SAVE LEAD TYPE, ELECTROCARDIOGRAPHIC WAVEFORM, AND ANALYSIS RESULT
S2108
INDICATE THAT ANALYSIS IS IN EXECUTION
S1210
DISPLAY ANALYSIS RESULT
S1211
TRANSMIT ANALYSIS RESULT
S2109
RECEIVE ANALYSIS RESULT
S2110
DISPLAY ANALYSIS RESULT
S1212
TRANSMIT DATA HAVING YET TO BE TRANSMITTED
S2111
RECEIVE DATA HAVING YET TO BE TRANSMITTED
S1213
TRANSMISSION COMPLETED?
NO
YES
S2112
TRANSMIT COMMUNICATION END REQUEST
S1214
DISCONNECT BLE COMMUNICATION
S2113
DISCONNECT BLE COMMUNICATION
END
END

FIG. 8

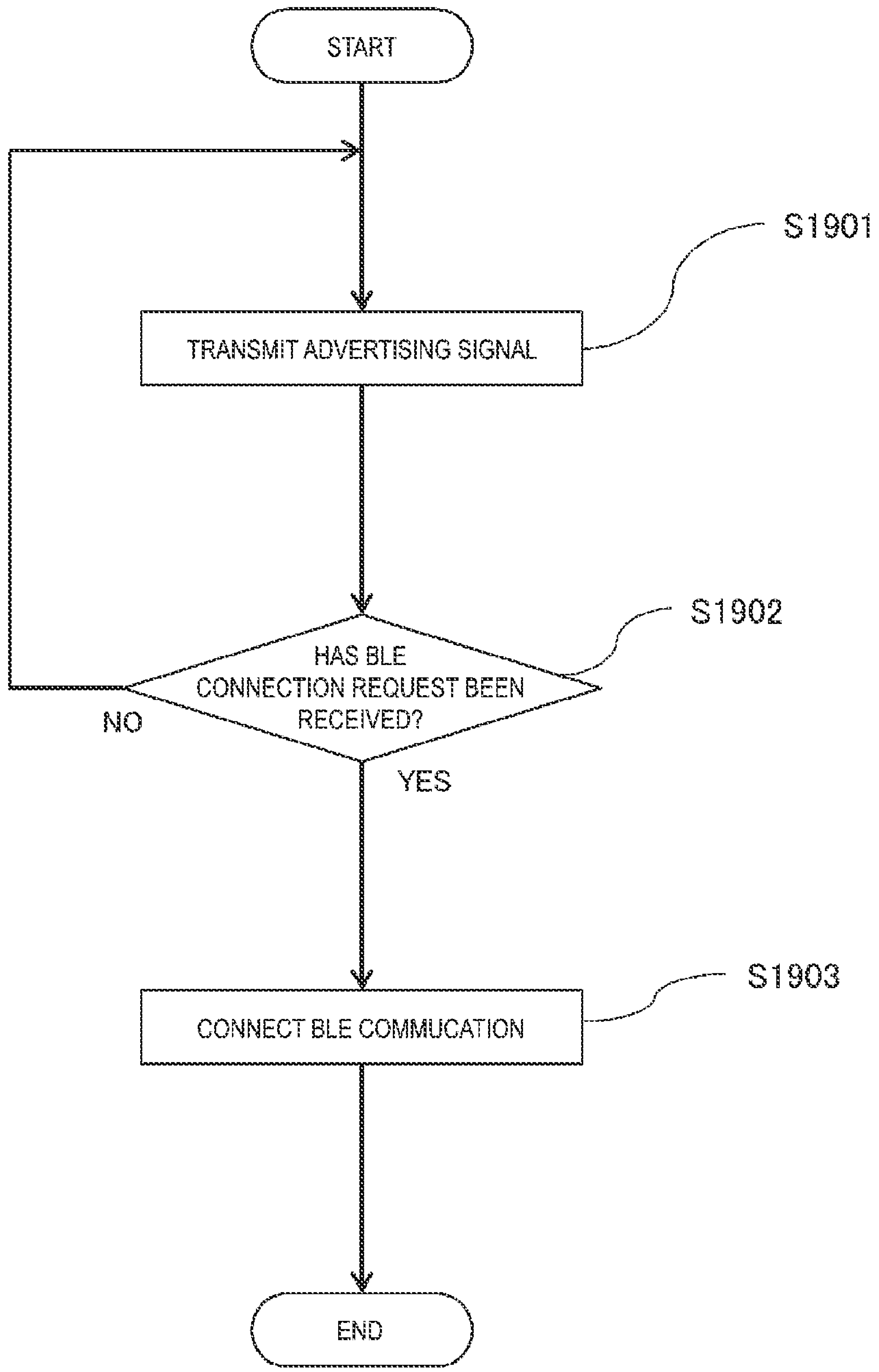

START
S1901
TRANSMIT ADVERTISING SIGNAL
S1902
HAS BLE
CONNECTION REQUEST BEEN
RECEIVED?
NO
YES
S1903
CONNECT BLE COMMUCATION
END

FIG. 9

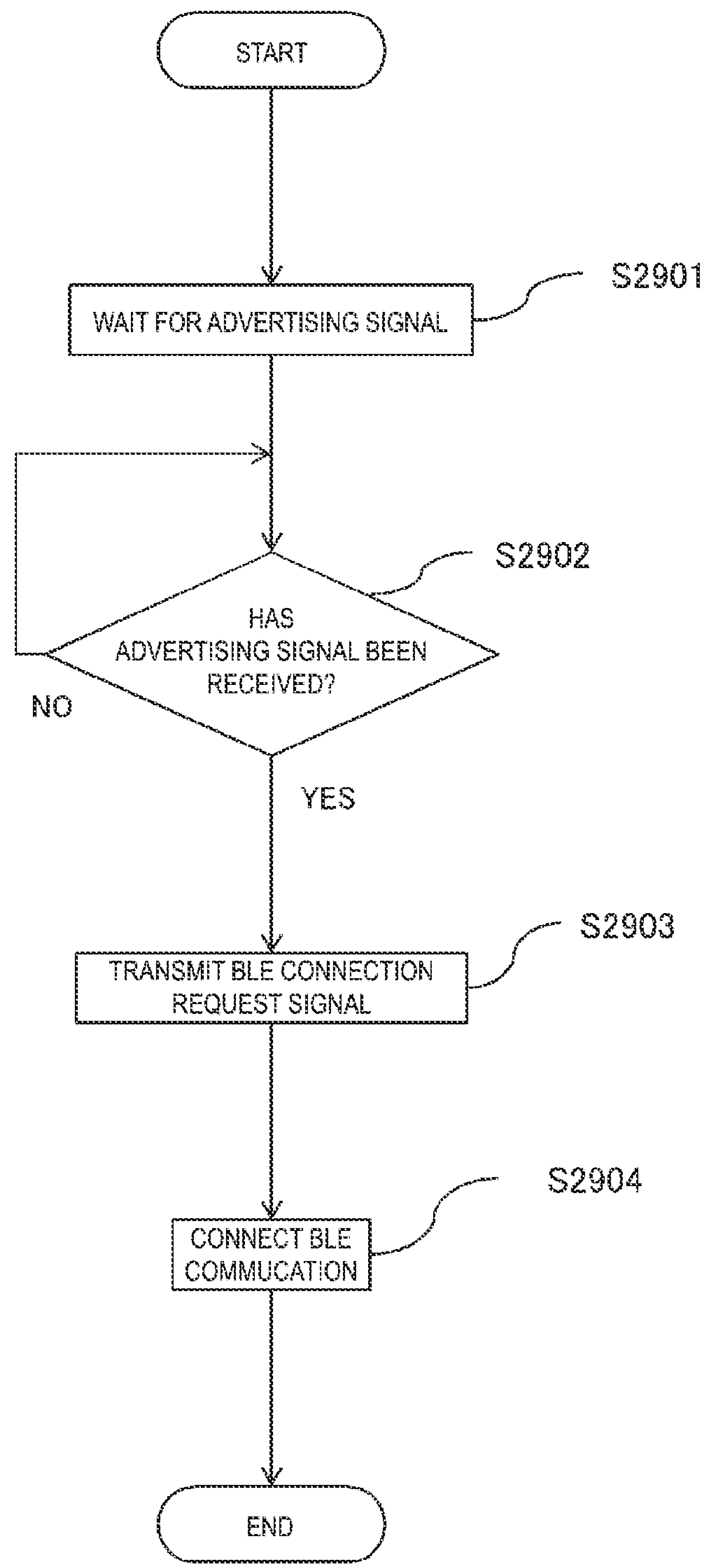

START
WAIT FOR ADVERTISING SIGNAL
S2901
HAS ADVERTISING SIGNAL BEEN RECEIVED?
S2902
NO
YES
TRANSMIT BLE CONNECTION REQUEST SIGNAL
S2903
CONNECT BLE COMMUCATION
S2904
END

FIG. 10(A)

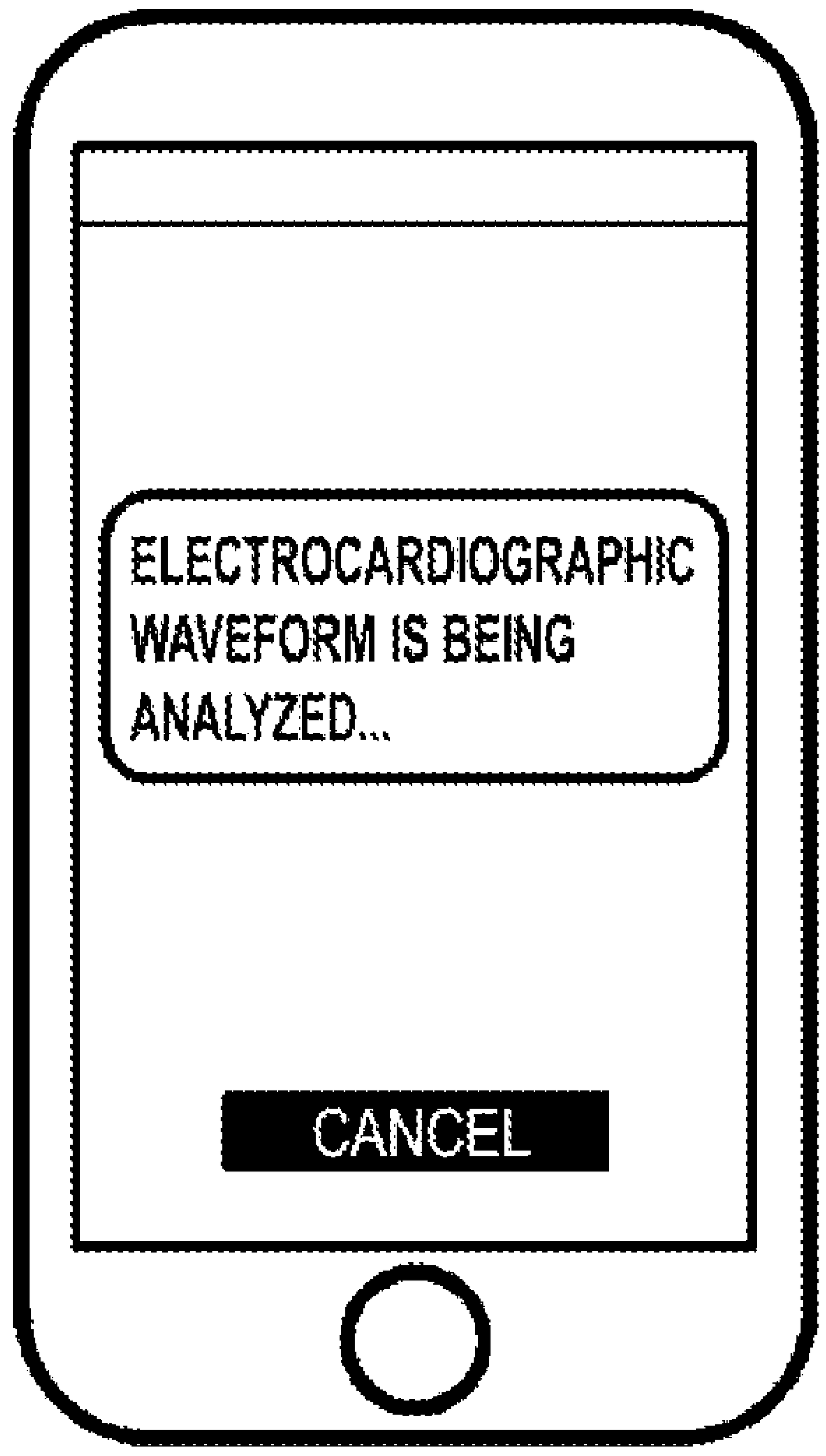
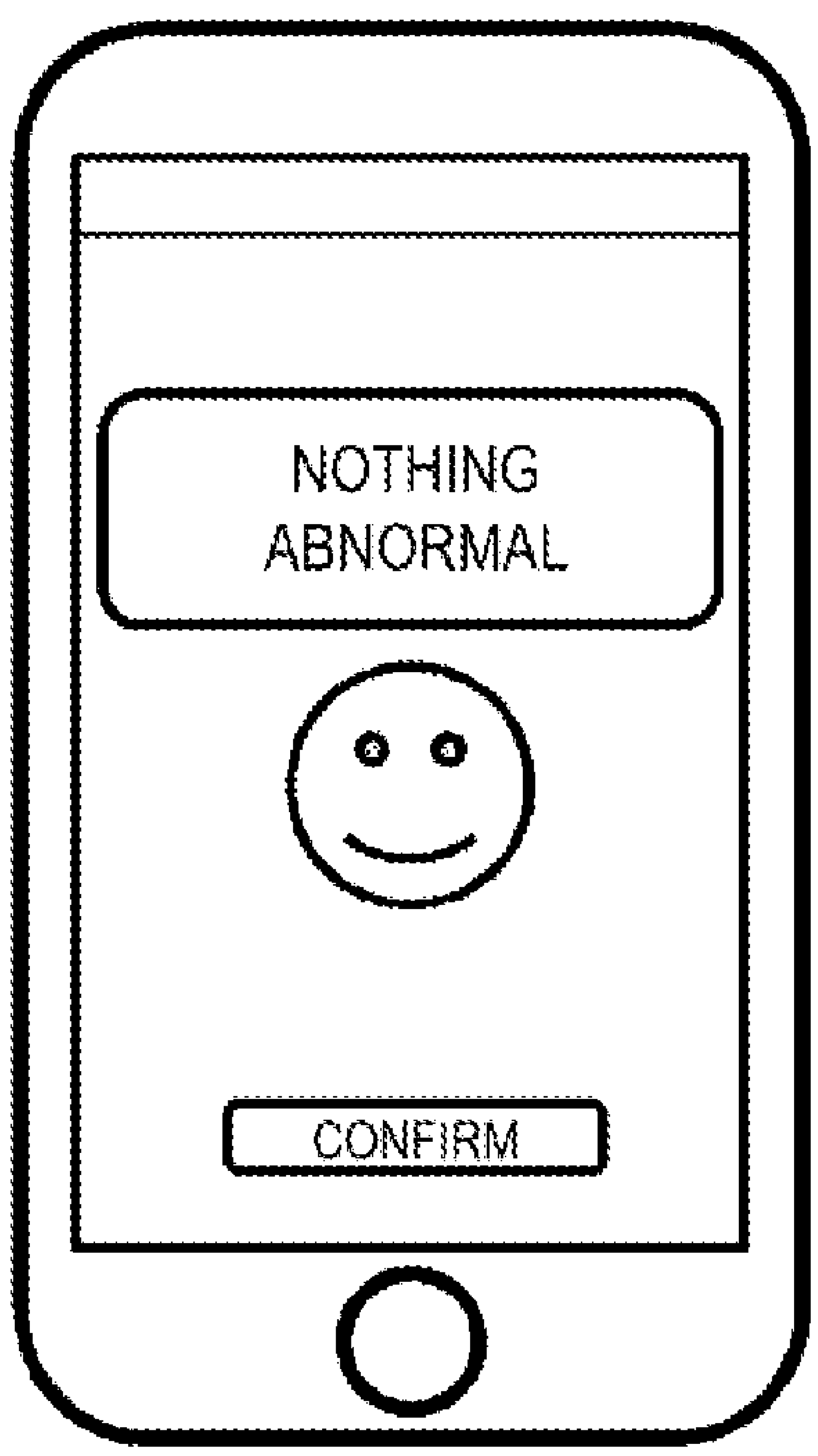


FIG. 10(B)



ELECTROCARDIOGRAPHIC WAVEFORM MEASUREMENT DEVICE, INFORMATION MANAGEMENT SYSTEM, ELECTROCARDIOGRAPHIC WAVEFORM MEASUREMENT DEVICE CONTROL METHOD, AND NON-TRANSITORY RECORDING MEDIUM INCLUDING PROGRAM RECORDED THEREIN

TECHNICAL FIELD

The present invention belongs to a technical field related to healthcare, and particularly relates to an electrocardiographic waveform measurement device, an information management system, a control method for the electrocardiographic waveform measurement device, and a program.

BACKGROUND ART

In recent years, health management has been becoming more and more common in which information related to individual bodies and health (hereinafter also referred to as "biological information") such as a blood pressure value and an electrocardiographic waveform is measured using a measurement device, with measurement results recorded and analyzed by an information processing terminal.

As an example of a measurement device as described above, a portable electrocardiographic measurement device has been proposed that measures, in everyday life, an electrocardiographic waveform immediately when an abnormality such as chest pain or palpitation occurs, and the portable electrocardiographic measurement device is expected to contribute to early detection and appropriate treatment of a heart disease (e.g., Patent Document 1).

In the measurement of the electrocardiographic waveform, the resulting electrocardiographic waveform data varies with different lead types corresponding to positions with which a measurement electrode is brought into contact, and when the electrocardiographic waveform is analyzed and utilized, the accuracy of analysis can be improved by also using information indicating which lead type is used to measure the electrocardiographic waveform. In other words, the measurement of the electrocardiographic waveform needs not only the electrocardiographic waveform data but also acquisition of information indicating which lead type is used for the measurement. Note that the lead types can be roughly divided into a set of chest leads and a set of limb leads and that simply determining which of the set of chest leads and the set of limb leads is used to measure the electrocardiographic waveform deserves useful information.

CITATION LIST

Patent Literature

Patent Document 1: JP 2005-468 A

SUMMARY OF INVENTION

Technical Problem

Patent Document 1 describes a portable electrocardiographic measurement device including a body that includes a sensor unit, a control processing unit, an input unit, a display unit, and a timer unit, the identical body performing the measurement of the electrocardiographic waveform, as well as display of information indicating that measurement is in execution, display of an analysis result, storage of results, and the like. A technology has been proposed in which when the electrocardiographic waveform is measured, the orientation (arrangement) of display of information displayed on the display unit can be changed according to the position in which the electrode is in contact (according to the lead type). In other words, Patent Document 1 discloses that the information of the lead type is used to switch the orientation of the display on the display unit.

However, in the technology disclosed in Patent Document 1, the user needs to manually set the lead types for measurement, and this is cumbersome and prevents exclusion of the possibility that the set lead types are different from the lead types used during the actual measurement. Note that the document indicates that the device may include a function of automatically detecting a measurement method, but discloses no specific solution for this purpose.

In view of the related technology described above, an object of the present invention is to provide a technology enabling an electrocardiographic waveform measurement device to accurately determine at least whether the data of the electrocardiographic waveform acquired is an electrocardiographic waveform acquired by chest lead measurement.

Solution to Problem

In order to solve the problem described above, an electrocardiographic waveform measurement device according to an aspect of the present invention includes a plurality of electrodes configured to measure an electrocardiographic waveform of a measurement target, a vibration detection unit configured to approach a chest region of the measurement target to detect vibration based on a beat of a heart of the measurement target, and a control unit configured to execute measurement processing for the electrocardiographic waveform. The control unit further executes lead type determination processing for determining, based on a detection result from the vibration detection unit, at least whether the electrocardiographic waveform measured by the measurement processing is an electrocardiographic waveform obtained by chest lead measurement.

Here, the "vibration based on a beat of a heart" includes vibration of air, that is, heart sounds. In such a configuration, when the electrocardiographic waveform is measured, information as to whether the lead type is the chest lead can be accurately acquired depending on whether the vibration is detected (and the degree of the vibration). In a case where the lead type is a chest lead, the vibration based on the beat of the heart can be detected. In a case where limb leads are used for the measurement, the vibration fails to be detected (or the detected vibration is faint).

Additionally, the lead type determination processing may include determining whether the lead type is a lead V4 or a lead I. In addition, in the lead type determination processing, the control unit may determine that the lead type is the lead V4 in a case where the vibration detected by the vibration detection unit exceeds a predetermined threshold, and may determine that the lead type is the lead I in a case where the vibration is equal to or less than the predetermined threshold. For example, a threshold can be set based on the position of the crest of the wave of the vibration detected.

Additionally, the vibration detection unit may also include a microphone and a microphone accommodation space, and may be disposed near one of the plurality of electrodes. This may allow the heart sounds to be detected.

Additionally, the electrocardiographic waveform measurement device may further include an output unit configured to output at least a determination result of the lead type determination processing. In such a configuration, the user can appropriately reference the lead type used to measure the electrocardiographic waveform.

In addition, the electrocardiographic waveform measurement device may further include a storage unit and a lead type setting unit configured to register at least one lead type desired by the user in the storage unit as a user-set lead type. The control unit may be configured so that in a case where a determination result of the lead type determination processing is different from the user-set lead type, the control unit uses the output unit to output information indicating that determination result is different from the user-set lead type.

In such a configuration, for example, in a case where the user is instructed by a physician or the like to measure the electrocardiographic waveform using predetermined lead types, then by setting the lead types, the user can be prevented from making measurement erroneously using different lead types.

Additionally, the electrocardiographic waveform measurement device may include a storage unit in which at least the electrocardiographic waveform measured is saved, and the control unit may be configured to further execute analysis processing for analyzing the electrocardiographic waveform by referencing a determination result of the lead type determination processing and using an analysis parameter corresponding to the lead type for the electrocardiographic waveform measured.

The electrocardiographic waveform measurement device including the function of analyzing the electrocardiographic waveform is an already known technique. However, in such a device, the accuracy of the analysis can be increased by performing analysis using information as to which lead type is used for measurement leading to acquisition of the electrocardiographic waveform and using an analysis parameter corresponding to the lead type.

Additionally, the electrocardiographic waveform measurement device may be a portable electrocardiographic waveform measurement device.

Additionally, the electrocardiographic waveform measurement device may further include a communication unit configured to communicate with an information processing terminal, and the control unit may be configured to transmit at least data of the electrocardiographic waveform measured, to the information processing terminal via the communication unit. By communicatively connecting to the information processing terminal and utilizing data, convenience of the electrocardiographic waveform measurement device can be improved in browsing, analysis, utilization, or the like of the data.

Additionally, an information management system according to an aspect of the present invention includes the electrocardiographic waveform measurement device including a communication unit, and an information processing terminal including a communication unit configured to communicate with the electrocardiographic waveform measurement device.

In addition, a control method according to an aspect of the present invention is a control method for an electrocardiographic waveform measurement device including a vibration detection unit configured to approach a chest region of a measurement target to detect vibration based on a beat of a heart of the measurement target. The method includes:

an electrocardiographic waveform measurement step of measuring an electrocardiographic waveform of the measurement target,

a vibration detection step of detecting at least presence or absence of the vibration, and

a lead type determination step of determining, based on information of the presence or absence of the vibration detected in the vibration detection step, at least whether the electrocardiographic waveform measured in the electrocardiographic waveform measurement step is an electrocardiographic waveform obtained by chest lead measurement.

Additionally, the method further includes an analysis step of analyzing the electrocardiographic waveform measured in the electrocardiographic waveform measurement step by referencing a determination result of the lead type determination step, and using an analysis parameter corresponding to a lead type for the electrocardiographic waveform measured.

Additionally, the electrocardiographic waveform measurement step and the vibration detection step may be executed in parallel. In such a method, efficient electrocardiographic measurement can be performed without requiring extra time for vibration detection.

Additionally, the vibration detection step and the lead type determination step may be executed before the electrocardiographic waveform measurement step, and in the electrocardiographic waveform measurement step, measurement processing may be executed based on the determination result of the lead type determination step. According to such a method, measurement can be performed using the measurement parameter corresponding to the lead type, allowing the accuracy of the measurement to be improved.

In addition, the present invention can be considered as a program for causing an electrocardiographic waveform measurement device to execute the above-described method, and a computer-readable recording medium including such a program recorded therein in a non-transitory manner.

Also, the configurations and processing operations described above can be combined with one another to constitute the present invention unless the combination leads to contradiction.

Advantageous Effects of Invention

The present invention enables the electrocardiographic waveform measurement device to accurately determine at least whether the data of the electrocardiographic waveform acquired is an electrocardiographic waveform acquired by chest lead measurement.

BRIEF DESCRIPTION OF DRAWINGS

FIG. **1**(A) is a front view illustrating a configuration of a portable electrocardiographic waveform measurement device according to an embodiment. FIG. **1**(B) is a rear view illustrating a configuration of a portable electrocardiographic waveform measurement device according to the embodiment. FIG. **1**(C) is a left side view illustrating a configuration of the portable electrocardiographic waveform measurement device according to the embodiment. FIG. **1**(D) is a right side view illustrating a configuration of the portable electrocardiographic waveform measurement device according to the embodiment. FIG. **1**(E) is a plan view illustrating a configuration of the portable electrocardiographic waveform measurement device according to the embodiment. FIG. **1**(F) is a bottom view illustrating a configuration of the portable electrocardiographic waveform measurement device according to the embodiment.

FIG. **2** is a partial cross-sectional view illustrating a structure of a vibration detection processing unit of the portable electrocardiographic waveform measurement device according to the embodiment.

FIG. **3** is a block diagram illustrating a functional configuration of the portable electrocardiographic waveform measurement device according to the embodiment.

FIG. **4** is a flowchart illustrating a flow of electrocardiograph measurement processing in the portable electrocardiographic waveform measurement device according to the embodiment.

FIG. **5** is a block diagram illustrating an overview of an information management system according to an embodiment.

FIG. **6** is a first flowchart illustrating parts of processing flows of a portable electrocardiograph and a smart phone communicatively connected in the information management system according to the embodiment.

FIG. **7** is a second flowchart illustrating parts of the processing flows of the portable electrocardiograph and the smart phone communicatively connected in the information management system according to the embodiment.

FIG. **8** is a flowchart illustrating a processing subroutine executed when BLE communication is performed by the portable electrocardiographic waveform measurement device according to the embodiment.

FIG. **9** is a flowchart illustrating a processing subroutine executed when BLE communication is performed by the information processing terminal according to the embodiment.

FIG. **10**(A) is a diagram illustrating an example of a screen provided when electrocardiographic waveform analysis-in-progress display is performed on a smart phone according to an embodiment. FIG. **10**(B) is a diagram illustrating an example of a screen provided when electrocardiographic waveform analysis result display is performed on the smart phone according to the embodiment.

DESCRIPTION OF EMBODIMENTS

First Embodiment

Embodiments of the present invention will be specifically described below with reference to the drawings. It should be noted that the dimension, material, shape, relative arrangement and the like of the components described in the present embodiment are not intended to limit the scope of this invention to them alone, unless otherwise stated.

Electrocardiographic Waveform Measurement Device

FIGS. **1**(A) through **1**(F) are diagrams illustrating a configuration of a portable electrocardiograph **10** according to the present embodiment. FIG. **1**(A) is a front view illustrating the front of the body. Similarly, FIG. **1**(B) is a rear view, FIG. **1**(C) is a left side view, FIG. **1**(D) is a right side view, FIG. **1**(E) is a plan view, and FIG. **1**(F) is a bottom view.

A bottom surface of the portable electrocardiograph **10** is provided with a left electrode **12*a*** brought into contact with the left side of the body during electrocardiographic measurement, and an opening of a vibration detection processing unit **111** is provided near the left electrode **12*a***, the vibration detection processing unit **111** detecting vibration based on the beat of the heart of a measurement target (hereinafter, simply referred to as the vibration). FIG. **2** is a partial cross-sectional view illustrating the structure of the vibration detection processing unit **111**. The vibration detection processing unit **111** includes a microphone opening **111*a*** that opens in a meshed shape toward the bottom surface side of the portable electrocardiograph **10**, and a microphone **111*c*** disposed at a position facing the microphone opening **111*a***, and a microphone space **111*b*** in which the microphone **111*c*** is accommodated. In a case where measurement is performed using the chest leads, the left electrode **12*a*** is brought into contact with the chest. In this case, heart sounds (i.e., vibration) based on the heart beat are detected by the microphone **111*c*** disposed near the left electrode **12*a***.

Additionally, a top surface side of the portable electrocardiograph **10** is provided with a first right electrode **12*b*** with which the center of the right-hand index finger is brought into contact during electrocardiographic measurement and a second right electrode **12*c*** with which the base of the right-hand index finger is brought into contact during electrocardiographic measurement. Note that the first right electrode **12*b*** functions as a GND electrode.

During electrocardiographic measurement, the portable electrocardiograph **10** is held by the right hand, and the right-hand index finger is placed on the top surface portion of the portable electrocardiograph **10** in proper contact with the first right electrode **12*b*** and the second right electrode **12*c***. Furthermore, the left electrode **12*a*** is then brought into contact with the skin at a location corresponding to a desired lead type. For example, when measurement is performed by the so-called lead I, the left electrode is brought into contact with the palm of the left hand, and when measurement is performed by the so-called V4 lead, the left electrode is brought into contact with the skin slightly to the left of the epigastric region of the left chest and below the papilla.

In addition, various operation units and indicators are disposed on a left side surface of the portable electrocardiograph **10**. Specifically, the left side surface includes a measurement switch **16**, a measurement mode LED **16*a***, a Bluetooth (trade name) low energy (BLE) communication button **17**, a BLE communication LED **17*a***, an available memory display LED **18**, a battery change LED **19**, and the like.

Additionally, a measurement state notification LED **13**, an analysis result notification LED **14**, and the like are provided at the front surface of the portable electrocardiograph **10**, and a battery housing opening and a battery cover **15** are arranged at the rear surface of the portable electrocardiograph **10**.

FIG. **3** illustrates a block diagram illustrating a functional configuration of the portable electrocardiograph **10**. As illustrated in FIG. **3**, the portable electrocardiograph **10** includes function units including a control processing unit **101**, an electrode unit **12**, an amplifier unit **102**, an analog to digital (AD) conversion unit **103**, a timer unit **104**, a storage processing unit **105**, a display unit **106**, an operation unit **107**, a power source unit **108**, a communication processing unit **109**, an analysis unit **110**, a vibration detection processing unit **111**, and a lead type determination unit **112**.

The control processing unit **101** manages the control of the portable electrocardiograph **10**, and includes a central processing unit (CPU) and the like, for example. In response to receiving operation of the user via the operation unit **107**, the control processing unit **101** controls each component of the portable electrocardiograph **10** to execute various processing operations such as electrocardiographic measurement and information communication in accordance with a predetermined program. Note that the predetermined program is stored in the storage processing unit **105** described below.

Additionally, the control processing unit **101** includes, as a functional module, the analysis unit **110** analyzing electrocardiographic waveforms and the lead type determination unit **112**. The analysis unit **110** analyzes the measured electrocardiographic waveform for the presence of disturbance or the like, and outputs a result indicating whether the electrocardiographic waveform obtained at least during measurement is normal. Based on the information of the vibration acquired by the vibration detection processing unit **111**, the lead type determination unit **112** determines whether the measured electrocardiographic waveform is obtained using the lead V4 or the lead I, and outputs this information.

The electrode unit **12** includes the left electrode **12***a*, the first right electrode **12***b*, and the second right electrode **12***c*, and functions as a sensor for detecting an electrocardiographic waveform. The amplifier unit **102** functions to amplify signals output from the electrode unit **12**. The AD conversion unit **103** functions to convert an analog signal amplified by the amplifier unit **102** into a digital signal and to transmit the converted signal to the control processing unit **101**.

The timer unit **104** functions to measure time with reference to a real time clock (RTC, not illustrated). As described below, for example, the period of time until the end of measurement is counted and output during the electrocardiographic measurement.

The storage processing unit **105** includes a main memory (not illustrated) such as a random access memory (RAM) and stores various types of information such as application programs, measured electrocardiographic waveforms, and analysis results. In addition to the RAM, for example, a long-term storage medium such as a flash memory may be provided.

The display unit **106** includes light emitting elements such as the measurement mode LED **16***a*, the BLE communication LED **17***a*, the available memory LED **18**, and the battery change LED **19** described above, and informs the user of the state of the device and the occurrence of an event by lighting, blinking, or the like of the LEDs. Additionally, the operation unit **107** includes the measurement switch **16**, the communication button **17**, and the like, and functions to receive an input operation from the user and to cause the control processing unit **101** to execute processing in accordance with the operation.

The power supply unit **108** includes a battery (not illustrated) that supplies power required for operation of the device. The battery may be, for example, a secondary battery such as a lithium ion battery, or a primary battery.

The communication processing unit **109** includes an antenna for wireless communication (not illustrated), and functions to communicate with another device such as an information processing terminal described below at least by BLE communication. Additionally, a terminal may be provided for wired communication.

The vibration detection processing unit **111** detects vibration in a case where the configuration described above is used to perform measurement using the chest leads.

Electrocardiographic Measurement Processing Using Portable Electrocardiograph

Now, based on FIG. **4**, a description will be given for operation of the portable electrocardiograph **10** that is performed when the electrocardiographic measurement is performed. FIG. **4** is a flowchart illustrating a procedure of processing executed when electrocardiographic measurement is performed using the portable electrocardiograph **10** according to the present embodiment.

Before measurement of an electrocardiographic waveform, when the user presses the measurement switch **16** down, the device is powered on to execute a measurement mode, and the measurement mode LED is lighted to indicate that the measurement mode is in execution. With the measurement mode in execution, the user holds the portable electrocardiograph **10** in the right hand, with the right-hand index finger in contact with the first right electrode **12***b* and the second right electrode **12***c*, and with the left electrode **12***a* in contact with the skin at a location to be measured. Then, the control processing unit **101** detects a contact state via the electrode unit **12** (S**1101**), and executes a process of determining whether a predetermined time has elapsed with the electrode correctly in contact (S**1102**). Here, in response to determining that the predetermined time has not elapsed, the control processing unit **101** repeats the same processing until the predetermined time has elapsed, and in response to determining that the predetermined time has elapsed, the control processing unit **101** proceeds to step S**1103**. The control processing unit **101** executes processing for detecting vibration via the vibration detection processing unit **111** (S**1103**), and determines, via the lead type determination unit **112**, whether the detected vibration exceeds a predetermined threshold (S**1104**). Here, in response to determining that the vibration exceeds the predetermined threshold, the control processing unit **101** assumes that the lead type is the lead V4, and executes lead V4 electrocardiographic measurement (S**1111**).

After step S**1111**, the control processing unit **101** executes processing for determining whether the predetermined electrocardiographic measurement time (for example, 30 seconds) has elapsed (step S**1112**). Here, in response to determining that the predetermined time has not elapsed, the control processing unit **101** returns to step S**1111** and repeats the subsequent processing. On the other hand, in response to determining that the predetermined measurement time has elapsed, the control processing unit **101** ends the measurement, and executes, via the analysis unit **110**, analysis processing for the electrocardiographic waveform (S**1113**). In accordance with the assumption that the lead type is the lead V4, the analysis processing is executed using an analysis parameter suitable for analysis of the electrocardiographic waveform data obtained by the lead V4 measurement.

When the analysis ends, the control processing unit **101** saves the electrocardiographic waveform data and an analysis result in the storage processing unit **105**, along with information indicating that the data has been acquired by the lead V4 measurement (S**1114**). Then, the control processing unit **101** displays the analysis result by lighting (blinking) the analysis result notification LED **14** (S**1115**), and ends the series of measurement processing. When the analysis result is displayed as well, the display preferably enables the user to recognize, based on the color of the LED and/or the blinking pattern and/or the like, that the lead type used for the measurement is the lead V4.

On the other hand, in step S**1104**, in response to determining that the vibration is less than or equal to the threshold, the control processing unit **101** assumes that the lead type is the lead I, and executes lead I electrocardiographic measurement (S**1121**). In the lead I electrocardiographic measurement, as is the case with the lead V4, the control processing unit **101** executes processing for determining whether the predetermined electrocardiographic measurement time has elapsed (step S**1122**). Then, in response to determining that the predetermined time has not elapsed, the control processing unit **101** returns to step

S1121 and repeats the subsequent processing. In response to determining that the predetermined measurement time has elapsed, the control processing unit **101** ends the measurement, and executes, via the analysis unit **110**, the analysis processing for the electrocardiographic waveform (S**1123**). In accordance with the assumption that the lead type is the lead I, the analysis processing is executed using the analysis parameter suitable for the analysis of the electrocardiographic waveform data obtained by the lead I measurement.

When the analysis ends, the control processing unit **101** saves the electrocardiographic waveform data and the analysis result in the storage processing unit **105**, along with information indicating that the data has been acquired by the lead I measurement (S**1124**). Then, the control processing unit **101** displays the analysis result by lighting (blinking) the analysis result notification LED **14** (S**1125**), and ends the series of measurement processing. When the analysis result is displayed as well, the display preferably enables the user to recognize, based on the color of the LED and/or the blinking pattern and/or the like, that the lead type used for the measurement is the lead I.

In the electrocardiographic waveform measurement device according to the present embodiment as described above, the information as to which of the lead V4 and the lead I is used to measure the electrocardiographic waveform is acquired before the electrocardiographic waveform measurement, and the information is used for measurement and analysis. Thus, parameters corresponding to each lead type are used for the measurement and analysis, enabling accurate results to be obtained. Additionally, the electrocardiographic waveform data is saved along with the information as to which lead type has been used to acquire the data, thus allowing an expert such as a physician to make efficient determination when the data is referenced later.

Second Embodiment

As in the first embodiment, the portable electrocardiograph **10** can singularly perform electrocardiographic waveform measurement, analysis of the measurement data, and display of the analysis result. However, by communicatively connecting the portable electrocardiograph **10** to the information processing terminal, the convenience of the portable electrocardiograph **10** can be further improved. Based on FIGS. **5** to **9**, description will be given below for an embodiment of an information management system **1** including the portable electrocardiograph **10** and a smart phone **20** corresponding to an example of the information processing terminal.

FIG. **5** is a schematic diagram illustrating a configuration example of the information management system **1** according to the present embodiment. As illustrated in FIG. **5**, the information management system **1** includes the portable electrocardiograph **10** and the smart phone **20**, which are communicatively connected with each other. Note that the portable electrocardiograph **10** is configured similarly to that described in the first embodiment, and will thus not be described.

Information Processing Terminal

As illustrated in FIG. **5**, the smart phone **20**, corresponding to an example of the information terminal, includes a control processing unit **21**, a communication processing unit **22**, a touch panel display **23**, and a storage processing unit **24**. The control processing unit **21** manages the control of the smart phone **20**, and includes, for example, a CPU and the like. The control processing unit executes various programs stored in the storage processing unit **24** to fulfill functions corresponding to the programs. The communication processing unit **22** includes an antenna for wireless communication, and is a function of communicating with another device such as the portable electrocardiograph **10**, and a wireless base station. Also, the communication processing unit **22** may include a terminal for wired communication.

The touch panel display **23** plays both a role of a display unit which is an aspect of an output unit, and a role of an input unit, and as described below, in a case where communicative connection to the portable electrocardiograph **10** is established, the touch panel display **23** can display status information such as the remaining time until the end of measurement, graph data of the electrocardiographic waveform, and the like. In addition, operations from the user are received via various input images.

The storage processing unit **24** includes, for example, a long-term storage medium such as a flash memory in addition to a main memory such as a RAM, and stores various information such as application programs, measurement electrocardiographic waveforms, and analysis results.

Description will be given below based on FIGS. **6** to **9** for processing that is executed in a case where electrocardiographic measurement is performed by allowing the portable electrocardiograph **10** and the smart phone **20** to cooperate with each other through BLE communication. FIGS. **6** and **7** are diagrams illustrating a flow of processing of each of the portable electrocardiograph **10** and the smart phone **20** connected to each other through BLE communication and also illustrating timings for transmitting information between the devices. Note that for the flow of the processing of the portable electrocardiograph **10**, the above-described processing operations are denoted by the same reference numerals, and the detailed description of the processing operations is omitted.

First, the user presses down the BLE communication button **17** of the portable electrocardiograph **10**, and the control processing unit **101** executes the processing of the subroutine for BLE communication (S**1201**). FIG. **8** shows a flowchart of the subroutine. Specifically, as illustrated in FIG. **8**, the control processing unit **101** first transmits an advertising signal for BLE communication from the communication processing unit **109** (S**1901**). Then, the control processing unit **101** determines whether a connection request for BLE communication has been received from the information processing terminal (S**1902**). Here, in response to determining that no connection request for BLE communication has been received, the control processing unit **101** repeats similar processing until the BLE communication processing is canceled due to the elapse of a predetermined time or operation of the operation unit **107**. On the other hand, in response to determining that a connection request for BLE communication has been received, the control processing unit **101** proceeds to step S**1903**, and makes BLE connection to a device transmitting the connection request. When the BLE communication connection is established, the control processing unit **101** ends the subroutine.

Additionally, the user enables the smart phone **20** to make BLE communication with the portable electrocardiograph **10**. Specifically, the user operates the touch panel display **23** to set the BLE connection settings to the ON state in a setting menu or the like. Alternatively, the BLE connection settings may be set to the ON state by initiating a dedicated application program for cooperation with the portable electrocardiograph **10**.

When the BLE connection settings are set to the ON state, the control processing unit **21** of the smart phone **20** executes the subroutine for BLE connection via the communication processing unit **22** (S**2101**). FIG. **9** illustrates the processing of the subroutine. Specifically, when the subroutine is initiated, the control processing unit **21** waits to receive the advertising signal from the portable electrocardiograph **10** (S**2901**). Then, the control processing unit **21** determines whether the advertisement signal has been received (S**2902**), and repeats the processing until the control processing unit **21** determines that the signal has been received. In response to determining in step S**2092** that the advertising signal is received, the control processing unit **21** transmits a BLE connection request signal to the portable electrocardiograph **10** via the communication processing unit **22** (S**2903**). Then, the control processing unit **21** makes BLE connection to the portable electrocardiograph **10** (S**2904**. Corresponding to S**1903** described above), and ends the subroutine. Then, in step S**2102** in FIG. **6**, the control processing unit **21** transmits a communication start request to the portable electrocardiograph **10**.

On the other hand, the control processing unit **101** of the portable electrocardiograph **10** detects an electrode contact state (S**1101**), and then transmits information related to the electrode contact state to the smart phone **20** (S**1202**), and the smart phone **20** receives the information (S**2103**).

The smart phone **20**, having received the information of the electrode contact state, displays the electrode contact state on the touch panel display **23** (S**2104**). The smart phone **20** may display, for example, the message "The electrodes are in proper contact", "The electrodes are not in proper contact", or the like.

After step S**1202**, the control processing unit **101** of the portable electrocardiograph **10** then executes processing for determining whether a predetermined time has elapsed with the electrodes in proper contact (S**1102**). Here, in response to determining that the predetermined time has not elapsed, then the control processing unit **101** returns to step S**1101**, and repeats the subsequent processing. In response to determining that the predetermined time has elapsed, the control processing unit **101** proceeds to step S**1203**. In step S**1203**, the electrocardiographic waveform measurement processing and the vibration detection processing are executed in parallel, and the electrocardiographic waveform data and the vibration data are sequentially saved in the storage processing unit **105**. In other words, in the present embodiment, the detection of vibration and the determination of the lead type are not performed before the measurement of the electrocardiographic waveform.

The control processing unit **101** executes processing for transmitting to the smart phone **20** the data of the electrocardiographic waveform and the electrocardiographic measurement time (the remaining time until the end of the measurement) that are measured in step S**1203** (S**1204**).

The data transmitted from the portable electrocardiograph **10** in step S**1204** is received in the smart phone **20** (S**2105**), and the electrocardiographic measurement time and the electrocardiographic waveform graph are displayed on the touch panel display **23** (S**2106**). Specifically, the graph of the electrocardiographic waveform may be displayed along with, for example, the countdown message "XX seconds until the end of the electrocardiographic measurement".

Then, in step S**1205**, the control processing unit **101** of the portable electrocardiograph **10** determines whether a predetermined measurement time has elapsed, and in a case where the predetermined time has not elapsed, returns to step S**1203** and repeats the subsequent processing. On the other hand, in a case where the control processing unit **101** determines in step S**1205** that the predetermined measurement time has elapsed, the lead type determination unit **112** executes the determination processing for the lead type (S**1206**). The determination processing is performed based on the vibration data saved in the storage processing unit **105**. The determination method itself is similar to that described in the first embodiment, and thus description of the method is omitted.

Then, the analysis unit **110** analyzes the detected electrocardiographic waveform by additionally using the information of the lead type determined in step S**1206** (S**1207**). Then, while the analysis is in execution, the control processing unit **101** transmits, to the smart phone **20**, information indicating that the analysis is in execution (S**1208**). When the analysis is ended, the control processing unit **101** saves the result of the analysis and the electrocardiographic waveform data and the lead type data in the storage processing unit **105** (S**1209**). Additionally, the control processing unit **101** displays the analysis result via the analysis result notification LED **14** (S**1210**), and transmits the analysis result information to the smart phone **20** (S**1211**). Note that for the display of the analysis result, for example, the LED may be lighted only in a case where the electrocardiographic waveform is found abnormal or may be lighted in accordance with a lighting and blinking method corresponding to the analysis result. Alternatively, the information of the lead type may be reflected in the display.

After step S**2106**, in response to receiving, via the communication processing unit **22**, information indicating that the electrocardiographic waveform is being analyzed (S**2107**), the control processing unit **21** of the smart phone **20** displays the information on the touch panel display **23** (S**2108**). FIG. **10**(A) illustrates an example of a screen displaying information indicating that the analysis is in execution. Then, in response to receiving, via the communication processing unit **22**, the analysis result information transmitted from the portable electrocardiograph **10** (S**2109**), the control processing unit **21** causes the touch panel display **23** to display the result (S**2110**). FIG. **10**(B) illustrates an example of a screen displaying the analysis result.

After step S**1211**, in a case where any data (electrocardiographic waveform, analysis result, lead type, or the like) has yet to be transmitted to the smart phone **20**, the control processing unit **101** of the portable electrocardiograph **10** transmits the data to the smart phone **20** (S**1212**). Then, the control processing unit **101** determines whether all data has been transmitted (S**1213**). Here, in response to determining that not all of the data has been transmitted, then the control processing unit **101** returns to step S**1212** and repeats the subsequent processing. On the other hand, in step S**1213**, in response to determining that all of the data transmission has been completed, the control processing unit **101** waits for a communication end request from the smart phone **20**, and disconnects the BLE communication (S**1214**), to end the series of processing operations.

After step S**2110**, in a case where data having yet to be transmitted is transmitted from the portable electrocardiograph **10**, the control processing unit **21** of the smart phone **20** receives the data (S**2111**), transmits, to the portable electrocardiograph **10**, a signal requesting the termination of the communication (S**2112**), and deletes the BLE connection (S**2113**) to end the series of processing operations.

As is described above, the portable electrocardiograph **10** and the information management system **1** of the present embodiment can be used in cooperation with an information processing terminal such as the smart phone **20** to display various data such as electrocardiographic waveform data on the display for browsing. Additionally, the data received can be saved, and can be effectively utilized by using an application program or the like.

Additionally, instead of the detection of vibration and the determination of the lead type being performed before the measurement of the electrocardiographic waveform, the detection of vibration is performed in parallel with the measurement of the electrocardiographic waveform, thus allowing efficient measurement processing to be executed.

Other Points

The description of each example described above is merely illustrative of the present invention, and the present invention is not limited to the specific embodiments described above. Within the scope of the technical idea of the present invention, various modifications and combinations may be made.

For example, in the example described above, the electrocardiographic waveform measurement device is of the portable type, but the device for electrocardiographic waveform measurement need not be of the portable type. Also, the vibration detection unit for detecting vibration based on the beat of the heart is illustrated as the microphone, but is not necessarily limited to the microphone, and any other vibration sensor may be used.

The information processing terminal is not limited to a smart phone, and may be another portable information processing terminal such as a tablet terminal, or may be a stationary terminal. Additionally, the communication processing unit is not limited to a communication processing unit intended for BLE communication, and may be an antenna enabling other wireless communication such as Wi-Fi (trade name) or infrared communication. Alternatively, the communication processing unit may communicate using a wired connection.

REFERENCE NUMERALS LIST

1 Biological information management system
10 Portable electrocardiograph
12*a* Left electrode
12*b* First right electrode
12*c* Second right electrode
13 Measurement state notification LED
14 Analysis result notification LED
15 Battery cover
16 Measurement switch
16*a* Measurement mode LED
17 Communication button
17*a* BLE Communication LED
18 Available memory display LED
19 Battery change LED
111*a* Microphone opening portion
111*b* Microphone space
111*c* Microphone
20 Smart phone

The invention claimed is:

1. An electrocardiogra waveform measurement device comprising:

a plurality of electrodes configured to measure an electrocardiogramaveform of a measurement target;

a vibration detection unit configured to approach a chest region of the measurement target to detect vibration based on a beat of a heart of the measurement target;

a storage unit in which at least the electrocardiogramaveform measured is saved; and,

a control unit configured to execute measurement processing for the electrocardiogra waveform, wherein the control unit further executes lead type determination processing for determining, based on a detection result from the vibration detection unit, at least whether the electrocardiogramaveform measured by the measurement processing is an electrocardiogramaveform obtained by chest lead measurement, wherein the control unit further executes analysis processing for analyzing the electrocardiogramaveform by referencing a determination result of the lead type determination processing and using an analysis parameter corresponding to the lead type for the electrocardiogramaveform measured,

an output unit configured to output at least a determination result of the lead type determination processing, and

an operation unit, wherein:

the control unit registers at least one lead type desired by the user in the storage unit as a user-set lead type by receiving operation input via the operation unit, and uses the output unit to output information indicating that the determimation result is different from the user-set lead type in a case where a determination result of the lead type determination processing is different from the user-set lead type.

2. The electrocardiogramaveform measurement device according to claim **1**, wherein the lead type determination processing includes determining whether the lead type is a lead V4 or a lead I.

3. The electrocardiogramaveform measurement device according to claim **2**, wherein in the lead type determination processing, the control unit determines that the lead type is the lead V4 in a case where the vibration detected by the vibration detection unit exceeds a predetermined threshold, and determines that the lead type is the lead I in a case where the vibration is equal to or less than the predetermined threshold.

4. The electrocardiogramaveform measurement device according to claim **1**, wherein the vibration detection unit includes a microphone and a microphone accommodation space, and is disposed near one of the plurality of electrodes.

5. The electrocardiogramaveform measurement device according to claim **1**, wherein the electrocardiogramaveform measurement device is a portable electrocardiogra waveform measurement device.

6. The electrocardiogramaveform measurement device according to claim **1**, further comprising a communication unit configured to communicate with an information processing terminal, wherein the control unit transmits at least data of the electrocardiogra waveform measured, to the information processing terminal via the communication unit.

7. An information management system comprising:

the electrocardiogramaveform measurement device according to claim **6**; and,

an information processing terminal including a communication unit configured to communicate with the portable electrocardiogramaveform measurement device.

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