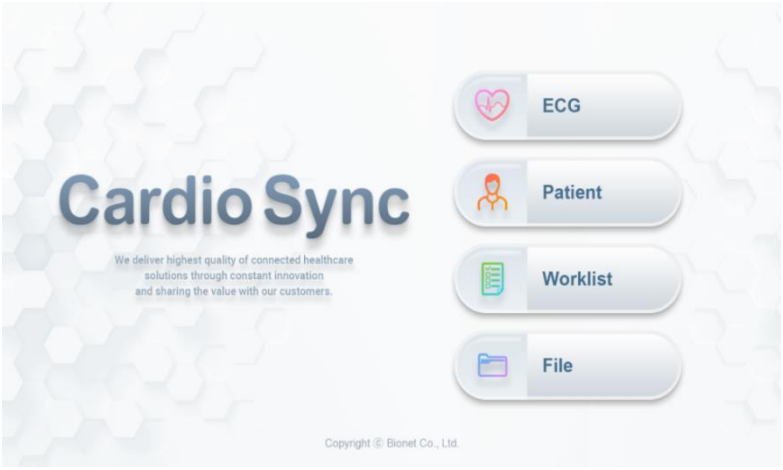
Cardio P1

SERVICE MANUAL

Version 1.01



Revision History

Edition	Date	Page	Comment
Ver. 1.00	2022-02-08	All	Initial Release
Ver. 1.01	2023-05-17	All	Change Logo

Section 1. General Information

1-1. Introduction

The CardioSync system is a system to measure and record ECG of a patient as an ECG recording machine with 12 channels.

In addition to providing the user with the parameters and automatic diagnosis required for the patient's ECG recording and diagnosis, when the patient's and user's information is entered, a report is output to the PC along with the ECG record, which can be effectively used for chart management and stored data can be managed as digital files.

The CardioSync is installed on a standalone PC. For all configurations, an independent PC is used that can be positioned for patient convenience. For device to ECG measurement is Cardio P1.

1-2. Features of the equipment

- Waves of ECG in 12 channels are configured with various channels in 3 channels + 3 rhythms, 3 channels + 1 rhythm, 6 channels + 1 rhythm and 12 channels and reports are printed on the PC.
- Rhythm in 1 channel is acquired for a long time (1, 3, 5, 10, 20 and 30min) and reports are printed on the PC.
- Print 12 channel rhythm continuously on a real time basis at a time.
- Heart rate, PR interval, RR interval, QRS interval, QT interval, QTc interval, P-R-T axis, SV1/RV1/R+S size needed for the diagnosis are automatically calculated and printed on the report with ECG.
- Provide automatic diagnosis results of ECG of pediatrics and adults.
- Provide real-time detection for 13 rhythm diagnoses.
- Provide disclosure function to save and show ECG data up to 30 minutes.
  Disclosure function helps diagnose arrhythmia.
- It is possible to print after changing the filter setup, sign size, printing speed, channel configuration and rhythm setup on ECG that is saved once helping diagnose.
- It is available to enter and show on screen patient or user information making it feasible to efficiently manage the chart.
- The number of patient data stored varies depending on the PC capacity, and the stored data can be moved to another PC. In addition, additional storage and data movement are possible in USB memory.
- It supports various protocols to be connected with hospital computer network (EMR, PACS, etc.) reinforcing the file or worklist DB functions.

1-3. Equipment description

The CardioSync system is comprised of the following components.

CardioSync System

1) CardioSync

- Software that analyzes and records the measured ECG
- Installed on a PC.

2) Cardio P1

- Device to ECG measurement

Cardio P1 Basic Configuration and Accessories

Make sure to open the package box and see if the following components are contained. In addition, make sure to see if body or components are damaged.

① Body (1EA) - Cardio P1 90.75(W) x 103.5(H) x 24.93(D)mm

② Patient Cable (1EA) - Length 1,400mm (Max)

③ Power (USB Data) Cable (1EA) - Length 2,450mm (Max)

④ Limb Electrodes (1SET)

⑤ Chest Electrodes (1SET)

⑥ Hanger (1EA)

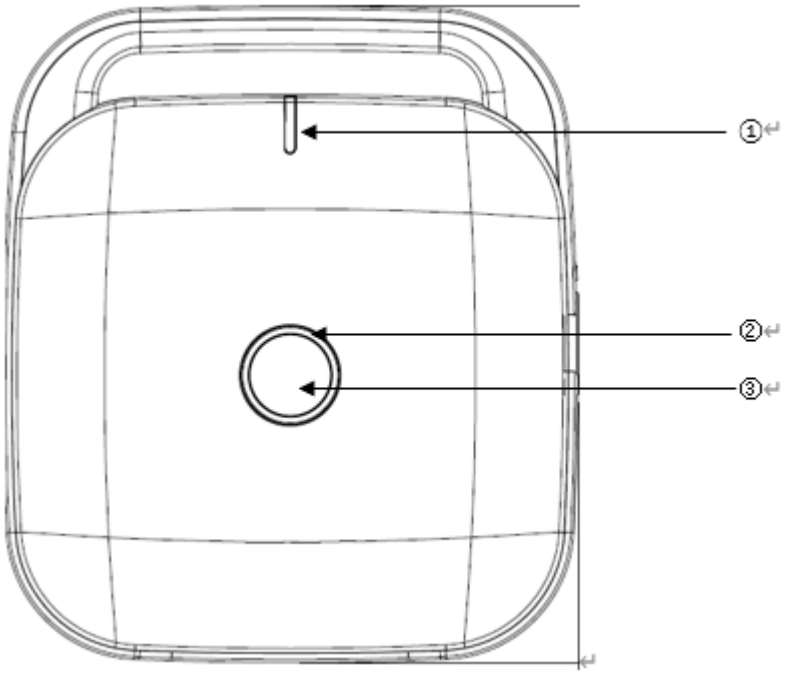
⑦ Silicone Pad (1EA)

⑧ USB Lock Key (1EA)

⑨ ECG Gel (1EA)

Main Unit

▣ Top View

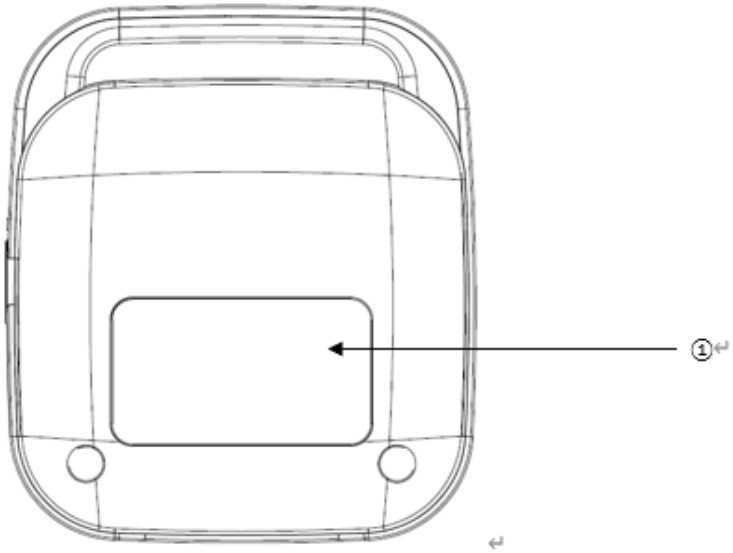


① Indication Part (LED) : Part showing the power connection status of a product

② Indication Part (LED) : Part that informs the lead connection status

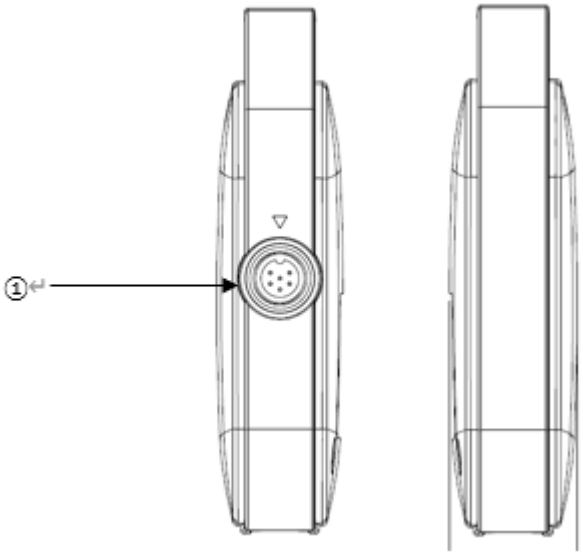
③ Function Switch : Start record (push more than 3 seconds), event marker key

▣ **Bottom View**



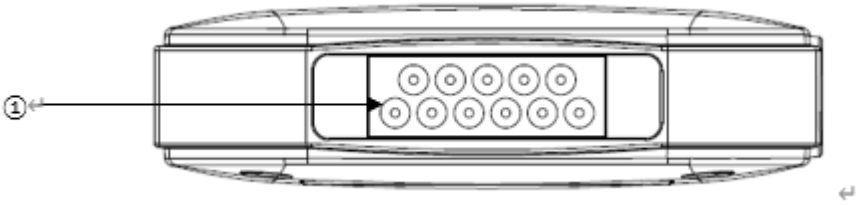
① ID Label : Part to attach ID Label

▣ Side View



① Power (USB Data) Cable Connection Port

▣ Rear View

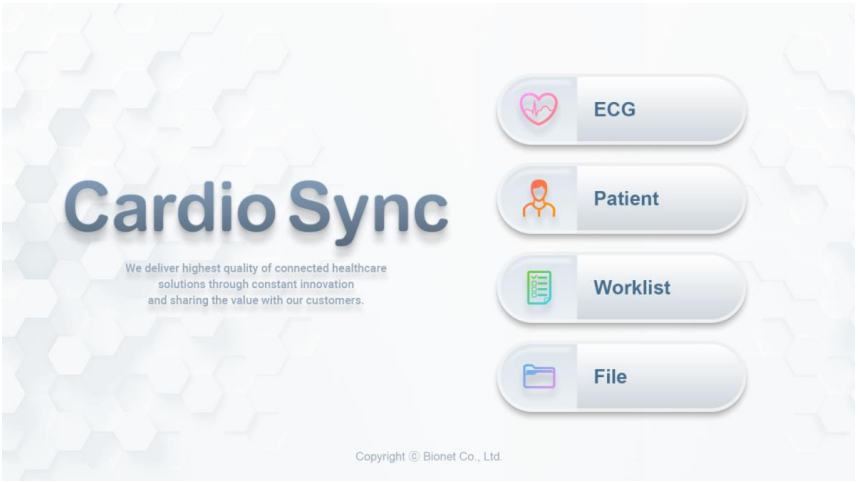


① ECG Cable Connection Port

Warning
If a stand for anchoring the device is damaged, or if a product is not anchored, there is a risk of electrocution. Make sure to immediately stop using the product and request manufacturer or seller for the repair.

Notes
Do not open the cover of the device to avoid electronic shock. Device can only be disassembled by qualified personnel of service of our company.

Initial Screen

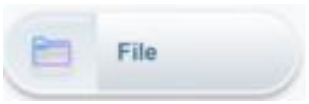


After completing all installation and running the program, you will see a menu to select the system version, company name, 'ECG', 'Patient', 'Worklist', and 'File' on the screen.
To select an ECG, find the menu box and click the selection box on the screen.

: ECG

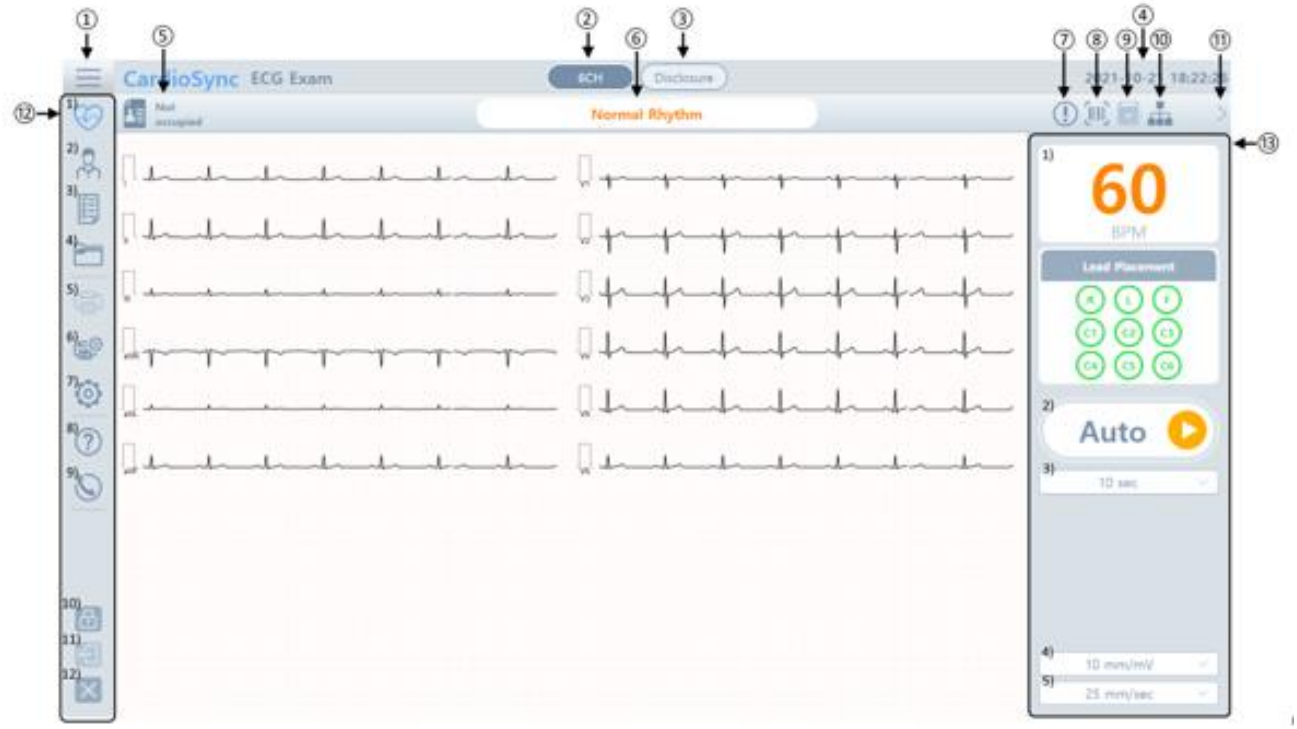
: Patient

: Worklist



: File

ECG Graphic Window



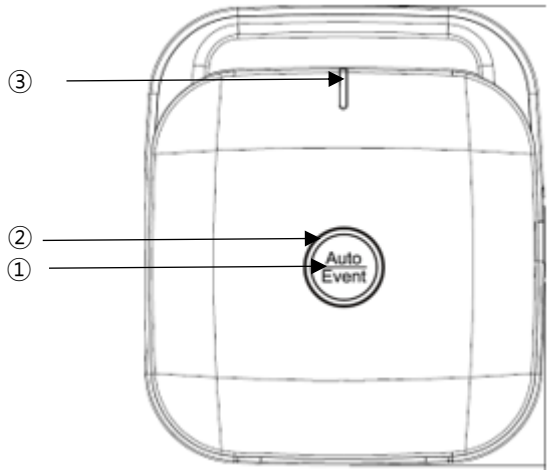
① Button for expand/collapse Quick Menu
② 6CH display button
③ Disclosure button
④ Display the current date or time
⑤ Menu button for indicating patient ID and name and entering patient information
⑥ Display the real-time diagnosis name display
⑦ Indicate study queue (sending failure list management) icon
⑧ Access status of external devices (barcode reader)
⑨ Access status of Cardio P1
⑩ Menu button for network connection status and setup
⑪ Button for expand/collapse Side Menu
⑫ Quick Menu bar
   1) Button for moving to ECG
   2) Button for moving to Patient list
   3) Button for moving to Worklist
   4) Button for moving to File
   5) Print button
   6) Print setup menu button
   7) Setup menu button
   8) Display manual button
   9) Show manual

10) Show contact us
11) Logout button
12) Close button

⑬ Side Menu bar
1) Indicate heart rate
2) AUTO button
3) Menu button for indicating ECG record mode (one of the 10s, 1m, 3m, 5m, 10m, 20m and 30m) and setup
4) Menu button for indicating or setting up signal size
5) Menu button for indicating or setting up print speed

Notes
The heart rate is between 30 and 300 bpm and the error range is ±3 bpm.

Function Key Panel



- Push Buttons

①		Auto / Event. 1. Long Press (more than 3 seconds) Perform the operation that is the most frequently performed in the saving, transmission, and printing of data in the ECG diagnosis test with one key 2. Short Press Performed to mark as a marker when abnormalities such as arrhythmias were felt in the ECG diagnostic test

- Indication lamp

②		Indicates the lead fault status when the patient cable is connected. The red LED is lit when in a lead fault condition. When everything is connected, the blue LED indicator lights up.
③		Indicate the DC power connection status. blue LED light turns on when DC power is connected on the equipment body.

1-4. System Installation

Notes of Attention for Installation

Care has to be taken on the followings when installing CardioSync system.

- Make sure to use the equipment within the ambient temperature of 10~40℃ and humidity of 30~85%.
- Confirm the connection status of power code and carefully handle patient handle.
- Do not put multiple cords in one outlet.
- Connect to the ground in case of noise.
- Do not use the electronic code to cause connection noise.
- Care has to be taken for the vulnerability of destruction from impact.
- Make sure to install in consideration of ambient temperature and humidity and also install away from flammable substances.

Power Connection

Plug the power (USB data) cable into the USB port of the PC and the side connection cord of the Cardio P1 and the device will work.

Patient Cable Connection

- Connect the patient cable to the patient cable connection port located on the bottom of the main unit.
- Make sure to connect limb electrode to the terminals in RL(N), LL(F), RA(R) and LA(L) of the patient and the chest electrode to the terminals in V1(C1), V2(C2), V3(C3), V4(C4), V5(C5) and V6(C6).

Warning
No modification of this equipment is allowed. Do not modify this equipment without authorization of the manufacturer. If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of equipment.

Network Connection

No one other than service personnel can connect this device to the network.

Consult with hospital IT staff in advance. It is recommended to follow IEC 80001-1 (Risk management of IT networks connected to medical devices)

LAN Network

LAN networks are usually configured through a star topology. Individual devices can be grouped together via a layer-n-switch. Other data traffic is separated by a separate VLAN network. Configure the device's network settings according to this user guide and network specifications.

LAN connection specifications are described in the following standard specifications.

- Wired network: IEEE 802.3
- Wireless network: IEEE 802.11 (a, b, g, n)

If the device is used as a layer-2-switch or layer-3-switch, the port settings must be configured on the network switch. "Bionet device" must be configured so that the network settings are compatible with the specifications of the operating organization.

These devices exchange data with other medical devices over a LAN network. The network must support the following transports and protocols.

- TCP/IP
- BROADCAST

VLAN Network

If data is exchanged within a single network, an independent VLAN network must be established for clinical information systems, such as a network dedicated to medical devices in hospitals. In addition, it is necessary to establish a network system that detects and defends against denial-of-service attacks by installing dedicated DDos defense system.

When using an inappropriate network

If the network does not meet the requirements, the following situations can occur:

- Without firewall and anti-virus software:
  - Your data is not protected.
  - Data is transmitted in an incomplete state or not transmitted at all.
  - Data may be transmitted to the wrong server.
  - Data may be blocked, forged or damaged.
- in case there is no independent network environment or DDos defense system
  - You may be subject to denial of service attacks (DDos). In this case, the deivce may become slow or may not work properly. In rare cases, the boot may be delayed or repeated reboots may occur.

Network Security

- It must be ensured that appropriate security measures are installed to protect the transmission of data.
- Security of the network is the sole responsibility of the network operator.
- In order to guarantee the security of the network, Bionet recommends the following:
  - defining access authorization for the configuration of the host system so that no unauthorised alterations of the system are possible.
  - installing the latest antivirus/firewall programs to prevent malware from affecting the system.
  - regularly installing security and software updates.
  - apply "Risk management of IT-networks" according to IEC 80001-1.

1-5. Terms of Warranty

- This product is manufactured and passed through strict quality control and thorough inspection. Compensation standard concerning repair, replacement, refund of the product complies with "Consumer's protection law" noticed by ministry of finance and economy.

- Cardio P1 is warranted by Bionet Co., Ltd. to be free from defects in material and workmanship for one year (two years in Europe) from date of purchase.

- Warranty repair or replacement will be made by Bionet Service Center at no charge for warranty period if properly used under normal condition in accordance with the instructions for use.

- In the event of a malfunction or failure during warranty period, customer should inform Bionet Co., Ltd. of the model name, serial number, date of purchase and explanation of failure of the defective equipment.

1-6. Specification

ECG Leads		Simultaneous 12 channel ECG and acquisition
Recording Channel		3CH+3RHY, 3CH+1RHY, 6CH+1RHY, 12CH, 6CH+ST map 1CH Long Time (1min, 3min, 5min,10min, 20min, 30min) and Special Beat Report (Text, Guide, Vector, ST map)
Gain		2.5, 5, 10, 20, Auto (I~aVF: 10, V1~V6: 5) mm/mV
Printing Speed		5, 12.5, 25, 50, 100 mm/sec
Sampling Rate		Analysis Sampling Rate - 500Hz Digital Sampling Rate - 8,000Hz
Filters		AC (50/60 Hz, -20dB or better), Muscle (25~35Hz, -3dB or better), Baseline Drift (0.05Hz, 0.1Hz, 0.2Hz, -3dB or better), Low Pass Filter(off, 40Hz, 100Hz, 150Hz)
Patient Data		ID, Name, Birthday, Age, Gender, Height, Weight, Race, Smoke, Department, Room No., Study Desc., Accession No., Referring Physician
Basic Measurement		Heart Rate (30~300bpm, ±3bpm), PR/RR Int, QRS Dur, QT/QTc Int, P-R-T axis, SV1/RV5/R+S Amp
Electrical		Internal Noise : 20uV(p-p)max Input Impedance : ≥ 50MΩ Input Voltage Range : ±5mV CMRR : > 105dB DC Offset Voltage : ≥ ±400mV Patient Leakage Current : < 10uA Frequency Response : 0.05~200 with in –3dB Isolated, Defibrillation and ESU Protected
Signal Quality Control		Pacemaker Pulse Detection Lead Fault Detection, Signal Saturation Detection
Input Power		5VDC (USB), Max. 0.5A
Communication		USB data communication (to PC)
Safety Conformity		Class I, Type CF applied parts: ECG electrodes
Environmental	**Operation**	Ambient temperature: 10 to 40°C Relative humidity: 30 to 85% Atmospheric pressure: 70 to 106KPa

	Storage/ Ship	Ambient temperature: -10 to 60℃ Relative humidity: 20 to 95% Atmospheric pressure: 50 to 106KPa
Dimensions		Body - 90.75(W) x 103.5(D) x 24.93(H)mm - Approx. 110g
Standard Accessory		Patient Cable (1EA), Limb Electrodes (1SET), Chest Electrodes (1SET), Power (USB Data) Cable (1EA), Hanger (1EA), Silicone Pad (1EA), ECG Gel (1EA), ECG Diagnosis Guide (1EA), USB Lock Key (1EA)

Warning
Do not touch patient cable or equipment when using heart ventricles defibrillation machine

Warning
Make sure not to have conductive parts or grounds contact the connector if connecting electrode or patient cable. Especially, care has to be taken not to have conductive parts or ground contact when attaching each electrode to the patient body.

Warning
Make sure to use the provided ECG patient cable only for measurement of ECG without measuring the respiration.

Caution
Make sure to use biocompatibility certificate authorized with international standards or provided for electrodes

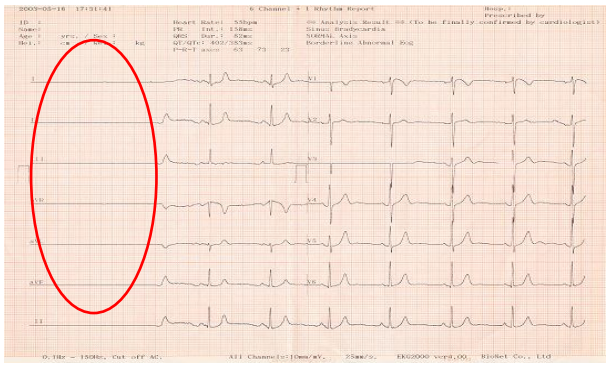
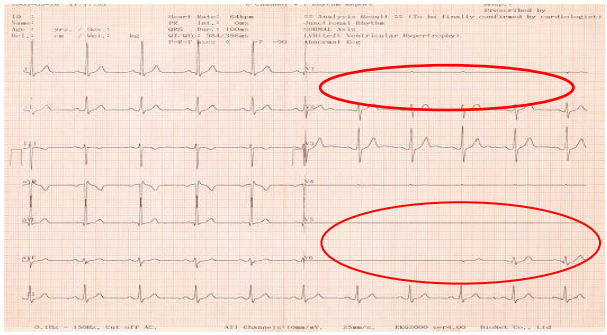
Caution
Make sure to have the experts (health care professional) present when using CardioSync system for patients who had surgery with heart aiding machines

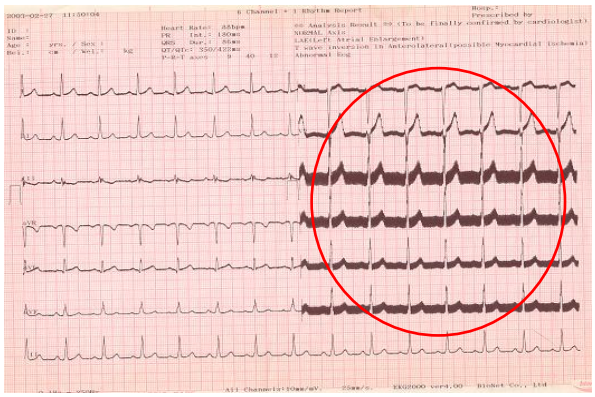
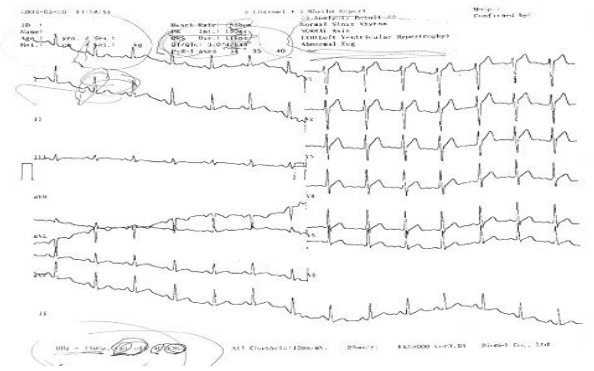
Section 2. Troubleshooting

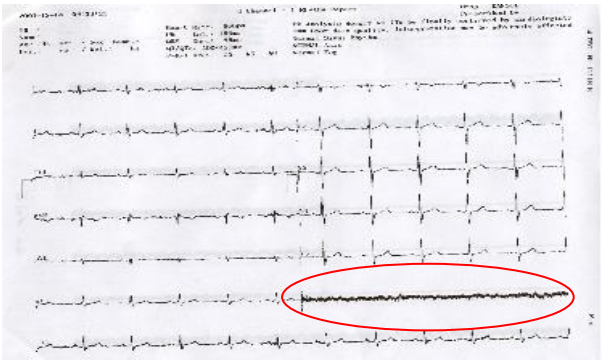
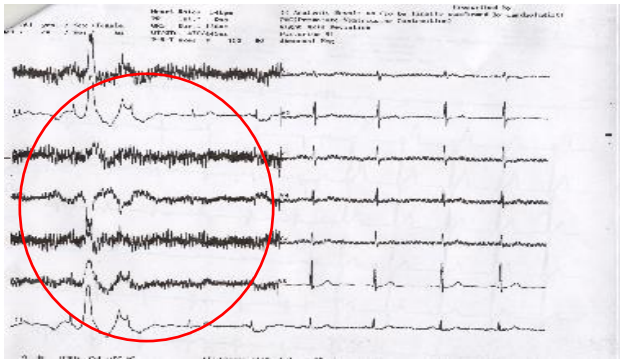
2-1. Power

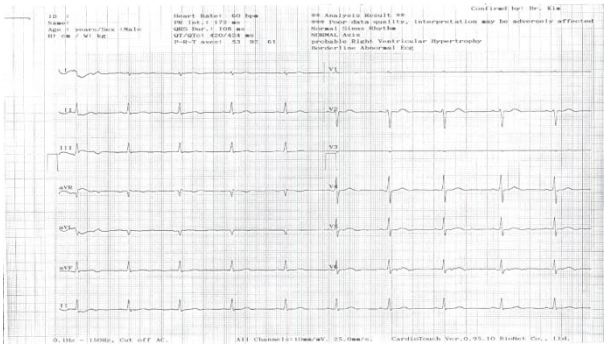
Problem	Solution
Case1. **The Cardio P1 open will turn on and off frequently.** **Case2.** **Power will not turn on.**	**< General Checking >** 1. Check the power (USB data) cable is connected with DC power terminal at the side of the device. 2. Check the power source of the PC with connection to the power (USB data) cable. (If power is connected, power indicator is lighted.) If not, please contact Bionet. **Case1:** Check if the soldering of J5 on the base board (DC Power + base board connector) is poor. → Re-solder the connector. ● When applying power to Cardio P1, the voltage of pin2 of J5 should always be 5V. 1) Is the pin's voltage is 5V→ Yes → replace the base board. 2) Is the pin's voltage is 5V→ No → contact Bionet

2-2. Wave Printing

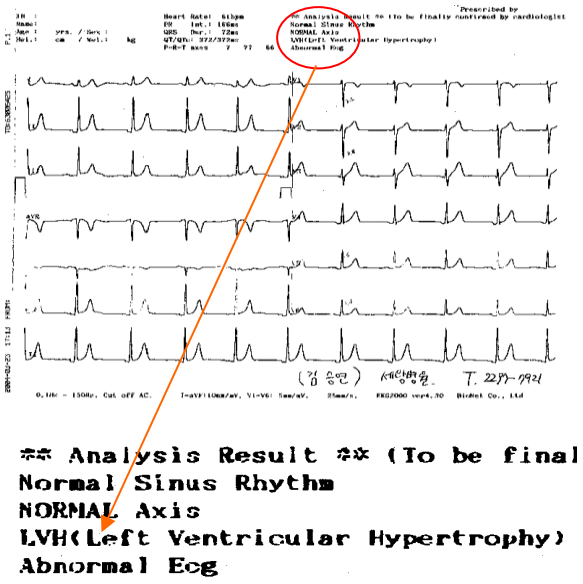
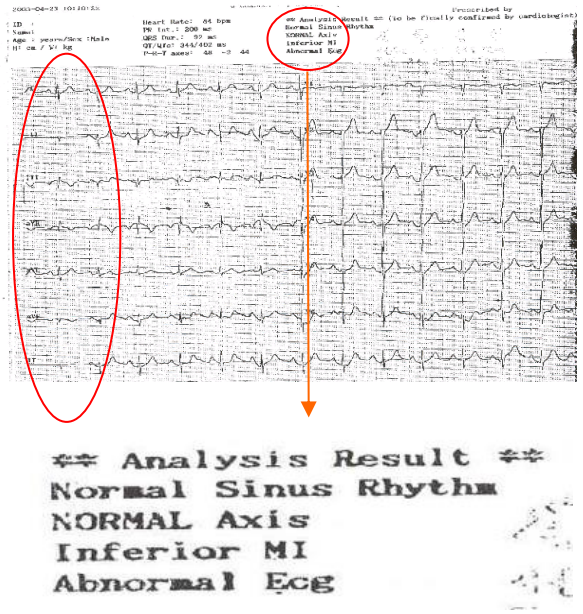
Problem	Resolution
 **1-1. The wave pattern changes from the flat line on the left to the wave forms on the right.**  **1-2. Some wave patterns are not shown in V1~6.**	1. The normal wave patterns will show if output is requested after the patient is stabilized by showing the ECG wave on the CardioSync display. 2. Check connection of the limb and the chest electrodes to the patient body parts. 3. If used on the dry skin or in the winter season, connectivity may be degraded. In that case, used water or ECG gel. The electrode must be washed after using ECG gel. Otherwise, the electrode will be rusted and corroded.

Problem	Resolution
 **2-1. The thick noise is made on the wave patterns.**  **2-2. The wave output looks like the noise and are not properly shaped.**	1. This problem occurs when the filter value is not corrected. 2. Since the noise occurs as in problems 2-1, if the AC filter is turned off or set at different frequency from the power source, the system must be set at 50Hz or 60Hz to correspond to the input power. (It is different each country) The AC filter status is shown at the left bottom of the printout. 3. Problems 2-2 occurs when the BASE filter is set at OFF. Change it to ON. Also the BASE filter status is shown at the left bottom of the printout.

Problem	Resolution
 **3. The wave output looks like the noise and are not properly shaped.**	1. This problem occurs when the chest electrode is not properly in contact with the body. 2. Check with simulator there is any cut on the patient cable. 3. Check there is any damage to the chest electrode. 4. Test it again after applying alcohol, water or ECG gel to the electrode. * If the problem can't be solved by the above procedures, please contact us.
 **4. Heavy noise on the wave forms**	1. The noise occurs as there is no signal from the limbs electrode. 2. If the polar plate in the limbs electrode is blacked or copper colored, or if ECG gel residue remains, the signal may not be detected. Replace it. 3. If discoloring is too noticeable in the limb electrodes, replace it.

 **5. The wave pattern shows the straight line among V1~6.**	1. If some wave patterns are too small as shown in the problem 5, the problem is most likely to be with the patient cable, limb or chest electrodes. 2. If the problem is not with the accessories, then the main board is the problem. 3. The main board must be shipped to us for repair since the condenser of the main board must be replaced.

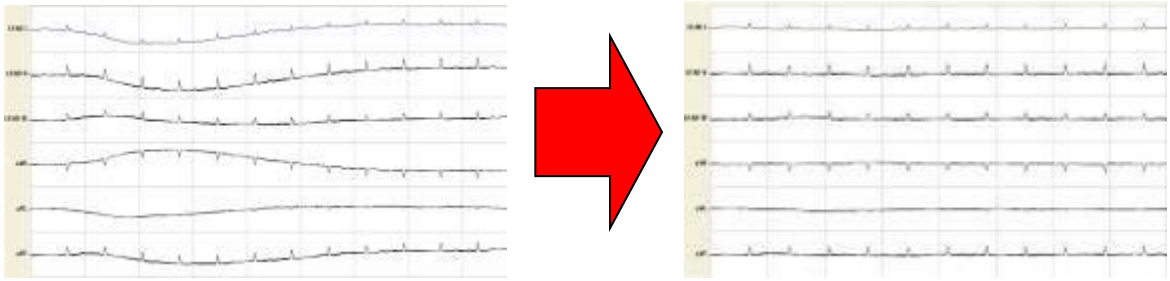
2-3. Diagnosis

Problem	Resolution
 **1. The diagnosis shows LVH.**	1. If disease is diagnosed, abnormal ECG always appears. 2. LVH occurs when the sum of one of V1 or V2 and one of V5 or V6 is 3.5 or higher. 3. Upgrade to the latest version of the software.
 **2. Diagnosis shows MI.**	1. If MI is diagnosed, it is likely that the print button was pressed before the wave patterns are stabilized. 2. Check HR before printout and print it again. 3. Upgrade to the latest version of the software.

2-4. Filter

- **Baseline Filter**

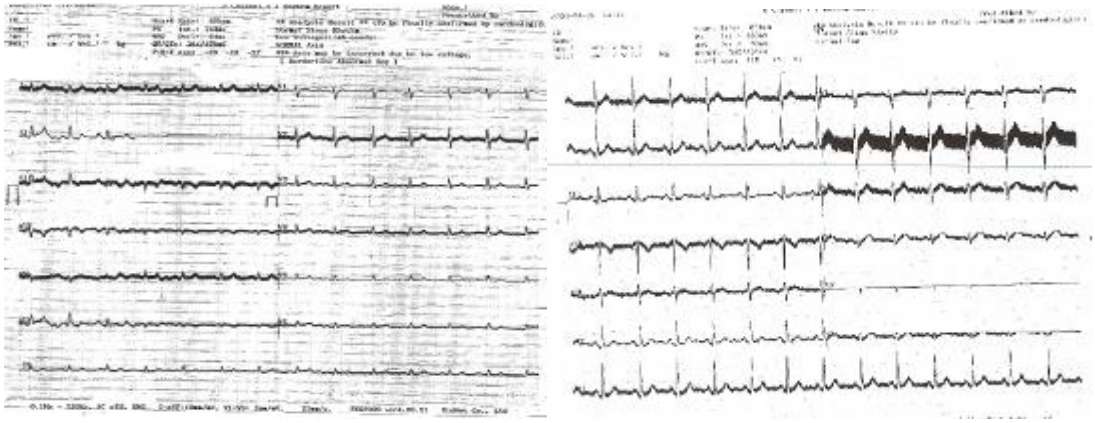
Baseline drift is caused by a patient's breathing. ECG signal is overlapped on a large parabola. If you want to set Baseline drift, can be applied as off, 0.05Hz, 0.1Hz and 0.2Hz in the base menu.



<BASE FILTER OFF> **<BASE FILTER ON>**

- **AC Filter**

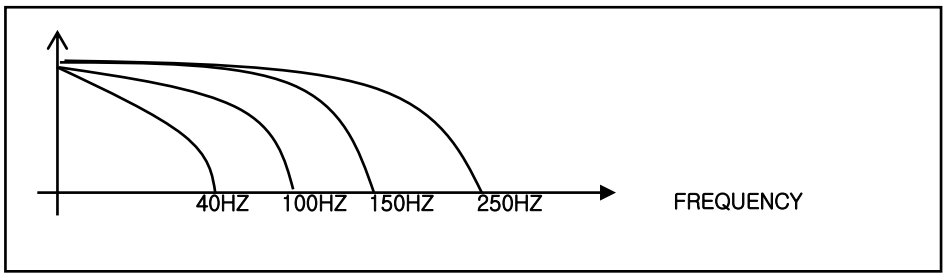
AC filter is a power noise removing filter and can be setup to off, 50Hz and 60Hz. 'Off' means not to remove power noise. 50Hz and 60Hz indicate to remove 50Hz of power noise and 60Hz of power noise, respectively. Europe and China use 50Hz and Korea and America use 60Hz as setup value. When using PC battery power, there is almost no noise. Therefore, ECG can be well recorded with 'off.'



<AC FILTER OFF>

- **Low Pass Filter**

When ECG is not clear even after all three filters are set to ON, the use of low frequency filter will produce clear ECG signal. The low frequency filter can be set to 40Hz, 100Hz, and 150Hz and OFF. Set to 40Hz, it eliminates all signals over 40Hz. The set value is indicated on the lower part of the printed form. If you set the filter to OFF, -250Hz is indicated. If set to 40Hz, -40Hz is indicated. Set to 100 Hz, -100Hz is indicated. If set to 150Hz, -150Hz is indicated.

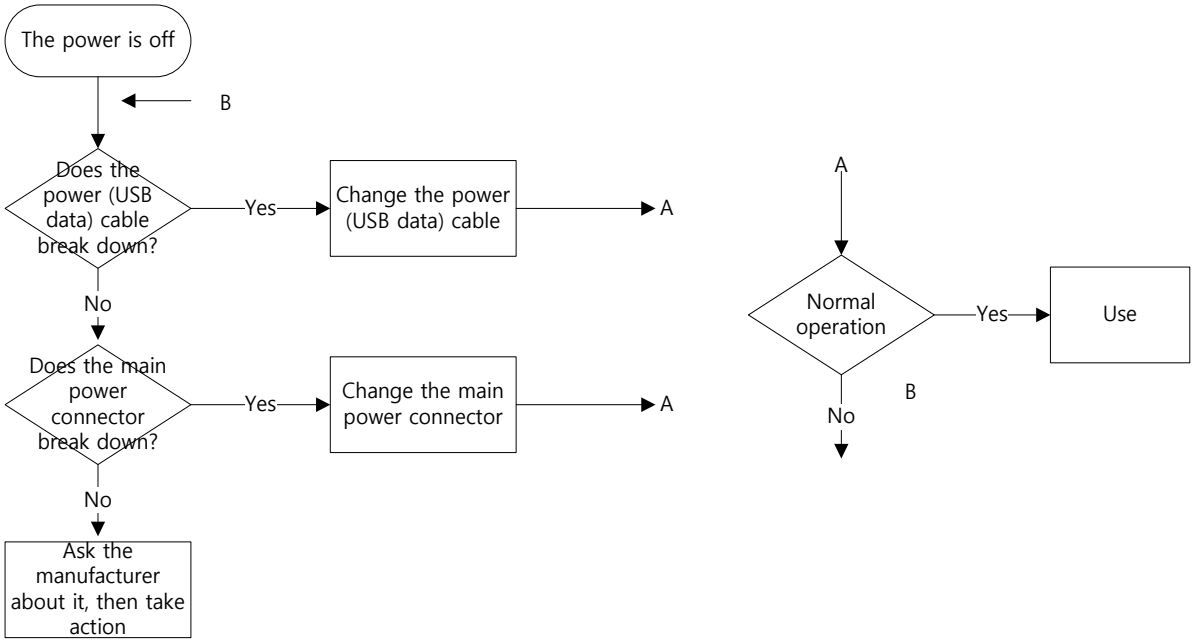


- **Muscle Filter**

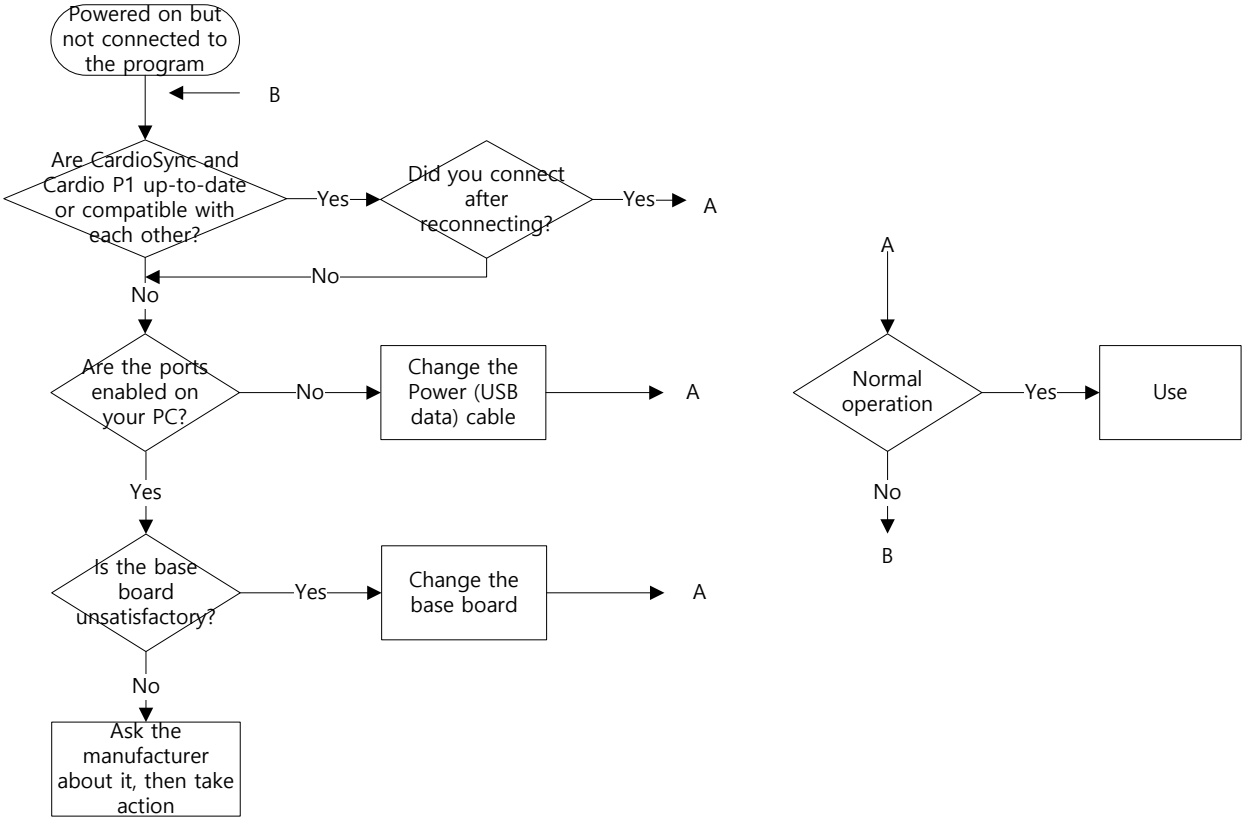
Muscle filter is EMG filter as a signal that occurs in muscle or organ of a patient. If measuring ECG with patients with especially high ECG, ECG is not well recorded. Therefore, it is required to remove noise. If applying ECG filter, 'off' can be selected if not using 'on'.

2-5. Trouble Shooting Guide

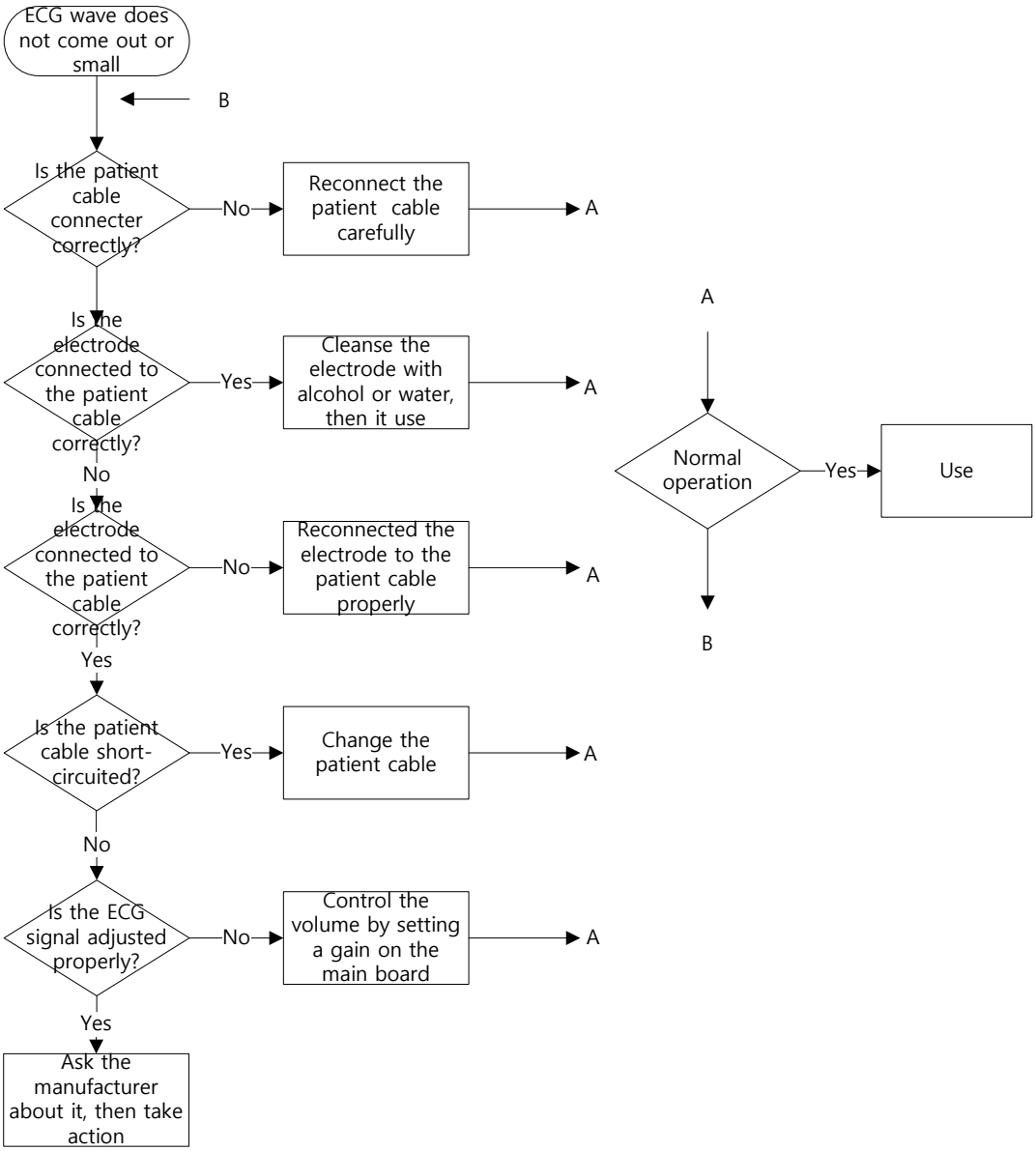
1) Power is off



2) When the device is not connected even when the program is turned on

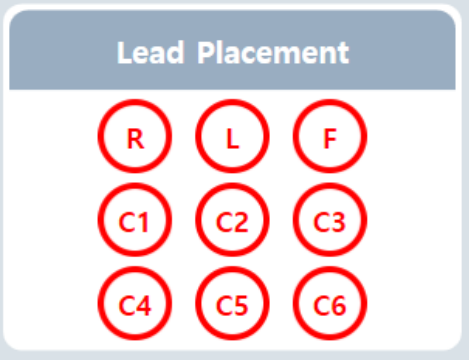


3) ECG wave does not come out or it's very small



Section 3. Adjustment

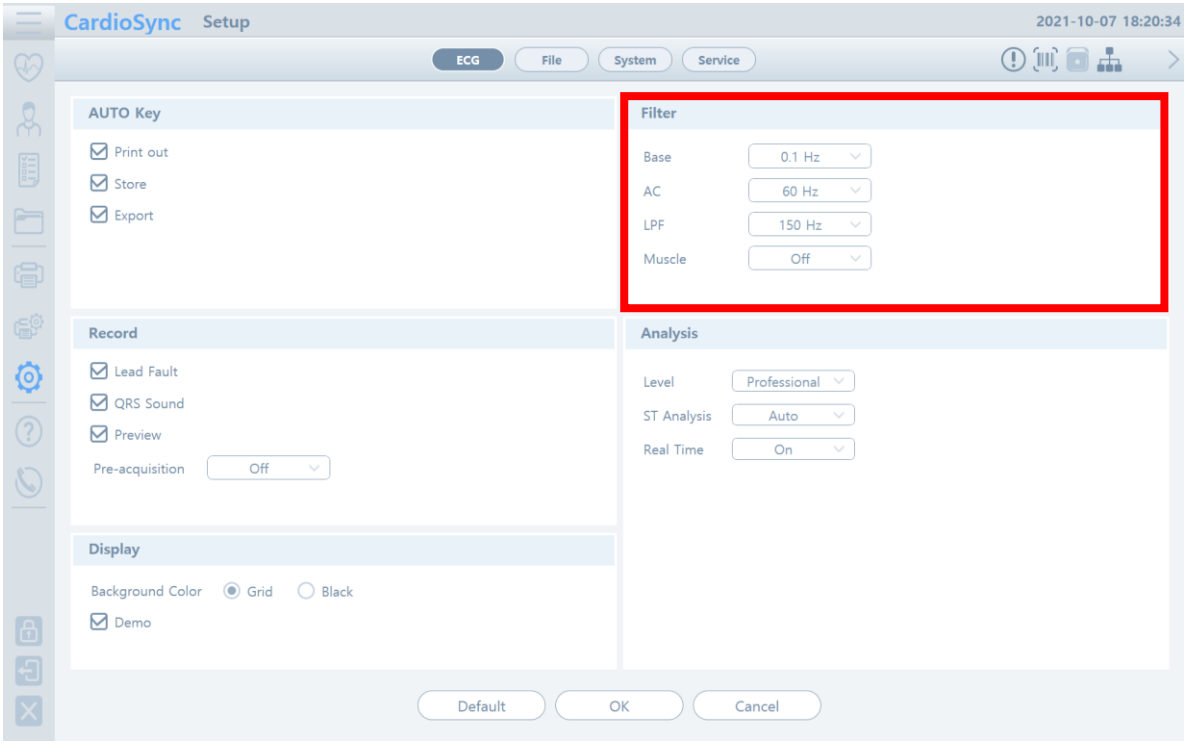
3-1. Lead Fault



- If 'RA' lead is fault, not all the lead waves are shown.
- If 'LA' lead is fault, I, V1 ~ V6 waves are not shown.
- If 'RL' lead is fault, lead fault message is not shown. All the lead waves can be shown.
- If 'LL' lead is fault, II, V1~V6 waves are not shown.
- In case of lead fault during the monitoring or recording, message is shown with sound.
- Pacemaker signals might not be detected during the lead fault. In addition, as it can influence on the diagnosis, it is required to perform data measurement for ECG in case of lead fault.

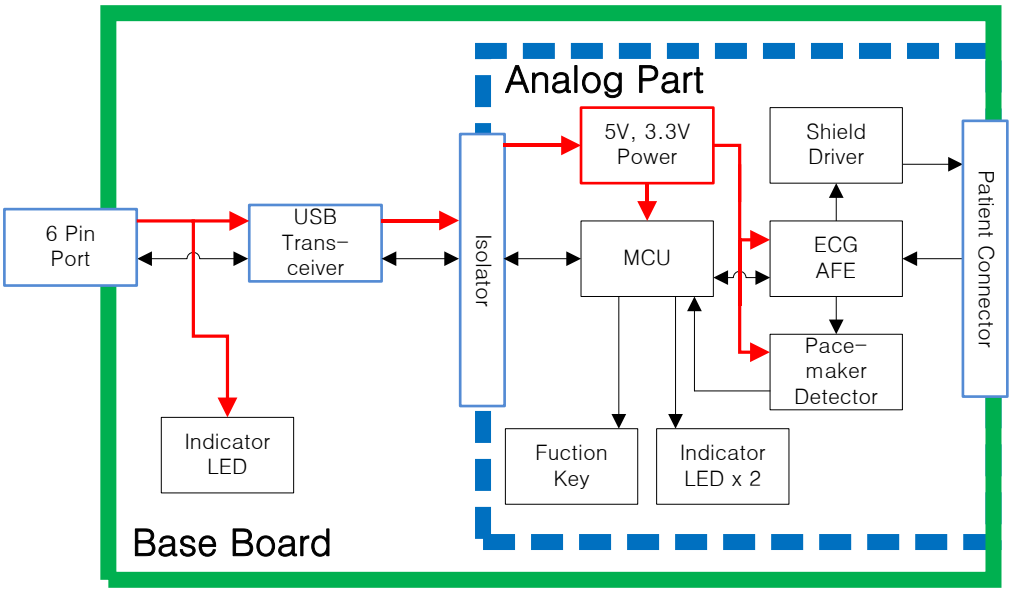
3-2. Filter Setting

To set the filter, click the 'Setup' item on all screens and go to ECG -> Filter tab.



Section 4. Block Diagram / Description

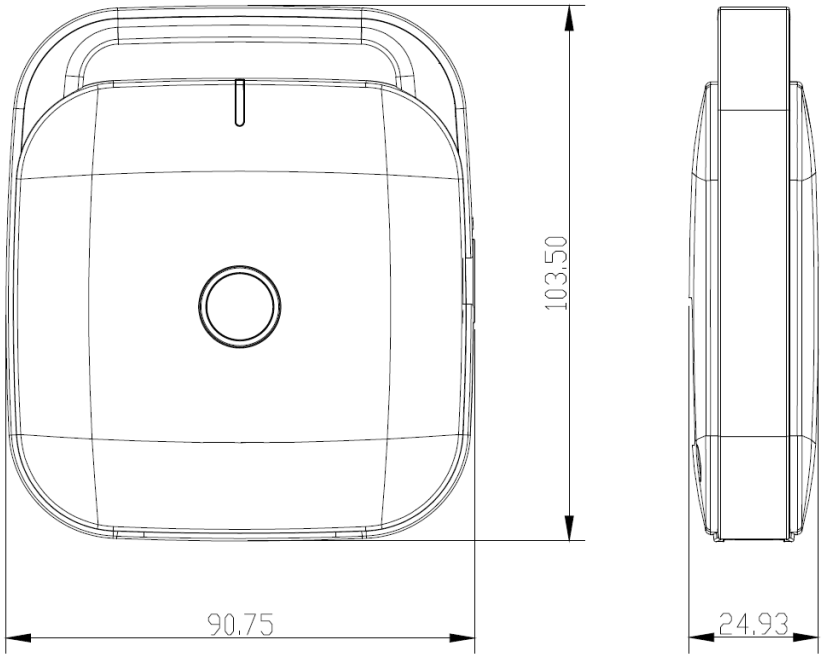
4-1. Circuit Block Diagram



4-2. Size and Weight

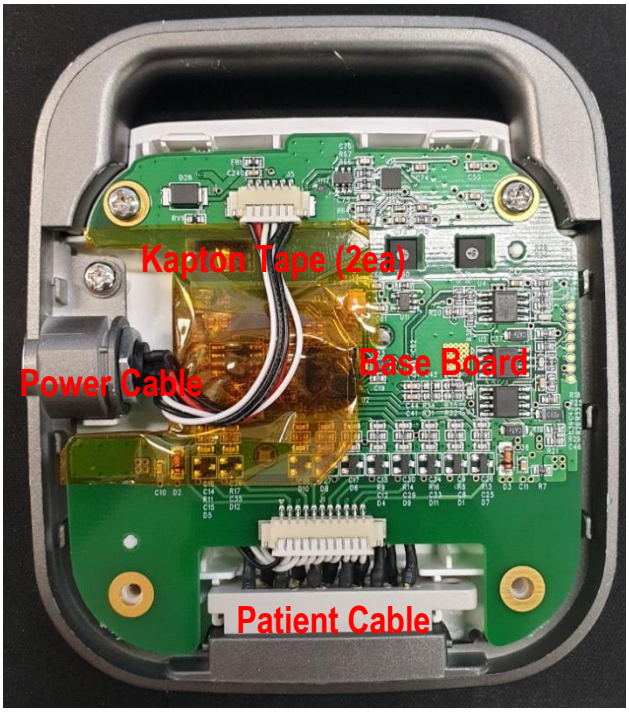
- Size
  - 90.75(W) x 103.5(D) x 24.93(H)mm

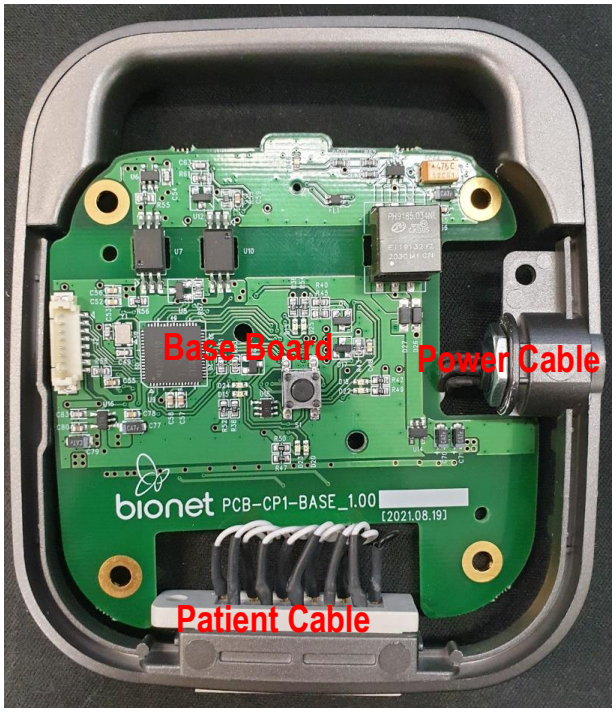
- Weight: approx. 85g



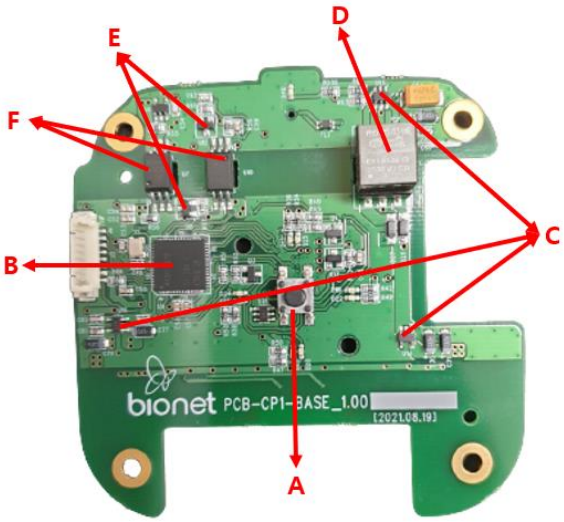
Section 5. Disassembly and Assembly

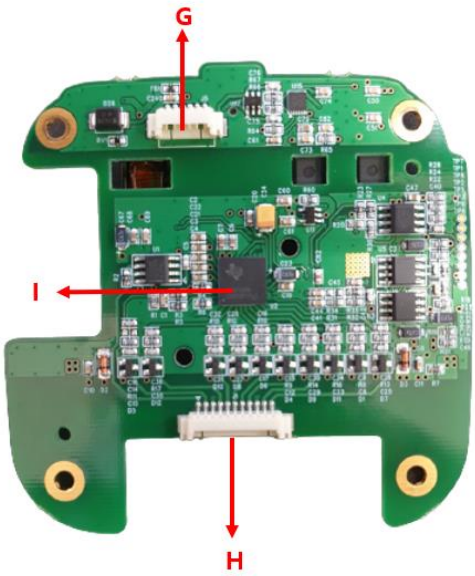
5-1. Module Description





1) Base(Power + Analog) Board



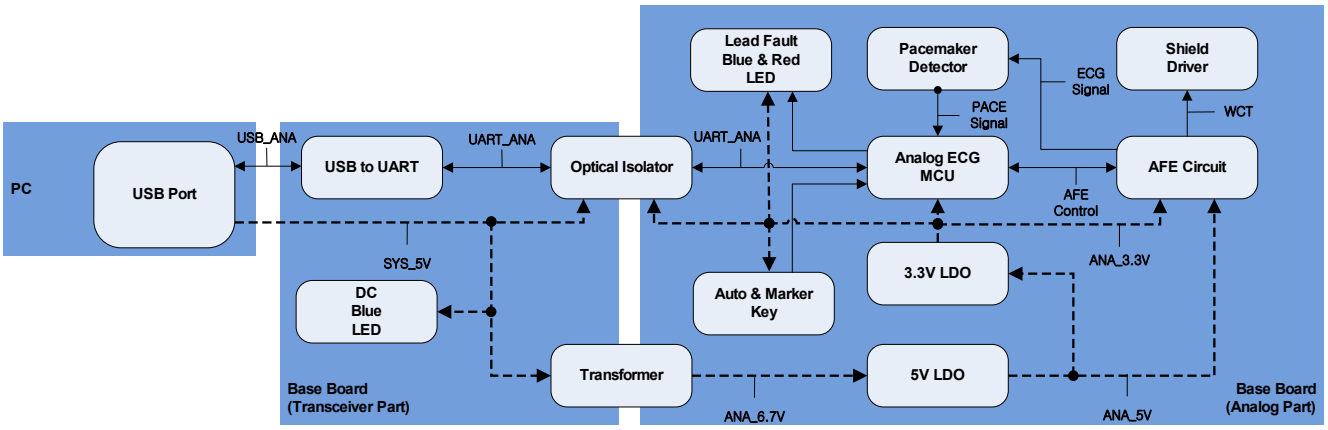


<Top> **<Bottom>**

A: Switch
B: MCU
C: Voltage Regulator
D: Transformer
E: Inverter
F: Optocoupler
G: Power Cable Connector
H: Patient Cable Connector
I: Front-End for Biopotential Measurements (ADS1298)

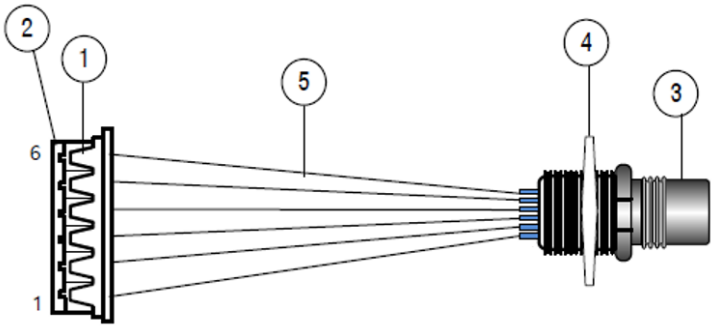
5-2. Block Diagram & Cable

1) Transceiver & Analog Block Diagram

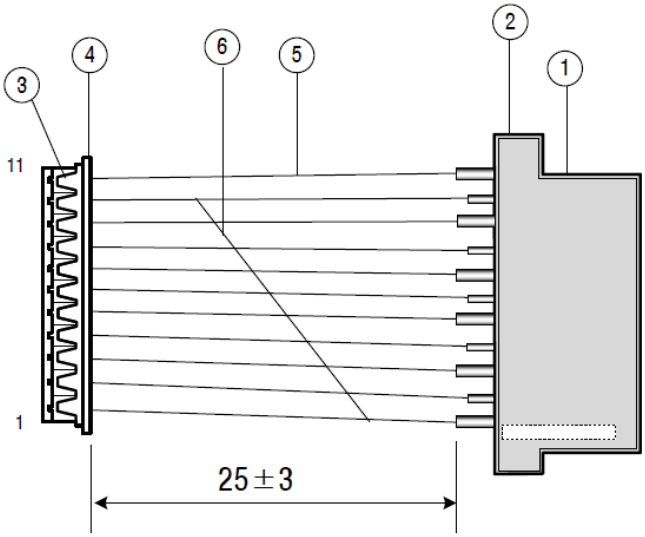


2) Cable

A: USB_CON Cable



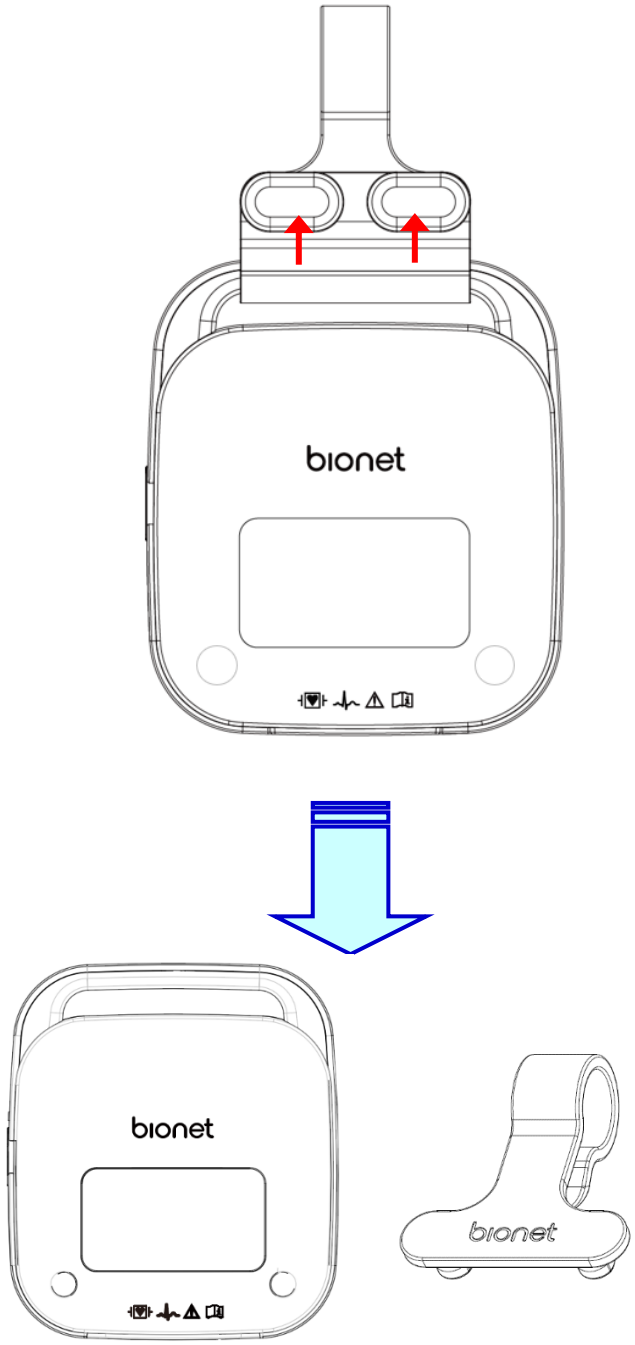
B: ECG_CON Cable



5-3. Disassembly

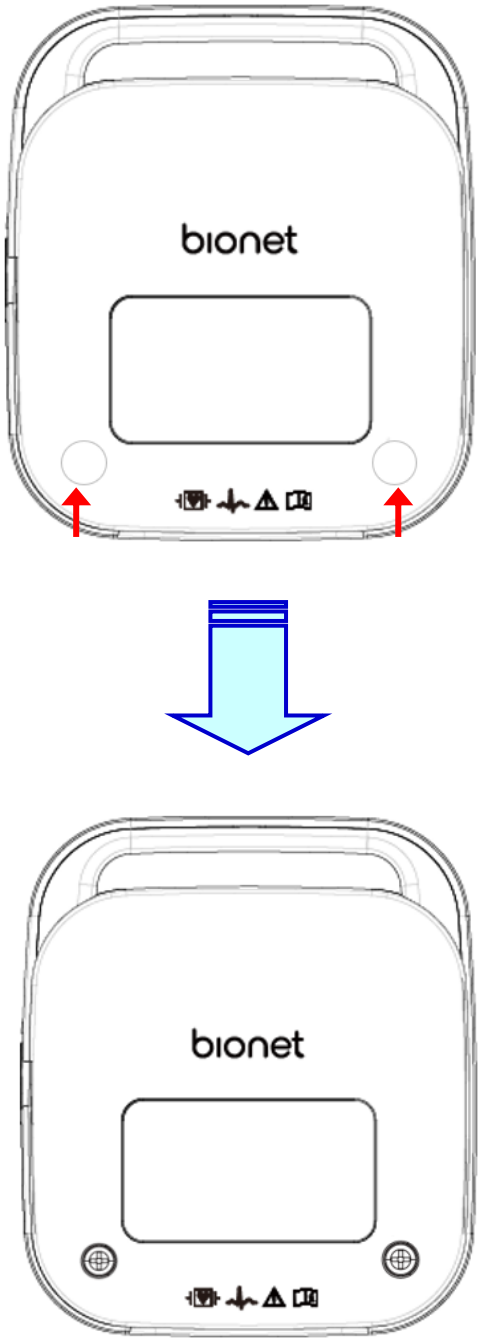
Step1. Removing the Hanger

a. Pull the silicone pad out of the hanger part.



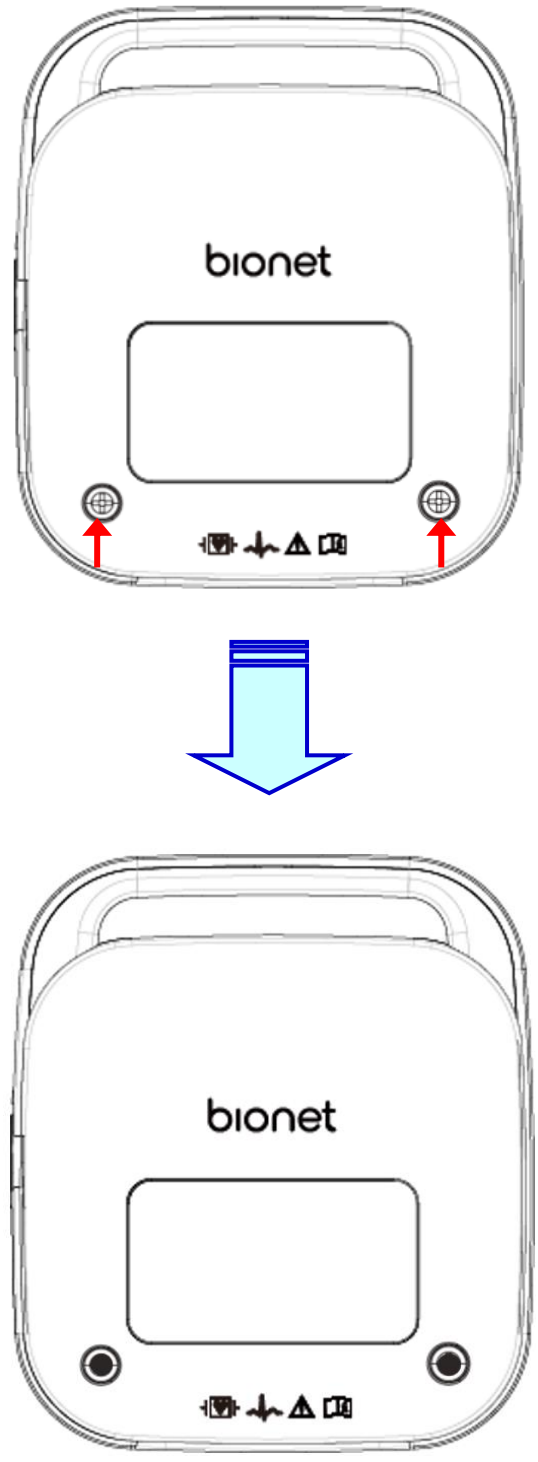
Step2. Removing the Silicone Stopper

a. Remove the two silicone stopper using tweezers, etc.



Step3. Removing the Bottom Case

a. Remove the 2 tab screws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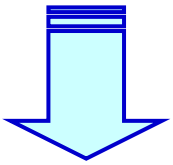
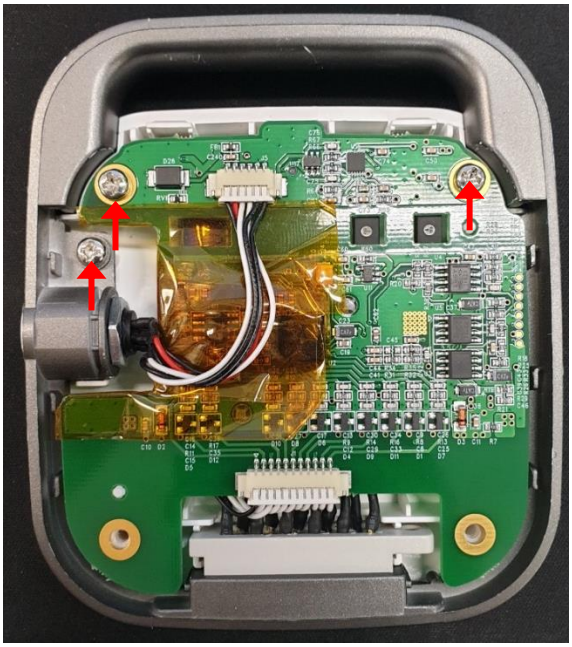
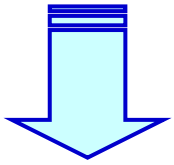
b. Remove the bottom case by pulling it from the bottom.



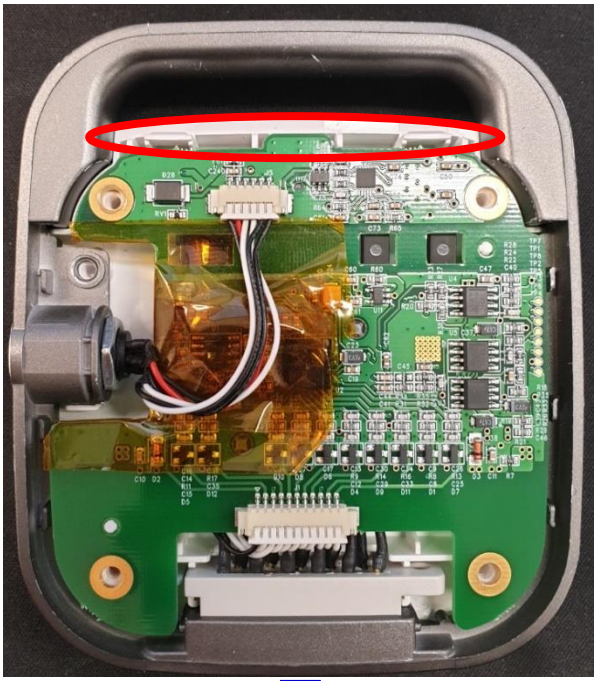
Step4. Removing the Top Case

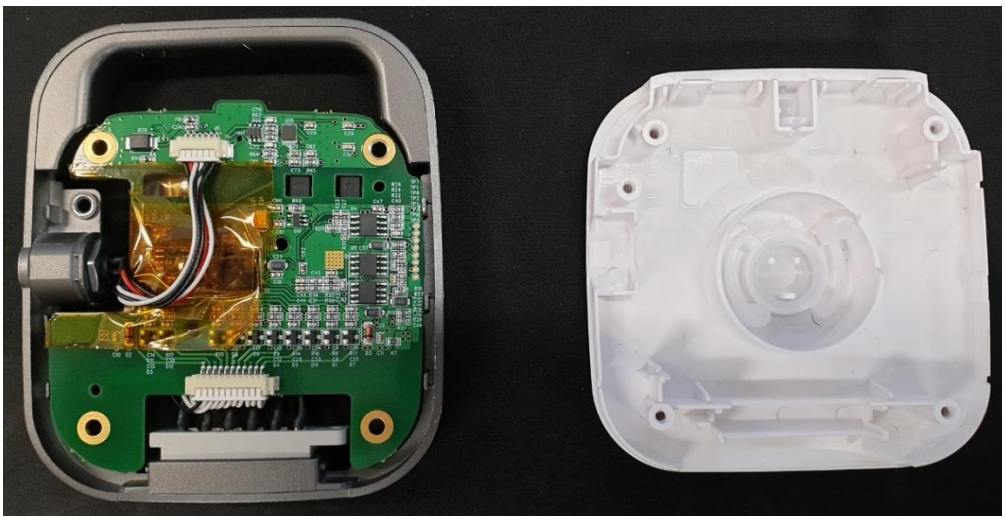
a. Remove the 3 tap screws





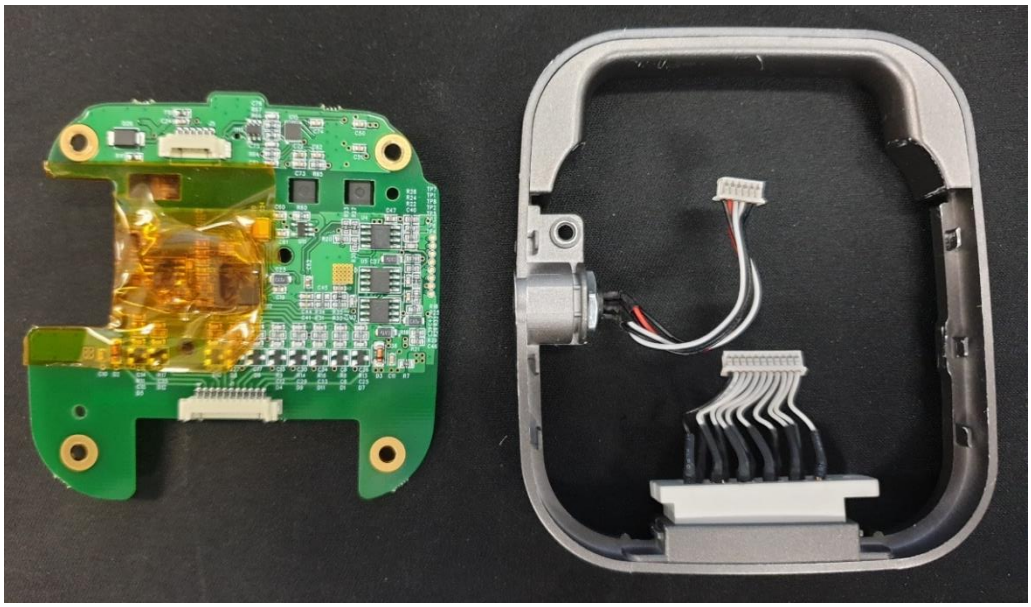
b. Remove the top case by sliding the upper part of the top case.



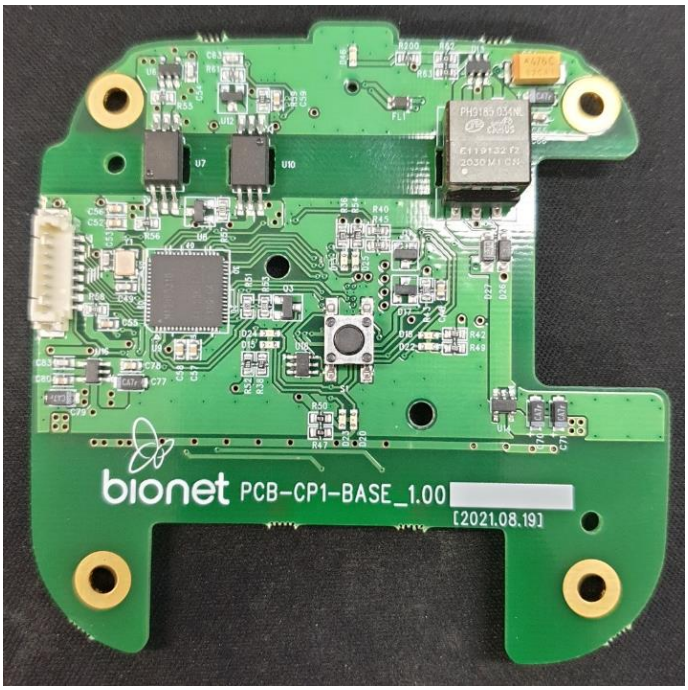


Step5. Replacing the Base Board

a. Remove and disconnect the cable from the connector

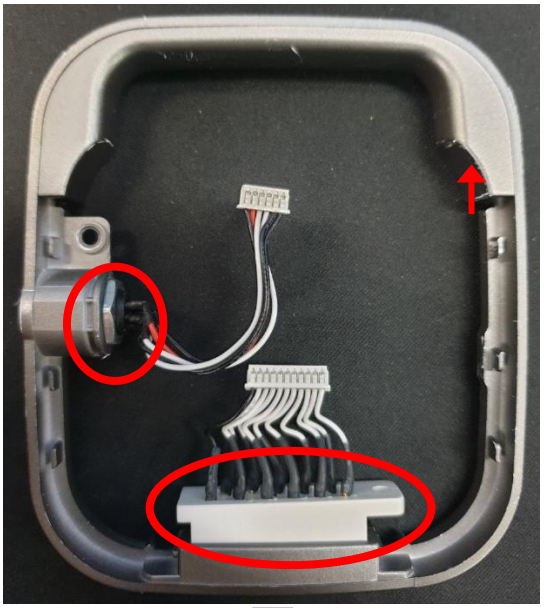


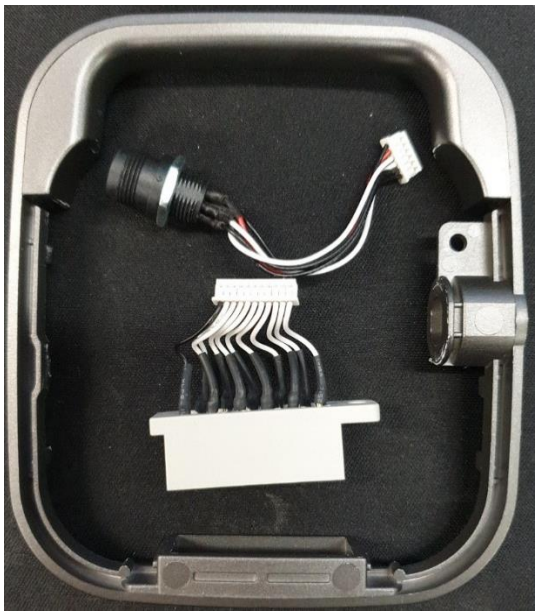
b. Remove the Kapton Tape



Step6. Remove the side cover

a. Remove the power cable nut
b. Disconnect the patient cable
c. Remove the side cover by pulling it from the marked area.



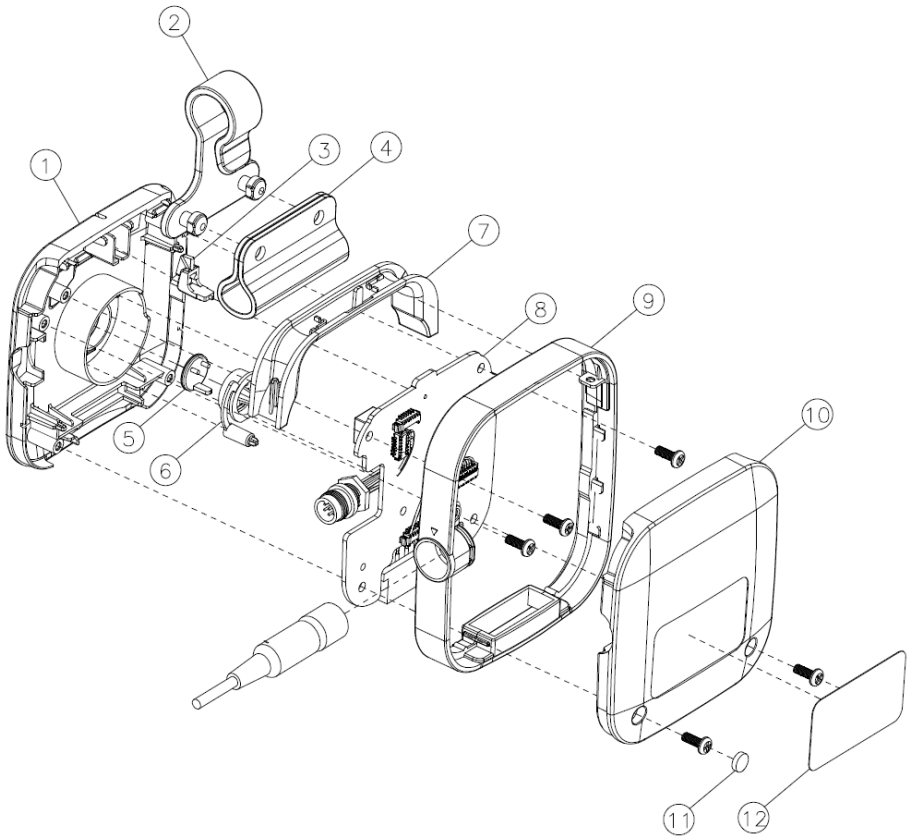


5-4. Assembly

Assemble the reverse way from Step.6 to Step.1

Section 6. Replaceable Parts List and Accessory

6-1. Replaceable Part List



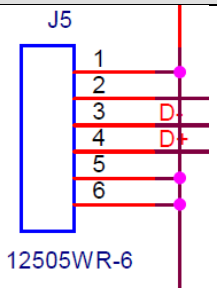
< Cardio P1 Ass'y >

NO.	PART NO.	PART NAME	QTY
1	141-M-COV-1010A	Cover-Top	1
2	141-M-COV-1050A	Hanger	1
3	141-M-COV-1040A	Lens-LED	1
4	141-R-BLT-1000A	Silicon Pad	1
5	141-M-COV-1030A	Knob-Cap	1
6	141-M-COV-1020A	Knob-Main	1
7	141-M-COV-1070A	Cover-Deco_IN	1
8	-	Mainboard	1
9	141-M-COV-1060A	Cover-Deco_OUT	1
10	141-M-COV-1000A	Cover-Bottom	1
11	141-R-CAP-1000A	Rubber-Cap_Screw	2
12	141-K-LBL-1010A	ID Label_EN	1
13	-	Tapping Screw(2종) BH+ M3xL8	5

Section 7. Base Board Connector

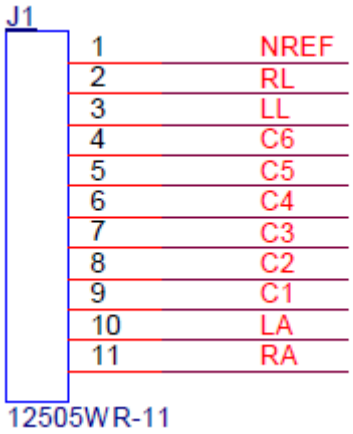
7-1. Power Connector

Pin Description	
Pin	Name
1	GND
2	VSYS_5.0V
3	DATA-
4	DATA+
5	GND
6	GND



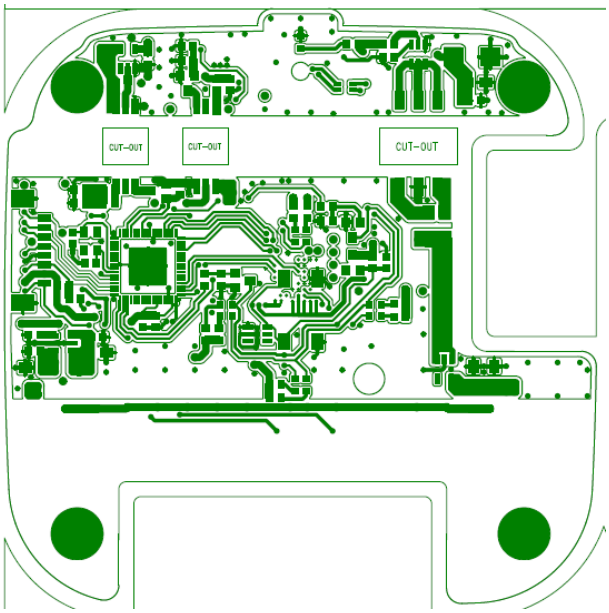
7-2. Patient Cable Connector

Pin Description	
Pin	Name
1	NREF
2	RL
3	LL
4	C6
5	C5
6	C4
7	C3
8	C2
9	C1
10	LA
11	RA



Section 8. PCB Part disposition

8-1. Base Board



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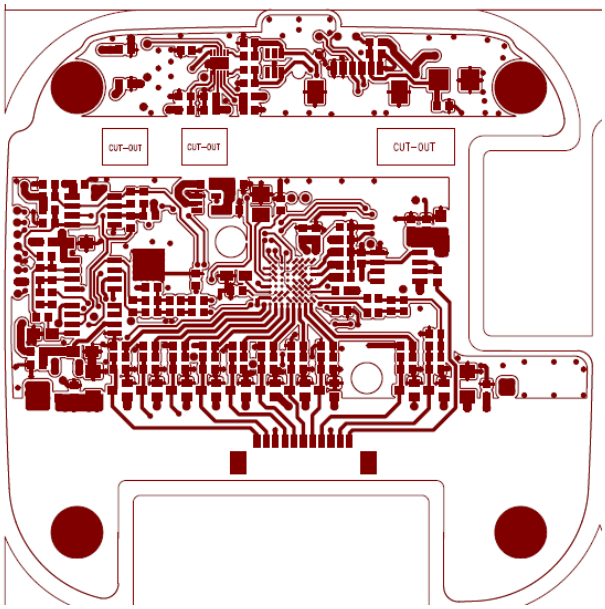


<Bottom>

Section 9. Software Install

9-1. Software Minimum Requirement

Install the program on a PC that meets the minimum specifications below.

Operation System	· Window 10
CPU	· Core2Duo 1.86GHz
RAM	· 2 GB
Graphics Adapter	· VGA RAM 256 MB 1,600 x 900
Hard Drive	· 500 GB
LAN Speed	· 10 Mbps
# of USB	· 2

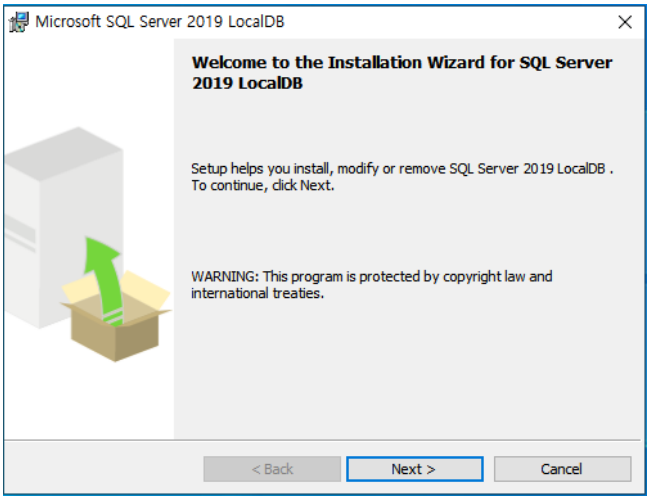
9-2. How to install the Software

Add software for the description below.

① Close every application before beginning installation.

② Execute "SqlLocalDB.msi" under your CD-ROM drive, download folder or USB memory.

③ Follow each instruction on each step.



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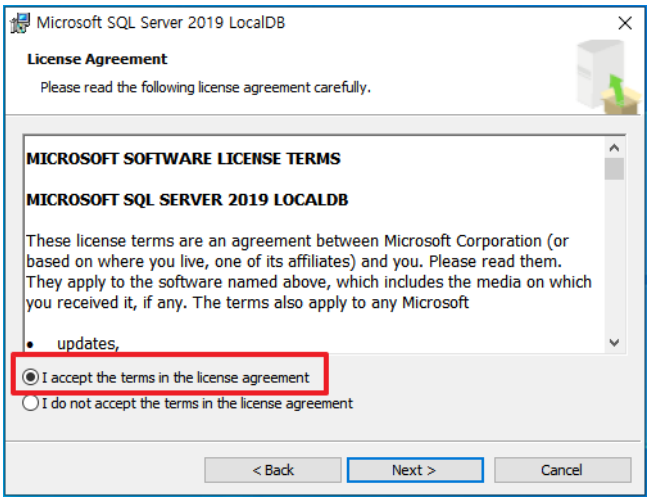

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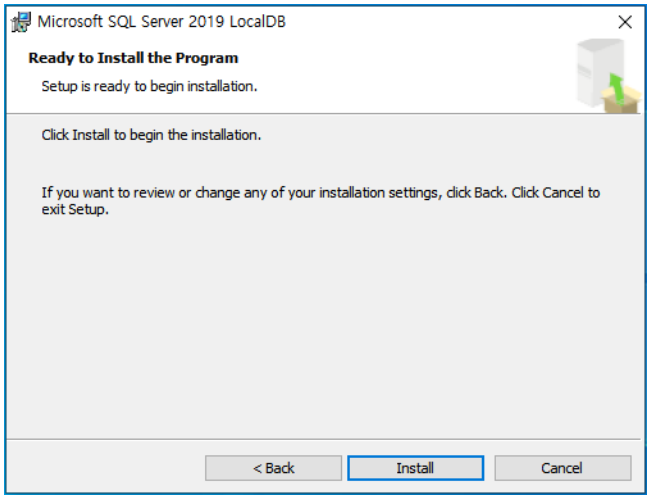
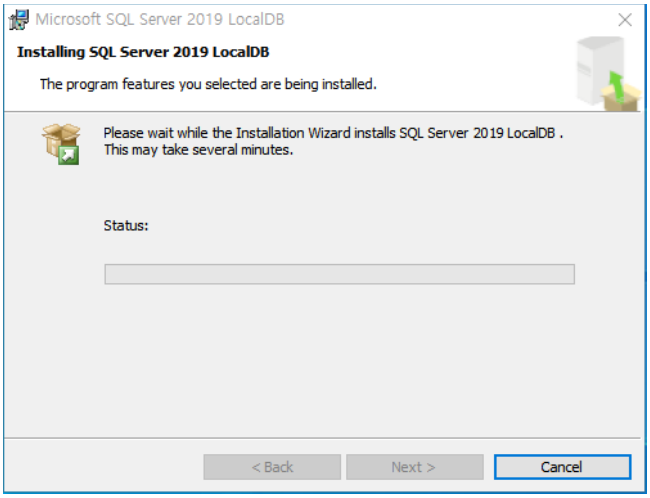


<Stop 3 >



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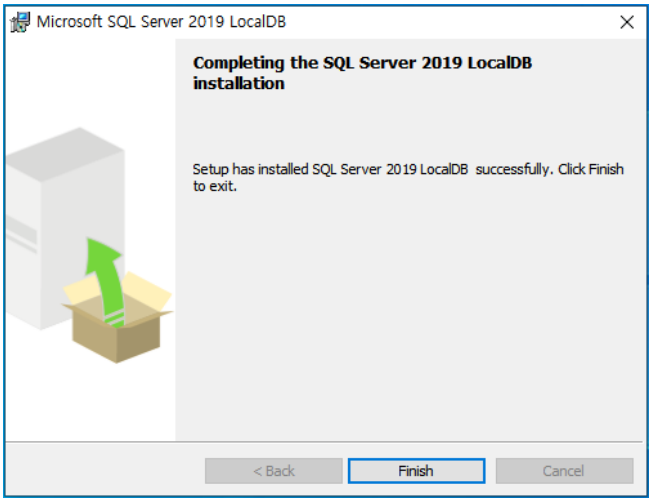
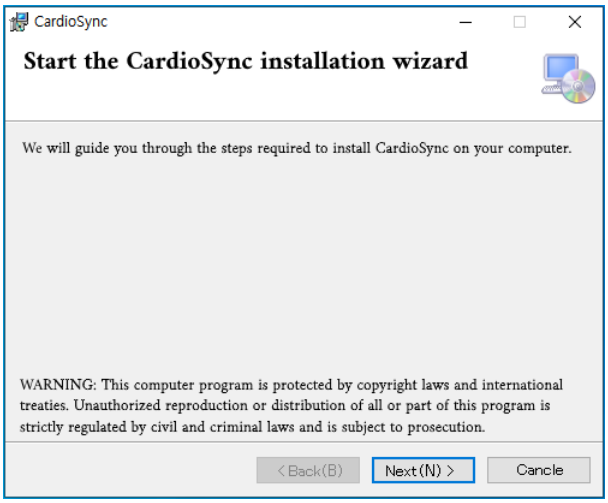


< Step 5 >

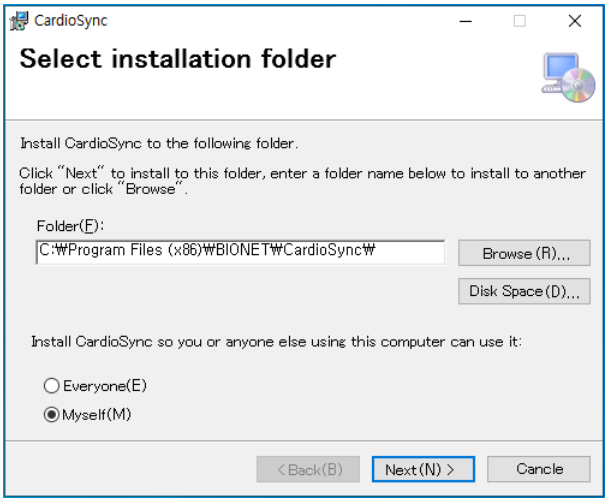
④ Execute "setup.exe" or "CardioSync ECG_X.XX.XXX_YYYYMMDD.msi" under your

CD-ROM drive, download folder or USB memory.

⑤ Follow each instruction on each step.



< Step 1 >



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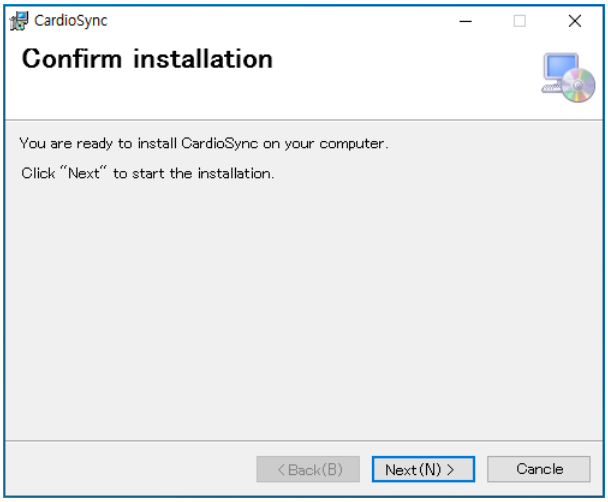

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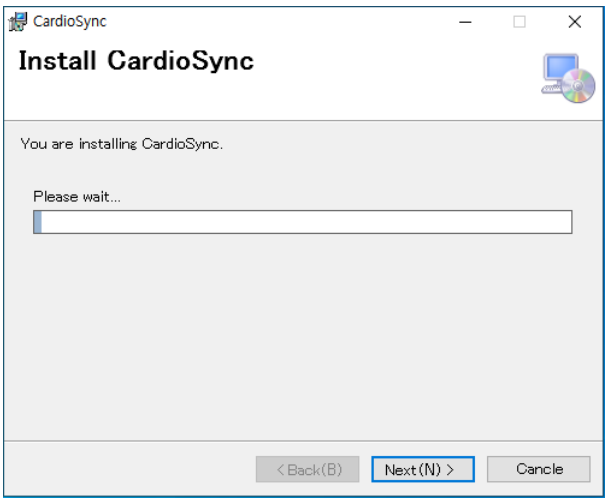

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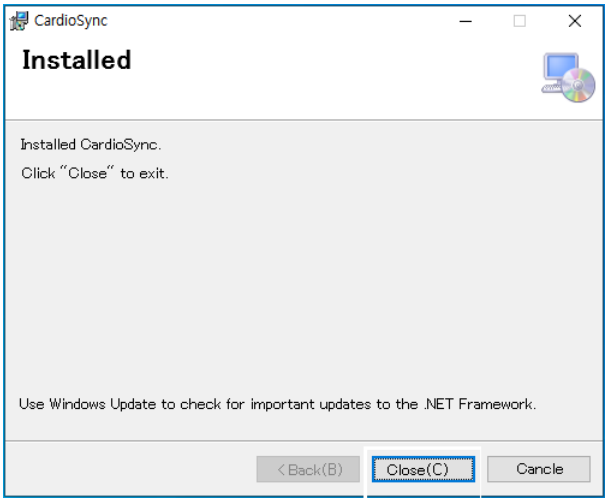

< Step 5 >