

## Electrocardiograph

# Cardio P1 Operation Manual



**Ver. 1.02**

2024. 02. 01

## REVISION HISTORY

| Revision No. | Date       | Contents                                                                                                                                                  | Page |
|--------------|------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|------|
| 1.00         | 2022.05.24 | First Written                                                                                                                                             | All  |
| 1.01         | 2023.04.04 | Modified to model name Cardio P1<br>Full translation reflected<br>Change logo<br>Correction of incorrect information (delete 'LAN network, WLAN network') | All  |
| 1.02         | 2024.02.01 | Update European Sales email and web address                                                                                                               | All  |
|              |            |                                                                                                                                                           |      |
|              |            |                                                                                                                                                           |      |

## Warranty

- This product is manufactured through our strict quality control and inspection process. Compensation standards for product repair and exchange follow the "Regulations of Compensation for Consumer's Damage" announced by the Fair-Trade Commission.
- Warranty period of this product is regulated to be 1 year while the warranty period of accessories is six months.
- If a malfunction occurs under normal use, our service center will repair it free of charge during the warranty period.
- If a problem occurs with the product during the warranty period, please notify us of the model name, serial number, date of purchase, and malfunction details.

| Caution                                                                     |
|-----------------------------------------------------------------------------|
| Federal law restricts this device to sale by or on the order of a physician |

| Note                                                                                                                                                                            |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| The product does not have shelf life. Its expected use life is 3 years. After 3 years, though the product still works normally, it is recommended to have it checked by Bionet. |

## Contact Bionet

If you have any questions or comments relating to our products or purchasing, please contact the telephone numbers or E-mail below. You can talk to our sales people.

Bionet always welcomes your enquiries. Please contact us.

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※ In the event of a malfunction or failure, contact Service Dept. Of Bionet Co., Ltd. along with the model name, serial number, date of purchase and explanation of failure.

## Paid Services

**A fee will be charged for all services except for breakdowns, so be sure to read this operation manual below before putting in a request.**

|                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                          |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------|
| <ul style="list-style-type: none"> <li>- Usage description and simple inspection without disassembly</li> <li>- In case of reinstallation due to poor installation by a distributor</li> </ul>                                                                                                                                                                                                                                                           | <p>Free the 1<sup>st</sup> time</p> <p>Charged starting the 2nd time</p> |
| <ul style="list-style-type: none"> <li>- Inadequate installation or loosening due to physical product movement, relocation, etc.</li> <li>- When re-installing after the first installation requested by the customer at the time of purchase</li> <li>- When reinstallation is required due to inexperienced installation by the customer</li> <li>- When a service is requested due to the input of foreign substances or improper cleaning</li> </ul> | <p>Charged starting the 1<sup>st</sup> time</p>                          |

### **1. Equipment cleaning, adjustment, and usage description are not product breakdowns.**

(Unfeasible repairs are subject to separate standards.)

### **2. Breakdowns caused by consumer negligence**

Breakdowns and damage due to careless handling by the customer or incorrect repair are caused by:

- Using incompatible electric capacity.
- Mishaps such as dropping the product.
- Using the third party replacements or options not specified by our company.
- Non-Bionet technicians or agency technicians in the process of repair.

### **3. Other cases**

- Breakdowns by natural disasters (fire, salt damage, flood damage, earthquake, etc.)
- When a consumable part has reached the end of its life (accessories)

## Warnings, Cautions, and Notes

- The following terms are used throughout this manual to emphasize important and critical information. You must read these statements to help ensure safety and to prevent product damage.
- The manufacturer or the product distributor is not liable for any loss or damage to the product caused by incorrect use or negligence in product maintenance.

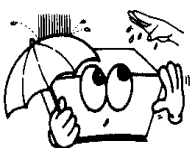
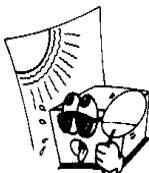
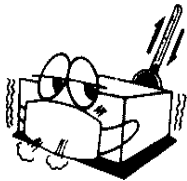
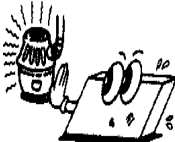
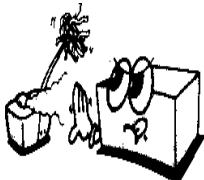
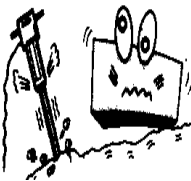
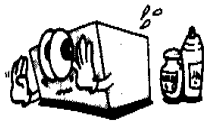
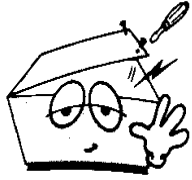
| Warning                                                                                                           |
|-------------------------------------------------------------------------------------------------------------------|
| <b>Warning</b> Failure to follow this message may cause severe injuries, casualty or physical damage to patients. |

| Caution                                                                                                            |
|--------------------------------------------------------------------------------------------------------------------|
| <b>Caution</b> Failure to follow this message may cause in non-life-threatening injury or damage to the equipment. |

| Note                                                                                                                                |
|-------------------------------------------------------------------------------------------------------------------------------------|
| <b>Note</b> indicates some important information and tips, which are not dangerous, about installation, operations and maintenance. |

## General Precautions on Environment

DO NOT store or operate the equipment in the places listed below.

|                                                                                     |                                                                                                                              |                                                                                      |                                                                                                        |
|-------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|
|    | A place exposed to moisture<br><br>(DO NOT touch the equipment with wet hands.)                                              |     | A place under direct sunlight                                                                          |
|    | A place in areas with highly fluctuating temperatures.                                                                       |    | A place in the vicinity of Electric heater                                                             |
|  | A place with excessive humidity rise or poor ventilation                                                                     |  | A place with sources that cause excessive shock or vibration                                           |
|  | A place exposed to chemicals or at risk of gas leakage                                                                       |  | Avoid the invasion of small objects/ particles such as dust, and especially avoid metallic material.   |
|  | DO NOT disjoint or disassemble the equipment.<br>(Bionet is not liable for broken products caused by attempted disassembly.) |  | DO NOT connect power until the product is completely installed.<br>It may cause damage to the product. |

# Safety Instructions for Electricity

**Please note the following precautions before using the product.**

- Is the power supply cord proper?
  1. Cardio P1 : 5Vdc, Max. 0.5A
- Is every cord connected properly to the product?
- There is a risk of electric shock if the Rest stand of the equipment is damaged or not be fixed to the equipment body. Do not use the product and immediately ask the manufacturer or seller for repairs.

## Classification

- This equipment is classified in accordance with IEC 60601-1 as follows.
- Class I protection against electric shock and Type CF defibrillation-proof
- Compatibility Requirements standard:- Parts
- Degree of protection against harmful ingress of water: Ordinary
- DO NOT use this product near flammable anesthetic or solvents.
- Continuous operation
- IEC/EN 60601-1-2 (Electromagnetic Compatibility Requirements) standard:

| Type    | Description                                                                                                                                                                                                                                                  |
|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Class A | The equipment or system is suitable for use in all establishments.<br>It requires a higher amount of power than the public low-voltage power supplied to typical residential buildings.<br>Mains power should be typical commercial or hospital environment. |

| Note                                                                                  |
|---------------------------------------------------------------------------------------|
| Diagnosis provided by CardioP1 must be confirmed by a qualified medical professional. |

| Note                                                                                                                                                                                                                                                                                                                                                                            |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such |

as relocating or re-orienting the equipment.

#### Caution



Warning: MR-unsafe!

DO NOT expose the device to a magnetic resonance (MR) environment.

- The device may present a risk of projectile injury due to the presence of ferromagnetic materials that can be attracted by the MR magnet core.
- Thermal injury and burns may occur due to the metal components of the device that can heat during MR scanning.
- The device may generate artifacts in the MR image.

The device may not function properly due to the strong magnetic and radiofrequency fields generated by the MR scanner.

## Safety Messages

The following messages are applied throughout the product. Certain statements may also appear elsewhere in the manual.

**WARNING:**

ACCIDENTAL SPILLS — If the equipment is penetrated with liquid, take it out of service and have it checked by a service technician before using it again.

DO NOT allow liquids to enter the equipment to prevent electric shock or equipment malfunction.

**WARNING:**

CABLES - To avoid possible strangulation, route all cables away from the patient's throat.

**WARNING:**

CONNECTION TO MAINS - This is class I equipment.

The mains plug must be connected to an appropriate power supply.

**WARNING:**

DEFIBRILLATOR PRECAUTIONS - Avoid physical contact with the patient during defibrillation, as it may cause serious injury or death.

Patient signal inputs labeled with the CF symbols with paddles are protected against damage resulting from defibrillation voltages.

The defibrillator paddles in relation to the electrodes should be placed properly to assure successful defibrillation.

Use only recommended cables and leads to ensure adequate defibrillation protection.

**WARNING:**

ELECTRODES - Polarized electrodes (stainless steel or silver constructed) may cause the electrodes to retain a residual charge after defibrillation. Residual charge blocks ECG signal acquisition.

Use non-polarized electrodes (silver or silver chloride construction) for ECG monitoring with each defibrillation.

**WARNING:**

MAGNETIC AND ELECTRICAL INTERFERENCE - Magnetic and electric fields may interfere with the proper operation of the equipment.

Therefore, make sure that all external devices operated in the vicinity of the equipment comply with the relevant EMC requirements.

X-ray equipment or MRI devices are possible sources of interference as they may emit higher

levels of electromagnetic radiation.

**WARNING:**

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

**WARNING:**

EXPLOSION HAZARD - Do NOT use in the presence of flammable anesthetics vapors or liquids.

**WARNING:**

INTERPRETATION HAZARD - Computerized interpretation is only significant when used in conjunction with clinical findings.

A qualified physician must verify all computer-generated diagnoses.

**WARNING:**

OPERATOR - Medical technical equipment such as this system must be used only by qualified and trained personnel.

**WARNING:**

SHOCK HAZARD - Improper use of this equipment may cause electric shock.

Strictly observe the following guidelines.

Failure to do so may endanger the lives of the patient, user, and bystanders.

To disconnect the equipment from the power line, first remove the power plug from the wall outlet before disconnecting the cables from the equipment; Otherwise, there is a risk that metal parts inadvertently inserted into the power cord socket will come into contact with line voltage.

Additional devices connected to medical electrical equipment shall comply with the respective IEC or ISO standards (e.g., IEC 60950 for data processing equipment).

Additionally, all configurations must comply with the requirements for medical electrical system. (See IEC 60601-1-2 or Clause 16 of IEC 60601-1)

Anyone who connects additional devices to medical electrical equipment is in the position of configuring medical system, and is responsible for complying with the requirements of medical electrical system.

Keep in mind that local legislation takes precedence over the above-mentioned requirements.

If in doubt, consult your local distributor or the technical service department.

**WARNING:**

SITE REQUIREMENTS - Improper placement of the device and/or accessories may result in a hazard to the patient, operator, or bystanders.

Do not route cables in a way that they may present a stumbling hazard.

For safety reasons, all connectors for patient cables and lead-wires are designed to prevent inadvertent disconnection, should someone pull on them.

For devices installed above the patient, adequate precautions must be taken to prevent them from dropping on the patient.

**WARNING:**

TREADMILLS - Avoid rapid changes in treadmill speed and/or grade during a stress test.

**WARNING:**

Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

**WARNING:**

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the [ME EQUIPMENT or ME SYSTEM], including cables specified by the manufacturer.

**CAUTION:**

PROPER LEADWIRE CONNECTION - Improper connection will cause inaccuracies in the ECG.

Trace each individual lead-wire from its acquisition module label to the colored connector and then to the proper electrode to ensure that it is matched to the correct label location.

**CAUTION:**

ACCESSORIES (SUPPLIES) - The parts and accessories used must comply with the requirements of the relevant IEC 60601 series safety standards and essential performance standards, and/or the system configuration must meet the requirements of the IEC 60601-1-2 medical electrical system standards.

**CAUTION:**

ACCESSORIES (EQUIPMENT) - The use of accessory equipment that does not comply with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system.

Considerations related to the choice of equipment shall include:

- Use of the accessory in the patient vicinity, and Evidence that the safety certification of the accessory has been performed in accordance with the appropriate IEC 60601-1 and/or IEC 60601-1-2 harmonized national standard.

**CAUTION:**

BEFORE INSTALLATION — Compatibility is critical to safe and effective use of this equipment. Please contact your local sales or service representative prior to installation to verify equipment compatibility.

**CAUTION:**

DISPOSABLES - Disposable devices are intended for single use only. They should not be reused as performance may degrade or contamination could occur.

**CAUTION:**

DISPOSAL — At the end of its service life, the product described in this manual, as well as its accessories, must be disposed of in compliance with local, state, or federal guidelines regulating the disposal of such products. If you have questions concerning the disposal of the product, please contact Bionet or its distributor.

**CAUTION:**

EQUIPMENT DAMAGE — Equipment intended for emergency application must not be exposed to low temperatures during storage and transport to avoid moisture condensation at the application site. Wait until all moisture has vaporized before using the equipment.

**CAUTION:**

ELECTRIC SHOCK — To reduce the risk of electric shock, do not remove cover or back of the equipment. Refer servicing to qualified personnel.

**CAUTION:**

OPERATOR — Medical technical equipment such as this electrocardiograph system must only be used by persons who have received adequate training in the use of such equipment and who are capable of applying it properly.

**CAUTION:**

POWER REQUIREMENTS - Before connecting the device to the power line, check that the voltage and frequency ratings of the power line are the same as those indicated on the unit's label. If this is not the case, do not connect the system to the power line until you adjust the unit to match the power source.

This equipment is suitable for laptop's USB power connection.

Equipment connected to the ECG system and in the patient, environment must be powered from a medically isolated power source or must be a medically isolated device. Equipment powered from a non-isolated source can result in chassis leakage currents exceeding safe levels. Chassis leakage current created by an accessory or device connected to a non-isolated outlet may add to the chassis leakage current of the ECG system.

**CAUTION:**

SERVICEABLE PARTS - This equipment contains no user serviceable parts.  
Refer servicing to qualified service personnel.

**CAUTION:**

SUPERVISED USE - This equipment is intended for use under the direct supervision of a licensed health care practitioner.

## Safety Symbols

| Symbols                                                                             | Contents                                                                                                                                                          |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|    | Attention<br>Consult accompanying documents                                                                                                                       |
|    | Consult Instructions for Use:<br>This symbol advises the reader to consult the operating instructions for information needed for the proper use of the equipment. |
|    | Safety Sign<br>To signify that the instruction manual must be read.<br>Reading the instruction manual before starting work or before operating equipment.         |
|   | General Prohibition Sign                                                                                                                                          |
|  | Defibrillation Proof-Type CF APPLIED PART                                                                                                                         |
|  | ECG Patient Cable Connector                                                                                                                                       |
|  | USB Connector                                                                                                                                                     |

| Symbols                                                                             | Contents                                              |
|-------------------------------------------------------------------------------------|-------------------------------------------------------|
|  | Auto operation / Event Marker Key                     |
|  | Power (USB data) cable insertion direction indication |
|  | Power (USB data) cable connection indication          |

|                                                                                     |                                                                                                                                                                                                                                                                                 |                                                                                     |                                                                                                  |
|-------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------|
|    | Manufacturer                                                                                                                                                                                                                                                                    |                                                                                     |                                                                                                  |
|    | Authorized Distributor in the European Community                                                                                                                                                                                                                                |                                                                                     |                                                                                                  |
|    | <p>Waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately.</p> <p>Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.</p> |                                                                                     |                                                                                                  |
|    | <p>MR Unsafe:</p> <p>DO NOT use this equipment in all MR environment.</p>                                                                                                                                                                                                       |                                                                                     |                                                                                                  |
|  | No sterilization                                                                                                                                                                                                                                                                |  | Do not use if package is damaged                                                                 |
|  | Recycling; Dispose of properly in accordance with all state, province, and country regulations                                                                                                                                                                                  |  | <p>This way up.</p> <p>For the duration of shipping/delivery, the carton should face upright</p> |
|  | Fragile; Handle with care                                                                                                                                                                                                                                                       |  | Use no hooks; Absolutely no hand hooks should be attached to pull the parcel                     |
|  | Keep away from rain                                                                                                                                                                                                                                                             |                                                                                     |                                                                                                  |

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Specifications or functions indicated on user manual are subject to change without notification for the improvement of product.

# Chapter 1. General Rules

## 1) Product Overview



### 1-1) Intended Use

The Cardio P1 Analysis System is intended to acquire, analyze, display, and record ECG information from adult and pediatric populations. The system provides 12-lead ECG and interpretive analysis. The 12-Lead ECG interpretation algorithm provides analytical information about the patient's heart condition, which must be confirmed by a qualified medical professional along with other relevant clinical information. Sending and receiving ECG data to and from the Hospital Information System is optional. The Cardio P1 is intended to be used by personnel trained in hospitals or medical professional facilities under the direct supervision of a licensed healthcare practitioner.

## 1-2) Indications

The ECG has proven to be among the most useful diagnostic tests in clinical medicine. It is now routine in the evaluation of patients with implanted defibrillators and pacemakers, as well as to detect myocardial injury, ischemia and the presence of prior infarction as well. In addition to its usefulness in ischemic coronary disease, the ECG is of particular use in the diagnosis of disorders of the cardiac rhythm and the evaluation of syncope.

## 1-3) Contraindications

There are no absolute contraindications to performing an ECG other than the patient's refusal. Some patients may be allergic or, more commonly, sensitive to the adhesive used to attach the electrodes. In this case, use hypoallergenic alternatives available from various manufacturers.

## 1-4) Side Effects

The ECG is a safe test that does not cause health complications. There are no medical conditions associated with increased risk or adverse side effects of ECG.

## 1-5) Warnings, Cautions and Adverse Reactions

- a. Modifications to this equipment are not allowed. Any unauthorized changes to the Cardio P1 device may compromise product safety and/or data and as such Cardio P1 cannot be held responsible and the equipment will no longer be supported.
- b. The Cardio P1 is not designed as sterile equipment. Always follow the safety instructions given by the manufacturer of cleaning and disinfectant chemicals.
- c. Do not expose the Cardio P1 to liquids.
- d. The Cardio P1 should not be used in the presence of flammable liquids or gases, dust, sand, or any other chemical substances.
- e. The Cardio P1 should never be outside accuracy limits.
- f. Service and repairs should be carried out only by the manufacturer or by Service Agents approved by Cardio P1.
- g. Maintenance must not be performed while the device is in use by a subject.
- h. Use of accessories and cables other than those specified or provided by Cardio P1 for this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of the Cardio P1 and result in improper operation.
- i. Non-medical equipment must be kept outside the subject environment i.e. any area in which intentional or unintentional contact between the subject and parts of the system, or

some other persons touching part of the system, can occur.

- j. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be more than 30cm (12 inches) away from any part of the Cardio P1, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- k. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- l. Only use the Cardio P1 with the power supply provided. Attempted use with other power sources may cause irreparable damage and invalidate the warranty.

## 2) Recording ECGs during Defibrillation

This equipment is protected against the effects of cardiac defibrillator discharge to ensure recovery, as required by test standards. The patient signal input of the acquisition module is defibrillation-proof, therefore, it is not necessary to remove the ECG electrodes prior to defibrillation.

When using stainless steel or silver electrodes a defibrillator discharge current may cause the electrodes to retain a residual charge causing a polarization or DC offset voltage.

This electrode polarization will block the acquisition of the ECG signal. To avoid this condition, use non-polarized electrodes, which will not form a DC offset voltage when subjected to a DC current, such as silver/silver-chloride types if there is a situation where there is a likelihood that a defibrillation procedure will be necessary.

If using polarized electrodes, disconnect the lead-wires from the patient before the shock is delivered. Electrode defibrillation recovery is the ability of the electrode to allow the ECG trace to return after defibrillation. It is recommended to use non-polarized disposable electrodes with a Defibrillation Recovery class as specified in AAMI EC12 4.2.2.4. AAMI EC12 requires that the polarization potential of an electrode pair does not exceed 100mV, 5 seconds after a defibrillation discharge.

## 3) Product Characteristics

- Waves of ECG in 12 channels are configured with various channels in 3 channels + 3 rhythms, 3 channels + 1 rhythm, 6 channels + 1 rhythm, 12 channels, and 6 channels + 1 rhythm (ST Map) 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.

- 
- The 12 channel rhythms are continuously printed simultaneously in real time.
  - The heart rate, PR interval, RR interval, QRS interval, QT interval, QTc interval, P-R-T axis, and SV1/RV1/R+S size required for diagnosis are automatically calculated and provided on the report along with the ECG.
  - Automatic ECG diagnostic results for pediatrics and adults are provided.
  - Real-time detection of 13 kinds of arrhythmia is provided.
  - A Disclosure function is provided to save and show ECG data up to 30 minutes.  
The Disclosure function helps diagnose an arrhythmia.
  - Once an ECG is saved, you can change its filter settings, gain, print speed, channel configuration and rhythm settings, and print it out, which is helpful for diagnosis.
  - 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.
  - Various protocols are supported to enable connection with the hospital computer network (EMR, PACS, etc.), and File and Worklist DB functions have been enhanced.

## 4) Product Configuration

The Cardio P1 system is comprised of the following components.

### Cardio P1

#### 1) CardioSync

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

#### 2) Cardio P1

- Device to ECG measurement

### Basic Configuration and Accessories

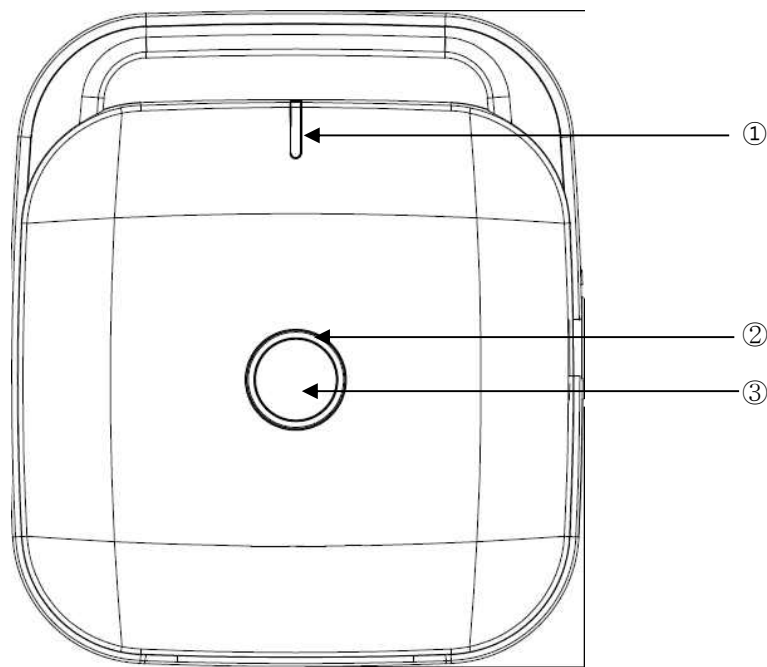
Make sure to open the package box and see if the following components are contained. In addition, make sure to see if body or components are damaged.



- 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)

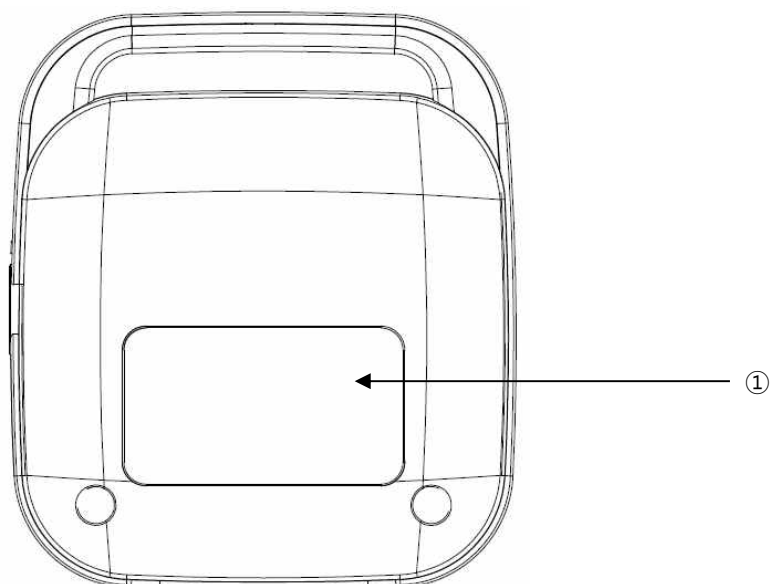
## Cardio P1 Body Configuration

### ■ Top View



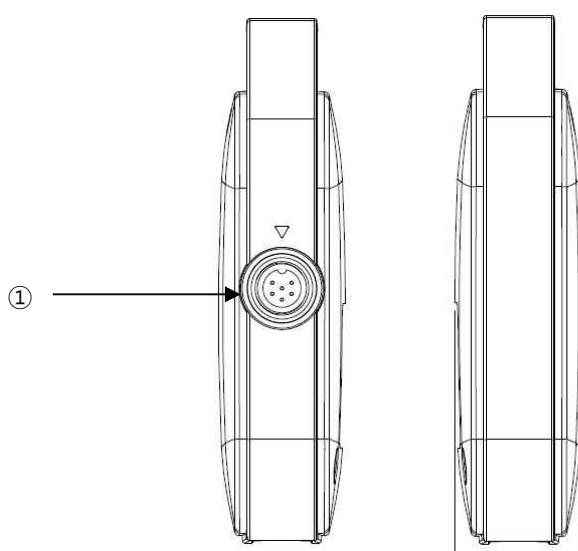
- ① Power Indication Part (LED) : Part showing the power connection status of a product
- ② Lead fault Indication Part (LED) : Part that informs the lead connection status
- ③ Function Switch : Auto operation (push more than 3 seconds), event marker key

### ■ Bottom View

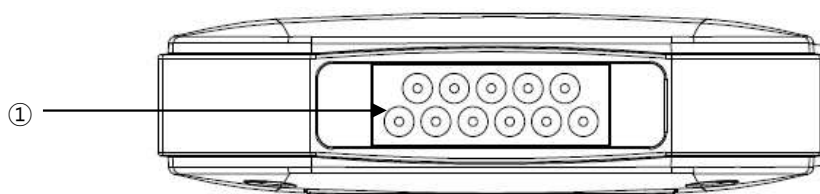


① ID Label : Part to attach ID Label

### ■ Side View



① Power (USB Data) Cable Connection Port

**■ Rear View**

① ECG Cable Connection Port

**Warning**

There is a risk of electric shock if the Rest stand of the equipment is damaged or cannot be fixed to the equipment body. Do not use the product and immediately ask the manufacturer and the seller for repair.

**Note**

Do not open the cover of the equipment; it may cause an electric shock. Repair or disassembly of the equipment can only be performed by those who have product repair qualifications recognized by Bionet.

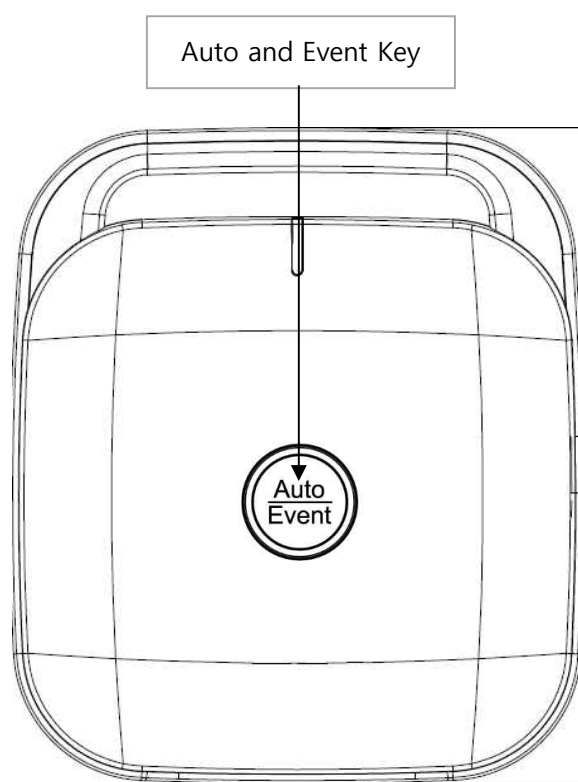
**Caution**

When using the device (Cardio P1) connected to the PC, the mouse may malfunction. In this case, reconnect the device's power (USB) cable to the PC.

## CardioSync Main Screen

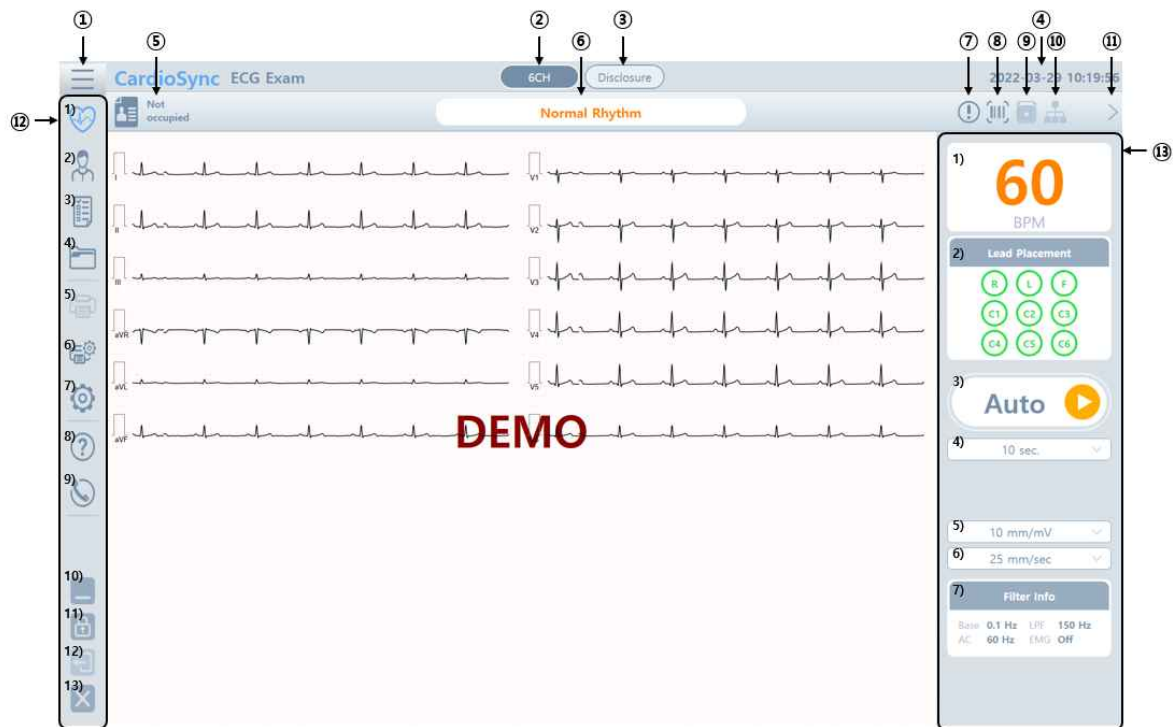


Graphic Display Window



## ECG Graphic Window

Explain the contents displayed in the graphic window.

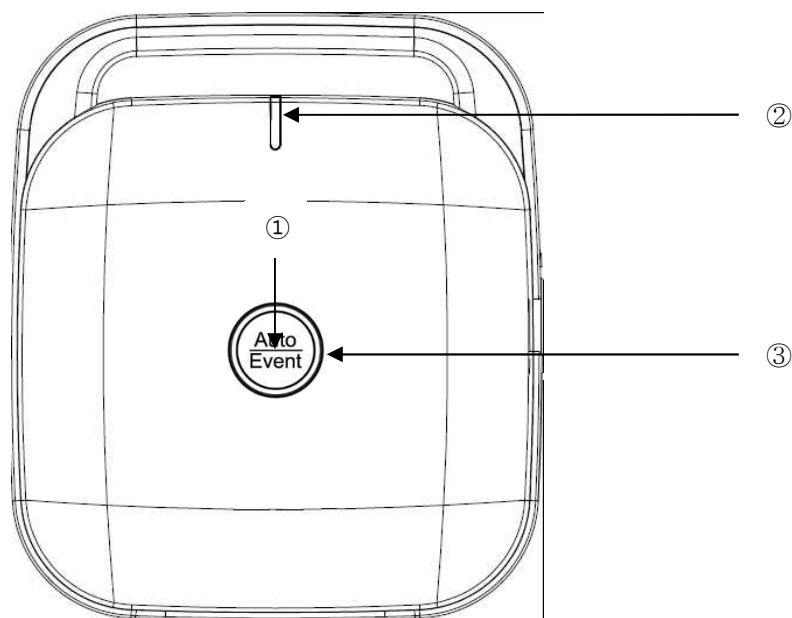


- ① Button for expand/collapse Quick Menu
- ② 6CH display button
- ③ Disclosure button
- ④ Display the current date or time
- ⑤ Menu button for indicating patient ID and name and entering patient information
- ⑥ Display the real-time diagnosis name display
- ⑦ Indicate Retry queue (sending failure list 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) Minimize button
  - 11) Show contact us
  - 12) Logout button
  - 13) Close button
- ⑬ Side Menu bar
- 1) Indicate heart rate
  - 2) Lead Fault status display and lead position display window button
  - 3) AUTO button
  - 4) Menu button for indicating ECG record mode (one of the 10s, 1m, 3m, 5m, 10m, 20m and 30m) and setup
  - 5) Menu button for indicating or setting up signal size
  - 6) Menu button for indicating or setting up print speed
  - 7) Set filter value display window

| Note                                                                             |
|----------------------------------------------------------------------------------|
| The detection range of heart rate is 30-300 bpm with $\pm 3$ bpm of error range. |

## Function Key Panel



### ■ Button

|   |                                                                                     |                                                                                                                                                                                                                                                                                                                                                                    |
|---|-------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| ① |  | <p>Auto / Event.</p> <p>1. Long Press (more than 3 seconds)</p> <p>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</p> <p>2. Short Press</p> <p>Performed to mark as a marker when abnormalities such as arrhythmias were felt in the ECG diagnostic test</p> |
|---|-------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

### ■ Indicating light

|   |                                                                                     |                                                                                                                                                                                         |
|---|-------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| ② |  | Indicate the DC power connection status. blue LED light turns on when DC power is connected on the equipment body.                                                                      |
| ③ |  | 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. |

## 5) Installing System

### Installation Precautions

Note the following when installing the Cardio P1

- Use the equipment within the ambient temperature of 10~40°C and humidity of 30~85%.
- Check the connection of the power cord and handle the patient cable with care.
- Handle the equipment with care as it is sensitive to impact.
- Install the equipment in a place with proper ambient temperature and humidity, and away from dust and flammable materials.

### Software Minimum Requirement

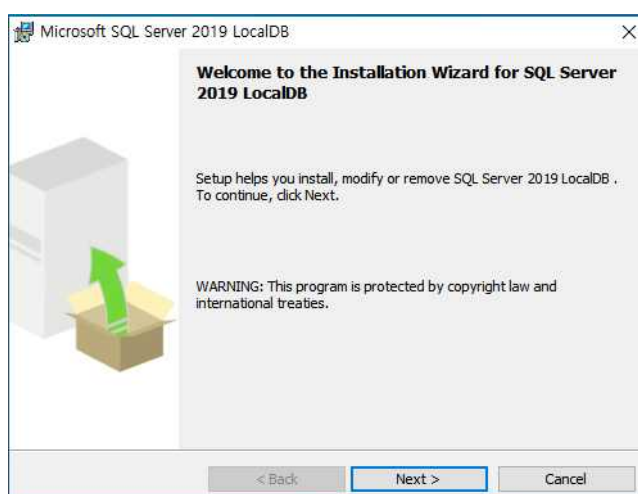
Install the program on a PC that meets the minimum specifications below.

|                  |                              |
|------------------|------------------------------|
| 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                          |

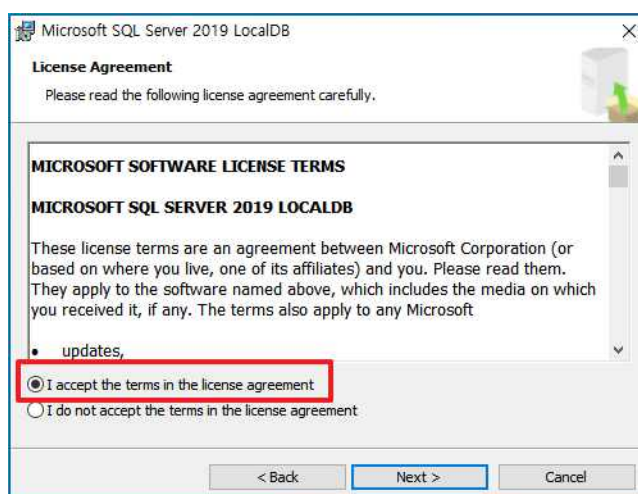
### How to install the Software

Add software for the description below.

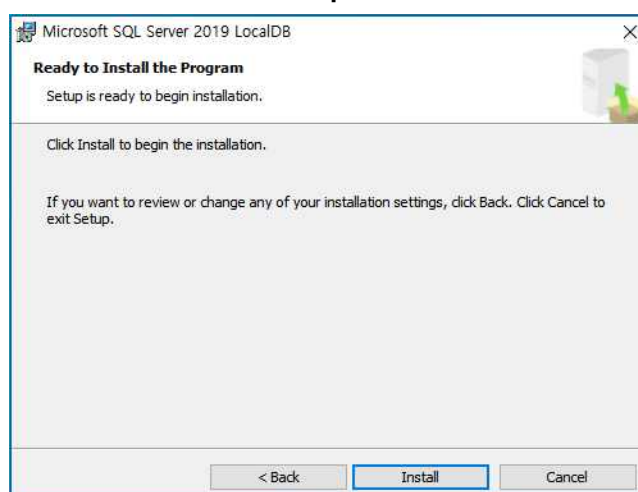
- ① Close every application before beginning installation.
- ② Execute "SqlLocalDB.msi" under your CD-ROM drive, download folder or USB memory.
- ③ Follow each instruction on each step.



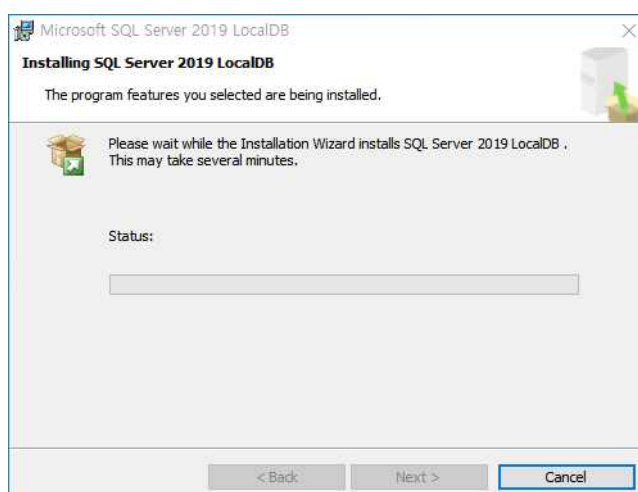
&lt; Step 1 &gt;



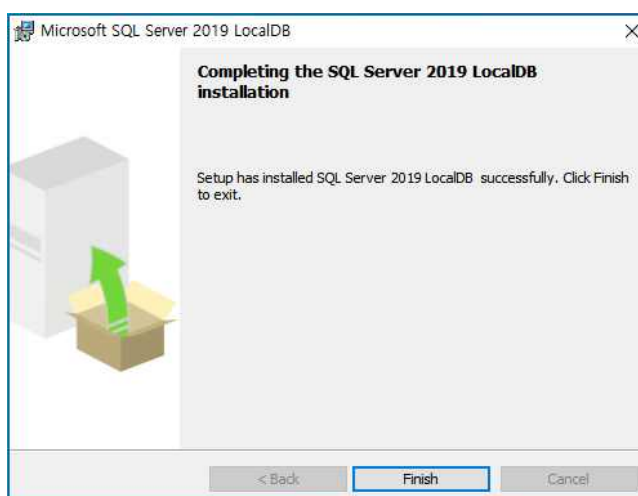
&lt; Step 2 &gt;



&lt; Step 3 &gt;

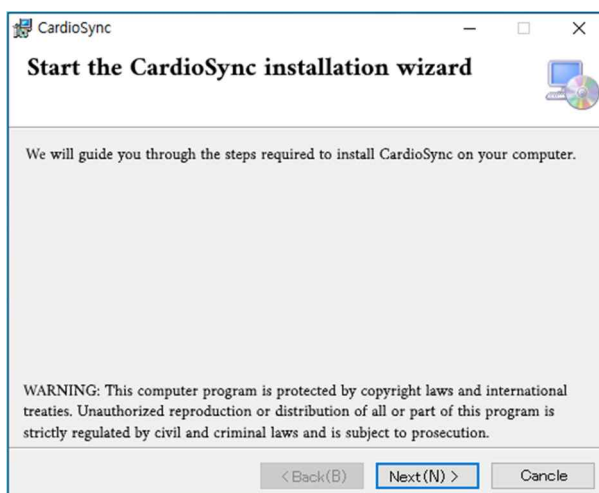


< Step 4 >

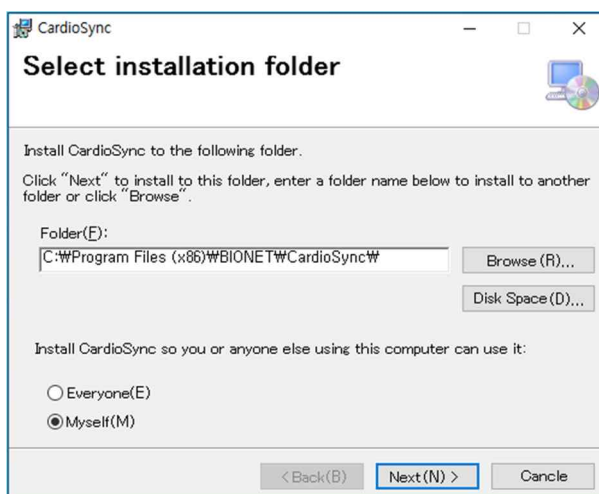


< Step 5 >

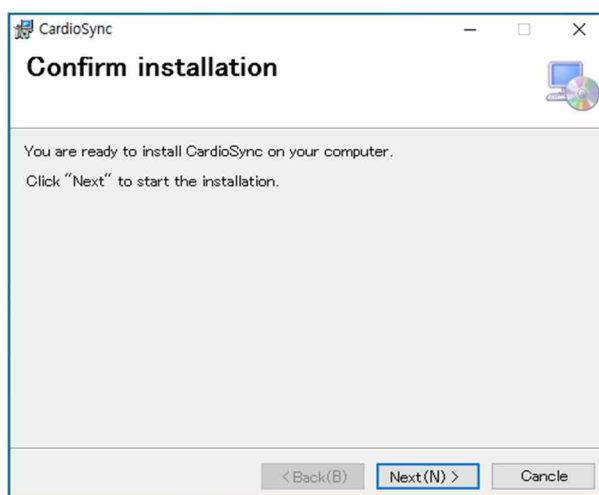
- ④ Execute "setup.exe" or "Cardio P1 ECG\_X.XX.XXX\_YYYYMMDD.msi" under your CD-ROM drive, download folder or USB memory.
- ⑤ Follow each instruction on each step.



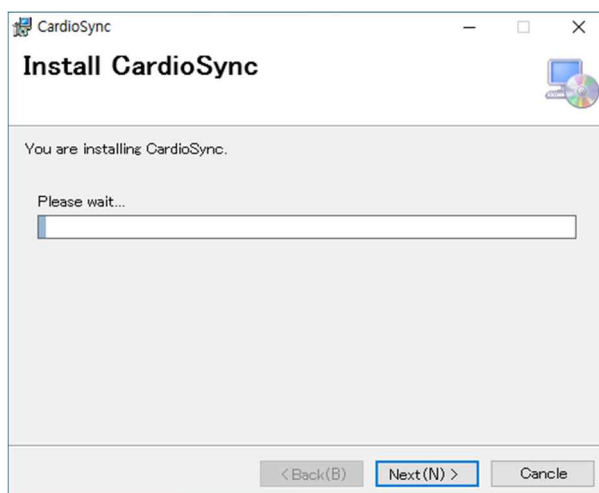
&lt; Step 1 &gt;



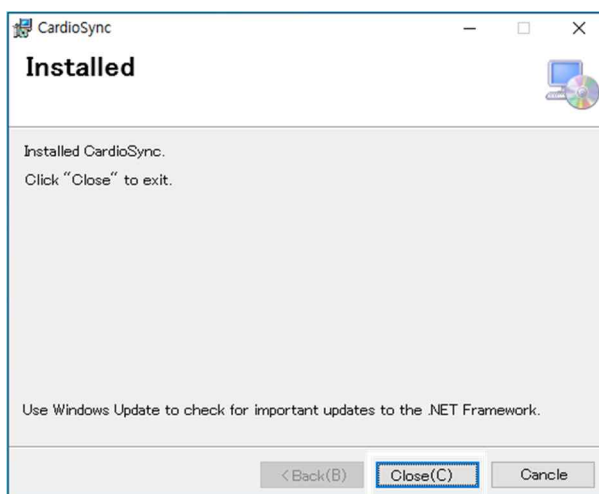
&lt; Step 2 &gt;



&lt; Step 3 &gt;



< Step 4 >



< Step 5 >

## 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**

Modifications to this equipment are not allowed.

Do not disassemble or modify this equipment without the manufacturer's approval.

Repair or disassembly of the equipment can only be performed by those who have product repair qualifications recognized by Bionet.

Bionet is not liable for any problems arising from the disassembly and modification of equipment by an unqualified person.

**General Precautions**

Please be aware of the following guidelines to ensure safe usage of the software

- Use strong passwords: Choose a strong password that includes a mix of uppercase and lowercase letters, numbers, and symbols. Never use the same password for multiple accounts.
- Use antivirus software: Install a reliable antivirus program and run regular scans to keep your computer safe from malware and viruses.
- Backup your data: Regularly backup your important files to an external hard drive or cloud storage to prevent data loss.

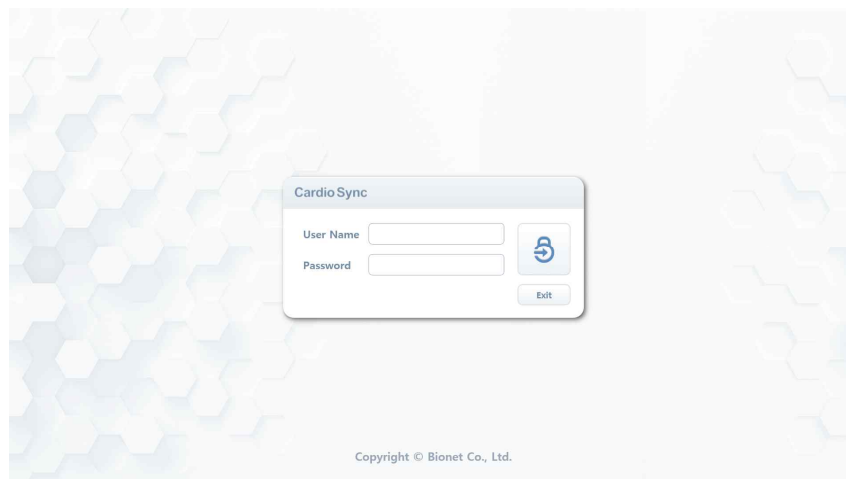
**Connecting the Network**

As only the service technicians can connect this equipment to the network, consult with the IT staff in the hospital in advance.

Follow IEC 80001-1, which is the Risk management of IT networks to which medical devices are connected.

## 6) System the Start

After everything is ready, run the software and you will see the login screen as shown.



### Login

Enter your ID and password.

Roles and privileges are assigned to individual users and may affect each user's scope of access to areas of the workflow and available functions.

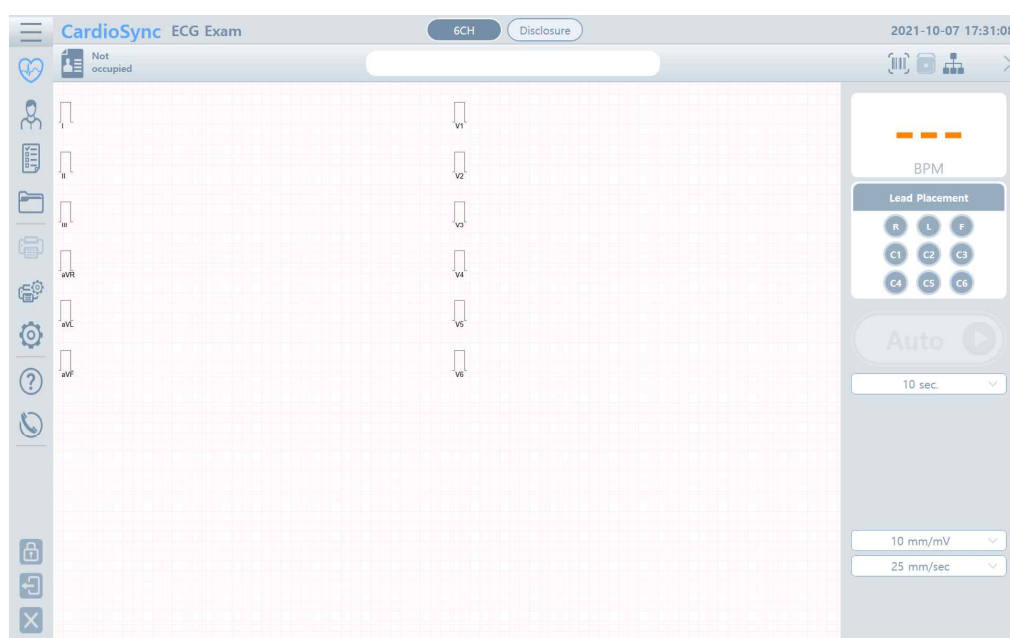
If a function is colored in gray and cannot be entered, it means that the user logged in does not have the privileges to perform the (greyed) task or the task is not available in the current screen.

See "Chapter 2. ECG Recording Preparation – 7) System Setup" for individual users and their privileges.

After login, the menu screen appears as shown below.

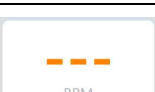


Click the items to inspect on the screen to move to the default screen on the selected menu. The figure below shows the initial ECG screen that moves when the 'ECG' menu is selected.



If you know the following on the ECG initial screen, you can use it more conveniently.

| Menu                                                                                             | explanation                                   |
|--------------------------------------------------------------------------------------------------|-----------------------------------------------|
|  Not occupied | Enter patient information or confirm contents |
|               | Real-time diagnosis name display              |
|  ECG          | ECG screen                                    |

|                                                                                     |             |                                                                                    |
|-------------------------------------------------------------------------------------|-------------|------------------------------------------------------------------------------------|
|    | Patient     | Patient management screen                                                          |
|    | Worklist    | Worklist screen                                                                    |
|    | File        | File screen                                                                        |
|    | Print       | Print execution                                                                    |
|    | Print Setup | Print setting                                                                      |
|    | Setup       | System setting                                                                     |
|    | Manual      | Help                                                                               |
|    | Contact Us  | Company information.                                                               |
|   |             | Minimize button                                                                    |
|  |             | Fix the screen.                                                                    |
|  |             | Log out                                                                            |
|  |             | End of the program.                                                                |
|  |             | Setup or indicate recording mode<br>(Displayed as 10s, 1m, 3m, 5m, 10m, 20m, 30m)  |
|  |             | Heart rate display                                                                 |
|  |             | Confirm lead fault information                                                     |
|  |             | Auto Button                                                                        |
|  |             | Move to the retry queue (error file management while sending to the server) screen |
|  |             | Indicate the connection of barcode reader                                          |

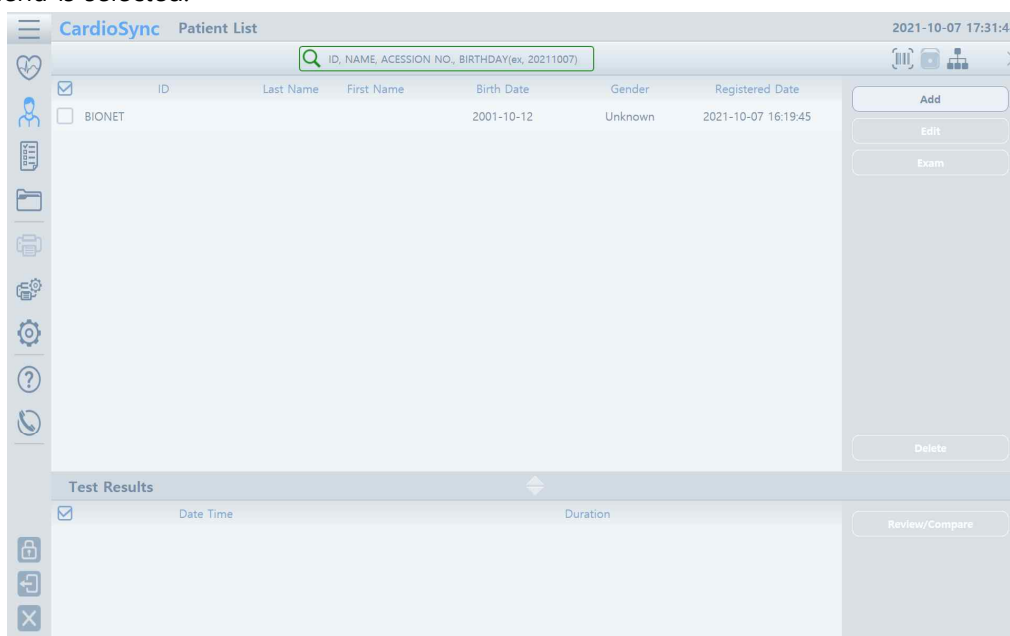
|                                                                                      |                                            |
|--------------------------------------------------------------------------------------|--------------------------------------------|
|     | Indicate Cardio P1 connection              |
|     | Indicate or setup network status           |
| 2021-10-06 20:05:06                                                                  | Indicate or setup the current date or time |
| 25 mm/sec                                                                            | Indicate or setup the print speed          |
| 10 mm/mV                                                                             | Indicate or setup the signal size          |
| <div>Filter Info</div> <div>Base 0.1 Hz LPF 150 Hz</div> <div>AC 60 Hz EMG Off</div> | Set filter value display window            |

### Note

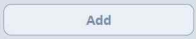
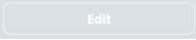
Function keys available in Cardio P1

- F9 Button : Auto
- F10 Button : Save
- F11 Button : Export
- F12 Button : Print

The following is the patient examination data management screen that moves when the 'Patient List' menu is selected.

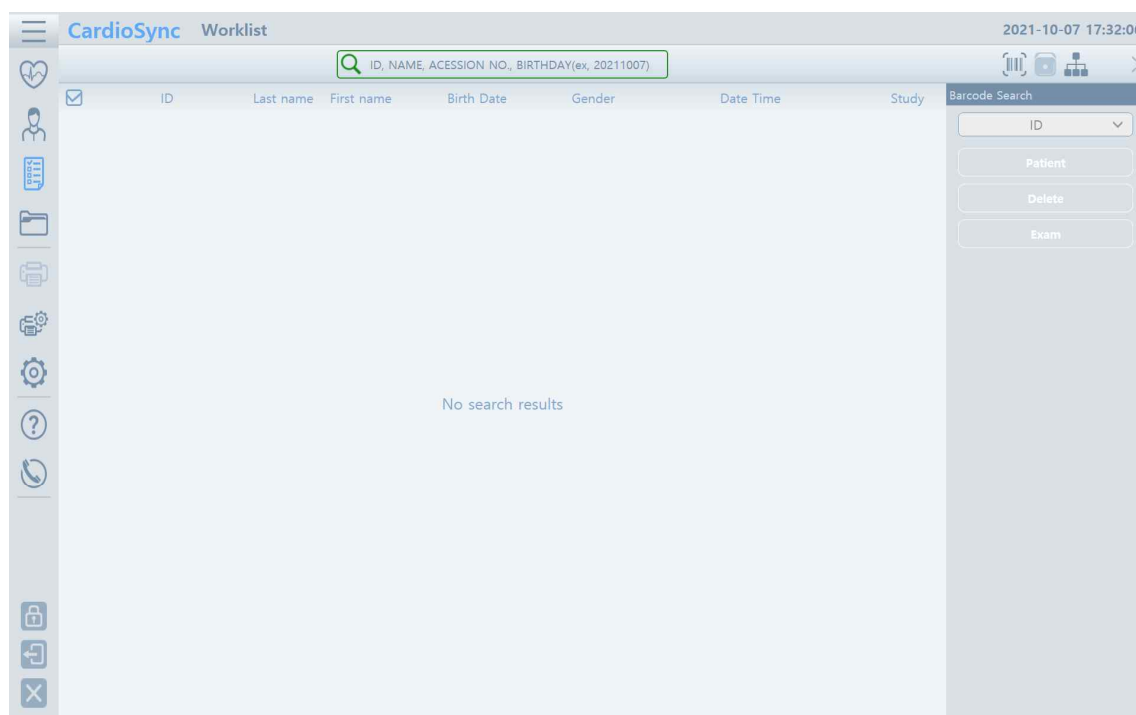


Followings are recommended to know on the exam request data managing screen for more convenient usage.

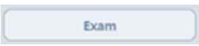
| Menu                                                                                                 | Explanation                                                    |
|------------------------------------------------------------------------------------------------------|----------------------------------------------------------------|
|  ID, NAME, BIRTHDAY | Search for data by entering search conditions                  |
|                     | Move to the exam screen                                        |
|                     | Add patient information                                        |
|                     | Edit patient information                                       |
|                     | Delete patient information                                     |
|                     | Check measurement information / Compare two measurement values |

| Note                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>Applicable matters when editing patient information.</p> <ul style="list-style-type: none"> <li>- Basic Item (ID, Name, Birth) : DB, All files</li> <li>- Additional items (ETC.) : DB, User decides whether to apply to all files</li> </ul> <div data-bbox="507 1234 1082 1655"> <p><b>Confirm</b></p>  <p>Would you like to apply changes to the patient's all files?<br/>           (*) The mandatory information (ID, NAME, BIRTH) is always kept in all files.</p> <p>Yes No</p> </div> |

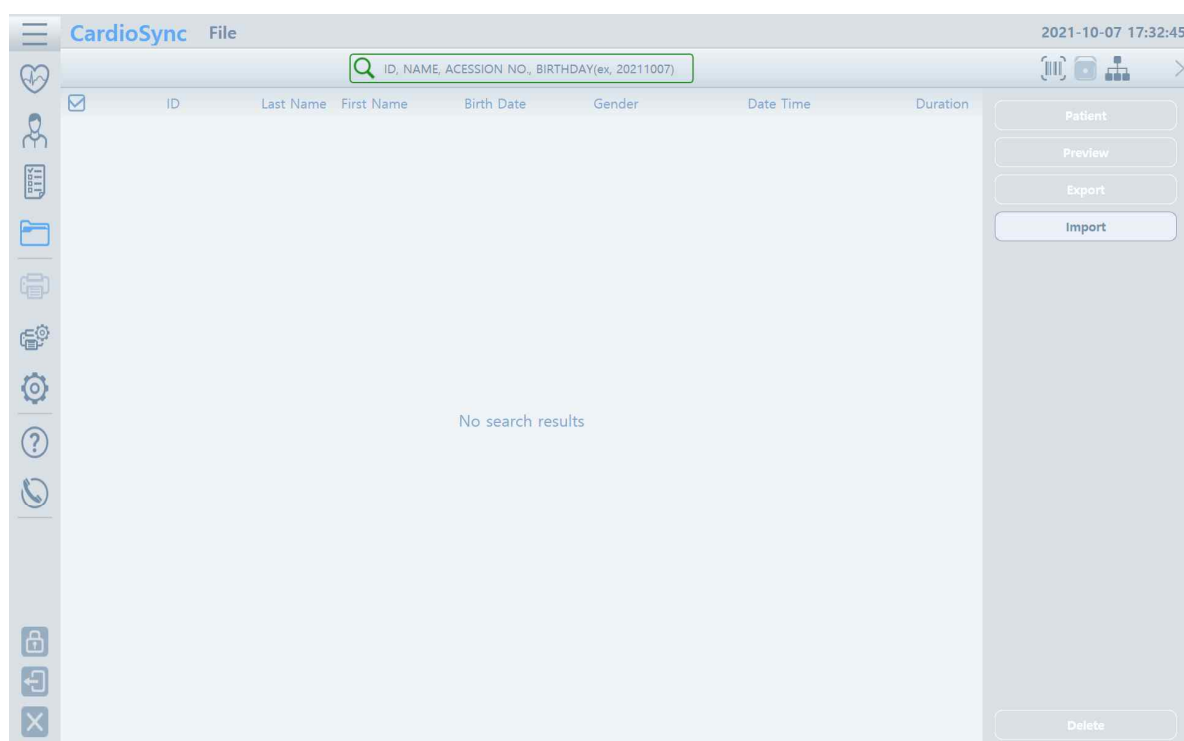
Following is the ECG data file managing screen when selecting 'Worklist' menu.



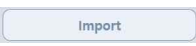
Followings are recommended to know on the data file managing screen for more convenient usage.

| Menu                                                                                                   | Explanation                                                            |
|--------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------|
|  ID, NAME, BIRTHDAY | Search for data after entering searching conditions                    |
|                     | Move to the exam screen                                                |
|                     | Get Worklist<br>Menu button that appears when PACS or GDT is connected |
|                     | Search condition setting                                               |
|                     | Check patient information                                              |

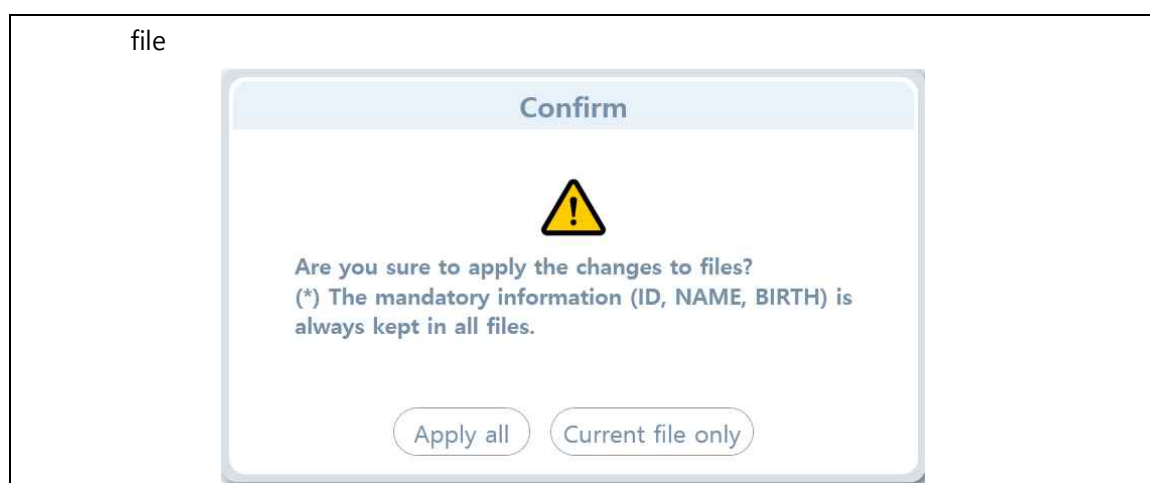
Following is the ECG data file managing screen when selecting 'File' menu.



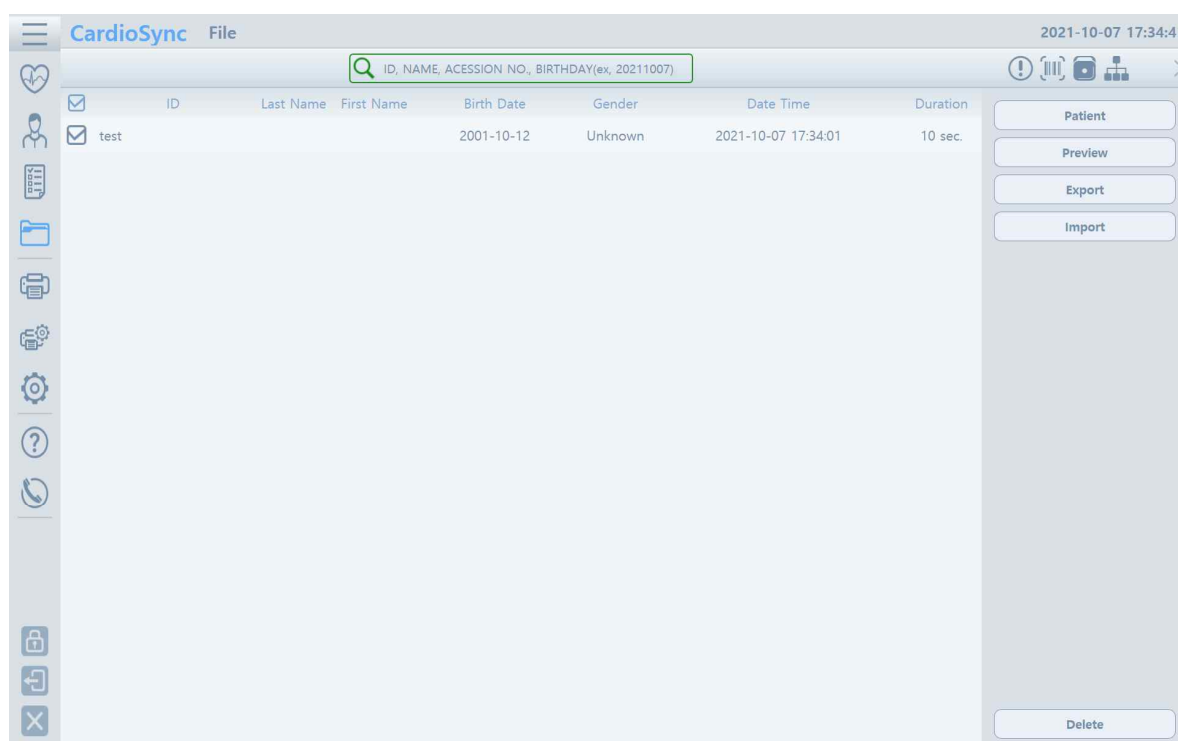
Followings are recommended to know on the data file managing screen for more convenient usage.

| Menu                                                                                | Explanation                                         |
|-------------------------------------------------------------------------------------|-----------------------------------------------------|
|  | Search for data after entering searching conditions |
|  | File export                                         |
|  | File import                                         |
|  | File preview                                        |
|  | Check patient information                           |

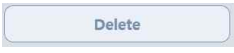
| Note                                                                                                                                                                                                                                                           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>Applicable matters when editing patient information.</p> <ul style="list-style-type: none"> <li>- Basic Item (ID, Name, Birth) : DB, All files</li> <li>- Additional Item (ETC.) : DB, User decides whether to apply to all files or the current</li> </ul> |



The following is the Retry Queue data management screen that moves when  (Retry Queue icon) is selected. The Retry Queue manages error data when an error occurs during transmission to the server.

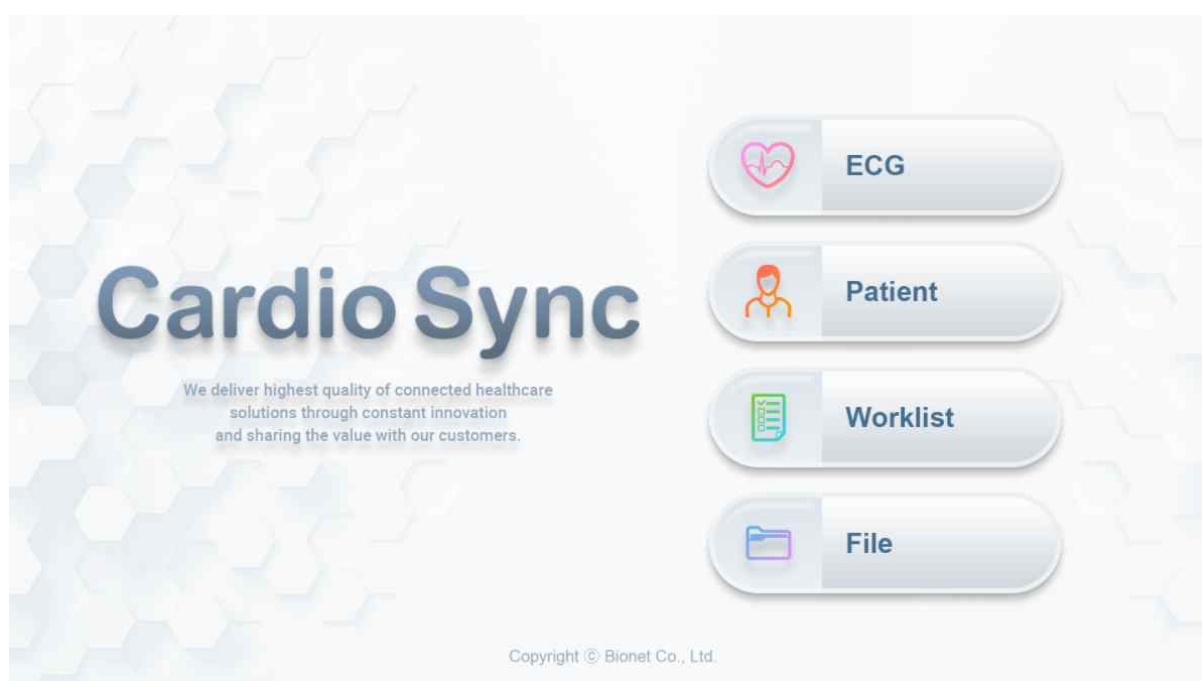


Followings are recommended to know on the Retry Queue managing screen for more convenient usage.

| Menu                                                                              | Explanation          |
|-----------------------------------------------------------------------------------|----------------------|
|  | Send selected data   |
|  | Delete selected data |

| Note                                                                                                                                                                                                                         |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"><li>-  icon is indicated on the right top corner only if there is an error while sending files.</li></ul> |

# Part I. Using ECG



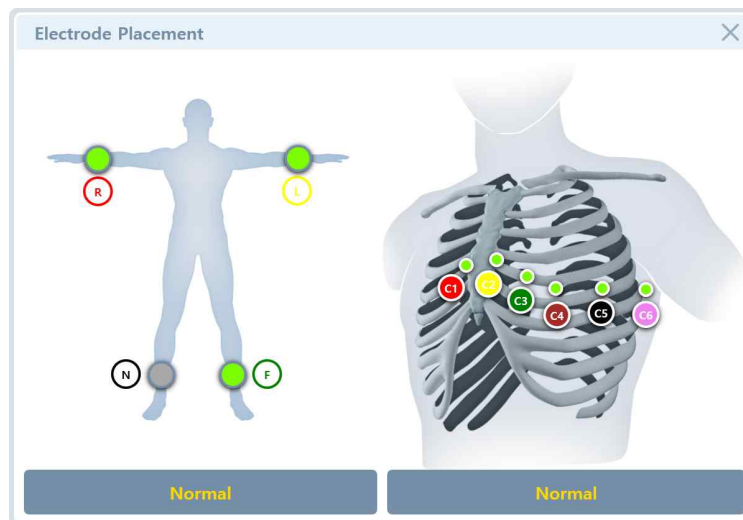
## Chapter 2. ECG Recording Preparation

### 1) Attaching the Electrodes



When you touch (Lead Fault Information) located in the center of the menu bar at the top of the ECG Main screen, a picture showing where to attach the electrodes is displayed.

To record a standard 12-lead ECG, attach electrodes to the patient's body as shown below.



The positions to attach limb electrodes are as follows:

- RL (N): Right leg
- LL (F): Left leg
- RA (R): Right arm
- LA (L): Left arm

The positions to attach the chest electrodes are as follows:

- V1 (C1): Boundary of fourth intercostal on right side of chest
- V2 (C2): Boundary of fourth intercostal on the left side of chest
- V3 (C3): Mid-location between V2(C2) and V4 (C4)
- V4 (C4): Mid-location of the front side of fifth intercostal collarbone
- V5 (C5): Front armpit on the horizontal line with V4(C4)
- V6 (C6): Mid-armpit on the horizontal line with V4(C4), V5(C5)

## 2) Connecting Electrodes

### \* Checklist

- Before the exam, check the condition of the equipment and patient, and whether each electrode is well attached.
- Make sure that there are no mechanical hazards.
- Check the status of cables and accessories connected externally.
- Check the status all the measuring devices for the patients

### Connecting Patient Cable

Connect the patient cable to the port on the right side of body and connect limb electrodes to the terminals of RL (N), LL (F), RA (R), and LA (L) of patient cable connected in the Cardio P1 and chest electrodes to the terminals V1 (C1), V2 (C2), V3 (C3), V4 (C4), V5 (C5) and V6 (C6).

### How to Attach the Electrodes

Have the patient lie down on the bed and release the tension in the skin area where the electrodes will be attached. Clean the area with disinfected alcohol or water before attaching electrodes. In case the patient is hairy on the attaching spots, shave them. If the attachment body part is curved and it is difficult to attach the electrodes, attach them to the positions that are as similar as possible without a curve.

If the noise is severe even if you have used alcohol or water, apply the ECG gel to the attaching spots before attaching the electrodes.

Be sure to wipe off the used ECG Gel, because if it gets dried and hardened, it can generate noise in the ECG signal.

#### Warning

Be sure to use only the electrodes and patient cable provided by Bionet. Bionet is not liable for any problems caused by your using unauthorized parts.

## What to Do with Poor Lead Connection

Turn on the equipment, enter the ECG mode, and check the connection of all leads and the noise level of the waveform. A message appears in case of a lead fault.



| Note                                                                                                                                                                                                                                                                                                                           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"> <li>- Lead fault message appears only when Lead fault is set to On in ECG General Setup. Otherwise, it will not appear.</li> <li>- Fault leads are shown in red and saturation leads in yellow.</li> <li>- Proceed with the ECG exam only when the leads are connected properly.</li> </ul> |

Take the following measures when the lead connection is poor.

- When the electrodes come off from the skin: Reattach the electrodes following the electrode attachment method.
- When conductivity between the skin and the electrodes is weak: Apply the ECG gel to the electrode-attaching spots and reattach the electrodes.

If the ECG signal is not accurately acquired even after you try all the solutions above, the patient cable may be non-conforming. Contact Bionet's service center.

## 3) Recording ECG

- Enter accurate patient information.
- Connect the ECG cable to the patient in compliance with the ECG measurement preparations.
- Check or change settings such as Filter, Gain, Output Speed, Channel Configuration, Rhythm, etc.
- Refer to What to Do with Poor Lead Connection if the waveform drawn in the LCD screen is

abnormal or there is too much noise.

- If the waveform displayed on the LCD screen is normal, press the [AUTO] key to record the ECG.
- Press the [STOP] key to stop printing or saving the ECG results.

## 4) Basic Setup

### General Information

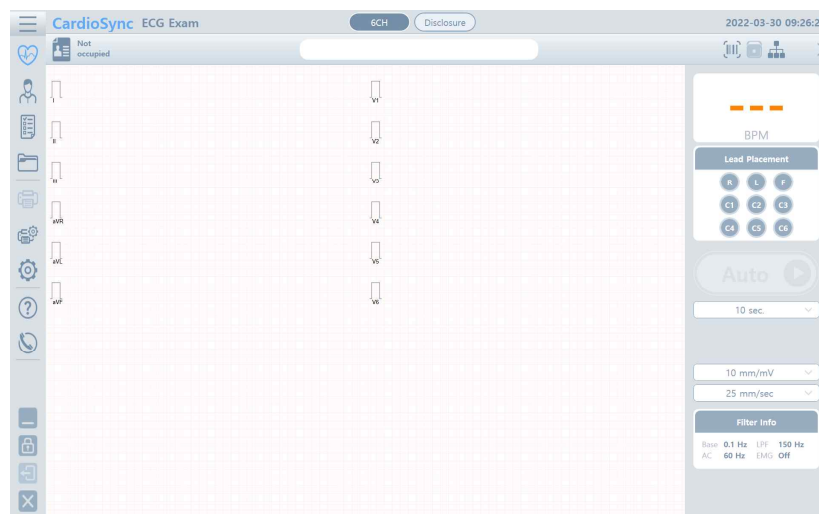
When you turn on the equipment, top and bottom menu bars and graphic window appear on the LCD screen.

Top menu bar: Patient Information, Test Mode, Heart Rate, Lead Fault, External Device

Connection Status, Network Status, Power Status, Current Date and Time

Bottom menu bar: Output Speed, Gain, Filter, Print Form, Disclosure, and Setup.

Touch the menu buttons on the LCD screen to change settings.



### Setting Values Using Touch Screen

- Selecting Menu

Touch the menu buttons on the screen.

- Setting the Value

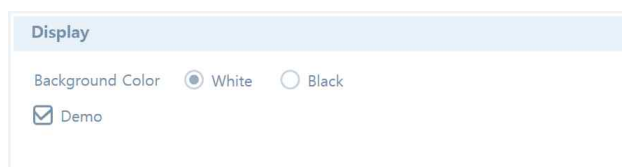
Select a menu and touch [OK].

### Screen Output

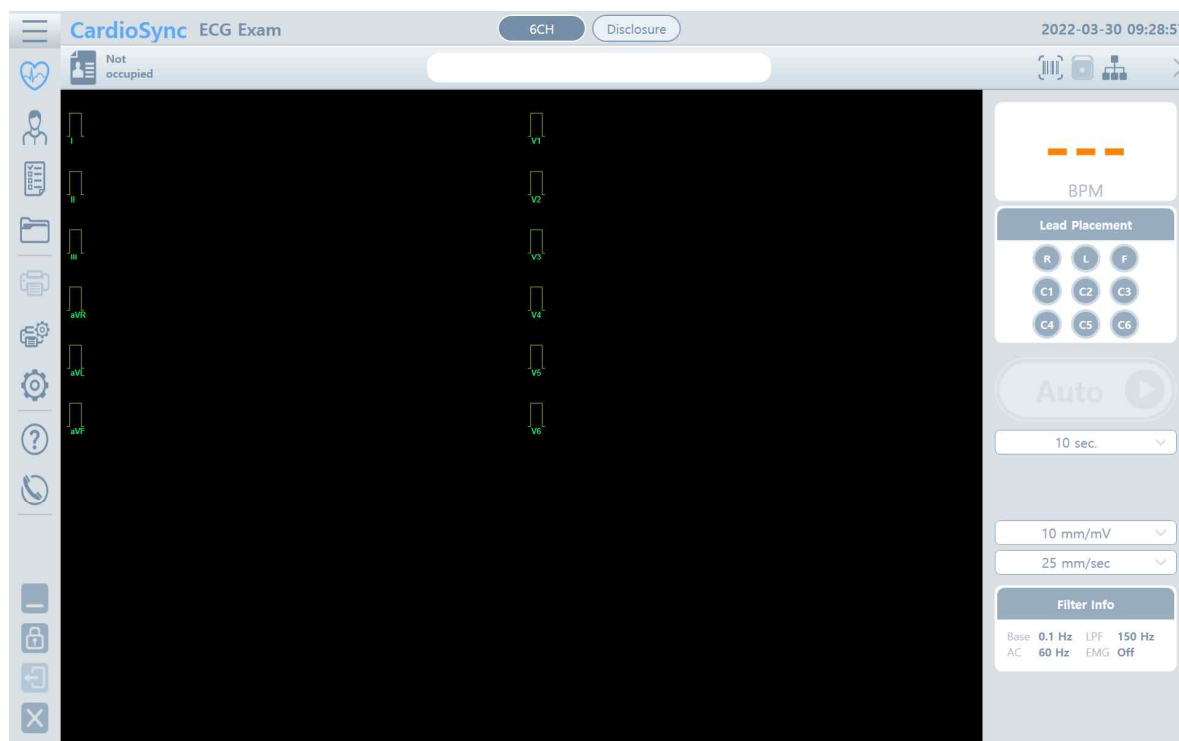
The current ECG signal is drawn on the LCD screen in real-time.

Start the test after confirming that the signal is correctly transmitted from all leads.

The screen output background color of the ECG waveform can be selected from either white or black and can be changed in the Setup → ECG → Display → Background menu.



In the black background, the waveform is drawn without a grid as shown below.



## Patient Information

Fields marked with  are required inputs.

Automatic diagnosis is made based on the ECG recording for 10 seconds and is available for pediatrics and adults. It is carried out according to the age of the patient.

### Patient ID

Enter a unique number used in the hospital to classify patient medical data. Touch the input field of ID to display the keypad window consisting of alphabets and numbers, and use it to enter patient ID.

| Note                                                                                                                                                                                                                                                                                                                              |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"> <li>- You cannot use ., ", &lt;, &gt;, ?, /, *,  , :, ¥ &amp; characters for ID.</li> <li>- Use only plain alphabets and numbers for ID. If you enter an ID in Latin extended characters or Russian, an error may occur when you transfer files with the IDs to a PC or USB memory.</li> </ul> |

### Patient Name

Enter the patient name in the same way as entering the ID.

### Date of Birth

Touch the input field of Date of Birth to calendar-type date input window as shown below appears. Enter the patient's date of birth. Patient's age is automatically calculated and entered.



### Age

Enter the patient's age directly.

Enter the age of pediatrics or adults. Enter the age in weeks or days if you cannot enter the age in years.

#### Note

- Age is automatically calculated when the date of birth is entered.
- If age is not entered, an adult diagnosis is provided.

### Gender

Touch the input field of Gender to select Male or Female.

### Height

Enter the patient height in the same way as entering the age.

If the Height Unit is set to inches in System General Setup, enter the height in ft and inches.

### Weight

Enter the patient weight in the same way as entering the age.

### Race

Enter the race of the patient. There are 3 registered races: Asian, White, and Black.

Touch the input field of Race to select the race type.

**Smoke**

Mark whether the patient is smoking.

**Urgent**

Mark whether the patient needs urgent care.

**Pacemaker**

Set whether to display the pacemaker position on the RHYTHM or on the diagnosis when a pacemaker signal is detected.

When set to On, pacemaker position is specified; Otherwise, it is not.

| Note                                                                                                                                                                                                                                                          |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"><li>- In general, 'pacemaker' items are set to be 'Off.' Only if it is the patient using pacemaker, it is recommended to set it as 'On.'</li><li>- In case of lead fault, pacemaker signal might not be detected.</li></ul> |

**Others**

Enter Department, Room No., Study Description, Accession No., Referring Physician in the same way as entering the ID. Set Urgent to Yes for urgent patients and Pacemaker to Yes for pacemaker patients.

Touch [OK] to save the settings or [Cancel] to cancel the settings. Touch [New] to initialize all the patient information you have entered.

**Using a Barcode Reader**

Place the cursor on each item in the patient information screen and scan the barcode. Information is entered automatically.

When you scan the barcode in the ECG main screen, the patient ID is entered automatically.

Basically, you can use any kind of barcode reader.

However, since the default setting of the entry method of each product may be different, check the method supported by Bionet before using them.

- Entry methods supported by Bionet products: International standard and USB
- The products that have been tested by connecting to Bionet equipment are listed below.

| N0. | Manufacturer | Product name | Product Image                                                                        |
|-----|--------------|--------------|--------------------------------------------------------------------------------------|
| 1   | Symbol       | LS-2208      |   |
| 2   | ZEBEX        | Z-3110       |   |
| 3   | Honeywell    | MS5145       |   |
| 4   | Honeywell    | DS2208       |  |

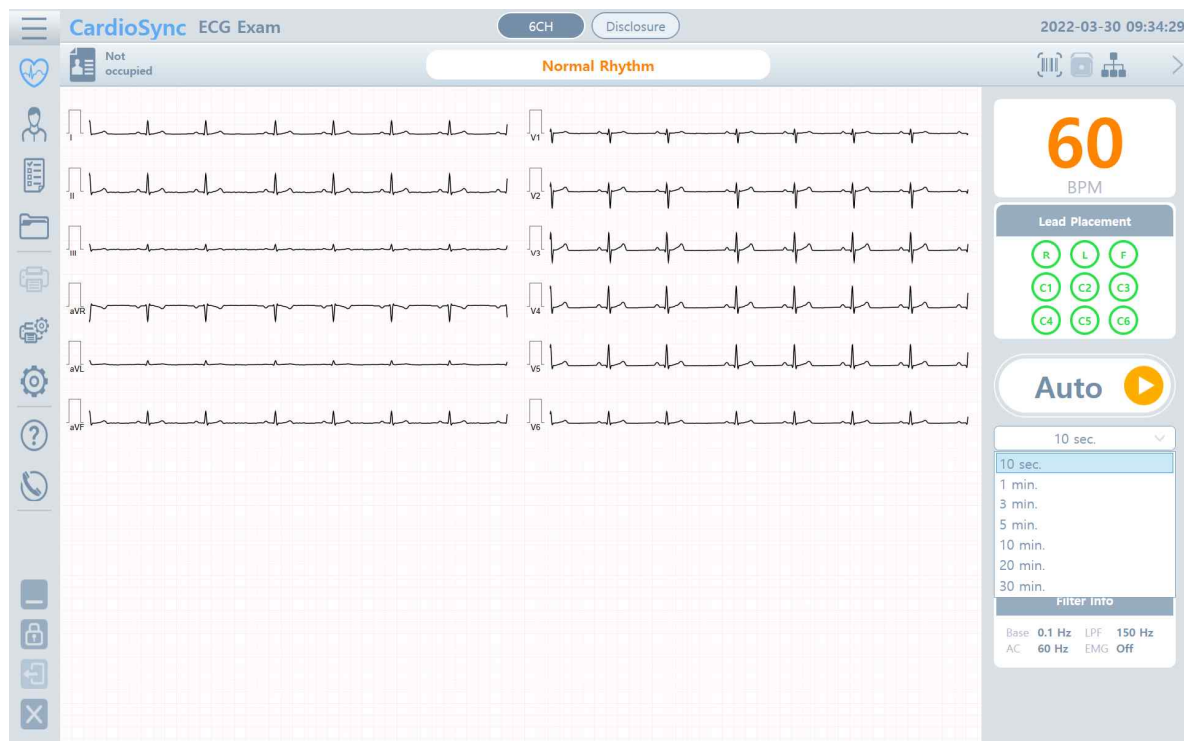
| Note |
|------|
|------|

|                                                                                                                                                                              |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>Each barcode reader has a product-specific initialization code.<br/>Be sure to read the user manual of the product and check the entry method before initializing it.</p> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

## Measurement Time Setting

The measurement time setting is used when you want to perform a 10-second recording measurement or output 1CH for a long time.

It can be set to 1, 3, 5, 10, 20, or 30 minutes, and at this time, it is output with the set lead.



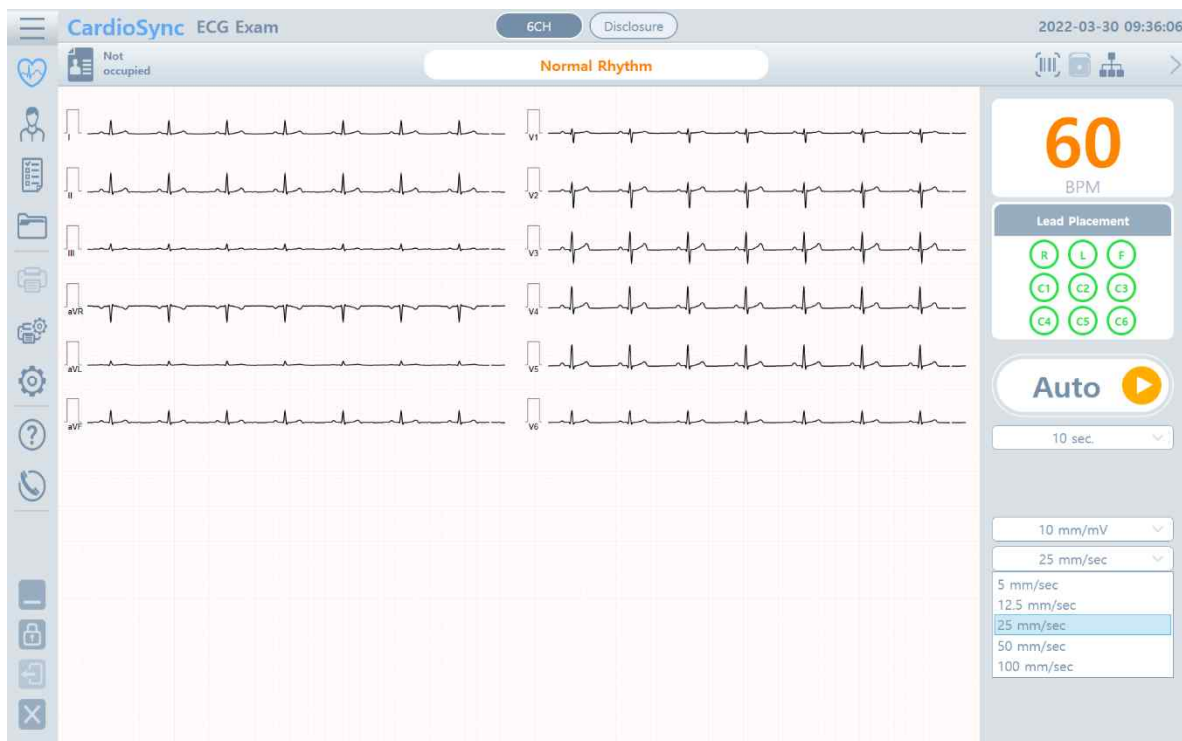
### Note

Real-time diagnosis is issued by referring to the leads of the Long-term ECG.

Set Lead II because it is the largest in general, however, if its waveform is not large enough, choose another lead with the largest and best waveform.

## Output Speed

Adjust the width of the output signal for screen output and printout. The available values are 5mm/sec, 12.5 mm/sec, 25mm/sec, 50mm/sec, and 100mm/sec. 25mm/sec means that the ECG signal for 1 second is recorded with a length of 25mm.



### Note

- When you set the recording mode to 3, 5, 10, 20 and 30min, the signal is always printed at 12.5mm/sec.

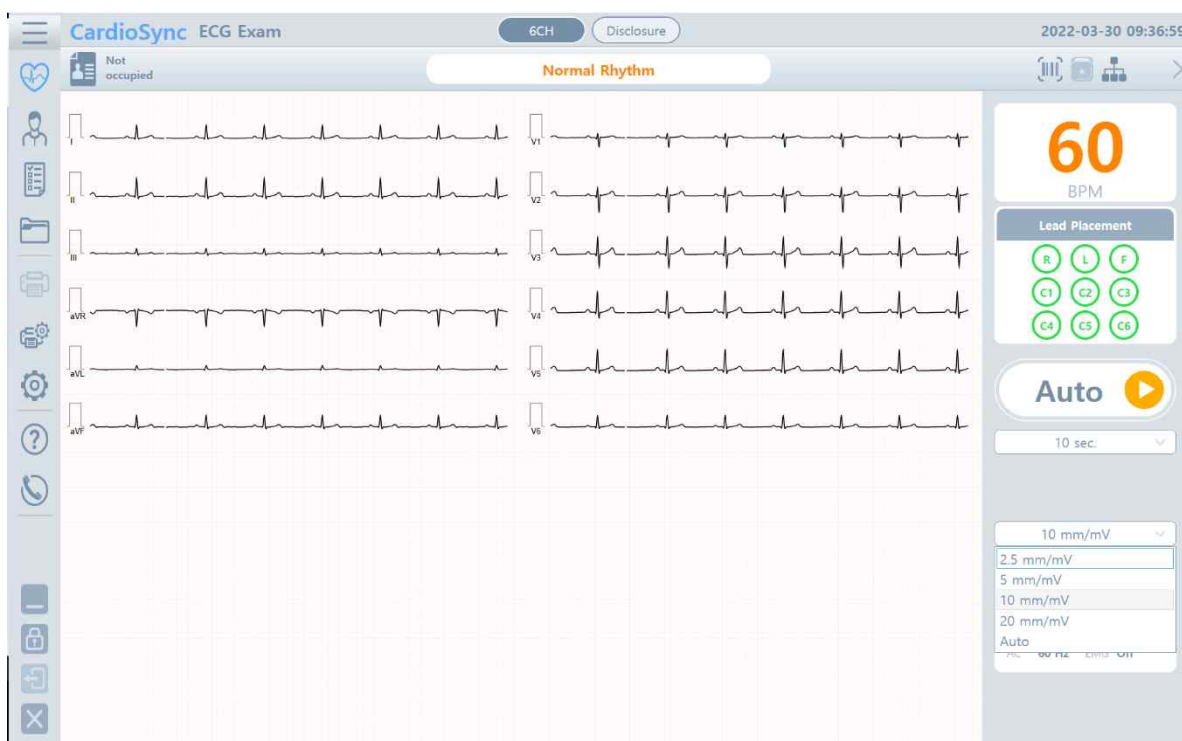
## Setup Signal Scale

If the scale of output signal is too high and is duplicated with signals in neighboring channel, or if the scale of output signal is too low making it difficult to decipher, this function is used to adjust the signal scale.

There are five auto setups function that all the 12 leads are setup to 2.5mm/mV, 5mm/mV, 10mm/mV and 20mm/mV, limb lead (I, II, III, aVR, aVL, aVF) is setup to 10mm/mV and chest lead (V1, V2, V3, V4, V5 and V6) is setup to 5mm/mV.

10mm/mV means to output the signal in 1mV in the size of 10mm.

Since the signal scale is indicted with the names of each channel on the left side of graphic window, it is possible to conveniently confirm the modified information.



### Note

- On the output of recording mode in the setup of 10sec, the preview gain window can modify
- On the output of recording mode in the setup of 1min, the preview gain window cannot be modified, output with preset gain.
- On the output of recording mode in the setup of 3, 5, 10, 20 and 30min, the preview gain window cannot be modified, and the output is fixed at 5.0mm/mV.

## Setup Print

### Printer

Setup the printer to print. If you click the Properties button, you can use the normal Windows printer settings.

### 10s Print Form

Set the diagnosis print format.

**Form**

| Output form | Explanation                                                                                                                                                                                                                                                         |
|-------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 3CH+3       | 10-second resting ECG recording: I, II, and III in the first 2.5 seconds; aVR, aVL, and aVF in the next 2.5 second; V1, V2, and V3 in the next 2.5 seconds; and V4, V5, and V6 in the next 2.5 seconds. The 3-lead rhythm is recorded at the bottom for 10 seconds. |
| 3CH+1       | 10-second resting ECG recording: I, II, and III in the first 2.5 seconds; aVR, aVL, and aVF in the next 2.5 second; V1, V2, and V3 in the next 2.5 seconds; and V4, V5, and V6 in the next 2.5 seconds. The 1 lead-rhythm is recorded at the bottom for 10 seconds. |
| 6CH+1       | 10-second resting ECG recording: I, II, III, aVR, aVL, and aVF in the first 5 seconds; V1, V2, V3, V4, V5, and V6 in the next 5 seconds. The 1 lead-rhythm is recorded at the bottom for 10 seconds.                                                                |
| 12CH        | The 12-lead rhythm is recorded simultaneously for 10 seconds in the order of I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, and V6.                                                                                                                                 |
| 6CH+1(ST)   | 8-second ECG recording: I, II, III, aVR, aVL, and aVF in the first 4 seconds; V1, V2, V3, V4, V5, and V6 in the next 4 seconds with ST Map displayed on the right. The 1 lead-rhythm is recorded at the bottom for 10 seconds.                                      |

**Rhythm Channel (Rhythm CH1, Rhythm CH2, Rhythm CH3)**

Set the rhythm-representative lead used in the 3CH+3, 3CH+1, 6CH+1 form for diagnosis printout. The 3CH+3 setting uses all 3 selected values, and only the first value is used for the 3CH+1 and 6CH+1 settings.

By default, it is set to II, V1, and V5. As for 3CH+1, 6CH+1, II is used. All II, V1, and V5 are all used for 3CH+3.

**Beat Form**

Select between Text, Guide, and Vector as additional print form after a diagnosis is printed. Printing speed is fixed at 50mm/sec regardless of the Output Speed setting.

| Output form | Explanation                                                                                                      |
|-------------|------------------------------------------------------------------------------------------------------------------|
| Text        | A representative beat and each diagnostic parameters are printed.                                                |
| Guide       | The representative beat and each diagnostic parameter are printed, along with a diagnostic guide for arrhythmia. |
| Vector      | The representative beat and each diagnostic parameters are printed, marking QRS Vector with an arrow.            |

|        |                                                                                         |
|--------|-----------------------------------------------------------------------------------------|
| ST Map | It outputs the representative bit and each diagnostic parameter and outputs the ST map. |
|--------|-----------------------------------------------------------------------------------------|

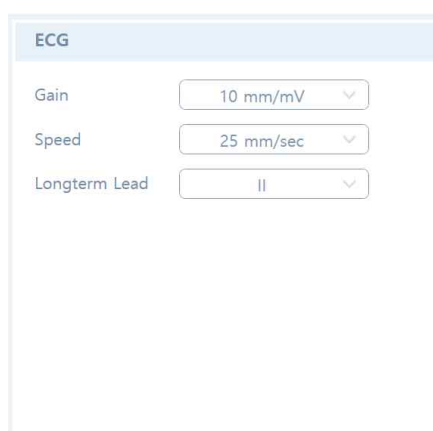
### ST Map Type

When selecting the bit form as ST Map, you can select the style of drawing the ST Map.

| Output form | Explanation                                                                                            |
|-------------|--------------------------------------------------------------------------------------------------------|
| ST Map (B)  | The representative beat and each diagnostic parameters are printed, drawing ST map in the form of Bar. |
| ST Map (D)  | The representative beat and each diagnostic parameters are printed, drawing ST map in the form of Dot. |

### ECG

Setup recording output form.



The screenshot shows a software interface for ECG setup. It has a title bar 'ECG' and three settings: 'Gain' set to '10 mm/mV', 'Speed' set to '25 mm/sec', and 'Longterm Lead' set to 'II'. Each setting is in a dropdown menu.

### Signal Scale Setup (Gain)

Please refer to 'signal scale setup' explained earlier in this manual.

### Output Speed Setup (Speed)

Please refer to 'output speed setup' explained earlier in the manual.

### Long Term Lead Setup

Long Term ECG recording is used when preferring to output 1CH for a long time.

It is available to setup and output 1, 3, 5, or 10 minutes. At this time, setup the lead to output.

**Note**

Real-time diagnosis is based on the lead of the Long Term ECG.  
Normally, the lead II is the largest, so you can set the lead II, but if the waveform is small, select the other lead with the largest and best waveform.

**Print Page**

Settings related to the printout

**Print Page**

Page(s)

Size

**Page(s)**

Set the number of prints. Up to 50 sheets

**Size**

Set the size of the prints

**Print Option**

Select the option to use when printing.

**Print Options**

☒ Rhythm Parameters

☐ Interpretation

☐ Comments

☐ HRV Paramteres

☐ Diagnosis CapsLock

**Rhythm parameters**

Select whether to output rhythm parameters when outputting records.

**Interpretation**

Select whether or not to output diagnostics when outputting records.

**Comments**

Select whether to output the observations added to the record results.

**HRV parameters**

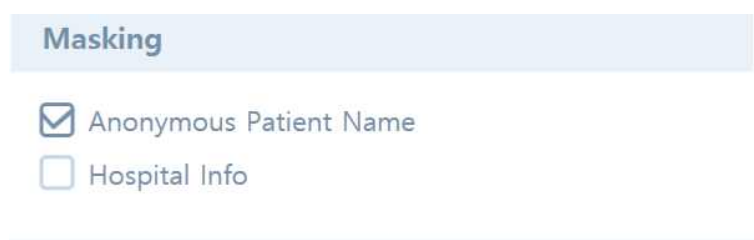
Select whether to output HRV parameters when outputting records.

**Diagnosis Caps Lock**

When outputting a record, the diagnosis name is output in uppercase.

**Masking**

Set to de-identify patient information when printing.

A screenshot of a 'Masking' settings dialog box. The title bar is light blue and contains the word 'Masking' in bold. Below the title bar, there are two options, each with a checkbox. The first option is 'Anonymous Patient Name' with a checked checkbox. The second option is 'Hospital Info' with an unchecked checkbox.

| Masking                             |                        |
|-------------------------------------|------------------------|
| <input checked="" type="checkbox"/> | Anonymous Patient Name |
| <input type="checkbox"/>            | Hospital Info          |

**Anonymous Patient Name**

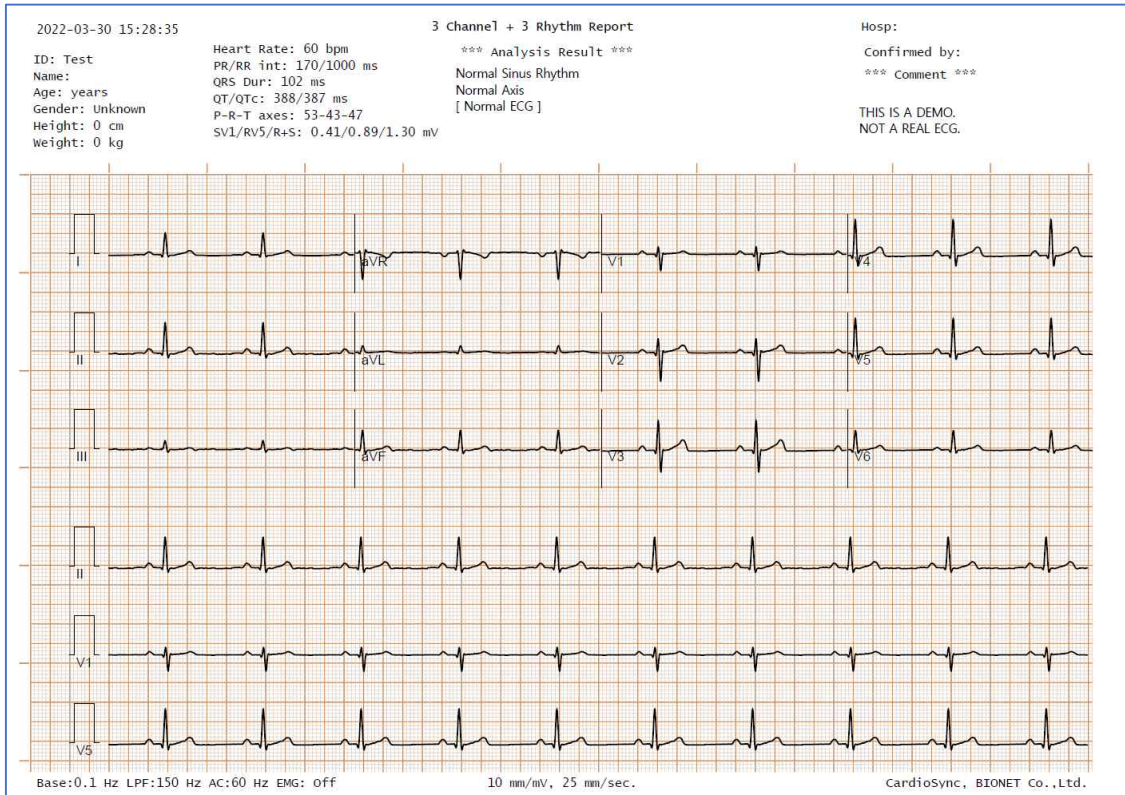
The patient's name is de-identified and hidden and printed.

**Hospital Info**

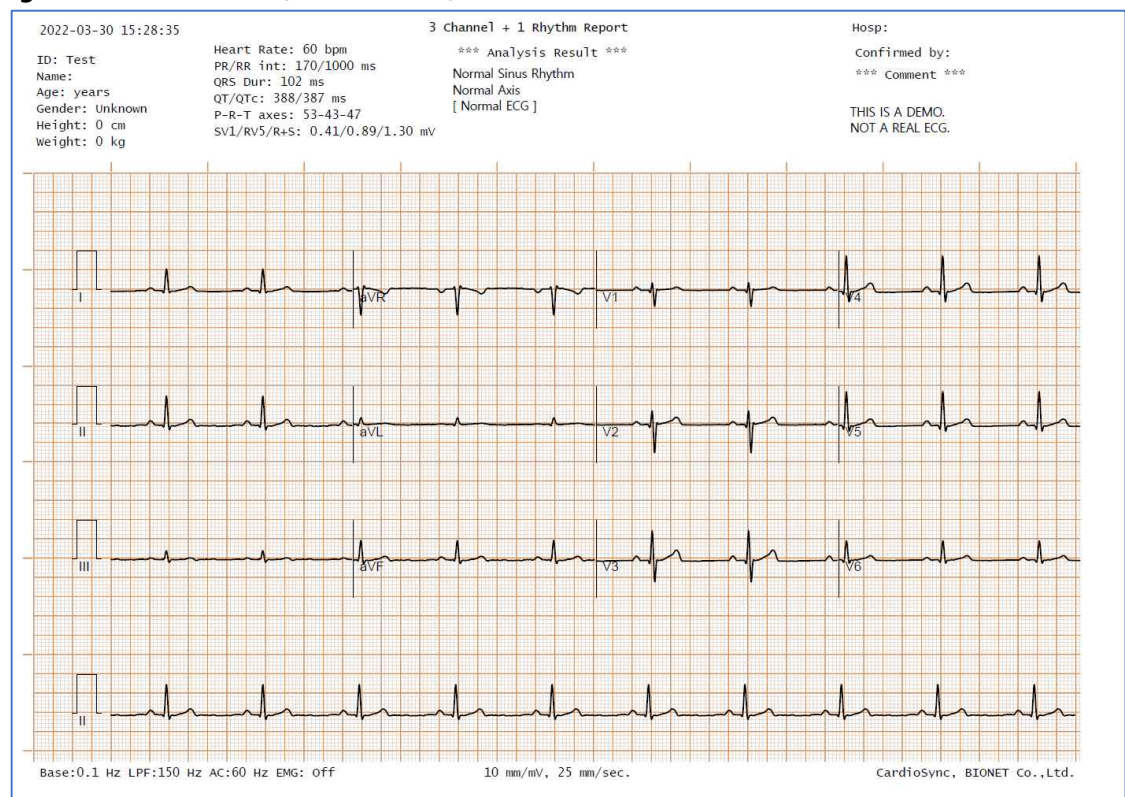
Hospital information is de-identified, hidden and printed.

The followings are examples of print formats:

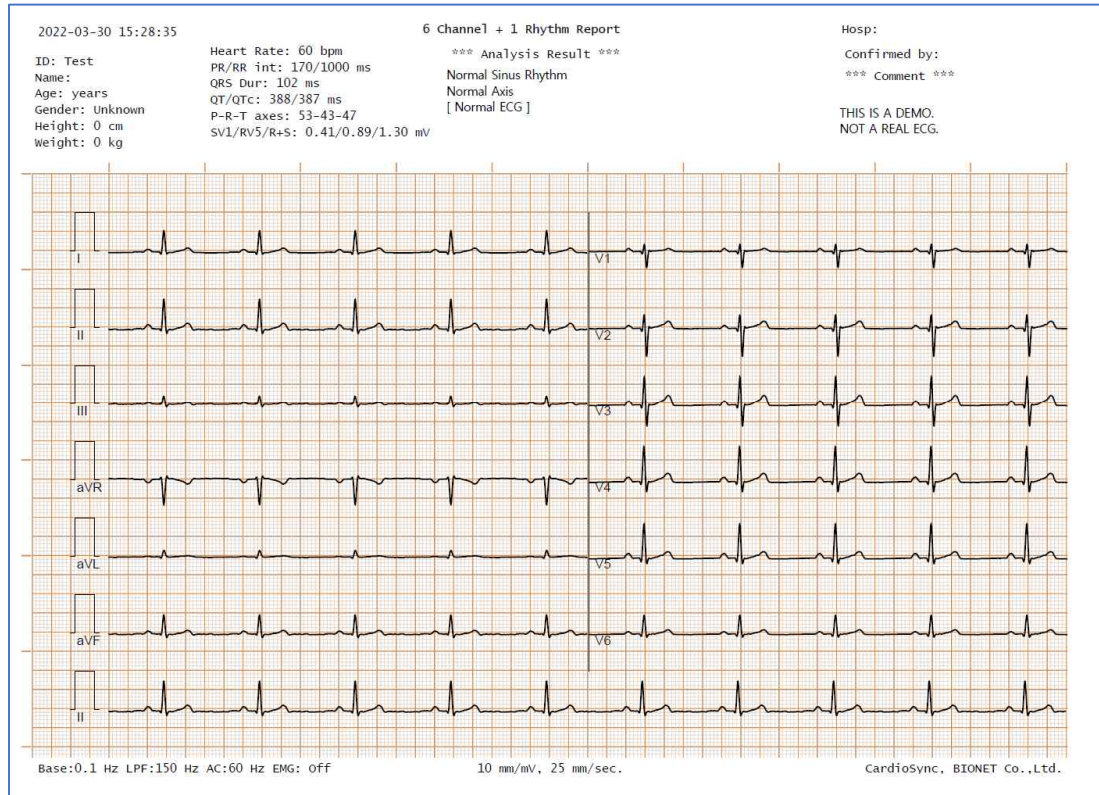
## Diagnosis Print Format (3CH + 3RHY)



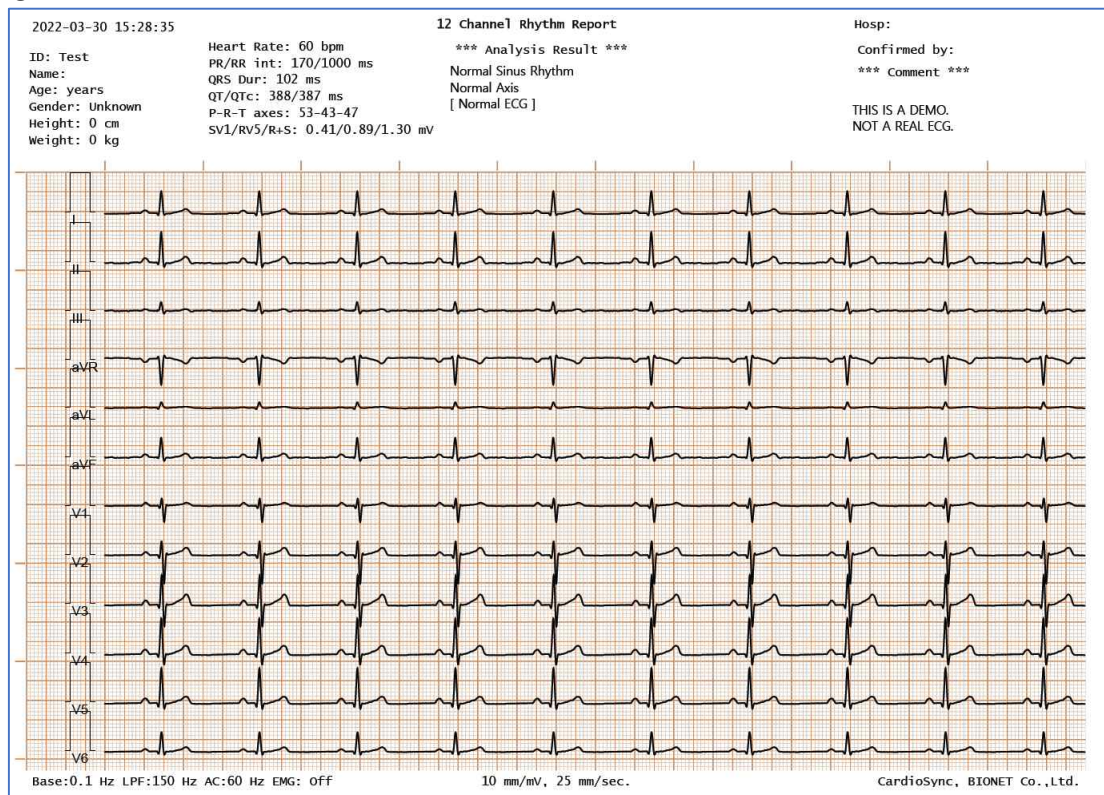
## Diagnosis Print Format (3CH + 1RHY)



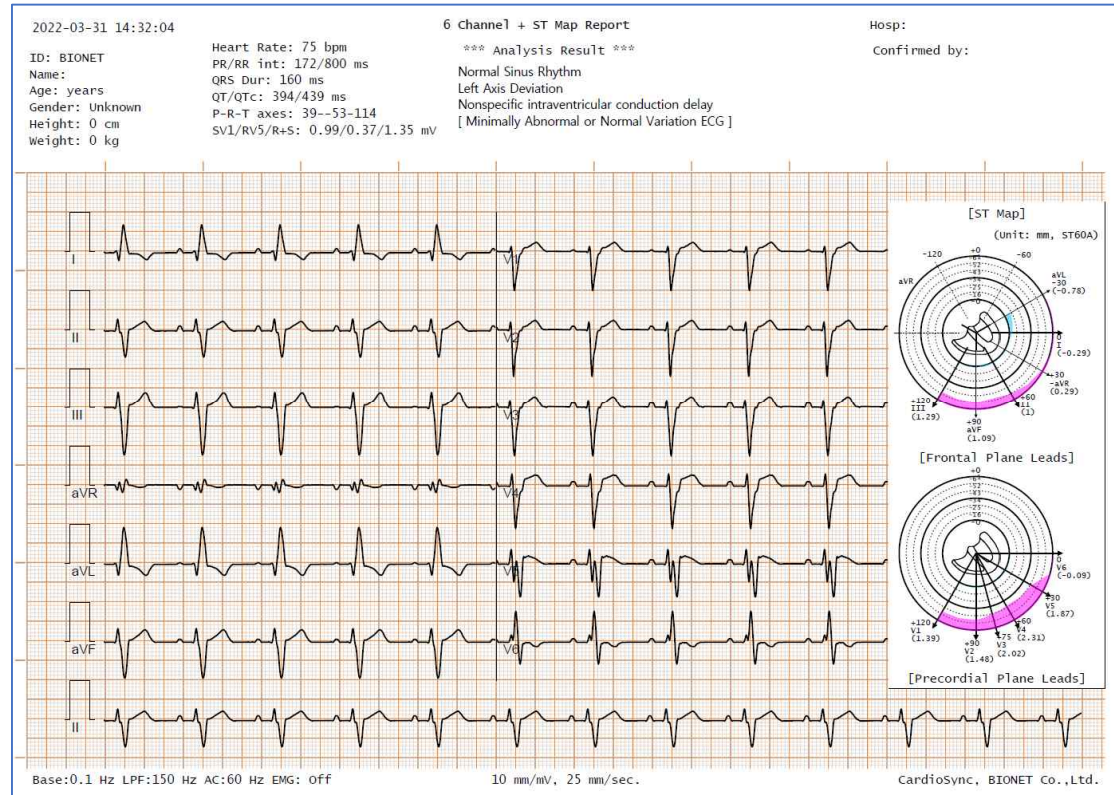
## Diagnosis Print Format (6CH + 1RHY)



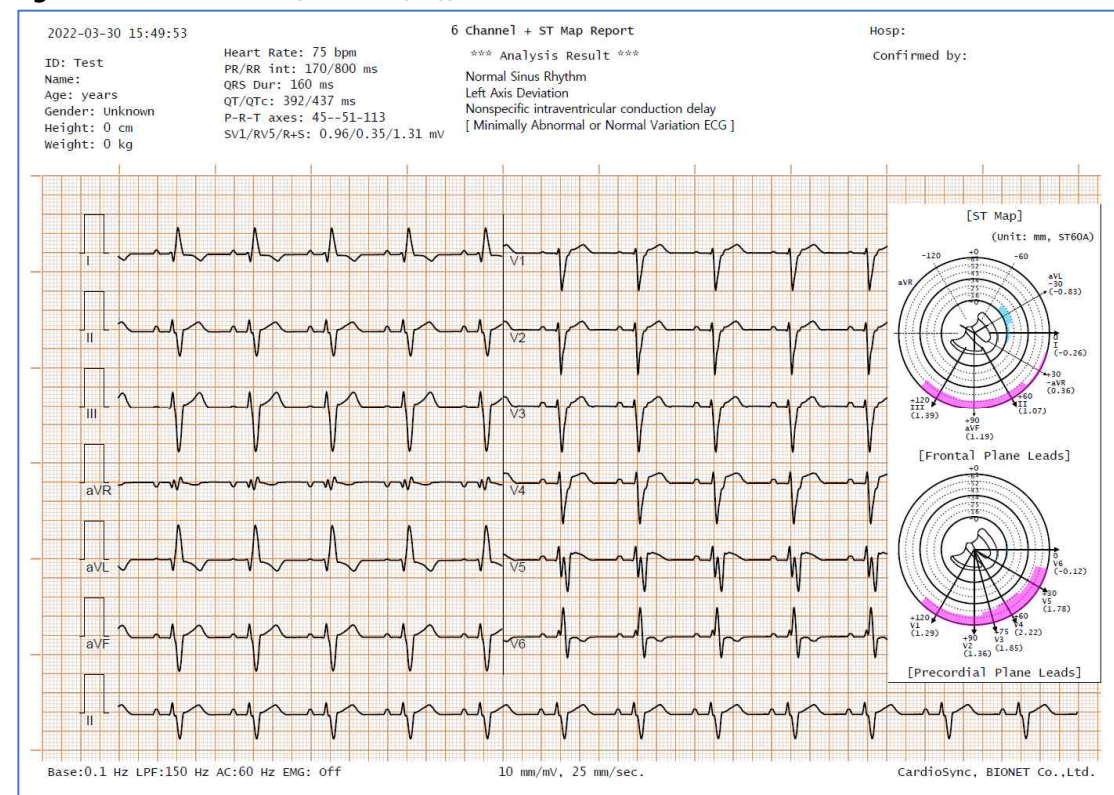
## Diagnosis Print Format (12CH)



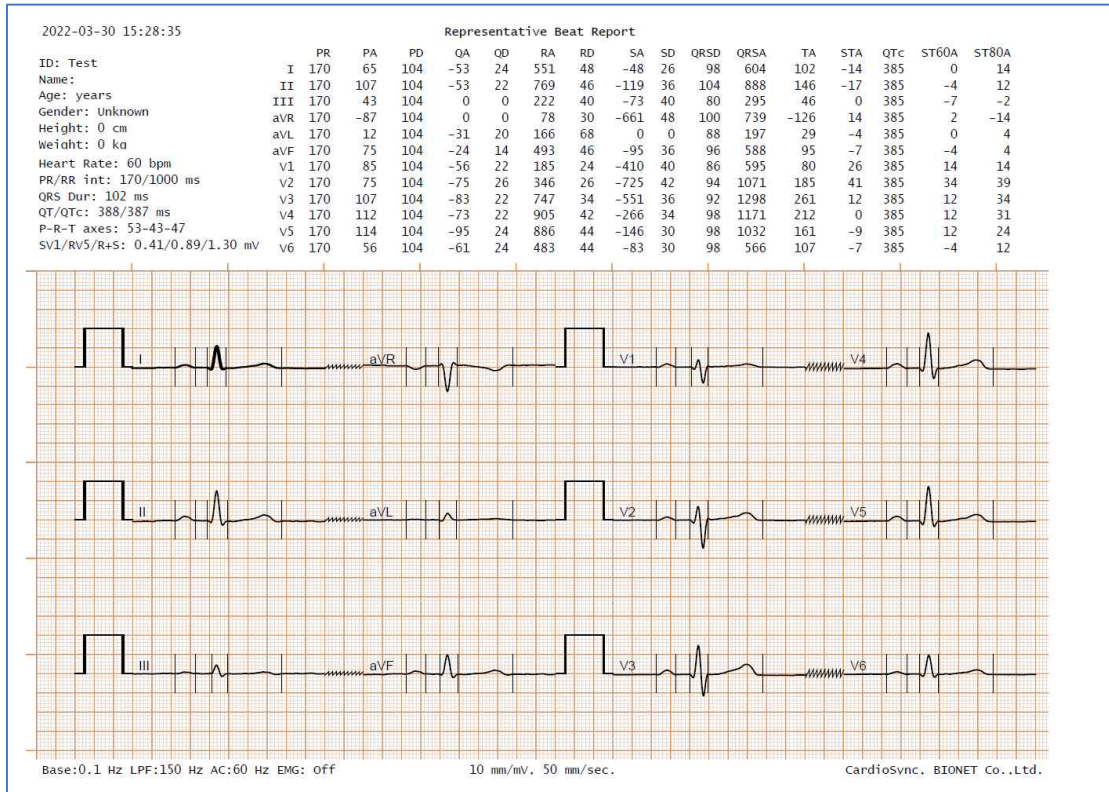
## Diagnosis Output Form (6CH+1(ST)-Dot)



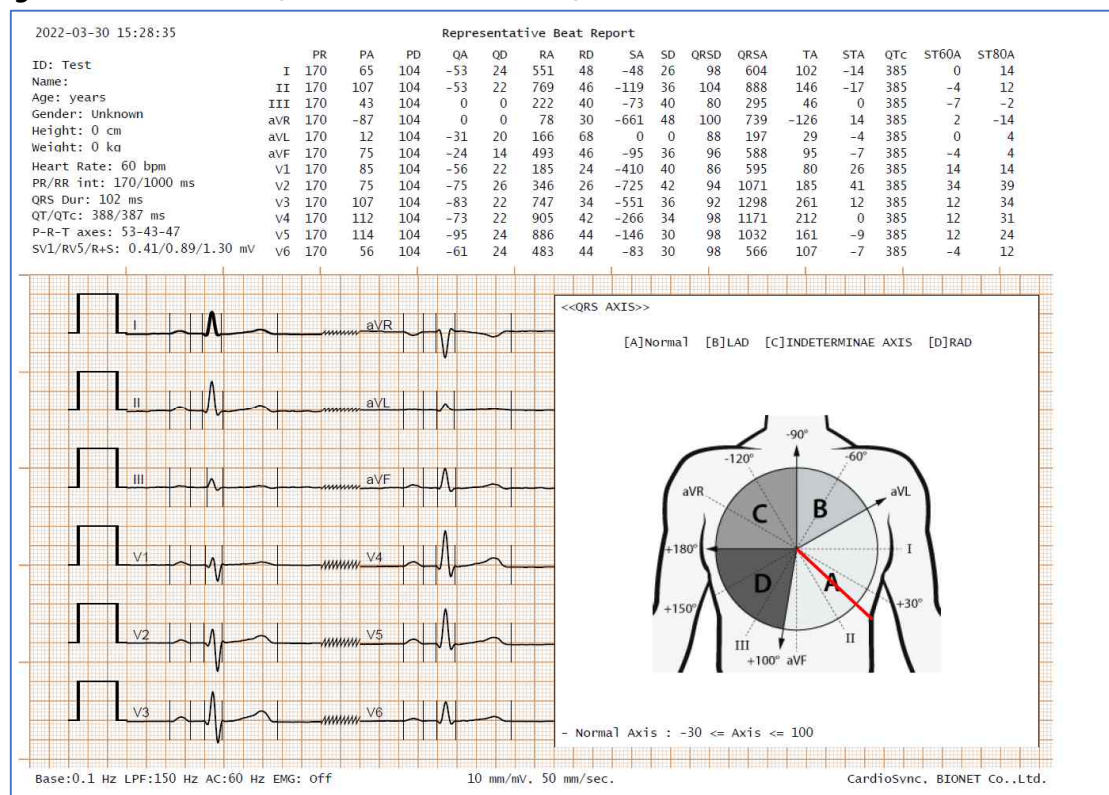
## Diagnosis Print Format (6CH+1 (ST))



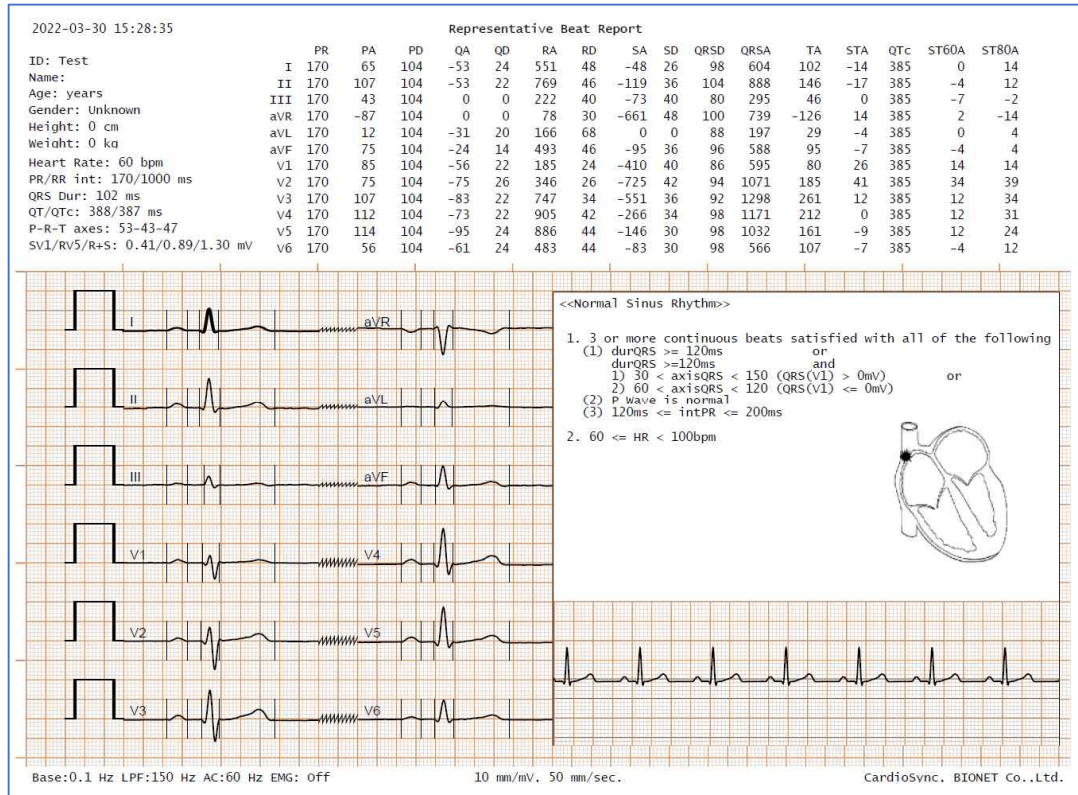
## Diagnosis Print Format (BEAT REPORT-TEXT)



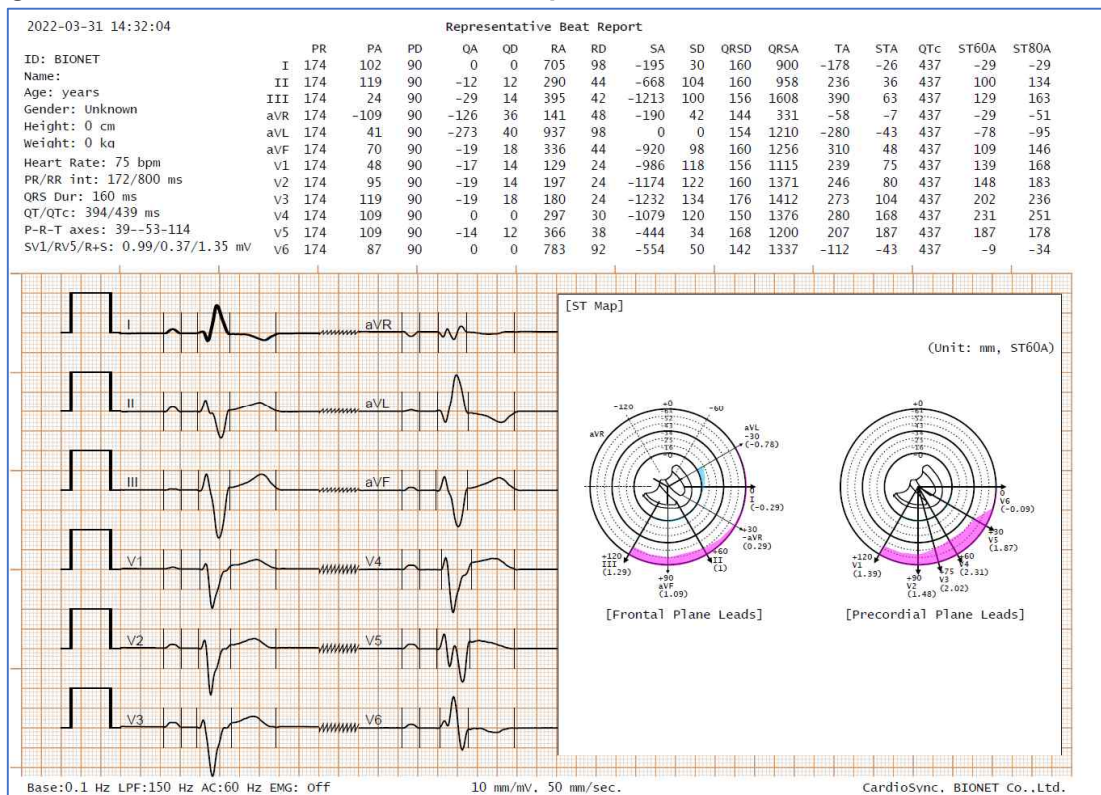
## Diagnosis Print Format (BEAT REPORT-VECTOR)



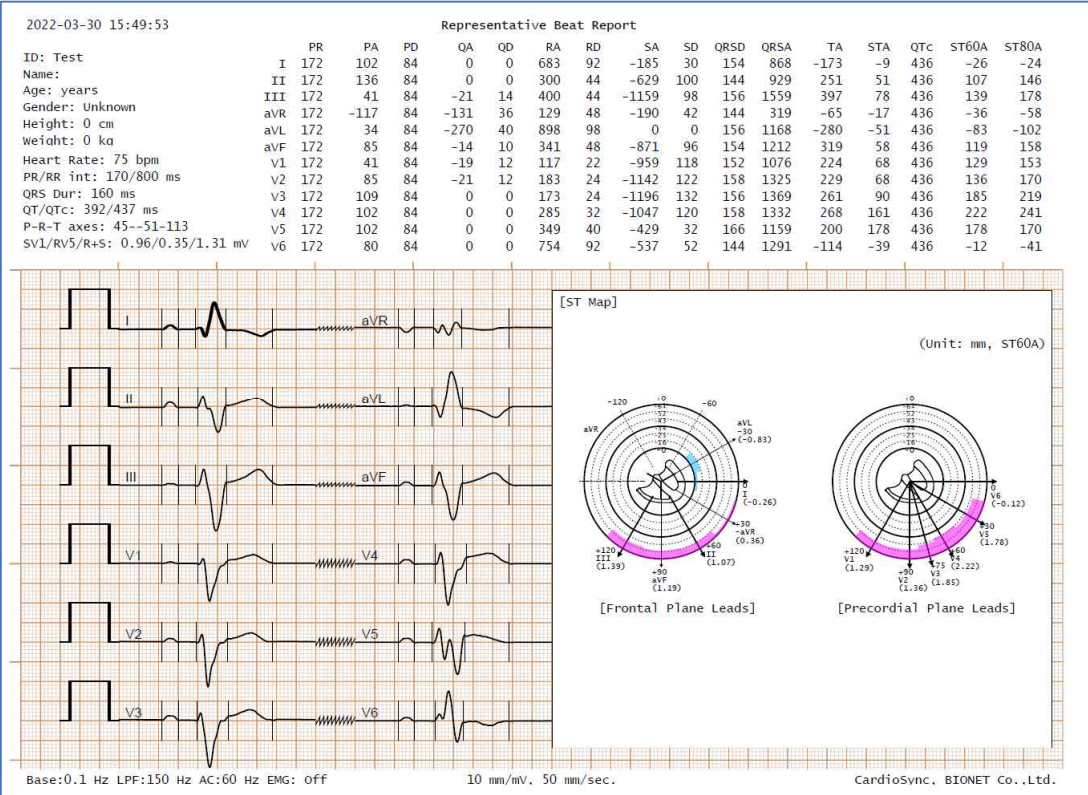
## Diagnosis Print Format (BEAT REPORT-GUIDE)



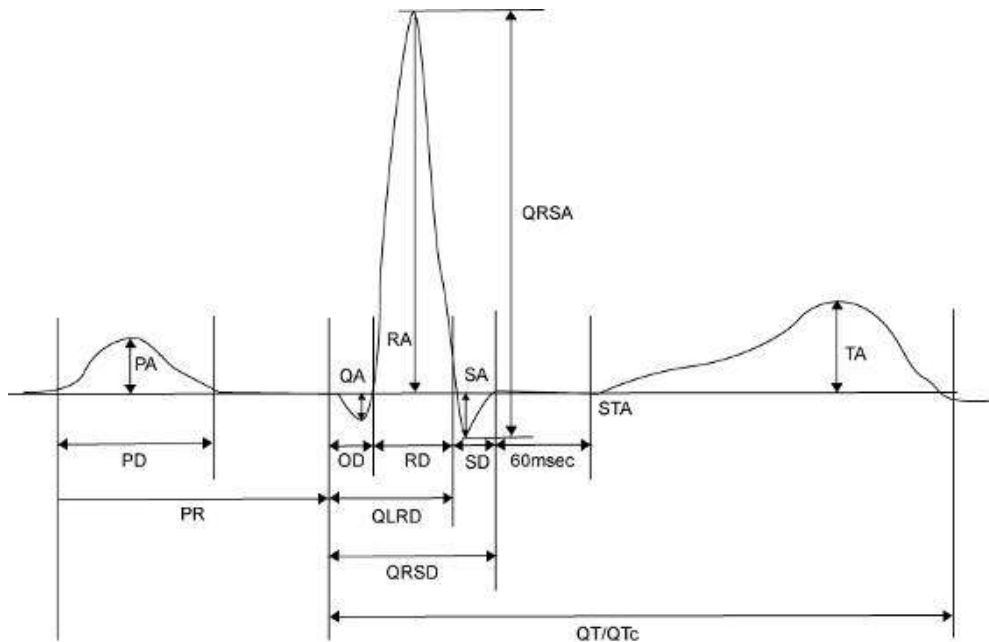
## Diagnosis Print Format (BEAT REPORT-ST Map (D))



Diagnosis Print Format (BEAT REPORT-ST Map (B))



### \* Explanation of BEAT REPORT Variables



- PR: PR Interval
- PA: Amplitude of P Wave (P Amplitude)
- PD: Duration of P Wave (P Duration)
- QA: Amplitude of Q Wave (Q Amplitude)
- QD: Duration of Q Wave (Q Duration)
- RA: Amplitude of R Wave (R Amplitude)
- RD: Duration of R Wave (R Duration)
- SA: Amplitude of S Wave (S Amplitude)
- SD: Duration of S Wave (S Duration)
- QRSD: Duration of QRS Wave (QRS Duration)
- QRSA: Amplitude of QRS Wave (QRS Amplitude)
- TA: Amplitude of T Wave (T Amplitude)
- STA: Amplitude of ST Wave (ST Amplitude)
- QTc: Correct Q-T Interval (collect Q-T Interval)
- ST60A: Amplitude of ST+60ms (ST60ms Amplitude)
- ST80A: Amplitude of ST+80ms (ST80ms Amplitude)

#### Note

The unit of parameter intervals (duration, interval) used in the Beat Report is *ms*, and the unit of height (amplitude) is *μV*.

**Note****Dextrocardia**

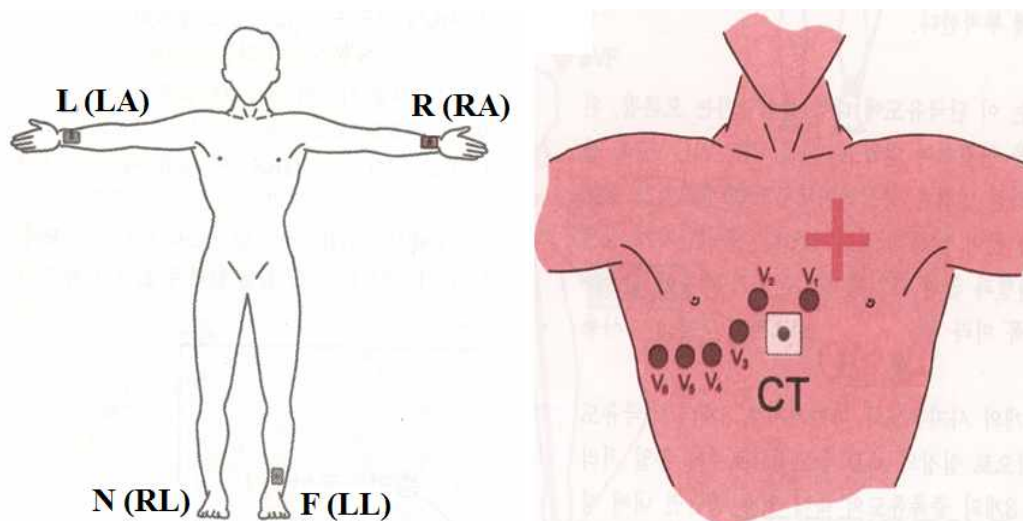
Normally, the heart is located in the left chest. However, there are cases where the heart is located in the right chest, which is called Dextrocardia.

You may suspect Dextrocardia in the following cases:

- If P, QRS and T are all reversed in Lead I
- If aVR and aVL are switched, and lead II and III are switched
- If R wave becomes smaller from V1 to V6 in chest lead

For Dextrocardia patients, change the electrode positions and measure as follows to obtain auto diagnostic results correctly.

- Switch the electrodes on right hand (R) and left hand (L).
- Attach the chest lead from the left in order, which used to be attached from the right.



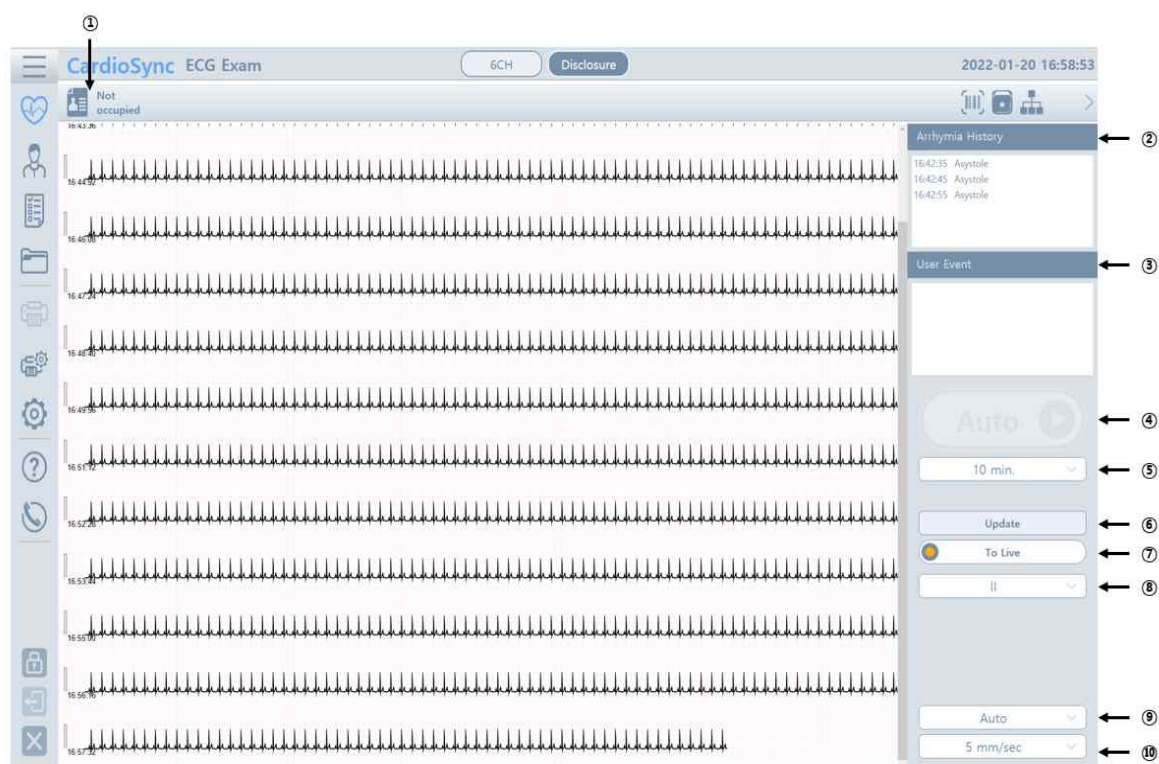
## 5) Disclosure

Touch the  Disclosure button on the menu bar at the bottom of the ECG main screen to switch to Disclosure screen. Disclosure is a function that stores ECG data in the equipment memory and shows it when executed.

In the Disclosure screen: The pre-stored 30 minutes of ECG data are displayed in 1CH. The interval section of the pre-set mode (10 seconds, 1 minute, 3 minutes, 5 minutes, 10 minutes, 20 minutes, or 30 minutes) is marked with a square, allowing you to print diagnosis for the selected area or transmit data of the area.

Touch the graph window and select the screen output section: your touch point becomes the center of the square-marked area. Select the screen output section and press the [AUTO] key on the control panel to print diagnosis or save and transmit the data.

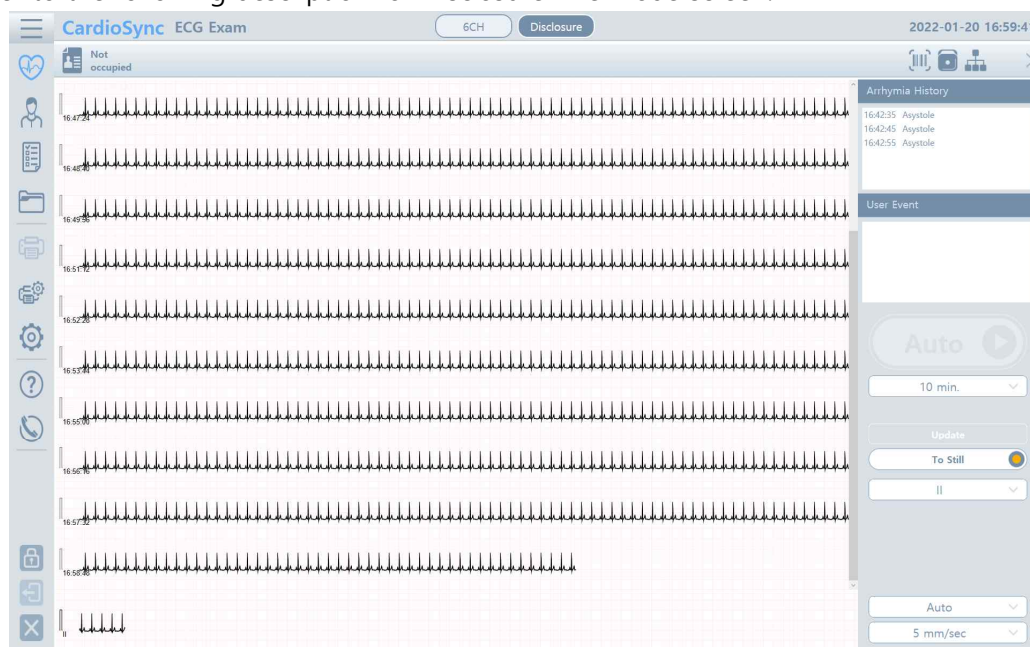
Refer to the following description for Disclosure screen.



- ① Patient ID and name: Touch this button to enter patient information.
- ② Number of events (Arrhythmia): Touch this button to set Event List (Arrhythmia History).
- ③ Event list display.
- ④ Selected area diagnosis execution button.
- ⑤ ECG recording mode display (10s, 1m, 3m, 5m, 10m, 20m, 30m) and setting menu button.

- ⑥ Touch the button to update EKG Wave data from the start of Disclosure to the present time.
- ⑦ Switch to Live mode button
- ⑧ Select output lead
- ⑨ Select the output size
- ⑩ Output speed selection

Refer to the following description for Disclosure Live mode screen.



ECG Wave data is drawn in real time in the grid-marked area at the bottom of the screen.

The abbreviation of the diagnosis name displayed on the screen is as follows:

| No. | Abbreviations | Diagnostic              |
|-----|---------------|-------------------------|
| 1   | Bigeminy      | PVC Bigeminy            |
| 2   | Trigeminy     | PVC Trigeminy           |
| 3   | Couplet       | PVC Couplet             |
| 4   | ShortRun      | Short run of PVC        |
| 5   | Vtachy        | Ventricular Tachycardia |
| 6   | Vrhythm       | Ventricular Rhythm      |
| 7   | Vbrady        | Ventricular Bradycardia |
| 8   | Paced         | Pacemaker Rhythm        |
| 9   | PVC           | PVC                     |
| 10  | Asystole      | Asystole                |
| 11  | Pause         | Pause                   |

|    |           |           |
|----|-----------|-----------|
| 12 | Irregular | Irregular |
| 13 | RonT      | R on T    |

### Arrhythmia Template

| No. | Diagnostic              | Description                                                                                                                                                                                             |
|-----|-------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1   | PVC Bigeminy            | Occurs when two or more bigeminal cycles (a ventricular beat followed by a non-ventricular beat) are detected.                                                                                          |
| 2   | PVC Trigeminy           | Occurs when two or more trigeminal cycles (a ventricular beat followed by two non-Ventricular beats) are detected.                                                                                      |
| 3   | PVC Couplet             | Occurs when two ventricular beats are detected and have non-ventricular beats before and after the couplet. The coupling interval must be less than 600 milliseconds.                                   |
| 4   | Short run of PVC        | Occurs 3~5 continuous Ventricular Premature Beats.                                                                                                                                                      |
| 5   | Ventricular Tachycardia | Occurs when six or more ventricular beats are detected when the average heart rate is greater than or equal to 100 beats per minute.                                                                    |
| 6   | Ventricular Rhythm      | Occurs when six or more ventricular beats are detected with an average heart rate for the ventricular beat between 50 and 100 beats per minute.                                                         |
| 7   | Ventricular Bradycardia | Occurs when a run of three or more ventricular beats is detected with an average heart rate that is less than or equal to 50 beats per minute.                                                          |
| 8   | Pacemaker Rhythm        | A pacemaker is indicated when electrical impulse conduction or formation is dangerously disturbed. It shows pacemaker spikes: vertical signals that represent the electrical activity of the pacemaker. |
| 9   | PVC                     | Isolated premature ventricular complexes occur when a premature ventricular beat is. Detected and has non-ventricular beats before and after.                                                           |
| 10  | Asystole                | Ventricular asystole occurs whenever the displayed heart rate drops to zero.                                                                                                                            |
| 11  | Pause                   | Occurs when the interval between two consecutive beats exceeds three seconds.                                                                                                                           |
| 12  | Irregular               | Occurs when six consecutive normal R-to-R intervals vary by 100 milliseconds or more.                                                                                                                   |
| 13  | R on T                  | Occurs when a ventricular complex is detected within the repolarization period of a Non-ventricular beat.                                                                                               |

**Note**

The diagnosis provided by Cardio P1 must be confirmed by a qualified medical professional.

## 6) One-key Diagnosis (AUTO key)

Press the [AUTO] key shortly to diagnose the ECG acquired during the set duration, and to save, transmit, and print the result. It functions according to the [AUTO] key settings set in System General Setup.



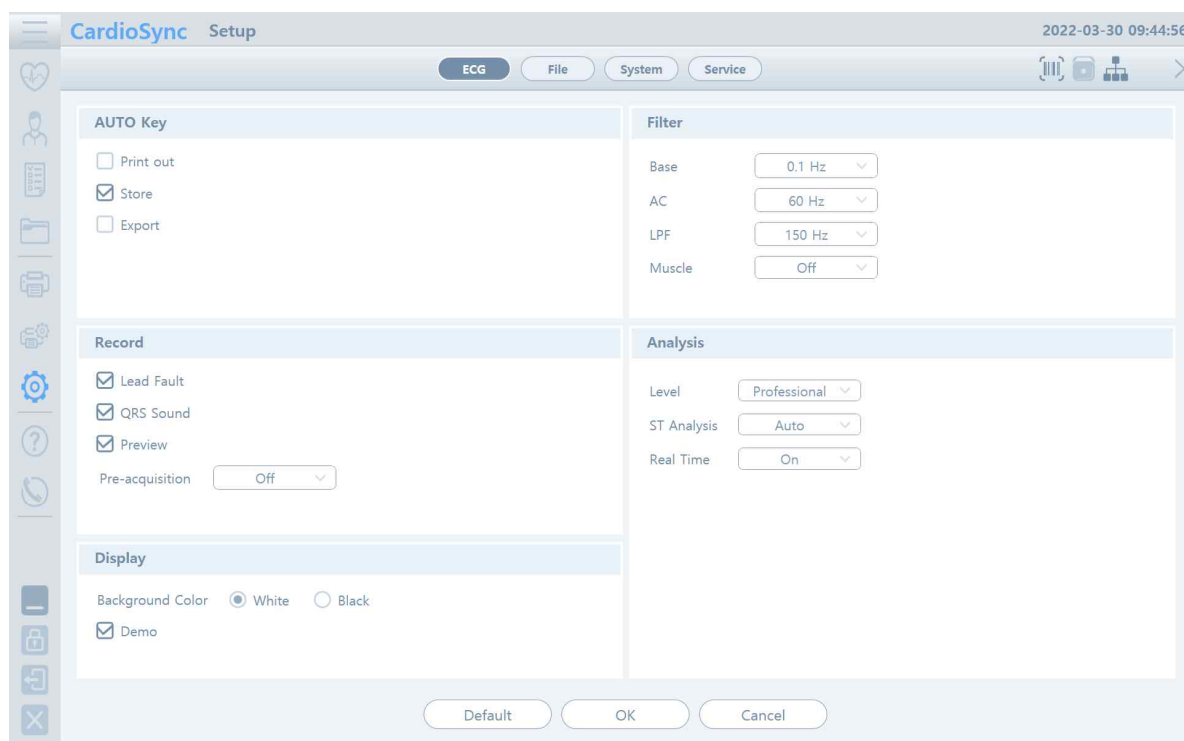
Press and hold the  key longer than 3 seconds to diagnose the ECG acquired during the set duration and to print the result.

## 7) System Setup

The Setup menu is used to set various contents related to the equipment.

You can set it by clicking the Settings button on the left side of the screen.

### ECG Setup



The screenshot shows the CardioSync Setup menu with the following sections:

- AUTO Key**
  - ☐ Print out
  - ☒ Store
  - ☐ Export
- Record**
  - ☒ Lead Fault
  - ☒ QRS Sound
  - ☒ Preview
  - Pre-acquisition:
- Display**
  - Background Color: ☒ White ☐ Black
  - ☒ Demo
- Filter**
  - Base:
  - AC:
  - LPF:
  - Muscle:
- Analysis**
  - Level:
  - ST Analysis:
  - Real Time:

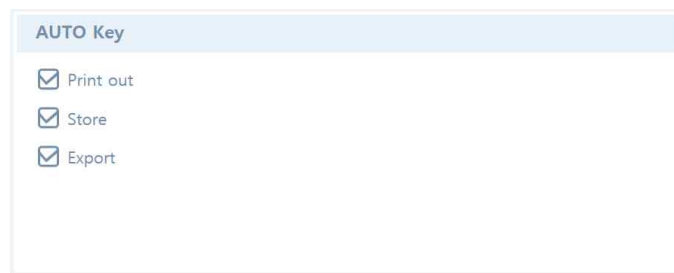
At the bottom, there are buttons for Default, OK, and Cancel.

If you select the 'Settings' button on the left menu bar of ECG, you can change the setting conditions. You can setup ECG related setups in each group.

'Default' button is shown on the setup currently shown on the screen.

If saving changed information after all the setups, select 'Ok' button. If cancelling, select 'Cancel' button.

## AUTO Key



Setup auto key of control panel.

Available to setup the saving, printing, and transmitting as follows.

### Store

Setup whether to save measured data.

If set to be 'ON,' results are automatically saved in the internal memory after the measurement. If set to be 'OFF,' data are not saved.

Saved data are available on the 'file' main screen.

### Print out

Setup whether to print measured data.

Print measured data if set to be 'ON.' If set to be 'OFF,' data are not printed.

### Export

Set whether to send measurement data to an external device.

-For setting of output location, refer to 'Chapter 4 Manage Data Files- 3) Setup - File Export'

## Record

Make settings related to ECG measurement.

You can set the lead fault, heartbeat alert, and preview as follows.

### Setting Lead Fead Lead Fault

A lead fault may occur if the lead connection of the patient cable is unstable. Set whether or not to display the Lead Fault message in this case.

Set it to On to show a Lead Fault message or Off not to.

Lead Fault message is displayed at the top center of the ECG Main screen as follows.



#### Note

- If RA Lead is faulted, no waveform is displayed.
- If LA Lead is faulted, waveforms of I and V1 ~ V6 Leads are not displayed.
- If RL Lead is faulted, Lead Fault does not appear and waveforms of all Leads can be displayed.
- If LL Lead is faulted, waveforms of II and V1 ~ V6 Leads are not displayed.
- If a lead fault occurs during monitoring or recording, a message is displayed with a beep.
- When a lead fault occurs, the pacemaker signal may not be detected. As it may affect the diagnosis, measure ECG again if a lead fault occurs.

## QRS Sound

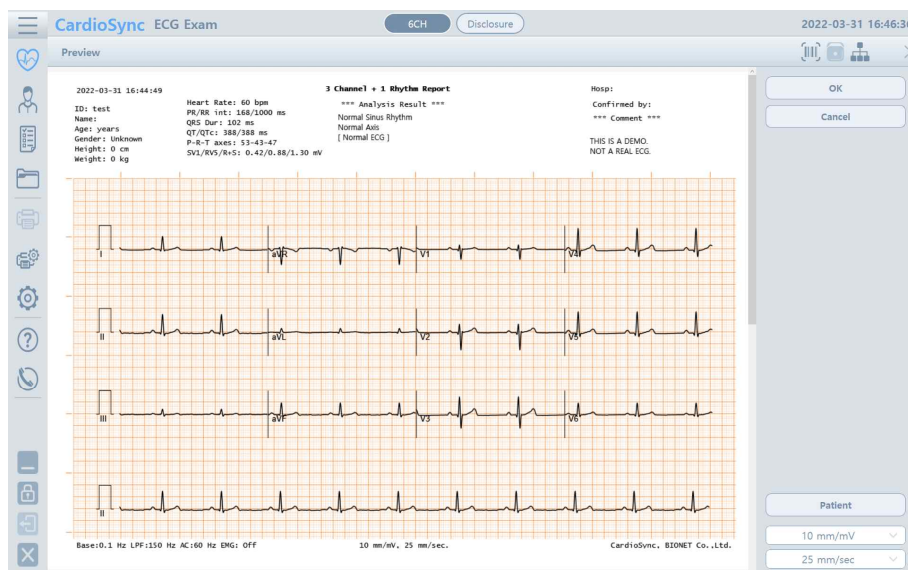
You can set the sound output according to the QRS beat.

When it is set to On, a sound is generated from the QRS beat, and when it is Off, no sound is produced.

## Preview

Preview shows the results of measurement in advance after performing the diagnosis with record, auto and network keys. If setting up the preview function, it is required to select 'On,' or 'Off' for vice versa.

If selecting 'Ok' on the preview screen, function of each key including the printing, saving, or transmitting is performed. If selecting 'cancel,' it is cancelled.



## Pre-acquisition

Set whether to acquire ECG information in advance, up to 10 seconds

## Display

Display

Background Color
☒ White
☐ Black

☒ Demo

Make settings related to the screen display.

You can set the background color and demo display as follows.

### background color

You can set the background for drawing the graph.

In the case of Grid, a red grid and black signal are displayed on a white background, and in the case of Black, a green signal is displayed on a black background.

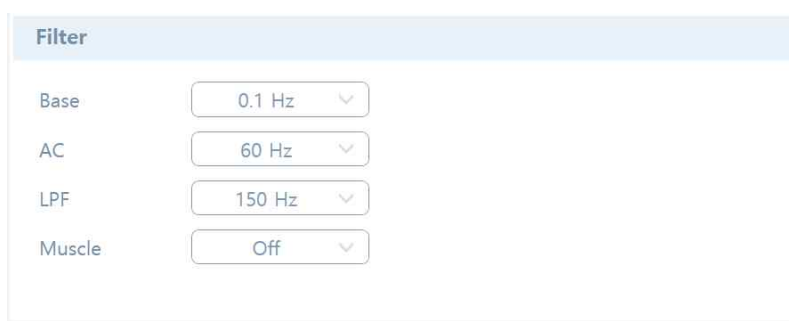
### Demo

Setup or discharge demo functions. If set to be ON, 60bpm Sinus Normal Rhythm signals are shown on the screen and 'Demo' is shown in the middle of screen. You can test all the functions including rhythm, diagnosis, copy and communication.

If turning the equipment off and on, demo function is discharged.

### Filter Setup

Power noise, baseline drift from breathing and EMG might be recorded as well besides ECG data on the acquired signal of ECG. Therefore, when the signal is bad, a good ECG signal can be obtained by using the filter properly.



| Filter |        |
|--------|--------|
| Base   | 0.1 Hz |
| AC     | 60 Hz  |
| LPF    | 150 Hz |
| Muscle | Off    |

#### Base

Baseline drift is noise occurring from respiration of a patient recording ECG on a huge arc. Baseline filter can be applied as 0.05Hz, 0.1Hz and 0.2Hz in the base menu.

#### AC

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.'

#### LPF

LPF filter is a low frequency filter providing off, 40Hz, 100Hz and 150Hz. 40Hz means to remove all the signals with 40Hz or above.

## Muscle

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 EMG, ECG is not well recorded. Therefore, it is required to remove noise. If applying ECG filter, 'off' can be selected if not using 'on'.

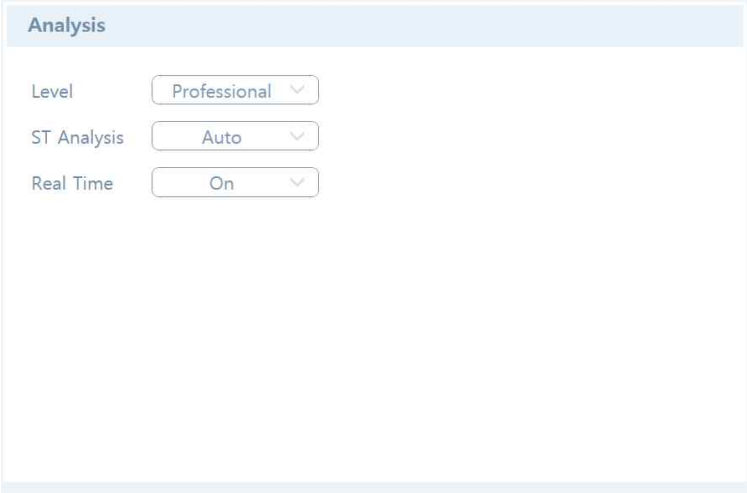
Setup of all the applied filters is indicated at the left bottom corner of output form.

### Note

It is recommended to apply baseline drift filter is 0.1Hz and AC filter is 50Hz or 60Hz at all times and appropriately use the EMG filter. In addition, it is also recommended to setup LPF to 150Hz in case of diagnosis output.

The best quality signal can be obtained when the recommended filter is used, otherwise the signal quality may be poor.

## Analysis



The screenshot shows a software window titled "Analysis". Inside the window, there are three settings, each with a label and a dropdown menu:

- Level:** The dropdown menu is set to "Professional".
- ST Analysis:** The dropdown menu is set to "Auto".
- Real Time:** The dropdown menu is set to "On".

### Level

This is the automatic diagnosis level setup menu for 10 seconds of recording.

In case of 'Basic,' diagnosis reference value is higher showing only the severe diagnosis names.

In case of 'Professional,' various diagnosis contents are shown according to the standard diagnosis values.

### ST Analysis

It is about the setup of ST segment diagnosis during the 10 seconds of recording automatic diagnosis.

In case of 'Auto,' J points related to ST level are automatically setup. In case of '60msec,' J points

are set to be 60msec. In case of '80msec,' J points are set to be 80msec.

## Real Time Diagnosis

This is the setup for real-time automatic diagnosis on the ECG main screen.

If detecting arrhythmia in the standby condition without recording, you can set it to 'ON' to show the diagnosis name.

If set to be 'On,' diagnosis name of arrhythmia is indicated on the top of ECG main screen in case of arrhythmia.

## System

Setup the system. It is available to setup general, hospital, server, and service in each group.

[illegible]

## General

| General                |              |
|------------------------|--------------|
| Language               | English ▼    |
| Start Option           | Home ▼       |
| Auto return after Exam | Off ▼        |
| Date Format            | YYYY-MM-DD ▼ |
| Height Unit            | cm ▼         |
| Weight Unit            | kg ▼         |
| Race Default           | Unknown ▼    |
| Remove Old File        | Manual ▼     |
| Lead Notation          | IEC ▼        |

## Language

Select the language and touch [OK].

| General                |           |
|------------------------|-----------|
| Language               | English ▼ |
| Start Option           | English   |
| Auto return after Exam | 한국어       |
| Date Format            | Français  |
| Height Unit            | Polski    |
| Weight Unit            | Deutsch   |
| Race Default           | 中文        |
| Remove Old File        | Portuguê  |
| Lead Notation          | Magyar    |
|                        | Română    |
|                        | Italiano  |
|                        | Trübe     |
|                        | Manual ▼  |
|                        | IEC ▼     |

### Note

Even if the set language is not English, some terms, such as diagnosis names, may be shown in English.

## Start Option

This is to setup the screen shown when the equipment turns on for the first time. Make sure to select the default screen with function that is frequently used among main, ECG, Patient, file and worklist.

## Auto return after Exam

- Off : Return to the measurement screen after the end of the test
- Worklist: After the inspection is finished, it goes to the Worklist screen.
- Review: Go to the Review screen after completing the test.

**Date Format**

Setup the date format.

Set format is applied to the screen and also the printing.

**Height Unit**

Setup the unit used for height entry of a patient. Cm and inch are available.

**Weight Unit**

Setup the unit used for weight entry of a patient. Kg and lbs are available.

**Race Default**

If the patient's race is not entered, you can select the race that will be selected by default.

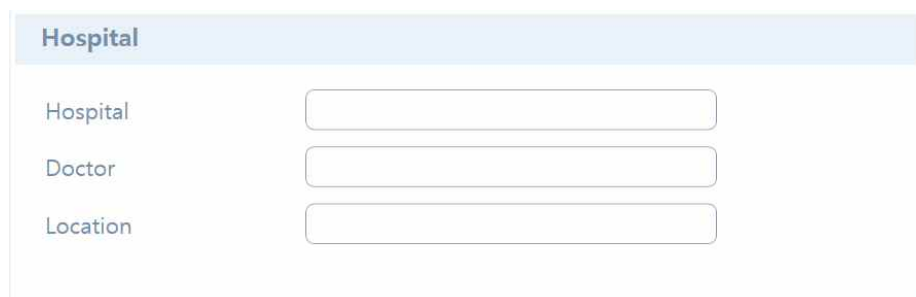
**Remove Old File**

Set how old files are removed

- Manual: Ask the user whether to delete the oldest files
- Auto: Automatically deletes the oldest file and saves the measured file

**Lead Notation**

You can select either IEC or AHA to mark each lead.

**Hospital**

| Hospital |                      |
|----------|----------------------|
| Hospital | <input type="text"/> |
| Doctor   | <input type="text"/> |
| Location | <input type="text"/> |

**Hospital Information**

Enter hospital name.

**Doctor Information**

Enter doctor name.

## Location Information

Enter location name.

## User List

Manage who will use the program.

## User Add

Click Add user to enter a new user.

User Dialog

User Name

Password

Retype Password

using a number and an uppercase, lowercase letter and a special letter, at least 10 characters in combination of 2 types or at least 8 characters in combination of 3 types.

Role

Physician ▾

Validity Period

6 Months ▾

OK

Cancel

- User Name : Enter the user name
- Password : Enter the user's password.
- Retype Password: Confirm by re-entering the user password.

- Role : Enter the user's permissions. In case of 'Admin,' user has authority over all functions, such as system setting, diagnosis setting, inspection, general setting and etc. In case of 'Physician,' user has authority over diagnosis settings, tests, general settings. In case of 'Technician,' user has authority for inspection, general settings.
- Validity Period : Set the expiration date of the user account.

| Note                                                                                                                                                                                                                                                                                                                                 |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Rules for Creating Passwords</b> <ul style="list-style-type: none"><li>- 10 or more characters: a combination of two of uppercase letters, lowercase letters, numbers, and special characters.</li><li>- 8 or more characters: 3 combinations of uppercase letters, lowercase letters, numbers, and special characters.</li></ul> |

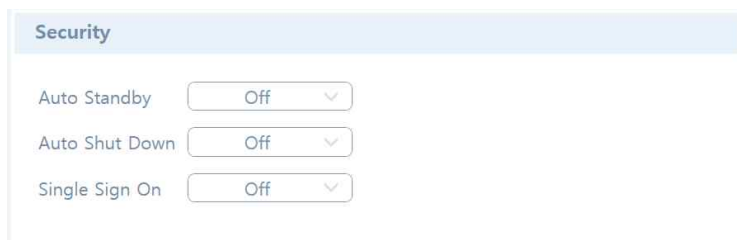
### User Edit

Click Edit User to edit the clicked user information.

### User Delete

Click Remove user to remove the clicked user information.

## Security Setup



The screenshot shows a 'Security' settings window with a light blue header. Below the header, there are three settings, each with a label and a dropdown menu. All three dropdown menus are currently set to 'Off'.

| Setting        | Value |
|----------------|-------|
| Auto Standby   | Off   |
| Auto Shut Down | Off   |
| Single Sign On | Off   |

### Auto Standby

Set On/Off to shut down the equipment when not used for the timeout period.

Set the timeout period to off, 10min, or 30min. If not used for a set period, the equipment will automatically shut down.

### Auto Shutdown

Set the device to automatically shut down when not in use for a certain period of time.

Off, 10min, 20min, 30min can be set and the equipment is automatically shut down if not used for the set time.

**Single Sign On**

Because single sign-on can compromise security, Bionet recommends this setting only for the devices used single or a limited user.

Activate it to enable system authentication of user ID and password.

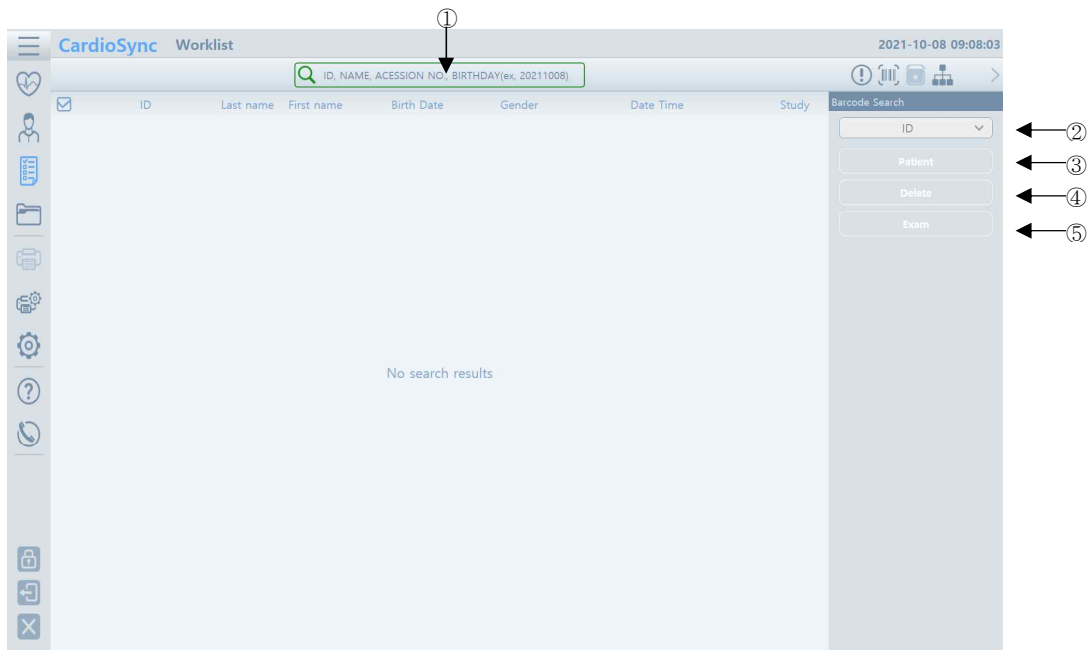
If it is set, no login is required at the start of the program because user authentication is carried out by the equipment.

Also, if the application timeout is set, you do not need a password to reactivate the application. Settings are only available with an administrator account.

# **Part II. Data and System Management**

## Chapter 3. Exam-requested Data Management

### 1) Screen Description



- ① Top list search menu button
- ② Search condition setting button
- ③ Retrieve patient information button
- ④ Delete selected information button
- ⑤ Test progress button

### 2) Function

#### Search

You can enter search conditions by clicking the search condition menu at the top right of the screen. The search condition menu window is activated only when PACS is linked.



Touch the magnifying glass button at the top left of the screen to enter a search condition.  
Touch Search Item to enter ID, Name, Accession No.

### **View patient information**

You can check or change patient information in the selected list.

### **Get inspection information**

Get the latest inspection information from the PACS server or GDT server.

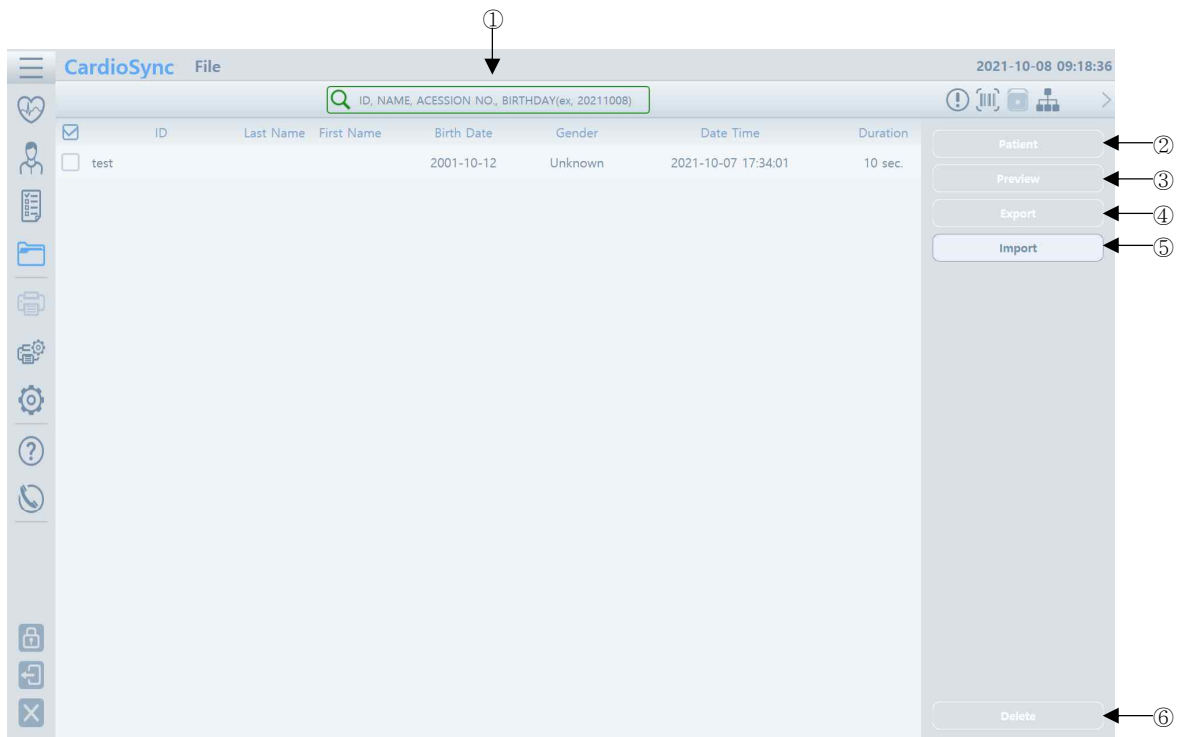
The 'Update' menu is displayed only when connected to the PACS server or GDT server.

### **Examination**

Click the 'Exam' button to move to the ECG main screen for ECG examination with patient information from the selected worklist.

# Chapter 4. Manage Data Files

## 1) Screen and Function Setup



- ① File list search menu button
- ② View selected patient information button
- ③ Selected file preview button
- ④ File export button
- ⑤ File import button
- ⑥ Delete file button

## 2) Function

**Search File**( ID, NAME, BIRTHDAY )

You can enter search conditions by clicking the magnifying glass input box at the top center of the screen.

### Delete Files

Delete selected files. It is available to delete one or multiple files.

| Note                                                     |
|----------------------------------------------------------|
| Care has to be taken as deleted data cannot be restored. |

## View Files

Preview of selected files

It is available to change and print speed, gain, and print form on the preview screen.

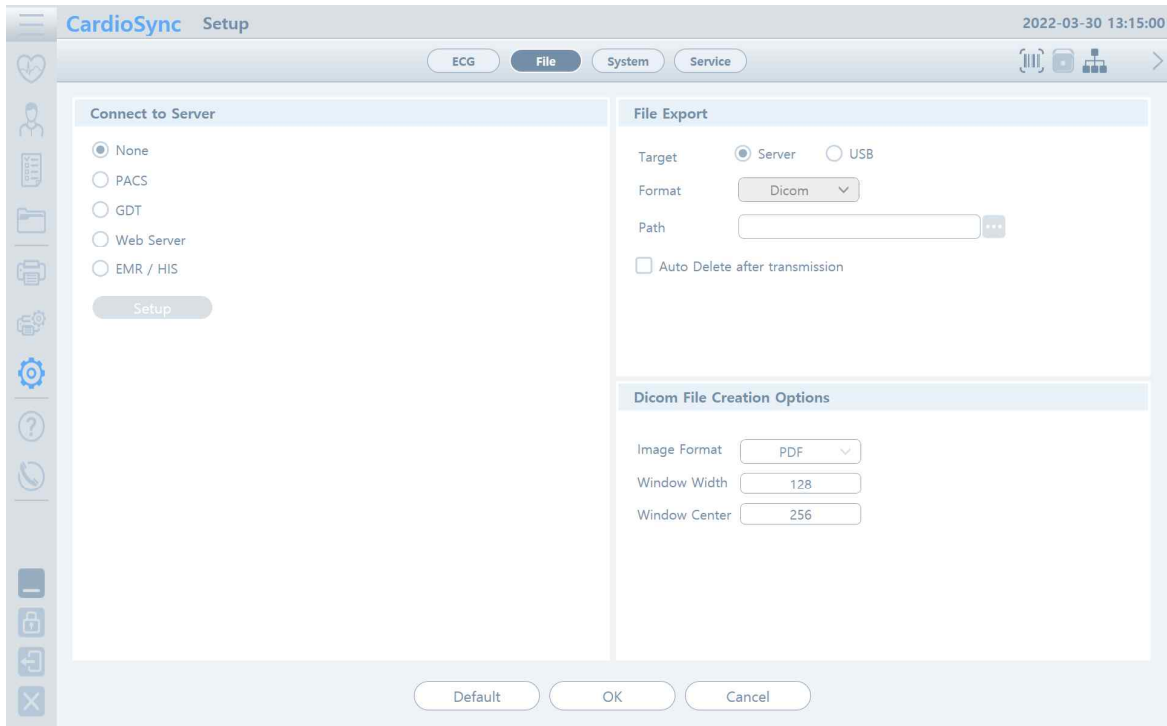
## View Patient Information

It is available to confirm or change patient information on selected files.

| Note                                                                                                                                                                              |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| When recording ECG for 10 seconds, adult diagnosis is applied to those aged 16 or above. However, for children under the age of 16, the pediatric diagnosis algorithm is applied. |

### 3) Setup

If clicking 'setup' button on the menu, 'file setup' window pops up.



#### Connect to Server



PACS, GDT, Web server or EMS/HIS can be selected from the menu to select the server interlocked with the equipment.

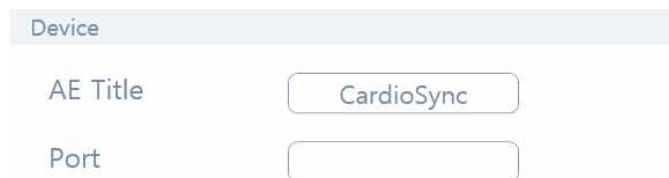
After selecting the type of server to be linked, select the 'Edit' button to display the server setting window.

**A. None**

No connection with the server.

**B. PACS Setting**

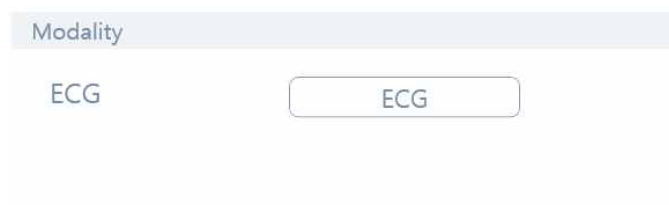
The PACS Setup dialog box is divided into four main sections: Device, Modality, Worklist, and Store. The Device section contains fields for AE Title (set to 'CP1') and Port. The Modality section contains a field for ECG (set to 'ECG'). The Worklist section contains fields for IP, Port, and AE Title, along with buttons for Echo Test and Ping Test, and a Date Range dropdown set to 'Today (today-today)'. The Store section contains fields for IP, Port, and AE Title, along with buttons for Echo Test and Ping Test, and dropdowns for Retry Count (set to 3), Retry Interval (set to 3), and Character Set (set to UTF-8 (ISO\_IR 192)). At the bottom are buttons for Default, OK, and Cancel.

**Device Information**

The Device Information form has a header 'Device' and two input fields: AE Title (set to 'CardioSync') and Port (empty).

**AE Title, Port**

Enter information such as AE Title and Port of Cardio P1.

**Modality**

The Modality form has a header 'Modality' and one input field: ECG (set to 'ECG').

Enter the Modality of ECG

## Worklist Server Settings

Worklist

IP

Port

AE Title

Echo Test

Ping Test

Date Range

Today (today-today) ▾

☐ Auto Update Worklist

### IP, Port, AE Title

Worklist Enter information such as the server's IP, AE Title, Port, etc.

### Server connection check

You can check the worklist server connection by pressing the 'Echo Test' button after entering the information of the worklist server. Click the "Ping Test" button to check the task list and ping.

### Select date range

You can set the date range from which worklists are fetched from the Worklist server.

| List                | Description                                                                                    |
|---------------------|------------------------------------------------------------------------------------------------|
| Today (today-today) | Get the worklist for today's date.<br>Set both start and end dates to today.                   |
| Today (today-blank) | Get the worklist for today's date.<br>Get the worklist by setting only the start date to today |
| Yesterday~Tomorrow  | Get the worklist from yesterday to tomorrow.                                                   |
| One Week            | Get a worklist from today to a week from now.                                                  |
| A Week ago          | Get the worklist from a week ago to today.                                                     |

### Auto Update Worklist

If you check Auto Update Worklist, the latest worklist is automatically imported every time you

enter the worklist screen.

## Store Server Settings

Store

IP

Port

AE Title

Echo Test

Ping Test

Retry Count 3

Retry Interval 3

Character Set UTF-8 (ISO\_IR 192)

### IP, Port, AE Title

Enter information such as IP, AE Title, and Port of the Store server.

### Echo Test & Ping Test

After entering the store server information click the "Echo Test" button or "Ping Test" button to check the connection to the store server.

### Retry Count

Select the number of retransmission attempts when a communication error occurs while sending data to the Store server.

### Retry Interval

Select the interval between retransmission attempts when a communication error occurs while sending data to the Store server.

### Character Set

You can select a character set for each language.

When sending a file to the PACS server, an appropriate character set must be set in order to display the contents of the characters according to each language.

**Note**

- When setting up a connection with the PACS server, the Device IP must be manually entered and used. When setting with DHCP, the Device IP may be changed, and if it is set differently from the equipment IP registered in the PACS server, it may not work with the server.

**C. GDT Setting**

When selecting GDT, additional information must be set through the Setting menu.

A screen for setting related settings such as Work type, GDT Directory, Component name, File name, Image type appears.

**Work type**

It sets how the GDT function of the device operates.

- Server: Cardio P1 receives requests and commands.
- Client: Cardio P1 sends requests and commands.

## Directory

Enter the format of sharing folder information and date information to be used by GDT protocol.

| Directory   |                                       |
|-------------|---------------------------------------|
| Path        | <input type="text"/>                  |
| User ID     | <input type="text"/>                  |
| Password    | <input type="text"/>                  |
| Date        | <input type="text" value="YYYYMMDD"/> |
| <hr/>       |                                       |
| File Format | <input type="text" value="PDF"/>      |

### Path

Enter the shared folder path to be used by the GDT protocol

ex) WW192.168.30.162/GDTShare

### User ID & Password

Enter shared folder access ID & password

### Date

Date information format setting

- YYYYMMDD, MMDDYYYY, DDMMYYYY

## Component

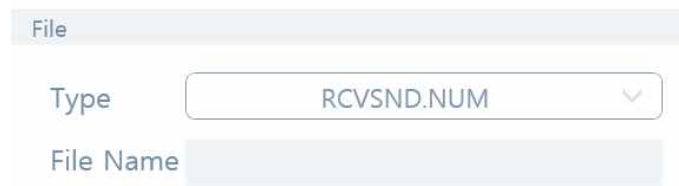
| Component         |                      |
|-------------------|----------------------|
| Receiver(EMR/HIS) |                      |
| Name              | <input type="text"/> |
| Short Name        | <input type="text"/> |
| Sender(Device)    |                      |
| Name              | <input type="text"/> |
| Short Name        | <input type="text"/> |

**Receiver (EMR/HIS)**

- Name: Enter the EMR name to use for the GDT protocol
- Short Name: Enter EMR abbreviation

**Sender (Device)**

- Name: Enter the device name to use for the GDT protocol
- Short Name: Enter device abbreviation

**File**

File

Type RCVSND.NUM

File Name

**Type**

Select the image format of the data file to be shared with the GDT protocol.

**File name**

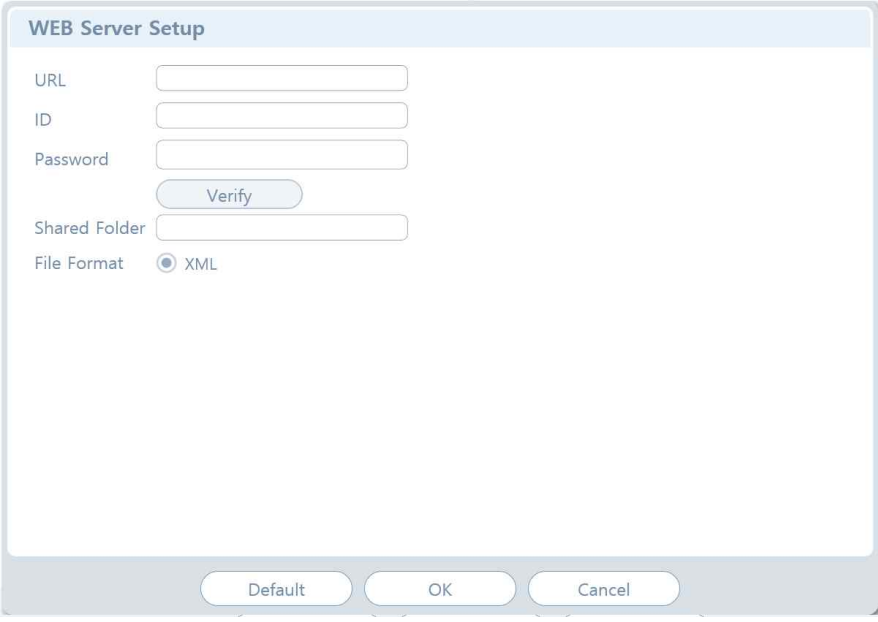
Select the file name type to be shared by GDT protocol.

If you select the input window of each item, a keyboard window appears, and you can enter the relevant content.

**WEB Setting**

When web transmission is selected, additional information must be set through the Setting menu.

A screen for setting related settings such as DNS Server, URL, ID, PW, and Path appears.

A screenshot of a 'WEB Server Setup' dialog box. It has a light blue header bar with the title 'WEB Server Setup'. Below the header, there are five input fields: 'URL', 'ID', 'Password', 'Shared Folder', and 'File Format'. The 'Password' field has a 'Verify' button next to it. The 'File Format' field has a radio button selected next to 'XML'. At the bottom of the dialog box, there are three buttons: 'Default', 'OK', and 'Cancel'.**URL**

The web address to connect to.

**ID**

User ID to use on the web to connect to.

**PW**

This is the user password to use on the web to access.

**Verify**

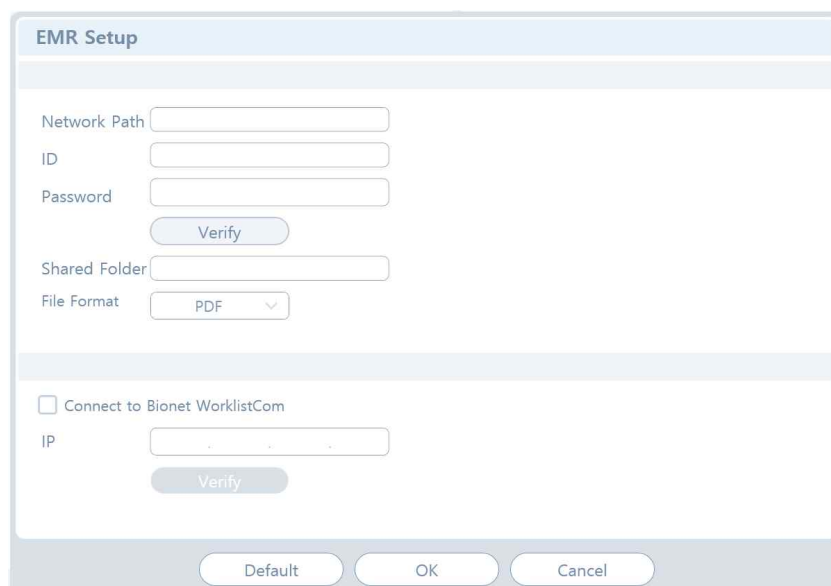
After entering the Web server information click the "Verify" button to check the connection to the Web server.

**Shared Folder**

The path within the server to transfer the file to.

If you select the input window of each item, a keyboard window appears, and you can enter the relevant content.

## D. EMR / HIS Edit

The image shows a software dialog box titled "EMR Setup". It contains several input fields and buttons. At the top, there's a "Network Path" text box. Below it are "ID" and "Password" text boxes, followed by a "Verify" button. Then there's a "Shared Folder" text box and a "File Format" dropdown menu currently set to "PDF". A horizontal separator line divides the dialog into two sections. The bottom section has a checkbox labeled "Connect to Bionet WorklistCom", an "IP" text box, and another "Verify" button. At the very bottom are three buttons: "Default", "OK", and "Cancel".

### Network Path

Enter network path

### ID & Password

Enter the ID & Password

### Verify

After entering the EMR information click the "Verify" button to check the connection to the EMR.

### Shared Folder

Write the shared folder path on the server in the shared folder

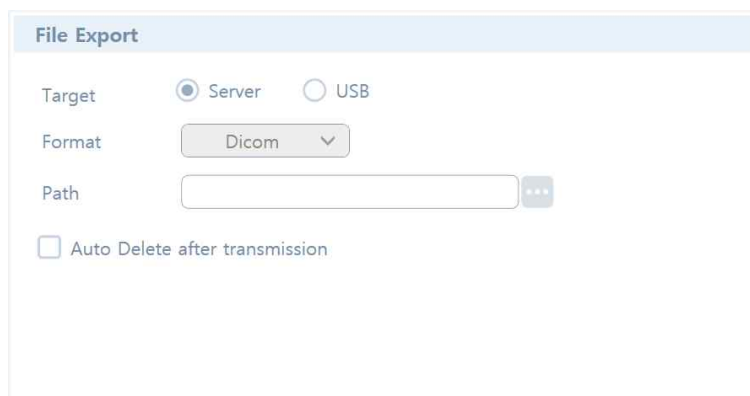
### File Format

Choose a file type to decide which files to share.

### WorklistCom

To manage worklists using WorklistCom provided by Bionet, check 'Connect to Bionet WorklistCom'. After entering the IP of the target using WorklistCom, you can check whether the verification button works normally by pressing the 'Verify' button.

## File Export

A screenshot of the 'File Export' dialog box. It has a title bar 'File Export'. Inside, there are four sections: 'Target' with radio buttons for 'Server' (selected) and 'USB'; 'Format' with a dropdown menu showing 'Dicom'; 'Path' with a text input field and a browse button (three dots); and 'Auto Delete after transmission' with an unchecked checkbox.

### Target

When transferring files by pressing the 'Auto' button on the ECG screen, or by pressing the 'Export' button, set the medium to be transferred. It can be set to USB memory or server.

When set to Server, you can select the server in System Server Setup.

### Format

Set the format of the file to be created by transferring the file.

In addition to the Bionet format, you can select formats such as Dicom, PDF, MFER, XML, BMP, JPG

#### Note

The Dicom format with MFER, XML, and Image format is RAW can only support a 10-second ECG test.

### Auto Delete after Transmission

Set whether to delete the file in Cardio P1 after completing the file transfer to the server.

When set to 'On', the device file is deleted after file transfer.

#### Note

The Delete option only applies when sending to the server.  
Files are not deleted when transferring to USB memory.

## Dicom File Creation Option



The dialog box titled "Dicom File Creation Options" contains three settings:

- Image Format:** A dropdown menu currently set to "PDF".
- Window Width:** A text input field containing the value "128".
- Window Center:** A text input field containing the value "256".

### Image Format

Determines the image format to use when transferring Dicom files.  
You can choose from PDF, BMP, JPEG, and RAW.

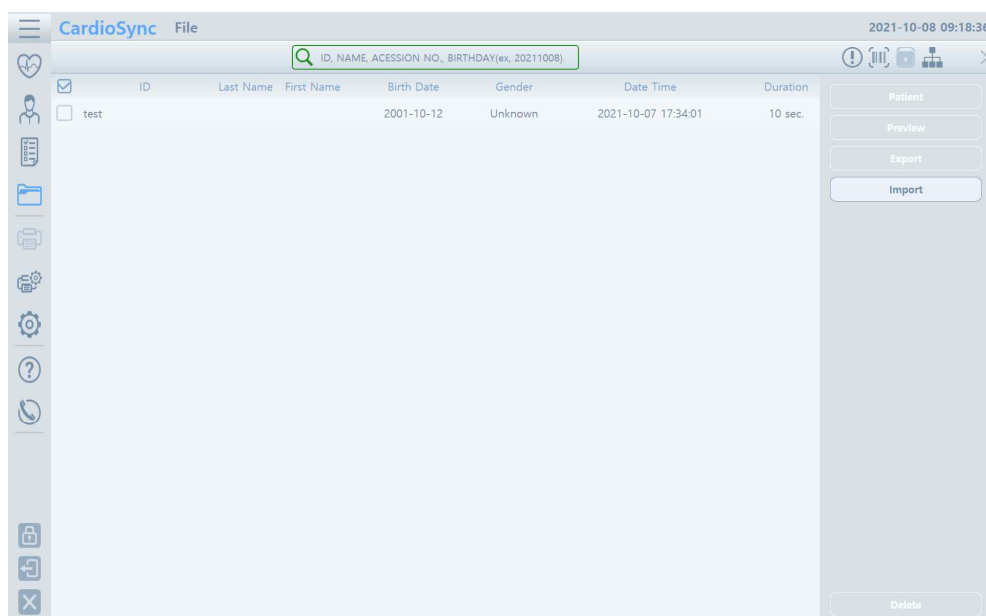
### Window Width

Specifies the image size in JPG, BMP format.

### Window Center

Specifies the center of the image in JPG, BMP format.

## 4) Transmit Data



The CardioSync File management interface shows a table of data with the following columns: ID, Last Name, First Name, Birth Date, Gender, Date Time, and Duration. A search bar at the top contains the text "ID, NAME, ACCESSION NO., BIRTHDAY(ex, 20211008)".

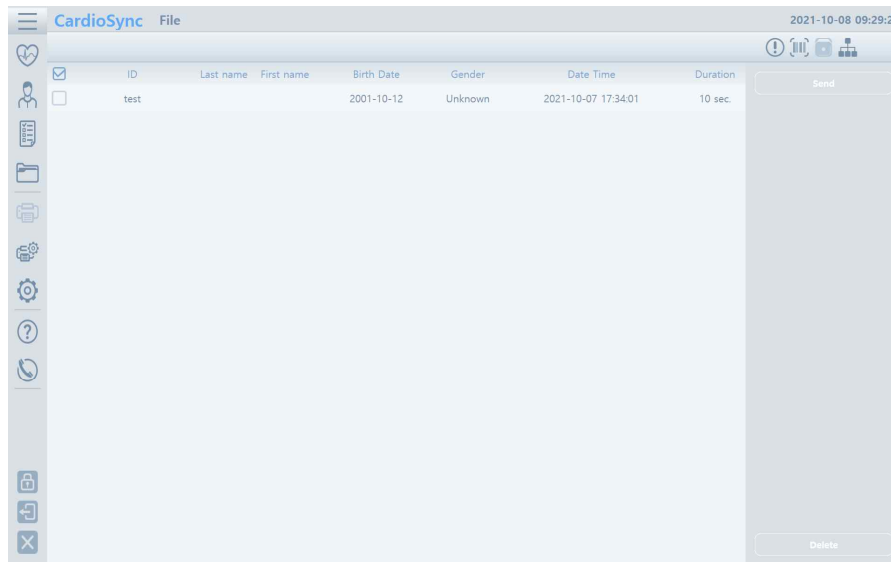
| ID                                       | Last Name | First Name | Birth Date | Gender  | Date Time           | Duration |
|------------------------------------------|-----------|------------|------------|---------|---------------------|----------|
| <input checked="" type="checkbox"/> test |           |            | 2001-10-12 | Unknown | 2021-10-07 17:34:01 | 10 sec.  |

On the right side, there are buttons for "Patient", "Preview", "Export", "Import", and "Delete".

It is available to send saved data out to connected external devices by using 'Export' button on the control panel on file screen.

If click 'Export' button on the control panel, selected data are sent. If failing to send data due to error in network while exporting, they are available to check on 'Retry Queue' screen.

Following is the main screen for 'Retry Queue.'

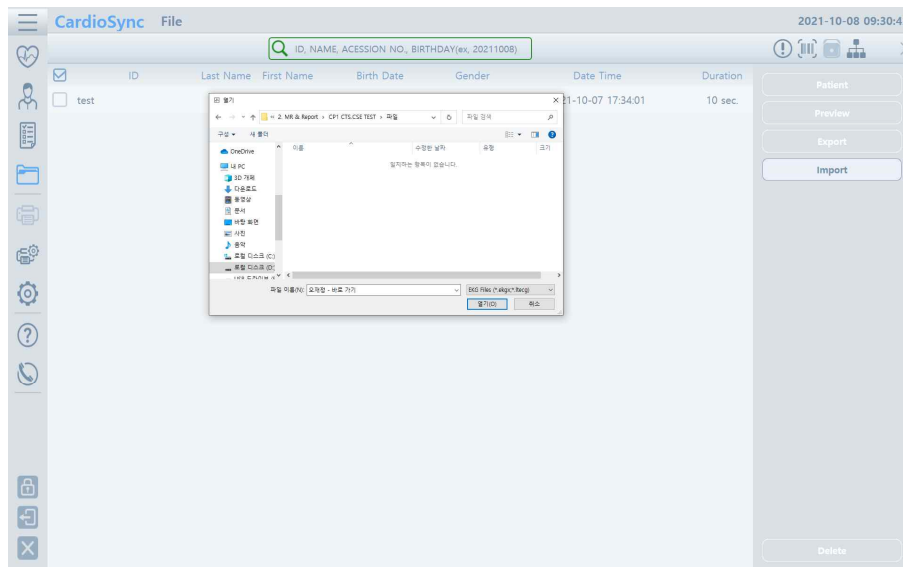


Files failed to be sent are indicated on 'Retry Queue' screen. Such files can be re-sent.

## 5) Import Data

It is available to import bionet format files saved on USB memory by using 'Import' button on the control panel from file screen.

If click 'Import' key on the control panel, following screen is shown.



If clicking 'open' button after selecting data to be loaded on the equipment, data can be loaded on the equipment.

### Note

Only the files in following formats can be imported:

➔ ekgx, ltecg, stecg

## Chapter 5. System Management

### 1) Maintenance and Cleanliness

Keep Cardio P1 equipment and handles clean. Avoid damaging or contaminating the equipment using the methods recommended below.

If you use the substances - including not allowed substances - that can damage on the product, warranty is not applied even during the warranty period.

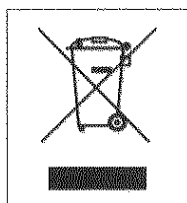
| Note                                                                                                        |
|-------------------------------------------------------------------------------------------------------------|
| Clean the equipment and examine the body and electrodes thoroughly.<br>Do not use old or damaged equipment. |

At least once a month, wipe the body and measuring electrodes with a soft cloth moistened with alcohol to keep them clean. Do not use lacquer, thinner, ethylene, or oxide. Keep cables and limb and chest electrodes free of dust and dirt, and wipe them with a cloth dampened in lukewarm water (40°C/104°F) after use. Wipe them with clinical grade alcohol at least once a week. Do not immerse equipment or ECG wires in liquids or detergents. Keep the equipment and cables away from liquids.

| Note                                                                                                                                             |
|--------------------------------------------------------------------------------------------------------------------------------------------------|
| If the equipment is determined to be visibly unclean at the end of the cleaning steps, you should repeat the relevant previous cleaning process. |

| Note                                                                                                                                                                                                                                            |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| If the equipment experiences unacceptable deterioration, such as corrosion, discoloration, dents, or cracked seals, contact the seller where you purchased the equipment and follow his or her instructions whether to dispose of or repair it. |

### **Existing Device Disposal**



1. Products bearing this symbol (X-marked wheeled bins) are subject to European Directive 2002/96/EC.
2. All electrical and electronic products must be disposed of separately from municipal waste at the collection facility designated by government or local authorities.
3. Proper disposal of old devices helps prevent potential adverse consequences against environmental and human health.
4. For more information on the disposal of existing devices, contact City Hall, Waste Disposal Service Center, or the store where you purchased the product.

## **2) Regular Examination**

As with any other medical equipment, have your Cardio P1 regularly safety inspected once a year. Refer to the service manual provided by Bionet for inspection items.

## **3) Simple Troubleshooting**

- **When the signal is output with a lot of noise**

: In this case, first check if the AC power filter is set. If there is still noise after setting, move the system to a power environment with less noise.

- **Cyber security Issues**

- 1) If equipment is stolen or lost, contact the hospital staff or manufacturer as soon as possible.

When a stolen or lost equipment report is filed, the hospital network administrator must take steps to prevent the equipment from accessing the hospital network.

- 2) If a cyber security threat is detected while using the equipment, immediately disconnect it from the network and contact the hospital staff or manufacturer.

**※ For manufacturer contact information, please refer to the table of contents of How to Contact Us.**

**System Message**

| ECG |                                                                                                                                                                      |                                                                                                      |                                                                                |
|-----|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|
| No. | Message                                                                                                                                                              | Causes                                                                                               | Solution                                                                       |
| 1   | "Do you want to save new disclosure data from now? Click Yes to discard the old data and save the new one. Click No to continue saving following the previous data." | When data is stored in Disclosure, when there is existing data and a decision to process is required | Click 'Yes' if you want to delete existing data, or 'No' if you don't want to. |

| Patient |                                                                                                               |                                                                                               |                                                                                |
|---------|---------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|
| No.     | Message                                                                                                       | Causes                                                                                        | Solution                                                                       |
| 1       | Please fill the required fields.                                                                              | When you click 'ok' without filling out the required fields when entering patient information | Retry after filling in required fields                                         |
| 2       | Please fill the ID field.                                                                                     | When entering patient information and clicking 'OK' without filling in the ID field           | Retry after filling in ID field                                                |
| 3       | Invalid ID                                                                                                    | In case of incorrect ID when entering patient information                                     | Retry after entering the correct ID                                            |
| 4       | The future cannot be set as the date of birth.                                                                | When entering a future date in 'Date of Birth' when entering patient information              | Retry after checking the date                                                  |
| 5       | "All patient related information including study order and result will be deleted. Are you sure to continue?" | Confirmation procedure when deleting patient information                                      | Click 'Yes' if you want to delete existing data, or 'No' if you don't want to. |

| File |                                                                                   |                                                                                  |                                                                                |
|------|-----------------------------------------------------------------------------------|----------------------------------------------------------------------------------|--------------------------------------------------------------------------------|
| No.  | Message                                                                           | Causes                                                                           | Solution                                                                       |
| 1    | "The study record being exported will be discarded.<br>Are you sure to continue?" | When the Cancel button is pressed when exporting a file                          | Click 'Yes' if you wish to cancel or 'No' if you do not wish to cancel.        |
| 2    | Deleting old files to get more storage space.                                     | Occurs when there is insufficient storage space in the computer                  | Retry after saving space                                                       |
| 3    | "There is a duplicate ID.<br>Do you want to change it?"                           | If there is a duplicate ID when importing a file, check if you want to change it | Click 'Yes' if you want to change, click 'No' if you do not want to change     |
| 4    | Not enough storage space. Please free up storage.                                 | When there is no storage space for 'File' and 'Patient'                          | Retry after saving space                                                       |
| 5    | "The selected study record files will be deleted.<br>Are you sure to continue?"   | Confirmation procedure when deleting saved ECG files                             | Click 'Yes' if you want to delete existing data, or 'No' if you don't want to. |

| Worklist |                                                 |                                               |                                                                                 |
|----------|-------------------------------------------------|-----------------------------------------------|---------------------------------------------------------------------------------|
| No.      | Message                                         | Causes                                        | Solution                                                                        |
| 1        | Are you sure to proceed to erase all user data? | When deleting data from worklist              | Click 'Yes' if you want to delete or 'No' if you don't want to.                 |
| 2        | Fail to update worklist                         | In case of failure after updating in Worklist | If there is no information to update or an error has occurred, check, and retry |

| Setup |                                       |                                                                                |                                          |
|-------|---------------------------------------|--------------------------------------------------------------------------------|------------------------------------------|
| No.   | Message                               | Causes                                                                         | Solution                                 |
| 1     | Please check device AE title.         | When device AE Title is entered incorrectly when setting PACS                  | Enter the correct value and try again    |
| 2     | Please check device port.             | When device port is entered incorrectly when setting up PACS                   | Enter the correct value and try again    |
| 3     | Please check server AE title.         | When the server AE Title is entered as an incorrect value when setting up PACS | Enter the correct value and try again    |
| 4     | Please check server port.             | When the server port is entered as an incorrect value when setting up PACS     | Enter the correct value and try again    |
| 5     | Echo failed.                          | In case of failure in PACS setting Echo Test                                   | Check IP, AE Title or Port and try again |
| 6     | Echo succeeded.                       | If the Echo setting Ping Test is successful                                    |                                          |
| 7     | Ping failed.                          | In case of failure in PACS setup ping test                                     | Check IP, AE Title or Port and try again |
| 8     | Ping succeeded.                       | If the PACS setting Ping Test is successful                                    |                                          |
| 9     | Please check the device (short)name.  | When device (short)name is entered incorrectly when setting GDT                | Enter the correct value and try again    |
| 10    | Please check the GDT Server settings. | When there is a GDT setting error                                              | Enter the correct value and try again    |
| 11    | Please check your ID.                 | When ID is entered incorrectly when setting GDT                                | Enter the correct value and try again    |

|    |                                          |                                                                                               |                                                                                                                                      |
|----|------------------------------------------|-----------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------|
| 12 | Please check a import/export short name. | When setting GDT, when import/export short name is entered as an incorrect value              | Enter the correct value and try again                                                                                                |
| 13 | Please check the shared folder.          | When the shared folder is entered incorrectly when setting up the Web server                  | Enter the correct value and try again                                                                                                |
| 14 | Please check Web Server URL.             | When URL information is entered as an incorrect value when setting up the Web Server          | Enter the correct value and try again                                                                                                |
| 15 | Please check the user login name.        | When ID is entered as an incorrect value when setting Web server, EMR/HIS                     | Enter the correct value and try again                                                                                                |
| 16 | Please check your password.              | When the password is entered as an incorrect value when setting up the web server and EMR/HIS | Enter the correct value and try again                                                                                                |
| 17 | Verification failed.                     | Web Server, EMR/HIS linkage verification failed                                               | In Web Server Setting, check URL, ID, and Password and retry.<br>In EMR/HIS Setting, check Network Path, ID, and Password and retry. |
| 18 | Verification successful.                 | Confirmation success when interworking with Web Server and EMR/HIS                            |                                                                                                                                      |
| 19 | Please check the Bionet WorlistCom's IP. | When Bionet WorlistCom's IP is entered incorrectly when setting EMR/HIS                       | Enter the correct value and try again                                                                                                |
| 20 | Please check server IP.                  | When the Server IP is entered as an incorrect value when setting EMR/HIS                      | Enter the correct value and try again                                                                                                |
| 21 | Please check the network path.           | When Network Path is entered as an incorrect value when setting EMR/HIS                       | Enter the correct value and try again                                                                                                |

|    |                                                                             |                                                                             |                                                      |
|----|-----------------------------------------------------------------------------|-----------------------------------------------------------------------------|------------------------------------------------------|
| 22 | The system erased all data.                                                 | When you click 'Delete all files' during factory reset                      |                                                      |
| 23 | Do you want to restore default settings?                                    | Confirmation procedure when clicking 'Restore Default' during factory reset | Click 'Yes' if you agree or 'No' if you do not agree |
| 24 | The system is made into factory default.                                    | Guidance message when trying to factory reset                               |                                                      |
| 25 | No printer configured!<br>Please add a printer first in Printer Setup Page. | When setting up a printer, when no printer is configured                    | Retry after printer configuration                    |
| 26 | Your account has expired.                                                   | When the account registered in the user list has expired                    | Add a new account or extend the term                 |

| Others |                                        |                                                                                    |                                                 |
|--------|----------------------------------------|------------------------------------------------------------------------------------|-------------------------------------------------|
| No.    | Message                                | Causes                                                                             | Solution                                        |
| 1      | No search results                      | When there are no results when searching                                           | Make sure you did your search correctly         |
| 2      | Network error                          | In case the server setting is wrong or when the network connection is not possible | Retry after checking server settings or network |
| 3      | PDF view application is not installed. | When there is no pdf view application when viewing the manual                      | Retry after installing pdf view application     |

Please contact A/S center of our company if issue has not been solved with solution above.

## 4) Manufacturer Declaration

### Electromagnetic Compatibility Information

| Phenomenon                                                                   | Basic EMC standard or test method | Test level/requirement                                                               |
|------------------------------------------------------------------------------|-----------------------------------|--------------------------------------------------------------------------------------|
| Mains terminal disturbance voltage                                           | CISPR 11<br>EN 55011              | Group1, Class A                                                                      |
| Radiated disturbance                                                         | CISPR 11<br>EN 55011              | Group1, Class A                                                                      |
| Harmonic Current Emission                                                    | IEC 61000-3-2<br>EN 61000-3-2     | Class A                                                                              |
| Voltage change,<br>Voltage fluctuations and<br>Flicker Emission              | IEC 61000-3-3<br>EN 61000-3-3     | Pst: 1<br>Plt: 0.65<br>Tmax:0.5<br>dmax: 4%<br>dc: 3.3%                              |
| Electrostatic Discharge<br>Immunity                                          | IEC 61000-4-2<br>EN 61000-4-2     | ±8 kV/Contact<br><br>±2, ±4, ±8, ±15 kV/Air                                          |
| Radiated RF<br>Electromagnetic Field<br>Immunity                             | IEC 61000-4-3<br>EN 61000-4-3     | 3 V/m<br>80 MHz - 2.7 GHz<br>80% AM at 1 kHz, 10 Hz                                  |
| Immunity to Proximity Fields<br>from RF wireless<br>Communications Equipment | IEC 61000-4-3<br>EN 61000-4-3     | Table 9 in<br>IEC 60601-1-2: 2014                                                    |
| Electrical Fast<br>Transient/Burst Immunity                                  | IEC 61000-4-4<br>EN 61000-4-4     | ±2 kV, 100 kHz<br>repetition frequency<br><br>±1 kV, 100 kHz<br>repetition frequency |
| Surge Immunity                                                               | IEC 61000-4-5<br>EN 61000-4-5     | Line to Line<br>±0.5 kV, ±1 kV<br><br>Line to Ground<br>±0.5 kV, ±1 kV, ±2 kV        |

|                                                         |                                 |                                                                                                               |
|---------------------------------------------------------|---------------------------------|---------------------------------------------------------------------------------------------------------------|
| Immunity to Conducted Disturbances Induced by RF fields | IEC 61000-4-6<br>EN 61000-4-6   | 3 V<br>0.15 MHz - 80 MHz<br><br>6 V in ISM bands<br>Between 0.15 MHz and 80 MHz<br><br>80% AM at 1 kHz, 10 Hz |
| Power Frequency Magnetic Field Immunity                 | IEC 61000-4-8<br>EN 61000-4-8   | 30 A/m<br>50 Hz and 60 Hz                                                                                     |
| Voltage dips                                            | IEC 61000-4-11<br>EN 61000-4-11 | 0 % $U_T$ ; 0.5 cycle<br>At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°                                     |
|                                                         |                                 | 70 % $U_T$ ; 1 cycle<br>and<br>70 % $U_T$ ; 25/30 cycles<br>Single phase: at 0°                               |
| Voltage interruptions                                   | IEC 61000-4-11<br>EN 61000-4-11 | 0 % $U_T$ ; 250/300 cycle                                                                                     |

### Electromagnetic compatibility - Guidance and manufacturer's declaration

| Guidance and manufacturer's declaration – electromagnetic emissions                                                                                                                      |            |                                                                                                                                                                                    |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| The Cardio P1 is intended for use in the electromagnetic environment specified below.<br>The customer or the user of the Cardio P1 should assure that it is used in such an environment. |            |                                                                                                                                                                                    |
| Emissions test                                                                                                                                                                           | Compliance | Electromagnetic environment - guidance                                                                                                                                             |
| RF emissions<br>CISPR 11                                                                                                                                                                 | Group 1    | The Cardio P1 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emissions<br>CISPR 11                                                                                                                                                                 | Class A    | The Cardio P1 is suitable for use in all establishments other than domestic and may be used in domestic establishments and those directly connected to the public low-voltage      |
| Harmonic emissions<br>IEC 61000-3-2                                                                                                                                                      | Class A    |                                                                                                                                                                                    |

|                                                             |          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-------------------------------------------------------------|----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Voltage fluctuations/<br>flicker emissions<br>IEC 61000-3-3 | Complies | <p>power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded:</p> <p><b>Warning:</b> This equipment/system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the Cardio P1 or shielding the location.</p> |
|-------------------------------------------------------------|----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

| Guidance and manufacturer's declaration – electromagnetic immunity                                                                                                                           |                                                                    |                                                                    |                                                                                                                                                    |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------|--------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>The Cardio P1 is intended for use in the electromagnetic environment specified below. The customer or the user of the Cardio P1 should assure that it is used in such an environment.</p> |                                                                    |                                                                    |                                                                                                                                                    |
| IMMUNITY test                                                                                                                                                                                | IEC 60601 test level                                               | Compliance level                                                   | Electromagnetic environment - guidance                                                                                                             |
| Electrostatic discharge (ESD)<br><br>IEC 61000-4-2                                                                                                                                           | ± 6 kV contact<br><br>± 8 kV air                                   | ± 6 kV contact<br><br>± 8 kV air                                   | Floors should be wood, concrete, or ceramic tile.<br>If floors are covered with synthetic material, the relative humidity should be at least 30 %. |
| Electrical fast transient/burst<br><br>IEC 61000-4-4                                                                                                                                         | ± 2 kV for power supply lines<br><br>± 1 kV for input/output lines | ± 2 kV for power supply lines<br><br>± 1 kV for input/output lines | Mains power quality should be that of a typical commercial or hospital environment.                                                                |
| Surge<br><br>IEC 61000-4-5                                                                                                                                                                   | ± 1 kV line(s) to line(s)<br><br>± 2 kV line(s) to earth           | ± 1 kV line(s) to line(s)<br><br>± 2 kV line(s) to earth           | Mains power quality should be that of a typical commercial or hospital environment.                                                                |

|                                                                                                                   |                                                                                                                                                                                                                 |                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                            |
|-------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>Voltage dips, short interruptions and voltage variations on power supply input lines</p> <p>IEC 61000-4-11</p> | <p>&lt;5%UT<br/>(&gt;95%dip in UT)<br/>for 0,5 cycle<br/>40 %UT<br/>(60 %dip in UT)<br/>for 5, 6 cycles<br/>70 %UT<br/>(30 %dip in UT)<br/>for 25,30 cycles<br/>&lt;5%UT<br/>(&gt;95%dip in UT)<br/>for 5 s</p> | <p>&lt;5%UT<br/>(&gt;95%dip in UT)<br/>for 0,5 cycle<br/>40 %UT<br/>(60 %dip in UT)<br/>for 5, 6 cycles<br/>70 %UT<br/>(30 %dip in UT)<br/>for 25,30 cycles<br/>&lt;5%UT<br/>(&gt;95%dip in UT)<br/>for 5 s</p> | <p>Mains power quality should be that of a typical commercial or hospital environment. If the user of the Cardio P1 requires continued operation during power mains interruptions, it is recommended that the Cardio P1 be powered from an uninterruptible power supply or PC battery.</p> |
| <p>Power frequency (50/60 Hz)<br/>magnetic field</p> <p>IEC 61000-4-8</p>                                         | <p>3 A/m</p>                                                                                                                                                                                                    | <p>3 A/m</p>                                                                                                                                                                                                    | <p>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or</p>                                                                                                                                                                 |
| <p>*Note: <math>U_T</math> is the AC voltage of the power before using test level</p>                             |                                                                                                                                                                                                                 |                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                            |

| Guidance and manufacturer's declaration – electromagnetic immunity                                                                                                                    |                            |                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| The Cardio P1 is intended for use in the electromagnetic environment specified below. The customer or the user of the Cardio P1 should assure that it is used in such an environment. |                            |                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| IMMUNITY test                                                                                                                                                                         | IEC 60601 test level       | Compliance level | Electromagnetic environment - guidance                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Conducted RF<br>IEC 61000-4-6                                                                                                                                                         | 3 Vrms<br>150 kHz to 80MHz | 3 V rms          | Portable and mobile RF communications equipment should be used no closer to any part of the Cardio P1, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br><br><b>Recommended separation distance</b><br><br>$d = \left[ \frac{3,5}{V_1} \right] \sqrt{P}$<br><br>$d = \left[ \frac{3,5}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$<br><br>$d = \left[ \frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$<br><br>where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and $d$ is there commended separation distance in meters (m). <sup>b</sup><br><br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey <sup>a</sup> should be less than the compliance level in each frequency range. <sup>b</sup> |
| Radiated RF<br>IEC 61000-4-3                                                                                                                                                          | 3 V/m<br>80 MHz to 2,5 GHz | 3 V/m            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |  |  |                                                                                                                                                                                |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|--|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |  |  | <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p>  |
| <p>Note 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |  |  |                                                                                                                                                                                |
| <p>Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |  |  |                                                                                                                                                                                |
| <p><sup>a</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Cardio P1 is used exceeds the applicable RF compliance level above, the Cardio P1 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Cardio P1.</p> |  |  |                                                                                                                                                                                |
| <p><sup>b</sup> Over the frequency range 150 kHz to 80 MHz, field strength should be less than 3 V/m</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |  |  |                                                                                                                                                                                |

| Recommended separation distances between portable and mobile RF communications equipment and the Cardio P1                                                                                                                                                                                                                                                                                                                                   |                                                                  |                   |                    |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|-------------------|--------------------|
| <p>The Cardio P1 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Cardio P1 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Cardio P1 as recommended below, according to the maximum output power of the communications equipment.</p> |                                                                  |                   |                    |
| Rated maximum output power of transmitter<br>[W]                                                                                                                                                                                                                                                                                                                                                                                             | Separation distance according to frequency of transmitter<br>[m] |                   |                    |
|                                                                                                                                                                                                                                                                                                                                                                                                                                              | 150 kHz to 80 MHz                                                | 80 MHz to 800 MHz | 800 MHz to 2,5 GHz |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | $d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$ | $d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$ | $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|--------------------------------------------|------------------------------------------|
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | V <sub>1</sub> = 3 Vrms                    | E <sub>1</sub> = 3 V/m                     | E <sub>1</sub> = 3 V/m                   |
| 0.01                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 0.12                                       | 0.12                                       | 0.23                                     |
| 0.1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 0.37                                       | 0.37                                       | 0.74                                     |
| 1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 1.17                                       | 1.17                                       | 2.33                                     |
| 10                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 3.70                                       | 3.70                                       | 7.37                                     |
| 100                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 11.70                                      | 11.70                                      | 23.30                                    |
| <p>For transmitters rated at a maximum output power not listed above, the recommended separation distance <math>d</math> in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where <math>P</math> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.</p> <p>Note 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.</p> <p>Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.</p> |                                            |                                            |                                          |

## Chapter 6. Product Specifications

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

|                           |                         |                                                                                                                                                                                                            |
|---------------------------|-------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Environmental</b>      | <b>Operation</b>        | Ambient Temperature : 10 to 40°C<br>Relative Humidity : 30 to 85%<br>Atmospheric Pressure : 700 to 1060hPa                                                                                                 |
|                           | <b>Storage/Shipping</b> | Ambient Temperature : -20 to 60°C<br>Relative Humidity : 10 to 95%<br>Atmospheric Pressure : 500 to 1060hPa                                                                                                |
| <b>Dimensions</b>         |                         | Body<br>- 90.75(W) x 103.5(D) x 24.93(H)mm<br>- Approx. 110g                                                                                                                                               |
| <b>Standard Accessory</b> |                         | Patient Cable (1EA), Limb Electrodes (1SET),<br>Chest Electrodes (1SET), Power (USB Data) Cable (1EA),<br>Hanger (1EA), Silicone Pad (1EA), ECG Gel (1EA)<br>ECG Diagnosis Guide (1EA), USB Lock Key (1EA) |

**Warning**

Do not touch patient cables or equipment when using a ventricular defibrillator.

**Warning**

When connecting electrodes or patient cables, do not allow connectors to touch conductive parts or ground. In particular, when attaching the electrodes to the patient's body, make sure that they do not come into contact with conductive parts or the ground.

**Warning**

Do not use the supplied ECG patient cables to measure respiration. They should be used for ECG measurement only.

**Caution**

For the electrode, use the same product as provided or a product with biocompatibility certified by international standards.

**Caution**

Cardio P1 should be used in the presence of a health care professional when used for patients who have undergone Cardiac Assist Device surgery.

## Product Warranty

|                                   |                                                  |
|-----------------------------------|--------------------------------------------------|
| Product Name                      | Electrocardiograph and Diagnostic Spirometer     |
| Model Name                        | Cardio P1                                        |
| Product Permit No.                |                                                  |
| Date of Issuing<br>Product Permit |                                                  |
| Lot Number                        |                                                  |
| Warranty Period                   | One year from the date of purchase               |
| Date of Purchase                  | Day    Month    Year                             |
| Customer<br>Information           | Name of Hospital:<br>Address:<br>Name:<br>Phone: |
| Name of Seller                    |                                                  |
| Name of<br>Manufacturer           |                                                  |

- ※ Thank you for purchasing Cardio P1
- ※ This product is a medical device.
- ※ This product has passed thorough quality control and strict inspection.
- ※ Compensation criteria for repair, exchange, and refund of this product are in accordance with the Fair Trade Commission Notice "Consumer Damage Compensation Regulations."



## **Headquarters & International Sales & service**

**Bionet Co., Ltd.**

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Model Name: Cardio P1