bionet

Electrocardiograph

Cardio P1

Operation Manual

Ver. 1.00

2023. 04. 04

bionet

www.ebionet.com

REVISION HISTORY

Revision No.	Date	Contents	Page
1.00	2023.04.04	First Written	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.

Headquarters & International Sales & Service	**Bionet Co., Ltd.:** 5F, 61 Digital-ro 31 gil, Guro-gu, SEOUL 08375, REPUBLIC OF KOREA Tel : +82-2-6292-6410 / Fax : +82-2-6499-7789 E-mail : service@ebionet.com Website: www.ebionet.com
U.S.A Sales & Service Representative	**Bionet America, Inc.** 2691 Dow Ave. Suite B Tustin, CA 92780 Toll Free : 1-877-924-6638 / Fax : 1-714-734-1761 E-mail : support@bionetus.com Website: www.bionetus.com
European Sales & Service Representative	**Bionet Europe GmbH :** 2Li Bessemerstr. 51, D-12103 Berlin, Germany Tel : +49-30-240-374-52 E-mail : bionetEU@ebionet.com Website: www.ebionet.com

※ 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.

- Usage description and simple inspection without disassembly - In case of reinstallation due to poor installation by a distributor	Free the 1st time Charged starting the 2nd time
- Inadequate installation or loosening due to physical product movement, relocation, etc. - When re-installing after the first installation requested by the customer at the time of purchase - When reinstallation is required due to inexperienced installation by the customer - When a service is requested due to the input of foreign substances or improper cleaning	Charged starting the 1st time

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.

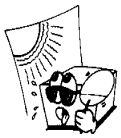
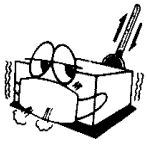
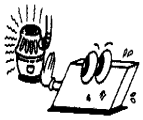
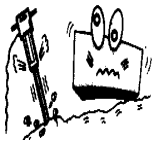
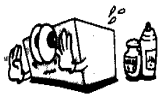
Warning
Warning Failure to follow this message may cause severe injuries, casualty or physical damage to patients.

Caution
Caution Failure to follow this message may cause in non-life-threatening injury or damage to the equipment.

Note
Note 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 (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. (Bionet is not liable for broken products caused by attempted disassembly.)		DO NOT connect power until the product is completely installed. 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. It requires a higher amount of power than the public low-voltage power supplied to typical residential buildings. 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 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		
	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		
	Waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.		
	MR Unsafe: DO NOT use this equipment in all MR environment.		
	No sterilization		Do not use if package is damaged
	Recycling; Dispose of properly in accordance with all state, province, and country regulations		This way up. For the duration of shipping/delivery, the carton should face upright

Commented [장사1]: Manufactory -> Manufacturer 수정함

	Fragile; Handle with care		Use no hooks; Absolutely no hand hooks should be attached to pull the parcel
	Keep away from rain		

Symbols	Contents
	Attention Consult accompanying documents
	Consult Instructions for Use: This symbol advises the reader to consult the operating instructions for information needed for the proper use of the equipment.
	Safety Sign To signify that the instruction manual must be read. 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

Table of Contents

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

Cardio P1 is a 12-channel ECG (Electrocardiogram) recording equipment that measures and records the patient's ECG. It not only provides parameters necessary for diagnosis, patient's ECG record and automatic diagnosis, but also increases chart management efficiency by providing ECG records and printing reports when patient or user information is entered. At the same time, it can transmit the saved data to a network-connected PC for file management. Its user-oriented design enables ECG examination with a single push of a button.

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

1-1) 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 tore turn 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.
- 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

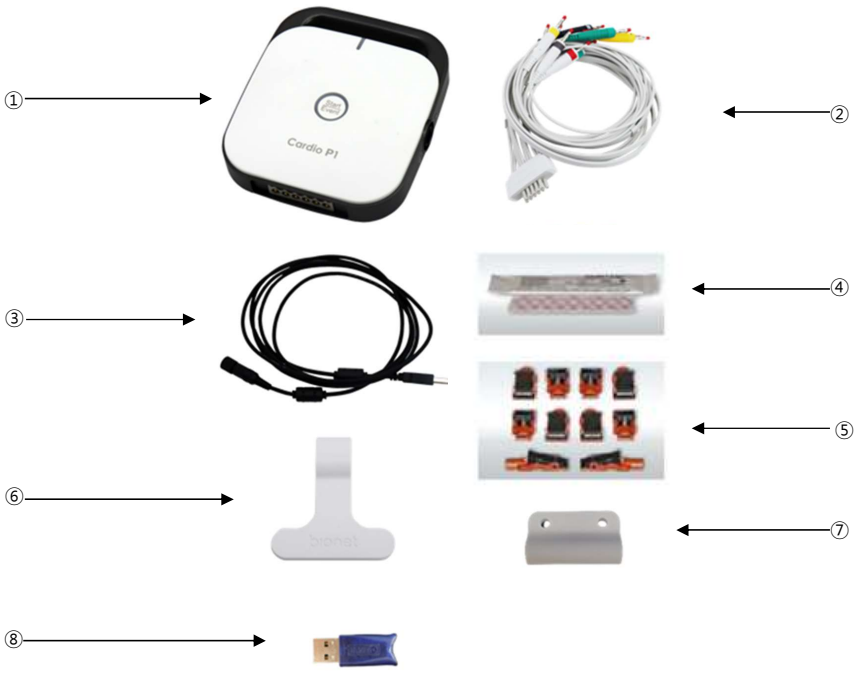
- Software that analyzes and records the measured ECG
- Installed on a PC.

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 Disposable electrodes (1set)

⑤ ECG clips (1set)

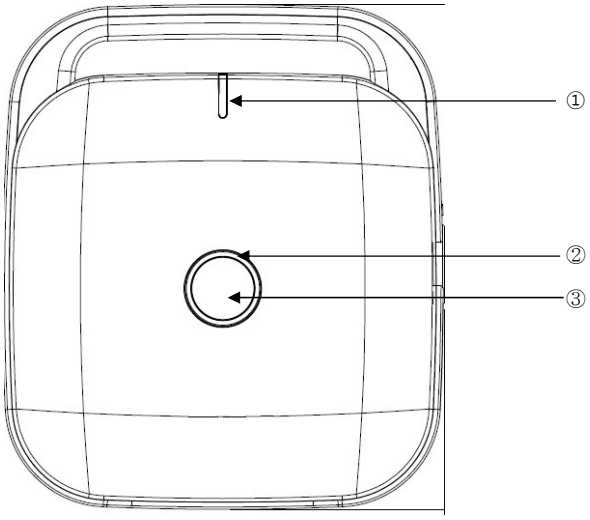
⑥ Hanger (1ea)

⑦ Silicone Pad (1ea)

⑧ USB Lock Key (1ea)

Cardio P1 Body Configuration

▣ Top View

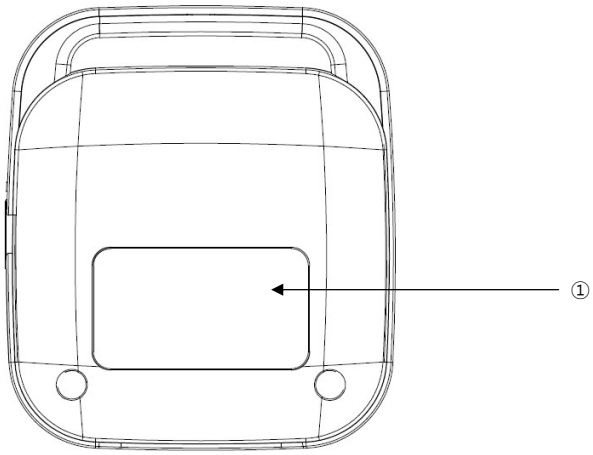


① Power Indication Part (LED) : Part showing the power connection status of a product

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

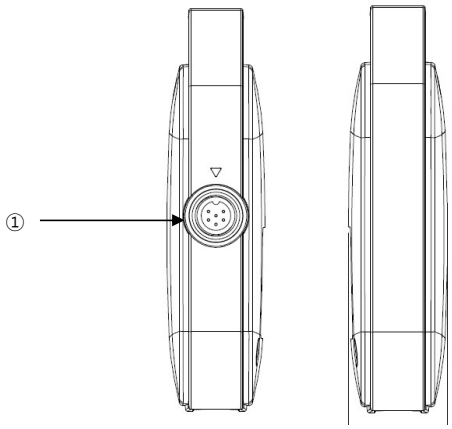
③ Function Switch : Auto operation (push more than 3 seconds), event marker key

▣ Bottom View



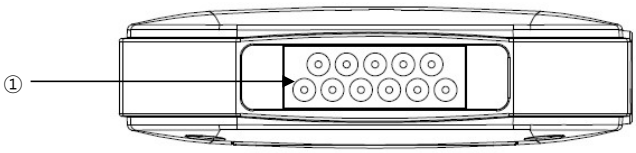
① ID Label : Part to attach ID Label

▣ Side View



① Power (USB Data) Cable Connection Port

▣ **Rear View**



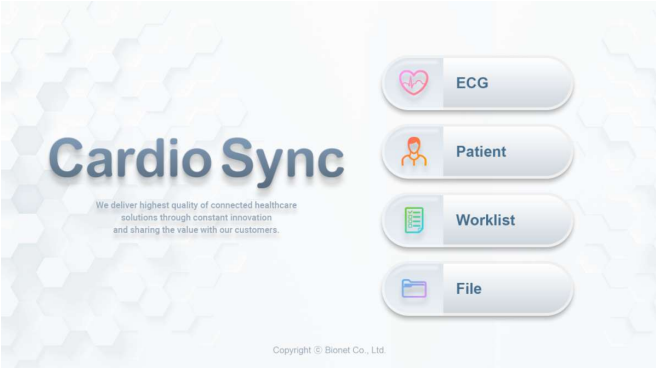
① ECG Cable Connection Port

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.

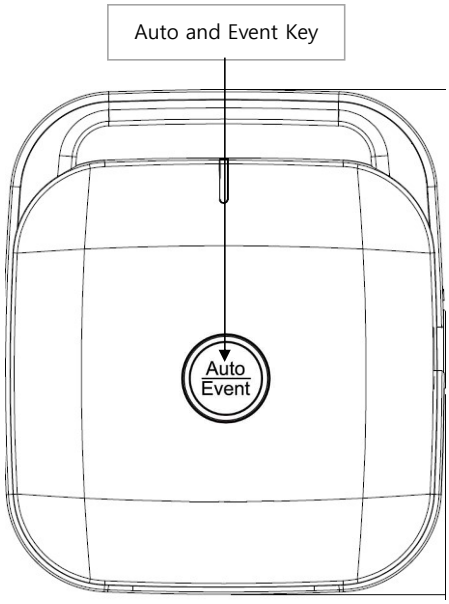
Note
Do not open the cover of the equipment; it may cause an electric shock. Repair or disassembly of the equipment can only be performed by those who have product repair qualifications recognized by Bionet.

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

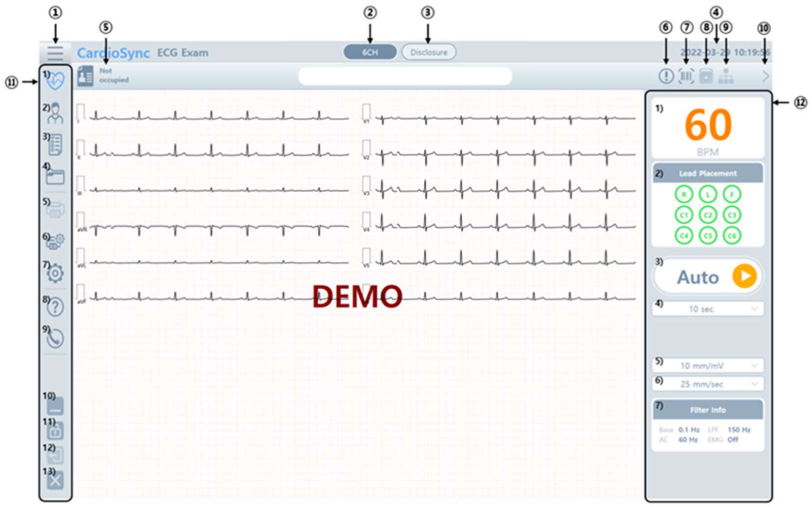


Graphic Display Window



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 Indicate Retry queue (sending failure list management) icon
⑦ Access status of external devices (barcode reader)
⑧ Access status of Cardio P1
⑨ Menu button for network connection status and setup
⑩ Button for expand/collapse Side Menu
⑪ 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

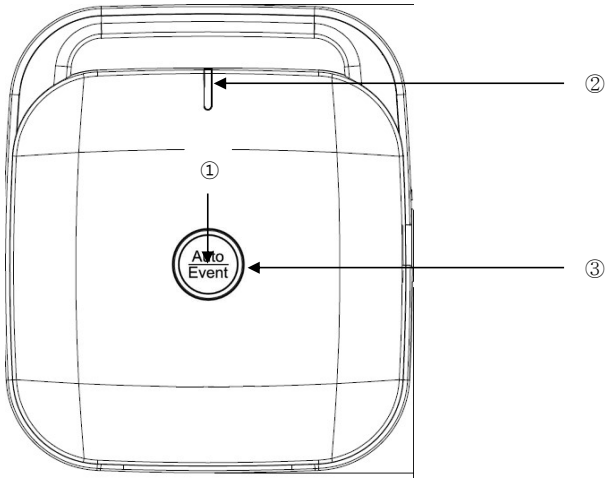
7) Setup menu button
8) Display manual button
9) Show manual
10) Minimize button
11) Show contact us
12) Logout button
13) Close button

⑫ 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 ± 3bpm of error range.

Function Key Panel



▣ Button

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

▣ 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℃ 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

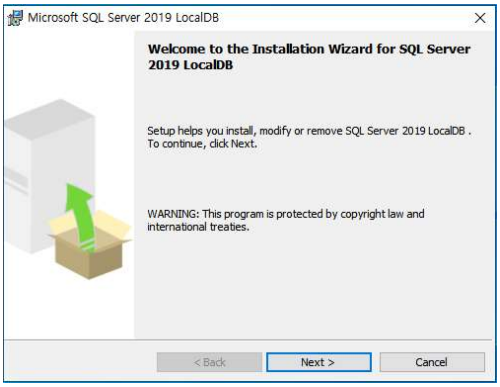
How to install the Software

Add software for the description below.

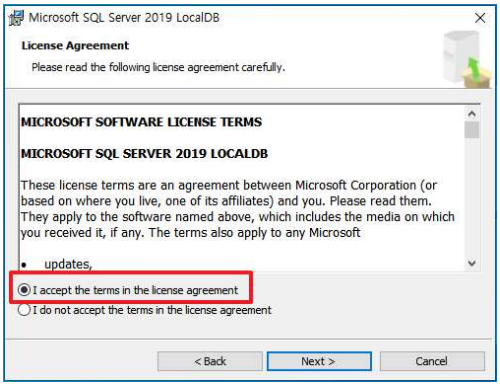
① Close every application before beginning installation.

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

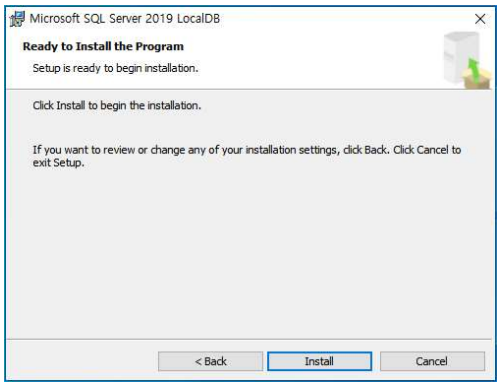
③ Follow each instruction on each step.



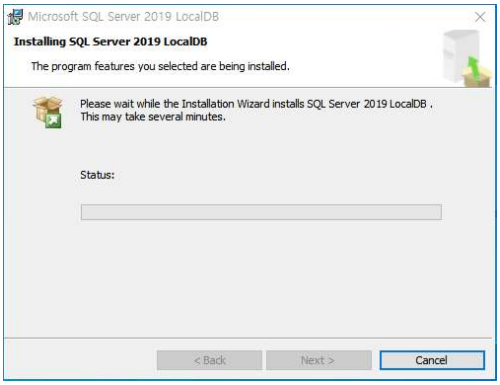
< Step 1>



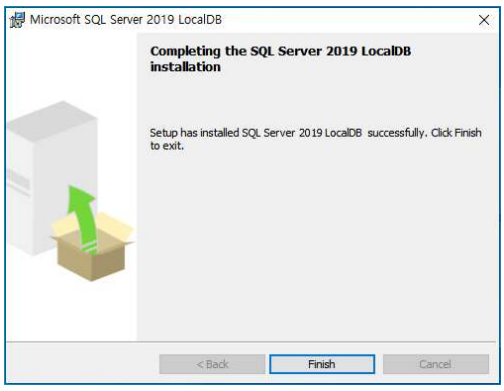
< Step 2 >



<Step 3 >



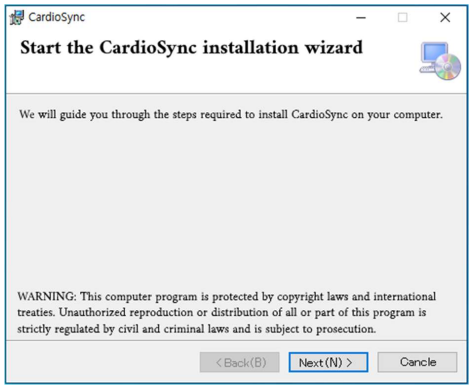
< Step 4 >



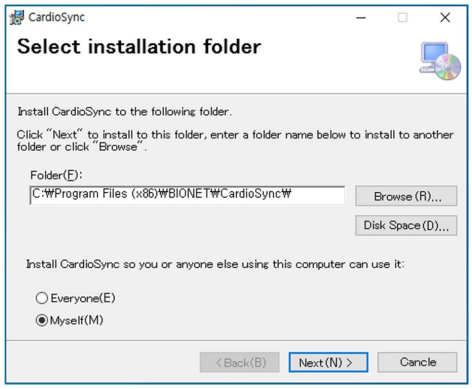
< Step 5 >

④ Execute "setup.exe" or "Cardio P1 ECG_X.XX.XXX_YYYYMMDD.msi" under your CD-ROM drive, download folder or USB memory.

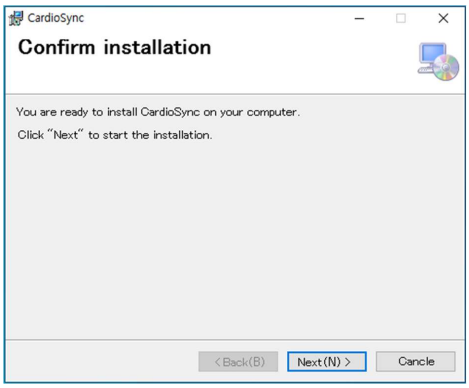
⑤ Follow each instruction on each step.



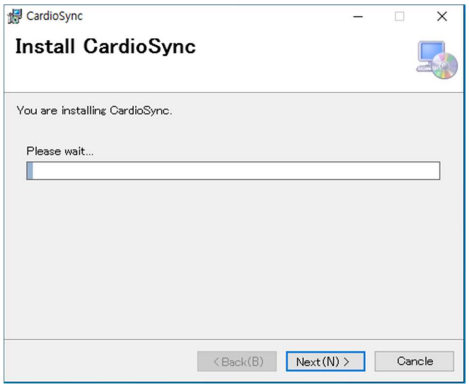
< Step 1 >



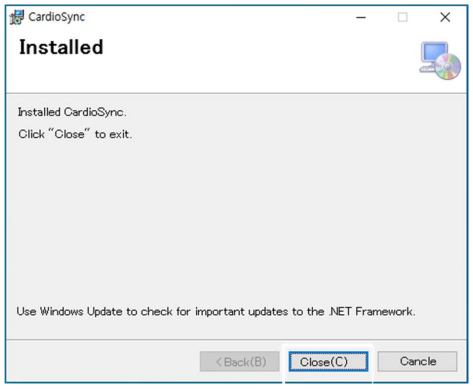
< Step 2 >



< Step 3 >



< 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.

LAN Network

Generally, the LAN networks are configured based on a star topology. You can group Individual computers together via layer-n-switch. Other data traffic is separated by other VLAN networks. Configure the network according to this manual and your network specifications.
LAN connection specifications are described in the following standards.

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

The data transmitted on the wireless network can be secured by one of the following methods:

- WEP
- WPA-PSK
- WPA2-PSK

If the computer on which the software is used as a layer-2-switch or layer-3-switch, the port settings must be configured on the network switch. Configure the network of computers on which the software to be compatible with the specifications of your operating organization.
The computer on which the software exchanges data with other medical devices via a LAN network. The network must support the following protocols:

- TCP/IP
- BROADCAST

VLAN Network

If data is exchanged within a single network, you must establish an independent VLAN network for clinical information systems, such as a network dedicated to medical devices in hospitals. Also, you should build a network system that detects and defends against denial-of-service attacks by establishing a system dedicated to DDos protection.

When using an inappropriate network

If your network does not meet the requirements, the following may occur:

- Without a firewall and antivirus software:
  - Data is not protected.
  - Data is transferred incomplete or not transferred at all.
  - Data may be sent to the wrong server.

- Data may be blocked, forged or damaged.

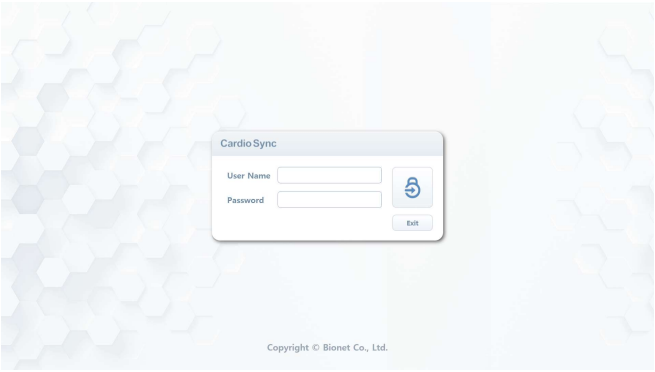
- Without an independent network configuration or dedicated system for DDos defense:
  - You may be subject to denial of service attacks (DDos). In this case, the equipment may become slow or may not work properly. In rare cases, you may experience the delayed or repeated booting.

Network Security

- Ensure that appropriate security measures are taken to protect data transmission.
- Security of the network is the sole responsibility of the network operator.
- Bionet recommends the following to guarantee the security of the network.
  - Define access authorization for the configuration of the host system so that no unauthorized alterations of the system can occur.
  - Install an up-to-date antivirus/firewall program so that any malware cannot jeopardize the system.
  - Update the security and software regularly.
  - Apply the "Risk Management of IT Networks" according to IEC 80001-1.

6) System the Start

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



Login

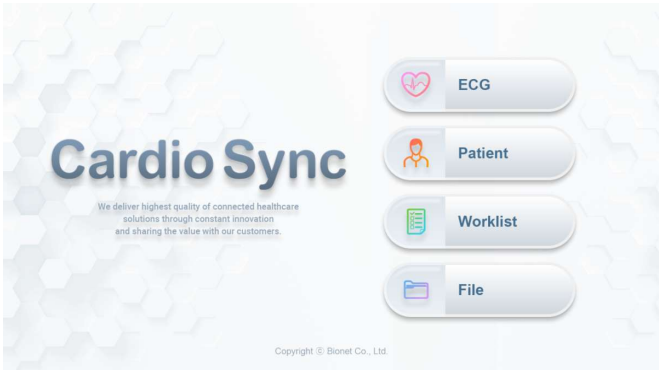
Enter your ID and password.

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.

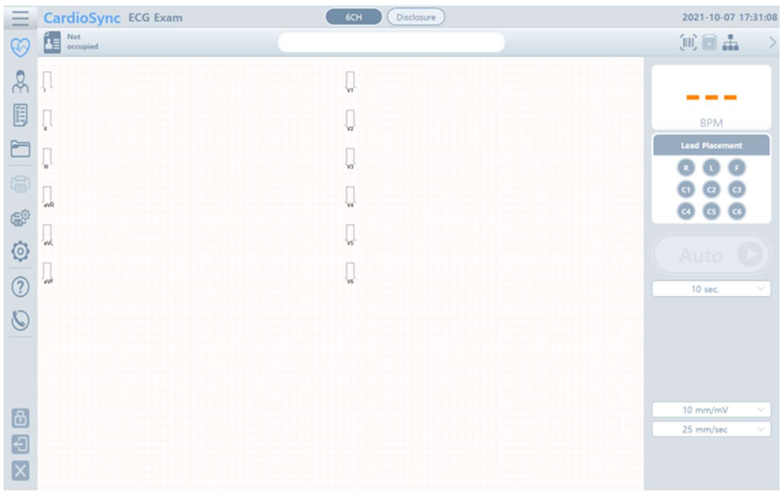
See "Chapter 2. ECG Recording Preparation – 7) System Setup" for individual users and their privileges.

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.



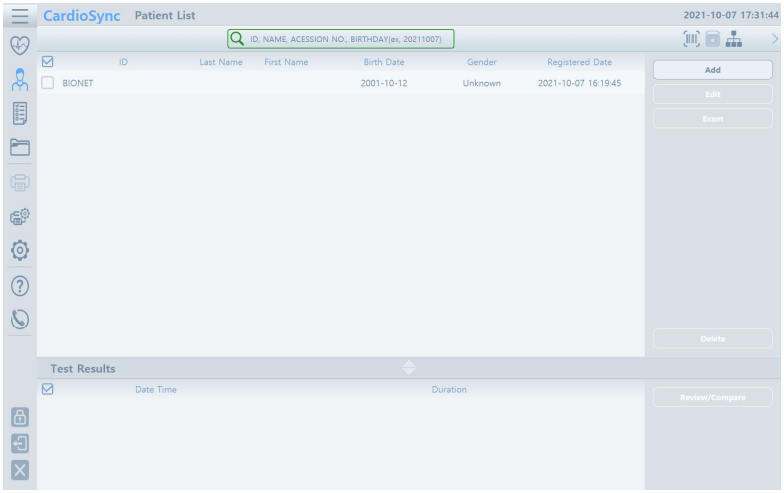
If you know the following on the ECG initial screen, you can use it more conveniently.

Menu	explanation
Not occupied	Enter patient information or confirm contents
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 (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
	Indicate or setup the current date or time
	Indicate or setup the print speed
	Indicate or setup the signal size
	Set filter value display window

Note
Function keys available in Cardio P1 - F9 Button : Auto - F10 Button : Save - F11 Button : Export - F12 Button : Print

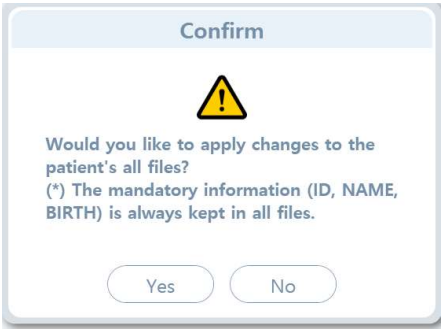
The following is the patient examination data management screen that moves when the 'Patient List' menu is selected.



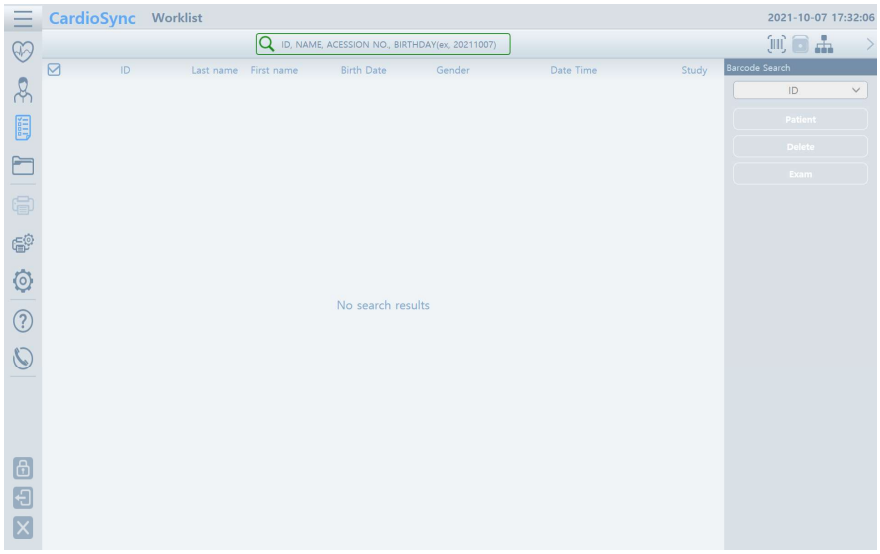
Followings are recommended to know on the exam request data managing screen for more convenient usage.

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

Note
Applicable matters when editing patient information. - Basic Item (ID, Name, Birth) : DB, All files - Additional items (ETC.) : DB, User decides whether to apply to all files



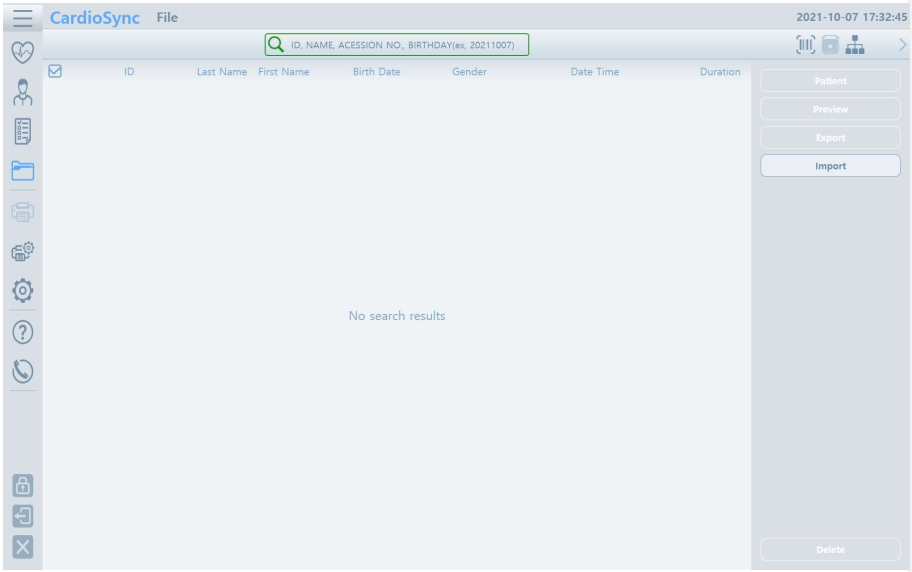
Following is the ECG data file managing screen when selecting 'Worklist' menu.



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
Exam	Move to the exam screen
Update	Get Worklist Menu button that appears when PACS or GDT is connected
ID	Search condition setting
Patient	Check patient information

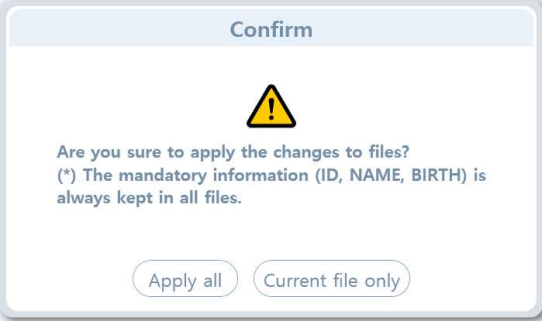
Following is the ECG data file managing screen when selecting 'File' menu.



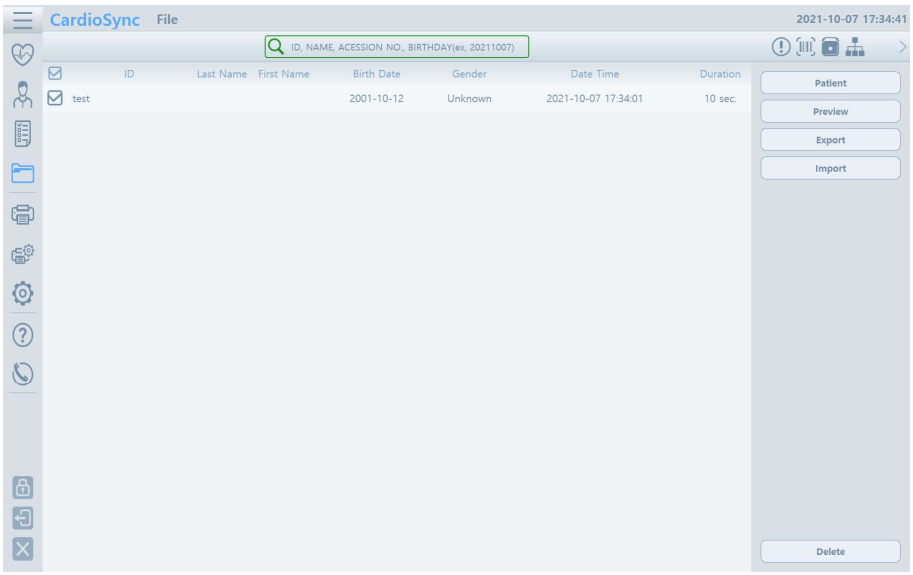
Followings are recommended to know on the data file managing screen for more convenient usage.

Menu	Explanation
	Search for data after entering searching conditions

Export	File export
Import	File import
Preview	File preview
Patient	Check patient information

Note
Applicable matters when editing patient information - Basic Item (ID, Name, Birth) : DB, All files - Additional Item (ETC.) : DB, User decides whether to apply to all files or the current file 

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.

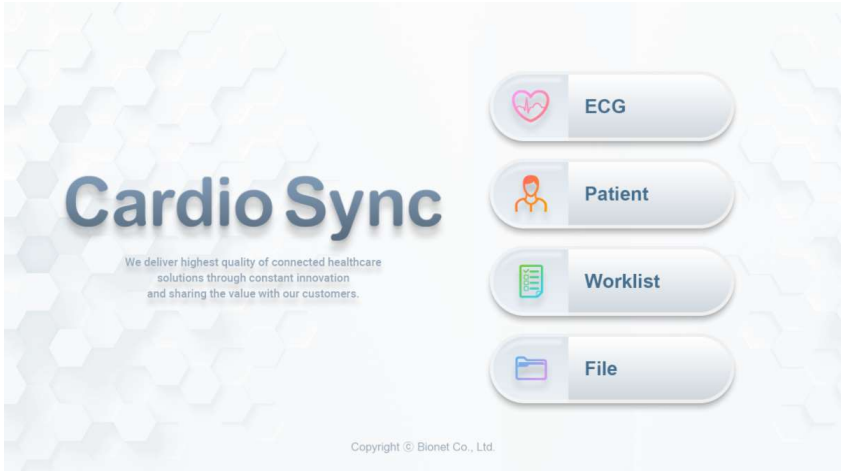


Followings are recommended to know on the Retry Queue managing screen for more convenient usage.

Menu	Explanation
Export	Send selected data
Delete	Delete selected data

Note
- icon is indicated on the right top corner only if there is an error while sending files.

Part I. Using ECG



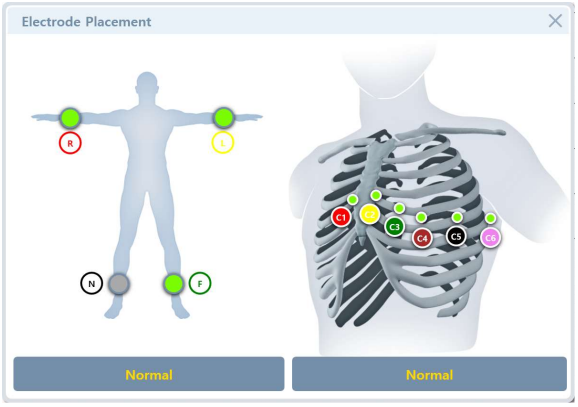
Chapter 2. ECG Recording Preparation

1) Attaching the Electrodes

If clicking 

(Lead Fault Information indication) located in the middle of upper menu bar of ECG main screen, the image will show to indicate the location for attaching the lead.

Make sure to attach electrode to the patient body as follows to record standard 12 lead ECG.



Location of limb electrode is as follows.

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

Location of chest electrode is 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) Electrode Connection

*** Confirmation**

- Make sure to check the attachment status of each electrode of patient as well as equipment prior to measurement
- Make sure to see if there is any mechanical risk
- Make sure to check the cable and accessories connected to outside
- Make sure to check all the measuring devices for the patients

Patient Cable Connection

Connect the patient cable to the port on the underside of body and connect limb electrodes to the terminals of 'RL(N), LL(F), RA(R), 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)'

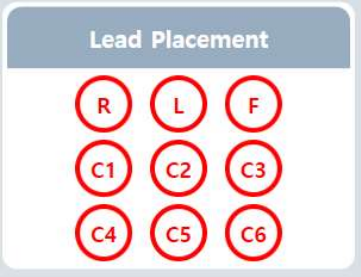
How to Attach Electrode

Lay the patient on the bed in stable manner, relax the area of body to attach the electrode and clean the area with disinfected alcohol or water before attaching electrode. If there is much hair on the body of a patient, make sure to remove hair. If it is difficult to attach electrode due to curve on the area to electrode, make sure to attach electrode on the area without curve as close as to the original spot.
In case of too much noise after using alcohol or water, make sure to apply ECG gel on the area and attach electrode.
If using ECG gel, make sure to remove ECG gel after using it. If ECG gel is hardened, there might be noise on ECG signal.

Warning
Make sure to use only the electrode and patient cable provided by our company. Our company is not responsible for accidents caused by ignoring them.

Actions to Take for Poor Lead Connection

Enter the ECG mode after turning the power switch on and confirm the waved of all the leads. At this time, it is available to confirm the degree of noise in wave as well as connection status while indicating the message in case of lead fault.



Note
- If 'Lead Fault' is on in the ECG General Setup, message is shown. If it is off, Lead Fault message is not shown. - Fault lead is in red and saturated lead is shown in yellow. - Make sure to attach the lead for normal indication prior to conducting the ECG test.

There are two types of error in lead connection.

- First of all, it is when lead is detached from patient body. At this time, make sure to attach the electrode again depending on how it is attached.
- Secondly, it is the low conductivity between the body of a patient and electrode. At this time, make sure to apply ECG gel or water on the appropriate area and re-attach electrode with right method.

If ECG signals do not come out well after trying these two methods, patient cable might be non-conforming. Make sure to contact A/S center of our company.

3) Start Recording ECG

- Enter the patient information according to the right method.
- Connect patient with ECG cable according to the preparation of ECG.
- Check setup status of filter, signal size, output speed, channel configuration and rhythm and setup to the preferred value if preferring to change.
- If wave shown on the LCD screen is abnormal, or if there is too much noise, make sure to take an action according to the 'action to take for poor lead connection.

- If wave shown on the LCD screen is normal, press 'AUTO' key to record ECG of a patient.
- To stop the operation during ECG measurement or saving, press the 'STOP' button.

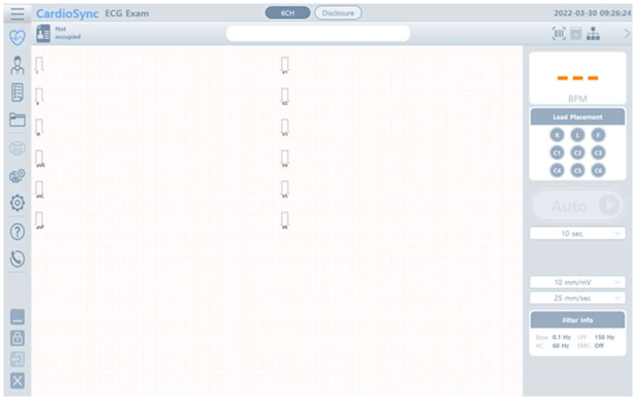
4) Basic Setup

General Information

When moving to the ECG window, a screen consisting of up, left, and right menu bars and a graphic display window is displayed on the screen.

The upper menu bar displays patient information, name, transmission failed file status, external device connection status, network setting button, ECG module connection, current date and time, and the left menu bar displays patient information, worklist, file, print, The menu buttons for print setup, system setup, help, program information, screen freeze, logout, and program end are displayed. are displayed in order.

If you click the menu button on the graphic, a menu window where you can change the information is displayed, and you can change the information easily.



Changing the setting value using the mouse

- Select menu

Press the on-screen menu button.

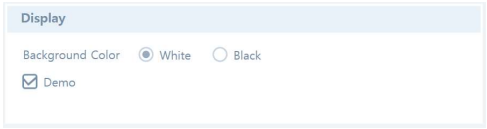
- Apply setup values

Select the relevant item in the menu window and click the OK button.

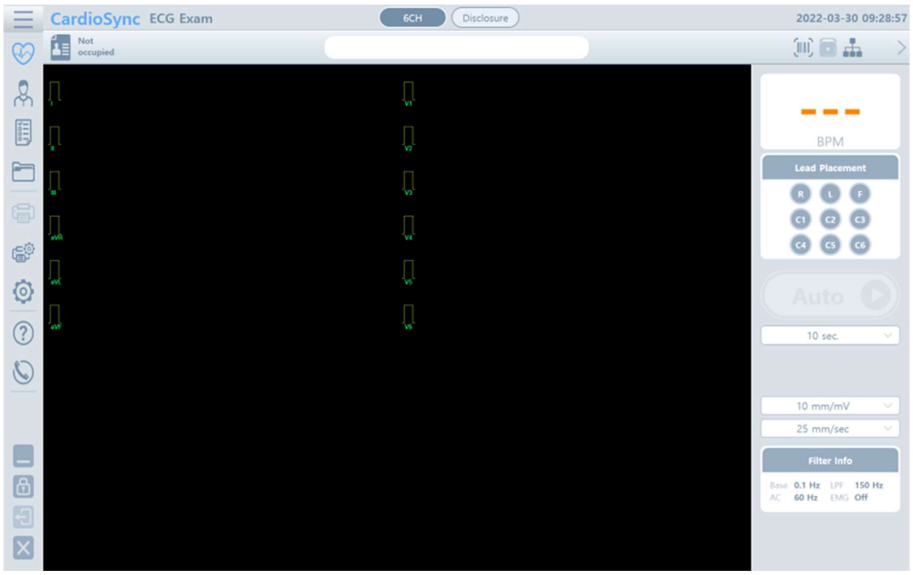
Screen Output

Output the signals of currently measured ECG on the LCD on a real-time basis
Make sure to check signals on the output prior to starting diagnosis and test after confirming that all the lead signals correctly come out

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.

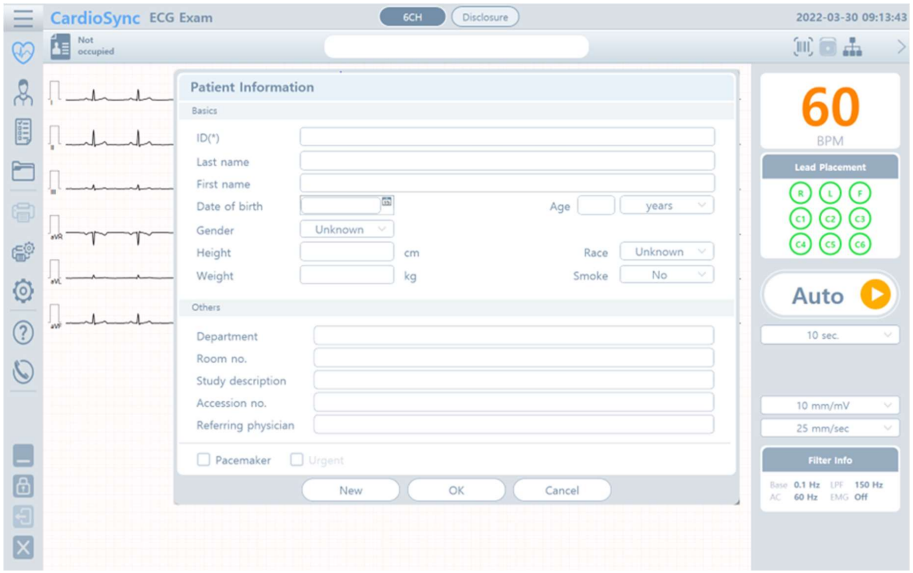


If black is selected, the screen below is displayed, and the grid is not displayed.



Enter Patient Information

It is available to enter ID, name, age, gender, height, and weight of a patient.
Items indicated with '*'on the patient information window are required items.
Automatic diagnosis for 10 seconds-recording is available in custom to pediatrics and adults.
Automatic diagnosis is provided according to the entered age of patient.



Enter ID

Enter the unique number used in the hospital to classify the patient's treatment results. If you select 'ID' input, you can enter your ID.

Note
- ., ", <, >, ?, /, *, |, :, ₩ & symbols shall not be used when entering ID. - When entering ID, make sure to enter only alphabets and numbers. If entering ID with Latin extended texts or Russian language, there might be an error when transmitting it to the PC or USB memory.

Enter Name

Entered in the same manner with ID

Enter Date of Birth

If you press the input field of Birthday, the calendar-type date input window as shown below appears. Enter the patient's date of birth manually or select it from the calendar. When you enter your date of birth, your age is automatically calculated and entered.

Enter Age

Enter the patient's age manually.

For Age, enter the age in years for children over 1 year old, and enter weeks or days for children under 1 year old.

Note
- Age is automatically calculated when entering birthday. - If age is not entered, adult diagnosis is provided.

Enter Gender

Select male or female if clicking gender window

Enter Height

Enter in the same manner with 'age'

If height unit in the system general setup is in inch, make sure to enter them in ft and inch values.

Enter Weight

Enter in the same manner with age

Enter Race

Enter the race of a patient. As for race, Asian, White and Black are registered. Click the race entry window and select items.

Enter Smoke

Enter smoking status of a patient.

Enter Urgent

Mark patients requiring urgent treatment

Enter Pacemaker

If pacemaker signal is entered, it is to setup whether to show pacemaker location on the output of rhythm or diagnosis.

If set to be 'On,' pacemaker location is shown. If set to be 'Off,' it is not shown.

Note
- 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.' - In case of lead fault, pacemaker signal might not be detected.

Other entries

Information of department, room no., study description, accession no. and referring physician can be entered in the same manner with ID.

If patient information is entered, make sure to confirm entered information and select 'Ok' button on the patient information widow to save the setup. If selecting 'Cancel' button, setup is cancelled. If clicking new button, all the entered patient information is initialized.

Enter Patient Information in the Use of Barcode Readers

It is available to enter patient information using barcode reader. Locate the cursor on each item of the patient information window and scan the barcode to automatically enter.

Patient ID is entered when scanning barcode on the ECG main screen.

Barcode reader is available with any products.

However, default setting of entry might be different for each product. Therefore, it is required to confirm how Bionet Corporation supports such entry.

- Entry method supported on products of Bionet Corporation: International standards, USB
- Following is the list of products connected to products of Bionet and tested hereof.

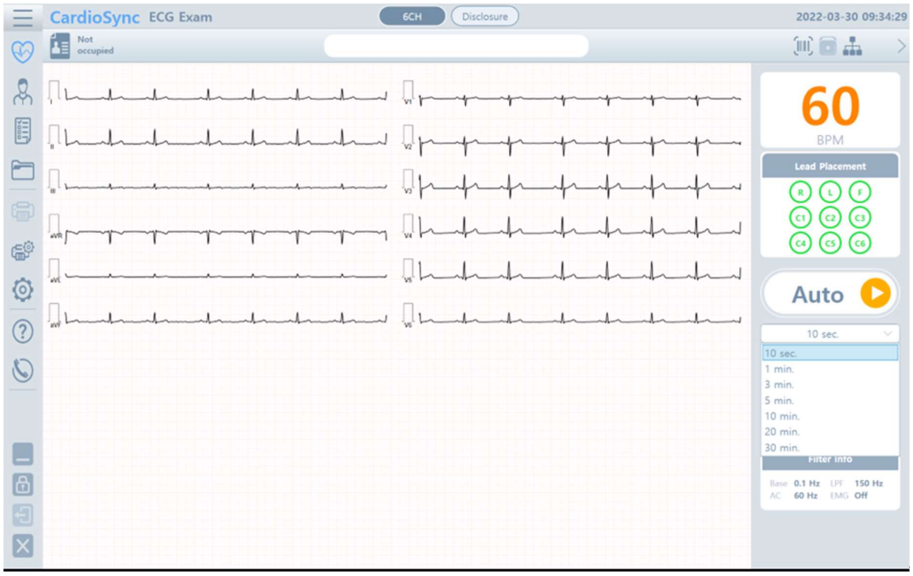
No.	Manufacturer	Product name	Product image
1	Symbol	LS-2208	
2	ZEBEX	Z-3110	
3	Honeywell	MS5145	
4	Honeywell	DS2208	

Note
Barcode reader includes initialization code in each product. Confirm the entry method in the user manual and initialize.

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.

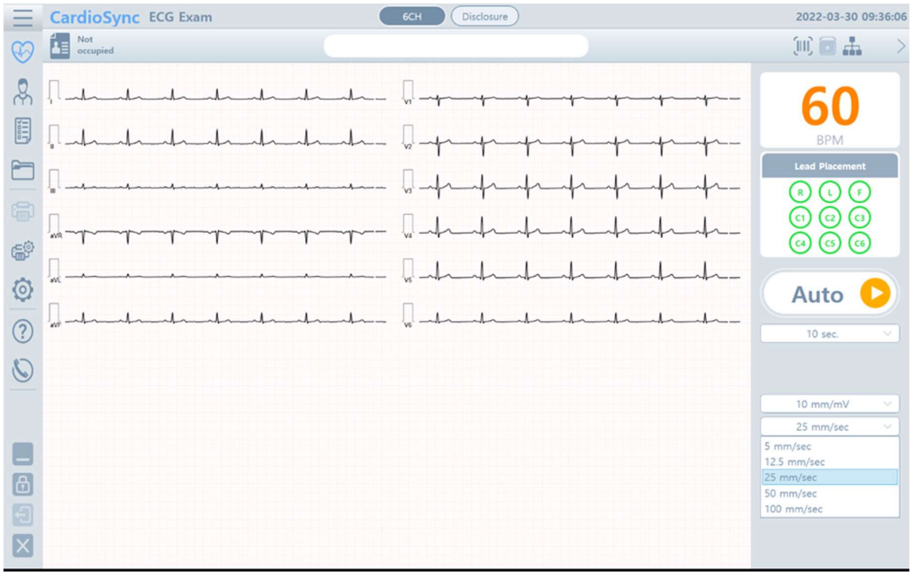
It can be set to 1, 3, 5, 10, 20, or 30 minutes, and at this time, it is output with the set lead.



Note
Usually, Lead II is the largest, so you can set Lead II, but if the lead II waveform is small, select another lead with the largest and best output.

Setup Output Speed

This is the function to adjust signal width on output. There are five values available as 5mm/sec, 12.5mm/sec, 25mm/sec, 50mm/sec, and 100mm/sec. 25mm/sec means that ECG signal is recorded on 25mm for 1 second.



Note
- 12.5mm/sec is always shown if setting the recording mode as 3, 5, 10, 20 and 30min.

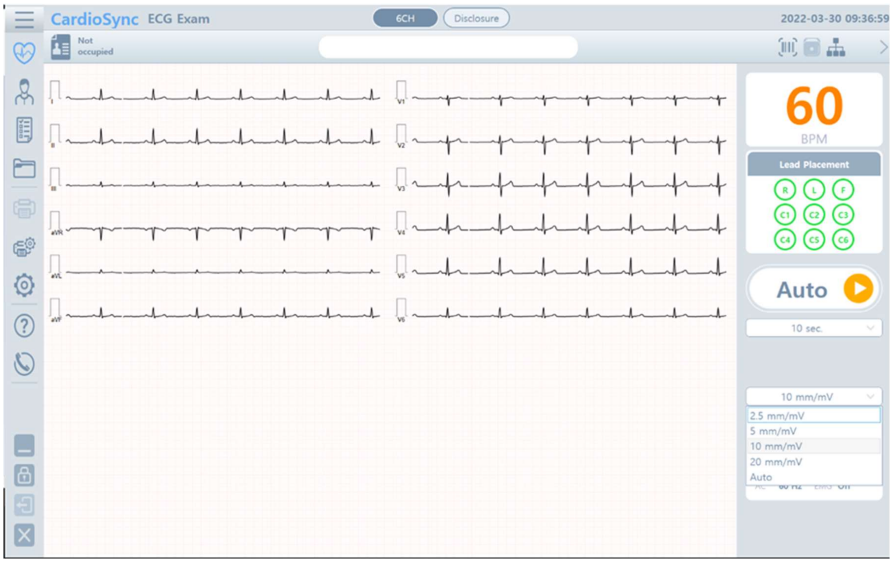
Setup Signal Scale

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.

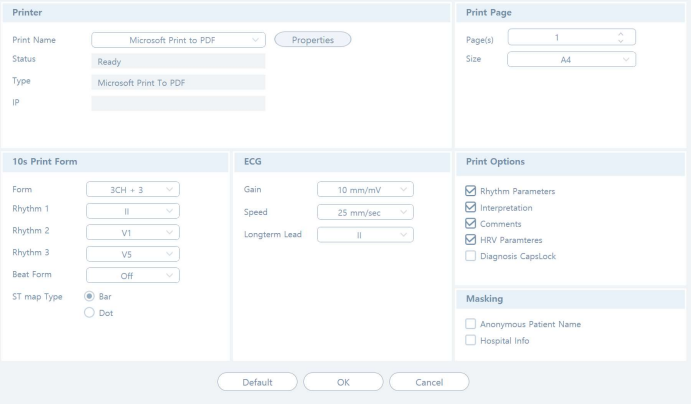
10mm/mV means to output the signal in 1mV in the size of 10mm.

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.



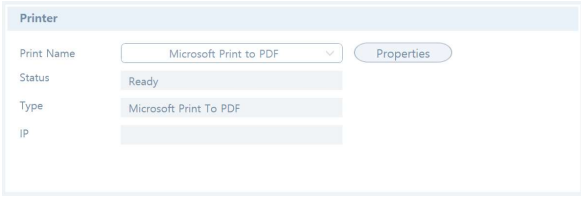
Note
- On the output of recording mode in the setup of 10sec, the preview gain window can modify. - On the output of recording mode in the setup of 1min, the preview gain window cannot be modified, output with preset gain. - On the output of recording mode in the setup of 3, 5, 10, 20 and 30min, the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

Setup Print



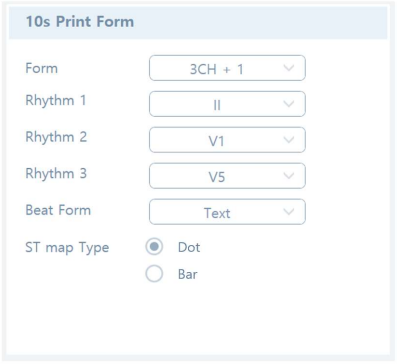
Printer

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



10s Print Form

Setup diagnosis output form.



Form

Output form	Explanation
3CH+3	Record ECG for I, II and III for the first 10 seconds, aVR, aVL and aVF for the next 2.5 seconds, V1, V2 and V3 for the next 2.5 seconds and V4, V5 and V6 for the next 2.5 seconds. Record rhythm of 3 leads at the bottom for 10 seconds.
3CH+1	Record ECG for I, II and III for the first 10 seconds, aVR, aVL and aVF for the next 2.5 seconds, V1, V2 and V3 for the next 2.5 seconds and V4, V5 and V6 for the next 2.5 seconds. Record rhythm of 1 lead at the bottom for 10 seconds.
6CH+1	Record ECG for I, II, III, aVR, aVL and aVF for the first10 seconds and V1, V2, V3, V4, V5 and V6 for the next 5 seconds, record rhythm of 1 lead at the bottom for 10 seconds.
12CH	Record rhythm of 12 leads in an order of I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6 at the same time for 10 seconds.
6CH+1(ST)	The 8-second ECG is recorded for I, II, III, aVR, aVL, aVF for the first 4 seconds, V1, V2, V3, V4, V5 and V6 for the next 4 seconds, the ST Map is marked on the right and the Record the rhythm at the bottom for 10 seconds.

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

In case of diagnosis output, representative rhythm lead used in 3CH+3, 3CH+1 and 6CH+1 is setup. If 3CH+3 is setup for the diagnosis output form, all three selected forms shall be used. If 3CH+1 and 6CH+1 are selected, only the first value shall be used.

Default is set to be II, V1 and V5. As for 3CH+1 and 6CH+1, II is to be used. In case of 3CH+3, all II, V1 and V5 shall be used.

Beat Form

Text, Guide and Vector can be selected as a form for additional output after diagnosis.

50mm/sec is to be shown regardless of output speed.

Output form	Explanation
Text	Output representative beat and each of the diagnosis parameters
Guide	Output the representative beat and each of the diagnosis parameters along with diagnosis guide for arrhythmia

Vector	Output the representative beat and each of the diagnosis parameters and indicate and output vectors of QRS in arrow
ST Map	It outputs the representative bit and each diagnostic parameter and outputs the ST map.

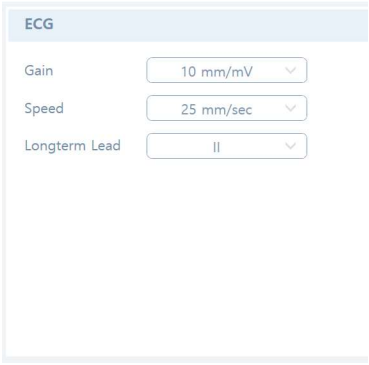
ST Map Type

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

Output form	Explanation
Bar	It outputs the ST map in the form of a bar.
Dot	It outputs the ST map in the form of dot.

ECG

Setup recording output form.



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.

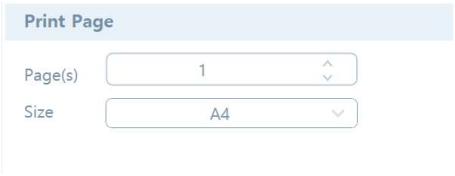
Long Term Lead Setup

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
Normaly, 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



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.

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

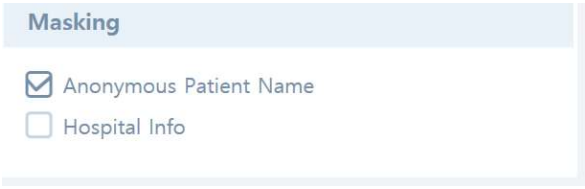
Select whether to output HRV parameters when outputting records.

Diagnosis Caps Lock

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

Masking

Set to de-identify patient information when printing.



Anonymous Patient Name

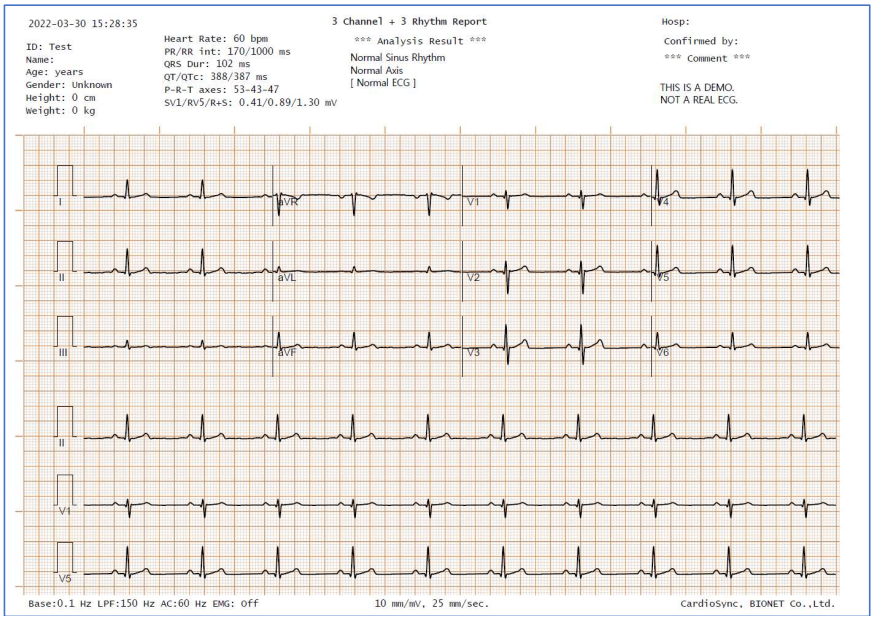
The patient's name is de-identified and hidden and printed.

Hospital Info

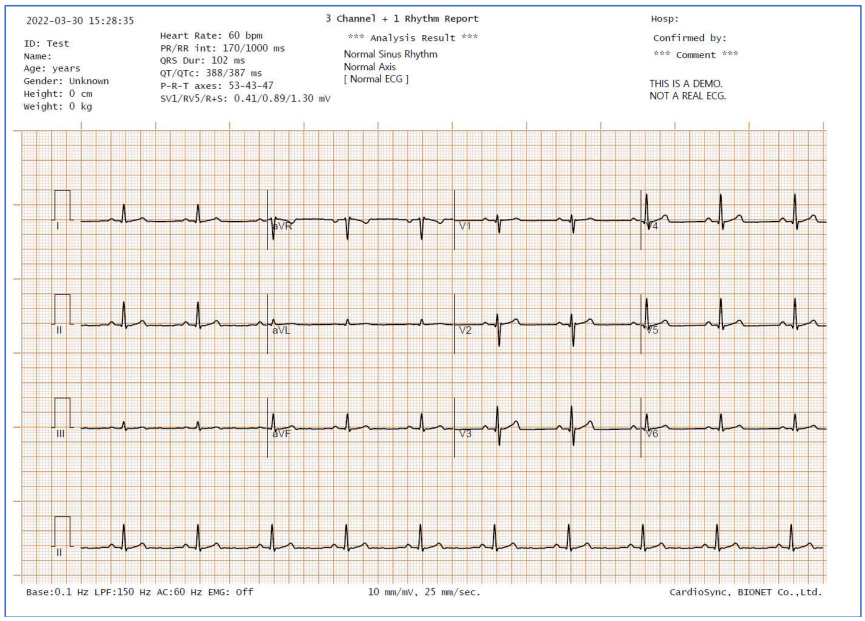
Hospital information is de-identified, hidden and printed.

Following is the example of output form.

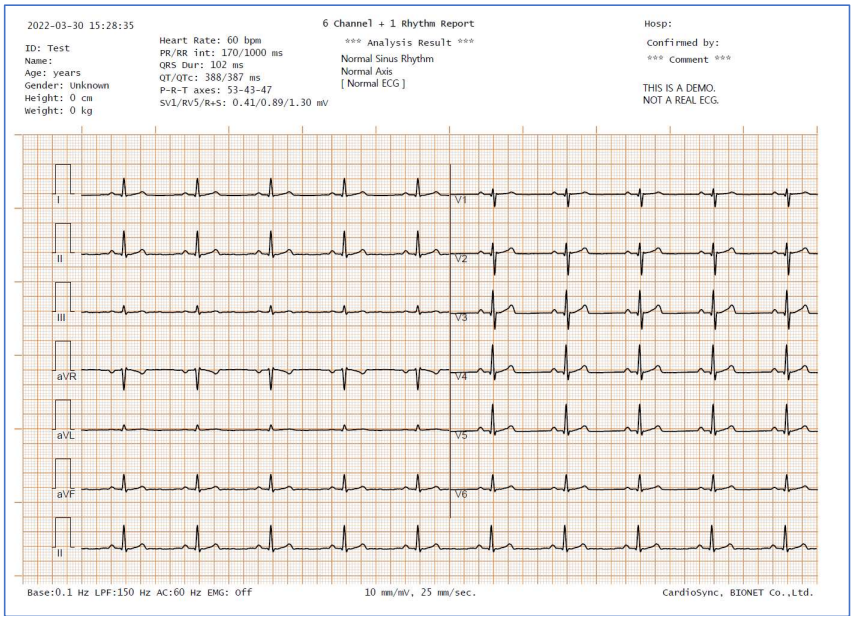
Diagnosis Output Form (3CH + 3RHY)



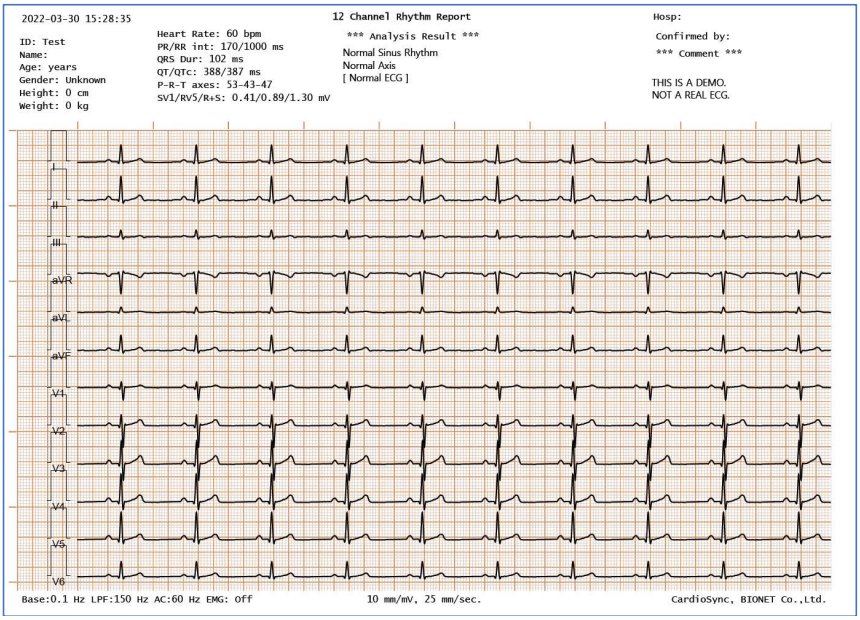
Diagnosis Output Form (3CH +1RHY)



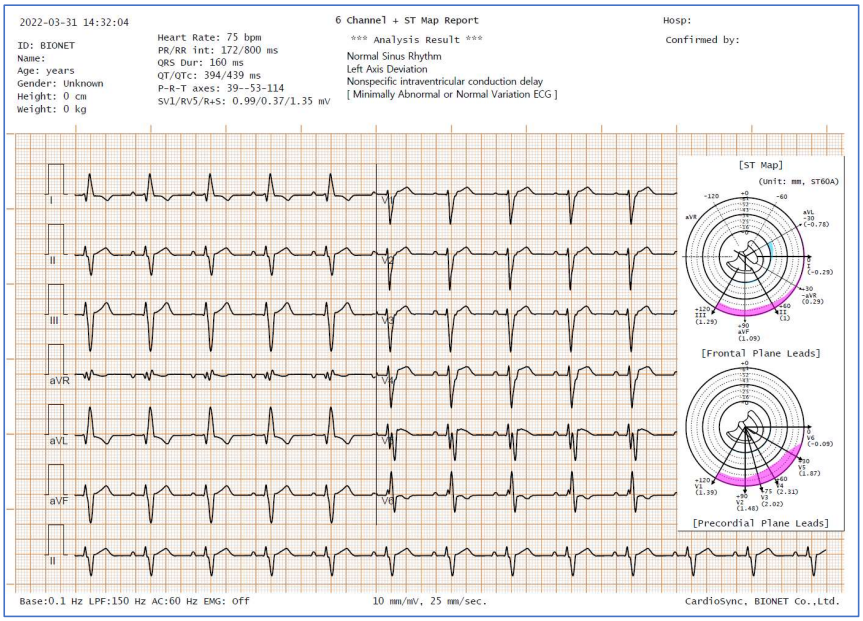
Diagnosis Output Form (6CH +1RHY)



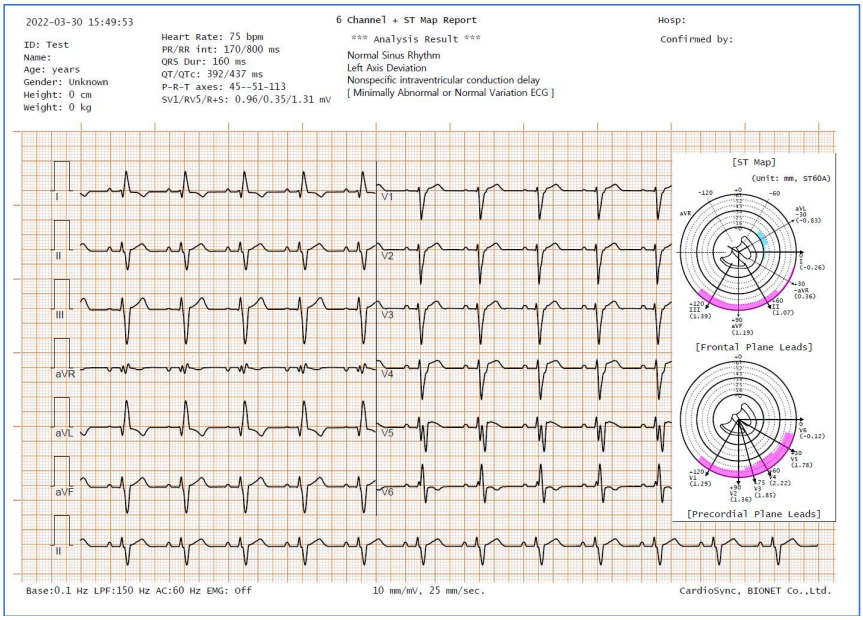
Diagnosis Output Form (12CH)



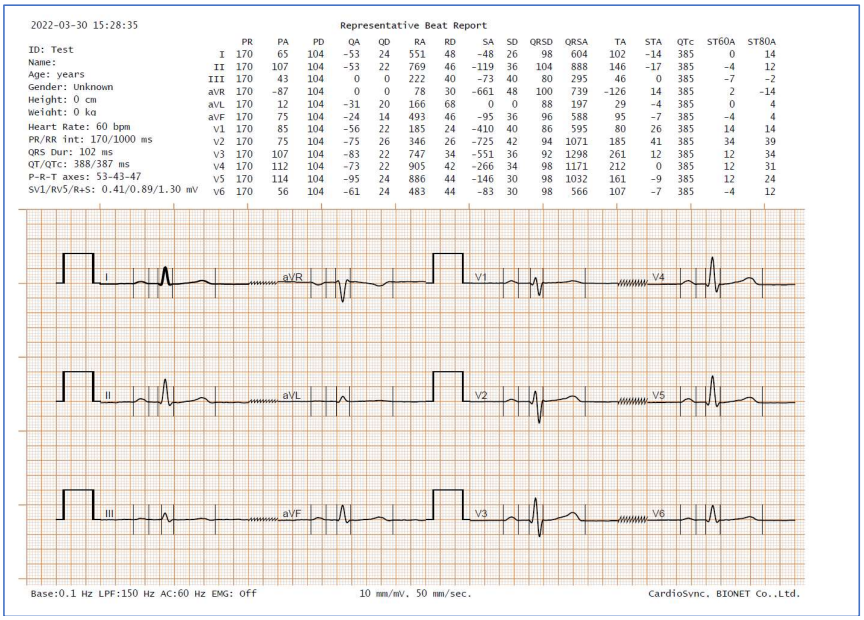
Diagnosis Output Form (6CH+1(ST)-Dot)



Diagnosis Output Form (6CH+1(ST)-Bar)



Diagnosis Output Form (BEAT REPORT - TEXT)



2022-03-30 15:28:35

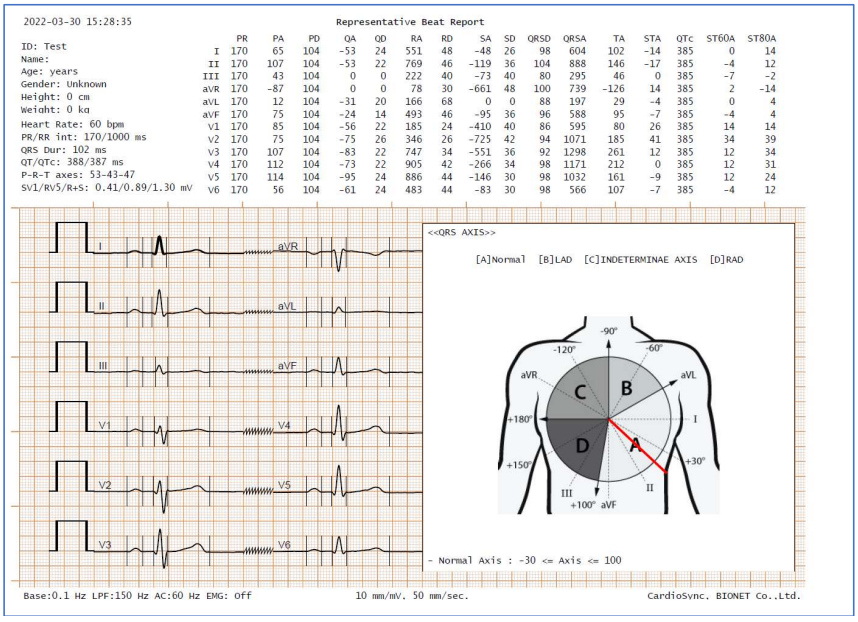
Representative Beat Report

ID: Test
Name:
Age: years
Gender: Unknown
Height: 0 cm
Weight: 0 kg
Heart Rate: 60 bpm
PR/RR int: 170/1000 ms
QRS Dur: 102 ms
QT/QTc: 388/387 ms
P-R-T axes: 53-43-47
SV1/RV5/R+S: 0.41/0.89/1.30 mV

	PR	PA	PD	QA	QD	RA	RD	SA	SD	QRSD	QRSA	TA	STA	QTc	ST60A	ST80A
I	170	65	104	-53	24	551	48	-48	26	98	604	102	-14	385	0	14
II	170	107	104	-53	22	769	46	-119	36	104	888	146	-17	385	-4	12
III	170	43	104	0	0	222	40	-73	40	80	295	46	0	385	-7	-2
aVR	170	-87	104	0	0	78	30	-661	48	100	739	-126	14	385	2	-14
aVL	170	12	104	-31	20	166	68	0	0	88	197	29	-4	385	0	4
aVF	170	75	104	-24	14	493	46	-95	36	96	588	95	-7	385	-4	4
V1	170	85	104	-56	22	185	24	-410	40	86	595	80	26	385	14	14
V2	170	75	104	-75	26	346	26	-725	42	94	1071	185	41	385	34	39
V3	170	107	104	-83	22	747	34	-551	36	92	1298	261	12	385	12	34
V4	170	112	104	-73	22	905	42	-266	34	98	1171	212	0	385	12	31
V5	170	114	104	-95	24	886	44	-146	30	98	1032	161	-9	385	12	24
V6	170	56	104	-61	24	483	44	-83	30	98	566	107	-7	385	-4	12

Base:0.1 Hz LPF:150 Hz AC:60 Hz EMG: Off 10 mm/mV, 50 mm/sec. CardioSync, BIONET Co.,Ltd.

Diagnosis Output Form (BEAT REPORT - VECTOR)



2022-03-30 15:28:35

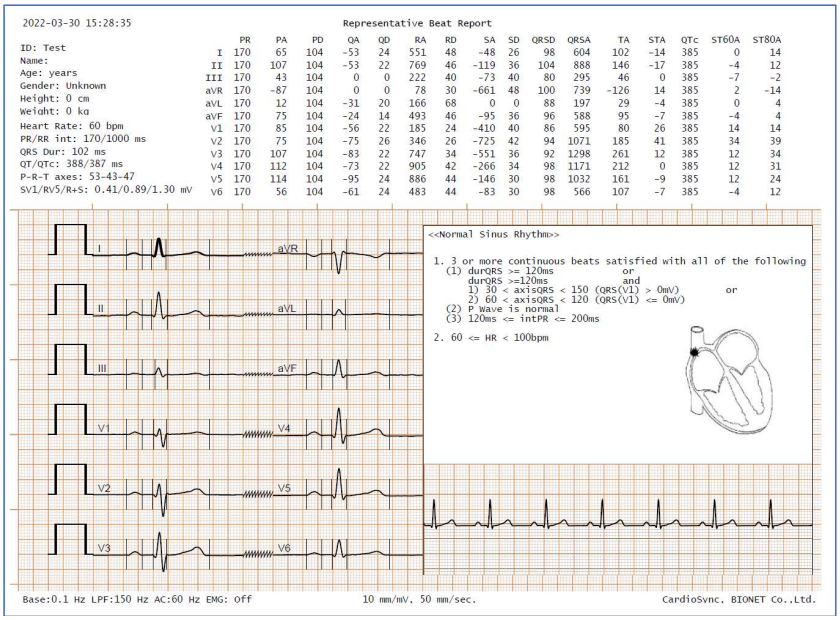
Representative Beat Report

ID: Test
Name:
Age: years
Gender: Unknown
Height: 0 cm
Weight: 0 kg
Heart Rate: 60 bpm
PR/RR int: 170/1000 ms
QRS Dur: 102 ms
QT/QTc: 388/387 ms
P-R-T axes: 53-43-47
SV1/RV5/R+S: 0.41/0.89/1.30 mV

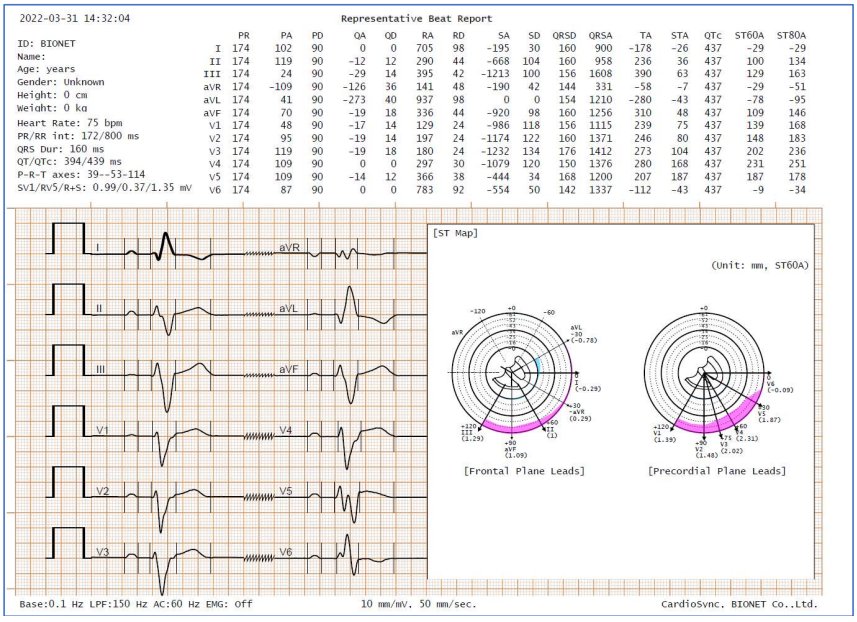
	PR	PA	PD	QA	QD	RA	RD	SA	SD	QRSD	QRSA	TA	STA	QTc	ST60A	ST80A
I	170	65	104	-53	24	551	48	-48	26	98	604	102	-14	385	0	14
II	170	107	104	-53	22	769	46	-119	36	104	888	146	-17	385	-4	12
III	170	43	104	0	0	222	40	-73	40	80	295	46	0	385	-7	-2
aVR	170	-87	104	0	0	78	30	-661	48	100	739	-126	14	385	2	-14
aVL	170	12	104	-31	20	166	68	0	0	88	197	29	-4	385	0	4
aVF	170	75	104	-24	14	493	46	-95	36	96	588	95	-7	385	-4	4
V1	170	85	104	-56	22	185	24	-410	40	86	595	80	26	385	14	14
V2	170	75	104	-75	26	346	26	-725	42	94	1071	185	41	385	34	39
V3	170	107	104	-83	22	747	34	-551	36	92	1298	261	12	385	12	34
V4	170	112	104	-73	22	905	42	-266	34	98	1171	212	0	385	12	31
V5	170	114	104	-95	24	886	44	-146	30	98	1032	161	-9	385	12	24
V6	170	56	104	-61	24	483	44	-83	30	98	566	107	-7	385	-4	12

Base:0.1 Hz LPF:150 Hz AC:60 Hz EMG: Off 10 mm/mV, 50 mm/sec. CardioSync, BIONET Co.,Ltd.

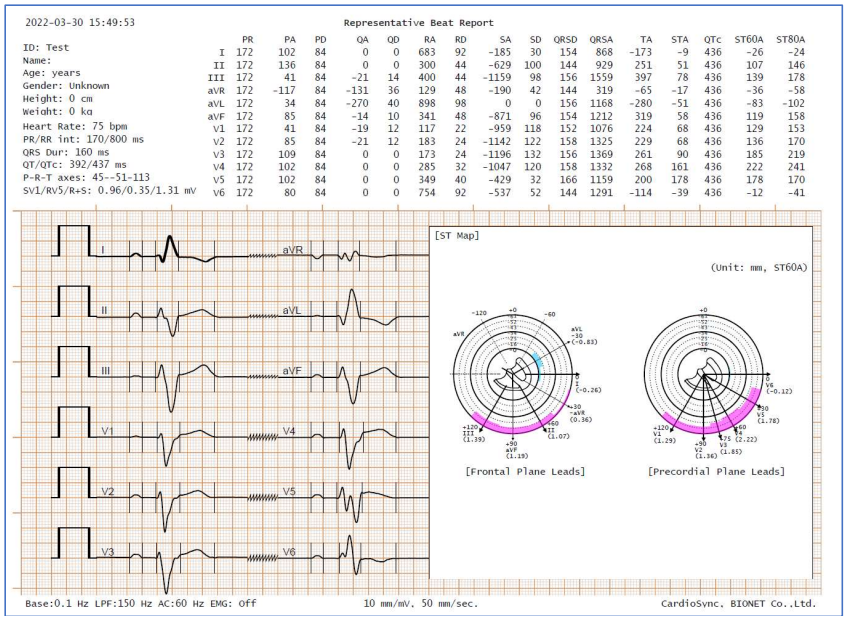
Diagnosis Output Form (BEAT REPORT - GUIDE)



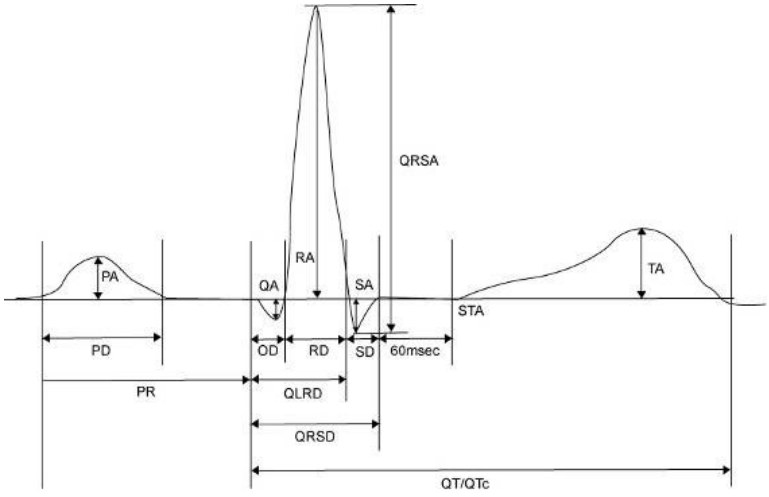
Diagnosis Output Form (BEAT REPORT – ST Map(D))



Diagnosis Output Form (BEAT REPORT - ST Map(B))



*** Explanation of BEAT REPORT Variables**



- PR : PR Interval
- PA : P Amplitude
- PD : P Duration
- QA : Q Amplitude
- QD : Q Duration
- RA : R Amplitude
- RD : R Duration
- SA : S Amplitude
- SD : S Duration
- QRSD : QRS Duration
- QRSA : QRS Amplitude
- TA : T Amplitude
- STA : ST Amplitude
- QTc : Correct Q-T Interval
- ST60A : ST60ms Amplitude
- ST80A : ST80ms Amplitude

Note
The interval (duration, interval) of the parameters output to the Beat Report is in ms and the unit of height (amplitude) is in uV.

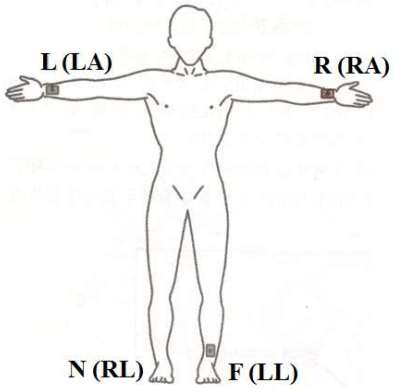
Note

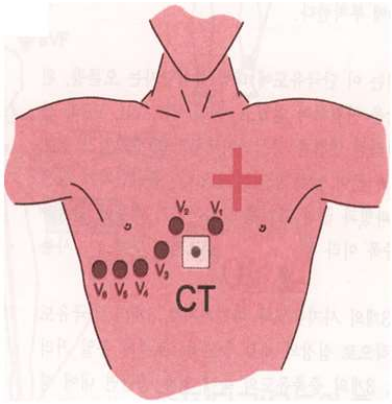
Dextrocardia

People normally have heart on the left side of chest. However, there are cases where heart is on the right side of chest, and this is called dextrocardia.

Followings are possible symptoms of dextrocardia.
- P, QRS and T are all reversed in Lead I.
- Lead II and III are switched in aVR and aVL.
- R wave becomes smaller from V1 to V6 in chest lead.

As for patients of dextrocardia, normal automatic diagnosis results can be obtained if measuring with electrode switched as follows.
- Switch electrode in right (R) and left (L) hands
- Attach chest lead that was attached from the right side from left side in order





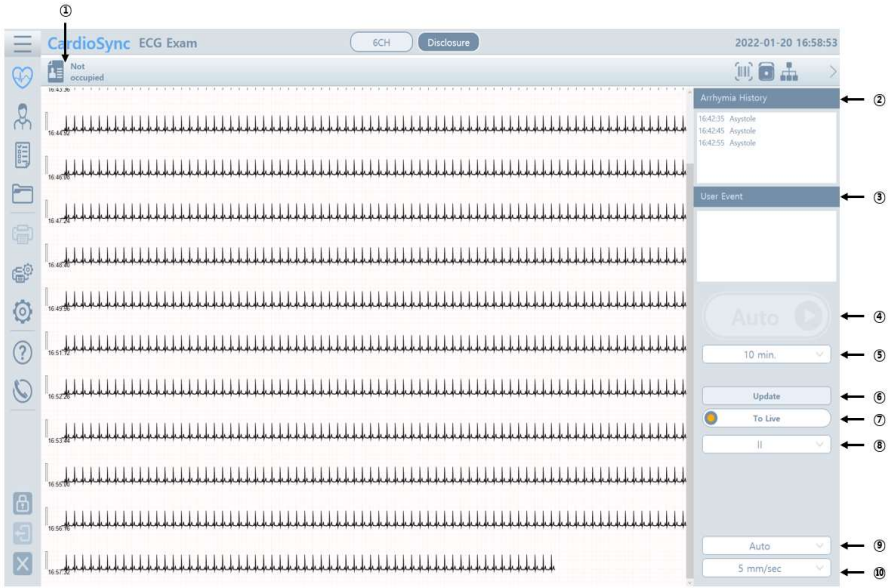
5) Disclosure

If clicking Disclosure button in the menu bar at the bottom of ECG main screen, the screen is converted to disclosure function. Disclosure function is to save ECG data in the equipment memory and show them when performing disclosure menu.

Once disclosure window is performed, previously saved ECG data for 30 minutes are shown with 1CH, while indicating the pre-set mode interval (10sec, 1min, 3min, 5min, 10min, 20min and 30min) in rectangular area so that users are able to output diagnosis in selected area and transmit data.

In order to select output intervals, graph window is clicked and selected. At this time, clicked point is the central point of the selected rectangular area. If selecting the output area, use 'AUTO' key on the control panel to perform functions such as diagnosis output, saving and transmitting.

Followings explain the contents shown on the disclosure screen.



① Patient ID, Name display and patient information input menu button.

② Display the number of Arrhythmia and execute button on the 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 EKG Wave Data update button from the time of entry into the Disclosure to the current time.

⑦ Switch to Live mode button

⑧ Select output lead

⑨ Select the output size

⑩ Output speed selection

Here is the Disclosure live mode screen.

ECG Wave Data is output in real time in the area marked with the grid at the bottom of the screen.

The abbreviations of the diagnostic names displayed on the screen are as follows.

No.	Abbreviations	Diagnostic Name
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 Name	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	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	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	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
Diagnosis provided by Cardio P1 must be confirmed by a qualified medical professional.

6) Perform Diagnosis with One Key ('AUTO' Key)

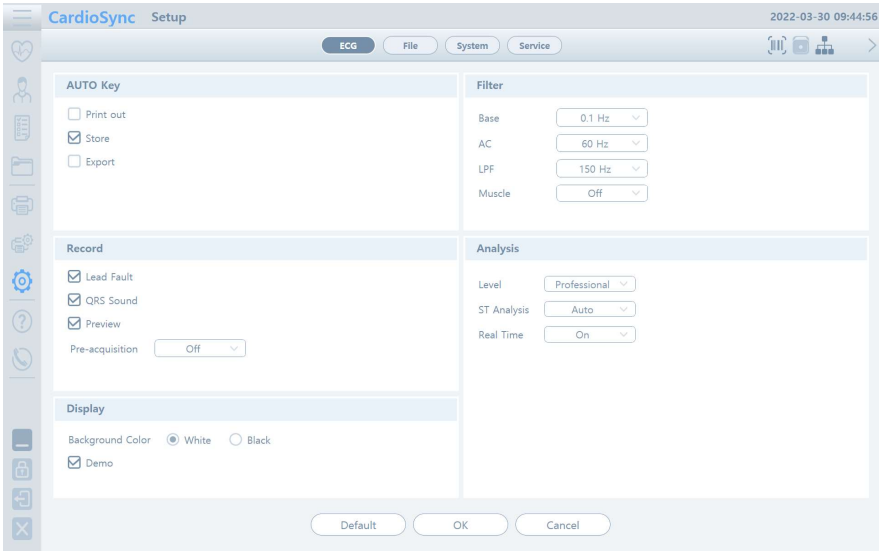
'AUTO' key is to acquire ECG during the diagnosis mode setup period and proceeds functions of saving, transmitting, and printing after diagnosis. It operates according to the setup of auto key of system general setup.

It can also be operated by pressing the button for more than 3 seconds.

7) System Setup

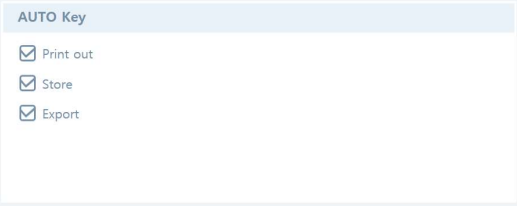
The Setup menu is used to set various contents related to the equipment.
You can set it by clicking the Settings button on the left side of the screen.

ECG Setup



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

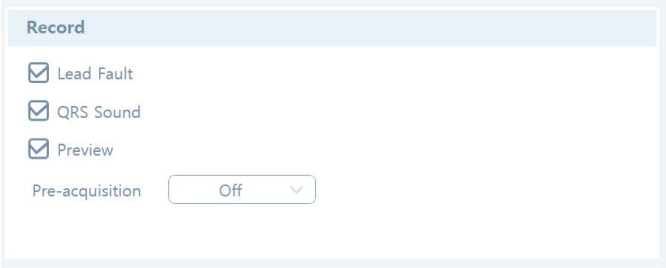
Setup whether to print measured data.
Print measured data if set to be 'ON.' If set to be 'OFF,' data are not printed.

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'

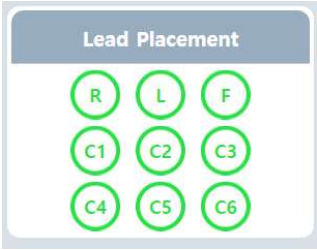
Record



Make settings related to ECG measurement.
You can set the lead fault, heartbeat alert, and preview as follows.

Lead Fault

In case of unstable contact of lead on patient cable, there might be lead fault. In this case, it is available to setup whether to indicate lead fault message.
If set to be 'On,' lead fault message is shown. If it is 'Off,' message is not shown.
Lead fault information shows lead fault information as specified in the middle of top main ECG screen.



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

QRS Sound

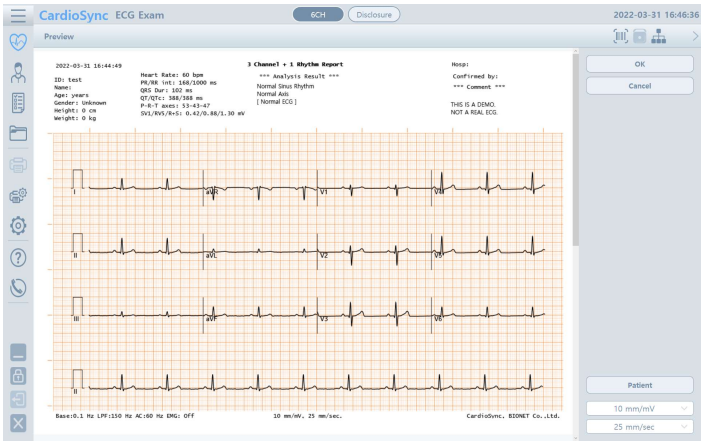
You can set the sound output according to the QRS beat.

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.

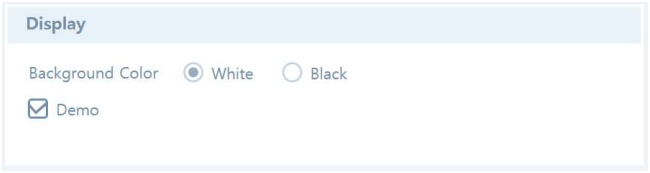
If selecting 'Ok' on the preview screen, function of each key including the printing, saving, or transmitting is performed. If selecting 'cancel,' it is cancelled.



Pre-acquisition

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

Display



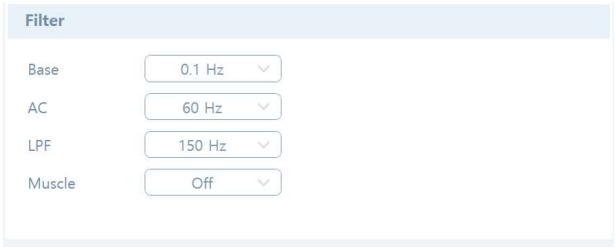
Make settings related to the screen display.
You can set the background color and demo display as follows.

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.



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

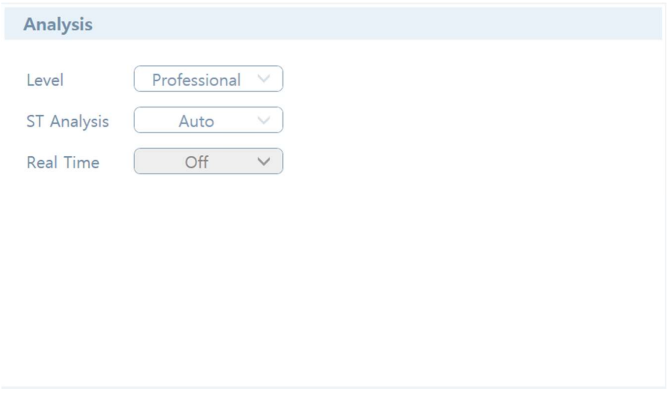
LPF filter is a low frequency filter providing off, 40Hz, 100Hz and 150Hz. 40Hz means to remove all the signals with 40Hz or above.

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



Level

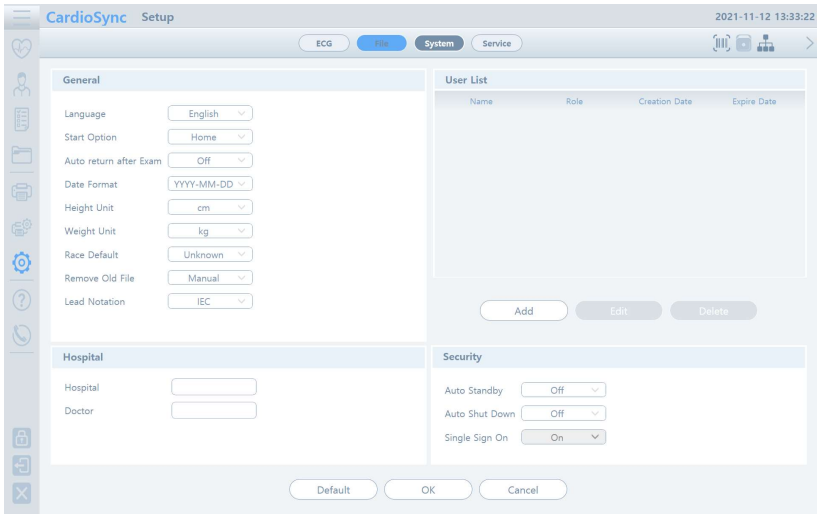
This is the automatic diagnosis level setup menu for 10 seconds of recording.
In case of 'Basic,' diagnosis reference value is higher showing only the severe diagnosis names.
In case of 'Professional,' various diagnosis contents are shown according to the standard diagnosis values.

ST Analysis

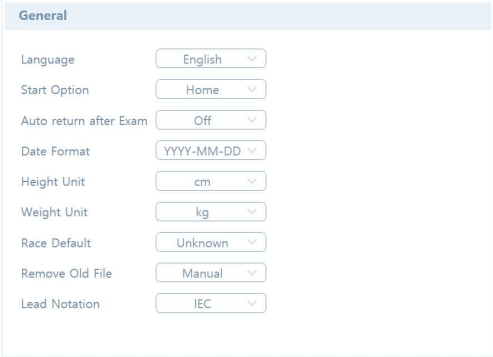
It is about the setup of ST segment diagnosis during the 10 seconds of recording automatic diagnosis.
In case of 'Auto,' J points related to ST level are automatically setup. In case of '60msec,' J points are set to be 60msec. In case of '80msec,' J points are set to be 80msec.

System

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

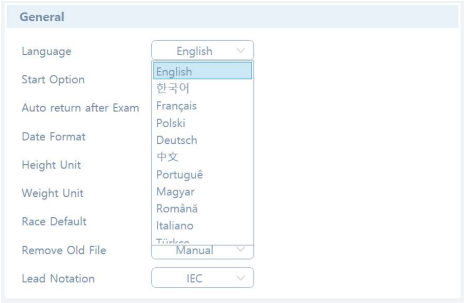


General



Language

Select the language you want to use, click the 'OK' button, and re-run the program to convert to the selected language.



Note
Even if language is set to be the one other than 'English,' some of the terms including diagnosis name might 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

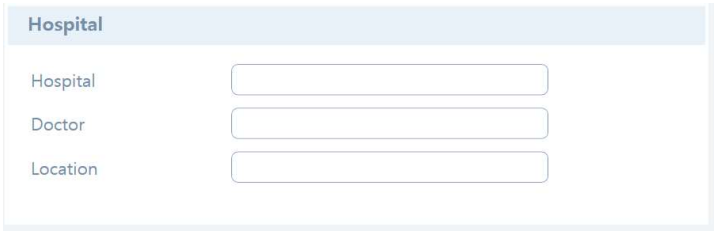
Set how old files are removed

- 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



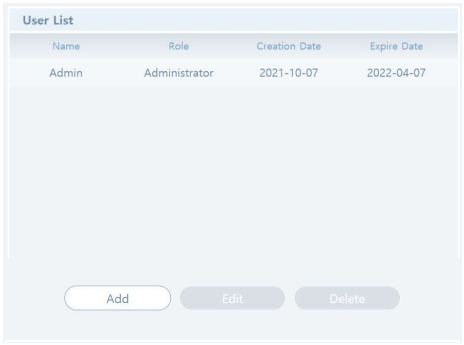
Hospital Information

Enter hospital name.

Doctor Information
Enter doctor name.

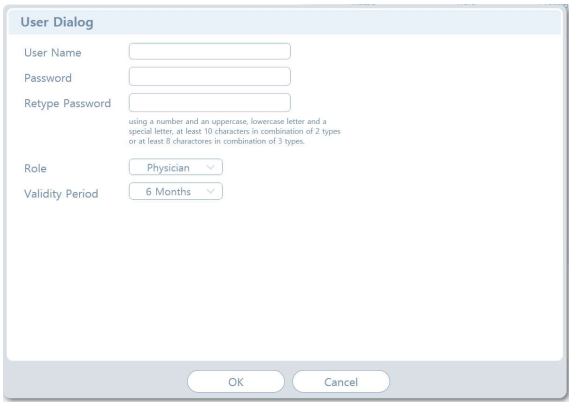
Location Information
Enter location name.

User List



Manage who will use the program.

User Add
Click Add user to enter a new user.



- User 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
Rules for writing passwords - 10 or more characters : a combination of two of uppercase letters, lowercase letters, numbers, and special characters. - 8 or more characters : 3 combinations of uppercase letters, lowercase letters, numbers, and special characters.

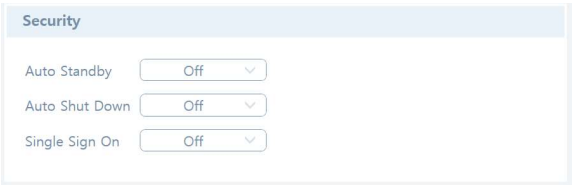
User Edit

Click Edit User to edit the clicked user information.

User Delete

Click Remove user to remove the clicked user information.

Security Setup



Auto Standby

This is a security setting to disable the program if no user input is made within a defined time. After the time-out period, the program is locked, and the user must login again to enable the program.

Off, 10min, 20min, 30min can be set and when switching to standby mode, it automatically logs out for security and lowers power consumption by dimming the screen.

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

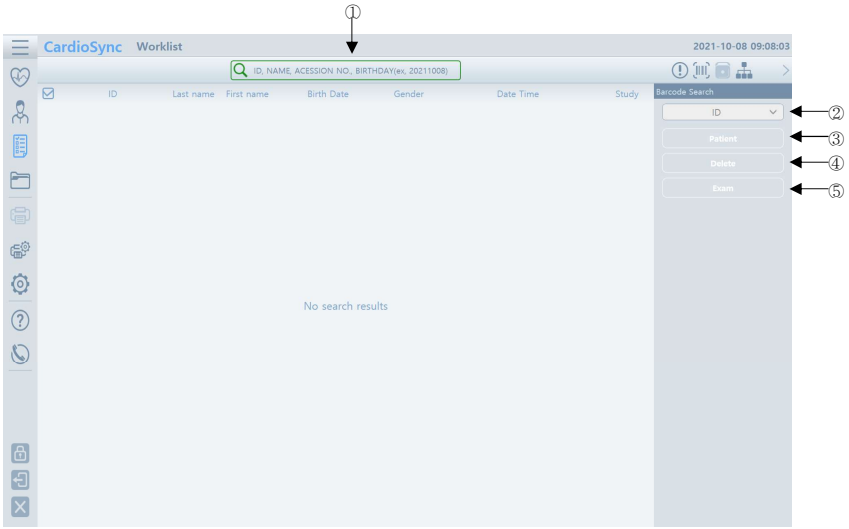
When Single Sign On is set, security can be compromised. It is recommended that this setting is only defined for device that are single or limited user.

Check this box to enable system authentication of user ID and password. This means that when the program is first opened no login is required because user authentication is carried out by the device system. Also when application time-out is set, no password is required to reactivate the program. Settings are possible only with an Admin account.

Part II. Data & System Management

Chapter 3. Manage Data Requested for Exam

1) Screen and function setup



① Top list search menu button

② Search condition setting button

③ Retrieve patient information button

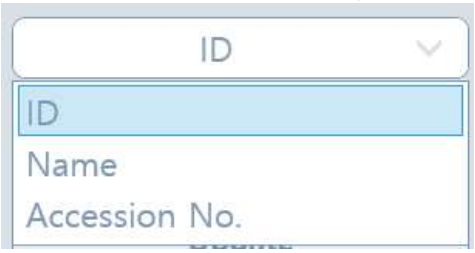
④ Delete selected information button

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.



After selecting items, enter your search criteria.
You can search by selecting ID, Name, or Accession No.

View patient information

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

Get inspection information

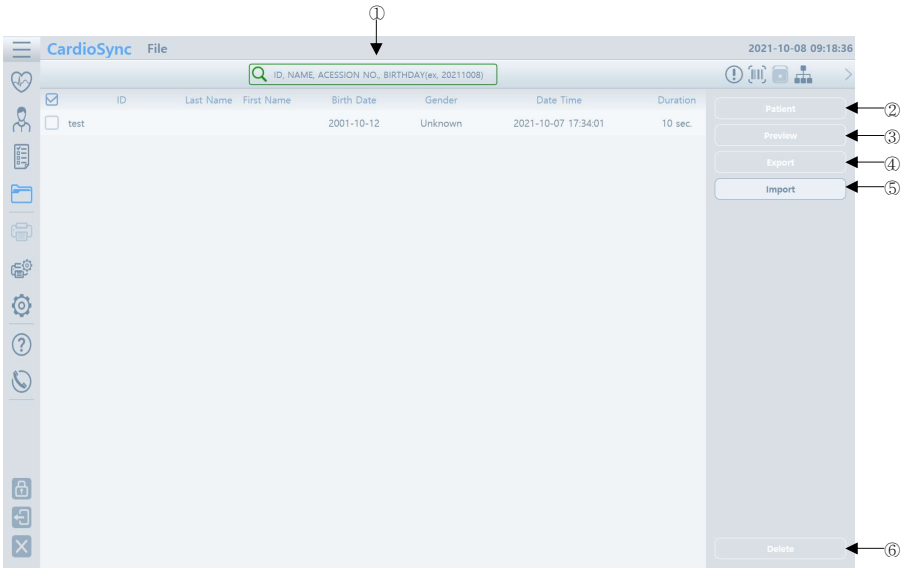
Get the latest inspection information from the PACS server or GDT server.
The 'Update' menu is displayed only when connected to the PACS server or GDT server.

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()

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.

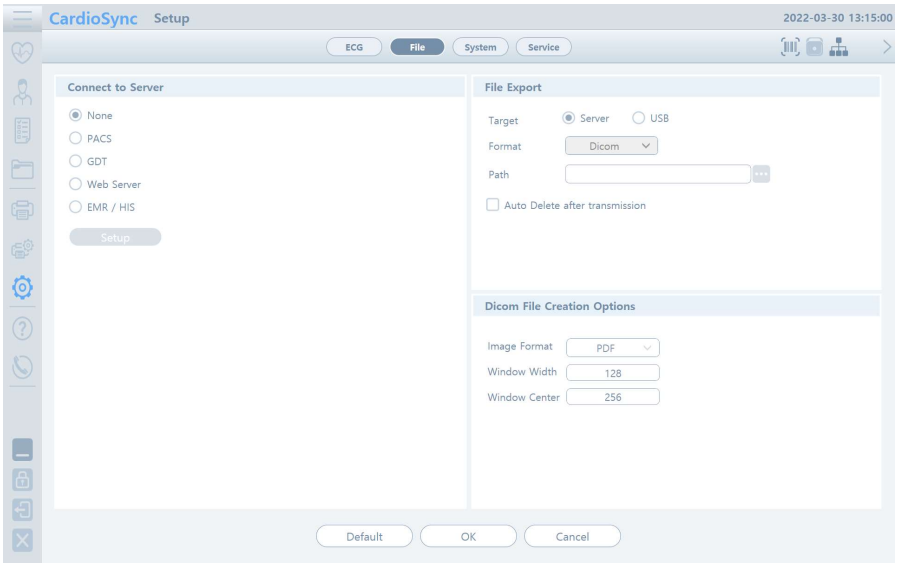
View Patient Information

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

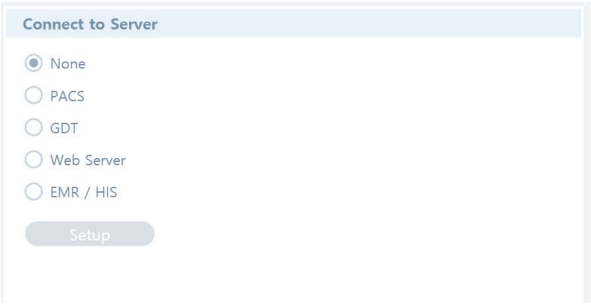
Note
Bionet provides Adult diagnosis and Pediatric diagnosis..

3) Setup

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



Connect to Server



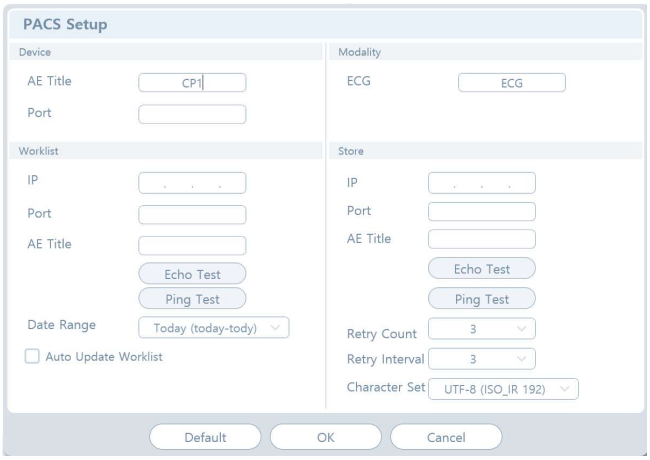
PACS, GDT, Web server or EMS/HIS can be selected from the menu to select the server interlocked with the equipment.

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

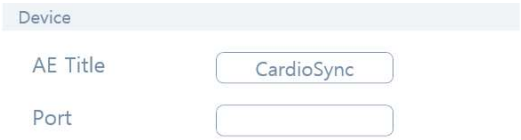
A. None

No connection with the server.

B. PACS Setting



Device Information



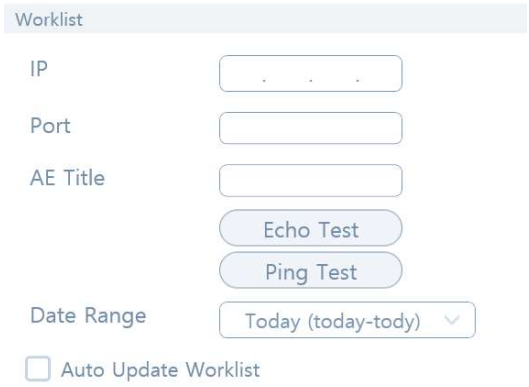
AE Title, Port

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

Modality

Enter the Modality of ECG

Worklist Server Settings



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.

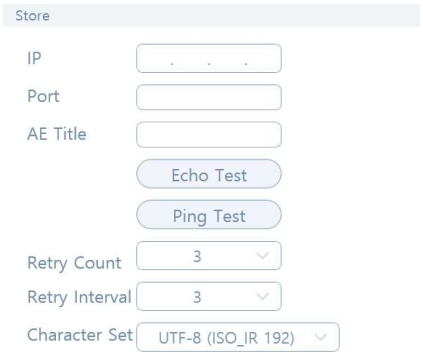
List	Description
Today (today-today)	Get the worklist for today's date. Set both start and end dates to today.
Today (today-blank)	Get the worklist for today's date. Get the worklist by setting only the start date to today
Yesterday~Tomorrow	Get the worklist from yesterday to tomorrow.
One Week	Get a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



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.

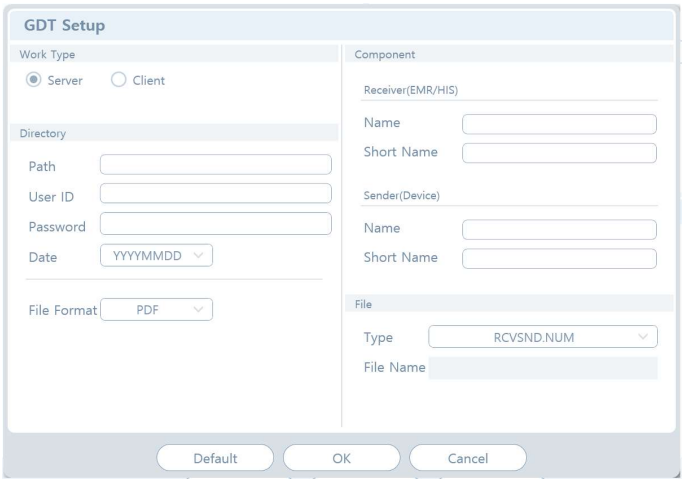
Character Set

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.



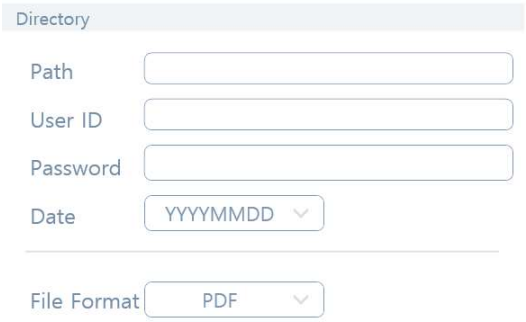
Work type

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.



Path

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

ex) ₩₩192.168.30.162/GDTShare

User ID & Password

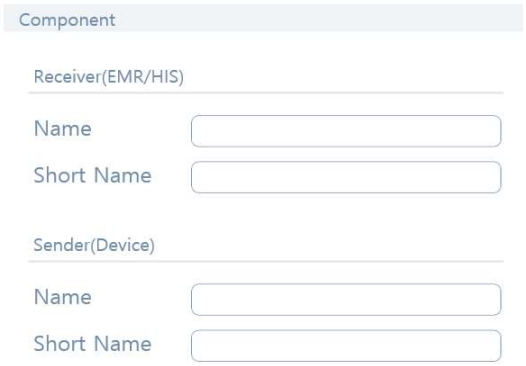
Enter shared folder access ID & password

Date

Date information format setting

- YYYYMMDD, MMDDYYYY, DDMMYYYY

Component



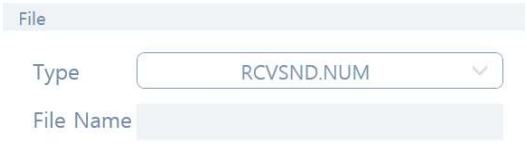
Receiver (EMR/HIS)

- 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



Type

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

File name

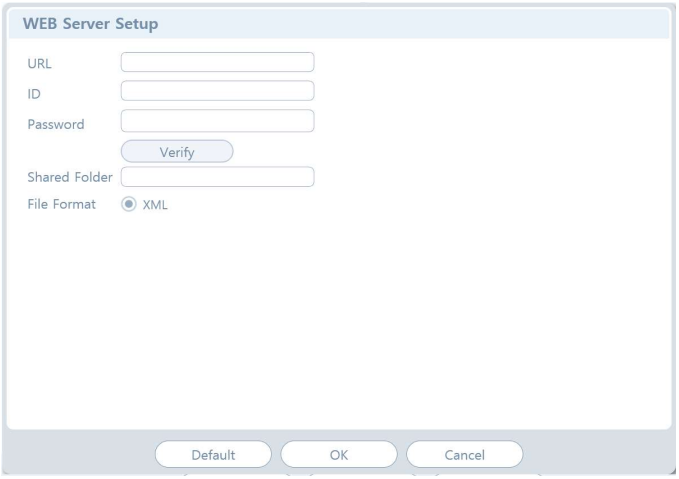
Select the file name type to be shared by GDT protocol.

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.



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.

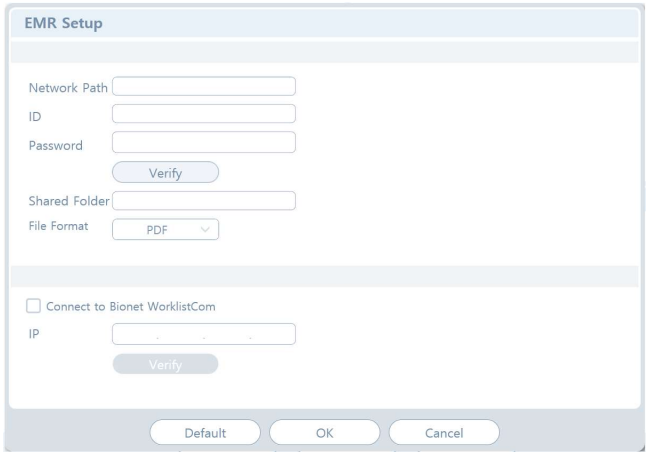
Verify

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



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.

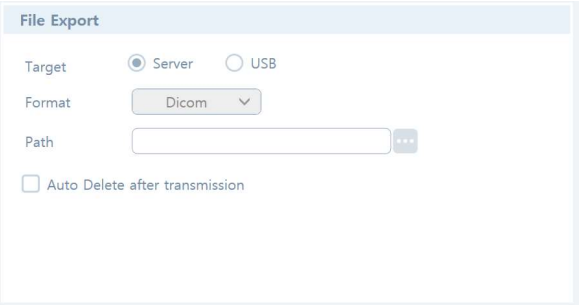
Shared Folder
Write the shared folder path on the server in the shared folder

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



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

Image Format

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

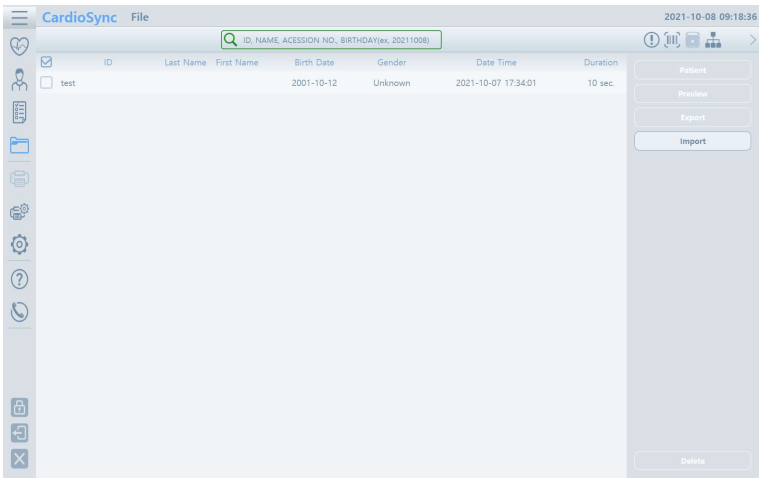
Window Width

Specifies the image size in JPG, BMP format.

Window Center

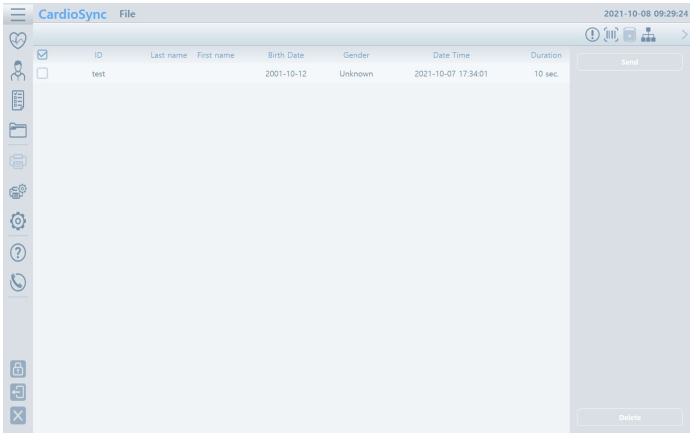
Specifies the center of the image in JPG, BMP format.

4) Transmit Data



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.'

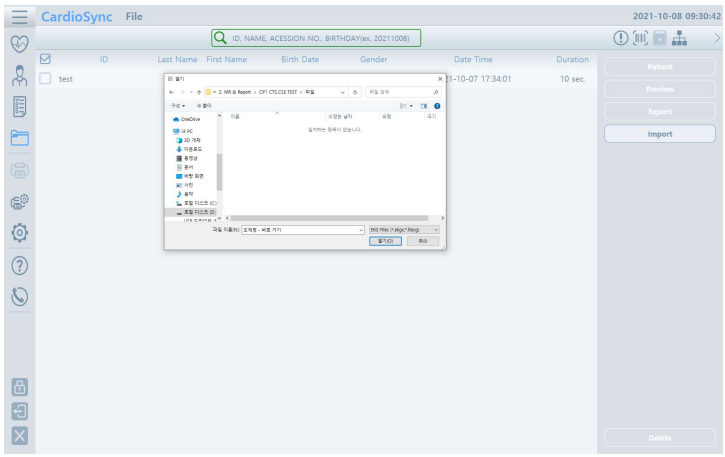


Files failed to be sent are indicated on 'Retry Queue' screen. Such files can be re-sent.

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
You can only import bionet format files with the following extensions. ➔ ekgx, ltecg, stecg

Chapter 5. System Management

1) Maintenance and Cleanliness

Cardio P1 can be maintained to be clean by using the various methods. However, it is required to use recommended methods as below to avoid damage or contamination on the device.
If using substances (not allowed substances) that can damage on the product, warranty is not applied even during the warranty period.

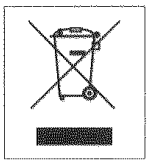
Note
Make sure to clean the equipment and carefully check electrode. Do not use the equipment if it is obsolete or damaged.

Make sure to apply alcohol on a soft piece of cloth for once a month and clean the body and measuring electrode. Do not use lacquer, thinner, ethylene and oxides. Cable, limb electrode and chest electrode shall be maintained without dust or foreign substances. After using them, make sure to wipe them out with a piece of cloth soaked with warm water (40˚C/104˚F). Use clinical alcohol to wipe them out for about once a week. Do not soak the device or ECG cable with liquid or detergent. In addition, make sure not to have any of liquid in the equipment or cable.

Note
If the device is determined not to be visually clean at the end of the cleaning step, it should be repeated the relevant previous cleaning steps.

Note
If the unacceptable deterioration such as corrosion, discoloration, pitting, cracked seals is found on the product, contact the store where you purchased the product and decide to dispose or repair it according to the instructions.

Disposal of your old appliance



1. When this crossed out wheeled bin symbol is attached to a product it means the product is covered by the European Directive 2002/96/EC.
2. All electrical and electronic products should be disposed of separately from the municipal waste stream via designated collection facilities appointed by the government or the local authorities.
3. The correct disposal of your old appliance will help prevent potential negative consequences for the environment and human health.
4. For more detailed information about disposal of your old appliance, please contact your city office, waste disposal service or the shop where you purchased the product.

2) Regular Examination

Make sure to have safety examination on a regular basis for at least once a year on Cardio P1 just like other medical equipment. Refer to the service manual provided by our company for exam 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.

- **Cybersecurity-related issues**

  1) In case of equipment theft or loss, immediately report it to the hospital staff or the manufacturer.
  When receiving a report, the hospital network administrator must take measures to prevent the device from accessing the hospital network.
  2) If a cyber security threat is detected while using the device, immediately disconnect the device from the network and contact the hospital official 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. 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. 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. 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. 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! 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 EN 55011	Group1, Class A
Radiated disturbance	CISPR 11 EN 55011	Group1, Class A
Harmonic Current Emission	IEC 61000-3-2 EN 61000-3-2	Class A
Voltage change, Voltage fluctuations and Flicker Emission	IEC 61000-3-3 EN 61000-3-3	Pst: 1 Plt: 0.65 Tmax:0.5 dmax: 4% dc: 3.3%
Electrostatic Discharge Immunity	IEC 61000-4-2 EN 61000-4-2	±8 kV/Contact ±2, ±4, ±8, ±15 kV/Air
Radiated RF Electromagnetic Field Immunity	IEC 61000-4-3 EN 61000-4-3	3 V/m 80 MHz - 2.7 GHz 80% AM at 1 kHz, 10 Hz
Immunity to Proximity Fields from RF wireless Communications Equipment	IEC 61000-4-3 EN 61000-4-3	Table 9 in IEC 60601-1-2: 2014
Electrical Fast Transient/Burst Immunity	IEC 61000-4-4 EN 61000-4-4	±2 kV, 100 kHz repetition frequency ±1 kV, 100 kHz repetition frequency
Surge Immunity	IEC 61000-4-5 EN 61000-4-5	Line to Line ±0.5 kV, ±1 kV Line to Ground ±0.5 kV, ±1 kV, ±2 kV
Immunity to Conducted Disturbances Induced by RF fields	IEC 61000-4-6 EN 61000-4-6	3 V 0.15 MHz - 80 MHz 6 V in ISM bands Between 0.15 MHz and 80 MHz 80% AM at 1 kHz, 10 Hz

Power Frequency Magnetic Field Immunity	IEC 61000-4-8 EN 61000-4-8	30 A/m 50 Hz and 60 Hz
Voltage dips	IEC 61000-4-11 EN 61000-4-11	0 % U_T: 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°
		70 % U_T; 1 cycle and 70 % U_T; 25/30 cycles Single phase: at 0°
Voltage interruptions	IEC 61000-4-11 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. 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 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 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 IEC 61000-3-2	Class A	

Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: **Warning**: 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.

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**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.

Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5%UT (>95%dip in UT) for 0,5 cycle 40 %UT (60 %dip in UT) for 5, 6 cycles 70 %UT (30 %dip in UT) for 25,30 cycles <5%UT (>95%dip in UT) for 5 s	<5%UT (>95%dip in UT) for 0,5 cycle 40 %UT (60 %dip in UT) for 5, 6 cycles 70 %UT (30 %dip in UT) for 25,30 cycles <5%UT (>95%dip in UT) for 5 s	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.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical
Note U_T is the a.c. mains voltage prior to application of the test level.			

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 IEC 61000-4-6	3 Vrms 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. **Recommended separation distance** $d = [\frac{3,5}{V_1}]\sqrt{P}$ $d = [\frac{3,5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz 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). [b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	

Note 1 At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

[a] 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.

[b] Over the frequency range 150 kHz to 80 MHz, field strength should be less than 3 V/m

Recommended separation distances between portable and mobile RF communications equipment and the Cardio P1			
The Cardio P1 is intended for use in an electromagnetic environment in which radiated RFdisturbances 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.			
Rated maximum output power of transmitter [W]	**Separation distance according to frequency of transmitter [m]**		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2,5 GHz

	$d = [\frac{3,5}{V_1}]\sqrt{P}$	$d = [\frac{3,5}{E_1}]\sqrt{P}$	$d = [\frac{7}{E_1}]\sqrt{P}$
	V1= 3 Vrms	E_1= 3 V/m	E1= 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

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Chapter 6. Product Specifications

ECG Leads	Simultaneous 12 channel ECG and acquisition
Recording Channel	3CH+3RHY, 3CH+1RHY, 6CH+1RHY, 12CH, 6CH+ST map 1CH Long Time (1min, 3min, 5min,10min, 20min, 30min) and Special Beat Report (Text, Guide, Vector, ST map)
Gain	2.5, 5, 10, 20, Auto (I~aVF: 10, V1~V6: 5) mm/mV
Printing Speed	5, 12.5, 25, 50, 100 mm/sec
Sampling Rate	Analysis Sampling Rate - 500Hz

		Digital Sampling Rate - 8,000Hz
Filters		AC (50/60 Hz, -20dB or better), Muscle (25~35Hz, -3dB or better), Baseline Drift (0.05Hz, 0.1Hz, 0.2Hz, -3dB or better), Low Pass Filter(off, 40Hz, 100Hz, 150Hz)
Patient Data		ID, Name, Birthday, Age, Gender, Height, Weight, Race, Smoke, Department, Room No., Study Desc., Accession No., Referring Physician
Basic Measurement		Heart Rate (30~300bpm, ±3bpm), PR/RR Int, QRS Dur, QT/QTc Int, P-R-T axis, SV1/RV5/R+S Amp
Electrical		Internal Noise : 20uV(p-p)max Input Impedance : ≥ 50MΩ Input Voltage Range : ±5mV CMRR : > 105dB DC Offset Voltage : ≥ ±400mV Patient Leakage Current : < 10uA Frequency Response : 0.05~200 with in –3dB Isolated, Defibrillation and ESU Protected
Signal Quality Control		Pacemaker Pulse Detection Lead Fault Detection, Signal Saturation Detection
Input Power		5VDC (USB), Max. 0.5A
Communication		USB data communication (to PC)
Safety Conformity		Class I, Type CF applied parts: ECG electrodes
Environmental	**Operation**	Ambient Temperature : 10 to 40ºC Relative Humidity : 30 to 85% Atmospheric Pressure : 700 to 1060hPa
	Storage/Ship	Ambient Temperature : -20 to 60℃ Relative Humidity : 10 to 95% Atmospheric Pressure : 500 to 1060hPa
Dimensions		Body - 90.75(W) x 103.5(D) x 24.93(H)mm - Approx. 110g

Standard Accessory	Patient Cable (1ea), Power (USB Data) Cable (1ea), Disposable electrodes (1set), ECG clips (1set), Hanger (1ea), Silicone Pad (1ea), USB Lock Key (1ea)

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

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

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

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

Caution
Make sure to have the experts (health care professional) present when using Cardio P1 for patients who had surgery with heart aiding machines

Product Certificate

Product Name	Electrocardiograph
Model Name	Cardio P1
Type Name	
License Number	
License Date	
Serial Number	
Warranty Period	1 year from date of purchase
Purchasing Date	(yyyy/mm/dd)
Customer Information	Hospital name: Address: Name Telephone:
Seller Name	
Manufacturer Name	

※ Thank you for purchasing Cardio P1.

※ This item is 'medical device.'

※ This product has passed through quality management and strict inspection.

※ Compensation criteria for the repair, replacement, or refund of this product follow 'consumer damage compensation regulations' from Fair Trade Commission.

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Bionet Co., Ltd

Model Name: Cardio P1