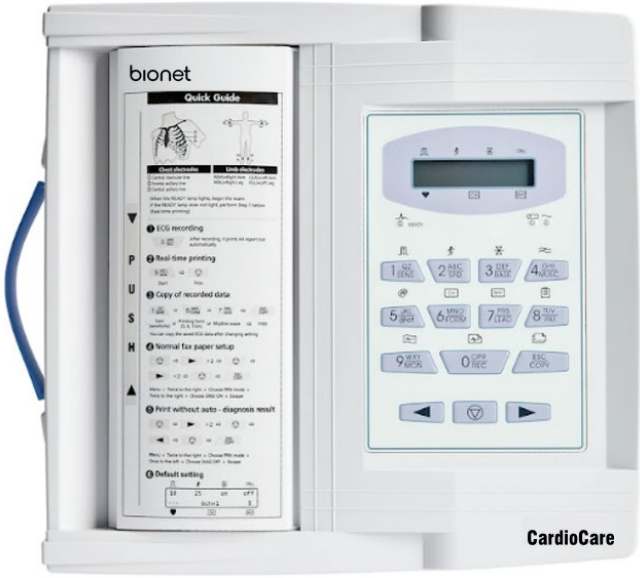
CardioCare2000

Operation Manual



Ver. 3.23

2023.05.11

www.ebionet.com

REVISION HISTORY

Revision No.	Date	Contents	Page
1.00	2023.04.04	1. First Written	All
3.22	2022.01.18	1. Change of representative number, change of form, deletion of unnecessary words in precautions	All
3.23	2023.05.11	1. Change Logo 2. Translation reflection	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

Contact

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.bioneteu.com
European Representative	**CMC Medical Devices & Drugs S.L. :** C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain Tel +34-951-214-054 / Fax +34-952-330-100 E-mail: info@cmcmedicaldevices.com Website: www.cmcmedicaldevices.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.

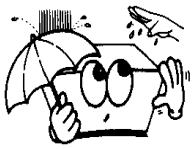
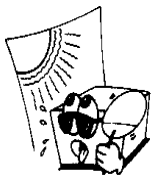
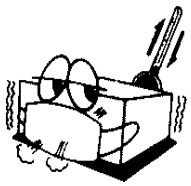
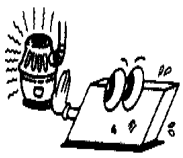
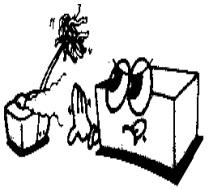
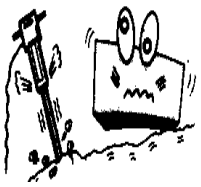
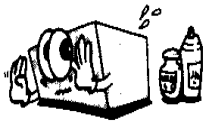
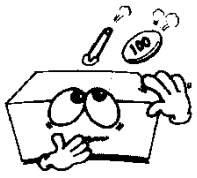
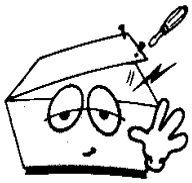
WARNING
WARNING Failure to follow this message may cause severe injuries, casualty or physical damage to patients.

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? (100 - 240V AC)
- Is every cord connected properly to the product?
- Is the product fully grounded? (Otherwise, noise may occur.)
- 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 CardioCare2000 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.

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:

BATTERY OPERATION - If the integrity of the electrical grounding is doubtful, use battery to operate the equipment.

WARNING:

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

WARNING:

CONNECTION TO MAINS — This is class I equipment.

Connect the mains power plug 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 devices should be avoided because it could result in improper operation. If such use is unavoidable, this equipment and other devices should be observed to verify that they are operating normally.

WARNING:

EXPLOSION HAZARD - Do not use this equipment in the presence of anesthetics vapors or liquids.

WARNING:

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

All computer-generated diagnostics are subject to be verified by a qualified physician.

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 equipment 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.

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

For equipment installed above the patient, take appropriate measures 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 may increase electromagnetic emission or reduce electromagnetic susceptibility, causing it to malfunction.

WARNING:

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

CAUTION:

PROPER LEAD-WIRE CONNECTION — Improper connection will cause inaccuracies in the ECG. Trace each individual lead-wire from the acquisition module label to the color-coded connector, then to the appropriate 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:

BATTERY POWER — If a device equipped with an optional battery pack will not be used or connected to the power line for a period of over six months, remove the battery.

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:

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

In the USA, if the installation of this equipment will use 240V instead of 120V, the source must be center tapped, 240V single-phase circuit.

This equipment is suitable for connection to public mains as defined in CISPR 11.

Equipment connected to the ECG system and to the patient's environment must be powered from a medically isolated power source or must be a medically isolated equipment.

Equipment powered from a non-isolated source can result in chassis leakage currents exceeding safe levels. Chassis leakage current generated by the accessories or equipment connected to a non-isolated outlet may be added to the chassis leakage current of the ECG system.

CAUTION:

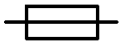
SERVICEABLE PARTS — This equipment contains no user serviceable parts.

Refer servicing to qualified service personnel.

CAUTION:

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

Safety Symbols

Symbols	Contents
	Attention: 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: It indicates that you should read the user manual. Read the user manual before starting work or operating the equipment.
	General Prohibition Sign
	Defibrillation Proof-Type CF APPLIED PART
	Type B APPLIED PART
~	AC Power
	Fuse
	Conductor provides a connection between equipment and the potential equalization bus bar of the electrical installation
	ECG Patient Cable Connector

	USB Connector

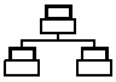
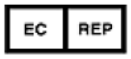
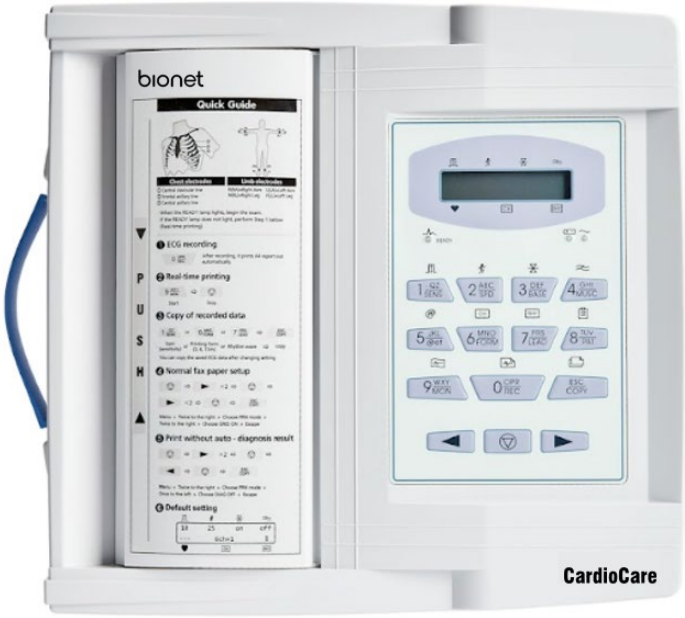
Symbols	Contents
	Local Area Network (LAN) connector
	Power Off
	Power On
	Battery Operation Indicator
	AC Power Connection Indicator
	Manufacturer name and address
	Authorized European representative
	Waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.

Table of Contents

Chapter 1. General Information

1) Product Overview



CardioCare2000 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. It saves, transfers and prints the data that has been acquired by automatic diagnosis.

It provides the user with the necessary parameters and automatic diagnostics, which are necessary for patient diagnosis, along with the spirometry record. After automatic diagnosis, you can print out a report on A4/letter paper together with the spirometer record to efficiently manage the patient's or user's chart. The stored data is forwarded to a network-connected PC that is in charge of managing digital files. In addition, the battery pack, which can be stored inside as an optional component, ensures high portability and makes it possible to inspect or use the equipment in an emergency.

2) Indication for Use

The CardioCare2000 ECG Analysis System is intended to acquire, analyze, display and record electrocardiographic information from adult and pediatric populations.

Basic systems deliver 12 lead ECG's, interpretive analysis, vector loops, and can be upgraded to provide software analysis options such as high-resolution signal averaging of QRS and P wave portions of the electrocardiogram. Transmission and reception of ECG data to and from a central ECG cardiovascular information system is optional.

The CardioCare2000 is intended to be used under the direct supervision of a licensed healthcare practitioner, by trained operators in a hospital or medical professional's facility.

2-1) 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.

2-2) 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.

3) 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.

4) Product Characteristics

- This equipment configures the 12-channel ECG waveforms in various configurations, such as 3 channels + 3 rhythm, 3 channels + 1 rhythm, 6 channels + 1 rhythm, and 12 channels, and prints them on A4 or Letter size paper.
- The 12 channel rhythms are continuously printed simultaneously in real time.
- The heart rate, PR interval, QRS interval, QT interval, QTc interval, P-R-T axis size required for diagnosis are automatically calculated and provided on the report along with the ECG.
- Get diagnostic reports using automatic detection functionality.
- Able to modify filter setting, signal sensitivity, printing speed, channel view settings and rhythm settings, and print on previously recorded ECG signals to aid data analysis.
- Able to attach a battery so that the device can become portable.
- Patient's data can be transferred to a PC through LAN.
- It offers various protocols to make it possible to link with hospitals' computing networks. Also, File Databases are strengthened.

5) Product Configuration

The CardioCare2000 system consists of the following components. Open the packaging box and check that all components below are included and make sure that the main body or components are not damaged.

5-1) Basic components and Accessories

① CardioCare2000 Body (1 EA) – Dimension: 300(W) x 290(D) x 97(H)mm

② Power Cable (1 EA) – Length: 2,500mm (Max)

③ User manual (1 EA)

④ Diagnosis Guide Book (1 EA)

⑤ ECG Gel (1 EA)

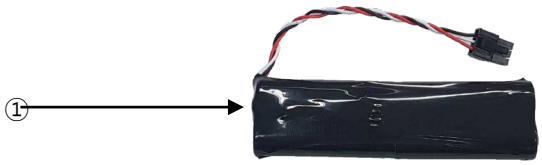
⑥ Patient Cable (1 EA) – Length: 3,700mm (Max)

⑦ Limb Electrodes (1 SET)

⑧ Chest Electrodes (1 SET)

⑨ ECG Paper (1 EA)

5-2) Optional Specifications



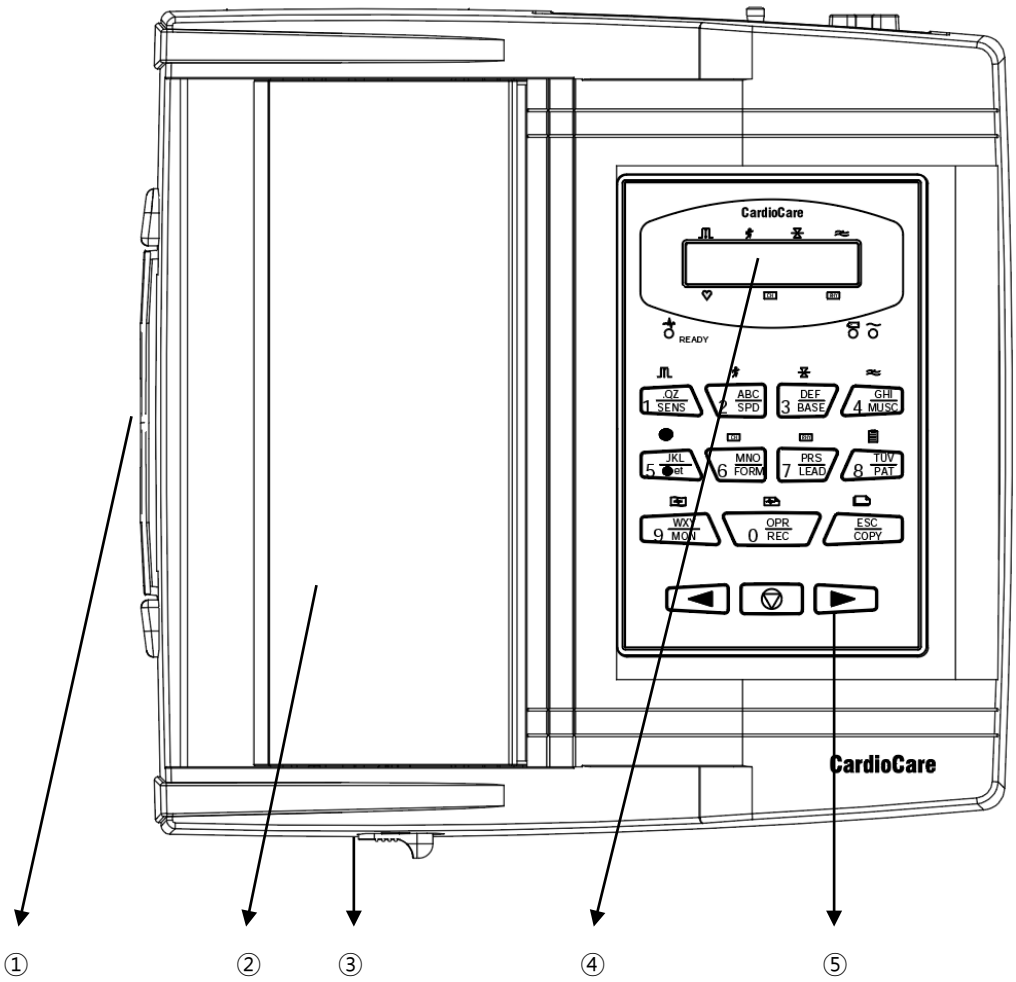
① Battery (1 EA): Replaceable and Rechargeable, Lithium ion, 3BL335-BIO-4 (10.8V, 3250mAh)

CAUTION
Using non-standard accessories other than the Bionet-provided supplies may cause signal distortion or noise. Be sure to use genuine accessories supplied by Bionet.

WARNING
Bionet is not liable for any problems caused by you not using the battery provided by Bionet. Make sure to use the genuine battery provided by Bionet.

5-3) Body Configuration

▣ Top View



① Handle

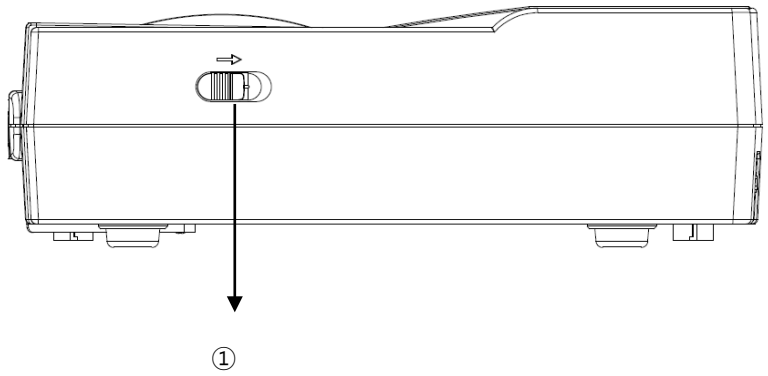
② Printer Cover

③ Printer Cover Switch

④ LCD

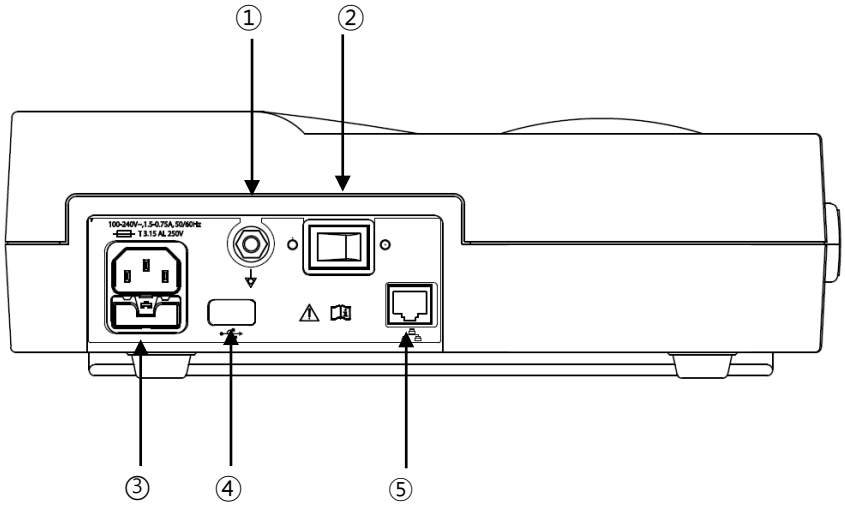
⑤ Control Panel

▣ Front View



① Printer Cover Switch

▣ Rear View



① Grounding Terminal: Connect it to an external ground terminal if there is no protective grounding in the power supply.

② Power Switch

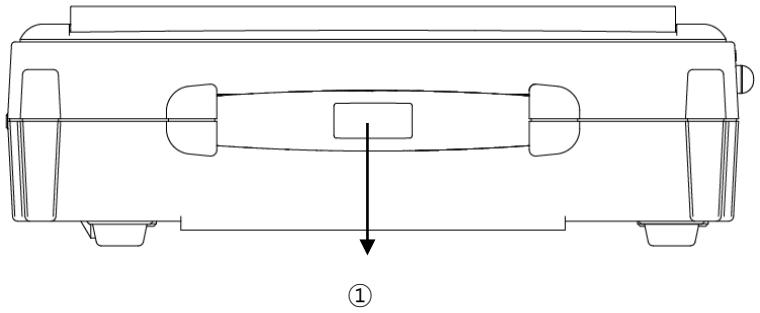
③ AC Power Terminal: AC power connection (+ Fuse (250V, 3.15AL) x 2)

④ USB Port: USB connection with external devices

⑤ LAN Port: LAN connection with external devices

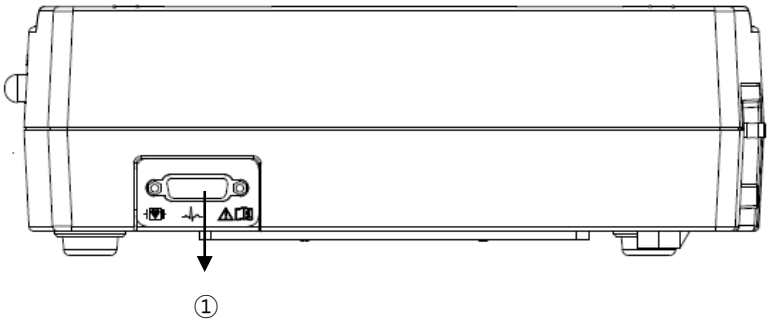
NOTE
Appliance inlet of separate power supply unit is used as mains disconnecting device.

▣ Left Side



① Handle

▣ Right Side



① Patient Cable Connection Port

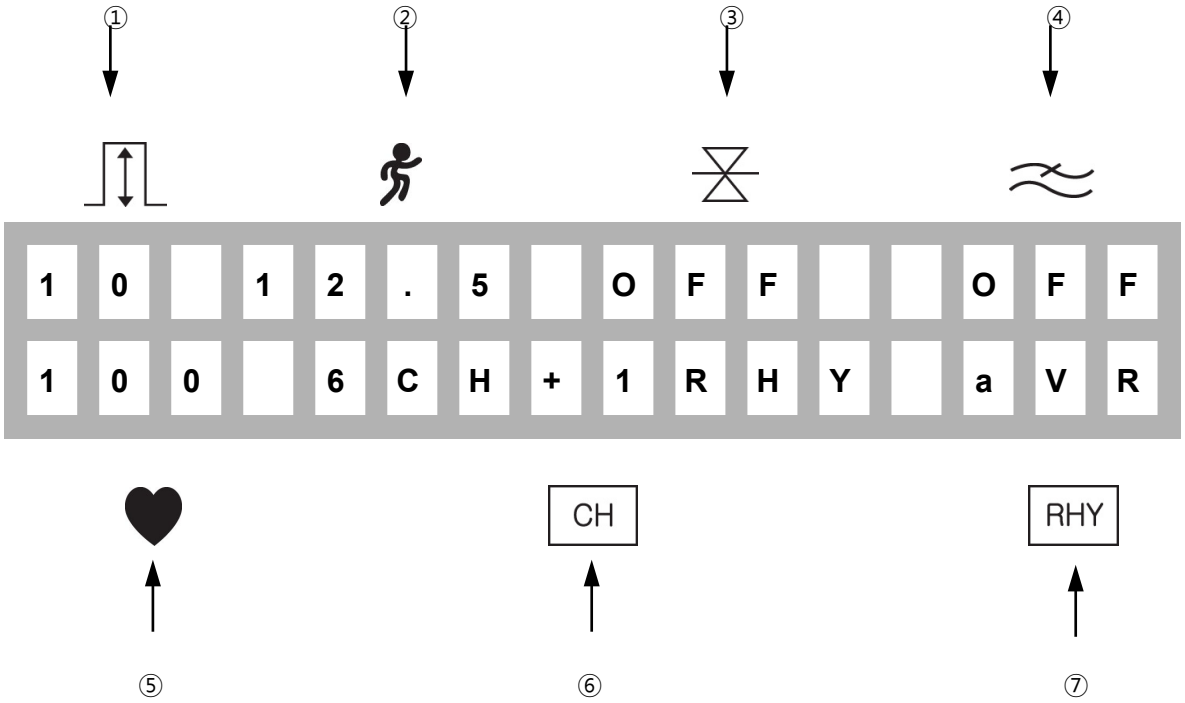
WARNING
There is a risk of electric shock if the Rest stand of the equipment is damaged or cannot be fixed to the equipment body. Do not use the product and immediately ask the manufacturer and the seller for repair.

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.

5-4) LCD Panel

LCD panel displays system setting status after indicating the version of the system and manufacturer name for 2 seconds when power is turned on.

Displayed items on the LCD are as follows.



① Display ECG signal level out of 5, 10, 20, aut (Auto Gain)

② Display printing speed out of 12.5, 25, 50

③ Display baseline filter setting off

④ Display EMG filter setting off, 0.05, 0.1, 0.2Hz

⑤ Display heart rate

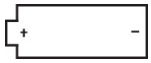
⑥ Display channel form of the output report out of 3ch+1rhy, 6ch+1rhy, 12chrhy, 60s 1rhy.

⑦ Display rhythm channel setting out of I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6.

NOTE
The detection range of heart rate is 30-300 bpm with ± 3bpm of error range.

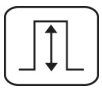
5-5) Control Panel

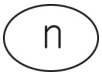
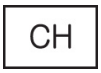
▣ Indicator Lamp

READY	I Indicate the lead connection status. If LED is illuminated green, connection status is good. If LED is off, connection status is bad. In this case, check off which one of lead connection is in lead-off status through monitor mode output. Caution: Start printing when LED is illuminated green. Indicate the battery capacity status: Green and Off colors are used to display 2 different statuses.
	The battery indicator is red when the device is operational without having an A/C power supply. When an A/C power is supplied, the battery indicator will be either red or green depending on the charge level. No color will be shown, if there is no battery installed in the device.
	Indicate AC power is operated if LED is illuminated green and not in use if LED is off.

NOTE
The READY lamp is related to'Lead Fault'. Regardless of whether the READY lamp is on, when diagnosing the patient's condition, the correct result should be performed after the heart rate stabilizes after connecting the Patient Cable to the patient about 4 - 5 seconds comes out

▣ Short Key

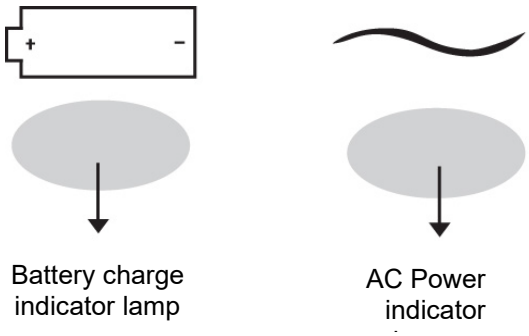
	Select signal level(mm/mV) out of 5, 10, 20, aut (I-aVF:10, V1-V6:5)
	Select printing speed(mm/sec) out of 12.5, 25, 50

	Select off, 0.05, 0.1, 0.2Hz whether or not to activate the filter that eliminates baseline drift
	Select on or off whether or not to activate the filter that eliminates EMG. ECG signal can be distorted by applying this filter.
	This key is except to use when network function is added ahead.
	Select channel form of the output report out of 3ch+1rhy, 6ch+1rhy, 12ch rhy, 60s 1rhy
	Select rhythm channel
	Call up the menu to enter patient ID, name, age, sex, height, weight
	Display real-time ECGs from the patient continuously or monitoring the patient ECGs for long time,
	Record ECGs for 10 seconds by pressing key and prints in A4 sized report form after calculating the measurement parameter of the recorded ECGs
	Print the same report as previously printed one in record mode or prints after changing system setting such as filter, signal level, output speed, channel form, rhythm cannel of previously recorded ECGs data in record mode.
	Exit during printing or recording of ECGs. Except that, call up the menu or select menu.
	Move the selected focus to the left in menu mode
	Move the selected focus to the right in menu mode

5-6) Power

▣ AC Power

When the equipment is connected to AC power, the Power LED on the front lights green. When a battery is mounted, it is charged in automatic charging mode.



If no battery is installed, battery indicator lamp will be off. Once a battery is plugged in and the device is powered on, it will change its power mode to supply power to the battery. If the device is running on the power from the battery, battery charge indicator lamp will light up red color. If the battery is running low on power, three continuous buzzer alarms will sound. If this occurs, turn off the device and connect the A/C power before turning the device back on.

▣ Battery Power

- Time required to fully charge the equipment that has been turned off after being completely discharged: Up to 3 hours
- Continuous battery operating time: 6hour

CAUTIONS
For the protection of environment, do NOT throw wasted battery away. Please inquire at the biomedical engineering lab of the hospital and dispose according to the appropriate procedure to the authorized place (according to national regulations).

WARNING
Pay attention to the polarity when replacing the battery. Bionet strongly recommends using the battery provided with the equipment. Using an unauthorized battery may damage the equipment.

The Effect of Lithium-Ion Technology on the Battery

Find out about lithium-ion battery technology here.

The battery is discharged naturally even when not installed in the equipment. Discharging is caused by the current demanded by the lithium-ion battery integrated circuit. Battery is self-discharged due to the nature of lithium-ion cells, and the self-discharge rate doubles for every 10°C (18°F) rise in temperature.

Battery retention loss is greater at higher temperatures. As the battery ages, it may not be fully charged, as a result, the total charge capacity used for saving and using gradually decreases.

Conditioning Guidelines

Check battery performance by fully charging and completely discharging it every 6 months.

Storage Guidelines

Store the battery between 20°C and 25°C (68°F and 77°F) when it is set aside separately. When the battery is installed in the equipment and connected to AC power, the temperature of the battery increases by 15°C to 20°C (59°F to 68°F) at room temperature, which shortens the life of the battery.

When a battery is installed in the equipment with AC power being connected, normally the equipment does not use the battery power. Battery life may be less than 12 months. Store the battery along with the equipment to prevent being lost and stolen, and separate the battery from the equipment when moving the equipment.

Recycling the Battery

Replace the battery when it is no longer charged. The battery can be recycled. Remove the old battery from the monitor and follow your local recycling guidelines.

WARNING
- Do not incinerate the battery or store it at high temperatures as it may explode, which may cause you serious injury. - Do not use the battery that has been impacted, disfigured, or submerged; dispose of it.

6) Installing System

6-1) Installation Precautions

Note the following when installing the CardioCare2000.

- Use the equipment within the ambient temperature of 10~40℃(50 to 104℉) and humidity of 30~85%.
- Check the connection of the power cord and handle the patient cable with care.
- Do not plug multiple cords into a single electrical outlet.
- Install the equipment body on a flat surface.
- Connect the ground if noise occurs.
- Do not use the electrical cords that generate connection noise.
- All settings stay saved in the internal memory even when the equipment is turned on and off.
- 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.

6-2) Connecting Power

- Connect the power cable to the power supply and the power terminal on the back of the CardioCare2000 to power on.

6-3) Connecting Patient Cable

- Connect the Patient Cable to the patient cable connection port on the right side of the equipment.
- Connect the limb electrodes to RL (N), LL (F), RA (R), and LA (L) terminals and chest electrodes to V1(C1), V2 (C2), V3 (C3), V4 (C4), V5 (C5) and V6 (C6) terminals of the patient cable.

6-4) Paper Installation

- Push the printer cover release switch to the right to open the printer door of the CardioCare2000. Install ECG paper with the side to be recorded appearing on top. Close the cover to finish the paper installation process.

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.

6-5) Connecting the Network

As only the service technicians can connect this equipment to the network, consult with the IT staff in the hospital in advance.
Follow IEC 80001-1, which is the Risk management of IT networks to which medical devices are connected.

6-6) LAN Network

Generally, the LAN networks are configured based on a star topology. You can group Individual devices 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)

If the equipment 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 Bionet equipment to be compatible with the specifications of your operating organization.
The equipment exchanges data with other medical devices via a LAN network. The network must support the following protocols:

- TCP/IP
- BROADCAST

6-6) 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.

6-7) 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.

7) Menu Structure

CardioCare2000 system provides 3 basic modes with preparation mode, output mode, and menu mode.

Preparation mode is an initial condition when system starts operating. LCD displays system settings and heart rate.

In preparation mode, system setting can be changed by pressing each short key SENS, SPD, BASE, MUSC, FORM, LEAD, PAT, MON, REC, COPY of the control panel.  key calls up the menu mode.

Output mode is to activate print operation in the preparation mode with pressing short keys MON, REC, COPY. Only with ESC key of the control panel stops printing in output mode.

Menu mode is activated by pressing  key in preparation mode and following window displays on the LCD.

PAT FLT PRN SYS
< PATient Info >

First line indicates menu selection, and second line indicates an explanation of the menu items or selected value.

- Press ◁ ▷ key to move the focus.
- Press  key to select the focused menu items.
- Press ESC key of control panel to move the menu above.

Menu structure is as follows:

PAT	< PATient Info > Enter the patient information including patient ID, name, age, sex, height, weight
FLT	< FiLTer setup > Select and adjust filter setting of baseline drift filter, EMG filter, ac filter, low pass filter.
PRN	< PriNter setup > Select and adjust signal level, printing speed, grid, numbers of channel, rhythm channel select, test printout
SYS	< SYStem setup > Enter system setting including date, time, hospital name, username.

8) System Setting

8-1) Initial Setting

Press 7key of the control panel for 3 seconds to initialize the system at the factory preset. After 5 seconds, following window message appears on the LCD for 1sec and system sets to initialize.

* FACTORY MODE *
initialize

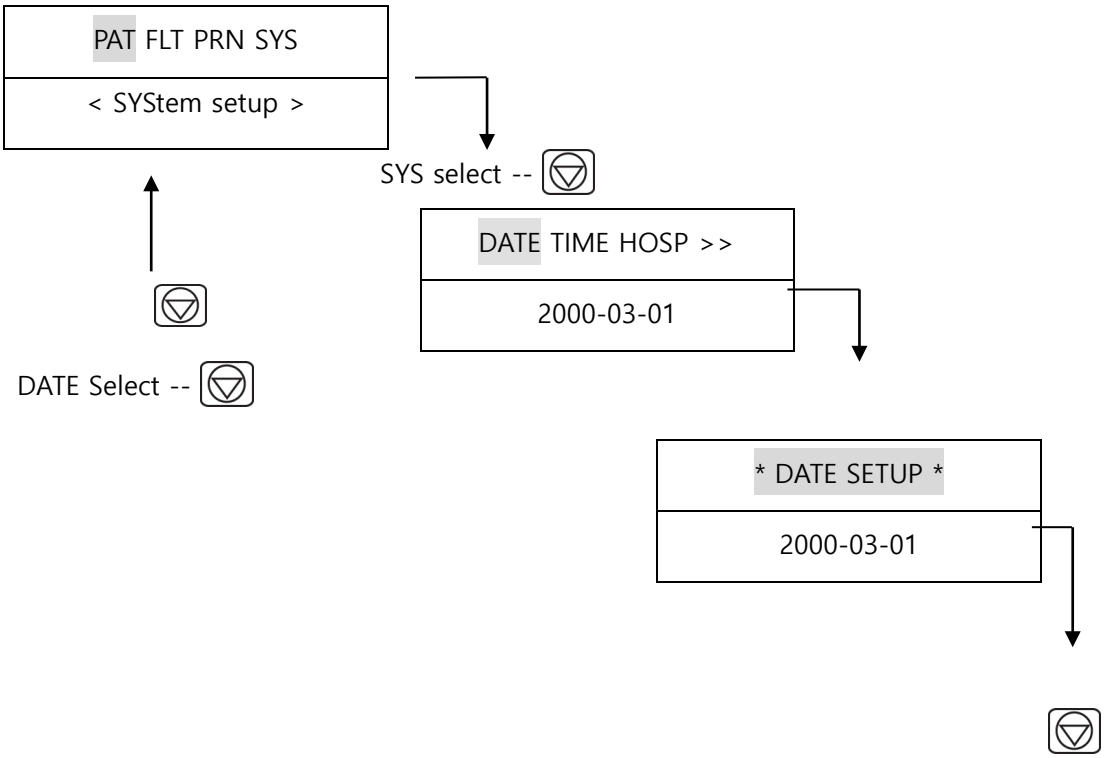
The following is a description of the ECG initial screen menu.

Signal level (SENS)	10mm/mV
Display speed (SPD)	25mm/s
Grid (GRID)	Off
Channel form (FORM)	3ch+1rhy

Rhythm lead (LEAD)	II
Baseline filter (BASE)	0.2Hz
EMG filer (MUSC)	Off
AC noise filter (AC)	60hz
Low pass filter	150Hz

8-2) Date and Time

To set the present date of CardioCare2000, move the menu to * **DATE SETUP** * as following steps:

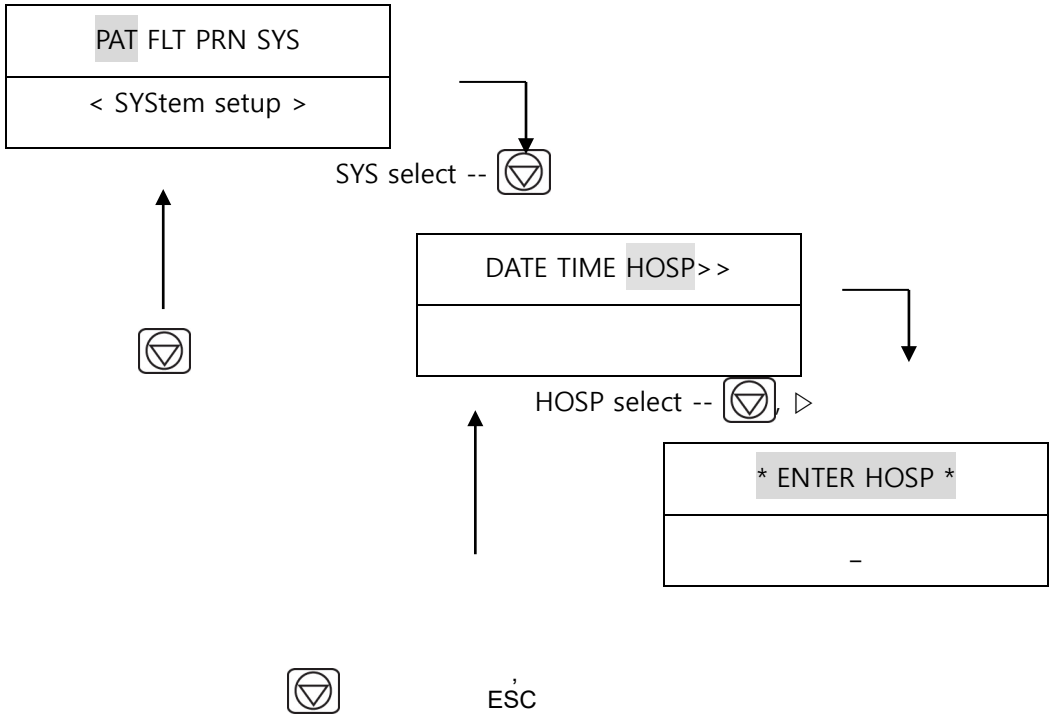


Number is entered by pressing 0, ..., 9 numeric keys in the current cursor position and cursor automatically moves to the right. To exit the date setting press key that moves to the menu above.

To set the time of CardioCare2000, move the menu to SYS → TIME → * TIME SETUP * as shown above. Then enter the time in the same way date is entered.

8-3) User Identification

User identification is to enter the hospital name and doctor name that operates the system. To enter the hospital name, move the menu to * **ENTER HOSP.** * as following steps.



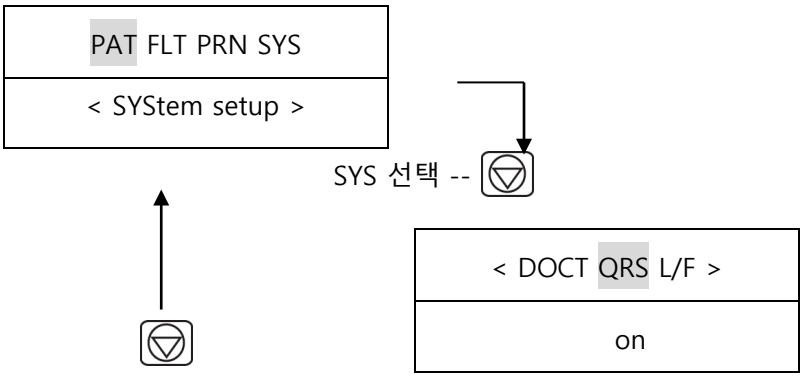
Hospital name can be entered in up to 16 characters. To enter the name, select the required character in the current cursor position. As for [1ABC] key, the key toggles in the order of A, B, C, 1, A, ...whenever pressing that key.

So, if you want to enter B character, press ▷ key to input B after pressing the [1ABC] key 2 times in the current cursor position. Then moves the cursor to the next. To exit the hospital name setting, press key that moves to the menu above.

To enter the doctor name, move the menu to * **ENTER DOCT.** *, SYS → DOCT → * ENTER DOCT. * as shown above. Then enter the doctor name in the same way hospital name is entered.

8-4) QRS Sound Setup

In this menu, users can set the device to ring an alarm sound when a QRS beat has generated while it is in waiting mode. To set the QRS Sound, moves the menu to QRS as following steps.



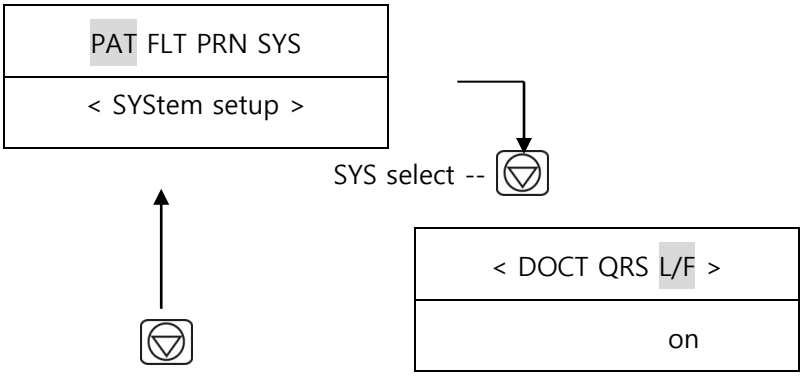
key switches on, off.

Users can either set the alarm ON or OFF by selecting the menu with ON turning on and OFF turning off the alarm sound.

Note
No sound will ring while printing even when the QRS sound is set to ON.

8-5) Lead fault LED Setting

When the connection between the patient and Leads is improper, lead fault can occur. In that case, you can choose whether to have the lead fault LED on the device or not. To set the lead fault LED, moves the menu to L/F as following steps.



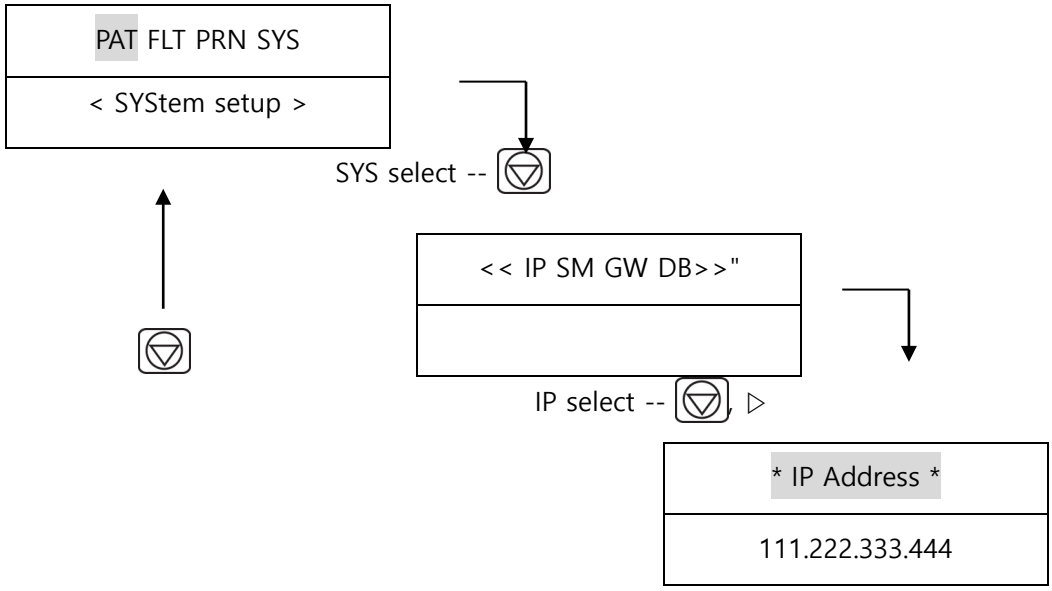
key switches on, off.

Users can either set the lead fault ON or OFF by selecting the menu with ON turning on and OFF turning off the lead fault LED.

Note
If 'RA' Lead becomes Fault, the wave types of all Leads will not be indicated. If 'LA' Lead becomes Fault, the wave types of I and V1-V6 Leads will not be indicated. If 'RA' Lead becomes Fault, Lead Fault LED might not be work, and the wave types of all Leads might be indicated. If 'LL' Lead becomes Fault, the wave type of II and V1-V6 Leads will not be indicated. If a Lead Fault occurs during monitoring or recording, a buzzer alarm will sound, and the lead fault LED will turn off.

8-6) Network Setting

User identification is to enter the hospital name that operates the system. To enter the hospital name, move the menu to IP as following steps.



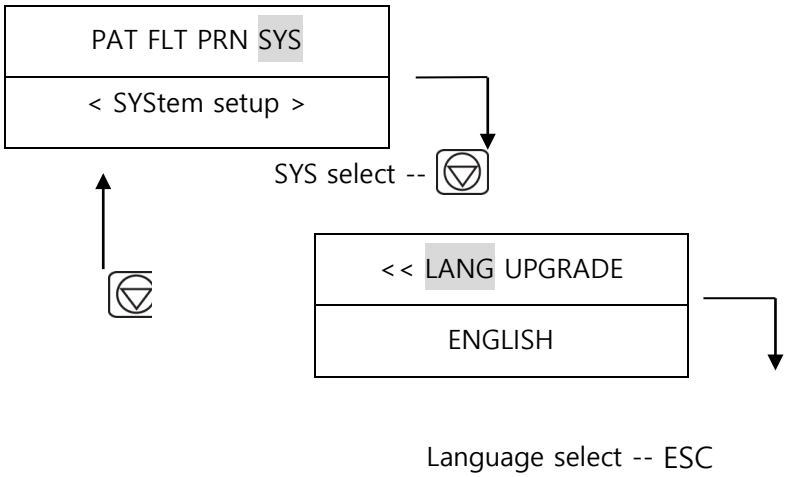
The automatic IP(DHCP) or fixed (Manually) can be selected through the 'ConfgIP'.

If the Configure is setup as automatic IP(DHCP), the Device IP, Subnet Mask, Gateway value is received automatically from the DHCP server on your network. If the Configure is set to manually, the user has to enter the Device IP, Subnet Mask, Gateway directly.

When selecting one of the 'Device IP', 'Subnet Mask', 'Gate Way', the keypad will show up. Then, input the information required and press '▽' button to save or 'ESC' to cancel the information.

8-7) Language

To set a language for CardioCare2000, move the menu to LANG as following steps.



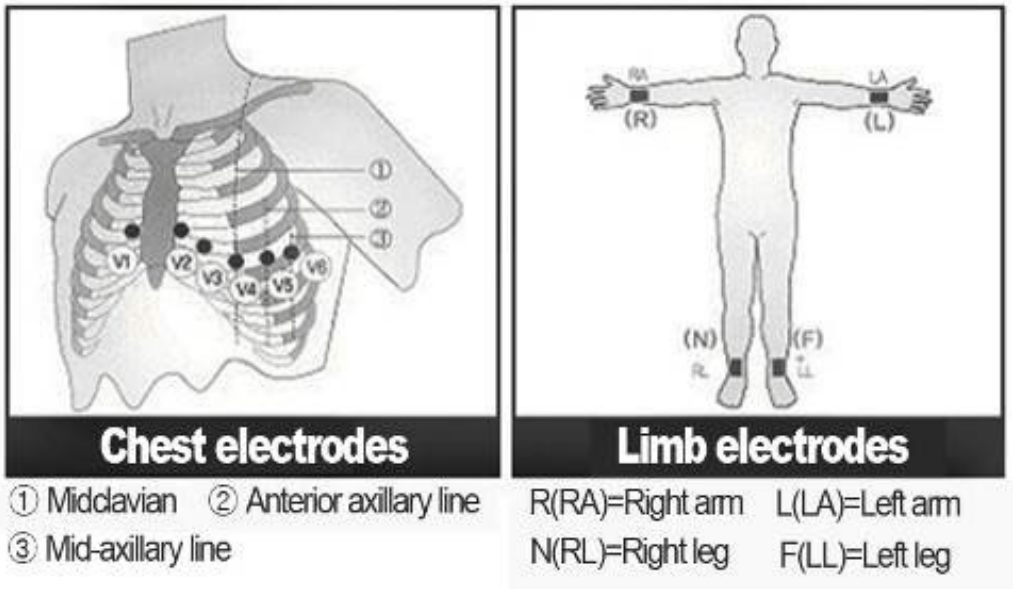
▽ key switches language. (English, English-US, Chinese, German, French, Russian, Spanish, Italian, Turkish, Polish, Romanian and Portuguese)

Chapter 2. ECG Recording Preparation

1) Attaching the Electrodes

When you touch [I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6], (Lead Fault Information) located in the center of the menu bar at the top of the ECG Main screen, a picture showing where to attach the electrodes is displayed.

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



The positions to attach limb electrodes are as follows:

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

The positions to attach the chest electrodes are as follows:

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

2) Connecting Electrodes

*** Checklist**

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

2-1) Connecting Patient Cable

Connect the patient cable to the port on the right side of body and connect limb electrodes to the terminals of RL (N), LL (F), RA (R), and LA (L) of patient cable connected in the CardioCare2000 and chest electrodes to the terminals V1 (C1), V2 (C2), V3 (C3), V4 (C4), V5 (C5) and V6 (C6).

2-2) How to Attach the Electrodes

Have the patient lie down on the bed and release the tension in the skin area where the electrodes will be attached. Clean the area with disinfected alcohol or water before attaching electrodes. In case the patient is hairy on the attaching spots, shave them. If the attachment body part is curved and it is difficult to attach the electrodes, attach them to the positions that are as similar as possible without a curve.
If the noise is severe even if you have used alcohol or water, apply the ECG gel to the attaching spots before attaching the electrodes.
Be sure to wipe off the used ECG Gel, because if it gets dried and hardened, it can generate noise in the ECG signal.

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

2-3) What to Do with Poor Lead Connection

Take the following measures when the lead connection is poor.

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

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

Chapter 3. Recording of ECGs

1) Introduction

1. Turn the power switch on after connecting leads to the patient according to preparation for ECGs recording of Chapter 2.
2. Set the filter, signal level, display speed, channel form, rhythm lead according to "Basic Setting" of Chapter3.
3. Enter the patient information according to "Basic Setting –Enter Patient Data" of Chapter 3.
4. Press the REC  key to record patient ECGs after READY indicator lamp lights up
5. In case READY indicator lamp does not light up, press MONI  key to check out the ECG signal. If you are still troubled with poor signal, take necessary steps according to "Lead-off troubleshooting" of Chapter 2.
6. Press COPY  key to print the same report as previously printed one. Press  key to exit during printing or recording of ECGs.

The following is a description of the ECG recording menu.

	MONITOR: Displays real-time ECGs from the patient continuously or monitoring the patient ECGs for long time,
	RECORD: Records ECGs for 10 seconds by pressing key and prints in A4 sized report form after calculating the measurement parameter of the recorded ECGs
	COPY: Prints the same report as previously printed one in record mode or prints after changing system setting such as filter, signal level, output speed, channel form, rhythm cannel of previously recorded ECGs data in record mode
	STOP: Exit during printing or recording of ECGs

2) Basic setting

2-1) General Information

LCD displays current system setting in the order of signal level, printing speed, baseline filter, EMG filter, heart rate, channel form, rhythm channel when system is turned on. These settings can be changed by two kinds of methods. First method is to use short keys. System setting can be easily changed by pressing short keys of control panel that accord with the icons displayed on the LCD screen. Second method is to use menu. Once, move to menu mode while LCD displays current system setting by presage  key and then select "PAT", "FLT", "PRN". "PAT" can be used to enter the patient information. "FLT" can be used to select the filter. "PRN" can be used to adjust printing.

2-2) Signal Level Setting

The signal level should be adjusted in case that signal overlaps with neighboring traces or the amplitude of pulse is too small to interpret.

Signal Level setting is adjustable in four ways. The entire 12 channel is set to each out of 5mm/mV, 10mm/mV, 20mm/mV and aut (Auto gain control) which sets I, II, III, aVR, aVL, aVF to 10mm/mV, V1, V2, V3, V4, V5, V6 to 5mm/mV.

As for 5mm/mV, it indicates that the amplitude of 1mV pulse is amplified into 5mm.

To change the signal level, press SENS  key to select the required one.

SENS  key toggles between 5, 10, 20, aut that are displayed on the LCD.

The selected setting is shown on the bottom line of the output report indicated by 'all channels: 5mm/mV, all channels: 10mm/mV, all channels: 20mm/mV' as for 5, 10, 20 and 'I-aVF': 10mm/mV, V1-V6: 5mm/mV' as for aut.

2-3) Display Speed Setting

Display speed setting is to adjust the width of the output signal. Adjustable value is 12.5mm/s, 25mm/s, 50mm/s. As for 25mm/s, it indicates that ECG signal for 1sec is recorded in the width of 25mm. So, 12.5mm/s is half the width of 25mm/s, 50mm/s is double the width of 25mm/s. For wide range of signal display, set large value.

To change the printing speed, press SPD  key to select the required one.

SPD  key toggles between 12.5, 25, 50 that are displayed on the LCD.

The selected setting is shown on the bottom line of the output report indicated by '12.5mm/s,

25mm/s, 50mm/s'. For your reference, set printing speed to 25mm/s when prints with A4 size.

2-4) Filter Setting

AC power noise, baseline drift caused by breathing, EMG signal can be recorded along with the output ECG signal. To set the AC noise filter, move to "FLT" menu to call up "AC" menu and press key. key toggles between off, 50hz, 60hz. Off indicates that filter does not suppress ac interference. As for 50Hz or 60Hz, filter suppresses 50Hz or 60Hz AC power noise. In case of battery power, ECG signal is clear only with Offsetting because AC noise interference hardly exist. The selection is 50Hz for most of Europe and 60Hz for USA and other countries. The selected setting is shown on the bottom line of the output form indicated AC 60Hz, AC 50Hz or AC OFF

Baseline drift is caused by patient breath. Baseline drift filter can be set by pressing key. BASE key switches on or off. off, 0.05, 0.1 or 0.2Hz indicates base lien filter is applied or not. The selected setting is shown on the bottom line of the output form indicated by '0.1hz-', as for filter on and '0hz-' as for filter off.

0.05Hz means all signals below 0.05Hz will be removed. If it is off at the bottom of the FORM, it is displayed as 0Hz-, if it is 0.05Hz, it is displayed as 0.05Hz-, if it is 0.1Hz, it is displayed as 0.1Hz-, and if it is 0.2Hz, it is displayed as 0.2Hz-.

EMG signal is induced from muscle and internal organs of the patient.
For clear ECG signal output, it is necessary to eliminate EMG signal interference.
EMG filter can be set by pressing MUSC key. MUSC key switches on or off.
On or off indicates EMG filter is applied or not. The selected setting is shown on the bottom line of the output form indicated 'EMG: On' or 'EMG: Off
Low pass filter can be selected to optimize ECG signal after applying above three filters and if ECG signal is still interfered. To set the low pass filter, move the menu to "FLT" to call up "LPF" menu and press key. key toggles between off, 40hz, 100hz, 150hz. As for 40Hz, it indicates filter suppresses higher frequency than 40Hz. The selected setting is shown on the bottom line of the output form indicated by 'Off' as for off, by'-40hz' as for 40hz, by'-100hz' as for 100hz, by '-150hz' as for 150hz.
To apply filter could result in ECG distortion. So, filter should be appropriately applied to reduce

the fluctuation without affecting the ECG signal when output signal is badly interfered only.

For your reference, baseline file and ac filter should be always active and EMG filter can be applied appropriately. It is recommended for LPF to set 150Hz during diagnosis.

2-5) Channel form Setting

Channel form setting is to adjust the numbers of channel of output form.
This system provides four kinds of channel form of 3ch+1rhy, 6ch+1rhy, 12ch rhy, 60s 1rhy.
As for 3ch+1rhy, 10 seconds of ECG data are recorded in four consecutive segments of 2.5 seconds such as I, II, III for first 2.5 seconds time segment, aVR, aVL, aVF for second 2.5 seconds time segment, V1,V2, V3 for third 2.5 seconds time segment, V4, V5, V6 for last 2.5 seconds segment. And 1 channel rhythm is recorded for 10 seconds in lower part of the output form.

As for 6ch+1rhy, 10 seconds of ECG data are recorded such as I, II, III, aVR, aVL, aVF for first 5 seconds time segment and V1, V2, V3, V4, V5, V6 for next 5 seconds time segment. And 1 channel rhythm is recorded for 10 seconds in lower part of the output form.

As for 12ch rhy, 12 channel rhythms are simultaneously and continuously recorded in the order of I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6.

As for 60s 1rhy, 1 channel rhythm is recorded with 6 lines, 10 seconds to every line, for 60 seconds.

To set the channel form, press FORM key. FORM key toggles between 3ch+1rhy, 6ch+1rhy, 12ch rhy, 60s 1rhy that are displayed on the LCD.
The selected setting is shown on the top line of the output form indicated by '3 Channels + 1Rhythm Report' as for 3ch+1rhy, '6Channels + 1Rhythm Report' as for 6ch+1rhy, '12Channels Rhythm Report' as for 12ch rhy, '1Rhythm Report (60sec) as for 60s 1rhy.

2-6) Rhythm Channel Setting

Rhythm channel setting is to adjust the lead of output form. To set rhythm lead, press LEAD key. LEAD key toggles between I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6 that are displayed on the LCD. The selected rhythm lead recorded in lower part of the output form for 10 seconds is the standard lead compared with another channel.

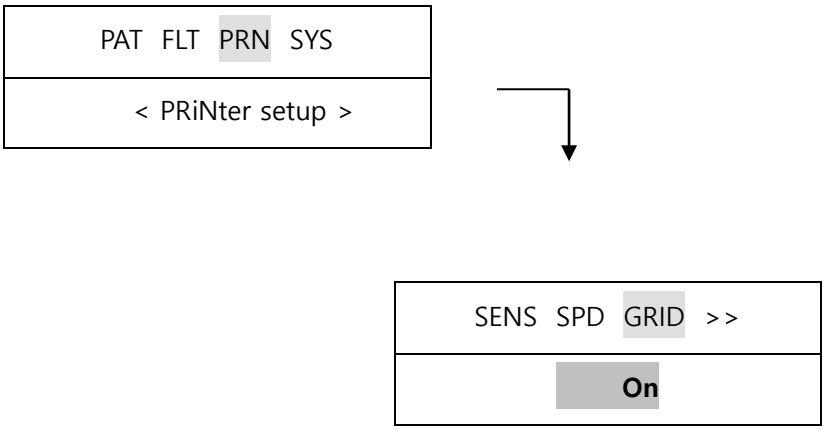
2-7) Grid Setting

Grid setting is needed if fax sheet is used as recording paper.

Grid is marked with solid line of 5mm X 5mm and with dot of 1mm X 1mm position.

In case of using standard ECG recording paper supplied from Bionet Co. Ltd instead of using fax sheet, grid setting should be off because grid is already marked on recording paper.

To set the grid, moves the menu to * **GRID** * as following steps.



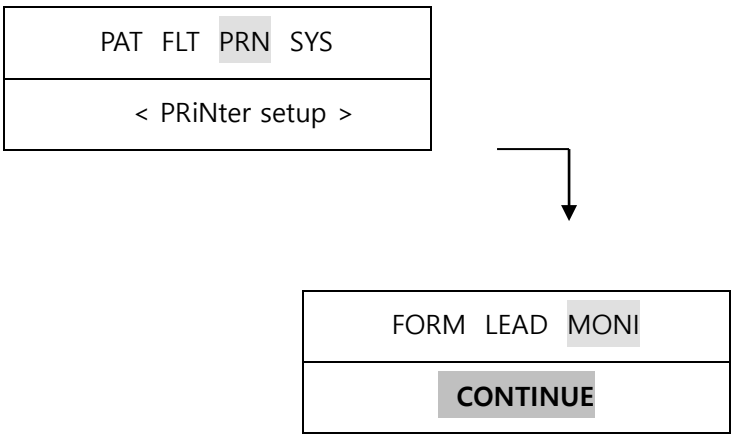
key switches on or off. If set to on, grid is recorded on the recording paper.

If set to off, grid is not recorded on the recording paper.

2-8) Monitoring form Setting

You can set up the real time printing size.

To set the monitoring form, moves the menu to * **MONI** * as following steps.

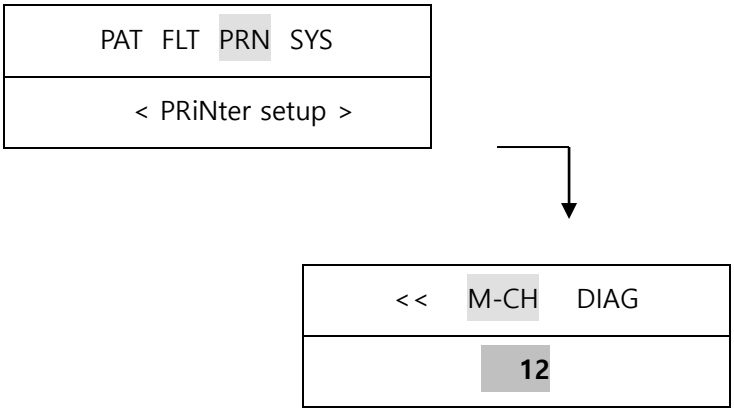


key switches continue or A4 report. If set to continue, the lead will be printed out continuously until you press the key on the control panel. If set to A4 report, print out the 10-second data in the form of A4 paper.

2-9) Monitoring Channel Setting

Monitoring channel setting is to adjust the numbers of channel of monitoring form. This system provides four kinds of channel form of 3ch, 6ch, 12ch.

To set the monitoring channel, moves the menu to * **M-CH** * as following steps.



key switches 3, 6 and 12. If set to 3, print 3 channels at the same time (I ~ III / aVR ~ aVF / V1 ~ V3 / V4 ~ V6) If you want to change the channel, press the on the control panel.

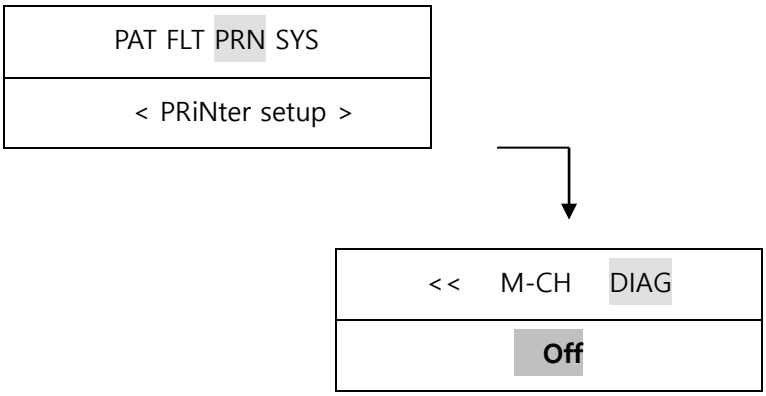
If set to 6, print 6 channels at the same time (I ~ aVF / V1 ~ V6) If you want to change the channel, press the on the control panel.

If set to 12, print 12 channels at the same time (I ~ V6).

2-10) Diagnosis On/Off Setting

When you print out the diagnosis report, you can choose the result of diagnosis is printed out or not on the report.

To set the diagnosis, moves the menu to * **DIAG** * as following steps.

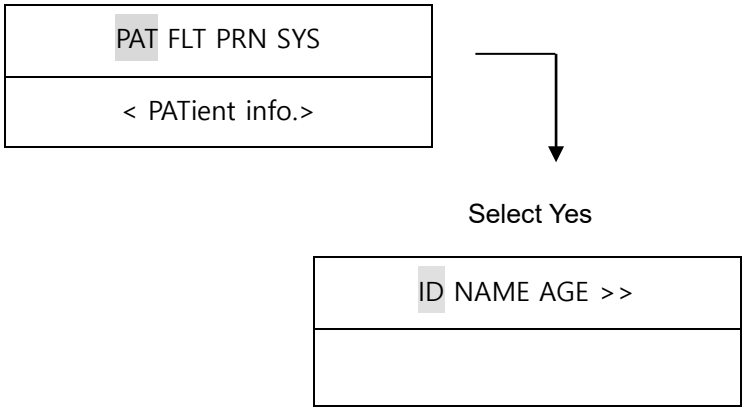


key switches off, Standard and Professional.

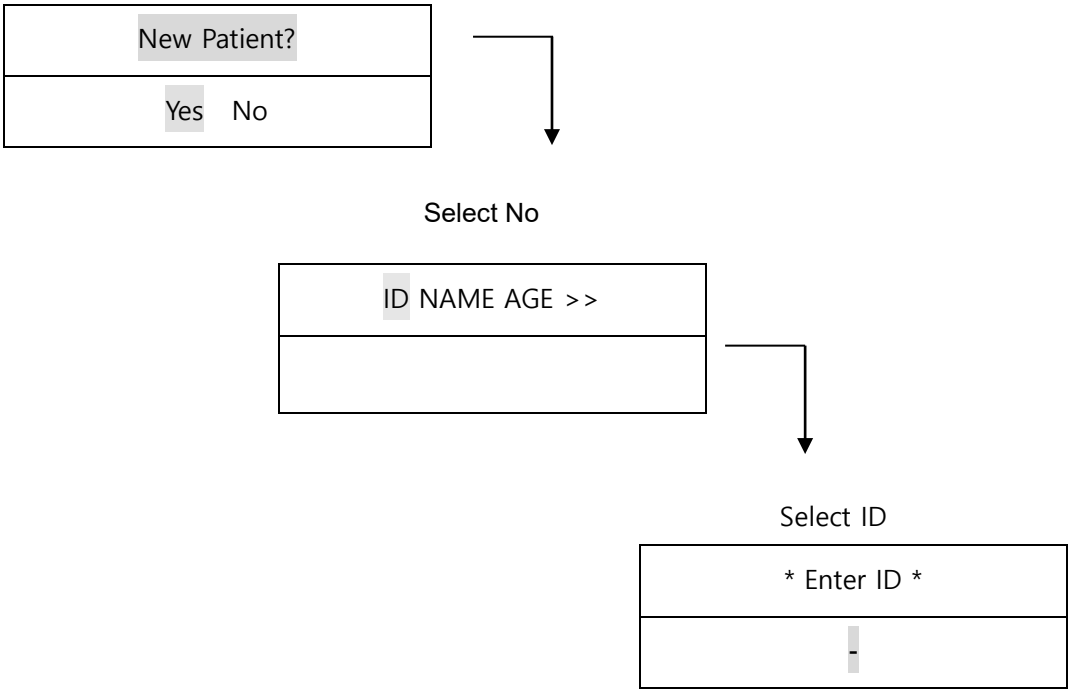
When 'OFF' is selected, the content of diagnosis will not be printed out, whereas when 'Standard' is selected, the basic information of diagnosis will be printed out at the top of the chart paper, In case of 'Professional', various information of diagnosis will be printed out.

2-11) Enter Patient Data

Patient information including patient ID, name, age, sex, height, weight can be entered. There are two methods to enter patient data. First, move the menu to patient data menu by pressing PAT key. Second, move the menu to **"ID"** as following steps.

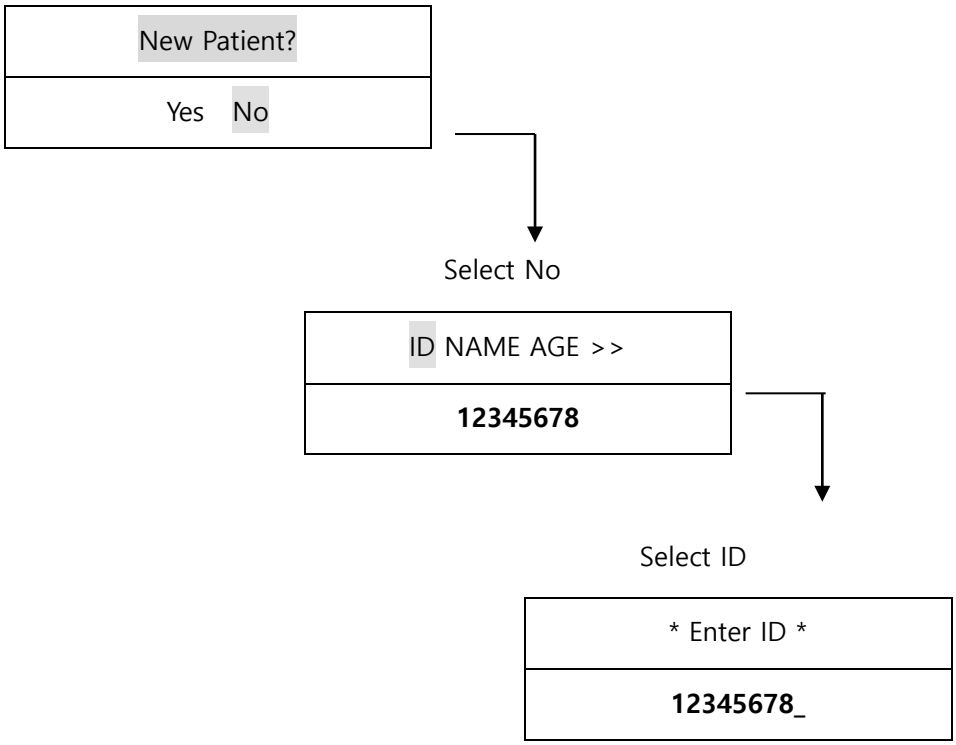


When there are previous patient data, following window appears on the LCD whether to change data of the previously recorded one or to select new patient.

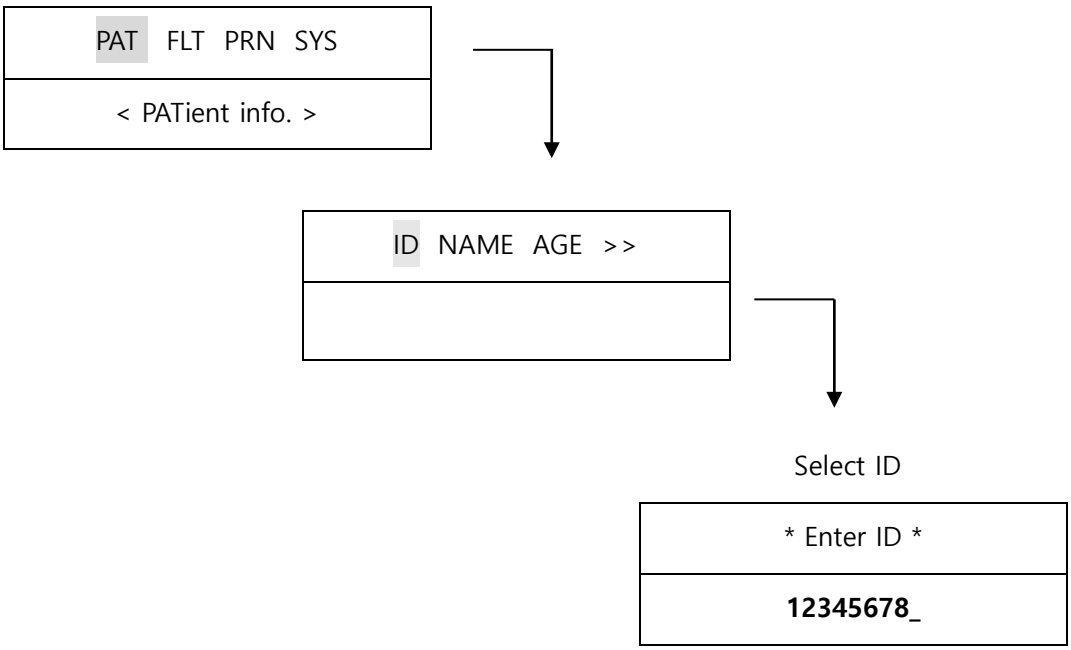


All the other patient data are deleted with selecting yes and then move the menu to **"ENTER ID"** for new patient data entry.

Previous patient data are displayed on the LCD as follows with selecting no:

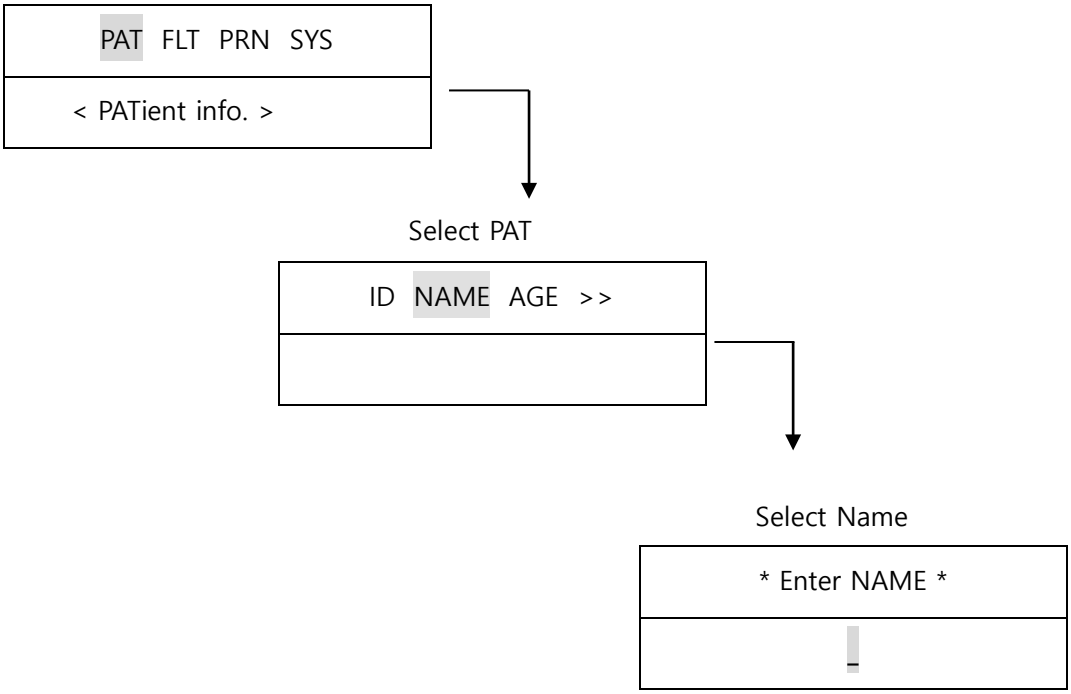


To enter patient ID, move the menu to **"ENTER ID"** as following steps:



Patient ID can be entered in up to 16 characters. ID number is entered by pressing 0, ..., 9 numeric keys in the current cursor position. Wrongly typed number can be deleted with ◁ key. Use ▷ key to enter '–'. ID entry can be combined with numbers of 123-456-789 and '-'. To exit the ID entry press key that moves to the menu above.

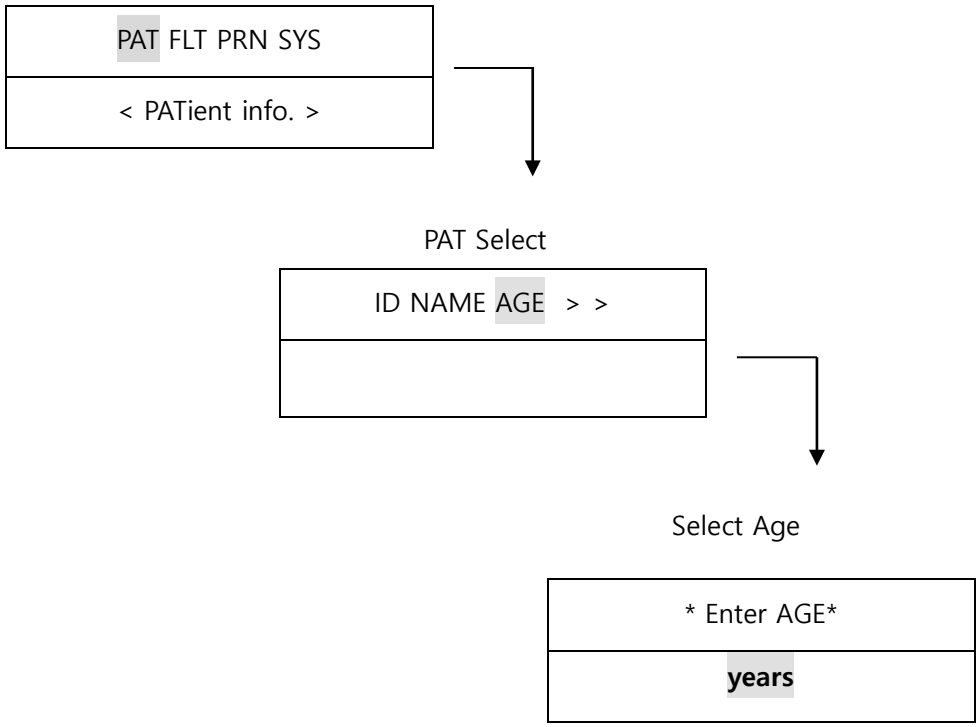
To enter patient name, move the menu to **"ENTER NAME"** as following steps:



Patient name can be entered in up to 16 characters. To enter the name, select the required character in the current cursor position. As for [1ABC] key, the key toggles in the order of A, B, C, 1, A, ...whenever pressing that key.

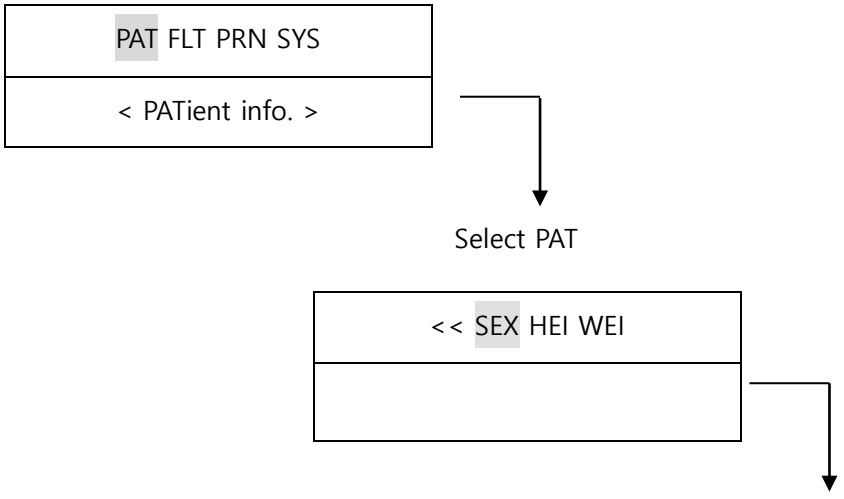
So, if you want to enter B character, press ▷ key to input B after pressing the [1ABC] key two times in the current cursor position. Then moves the cursor to the next. To exit the patient name press key that moves to the menu above.

To enter age, move the menu to **"ENTER AGE"** as following step:



Age can be entered in up to 3 figures. Age is entered by the unit of year. Age is entered with pressing 0, ..., 9 numeric keys in the current cursor position and cursor automatically moves to the right. To exit Age press key that moves to the menu above.

To enter sex, move the menu to "ENTER SEX" as following steps:



Select SEX

* Enter Sex *
male **female**

Sex can be selected between male and female with ◁ ▷ key. To exit sex press  key or ESC key that moves to the menu above.

To enter height, move the menu to "ENTER HEIGHT" as following step:

PAT FLT PRN SYS
< PATient info. >

Select PAT

<< SEX HEI WEI

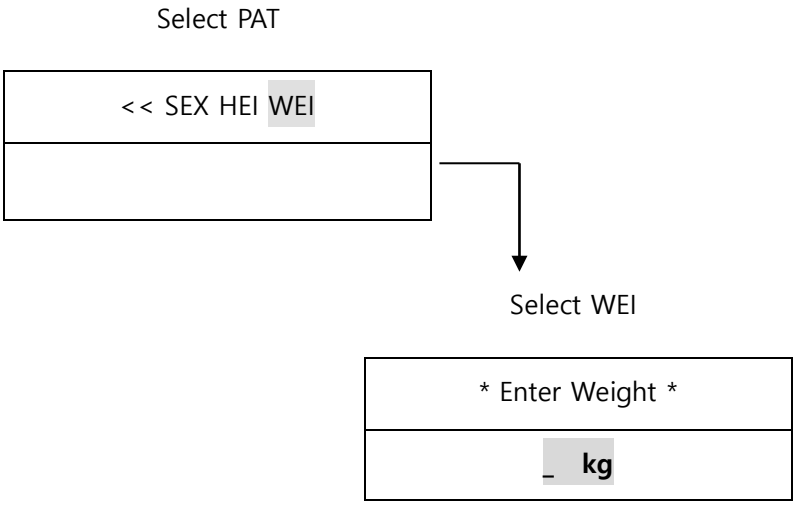
Select HEI

* Enter Height *
_ **cm**

Height can be entered in up to 3 figures. Height is entered by the unit of cm. Height is entered with pressing 0, ..., 9 numeric keys in the current cursor position and cursor automatically moves to the right. To exit height press  key that moves to the menu above.

To enter weight, move the menu to "ENTER WEIGHT" as following steps:

PAT FLT PRN SYS
< PATient info. >



Weight can be entered in up to 3 figures. Weight is entered by the unit of kg. Weight is entered with pressing 0, ..., 9 numeric keys in the current cursor position and cursor automatically moves to the right. To exit Weight press key that moves to the menu above.

3) Monitor mode output

In monitor mode output, the measured ECGs is displayed in real-time.
This output function can be used for the purpose of checking out that the entire channel signal is active before recording ECGs and monitoring ECGs of the patient for long time.

Printing speed can be set to 12.5 mm/s, 25mm/s, 50mm/s and signal level can be set to 5mm/mV, 10mm/mV, 20mm/mV, aut.

3-1) Output Method

Filter setting value is fixed. Set the required printing speed and signal level and press MON key. Then, the system starts printing according to the selected speed with the following message on the LCD.

* MONITOR *
Continue

Press key or key to stop printing. Then system stops printing and displays system setting after indicating following message for 1 second on the LCD.

* MONITOR *
aborted!

3-2) Output Form

In monitor mode output, 12 channel rhythms are printed simultaneously and continuously as shown below.

Indicated heart rate is the average of previous 4 heart rates.

If the MONI M-CH is set at 3 or 6, please press key to start printing.

When you press key again the lead is changed to next group and the printing starts.

If you want to stop in the middle of printing, press the key.

4) Record mode output

In record mode output, ECGs is recorded on the memory first and displayed according to the selected signal level, output display speed, channel form after applying the selected filter and calculating the measurement parameter including heart rate, PR interval, QRS duration, QT/QTc, P-R-T axes of the recorded ECGs.

4-1) 10 seconds ECG Recording

Press key when channel form is set to 3ch+1rhy, 6ch+1rhy, 12ch rhy

Then, the system starts recording data for 10 seconds on the memory with the following message indicates recording time on the LCD.

* RECORD (10s) *
10sec

After recording data for 10 seconds, the system starts applying the selected filter and calculating the measurement parameter of the recorded ECGs with the following message on the LCD.

* RECORD (10s) *
Processing

After data processing, the system starts printing with the following message on the LCD.

* RECORD (10s) *
Printing

Press key to exit during recording or printing data. Then, system stops recording or printing and displays system setting after following message for 1 second on the LCD.

* RECORD (10s) *
Aborted!

4-2) 60 seconds ECG Recording

Press key when channel form is set to 60s 1rhy.

Then, the system starts recording data on the selected rhythm channel for 60 seconds on the memory with the following message indicates recording time on the LCD.

* RECORD (10s) *
60 sec

After recording data for 60 seconds, the system starts applying the selected filter and calculates the heart rate of the recorded ECGs with the following message on the LCD.

* RECORD(60s) *
Processing

After data processing, the system starts printing with the following message on the LCD.

* RECORD(60s) *
Printing

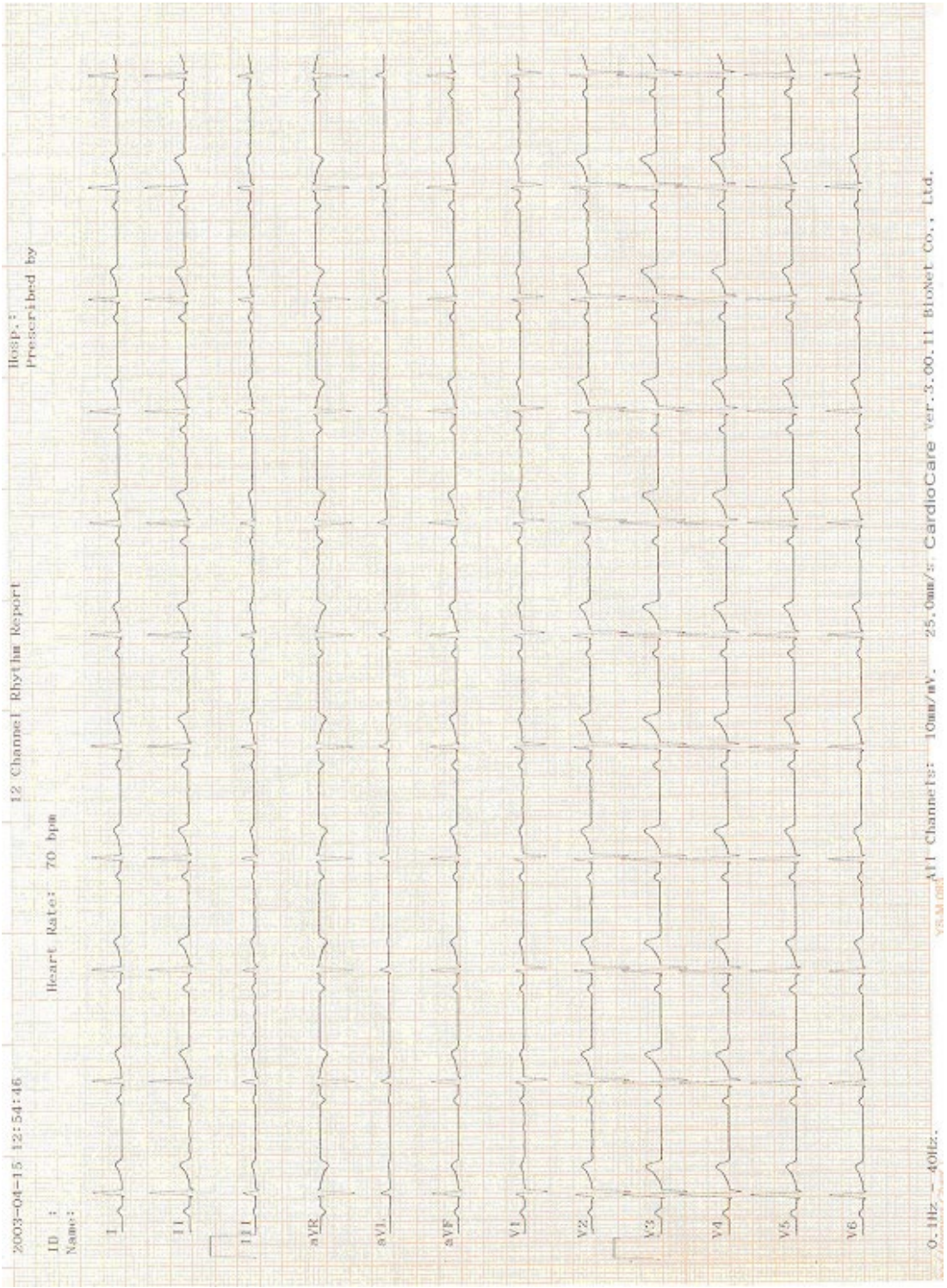
Press  key to exit during recording or printing data. Then, system stops recording or printing and displays system setting after indicating following message for 1 second on the LCD.

* RECORD(60s) *
Aborted!

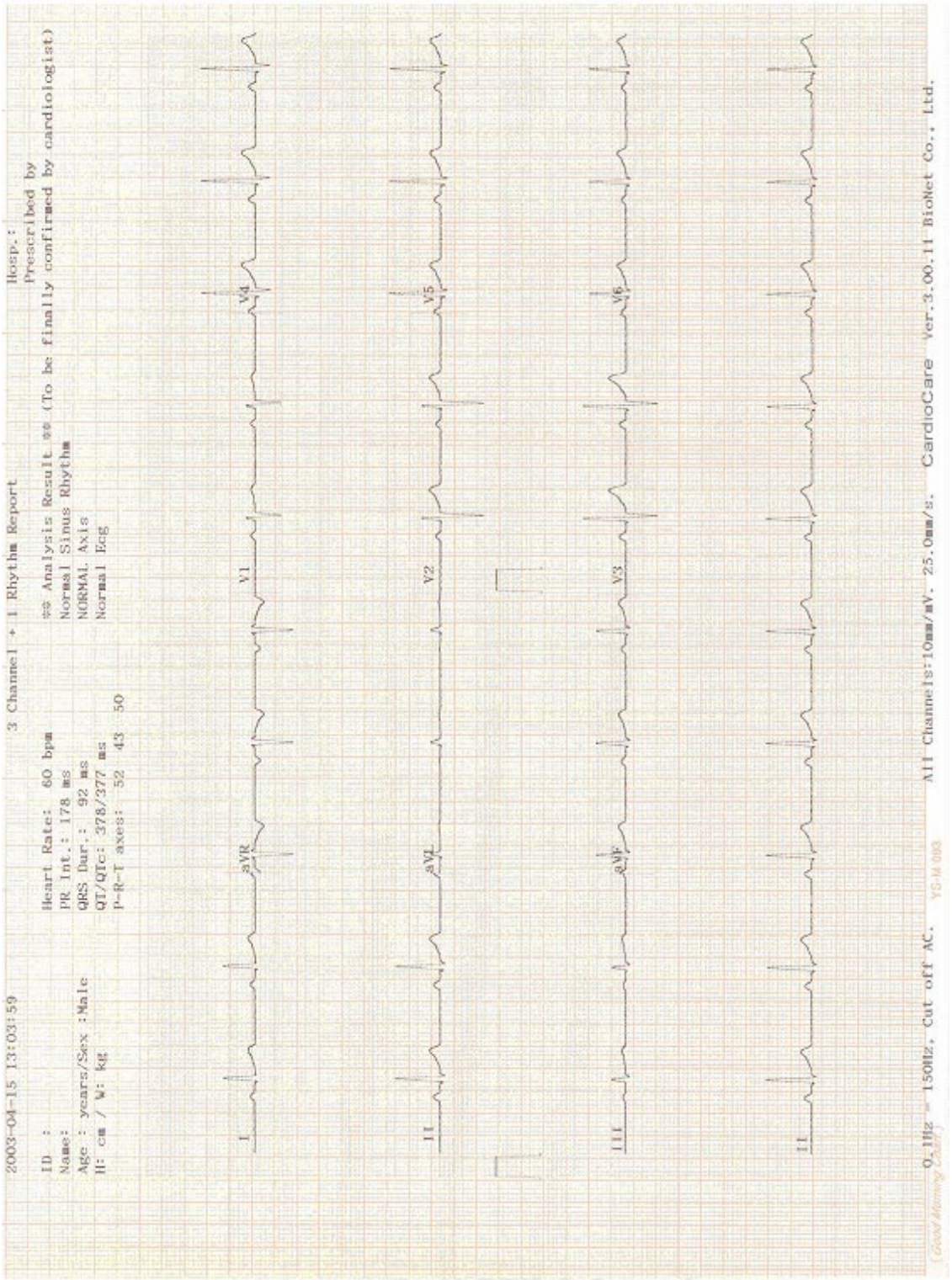
4-3) Output FORM

The followings are examples of print formats:

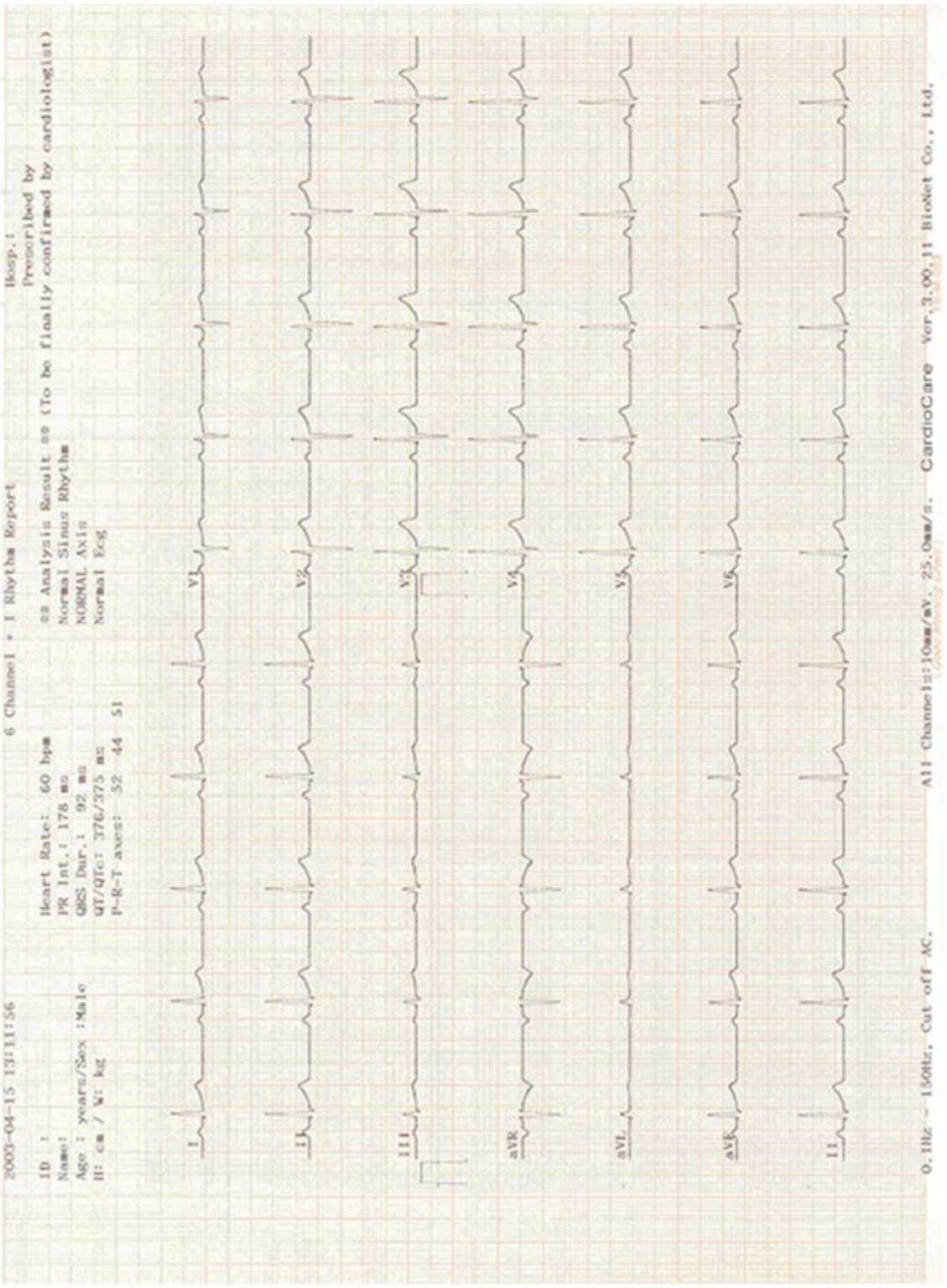
RHYTHM REPORT FORM



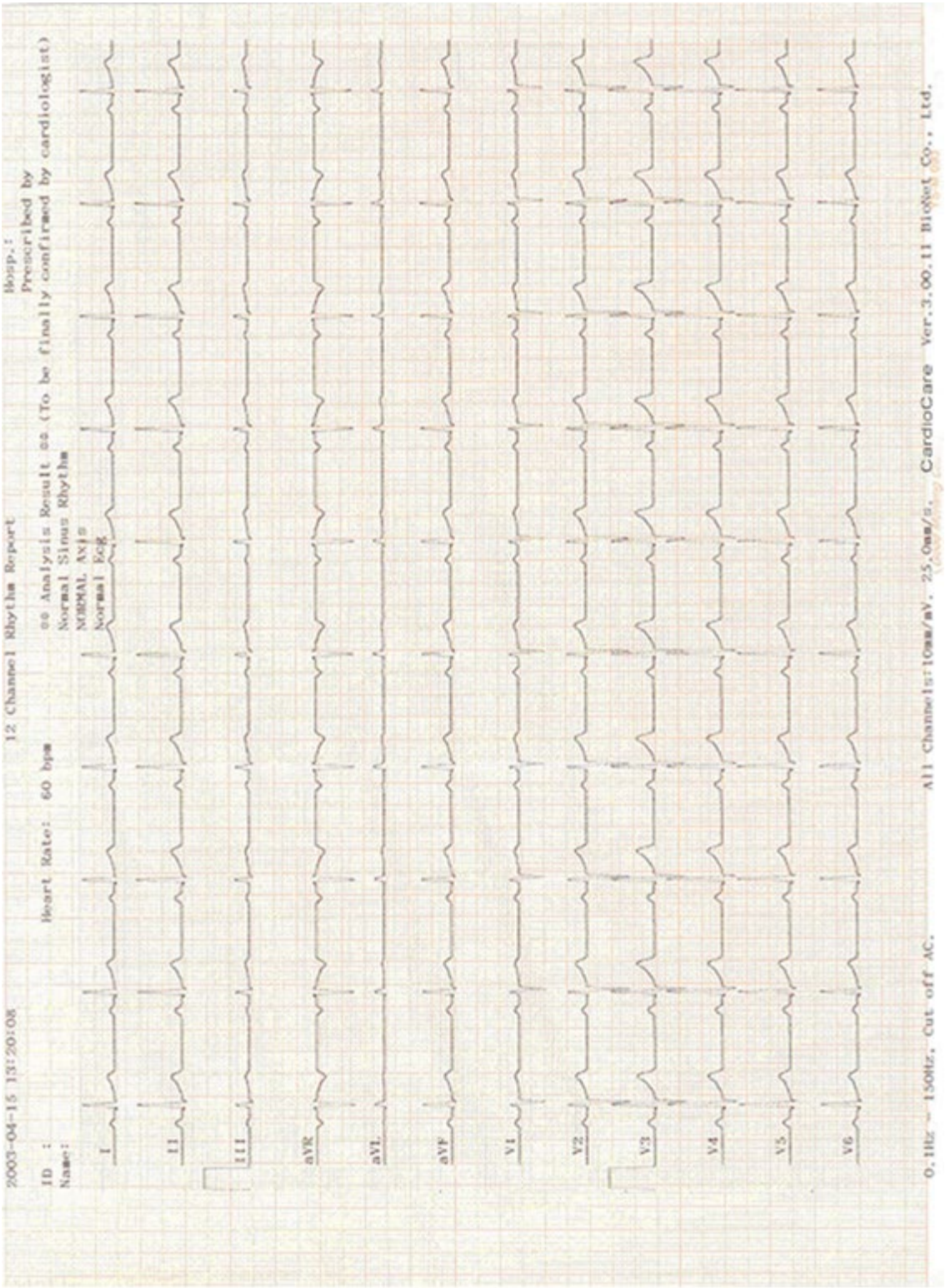
RECORD REPORT FORM (3ch+1rhy)



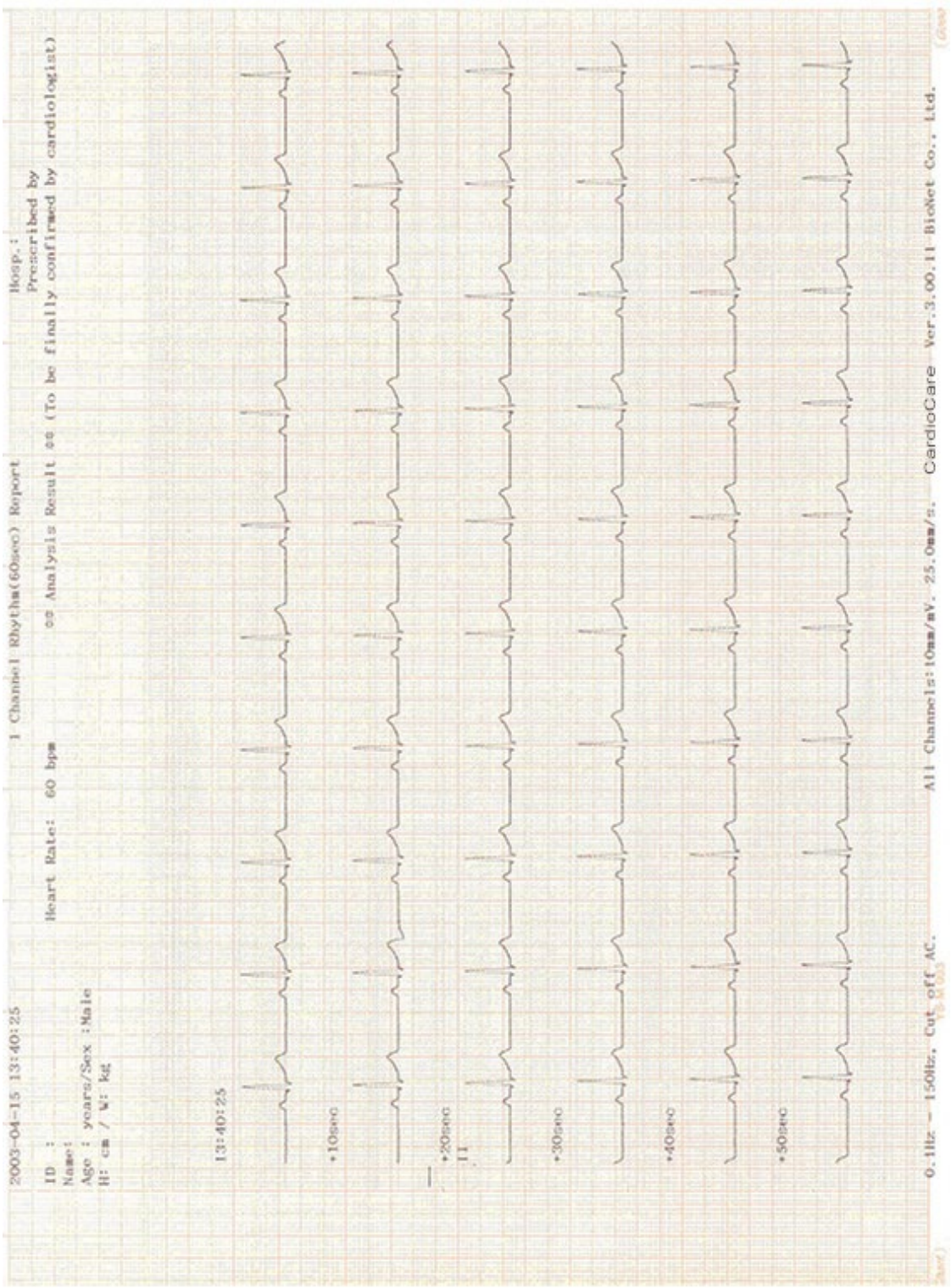
RECORD REPORT FORM (6ch+1rhy)



RECORD REPORT FORM (12ch rhy)



RECORD REPORT FORM (60s 1rhy)



5) Copy mode output

Copy mode output function is to print the same report as previously printed one or print after changing setting such as filter, signal level, output display speed, channel form, rhythm cannel of previously recorded ECG data.

System starts printing the same report as previously printed one with the following message on the LCD by pressing  key after record mode printing.

* COPY *
Printing

If copy mode printing is tried without operating record mode printing, system displays system setting after indicating following message for 1 second on the LCD.

* COPY *
!!No Record Data

If filter setting is changed to the previously recorded ECG data, the system starts applying changed filter with the following message on the LCD.

* COPY *
processing

After filter processing, the system starts printing with the following message on the LCD.

* COPY *
printing

After printing is finished, the system displays system setting after indicating following message for 1 second on the LCD.

* COPY *
Finished!

Press  key to exit during printing data. Then, system stops printing and displays system setting after indicating following message for 1 second on the LCD.

* COPY *
Aborted!

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

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

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

CAUTIONS
Do not use CardioCare2000 in combination with any Electro-Surgical (ES) equipment.

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

CAUTIONS
CardioCare2000 should be used in the presence of a health care professional when used for patients who have undergone Cardiac Assist Device surgery.

Chapter 4. System Management

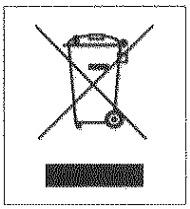
1) Maintenance and Cleanliness

Keep CardioCare2000 equipment and handles clean. Avoid damaging or contaminating the equipment using the methods recommended below.
If you use the substances - including not allowed substances - that can damage on the product, warranty is not applied even during the warranty period.

NOTE
Clean the equipment and examine the body and electrodes thoroughly. Do not use old or damaged equipment.

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

Existing Device Disposal



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

2) Regular Examination

As with any other medical equipment, have your CardioCare2000 regularly safety inspected once a year. Refer to the service manual provided by Bionet for inspection items.

3) Trouble Shooting

1. In case that buzzer alarms for 1 second during printing and following message appears on the LCD:

* RECORD *
Paper empty!

This indicates that printer run out of printing paper. Operate again after replacing printing paper.

2. In case that nothing can be printed out or printout fades; Top cover of the printer is not closed completely. Operate again after closing firmly

3. In case that buzzer alarms three times in series when system is on battery power, following message appears on the LCD.:

* Low Battery *
Power off

This indicates that the battery is almost discharged. Turn the system power off and connect the ac power source. Then turn the system power on again.

.

4. In case that ECGs is interfered with power noise:

First, move the menu to FLT → AC and check if AC is set to 50Hz.

If ECGs is still interfered even if ac filter is set to 60Hz, connect the potential equalization connector with the common ground conductor. Do not connect the potential equalization conductor with the ac power system ground. The metallic frame of the patient's bed or another metallic object connected with building can be used for grounding.

4) Manufacturer's Declaration

4-1) Electromagnetic Compatibility Information

Phenomenon	Basic EMC standard or test method	Test level/requirement
Mains terminal disturbance voltage	CISPR 11	Group1, Class A
Radiated disturbance	CISPR 11	Group1, Class A
Harmonic Current Emission	IEC 61000-3-2	Class A
Voltage change, Voltage fluctuations and Flicker Emission	IEC 61000-3-3	Pst: 1 Plt: 0.65 Tmax:0.5 dmax: 4% dc: 3.3%
Electrostatic Discharge Immunity	IEC 61000-4-2	± 8 kV/Contact ± 2, ± 4, ± 8, ± 15 kV/Air
Radiated RF Electromagnetic Field Immunity	IEC 61000-4-3	3 V/m 80 MHz - 2.7 GHz 80% AM at 1 kHz
Immunity to Proximity Fields from RF wireless Communications Equipment	IEC 61000-4-3	Table 9 in IEC 60601-1-2: 2014
Electrical Fast Transient/Burst Immunity	IEC 61000-4-4	± 2 kV, 100 kHz repetition frequency ± 1 kV, 100 kHz repetition frequency
Surge Immunity	IEC 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	3 V 0.15 MHz - 80 MHz 6 V in ISM bands Between 0.15 MHz and 80 MHz

		80% AM at 1 kHz
Power Frequency Magnetic Field Immunity	IEC 61000-4-8	30 A/m 50 Hz and 60 Hz
Voltage dips	IEC 61000-4-11	0 % U_T: 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°
		0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles Single phase: at 0º
Voltage interruptions	IEC 61000-4-11	0 % U_T; 250/300 cycle

4-2) Electromagnetic compatibility - Guidance and manufacturer's declaration

Guidance and manufacturer's declaration – electromagnetic emissions		
The CardioCare2000 is intended for use in the electromagnetic environment specified below. The customer or the user of the CardioCare2000 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The CardioCare2000 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 CardioCare2000 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 CardioCare2000 or shielding the location

Guidance and manufacturer's declaration – electromagnetic immunity			
The CardioCare2000 is intended for use in the electromagnetic environment specified below. The customer or the user of the CardioCare2000 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	The quality of supplied power should be suitable for general business site 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	The quality of supplied power should be suitable for general business site 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 residential or hospital environment. If the user of the CardioCare2000 requires continued operation during power mains interruptions, it is recommended that the CardioCare2000 be powered from an uninterruptible power supply or a battery be used with the system power source.
Power frequency (50/60 Hz) magnetic field	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 AC voltage of the power before using test level			

Guidance and manufacturer's declaration – electromagnetic immunity			
The CardioCare2000 is intended for use in the electromagnetic environment specified below. The customer or the user of the CardioCare2000 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 80 MHz	3 V rms	Portable and mobile RF communications equipment should be used no closer to any part of the CardioCare2000, including cables, than the recommended separation distance calculated from the

Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	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 the recommended separation distance in meters (m). 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: 

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 CardioCare2000 is used exceeds the applicable RF compliance level above, the CardioCare2000 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the CardioCare2000.

[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 CardioCare2000

The CardioCare2000 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the CardioCare2000 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the CardioCare2000 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 $d = [\frac{3,5}{V_1}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3,5}{E_1}]\sqrt{P}$	800 MHz to 2,5 GHz $d = [\frac{7}{E_1}]\sqrt{P}$
	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 5. Product Specifications

ECG Leads	Simultaneous 12 Leads Resting ECG
Recording Channel	3CH+1RHY, 6CH+1RHY, 12CH, 1CH Long Time (1min)
Gain	5, 10, 20, Auto (I~aVF: 10, V1~V6: 5) mm/mV
Printing Speed	12.5, 25, 50 mm/sec
Sampling Rate	Analysis Sampling Rate – 500sample/sec Digital Sampling Rate - 8,000sample/sec
Filters	AC (50/60Hz, -20dB or better), Muscle (25~35Hz, -3dB or better), BaseLine Drift (off, 0.05, 0.1, 0.2Hz, -3dB or better), Low Pass Filter (off, 40Hz, 100Hz, 150Hz)
Display	2 x 16 Char LCD Display Gain, Speed, Filter Status, HR, Printing Form, Rhythm Lead
User Interface	Short Key
Printer Resolution	Thermal Print Head, Roll Paper Report Paper - Width: A4 – 215mm (8.5") - Length: A4 – 297mm (11.7") Resolution: 8dot/mm (0.125mm pitch)
Patient data	ID, Name, Age, Gender, Height, Weight
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
Line Power		Input: 100- 240Vac, 1.5-0.75A, 50-60Hz Output: 15Vdc, 4.2A
Battery type		Replaceable and Rechargeable, Lithium ion, 10.8V, 3250mA
Battery Capacity		6 hours of normal use or print 200 ECG pages (12 channel format at 25mm/s and 10mm/mV) The battery will charge to its full capacity within 3 hours with the power off.
Communication		LAN
Safety Conformity		Class I, Type CF Defibrillation-proof applied Part.
Environmental	**Operation**	Ambient Temperature: 10~40℃ Relative Humidity: 30~85%RH Atmospheric Pressure: 70~106KPa
	Storge/Ship	Ambient Temperature: -20~60℃ Relative Humidity: 10~95%RH Atmospheric Pressure: 50~106KPa
Dimensions		300(W) x 290(D) x97(H)mm, Approx. 3.0kg (Main Body)
Standard Accessory		Patient Cable (1 EA), Limbs Electrodes (1 SET), Chest Electrodes (1 SET), ECG Paper (1 EA), Power Cord (1 EA), ECG Gel (1 EA), Operation manual (1EA), ECG diagnosis guide (1EA)
Options		Rechargeable Battery (1 EA),

Warranty

Product Name	Electrocardiograph
Model Name	CardioCare2000
License Number	
License Date	
Serial Number	
Warranty period	1 year from the date of purchase
Date of purchase	(yyyy/mm/dd)
Customer	Hospital: Address: Name: Contact No:
Seller's Name	
Manufacturer's Name	Bionet Co., Ltd

※ Thanks for purchasing CardioCare2000.

※ This product is a medical machine.

※ This product meets the strict quality requirements thoroughly.

※ The repairing and compensation standards follow the consumer damage compensation regulations of the Ministry of Finance and Economy.

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CE 0123 **Bionet Co., Ltd**

Model Name: CardioCare2000