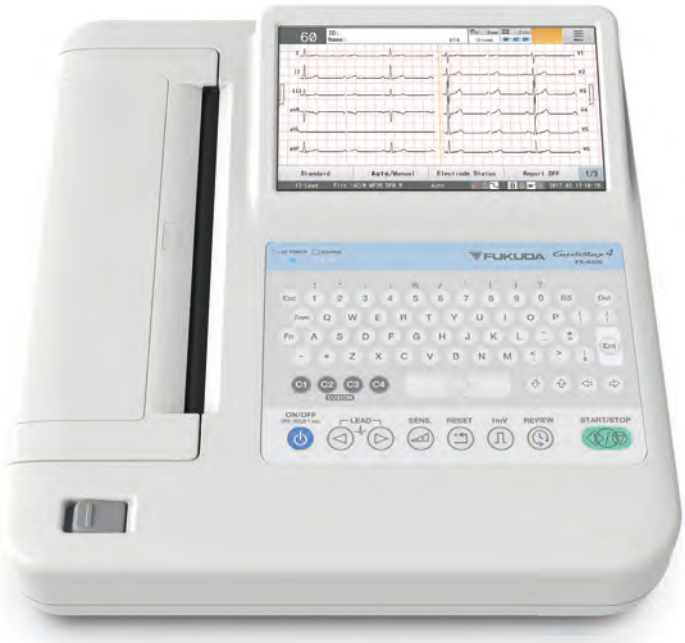
CardiMax 4

ELECTROCARDIOGRAPH

FX-8400

Ver. 03

Operation Manual



* Before using the product, please read this manual thoroughly.
* Store this manual where it can be always referred to.

FUKUDA

This manual is for the FX-8400 System Version 03.

⚠CAUTION	Federal Law restricts this device to sale by or on the order of a physician.

CAUTION

- Only physician or persons instructed by physicians are allowed to use the equipment.
- The information contained in this document is subject to change without notice due to improvement in the equipment.

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If this manual has pages missing or out of order, contact Fukuda Denshi for replacement.

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Preface

Introduction

Thank you for purchasing our new electrocardiograph.
This operation manual is intended as a guide to properly operate the CardiMax series FX-8400.
Read this operation manual carefully and make sure that you understand the instructions before using this device.
We recommend that you keep this operation manual handy when operating this product.
If you have any questions or opinions on the product or the manual, contact your local Fukuda Denshi service representative.

❑Precaution from Fukuda Denshi

Fukuda Denshi is liable for the safety, reliability, and performance of its device only if;
Maintenance, modifications, and repairs are carried out by authorized personnel.
Components are used in accordance with Fukuda Denshi operating instructions.
When repairing or replacing the parts, contact your nearest service representative.
If the device is used incorrectly and becomes unusable as a result, Fukuda Denshi is not liable for the malfunction.
Use the device only for the purposes specified in this manual.

❑Contact

If you need more detailed information or information about security risk, please contact following.

(1) Fukuda Denshi Co., Ltd.

3-39-4 Hongo, Bunkyo-ku, Tokyo, Japan
Tel:+81-3-5684-1455 Fax:+81-3-3814-1222
E-mail: info@fukuda.co.jp
Website: https://fukuda.com/

(2) Sales Representative

Write the name, address, phone, fax number of your local sales representative.

(Name of Sales Representative, Address, Phone/Fax)

- If a serious incident has occurred in relation to this device, please report it to the manufacturer and to the competent authority of the country where the user and/or the patient is established.
- In case you need the contact information for your national competent authority, please ask the manufacturer or the distributor from whom you purchased the device.

About This Manual

Expression Used in This Manual

❑Indications for the Screens and Keys

The keys displayed on the screen are indicated by [ ].
(Ex.: [Setting], [To exam], [1/2], etc.)

Other indications on the screen are indicated by " ".
(Ex.: "12-Lead Exam.", "ID", etc.)

The messages displayed on the screen will be indicated by < >.
(Ex.: <Acquiring waveforms>, etc.)

Composition of This Manual

This operation manual is composed of the following chapters.

Chapter Title	Description
Preface	General Description, Precautions for Safety, Displayed Messages and Solution
1.General Description	Features of this Device, Names of Parts and Their Function, How to View the LCD, Basic Operation Procedure
2.Installation	AC Power Connection, Battery Usage, Network Connection, Optional Device Connection
3.Preparation before Examination	Electrode Attachment, Checking the Date/Time, Filter/Sensitivity Setup
4.Entering Patient Information	Patient Data Categories, Procedure to Enter the Patient Information
5.12-Lead Examination	Manual Printing, Auto Printing, Review Printing, Commentary Printing, Extend Printing
6.12-Lead Examination (Advanced Function)	Freeze, Extend Printing, Post-Exercise Examination, ACS Diagnostic Support, Auto Capture
7.Arrhythmia ECG Examination	Required Settings, Printing Procedure
8.Rhythm Measurement	Rhythm Measurement Recording Procedure
9.File Transfers	Initializing the Media, Saving/Reading/Deleting/Correcting the Examination Data, Communication History
10.DICOM Work List	Procedure to Use the DICOM Work List
11. Ordering System	Communication Setup, Operation Procedure
12. Printing Daily Report	Printing Procedure of Daily Report
13. Settings	Displaying the Settings Screen, Saving/Printing the Settings
14. Maintenance and Inspection	Periodic Checks, Consumable Parts, Cleaning and Disinfecting, Correcting the Date/Time
15. Appendix	Specification, Accessories/Optional Accessories, Check List, Glossary

Reminders to Use the Device Safely

Always use the product in accordance with the method of operation and periodic inspection method described in this manual.

Read this manual thoroughly and understand it before using the device.

Safety Notations

The following safety notations are used throughout this manual. Each of these notations has a different meaning as shown below.

Read the following information thoroughly to ensure proper, correct and safe use of the product.

DANGER	Indicates a potentially hazardous situation which, if not avoided, will result in death, serious injury, or fire.
WARNING	Indicates a potentially hazardous situation which, if not avoided, could result in death, serious injury, or fire.
CAUTION	Indicates a potentially hazardous situation which, if not avoided, could result in minor or moderate injury, or property damage.
	This mark is attached to the main unit to protect the device from being damaged. The manual provides detailed information on items to which you have to pay attention.
NOTE	A note is not related to product safety, but provides information on proper use to prevent incorrect operation or malfunction.

An Example of Safety Symbol

	Indicates prohibited actions. Refer to the instruction stated near the symbol.
	Indicates a matter of Danger, Warning, or Caution that calls attention for safety. Refer to the instruction stated near the symbol.
	Indicates mandatory or instructed actions. Refer to the instruction stated near the symbol.

Symbols on the Device

The following is a list of symbols used on the FX-8400.

	Failure to follow operating instructions could place the patient or operator at risk.
	Indicates the need to refer to the related accompanying documents before operation.
	Indicates a matter of Danger, Warning that calls attention for safety.
	Indicates Type CF applied part with defibrillation-proof.
	Indicates the potential equalization terminal.
	Indicates the alternating current (AC) power supply.

	Indicates the LAN port.
	Indicates the USB port.
	Indicates the SD card slot.
	Indicates the serial connector.
 R-SYNC.	Indicates the ECG synchronized signal output connector.
	Name and Address of Manufacturer / Date of Manufacture Indicates the name and address of manufacturer, and date of manufacture.
	WEEE (Waste Electrical and Electronics Equipment) Indicates a separate collection for electrical and electronic equipment.
	Indicates the item is a medical device.
	Indicates the European authorized representative.
	Indicates the manufacturer's serial number.
	Indicates the manufacturer's batch code.

The following symbol is used on the External VGA Adapter

	Indicates the video output connector.

Safety

❑Design Specifications

This device meets the requirements of IEC 60601-1(2005) +A1(2012), ANSI AAMI / ES 60601-1: A1: 2012+C1: 2009/(R)2012+ A2: 2010/(R)2012 "Medical electrical equipment – Part 1: General requirements for basic safety and essential performance" and is classified as follows.

1 Protection against electrical shock
Class I Equipment, Internally Powered Device

2 Degree of protection against electrical shock
Type CF Applied Part

3 Degree of protection against ingress of water
No special protection against ingress of water (IPX0).

4 Classification according to the degree of safety when using in the presence of air or flammable anesthetic gas or oxygen or nitrous oxide and flammable anesthetic gas.
To be used in environments without flammable anesthetic gas or other flammable substances

5 Operation Mode
Can be used continuously

6 Classification of Sterilization Method
Not intended to be sterilized

7 Target
Neonate, Child, Adult

❑Essential Performance

The essential performance of this device is displaying and saving the electrocardiogram.

For necessary information to perform the test for essential performance and basic safety, refer to service personnel.

❑Preventive Maintenance

The purpose of preventive maintenance is to ensure that the device is in safe operating conditions at all times and prevent potential future problems.

Perform preventive maintenance at least once every three months.

Inspect the main unit and all connectors and cables for any external damage.

Perform maintenance if one of the following should occur. Do not repair or perform maintenance when the device is in use.

- When the device gets a strong impact due to dropping, etc.
- When liquid spills on or into the device
- When the device does not function normally
- When the enclosure of the device is cracked, broken or damaged
- Cables such as the power cable and lead wires have deteriorated in performance

Check all cables, devices and system components for damage, earth impedance, leakage current and accuracy.

Precautions when Using with Other Device

⚠ DANGER Non-Explosion Proof

- Never operate the device where flammable gas or fluid such as anesthetic, oxygen, and hydrogen are used. Explosion or fire may result.
- Never operate the device in the presence of flammable anesthetics, high concentration of oxygen. This may cause an explosion or fire.
- Never use the device in the hyperbaric oxygen therapy chamber. This may cause an explosion or fire.
- Do not ground with a gas pipe. Explosion or fire may result.

⚠ DANGER MRI

- Do not use this device with a magnetic resonance imaging (MRI) device. The device may be pulled towards the MRI device. Also it may cause failure, damage of this device or burn injury to the patient.

⚠ WARNING Defibrillator

- When using this device with a defibrillator, use only the specified patient cable. The use of a patient cable other than the specified defibrillation-proof type may damage the device or compromise safety when the device is used along with a defibrillator.
- Do not touch this device or patient during defibrillation. It may cause an electric shock.
- While using a defibrillator, ECG cannot be displayed or recorded.

⚠ WARNING High-frequency Surgical Devices

- When using this device with a high frequency external surgical device (electrosurgical instrument), make sure the contact between the patient and the ground plate is secured. If the connection is incomplete, the patient may suffer a burn at the electrode site.
- When using with electrosurgical instruments, make sure the contact between the patient and the ground plate can be sufficiently secured. If the connection is incomplete, the current from the electrosurgical instrument may run into the electrodes of this device and the patient may suffer a burn at the electrode site. The electrode should also be attached as far away from the surgery site as possible to decrease the risk of burns.
- The amount of noise interference is considerably different depending on the electrode position and surgery site. Place the ECG electrodes as far away as possible from the surgery site and the ground plate.

- Plug the electrosurgical instrument into a hospital grade outlet as far away as possible from the outlet of this device. This will reduce interference from the electrosurgical instrument.
- While using a high frequency surgical device, ECG cannot be displayed or recorded.

WARNING Other Product

- Do not connect any unauthorized device.
- Connect so that all products satisfy the conditions of operating environment.
- Connect only the specified system components in patient environment. (☞"Combination Example of Medical and Non-Medical Equipments" P15-5)
- The connecting device outside the patient environment should be provided with the safety level equivalent with the IEC or ISO standards. Otherwise, it may cause hazardous situation such as electric shock to the patient and operator. For details of the connecting device, contact your local Fukuda Denshi service representative.
- The connecting network equipment outside the patient environment should comply with the EMC standard (equivalent with CISPR 32 and CISPR 24).
- Only the peripheral products and cables specified by Fukuda Denshi should be connected to this device using the specified procedure. For details of the connection procedure, contact your local Fukuda Denshi service representative.
- When using with other products, the environment conditions (including transport/storage) of the connecting devices should be also observed. Failure to do so may damage the device. For the environment conditions, refer to the operation manual of each device.
- The operator should not touch the patient and the system composed of this device at the same time. It may cause hazardous situation such as electric shock to the patient and operator.
- When connecting system components to this device, do not use multiple portable socket-outlet or extension cable.

System Components (Accessories)

WARNING

- Use only the cables specified by Fukuda Denshi.Use of other cables may result in increase in emission or decrease in immunity.

Application to Heart

CAUTION

- This device is a type CF applied part, but it is not intended for direct applications to patients' heart.

Connecting the Power Cable

WARNING

- When operating this device using an AC power supply, make sure to connect the power cable to 115 V AC hospital grade outlet. Use the battery when operating in areas with no hospital grade outlet. Use an outlet that can provide sufficient power to the device.
- Do not use multiple portable socket-outlet, as safety of the patient and operator may not be

ensured.

- Use only the supplied 3-way AC power cable. Use of other cables may result in electric shock to the patient and the operator.

Leakage Current

⚠ CAUTION

- If multiple devices are plugged into the same outlet, this may cause greater current leakage in the devices, causing potential danger to patients.
- This danger may occur if the patient has a pacemaker or other heart equipment using electrical stimulation. Take particular care with safety when recording ECGs in these conditions. Current leakage needs to be below the allowable limit for safety purposes. Follow the instructions in the operation manual of the pacemaker or other heart equipment using electrical stimulation.
- When using this device with other devices, perform equipotential grounding to prevent potential difference between the devices. If potential difference occurs between the devices, danger may result to the patient and operator.
- Do not touch the electrodes of this device or the conductive part of the attached connectors. Touching these may cause a danger to the patient.

Precautions for Safe Operation of Medical Electrical Equipment

⚠ WARNING

- Do not disassemble or modify this device. It may cause a fire hazard or electric shock.
- The installation of the battery will be performed by our service representative. Users should not perform this procedure as it may cause electric shock or burn injury to the operator or malfunction of the device may occur.

⚠ CAUTION

- Although this device is a transportable device that is designed to be used in different areas, safe operation may be compromised if it is subjected to strong impact such as being dropped or getting caught in elevator doors during transportation.
- Do not use or store the device in an area where it will be subject to splashing water. Otherwise, it may cause hazardous situation such as electric shock to the patient and operator.
- Do not drop the device or subject it to strong impact or vibration. It may result in electric shock or a fire hazard. Contact your local Fukuda Denshi service representative if this device is dropped or damaged.
- Do not subject the LCD screen to strong impact. Doing so may cause damage.
- Do not touch the LAN connector and ECG connector at the same time. It may cause electric shock.
- Do not allow the patient to come in contact with this device, other electrical devices or surfaces such as metal. This increases current leakage, which may result in danger to the patient.
- Do not insert the SD card, USB memory in reverse direction or use excessive force when inserting it. It may damage both the device and the media.
- Always hold the plug when removing cables. Do not pull on the cable. Do not insert or remove cables with wet hands. This may cause electric shocks, short circuiting or injury.
- To disconnect this device from commercial power source, unplug the power supply cable from hospital grade outlet or AC inlet of this device.

- Operate the touch panel display with your finger. Using other items may cause damage such as scratching the surface of the touch panel.
- Do not attach film or adhesive tape to the touch panel. This may result in malfunction or failure.
- Wipe the surface with a soft cloth moistened with ethanol.
- Do not put your hands close to the feeding area of the recorder while printing is in progress. Your fingers may get caught or you may be injured.
- Make sure to use the specified Li-ion battery pack when operating the device on battery power. Otherwise, acid leakage, overheating or explosion may occur.
- Do not disassemble or remodel the Li-ion battery pack. A protection circuit is incorporated inside the battery for safety.
- When the ECG cannot be properly displayed, "Lead Off" will be displayed.

⚠ CAUTION Inspections

- Perform daily checks to maintain safety.
- Perform periodic checks once a year to maintain safety.
- Check all cables, devices, system components, earth impedance, leakage current, and accuracy.

⚠ CAUTION

- User should have a thorough knowledge of the operation before using the device.
- For installation and storage of the device, pay attention to the following.
- Install or store in an area where environmental conditions such as atmospheric pressure, temperature, humidity, ventilation, sunlight, dust, sodium, and sulfur will not adversely affect the system.
- Install the device on a stable surface where there is no inclination, vibration, or shock (including during transportation).
- Place the device with the bottom side downward. Do not place other sides (back or sides) on the floor.
- Do not install or store in an area where chemicals are stored or gases are evolved.
- Do not subject the device to excessive vibration or impact when moving to a new installation location.
- Verify the power frequency, voltage and allowable current (or power consumption).
- Ensure the grounding is proper by connecting the accompanying power cable to the hospital grade outlet.
- To ensure the safety of medical device, do not place other general electrical equipments within 1.5 meters from areas where patients are present.

⚠ CAUTION Before operating the device

- Verify the power voltage.
- Do not use multiple portable socket-outlet, as safety of the patient and operator may not be ensured.
- Check the cable connection and polarity to ensure proper operation of the device.
- Make sure the power system has adequate earth ground.
- Ensure that all cables are connected properly and safely.

⚠ CAUTION During operation of the system

- Make sure that the electrodes and patient cable tips do not touch metal areas of the bed or other conductive items.
- Always observe the device and patient to ensure safe operation.
- If any abnormality is found on the device or patient, take appropriate measures such as ceasing operation of the device to ensure safety of the patient.
- Do not allow the patient to come in contact with the device.
- Do not block the vents. This may result in overheating or a fire hazard.
- Do not drop the device or subject it to strong impact or vibration. It may result in electric shock or a fire hazard.

If the device is dropped or damaged, contact your local Fukuda Denshi service representative.

- Do not pull strongly on the cables such as patient cable.

⚠ CAUTION After using the device

- Unplug all the cables from the patient before turning off the power.
- When unplugging the cables, do not apply excessive force on the cables.
- Keep the accessories and cables together in one place after cleaning.
- Keep the device clean to ensure proper operation for the next use.
- If the device is damaged, users should not attempt repair. Label the unit "OUT OF ORDER" and contact your nearest service representative.
- Do not remodel the device.
- If using a defibrillator while using this device, check the paste volume, output energy, etc. to prevent the risk of burn injury of the patient. Also, verify that each device is properly grounded.

⚠ CAUTION SD card, USB memory

- Use a media specified by Fukuda Denshi. Using unspecified media may cause failure to the device, such as damage or loss of ECG data. The warranty does not cover data retrieval or repair that is required when problems such as these are caused by using unspecified items. When the specified media is inserted, corresponding icon will be displayed on the status display area.
- Do not remove media while data is being saved to the media. The data may become unreadable. This may include the data that was already saved in addition to the data that was being saved at the time. If connecting an extension cable to the USB port, use an extension cable not longer than 2 m. The device may not operate properly if a cable longer than 2 m is used.

Other precautions specific to each medium can be found on the corresponding pages. Make sure to also read these precautions.

Precautions for Battery Pack

⚠ DANGER

- Do not throw into fire, heat, disassemble or modify.
- Do not drop or apply strong impact.
- Do not use on unspecified device.
- Do not short-circuit the terminals.
- The battery must be charged on specified device.

⚠ CAUTION Recycling

- To effectively use these limited resources, your cooperation in recycling the battery will be appreciated.
- For recycling procedure, refer to Fukuda Denshi service representative, or follow the disposal processing procedure.

Precautions Concerning the LAN

⚠ WARNING Network Equipment

- Network equipment including PC and hub should be located "outside patient environment (IEC 60601-1(2005) +A1(2012), ANSI AAMI / ES 60601-1: A1: 2012+C1: 2009/(R)2012+ A2: 2010/(R)2012)". If located in patient environment, it may cause hazardous situation such as electric shock to the patient and operator.

⚠ CAUTION Inspections

- Use only Ethernet hubs specified by Fukuda Denshi when connecting this device to the network (LAN).
- When connecting this device to the network (LAN), the LAN cable should be not longer than 50 m.

⚠ CAUTION Precautions Concerning Use of the USB Wireless LAN Adapter

- When using a wireless LAN, follow the management policy of each medical institution.
- Turn OFF the power of this device before inserting the wireless LAN adapter. Never remove the wireless LAN adapter during wireless LAN communication. An error may occur if the wireless LAN adapter is inserted or removed during operation.
- Do not use this device in areas with static electricity or electromagnetic interference, in rooms insulated with a metal door or near devices that emit radio waves (microwaves, thermotherapy devices, etc.)
- The device may not be able to receive radio waves in some operating environments.
- Due to the characteristics of radio waves, the communication range and communication speed vary depending on the installation location and operating environment.

⚠ CAUTION Precautions when Using with Wireless LAN Adapter

- When using a wireless LAN, make sure to check the operation of any medical devices nearby. Stop using the wireless LAN immediately if unexpected waveform noise occurs or there is interference from surrounding device.

⚠ CAUTION Precautions Concerning the Wireless LAN Adapter

- Use a wireless LAN adapter specified by Fukuda Denshi.
- If an unspecified wireless LAN is used, not only that the communication failure with the DMS may occur, but the damage of the main unit may also occur. The warranty does not cover data retrieval or repair that is required when problems such as these are caused by using unspecified items.

⚠ CAUTION Precautions about the Static Electricity

- The wireless LAN adapter is extremely delicate and is very vulnerable to damage from electrostatic discharge. If the human body comes in contact with the metal part of the wireless LAN adapter, static electricity may be discharged onto the parts or into the circuit of the wireless LAN adapter, which may damage the wireless LAN adapter. Make sure to follow the precautions below to protect the wireless LAN adapter and this device from damage caused by static electricity.
- Remove static electricity from the body before using.
- Hold the end of the wireless LAN adapter when handling it. Never touch the metal part of the wireless LAN adapter.

Storage, Transportation, and Disposal

⚠ CAUTION Storage and Cleaning

- Do not open the housing.
- To clean the housing, use a soft cotton cloth, or non-woven cloth (pulp, rayon, polyethylene, etc.).
- Clean the device frequently so stains can be removed easily.
- To prevent injury, it is recommended to wear gloves when cleaning the device.
- Pay attention not to allow chemical solution to enter the device or connectors.
- Do not use organic solvents, thinner, toluene or benzine to avoid damaging the resin case.
- Do not polish the device with abrasive, chemical cleaner, alkaline or acidic detergent.
- Perform daily checks to maintain safety.
- Perform regular inspections every 12 months to maintain safety.
- Check all cables, devices, accessories, earth impedance, leakage current, and accuracy.

- If the device has not been used for a while, make sure to check that the device operates properly and safely before using it.
- Do not allow alcohol or other liquids to enter the device.
- For procedure to store the system device connecting to this device, follow the instruction on the operation manual of the respective connecting device. For details, refer to the manufacturer of the connecting device.

⚠ CAUTION Transportation

- When transporting this device, pack it with specified packing materials.
- This device does not have handles. Carry it by holding it with both hands.
- For procedure to transport the system device connecting to this device, follow the instruction on the operation manual of the respective connecting device. For details, refer to the manufacturer of the connecting device.

⚠ WARNING Disposing the device and accessories

- When disposing of this device and accessories, entrust disposal to a specialized waste disposal contractor.

Cleaning and Disinfection

⚠ WARNING Electrodes, Patient Cables

- Do not use organic solvents, thinner, toluene, benzine, or cresol soap solution as it may damage or break the cable.
- Do not heat-disinfect the electrodes with water, steam or air.

⚠ CAUTION Main Unit

- Clean the device frequently so stains can be removed easily. To prevent injury, it is recommended to wear gloves when cleaning the device.
- When cleaning or disinfecting, do not allow chemical solution to enter the device or connectors.
- Do not use organic solvents, thinner, toluene or benzine to avoid damaging the resin case.
- Do not polish the device with abrasive, chemical cleaner, alkaline or acidic detergent.The surface resin coating may damage, resulting in discoloration, scratches, and malfunction.
- For the precautions for storing and handling the chemicals, refer to the instruction manual for the respective chemical.

⚠ CAUTION Thermal Print Head

- Printing paper dust adhering to the thermal print head lowers the print quality. Use a cotton swab moistened in alcohol (ethanol, isopropyl alcohol) to wipe away print residue.
- Never use sandpaper as it will damage the heating element.

⚠ CAUTION System products

- Clean the connected devices according to the instructions in their respective manuals. For details, refer to the manufacturer of the connecting device.

Precautions for Safe Operation under Electromagnetic Disturbances

⚠ CAUTION Malfunctions due to Electromagnetic Disturbances

- While this device complies with IEC 60601-1-2: 2007 and IEC 60601-2-25 (2011), malfunctions may occur if there are strong electromagnetic waves nearby that exceed the limit.
- Please take the necessary countermeasures in such cases.

⚠ CAUTION Effect of Electromagnetic Emission

- The use of mobile phones may cause malfunction. Mobile phones and radio sets should be turned OFF in the facility where the medical device is located.

- The use of microwave therapy devices nearby or in an adjacent room may cause malfunction or damage to the ECG. Keep these devices a sufficient distance apart according to the Guidance on Electromagnetic Compatibility.

⚠ CAUTION Effect of Burst and Conducted Electromagnetic Waves

- High frequency noise interference may occur from other devices through the power outlet. Check the source of the noise and stop the device that is causing the noise if it is possible to do so. If it cannot be stopped, take countermeasures to change the path of the noise, such as using a filtering device.

⚠ CAUTION Malfunction due to Static Electricity

- Malfunctions may be caused by the discharge of static electricity in dry environments (rooms), such as in winter. Humidify the room, or discharge the static electricity from the operator and the patient before using the device.

⚠ CAUTION Malfunction due to Surge (lightning)

- A lightning nearby may induce excessive voltage to the device. Unplug the power cable from the AC outlet in such situation.
- Use the uninterruptible power supply system if available.

⚠ CAUTION Malfunction due to Location with Other Device

- If this device is installed close to, or stacked with other device, malfunction may occur. Make sure to verify that the device operates properly in a used location.

⚠ CAUTION Malfunction due to Use of Unspecified Cables, Accessories

- This device complies with the EMS standard only if it is used with the specified cables and accessories. Do not use unspecified cables or accessories as it may degrade the electromagnetic emission, electromagnetic immunity.

Precautions Concerning Interpretation

⚠ CAUTION

- The interpretation name and Minnesota code are classified only by ECG information, which means that the interpretation may not match the diagnosis of the doctor reading the ECG. When making a final diagnosis, doctors should take an overall view that includes the patient's general state and other examinations (biochemical examinations, X-rays, Holter ECG, stress, lung function, etc.)

Precautions Concerning Automatic Analysis of ECG

⚠ CAUTION

- Automatic analyses of ECGs are classified only by ECG information, which means that they may not match the diagnosis of the doctor reading the ECG. When making a final diagnosis, doctors should take an overall view that includes the patient's general state and other examinations (biochemical examinations, X-rays, Holter ECG, stress, lung function, etc.)

Troubleshooting

If a trouble should occur, find the cause and take appropriate measures for recording stable ECG.

❑AC Interference

Caused by the Patient

Wash the skin with alcohol or soapy water, and when clip electrodes or chest electrodes are applied, apply enough keratin cream.

Caused by the Electrodes

When clip electrodes or chest electrodes are applied, clean the electrodes with alcohol or soapy water. For stubborn stain, rub with sandpaper.

If the clip electrodes or chest electrodes are loose, tighten them to an extent that is not painful for the patient.

Caused by the Environment

If interference is caused by X-ray devices, ultrasound devices or other electric devices, turn OFF these devices or conduct the examination elsewhere.

If using next to a metal bed, ground the bed.

Other Cause

Check that the device is grounded properly and that the ground cable is not disconnected.

Replace the patient cable if there is any sign of wire breakage.

❑Irregular Wavering of ECG Baseline

Caused by the Patient

When the patient is nervous, calm them down by taking measures such as instructing them to take deep breaths.

If the patient is moving or talking, instruct them to stop.

Caused by the Electrodes

If the electrodes are attached too tightly, loosen them to an extent which will not fall off.

Caused by the Environment

Conduct the examination in a room temperature where the patient will not feel cold.

Make sure that the bed is wide enough for the patient to relax.

❑Unstable ECG

Caused by the Patient

Wash the skin with alcohol or soapy water, and when clip electrodes or chest electrodes are applied, apply enough keratin cream.

If the patient is nervous, tell him/her to relax, take a deep breath and clam.

If the patient is moving or talking, instruct them to stop.

Instruct the patient to hold their breath briefly while recording the ECG.

Caused by the Electrodes

When clip electrodes or chest electrodes are applied, clean the electrodes with alcohol or soapy water. If this does not remove the dirt, polish the electrodes with sandpaper.

If the clip electrodes or chest electrodes are loose, tighten them to an extent that is not painful for the patient.

Do not use new electrodes together with electrodes that have been used before.

Caused by the Environment

Avoid conducting examinations in an area hot enough to make the patient sweat.

Guidance on Electromagnetic Disturbances

This device complies with IEC 60601-1-2: 2007 and IEC 60601-2-25 (2011). However, if portable transmitter or wireless LAN equipment is used extremely nearby, the electromagnetic influence may largely exceed the compliance level and may cause unexpected phenomenon such as noise interference on the waveform, etc.
This device should be used in a location specified by each medical institution.
If any unexpected noise interference on the waveform or failure to the peripheral device occurs, stop using the device and follow the instruction of the technical engineer.
The following is the information relating to electromagnetic disturbances (electromagnetic compatibility).
(When using the device, verify that it is used within the environment specified below.)
To ensure basic safety and essential performance related to electromagnetic disturbances during the expected service life of this device, daily inspections and periodic inspections must be performed.
If this device is installed close to, or stacked with other device, malfunction may occur. Make sure to verify that the devices operate properly in a used location.
The portable RF communications equipment (including antenna cable and peripheral equipment such as external antenna) with the specified cable should be used in a location at least 30 cm apart from any part of this device. Otherwise, it may result in performance degradation of this device.

❑Compliance to the Electromagnetic Emissions

The device is intended for use in the electromagnetic environment specified below.

Emission Test	Compliance	Electromagnetic Environment/Guidance
RF Emissions CISPR 11	Group 1	The device 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 B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/Flicker Emissions IEC 61000-3-3		

❑Compliance to the Electromagnetic Immunity

This device is intended for use in the electromagnetic environment specified below. The customer or the user of this device should assure that it is used in such an environment.

Immunity Test	Test Level	Compliance Level	Electromagnetic Environment/Guidance
Electrostatic Discharge IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 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 IEC 60601-2-25	±2 kV (AC mains) ±1 kV (input/output lines, patient cable) 100 kHz repetition frequency	±2 kV (AC mains) ±1 kV (input/output lines, patient cable) 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surges Line-to-line IEC 61000-4-5	±0.5 kV and ±1 kV Phase 0°, 90°, 180°, 270°	±0.5 kV and ±1 kV Phase 0°, 90°, 180°, 270°	Mains power quality should be that of a typical commercial or hospital environment.
Surges Line-to-ground IEC 61000-4-5	±0.5 kV, ±1 kV, ±2 kV (AC mains) Phase 0°, 90°, 180°, 270°	±0.5 kV, ±1 kV, ±2 kV (AC mains) Phase 0°, 90°, 180°, 270°	
Power Frequency Magnetic Field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips IEC 61000-4-11	0% U_T (AC Power Supply Voltage) 0.5 cycles Phase 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°	0% U_T (AC Power Supply Voltage) 0.5 cycles Phase 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°	Mains power quality should be that of a typical commercial or hospital environment. If it is required to continuously operate this device during power failure, it is recommended to operate on an uninterrupted power supply.
	0% U_T 1 cycle and 70% UT 0.5 sec. Single Phase/Phase Angle 0°	0% U_T 1 cycle and 70% UT 0.5 sec. Single Phase/Phase Angle 0°	
Voltage Interruptions IEC 61000-4-11	0% U_T 5 sec.	0% U_T 5 sec.	

NOTE

- U_T is the AC mains voltage prior to application of the test level.
- Voltage dips and voltage interruptions are tested with battery installed.

Immunity Test	Test Level	Compliance Level	Electromagnetic Environment/Guidance
Radiated RF EM Fields IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% AM (2 Hz)	3 V/m 80 MHz to 2.7 GHz 80% AM (2 Hz)	Portable and mobile RF communications equipment should be used no closer to any part of the FX-8400, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended Separation Distance d=1.2 $\sqrt{P}$ 150 kHz to 80 MHz d=1.2 $\sqrt{P}$ 80 MHz to 800 MHz d=2.3 $\sqrt{P}$ 800 MHz to 2.7 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*1, should be less than the compliance level in each frequency range*2. Interference may occur in the vicinity of equipment marked with the following symbol. :
Conducted disturbances induced by RF fields IEC 61000-4-6	3V when 0.15 MHz to 80 MHz 6 V when 0.15 MHz to 80 MHz (ISM bands) 80% AM (2 Hz)	3V when 0.15 MHz to 80 MHz 6 V when 0.15 MHz to 80 MHz (ISM bands) 80% AM (2 Hz)	
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. Note 3: Tested with modulating frequency of 2 Hz. This is because 1 kHz which is specified in the standard is outside the ECG bandwidth and its visibility is blocked by the system filter. It was decided that testing with modulating frequency of 2 Hz which is within the physiological ECG bandwidth is appropriate.			
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 can not 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 this device is used exceeds the applicable RF compliance level above, this device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device. b): Over the frequency range 150 kHz to 80 MHz, field strength should be less than 3 V/m.			

	Test Frequency (MHz)	Band [a] (MHz)	Service[a]	Modulation [b]	Maximum Power (W)	Distance (V/m)	Test Level (V/m)
Immunity test specifications for RF wireless communications equipment IEC 61000-4-3	385	380 to 390	TETRA 400	PM [b] 18 Hz	1.8	0.3	27
	450	430 to 470	GMRS 460 FRS 460	FM [c] ±5kHz deviation 1 kHz sine	2	0.3	28
	810 870 930	800 to 960	GSM 800/900 TETRA 800 iDEN 820 CDMA 850 LTE Band 5	PM [b] 18 Hz	2	0.3	28
	1445.4	1427.9 to 1462.9	Mobile station for cellular telephones	PM [b] 217 Hz	2	0.3	28
	1720 1845 1970	1700 to 1990	GSM 1800 CDMA 1900 GSM 1900 DECT LTE Band 1,3,4,25 UMTS	PM [b] 217Hz	2	0.3	28
	2450	2400 to 2570	Bluetooth WLAN 802.11 b/g/n RFID 2450 LTE Band 7	PM [b] 217 Hz	2	0.3	28
	5240 5500 5785	5100 to 5800	WLAN 802.11 a/n	PM [b] 217 Hz	0.2	0.3	9
Note: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and this device may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.							
a) For some services, only the uplink frequencies are included. b) The carrier shall be modulated using a 50% duty cycle square wave signal. C) As an alternative to FM modulation, the carrier may be pulse modulated using a 50% duty cycle square wave signal at 18 Hz. While it does not represent actual modulation, it would be worst case.							

❑Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the Device

The device is intended for use in an electromagnetic environment where RF emission interference is controlled. When using the product, electromagnetic interference can be prevented by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device 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 $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.7 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined 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.

❑Interference by Electrosurgical Instrument

This device is protected against any malfunctions that may be caused by the usage with the electrosurgical instrument specified below.

Immunity Test	IEC 60601-2-25 Test Level	Compliance Level	Electromagnetic Environment/Guidance
Cut mode	Output power 300 W	Output power 300 W	When an electrosurgical instrument generates high-frequency energy, the noise level of the displayed/ recorded waveforms increase, but it returns to original level within 10 seconds. If waveforms during the period including generation of RF energy are measured, effective measurement result may not be obtained.
Coagulation mode	Output power 100 W	Output power 100 W	

Messages and Remedies

The displayed error messages along with the countermeasures are listed below.

REFERENCE

- If the error message is still displayed even after trying the countermeasure, stop the examination and contact your local Fukuda Denshi service representative.

Battery

Message	Cause	Solution
<Replace the backup battery. The clock will be initialized. (Contact your dealer for details.)>	The backup battery for the clock is running out.	The backup battery needs to be replaced. For details, refer to "Maintenance".
<To not run out of battery, the power supply will be switched off automatically.>	During battery-powered operation, the power will automatically turn OFF if the operation is not performed within the specified duration.	Turn the power OFF and then turn it back ON.
<Battery is running low. Please recharge the battery.>	The battery installed in the device is running low.	Charge the battery.
<Cannot record due to low battery voltage.>	The printing could not be started due to low battery level.	Connect the power cable to switch to AC power operation, or charge the battery.
<The battery voltage is too low. Printing has been canceled.>	The printing has been canceled due to low battery level.	Connect the power cable to switch to AC power operation, or charge the battery.
<The battery voltage is too low. Cannot access Media.>	The device could not access the media due to low battery level.	Connect the power cable to switch to AC power operation, or charge the battery.

Thermal

Message	Cause	Remedies
<There is no thermal paper.>	No thermal paper is loaded.	Load thermal paper properly.
<Stopped recording due to overheated thermal head. Turn off the power.>	The thermal head for recording is abnormally overheating.	Wait for a while after turning off the power, and then restart recording. If this occurs frequently, the system may be faulty. Contact your local Fukuda Denshi service representative.
<Paper tray open>	Paper tray is open	Close the paper tray.

Examination

Message	Cause	Solution
<This patient ECG has already been recorded.>	This patient has already been recorded.	Check the entered ID and name of the patient.
<Failed to retrieve patient information.>	The patient information could not be retrieved.	Make sure that the correct media is used.
<Lead Off.>	The lead is off.	Check the electrode attachment.
<Please check the electrodes are correctly placed.>	Measurement could not be performed due to incorrect placement of the electrodes.	Check the electrode attachment.
<Operation was stopped because lead Off.>	Lead-off condition has occurred during the waveform acquisition.	Check the electrode attachment and start the recording again.

File

Message	Cause	Solution
<Failed to format (Media).>	Formatting of the media has failed.	The failure of the media can be considered. Contact your local Fukuda Denshi service representative.
<There is not enough space on (media). Please replace the media with another one.>	There is not enough space on the media to save the data.	Replace with a media with enough capacity, or format the media.
<Cannot write due to insufficient space on (media).>	The data could not be saved on the media as the maximum number of recordable data has been reached.	When this message is displayed, the data is not saved. Insert a new media and save the data again.
<Cannot store data.>	Failed to save the data to the media.	The failure of the media can be considered. Write down the error code at the end of the message and contact your local Fukuda Denshi service representative.
<Please set (media).>	The media is not set.	Set the media.
<Failed to read from the file.>	Failed to read the data from the file.	The failure of the media can be considered. Write down the error code at the end of the message and contact your local Fukuda Denshi service representative.
<The examination data was not saved.>	The examination data was not saved when proceeding to the next examination.	Save the examination data before proceeding to the next examination.
<Failed to delete data.>	Failed to delete ECG data.	The failure of the media can be considered. Contact your local Fukuda Denshi service representative.
<No data selected.>	A process was performed without selecting data.	Select data before performing the process.
<Failed to save the settings.>	Failed to save the settings to the media.	The failure of the media can be considered. Contact your local Fukuda Denshi service representative.
<Failed to load settings.>	Failed to load the settings from the media.	Make sure to use the correct media to which settings are saved. If failure occurs even though the correct media is used, it may be defective. Contact your local Fukuda Denshi service representative.

Communication

Message	Cause	Solution
<Cannot send to host.>	The data could not be sent to the DMS (Data Management System).	When this message is displayed, the data is not sent to the DMS (Data Management System). Contact your local Fukuda Denshi service representative.

<Failed to retrieve patient information.>	No corresponding patient information was found when using the function for obtaining patient information.	Check that the correct ID was entered and that the ID is registered to the DMS (Data Management System).
<There is no relevant data.>	There was no data found on the DMS (Data Management System).	Check the details of the data requested to the DMS (Data Management System).
<Failed to connect.>	Initial connection to the DMS (Data Management System) failed.	Check the DMS (Data Management System) status and connection to the DMS (Data Management System). Also check the communication settings with the DMS (Data Management System).
<Operation has timed out.>	The time limit for communication with the DMS (Data Management System) was exceeded.	Check the connection and start the connection again.
<Communication error has occurred.>	An error occurred during communication with the DMS (Data Management System).	When this message is displayed, the DMS (Data Management System) is not connected. Contact your local Fukuda Denshi service representative.

Chapter 1 General Description

This chapter provides information about features, names, functions and basic operation procedure of CardiMax series FX-8400.

Features of this ECG

The CardiMax series FX-8400 measures a standard 12-lead electrocardiogram (ECG) with high accuracy.
The results and ECG waveforms can be recorded and printed. ECG data can be saved on a SD card or USB memory.
By installing the optional software, FP-811, analysis of interpretation classification can be performed with high accuracy.

Examinations that can be conducted on this device

Type of Examinations	Description
Standard ECG Examination	12-lead examinations can be carried out.
Arrhythmia Examination	Long 3-lead arrhythmia examination can be carried out.
Rhythm Measurement	One-lead R-R measurement can be carried out.
Post-Exercise Examination	Interval recording of 12-lead measurement after exercise can be carried out.

Intended Purpose

This device is intended to be used for the examination of the cardiovascular system in pediatric and adult populations for diagnosis or group health checkup. This device is neither for home-use nor for monitoring the cardiovascular system. It intends to help doctor to make the diagnosis and does not intend to make the diagnosis solely by itself.

Indication for Use

❑Application

- Presence or absence of arrhythmias
- Conduction defects
- Chamber enlargement
- Myocardial hypertrophy
- Myocardial ischemia
- Myocardial infarction
- Myocardial necrosis
- Pericardial inflammation
- Electrolyte disturbance

❑Intended User

- Medical doctor
- Qualified healthcare professional under instruction of medical doctor
  (nurse, ECG technician etc. depending on the conditions in each country)

❑Intended Patient

- Patients/examinee who needs electrocardiogram examination
  - Adults
  - Adolescents
  - Children

For ECG measurement, place the electrodes correctly without shorting each other.

❑Intended Use Environment

- Examination rooms or in/out-patient wards of the hospitals, clinics
- Examination rooms of the health check-up facilities
- General environment such as office buildings or schools for group health check-up provided by the employers or the educational institutes

Convenient Functions

REFERENCE

- The analysis function can be used by installing the optional software, FP-811.

❑Information for interpreting ECG is provided.

A 12-lead analysis function is provided. This analysis program uses a clinically improved diagnosis standard classified according to Minnesota code, disease name, age and sex to raise the accuracy of diagnosis.

The analysis results adopt a new report format that is useful to the multifaceted aspects of ECG diagnosis.

❑Detailed explanation of the interpretation obtained from the ECG analysis result can be printed.

For interpretations displayed as analysis results, criteria (analysis guide) for the interpretations and various reports on detailed information about the interpretation (commentary) can be printed. (☞"Printing Commentary" P5-14)

Detailed information can also be checked from the interpretation name even if it is not immediately after the examination.

❑The following ECG can be acquired.

Not only resting ECG recording but also various measurements including interval recording can be carried out.

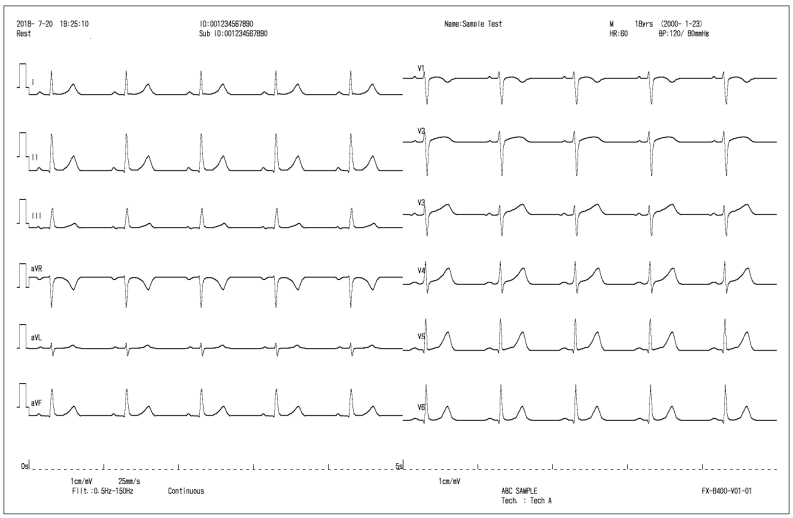
For these ECG recordings, the recording channel and report format can be changed according to the monitoring purpose.

❑Important examination data can be saved on a SD card, USB memory.

The device is equipped with SD card slot and USB connector which enables to save the ECG data on a medium. A maximum of 1000 ECG data can be saved in internal memory.

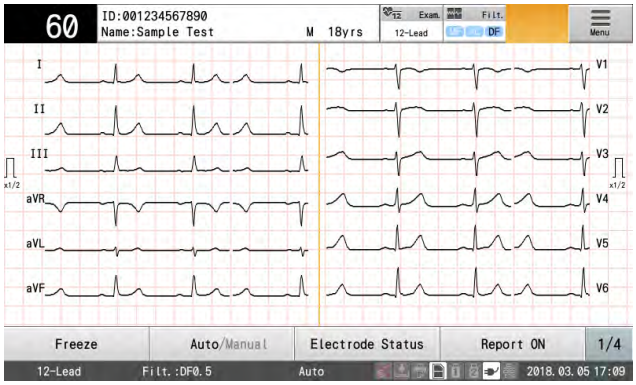
❑Examination data can be printed clearly on recording paper.

By adopting a high-density thermal printing method, clear ECG waveforms can be printed on a 210 mm wide recording paper. Furthermore, patient data and ECG analysis can be printed at the same time.



❑The ECG waveforms can be checked on a large color LCD.

The ECG waveforms can be viewed clearly on a large color LCD. The patient conditions such as heart rate as well as the status of electrodes, recorder, etc. can also be checked on the screen. Since the LCD is a touch panel, most of the operations can be made by just touching the keys on the screen.



NOTE

- Make sure to use your finger when touching the keys on the color LCD and the operation panel.

❑By using the Li-ion battery pack, the device can be used in any place.

The Li-ion battery pack is provided as an accessory. The battery operation is possible allowing to perform ECG measurement in any place without a power outlet.

❑The device can be used with an electrosurgical instrument.

The device can be used without malfunction caused by a high-frequency current generated by an electrosurgical instrument.

❑A wireless LAN can be used.

By connecting the optional wireless LAN adapter, ordering function and communication with the data management system can be performed without connecting the cables.

Names of Parts and Their Functions

This section describes parts and their functions of this device.

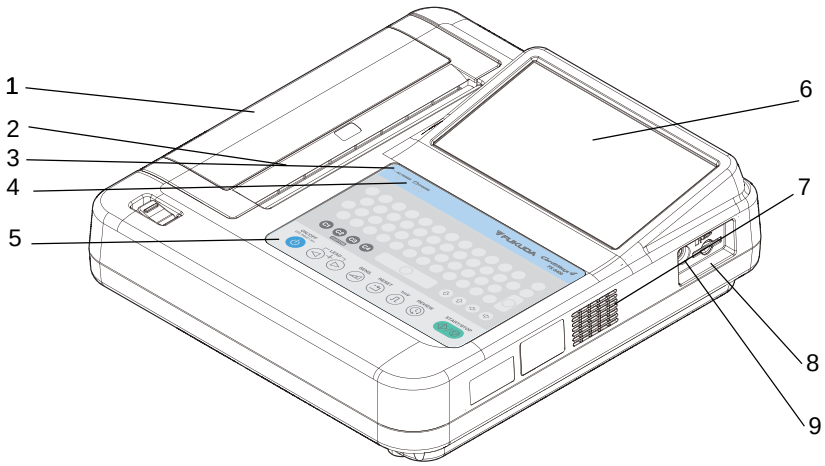
WARNING

- Contact your local Fukuda Denshi service representative when connecting with other devices.
  Otherwise, it may cause hazardous situation such as electric shock to the patient and operator.
- Make sure to use the supplied patient cable.
  The use of a patient cable other than the specified defibrillation-proof type may damage the device or compromise safety when the device is used along with a defibrillator.

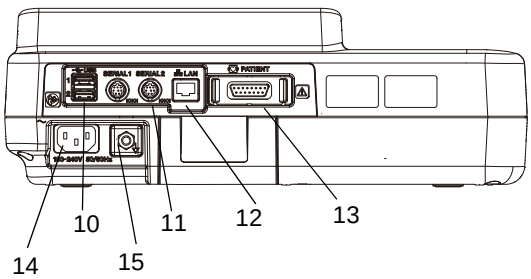
CAUTION

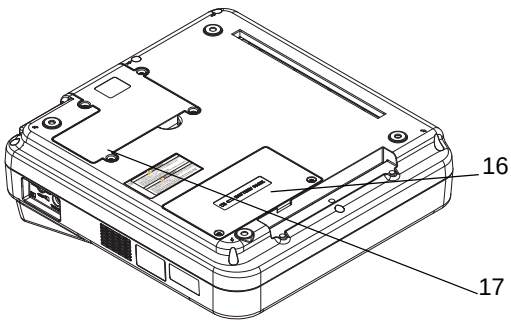
- Do not bend or drop the SD card or USB memory or subject them to impact.
- Do not subject this device to impact while the SD card or USB memory is in operation. It may damage the data or break the media.
- Do not touch the terminal parts of the SD card or USB memory with your hands or metal objects.

❑Front View



❑Rear View, Bottom View





1 Paper tray

The recording paper is loaded inside.

2 Thermal Print Head

Prints ECG waveforms and measurement values on the recording paper.

3 AC Power Indicator (Blue)

When connected to an AC outlet, the indicator will light.

4 Charge Indicator (Blue/Orange)

During charging, it will light in blue. When charging is completed, it will turn OFF. If an error occurs during charging, it will light in orange. (☞"Charging the Battery" P2-3)

5 Operation Panel

Keys for turning ON/OFF the power or starting the ECG recording are located.

6 LCD Monitor

Displays ECG waveforms and patient information (☞"How to Read the LCD" P1-7).

NOTE

- Although the color LCD utilizes highly advanced technologies, occasionally, there may be a few pixels which do not light (dots) or constantly light. Temperature changes may also cause some irregularities due to the characteristics of the LCD. Please note that this is not a device failure.
- Remove dust and stains from the LCD screen by wiping with a cloth that has been dampened in ethanol or other alcohol and thoroughly wrung out.

7 Vents

Used as air inlets and outlets.

NOTE

- To ensure the necessary air flow, do not block these vents. A minimum space of 5 cm is required between the back/sides of the device and the wall.

8 SD Card Connector

Insert an SD card (optional).

9 R-SYNC Connector

Outputs ECG synchronized signal.

10 USB connectors 1 to 2

Connects a USB memory (optional) or external device such as a barcode reader.

NOTE

- Do not unplug a USB memory or turn OFF the power while the USB memory is in operation.

11 Serial Connector 1, 2

Connects the serial cable.

12 LAN connector

Connects to the DMS (data management system) via LAN.
(☞"Connecting to the Network" P2-11)

13 ECG connector (ECG waveform input)

Connects the ECG patient cable. (☞"Connecting the Cables" P2-5)

14 AC Power Supply Connector

Connects the power cable. (☞"Connecting the Cables" P2-5)
To disconnect from the power source, unplug the power cable from this connector.

15 Potential Equalization Terminal

Connects an equipotential line.

16 Battery Slot

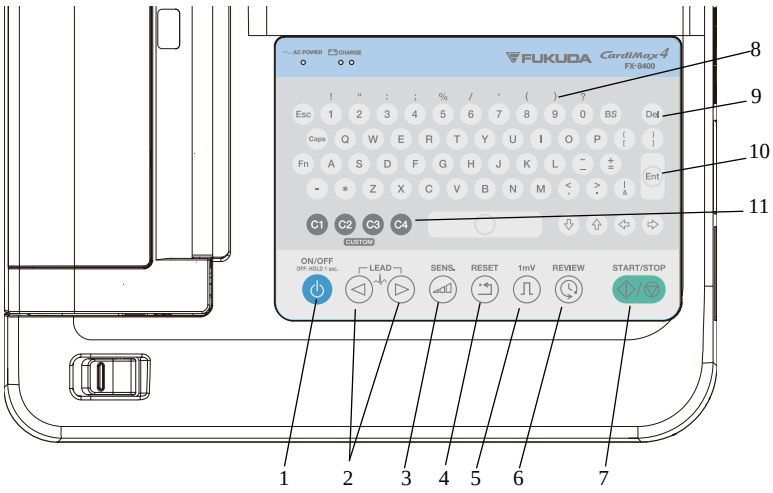
Insert the Li-ion battery pack here.

17 Wireless LAN Adapter Slot / External VGA Adapter Slot

It is located inside the dummy cover. Insert the optional wireless LAN adapter or attach the external VGA adapter here.

Types and Functions of Operation Panel Keys

The operation panel keys are used for operation. The function of each key on the operation panel is as follows.



1 Power Supply Key
Turns the power ON/OFF. To turn OFF the power, hold down the key for 1 second.
When the power is turned OFF, the device will enter into standby mode and the AC power indicator will light.

NOTE

- When turning OFF the power completely, make sure to disconnect the power supply cable.

2 Lead Key
Changes the lead during an ECG examination. Moves the cursor to left or right while entering texts.

3 Sensitivity Key
Changes the sensitivity during an ECG examination.

4 Reset Key
Resets the waveforms while the key is pressed.

5 1mV Key
Outputs the calibration waveform.

6 Review Key
Starts/stops the review printing during an ECG examination. (☞"How to Perform Review Printing" P5-13)

7 Start/Stop Key
Starts/stops the recording. When pressed during recording, recording will stop.

8 Alphanumeric Keys
Enters characters and numbers. Use "." to enter a decimal point.

9 Delete Key
Deletes entered characters.

10 Enter Key
Sets the entered item.

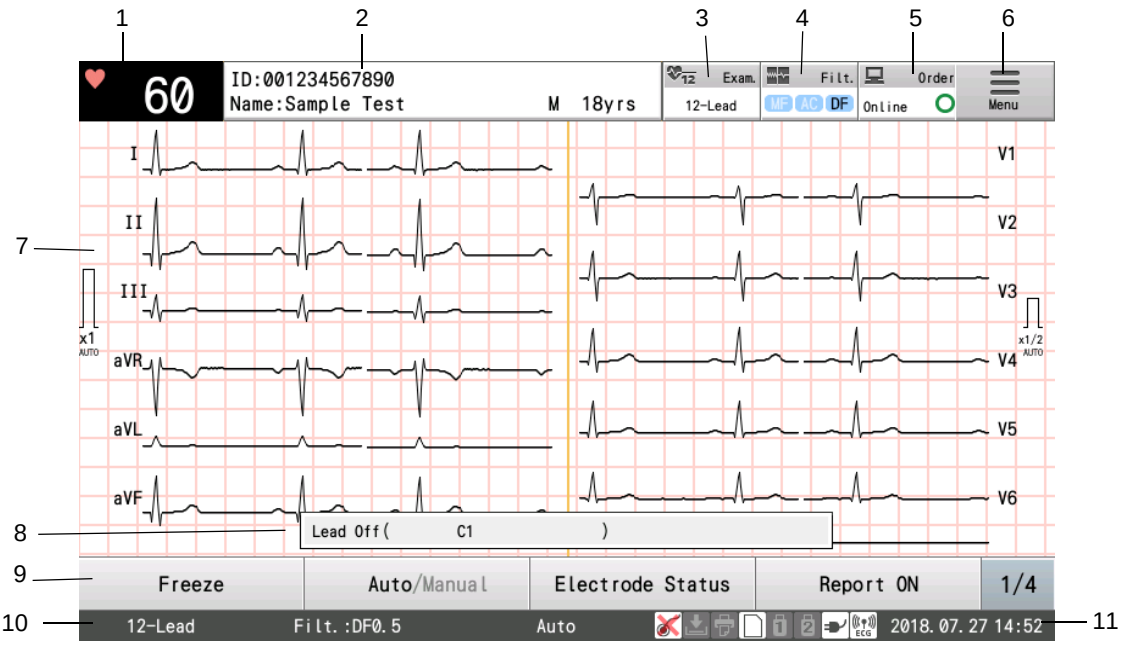
11 Custom Key
Users can assign the function to these keys. (4 keys)

REFERENCE

- Other than the displayed touch keys, keys on the operation panel can be used to enter characters and numbers.

How to Read the LCD

The LCD displays the status of examination, ECG waveforms, patient information, device status, etc.



1 Heart rate display area

The heart rate is displayed.

2 Patient Information Display

The ID, name and age of the patient are displayed. Touch this to display the window for entering patient information.

3 [Examination] key/Examination Status Message

The currently selected examination is displayed. Touching this button displays the "Select Examination" window for selecting an examination.

4 [Filter] key

The currently selected filter is displayed. Touch this to display the Filter Settings window.

5 [Order] key

Touch this to display order information list (Refer to "Chapter 9 Ordering System".)

6 [Menu] key

Touch this to display the Menu screen.

7 ECG Display Area

Displays ECG waveforms.

8 Message Display Area

The alarm message is displayed.

9 Function Keys

These are the keys to control this device. The [1/3] key is used to display the next page when there are two or more rows of function keys.

10 Examination Status Message

Displays the status of the examination.

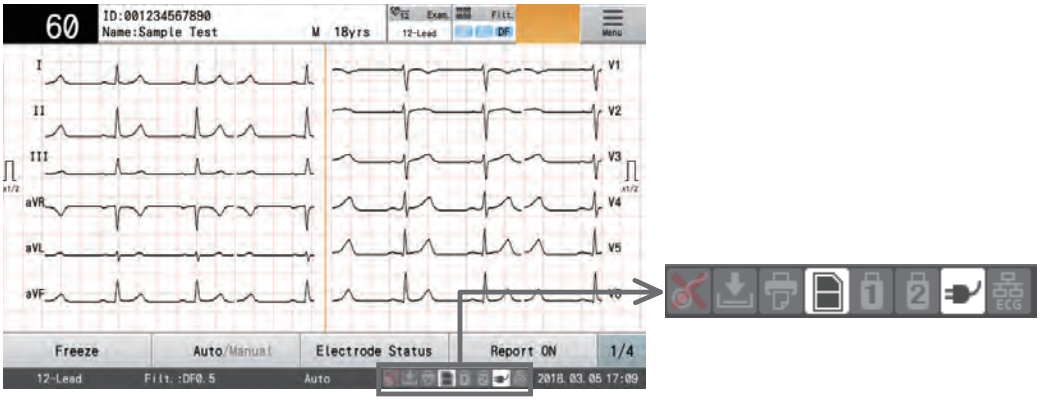
11 Date/Time Display Area

Displays the current time and date.

How to View the Icons

❑Home Display

The icons indicating the status of external device are displayed at the bottom of the screen.



The following information of the device, etc. is displayed from left to right.

Electrode	Recorder	External Printer	SD Card	USB Memory 1	USB Memory 2	Power Supply/ Battery	ECG LAN

❑List of Icons

Item	Icon	Description
Electrode		Lead off/electrode misattached/ noise
		Normal
Recorder		Paper Out/Tray Up/Misselection of paper type (roll paper/Z-fold paper)
		Normal

Item	Icon	Description
Power Supply/ Battery		Power Cable Connection
		Remaining Battery Capacity: 30% to 0%
		Remaining Battery Capacity: 60% to 30%
		Remaining Battery Capacity: 100% to 60%

USB Memory		USB Connection Error
		USB Connection Remaining Capacity of Saving Data: 500 and above
		USB Connection Remaining Capacity of Saving Data: 100 to 499
		USB Connection Remaining Capacity of Saving Data: Less than 100
		ID Reader Connection
		Not Used
SD Card		SD Card Connection Error
		SD Card Connection Remaining Capacity of Saving Data: 500 and above
		SD Card Connection Remaining Capacity of Saving Data: 100 to 499
		SD Card Connection Remaining Capacity of Saving Data: Less than 100
		Not Used

		Battery Error
ECG LAN		LAN Connection
		LAN Connection Error
		Wireless LAN Connection
		Wireless LAN Error
		Not Used
External Printer		Connected
		Error
		Not Used

❑Icons Displayed in Other Windows

Display Area	Icon	Description
During file operations		USB1
		USB2
		SD Card
		DMS
		DICOM (icon color: blue)
		Shared Folder (icon color: orange)
		Internal Memory
		Folder
		Trash

Display Area	Icon	Description
Message Display		Caution
		Warning
Examination Window		Lead off base
		Lead off Electrode Part: Poor (icon color: red)
		Lead Off Electrode Part: Fair (icon color: yellow)
		Lead Off Electrode Part: Good (icon color: green)

Basic Operation Procedure

This section describes setting value selection, numeric input, character input, and common operation procedures.

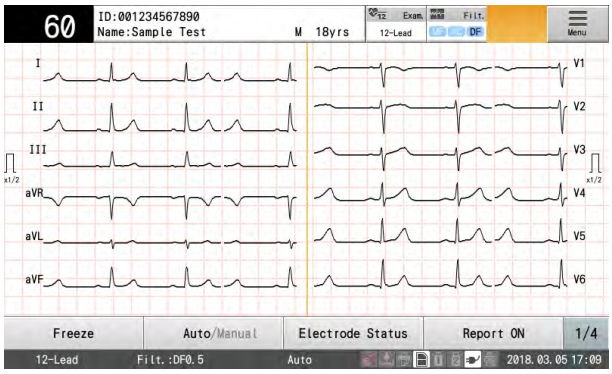
Display Operation

❑Touch key operation

This device is operated using operation panel button and keys that appear in the display.

- Touch operation

  The touch key will respond by pressing any part of the key.

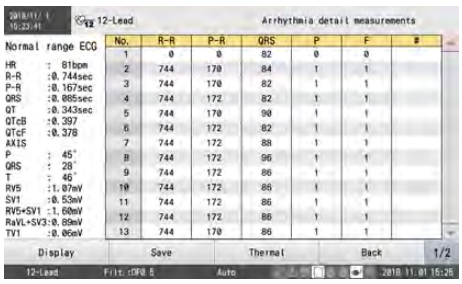


- Flick Operation

  Flick left or right on the screen (slide your finger quickly across the screen) to switch display screens.
  For example, when the analysis result window is displayed, the window can be changed to the detailed measurement window or dominant waveform window by flicking on the screen.

Analysis Result Window

Detailed Measurement Window



- Double Touch Operation

  Touch the screen twice quickly to zoom in waveforms.
  For example, double touch the desired part in the dominant waveform window to display enlarged waveforms.

❑Selecting Setting Values

Below are procedures for selecting one or more items from multiple setting values displayed.

1 Press the desired setting value.

▸ The display changes as shown below.

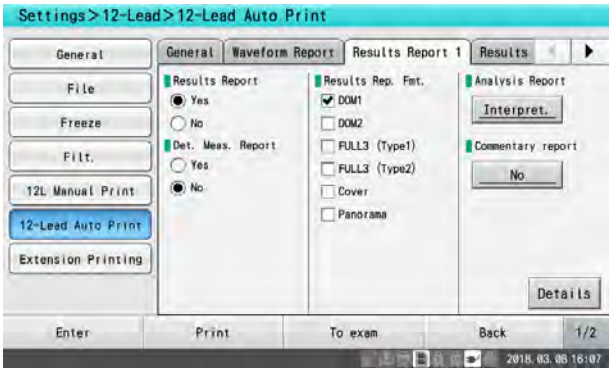
	Unselected	Selected
When only one item can be selected	○ Interpret.	◉ Interpret.
When multiple items can be selected	☐ DOM1	☑ DOM1

❑Selecting Items by Touching Buttons

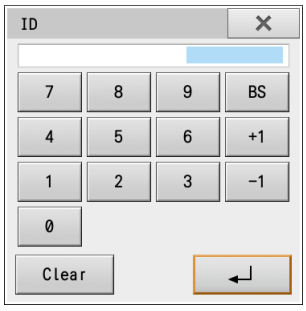
Below are instructions on selecting items by touching the desired button in a set of multiple displayed buttons.

1 Touch the button corresponding to the desired item.

▸ More detailed setup items are displayed.



❑Common operation in the windows



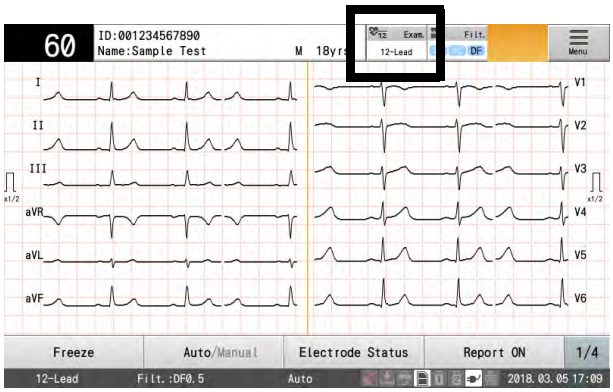
[x]: Closes the window.

[Clear]: All numbers entered are cleared.

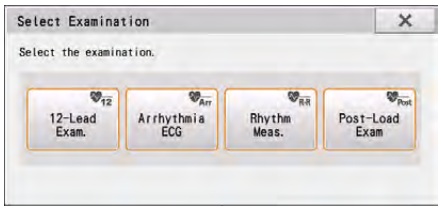
[↵]: The content entered is reflected in the window.

Changing the Examination Type

1 Touch [Exam.].

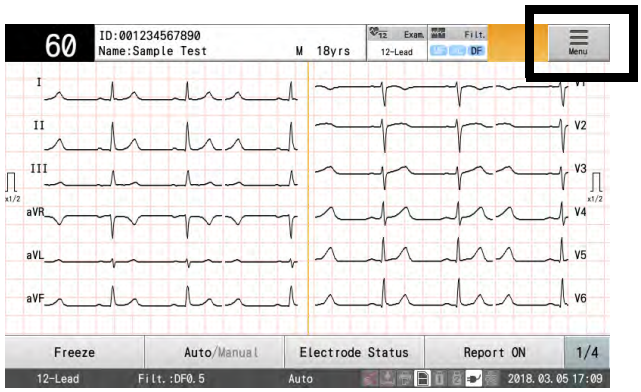


2 Select the examination.

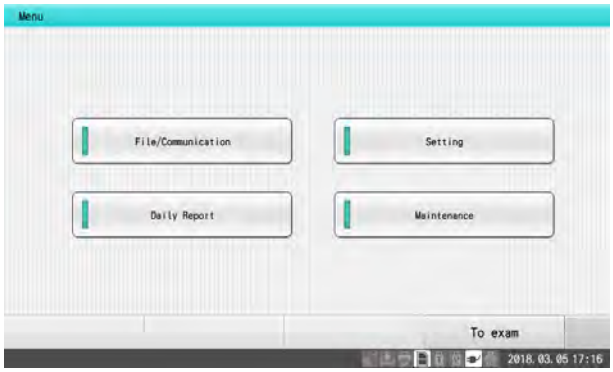


Displaying the Menu

1 Touch [Menu].



2 Touch the desired item.

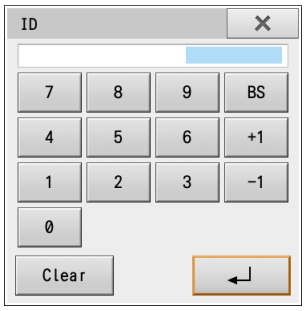


Character Entry

❑Entering ID, Height, Weight

Use the alphanumeric keys to enter the patient's height, weight, and ID number.

1 Enter the alphanumeric characters.



- [Clear]: All entered alphanumerics are cleared.
- [BS]: The alphanumeric to the left of the cursor is cleared.
- [+1] or [-1] 1 is added to or subtracted from the current numeric.

❑Entering Name

Patient's name and doctor's name can be entered using the alphanumeric keys.

1 Enter the alphanumeric characters.
Touch the alphanumeric characters to be entered.

- [A→a] [a→A]: Switches between uppercase and lowercase characters when characters are entered.
- [Alphanum.]: Switches to alphanumeric characters.
- [Symbol]: Switches to symbols.
- [BS]: The alphanumeric to the left of the cursor is cleared.
- [Clr All]: All entered characters are cleared.
- [←]: [→]Moves the cursor to the left or right.
- [Space]: Makes a space.

Chapter 2 Installation

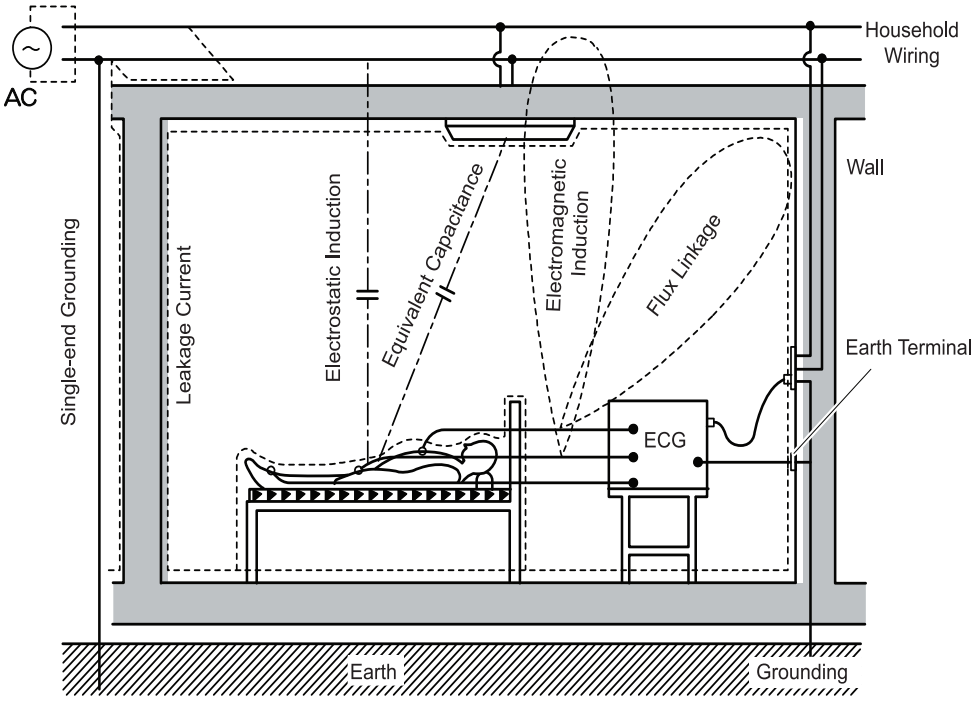
This section describes ECG installation, cable connection, power ON/OFF, and paper replacement procedures.

Notes on Installation Site

Take the following precautions when selecting the installation location.

⚠ CAUTION

- Radio interference occurs if there are strong radiated radio waves nearby (leakage currents, static induction and electromagnetic induction enter by the path shown in the figure). Select a location where no high-voltage power cables or power lines with a high load will pass by the device or the patient's bed.
- Equipment such as X-ray devices, ultrasound devices, radio devices, stands and fluorescent lighting also causes interference.
- Select a location where the room temperature will remain at 20°C to 25°C.
- Select a location with low humidity.
- Install the device where there is enough space between the wall to connect/disconnect the power supply cable.
- If any abnormality is found on the device, immediately turn OFF the power, and disconnect the power supply cable from the outlet.
- Do not install the device in a location where it is difficult to disconnect the power supply cable.
- Install this device in a place where power supply cable can be easily disconnected.



Using the Optional Battery

This section explains how to install and charge the optional battery pack.

⚠ WARNING

- Installation of the battery should be performed only by our service representative, to avoid any risk of electric shock and burn to the operator or malfunction of the device.
- Do not throw into fire. If the battery is placed in fire, it may explode.
- Charge the battery only with this device. Otherwise, acid leakage, overheating or explosion may occur.
- Do not disassemble or remodel or stub a nail or strike with hammer. The battery incorporates protection circuitry for safety purpose.
- If the leaked solution of the battery pack gets into the eyes, do not rub the eyes. Wash thoroughly with clean water and immediately receive medical treatment from a doctor. If the leaked solution gets on to the skin or clothes, wash it off with clean water immediately.
- Do not use the battery with any other device. Otherwise, acid leakage, overheating or explosion may occur.
- Do not short-circuit the terminal. Otherwise, acid leakage, overheating or explosion may occur.
- If charging is not completed after the prescribed charging time, stop charging the battery. Otherwise, acid leakage, overheating or explosion may occur.
- Do not drop the battery or subject it to strong impact.
- When disposing of a battery pack, entrust disposal to a specialized waste disposal contractor.
- Do not use on unspecified device.

⚠ CAUTION

- Make sure to use the specified battery pack. Otherwise, acid leakage, overheating or explosion may occur.

Precautions when handling a battery

Take the following precautions when using the battery.

❑Battery Life

The battery can be recharged and discharged (used) for about 300 times. Note that the service life varies depending on the frequency of use and the charging/discharging pattern of the battery. If the battery power decreases in a short time even when it is fully charged, it's service life may expire soon. Replace it with a new one in such cases.

❑Storing the Battery

If not using the equipment for a long time, remove the battery from the equipment and store it. Every three months, install the battery in the equipment and fully charge it. If left for a long period of time, the battery may self-discharge to the point where it can no longer be used.

Avoid storing the battery in an area below 0°C or above 35°C.

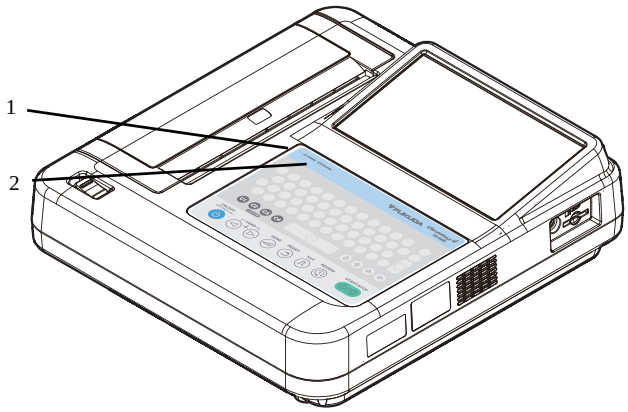
Charging the Battery

1 Turn OFF the power. (☞"Turning ON/OFF the Power" P2-7)

REFERENCE

- The battery will not be charged while the device is operating.

2 Connect the power cable to the device.(☞"Connecting the Cables" P2-5.)



1 AC Power Indicator

2 Charge Indicator

▸ The AC power indicator and charge indicator will light and charging will start.
Depending on the charging condition, the charge indicator will light differently.
Blue: Charging
Unlit: Charging completed
Orange: Charging error

NOTE

- The charge indicator will light in orange for the following cases.
  The battery temperature is too high or too low.
  An error occurred in the main unit or battery.
- Remove the power cable, wait for a while and then charge the battery again.
- If the charge indicator still lights in orange even after recharging, contact Fukuda Denshi.

▸ Charging the empty battery will be completed within 3 hours. The charging time varies depending on factors such as the level from which the battery is charged and the ambient temperature.

▸ If the battery is nearly full, charging will not start to prevent overcharging.

▸ It is recommended to charge the battery near room temperature (10°C to 30°C (50°F to 86°F)).

REFERENCE

- To ensure that the battery can be used at any time, do not unplug the power cable immediately after turning OFF the power. Allow the battery to charge until the charge indicator goes out.
- When the battery temperature is 40°C or above, charging will not start.

Operating by Battery Power

Turn ON the device by pressing the (ON/OFF) key on the operation panel with the power cable unplugged. (☞"Turning ON/OFF the Power" P2-7)

REFERENCE

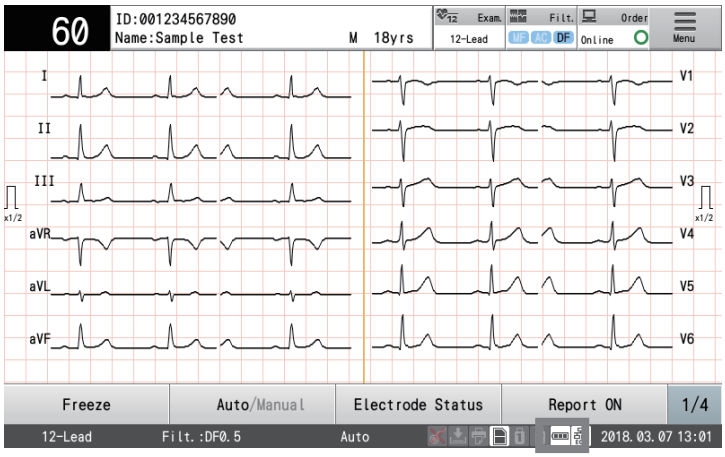
- The device automatically switches to battery operation when the power cable is unplugged or a power failure occurs while operating on AC power.

Checking the Remaining Battery Power

When the battery is fully charged, continuous operation of approximately 4 hours is possible.
However, the usable duration depends on the usage and storage condition of the battery.
While the device is operated with a battery, the remaining battery capacity is displayed with an icon in the device status display area.

For example, the device can be used for approximately 4 hours on a single charge under the following operating conditions.

- No optional accessories
- A new battery is used within one hour after charging.
- Normal ECG of 60 bpm
- In an environment at the temperature of 10°C
- Automatic printing performed every 3 minutes after displaying waveform fully in the examination window (1 cm/mV, 6 ch, filter OFF)
- The printing format is Direct Waveform Report + Result Report + Detailed Measurement Report.
- LCD brightness is minimum



The icon changes as the remaining battery capacity decreases.
When the battery icon changes to , the battery needs to be charged.
The following message may be displayed on the screen when the battery is low. Switch to AC power or charge the battery.

- <To not run out of battery, the power supply will be switched off automatically.>
- <Battery is running low. Please recharge the battery.>

- <Cannot record due to low battery voltage.>
- <The battery voltage is too low. Printing has been canceled.>
- <Battery operating. Please switch to the AC power supply.>
- <The battery voltage is too low. Cannot access media.>
- <The battery voltage is too low. Cannot perform the measurement.>
- <The battery voltage is too low. The measurement has been canceled.>

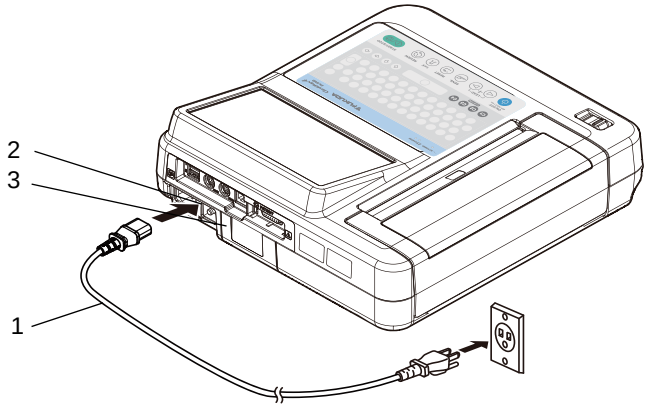
NOTE

- If the device is continued to be operated when a message indicating low battery voltage is displayed, the power will automatically turn OFF. Connect the power cable and charge the battery immediately, as this means that the battery has run out. If left in low battery state, the battery may self-discharge to the point where it can no longer be used.
- Avoid using the battery in a place where the room temperatures is below 0°C or above 40°C.

Connecting the Cables

This section describes procedure for connecting cables to the device.

1 Connect the supplied three-prong power cable to the power supply connector. Connect the other end to a hospital-grade outlet.



1 Power Supply Cable

2 Power Supply Connector

3 Potential Equalization Terminal

▸ Connect the three-prong power cable to a hospital grade power outlet (three-prong grounded AC power outlet). This will automatically ground the device. Use only the supplied AC power cable. If unspecified cable is used, it may cause hazardous situation such as electric shock to the patient and operator.

NOTE

- Do not use with on-board inverters such as those in an ambulance, as the device is not intended for this use.
- Operate this device with the optional Li-ion battery pack if the grounding conditions cannot be confirmed. Using the device which is not properly grounded may cause hazardous situation such as electric shock to the patient and operator.

- Make sure to plug in the power cable all the way in.

2 To equalize the potential between the devices, connect the potential equalization terminals of this device and other device with the optional potential equalization cable.

NOTE

- When connecting multiple devices, electrical potential difference may be generated between the devices. This may cause electric shock to the patient connected to these devices. To avoid such electrical potential difference, a ground cable is used to connect each device's potential equalization terminal to the same ground terminal. This is called equipotential grounding.

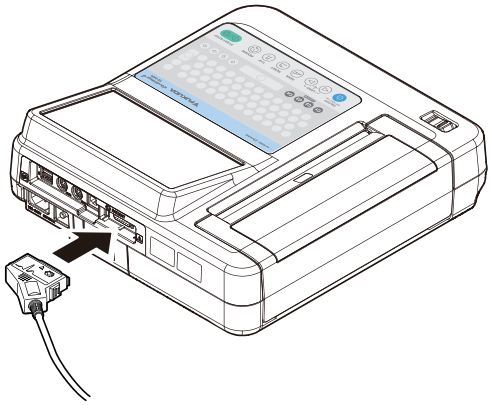
⚠ DANGER

- Do not ground with a gas pipe. This is dangerous. Explosion or fire may occur.

⚠ CAUTION

- When using with other medical devices, perform equipotential grounding to prevent potential difference between the devices.
  If potential difference occurs between the devices, it may cause hazardous situation such as electric shock to the patient and operator. Special care must be taken when using the device in operating room, ICU, CCU, cardiac catheter laboratory, and cardiovascular X-ray room.
- Check that the ground cable is not loose or disconnected.
- Attach the clip of the ground cable securely to the ground bus.
- If there is no ground bus, insert the metal rod into the ground. This is more effective if the surrounding area is sufficiently wet with water.
- Do not connect to ungrounded items. (metal window frames, plastic water pipes, ground terminals of other devices, etc.)
- Avoid using water pipes as a ground conductor as they may not provide stable grounding.

3 Connect the supplied patient cable to the ECG connector.



⚠ WARNING

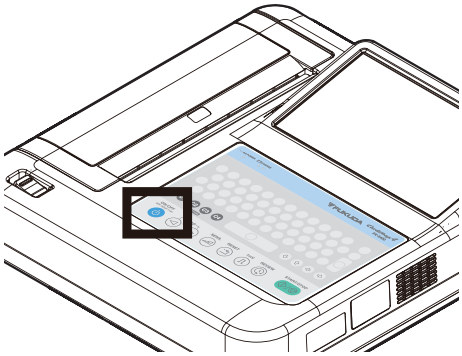
- Make sure to use the supplied patient cable.
  The use of a patient cable other than the specified defibrillation-proof type may damage the device or compromise safety when the device is used along with a defibrillator.

Turning ON/OFF the Power

To Turn ON the Power

1 Check that the AC power indicator is lit in blue.

2 Press the ⏻ (Power) key on the control panel.



- Check that a beep sounds when the key is pressed.
- If no sound is heard, the power cable may not be connected properly. Reconnect the power cable.
- When the device is operated on battery power, a beep sound is generated even when the power cable is not connected.

NOTE

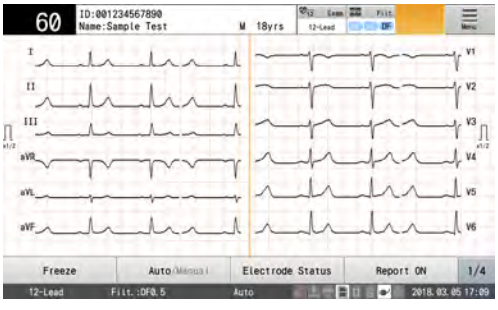
- The device may take longer to start up after the power is turned ON when the temperature in the room (or other area where the device is being used) is below 10°C. This is not a malfunction. Use the device within the specified temperature range (10°C to 40°C).

3 An initial display appears after the power is turned ON, followed by the home display.

Initial Display

Home Display

The 12-lead examination screen appears.



To Turn OFF the Power

1 Check that all operations such as measurements, saving on a media, and transmissions to the PC have been completed.

2 Remove all cables from the patient.

3 Press the ⏻ (Power) key on the operation panel for 1 second.

NOTE

- If the device will not be used for a long time, remove the power cable from the main unit for safety purposes.If the power does not turn OFF by pressing down the ⏻ (Power) key on the operation panel for 1 second, keep pressing the key. Pressing down the key for about 10 seconds stops the operation and turns OFF the power.

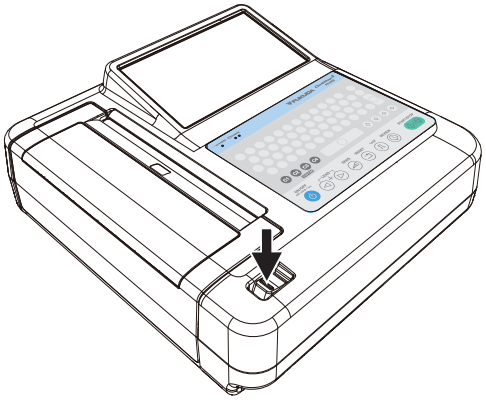
Loading the Recording Paper

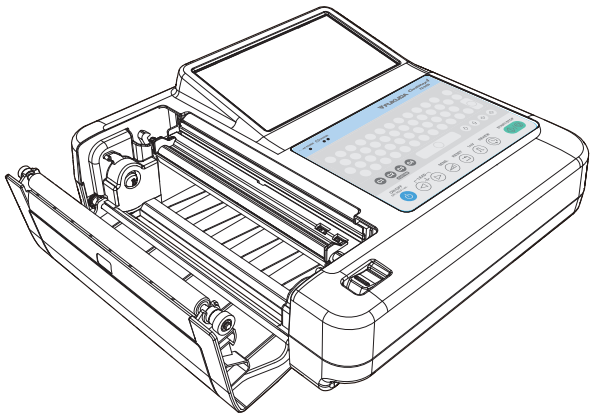
NOTE

- The paper is thermal sensitive at 70°C. Avoid exposing it to direct sunlight or storing in a room with high temperature or humidity.
- Do not expose the paper to fluorescent light for a long time.
- When storing the paper, do not file it using a PVC film.
- If the paper is stored with the printed surfaces appressed, the printed waveforms may be transferred to the opposite surface.
- When the recording paper does not stop at the perforation, adjust it with [Adjust perforations] under maintenance menu.

❑To Set the Z-fold Paper

1 Press the button to open the paper tray cover.



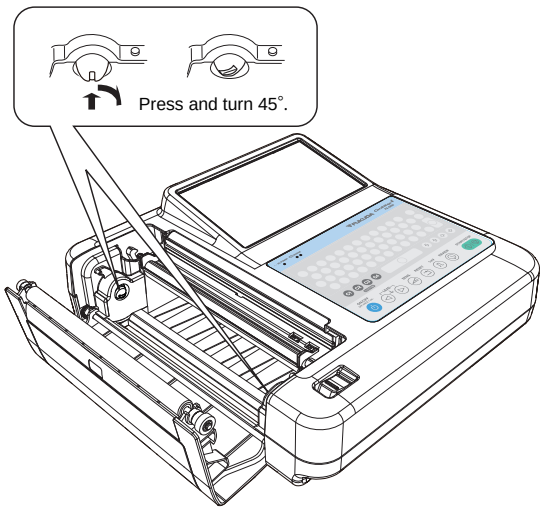


NOTE

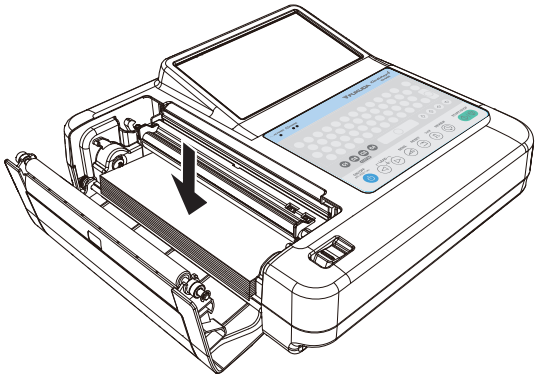
- If the paper tray button is not pressed down completely, the button and paper tray cover

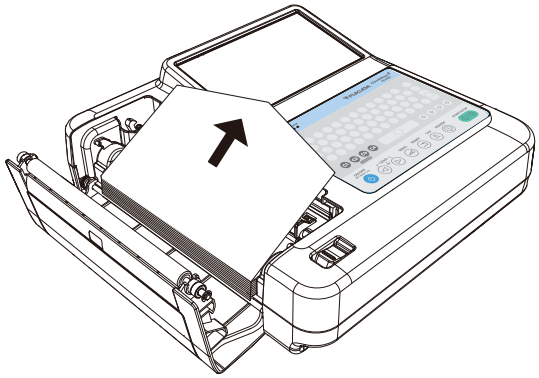
will stop halfway. Make sure that the button is pressed down completely.

2 Turn the paper support and push it in.

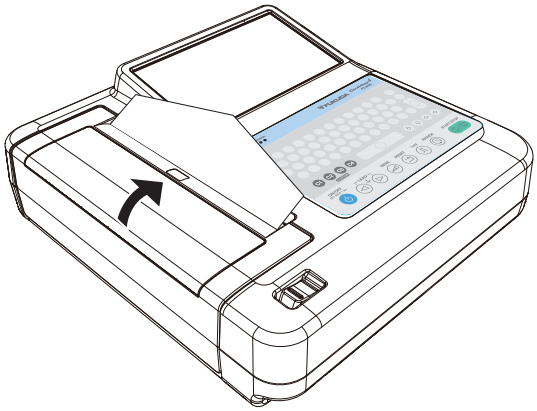


3 Set the Z-fold paper, and pull out the first page of Z-fold paper approximately 10 cm.





4 Close the paper tray cover by pressing the center part of the cover. Press down the paper tray cover until a clicking sound is heard.

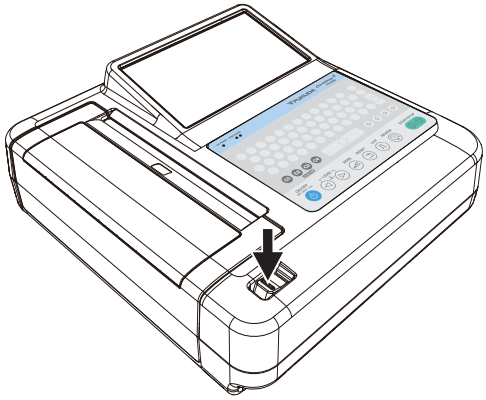


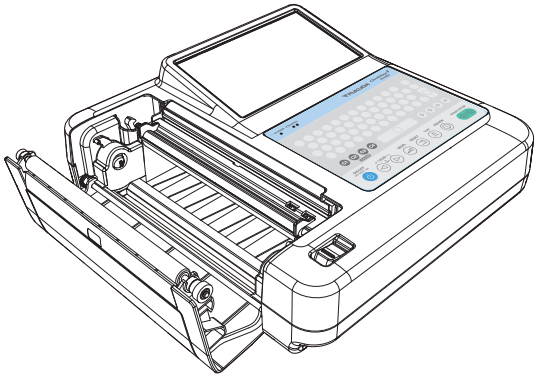
NOTE

- If the paper tray button is stopped halfway, it means that the paper tray cover is not securely closed. In that case, the ECG waveforms will not be properly printed. Open the paper tray cover again, and close it securely.

❑To Set the Roll Paper

1 Press the button to open the paper tray cover.

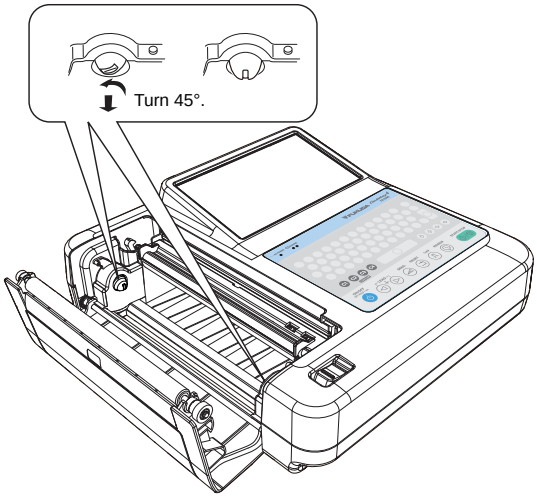




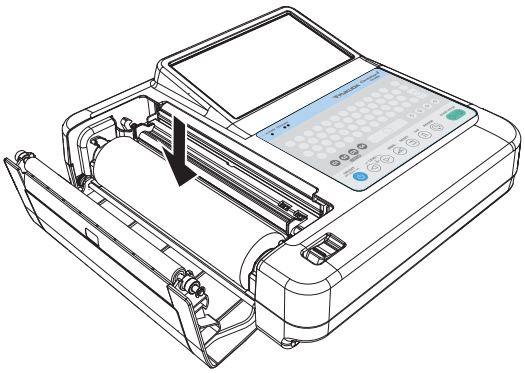
NOTE

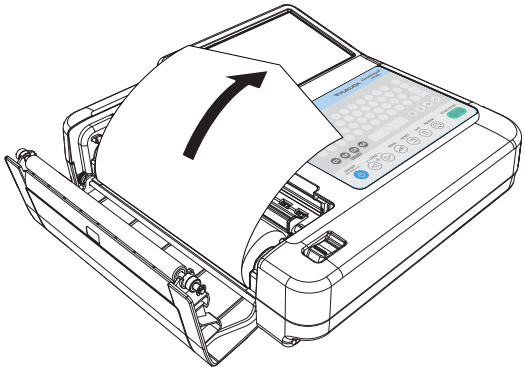
- If the paper tray button is not pressed down completely, the button and paper tray cover will stop halfway. Make sure that the button is pressed down completely.

2 Turn the paper support, and pull it out.

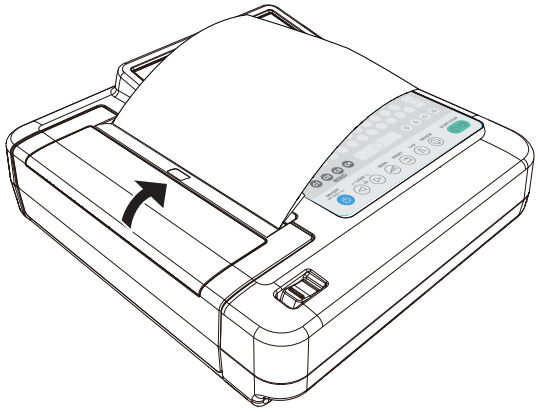


3 Set the roll paper so that paper supports on both sides are properly fit inside the roll paper. Hold the edges of the paper, and pull it out approximately 10 cm.



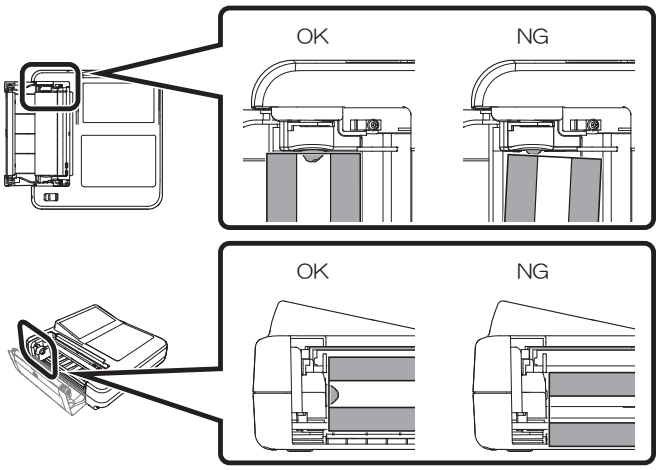


4 Close the paper tray cover by pressing the center part of the cover. Press down the paper tray cover until a clicking sound is heard.



NOTE

- If the paper tray button is stopped halfway, it means that the paper tray cover is not securely closed. In that case, the ECG waveforms will not be properly printed. Open the paper tray cover again, and close it securely.
- The paper tray will not properly close if the roll paper is not correctly set. Make sure that paper supports on both sides are properly fit inside the roll paper before closing the paper tray.



Connecting to the Network

Follow the steps below to connect to the network to send examination results from the device to a computer.

Example of Network Configuration

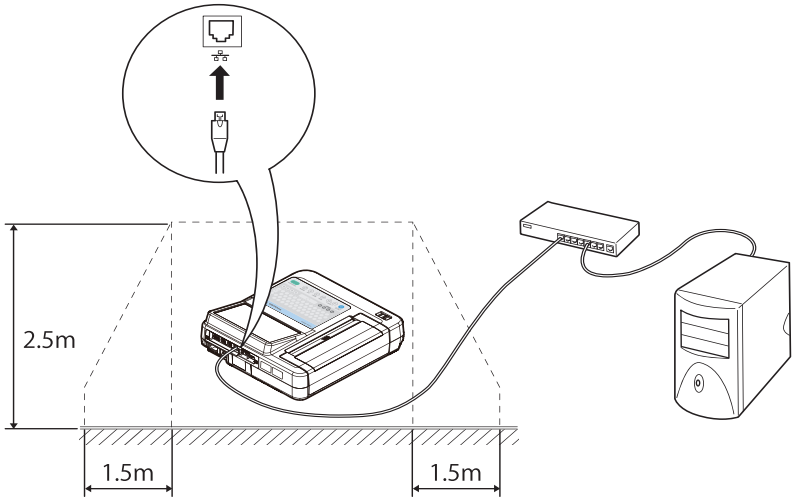
Connect the devices as shown in the figure below.

Prepare Ethernet hub and LAN cables (2 straight cables). Connect the LAN cable to the LAN connector of the main unit and connect the other end to the Ethernet hub. Connect the PC in the same way.

If the settings need to be changed according to an existing network environment, refer to "Network Configuration" and change the settings.

⚠ CAUTION

- Configure and connect to the network as specified by Fukuda Denshi.
- Use the Ethernet hub recommended by Fukuda Denshi (IEC 60950 compliant).
- The devices connected to the network such as Ethernet hub and PC must be installed 1.5 meters away from the patient area (IEC 60601-1(2005) +A1(2012), ANSI AAMI / ES 60601-1: A1: 2012+C1: 2009/(R)2012+ A2: 2010/(R)2012).
- Make sure to ground the Ethernet hub when using it.
- Use a LAN cable without any damage on the cable coating, etc.



NOTE

- The network must be used only for this device and must be separated from other hospital networks.
- When two or more devices are connected to the same network, assign a separate IP address to each device. (☞"Communication" P13-10)
- The software such as EFS-250 is required to connect this device to a PC.

Configuring Network Settings

Steps for Configuring Network Settings

Enable communication

↓

Configure network settings on the device
- Set the examination device name
- Set the IP address
- Set the gateway information

↓

Register the host
- Host name
- Enter the IP address
- Enter the port number

↓

Select the host to be used

REFERENCE

- Consult the network administrator to confirm the IP addresses (e.g. 192.168.0.3) and port numbers that can be assigned to the device and computer.
- Contact Fukuda Denshi for more information on configuring the wireless LAN settings.

Connecting Optional Devices

Connect an ID card reader or barcode reader to the USB port of the device.
Connect the wireless LAN adapter to the connector inside the dummy cover.

WARNING

- When connecting other devices to this device, contact your local Fukuda Denshi service representative. Otherwise, it may cause hazardous situation such as electric shock to the patient and operator.
- Make sure to use the specified ID reader, barcode reader and USB wireless LAN adapter. (☞"System Components" P15-3)
- The systems that do not comply with IEC 60601-1(2005) +A1(2012), ANSI AAMI / ES 60601-1: A1: 2012+C1: 2009/(R)2012+ A2: 2010/(R)2012 cannot be connected to this device. (☞"Combination Example of Medical and Non-Medical Equipments" P15-5)

REFERENCE

- The connection cables to connect the optional devices differ depending on the type of optional devices. Contact Fukuda Denshi when connecting optional devices, as improper connection may damage the devices.

Chapter 3 Preparation before Examination

This section describes procedures for attaching the electrodes, handling external media, and setting filter.

Attaching the Electrodes

Attach the electrodes to the patient. ECG recordings are affected significantly by the way the electrodes are attached. Read the following explanation carefully and take care to attach the electrodes correctly.

⚠ CAUTION

- Do not allow the patient to come into contact with this device, other electrical appliances, or surfaces such as metal.

Before the Attachment

❑Check the condition of the patient.

Check the condition of the patient and make sure that the patient is relaxed. If the patient is nervous, tell him/her to relax or breath normally.

If the patient's hands or feet are tense or if there is body motion, the ECG may not be recorded/printed correctly. Electromyography may appear in the ECG or the baseline may be unstable.

❑Clean the patient's skin

Thoroughly wipe the area where the electrodes will be attached using cotton damped with alcohol to remove dirt and oil.

If the skin or the electrode is dirty, this increases contact impedance, resulting in an unstable recording/printing.

❑Applying Keratin Cream

When using the clip electrodes, or chest electrodes, apply keratin cream to improve contact between the skin and the electrode. Rub the cream in thoroughly with the finger pads until the skin is slightly red.

The Wilson's central terminal is produced from the four-limb electrodes. When noise such as humming occurs in any of the four-limb electrodes, this causes noise to occur in the chest leads too.

When applying keratin cream for chest leads, make sure that the patches of keratin cream do not touch each other. Applying too much keratin cream causes adjacent leads to become connected via the cream, resulting in an incorrect ECG.

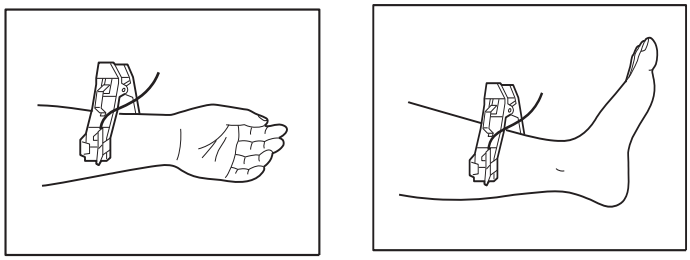
Attachment

❑Attaching the Electrodes: Limbs (4 areas)

When "Clip electrodes TE- " or "Clip electrodes TEE-" is applied

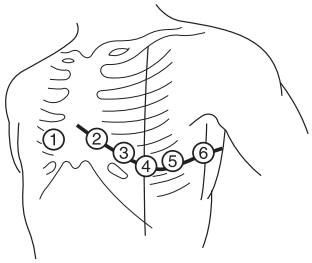
Attach the wrist clips several centimeters above the wrist and close them securely so that they do not wobble. Attach the ankle clips so that the electrodes touch the backs of the inner ankles and close them securely so that they do not wobble.

Take care to ensure that the patient is not in pain.



❑Attaching the Electrodes: Chest (6 areas)

Attach the chest electrodes in the following positions. Take care to ensure that the patient does not feel pain.



V1 (1): 4th intercostal space at the right edge of the sternum

V2 (2): 4th intercostal space at the left edge of the sternum

V3 (3): Center of the line between (2) and (4)

V4 (4): The point of intersection between the 5th intercostal space and the vertical line from the left midclavicular line

V5 (5): The point of intersection between the horizontal line at the height of (4) and the anterior axillary line

V6 (6): The point of intersection between the horizontal line at the height of (4) and the midaxillary line

REFERENCE

- The following colors and letters are assigned to indicate the attachment position of each lead chip and electrode. Check these carefully and make sure to attach the lead chips and electrodes properly.

Chip color	White	Black	Red	Green	Red/ Brown	Yellow/ Brown	Green/ Brown	Blue/ Brown	Orange/ Brown	Violet/ Brown
Symbol	RA	LA	LL	RL	V1	V2	V3	V4	V5	V6
Electrode position	Right arm	Left arm	Left leg	Right leg	(1)	(2)	(3)	(4)	(5)	(6)

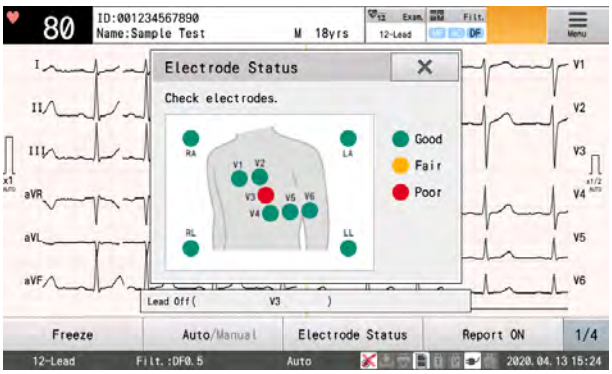
NOTE

- When the device is used with a defibrillator, use the optional silver chloride (Ag-AgCl) electrodes. Using the supplied electrodes may result in a long recovery time for the ECG waveform after discharging the defibrillator.

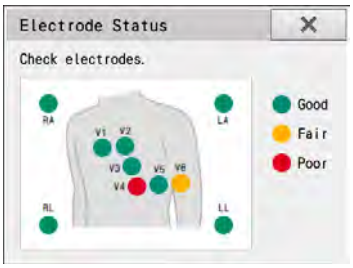
Performing Electrode Check

Check the condition of electrode attached to the patient and the condition of lead.
When "Lead Off Display" is set to [Picture] in the setting, electrodes can be checked.

1 Touch [Electrode Status] to display the electrode status window.



2 Check the electrode condition.



▸ The electrode condition is displayed as follows:

Green:	Good	The electrode condition is good.
Yellow:	Fair	Pretreatment of skin improves the electrode condition.
Red:	Poor	Electrode is detached. Check electrodes.

REFERENCE

- Refer to ☞"Attaching the Electrodes" P3-1 for checking electrodes.

3 Touch [X] to close the electrode status window.

Checking the Date and Time

Check the date and time at the bottom right of the home display
and set the correct date and time if they are not correct by referring to ☞"Correcting the Date and Time" P14-12.

REFERENCE

- If the clock becomes fast or slow immediately after setting the date and time, the built-in battery for the clock may have reached the end of its life.
  Replace the battery ahead of time.

Selecting the Filters

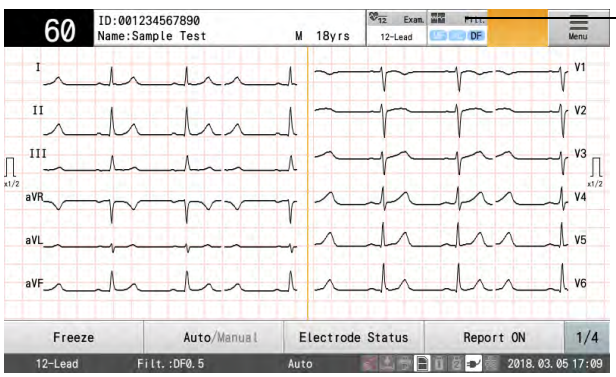
A filter can be used to remove noise that affects ECG waveforms.
Types of filters that can be set are as follows: The following filters can be turned ON (enabled) or OFF (disabled).

Filter Types	On-screen Display	Description
EMG Filter	MF	Turn this ON if noise occurs due to movement of the patient's muscles. The strength can be adjusted.
AC Filter	AC	Turn this ON if cyclic waves occur in the waveforms due to noise from the power supply. The strength can be adjusted.
Drift Filter	DF	Turn this ON if the baseline is drifting up and down. The strength can be adjusted.

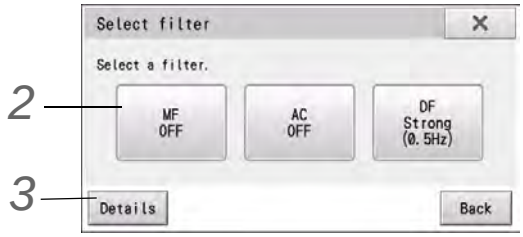
REFERENCE

- Using the muscle filter may increase distortion in QRS waveforms. Use it only when necessary.
- The high-area blocking filter is automatically set to about 75 Hz when the AC filter is set to [Weak] and about 50 Hz when the AC filter is set to [Strong]. (It will be printed as 75 Hz.) The original frequency is restored when the AC filter is turned OFF. When both the AC filter and the muscle filter are turned ON, the high-area blocking filter is set to the value set for the muscle filter.
- When the drift filter is set to "Strong (0.5 Hz)" for ECG with a heart rate of 50 or lower, distortion may occur in ST waveforms. It is recommended to turn OFF the drift filter or set to "Weak (0.25 Hz)" for bradycardia examinations.When the drift filter is turned OFF or set to [0.25 Hz], this device complies with the IEC 60601-2-25 regarding the characteristics stated for low frequency (impulse) response.

1 Touch [Filter].

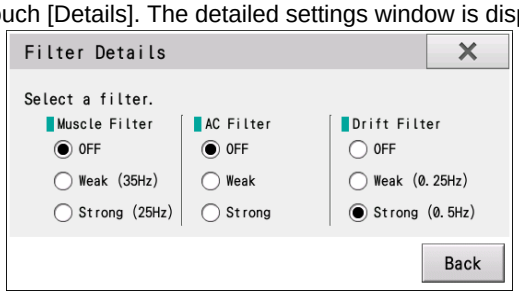


2 Set the filters. Touch the filter for the applicable noise.



▸ The touched filter will be turned ON/OFF.

3 To carry out detail setup, touch [Details]. The detailed settings window is displayed.



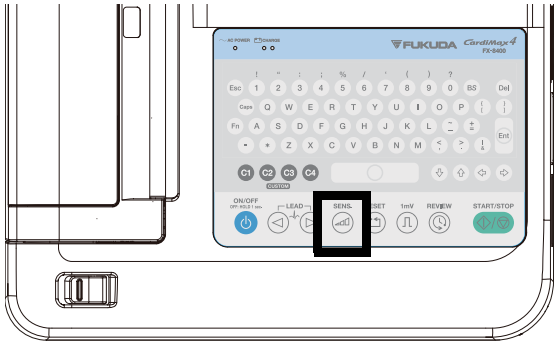
- Set the filter property to "Strong", "Weak" or "OFF" for each filter.

4 Press [X] or [Back] to end the setting.

Setting the Sensitivity

It is possible to set the sensitivity (waveform amplitude) of waveforms that are displayed or printed.

1 Press the (Sensitivity) key on the operation panel.



- Each time the (Sensitivity) key is pressed, the selection will sequentially change in the order of "AUTO" → "x1" → "x1/2" → "x1/4" → "x2" → "AUTO"→ ...(cm/mV).
- When "AUTO" is selected, the optimum sensitivity for display and printing is selected from 1 cm/mV, 1/2 cm/mV and 1/4 cm/mV.
- Waveforms are displayed with the selected sensitivity.

Check Carefully

To ensure the patient's safety and to record/print the stable ECG waveforms without noise interference, check the following.

❑Is the place of examination appropriate?

- Check for noise generating electrical devices such as X-ray imaging machine or ultrasonic instruments nearby. If there is, turn OFF the power of those device or select another place for examination.If the bed is metallic, ground the bed.
- Is the temperature of the place of examination kept within 20°C to 25°C (68°F to 77°F) range?
- Select a location with low humidity.

❑Is the power cable connected properly when used with the AC power?

- Is the cable connection secure?
- Is the power cable properly arranged and are not tangled with other cables?

❑Is the battery fully charged when used with the battery?

❑Is the patient cable connected properly?

- Is the supplied cable used? Make sure to use the supplied cable.
- Is the plug secure?
- Is the patient cable located far enough from the power cable?
- Is the pin of the patient cable connected to the correct electrode?

❑Is the electrode status good?

- Is the electrode attaching area of the patient's skin thoroughly wiped?
- When using the clip electrode or chest electrode, is keratin cream applied to the patient's skin properly?
- Are the electrodes clean?
  If not, wipe off dirt with alcohol or soap solution. For stubborn stain, rub with sandpaper.
- Are the electrodes attached securely?
  If the electrodes are loose, attach them securely to the extent the patient does not feel pain.
- Are proper electrodes used? New and old electrodes or different types of electrodes should not be mixed up.

❑Is the patient condition good?

- Is the patient calm?
  If not, make the patient feel relaxed by explaining that electrocardiography is simple and harmless.
- Is the patient motionless and not speaking?
- Is the bed large enough?
- Are the arms and legs of the patient properly located and are not in contact with metallic part such as bed?

❑Is sufficient amount of recording paper present?

Chapter 4 Entering Patient Information

Enter the name, age, and gender of the patient. There are following 5 methods to enter the information.

1 Procedure for manually entering items such as age, gender, name, height, weight, and medicine information.
(☞"Entering Patient Information" P4-2)

2 Load information from the DMS.
(☞"Loading Information from the DMS (Master ID)" P4-7)

3 Load information from the SD card.
(☞"Using Information on SD Card" P4-8)

4 Load information along with an examination order.
(☞"Ordering System" P11-1)

5 Read information from a magnetic card, barcode, etc.
(☞"Displaying Order Information Using ID Reader" P11-6)

Select an appropriate method depending on the situation.

Patient Data Categories

The following information can be entered.

Display	Description	Setting Range	Note
ID	Patient ID	3 digits to 20 digits	Can be entered in alphanumeric characters
Sub ID	Patient Sub ID	3 digits to 20 digits	Can be entered in alphanumeric characters
Age	Age	3 digits (0 to 150)	Separate input fields are used for the years, month, week and day. The date of birth can also be entered.
Gender	Gender	Male/Female	
Name	Name	24 single-byte characters	Alphanumeric characters and symbols can be entered.
Height	Height	3-digit integer + 1 decimal place	Unit: cm, inch Max. 300 cm
Weight	Weight	3-digit integer + 1 decimal place	Unit: kg, lb Max. 300 kg
Medicine	Medicine code or medicine information	Code: 2 digits to 4 digits 16 single-byte characters	Up to 20 items can be registered
Symptoms	Subjective symptoms	Code: 2 digits to 4 digits 16 single-byte characters	Up to 20 items can be registered
Blood Pressure	Systolic/diastolic blood pressure	3 digits each	Unit: mmHg, kPa Max. 300 mmHg
Dept.	Department information such as the ward (Dept. 1) and department (Dept. 2)	Up to 2 items can be entered for Dept. 1 to Dept. 4. Code: 4 digits to 8 digits 16 single-byte characters	Up to 100 items can be registered for each department.
Comment	Comment	Code: 2 digits to 4 digits 100 single-byte characters	Alphanumeric characters and symbols can be entered. Up to 20 items can be registered
Body Position	Body position for measurement	Supine, Sitting, Standing	

Respiration Rate	Respiration Rate	3 digits	Max. 999
Doctor	Name of the doctor in charge	Code: 2 digits to 12 digits Doctor 1-2 can be used to enter a total of 2 items 24 single-byte characters	Alphanumeric characters and symbols can be entered. Up to 100 items each can be registered for Doctor 1 and Doctor 2.
Technician	Name of the technician in charge	Code: 2 digits to 12 digits 24 single-byte characters	Alphanumeric characters and symbols can be entered. Up to 100 items can be registered

REFERENCE

- Other than the displayed touch keys, keys on the operation panel can be used to enter characters and numbers.
- The settings such as number of ID digits, fixing first digit of ID, ID auto increment, unit of each item are available. Set these in advance (☞"Patient Information" P13-5) .

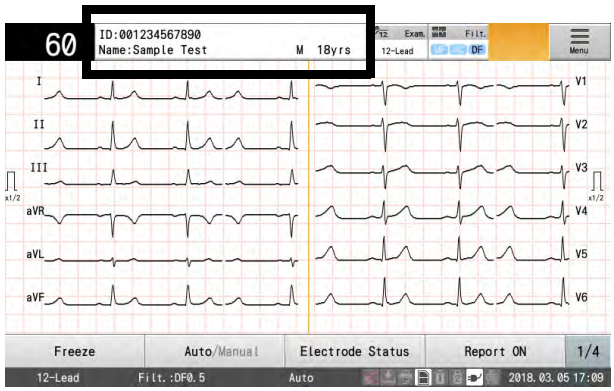
Items for "Dept.", "Med.", "Symp.", "Comment", "Doctor" and "Technician" can be registered in advance.(☞"Patient Information" P13-5).

Entering Patient Information

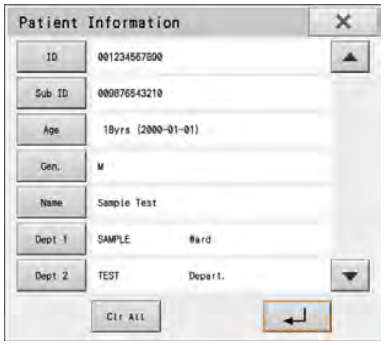
For procedure to use numeric keys and entering characters, refer to ☞"Character Entry" P1-13.

1 Turn ON the power. (☞"To Turn ON the Power" P2-7)

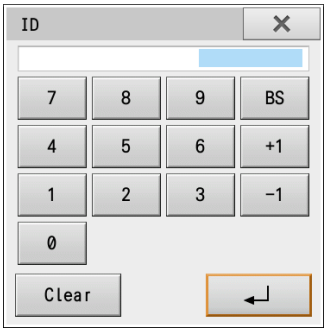
2 Touch the patient information display area.



▸ The patient information list is displayed.



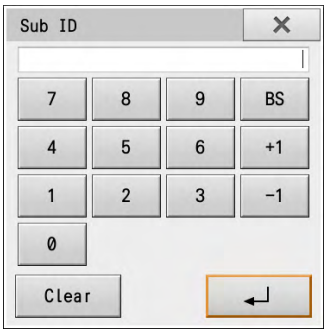
3 Enter the ID number using the numeric keys.



REFERENCE

- The window set under [Patient Information] - [Patient] - [General] - [Auto Window (Other)] will be displayed.
  For example, when set to "ID", "ID" window will be displayed.
- This window is not displayed when "No" is set for "Enter" under [Patient Information] - [Patient] - [ID].

4 Enter the sub ID number using the numeric keys.



5 Enter the patient's birth date.

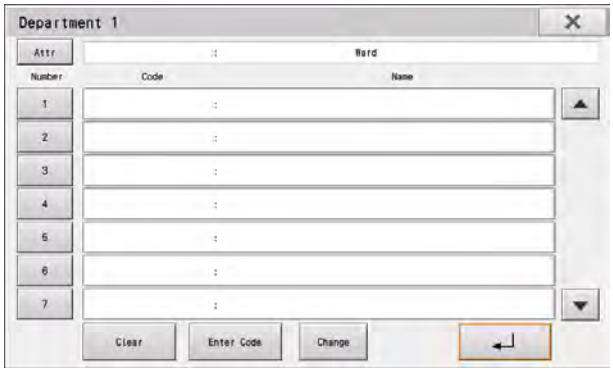
1. Enter the year of birth using the numeric keys.
   - [Years], [Mths], [Weeks], [Days]: Select the age unit.
   - [Age]/[D.O.B]: Select the age entering method, age or birth date.
2. Touch [→] to move the cursor to the Month input field and enter the month using the numeric keys.
3. Similarly, enter the day.
4. Touch [↵]. The age calculated from the entered date of birth will be displayed in the patient information window.

6 Select the patient's gender. Touch "Male" or "Female".

7 Enter the name of the patient.

Refer to ☞"Character Entry" P1-13 for the procedure to enter characters.

8 Select the department. Touch the appropriate department classification (Dept. 1 or 2) .



1 To enter a department code, touch [Enter Code] and enter the code using the numeric keys.

- Touch [↵] to enter the code in the department selection window.

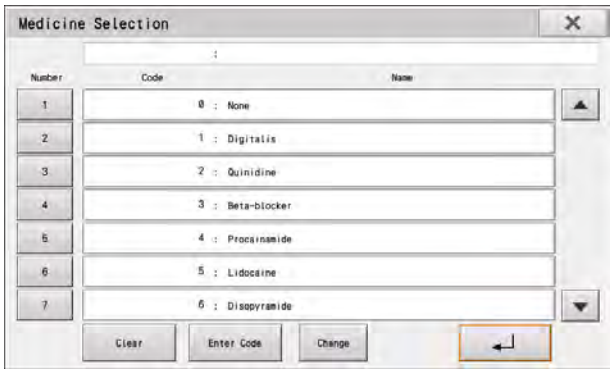
2 To create a new department, touch a blank department classification, and then touch [Change].
Enter the code and department name, and then touch [↵].

3 To edit the existing department, touch the department classification to be edited, and then touch [Change].
Enter the code and department name, and then touch [↵].

9 Enter the height and weight using numeric keys.

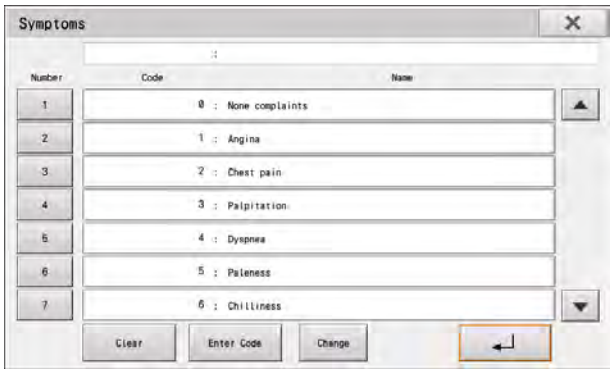
10 Enter medicine.

The code and medicine name can be changed by touching the applicable medicine and then touching [Change]. (The medicines with codes 1 to 10 cannot be changed.)



11 Enter the symptoms.

The code and symptom name can be changed by touching the applicable symptom and then touching [Change]. (The symptoms with codes 1 to 10 cannot be changed.)



12 Enter a comment.

The code and comment can be changed by touching the applicable comment and then touching [Change].

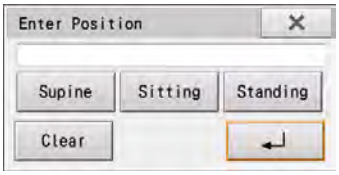
13 Enter the blood pressure. Enter the systolic blood pressure using the numeric keys.

1 Enter the systolic blood pressure.

2 Enter the diastolic pressure by touching [DIA].

- Touch [↵] to finalize the entered BP value which will be displayed in the patient information window.

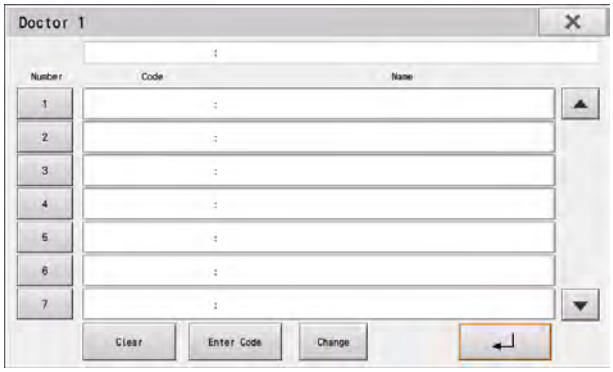
14 Enter the body position. Touch Supine/Sitting/Standing.



15 Enter the respiration rate. Enter the respiration rate using the numeric keys.

16 Enter the doctor and technician.

The code, doctor, and technician names can be changed by touching the applicable number and then touching [Change].



17 Check the information entered in the patient information, and touch [↵].

- The display will return to the home display.
- The entered information will be displayed in the patient information display area.
- [Clr All]: All entered information is cleared.
- [x]: Saves the entered information and returns to the home display.

REFERENCE

- If any information needs to be changed, touch the item to display the input window and correct the information.

Loading Information from the DMS (Master ID)

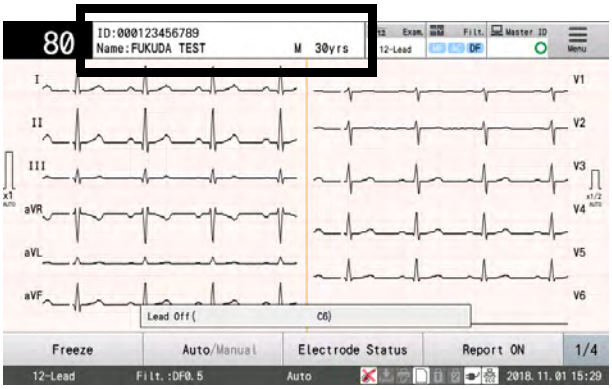
The patient information can be searched and loaded from the DMS by entering the ID number.
The following items can be loaded using Master ID.

First name/Last name	Weight	Medicine 1
Birth date	Systolic pressure	Subjective symptoms
Age	Diastolic pressure	Comment (max.: 22 single-byte characters)
Gender	Ward (Department Code 1)	
Height	Depart (Department Code 2)	

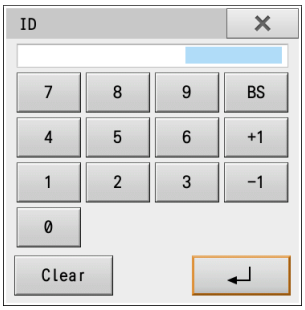
REFERENCE

- Set [Patient] - [Patient Reference] to [Master ID] for patient information setting beforehand. Also, configure the communication settings. (☞"Communication" P13-10)

1 Touch the patient information display area to display the Patient Information Setting window and then touch [ID].



2 Enter the ID number using the alphanumeric keys.



3 Touch [↵] .

- The ID entered is reflected in the "Patient Information Setting" window.
- The patient information is loaded from the DMS using the ID number entered as a key and displayed in the Patient Information Setting window.

REFERENCE

- The message "No patient information was found for the entered ID number" is displayed if

there is no patient information corresponding to the specified ID number.

- ID numbers can also be loaded from an ID reader. In this case, the patient information is loaded from the DMS automatically when the ID number is loaded from the ID reader. (☞"External Device" P13-14).

Using Information on SD Card

Patient information entered when conducting an examination can be registered on a SD card to be used again for the next examination.

REFERENCE

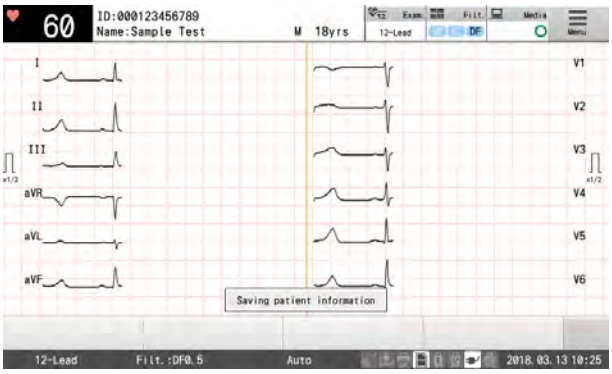
- Set [Patient] - [Patient Reference] to "Media" to use the function of registering patient information.
- The patient information items that can be registered are ID number, name, date of birth, and gender. Enter the date of birth, not an age, as the patient's age may change depending on the examination date(☞"Entering Patient Information" P4-2).
- Insert a SD card in the SD card slot and format it beforehand (☞"Initializing the Data" P9-2).
- A maximum of 5,000 patient information can be registered on a SD card.

Registering the Patient Information

Enter patient information, perform examination, and register the patient information on the SD card.

1 Insert a formatted SD card in the SD card slot.

2 Enter the patient information, and perform an examination.



- When the examination is completed, the patient information used in the examination will be automatically registered on the SD card.
- <There is no folder to save the patient information on the SD card. Do you want to create the folder?> will be displayed when registering patient information for the first time. Touch [Yes].

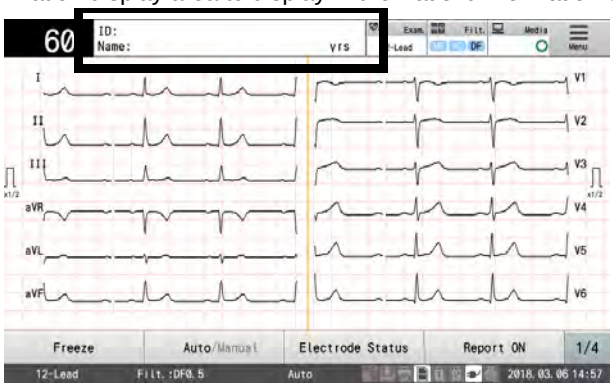
NOTE

- The patient information is registered on the USB memory after the examination is completed. Removing the SD card or turning OFF the power too soon may damage the SD card.

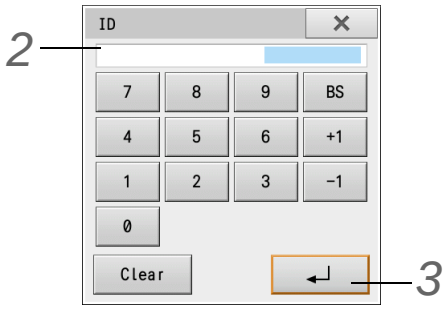
Retrieving the Patient Information Using the ID Number

Use the ID number to load the patient information from the SD card.

1 Touch the patient information display area to display in the Patient Information Setting window.



2 Enter the ID number.



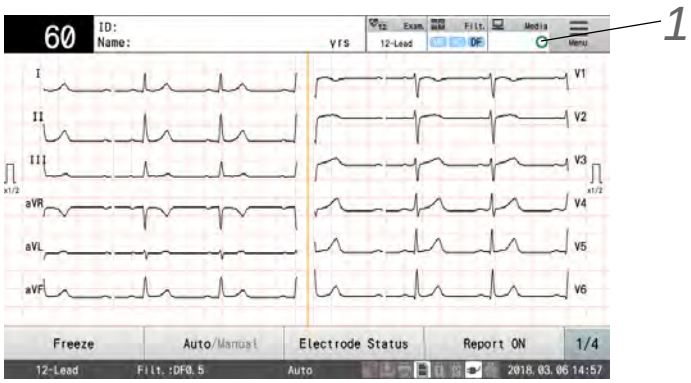
3 Touch [↵].

- The ID entered is reflected in the "Patient Information Setting" window.
- The patient information will be searched on the SD card from the ID entered, and the information searched will be displayed in the patient information display area.
- The message "No patient information was found for the entered ID number" is displayed if there is no patient information corresponding to the specified ID number.

Retrieving the Patient Information by Specifying the Patient

Load the patient information from the SD card before performing an examination.

1 Touch "Media".

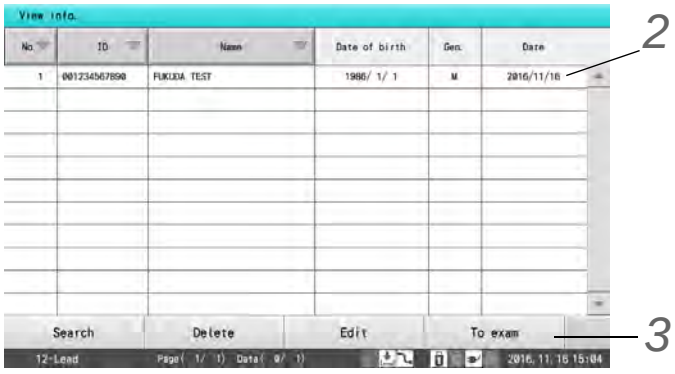


- The patient information list is displayed.

2 Select a patient.

- When the applicable patient information is not displayed, use the scroll bar to scroll up and down the list.

3 Selecting a patient on the list will highlight the corresponding row in black. Touch [To exam] to display the selected information in the patient information display area.



REFERENCE

- The patient information items that are registered are examination date, ID number, name, date of birth, and gender. Enter other patient information separately as needed.

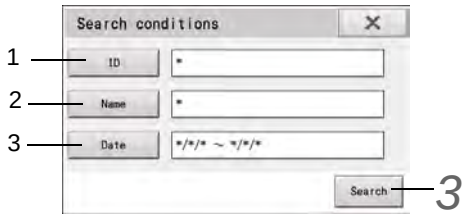
Searching the Patient Information

The patient information can be searched using the search condition.

1 Touch [Search] in the patient information list.

- The search condition window appears.

2 Specify search conditions (ID number/name/examination date).



1 When searching by ID number, enter the ID number of the desired data.

- All ID numbers are set as search targets by default.
- Wild cards can be specified with a "*". For example, "123*" will retrieve items such as "12345" and "1234567890" in addition to "123".

2 When searching by name, enter the patient name.

- All patients are set as search targets by default.
- When the name is entered, the names containing character strings are searched. For example, when "Fuku" is entered, names such as "Fukuda", "Fukuyama" and "Kofuku" will be retrieved.

3 When searching by examination date, enter the examination date of the desired data.

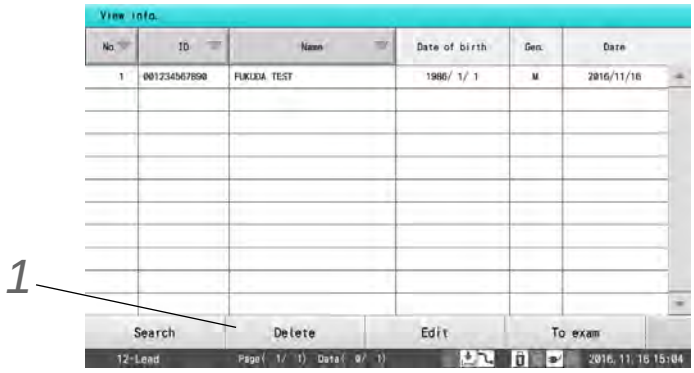
- All examination dates are set as search targets by default.
- An examination start date and end date can be entered. If no start date is entered, all data items before the end date are search targets. If no end date is entered, all data items from the start date onward are search targets.

3 Touch the [Search] button to display a list of items that match the ID number, name or examination date entered.

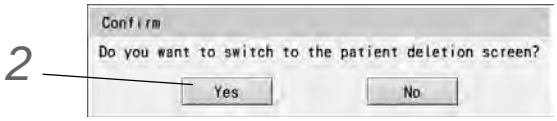
Deleting the Unnecessary Patient Information

Unnecessary patient information can be deleted from the SD card.

1 Touch [Delete] in the patient information list.



▸ Confirmation window for switching to the delete confirmation window.

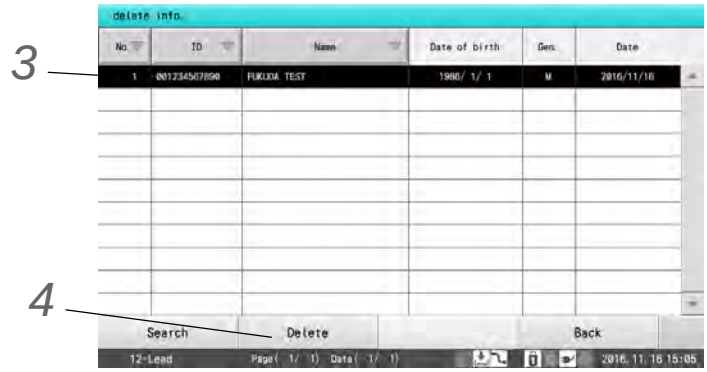


2 Touch the [Yes] key if the window may be switched.

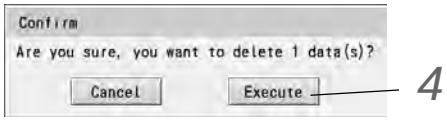
3 Select the data from the list.

▸ The selected patient information is highlighted.

- More than one patient information can be selected for deletion.



4 Touch [Delete]. When the confirmation message window appears, touch [Execute].



- The specified patient information is deleted from the SD card.
- Touch [Back] to return to the patient information list.

Chapter 5 12-Lead Examination

This chapter describes the basic method for recording an ECG.
The basic process for conducting standard ECG examinations is as follows:

❑Setup

Configure the various settings as necessary.
☞"Selecting the Filters" P3-4
☞"Setting the Sensitivity" P3-5
☞"12-Lead Examination" P13-15

❑Preparation

1. Set the examination mode to “12-Lead Exam.”
2. Enter the patient information.

☞"Entering Patient Information" P4-2
☞"Loading Information from the DMS (Master ID)" P4-7
☞"Using Information on SD Card" P4-8

❑Recording/Printing the Waveform

☞"Recording/Printing Automatically" P5-4
☞"Printing Waveforms from Several Seconds Before (Review Recording/Printing)" P5-13
☞"Manual Recording/Printing" P5-10

❑Checking/Printing the Results

☞"Function that can be used after measurement" P5-9

❑Saving

☞"Saving Examination Data" P9-3

Function Keys Used in Examinations

The function keys vary depending on the operating mode and whether printing is in progress.

❑Auto Mode (while not printing)

Freeze	Auto/Manual	Electrode Status	Report ON/OFF	1/4

↓ Touch [1/4] to switch displays.

Interval	Previous Exam.	Window Selection	Feed	2/4

↓ Touch [2/4] to switch displays.

R wave detection lead			Switch Reference	3/4

↓ Touch [3/4] to switch displays.

Measurement Result*1	Save*1	Copy*1		4/4

❑Auto Mode (while printing)

Hold*2	Mark	Extend Printing		

❑Manual Mode (while not printing)

Freeze	Auto/Manual	Electrode Status	25mm/s	1/4

↓ Touch [1/4] to switch displays.

Interval	Channels	Window Selection	Feed	2/4

↓ Touch [2/4] to switch displays.

R wave detection lead		Previous Exam.	Switch Reference	3/4

↓ Touch [3/4] to switch displays

Measurement Result*1	Save*1	Copy*1		4/4

❑Manual Mode (while printing)

25mm/s	Mark			

❑Interval Printing at Rest/Auto (while not printing)

Freeze	Auto/Manual	End	Report ON/OFF	1/3

↓ Touch [1/3] to switch displays.

	Channels	Window Selection	Feed	2/3

↓ Touch [2/3] to switch displays.

Measurement Result*1	Save*1	Copy*1		3/3

❑Interval Printing at Rest/Manual (while not printing)

Freeze	Auto/Manual	End	25mm/s	1/3

↓ Touch [1/3] to switch displays.

	Channels	Window Selection	Feed	2/3

↓ Touch [2/3] to switch displays.

Measurement Result*1	Save*1	Copy*1		3/3

❑Interval Printing at Rest/Auto (while printing)

Hold*2	Mark	Extend Printing	End	

❑Interval Printing at Rest/Manual (while printing)

25mm/s	Mark	End		

❑While printing compressed waveform

	Mark	End		

*1: Displayed only when there is a previous examination.

*2: By touching [Hold], extended recording/printing of the lead block currently being recorded/printed will be performed. (☞"Extending Printing" P5-16)

Type of Waveform Recording/Printing

The following types of printing are available.

Auto Printing	ECG waveform is printed in a fixed format according to the preset items. (☞"Recording/Printing Automatically" P5-4)
Review Printing	ECG waveform is printed for the specified period until the (Review) key is pressed. (☞"Printing Waveforms from Several Seconds Before (Review Recording/Printing)" P5-13)
Manual Printing	ECG waveform is printed manually while changing lead and sensitivity freely as necessary. (☞"Manual Recording/Printing" P5-10)

❑Printing Format for Auto Printing

The printing format for auto printing is composed of the following.

♦Waveform Report

Waveform report settings can be configured under [Setting] > [12 Lead Exam.] > [12-Lead Auto Print] > [Waveform Report]. Settings such as the waveform recording time, waveform report output and waveform report format can be configured.
(☞"Waveform Report" P13-20)

♦Measurement Result Report

For the result reports, "Cover", "DOM1", "DOM2", "DOM3", "FULL3", "FULL6", "Panorama", "Time Comparison" are available.
The printing details can be configured under [Setting] > [12-Lead Exam.] > [12-Lead Auto Print] > [Result Report]. Refer to ☞"Examples of Printing" P5-6 for printing details of the DOM1 report, printing procedure of detailed measurement report, etc.

♦ACS Summary Report

♦ACS Guide Report

♦Brugada Risk Analysis Report.

♦Analysis Report

♦Commentary Report

♦Detailed Measurement Report

To print detailed measurements, set "Yes" for "Det. Meas. Report" under [Setting] > [12-Lead Exam.] > [12-Lead Auto Print] > [Result Report 1]. (☞"Results Report" P13-20)

Waveform Report	Measurement Result Report	ACS Summary Report	ACS Guide Report	Analysis Guide Report	Commentary Report	Detailed Measurement Report

Refer to ☞"12-Lead Examination" P13-15 for setting the printing method of each report.

REFERENCE

- When an optional software is installed, analysis result report will be recorded/printed instead of measurement result report during the auto recording/printing.

- Panorama report, ACS summary report, ACS guide report, Brugada risk analysis report, analysis report, and commentary report can be printed only when an optional software is installed.

Recording/Printing Automatically

EGC data are recorded automatically. ECG waveforms are measured according to the settings and printed in a prescribed format.

Preparation

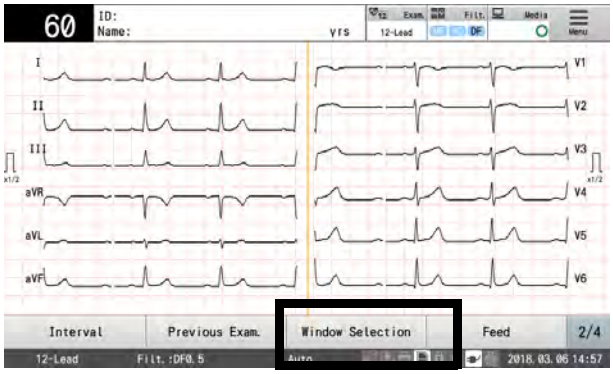
❑Settings for 12-Lead Auto Printing

Perform settings under [Setting] > [12-Lead Exam.] > [12-Lead Auto Print] in advance.(☞"12-Lead Examination" P13-15).

❑Selection of Display Type

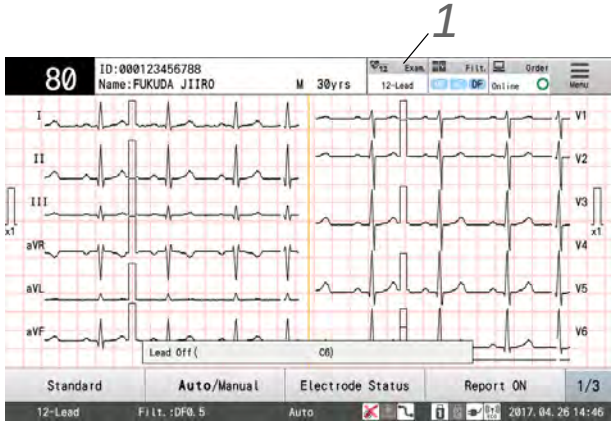
Touch [Window Selection] in the function key area to select the display type.

Each time [Window Selection] is touched, the display switches in the order of "6chx2"→ "6ch" →"3ch" →….



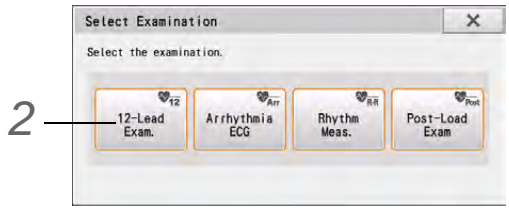
Starting Printing

1 Touch [Exam.].



2 Touch [12-Lead Exam.].

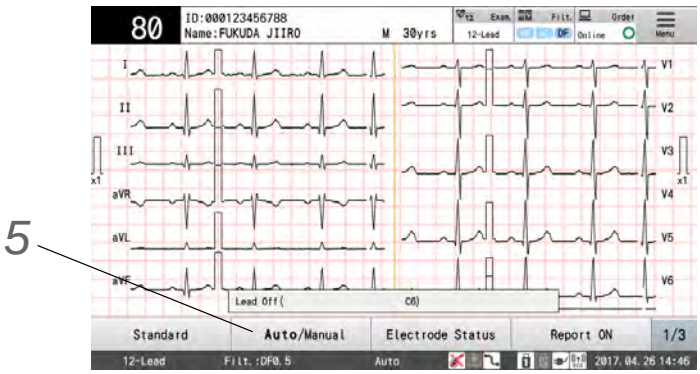
- When the power is turned ON, the 12-lead examination is displayed.



3 Enter patient information. (Refer to Chapter 4 "Entering Patient Information".)

4 Attach the ECG electrodes and check that an ECG appears in the display. (☞"Attaching the Electrodes" P3-1)

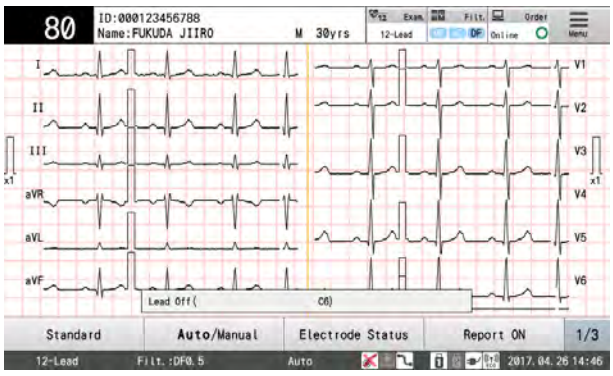
5 Select auto printing.



- The default setting is "Auto".
- Touch [Auto/Manual] to switch between automatic and manual printing. The printing currently set is displayed in bold face.
- Automatic printing: Lead is normally displayed.
- Manual printing: Lead is highlighted (white text on a black background).

6 Check the ECG waveforms.

- Check the current waveforms shown in the display.



- When the waveforms of 6 channels/3 channels are displayed, the displayed leads will change.
- Press the ◁/▷ (LEAD) key on the operation panel to switch the lead.

7 Press the ◇/▽ (START/STOP) key on the operation panel to start collecting waveforms.

- Waveforms will be started to be collected, and <Acquiring waveforms...> will be displayed.

- The recorded content is printed in the specified waveform report format. The printing will automatically stop when completed.
- To stop printing press the (START/STOP) key.
- Printing can be extended by touching [Extend Printing] on the touch panel while printing ECG.
- Printing can be extended automatically when R-R interval exceeds the fixed value.
  (☞"Extending Printing" P5-16)

8 The measurement results will be displayed when the automatic measurement is completed.

- Press the (START/STOP) key to print and automatically save the set report.

NOTE

- When the (START/STOP) key is pressed on the second time or onward in the measurement result window, a report will be printed but auto saving will not be carried out.
- When [Back] is touched during the ECG examination, the results are not saved to the external media even if "Auto Save" is set to "ON".

REFERENCE

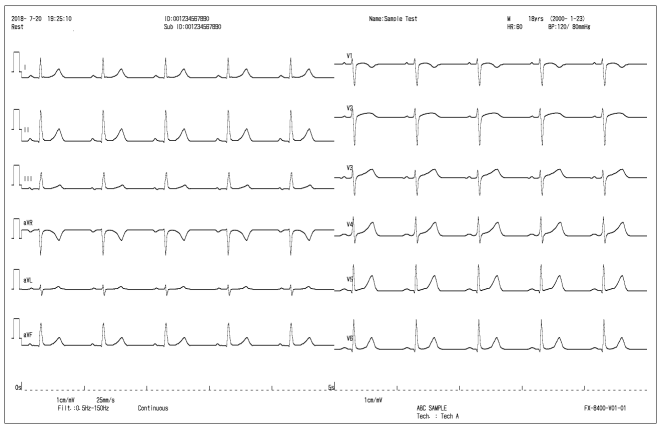
- When the optional software is installed, the analysis result window will be displayed instead of the measurement result window.
- Refer to ☞"Function that can be used after measurement" P5-9 for operation in the measurement result window.

Examples of Printing

REFERENCE

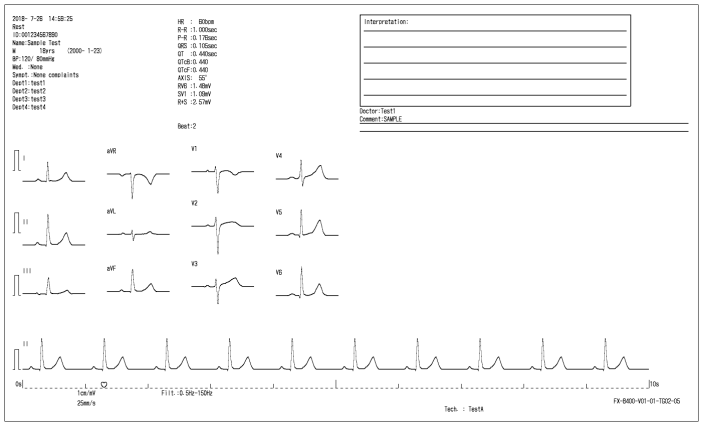
- When an optional software is installed, analysis result report will be recorded/printed instead of measurement result report during the auto recording/printing.
- Analysis report and commentary report can be printed only when an optional software is installed.

● Auto Printing (Directly Written Printing)



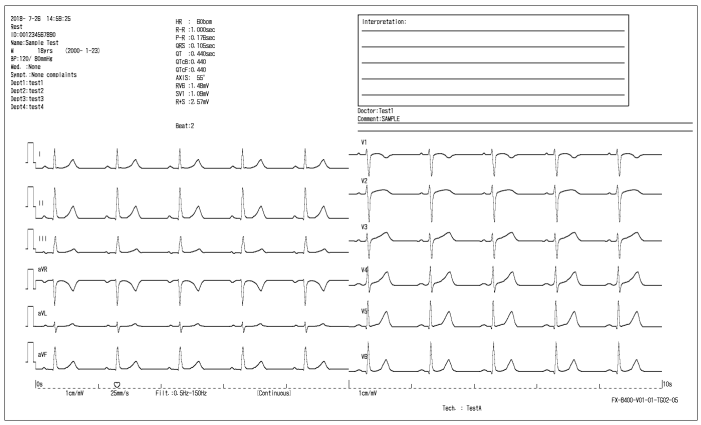
The printing example of the following is shown:
Waveform Report: 6chx2
Waveform Acquiring Time: 10 seconds

● Auto Printing (Result Report)



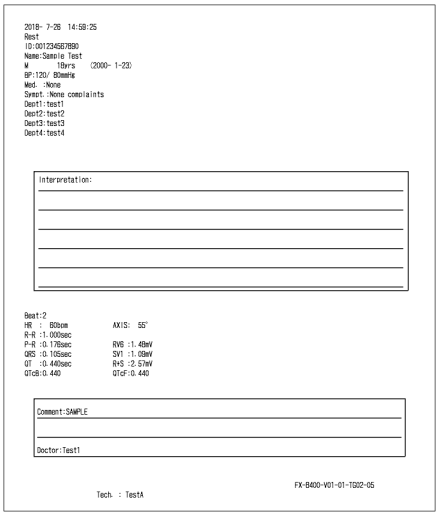
The printing example of the following is shown:
Result Report: DOM1

● Auto Printing (Result Report)



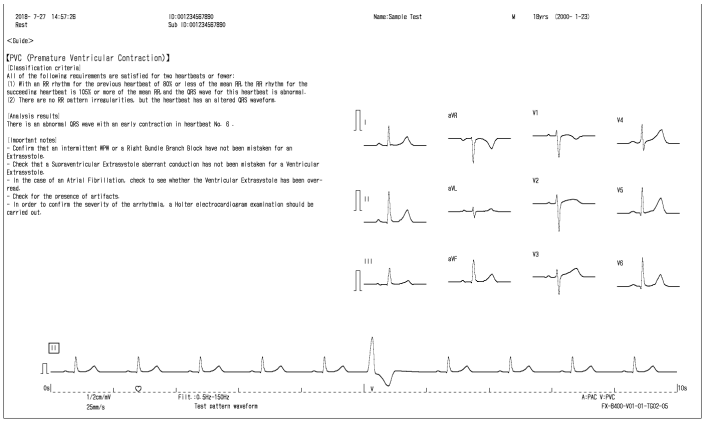
The printing example of the following is shown:
Result Report: FULL6

● Auto Printing (Result Report)



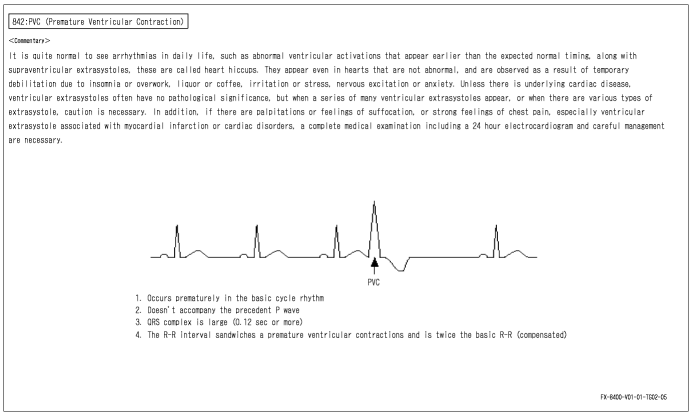
The printing example of the following is shown:
Result Report: Cover

● Analysis Report



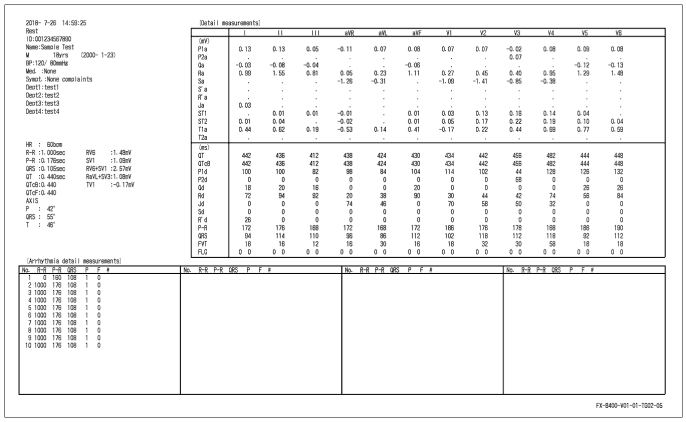
The following settings are required.
Set “Interpret.” for [12-Lead Exam.] - [12-Lead Auto Print] - [Results Report 1] - [Analysis Report].

● Commentary Report



The following settings are required.
Set “Interpret.” for [12-Lead Exam.] - [12-Lead Auto Print] - [Results Report 1] - [Commentary Report].

●Detailed Measurement Report



The following settings are required.
Set "Yes" for [12-Lead Exam.] - [12-Lead Auto Print] - [Results Report 1] - [Det. Meas. Report].

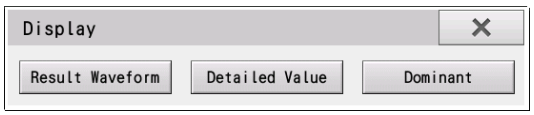
Function that can be used after measurement

The following items can be confirmed in the Measurement Result window before printing a result report.
Flick left or right on the screen to switch display in the Measurement Result window.
It is also possible to select the window to be shown by touching [Window] and selecting the display from the Window Selection window.
To zoom in on a waveform in the measured waveform or measurement result window, double click the area to be examined to display an enlarged waveform.

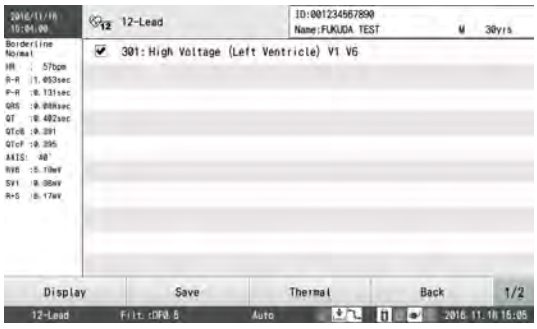
REFERENCE

- The [Analysis Result] key will be displayed only when an optional software is installed.
- Analysis report and commentary report can be printed only when an optional software is installed.

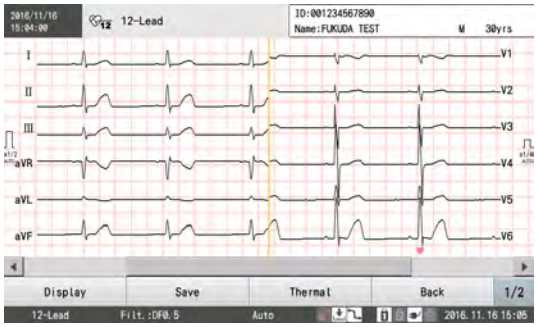
● Display selection window
The desired measurement result window can be selected.



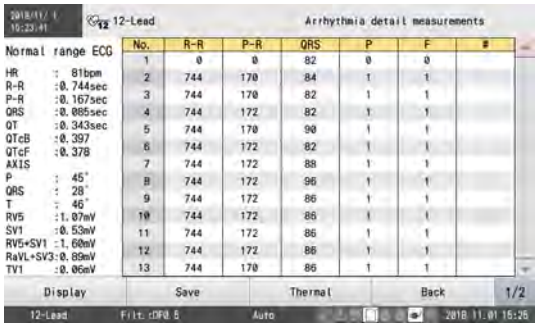
● [Analysis Result]
The Analysis Result appears. The analysis report and commentary report of the checked commentary can be output.



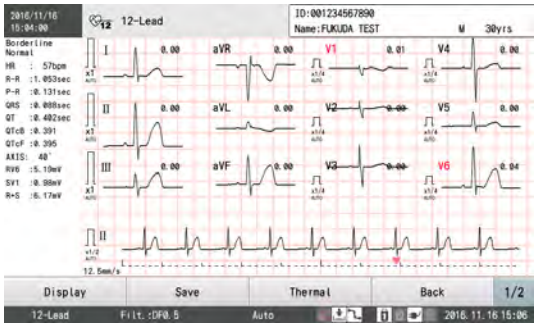
● [Result Waveform]
The result waveform can be verified.



● [Detailed Value]
Detailed measurements are displayed.

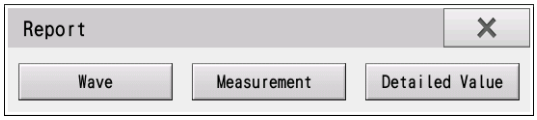


● [Dominant]
The dominant waveforms are displayed.



● [Save]
Touching this button displays the "Save to" window.
Select the media to save data.

● [Thermal]
The report can be printed to the internal thermal recorder.
Touch the report to output. Refer to ☞"Examples of Printing" P5-6 for printing contents.



Correcting the Patient Information

In the examination result display, patient information can be corrected.
Refer to Chapter 4 "Entering Patient Information" for the operation procedure.

NOTE

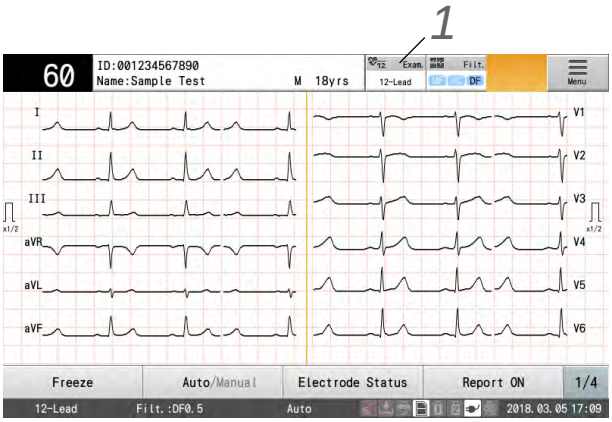
- Make sure to save data in order to enable editing. If it is not saved, edits will not be reflected.

Manual Recording/Printing

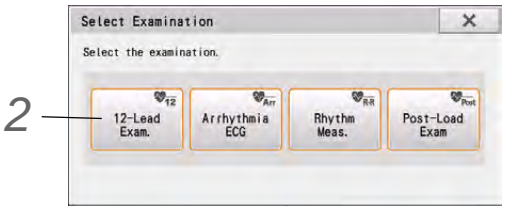
The ECG can be printed by manually changing lead and sensitivity.

Starting Manual Recording/Printing

1 Touch [Exam.].



2 Touch [12-Lead Exam.].

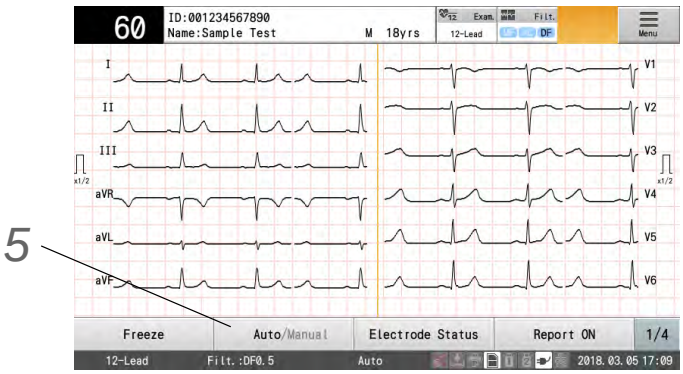


▸ When the power is turned ON, the 12-lead examination is displayed.

3 Enter patient information. (☞"Entering Patient Information" P4-1)

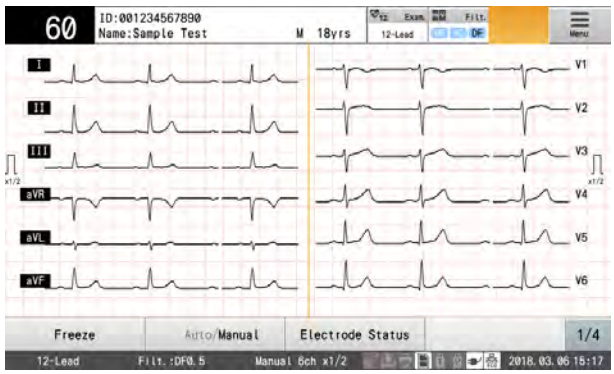
4 Attach the ECG electrodes and check that ECG waveforms appear on the display. (☞"Attaching the Electrodes" P3-1)

5 Select manual printing.



- The default setting is "Auto".
- Touch [Auto/Manual] to switch between auto printing and manual printing. The current setting is displayed in bold.
- When "Auto" is set: The leads will be normally displayed.
- When "Manual" is set: The leads will be highlighted (white text on a black background).

6 Check the ECG waveforms.



- Check the current waveforms shown in the display.When the waveform is unstable, press the (RESET) key.
- Dominant waveforms of 6 channels or 6 channels x 2 are displayed and the lead to be printed will be displayed in white text with black background.
  Each time [Display] (function key 1/4) is touched, the display switches in the order of "6 ch x 2 " → "6 ch" → → "6 ch x 2" → and so forth.
- When the (LEAD) key on the operation panel is pressed, the lead block will change in the order of "Block 1" <=> "Block 2" <=> ..."STD" <=> "Block 1", and so forth, in the direction of the key. The lead type of the waveform to be printed is highlighted.

Lead Mode	12-lead	
Channels	3 ch	6 ch
STD	STD	STD
Block 1	I to III	I to aVF
Block 2	aVL to aVF	V1 to V6
Block 3	V1 to V3	Spare 1 (6ch)
Block 4	V4 to V6	-
Block 5	Spare 1 (3ch)	-
Block 6	Spare 2 (3ch)	-

7 Press the (START/STOP) key on the operation panel to start acquiring waveforms.

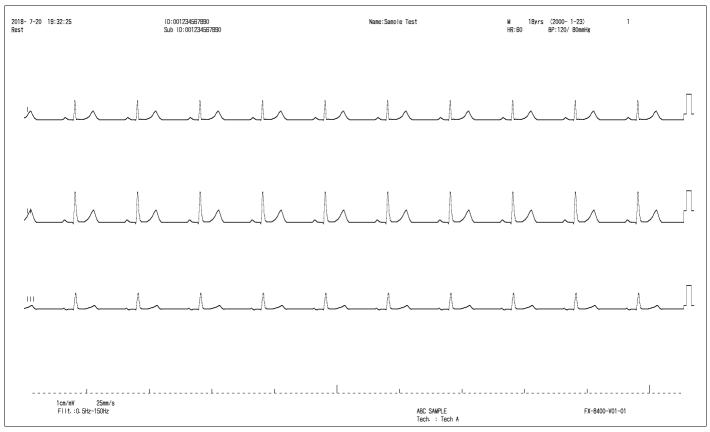
- Acquiring of waveforms will start, and <Acquiring waveforms...> will be displayed.
- Press the (1mV) key on the operation panel to print the 1 mV calibration waveforms.
- Touch [Mark] to print a thick line on the thermal printer output. (☞"Printing Marks" P5-18)
- Touching the speed keys such as [25 mm/s], [50 mm/s] switches the printing speed in the order of "5 mm/s" → "10 mm/s" → "12.5 mm/s" → "25 mm/s" → "50 mm/s".

8 To stop printing, press the (START/STOP) key on the operation panel.

Examples of Printing

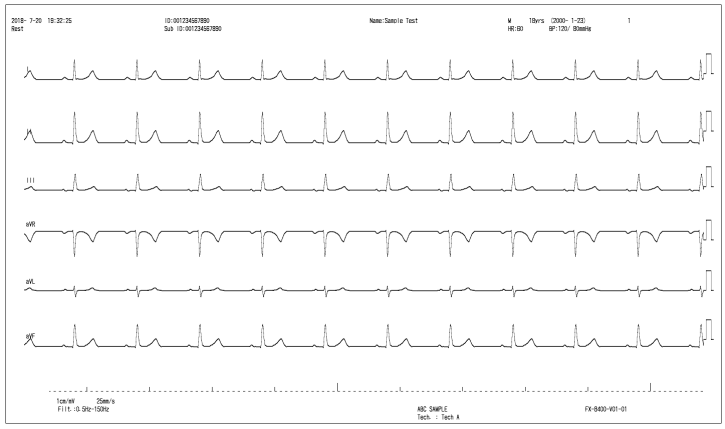
- Manual printing (3 ch)

This is an example printing of the following:
Lead: Limb (I, II, III)



- Manual printing (6 ch)

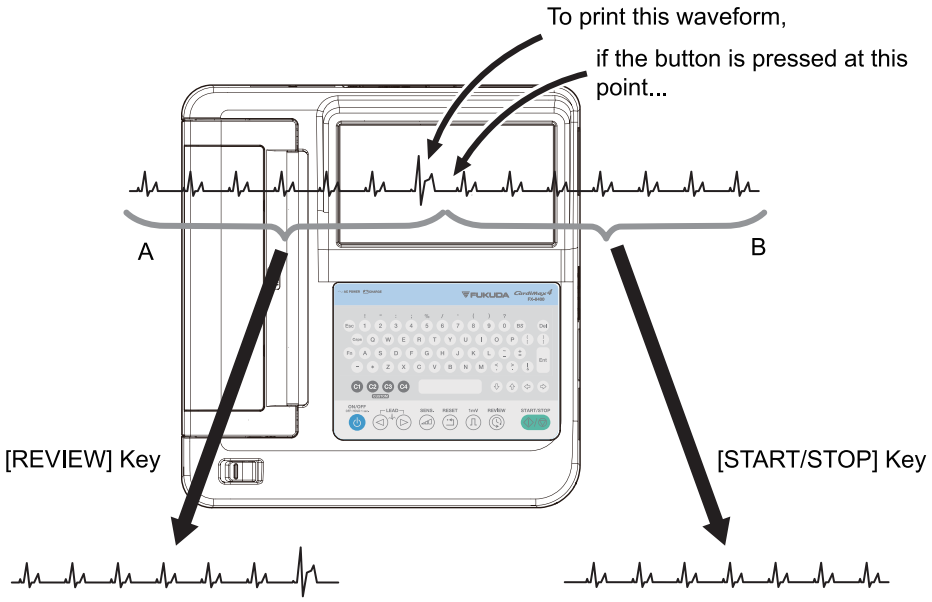
This is an example printing of the following:
Lead: Limb (I, II, III, aVR, aVL, aVF)



Printing Waveforms from Several Seconds Before (Review Recording/Printing)

Principle of Review Printing

Usually, waveforms are printed by pressing the (START/STOP) key on the operation panel, which prints waveforms for the specified period of time from the time the key was pressed.
When the (REVIEW) key is pressed, ECG of the specified time period will be printed up to the point when the key was pressed.
While checking the waveforms on the screen, the desired waveform can be printed by pressing the (REVIEW) key.



Pressing the (REVIEW) key prints part A of the waveform, allowing the desired waveform to be printed.
Pressing the (START/STOP) key prints part B of the waveform. The desired waveform is therefore not printed.

How to Perform Review Printing

1 When the waveform you want to print appears on the screen, press the (Review) key on the operation panel.

- The ECG up to the point when the key is pressed will be printed.

2 The operations after this are the same as those for auto printing.(☞"Recording/Printing Automatically" P5-4)

Printing Commentary

REFERENCE

- Analysis report and commentary report can be printed when an optional software is installed.

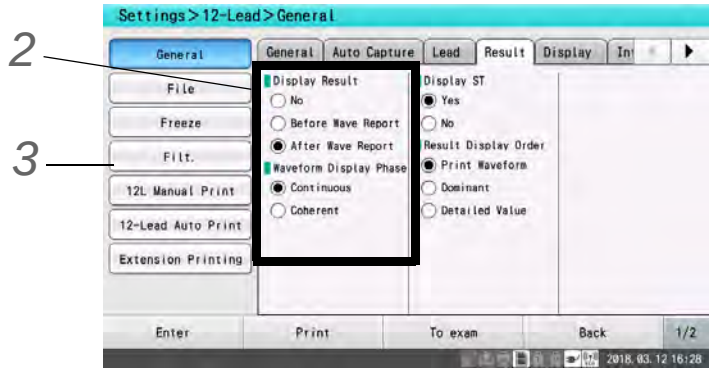
What is Commentary?

Two types of reports are printed for the interpretations obtained in analyses: an Analysis Report, which explains why that interpretation was given and a Commentary Report, which provides a detailed explanation of the interpretation.

Setting to Print Commentary

1 Touch [Menu] - [Settings] - [12-Lead Exam.] - [General] - [Result].

2 Configure the following settings.

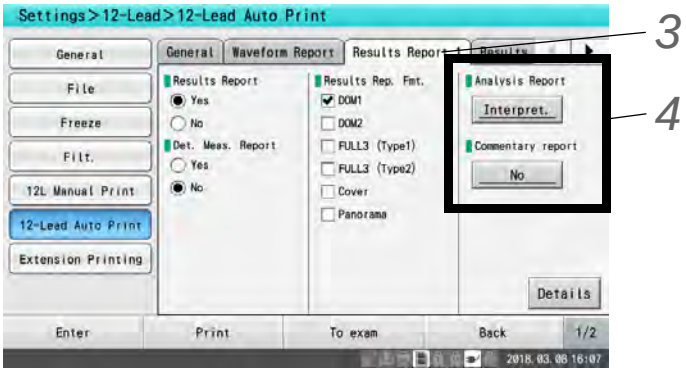


▸ "Display Result"

- No: Analysis results are not displayed.
- Before Wave Report: The analysis results are displayed before printing the Waveform Report.
- After Wave Report: The analysis results are displayed after printing the Waveform Report.

3 Touch [12-Lead Auto Print] - [Results Report 1].
Whether to print an analysis guide or commentary can be set.

4 Configure the following settings.



▸ "Analysis Report", "Commentary Report"

- [Interpret.]: The content is printed for all interpretations.
- [No]: Analysis guides and commentary are not printed.

Printing

❑Printing Analysis Report

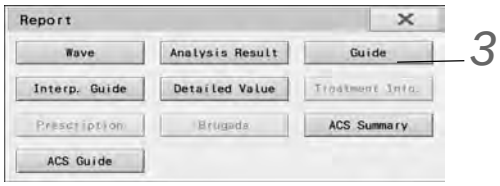
1 Conduct 12-lead examination.

2 When the examination results appear, swipe the display left or right to display the "Analysis Results" and select the interpretation to print.

REFERENCE

- The interpretations will be displayed in following colors according to the grade.
  Grade 6: Red, Grade 4: Blue, Grade 2, 0: Black

3 Touch [Thermal] - [Guide]

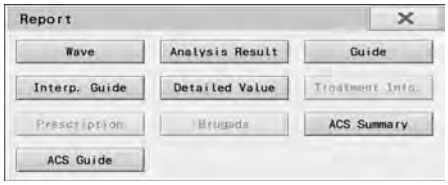


▸ The Analysis Report will be printed.

❑Printing Commentary Report

1 Follow the steps in "Printing Analysis Report" in the previous section, display the [Analysis Results] window, and check the finding you want to print.

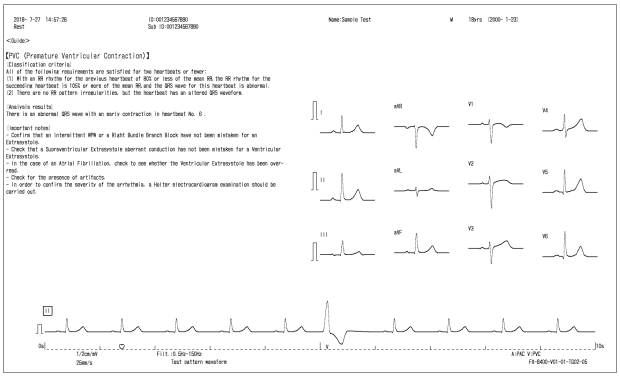
2 Touch [Thermal] - [Interp. Guide].



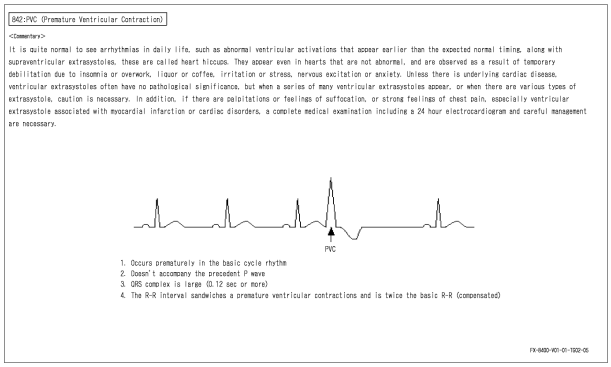
3 The Commentary Report will be printed.

Examples of Printing

● Analysis Report



● Commentary Report



Extending Printing

Auto Extension

REFERENCE

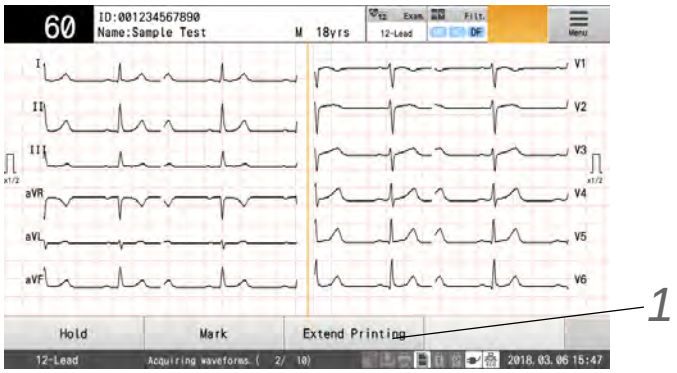
- To extend printing automatically, set "Yes" for [12-Lead Exam.] - [12-Lead Auto Print] - [Auto Extension] - [Auto Print Extension] in the Settings beforehand.

Printing can be extended automatically when the finding grade exceeds a fixed value.
Printing can also be extended automatically when a specific type of arrhythmia occurs.

Optional Extension

Extension printing can be performed manually. Printing is extended for a desired length of time.

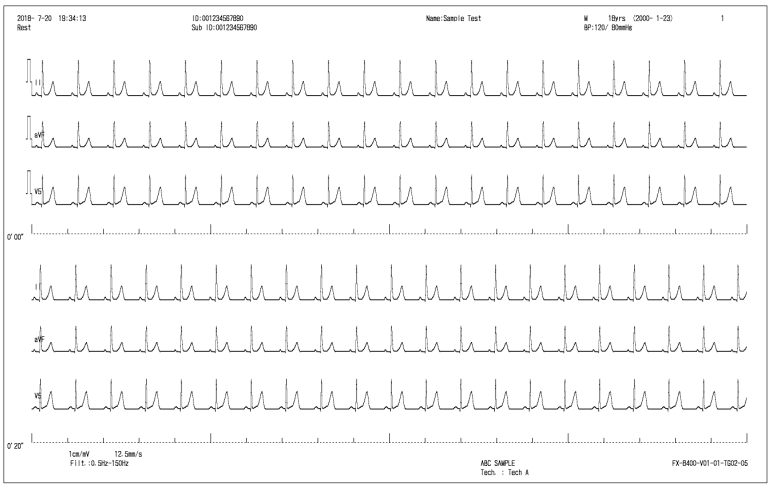
1 Touch [Extend Printing].



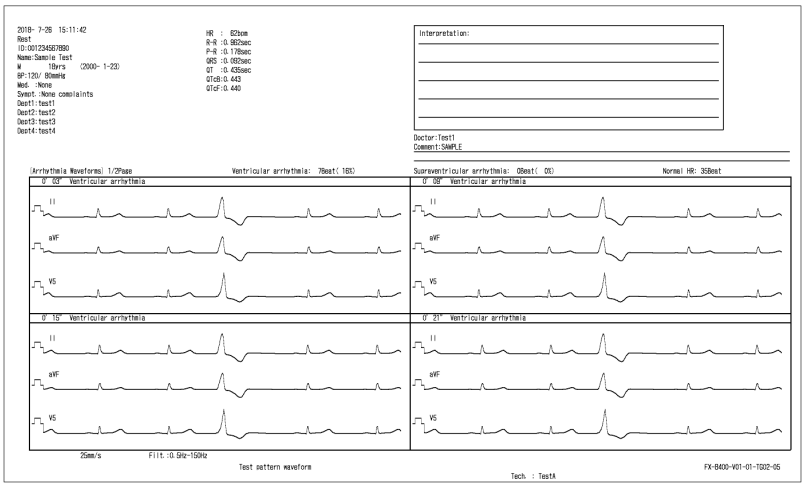
2 To stop printing, press the (START/STOP) key.

Examples of Printing

●Extension Printing (Waveform Report)



●Extension Printing (Result Report)



Printing the Time Comparison Report

For the standard ECG examination, the 12-lead dominant waveforms of the previous examination can be printed on the results report along with the waveforms of the current examination.

1 As usual, enter the patient ID and other patient information, and press the (START/STOP) key on the operation panel to start examination.

2 The time series comparison will be printed along with other results.

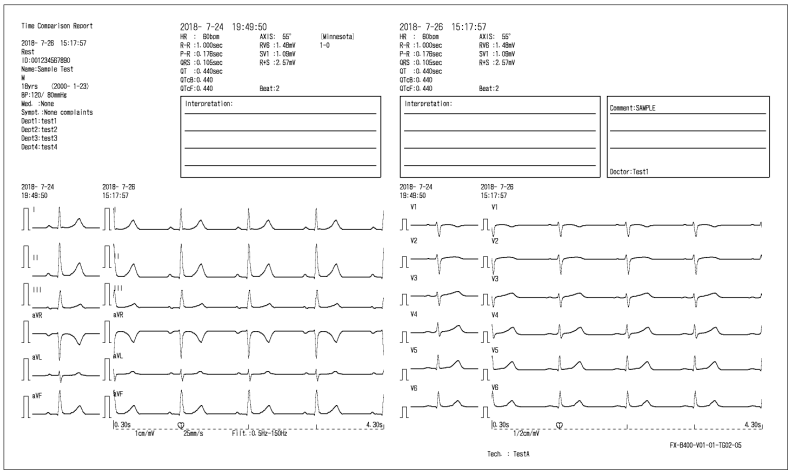
REFERENCE

- Select "Yes" for "Time Comparison" under [Setting] - [12-Lead] - [General].- [Time Comparison] in advance.
- The time comparison report can be printed only when the examination data of the same patient ID with the currently examining patient exists in the internal memory or external media.

- If a password is set to access the file list, an authentication window will be displayed before printing.In such case, enter the password to start printing.

Examples of Printing

●Time Comparison Report



4 seconds of waveforms for both limb lead and chest lead will be printed.
At the beginning of each lead, extracted waveform of the data to be compared will be printed.

Other Functions

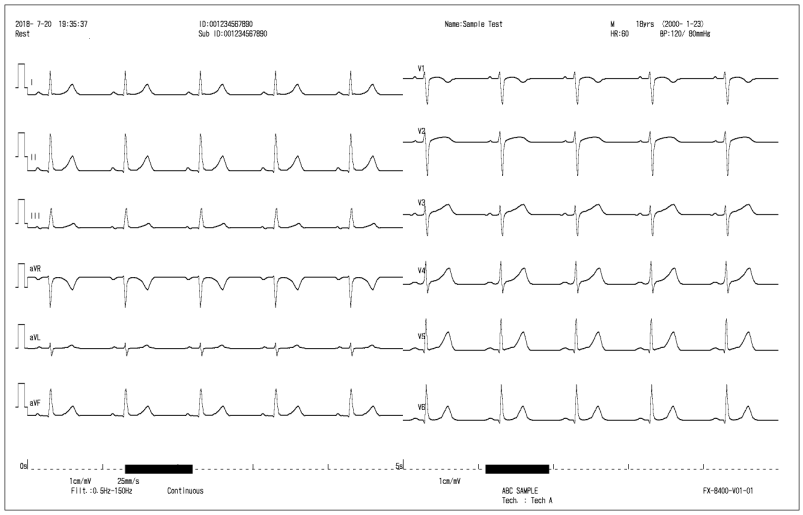
Printing Marks

Touching [Mark] during printing will print a mark on the recording paper.

Marks are printed for the number of times the key is pressed. Keep pressing down [Mark] to print the marks continuously.

1 Touch [Mark].

2 Marks will be printed.



Resetting the Waveform

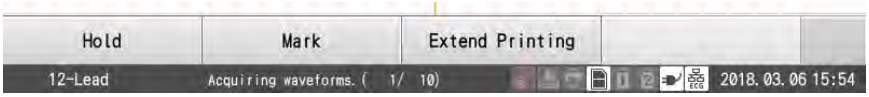
Pressing the (RESET) key on the operation panel resets the input waveform and displays and prints a baseline for the duration that the key is pressed.

1 Press the (RESET) key on the operation panel.

Continuously Printing the Same Lead

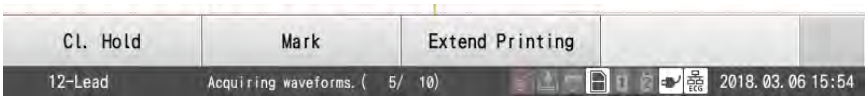
The same lead can be continuously printed using Auto Printing.

1 Touch [Hold] during printing.



▸ The same lead is continuously printed.

2 To stop extension, touch [Cl. Hold].



REFERENCE

- Even if printing is extended by [Hold], waveforms are analyzed and saved into a file only for a preset period of time (up to 24 seconds).

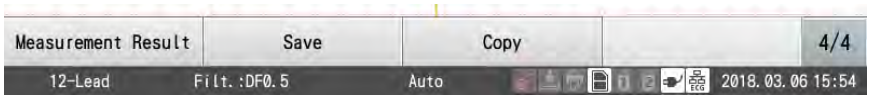
Printing Two or More Copies of the Same ECG Data

Copies of the previously printed data by auto printing, arrhythmia printing (3 ch, 40 seconds), or review printing can be printed.

REFERENCE

- ECG data printed manually cannot be copied.

1 Touch [Copy] (function key [4/4]).

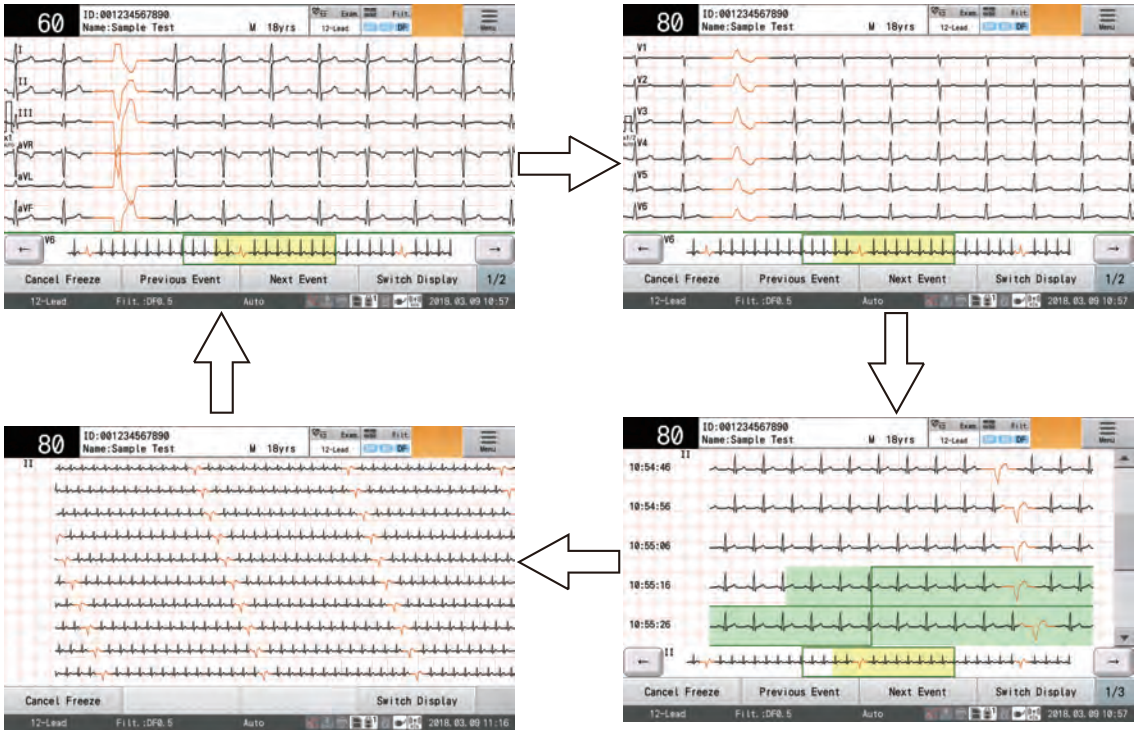


Chapter 6 12-Lead Examination (Advanced Function)

This section explains the advanced operation procedure of the 12-lead examination.

Checking the Waveforms using the Freeze Function

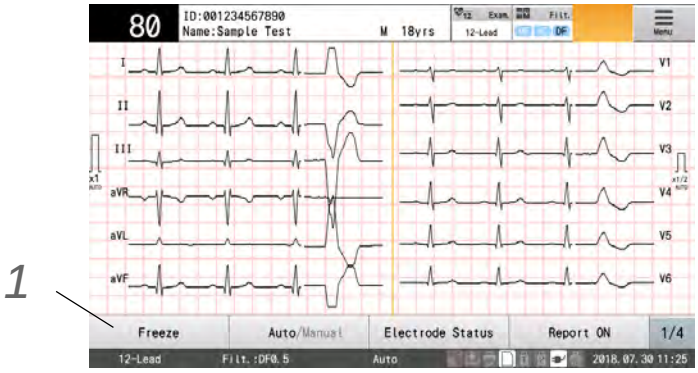
When arrhythmia appears, the ECG waveform can be printed or the waveform trace can be stopped for closer observation.Waveforms of up to 5 minutes are captured and displayed.



On the freeze display, swipe left or right, or touch [Switch Display] to switch the display in the order of 6ch waveform (limb) → 6ch waveform (chest) → rhythm waveform → all waveforms.

Freezing the Waveforms

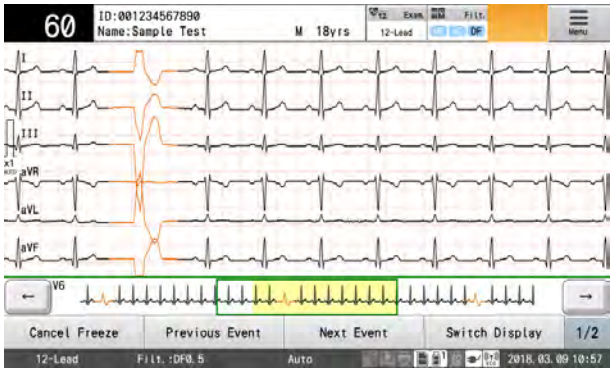
1 Touch [Freeze] when arrhythmia appears.



REFERENCE

- The capturing of waveform starts from the point when the limb electrodes recovers.

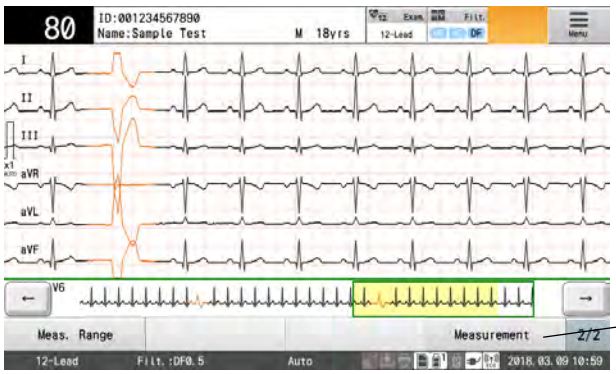
2 Check the waveform on the freeze display.



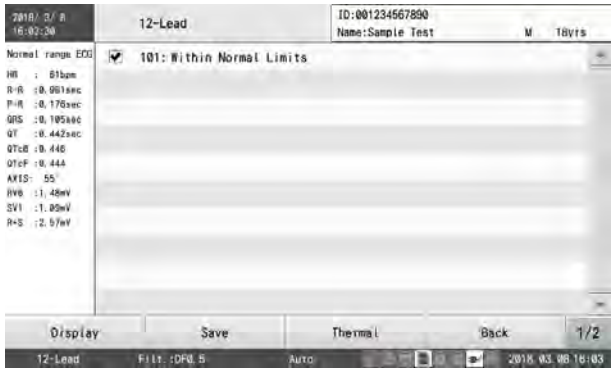
The following operations can be performed.

- Viewing the Waveforms of Other Leads
  Flick the screen, or touch [Switch Display] to switch the display between limb lead and chest lead of 6ch waveform.
- Changing the Sensitivity
  Press the (Sensitivity) key on the operation panel to change the sensitivity.
- Changing the [Meas. Range].
  Touch [Meas. Range] to display the window which allows to increase or decrease the range.
- Auto Measurement
  Touch [Measurement] to perform measurement.
- Changing the Range of Display/Auto Printing
  The range of display/auto printing can be changed by touching [←] and [→] at the ends of the compressed waveform or by touching [Previous Event] [Next Event].
  - [←]: Displays the waveform one second older. By keep touching the key, the waveform can be moved in five-second increments.
  - [→]: Displays the waveform one second newer. By keep touching the key, the waveform can be moved in five-second increments.
  - [Previous Event]: Displays the previous arrhythmia event.
    [Next Event]: Displays the next arrhythmia event.

3 Touch [Measurement].

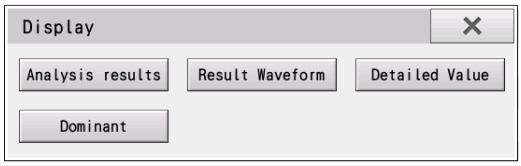


- The waveforms with green background will be measured, and the results will be displayed.

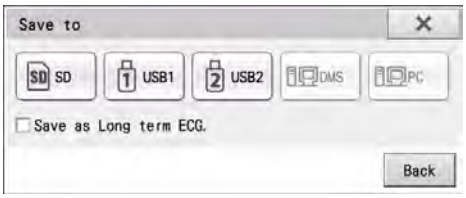


The following operations can be performed.

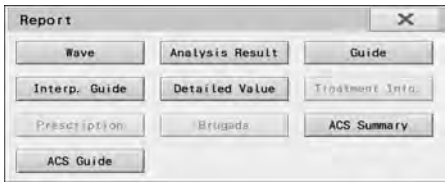
- Switching the Display
  Touch [Display] to display the selection window for the display type. Select the display type.



- Saving the [Measurement Result].
  Touch [Save] to display the selection window for the saving media type. Select the media to save the Measurement Result.



- Report Printing
  Touch [Thermal] to display the selection window for the report type. Select the report to print.



4 After checking the waveforms, touch [Cancel Freeze].

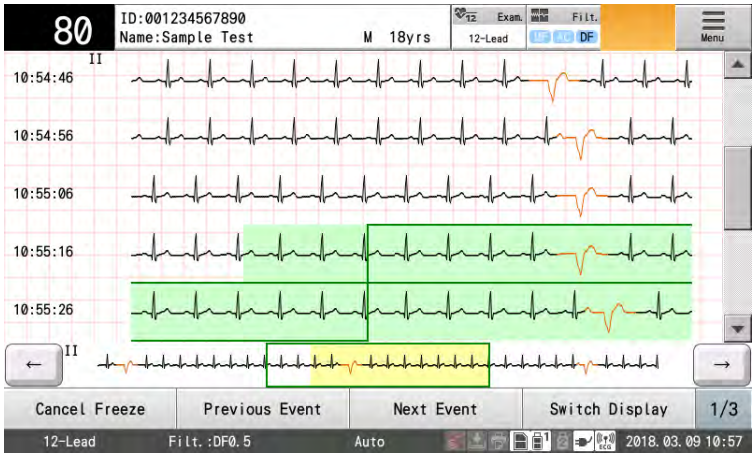
Checking the Saved Waveforms

When the freeze operation is performed, the ECG waveform of maximum 5 minutes will be saved.
The saved waveform can be displayed as rhythm waveform, and can be printed automatically or manually.

1 Touch [Freeze].
(☞"Checking the Waveforms using the Freeze Function" P6-2)

2 Flick the screen, or touch [Switch Display] to display the rhythm waveform.

3 The saved waveform will be displayed as a rhythm waveform of 10 seconds per line.



▸ The waveform status is indicated with the following colors.

- ♦Red: Lead Off
- ♦Gray: Reset
- ♦Orange: Suspected Arrhythmia Range
- ♦Green Border: Meas. Range
- ♦Pale Green Area: Recording Range
- ♦Yellow Area: Waveform Display Range

REFERENCE

- ♦ The default range of Meas. Range, recording range can be specified under "Setting". (☞"Record Time" P13-18)

▸ On this screen, the following operations can be performed.

♦Searching the Event (Suspected Arrhythmia Range)
[Previous Event]: Searches the event to past direction, and moves the auto printing range.
[Next Event]: Searches the event to present direction, and moves the auto printing range.

♦Switching the Display
The waveform display can be switched in the order of rhythm display, 6 ch (limb), 6 ch (chest), and all waveforms display.

To Perform Auto Printing

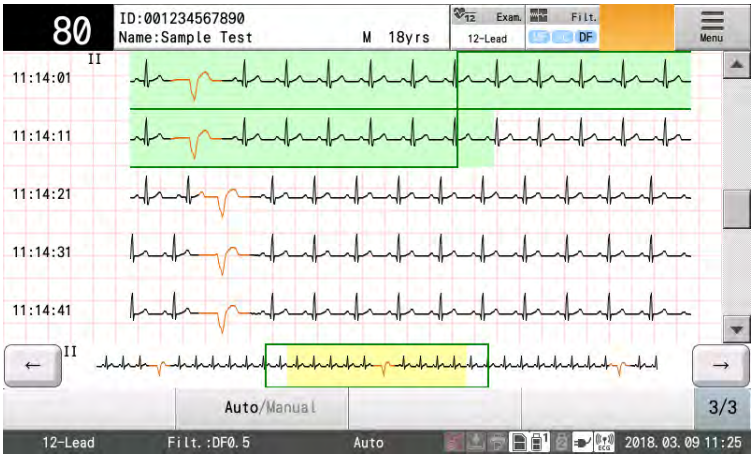
1 Freeze the waveform and display the rhythm waveform. (☞"Checking the Saved Waveforms" P6-5)

2 Touch [Auto/Manual] to set to auto printing mode.

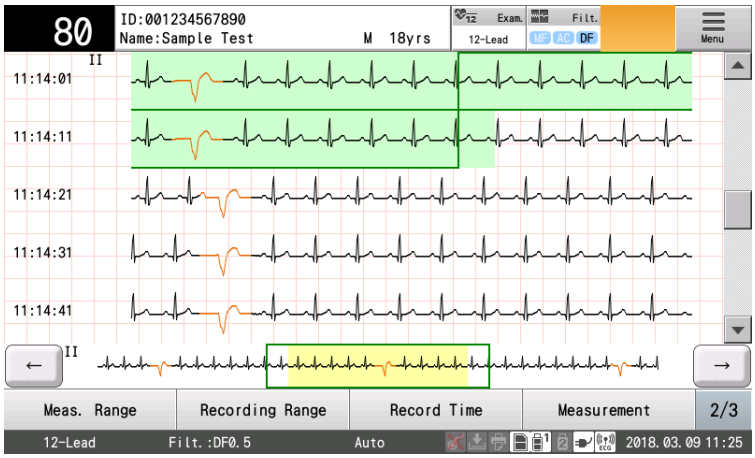
▸ Verify that "Auto" is displayed for the function key.

3 Touch [Rhythm Waveform] to set the auto printing range.

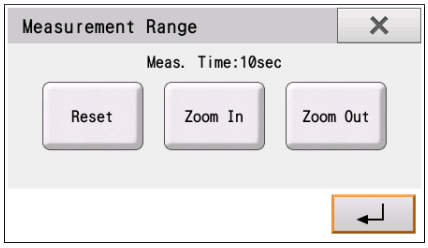
▸ The auto printing range is indicated with green background.
The auto printing range can be moved by touching the desired range.



4 Touch [Meas. Range].



5 Change the [Meas. Range].



1 Select one of the following to change the Meas. Range.
Reset: The range set under "Setting" will be applied.
Zoom In: Adds one second each to the beginning and end of the recording range.
Zoom Out: Reduces one second each to the beginning and end of the recording range.

2 Touch ↵ .

6 Touch [Measurement].

▸ The waveforms of displayed range will be automatically measured, and the results will be displayed.

NOTE

- If the calibration wave created by switching the filter, etc. is included in the range, printing cannot be performed.

7 Press the ⏎/▽ (START/STOP) key on the operation panel.

▸ The waveform report and result report will be printed according to the settings.

8 Touch [Back] to return to the freeze display.

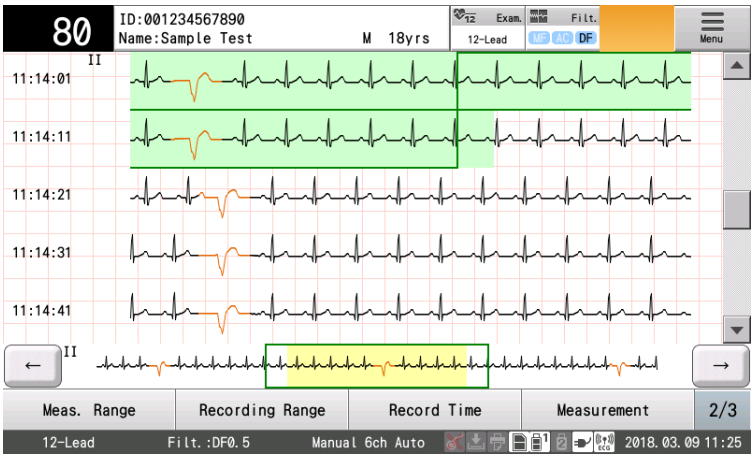
To Perform Manual Printing

1 Freeze the waveform and display the rhythm waveform. (☞"Checking the Saved Waveforms" P6-5)

2 Touch [Auto/Manual] to set to manual printing mode.

▸ Verify that "Manual" is displayed for the function key.

3 Touch [Recording Range].



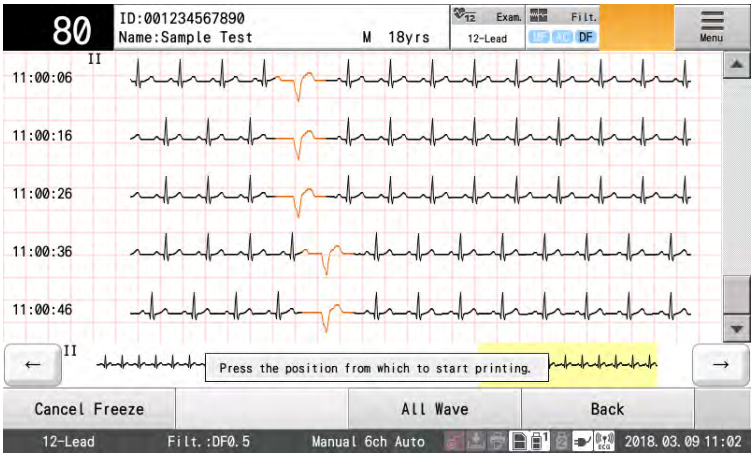
4 Specify the starting and ending point.

[Start Point]: Allows to set the starting point.

[End Point]: Allows to set the ending point.

[All Wave]: All waveforms will be included in the range.

[Back]: The range setting mode will end.



- The color of the specified range will change.

5 Press the (START/STOP) key on the operation panel.

- The waveform of the displayed range will be printed.
- Touching the speed keys such as [25 mm/s], [50 mm/s] switches the printing speed in the order of "5 mm/s" → "10 mm/s" → "12.5 mm/s" → "25 mm/s" → "50 mm/s".

6 Press the (START/STOP) key on the operation panel to stop printing.

Recording the ECG Waveforms at Rest and After Exercise

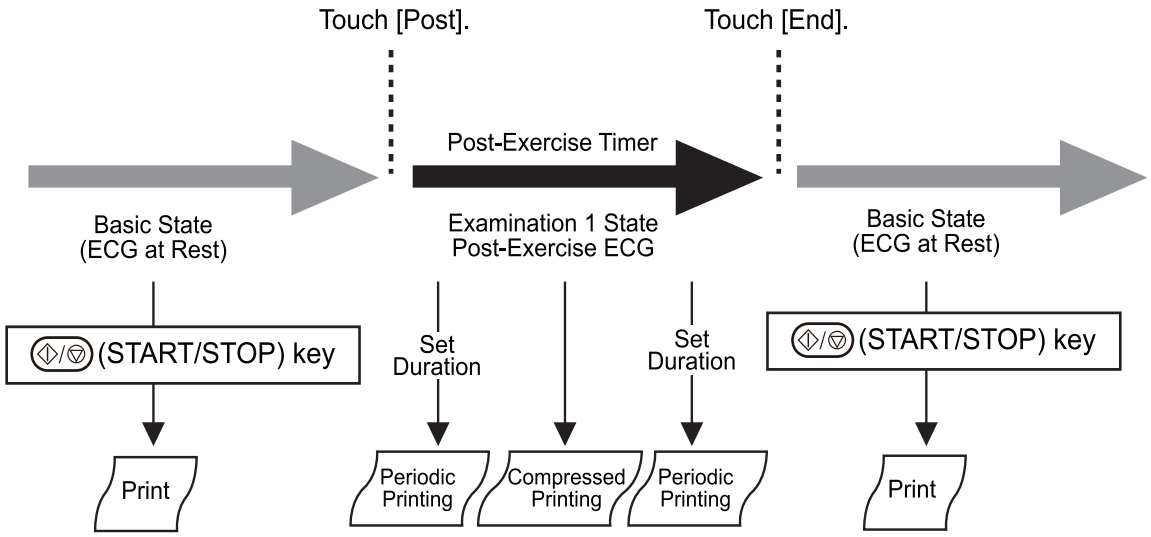
By using this function, ECG waveforms at rest and after exercise can be recorded.

Details of the Examination

The ECG waveforms of the following two conditions can be recorded.

Status	Examination Type	Function
Basic	Resting ECG	The ECG waveforms at rest are recorded/printed.(Auto Printing, Manual Printing, Arrhythmia Printing)
Examination	Post-Exercise ECG	The ECG waveforms after exercise such as walking are recorded/ printed.

The operation flow is as follows.

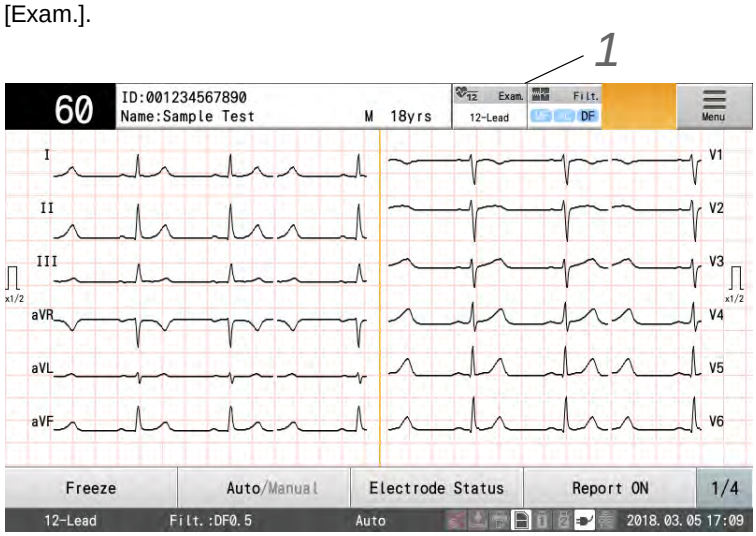


REFERENCE

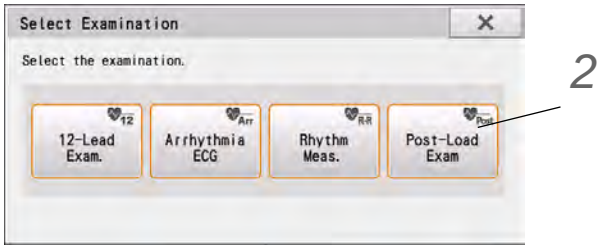
- Depending on the periodic printing setting, waveform acquisition or printing may be in progress at the set time.In such case, periodic printing will not be performed.
- Post-exercise printing can be also performed by pressing the (START/STOP) key on the operation panel.
- During lead-off condition, periodic printing will not be performed.

To Start Recording

1 Touch [Exam.].



2 Touch [Post].

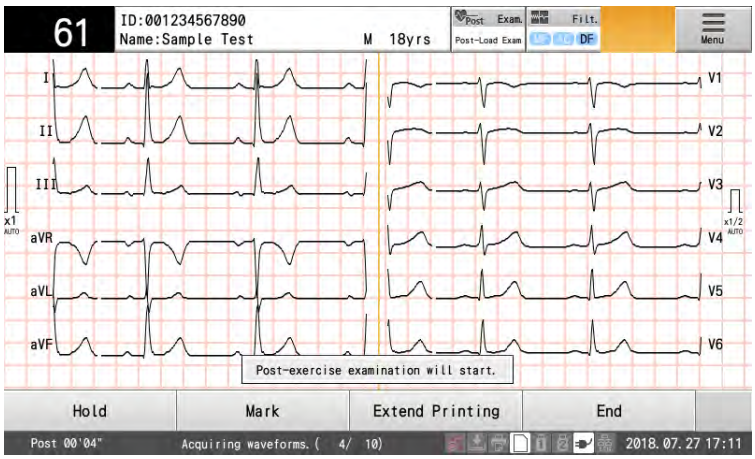


3 Record the resting ECG waveform. ('☞"12-Lead Examination" P5-1')

4 Have the patient do some exercise such as walking.

5 Touch [Interval].

▸ The post-exercise timer will start, and the elapsed time will be displayed.



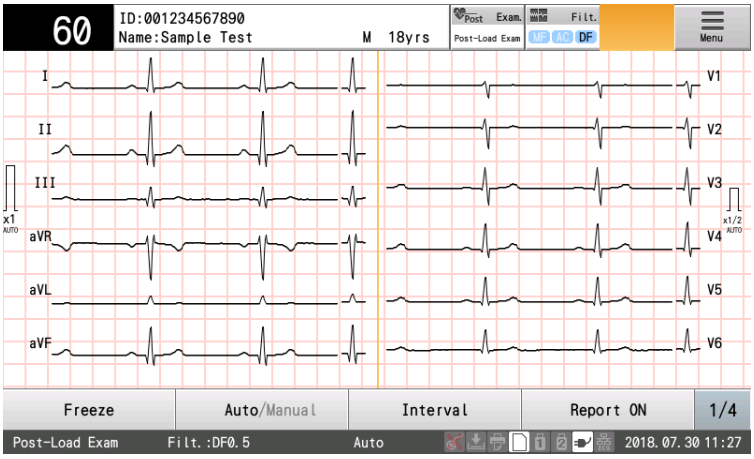
REFERENCE

- By configuring [Setting] - [Post-Load Exam] - [Post (Period. Print)] - [Interval Printing] - [Print at Set Time], printing can be performed at specified time.
- By configuring [Setting] - [Post-Load Exam] - [Post (Period. Print)] - [General] - [Compress. Print], compressed printing during the print intervals can be performed.
- During lead-off condition, periodic printing will not be performed.

6 To print on the recording paper, press the (START/STOP) key on the operation panel.

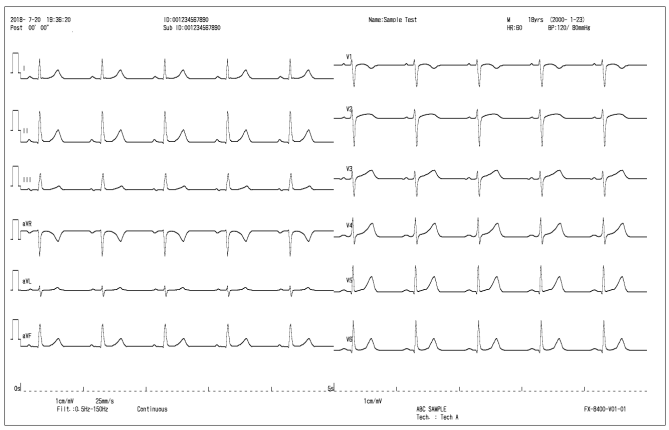
7 Touch [End].

- The display will return to resting ECG waveform.
- When "Yes" is set for "Summary Report" under [Setting] - [Post-Load Exam] - [Post (Other)] - [General], a report will be output.



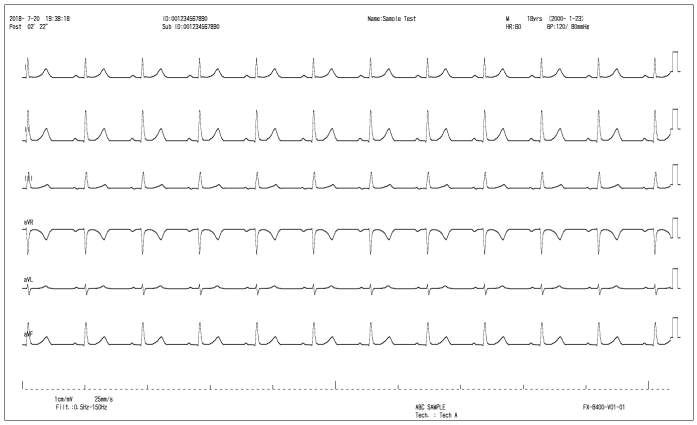
Examples of Printing

●Post-Exercise (Auto Printing)

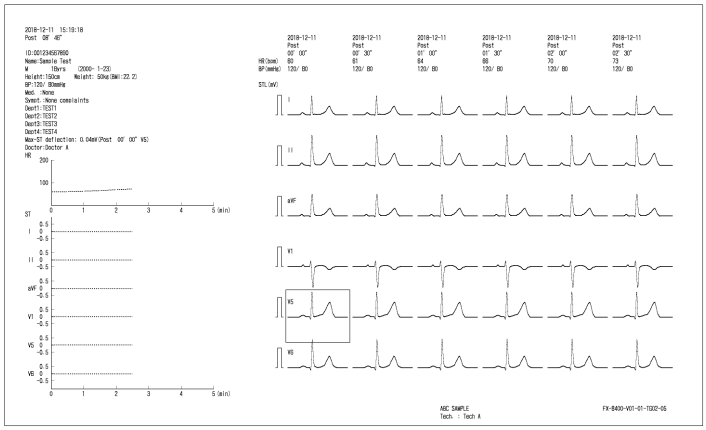


The printing example of the following is shown:
Waveform Acquiring Time: 10 seconds
Calibration Position: Beginning

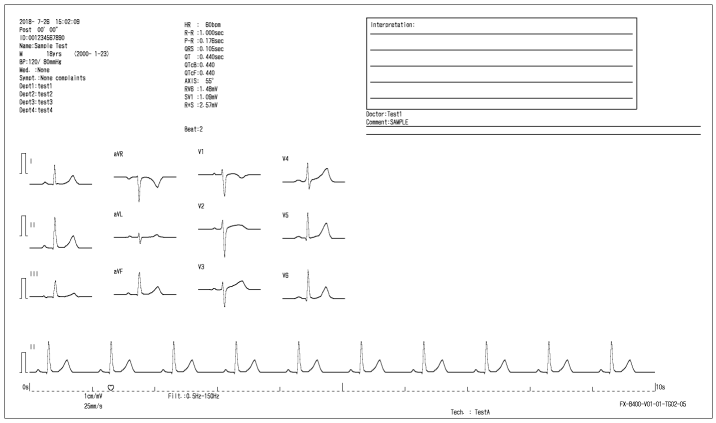
●Post-Exercise (Manual Printing)



●Post-Exercise (Summary Report)

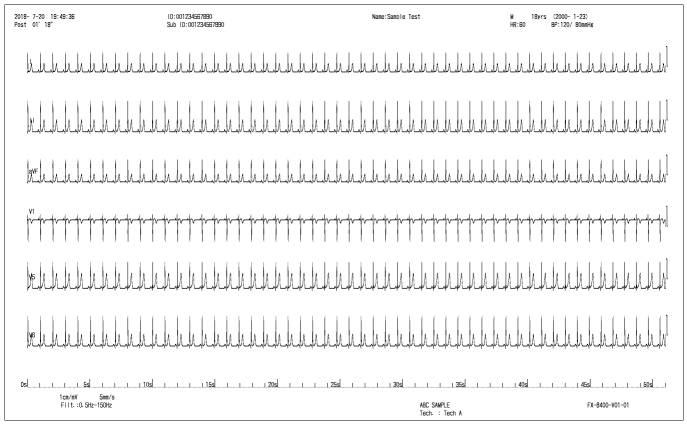


●Post-Exercise (Result Report)



The printing example of the following is shown:
Result Report: DOM1

●Periodic Compressed Printing



The printing example of the following is shown:
Compressed Printing: 5 mm/s
Lead: Spare Lead 1 (6ch)
Calibration Position: After Waveform

ACS Diagnostic Support Function

REFERENCE

- The ACS diagnostic support function can be used when the optional software is installed.

Analyzing using the ACS diagnostic support function can be performed during the 12-lead examination. The basic operation flow of ACS diagnostic support function is as follows.

❑Setup

Configure the settings as necessary.

Setting the Filters (☞P3-4)
Setting the Sensitivity (☞P3-5)
Setting the 12-lead printing conditions (checking the results, printing, etc.) (☞P13-15)
Setting the ACS diagnostic support function (☞P6-14)

❑Preparation

1. Set the examination mode to [12-Lead Exam.].
2. Enter the patient information.
   Entering Information (☞P4-2)
   Loading Information from the DMS (☞P4-7)
   Using Patient Information Saved on a SD Card (☞P4-8)
3. Enter the ACS inquiry before the examination. (☞P6-15)

❑Waveform Printing

Auto Printing (☞P5-4)
Review Printing (Printing Waveforms from Several Seconds Before) (☞P5-13)

❑Analysis

Enter the ACS inquiry at abnormal condition. (☞P6-14)

❑Checking the Results and Printing

Functions that can be used after analysis (☞P5-9)
Functions on the ACS Analysis Result Display (☞P6-17)

❑Save

Saving the Examination Data (☞P9-3)

NOTE

- The ACS inquiry can be entered before the examination, after the analysis, or during checking the analysis result. For details, refer to each section.

Required Settings

Select "Yes" for "ACS Diagnostic Support Function" under [Setting] - [12-Lead] - [General] - [ACS Diagnostic Support].

REFERENCE

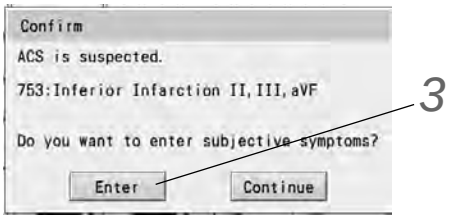
- By selecting "Yes" for "ACS Diagnostic Support Function", analysis will be automatically performed.

Entering the ACS Inquiry when Abnormal Finding

1 Select "Abnormal Finding" for "Check Subjective Symptoms" under [Setting] - [12-Lead] - [General]- [ACS Diagnostic Support].

2 Conduct the ECG examination at rest. (☞"12-Lead Examination" P5-1)

3 At abnormal finding, ACS inquiry window will be automatically displayed.

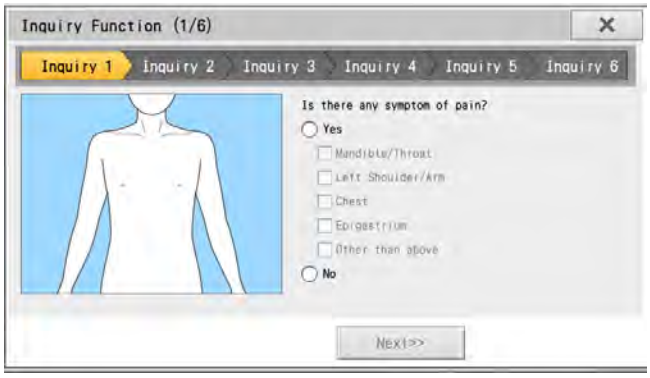


▸ Touch [Enter].

NOTE

- If abnormal finding is not detected, ACS inquiry window will not be displayed.
- If not entering the ACS inquiry, touch [Continue] to continue the ACS analysis.

4 Enter the ACS inquiry.



- [Next]: Proceeds to next inquiry.
- [Complete]: Ends the inquiry.

5 The analysis result will be displayed. (☞"Functions on the ACS Analysis Result Display" P6-17)

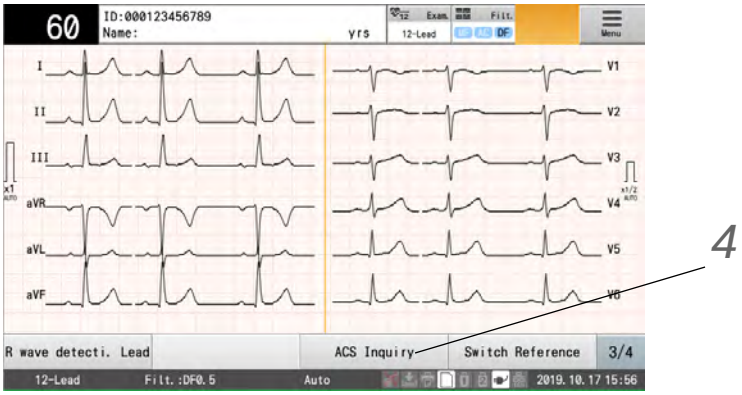
Entering the ACS Inquiry Before the Examination

1 Select "Always" for "Check Subjective Symptoms" under [Setting] - [12-Lead] - [General]- [ACS Diagnostic Support].

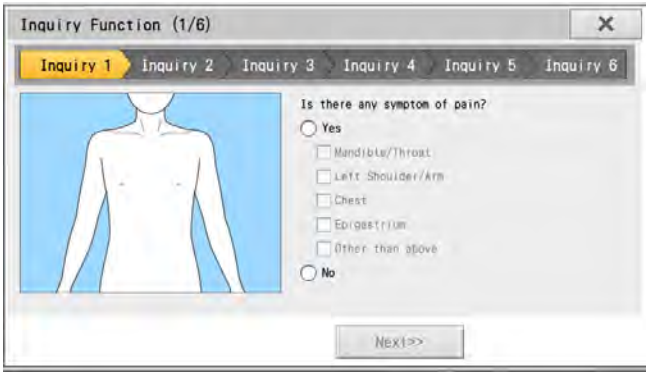
2 Conduct the ECG examination at rest. (☞"12-Lead Examination" P5-1)

3 Enter the patient information. (☞"Entering Patient Information" P4-1)

4 Touch [ACS Inquiry] on the function key (3/4).



5 Enter the ACS inquiry.

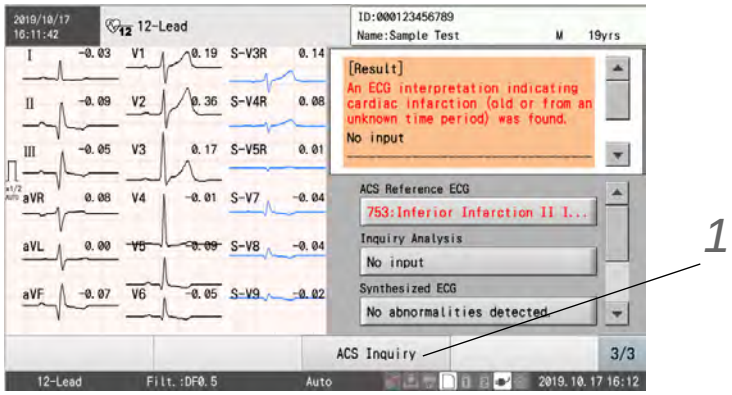


- [Next]: Proceeds to next inquiry.
- [Complete]: Ends the inquiry.

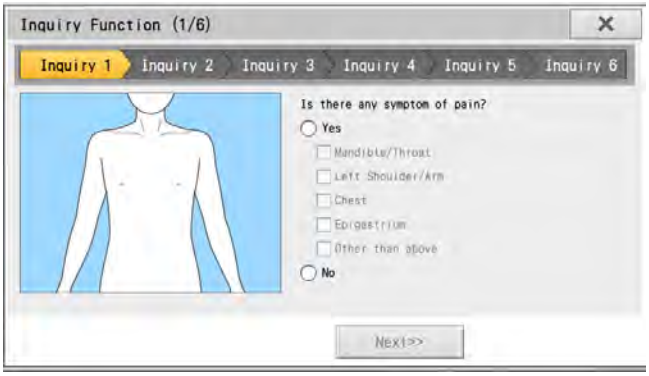
6 Continue the ECG examination at rest. (☞"12-Lead Examination" P5-1)

Entering the ACS Inquiry from the Analysis Result Display

1 On the analysis result display, touch [ACS Inquiry] on the function key (3/3).



2 Enter the ACS inquiry.



- [Next]: Proceeds to next inquiry.
- [Complete]: Ends the inquiry.

3 Reanalysis will be performed, and result will be displayed.

REFERENCE

- The result may change when reanalysis is performed.
- ACS inquiry cannot be entered from the file analysis result display.

Functions on the ACS Analysis Result Display

❑The synthesized ECG waveform can be displayed.

6 channels of waveform synthesized with 12-lead waveform will be displayed in extracted waveform display area.

NOTE

- The synthesized 6 channels of waveform may slightly differ from the actually measured waveforms.

❑The ACS reference ECG findings can be displayed.

The ACS ECG diagnosis comment will be displayed in explanation area.

❑The inquiry analysis result can be displayed.

The subjective symptoms summary comment will be displayed in explanation area.

❑The synthesized ECG analysis result can be displayed.

The synthesized ECG diagnosis comment will be displayed in explanation area.

❑The occluded vessel analysis result can be displayed.

The occluded vessel diagnosis comment will be displayed in explanation area.

❑The clinical ECG findings can be displayed.

All interpretations detected from the 12-lead ECG will be displayed in explanation area.

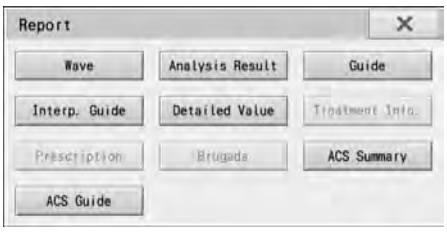
Printing Reports

The report can be printed on the built-in thermal recorder.

1 Touch [Thermal] on the analysis result display.

2 The report selection window will be displayed.

▸ Select the report to print.

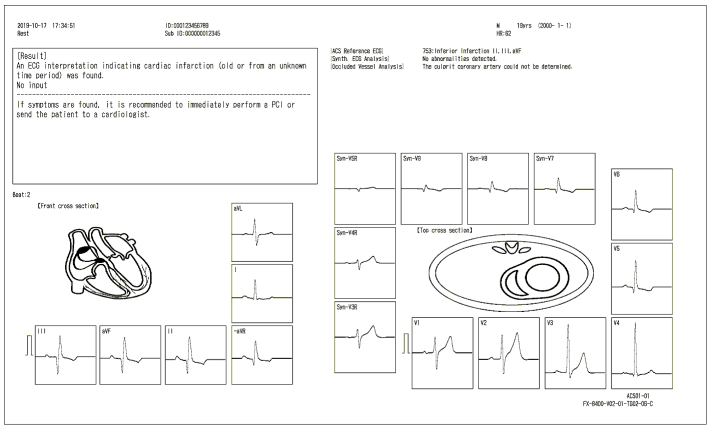


3 The selected report will be printed on the thermal recorder.

Examples of Printing

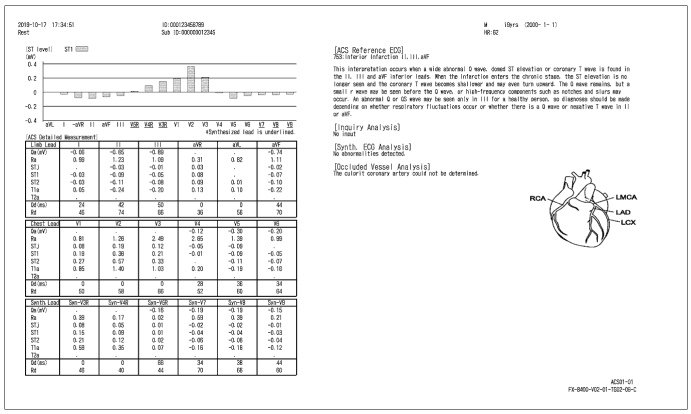
●ACS Summary Report

The following setting is required.
Select "Always" or "Abnormal Finding" for "ACS Summary Report" under [Setting] - [12-Lead Exam.] - [12-Lead Auto Print] - [Result Report 2].



●ACS Guide Report

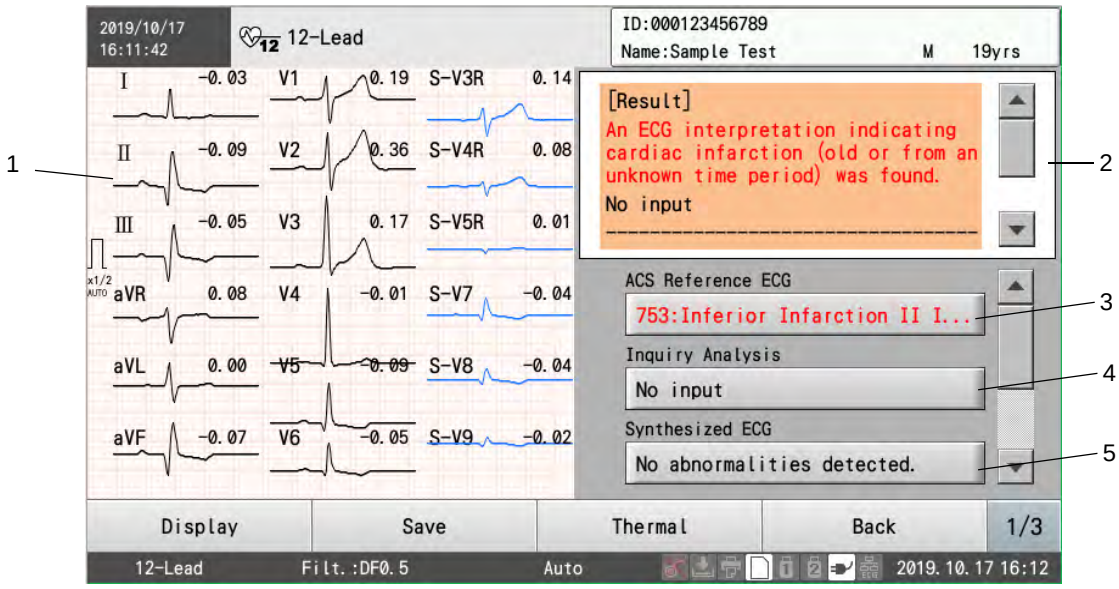
The following setting is required. Select "Always" or "Abnormal Finding" for "ACS Guide Report" under [Setting] - [12-Lead Exam.] - [12-Lead Auto Print] - [Result Report 2].

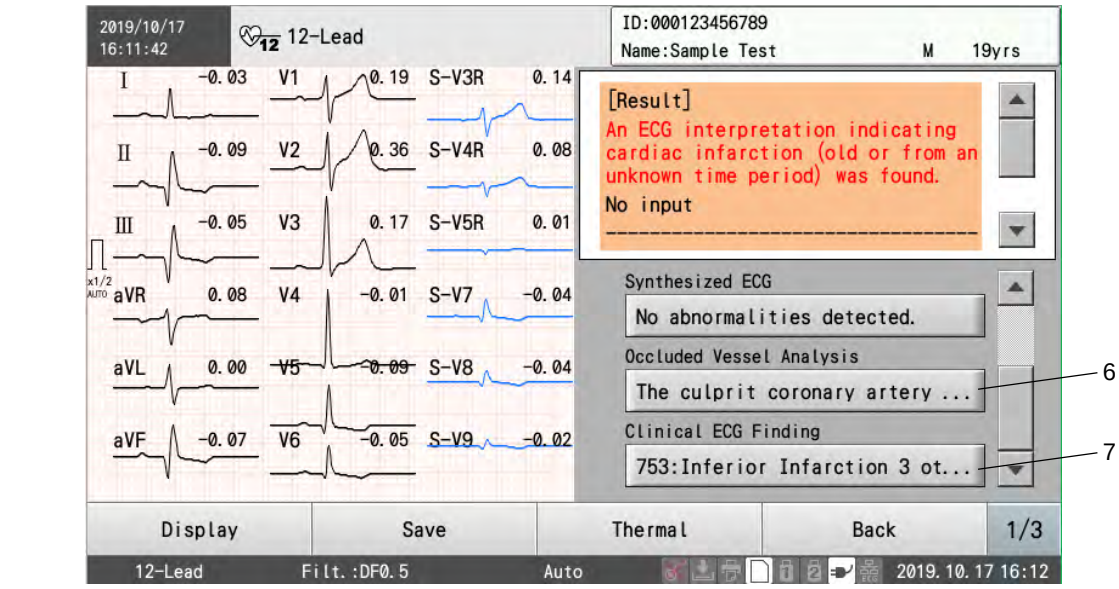


REFERENCE

- The ACS summary report and ACS guide report are output from the inquiry input and ECG.
- The final diagnosis should be made by a doctor taking into considerations the patient's condition, other examination result, etc.

Explanation of the Analyzed Result





1 Extracted Waveform Display Area
The extracted waveform is displayed.
When the synthesized ECG analysis is performed, the synthesized waveform of the analyzed lead will be displayed.

2 Overall Result Display Area
ACS diagnostic comment, overall comment will be displayed.

3 ACS Analysis Result
The representative interpretation of suggestive ACS will be displayed.

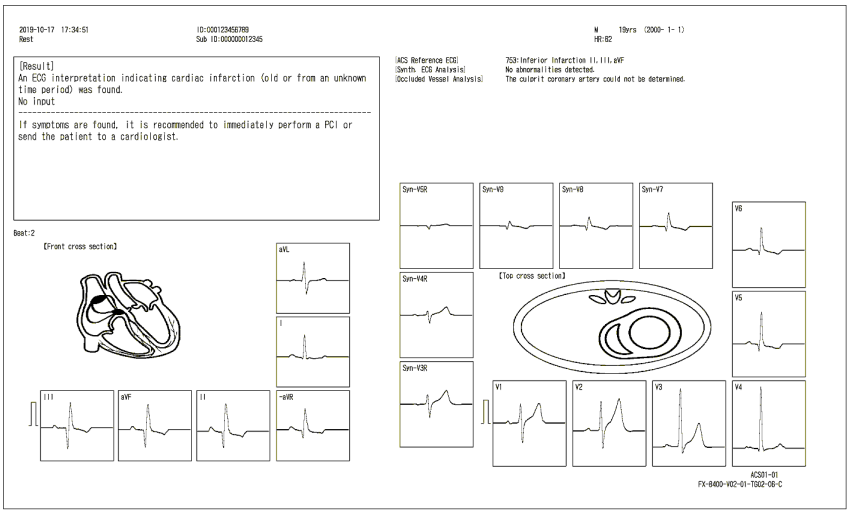
4 Inquiry Analysis Result
The inquiry analysis comment will be displayed.

5 Synthesized ECG Analysis Result
The result comment for synthesized ECG analysis will be displayed.

6 Occluded Vessel Analysis Result
The result comment for occluded vessel analysis will be displayed.

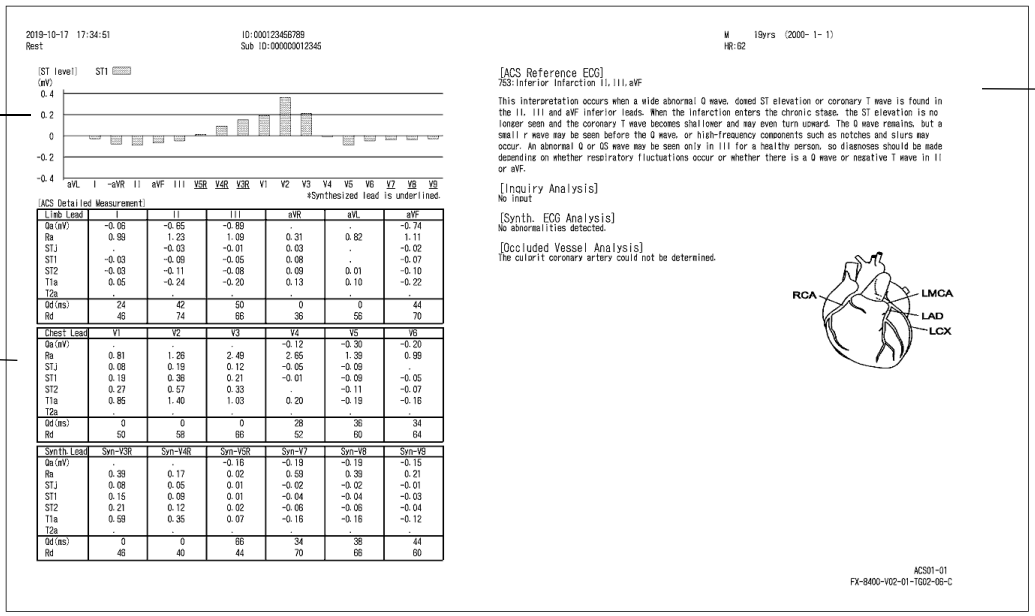
7 Clinical ECG Analysis Result
The 12-lead analysis result will be displayed.

Explanation of the ACS Summary Report



1 ECG Waveform Area
The dominant waveforms are displayed.
When the synthesized ECG analysis is performed, the synthesized waveform of the analyzed lead will be displayed.

Explanation of the ACS Guide Report



1 ST Level
The ST level of right-sided leads, posterior leads will be displayed.

2 ACS Detailed Measurement
The detailed measurement of right-sided leads, posterior leads will be displayed.

3 Result Display Section
[ACS Reference ECG]
The representative interpretation and explanation of suggestive ACS will be displayed.
[Inquiry Analysis]
The inquiry analysis result and entered items will be displayed.
[Synthesized ECG Analysis]
The result comment for synthesized ECG analysis will be displayed.
[Occluded Vessel Analysis]
The occluded vessel analysis comment will be displayed.

Auto Capture Function

By using the auto capture function, the waveforms of high severity with less noise can be saved automatically. The basic operation flow is as follows.

❑Setup

Configure the settings as necessary.
Setting the Filters (☞P3-4)
Setting the Sensitivity (☞P3-5)
Setting the 12-lead printing conditions (checking the results, printing, etc.) (☞P13-15)
Setting the auto capture function (☞P6-22)

❑Preparation

1. Set the examination mode to 12-Lead Exam.
2. Enter the patient information.
Entering Information (☞P4-2)
Loading Information from the DMS (☞P4-7)
Using Patient Information Saved on a SD Card (☞P4-8)
3. Attach the electrodes.

❑Waveform Acquisition

Acquiring the Waveforms (☞P6-22)

❑Checking the Results and Printing

Functions on the Measurement Result Display (☞P5-9)

❑Save

Saving the Examination Data (☞P9-3)

NOTE

- This function cannot be used simultaneously with ordering function.

Required Settings

Select "Yes" for "Auto Capture Function" under [Setting] - [12-Lead] - [General].

NOTE

- If the ordering function is enabled, the setting can not be changed.

Waveform Acquisition

1 When the electrodes are attached, or when the lead-off condition is resolved, the waveform acquisition will start.

NOTE

- If lead-off occurs, the waveform acquisition will be suspended.

REFERENCE

- The waveform acquisition duration can be changed under [Setting] - [12-Lead] - [General] - [Auto Capture] - [Capture End Time].
- The following operations can be performed even during the waveform acquisition.
  - ♦Auto Printing
    Press the (START/STOP) key on the operation panel. (☞"Starting Printing" P5-4)
  - ♦Manual Printing
    Touch [Auto/Manual]. (☞"Starting Manual Recording/Printing" P5-10)
  - ♦Review Printing
    Press the (REVIEW) key on the operation panel. (☞"How to Perform Review Printing" P5-13)
  - ♦Freeze Operation
    Touch [Freeze]. (☞"Checking the Waveforms using the Freeze Function" P6-2)

2 When the waveform acquisition is completed, the waveform list will be displayed.

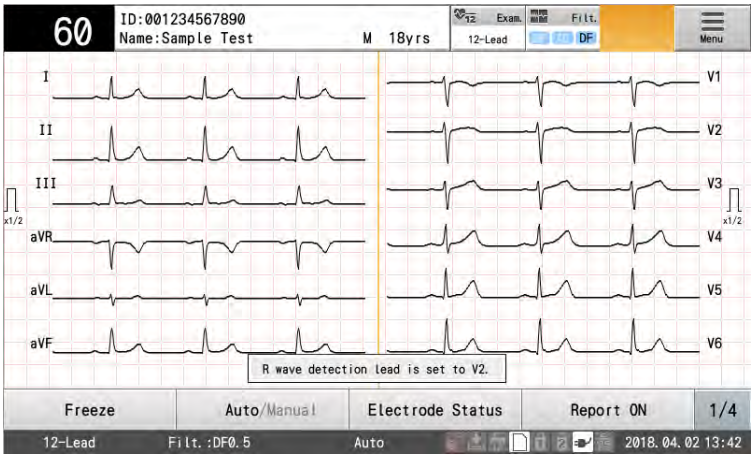
R Wave Detection Lead Auto Switch Function

The R wave detection lead can be automatically switched.

1 Select "Auto" for "R wave detection lead" under [Setting] - [12-Lead] - [General] - [Lead].

2 Display the examination screen.

3 The R wave detection lead will automatically switch to the most appropriate lead.



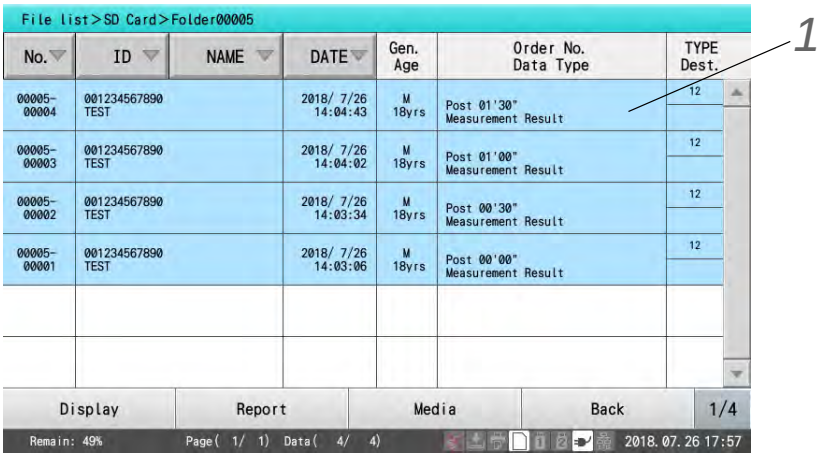
REFERENCE

- The message for R wave detection lead will disappear when touched.
- Minimum of 4 beats are required to automatically switch the R wave detection lead.

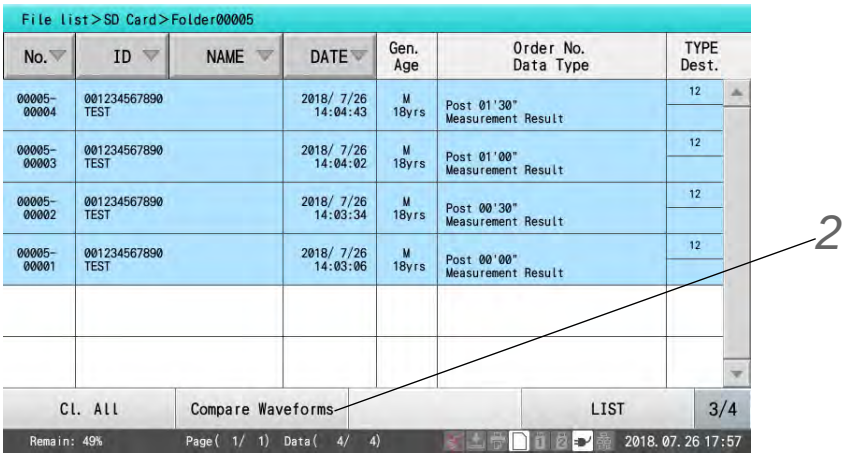
Wave Comparison Report

By selecting more than one data on the file list, the wave comparison report can be printed.

1 Touch [Menu] - [File/Communication] - [File List] to display the file list, and select the data to compare the waveforms.



2 Touch the [Compare Waveforms] function key.



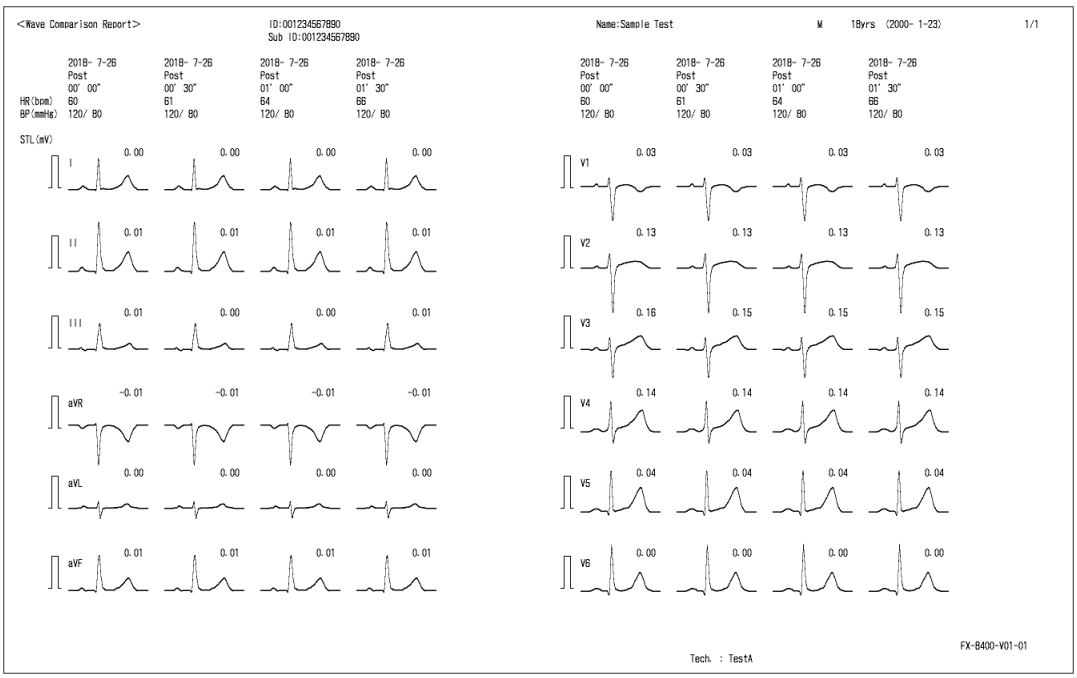
▸ The wave comparison report will be printed.

REFERENCE

- Maximum of 10 data can be selected for wave comparison report.If more than 10 data are selected, the wave comparison report of the latest 10 data will be printed.
- The wave comparison report can be printed only for the examination data of the same patient ID with the latest examination data.

Examples of Printing

● Wave Comparison Report



Chapter 7 Arrhythmia ECG Examination

This chapter explains the procedure for 3-lead arrhythmia examination.
The basic procedure for arrhythmia examination is as follows.

❑Setup

Configure the settings as necessary.
Configuring Settings for Arrhythmia Examinations (Leads, Filters, Files, etc.) (☞P13-23)
Setting the Examination Leads(☞P7-1)
Setting the Waveform Recording Time (☞P7-2)

❑Preparation

1. Set the examination mode to [Arrhythmia ECG].
2. Enter the patient information.
Entering Information (☞P4-2)
Loading Information from the DMS (☞P4-7)
Using Patient Information Saved on a SD card(☞P4-8)

❑Waveform Recording

Performing Arrhythmia Recording while Measuring (☞P7-2)

❑Printing the Results

Printing the Measurement Result

❑Save

Saving the Examination Data (☞P9-3)

Required Settings

Configure the following settings.
Examination leads
Waveform recording time

REFERENCE

- These settings can also be changed in the Arrhythmia ECG display.
- The number of leads is fixed at 3 ch.
- Settings for arrhythmia examinations such as leads, filters, files, etc. need to be configured. (☞"Arrhythmia ECG Examination" P13-23)

Setting the Examination Lead

Set the type of leads to be used in the examination.
This can be set in [Arrhythmia ECG] - [General] - [Lead] in the Settings.

It can also be set by touching [Lead] in the examination display.

Setting the Waveform Recording Time

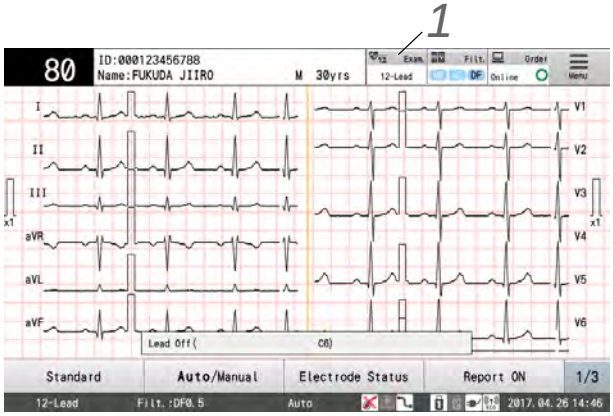
Select the duration to acquire waveforms.
This can be set in [Arrhythmia ECG] - [Auto Printing] - [Duration] in the Settings.
It can also be set by touching [Time] in the examination display.

Printing while Measuring Arrhythmia

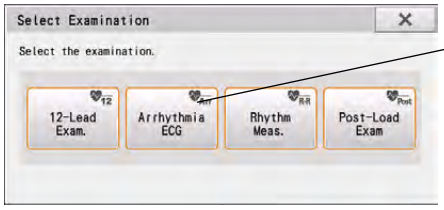
A three-channel arrhythmia recording is taken for 40 seconds to 3 minutes and the results are printed in the prescribed format.

Starting Recording/Printing

1 Touch [Exam.].



2 Touch [Arrhythmia ECG].



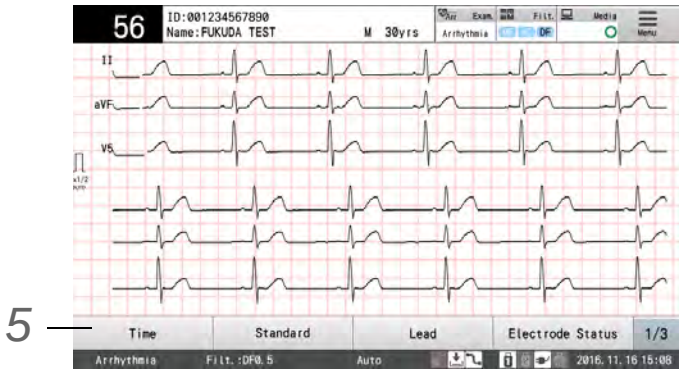
3 Enter patient information. (Refer to Chapter 4 "Entering Patient Information".)

4 Attach the ECG electrodes and check that ECG waveforms appear on the display. (☞"Attaching the Electrodes" P3-1)

REFERENCE

- The examination leads can be set under [Settings] or by touching the [Lead] function key. (Default values: II, aVF and V5 leads)

5 Touch [Time] and select the examination time.



▸ Touch any of [40 sec]/[1 min]/[2 min]/[3 min].

6 Press the (Start/Stop) key on the operation panel.

▸ Press the (Start/Stop) key to start acquiring waveforms of the selected 3 (three) leads.

▸ The message "Acquiring waveforms" is displayed along with the elapsed time and examination time. When the specified examination time has elapsed, waveform acquiring will automatically finish.

▸ A waveform report will be recorded when the measurement is finished.

▸ To stop recording, press the (Start/Stop) key.

7 The results will be displayed after the waveform is acquired.

⚠ CAUTION

- Press [Back] to return to the home display without saving the results.

Function that can be used after Measurement

The following items can be checked on the result display before printing a report.
The display can be switched in two ways.

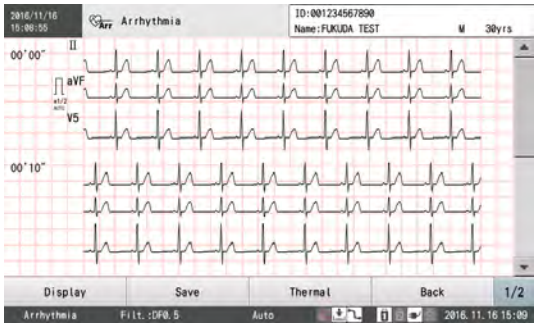
Flick left or right on the screen

Touch [Display] directly.

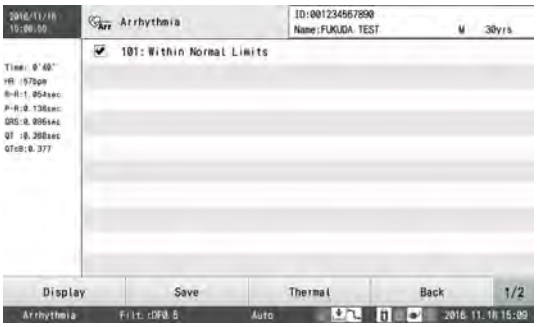
REFERENCE

- The [Analysis Result] key will be displayed only when an optional software is installed.

● [Result Waveform]
All waveforms will be displayed.

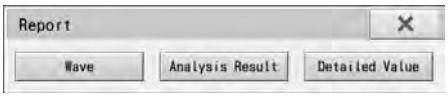


● [Analysis Result]
The analysis result will be displayed.



● [Save]
The media selection window will be displayed. Select the media to save the data.

● [Thermal]
The selected report can be printed. Select the report to output.
Refer to ☞"Examples of Printing" P7-5 for printing contents.



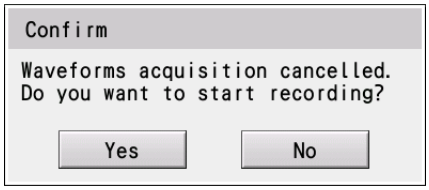
Aborting the Examination

If the (START/STOP) key on operation panel is pressed or the electrodes are detached during examination, the examination is aborted.

When the examination is aborted, a message appears to confirm whether to record the acquired data.

[Yes]: Records the data acquired up to the point when the examination was aborted.

[No]: Erases the acquired data and cancels the examination.



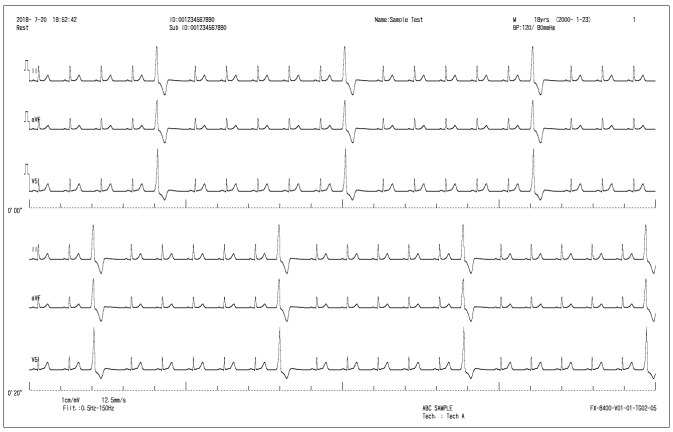
NOTE

- If data acquired is less than 7 seconds, the examination is invalid and the acquired data is not kept.

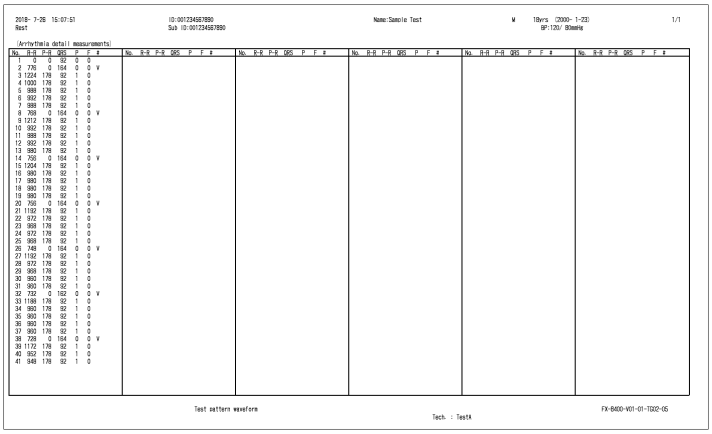
Examples of Printing

● Arrhythmia Waveform Report

The printing example of the following is shown:
Examination Lead: II, aVF, V5
Waveform Acquiring Time: 40 seconds
Waveform Report Format: 10 mm/s

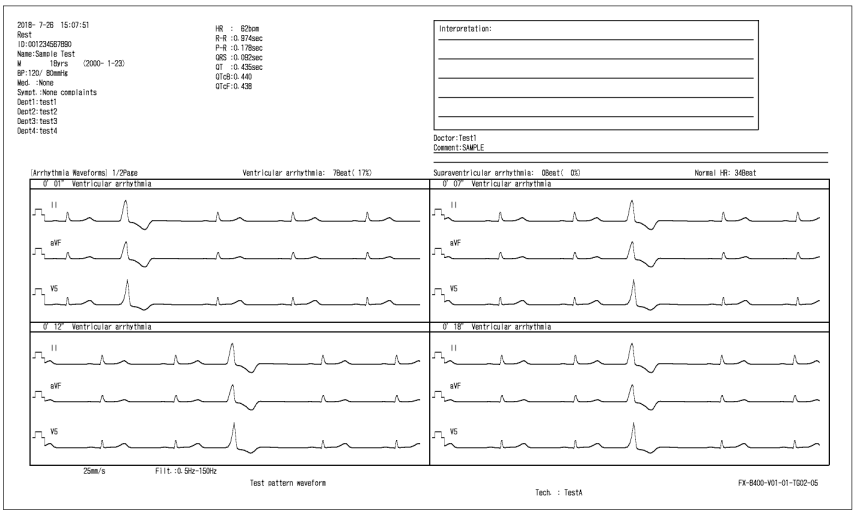


● Arrhythmia Detailed Measurement Report



●Arrhythmia Analysis Result Report

The printing example of the following is shown:
Examination Lead: II, aVF, V5
Waveform Acquiring Time: 40 seconds



Chapter 8 Rhythm Measurement

This chapter describes the rhythm measurements examination.
The basic process for conducting rhythm measurement examination is as follows:

❑Setup

Configure the various settings as necessary.
☞"Rhythm Measurement" P13-25

❑Preparation

1. Set the examination mode to “Rhythm Meas.”
2. Enter patient information.

☞"Entering Patient Information" P4-2
☞"Loading Information from the DMS (Master ID)" P4-7
☞"Using Information on SD Card" P4-8

❑Recording/Printing the Waveform

☞"Printing while Measuring Rhythm Waveform" P8-1

❑Printing the Results

The measurement results are automatically printed.

❑Saving

☞"Saving Examination Data" P9-3

Printing while Measuring Rhythm Waveform

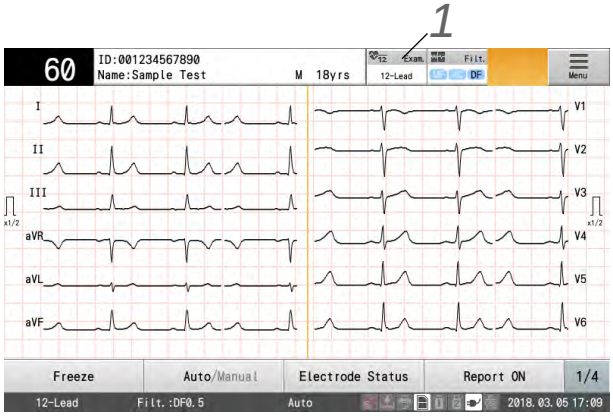
A rhythm lead (R-R measurement) waveform for each lead is collected over a period of 40 seconds to 10 minutes or for 100 or 200 beats, and an R-R histogram and R-R trend graph are output as an examination report.

REFERENCE

- In this case, arrhythmia analysis is not performed. Only the R-R section is measured.

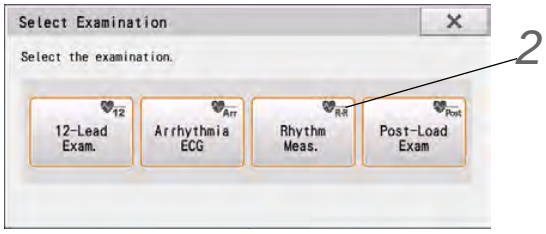
Starting Recording/Printing

1 Touch [Exam.].



2 Touch [Rhythm Meas.].

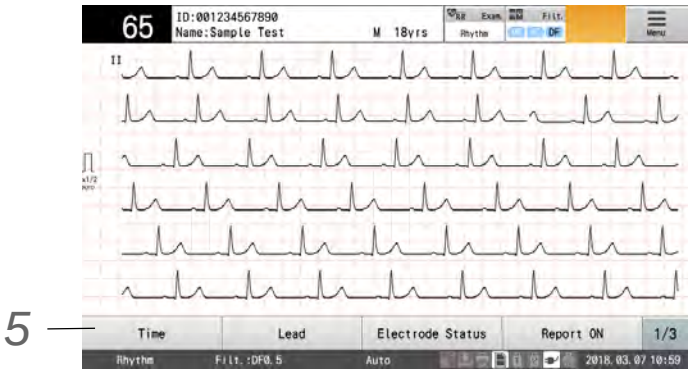
▸ When the power is turned ON, the 12-lead examination is displayed.



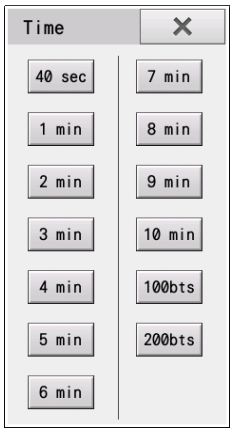
3 Attach the electrodes of the recording lead to the patient. (☞"Attaching the Electrodes" P3-1)

4 Enter patient information. (☞"Entering Patient Information" P4-2)

5 Touch [Time] and select the examination time.



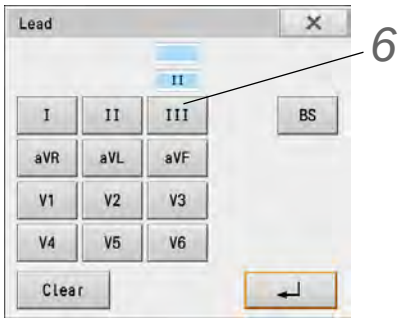
▸ Select the duration to acquire waveforms.



NOTE

- The maximum time is 10 minutes. The examination stops after 10 minutes even if 100 bts or 200 bts is set.

6 Select the examination lead.



7 Press the (Start/Stop) key on the operation panel.

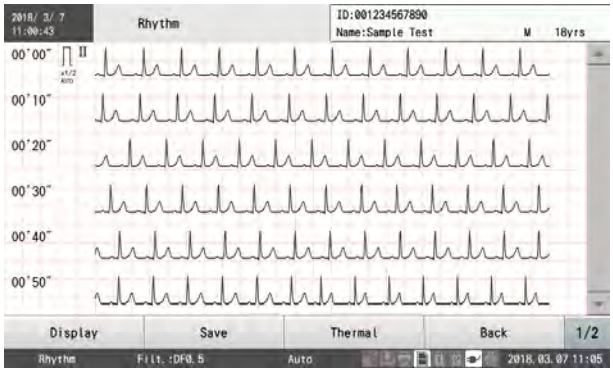
- The examination starts. "Acquiring waveforms..." is displayed and the time count starts.

8 When the time set in step 5 has elapsed, the examination finishes and the acquired waveforms are printed on the recording paper.

- Pressing the (Start/Stop) key during the examination will suspend the examination.

Functions that can be used after Examination

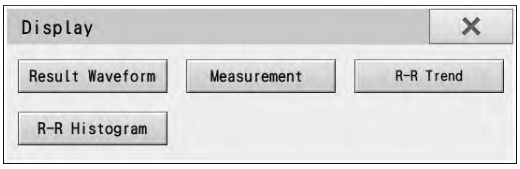
When the examination is completed, the examination result display appears.
Waveforms are displayed for all measured heartbeats.



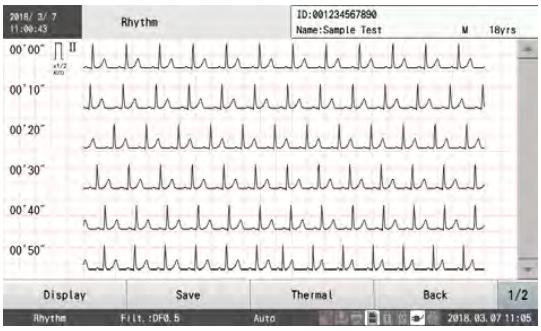
The following items can be checked on the result display before printing a report.
Flick left or right on the screen to switch the display type.
It is also possible to select the display by touching [Display] and selecting the display type.

●[Display]

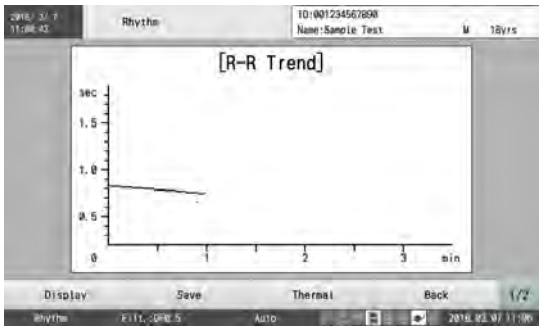
The result display type can be selected.



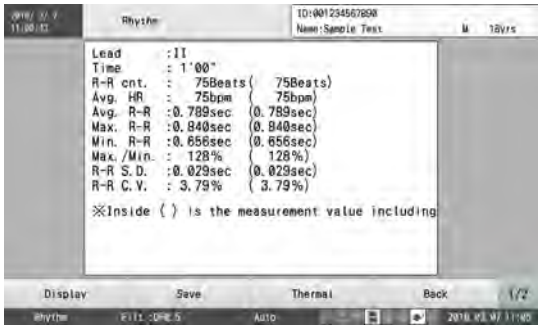
●[Result Waveform]
The measured rhythm waveform will be displayed.



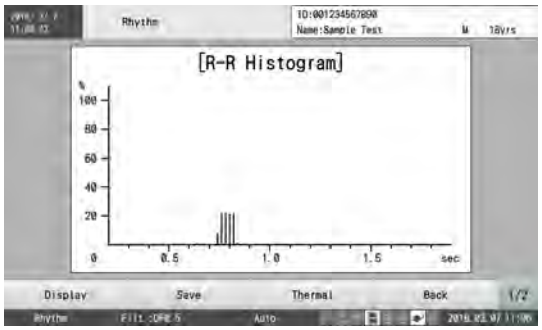
●[R-R Trend]
The R-R trend graph will be displayed.



●[Detailed Value]
The detailed measurement value will be displayed.



●[R-R Histogram]
The R-R histogram will be displayed.



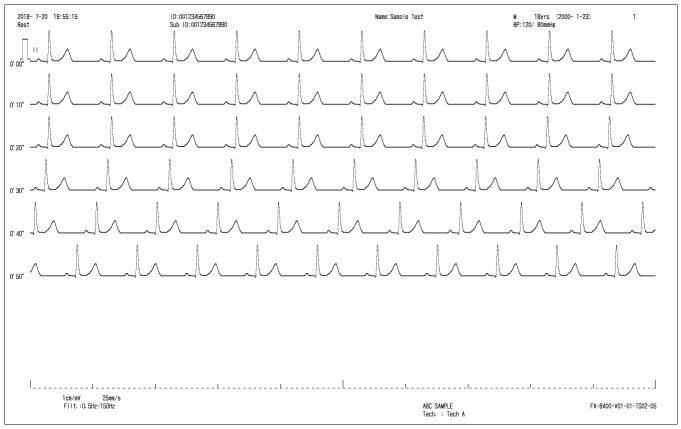
● [Save]
The media selection window will be displayed. Select the media to save the data.

● [Thermal]
The selected report can be printed. Select the report to output. Refer to ☞"Examples of Printing" P8-5 for printing contents.

Examples of Printing

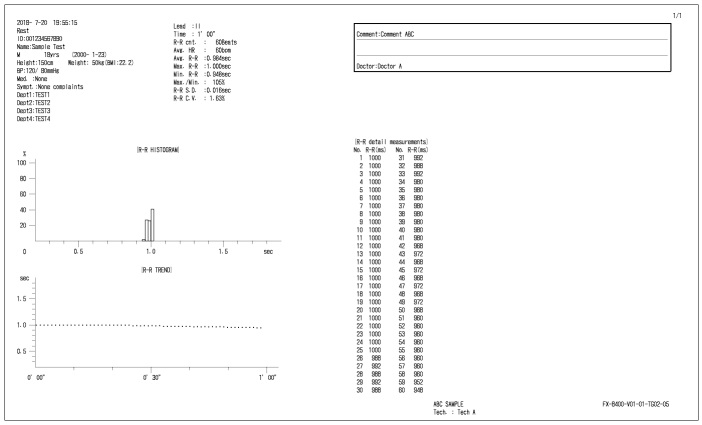
● R-R Measurement Waveform Report (Waveform)

Examination condition
Examination time: 1 minute
Examination lead: II



● Rhythm Result Report

Examination condition
Examination time: 1 minute
Examination lead: II



REFERENCE

- The values before and after extrasystole and those deviating from the average R-R by 20% or more are regarded as abnormal R-R values, and an asterisk (*) is printed after the [R-R Meas.]. The abnormal R-R values are not used for calculating the average R-R, standard deviation, and R-R coefficient variation. Also, these are not plotted in "R-R histogram".

Chapter 9 File Transfers

This section explains how to transfer files by connecting a memory device to this device or using a LAN.

Functions

Measurement data and examination results can be saved on a SD card, USB memory. Data can also be sent to other devices via a LAN cable. Saved data can be loaded when needed and then compared with other data, modified, copied, or deleted if it is no longer needed.

The usable media and capacity are as follows.

- SD Card: 2 GB
- USB memory: 1 GB / 4 GB
- DMS (Data Management System): The DMS can also be used as media for saving, loading and copying data. This device is compatible with Fukuda Denshi DMS, EFS-250. The data saved on other devices can be received or retrieved. (☞"Reading Examination Data" P9-12)
- Shared Folder
- DICOM: Various examination reports can be saved as DICOM image files.

NOTE

- Floppy disk, PC card, and CF card cannot be used.

Handling Media

This section provides cautions when using a USB memory.

Precautions when Using the SD Card/USB Memory

Pay attention to the following when handling the USB memory.

⚠ CAUTION

- Make sure to use the specified USB memory.
- If media other than those specified by Fukuda Denshi are used, examination data may not be saved correctly or the recorded data may not be loaded.
- Make sure to format the media before using it for the first time.
- Do not bend the media, drop it or subject it to impact.
- Do not remove the media or turn off the power during operation. Also, do not subject this device to impact or vibration. This may damage the recorded data or break the media.
- Do not allow any dust to enter the connectors. Do not touch the connectors and terminals of the USB memory with your hand or metallic object. Doing so may cause damage.
- Make sure to back up any important data, as data may be damaged as a result of improper handling.
- Other Precautions (Failure to observe these precautions may cause damage.)
- Do not place the media in areas with high temperatures or high humidity, such as near a

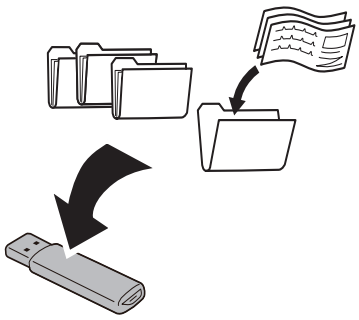
heater or in direct sunlight.

- Avoid using or storing media in areas with extreme changes in temperature.
- Do not allow media to get wet.
- Do not disassemble media.
- Avoid using or storing media near magnets or devices with a magnetic field.
- Insert the media in the correct direction.

Files and Folders

It is difficult to organize and manage data if a large number of data items (files) are recorded. Folders are therefore used to organize files in a functional way by keeping multiple files together.

Folder1 is the first folder to be created. Data is saved to Folder1 until Folder1 becomes full. Data is then saved to Folder2. Maximum of 100 folders can be used.



REFERENCE

- A folder is created when the SD card, USB memory is formatted.
- The folder to save the data can be changed. (☞"Changing Folder to Save Data" P9-20)

Initializing the Data

Make sure to format the SD card, USB memory before using it for the first time. Examination data can be saved after the media has been formatted.

There are following differences depending on the types of media and format.

Storage Media	Format	Intended Use	Maximum number of data per folder	Maximum number of folder
SD Card	For ECG (Fukuda)	Saving original data	300 data	100
	For ECG (FDA-XML)	Saving FDA-XML data	10,000 data	100
USB Memory	For ECG (Fukuda)	Saving original data	10,000 data	100
	For ECG (FDA-XML)	Saving FDA-XML data	10,000 data	100

REFERENCE

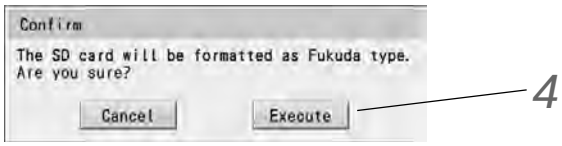
- DMS (Data Management Systems) connected by LAN cannot be formatted.
- Formatting these will clear all data saved on the media. Make sure to check that important data is not contained in the media before formatting it. (☞"Reading Examination Data" P9-12)
- Use only the SD card, USB memory specified by Fukuda Denshi.

1 Insert the storage media into this device.

2 Touch [Menu] - [File/Communication] - [Media Mgmt.] - [Format].

3 Select the media and format type.

4 Make sure that correct media and format type is selected, and touch [Execute].



- Formatting will start.
- When the formatting is completed, <Finished formatting media> will be displayed.

Saving Examination Data

Examination data recorded on the device can be saved to media or sent to another device for storage.

How to Save Data

The data can be saved to USB memory, SD card, DMS, shared folder in the following ways.

1 Save automatically after examination
The examination data is automatically saved immediately after each examination according to the settings.
(☞"Saving Data Automatically" P9-3)

2 Save manually during examination (simple operation)
The examination data can be saved during examination using the function keys.
(☞"Saving Data Manually (Simple Operation)" P9-4)

3 Save manually during examination (file utility operation)
The examination data can be saved using the file utility function.
(☞"Saving Manually (File Utility Operation)" P9-4)

Saving Data Automatically

Examination data is automatically saved on the specified media after each examination is finished.

Configure the following items in the Settings.

- Set [File] - [General] - [Auto Save] to "Yes".
- Specify the desired media in [File] - [General] - [Media (Save)].

Saving Data Manually (Simple Operation)

Manually save examination data on the specified media after each examination is finished.

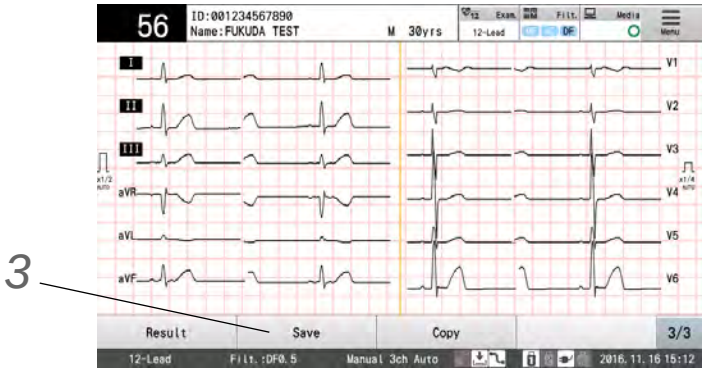
1 Perform an examination.

2 Insert the storage media into this device.

- If the media is not formatted, format it first.
  (☞"Initializing the Data" P9-2)

3 Touch [Save] after the examination is finished.

- The media selection window will be displayed.



4 Touch the media to save the data.

- The data will be saved on the selected media.

Saving Manually (File Utility Operation)

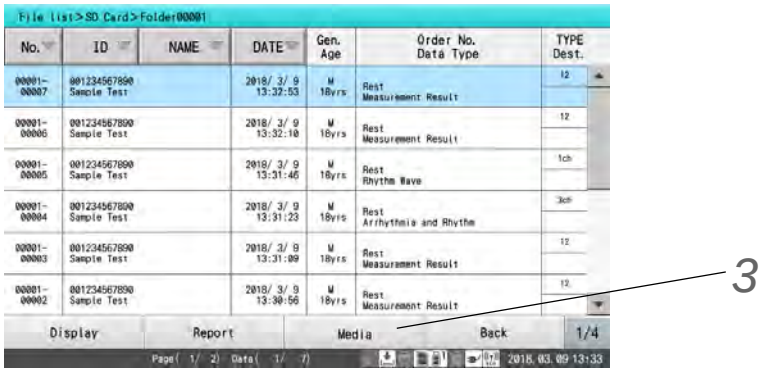
The data can be saved to the media. The storage media can also be selected.

1 Conduct the examination.

2 Insert the storage media into this device.

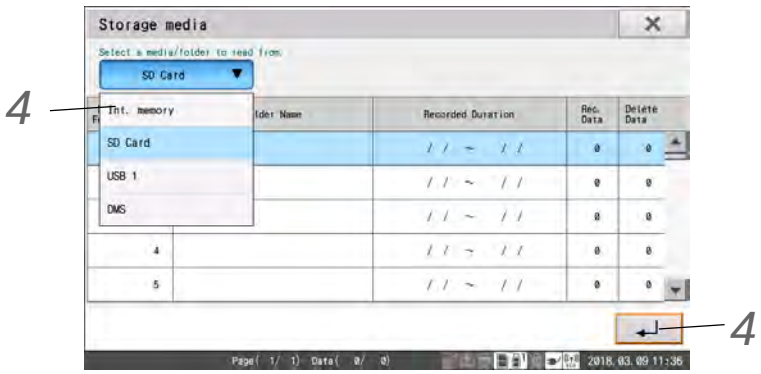
- If the media is not formatted, format it first.
  (☞"Initializing the Data" P9-2)

3 Touch [Menu] - [File/Communication] - [File List], then touch [Media] function key.

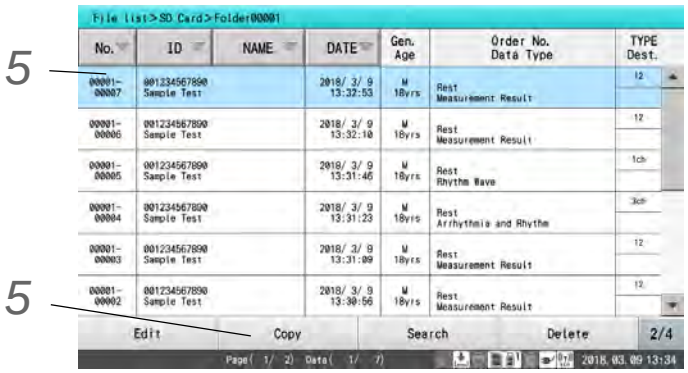


4 Select internal memory for the copy source.

Touch [Internal Memory], and then touch [↵].



5 Touch the data to save. When the data is highlighted, touch [Copy] (function key).



6 [Touch [↵] and copy.

- The selected data is copied.
- To change the media to copy the data, touch [Change] and specify the media.

Saving the Reports in DICOM Format

The examination reports recorded on this device can be saved in DICOM formats.
The destination to save the reports can be selected from the following.

- Save to DICOM Storage with online operation.
- Save to DICOM DIR (SD card) with offline operation.

Procedure to Save in DICOM Format

There are following 3 ways to save the examination reports in DICOM format.

- Automatically save the report after each examination.
  (☞"Saving Automatically" P9-6)
- Manually save the report during the examination using the function key.
  (☞"Saving Manually (Simple Operation)" P9-6)
- Manually save the report selected from the file utility function.
  (☞"Saving Manually (File Utility Operation)" P9-7)

Saving Automatically

The report image can be saved automatically after each examination if the setting is made in advance.
Configure the following items under "Setting" in advance.

- Set "Yes" for "Auto Save" under [Setting] - [File] - [General].
- Set "DICOM" for "Media (Save)" under [Setting] - [File] - [General].
- To save to DICOM Storage, set "Yes" for "Save to DICOM" under [Setting] - [Communication] - [DICOM] - [General].
  To save to DICOM DIR, set "Yes" for "DICOM DIR" under [Setting] - [Communication] - [DICOM] - [General].

If auto saving fails, a confirmation message will be displayed.
[Cancel]: Saving to DICOM will be canceled. If there is other media, saving to other media will be performed.

Saving Manually (Simple Operation)

The report image can be saved manually after each examination.

1 Conduct the examination.

2 Connect the DICOM Storage or set the SD card for DICOM DIR to this device.

▸ Perform the settings for saving DICOM in advance.
(☞"DICOM" P13-12)

3 Touch the [Save] function key.

▸ The media selection window will be displayed.

4 Select [DICOM] on the media selection window.

Saving Manually (File Utility Operation)

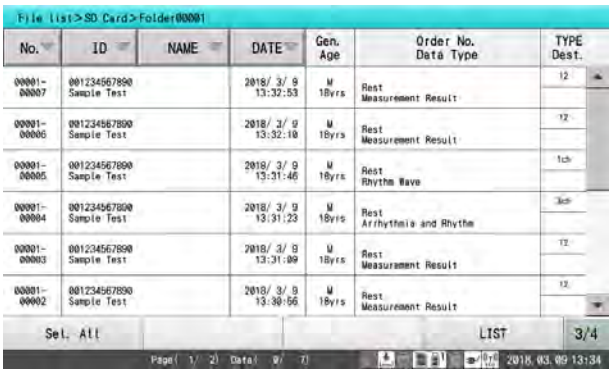
The report image to save can be selected using the file utility function.

1 Conduct the examination.

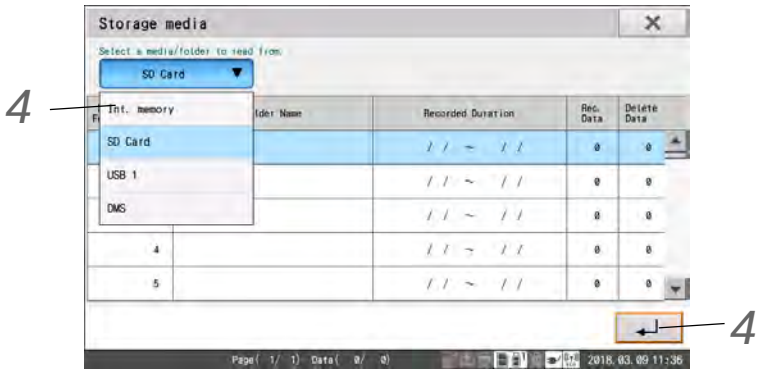
2 Connect the DICOM Storage or set the SD card for DICOM DIR to this device.

- Perform the settings for saving DICOM in advance.
  (☞"Save to DICOM" P13-12)

3 Touch [Menu] - [File/Communication] - [File List] - [Media].

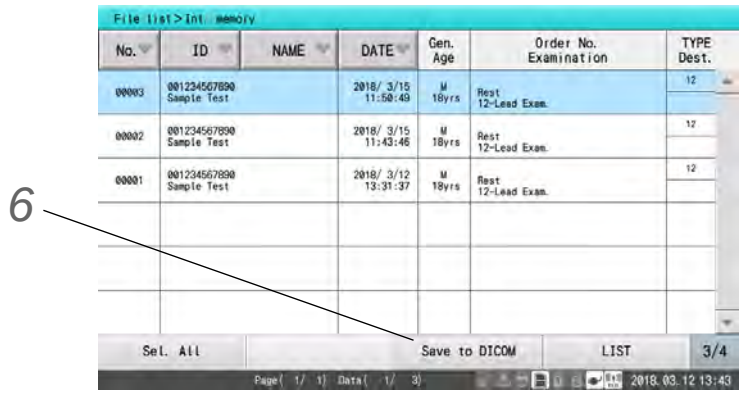


4 Select internal memory for the copy source.
Touch [Internal Memory], and then touch [↵].



5 Touch the data to save. When the data is highlighted, display the function key [3/4].

6 Touch [Save to DICOM].



Saving the Reports in PDF Format

The examination reports can be saved in PDF format to SD card, USB memory, or shared folder.

Procedure to Save in PDF Format

There are following 2 ways to save the examination reports in PDF format.

- Automatically save the report after each examination.
  (☞"Saving Automatically" P9-8)
- Manually save the report using the function key on the examination result screen.
  (☞"Saving Manually (Simple Operation)" P9-8)

Saving Automatically

The report can be saved automatically in PDF format after each examination if the setting is made in advance. Configure the following items under "Setting" in advance.

- Set "Yes" for "Auto Save" under [Setting] - [File] - [PDF].
- Select the report type to save by touching [Printer Output/PDF] on each examination screen.

REFERENCE

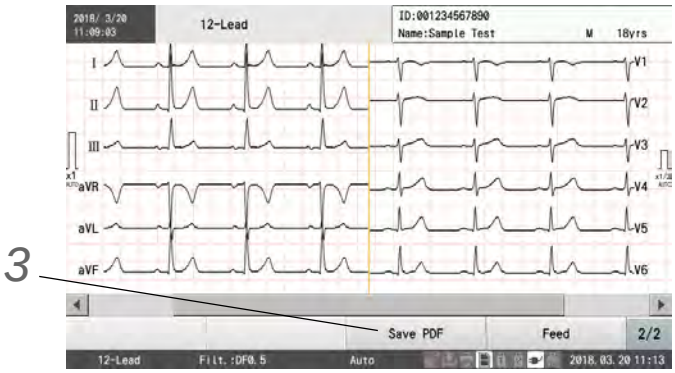
- The report type to save in PDF format can be selected using the [Printer Output/PDF] function key on each examination screen.

Saving Manually (Simple Operation)

The report can be saved manually in PDF format from the examination result screen.

1 Conduct the examination.

2 Touch [Save PDF] on the result screen when the examination is completed.



REFERENCE

- The [Save PDF] key is displayed only when "Thermal" is selected for "Print Method" under [ECG Control] - [Lead/Print].

3 Select the report type on the "Save PDF" window.

4 Touch [Save].

▸ The "Storage Media" window will be displayed.

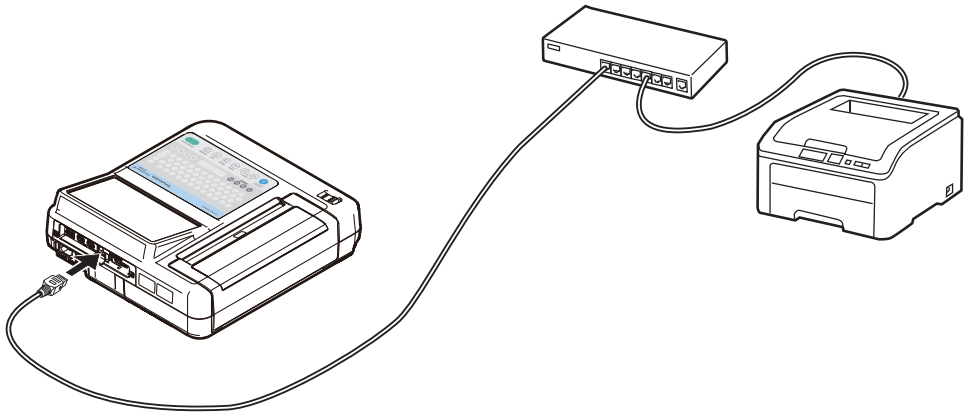
▸ When a media is selected, the report will be saved in PDF format.

Printing the Reports on External Printer

The examination reports recorded on this device can be printed on external printer.

Connecting the External Printer

Connect the Ethernet hub to the LAN connector of this device.



NOTE

- For information on LAN network, contact your local Fukuda Denshi service representative.
- Use the IEC 60950 compliant Ethernet hub.

Procedure to Print on the External Printer

There are following 2 ways to print the examination reports on external printer.

- Automatically print the report after each examination.
  (☞"Printing Automatically" P9-10)
- Manually print the report using the function key on the examination result screen.
  (☞"Printing Manually (Simple Operation)" P9-11)

Printing Automatically

The report image can be printed automatically on external printer after each examination if the setting is made in advance. Configure the following items under "Setting" in advance.

- Set "External Printer" for "Print Method" under [ECG Control] - [Lead/Print].
- Set "Yes" for "Auto Print" under [ECG Control] - [Printer Output].
- Select the report type to print by touching [Printer Output/PDF] on each examination screen.

NOTE

- The reports cannot be printed simultaneously on both the thermal printer and external printer.
- If [Report OFF] is displayed for the function key, printing will not be performed.

- The directly written waveform report will be printed only on the thermal printer regardless of the setting.

REFERENCE

- The report type to print on the external printer can be selected using the [Printer Output/PDF] function key on each examination screen.

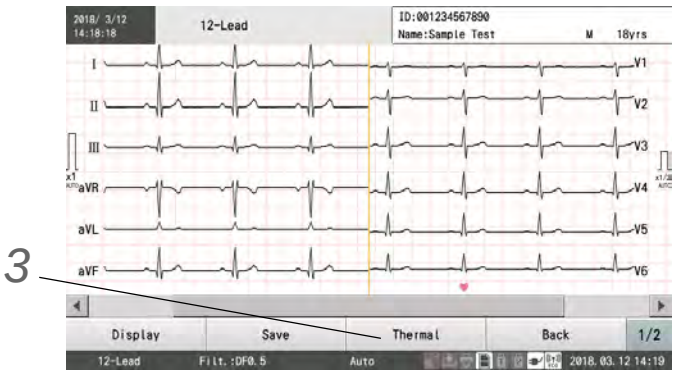
Printing Manually (Simple Operation)

The report can be printed manually on external printer from the examination result screen.

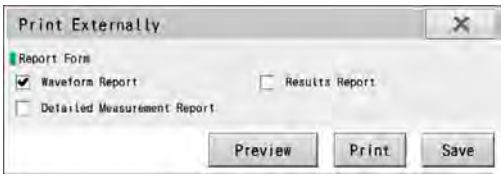
1 Conduct the examination.

2 Connect the external printer to this device.

3 Touch [Thermal] on the result screen when the examination is completed.



4 Select the report type on the "Printer Output" window.



5 Touch [Print].

▸ The selected report will be printed.

NOTE

- The reports cannot be printed simultaneously on both the thermal printer and external printer.

REFERENCE

- The report type to print on the external printer can be selected using the [Printer Output/PDF] function key on each examination screen.

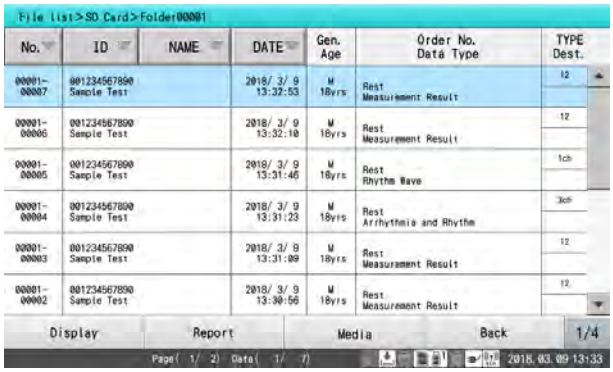
Reading Examination Data

The examination data can be read from the media to review on this device.
This section also explains how to print the loaded data and data list.

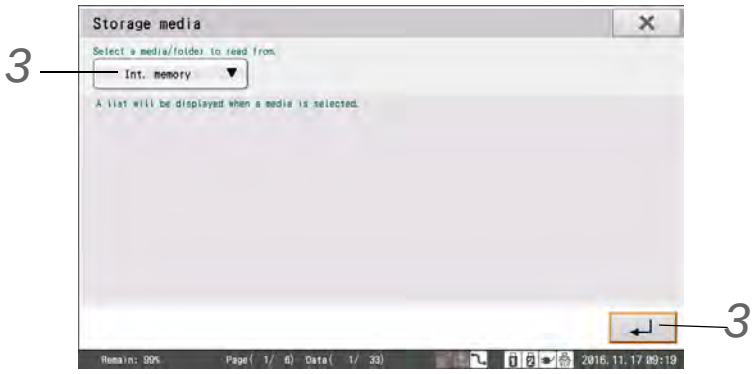
Loading

1 Insert the media to read the data.

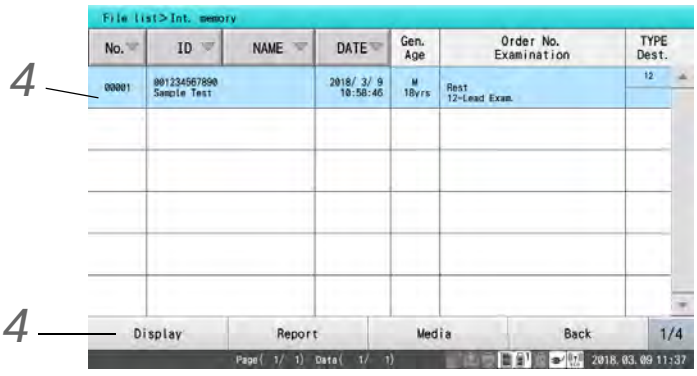
2 Touch [Menu] - [File/Communication] - [File List] - [Media].



3 Specify the location of the data to be retrieved.
Touch the location to retrieve the data from, and then touch [↵].



4 Touch the data to be retrieved. When the data is highlighted, touch [Display].



- The selected data will be retrieved and the examination result will be displayed. Examination results can be displayed and printed from this display.

- Touch [Back] to return to the file list display.
- When multiple data are selected, the examination results will be displayed sequentially. Touch [Next] in the result display to display the next examination results.
- Touch[Cl. All] to clear all selected data.

REFERENCE

- An analysis guide and commentary are not printed if the data was analyzed on an analysis version different from this device.
- For the FDA-XML formatted data, only the file list is displayed. The examination data is not displayed.

Searching Data

If any of ID number, patient name, examination date, or data number is known, data can be searched.

1 Follow the steps 1-3 in ☞"Loading" P9-12.

2 Touch [Search].

- A window for entering search conditions is displayed.

3 Touch the item to be used as a search condition and enter the condition.

- Parts of the display indicating the search conditions that can be entered differ depending on the media being searched.
  - USB Memory: [ID], [Name], [Date], [Folder], [Data not saved] and [Data Type] are displayed.
  - DMS: [ID], [Name], [Date], [Media Number] and [Data Type] are displayed.

1 When searching by ID number, enter the ID number of the desired data.

- All ID numbers are set as search targets by default.
- Wild cards can be specified with a "*".

2 When searching by patient name, enter the patient name.

- All patients are set as search targets by default.

3 When searching by examination date, enter the examination date of the desired data.

- All examination dates are set as search targets by default.
- An examination start date and end date can be entered. If no start date is entered, all data items before the end date are search targets. If no end date is entered, all data items from the start date onward are search targets.

4 When searching by folder number, enter the folder number of the desired data.

- All folder numbers are set as search targets by default.
- A start number and end number can be entered. If no start number is entered, all data items below the end number are search targets. If no end number is entered, all data items above the start number are search targets.
- Media numbers are displayed in place of folder numbers when searching the DMS.

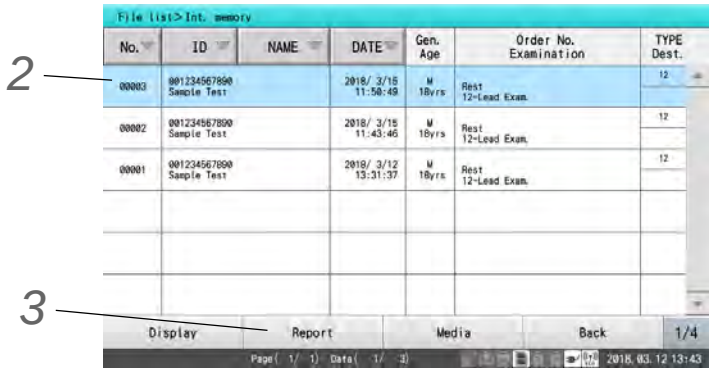
4 Touch [Search].

▸ The time search will start.

Printing Thermal Reports

1 Follow the steps 1-3 in ☞"Loading" P9-12.

2 Touch the data to be printed.



3 Touch [Report].

▸ A thermal report for the selected examination data is printed.

REFERENCE

- The report format can be selected under [Setting] - [12-Lead] / [Arrhythmia ECG] / [Rhythm Meas.]- [File].

Printing the Data List

1 Touch [1/4] - [2/4] - [LIST] in the data list window.

▸ The data list is printed.

Deleting Examination Data

Deleting Data from the List

Deleting data from the list simply means that it is no longer displayed in the list. The data is still stored on the media.

NOTE

- Data stored in the internal memory or DMS cannot be deleted.

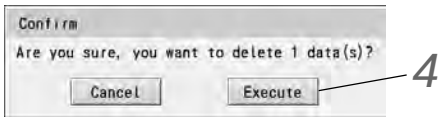
1 Follow the steps 1-3 in ☞"Loading" P9-12.

2 Touch the data to be deleted. When the data is highlighted, touch [1/4].

3 Touch [Delete].

4 Touch [Execute].

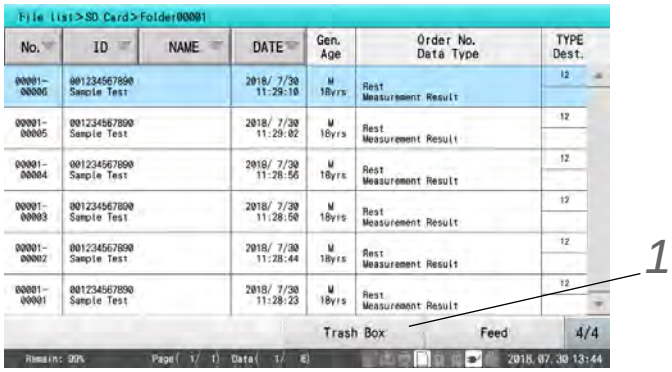
- The data is deleted from the list.
- To restore the deleted data, follow the steps in ☞"Restoring Deleted Data" P9-16.



Restoring Deleted Data

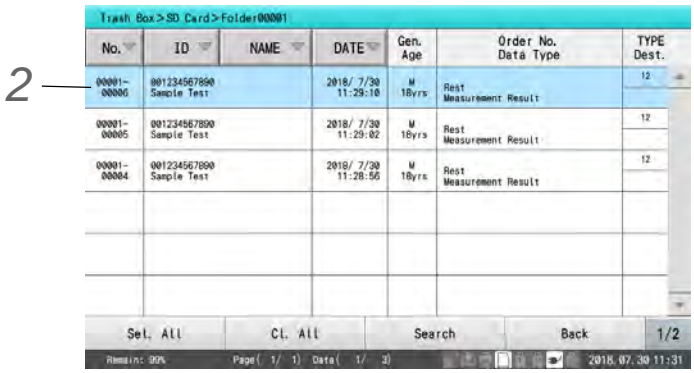
Data deleted from the list is moved to the [Trash Box]. Data in the Trash Box can be restored.

1 Touch [1/4] - [Trash Box] in the data list window.



- Data in the Trash Box will be displayed.

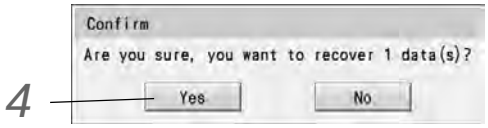
2 Select the data to be restored.



- Touch the data to be restored, Alternatively, touch [Search] to search for data and then select data from the results.

3 Touch [1/4] - [Recover].

4 In the confirmation window, touch [Yes].



▸ The data is restored.

REFERENCE

- Data in the Trash Box cannot be completely removed from media.

Correcting Examination Data

Examination data can be edited before saving or retrieving the data.

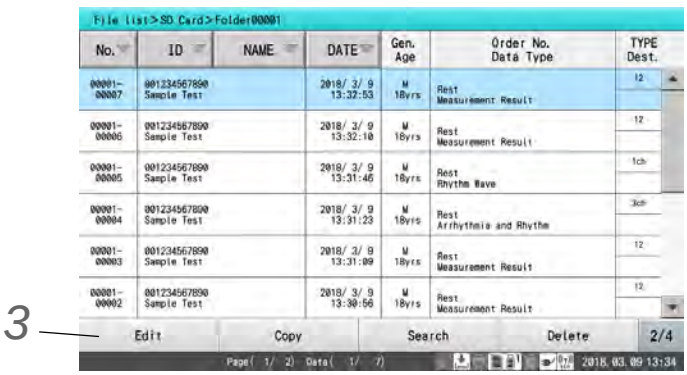
NOTE

- Editing here involves changes to individual items. The grade will not automatically change when the interpretation is changed.

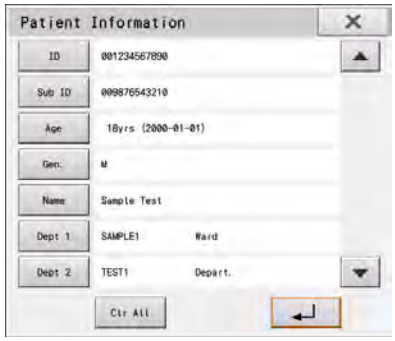
1 Follow the procedure from step 1 to step 3 in ☞"Loading" P9-12.

2 Touch the data to be edited and touch [1/4].

3 Touch [Edit].



4 Touch the information display area to edit.



1 When the "Patient Information" display area is touched:

- Touch the patient information item to be corrected, correct the information (☞"Entering Patient Information" P4-2), and then touch [↵].

2 When the "Interpretation Code" display area is touched:

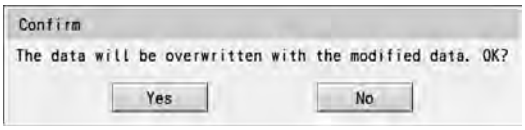
- Touch the desired interpretation code, and touch [Enter].

3 When the "Overall Judgment" display area is touched:

- Touch the desired overall judgment and then touch [Enter].

5 Touch [Save] after editing is finished.

6 In the confirmation window, touch [Yes].



Copying Examination Data

Examination data can be copied between different media.

REFERENCE

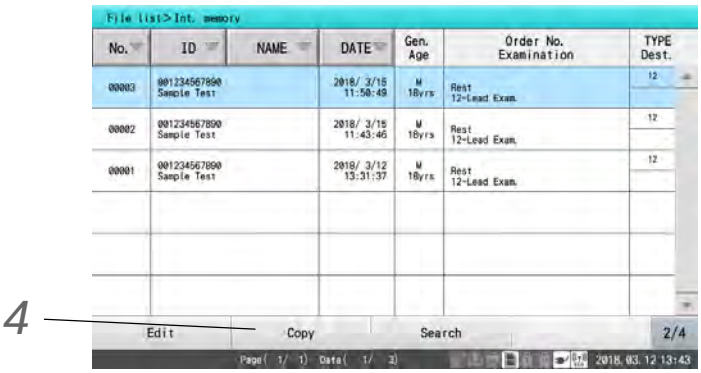
- The copy source media can be selected from SD card, USB memory, DMS, or internal memory.
- The copy destination media can be selected from SD card, USB memory or DMS.
- The data cannot be copied from FDA-XML format media to DMS or FUKUDA format media.

1 Insert the media of copy source and copy destination to this device.

2 Follow the procedure from step 1 to step 3 in ☞"Loading" P9-12.

3 Touch the data to be copied, and then touch [1/4].

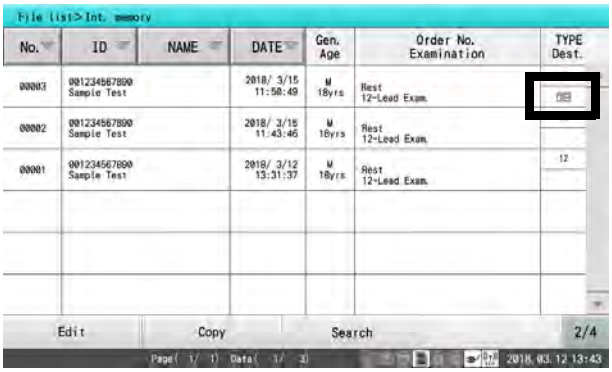
4 Touch [Copy].



5 Check the media to copy the data and touch [↵].

- To change the media to copy the data, press [Change].

6 When data is copied from media to DMS, the registered icon is displayed.



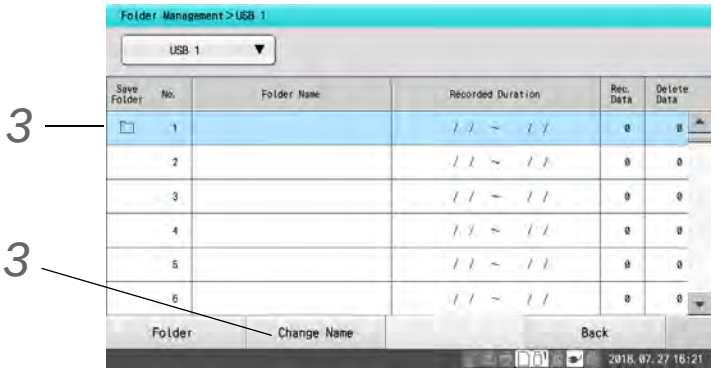
Naming Folders

Folders on USB memory can be named to organize the saved data clearly.

1 Insert a USB memory into this device.

2 Touch [Menu] - [File/Communication] - [Media Mgmt.] - [Folder Management].

3 Select the folder to change the name. Touch the folder, and then touch [Change Name].



4 Enter the new name.

- Enter any name in alphanumeric characters.
  This is entered in the same way as the name in Patient Information. (Refer to Chapter 4 "Entering Patient Information".)

5 [Touch [↵].

- The name of the folder is registered.
- If [x] is touched, the entered folder name will not be registered.

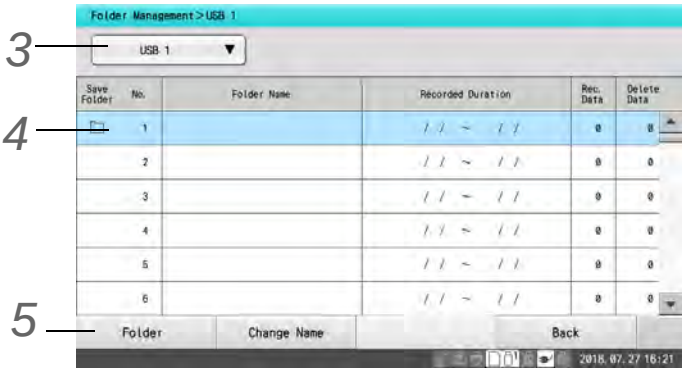
Changing Folder to Save Data

When saving the data on a SD card, USB memory, the folder to save the data can be changed.
The folder can also be changed at the timing of saving the data. (☞"Saving Manually (File Utility Operation)" P9-4)

1 Set the SD card, USB memory to change the saving destination folder.

2 Touch [Menu] - [File/Communication] - [Media Mgmt.] - [Folder Management].

▸ The folder management screen will be displayed.



3 Select the media to save the data.

4 Select the folder to save the data.

5 Touch [Folder].

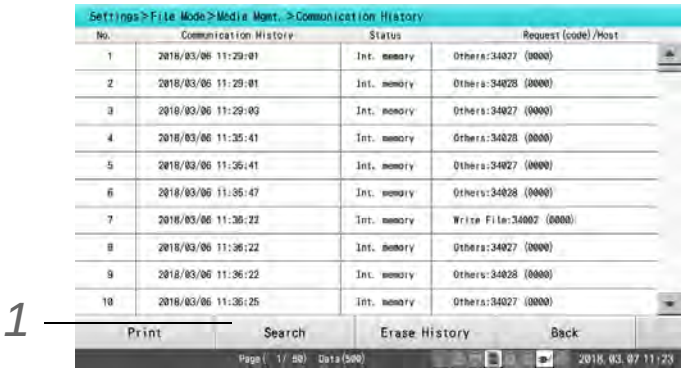
Communication History

The latest 500 communication data items are recorded.
This section explains how to search or erase history of communication with DMS or media.

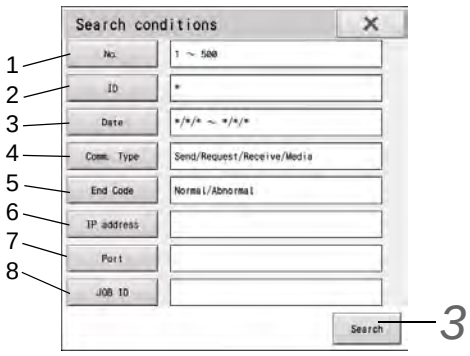
Searching Communication History Data

Specify search conditions to search communication history.

1 Touch [Search].



2 Touch the item to be used as a search condition and enter the condition.



1 Searching by Data Number

- Enter the desired data number.
- All numbers are set as search targets by default.
- A start number and end number can be entered. If no start number is entered, all data items below the end number are search targets. If no end number is entered, all data items above the start number are search targets.

2 Searching by ID Number

- Enter the desired ID number.
- All ID numbers are set as search targets by default.
- Wild cards can be specified with (*).

3 Searching by Examination Date

- Enter the desired examination date.
- All access dates are set as search targets by default.
- A start date and end date can be entered. If no start date is entered, all data items before the end date are search targets. If no end date is entered, all data items from the start date onward are search targets.

4 Searching by Communication Type

- Select the desired communication type.
- All communication types are set as search targets by default.

5 Searching by End Code

- Select the desired end code.
- All end codes are set as search targets by default.

6 Searching by IP Address

- Select the desired IP address.
- All IP addresses are set as search targets by default.

7 Searching by Port Number

- Select the desired port number.
- All port numbers are set as search targets by default.

8 Searching by Job ID

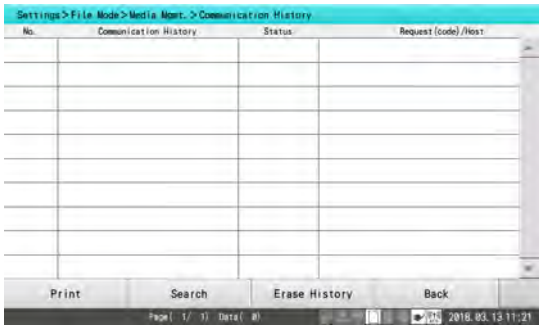
- Select the desired job ID.
- All job ID numbers are set as search targets by default.

3 Touch [Search].

- The time search will start.

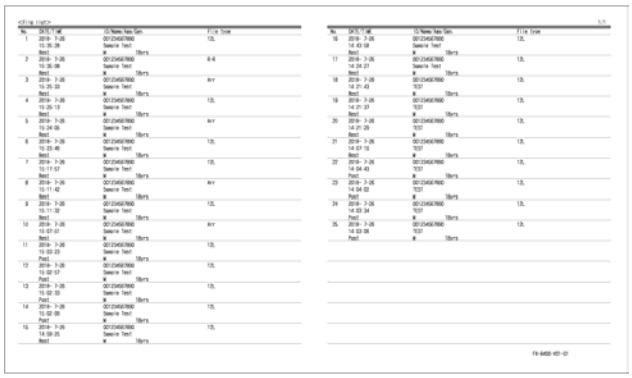
Erasing the Communication History

1 Touch [Erase History] to erase communication history.



Examples of Printing

- File List



Chapter 10 DICOM Work List

This section describes the DICOM work list function.

Functions

The work list can be received from the MWM to perform the examination on this device, and the completion of examination can be notified to the MPPS.

1 Receive the work list from DICOM MWM.

2 Select the work list and perform the examination.

3 Notify the completion of examination to the DICOM MPPS.

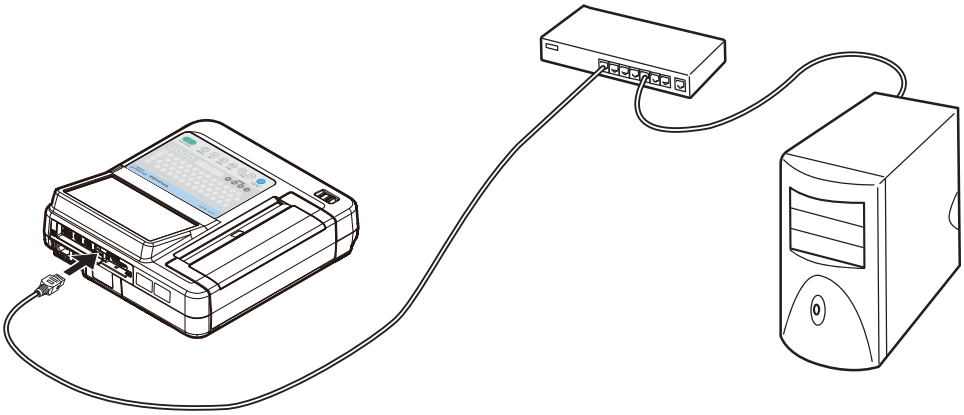
REFERENCE

- MWM (Modality Worklist Management)
  The work list will be notified from DICOM server to modality.
- MPPS (Modality Performed Procedure Step)
  The examination status will be notified from modality to DICOM server.)

Preparing for Communication with External Device

Connecting the External Device

Connect the Ethernet hub to the LAN connector of this device.



NOTE

- For information on LAN network, contact your local Fukuda Denshi service representative.
- Use the IEC 60950 compliant Ethernet hub.

Settings Required for Communication

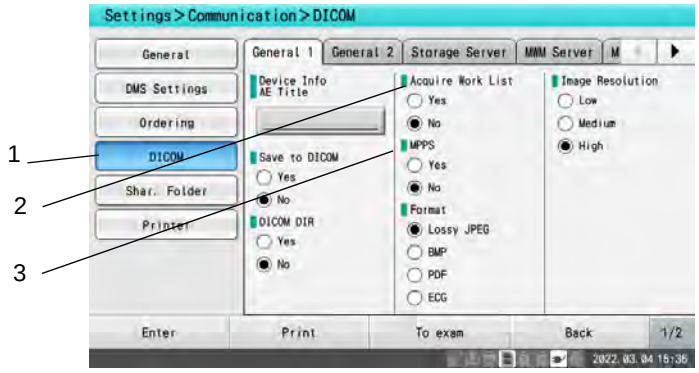
Set the name, IP address, sub-network mask of this device and the host as well as the port number and the host number for connection.

NOTE

- Contact Fukuda Denshi for setting the IP address, port number, etc. required for communication via LAN connection.

1 Touch [Menu] - [Settings] - [Communication].

2 Perform settings for DICOM.

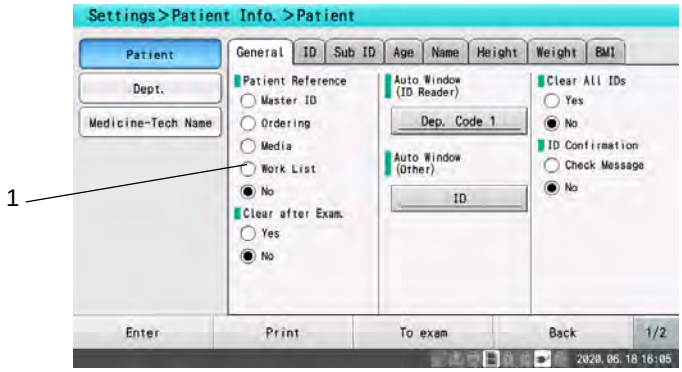


1 Touch [DICOM].

2 Set "Yes" for "Acquire Work List".

3 Set "Yes" for "MPPS".

3 Touch [Menu] - [Setting] - [Patient Info.].
Perform settings for "Patient Reference".

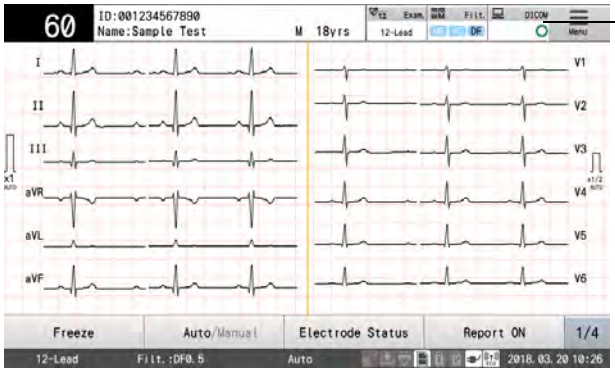


1 Set "Work List" for "Patient Reference".

Selecting Work List and Conducting Examination

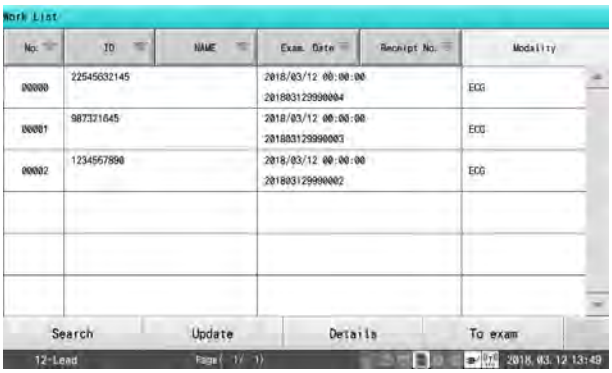
This device can be connected to the DICOM MWM server via LAN.
The patient information such as name, age, gender can be retrieved from the work list information on the DICOM MWM server.

1 Touch [DICOM].



1

2 The work list will be displayed.



- No.: Sorts the list in ascending/descending order of number.
- [Patient Info.]: Sorts the list in ascending/descending order of ID, name.
- Exam. Date: Sorts the list in ascending/descending order of examination date.
- Receipt No.: Sorts the list in ascending/descending order of receipt number.
- Modality: Displays the modality code.
- [Search]: Displays the search window.
- [Update]: Updates the work list.
- [Details]: Displays the detailed window of the selected patient on the work list.
  ID No./Name/Age/Gender/Height/Weight/Exam. ID/Receipt No./Exam. Date/Modality Code will be displayed.
- [To exam]: Displays the examination screen of the selected patient on the work list.

3 Touch [To exam].

The patient information of the selected work list will be reflected.

- When the patient information window is closed, starting of the examination will be notified to the MPPS server.

Searching the Work List Information

The work list information can be searched with the following search condition.

- ID: Partial match search will be performed with the entered ID.
- Receipt No.: Exact match search will be performed with the entered receipt number.
- Date: Searching will be performed within the entered examination date range.

REFERENCE

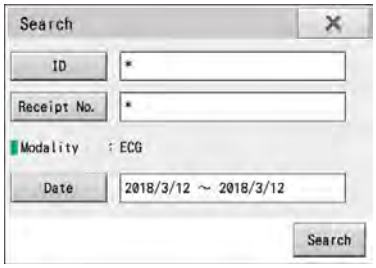
- Wild cards (*) can be used for searching.For example, "123*" will retrieve items such as "123", "12345", "1234567890".

1 Touch [DICOM], and display the work list.

2 Touch [Search] on the work list, and display the search window.

1 Enter the search condition.
Touch [ID], [Receipt No.], [Date] to display the corresponding window.

2 Touch [Search].



REFERENCE

- The work list request to the DICOM MWM server can be performed only before the

examination.

- When the patient information is entered from the work list, the current patient information will be overwritten.
- If the ID is changed after the work list is fixed, the canceling of work list will be notified to the MPPS.

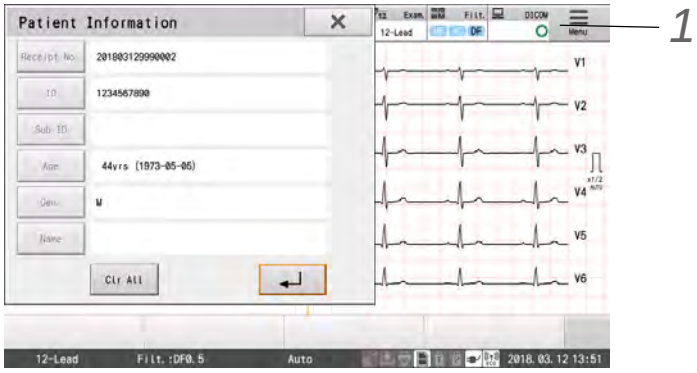
Fixing the Work List by Connecting the ID Reader

By connecting the ID reader, the work list of the searched condition can be fixed.

1 Touch [DICOM], and display the work list.

2 Load the patient information from the ID reader.

3 The work list will be automatically fixed, and the examination screen will be displayed.



REFERENCE

- Select "ID" for "ID Reader Search" under [Setting] - [Communication] - [Ordering] in advance.
- When the patient information window is closed, starting of the examination will be notified to the MPPS server.

Chapter 11 Ordering System

This section describes the ordering system of this device.

Functions

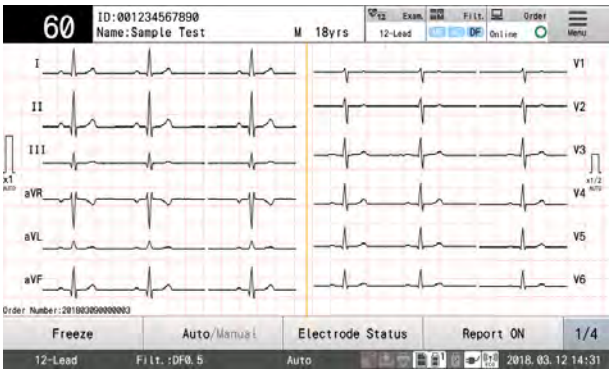
The results of the examination conducted by receiving requests (ordering function) can be saved to the specified media or data management system (DMS) and notified to the DMS or ordering PC.
To enable ordering function, select "Ordering" under [Patient Information] - [General] - [Patient Reference].

❑Operation Procedure

(1) Receive an order on this device.
(2) Select an order and perform the examination.
(3) Save the examination results on SD card or DMS.
(4) Notify the DMS (or ordering PC) of completion of the examination.
(5) When there are more than one examination, the next examination will automatically start.

❑Types of Order Icons

By the order icon display, the current communication status of ordering can be verified.



Normal LAN	LAN Error
	

❑Types of Examination Icons

By the examination icon display, the examination status can be verified.

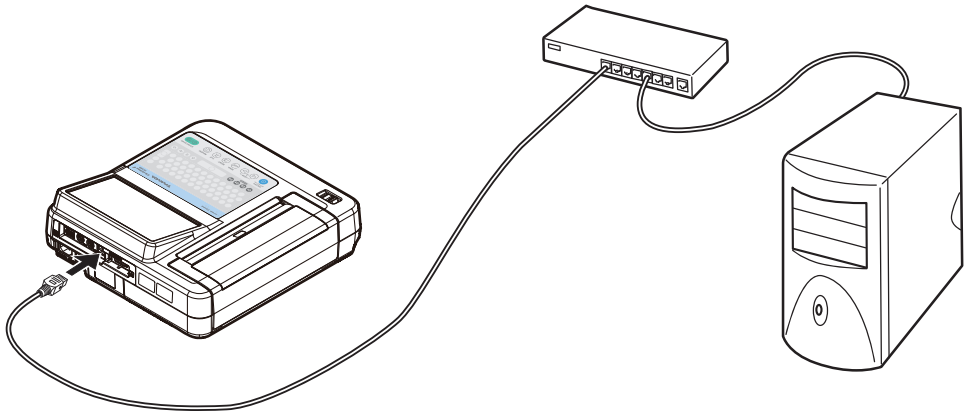
Examination Status Icons			
(Blue): Not examined	(Green): During examination	(Red): Examined	(Yellow): Next examination
			

Examination Type Icons				
12-Lead	Arrhythmia	Rhythm	Post-Load	Full Disclosure Waveform (12-Lead)
				

Preparing for Communication with External Devices

Connecting the Communication Device

Connect the Ethernet hub to the LAN connector of this device.



NOTE

- For information on LAN network, contact your local Fukuda Denshi service representative.
- Use the IEC 60950 compliant Ethernet hub.

Settings Required for Communication

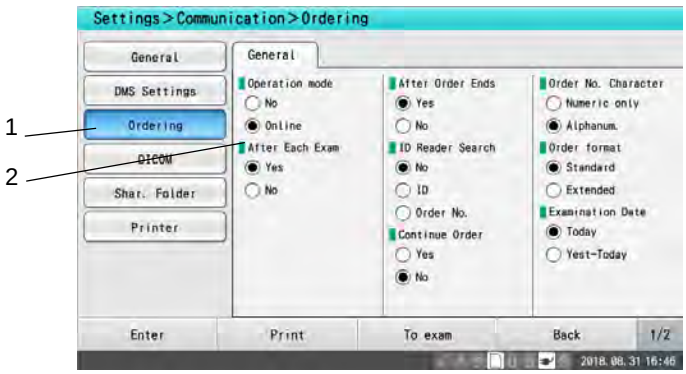
Set the name, IP address, sub-network mask of this device and the host as well as the port number and the host number for connection.

NOTE

- Contact Fukuda Denshi for setting the IP address, port number, etc. required for communication via LAN connection.

1 Touch [Menu] - [Settings] - [Communication].

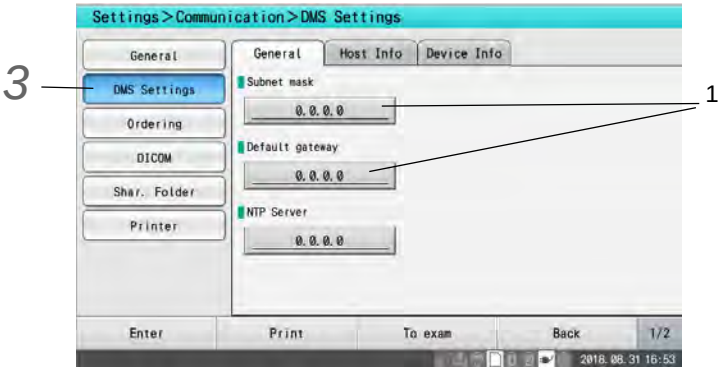
2 Specify the operation mode for ordering.



1 Touch [Ordering].

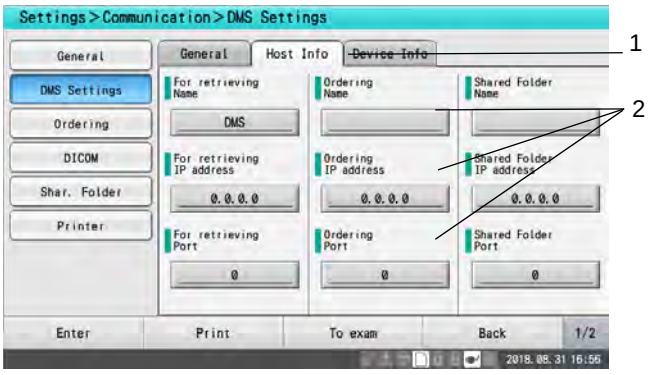
2 Set the operation mode to "Online".

3 Touch [DMS Settings].



1 Set the [Subnet mask], [Default gateway].

4 Set the host information.



1 Touch [Host Info].

2 Enter "Host Name", "IP Address", and "Port Number" under "Host Information 2".

5 Touch [Enter] to finalize the settings.

6 Turn OFF the power, then turn it back ON.

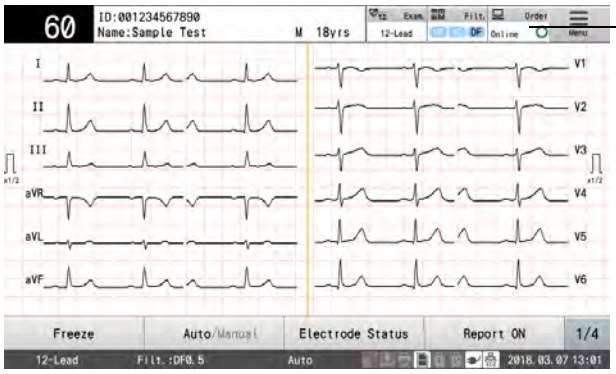
Selecting Order Information and Conducting Examination

Obtain the order information, and display the order information list.
Select an order from the list and perform the examination.

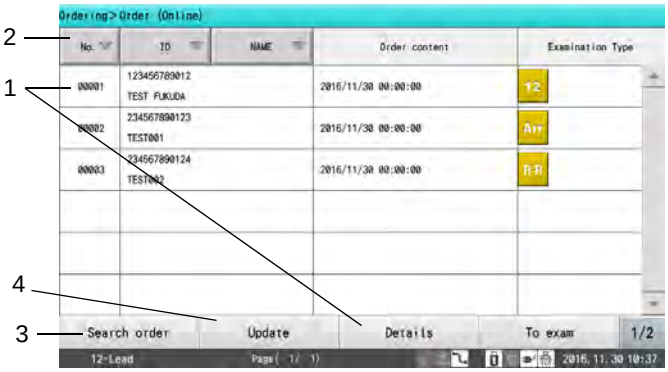
REFERENCE

- For procedure of each examination, refer to the respective chapter in this operation manual.

1 Touch [Order].



- The order information list will be obtained.
- A maximum of 500 order information can be displayed.



1 Touch the data to be loaded. When the data is highlighted, touch [Details] to check the detailed order information.

2 Touch the title area to sort the list in ascending or descending order.

3 [Search Order]: Order can be searched. (☞"Searching Order Information" P11-5)

4 [Update]: The latest order information will be obtained and displayed.

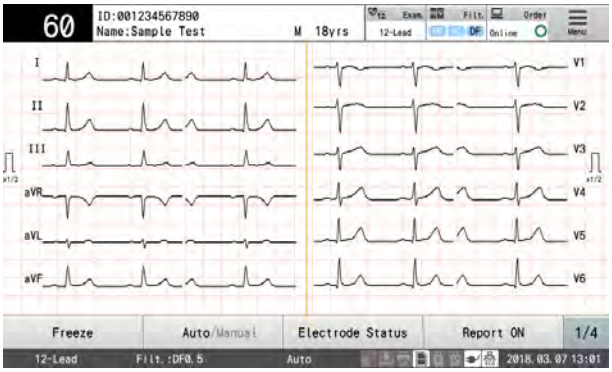
2 Touch and highlight the data to be loaded.

- Confirm the order selection.
- Only one order can be specified.

3 Touch the examination type icon for the conducting examination. A mark will be displayed for the icon.

4 Touch [To exam].

- The order information list will close, and automatically switches to the selected examination mode.
- The specified order number and patient information will be displayed.
- When [To exam] is touched without selecting an order, the previous screen will be displayed.

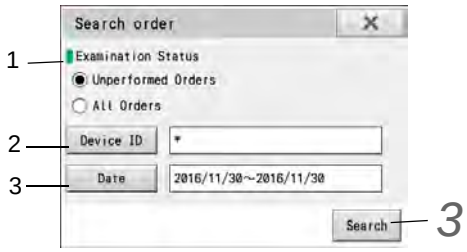


Searching Order Information

Search order information matching search conditions and display it.

1 Touch [Search Order].

2 Specify search conditions.



1 Examination status

- Specify the examination status
- When "Unperformed Orders" is selected, an order for which examination has not been performed is specified.

2 Device ID

- Enter the device ID.
- A wild card (*) can be used.

REFERENCE

- The device ID can be checked in [ECG Control] - [General] - [Device ID] in the Settings.

3 Date

- Enter the examination date.
- Touch [Today] to enter today's date.

3 Touch [Search].

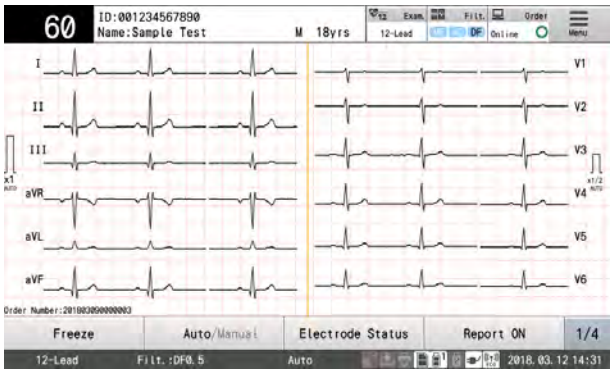
- Search is carried out and the relevant order information is displayed.
- Touch [X] to stop searching and close order search.

Displaying Order Information Using ID Reader

Connect the ID reader to display order information that met search conditions.

1 Load patient data from the ID card and search order information.

- Order information that met searched conditions will be displayed.



REFERENCE

- Search conditions for the ID reader (ID number or order number) can be specified under [Setting] - [Communication] - [Ordering] - [ID Reader Search].
- Search conditions specified under [Setting] - [Communication] - [Ordering] - [ID Reader Search] and those specified in the Search Order display will be used.
- For more information on how to configure the ID reader settings, ☞"External Device" P13-14.

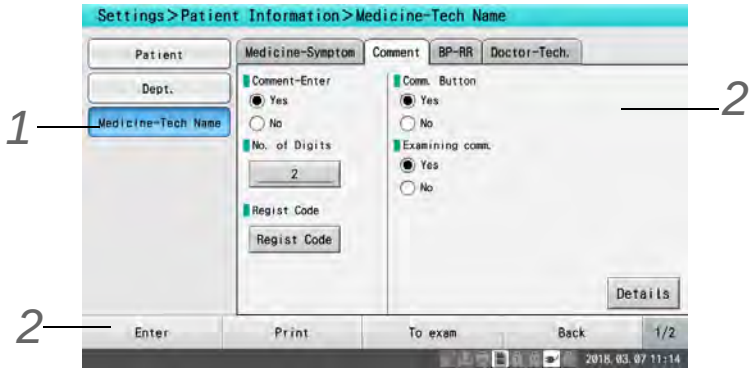
Displaying Comments

Comment specified in DMS (Data Management System) when ordering is displayed.
The comment received from DMS is specified in [Patient Info.] - [Medicine - Tech Name] -[Comment] in the Settings.

Specify whether or not to enter comment.

1 Touch [Menu] - [Settings] - [Patient Information] - [Medicine - Tech Name].

2 Set [Comment - Enter] to "Yes" and touch [Enter] to save the settings.



▸ When a comment is received from DMS, the comment will be displayed.

Chapter 12 Printing Daily Report

This chapter explains how to save/print the examination daily report.

Contents of Daily Report

To check the status of examinations that have been conducted, the recorded data can be saved as a daily report list in CSV format on a SD card.It can be also printed on the thermal printer.

The daily reports is listed in the order in which the examination were performed and includes the following information.

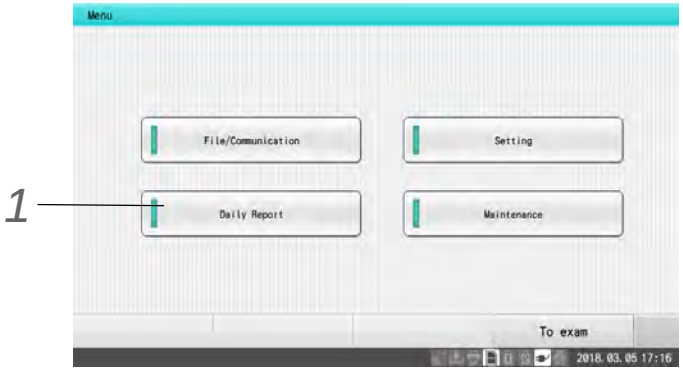
- Examination Date/Time
- Examination Information
- Patient Information (ID, name, age, gender)

REFERENCE

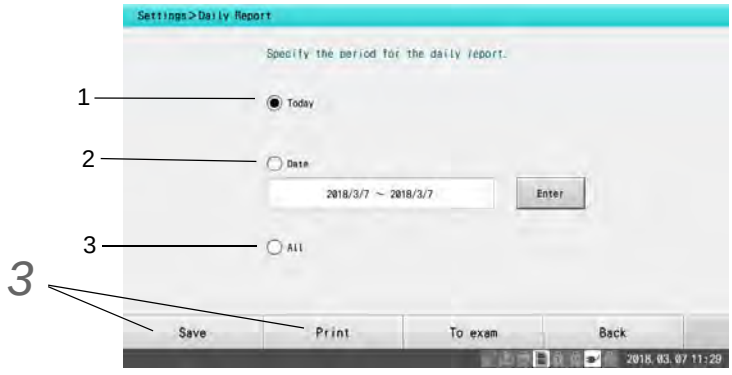
- The maximum storage capacity of daily reports is 500. When the maximum number is exceeded, older daily reports are deleted automatically.
- When the number of daily reports exceeds the maximum storage capacity in a day, the message "Daily report data is full" appears once.
- The daily reports can be saved to SD card only.

Printing Daily Report

1 Touch [Menu] - [Daily Report].



2 Touch the desired recording method.



1 Today: Today's daily report is saved.

2 Date: Daily report for the specified date is saved.

- Touch [Enter] and specify the date, and then touch [ ].

3 All: All the daily reports recorded in the device are saved.

3 Touch [Save] or [Print].

- [Save]: The daily reports during the selected period will be stored on SD card in CSV format. The daily reports can only be stored on SD card.
- [Print]: The daily reports during the selected period will be printed.

Chapter 13 Settings

Detailed settings relating to the operations of this device can be configured to suit your purpose. This chapter explains how to configure the settings.

Overview of Settings

The settings relating to the device operations and each examination method can be configured as necessary.

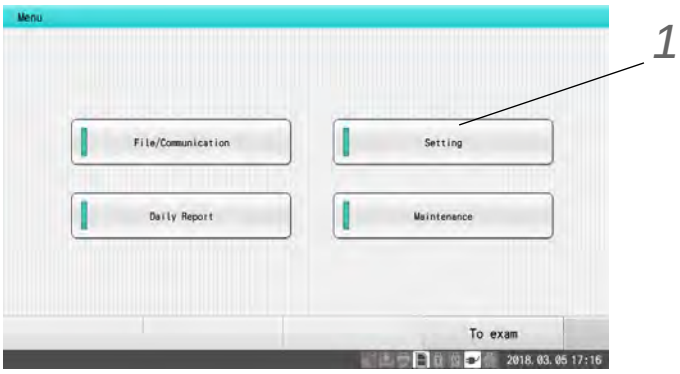
Item	Description	Reference
ECG control	Configure general settings relating to ECG operations.	☞P13-2
Patient Information	Set which item to enter as patient information.	☞P13-5
File	Configure settings such as the methods for saving and loading examination data.	☞P13-9
Communication	Configure settings for communication methods with other devices.	☞P13-10
External Device	Configure settings for connections with external devices.	☞P13-14
12-Lead Examination	Configure settings concerning examination methods and recording/ printing content for standard ECG examinations.	☞P13-15
Arrhythmia ECG	Configure settings concerning examination methods and recording/ printing content for arrhythmia examinations.	☞P13-23
Rhythm Measurement	Configure settings concerning examination methods and recording/ printing content for rhythm measurement examinations.	☞P13-25
Post-Load Examination	Configure settings concerning examination methods and recording/ printing content for post-exercise examination.	☞P13-26

Window Operation Procedure

⚠ CAUTION

- Contact Fukuda Denshi for more information on connecting and configuring the settings of ID readers.

1 Touch [Menu] - [Settings].

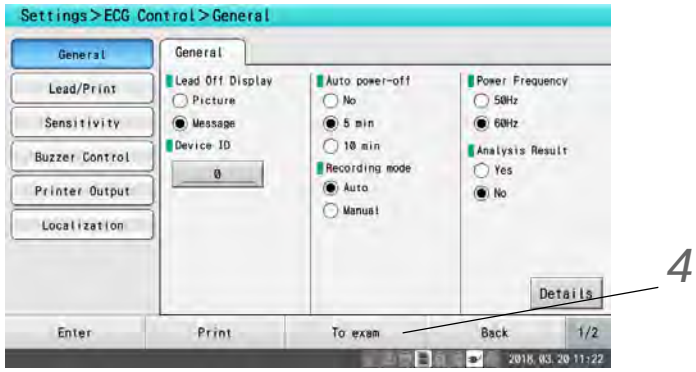


2 Touch the desired item to set.

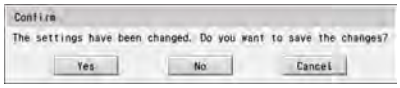
3 Change the settings.

- Refer to the items below for information on the settings and setting values for each item.
- For text entry method, refer to "☞"Character Entry" P1-13".

4 Touch [To exam] after configuring the settings.



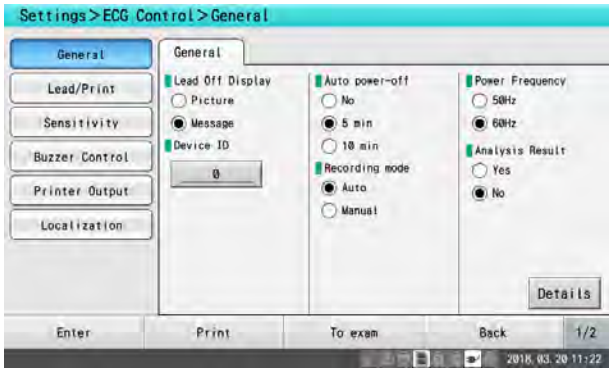
5 A confirmation message will be displayed.



- To enable the setting changed, touch [Yes].
- Touching [No] will discard the changes and return to the examination display.
- Pressing [Cancel] will return to the settings display.

ECG Control

Configure the device settings.



REFERENCE

- The text in [] indicates the factory default setting.
- Items with an asterisk (*) can be configured in the detailed settings window which will be displayed by pressing the [Details] key.

General

General

Setup Item	Description	Setting Range
Lead Off Display	Picture:The lead off position is indicated as a picture in the patient body illustration. Message:The name of the lead off electrode is displayed.	Picture, [Message]
Device ID	Specify the device ID.	0 to 255
Auto Power-Off	Turns the power off automatically if no operations are performed for the prescribed period of time when using the battery.	No, [5 min], 10 min
Recording Mode	Specify printing mode at power ON.	[Auto], Manual
Power Frequency	Specify the frequency of the AC power supply to which the device is connected.	50Hz, [60Hz]
Analysis Result	Specify whether to perform analysis.	[Yes], No
Password*	A password for entering the settings function (4 digits) can be set.	-
File Password*	A password for entering Filing and Networking (4 digits) can be set.	-

REFERENCE

- "Analysis" is displayed when the optional software is installed.

Lead/Print

Lead

Setup Item	Description	Setting Range
Spare Lead 1 (3 ch)	Specify the spare lead for 3ch manual printing.	[II aVF V5] STD I II III aVR aVL aVF -aVR V1 V2 V3 V4 V5 V6
Spare Lead 2 (3 ch)	Specify the spare lead for 3ch manual printing.	[V1 V5 V6] STD I II III aVR aVL aVF -aVR V1 V2 V3 V4 V5 V6
Spare Lead (6 ch)	Specify the spare lead for 6ch manual printing.	[I II aVF V1 V5 V6] STD I II III aVR aVL aVF -aVR V1 V2 V3 V4 V5 V6
Auto Reset*	Specify whether to perform auto reset.	[Yes], No

Print

Setup Item	Description	Setting Range
Print Method	Specify the printing method.	[Thermal], External Printer
Recording Paper	Specify the type of recording paper to be used.	[Roll Paper], Z-fold Paper Roll w/o grid, Z-fold w/o grid
Feed	When a roll paper is used, feed the paper after recording is finished.	[Yes] No

Print

Wave Thickness	Specify the printing waveform thickness.	Thin, [Normal], Thick, Very Thick
Register Facility Name	Register the hospital name to be printed on the recording paper. (30 characters)	-
Time Unit*	Specify the time unit to be used for measurements printed on recording paper. ms is always used as the unit for detailed measurements and arrhythmia measurements.	[sec.], ms
Filt.*	Specify the filter printing method. Simple:Print whether the filter is "ON" or "OFF". Type:Print the type of filter (DF, MF, AC). Frequency:Print the frequency characteristics (0.05 Hz to 150 Hz).	Simple Type [Frequency]
Lead Switch*	Specify whether to indicate a lead switch by printing a dashed line when printing a waveform.	Yes, [No]

Sensitivity

General

Setup Item	Description	Setting Range
Sensitivity	Specify the default of sensitivity.	1cm/mV, [Auto]

Custom Key

Setup Item	Description	Setting Range
Custom 1	Specify the function to assign to the custom key.The following keys can be selected.No, Start, Stop, ID+1, ID-1, Auto Printing, Manual recording, Age, Gen. Copy, Patient/Delete All, Hold, Save, Result, Hum Filter, Muscle Filter, Drift Filter, Cabrera Lead, Standard 12-Lead, File, Exam. Switch, Freeze	[Start]
Custom 2		[Stop]
Custom 3		[No]
Custom 4		[No]

Buzzer Control

General

Setup Item	Description	Setting Range
Volume Setting	All: Adjust all volumes at once.Individual: Adjust each volume individually.	[All], Individual
Set All Volumes	Specify all volumes at once.	0 1 2 [3] 4 5
Lead Off Sound Volume	Specify the volume of the lead off sound.	0 1 2 [3] 4 5
Event Sound Volume	Specify the volume of the event sound.	0 1 2 [3] 4 5
Warning Tone Volume	Specify the volume of the warning tone.	1 2 [3] 4 5
Error Tone Volume	Specify the volume of the abnormality tone.	1 2 [3] 4 5
File Save Tone Volume	Specify the volume of the file save tone.	0 1 2 [3] 4 5
Prohibited Tone Volume	Specify the volume of the prohibited tone.	0 1 2 [3] 4 5
Print Start Volume	Specify the volume of the print start sound.	0 1 2 [3] 4 5
Key Sound Volume*	Specify the volume of the key sound.	0 1 2 [3] 4 5
Heartbeat Sound Volume*	Specify the volume of the heartbeat sound.	0 1 2 [3] 4 5
Ex. Start Sound Volume*	Specify the volume of the examination start sound.	0 1 2 [3] 4 5
Ex. End Sound Volume*	Specify the volume of the examination end sound.	0 1 2 [3] 4 5

General

Process End Tone Volume*	Specify the volume of the process end tone.	0 1 2 [3] 4 5

Printer Output

ECG Common

Setup Item	Description	Setting Range
Grid	Specify whether to print grids.	[No], Black, Color
Wave Thickness	Specify the printing waveform thickness.	Thin, [Normal], Thick

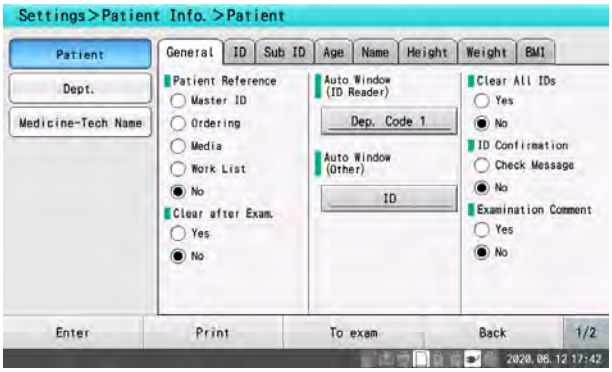
Localization

General

Setup Item	Description	Setting Range
Language	Select the displayed language.	[ENGLISH], Japanese, FRANÇAIS, ITALIANO, ESPAÑOL, DEUTSCH, русский, PORTUGUÊS, Tiếng Việt
Length Unit	Select the height unit.	[cm], inch
Weight Unit	Select the weight unit.	[kg], lb
Pressure Unit	Select the blood pressure unit.	[mmHg], kPa
Date Format	Select the date format.	[YYYY/MM/DD], MM/DD/YYYY, DD/MM/YYYY
UTC +/-	Sets the time difference between the UTC (Coordinated Universal Time).	+09:00
Decimal Marker	Specify the character to be used for the decimal point.	[(period)], (comma)

Patient Information

Configure settings relating to entering the patient information.



Patient

General

Setup Item	Description	Setting Range
Patient Reference	Specify the source to refer the patient information.	Master ID Ordering Media Work List [No]
Clear after Exam.	Specify whether to automatically delete the patient information after saving the examination data to the specified media.	Yes, [No]
Auto Window (ID Reader)	Specify the window to be opened when patient information is entered using an ID card or barcode.	ID, Sub ID, Age, Gen., Name, [Dep. Code 1], Dep. Code 2-4, Height, Weight, Medicine, Symptom, Comment, BP, Doctor, Tech.
Auto Window (Other)	Specify the window to be opened when patient information is entered by means other than an ID card or barcode.	[ID], Sub ID, Age, Gen., Name, Dep. Code 1-4, Height, Weight, Medicine, Symptom, Comment, BP, Doctor, Tech.
Clear All IDs	Specify whether to clear the previous patient information after entering the ID number.	Yes, [No]
ID Confirmation	A caution message can be displayed if the same ID number is entered for the same examination on the same day.	Check Message, [No]
Examination Comment	Specify whether to display the examination comment.	Yes, [No]

ID

Setup Item	Description	Setting Range
Enter	Specify whether to enter, display and print ID numbers.	[Yes], No
Number of digits	Specify the number of digits to be used in ID numbers.	[12], 3 to 20
ID Auto Increment	Automatically generates ID numbers by adding 1 after using automatic recording.	Yes, [No]
Prefix*	Desired alphanumeric characters can be added as a prefix to ID numbers.	Desired alphanumeric characters
Hyphen Position*	Specify up to 3 hyphen positions in th ID numbers.	-
ID Format*	Numeric only: Allows numbers to be input only using the number keys. Alphanum.: Allows numbers to be input using the number keys and alphabetical characters using the full keyboard.	[Numeric only], Alphanum.
Backup*	Yes: Data is backed up. The content from before the power was turned off is called the next time the power is turned on. No: Data is not backed up. Daily: Recorded data is erased at the end of each day.	Yes, [No], Daily

Sub ID

Setup Item	Description	Setting Range
Enter	Specify whether to enter, display and print ID numbers.	[Yes], No
Number of digits	Specify the number of digits to be used in ID numbers.	[12], 3 to 20
ID Auto Increment	Specify whether to automatically increment the ID.	Yes, [No]
Name	Specify the name of the sub ID.	[Sub ID] Maximum of 8 characters.
Prefix*	Desired alphanumeric characters can be added as a prefix to ID numbers.	Desired alphanumeric characters
Hyphen Position*	Specify up to 3 hyphen positions in th ID numbers.	-
ID Format*	Numeric only: Allows numbers to be input only using the number keys. Alphanum.: Allows numbers to be input using the number keys and alphabetical characters using the full keyboard.	[Numeric only], Alphanum
Backup*	Yes: Data is backed up. The content from before the power was turned off is called the next time the power is turned on. No: Data is not backed up. Daily: Recorded data is erased at the end of each day.	Yes, [No], Daily

Age

Setup Item	Description	Setting Range
Entering Method	Birthday: Entering the birthday will automatically calculate the age. Age: Enter the patient's age.	[Birthday], Age
Backup*	Yes: Data is backed up. The content from before the power was turned off is called the next time the power is turned on. No: Data is not backed up. Daily: Recorded data is erased at the end of each day.	Yes, [No], Daily

Name

Setup Item	Description	Setting Range
Input Area	Specify the quantity of name input field.	[0 (None)], 1, 2
Name-Backup*	Yes: Data is backed up. The content from before the power was turned off is called the next time the power is turned on. No: Data is not backed up. Daily: Recorded data is erased at the end of each day.	Yes, [No], Daily
Gen.-Backup*	Yes: Data is backed up. The content from before the power was turned off is called the next time the power is turned on. No: Data is not backed up. Daily: Recorded data is erased at the end of each day.	Yes, [No], Daily

Height

Setup Item	Description	Setting Range
Enter	Specify whether or not to enter, display and print the patient's height.	Yes, [No]

Weight

Setup Item	Description	Setting Range
Enter	Specify whether or not to enter, display and print the patient's weight.	Yes, [No]

BMI

Setup Item	Description	Setting Range
Display	Specify whether or not to display and print the patient's BMI. (BMI = Weight (kg) / Height (m))2)	[Yes], No

Dept.

Dept. 1-2/Dept 3-4

Setup Item	Description	Setting Range
Enter	Specify whether or not to enter, display and print the department code.	Yes, [No]
Attr	Specify the character string displays after the name of the department.	Dept. 1: [Ward] Dept. 2: [Depart.] Dept. 3, 4: —
No. of Digits	Specify the number of digits of department codes.	4-8 digits [4 digits]
Regist Code	Register a department code. A total of up to 200 codes can be registered. (16 characters)	—
Input Prohibit.*	Set the current content so that it cannot be changed.	Yes, [No]
Backup*	Yes: Data is backed up. The content from before the power was turned off is called the next time the power is turned on. No: Data is not backed up. Daily: Recorded data is erased at the end of each day.	Yes, [No], Daily

Medicine-Tech. Name

Medicine-Symptom

Setup Item	Description	Setting Range
<Medicine>		
Medicine-Enter	Specify whether or not to enter medicine information.	Yes, [No]
No. of Digits	Specify the number of digits of medicine codes.	2 to 4 [2]
Regist Code	Register a medicine code. Up to 20 codes can be registered. (16 characters)	-
Backup*	Yes: Data is backed up. The content from before the power was turned off is called the next time the power is turned on. No: Data is not backed up. Daily: Recorded data is erased at the end of each day.	Yes, [No], Daily
<Symptom>		
Symptom-Enter	Specify whether or not to enter, display and print subjective symptoms.	Yes, [No]
No. of Digits	Specify the number of digits of subjective symptom codes.	2 to 4 [2]
Regist Code	Register a subjective symptom code. Up to 20 codes can be registered. (16 characters)	-
Backup*	Yes: Data is backed up. The content from before the power was turned off is called the next time the power is turned on. No: Data is not backed up. Daily: Recorded data is erased at the end of each day.	Yes, [No], Daily

Comment

Setup Item	Description	Setting Range
Comment-Enter	Specify whether or not to enter, display and print comments.	Yes, [No]
No. of Digits	Specify the number of digits of comment codes.	2 to 4 [2]
Regist Code	Register a comment code. Up to 20 codes can be registered. (16 characters)	-
Comm. Button	Specify whether or not to display the comment input window on the examination screen.	Yes, [No]
Comment Display	Specify whether or not to display ordering comments on the examination screen.	Yes, [No]
Comment	Specify the ordering comment type.	[Comment 1], Comment 2, Interpretation Comment 1 to 5, Purpose Comments 1 to 5, Free Comments 1 to 10
Examination Comment	Specify the examination comment type for ordering.	Comment 1, Comment 2, Interpretation Comment 1 to 5, [Purpose Comments 1], 2 to 5, Free Comments 1 to 10

BP-RR

Setup Item	Description	Setting Range
Enter BP	Specify whether or not to enter, display and print the patient's blood pressure.	Yes, [No]
Input body position	Specify whether or not to enter, display and print the patient's body position.	Yes, [No]
Enter RR	Specify whether or not to enter, display and print the patient's respiration rate.	Yes, [No]

Doctor-Tech.

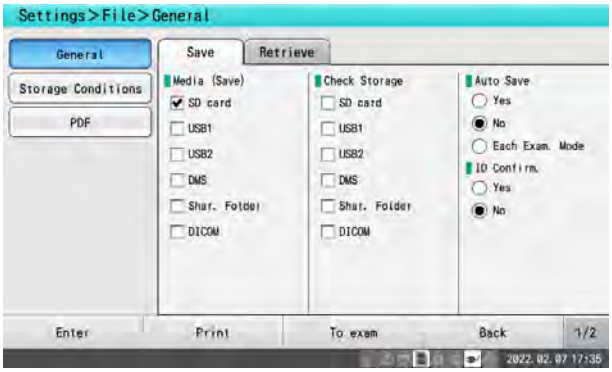
Setup Item	Description	Setting Range
<Doctor Name 1-2>		

Doctor-Tech.

Doctor 1, 2 Enter	Specify whether or not to enter, display and print the doctor name.	Yes, [No]
No. of Digits	Specify the number of digits of doctor codes.	2 to 12, [4]
Regist Code	Register doctor names (100 each). (24 characters)	-
Input Prohibit.*	Set the current content so that it cannot be changed.	Yes, [No]
Clear All*	Specify whether or not to keep the doctor names when clearing all other information.	[Delete], Keep
Backup*	Yes: Data is backed up. The content from before the power was turned off is called the next time the power is turned on. No: Data is not backed up. Daily: Recorded data is erased at the end of each day.	Yes, [No], Daily
<Technician>		
Tech.-Enter	Specify whether or not to enter, display and print technician names.	Yes, [No]
No. of Digits	Specify the number of digits of technician codes.	2 to 12, [4]
Regist Code	Register doctor names (100 each). (24 characters)	-
Input Prohibit.*	Set the current content so that it cannot be changed.	Yes, [No]
Clear All*	Specify whether to keep the technician names when clearing all other information.	[Delete], Keep
Backup*	Yes: Data is backed up. The content from before the power was turned off is called the next time the power is turned on. No: Data is not backed up. Daily: Recorded data is erased at the end of each day.	Yes, [No], Daily

File

Configure settings relating to saving and loading data and communication with other devices.



General

Save

Setup Item	Description	Setting Range
Media (Save)	Specifies the media to save the data. Multiple items can be specified.	[SD Card], USB1, USB2, DMS, Shar. Folder, DICOM
Check Storage	Specify the media to display the confirmation message when the examination result is not saved. Multiple items can be specified.	SD Card, USB1, USB2, DMS, Shar. Folder, DICOM
Auto Save	Specify whether to automatically save the data. Yes: Data will be automatically saved. No: Auto saving will not be performed.	Yes, [No], Each Exam. Mode
ID Confirm.	Specify whether or not to display the confirmation window to save or re-enter ID when the ID is not entered.	Yes, [No]

Retrieve

Setup Item	Description	Setting Range
Media (Read)	Specify the media to load the data.	[SD card], USB1, USB2 DMS, Int. Memory
Reanalyze	Specify whether to reanalyze when a file is retrieved.	Yes, [No]
Display List*	Set the display format for the file list. Date Order: Sorted by date and displayed starting with the latest date. Index Order: Sorted by index and the first page is displayed. Index (Newest): Sorted by index and the latest page is displayed.	[Date Order], Index Order, Index (Newest)
List Display*	Specify whether to automatically display a list when reading data from DMS. Yes: Examination data list will be displayed. No: List will not be displayed	Yes, [No]
Full Disclosure Wave Format*	Specify the type of the retrieving full disclosure waveform. Only Analysis: Outputs the waveform report + the measurement report of the measured range. All waveform: Outputs all the full disclosure waveform report. Analysis + Waveform: Outputs the waveform report +measurement report + all waveform report of the measured range.	[Only Analysis], All waveform, Analysis+Waveform

Storage Conditions

File Name

Setup Item	Description	Setting Range
Naming Rule	Specify the file name for FDA-XML, PDF.Multiple items can be selected.	ID, Sub ID, [Examination Date],Birth Date
Symbol	Specify whether to use symbol for the file name.	[Yes], No

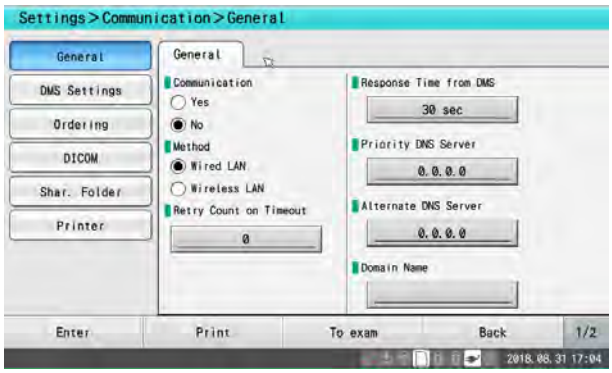
PDF

General

Setup Item	Description	Setting Range
Auto Save	Specify whether to automatically save the data after the examination.	Yes, [No]
Media (Save)	Specify where to automatically save the PDF file.	[SD card], USB1, USB2, Shar. Folder

Communication

Configure network communication settings.



General

General

Setup Item	Description	Setting Range
Communication	Specify whether to communicate with other devices.	Yes, [No]
Method	Specify whether to use wired LAN or wireless LAN.	[Wired LAN], Wireless LAN
Retry Count on Timeout	Specify the retry count when a timeout occurs during communication.	0 to 5, [0]
Response Time from DMS	Specify the response time to receive data from DMS.	[30 sec], 10 sec to 180 sec
Priority DNS Server	Specify the IP address of the priority DNS server. *When "Host Info" is set, connection with the host information server will be prioritized.	0.0.0.0
Alternate DNS Server	Specify the IP address of the alternate DNS server. *When "Host Info" is set, connection with the host information server will be prioritized.	0.0.0.0
Domain Name	Specify the domain name of the DNS server. *When "Host Info" is set, connection with the host information server will be prioritized.	—

DMS Settings

DMS Settings

Setup Item	Description	Setting Range
Subnet Mask	Set the subnet mask of the gateway.	[0.0.0.0]
Default Gateway	Set the IP address of the gateway.	[0.0.0.0]
NTP Server	Set the IP address of the NTP server.	[0.0.0.0]

Host Info

Setup Item	Description	Setting Range
For Retrieving Name	Specify the host name of the recording/reviewing server.	[DMS]
For Retrieving IP Address	Specify the IP address of the recording/reviewing server.	[0.0.0.0]
For Retrieving Port	Specify the port number of the recording/reviewing server.	[0], 5 digits
Ordering Name	Specify the host name of the ordering server.	—
Ordering IP Address	Specify the IP address of the ordering server.	[0.0.0.0]
Ordering Port	Specify the port number of the ordering server.	[0], 5 digits
Shared Folder Name	Specify the host name of the save destination of the shared folder.	—
Shared Folder IP Address	Specify the IP address of the save destination of the shared folder.	[0.0.0.0]
Shared Folder Port	Specify the port number of the save destination of the shared folder.	[0], 5 digits

Device Info.

Setup Item	Description	Setting Range
Device Name	Specify the device name.	[ECG]
IP Address	Specify the IP address of ECG.	Auto, [Manual (0.0.0.0)]
SSID	Specify the SSID.	Up to 32 single-byte alphanumeric characters and symbols
Authentication	Specify the authentication method.	WEP64Bit, WEP128Bit, [WPA], WPA2
Network key	Specify the network key.	Up to 64 single-byte alphanumeric characters and symbols

Ordering

General

Setup Item	Description	Setting Range
Operation mode	Specify the operation mode for the ordering system. No: Ordering function will not operate. Online: Ordering information will be obtained from the data management system (DMS).	[No], Online
After Each Exam	Select whether or not to display the order information list at the end of each examination when one order contains multiple examinations.	[Yes], No
After Order Ends	Displays the order information list when the order is completed.	[Yes], No
ID Reader Search	Links the order information search function with ID reader. The ID number or order number from the order information is used as a search condition.	[No], ID, Order No.
Continue Order	Specify whether or not to continue to use the order number when conducting an unordered examination for the same patient after conducting an ordered examination.	Yes, [No]
Order No. Character	Specify the order number characters.	Numeric only, [Alphanum.]
Order Format	Specify the order format.	[Standard], Extended
Examination Date	Specify the default display of examination date of the search order window.	[Today], Yest-Today

DICOM

General 1

Setup Item	Description	Setting Range
Device Info. AE Title	Specify the AE title name of the ECG. Up to 16 single-byte alphanumeric characters and symbols can be entered.	-
Save to DICOM	Specify whether or not to save to DICOM.	Yes, [No]
DICOM DIR	Specify whether or not to save to DICOM DIR.	Yes, [No]
Acquire Work List	Specify whether or not to acquire work list.	Yes, [No]
MPPS	Specify whether or not to perform MPPS.	Yes, [No]
Format	Specify the image format to save to DICOM.	[Lossy JPEG], BMP, PDF, ECG
Image Resolution	Specify the image resolution to save to DICOM.	Low, Medium, [High]

General 2

Setup Item	Description	Setting Range
ID Zero Suppress	Specify whether or not to remove redundant zeros from ID or sub ID when saving to DICOM or DICOM DIR. Yes: Zero will be removed. No: Zero will not be removed.	Yes, [No]

Storage Server

Setup Item	Description	Setting Range
Storage Server AE Title	Specify the AE title of the storage server. Up to 16 single-byte alphanumeric characters and symbols can be entered.	-
Storage Server IP Address	Specify the IP address of the storage server.	[0.0.0.0]
Storage Server Port	Specify the port number of the storage server.	[104], 0 to 65535
Save Image Modality Code	Specify the modality code to communicate with the storage server. Up to 16 single-byte alphanumeric characters and symbols can be entered.	[ECG]

MWM Server

Setup Item	Description	Setting Range
MWM Server AE Title	Specify the AE title of the MWM server. Up to 16 single-byte alphanumeric characters and symbols can be entered.	-
MWM Server IP Address	Specify the IP address of the MWM server.	[0.0.0.0]
MWM Server Port	Specify the port number of the MWM server.	[104], 0 to 65535
Save Image Modality Code	Specify the modality code to communicate with the MWM server. Up to 16 single-byte alphanumeric characters and symbols can be entered.	[ECG]

MPPS Server

Setup Item	Description	Setting Range
MPPS Server AE Title	Specify the AE title of the MPPS server. Up to 16 single-byte alphanumeric characters and symbols can be entered.	-
MPPS Server IP Address	Specify the IP address of the MPPS server.	0.0.0.0
MPPS Server Port	Specify the port number of the MPPS server.	[104], 0 to 65535

Shared Folder

General

Setup Item	Description	Setting Range
Mounted Directory	Specify the name of the shared folder set on the Windows computer. Up to 128 single-byte characters can be entered.	-
Login name	Specify the login name to access the shared folder. Up to 32 single-byte characters can be entered.	-
Password	Specify the password to access the shared folder. Up to 32 single-byte characters can be entered.	-
Domain	Specify the domain if the user belongs to a domain. This setting is not necessary if the user does not belong to a domain. Up to 32 single-byte characters can be entered.	-

Printer

General

Setup Item	Description	Setting Range
Network Printer	Specify whether or not to use the network printer.	Yes, [No]
IP Address	Specify the IP address of the network printer.	[0.0.0.0]
Port	Specify the port number of the network printer.	[9100], 0 to 65535

External Device

ID Reader 1 and 2

Set the type, operations and data format of the ID reader.
The settings for ID Reader 1, 2 will be also set for USB Port 1, 2 respectively.

ID Reader Type 1, 2

Specify the type of ID reader.

Setup Item	Description	Setting Range
Control Type	Specify the control type of the ID reader.	No protocol, [ACK response]
Comm. speed	Specify the communication speed.	1200, 2400, 4800, [9600]
Data bit Length	Specify the data bit length.	[7], 8
Stop bit Length	Specify the stop bit length.	[1], 2
Parity	Specify the parity bit.	No, [Even], Odd
Bit Eff. Length	Specify the bit efficiency length of the received ID data.	6, [7], 8
Retry times	Specify the retry times.	[1], 2 to 9
Data type	Specify the data type.	TYPE0 (Fixed), TYPE1 (CR, LF), TYPE2 (STX-ETX), [TYPE3 (STX-ETX,BCC)]
Max data size	Specify the maximum data size.	[72], 1 to 256

ID Data Format 1

Specify the start position and end position for loading each item.

Setup Item	Description	Setting Range
Check window	ID card confirmation window will be displayed.	-
Start/End pos.	ID/Sub ID/Name/D.O.B./Gen./Age/Weight/Height/Dept.(1-4)/ Comment/BP(SYS/DIA)/Doctor(1-2)/Doctor Code(1-2)/Tech./ Tech Code/Order No.	-

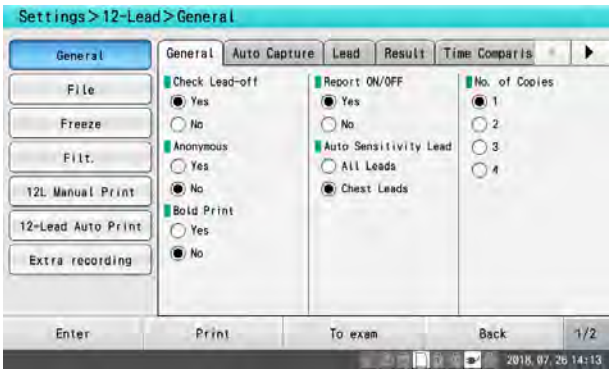
ID Data Format 2

Specify the format of each item on the ID card.

Setup Item	Description	Setting Range
ID Format	Specify the ID format.	[Numeric only], Alphanum., 0 Replacement
Sub ID Format	Specify the sub ID format.	[Numeric only], Alphanum., 0 Replacement
Female Character	Specify the character to indicate "Female".	[F]
Male Character	Specify the character to indicate "Male".	[M]

12-Lead Examination

Set the items for 12-lead examinations.



General

General

Setup Item	Description	Setting Range
Check Lead-off	Specify whether to stop recording if lead-off occurs during recording.	[Yes], No
Anonymous	Specify whether or not to make patient information anonymous.	Yes, [No]
Bold Print	Specify whether or not to print the patient information and interpretation in bold text.	Yes, [No]
Report ON/OFF	Specify whether or not to print the report automatically.	[Yes], No
Auto Sensitivity Lead	Specify the leads for performing auto sensitivity for waveform reports by the 12-lead examination.	All Leads, [Chest Leads]
No. of Copies	Specify the number of copies to be printed.	[1], 2 to 4
Display Interpretation	Specify whether to print interpretation name on the result report	[Yes], No

Auto Capture

Setup Item	Description	Setting Range
Auto Capture	Specify whether or not to use the auto capture function.	Yes, [No]
Capture End Time	Specify the auto capture end time.	[1min 0sec], 30sec-5min

Lead

Setup Item	Description	Setting Range
Lead Setting	Specify the leads for conducting examinations.	[Standard 12-Lead], Cabrera Lead
R wave detection lead	Specify the lead and the method for detecting R waves.	I, [II], III, V1 to V6 [Fixed], Auto

Result

Setup Item	Description	Setting Range
Display Result	Specify whether or not to display the measurement result after the automatic measurement. This is enabled only when resting. No: Measurement results are not displayed. Before Wave Report: The measurement results are displayed before printing the waveform report. After Wave Report: The measurement results are displayed after printing the waveform report.	No, Before Wave Report, [After Wave Report]
Waveform Display Phase	Specify the waveform display phase on the result display.	[Continuous], Coherent
ST Display	Specify whether to display ST values for extracted waveforms in the result display.	[Yes], No

Result

Result Display Order	Specify the initial setting of the result display.	[Result], Waveform, Dominant, Detail Measurements

Time Comparison

Setup Item	Description	Setting Range
Time Comparison	Specify whether to perform time comparison.	Yes, [No]

Display

Setup Item	Description	Setting Range
Waveform Display	Specify the display type of real time waveforms when the power is turned ON.	3ch, 6ch, [6ch×2]
Waveform Display Phase	Specify the waveform phase when the waveform display is 6ch x 2.	Continuous, [Coherent]

Print Interval

Setup Item	Description	Setting Range
Print Interval	Specify the print interval for automatic printing.	No, 30 sec, 1 min, 2 min, [3 min], 4 min, 5 min, 10 min, 15 min, 30 min, 60 min
Print at Set Time	Specify the time to perform automatic printing. A maximum of 10 times can be specified.	0 to 59 minutes [0, 1, , , , , , , min]
Compressed Print Ch.	Specify number of leads of the compressed waveform report.	3ch, [6ch],12ch
Compress. Print*	Specify compressed printing between periodic printing and the next periodic printing.	[No] 5 mm/s 10 mm/s 12.5mm/s
Wave Comparison Report*	Specify whether or not to output the wave comparison report.	Yes, [No]
Summary Report*	Specify whether or not to output the summary report after the periodic printing.	Yes, [No]
Stop Print at Lead-OFF	Specify whether to stop printing when lead-off occurs during periodic printing.	[Yes], No

REFERENCE

- Interval period and the specified time are ignored while capturing and recording waveforms.

ACS Diagnostic Support

Setup Item	Description	Setting Range
ACS Diagnostic Support Function	Specify whether to use the ACS diagnostic support function.	Yes, [No]
Check Subjective Symptoms	Specify whether or not to enter the subjective symptoms. If [Yes] is selected, select also the timing to enter the symptoms from “Always” or “Abnormal Finding”.	[Yes], Always, [Abnormal Finding], No
Synthesized Lead Analysis	Specify whether to perform the synthesized lead analysis.	[Yes], [Right-sided Leads (V3R,V4R,V5R)], Posterior Leads (V7,V8,V9), No
Occluded Vessel Analysis	Specify whether or not to perform occluded vessel analysis.	[Yes], No
ACS Analysis Result	Specify the condition to display the results display. Always: The results will be always displayed regardless of the ACS analysis result. At abnormal condition: Displays the results only at the abnormal condition.	[Always], Abnormal Finding

File

General

Setup Item	Description	Setting Range
Auto Save	Specify whether to automatically save the examination data to the media after the examination.	Yes, [No]
Save at Periodic Print.	Specify whether to automatically save the examination data to the media after the periodic print.	Yes, [No]

General

Save to	Specify the media to save the data.	[SD Card], USB1, USB2, DMS, Shar. Folder, DICOM
At Analysis Error	Specify whether to save results when error occurs.	[Cancel], Continue

Waveform Report

Setup Item	Description	Setting Range
Waveform Report	Specify whether or not to output the waveform report.	[Yes], No
Report Format	Specify the report format.	3ch×4, 3ch×4+Rhythm 1 ch, 3ch×4+Rhythm 2 ch, [6ch×2] 6ch×2+Rhythm 1 ch, 12ch
Wave. Type	Continuous: Outputs the continuous waveform report. Coherent (In-Phase): Outputs a report in coherent form for a specified number of seconds. Coherent (Full): Outputs the full waveform in coherent form.	[Continuous], Coherent (In-Phase), Coherent (Full)
Rhythm Lead	Specify the rhythm lead.	I, [II], III, aVR, aVL, aVF, V1, V2, V3, V4, [V5], V6
Print HR	Specify whether to print HR on the waveform report.	[Yes], No

Results Report 1

Setup Item	Description	Setting Range
Results Report	Specify whether or not to output the results report.	[Yes], No
Det. Meas. Report	Specify the report format.	Yes, [No]
Results Rep. Fmt.	Specify the results report format.	[DOM1], DOM2+Rhythm 1ch, DOM2+Rhythm 2ch, DOM3 FULL3+Rhythm 1ch, FULL3+Rhythm 2ch, FULL6, FULL6+Rhythm 1ch, Cover, Panorama, Time Comparison
Analysis Report	Specify the grade of findings to be output in the analysis report. Interpret.: Prints analysis report for all interpretations. Auto: Prints the report for high-grade interpretations. Grade 6 Only: Prints the report only for the grade 6. Grade 4 or higher: Prints the report for grade 4 or higher. Grade 2 or higher: Prints the report for grade 2 or higher. No: Analysis report is not printed.	Interpret., Auto, Grade 6 Only, Grade 4 or higher, Grade 2 or higher, [No]
Commentary Report	Specify the grade of findings to be output in the commentary report. Interpret.: Prints report for all interpretations. Auto: Prints the report for high-grade interpretations. Grade 6 Only: Prints the report only for the grade 6. Grade 4 or higher: Prints the report for minimum grade 4 or higher. Grade 2 or higher: Prints the report for minimum grade 2 or higher. No: Commentary report is not printed.	Interpret., Auto, Grade 6 Only, Grade 4 or higher, Grade 2 or higher, [No]
Extracted Wave.*	Specify the extracted waveform.	[Dominant], Average
Full Lead Waveform*	Specify the type of the full lead waveform for FULL3 and FULL6.	[Continuous], Coherent
Print mild interpre.*	Specify whether or not to print the mild interpretations.	[Yes], No
Warning Comment*	Specify whether or not to print the warning comment.	Yes, [No]

Results Report 1

Edit Abnormal wave*	Specify whether or not to print abnormal waves such as misplacing electrodes or recording failure.	Priority, [Standard]
Print ST*	Specify whether to print ST value on the upper right of the dominant.	Yes, [No]
PAC, PVC Mark*	Specify whether or not to print the PAC and PVC mark.	[Yes], No
Plot measurement*	Specify whether or not to print the point used for the waveform measurement.	Yes, [No]
Auto Sensitive*	Specify the auto sensitivity for the dominant waveform of the results report.	No, [Chest Leads], All Leads

Results Report 2

Setup Item	Description	Setting Range
Check Comment	Specify whether or not to include check comment.	[Yes], No
Edit Interpretation	Specify the method for editing the interpretation section. Judgment+Interp.: Interpretation is printed when general judgment+interpretation name+Brugada code exist. Interp.: Interpretation is printed when interpretation name+Brugada code exist. Interp. Title Only: Only the interpretation title is printed.	[Judgment+Interp.], Interp., Interp. Title Only
Brugada Risk Analysis	Specify whether or not to include the Brugada risk analysis.	Yes, [No]
Brugada Risk Report	Specify whether or not to include the Brugada risk report.	Yes, [No]
ACS Summary Report	Specify the output condition for the ACS summary report. Always: Always outputs the report regardless of the ACS analysis result. Abnormal Finding: Outputs only at abnormal condition. No: Nothing is outputted.	[Always], Abnormal Finding, No
ACS Guide Report	Specify the output condition for the ACS guide report. Always: Always outputs the report regardless of the ACS analysis result. Abnormal Finding: Outputs only at abnormal condition. No: Nothing is outputted.	[Always], Abnormal Finding, No

Freeze

Freeze

Setup Item	Description	Setting Range
Record Time	Specify the waveform recording duration at freeze condition.	[1min] 1-5
Save Extension	Specify the default of the check box for the save extension of the full disclosure wave. Auto save is also performed as the save extension.	Yes, [No]
Freeze/Result Display	Specify whether or not to display the freeze/result display. Same w/Exam. Result: The result display will be according to the setting under [General>Display>Display Result]. No: Results are not displayed. Before Wave Report: The result display is displayed before printing the waveform report. After Wave Report: The result display is displayed after printing the waveform report.	[Same w/Exam. Result], No, Before Wave Report, After Wave Report
Save Freeze Analysis	Specify whether or not to save each freeze analysis when auto save function is set.	[Yes], No
Freeze Position	Specify the default of the analysis position for displaying the freeze display.	First, Middle, [Last]

Filter

General

Setup Item	Description	Setting Range
LP filter prop.	Specify high frequency characteristics.	75 Hz, 100 Hz, [150 Hz], 250 Hz
Drift Filter	Specify drift removal filter characteristics.	OFF, [Strong (0.5 Hz)], Weak (0.25 Hz)
Muscle Filter	Specify EMG filter characteristics.	[OFF], Strong (25 Hz), Weak (35 Hz)
Hum Filter	Specify ON/OFF for AC filter.	[OFF], Strong, Weak

12-Lead Manual Printing

General

Setup Item	Description	Setting Range
No. of Print Channels	Specify the number of channels for 12-lead manual printing.	3 ch, [6 ch], 12ch
Analyze	Specify whether or not to measure.	Yes, [No]
Adjust Print Position	Adjust the print position of the waveform. No: Adjustment is not performed. (0mV is the center) Centered: Adjusts the baseline to be the center. Proportional: Equalizes the blank space between each channel to avoid overlapping of the waveforms.	No, Centered, [Proportional]
Calibration Wave	STD: Prints the calibration waveform on the baseline position. Overlap: Prints the calibration waveform overlapped with the waveforms.	STD, [Overlap]
Auto Printing	Specify whether to automatically print the calibration waveform when switching leads of the manual printing, etc. No: Calibration waveform is not printed. Before Waveform: Prints before waveform. After Waveform: Prints after waveform.	No, Before Waveform, [After Waveform]

12-Lead Auto Printing

General

Setup Item	Description	Setting Range
Auto Sensitivity	Specify the automatic sensitivity method. 1 + Auto: When a large waveform appears while recording with a sensitivity of 1 cm/mV, its lead block will be recorded again with auto sensitivity.	[Auto], 1+Auto, Auto+1, Sensitivity1
Adjust Print Position	Adjust the print position of the waveform. No: Adjustment is not performed. (0mV is the center) Centered: Adjusts the baseline to be the center. Proportional: Equalizes the blank space between each channel to avoid overlapping of the waveforms.	No, Centered, [Proportional]
Check Electrode Message	Specify whether or not to display the message for misplacing the leads.	[Yes] No
Insert CAL	Specify the condition for the calibration waveform. Yes: Prints the calibration waveform on all leads. No: Prints the calibration waveform on only the first block. When changed: Prints the calibration waveform when the sensitivity is other than 1cm/mV.	Yes, No, [When changed]
Print Position	Specify the print position of the calibration waveform.	[Before Waveform], After Waveform
Review Printing Time Shift	Set the time shift for review printing.	[10 sec], 8 sec to 12 sec

Waveform Report

Setup Item	Description	Setting Range
Waveform Report	Specify whether or not to output the waveform report.	[Yes], No
Rec. Range (Z-Fold)	Specify the waveform recording duration.	[1 sheet], 2 sheets
Rec. Range (Roll)	Specify the waveform recording duration.	[10 sec], 8 sec to 24 sec
Report Format	Specify the format for 12-lead printing.	3ch×4, 3ch×4+Rhythm 1ch, 3ch×4+Rhythm 2ch, [6ch×2], 6ch×2+Rhythm 1ch, 12ch
Wave. Type	Continuous: Prints the waveform of each lead block as a continuous report, total time to be the specified time. Coherent (In-Phase): Prints the waveform of each lead block with in-phase, total time to be the specified time. Coherent (Full): Prints the waveform of each lead block with full wave.	[Continuous], Coherent (In-Phase), Coherent (Full)
Rhythm Lead	Specify the waveform of the rhythm lead.	I, [II], III, aVR, aVL, aVF, V1, V2, V3, V4, [V5], V6
Print HR	Specify whether to print HR on the waveform report.	[Yes], No

Results Report 1

Setup Item	Description	Setting Range
Results Report	Specify whether or not to output the results report.	[Yes], No
Det. Meas. Report	Specify the report format.	Yes, [No]
Results Rep. Fmt.	Specify the results report format.	[DOM1], DOM2+Rhythm 1ch, DOM2+Rhythm 2ch, DOM3 FULL3+Rhythm 1ch, FULL3+Rhythm 2ch, FULL6, FULL6+Rhythm 1ch, Cover, Panorama, Time Comparison
Analysis Report	Specify the grade of findings to be output in the analysis report. Interpret.: Prints analysis report for all interpretations. Auto: Prints the report for high-grade interpretations. Grade 6 Only: Prints the report only for the grade 6. Grade 4 or higher: Prints the report for grade 4 or higher. Grade 2 or higher: Prints the report for grade 2 or higher. No: Analysis report is not printed.	Interpret., Auto, Grade 6 Only, Grade 4 or higher, Grade 2 or higher, [No]
Commentary Report	Specify the grade of findings to be output in the commentary report. Interpret.: Prints report for all interpretations. Auto: Prints the report for high-grade interpretations. Grade 6 Only: Prints the report only for the grade 6. Grade 4 or higher: Prints the report for minimum grade 4 or higher. Grade 2 or higher: Prints the report for minimum grade 2 or higher. No: Commentary report is not printed.	Interpret., Auto, Grade 6 Only, Grade 4 or higher, Grade 2 or higher, [No]
Extracted Wave.*	Specify the extracted waveform.	[Dominant], Average
Full Lead Waveform*	Specify the type of the full lead waveform for FULL3 and FULL6.	[Continuous], Coherent
Print mild interpre.*	Specify whether or not to print the mild interpretations.	[Yes], No
Warning Comment*	Specify whether or not to print the warning comment.	Yes, [No]

Results Report 1

Edit Abnormal wave*	Specify whether or not to print abnormal waves such as misplacing electrodes or recording failure.	Priority, [Standard]
Print ST*	Specify whether to print ST value on the upper right of the dominant.	Yes, [No]
PAC, PVC Mark*	Specify whether or not to print the PAC and PVC mark.	[Yes], No
Plot measurement*	Specify whether or not to print the point used for the waveform measurement.	Yes, [No]
Auto Sensitive*	Specify the auto sensitivity for the dominant waveform of the results report.	No, [Chest Leads], All Leads

Results Report 2

Setup Item	Description	Setting Range
Check Comment	Specify whether to include the check comment.	[Yes], No
Edit Interpretation	Specify the method for editing the interpretation section. Judgment+Interp.: Can be printed when general judgment+interpretation name+Brugada code exist. Interp.: Can be printed when interpretation name+Brugada code exist. Interp. Title Only: Only the interpretation title is printed.	[Judgment+Interp.],Interp., Interp. Title Only
Brugada Risk Analysis	Specify whether or not to include the Brugada risk analysis.	Yes, [No]
Brugada Risk Report	Specify whether or not to include the Brugada risk report.	Yes, [No]
ACS Summary Report	Specify the output condition for the ACS summary report. Always: Always outputs the report regardless of the ACS analysis result. Abnormal Finding: Outputs only at abnormal condition. No: Nothing is outputted.	[Always], Abnormal Finding, No
ACS Guide Report	Specify the output condition for the ACS guide report. Always: Always outputs the report regardless of the ACS analysis result. Abnormal Finding: Outputs only at abnormal condition. No: Nothing is outputted.	[Always], Abnormal Finding, No

Auto Extension

Setup Item	Description	Setting Range
Auto Print Extension	Specify whether to start arrhythmia recording automatically when the specified finding code and grade are obtained after automatic analysis.	[No], Yes
Extension Conditions	Specify the condition to perform auto extension.	[Extension Code], Grade 6 Only, Grade 4 or higher, Grade 2 or higher, No
Extension Code	Set the interpretation code to perform the extra recording when the extension code is set.	[412, 413, 414, 415, 803, 804, 816, 831, 841, 842, 843, 844, 845, 846, 847, 848, 851, 852, 862, 864, 865, 866, 867, 871, 872, 881]

Printer Output/PDF1

Setup Item	Description	Setting Range
Waveform Report	Specify whether or not to automatically print the waveform report.	Yes, [No]
Report Format	Specify the report format.	3ch×4, 3ch×4+Rhythm 1ch, 3ch×4+Rhythm 2ch, [6ch×2], 6ch×2+Rhythm 1ch, 12ch (Vertical)
Results Report	Specify whether or not to automatically print the results report.	Yes, [No]

Printer Output/PDF1

Results Rep. Fmt.	Specify the results report format.	[DOM1], DOM2+Rhythm 1ch, DOM2+Rhythm 2ch, DOM3 FULL3+Rhythm 1ch, FULL3+Rhythm 2ch, FULL6 FULL6+Rhythm 1ch, Panorama
Det. Meas.Report	Specify whether or not to output the detailed measurements report.	Yes, [No]
Analysis Report	Specify whether to print analysis report automatically. Interpret.: Prints analysis report for all interpretations. Auto: Prints the report only for high-grade interpretations. Grade 6 Only: Prints the report only for grade 6. Grade 4 or higher: Prints the report for grade 4 or higher. Grade 2 or higher: Prints the report for grade 2 or higher. No:Analysis report is not printed.	Interpret. Auto Grade 6 Only Grade 4 or higher Grade 2 or higher [No]
Commentary Report	Specify whether to print commentary report automatically. Interpret.: Prints commentary report for all interpretations. Auto: Prints the report only for high-grade interpretations. Grade 6 Only: Prints the report only for grade 6. Grade 4 or higher: Prints the report for grade 4 or higher. Grade 2 or higher: Prints the report for grade 2 or higher. No: Commentary report is not printed.	Interpret. Auto Grade 6 Only Grade 4 or higher Grade 2 or higher [No]

Printer Output/PDF2

Setup Item	Description	Setting Range
Brugada Risk Report	Specify whether or not to output the Brugada risk report.	Yes, [No]
ACS Summary Report	Specify whether or not to output the ACS summary report.	[Always], Abnormal Finding, No
ACS Guide Report	Specify whether or not to output the ACS guide report.	[Always], Abnormal Finding, No

Extra Recording

General

Setup Item	Description	Setting Range
Extra Recording	Specify the extra recording details.	Rhythm Meas. 1 min, Rhythm Meas. 3 min, [Arrhythmia 40 sec], Arrhythmia 1 min, 12-lead

Arrhythmia Printing

Setup Item	Description	Setting Range
Arrhythmia Lead	Specify examination lead.	[II, aVF, V5] I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6
Waveform Report	Specify whether or not to print the waveform report.	[Yes], No
Report Format	Specify the waveform speed of the waveform report.	10mm/s, 12.5mm/s, [25mm/s]
Results Report	Specify whether or not to print the results report.	[Yes], No
Arrhy. Meas. Report	Specify whether or not to output the detailed measurements report.	Yes, [No]
ECG Analysis*	Specify whether or not to print the ECG analysis.	No, [Clinical analysis]

Print Rhythm Measurement

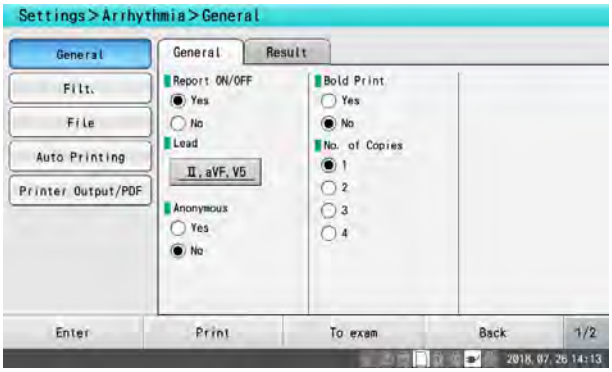
Setup Item	Description	Setting Range
Rhythm Lead	Specify the rhythm lead.	[II] I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6
Waveform Report	Specify whether or not to print the waveform report.	[Yes], No
Report Format	Specify the waveform speed of the waveform report.	10mm/s, 12.5mm/s, [25mm/s]

Print Rhythm Measurement

Meas. Report	Specify whether or not to print the measurement report.	[Yes], No
Lines per page*	Specify the number of lines per page.	6 lines, [8 lines]

Arrhythmia ECG Examination

Set the items for arrhythmia examinations.



General

General

Setup Item	Description	Setting Range
Report ON/OFF	Specify whether or not to print the report automatically.	[Yes], No
Lead	Specify examination lead.	[II, aVF, V5] I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6
Anonymous	Specify whether or not to make patient information anonymous.	Yes, [No]
Bold Print	Specify whether or not to use bold print.	Yes, [No]
No. of Copies	Specify the number of copies to be printed.	[1], 2 to 4

Result

Setup Item	Description	Setting Range
Display Result	Specify whether to display the measurement results and interpretation guide after measurement.	[Yes], No

Filter

General

Setup Item	Description	Setting Range
LP filter prop.	Specify high frequency characteristics.	75 Hz, 100 Hz, [150 Hz], 250 Hz
Drift Filter	Specify drift removal filter characteristics.	OFF, [Strong (0.5 Hz)], Weak (0.25 Hz)
Muscle Filter	Specify EMG filter characteristics.	[OFF], Strong (25 Hz), Weak (35 Hz)
Hum Filter	Specify ON/OFF for AC filter.	[OFF], Strong, Weak

File

General

Setup Item	Description	Setting Range
Auto Save	Specify whether to automatically save the examination data to the media after the examination.	Yes, [No]
Save to	Specify the media to save the data.	[SD Card], USB1, USB2, DMS, DICOM
When meas. error	Specify whether to save measurement results when measurement result error occurs.	[Cancel], Continue

REFERENCE

- When using an optional software, "When meas. error" ([File] > [General]) is displayed as "At Analysis Error".

Auto Printing

General

Setup Item	Description	Setting Range
Duration	Specify the waveform recording duration. When the specified duration elapse, the recording will automatically stop.	40 sec, 1 min, 2 min, [3 min]
Sensitivity	Specify the waveform sensitivity for reviewing the file.	[Auto], Sensitivity1
Waveform Report	Specify whether or not to output the waveform report.	[Yes], No
Report Format	Specify the feeding rate to print the ECG waveform.	10mm/s, 12.5mm/s, [25mm/s]
Results Report	Specify whether to output reports for which event waveforms have been edited.	[Yes], No
Det. Meas.Report	Specify whether or not to output the detailed measurements report.	Yes, [No]
Warning Comment*	Specify whether or not to print the warning comment.	Yes, [No]
Check Cancel Operation*	Specify the operation when Start/Stop key is pressed during the examination (after 8 sec.) Confirm: Displays the confirmation message for whether or not to record. Continue: Finishes the examination and starts recording. Cancel: Cancels the examination and recording will not be performed.	[Confirm], Continue, Cancel

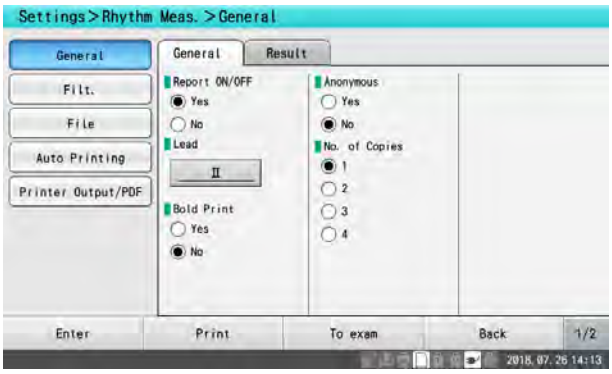
Printer Output/PDF

Printer Output/PDF

Setup Item	Description	Setting Range
Waveform Report	Specify whether or not to automatically print the waveform report.	Yes, [No]
Results Report	Specify whether or not to automatically print the results report.	Yes, [No]
Det. Meas. Report	Specify whether or not to output the detailed measurements report.	Yes, [No]

Rhythm Measurement

Configure items for rhythm measurements.



General

General

Setup Item	Description	Setting Range
Report ON/OFF	Specify whether or not to print the report automatically.	[Yes], No
Lead	Specify examination lead.	I, [II], III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6
Bold Print	Specify whether or not to use bold print.	Yes, [No]
Anonymous	Specify whether or not to make patient information anonymous.	Yes, [No]
No. of Copies	Specify the number of copies to be printed.	[1], 2, 3, 4

Result

Setup Item	Description	Setting Range
Display Result	Specify whether or not to display the measurement result.	[Yes], No

Filter

General

Setup Item	Description	Setting Range
LP filter prop.	Specify high frequency characteristics.	75 Hz, 100 Hz, [150 Hz], 250 Hz
Drift Filter	Specify drift removal filter characteristics.	OFF, [Strong (0.5 Hz)], Weak (0.25 Hz)
Muscle Filter	Specify EMG filter characteristics.	[OFF], Strong (25 Hz), Weak (35 Hz)
Hum Filter	Specify ON/OFF for AC filter.	[OFF], Strong, Weak

File

General

Setup Item	Description	Setting Range
Auto Save	Specify whether to automatically save the examination data to the media after the examination.	Yes, [No]

General

Save to	Specify the media to save the data.	[SD card], USB1, USB2, DMS, DICOM
When meas. error	Specify whether to save measurement results when measurement result error occurs.	[Cancel], Continue

Auto Printing

General

Setup Item	Description	Setting Range
Duration	Specify the waveform recording duration. When the specified duration elapse, the recording will automatically stop.	[1 min] 40 sec, 1 min to 10 min, 100 bts, 200 bts
Waveform Report	Specify whether or not to output the waveform report.	[Yes], No
Report Format	Specify the feeding rate to print the ECG waveform.	10mm/s, 12.5mm/s, [25mm/s]
Meas. Report	Specify whether to output reports for which findings and event waveforms have been edited.	[Yes], No
Check Cancel Operation*	Specify the operation when Start/Stop key is pressed during the examination (after 8 sec.) Confirm: Displays the confirmation message for whether or not to record. Continue: Finishes the examination and starts recording. Cancel: Cancels the examination and recording will not be performed.	[Confirm], Continue, Cancel
Lines per page*	Specify the number of lines per page.	6 lines, [8 lines]

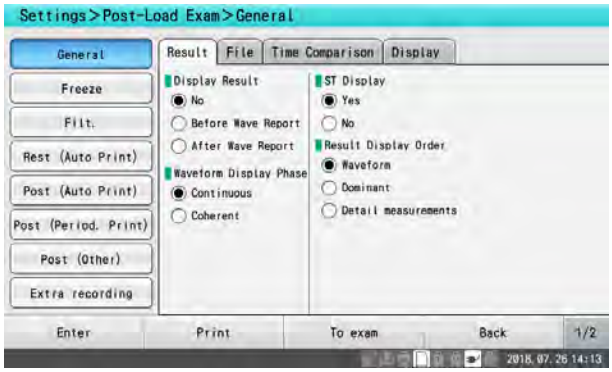
Printer Output/PDF

General

Setup Item	Description	Setting Range
Waveform Report	Specify whether or not to automatically print the waveform report.	Yes, [No]
Value+Trend+Histogram	Specify whether to print Value+Trend+Histogram report automatically.	Yes, [No]

Post-Load Examination

Set the items for post-load examination.



General

Result

Setup Item	Description	Setting Range
Display Result	Specify whether or not to display the measurement result after the automatic measurement. This is enabled only when resting. No: Measurement results are not displayed. Before Wave Report: The measurement results are displayed before printing the waveform report. After Wave Report: The measurement results are displayed after printing the waveform report.	No, Before Wave Report, [After Wave Report]
Waveform Display Phase	Specify the waveform display phase on the result display.	[Continuous], Coherent
ST Display	Specify whether to display ST values for extracted waveforms in the result display.	[Yes], No
Result Display Order	Specify the initial setting of the result display.	[Result], Waveform, Dominant, Detail measurements

File

Setup Item	Description	Setting Range
Auto Save	Specify whether to automatically save the examination data to the media after the examination.	Yes, [No]
Save at Periodic Print	Specify whether to automatically save the examination data to the media after the periodic print.	Yes, [No]
Save to	Specify the media to save the data.	[SD Card], USB1, USB2, DMS, Shar. Folder, DICOM
At Analysis Error	Specify whether to save analysis results when analysis result error occurs.	[Cancel], Continue

Time Comparison

Setup Item	Description	Setting Range
Time Comparison	Specify whether or not to perform time comparison.	Yes, [No]

Display

Setup Item	Description	Setting Range
Waveform Display	Specify the display type of real time waveforms when the power is turned ON.	3ch, 6ch, [6ch×2]
Waveform Display Phase	Specify the waveform phase when the waveform display is 6ch×2.	Continuous, [Coherent]

Freeze

Freeze

Setup Item	Description	Setting Range
Record Time	Specify the waveform recording duration at freeze condition.	[1min] 1-5
Save Extension	Specify the default of the check box for the save extension of the full disclosure wave. Auto save is also performed as the save extension.	Yes, [No]
Freeze/Result Display	Specify whether or not to display the freeze/result display. Same w/Exam. Result: The result display will be according to the setting under [General>Display>Display Result]. No: Results are not displayed. Before Wave Report: The result display is displayed before printing the waveform report. After Wave Report: The result display is displayed after printing the waveform report.	[Same w/Exam. Result], No, Before Wave Report, After Wave Report
Save Freeze Analysis	Specify whether or not to save each freeze analysis when auto save function is set.	[Yes], No

Freeze

Freeze Position	Specify the default of the analysis position for displaying the freeze display.	First, Middle, [Last]

Filter

There are 2 types of filter setting. [Filter 1] is for during resting, and [Filter 2] is for during exercise.

General

Setup Item	Description	Setting Range
LP filter prop.	Specify high frequency characteristics.	75 Hz, 100 Hz, [150 Hz], 250 Hz
Drift Filter	Specify drift removal filter characteristics.	OFF, [Strong (0.5 Hz)], Weak (0.25 Hz)
Muscle Filter	Specify EMG filter characteristics.	[OFF], Strong (25 Hz), Weak (35 Hz)
Hum Filter	Specify ON/OFF for AC filter.	[OFF], Strong, Weak

Rest (Auto Print)

General

Setup Item	Description	Setting Range
Auto Sensitivity	Specify the automatic sensitivity method. 1 + Auto: When a large waveform appears while recording with a sensitivity of 1 cm/mV, its lead block will be recorded again with auto sensitivity.	[Auto], 1+Auto, Auto+1, Sensitivity1
Adjust Print Position	Adjust the print position of the waveform. No: Adjustment is not performed. (0mV is the center) Centered: Adjusts the baseline to be the center. Proportional: Equalizes the blank space between each channel to avoid overlapping of the waveforms.	No, Centered, [Proportional]
Check Electrode Message	Specify whether or not to display the message for misplacing the leads.	[Yes] No
Insert CAL	Specify the condition for the calibration waveform. Yes: Prints the calibration waveform on all leads. No: Prints the calibration waveform on only the first block. When changed: Prints the calibration waveform when the sensitivity is other than 1cm/mV.	Yes, No, [When changed]
Print Position	Specify the print position of the calibration waveform.	[Before Waveform], After Waveform
Review Printing Time Shift	Set the time shift for review printing.	[10 sec], 8 sec to 12 sec

Waveform Report

Setup Item	Description	Setting Range
Waveform Report	Specify whether or not to output the waveform report.	[Yes], No
Rec. Range (Z-Fold)	Specify the waveform recording duration.	[1 sheet], 2 sheets
Rec. Range (Roll)	Specify the waveform recording duration.	[10 sec], 8 sec to 24 sec
Report Format	Specify the format for 12-lead printing.	3ch×4, 3ch×4+Rhythm 1ch, 3ch×4+Rhythm 2ch, [6ch×2], 6ch×2+Rhythm 1ch, 12ch

Waveform Report

Wave. Type	Continuous: Prints the waveform of each lead block as a continuous report, total time to be the specified time. Coherent (In-Phase): Prints the waveform of each lead block with in-phase, total time to be the specified time. Coherent (Full): Prints the waveform of each lead block with full wave.	[Continuous], Coherent (In-Phase), Coherent (Full)
Rhythm Lead	Specify the waveform of the rhythm lead.	I, [II], III, aVR, aVL, aVF, V1, V2, V3, V4, [V5], V6
Print HR	Specify whether to print HR on the waveform report.	[Yes], No

Results Report 1

Setup Item	Description	Setting Range
Results Report	Specify whether or not to output the results report.	[Yes], No
Det. Meas. Report	Specify the report format.	Yes, [No]
Results Rep. Fmt.	Specify the results report format.	[DOM1], DOM2+Rhythm 1ch, DOM2+Rhythm 2ch, DOM3 FULL3+Rhythm 1ch, FULL3+Rhythm 2ch, FULL6, FULL6+Rhythm 1ch, Cover, Panorama, Time Comparison
Analysis Report	Specify the grade of findings to be output in the analysis report. Interpret.: Prints analysis report for all interpretations. Auto: Prints the report for high-grade interpretations. Grade 6 Only: Prints the report only for the grade 6. Grade 4 or higher: Prints the report for grade 4 or higher. Grade 2 or higher: Prints the report for grade 2 or higher. No: Analysis report is not printed.	Interpret., Auto, Grade 6 Only, Grade 4 or higher, Grade 2 or higher, [No]
Commentary Report	Specify the grade of findings to be output in the commentary report. Interpret.: Prints report for all interpretations. Auto: Prints the report for high-grade interpretations. Grade 6 Only: Prints the report only for the grade 6. Grade 4 or higher: Prints the report for minimum grade 4 or higher. Grade 2 or higher: Prints the report for minimum grade 2 or higher. No: Commentary report is not printed.	Interpret., Auto, Grade 6 Only, Grade 4 or higher, Grade 2 or higher, [No]
Extracted Wave.*	Specify the extracted waveform.	[Dominant], Average
Full Lead Waveform*	Specify the type of the full lead waveform for FULL3 and FULL6.	[Continuous], Coherent
Print mild interpre.*	Specify whether or not to print the mild interpretations.	[Yes], No
Warning Comment*	Specify whether or not to print the warning comment.	Yes, [No]
Edit Abnormal wave*	Specify whether or not to print abnormal waves such as misplacing electrodes or recording failure.	Priority, [Standard]
Print ST*	Specify whether to print ST value on the upper right of the dominant.	Yes, [No]
PAC, PVC Mark*	Specify whether or not to print the PAC and PVC mark.	[Yes], No
Plot measurement*	Specify whether or not to print the point used for the waveform measurement.	Yes, [No]
Auto Sensitive*	Specify the auto sensitivity for the dominant waveform of the results report.	No, [Chest Leads], All Leads

Results Report 2

Setup Item	Description	Setting Range
Check Comment	Specify whether to include the check comment.	[Yes], No
Edit Interpretation	Specify the method for editing the interpretation section. Judgment+Interp.: Interpretation is printed when general judgment+interpretation name+Brugada code exist. Interp.: Interpretation is printed when interpretation name+Brugada code exist. Interp.Title Only: Only the interpretation title is printed.	[Judgment+Interp.] Interp. Interp. Title Only
Brugada Risk Analysis	Specify whether or not to perform the Brugada risk analysis.	Yes, [No]
Brugada Risk Report	Specify whether or not to perform the Brugada risk report.	Yes, [No]

Auto Extension

Setup Item	Description	Setting Range
Auto Print Extension	Specify whether to start arrhythmia recording automatically when the specified finding code and grade are obtained after automatic analysis.	[No], Yes
Extension Conditions	Specify the condition to perform auto extension.	[Extension Code], Grade 6 Only, Grade 4 or higher, Grade 2 or higher, No
Extension Code	Set the interpretation code to perform the extra recording when the extension code is set.	[412, 413, 414, 415, 803, 804, 816, 831, 841, 842, 843, 844, 845, 846, 847, 848, 851, 852, 862, 864, 865, 866, 867, 871, 872, 881]

Printer Output/PDF1

Setup Item	Description	Setting Range
Waveform Report	Specify whether or not to automatically print the waveform report.	Yes, [No]
Report Format	Specify the report format.	3ch×4, 3ch×4+Rhythm 1ch, 3ch×4+Rhythm 2ch, [6ch×2], 6ch×2+Rhythm 1ch, 12ch (Vertical)
Results Report	Specify whether or not to automatically print the results report.	Yes, [No]
Results Rep. Fmt.	Specify the results report format.	[DOM1], DOM2+Rhythm 1ch, DOM2+Rhythm 2ch, DOM3 FULL3+Rhythm 1ch, FULL3+Rhythm 2ch, FULL6 FULL6+Rhythm 1ch, Panorama
Det. Meas.Report	Specify whether or not to output the detailed measurements report.	Yes, [No]
Analysis Report	Specify whether to print analysis report automatically. Interpret.: Prints analysis report for all interpretations. Auto: Prints the report only for high-grade interpretations. Grade 6 Only: Prints the report only for grade 6. Grade 4 or higher: Prints the report for grade 4 or higher. Grade 2 or higher: Prints the report for grade 2 or higher. No:Analysis report is not printed.	Interpret. Auto Grade 6 Only Grade 4 or higher Grade 2 or higher [No]
Commentary Report	Specify whether to print commentary report automatically. Interpret.: Prints commentary report for all interpretations. Auto: Prints the report only for high-grade interpretations. Grade 6 Only: Prints the report only for grade 6. Grade 4 or higher: Prints the report for grade 4 or higher. Grade 2 or higher: Prints the report for grade 2 or higher. No: Commentary report is not printed.	Interpret. Auto Grade 6 Only Grade 4 or higher Grade 2 or higher [No]

Printer Output/PDF2

Setup Item	Description	Setting Range
Brugada Risk Report	Specify whether or not to output the Brugada risk report.	Yes, [No]

Post (Auto Print)

General

Setup Item	Description	Setting Range
Auto Sensitivity	Specify the automatic sensitivity method. 1 + Auto: When a large waveform appears while recording with a sensitivity of 1 cm/mV, its lead block will be recorded again with auto sensitivity.	[Auto], 1+Auto, Auto+1, Sensitivity1
Adjust Print Position	Adjust the print position of the waveform. No: Adjustment is not performed. (0mV is the center) Centered: Adjusts the baseline to be the center. Proportional: Equalizes the blank space between each channel to avoid overlapping of the waveforms.	No, Centered, [Proportional]
Check Electrode Message	Specify whether or not to display the message for misplacing the leads.	[Yes], No
Insert CAL	Specify the condition for the calibration waveform. Yes: Prints the calibration waveform on all leads. No: Prints the calibration waveform on only the first block. When changed: Prints the calibration waveform when the sensitivity is other than 1cm/mV.	Yes, No, [When changed]
Print Position	Specify the print position of the calibration waveform.	[Before Waveform] After Waveform

Waveform Report

Setup Item	Description	Setting Range
Waveform Report	Specify whether or not to output the waveform report.	[Yes], No
Rec. Range (Z-Fold)	Specify the waveform recording duration.	[1 sheet], 2 sheets
Rec. Range (Roll)	Specify the waveform recording duration.	[10 sec], 8 sec to 24 sec
Report Format	Specify the format for 12-lead printing.	3ch×4, 3ch×4+Rhythm 1ch, 3ch×4+Rhythm 2ch, [6ch×2], 6ch×2+Rhythm 1ch, 12ch
Wave. Type	Continuous: Prints the waveform of each lead block as a continuous report, total time to be the specified time. Coherent (In-Phase): Prints the waveform of each lead block with in-phase, total time to be the specified time. Coherent (Full): Prints the waveform of each lead block with full wave.	[Continuous], Coherent (In-Phase), Coherent (Full)
Rhythm Lead	Specify the waveform of the rhythm lead.	I, [II], III, aVR, aVL, aVF, V1, V2, V3, V4, [V5], V6
Print HR	Specify whether to print HR on the waveform report.	[Yes], No

Results Report 1

Setup Item	Description	Setting Range
Results Report	Specify whether or not to output the results report.	[Yes], No
Det. Meas. Report	Specify the report format.	Yes, [No]

Results Report 1

Results Rep. Fmt.	Specify the results report format.	[DOM1], DOM2+Rhythm 1ch, DOM2+Rhythm 2ch, DOM3 FULL3+Rhythm 1ch, FULL3+Rhythm 2ch, FULL6, FULL6+Rhythm 1ch, Cover, Panorama Time Comparison
Analysis Report	Specify the grade of findings to be output in the analysis report. Interpret.: Prints analysis report for all interpretations. Auto: Prints the report for high-grade interpretations. Grade 6 Only: Prints the report only for the grade 6. Grade 4 or higher: Prints the report for grade 4 or higher. Grade 2 or higher: Prints the report for grade 2 or higher. No: Analysis report is not printed.	Interpret., Auto, Grade 6 Only, Grade 4 or higher, Grade 2 or higher, [No]
Commentary Report	Specify the grade of findings to be output in the commentary report. Interpret.: Prints commentary report for all interpretations. Auto: Prints the report for high-grade interpretations. Grade 6 Only: Prints the report only for the grade 6. Grade 4 or higher: Prints the report for minimum grade 4 or higher. Grade 2 or higher: Prints the report for minimum grade 2 or higher. No: Commentary report is not printed.	Interpret., Auto, Grade 6 Only, Grade 4 or higher, Grade 2 or higher, [No]
Extracted Wave.*	Specify the extracted waveform.	[Dominant], Average
Full Lead Waveform*	Specify the type of the full lead waveform for FULL3 and FULL6.	[Continuous], Coherent
Print mild interpre.*	Specify whether or not to print the mild interpretations.	[Yes], No
Warning Comment*	Specify whether or not to print the warning comment.	Yes, [No]
Edit Abnormal wave*	Specify whether or not to print abnormal waves such as misplacing electrodes or recording failure.	Priority, [Standard]
Print ST*	Specify whether to print ST value on the upper right of the dominant.	Yes, [No]
PAC, PVC Mark*	Specify whether or not to print the PAC and PVC mark.	[Yes], No
Plot measurement*	Specify whether or not to print the point used for the waveform measurement.	Yes, [No]
Auto Sensitive*	Specify the auto sensitivity for the dominant waveform of the results report.	No, [Chest Leads], All Leads

Results Report 2

Setup Item	Description	Setting Range
Check Comment	Specify whether to include the check comment.	[Yes], No
Edit Interpretation	Specify the method for editing the interpretation section. Judgment+Interp.: Interpretation is printed when general judgment+interpretation name+Brugada code exist. Interp.: Interpretation is printed when interpretation name+Brugada code exist. Interp.Title Only: Only the interpretation title is printed.	[Judgment+Interp.] Interp. Interp. Title Only
Brugada Risk Analysis	Specify whether or not to perform the Brugada risk analysis.	Yes, [No]
Brugada Risk Report	Specify whether or not to perform the Brugada risk report.	Yes, [No]

Auto Extension

Setup Item	Description	Setting Range
Auto Print Extension	Specify whether to start arrhythmia recording automatically when the specified finding code and grade are obtained after automatic analysis.	[No], Yes

Auto Extension

Extension Conditions	Specify the condition to perform auto extension.	[Extension Code], Grade 6 Only, Grade 4 or higher, Grade 2 or higher, No
Extension Code	Set the interpretation code to perform the extra recording when the extension code is set.	[412, 413, 414, 415, 803, 804, 816, 831, 841, 842, 843, 844, 845, 846, 847, 848, 851, 852, 862, 864, 865, 866, 867, 871, 872, 881]

Printer Output/PDF1

Setup Item	Description	Setting Range
Waveform Report	Specify whether or not to automatically print the waveform report.	Yes, [No]
Report Format	Specify the report format.	3ch×4, 3ch×4+Rhythm 1ch, 3ch×4+Rhythm 2ch, [6ch×2], 6ch×2+Rhythm 1ch, 12ch (Vertical)
Results Report	Specify whether or not to automatically print the results report.	Yes, [No]
Results Rep. Fmt.	Specify the results report format.	[DOM1], DOM2+Rhythm 1ch, DOM2+Rhythm 2ch, DOM3 FULL3+Rhythm 1ch, FULL3+Rhythm 2ch, FULL6 FULL6+Rhythm 1ch, Panorama
Det. Meas.Report	Specify whether or not to output the detailed measurements report.	Yes, [No]
Analysis Report	Specify whether to print analysis report automatically. Interpret.: Prints analysis report for all interpretations. Auto: Prints the report only for high-grade interpretations. Grade 6 Only: Prints the report only for grade 6. Grade 4 or higher: Prints the report for grade 4 or higher. Grade 2 or higher: Prints the report for grade 2 or higher. No:Analysis report is not printed.	Interpret. Auto Grade 6 Only Grade 4 or higher Grade 2 or higher [No]
Commentary Report	Specify whether to print commentary report automatically. Interpret.: Prints commentary report for all interpretations. Auto: Prints the report only for high-grade interpretations. Grade 6 Only: Prints the report only for grade 6. Grade 4 or higher: Prints the report for grade 4 or higher. Grade 2 or higher: Prints the report for grade 2 or higher. No: Commentary report is not printed.	Interpret. Auto Grade 6 Only Grade 4 or higher Grade 2 or higher [No]

Printer Output/PDF2

Setup Item	Description	Setting Range
Brugada Risk Report	Specify whether or not to output the Brugada risk report.	Yes, [No]

Post (Periodic Print)

General

Setup Item	Description	Setting Range
Auto Sensitivity	Specify the automatic sensitivity method. 1 + Auto: When a large waveform appears while recording with a sensitivity of 1 cm/mV, its lead block will be recorded again with auto sensitivity.	[Auto], 1+Auto, Auto+1, Sensitivity1

General

Adjust Print Position	Adjust the print position of the waveform. No: Adjustment is not performed. (0mV is the center) Centered: Adjusts the baseline to be the center. Proportional: Equalizes the blank space between each channel to avoid overlapping of the waveforms.	No, Centered, [Proportional]
Check Lead Message	Specify whether or not to display the message for misplacing the leads.	[Yes], No
Compress. Print	Specify the compressed printing condition.	[No], 5mm/s, 10mm/s, 12.5mm/s
Insert CAL	Specify the condition for the calibration waveform. Yes: Prints the calibration waveform on all leads. No: Prints the calibration waveform on only the first block. When changed: Prints the calibration waveform when the sensitivity is other than 1cm/mV.	Yes, No, [When changed]
Print Position	Specify the print position of the calibration waveform.	[Before Waveform], After Waveform

Waveform Report

Setup Item	Description	Setting Range
Waveform Report	Specify whether or not to output the waveform report.	[Yes], No
Rec. Range (Z-Fold)	Specify the waveform recording duration.	[1 sheet], 2 sheets
Rec. Range (Roll)	Specify the waveform recording duration.	[10 sec], 8 sec to 24 sec
Report Format	Specify the format for 12-lead printing.	3ch×4, 3ch×4+Rhythm 1ch, 3ch×4+Rhythm 2ch, [6ch×2], 6ch×2+Rhythm 1ch, 12ch
Wave. Type	Continuous: Prints the waveform of each lead block as a continuous report, total time to be the specified time. Coherent (In-Phase): Prints the waveform of each lead block with in-phase, total time to be the specified time. Coherent (Full): Prints the waveform of each lead block with full wave.	[Continuous], Coherent (In-Phase), Coherent (Full)
Rhythm Lead	Specify the waveform of the rhythm lead.	I, [II], III, aVR, aVL, aVF, V1, V2, V3, V4, [V5], V6
Print HR	Specify whether to print HR on the waveform report.	[Yes], No

Results Report 1

Setup Item	Description	Setting Range
Results Report	Specify whether or not to output the results report.	[Yes], No
Det. Meas. Report	Specify the report format.	Yes, [No]
Results Rep. Fmt.	Specify the results report format.	[DOM1], DOM2+Rhythm 1ch, DOM2+Rhythm 2ch, DOM3 FULL3+Rhythm 1ch, FULL3+Rhythm 2ch, FULL6, FULL6+Rhythm 1ch, Cover, Panorama Time Comparison
Analysis Report	Specify the grade of findings to be output in the analysis report. Interpret.: Prints analysis report for all interpretations. Auto: Prints the report for high-grade interpretations. Grade 6 Only: Prints the report only for the grade 6. Grade 4 or higher: Prints the report for grade 4 or higher. Grade 2 or higher: Prints the report for grade 2 or higher. No: Analysis report is not printed.	Interpret., Auto, Grade 6 Only, Grade 4 or higher, Grade 2 or higher, [No]

Results Report 1

Commentary Report	Specify the grade of findings to be output in the commentary report. Interpret.: Prints commentary report for all interpretations. Auto: Prints the report for high-grade interpretations. Grade 6 Only: Prints the report only for the grade 6. Grade 4 or higher: Prints the report for minimum grade 4 or higher. Grade 2 or higher: Prints the report for minimum grade 2 or higher. No: Commentary report is not printed.	Interpret., Auto, Grade 6 Only, Grade 4 or higher, Grade 2 or higher, [No]
Extracted Wave.*	Specify the extracted waveform.	[Dominant], Average
Full Lead Waveform*	Specify the type of the full lead waveform for FULL3 and FULL6.	[Continuous], Coherent
Print mild interpre.*	Specify whether or not to print the mild interpretations.	[Yes], No
Warning Comment*	Specify whether or not to print the warning comment.	Yes, [No]
Edit Abnormal wave*	Specify whether or not to print abnormal waves such as misplacing electrodes or recording failure.	Priority, [Standard]
Print ST*	Specify whether to print ST value on the upper right of the dominant.	Yes, [No]
PAC, PVC Mark*	Specify whether or not to print the PAC and PVC mark.	[Yes], No
Plot measurement*	Specify whether or not to print the point used for the waveform measurement.	Yes, [No]
Auto Sensitive*	Specify the auto sensitivity for the dominant waveform of the results report.	No, [Chest Leads], All Leads

Results Report 2

Setup Item	Description	Setting Range
Check Comment	Specify whether to include the check comment.	[Yes], No
Edit Interpretation	Specify the method for editing the interpretation section. Judgment+Interp.: Interpretation is printed when general judgment+interpretation name+Brugada code exist. Interp.: Interpretation is printed when interpretation name+Brugada code exist. Interp.Title Only: Only the interpretation title is printed.	[Judgment+Interp.] Interp. Interp. Title Only
Brugada Risk Analysis	Specify whether or not to perform the Brugada risk analysis.	Yes, [No]
Brugada Risk Report	Specify whether or not to perform the Brugada risk report.	Yes, [No]

Interval Printing

Setup Item	Description	Setting Range
Print Interval	Automatically starts recording in intervals of the set time. Interval time is ignored while capturing and recording waveforms.	No, 30sec, 1min, 2min, [3min] 4min, 5min, 10min, 15min, 30min, 60min
Print at Set Time	Automatically starts recording at specified time. Specified time is ignored while capturing and recording waveforms.	0,1, , , , , , , ,min

Auto Extension

Setup Item	Description	Setting Range
Auto Print Extension	Specify whether to start arrhythmia recording automatically when the specified finding code and grade are obtained after automatic analysis.	[No], Yes
Extension Conditions	Specify the condition to perform auto extension.	[Extension Code], Grade 6 Only, Grade 4 or higher, Grade 2 or higher, No
Extension Code	Set the interpretation code to perform the extra recording when the extension code is set.	[412, 413, 414, 415, 803, 804, 816, 831, 841, 842, 843, 844, 845, 846, 847, 848, 851, 852, 862, 864, 865, 866, 867, 871, 872, 881]

Printer Output/PDF1

Setup Item	Description	Setting Range
Waveform Report	Specify whether or not to automatically print the waveform report.	Yes, [No]
Report Format	Specify the report format.	3ch×4, 3ch×4+Rhythm 1ch, 3ch×4+Rhythm 2ch, [6ch×2], 6ch×2+Rhythm 1ch, 12ch (Vertical)
Results Report	Specify whether or not to automatically print the results report.	Yes, [No]
Results Rep. Fmt.	Specify the results report format.	[DOM1], DOM2+Rhythm 1ch, DOM2+Rhythm 2ch, DOM3 FULL3+Rhythm 1ch, FULL3+Rhythm 2ch, FULL6 FULL6+Rhythm 1ch, Panorama
Det. Meas.Report	Specify whether or not to output the detailed measurements report.	Yes, [No]
Analysis Report	Specify whether to print analysis report automatically. Interpret.: Prints analysis report for all interpretations. Auto: Prints the report only for high-grade interpretations. Grade 6 Only: Prints the report only for grade 6. Grade 4 or higher: Prints the report for grade 4 or higher. Grade 2 or higher: Prints the report for grade 2 or higher. No:Analysis report is not printed.	Interpret. Auto Grade 6 Only Grade 4 or higher Grade 2 or higher [No]
Commentary Report	Specify whether to print commentary report automatically. Interpret.: Prints commentary report for all interpretations. Auto: Prints the report only for high-grade interpretations. Grade 6 Only: Prints the report only for grade 6. Grade 4 or higher: Prints the report for grade 4 or higher. Grade 2 or higher: Prints the report for grade 2 or higher. No: Commentary report is not printed.	Interpret. Auto Grade 6 Only Grade 4 or higher Grade 2 or higher [No]

Printer Output/PDF2

Setup Item	Description	Setting Range
Brugada Risk Report	Specify whether or not to output the Brugada risk report.	Yes, [No]

Post (Other)

General

Setup Item	Description	Setting Range
Wave Comparison Report	Specify whether or not to output the wave comparison report.	Yes, [No]
Summary Report	Specify whether or not to output the summary report after the periodic printing.	Yes, [No]

Extra Recording

General

Setup Item	Description	Setting Range
Extra Recording	Specify the extra recording details.	Rhythm Meas. 1 min, Rhythm Meas. 3 min, [Arrhythmia 40 sec], Arrhythmia 1 min, 12-lead

Arrhythmia Printing

Setup Item	Description	Setting Range
Arrhythmia Lead	Specify examination lead.	[II, aVF, V5] I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6
Waveform Report	Specify whether or not to print the waveform report.	[Yes], No
Report Format	Specify the waveform speed of the waveform report.	10mm/s, 12.5mm/s, [25mm/s]
Results Report	Specify whether or not to print the results report.	[Yes], No
Arrhy. Meas. Report	Specify whether or not to output the detailed measurements report.	Yes, [No]
ECG Analysis*	Specify whether or not to print the ECG analysis.	No, [Clinical analysis]

Print Rhythm Measurement

Setup Item	Description	Setting Range
Rhythm Lead	Specify the rhythm lead.	[II] I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6
Waveform Report	Specify whether or not to print the waveform report.	[Yes], No
Report Format	Specify the waveform speed of the waveform report.	10mm/s, 12.5mm/s, [25mm/s]
Meas. Report	Specify whether or not to print the measurement report.	[Yes], No
Lines per page*	Specify the number of lines per page.	6 lines, [8 lines]

REFERENCE

- When an optional software is installed, there are following differences.
  - “Display Interpretation” under [General] tab is displayed only when using an optional software.
  - "Check Comments", "Edit Interpretation", "Analysis Report"," Commentary Report", "Brugada Risk Analysis", "Brugada Risk Report", "Print mild interpre.", "Warning Comment", "Edit Abnormal wave", "ACS Summary Report", "ACS Guide Report" under [Results Report 1], [Results Report 2] tab are displayed only when using an optional software.
  - "Panorama" of the "Results Rep. Fmt." under [Results Report 1] tab is displayed only when using an optional software.
  - ACS diagnostic aid function can be used when using an optional software.
  - "Measurement Result" ([12L Manual Print] > [General]) is displayed as "Analyze" when using an optional software.
  - "Extension Conditions" and "Extension code" under [Auto Extension] tab are displayed only when using an optional software.
  - "Panorama" of the "Results Rep. Fmt." under [Printer Output/PDF] tab is displayed only when using an optional software.
  - "Analysis Report" and "Commentary report" under [Printer Output/PDF] tab are displayed only when using an optional software.

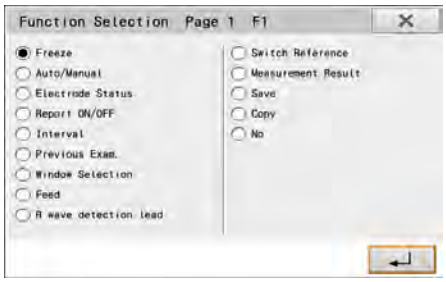
Changing Functions Keys on the Examination Screen

Function keys in the 12-lead Examination window (Auto, Manual), Arrhythmia ECG window, and Rhythm Measurement window are sorted.

1 Touch [Menu] - [Settings] - [Functions Key] .

2 Touch the [Examination Name] tab to configure the settings and select the position of the function keys.

3 Touch the functions to locate them in the positions of the function keys selected in step 2.



4 When the location of the function keys has been determined, touch [Enter].

5 This allows to use the selected functions in each examination.

REFERENCE

- To restore the function keys to the default layout, touch [Reset] in the function key setting displays for each examination.

Saving and Printing the Settings

The current settings can be saved on a USB memory or printed on a recording paper.

Saving Settings on a SD Card

1 Insert the SD card into a SD card slot on the main unit.

2 Touch [Menu] - [Settings].

3 Touch the [1/2] function key.

4 Touch the [Save Settings] function key.

- The current settings will be saved on a SD card.
- Similarly, the settings saved on a SD card can be loaded using [Load Settings]. This is useful when operating multiple devices with the same settings.

NOTE

- Network-related settings (device name, IP address, etc.) are not saved.

Printing Settings

1 Press the (START/STOP) key on the operation panel during setting.

- The content to be printed varies depending on the window displayed.
- Setting list window is displayed: All common settings
- Settings for each item window is displayed: Settings for each item

2 To stop printing, press the (START/STOP) key.

Chapter 14 Maintenance and Inspection

To operate this device safely for a long time, it is essential to inspect the device and replace consumable parts

This chapter describes the maintenance and inspection procedures for this device.
Make sure to perform daily checks and periodic checks to maintain functionality, performance and reliability.
Please note that Fukuda Denshi shall not be liable for accidents arising from failure to perform maintenance and inspections.

⚠ WARNING

- Other than replacing with specified parts, do not disassemble or modify this device. Disassembly may cause a fire hazard or electric shock.

⚠ CAUTION

- Do not perform any maintenance procedure which is not described in this manual. Failure to observe this caution may result in a malfunction.

Daily Check

Perform the Daily Check Procedure described below everyday.

- If the device fails any check item in the Daily Check List (☞P15-6), the overall judgment will be "Fail". Repair the device so that it passes all the check items.
- Use the device only if the judgments for all the items are "OK".

Daily Check Procedure

❑Appearance

Visually check the following items.

Item	Inspection Item	Procedure	Criteria
Main Unit	1) Enclosure	Check that there is no scratch, crack, deformation or rust on the main unit.	Should be free of exterior flaws, cracks, deformation, rust.
	2) Label, Panel	Check that labels and panels are not peeled off or stained. Check that it is clean.	No peeling or staining should be found.
	3) Key	Check the key for damage.	No damage should be found.
Accessories	1) Power Cable, Patient Cable	Check for scratch and damage.	No scratch or damage should be found.
	2) Clip Electrodes, Chest Electrodes	Check for dirt, rust, scratch, and damage.	Should be free of dirt, rust, scratch or damage
	3) Recording paper	Check the loading condition of the recording paper.	The recording paper should be loaded properly.
	4) Operation Manual	Check that the operation manual is kept in specified location.	It should be kept in specified location.

❑Mechanical Check

Check the device for mechanical failures while actually operating the device.

Item	Inspection Item	Procedure	Criteria
Main Unit	1) Key	Check that key operation is smooth.	The operation should be smooth.
	2) Printer	Check that operation is smooth, and no abnormal sound is heard.	The operation should be smooth and no abnormal sound should occur.
Accessories	1) Power Cable, Patient Cable	Check whether the power cable and the patient cable can be connected to or disconnected from the main unit smoothly.	The power cable and the patient cable should be connected to or disconnected from the main unit smoothly.
	2) Clip Electrodes, Chest Electrodes	Check the connection of the patient cables.	The cables should be connected properly.

❑Electrical Check

Item	Inspection Item	Procedure	Criteria
Performance	1) Power supply	Turn the power ON and check the screen.	Check that the screen is displayed when the power is turned ON.
	2) Display	Check whether waveforms are displayed on the waveform display screen.	No abnormality or flickering should be found. Waveform should be properly displayed.
	3) Printing	Check if waveforms are properly printed.	Waveforms should be printed.
	4) Printing Speed (25 mm/s)	Perform printing at 25 mm/s for 10 seconds and check whether the error falls within ±2%.	The error for 10 seconds should be within ±2%.
	5) Calibration Voltage	Check that the error does not exceed 5% by holding down the 1 mV button.	The error should be within 5%.

Periodic Check

The periodic inspections should be performed by service personnel according to the following "Periodic Inspection Procedure".

- Perform checks described in the “Periodic Check Procedure” once a year.
- If the device fail any check item in the Periodic Check Procedure (☞P15-7), the overall judgment will be "Fail". Repair the device so that it passes all the check items.
- Use the device only after the judgment for all the items is "OK".
- Check all cables, devices, accessories, grounding resistance, leakage current, and accuracy.

Periodic Check Procedure

❑Appearance

Visually check the following items.

Item	Inspection Item	Procedure	Criteria
Main Unit	1) Enclosure	Check that there is no scratch, crack, deformation or rust on the main unit.	Should be free of exterior flaws, cracks, deformation, rust.
	2) Label, Panel	Check that the label and panel are not peeled off or stained.	No peeling or staining should be found.
	3) Key	Check the key for damage.	No damage should be found.
Accessories	1) Power Cable, Patient Cable	Check for scratch and damage.	No scratch or damage should be found.
	2) Clip Electrodes, Chest Electrodes	Check for dirt, rust, scratch, and damage.	Should be free of dirt, rust, scratch or damage
	3) Recording Paper	Check the loading condition of the recording paper.	The recording paper should be loaded properly.
	4) Operation Manual	Check that the operation manual is kept in specified location.	It should be kept in specified location.

❑Mechanical Check

Check the device for mechanical failures while actually operating the device.

Item	Inspection Item	Procedure	Criteria
Main Unit	1) Key	Check that key operation is smooth.	The operation should be smooth.
	2) Printer	Check that operation is smooth, and no abnormal sound is heard.	The operation should be smooth and no abnormal sound should occur.
Accessories	1) Power Cable, Patient Cable	Check whether the power cable and the patient cable can be connected to or disconnected from the main unit smoothly.	The power cable and the patient cable should be connected to or disconnected from the main unit smoothly.
	2) Clip Electrodes, Chest Electrodes	Check the connection of the patient cables.	The cables should be connected properly.

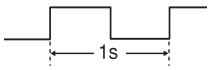
❑Electrical Check

Item	Inspection Item	Procedure	Criteria
Performance	1) Power Supply	Turn the power ON and check the screen.	Check that the screen is displayed when the power is turned ON.
	2) Display	Check whether waveforms are displayed on the waveform display screen.	No abnormality or flickering should be found. Waveform should be properly displayed.
	3) Printing	Check if waveforms are properly printed.	Waveforms should be printed.
	4) Printing Speed (25 mm/s)	Perform printing at 25 mm/s for 10 seconds and check whether the error falls within ±2%.	The error for 10 seconds should be within ±2%.
	5) Calibration Voltage	Check that the error does not exceed 5% by holding down the 1 mV button.	The error should be within 5%.

❑Maintenance Test

REFERENCE

- To enter maintenance mode, touch [Menu] - [Maintenance] from the examination screen.

Item	Inspection Item	Procedure	Criteria
Performance	1) Check Date/Time	Touch [Set Date/Time] on the maintenance menu screen.	Check that current date/time is displayed.
	2) Thermal Printing Test	1) Touch [Thermal Printing Test] on the maintenance menu screen. 2) Touch [Rectangular Pattern]. Touch [Speed] to change the printing speed.	The paper should not move in a zigzag direction. The paper should not be folded on the left and right edges. There should be no irregular or smeared printing. There should be no missed dots. Printing Speed  Printing Speed 5mm/s: 5mm (Within ±2%) Printing Speed 10mm/s: 10mm (Within ±2%) Printing Speed 12.5mm/s: 12.5mm (Within ±2%) Printing Speed 25mm/s: 25mm (Within ±2%) Printing Speed 50 mm/s: 50 mm (Within ±2%)
	3) LCD Test	Touch [LCD Test] on the maintenance menu screen.	All dots should appear. The colors must be correct.
	4) Key Test	1) Touch [Key Test] on the maintenance menu screen. 2) Touch each key.	The display corresponding to the pressed key must be highlighted.
	5) Touch Panel Test	1) Touch [Touch Panel Test] on the maintenance menu screen. 2) Touch + symbol.	Correct reaction should occur at the touch point.
	6) Sound Test	1) Touch [Sound Test] on the maintenance menu screen. 2) Touch each sound.	Sounds should be generated at a proper volume level.
	7) Adjust Perforations	1) Touch [Adjust perforations] on the maintenance menu screen. 2) Touch [Feed] to check if the perforation position is correct.	The perforation position should be correct. If not, adjust it by changing the value of the feeding paper length.The feeding paper length will increase by setting a larger value (plus side), and decrease by setting a smaller value (minus side).

❑Status Check

Inspection Item	Criteria
Backup Battery	Should be 2.5 V and above.
Thermal Print Head Status	Should be within ±10ºC of room temperature.
Paper Tray Status	Should display "UP" when the paper tray is open and "SET" when it is closed.
Sensor detecting presence/absence of paper	"Yes" should appear when paper is loaded, and "No" should appear when paper is removed.

❑Electrical Safety

Refer to the following section, "Electrical Safety Inspection Procedure".

❑Other

Item	Inspection Item	Procedure	Criteria
Other	1) Power Supply	Check that the power can be turned ON/ OFF both with AC power and battery power.	The power should turn ON/OFF both with AC power and battery power.
	2) Power cable	Perform continuity test using a tester.	Perform continuity test using a tester and check that it is conducting.

Electrical Safety Inspection Procedure

Electrical safety-related testing methods and measurement device are stipulated in safety standards (IEC 60601-1 and ANSI AAMI / ES 60601-1). A dedicated safety test measuring instrument is required for performing this measurement. Check that the measurement results do not exceed the threshold value and record the numerical values.

❑Safety Evaluation Test Device

Testing and inspection items in this manual are described based on the assumption that a dedicated electrical safety tester with its accuracy controlled is used. Considering ease of test and ensuring accuracy, it is recommended to use a dedicated safety test measuring instrument.

Contact our service personnel for more information on safety test measuring instrument.

❑Check Items

Electrical safety check items include the following types.

(1)	Earth Leakage Current	Leakage current that runs to the protective earth conductor.
(2)	Touch Current	Leakage current that runs through the ground from the enclosure of the device
(3)	Patient Leakage Current (From patient connection to earth)	Leakage current that runs through the ground via patient from the attaching part There are two types of measuring method - direct current and alternating current.
(4)	Patient Leakage Current (Current when external voltage is applied to SIP/SOP)	Leakage current that runs through the ground via patient from the attaching part by means of the supply voltage carried on the signal input/output There are two types of measuring method - direct current and alternating current.
(5)	Patient Leakage Current (When external voltage is applied to patient connection of Type F Applied Part)	Leakage current that runs through the ground from the device by means of the supply voltage carried on the F type attaching part through patient
(6)	Patient Auxiliary Current	Current that runs between attaching parts through patient There are two types of measuring method - direct current and alternating current.

Measurement is performed under the following two conditions.

(1)	Normal Condition	Measurement in normal condition
(2)	Single Fault Condition	Condition under which a single fault occurs

❑Maximum allowable leakage current

Leakage Current (Unit: mA)		Type B		Type BF		Type CF	
		Normal Condition	Single Fault Condition	Normal Condition	Single Fault Condition	Normal Condition	Single Fault Condition
Earth Leakage Current		5	10	5	10	5	10
Touch Current		0.1	0.5	0.1	0.5	0.1	0.5
Patient Leakage Current (From patient connection to earth)	Direct Current	0.01	0.05	0.01	0.05	0.01	0.05
	Alternating Current	0.1	0.5	0.1	0.5	0.01	0.05
Patient Leakage Current (Current when external voltage is applied to SIP/SOP)	Direct Current	0.01	0.05	0.01	0.05	0.01	0.05
	Alternating Current	0.1	0.5	0.1	0.5	0.01	0.05
Patient Leakage Current (When external voltage is applied to patient connection of Type F Applied Part)		-	-	-	5	-	0.05
Patient Auxiliary Current	Direct Current	0.01	0.05	0.01	0.05	0.01	0.05
	Alternating Current	0.1	0.5	0.1	0.5	0.01	0.05

The "Type CF" part is applied to this device.

⚠ WARNING

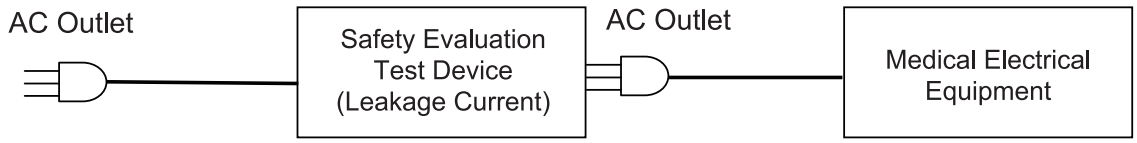
- If value that exceeds the allowable limit is identified during an electrical safety inspection, immediately stop using the device and make appropriate repairs.
  Failure to repair the device can lead to a serious accident.

Safety Specification of this Device

Classification by type of protection: Class I
Classification of applied part by degree of protection: Type CF applied part

Earth Leakage Current

1. Measurement wiring diagram

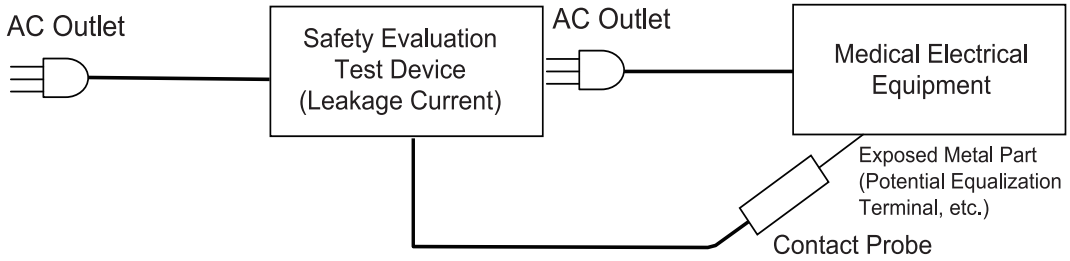


2. Allowable value

Normal Condition	Single Fault Condition
5 mA	10 mA

Touch Current

1. Measurement wiring diagram

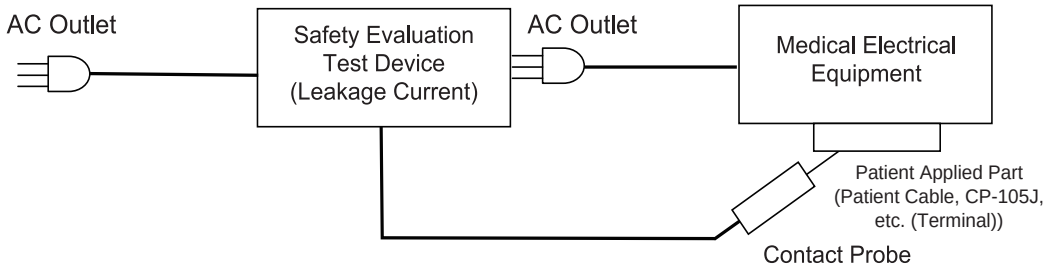


2. Allowable value

Normal Condition	Single Fault Condition
0.1 mA	0.5 mA

Patient Leakage Current (From Patient Connection to Ground)

1. Measurement wiring diagram

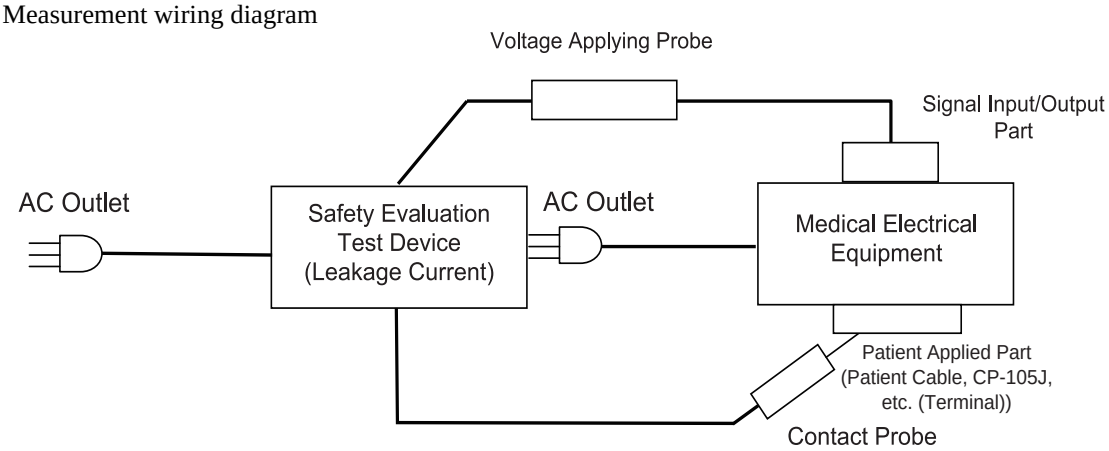


2. Allowable value

	Normal Condition	Single Fault Condition
Direct Current	0.01 mA	0.05 mA
Alternating Current	0.01 mA	0.05 mA

Patient Leakage Current (When external voltage is applied to SIP/SOP)

1. Measurement wiring diagram

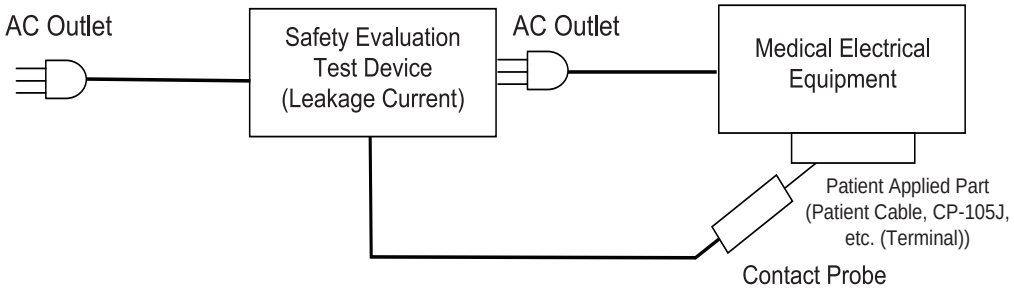


2. Allowable value

	Normal Condition	Single Fault Condition
Direct Current	0.01 mA	0.05 mA
Alternating Current	0.01 mA	0.05 mA

Patient Leakage Current (When external voltage is applied to patient connection of Type F Applied Part)

1. Measurement wiring diagram

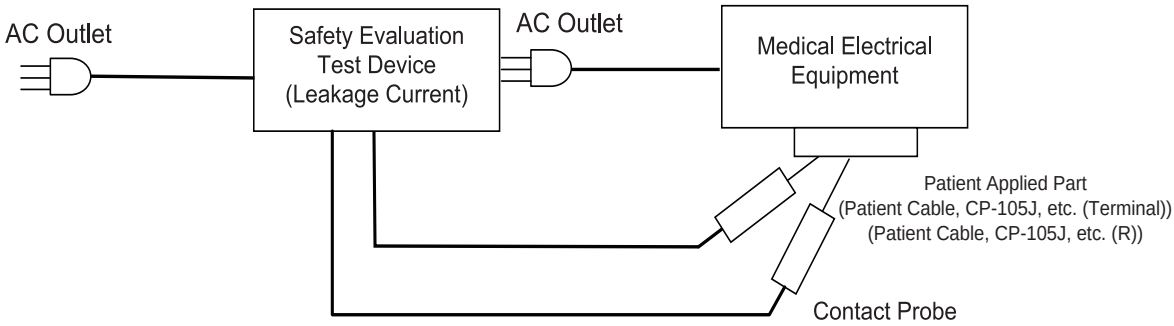


2. Allowable value

Single Fault Condition
0.05 mA

Patient Auxiliary Current

1. Measurement wiring diagram



2. Allowable value

	Normal Condition	Single Fault Condition
Direct Current	0.01 mA	0.05 mA
Alternating Current	0.01 mA	0.05 mA

Consumable Parts

Replacement Period of Consumable Parts

The following parts and accessories are consumable parts. The standard replacement time is as follows: The parts may need to be replaced earlier than the time described depending on operating environment.

Any deterioration or abnormal condition is identified during operation or inspection, replace those parts immediately.

1. Backup Battery (when stored at a temperature of 25°C)

The battery powers the internal clock. When the battery is depleted, the date and time cannot be correctly recorded. The service life may be shortened when used in high temperature, low temperature or high humidity conditions. When the battery is depleted and the message <Replace the backup battery. The clock will be initialized. (Contact your dealer for details.)>is displayed, replace the battery as soon as possible.

2. Li-ion Battery Pack: 300 times of charging/discharging

If the Li-ion battery pack is degraded, the operation time decreases even if the battery is fully charged.

3. Display Unit Backlight: 20,000 hours

A worn LCD backlight lowers the LCD brightness and may prevent the LCD from illuminating.

4. Paper Driver Motor: Approx 1,000 hours of use (continuous printing)

A worn paper drive motor results in unstable printing due to irregular paper feed and fluctuating printing speed.

5. Thermal Print Head: Approx. 50 km (continuous printing)

A worn thermal print head lowers the overall printout density and causes missed dots.

❑Replacing the Li-ion Battery Pack

If the battery operating time becomes extremely short even if it is fully charged, replace with a new battery.

⚠ WARNING

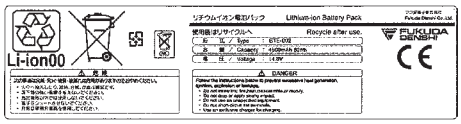
- Users should not attempt to install or replace the battery pack. Otherwise, it may result in electric shock.
- Do not throw the battery into fire. If the battery is placed in fire, it may explode.
- Charge the battery only with this device. Otherwise, acid leakage, overheating or explosion may occur.
- Do not disassemble or remodel the battery. If the leaked solution of the battery gets into the eyes, do not rub the eyes. Wash thoroughly with clean water and immediately receive medical treatment from a doctor. If the leaked solution gets on to the skin or clothes, wash it off with clean water immediately.
- Do not use the battery with any other device. Otherwise, acid leakage, overheating or explosion may occur.
- Do not short-circuit the terminal. Otherwise, acid leakage, overheating or explosion may occur.
- If charging is not completed after the prescribed charging time, stop charging the battery. Otherwise, acid leakage, overheating or explosion may occur.
- Do not drop the battery or subject it to strong impact.
- When disposing of a battery, entrust disposal to a specialized waste disposal contractor.
- The Li-ion battery pack should be replaced by well-trained service personnel. When installing or replacing the Li-ion battery pack, contact our service representative. Otherwise, it may cause a fire hazard or electric shock.

⚠ CAUTION

- Make sure to use the specified battery (BTE-002). Acid leakage, overheating or explosion may occur if a battery other than the specified battery is used.
- Follow the precautions below when using the battery.
  Battery Life
  The battery can be charged and discharged (used) for approximately 300 times or within 1 year. Note that the service life varies depending on the frequency of use and the charging/ discharging pattern of the battery.If the battery runs out shortly after being charged, this means that it has reached the end of its life and needs to be replaced with a new battery.
  Storing the Battery
  If not using the device for a long time, remove the battery from the device and store it. Every three months, install the battery in the device and fully charge it. If left for a long period of time, the battery may self-discharge to the point where it can no longer be used.
  Avoid storing the battery in a place where the temperature is lower than 0°C or higher than 35°C.

NOTE

- The month/year of manufacture is indicated on a label of the battery pack.



Manufactured Month/Year
□ □
Month: (Jan.: A, Feb.: B, ... Dec.: L)
Year: (2018: W, 2019: X, ...)

Cleaning and Disinfection

Cleaning the Device

❑Cleaning

Wipe using a tightly squeezed cloth dampened with alcohol (ethanol, isopropyl alcohol). Then wipe with a dry cloth.
Usable Cloth:

- Soft cloth (cotton)
- Soft non-woven cloth (pulp, rayon, polyethylene, etc.)

❑Disinfection

Wipe with a cloth dampened with one of the following chemicals. Then, wipe off with dry cloth.
Chemicals:

- Glutaral 2%
- Alcohol (ethanol, isopropyl alcohol)
- Benzalkonium Chloride 0.2%
- Benzethonium Chloride 0.2%
- Alkyldiaminoethylglycine Hydrochloride 0.5%

Usable Cloth:

- Soft cloth (cotton)
- Soft non-woven cloth (pulp, rayon, polyethylene, etc.)

⚠ CAUTION

- Clean the device frequently so stains can be removed easily.
- To prevent injury, it is recommended to wear gloves when cleaning the device.
- When cleaning or disinfecting, do not allow chemical solution to enter the device or connectors.
- Do not use organic solvents, thinner, toluene or benzine to avoid damaging the resin case.
- Do not polish the device with abrasive, chemical cleaner, alkaline or acidic detergent. Otherwise, the surface resin or paint coating may be damaged, resulting in discoloration, scratches, and other problems.
- For the precautions for storing and handling the chemicals, refer to the instruction manual for the respective chemical.

❑Cleaning the Paper Sensor

Misdetection of marks and paper may occur if paper scraps and dust are attached on the sensor. In such case, use an air duster to remove the paper scraps and dust.

⚠ CAUTION

- Do not use liquid such as water or alcohol when cleaning the sensor. It may cause failure to the device.

❑Cleaning the Thermal Print Head

The recording paper dust adhering to the thermal print head lowers the print quality. If the printed ECG data or characters begin to fade or become unclear, clean the thermal print head. Use a cotton swab moistened in alcohol to wipe away print residue.

⚠ CAUTION

- Never use sandpaper as it will damage the heating element.
- Contact your Fukuda Denshi representative when the thermal print head requires cleaning.

❑Cleaning the Touch Panel

Since the display panel uses a touch panel, finger prints and other stains are likely to appear.
Wipe the touch panel using a soft cloth.

⚠ CAUTION

- Never use strong-acidic cleaning solution.

Cleaning the Accessories

❑Patient Cables, Connection Cables

- Wipe with a tightly squeezed cloth dampened with ethanol or 70% isopropyl alcohol. Then, wipe off with a dry cloth.
- Do not use organic solvents, thinner, toluene, benzine, or cresol soap solution as it may damage or break the cable.

- Do not heat-disinfect the electrodes with water, steam or air.

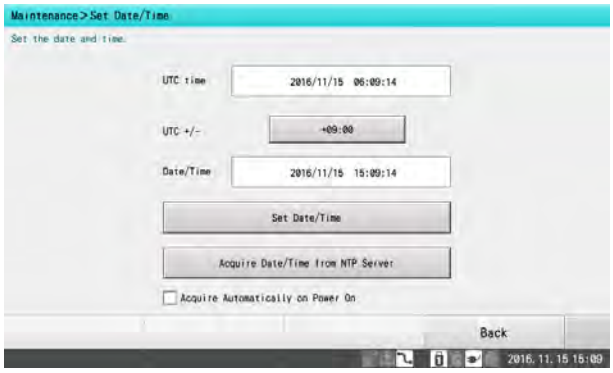
❑Electrodes, Clip Electrodes

- Wipe with a tightly squeezed cloth dampened with ethanol. Then, wipe off with dry cloth.
- Do not use organic solvents, thinner, toluene or benzine.
- Infection can occur via electrodes. The electrodes must therefore always be kept clean by cleaning and disinfecting.
- Do not reuse disposable electrodes designed for single use. This may cause infection.
- Do not heat-disinfect the electrodes with water, steam or air.

Correcting the Date and Time

1 Press [Menu] - [Maintenance] -[Set Date/Time].

2 Check that the date and time are correct.



▸ Proceed to step 5 if the date and time are correct or step 3 if they need to be corrected.

3 To change the date and time, touch [Set Date/Time].

▸ When the device is already connected to the network and the date and time can be obtained from the NTP server, the date and time can be set automatically by touching [Acquire Date/Time from NTP Server].

▸ The date and time can be automatically obtained from the NTP server each time the device is turned on if [Acquire Automatically on Power On] has been touched and checked.

REFERENCE

- To use the NTP server, the IP address of the NTP server should be set. (☞"Communication" P13-10)

4 Enter the date and time.

1 Touch [←] and [→] to select the item to be changed.

2 Enter the current date and time.

3 [Touch [↵].
To close the "Set Date/Time" window without saving the changes, touch [x].

5 Touch [Back] after configuring the settings.

Chapter 15 Appendix

Specifications

The specifications of the device are as follows.

REFERENCE

- Specifications are subject to change without prior notice to improve the quality of products.

❑ECG

Operation Panel	Power key, START/STOP key, Review key, Reset Key, 1 mV key, Lead key, Sensitivity key, custom keys, alphanumeric keys
Standard Sensitivity	10 mm/mV
Sensitivity Selection	1/4, 1/2, 1, 2, Auto
HR Detection Range/Accuracy	20 bpm to 300 bpm, Error: ±2 or less
Input impedance	2.5 MΩ and above
Differential and Common-Mode Offset Voltage (Electrode-Skin Voltage)	±600 mV and above
Recovery Time	Within 1 second
Tolerable Overload Voltage	1 Vp-v, 10 seconds
Sine Wave Characteristics	0.05 Hz to 250 Hz
Low Frequency Characteristics (Time Constant)	3.2 sec. and above
Common-Mode Signal Suppression	103 dB and above (2 mm [p-v] and below at sensitivity level 1)
Leads	Standard 12-lead
Lead Selector	Error: within 5%
Skew between Leads	0 sec.
Noise Level	20μV (p-v) and below (input conversion)
Filter	AC filter: -20 dB or less at 50 Hz or 60 Hz Muscle filter: -3 dB (-6 dB/oct) or less at 35 Hz or 25 Hz Drift: -3 dB (-12 dB/oct) or less at 0.25 Hz or 0.5 Hz
Printing	Thermal Print Head Method
Printing Speed	5, 10, 12.5, 25, 50 mm/s ±2% or less
Printing Density	Amplitude direction: 8 dots/mm Direction of the time axis: 5 ms (5 mm/s), 2.5 ms (10 mm/s), 2 ms (12.5mm/s), 1 ms (25 mm/s), 500 μs (50 mm/s)
Printing Channel	3 ch, 6 ch, 12 ch
Printing Paper	Roll paper with grids: OP-69TE Z-fold paper with grids: OP-618TE, OP-621TE
Display	Color LCD, 800 x 480 dots (with LED backlight)
LED	AC power supply LED, battery charging LED
A/D Conversion	24-bit
Sampling Rate	8000 samples/sec.
LAN Port	Conforms to IEEE802.3u 100BASE-TX (The cable must be within 50 m.)
Wireless LAN	Compatible with IEEE802.11 a/b/g/n
Filing	USB memory, SD card

USB port	Compatible with USB2.0 Full Speed, 3 ports
SD Card	Compatible with SD Card Specification 2.0
Serial Port	Compatible with RS-232C, 2 ports
R-SYNC Port	5V output

❑ Processing Unit

Patient Information	ID number, age, gender, height, weight, etc.
Basic Measurement	Heart rate, RR, PR, QRS, QT time, QTcB, QTcF, electrical axis, SV1, RV5 (6), TV1, R+S
Interpretations and Codes	More than 130 types
Minnesota Code	Approximately 130 types
Grade Judgment	4 types

❑Whole Equipment

Safety	Class I equipment and internally powered equipment
	Type CF Applied Part
Applicable Standards	Safety Standard: IEC 60601-1(2005) +A1(2012), ANSI AAMI / ES 60601-1: A1: 2012+C1: 2009/(R)2012+ A2: 2010/(R)2012
	EMC Standard: IEC 60601-1-2: 2007
Cardiac Defibrillator Recovery Time	Within 5 seconds
Power Supply	AC power: 115 V AC, 50/60 Hz
	DC power: 14.8 V DC / Approx. 4,600 mAh (Battery)
Power Consumption	100 VA (AC)
On-Board 12 V Power Supply	Unusable
Dimensions	Approximately 330 mm (W) × 350 mm (D) × 85 mm (H) (not including the protrusion) Approximately 330 mm (W) × 350 mm (D) × 112.6 mm (H) (including the protrusion)
Weight	Approximately 4.0 kg (main unit only) Approximately 4.5 kg (including options such as battery)

❑Operating Environment

Temperature	10°C to 40°C
Humidity	25% to 95% (Non-condensing)
Atmospheric Pressure	80 kPa to 106 kPa

❑Transport/Storage Environment (Whole Device)

Temperature	-10°C to 60°C
Humidity	10% to 95% (at 40°C, non-condensing)
Atmospheric Pressure	80 kPa to 106 kPa

❑Transport/Storage Environment (Specified Products: Recording Paper)

Temperature	-10°C to 35°C
Humidity	20% to 80% (Non-condensing)
Atmospheric Pressure	80 kPa to 106 kPa

❑Transport Environment (Specified Products: Li-ion Battery Pack)

Temperature	-20°C to 35°C
Humidity	45% to 85% (Non-condensing)
Atmospheric Pressure	80 kPa to 106 kPa

❑Storage Environment (Specified Products: Li-ion Battery Pack)

Temperature	-20°C to 60°C (Within 30days) -20°C to 45°C (30days to 90days) -20°C to 35°C (90days to 1year)
Humidity	45% to 85% (Non-condensing)
Atmospheric Pressure	80 kPa to 106 kPa

Standard Items

Item	Model	Quantity	Remarks
Operation Manual	FX-8400 Operation Manual	1	
Language Sheet Set	FX-8400 Language Sheet Set	1 set (Contains 8 sheets)	English, French, German, Spanish, Italian, Russian, Portuguese, Vietnamese

System Components

NOTE

- To satisfy the intended safety and performance of the product, use only the specified items below.
- When placing an order, specify the item name and model type.
- Specifications are subject to change without prior notice to improve the quality of products.

❑Accessories

Item	Model Type	Quantity	Remarks
Power Cable	CS-24	1	
Li-ion Battery Pack	BTE-002	1	
ECG Interpretation Software	FP-811	1	
Recording Paper	OP-69TE	1	Roll paper with grid
	OP-621TE	1	Z-fold paper with grid
SD Card	SD-2G	1	Capacity:2 GB
Serial 8P Cross Cable	CJS-03DA5-C	1	for connecting the external device, Length 5 m

❑The Other Medical Devices

The other medical devices to be used in combination with this device as a system are shown below.

Item	Model Type	Quantity	Remarks
Patient Cable	CP-105L-2038	1	
Clip electrodes	TE-43	1 set (Contains: 4)	Adult
Chest electrodes	TE-01	1 set (Contains: 6)	Adult

❑The Other Products

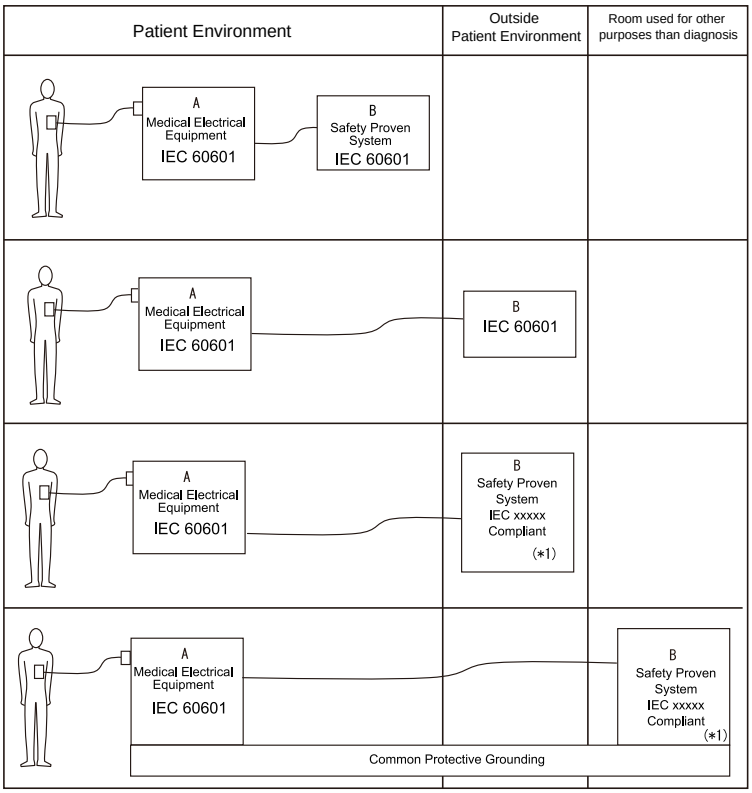
The other non-medical products to be used in combination with this device as a system are shown below.

Item	Model Type	Quantity	Remarks
USB Memory	USB-1G	1	Capacity: 1 GB
	SFU34096C1AE2TO-C-GE-1AP-STD	1	Capacity: 4 GB
USB Wireless LAN adapter	EW-7822ULC	1	
LAN Cable	general commercial product	1	Local purchase
Barcode Reader	(*)	1	USB type, local purchase
Personal Computer	(*)	1	
Ethernet Hub	(*)	1	For data transmission via wired LAN
Color Printer	(*)	1	For outputting A4 report via wired LAN

*: Contact your local service representative for usable model type.

Combination Example of Medical and Non-Medical Equipments

The general description of possible combination of different equipments in different medical environment as specified in IEC 60601-1 and ANSI AAMI / ES 60601-1, "Medical electrical equipment – Part 1: General requirements for basic safety and essential performance" is described below.
The system must provide the level of safety equal to that of medical electrical equipments that comply with IEC 60601-1 and ANSI AAMI / ES 60601-1 in the patient environment. The system must be as safe as non-medical electrical equipments that comply with other IEC or ISO safety standards outside the patient environment. IEC 60601-1 and ANSI AAMI / ES 60601-1 specifies that the level of safety offered by non-medical electrical equipments used outside the patient environment is acceptable if it conforms to the technical standards established in the applicable IEC or the safety equivalent to those is ensured. (*1)
To construct a medical electrical system, install Equipment B as shown below assuming that ECG is Equipment A. Refer to the "List of System Equipment" for the connectable equipment inside/outside the patient environment.



List of System Equipment

Item	Model Type
[Outside Patient Environment]	
Personal Computer	(*)
Ethernet Hub	(*)
Color Printer	(*)

*: Contact your local service representative for usable model type.

Check List

❑Daily Check List

Item	Inspection Item	Procedure, Measurement, Criteria	Judgment	Remarks (Repair required)
Appearance				
External Appearance	1 Exterior flaws, cracks, deformation, rust	Check that flaws, cracks, deformation and rust are not found on the main unit.	OK/NG	
	2 Peeling and dirt on label and panel	Check that peeling or dirt is not found on the label or the panel.	OK/NG	
	3 Key	Check that the keys are not damaged.	OK/NG	
Accessories	1 Power cable, patient cables, nip lead	Check that flaws and damage are not found.	OK/NG	
	2 (when used) Clip electrode, chest electrode	Check for dirt, rust. Check that flaws and damage are not found.s	OK/NG	
	3 Recording Paper	Check that paper is properly loaded.	OK/NG	
	4 Operation Manual	Check that it is stored in specified location.	OK/NG	
Mechanical Check				
Main Unit	1 Key	Check that the key operation is smooth.	OK/NG	
	2 Printer	Check that the operation is smooth and that abnormal sound is not heard.	OK/NG	
Accessories	1 Power cable, patient cables, nip lead	Check for smooth operation without looseness	OK/NG	
	2 (when used) Clip electrode, chest electrode	Check that no problem is found with the connection.	OK/NG	
Electrical Check				
Performance	1 Power Supply	Check that the display appears when the power is turned ON.	OK/NG	
	2 Display	Check that waveforms are displayed.	OK/NG	
	3 Printing Test	Check that waveforms can be printed.	OK/NG	
	4 Printing Speed (25 mm/s)	Check that the error for 10 seconds falls within ±2% range.	OK/NG	
	5 Calibration Voltage	Check that the error is within 5%.	OK/NG	
	6 Internal Memory	After changing the setting, close the setting screen and open it again. Check that the change in setting is reflected. (It should not return to original setting.)	OK/NG	
Overall Judgment			OK/NG	

Model Name		Installation location	
Model	FX-8400	Date of Inspection	
Serial Number		Checked by	
Date of Purchase		Approval	

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❑Periodic Check List

Item	Inspection Item	Procedure, Measurement, Criteria	Judgment	Remarks (Repair required)
Appearance				
External Appearance	1 Exterior flaws, cracks, deformation, rust	Check that flaws, cracks, deformation and rust are not found on the main unit.	OK/NG	
	2 Peeling and dirt on label and panel	Check that peeling or dirt is not found on the label or the panel.	OK/NG	
	3 Key	Check that the keys are not damaged.	OK/NG	
Accessories	1 Power cable, patient cables, nip lead	Check that flaws and damage are not found.	OK/NG	
	2 (when used) Clip electrode, chest electrode	Check for dirt, rust.Check that flaws and damage are not found.	OK/NG	
	3 Recording Paper	Check that paper is properly loaded.	OK/NG	
	4 Operation Manual	Check that it is stored in specified location.	OK/NG	
Mechanical Check				
Main Unit	1 Key	Check that the key operation is smooth.	OK/NG	
	2 Printer	Check that the operation is smooth and that abnormal sound is not heard.	OK/NG	
Accessories	1 Power cable, patient cables, nip lead	Check for smooth operation without looseness	OK/NG	
	2 (when used) Clip electrode, chest electrode	Check that no problem is found with the connection.	OK/NG	
Electrical Check				
Performance	1 Power Supply	Check that the display appears when the power is turned ON.	OK/NG	
	2 Display	Check that waveforms are displayed.	OK/NG	
	3 Printing Test	Check that waveforms can be printed.	OK/NG	
	4 Printing Speed (25 mm/s)	Check that the error for 10 seconds falls within ±2% range.	OK/NG	
	5 Calibration Voltage	Check that the error is within 5%.	OK/NG	
	6 Internal Memory	After changing the setting, close the setting screen and open it again. Check that the change in setting is reflected. (It should not return to original setting.)	OK/NG	
Maintenance	1 Backup battery	Backup Battery Voltage 2.5V and above	OK/NG	
	2 Clock Setting	Check that correct time is displayed.	OK/NG	
	3 Printing Test	Check that the recording paper is fed straight. Check that both sides of the recording paper are not creased. Check that the printing is not uneven or too light. Check that there is no missing dots. Check that printing speed is 5, 10, 25 or 50 mm/s (within ±2%) (☞"2) Thermal Printing Test" P14-4)	OK/NG	
	4 Touch Panel Adjustment Display/touch panel test	Adjust the touch panel using an object with soft end. Check that all dots are lit and correct text, lines and colors are displayed. It should correctly respond at the touch point.	OK/NG	
	5 Key/LED/Sound Test	Check that the pressed key is displayed, the LED lights, and buzzer sounds.	OK/NG	

Item	Inspection Item	Procedure, Measurement, Criteria		Judgment	Remarks (Repair required)
Electrical Safety	1 Earth Leakage Current				
	Normal Condition	5 mA and below	mA	OK/NG	
	Single Fault Condition	10 mA and below	mA	OK/NG	
	2 Touch Current				
	Normal Condition	0.1 mA and below	mA	OK/NG	
	Single Fault Condition	0.5 mA and below	mA	OK/NG	
	3 Patient Leakage Current (from patient connection to earth)				
	Direct Current				
	Normal Condition	0.01 mA and below	mA	OK/NG	
	Single Fault Condition	0.05 mA and below	mA	OK/NG	
	Alternating Current				
	Normal Condition	0.01 mA and below	mA	OK/NG	
	Single Fault Condition	0.05 mA and below	mA	OK/NG	
	4 Patient Leakage Current (Current when external voltage is applied to SIP/SOP)				
	Direct Current				
	Normal Condition	0.01 mA and below	mA	OK/NG	
	Single Fault Condition	0.05 mA and below	mA	OK/NG	
	Alternating Current				
	Normal Condition	0.01 mA and below	mA	OK/NG	
	Single Fault Condition	0.05 mA and below	mA	OK/NG	
	5 Patient leakage current (Current when external voltage is applied to the patient connecting part in the Type F attaching part)				
	Single Fault Condition	0.05 mA and below	mA	OK/NG	
	6 Patient Auxiliary Current				
	Direct Current				
	Normal Condition	0.01 mA and below	mA	OK/NG	
	Single Fault Condition	0.05 mA and below	mA	OK/NG	
	Alternating Current				
	Normal Condition	0.01 mA and below	mA	OK/NG	
	Single Fault Condition	0.05 mA and below	mA	OK/NG	

Item	Inspection Item	Procedure, Measurement, Criteria	Judgment	Remarks (Repair required)
Other	1 Power Supply	Check that both AC power and rechargeable battery power can be turned on/off.	OK/NG	
	2 Power Supply Cable	Perform a continuity test using a tester and check that the device is conducting.	OK/NG	
Overall Judgment			OK/NG	

Model Name		Installation location	
Model	FX-8400	Date of Inspection	
Serial number		Checked by	
Date of Purchase		Approval	

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Glossary

❑Terms for Measurement Mode

Basic Waveform Measurement	Average of detailed waveform measurement
Detailed Waveform Measurement	Dominant waveform measurement of each lead
Basic Arrhythmia Measurement	Average of detailed arrhythmia measurement
Detailed Arrhythmia Measurement	Raw waveform (I, II, V2, V5) measurement of each heart rate

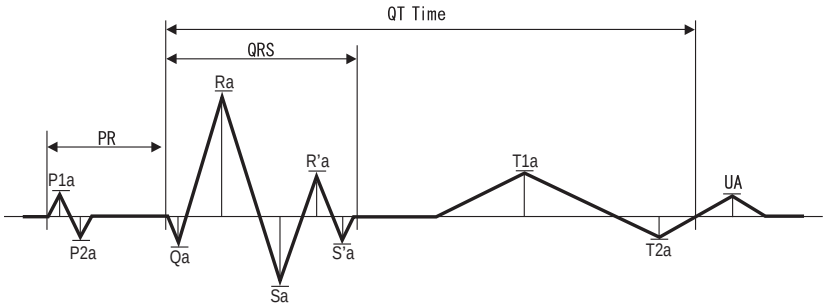
❑Basic Measurement

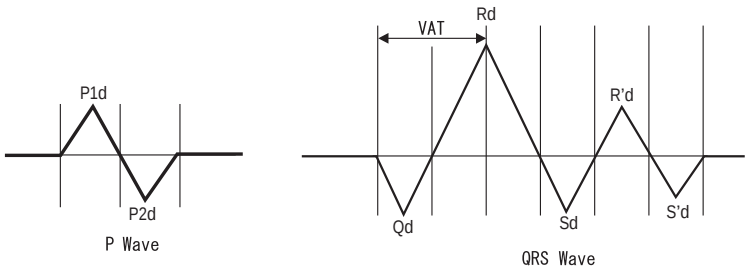
HR	Heart rate of basic arrhythmia measurement Heart rate calculated from the average R-R duration of detailed arrhythmia measurement
R-R	R-R duration of basic arrhythmia measurement Average value of the R-R duration within ±25% of the average of heartbeats which one P wave is measured
P-R	P-R duration of basic waveform measurement Average of the measurements of leads I to V6
QRS	QRS duration of detailed waveform measurement The isoelectric segments within the QRS are excluded from the Q-, R- or S- waves.
QT	QT duration of basic waveform measurement Average of the measurements of leads I to V6
QTcB	QTc duration of basic arrhythmia measurement Value calculated from the following formula (Bazett's formula): QTcB = Average waveform QT time/$\sqrt{\text{(Arrhythmia Average R-R Time (sec.))}}$
QTcF	Value calculated from the following formula (Fredencia's formula): QTcF = Average waveform QT time/$\sqrt[3]{\text{(Arrhythmia Average R-R Time (sec.))}}$
Axis	QRS axis of basic waveform measurement Axis (°) = Tan^{-1} ($\sqrt{3}$ (II+III) / (2×I+II-III)) where, I, II, and III are the sums of the maximum amplitude values (signed) of Q, R, S, R', and S' waves from each lead.
RV5/RV6	Maximum amplitude of R and R' waves of lead V5 or V6 of detailed waveform measurement Lead V5 > Lead V6: RV5 Lead V5 ≤ Lead V6: RV6
SV1	Maximum amplitude (absolute value) of Q wave, S wave, and S' wave of lead V1 of detailed waveform measurement
TV1	Maximum amplitude of T wave of lead V1 of detailed waveform measurement
R+S	Sum of the "RV5/RV6" and "SV1" amplitudes

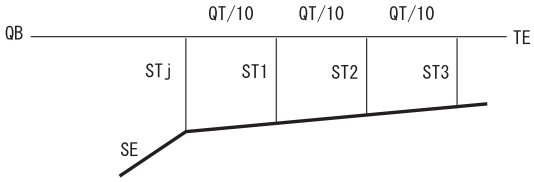
❑Detailed Measurement

P1a	P1 amplitude of detailed waveform measurement
P2a	P2 amplitude of detailed waveform measurement
Qa	Q amplitude of detailed waveform measurement
Ra	R amplitude of detailed waveform measurement
Sa	S amplitude of detailed waveform measurement
R'a	R' amplitude of detailed waveform measurement
Ja	J amplitude of detailed waveform measurement
ST1	ST1 amplitude of detailed waveform measurement

ST2	ST2 amplitude of detailed waveform measurement
T1a	T1 amplitude of detailed waveform measurement
T2a	T2 amplitude of detailed waveform measurement
P1d	P1 duration of detailed waveform measurement
P2d	P2 duration of detailed waveform measurement
Qd	Q duration of detailed waveform measurement
Rd	R duration of detailed waveform measurement
Sd	S duration of detailed waveform measurement
R'd	R' duration of detailed waveform measurement
Jd	J duration of detailed waveform measurement
P-R	P-R duration of detailed waveform measurement
QRS	QRS duration of detailed waveform measurement
FVT	FVT duration of detailed waveform measurement
FLG	Notch flag and noise level of the QRS wave of detailed waveform measurement







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