Operator's Manual

cardiofax© Electrocardiograph





About This Manual

In order to use this product safely and fully understand all its functions, read this manual before using the product. Keep this manual near the instrument or in the reach of the operator and refer to it whenever the operation is unclear.

- Accompanying Documentation -

The product comes with the following manuals. Refer to the manual depending on your needs.

Operator's Manual (this manual)

Describes the operation and settings of the product. Read this manual before use.

Service Manual

For qualified service personnel. Describes information on servicing the product. Only qualified service personnel can service the product.

Copyright Notice

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This product stores personal patient information. Manage the information appropriately.

Patient names on the screen shots and recording examples in this manual are fictional and any resemblance to any person living or dead is purely coincidental.

The contents of this manual are subject to change without notice. If you have any comments or suggestions on this manual, please contact us at: https://www.nihonkohden.com/



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GENERAL HANDLING PRECAUTIONS

This device is intended for use only by qualified medical personnel.

Use only Shanghai Kohden approved products with this device. Use of non-approved products or in a non-approved manner may affect the performance specifications of the device. This includes, but is not limited to, batteries, recording paper, pens, extension cables, lead wires, input boxes and AC power.

The intended use is just only for diagnosis, not for monitoring of vital physiological parameters.

Please read these precautions thoroughly before attempting to operate the device.

1. To safely and effectively use the device, its operation must be fully understood.

2. When installing or storing the device, take the following precautions:

- (1) Avoid moisture or contact with water, extreme atmospheric pressure, excessive humidity and temperatures, poorly ventilated areas, and dust, saline or sulphuric air.
- (2) Place the device on an even, level floor. Avoid vibration and mechanical shock, even during transport.
- (3) Avoid placing in an area where chemicals are stored or where there is danger of gas leakage.
- (4) The power line source to be applied to the device must correspond in frequency and voltage to product specifications, and have sufficient current capacity.
- (5) Choose a room where a proper grounding facility is available.

3. Before Operation

- (1) Check that the device is in perfect operating order.
- (2) Check that the device is grounded properly.
- (3) Check that all cords are connected properly.
- (4) Pay extra attention when the device is combined with other devices to avoid misdiagnosis or other problems.
- (5) All circuitry used for direct patient connection must be doubly checked.
- (6) Check that battery pack level is acceptable and battery pack condition is good when using battery pack-operated models.

4. During Operation

- (1) Both the device and the patient must receive continual, careful attention.
- (2) Turn power off or remove electrodes and/or transducers when necessary to assure the patient's safety.
- (3) Avoid direct contact between the device housing and the patient.
- (4) The operator must not touch patients and the input/output interface of the equipment simultaneously, this may cause electric shock.

5. To Shutdown After Use

- (1) Turn the power off with all controls returned to their original positions.
- (2) Remove the cords gently; do not use force to remove them.
- (3) The mains plug or appliance coupler is intended to be used as an isolation device from the supply mains. Always make sure that the mains plug or appliance coupler is easy to operate.
- (4) Clean the device together with all accessories for their next use.
- 6. The device must receive expert, professional attention for maintenance and repairs. When the device is not working properly, it should be clearly marked to avoid operation while it is out of order.

- 7. The device must not be altered or modified in any way.
- 8. Maintenance and Inspection
 - (1) The device and parts must undergo regular maintenance inspection at least every 6 months.
 - (2) If stored for extended periods without being used, make sure prior to operation that the device is in perfect operating condition.
 - (3) Technical information such as circuit diagrams, component part lists, descriptions, calibration instructions or other information is available for SERVICE PERSONNEL upon request from your Nihon Kohden representative.
- 9. When the device is used with an electrosurgical device, pay careful attention to the application and location of electrodes and transducers to avoid possible burn to the patient.
- 10. When the device is used with a defibrillator, make sure that the device is protected against defibrillator discharge. If not, remove patient cables and transducers from the device to avoid possible damage.
- 11. Contraindications: None.
- 12. The electrodes cannot be applied directly on the heart.

WARRANTY POLICY

Shanghai Kohden Medical Electronic Instrument Corp. (SKC) shall warrant its products against all defects in materials and workmanship for one year from the date of delivery. However, consumable materials such as recording paper, ink, stylus and battery pack are excluded from the warranty.

SKC or its authorized agents will repair or replace any products which prove to be defective during the warranty period, provided these products are used as prescribed by the operating instructions given in the operator's and service manuals.

No other party is authorized to make any warranty or assume liability for SKC's products. SKC will not recognize any other warranty, either implied or in writing. In addition, service, technical modification or any other product change performed by someone other than SKC or its authorized agents without prior consent of SKC may be cause for voiding this warranty.

Defective products or parts must be returned to SKC or its authorized agents, along with an explanation of the failure. Shipping costs must be pre-paid.

This warranty does not apply to products that have been modified, disassembled, reinstalled or repaired without Shanghai Kohden approval or which have been subjected to neglect or accident, damage due to accident, fire, lightning, vandalism, water or other casualty, improper installation or application, or on which the original identification marks have been removed.

EMC RELATED CAUTION

This equipment and/or system complies with IEC 60601-1-2 International Standard for electromagnetic compatibility for medical electrical equipment and/or system. However, an electromagnetic environment that exceeds the limits or levels stipulated in IEC 60601-1-2, can cause harmful interference to the equipment and/or system or cause the equipment and/or system to fail to perform its intended function or degrade its intended performance. Therefore, during the operation of the equipment and/or system, if there is any undesired deviation from its intended operational performance, you must avoid, identify and resolve the adverse electromagnetic effect before continuing to use the equipment and/or system.

The following describes some common interference sources and remedial actions:

- 1. Strong electromagnetic interference from a nearby emitter source such as an authorized radio station or cellular phone:
 - Install the equipment and/or system at another location. Keep the emitter source such as cellular phone away from the equipment and/or system, or turn off the cellular phone.
- 2. Radio-frequency interference from other equipment through the AC power supply of the equipment and/or system:
 - Identify the cause of this interference and if possible remove this interference source. If this is not possible, use a different power supply.
- 3. Effect of direct or indirect electrostatic discharge:
 - Make sure all users and patients in contact with the equipment and/or system are free from direct or indirect electrostatic energy before using it. A humid room can help lessen this problem.
- 4. Electromagnetic interference with any radio wave receiver such as radio or television:
 - If the equipment and/or system interferes with any radio wave receiver, locate the equipment and/or system as far as possible from the radio wave receiver.
- 5. Interference of lightning:
 - When lightning occurs near the location where the equipment and/or system is installed, it may induce an excessive voltage in the equipment and/or system. In such a case, disconnect the AC power cord from the equipment and/or system and operate the equipment and/or system by battery power, or use an uninterruptible power supply.
- 6. Use with other equipment:
 - When the equipment and/or system is adjacent to or stacked with other equipment, the equipment and/or system may affect the other equipment. Before use, check that the equipment and/or system operates normally with the other equipment.
- 7. Use of unspecified accessory, transducer and/or cable:
 - When an unspecified accessory, transducer and/or cable is connected to this equipment and/or system, it may cause increased electromagnetic emission or decreased electromagnetic immunity. The specified configuration of this equipment and/or system complies with the electromagnetic requirements with the specified configuration. Only use this equipment and/or system with the specified configuration.

Caution - continued

8. Use of unspecified configuration:

When the equipment and/or system is used with the unspecified system configuration different than the configuration of EMC testing, it may cause increased electromagnetic emission or decreased electromagnetic immunity. Only use this equipment and/or system with the specified configuration.

9. Measurement with excessive sensitivity:

The equipment and/or system is designed to measure bioelectrical signals with a specified sensitivity. If the equipment and/or system is used with excessive sensitivity, artifact may appear by electromagnetic interference and this may cause mis-diagnosis. When unexpected artifact appears, inspect the surrounding electromagnetic conditions and remove this artifact source.

If the above suggested remedial actions do not solve the problem, consult your Nihon Kohden representative for additional suggestions.

For EMC compliance, refer to "Specification - Electromagnetic Compatibility" in the Reference section.

NOTE about Waste Electrical and Electronic Equipment (WEEE) Directive 2002/96/EC

For the member states of the European Union only:

The purpose of WEEE directive 2002/96/EC is, as a first priority, the prevention of waste electrical and electronic equipment (WEEE), and in addition, the reuse, recycling and other forms of recovery of such wastes so as to reduce the disposal of waste. Contact your Nihon Kohden representative for disposal.

Conventions Used in this Manual and Device

Warnings, Cautions and Notes

WARNING: A warning alerts the user to possible injury or death associated with the use or misuse of the instrument.

CAUTION: A caution alerts the user to possible injury or problems with the instrument associated with its use or misuse such as instrument malfunction,

instrument failure, damage to the instrument, or damage to other property.

NOTE: A note provides specific information, in the form of recommendations,

prerequirements, alternative methods or supplemental information.

Text Conventions in this Manual

- Name of keys on the screen are enclosed in square brackets: [OK]
- Messages that are displayed on the screen are enclosed in quotation marks: "Continue?"
- Names of items that are displayed on the screen are enclosed in angle brackets: «Communication settings»
- Name of keys on the operation panel are enclosed in bold form: POWER key

General Safety Information

General

MARNING

Never use the electrocardiograph in the presence of any flammable anesthetic gas or high concentration oxygen atmosphere. Failure to follow this warning may cause explosion or fire.

MARNING

When the electrocardiograph is used with an electrosurgical unit (ESU), firmly attach the entire area of the ESU return plate. Otherwise, the current from the ESU flows into the electrodes of the electrocardiograph, causing electrical burn where the electrodes are attached. For details, refer to the ESU manual.

MARNING

Before defibrillation, remove everything including electrodes and patches from the patient's chest. If the defibrillator paddle contacts an object on the patient's chest, the discharged energy may be insufficient and cause skin burn.

MARNING

Use only the specified patient cables. Failure to follow this warning may cause skin burn where the electrode is attached and damage the electrocardiograph due to discharge energy when defibrillation is performed.

A WARNING

Transport only under conditions described in instructions for use or marked on ME EQUIPMENT with an indication of RESIDUAL RISK if ME EQUIPMENT or its parts overbalances.

MARNING

Never use the electrocardiograph in a hyperbaric oxygen chamber. Failure to follow this warning may cause explosion or fire.

MARNING

When performing MRI test, remove all electrodes and transducers from the patient which are connected to this device. Failure to follow this warning may cause skin burn on the patient. For details, refer to the MRI manual.

MARNING

Before defibrillation, all persons must keep away from the bed and must not touch the patient or any equipment or cable connected to the patient. Failure to follow this warning may cause electrical shock or injury.

MARNING

No modification of this equipment is allowed.

MARNING

This device is used for diagnosis only.

Do NOT use for monitoring in ICU/CCU or emergency room.

Installation

MARNING

Only connect Shanghai Kohden specified device to the electrocardiograph and follow the specified procedure. Failure to follow this warning may result in electrical shock or injury to the patient and operator, and cause fire or device malfunction.

MARNING

Install non-medical devices which are connected to the electrocardiograph outside the patient environment (IEC 60601-1:2012). If they are installed inside the patient environment, the patient or operator may receive electrical shock or injury.

MARNING

When the electrocardiograph is connected to an external device, ground all devices to the same one-point ground and use the specified isolation transformer for the external device even when the electrocardiograph is operated on battery pack. Otherwise, the patient and operator may receive electrical shock from leakage current from the external device.

⚠ WARNING

Do not connect the USB hub power cord to a wall power socket. Failure to follow this warning may cause electrical shock to the patient and operator.

MARNING

When the external device does not comply with the IEC 60601-1, use a local purchase medical isolation transformer unit between the external device and the wall power socket.

MARNING

Additional equipment connected to the medical electrical equipment must comply with the respective IEC or ISO standards (e.g. IEC 60950 for data processing equipment). Furthermore all configurations shall comply with the requirements for medical electrical systems (see IEC 60601-1). Anybody connecting additional equipment to medical electrical equipment configures a medical system and is therefore responsible that the system complies with the requirements for medical electrical systems. Attention is drawn to the fact that local laws take priority over the above mentioned requirements. If in doubt, consult your local representative or the technical service department.

MARNING

When several medical devices are used together, ground all devices to the same one-point ground. Any potential difference between devices may cause electrical shock to the patient and operator.

⚠ WARNING

Use only the provided power cord. Otherwise, the patient and operator may receive electrical shock or injury.

MARNING

Do not use an additional multiple portable socket outlet or extension cord. The impedance of the protective earth increases and the patient and operator may receive electrical shock or injury.

MARNING

Do not put the multiple portable socket outlet on a floor. If the multiple portable socket outlet gets dusty, damaged or contacts liquid, it may cause device malfunction and electrical shock to the patient or operator.

⚠ WARNING

To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

⚠ WARNING

The multiple socket-outlet, when provided as a separate item must not be placed on the floor. This may cause electric shock.

MARNING

To use non-medical equipment that requires an isolation transformer, only connect it to a specified multiple portable socket outlet that has an isolation transformer. Do not connect the non-medical equipment to a wall power socket or to a multiple portable socket that does not have an isolation transformer. Do not connect unspecified electrical devices to a multiple portable socket outlet in the system. If unspecified electrical devices are connected, leakage current increases and the patient and operator may receive electrical shock or injury.

A CAUTION

Before connecting or disconnecting devices, make sure that each device is turned off and the power cord is disconnected from the power socket. Otherwise, the patient or operator may receive electrical shock or injury.

MARNING

Install the laser printer which is connected to the electrocardiograph outside the patient environment (IEC 60601-1). If the laser printer is installed inside the patient environment, the patient or operator may receive electrical shock or injury. For installation, contact your Nihon Kohden representative.

A WARNING

Additional multiple socket-outlets or extension cords must not be connected to the system.

MARNING

Connect only items that have been specified as part of the system or specified as being compatible with the system.

MARNING

Follow IEC 60601-1 for connecting the electrocardiograph to other instruments.

A CAUTION

Do not install the electrocardiograph where it will be exposed to water or chemical solutions. Avoid direct sprinkling, spray or moist air from a nebulizer or humidifier. These cause malfunction and shorten the life of the electrocardiograph.

⚠ CAUTION

Do not place electrocardiograph upright. Failure to follow this instruction may cause the electrocardiograph to fall over.

⚠ CAUTION

The electrocardiograph should not share the power line with any device which consumes a lot of power, such as an X-ray device, because it may cause artifact.

A CAUTION

- Do not install the electrocardiograph near a power line, dynamo or motor which has electromagnetic induction.
- Do not install the electrocardiograph near an electrosurgical unit or RF therapeutic equipment.
- Select a room without excessive noise, vibration, sunlight, high humidity or water splashes.
- Make sure that there is no influence from a mobile phone.

⚠ CAUTION

When installing the electrocardiograph, take care not to pinch your finger under the electrocardiograph.

A CAUTION

Avoid locations where the electrocardiograph may receive strong electromagnetic interference such as radio or TV stations, mobile phones or mobile two-way radios.

A CAUTION

Make sure that there is enough space between the electrocardiograph and the wall for adequate ventilation. Leave more than 5 cm of space between the wall and electrocardiograph so that the operating temperature does not exceed 40 °C (104 °F). Otherwise the internal temperature of the electrocardiograph rises, which leads to inaccurate operation and shortens the electrocardiograph life.

Battery Pack

MARNING

- Never short-circuit the + and terminals on the battery pack. It may cause overheating and fire.
- Keep the battery pack away from fire. It may explode.
- Do not damage, disassemble, drop or give impact to the battery pack.
- Never use the battery pack on unspecified devices.
- Never charge the battery pack on unspecified devices.
- Never install the battery pack with the wrong polarity.
- Keep the battery pack away from patients and out of the reach of children.

⚠ WARNING

- Keep the battery pack away from fire, and never heat the battery pack, or it may result in leakage and explosion of the battery pack.
- Do not handle or store the battery pack with metals like necklace or hair clipper, because this has the risk of leakage and explosion due to short circuit of the battery pack.
- Do not use a battery pack which is damaged or dropped. There is a gas release valve inside the battery pack, and if the valve is damaged due to dropping, etc. the gas won't be released during operation, and this will induce explosion.

⚠ WARNING

If the battery pack is damaged and the substance inside the battery pack contacts the eyes or skin, wash immediately and thoroughly with water and see a physician. Never rub your eyes, because you may lose your eyesight.

MARNING

Only use the SB-301DC battery pack.

⚠ WARNING

Never connect the battery pack to an AC jack or ignition socket of an automobile. Failure to follow this warning may result in leakage and explosion of battery pack.

MARNING

- Avoid strong mechanical impact to the battery pack, may cause leakage and explosion of battery pack.
- Do not use a battery pack which is damaged, polluted or leaking. Failure to follow this warning may result in explosion.

MARNING

Do not charge the battery pack with any equipment other than the electrocardiograph. Otherwise, abnormal current will cause the leakage and explosion of battery pack.

⚠ CAUTION

Always install the battery pack even when the electrocardiograph operates on AC power. Otherwise sudden power off occurs when an electrode is detached during recording.

⚠ WARNING

- Do not immerse the battery pack in water. The battery pack may overheat and rust and the substance inside the battery pack may leak.
- Do not leave the battery pack unused for more than about one year. The battery pack may leak.

⚠ WARNING

It's strictly forbidden to disassemble, reconstruct, or damage the battery pack, or weld the shell directly. Failure to follow this warning may result in leakage and explosion.

MARNING

Check the direction of the connector when connecting the battery pack cable. Don't force the battery pack cable into the battery pack connector if abnormality is felt.

⚠ WARNING

Remove the battery pack from the electrocardiograph when it will not be used for more than 1 month. Otherwise the battery pack may leak and rust.

⚠ CAUTION

Do not bend or pull the connector of the battery pack with strong force. This may damage the battery pack cable or battery pack cable connector.

⚠ CAUTION

If the operation time of a fully charged battery pack is less than 30 minutes, the battery pack may have become deteriorated. Do not use a deteriorated battery pack. Charging a deteriorated battery pack may cause the electrocardiograph to fail to operate in both battery pack and AC power.

⚠ CAUTION

Replace the battery pack with a new one every year to assure maximum performance from the electrocardiograph.

⚠ CAUTION

Before inserting or removing battery pack, make sure that the electrocardiograph is turned off and the power cord is disconnected from the power socket. Otherwise, the operator may receive electrical shock.

A CAUTION

If the ambient temperature is over 30 °C (86 °F), charge it every three months because it self-discharges quickly.

A CAUTION

The SB-301DC battery pack is Ni-MH (Nickel-Metal Hydride). Before disposing of the battery pack, check with your local solid waste officials for details in your area for recycling options or proper disposal. The battery pack is recyclable. At the end of its useful life, under various state and local laws, it may be illegal to dispose of this battery pack into the municipal waste stream.

A CAUTION

- Charge the battery pack at ambient temperatures of 5 °C to 40 °C (41 °F to 104 °F). If the battery pack is charged below 5 °C or over 40 °C, the battery pack may leak or heat up. This may damage the battery pack.
- Store the battery pack at temperatures:
 - -20 °C to +65 °C (Less than 1 week)
 - -20 °C to +55 °C (Less than 1 month)
 - -20 °C to +45 °C (Less than 6 months)
 - -20 °C to +35 °C (Less than 1 year) in a dry place to prevent rusting and leakage.

A CAUTION

Do not expose the battery pack to direct sunlight or leave in a high temperature place. The lifetime of the battery pack may be shortened, the performance of the battery pack may be degraded and the battery pack may leak.

⚠ CAUTION

When the battery pack is stored more than 1 month, charge it before use because the battery pack may have self-discharged.

A CAUTION

The battery pack must be replaced by qualified service personnel.

Accessories and Consumables

A CAUTION

Do not leave accessories and consumables such as electrodes or electrolyte cream (Cardio Cream) near the patient or in reach of children. If they are swallowed, consult a physician immediately.

A CAUTION

Only use a Shanghai Kohden specified USB flash disk. Otherwise, the USB flash disk may not be available.

A CAUTION

Only use the Shanghai Kohden specified 63 mm recording paper. When a narrower recording paper is used and the paper detection circuit cannot detect it, the thermal head may be activated. The thermal head may be damaged where there is no recording paper and the rubber paper feed roller may get burned.

A CAUTION

- If unspecified recording paper is used, it might not print properly or send multiple pages.
- Follow the procedure to set the recording paper. Otherwise, the recording paper might not feed normally or the feeding motor may stop operation.
- When pasting the recording paper, use paste with a starch base, PVA base, arabic gum base paste, CMC base synthetic paste, or paper bond.

⚠ CAUTION

Only use Shanghai Kohden specified parts and accessories to assure maximum performance from your electrocardiograph. Using unspecified recording paper or electrodes may cause incorrect ECG recording and accelerate deterioration of the electrocardiograph.

A CAUTION

Do not leave the USB flash disk near patients or in reach of children.

A CAUTION

Prolonged storage under conditions such as high temperatures, excessive humidity, direct sunlight, and fluorescent light causes fading of the colored surface. Avoid high temperatures exceeding 50 °C (122 °F) and excessive humidity. Store the recording paper in a cool, dry and dark place if possible.

A CAUTION

- Do not apply high pressure to the recording paper. Rubbing or scratching the surface with a hard object discolors it.
- Do not use recording paper which is contaminated with ECG electrolyte cream (cardioCream) or saline solution because the recording paper will fade by the chloride and the contaminated thermal head may cause missing dots. If the thermal head gets contaminated, clean it with the thermal head cleaner pen.
- Do not set the recording paper immediately after recording because the thermal head is still hot.

A CAUTION

Organic solvents and plastics may develop color on the white surface or cause the recording paper to fade.

Examples of color-developing materials containing organic solvents: adhesives, paste, felt-tip pens, and semi-dry diazo paper.

Examples of color-fading materials made of soft vinyl chloride: document cases, albums, and desk pads including.

Examples of color-fading materials containing plastics: erasers, adhesive tapes, and some fluorescent pens.

⚠ CAUTION

- Clean the thermal head with the thermal head cleaner after every 100 m printing. A dirty thermal head degrades printing quality.
- Do not touch the thermal head with your fingers.
 If accidentally touched, clean the thermal head with the thermal head cleaner pen.

⚠ CAUTION

- · Never disassemble or modify the USB flash disk.
- Do not bend or give a strong impact to the USB flash disk.
- Do not handle the USB flash disk while smoking or eating. Do not get the USB flash disk wet.
- Do not touch any metal part of the USB flash disk.
- Do not peel off the label or sticker on the USB flash disk or put another label or sticker on the USB flash disk.
- Only use the USB flash disk in the specified device.
- Do not scratch the insertion part of the USB flash disk. The electrocardiograph might not operate if dust gets into the insertion part.

⚠ CAUTION

- Put the USB flash disk in the case when the USB flash disk is removed from the electrocardiograph. Store it where patients cannot accidently swallow the USB flash disk.
- Do not expose the USB flash disk to direct sunlight or leave in a place of high temperature and high humidity.
- Operating environment
 Temperature: -25 °C to +85 °C (-13 °F to +185 °F)
 - Humidity: -25 % RH to 95 % RH (noncondensing)
 - Storage environment
 Temperature: -40 °C to +85 °C (-40 °F to +185 °F)
 - Humidity: -25 % RH to 95 % RH (noncondensing)
- Do not store the USB flash disk in a corrosive gas environment.

MARNING

Additional equipment connected to the medical electrical equipment must comply with the respective IEC or ISO standards (e.g. IEC 60950 for data processing equipment). Furthermore all configurations shall comply with the requirements for medical electrical systems (see IEC 60601-1). Anybody connecting additional equipment to medical electrical equipment configures a medical system and is therefore responsible that the system complies with the requirements for medical electrical systems. Attention is drawn to the fact that local laws take priority over the above mentioned requirements. If in doubt, consult your local representative or the technical service department.

⚠ CAUTION

To ensure the cybersecurity of the electrocardiograph, implement the following security measures in the network environment to which the product is connected.

- 1. All communication (incoming and outgoing) between the electrocardiograph and the local area network (HIS, etc.) is subject to packet filtering by a firewall or router.
- 2. When the electrocardiograph is connected to the local area network (HIS, etc.), all communication with the internet or other external networks is restricted to essential transmissions under the supervision of the appropriate personnel with responsibility for information security of medical equipment.

A CAUTION

Use the electrocardiograph in a securely managed environment.

MARNING

Enter the patient information correctly. Otherwise, the ECG data may be lost or mixed up with another patient's ECG data. When managing test data that is only in electronic file, make sure to enter the patient information. After sending the DICOM data to an external system (such as PACS, etc.), make sure the ECG data is received and displayed correctly and the displayed patient information are consistent with the entered patient information.

MARNING

Connect the electrocardiograph to a network as specified. Otherwise the patient and operator may receive electrical shock or injury. To connect the network, contact your Nihon Kohden representative.

⚠ CAUTION

The network must be managed by the network administrator. Only the network administrator can change the network settings on the ECG-3150 electrocardiograph and connect the electrocardiograph to the network. Incorrect settings or connection may cause failure of the network system and device.

⚠ CAUTION

Select an installation location where patient information cannot be seen or accessed by unauthorized personnel.

A CAUTION

Personal information stored on the electrocardiograph, or the PC, is vulnerable to unauthorized access. Follow the provisions of the user agreement for the electrocardiograph related to information security.

A CAUTION

Information can be browsed through web client only when a medical institution is compliant with ISMS (Information Security Management System). Accessing the information from a global network environment is not allowed.

⚠ CAUTION

When sending/receiving patient test data or patient information, the communication should be carried out through the security network environment inside the medical institution.

Cart

⚠ CAUTION

Only use the KD-105D/105E, KD-108D/108E cart for this electrocardiograph. If another cart is used, it may tip over or the electrocardiograph may fall off.

↑ CAUTION

- Do not move the cart with the casters locked.
 The cart may tip over.
- · When moving the cart, hold the handle only.

A CAUTION

When moving the cart with patient cable hanger mounted, fold the upper and lower arms together, rotate the arms so that they point toward the handle and do not protrude beyond the edges of the cart.

A CAUTION

To prevent the cart from tipping over or the electrocardiograph falling off the cart:

- · Do not put or hook anything on the handle.
- Do not ride on the cart. Do not lean on the handle or put your weight on the cart.
- Periodically check that the casters, handle and frame are firmly attached and not wobbly.
- Always lock the casters so that the cart does not move accidentally.

Operation

⚠ WARNING

Do not connect the tip of the electrode lead to anything other than an electrode. Connect all the tips to the corresponding electrodes and attach them to the patient. If unconnected tips or electrodes contact an item which is not equipotentially grounded, the patient may receive electrical shock. Also, noise may superimpose on the ECG waveforms and measurement data may be incorrect.

MARNING

Only use the BJ-961D, BJ-962D, BJ-901D, BJ-902D, BJ-903D or BA-901D patient cables when using with a defibrillator. When the specified patient cable is connected, the electrocardiograph is type CF defibrillation-proof compliance. Failure to follow this warning may cause skin burn where the electrode is attached and damage the electrocardiograph due to discharge energy when defibrillation is performed.

⚠ WARNING

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ECG-3150, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

riangle warning

Do not touch the patient while touching any metal part of non-medical electrical equipment or an exposed part when a connector or cover is removed. Failure to follow this warning may cause electrical shock or injury to the patient.

⚠ WARNING

Do not use a damaged network cable. The patient or operator may receive electrical shock when the damaged part is touched.

MARNING

Do not diagnose a patient based on DICOM or PDF data acquired by the electrocardiograph. Otherwise, it may cause incorrect judgment.

MARNING

The operator should not touch patient and the input/output interface of the instrument simultaneously. This may cause electric shock.

A CAUTION

Do not use the output signal from the output connector of the electrocardiograph for a synchronization signal on a defibrillator. There is a time delay between the input signal and output signal. When using the output signal from the electrocardiograph for the synchronization signal on other device, always consider this time delay.

⚠ CAUTION

The paper cutter in the recording paper container is sharp. When setting the recording paper, be careful not to cut your finger. Set the recording paper as specified.

A CAUTION

Enter the patient information correctly. Otherwise, the ECG data may be lost or mixed up with another patient's ECG data.

⚠ CAUTION

The filter, auto gain and layout of the DICOM or PDF data which is output from the electrocardiograph are not entirely consistent with those on the recording paper.

A CAUTION

Changing the number of digits in ID will delete all ECG data in the internal memory. Back up the necessary data before changing the number of digits in ID.

A CAUTION

Do not remove the USB flash disk or turn the power off while formatting or data is being written to or read from the USB flash disk. This may damage the USB flash disk or saved data.

⚠ CAUTION

Do not use new and old electrodes together, or re-usable and disposable electrodes together (such as clip electrodes, suction electrodes and disposable electrodes). If different types are used together, it may cause a high polarization voltage and prevent displaying and recording of the ECG waveforms.

⚠ CAUTION

- Insert only a Shanghai Kohden specified USB flash disk in the USB flash disk connector.
- Insert or remove the USB flash disk straight into or out of the USB flash disk connector.

⚠ CAUTION

The parts of electrodes and other connectors should not contact other conductive parts including earth.

A CAUTION

During recording, if artifact superimposes on the ECG waveform, immediately stop the recording and remove the cause of the artifact. Refer to Troubleshooting in Section 9. Failure to follow this instruction causes overheating and damage to the electrocardiograph.

A CAUTION

Only use clean and undamaged electrodes with no scratches on the surface. Electrodes with a deteriorated surface may cause high contact impedance and distorted ECG waveforms.

A CAUTION

Only format or write data to the USB flash disk in the specified device. Otherwise, the USB flash disk may become unusable.

A CAUTION

- Format the USB flash disk before the first use.
- Format the USB flash disk only in an ECG-3150 electrocardiograph. The USB flash disk formatted in other ECG models cannot be used in this electrocardiograph.

A CAUTION

Make sure that the electrocardiograph power is turned off, when inserting or removing an USB flash disk. Otherwise, the data in USB flash disk may get damaged and operation of the electrocardiograph may become unstable.

A CAUTION

When using an ESU and defibrillator with the electrocardiograph, use silver chloride disposable electrodes.

A CAUTION

When baseline drift suppression is set to "Strong", distortion may occur in the ST segment with a decrease of heart rate when heart rate is less than 50. For bradycardia, set this item to "Weak". The "Weak" setting has characteristics conforming to the AHA recommendations.

A CAUTION

Always replace all the electrodes with new ones at the same time.

ECG Recording Judgement

A CAUTION

- The automatic ECG interpretation is performed for acquired ECG waveforms only and does not reflect all conditions of the patient. The results of the analysis might not correspond to the judgement of a physician.
- Overall judgement must be performed by the physician, referring to the analysis result, clinical findings, and other examination results. After the physician's overall judgement, the analysis results should be signed or initialed by the physician.

A CAUTION

When the patient sex and age is not entered, ECG analysis is performed with the patient as male and 35 years old.

Maintenance

MARNING

- Replacement of a component could result in an unacceptable risk, cause electric shock or discard the device.
- Only promise that the service personnel can replace the component.

⚠ CAUTION

The "CAUTION LABEL" contains important information for operating the electrocardiograph. Clean the label if it is dirty. If the label is damaged or difficult to read, contact local agents to replace it with a new one.

A CAUTION

Never sterilize the electrocardiograph because the materials may deform, crack or discolor.

⚠ CAUTION

Take care when interpreting the ECG recording because the EMG filter may cause distortion of P-waves and QRS-waves depending on the waveform shape.

A CAUTION

Do not turn the power off during saving or sending ECG data file, otherwise the data may be lost.

⚠ CAUTION

- Wipe the electrocardiograph thoroughly after disinfecting it with spray.
- Do not sterilize or disinfect the electrocardiograph with ultraviolet light or ozone.

A CAUTION

After cleaning, make sure that the electrocardiograph is completely dried.

A CAUTION

- Do not use a rough cloth.
- Do not use acidic, alkaline detergents, or alcohol other than ethanol or isopropyl.

⚠ CAUTION

- Do not clean the thermal head immediately after recording because the head is still hot.
- Only clean the head with the provided thermal head cleaner pen. Otherwise the thermal head may be damaged.

A CAUTION

Do not sterilize electrodes by boiling. It may damage the electrode.

⚠ CAUTION

Before maintenance, cleaning or disinfection, turn the electrocardiograph power off and disconnect the AC adapter. Failure to follow this instruction may result in electrical shock and electrocardiograph malfunction.

A CAUTION

- Do not use hypochlorous acid for disinfecting.
- Wipe the patient cable thoroughly after disinfecting it with spray.

A CAUTION

- Do not immerse the connector in liquid.
- Do not use volatile liquids such as thinner or benzine, because these will cause the materials to melt or crack.

NOTE: The qualified service personnel refer to those who are trained and appointed by Shanghai Kohden.

Explanations of Symbols

The following symbols are used with the electrocardiograph. The names and descriptions of each symbol are shown in the table below.

On Electrocardiograph Main Unit

| Symbol | Description | Symbol | Description |
|------------------------|---|--------------|---|
| background color: blue | Follow instructions for use. | | General warning sign |
| M | Date of manufacture | *** | Manufacturer |
| \triangle | Caution | EC REP | Authorised representative in the European Community |
| 4 9 F | Defibrillation-proof type CF applied part | \downarrow | Equipotentiality |
| INPUT 15V === | Direct current input voltage | SN | Serial number |
| ⊕ > | Input/output | 8 | Computer Network |
| Č € | The CE mark is a protected conformity mark of the European Community. The four digits after the CE mark indicate the identification number of the Notified Body involved in assessing the product's conformity as a medical device. | MD | Medical Device The MD symbol is applied in accordance with European Union legislation. |
| | Products marked with this symbol comply with the European WEEE directive 2002/96/EC and require separate waste collection. For Shanghai Kohden products marked with this symbol, contact your Nihon Kohden representative for disposal. | UDI | Unique device identifier |
| # | Model | | |

On Operation Panel

| Symbol Description | | Symbol | Description |
|-------------------------------|------------------------------|-------------------|----------------|
| \odot | "On" for a part of equipment | ð | Function |
| "Off" for a part of equipment | | ? | Help |
| → □ | → Battery pack charging | | Paper feed |
| Battery pack check | | •> | Mark |
| Alternating current | | ≈ | EMG filter |
| START/STOP recording | | \Leftrightarrow | Сору |
| @ | Automatic control | Zm | Manual control |
| 44 | Rhythm | | |

On Screen

| Symbol Description | | Symbol | Description |
|-----------------------------|------------------------------------|--------|------------------------------|
| QRS sync mark | | Л | CAL mark |
| Network Icon (Wireless LAN) | | | Network Icon (Wired LAN) |
| | Media Icon (Internal memory) | | Media Icon ((USB flash disk) |
| ? | Operation guide | ·W | Battery check |
| ₽ €? | Synchronize clock with server mark | | |

On Patient Cable

| Symbol | Description | Symbol | Description |
|-------------|-------------|-------------|---|
| \triangle | Caution | - W | Defibrillation-proof type CF applied part |

Transport Package

| Symbol | Description | Symbol | Description |
|--------------------------------|---|------------|---|
| <u> </u> | This way up | | Fragile |
| Keep away from rain | | | Stacking limit by number ("n" is the limiting number) |
| Temperature limitation | | 95% 10% | Humidity limitation |
| 1060 hPa (5 × 5) 700 hPa | Atmospheric pressure limitation | | Recycle mark |
| Manufacturer | | EC REP | Authorised representative in the European Community |
| Č € | The CE mark is a protected conformity mark of the European Community. The four digits after the CE mark indicate the identification number of the Notified Body involved in assessing the product's conformity as a medical device. | MD | Medical Device The MD symbol is applied in accordance with European Union legislation. |

General

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Introduction

The cardiofax C ECG-3150 has a rechargeable battery pack, multiple recording methods, LCD electrocardiogram waveform display. It meets the demands of hospitals, scientific research, general wards, rescue and visiting a patient at home.

NOTE: Use only Shanghai Kohden parts and accessories to assure maximum performance from your device.

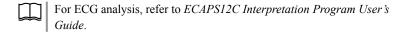
Intended Use

The Shanghai Kohden ECG-3150 electrocardiograph is intended for medical use to process the electrical signals produced by the heart, which are acquired through two or more electrodes, and to display waveforms and/or prepare a record of these electrical signals. This device is a portable ECG acquisition terminal which measures up to 12-lead ECG waveforms. The intended use is only for diagnosis, not for monitoring of vital physiological parameters.

ECG-3150 is intended to be used by qualified medical personnel within a medical facility, such as hospital or clinic and children and adults can be diagnosed with this electrocardiograph.

Features

- Compact, lightweight and easy to carry smaller than A4 paper, approx 1.1 kg without battery pack and recording paper
- Prints up to 3 channels on 63 mm recording paper
- A color LCD screen allows you to preview 5 seconds of 12 leads ECG waveforms
- USB flash disk available
- · Data transmission through wired LAN or wireless LAN to personal computer



Composition

Standard Accessories

- · AC Adapter, FSP065-DGBM1
- · Recording paper, RQS63-3A
- · Thermal head cleaner
- · Input check jig
- · Operator's Manual
- · Service Manual CD
- ECAPS12C CD

Options

- Battery pack, SB-301DC
- CardioCream, Z-101BC
- Cart, KD-105D/105E, KD-108D/108E
- · Ground lead, OEM-V1125A
- Patient cable hanger, KH-100D, KH-200D
- Patient cable, BJ-961D, BJ-962D, BJ-901D, BJ-902D, BJ-903D, BA-901D
- Electrode

Chest electrode, 3 mm diameter tip, for adult,3 pcs/set

Chest electrode, 4 mm diameter tip, for adult,3 pcs/set

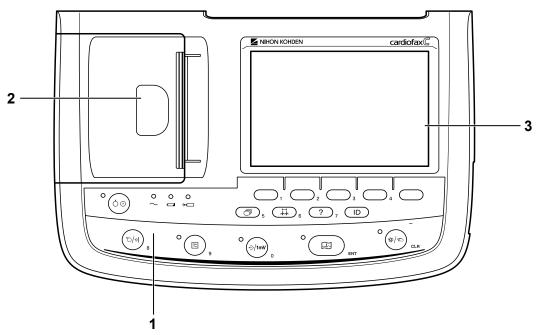
Clip-on limb electrode, 3 mm diameter tip, 4 pcs/set, Fast clip

Clip-on limb electrode, 4 mm diameter tip, 4pcs/set, Fast clip

- USB flash disk, Kingston 16 GB USB flash disk (DTSE9G2/16GB) or the equivalent
- Wireless LAN Module, QI-330D
- QR code reader, Honeywell Xenon 1900 or the equivalent
- Bar code reader: LS2208 or the equivalent
- Magnetic card reader: CRF-200U-5101-00, or the equivalent
- · Medical isolation transformer

Panel and Parts Description

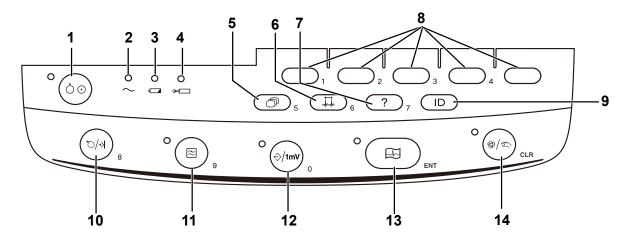
Top View



| Name | Function |
|------|----------|
|------|----------|

- Operation panel Refer to the "Operation Panel" section.
- 2 Paper magazine Contains the recording paper.
- 3 LCD screen Displays ECG waveforms, patient information, marks and messages.

Operation Panel



Name Function

1 POWER key/lamp

Turns the electrocardiograph on/off. For details, refer to "Turning the Power On or Off" in section 2.

NOTE: Press the POWER key for 10 seconds to turn the power off when the electrocardiograph system crashes.

2 AC power lamp ~

When AC power is supplied, the lamp is lighting.

3 Battery operation lamp

During battery operation, indicates the remaining battery power with the color and lighting state.

Blinking in orange indicates that the battery pack is almost discharged.

Blinking in green indicates that the battery pack is failed, do not use the electrocardiograph and contact your Nihon Kohden representative.

When AC power is supplied, the lamp is off.

4 Battery charge lamp →

Indicates the battery pack charge status. Lights when the battery pack is charging.

5 **FUNCTION** key ("5" number key)

Calls up the FUNCTION screen. On some screens, this key enters the number "5".

6 RHYTHM key/lamp ("6" number key)

Performs rhythm recording in resting ECG examination. The lamp is lit while waveforms are acquired. On some screens, this key enters the number "6".

7 **HELP** key ("7" number key)

Display the <Operation guide> screen.

If there is an error, the "?" mark is displayed in the lower right corner of the screen. Press the HELP key on the operation panel to display the operation guide.

8 **F1, F2, F3, F4, F5 function keys** ("1", "2", "3", "4", number keys)

Correspond to the four items at the bottom of the screen. On some screens, these keys enter the number "1", "2", "3", and "4".

9 ID key

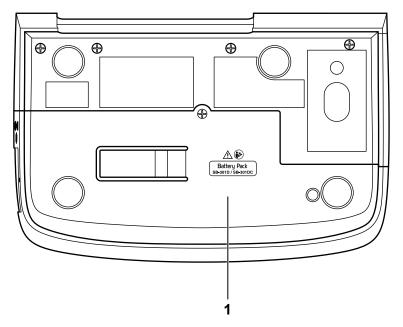
Use to enter patient information.

| | Name | Function |
|----|----------------------------------|---|
| 10 | 10 FEED/MARK key ("8" | Paper feeding: |
| | number key) | Feeds the paper while the key is pressed. |
| | | Event mark: |
| | | In manual recording mode, adds an event mark to the ECG waveform. |
| | | On some screens, this key enters the number "8". |
| 11 | FILTER key/lamp ("9" number key) | Turns the EMG filter on/off. The lamp lights when the EMG filter is turned on. On some screens, this key enters the number "9". |
| 12 | 3 1 \ | Automatic recording mode and rhythm recording mode: |
| | number key) | Prints copies of the recording results. The lamp lights when copy is available and during printing. |
| | | Manual recording mode: |
| | | Records the calibration waveforms. This key does not function for external input signals. |
| | | On some screens, this key enters the number "0". |
| 13 | START/STOP key/lamp | Starts or stops recording. The lamp lights during recording. |
| 14 | AUTO/MANUAL key/lamp | Selects automatic or manual recording. |
| | | Lamp on: automatic recording |
| | | Lamp off: manual recording |



The FUNCTION, RHYTHM, HELP, F1, F2, F3, F4, FEED/MARK, FILTER and COPY/CAL keys are used to enter numbers in the System Setup screen and patient information. Refer to "Changing the System Setup Settings" in Section 3 and "Entering the Patient Information" in Section 4.

Bottom View



Name Function

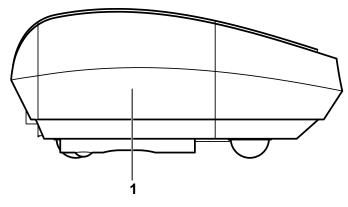
1 Battery compartment

Contains the battery pack.

A CAUTION

Always install the battery pack even when the electrocardiograph operates on AC power. Otherwise sudden power off occurs when an electrode is detached during recording.

Left View

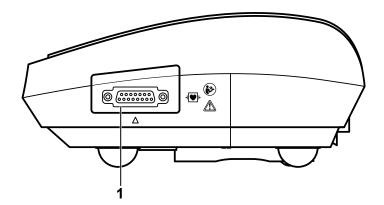


Name Function

1 Paper magazine

Contains the recording paper.

Right View



MARNING

Connect only the specified instrument to the electrocardiograph and follow the specified procedure. Failure to follow this warning may result in electrical shock or injury to the patient and operator, and cause fire or instrument malfunction.

MARNING

Install non-medical instruments which are connected to the electrocardiograph outside the patient environment (IEC 60601-1). If they are installed inside the patient environment, the patient or operator may receive electrical shock or injury. For installation, contact your Nihon Kohden representative.

⚠ WARNING

Follow IEC 60601-1 for connecting the electrocardiograph to other instruments.

⚠ WARNING

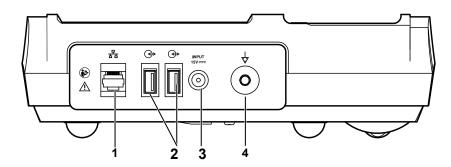
The operator should not touch patient and the input/ output interface of the instrument simultaneously. This may cause electric shock

Name Function

1 Patient cable connector

Connects the patient cable.

Rear View



MARNING

Connect only the specified instrument to the electrocardiograph and follow the specified procedure. Failure to follow this warning may result in electrical shock or injury to the patient and operator, and cause fire or instrument malfunction.

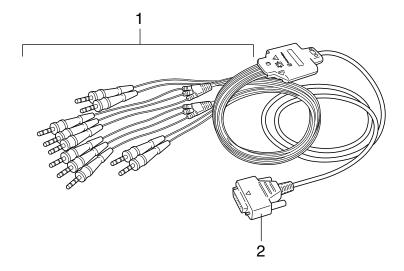
MARNING

Install non-medical instruments which are connected to the electrocardiograph outside the patient environment (IEC 60601-1). If they are installed inside the patient environment, the patient or operator may receive electrical shock or injury. For installation, contact your Nihon Kohden representative.

| | Name | Function |
|---|---------------------------------|--|
| 1 | LAN port | Connects a network cable. |
| 2 | USB connector | Connects a USB bar code reader, a magnetic card reader or a USB flash disk. |
| 3 | AC adapter socket | To supply DC power for an electrocardiograph, connect the AC adapter. |
| 4 | Equipotential grounding termial | Connect to an external equipotential grounding system by an equipotential grounding conductor. |

2 Connector

Patient Cable



| | Name | Function |
|---|------------|---------------------------------------|
| 1 | Lead wires | Connects to chest or limb electrodes. |
| | | |

Connects the patient cable to the electrocardiograph.

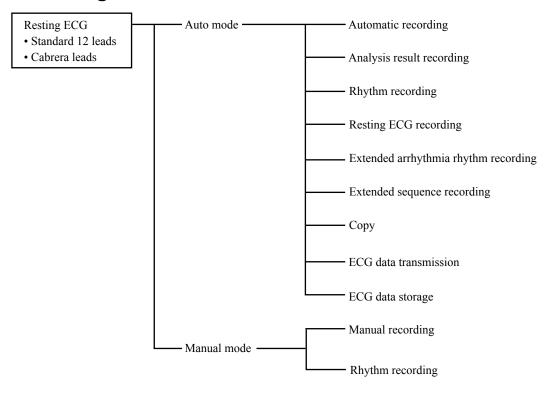
NOTE: The applied part includes the electrodes and those parts patient cable and lead wires to physically contact the PATIENT in NORMAL USE.

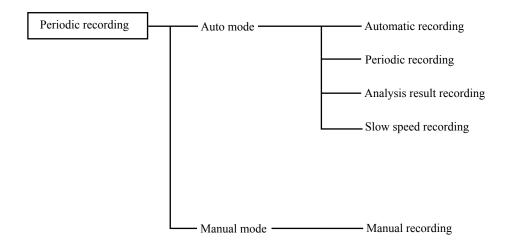
Defibrillation-proof function

Patient cable: BJ-961D, BJ-962D, BJ-901D, BJ-902D, BJ-903D, BA-901D are in compliance with IEC 60601-2-25 standard. Waveforms and electrode recovery time are within 5 seconds.

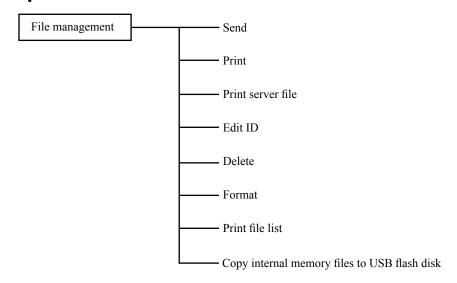
Functions

About Recordings

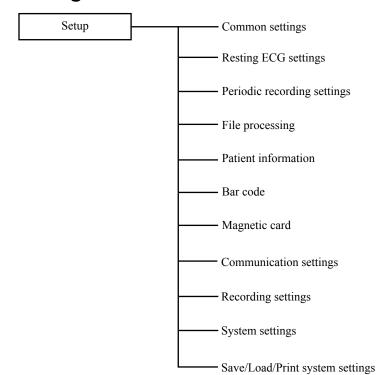




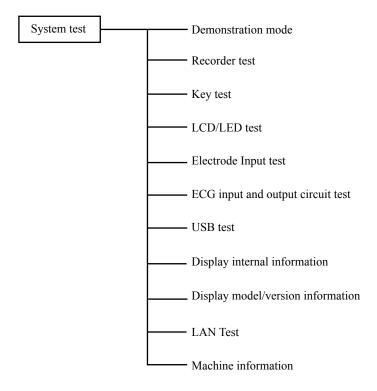
About Operations



About Settings



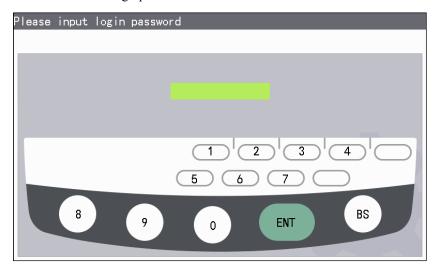
About Maintenance



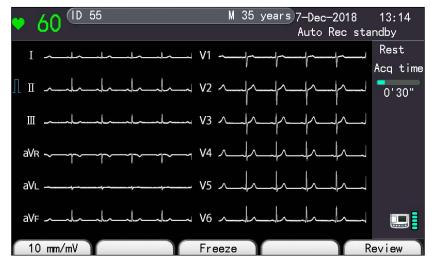
Login Window and Switching Screens

Login Window

1 When the "Password bypass" is set to "Off" on "Setup-System settings-Password bypass", the <Login Window> screen appears when you turn on the electrocardiograph.



2 Input the login password (factory default: <u>1234</u>), the <Resting ECG> recording screen appears.

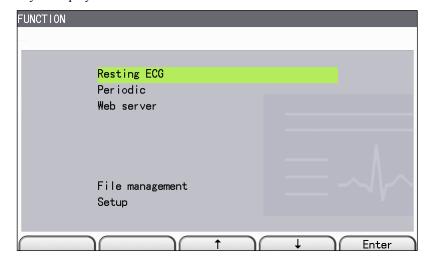


NOTE: When the "Password bypass" is set to "On" on "Setup - System settings - Password bypass", the <Login Window> screen will not appears when you turn on the electrocardiograph. And you will enter to <Resting ECG> recording screen directly.

Switch to Another Screen



1 When the <Resting ECG> recording screen appears, press the **FUNCTION** key to display the <FUNCTION> screen.



NOTE: If Setting "Off" to "Web server" on "Setup-Communication settings-Web server settings". "Web server" will not display in <FUNCTION> screen.

Press the [↑] or [↓] function key to select the desired item. Press the [Enter] key, the screen of the selected item is displayed.

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Selecting a Suitable Location

Select a suitable examination location according to the following WARNINGS, CAUTIONS and NOTES and refer to *GENERAL HANDLING PRECAUTIONS*.

MARNING

- Never use the electrocardiograph in the presence of any flammable anesthetic gas or high concentration oxygen atmosphere. Failure to follow this warning may cause explosion or fire.
- Never use the electrocardiograph in a hyperbaric oxygen chamber.
 Failure to follow this warning may cause explosion or fire.
- Connect only the specified device to the electrocardiograph and follow the specified procedure. Failure to follow this warning may result in electrical shock or injury to the patient and operator, and cause fire or device malfunction.

A CAUTION

- The electrocardiograph should not share the power line with any device which consumes a lot of power, such as an X-ray device, because it may cause artifact.
- Do not install the electrocardiograph near a power line, dynamo or motor which has electromagnetic induction.
- Do not install the electrocardiograph near an electrosurgical unit or RF therapeutic equipment.
- Select a room without excessive noise, vibration, sunlight, high humidity or water splashes.
- Make sure that there is no influence from a mobile phone.
- Avoid locations where the electrocardiograph may receive strong electromagnetic interference such as radio or TV stations, mobile phones or mobile two-way radios.
- Do not install the electrocardiograph where it will be exposed to water or chemical solutions. Avoid direct sprinkling, spray or moist air from a nebulizer or humidifier. These cause malfunction and shorten the life of the electrocardiograph.
- Make sure that there is enough space between the electrocardiograph and the wall for adequate ventilation. Leave more than 5 cm of space between the wall and electrocardiograph so that the operating temperature does not exceed 40 °C (104 °F). Otherwise the internal temperature of the electrocardiograph rises, which leads to inaccurate operation and shortens the electrocardiograph life.
- Only use the KD-105D/105E, KD-108D/108E cart for this electrocardiograph. If another cart is used, it may tip over or the electrocardiograph may fall off.

A CAUTION

- When installing the electrocardiograph, take care not to pinch your finger under the electrocardiograph.
- Do not place electrocardiograph upright. Failure to follow this instruction may cause the electrocardiograph to fall over.
- NOTE Install the electrocardiograph where the screen can be seen clearly and does not reflect light.
 - Do not place blankets or cloth over the electrocardiograph.
 - Do not install the electrocardiograph in a dusty area.

Mounting the Electrocardiograph on the Optional Cart

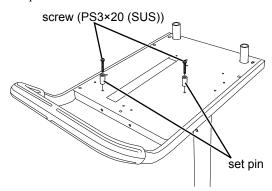
⚠ CAUTION

Only use the KD-105D/105E, KD-108D/108E cart for this electrocardiograph. If another cart is used, it may tip over or the electrocardiograph may fall off.

Mounting the Electrocardiograph on the Cart

Use the two set pins and two screws (option, contact your Nihon Kohden representative) to mount the electrocardiograph on the cart.

1 Attach the set pins to the holes (KD-105D/105E, KD-108D/108E) on the top cover of the cart.



2 Mount the electrocardiograph by aligning the holes on the rear panel over the set pins.

For details, refer to the installation guide of the cart.

KH-100D, KH-200D patient cable hanger:

You can attach the KH-100D, KH-200D patient cable hanger to the cart and put the cables and hook limb leads on the hanger. The hanger prevents the cables from getting tangled or the limb leads from getting in the way.

The information of the cart:

The weight of the cart: KD-105D/E: $15 \text{ kg} \pm 2 \text{ kg}$

 $KD-108D/E: 16 \text{ kg} \pm 2 \text{ kg}$

Bearable weight of the cart: KD-105D/E: 26.2 kg

KD-108D/E: 27.9 kg

Connecting the Power Cord and Grounding the Electrocardiograph

Connecting the Power Cord

MARNING

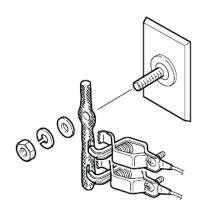
Only use the provided power cord. When the provided power cord cannot be used or when equipotential grounding is doubtful (such as in a facility with poor grounding), operate the electrocardiograph on battery power. Otherwise, the patient and operator may receive electrical shock or injury.

⚠ WARNING

To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

- NOTE Make sure that there is always a battery pack inside the electrocardiograph in case the power cord is disconnected or there is a power failure.
 - When there is no battery pack inside the electrocardiograph, noise may be superimposed on the waveform or the electrocardiograph may be reset so that measurement data is lost
 - Connect the AC/DC adapter power cord to the power socket of the electrocardiograph, and connect power cord to AC/DC adapter and 3-prong AC socket of main power supply.
 - The AC adapter is intended to be used as an isolation device from the supply mains. Please always make mains plug or appliance coupler easy to operate.

Grounding the Electrocardiograph



⚠ WARNING

When several medical devices are used together, ground all devices to the same one-point ground. Any potential difference between devices may cause electrical shock to the patient and operator.

When more than one electrical device is used, there may be electrical potential difference between the devices. The potential difference between the devices may cause current to flow to the patient connected to the devices, resulting in electrical shock.

Always perform equipotential grounding when required. It is often required in the operating room, ICU room, CCU room, cardiac catheterization room and X-ray room. Consult with a biomedical engineer to determine if it is required.

When equipotential grounding is required to ensure patient safety, use the equipotential grounding conductor to connect an external equipotential grounding system.

Cutting off the Power Supply to the Electrocardiograph

To cut off the power supply to the electrocardiograph, disconnect the power cord of the electrocardiograph from the wall AC outlet. When installing the electrocardiograph, position the electrocardiograph so that it is easy to disconnect the power cord from the wall AC outlet.

Operating on Battery Pack

The electrocardiograph can operate on battery pack power with an optional SB-301DC battery pack. When a battery pack is inserted, the electrocardiograph automatically switches to battery power if the power cord is disconnected or there is a sudden power failure.

Battery Pack Handling

⚠ WARNING

- Keep the battery pack away from fire, and never heat the battery pack, or it may result in leakage and explosion of the battery pack.
- Never short-circuit the + and terminals on the battery pack. Do not handle or store the battery pack with metals like necklace or hair clipper, because this has the risk of leakage and explosion due to short circuit of the battery pack.
- It's strictly forbidden to disassemble, reconstruct, or damage the battery pack, or weld the shell directly. Failure to follow this warning may result in leakage and explosion.
- Do not use a battery pack which is damaged or dropped. There
 is a gas release valve inside the battery pack, and if the valve is
 damaged due to dropping, etc. the gas won't be released during
 operation, and this will induce explosion.
- Avoid strong mechanical impact to the battery pack, may cause leakage and explosion of battery pack.
- If the battery pack is damaged and the substance inside the battery
 pack contacts the eyes or skin, wash immediately and thoroughly
 with water and see a physician. Never rub your eyes, because you
 may lose your eyesight.
- Never connect the battery pack to an AC jack or ignition socket of an automobile. Failure to follow this warning may result in leakage and explosion of battery pack.
- Only use the SB-301DC battery pack as specified by Shanghai Kohden.
- Do not immerse the battery pack in water. The battery pack may overheat and rust and the substance inside the battery pack may
- Do not use a battery pack which is damaged, polluted or leaking.
 Failure to follow this warning may result in explosion.
- Check the direction of the connector when connecting the battery pack cable. Don't force the battery pack cable into the battery pack connector if abnormality is felt.

A CAUTION

- Do not bend or pull the connector of the battery pack with strong force. This may damage the battery pack cable or battery pack cable connector.
- Keep the battery pack away from patients and out of the reach of children.
- NOTE The operation time in continuous recording with a new fully charged battery pack is about 60 minutes; the simulated actual use(record once each 3 minutes) time is more than 180 minutes, when the ambient temperature is 25 °C(77 °F). If the ambient temperature is more than 25 °C (77 °F), or depending on waveform quality, the operation time may be decreased.
 - The lifetime of the battery pack is about 1 year. When operating
 the electrocardiograph with the battery pack, check the date
 when the battery pack was last replaced on the start date label
 attached to the electrocardiograph.

Battery Pack Replacement

A CAUTION

- The battery pack must be replaced by qualified service personnel.
- Before inserting or removing battery pack, make sure that the electrocardiograph is turned off and the power cord is disconnected from the power socket. Otherwise, the operator may receive electrical shock.

Charging

MARNING

Do not charge the battery pack with any equipment other than the electrocardiograph. Otherwise, abnormal current will cause the leakage and explosion of battery pack.

A CAUTION

If the operation time of a fully charged battery pack is less than 30 minutes, the battery pack may have become deteriorated. Do not use a deteriorated battery pack. Charging a deteriorated battery pack may cause the electrocardiograph to fail to operate in both battery pack and AC power.

A CAUTION

Charge the battery pack at ambient temperatures of 5 $^{\circ}$ C to 40 $^{\circ}$ C (41 $^{\circ}$ F to 104 $^{\circ}$ F). If the battery pack is charged below 5 $^{\circ}$ C or over 40 $^{\circ}$ C, the battery pack may leak or heat up. This may damage the battery pack.

- NOTE Before using a new battery pack, charge it with the ECG-3150 electrocardiograph.
 - The charging time of the battery pack is within 3 hours when the ambient temperature of the battery pack is between 5 °C to 40 °C (50 °F to 95 °F). The charging time changes depending on the ambient temperature of the battery pack. When the surface temperature of the battery pack is below 5 °C (50 °F) or over 40 °C (95 °F), the battery pack charging time may be changed.
 - During charging, the battery pack may heat up. Do not put anything on or over the electrocardiograph.

Storage

MARNING

Remove the battery pack from the electrocardiograph when it will not be used for more than 1 month. Otherwise the battery pack may leak and rust.

A CAUTION

- Do not expose the battery pack to direct sunlight or leave in a high temperature place. The lifetime of the battery pack may be shortened, the performance of the battery pack may be degraded, and the battery pack may leak.
- Store the battery pack at temperatures:
 - -20 °C to +65 °C (Less than 1 week)
 - -20 °C to +55 °C (Less than 1 month)
 - -20 °C to +45 °C (Less than 6 months)
 - -20 $^{\circ}$ C to +35 $^{\circ}$ C (Less than 1 year) in a dry place to prevent rusting and leakage.
- If the ambient temperature is over 30 °C (86 °F), charge it every three months because it self-discharges quickly.
- When the battery pack is stored more than 1 month, charge it before use because the battery pack may have self-discharged.
- Replace the battery pack with a new one every year to assure maximum performance from the electrocardiograph.
- When the battery pack is stored for a long time, it may become inactivated and cannot be fully charged. The battery pack charge may be recovered by discharging and charging the battery pack several times.

After the storage over one month, please charge the battery pack first before
use. Even if the battery was fully charged before a short-term storage, the
battery pack would discharge itself, which shortens the operating time of the
device. Thus, please replace the battery pack with a new one every year from
the date of first use.



The phenomenon of inactivation is likely to occur after the battery pack has been stored for a long term, which leads to the unavailability of the intended 100 % battery capacity. The full battery capacity could be restored if you discharge and fully charge the battery pack to the rated value for several times.

Disposing

A CAUTION

SB-301DC battery pack is Ni-MH (Nickel-Metal Hydride). Before disposing of the battery pack, check with your local solid waste officials for details in your area for recycling options or proper disposal. The battery pack is recyclable. At the end of its useful life, under various state and local laws, it may be illegal to dispose of this battery pack into the municipal waste stream.

NOTE: Remove the battery pack when disposing of the electrocardiograph and attach tape to the battery pack cable. Otherwise, it may explode at waste disposable services.

Inserting the Battery Pack

MARNING

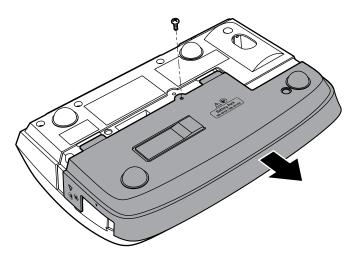
Do not touch the patient while touching any metal part of non-medical electrical equipment or an exposed part when a connector or cover is removed. Failure to follow this warning may cause electrical shock or injury to the patient.

A CAUTION

Only use the SB-301DC battery pack.

The electrocardiograph is shipped from the factory with no battery pack installed. Follow the procedure below to insert a battery pack into the electrocardiograph before use.

- 1 Turn the power off. Make sure the power cord is removed from the electrocardiograph.
- 2 Remove the screw from the battery pack cover and pull off the battery pack cover.

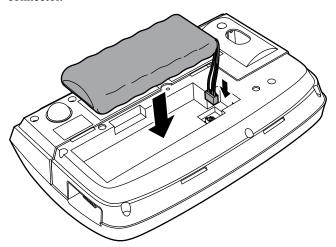


3 Record the date of first use of the battery pack on the label of the battery pack.

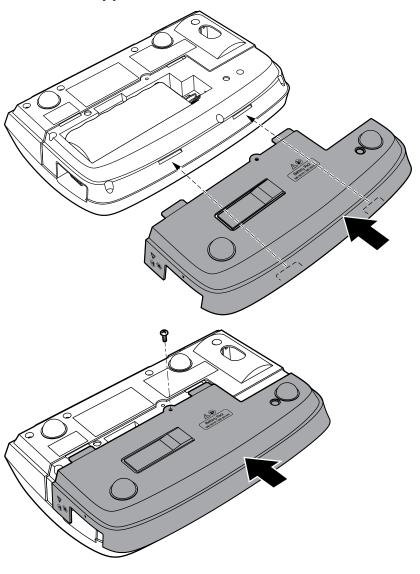


Write down the date of first use.

4 Insert the battery pack into the battery pack compartment. Connect three battery pack cables with the color of red, blue, and black to the battery pack connector.

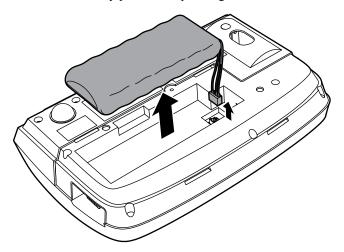


5 Reattach the battery pack cover and secure it with the screw.



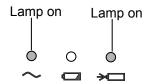
Removing the Battery Pack

Remove the battery pack while pressing the lock under the battery pack cable.



NOTE: Pull the cable slowly and carefully. Otherwise, this may damage the connector.

Charging the Battery Pack



The battery pack can be charged when AC power is supplied to the electrocardiograph even the POWER key is not pressed. Fully discharged battery pack will take about 2.5 hours to charge to 90% remaining power. To be fully charged, it will take about 3 hours. Continuous recording: about 60 minutes

Recording once each 3 minutes: more than 180 minutes

To charge the battery pack:

Connect the electrocardiograph to a wall power socket. The AC power lamp and battery pack charge lamp light.

- Please always charge the battery pack. Please do not leave the device
 unattended when the remaining battery pack capacity is zero. If the battery
 pack runs out of power and is still installed in the device with no AC power
 supplied, the battery pack might become unusable because of over discharge.
- Please do not leave the battery pack inside the device for a long term (above one month) without the supply of AC power even if the battery pack has been charged already. The battery pack will gradually discharge and might become unusable because of over discharge. If you did leave the device as it is for a long term, please contact your Nihon Kohden representative.

Battery pack charge lamp

Lit: Charging

NOTE: Battery pack charging will be temporarily interrupted during recording. But the the battery pack charge lamp is still lighting until the battery pack is fully charged.

For battery pack operation time, refer to *Operating on Battery Pack* in this Section.

Setting the Recording Paper

Handling the Recording Paper

Recording Paper

A CAUTION

- Only use the Shanghai Kohden specified 63 mm recording paper.
 When a narrower recording paper is used and the paper detection
 circuit cannot detect it, the thermal head may be activated. The
 thermal head may be damaged where there is no recording paper
 and the rubber paper feed roller may get burned.
- If unspecified recording paper is used, it might not print properly or send multiple pages.

Model: ROS63-3A

Type: Roll
Length: 30 m
Paper marks: No
Grid: Yes

Paper location: In the electrocardiograph

Storage

A CAUTION

Prolonged storage under conditions such as high temperatures, excessive humidity, direct sunlight, and fluorescent light causes fading of the colored surface. Avoid high temperatures exceeding 50 $^{\circ}\text{C}$ (122 $^{\circ}\text{F}$) and excessive humidity. Store the recording paper in a cool, dry and dark place if possible.

Usage

⚠ CAUTION

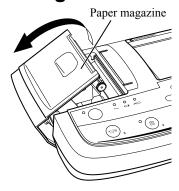
- Organic solvents and plastics may develop color on the white surface or cause the recording paper to fade. Examples of color-developing materials containing organic solvents: adhesives, paste, felt-tip pens, and semi-dry diazo paper. Examples of color-fading materials made of soft vinyl chloride: document cases, albums, and desk pads including. Examples of color-fading materials containing plastics: erasers, adhesive tapes, and some fluorescent pens.
- The paper cutter in the recording paper container is sharp. When setting the recording paper, be careful not to cut your finger. Set the recording paper as specified.
- When pasting the recording paper, use paste with a starch base, PVA base, arabic gum base paste, CMC base synthetic paste, or paper bond.
- Do not apply high pressure to the recording paper. Rubbing or scratching the surface with a hard object discolors it.
- Clean the thermal head with the thermal head cleaner after every 100 m printing. A dirty thermal head degrades printing quality.
- Do not use recording paper which is contaminated with ECG electrolyte cream (cardioCream) or saline solution because the recording paper will fade by the chloride and the contaminated thermal head may cause missing dots. If the thermal head gets contaminated, clean it with the thermal head cleaner pen.
- Do not touch the thermal head with your fingers. If accidentally touched, clean the thermal head with the thermal head cleaner pen.
- Follow the procedure to set the recording paper. Otherwise, the recording paper might not feed normally or the feeding motor may stop operation.

Replacement

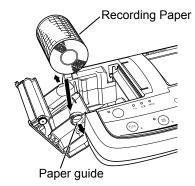
⚠ CAUTION

Do not set the recording paper immediately after recording because the thermal head is still hot.

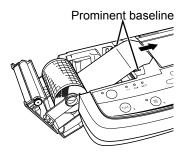
Setting the Recording Paper



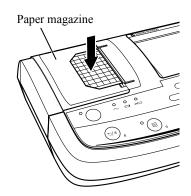
1 Place your finger in the hole of the magazine cover and lift it to the left to open the recorder.



2 Set the recording paper in the recorder cover by spreading the paper guides.



3 Pull out the recording paper and align it with the prominent baseline.



4 Close the recorder cover to the recorder while holding the paper until it clicks.

NOTE: When recording paper is not aligned with the paper guide, skewing may occur.

Feeding the Paper

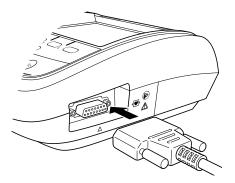


You can feed the paper by pressing the **FEED/MARK** key anytime before or after recording. The lentgh of paper feeding is determined by the time of pressing the key.

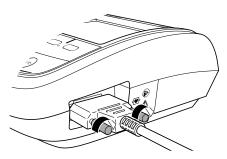
Connecting the Patient Cable

MARNING

Only use the BJ-961D, BJ-962D, BJ-901D, BJ-902D, BJ-903D or BA-901D patient cables when using with a defibrillator. When the specified patient cable is connected, the electrocardiograph is type CF defibrillation-proof compliance. Failure to follow this warning may cause skin burn where the electrode is attached and damage the electrocardiograph due to discharge energy when defibrillation is performed.



Connect the patient cable to the patient cable connector on the right side panel of the electrocardiograph.



2 Secure the connector to the electrocardiograph with the screws on the connector.

NOTE: Do not lift the electrocardiograph while holding the patient cable and do not bend or pull the patient cable strongly. This may cut or break the cable. Do not contact the AC adapter with the patient cable when using, it may cause noise.

When the "Fail:Limb" message is displayed on the screen, check that the patient cable is properly connected to the electrocardiograph. Otherwise, it affects the safety.

Cybersecurity

Information Security User Agreement

The user agrees to implement the following measures with respect to the cybersecurity of the electrocardiograph, including measures for the protection of confidentiality of personal information.

Ensure that you have thoroughly read and complied with the contents of this user agreement before using the electrocardiograph.

A CAUTION

Use the electrocardiograph in a securely managed environment.

⚠ CAUTION

Personal information stored on the electrocardiograph, or the PC, is vulnerable to unauthorized access. Follow the provisions of the user agreement for the electrocardiograph related to information security.

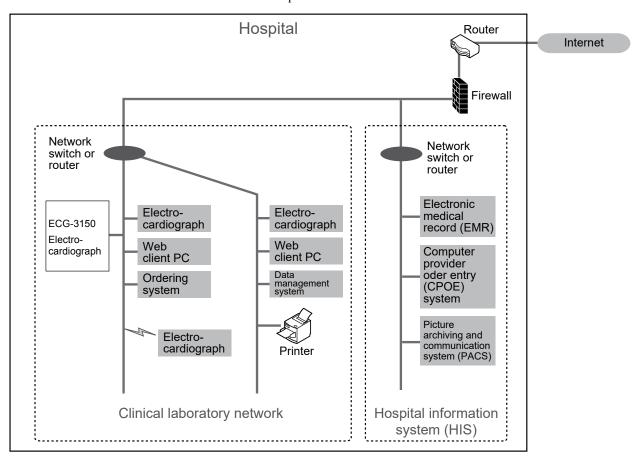
User Agreement with Relation to the Information Security of the Electrocardiograph

- NOTE The electrocardiograph processes name, gender and age information that constitutes personal information. As well as being displayed on screen, this information is also stored as review data in the memory of the electrocardiograph. Implement effective cybersecurity measures to protect the electrocardiograph before using it.
 - Operation other than by the designated operator could affect the stability of the electrocardiograph and cause data loss.
 Implement appropriate security measures to prevent outsiders from approaching the electrocardiograph.
 - Establish rules for accessing data and exercise caution to prevent data leaks.
 - The electrocardiograph (including data back-up devices) stores personal information inside it. Delete all personal information on the electrocardiograph when transferring or disposing of it. Consult a security expert and follow their advice to prevent leakage of personal information.

- Refer to the operator's manuals for installation and connection
 of the electrocardiograph and its components and connection to
 peripheral devices. Only install and connect devices specified
 or recommended by Nihon Kohden, in accordance with the
 specified procedures. Refer to the operator's manuals for
 correct usage of the electrocardiograph and its connected
 devices. Incorrect connection or use of the electrocardiograph
 could interfere with other devices connected to the same
 network.
- Implementing effective cybersecurity measures to prevent infection by viruses when connecting external media to the electrocardiograph is the responsibility of the user.
- To prevent confusing data from different patients, double-check the patient's name and patient ID when importing data from an external source.
- When connecting to information networks, use the appropriate transmission protocols and other settings to allow communication between the systems. Incorrect settings or unintended changes may cause data inconsistencies that prevent interoperation between the systems.

Network Environment

The electrocardiograph is intended for use in the following network environment and network composition.



⚠ CAUTION

To ensure the cybersecurity of the electrocardiograph, implement the following security measures in the network environment to which the product is connected.

- 1. All communication (incoming and outgoing) between the electrocardiograph and the local area network (HIS, etc.) is subject to packet filtering by a firewall or router.
- 2. When the electrocardiograph is connected to the local area network (HIS, etc.), all communication with the internet or other external networks is restricted to essential transmissions under the supervision of the appropriate personnel with responsibility for information security of medical equipment.

NOTE • Changing the network after installation creates new cybersecurity risks and requires a new risk analysis. The responsible organization should take action to isolate, analyze and manage these risks.

"Changing the network" includes changing the network configuration, connecting additional devices to the network, removing devices from the network and updating or upgrading of connected devices, etc.

Product Specifications Related to the Intended Usage Environment of the Electrocardiograph

Security Risks Related to the Product Specifications of the Electrocardiograph

The electrocardiograph is not intended to be connected to external networks such as the internet. If the electrocardiograph is installed in a network that is connected to external networks such as the internet, there is a risk that the electrocardiograph could be interfered with by external attackers.

Operating Environment Required for Security of the Electrocardiograph

- When devices connected to a network (such as HIS etc.) communicate with external networks such as the internet, installation of firewalls to protect security critical areas of the network and configuration of appropriate settings such as ACLs (access control lists) must be performed under the supervision of the information security manager at the facility.
- When transmitting medical information containing personal information from the electrocardiograph to an external facility over a network, security measures such as encryption must be used to prevent leakage of confidential information or alteration of data. In addition, security measures must be employed to protect the route between the institutions exchanging data, such as using a closed IP network or other closed network.

When Cybersecurity Incidents Occur

Status of the Electrocardiograph at the Time of the Incident

When an incident occurs that affects the cybersecurity of the electrocardiograph, any of the following hazardous situations may occur.

DoS attack 1

- · The network may disconnect suddenly.
- ECG waveforms stop being displayed or are frozen.

Infection by a computer virus 2 or malware 3

- Messages are displayed that have no relation to the contents of the screen.
- The waveform display on the screen is frozen.

¹ DoS attack (Denial of Service attack)

Abbreviation of Denial of Service attack. An attack where a malicious attacker sends a large volume of service request data to a network device so that the targeted device cannot handle the excessive load, causing the service to be disrupted.

² Computer Virus

A program with the ability to self replicate and infect other devices, created to access another computer without permission and intentionally cause damage.

³ Malware

A contraction of malicious software. Software created to perform unauthorized and harmful operations.

Checking the Status of the Electrocardiograph at the Time of the Incident

Recording Status Information

Use a recording device such as a digital camera to quickly and accurately record the following status information and settings.

- Connection status of the network cable
- Network settings
- Status of the indicators and other lamps on the electrocardiograph.

Reporting Information

Put together the information in written form as follows.

• Where: "At XX hospital"

• Who: "A nurse"

• When: "XX / XX / XXXX at XX:XX"

• Which device: "Electrocardiograph XX"

· What kind of information:

"The electrocardiograph shows incorrect information."

• How did you learn about the situation:

"By looking at the electrocardiograph"

• What happened: "The electrocardiograph stopped displaying waveforms and 'XX' is displayed on the screen."

Report the above information according to the protocols for reporting incidents at your facility.

Initializing the Electrocardiograph When Required for Recovery from a Security Incident

When required for recovery from a security incident and to eliminate any remaining problems, the electrocardiograph can be initialized to restore it to the factory default settings.

This must be performed by an administrator.

Software Updates Related to Cybersecurity

Please contact your Nihon Kohden representative for performing software updates.

Deleting Personal Information Saved on the Electrocardiograph

When transferring or disposing of the electrocardiograph, initialize all settings on the electrocardiograph and delete all personal information stored on it.

Other Security Information

In addition to the information in this manual, security information is also posted on the Security Information section of the Nihon Kohden website.

Inquiries in Relation to Cybersecurity

For inquiries in relation to the cybersecurity of the electrocardiograph, use the contact form on the Nihon Kohden website (URL: https://www.nihonkohden.com/contact/index.html).

Turning the Power On or Off

MARNING

Use only the provided power cord. Otherwise, the patient and operator may receive electrical shock or injury.

Turning the Power On

Before turning the power on, check the following items. If there is any damage or the electrocardiograph is suspected to be faulty as a result of checking, attach an "Unusable" or "Repair request" label to the electrocardiograph and contact your Nihon Kohden representative.

Check Items Before Turning the Power On

Overview:

- Electrocardiograph is not dirty, damaged, or in contact with liquid.
- No peeling or tear in the operation panel.
- · No key or button is broken.
- Power cord and AC adapter is not damaged.
- Patient cable is not damaged.
- Electrodes are clean and not damaged.
- Cable hanger is not damaged.
- · Paper magazine is not damaged.
- Battery pack is installed.

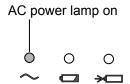
Connection and setting:

- · Power cord and AC adapter is securely connected.
- Electrocardiograph is securely connected to an external device.
- Patient cable is securely connected to input box.
- Patient cable is securely connected to the electrocardiograph.
- · Recording paper is properly set.
- · Battery pack is fully charged.

Accessories:

- Confirm the electrode and patient cable are not damaged.
- No crack in the rubber of chest electrode.
- Normal force of electrode holders for 4 limbs.
- Enough disinfected or sterilized dry electrode.
- Enough electrolyte cream.
- Enough recording paper.
- New and used electrodes are not used together.

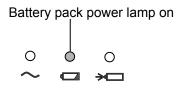
Operating on AC Power



The electrocardiograph operates on AC power if the AC power lamp lights, AC power is supplied.

NOTE: The battery pack must be installed even if AC power is used for operation of electrocardiograph, otherwise the power supply may be interrupted or restarted in large volume of waveform printing.

Operating on Battery Pack Power



When AC power is not used for operation, the electrocardiograph automatically switches to operate on battery pack power, and the battery pack operation lamp lights to indicate the remaining power.

NOTE: When the battery pack is almost discharged, the battery pack operation light blinks in orange, after a prompt sound, then the electrocardiograph shut down immediately.

Automatic shutdown

If the battery pack is used for operation, the electrocardiograph power turns off automatically if the screen displays "Fail:Limb" and no key is pressed for 3 minutes. This prevents unnecessary consumption of the battery pack. In this condition, temporarily changed settings will be lost. To prevent loss of settings, turn the power on and set the "Auto power off" to "Off" on "Setup-System settings-Power management".

The backlight will turn off automatically if AC power is used for operation, the screen displays "Fail:Limb" and no key is pressed for 3 minutes. To turn on the backlight, press the **POWER** key, or set the "Backlight auto off" to "Off" on "Setup-System settings-Power management", and this may prevent backlight from turning off automatically.

Check Items After Turning the Power On

- AC power lamp or battery pack power lamp lights normally.
- The backlight of the LCD is lit.
- No fire, smoke or smell.
- No electrical shock when touching the electrocardiograph.
- Electrocardiograph is not too hot.
- Electrocardiograph does not affect surrounding equipment.
- Screen display is correct (such as brightness, contrast, no distortion, normal color, etc.)
- All operation indicators are lit.
- All keys on the operation panel operate correctly.
- All settings are correct.

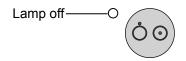
- Calibration waveform is properly displayed and recorded. Amplifier of calibration waveform is correct. No noise on the calibration waveform.
- No error messages or malfunction during operation.
- Battery pack is fully charged.
- Printing is correct (paper feeding without skewing or catching, no jamming, printing darkness, no faded or missing dots, correct date and time).
- External device operates correctly.
- Save and send of ECG data files function correctly.

Battery Pack Remaining Power

NOTE: When the orange lamp is blinking, please save the data as soon as possible, or access AC power supply. Otherwise the data maybe lost.

| Battery pack operation lamp | Recording time remaining |
|------------------------------------|------------------------------|
| Green lamp on | At least 15 minutes. |
| Orange lamp on | At most 15 minutes. |
| Orange vellow lamp blinks | Power turns off in 1 minute. |

Turning the Power Off



Press the **POWER** key on the operation panel to turn the power off.

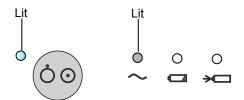
The screen becomes dark and the POWER lamp on the operation panel turns off.

- NOTE Do not turn off the power if there is still processing of ECG data.

 Turn the power off after the processing is ended.
 - Do not press and hold the **POWER** key. This operation turns the power off without saving data. If the power key is pressed and held more than 10 seconds during normal operation, the power is shut off, and data may be lost.
 - Within 10 seconds after the power on, the power key will not shut down even if it is pressed.

Power and Battery Status Indications

Power and battery status are indicated by 4 lamps on the front panel. A discharged battery pack is also indicated by a screen message.

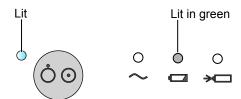


• Operating on AC power

Power lamp: Lit in blue

Battery charging lamp: Off/On Battery operation lamp: Off

AC power lamp: Lit in green



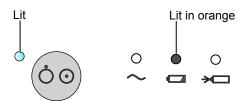
• Operating on battery power and battery pack operation time is more than 15 minutes

Power lamp: Lit in blue

Battery charging lamp: Off

Battery operation lamp: Lit in green

AC power lamp: Off



• Operating on battery power and battery operation time is less

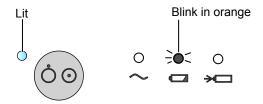
than 15 minutes

Power lamp: Lit in blue

Battery charging lamp: Off

Battery operation lamp: Lit in orange

AC power lamp: Off



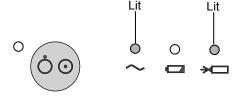
• Operating on battery power and battery needs recharging

Power lamp: Lit in blue

Battery charging lamp: Off

Battery operation lamp: Blink in orange

AC power lamp: Off



• Power off and charging battery

Power lamp: Off

Battery charging lamp: Lit in green

Battery operation lamp: Off AC power lamp: Lit in green

Connecting Optional Accessories to the Electrocardiograph

MARNING

- Only connect Shanghai Kohden specified device to the electrocardiograph and follow the specified procedure. Failure to follow this warning may result in electrical shock or injury to the patient and operator, and cause fire or device malfunction.
- Install non-medical devices which are connected to the electrocardiograph outside the patient environment (IEC 60601-1:2012). If they are installed inside the patient environment, the patient or operator may receive electrical shock or injury.

Connectable Optional Accessories

• Bar code reader LS2208 or the equivalent

Compatible bar codes

WPC (UPC, EAN/ JAN), CODE-39, NW-7, Industrial 2 of 5, Interleaved 2 of 5, CODE-93, CODE-128

- Magnetic card reader: CRF-200U-5101-00, or the equivalent
- Wireless module: QI-330D
- QR code reader, Honeywell Xenon 1900 or the equivalent

Connection

Use the specified USB device and connect it to the USB connector of electrocardiograph.

NOTE: Do not connect USB devices during operation. It may disturb the operation.

Remove

Hold and pull the connector to remove the cable.

NOTE • Do not remove USB devices during operation. It may disturb the operation.

When you remove the cable, hold and pull the connector.
 Otherwise, the cable may break.

Connect a Bar Code Reader

Use the specified bar code reader (LS2208), do the procedure correctly as follows and set the setings below.

- [Connector setting]
- System setting [Bar code setting]

Connection

Do the following steps to connect the cable of the bar code reader accessories.

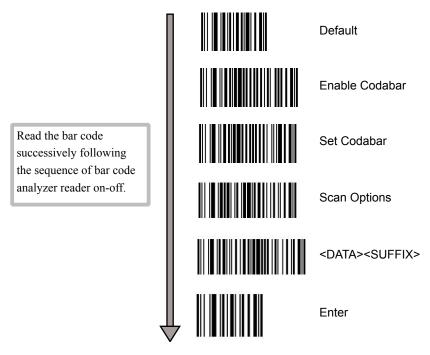
- 1 Connect the USB cable to the LS2208 bar code reader.
- **2** Confirm that the power is off.
- 3 Connect the other end of the USB cable to the electrocardiograph USB connector.
- 4 Turn the power on and confirm the bar code reader sound.

Connector setting

Set the connector of the bar code reader.

NOTE: The settings must to be set when connecting the LS2208 bar code reader for the first time.

- 1 Display the test screen.
- 2 Read the following bar codes one after the other.



- 3 Read the bar codes until to the "Enter" location, then save the settings of the bar code reader within 5 seconds.
- 4 Turn the power off. Restart the electrocardiograph.
- 5 Set the settings on "System setting Bar code".
- 6 Confirm that the bar code was read successfully.

Failure to read the bar code correctly

If the bar code cannot be read correctly, check the connection again and initialize the bar code settings.

If you still cannot read the bar code, there may be a bar code reader failure. Contact your Nihon Kohden representative.

Connecting an External Device to the Electrocardiograph

⚠ WARNING

- Only connect Shanghai Kohden specified device to the electrocardiograph and follow the specified procedure. Failure to follow this warning may result in electrical shock or injury to the patient and operator, and cause fire or device malfunction.
- When several medical devices are used together, ground all devices to the same onepoint ground. Any potential difference between devices may cause electrical shock to the patient and operator.

⚠ CAUTION

Before connecting or disconnecting instruments, make sure that each instrument is turned off and the power cord is disconnected from the power socket. Otherwise, the patient or operator may receive electrical shock or injury.

When more than one electrical device is used, there may be electrical potential difference between the devices. The potential difference between the devices may cause current to flow to the patient connected to the devices, resulting in electrical shock.

Always perform equipotential grounding when required. It is often required in the operating room, ICU room, CCU room, cardiac catheterization room and X-ray room. Consult with a biomedical engineer to determine if it is required.

Refer to "General Requirements for Connecting Medical Electrical Systems" in Section 11.

Preparing for Data Management

About the Media

The electrocardiograph can save the acquired ECG waveforms, patient information and analysis result as a file in the internal memory or USB flash disk (here in after referred to as media) and send the file through a network.

Internal Memory

Up to 800 files can be saved in the memory regardless of the data compression type.

USB flash disk

Up to 780 (type 1, normal) or 3000 (type 2, compressed) files can be saved in a Kingston 16 GB USB flash disk (DTSE9G2/16GB) or an equivalent USB flash disk. Refer to Section 8 *File Management*.

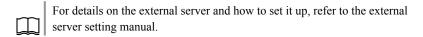
A CAUTION

Only use a Shanghai Kohden specified USB flash disk. Otherwise, the USB flash disk may not be available.

- NOTE The electrocardiograph can only read 64 MB data, even if the capacity of the USB flash disk is larger than 64 MB.
 - If the capacity of a USB flash disk is over 32 GB, the electrocardiograph may not be able to recognize the USB flash disk even if the USB flash disk is correctly inserted into the electrocardiograph.

About the External Server

The electrocardiograph can send files to an external server through a network using wired or wireless LAN.



- Wired LAN (Wired Local Area Network)
 Connects to network and sends files to an external server in the network.
- Wireless LAN (Wireless Local Area Network)

Using the Internal Memory

Set "Media" to "Internal memory" on the <Setup-File processing> screen.

Refer to List of Settings - File processing in Section 3 Changing Settings Before Measurement.

Preparing the USB Flash Disk

Refer to the USB flash disk manual and the following precautions for operation and cautions.

A CAUTION

Do not leave the USB flash disk near patients or in reach of children.

Handling

A CAUTION

- · Never disassemble or modify the USB flash disk.
- · Do not bend or give a strong impact to the USB flash disk.
- Do not handle the USB flash disk while smoking or eating. Do not get the USB flash disk wet.
- Do not touch any metal part of the USB flash disk.
- Do not peel off the label or sticker on the USB flash disk or put another label or sticker on the USB flash disk.
- Only use the USB flash disk in the specified device.
- Do not scratch the insertion part of the USB flash disk. The electrocardiograph might not operate if dust gets into the insertion part.
- Put the USB flash disk in the case when the USB flash disk is removed from the electrocardiograph. Store it where patients cannot accidently swallow the USB flash disk.
- Do not expose the USB flash disk to direct sunlight or leave in a place of high temperature and high humidity.
- · Operating environment

Temperature: -25 °C to +85 °C (-13 °F to +185 °F)

Humidity: -25 % RH to 95 % RH (noncondensing)

Storage environment

Temperature: -40 °C to +85 °C (-40 °F to +185 °F)

Humidity: -25 % RH to 95 % RH (noncondensing)

• Do not store the USB flash disk in a corrosive gas environment.

Operation

⚠ CAUTION

- Only format or write data to the USB flash disk in the specified device. Otherwise, the USB flash disk may become unusable.
- Do not remove the USB flash disk or turn the power off while formatting or data is being written to or read from the USB flash disk. This may damage the USB flash disk or saved data.
- Only use a Shanghai Kohden specified USB flash disk, or the USB flash disk cannot be operated.

Recommended USB flash disk:

Kingston 16 GB USB flash disk (DTSE9G2/16GB) or the equivalent.

Inserting and Removing the USB Flash Disk

A CAUTION

- Insert only a Shanghai Kohden specified USB flash disk in the USB flash disk connector.
- Insert or remove the USB flash disk straight into or out of the USB flash disk connector.
- Make sure that the electrocardiograph power is turned off, when inserting or removing an USB flash disk. Otherwise, the data in USB flash disk may get damaged and operation of the electrocardiograph may become unstable.

To insert the USB flash disk:

- 1 Turn the electrocardiograph power off.
- Insert the USB flash disk straight into the USB flash disk connector.

To remove the USB flash disk:

- 1 Turn the electrocardiograph power off.
- 2 Remove the USB flash disk from the USB flash disk connector.

Media Capacity Indication





Media Icon

You can check the free space of the internal memory or the USB flash disk with the media icon on the test screen.

If there is no enough free space for the ECG data file after the measurement, you can save the data after replacing the media.

NOTE: Once the ID is changed, the file will not be saved and thus further processing will not be available.

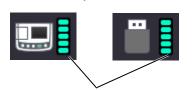
For the precautions for the USB flash disk, refer to *Preparing the USB Flash Disk* in this section. For the file settings, refer to *List of Settings* in Section 3.

- Make space in the media by reducing data.
 - Reduce the data in the media by sending, recording and deleting the ECG data file.
- · Replace the media.
 - Replace the media with enough free space.
- Change the media to save the file.

Change the media to save the file to another media with enough free space.

Media Icon

For For Internal memory USB flash disk



Indicator shows the media capacity.

The media icons are as following.

| Media Icon | Description |
|------------|----------------------------------|
| | Media capacity is 50 % to 100 %. |
| | Media capacity is 25 % to 50 %. |
| | Media capacity is 13 % to 25 %. |
| | Media capacity is 6 % to 13 %. |
| | Media capacity is 3 % to 6 %. |
| | Media capacity is 0 % to 3 %. |
| | Saving data |
| | USB flash disk failure |
| | No USB flash disk |

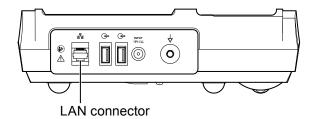
Connecting the Electrocardiograph to a Network

MARNING

Do not use a damaged network cable. The patient or operator may receive electrical shock when the damaged part is touched.

NOTE: Consult the network administrator about network connection.

Connect the network cable to the LAN connector on the back of the electrocardiograph, and connect it to the network. Use category 5, unshielded twist pair (UTP) cable for the network cable.



The electrocardiograph can send files to an external server through a network using wired or wireless LAN.

You can enter the patient information by using data on the server.

The connection method and grounding method depends on the location where the electrocardiograph is installed and the types and installation locations of other devices. Follow the international safety standards of medical electrical equipment IEC 60601-1. Refer to the *General Requirements for Connecting Medical Electrical Systems* in Section 11. Contact an authorized LAN construction company or telephone line company locally.

Using the Wired LAN

- 1 Set "LAN type" to "Wired" on "Setup-Communication settings-Common settings".
- 2 Set the "IP address" of the electrocardiograph on "Communication settings" in the <Setup> screen. Refer to Setting the IP Address, Subnet mask and Default gateway on the Electrocardiograph later in this section.
- 3 Set the external server on the "Communication settings" in the <Setup> screen. Refer to *List of Settings Communication settings Common settings* in section 3.
- 4 Connect the network cable. Refer to *Connecting the Network Cable to the Electrocardiograph* later in this section.

Using the Wireless LAN

This equipment should be installed and operated keeping Main Unit at least 20 cm or more away from person's body.

- 1 Set "LAN type" to "Wireless" on "Setup-Communication settings-Common settings".
- 2 Set the "IP address" of the electrocardiograph on "Communication settings" in the <Setup> screen. Refer to Setting the IP Address, Subnet Mask and Default Gateway on the Electrocardiograph later in this section.
- **3** Set the external server on the "Communication settings" in the <Setup> screen. Refer to *List of Settings Communication settings* in Section 3.
- 4 Set the following wireless LAN settings on "Setup-Communication settings-Common settings" or refer to *List of Settings Communication settings Common settings* in Section 3.

• SSID (setting range: up to 32 characters, case-sensitive)

The Service Set Identifier (SSID) selects the wireless network to access. When the access point is not set to use broadcast SSID, set the SSID to the same setting as the access point. When the broadcast SSID is used, leave this setting blank. All access points on the network can be communicated.

• Authentication mode (Shared, Open, WPA-PSK or WPA2-PSK)

Select how the electrocardiograph authenticates to the access point.

• Encryption (WEP, WPA-TKIP, WPA-AES or Off)

Select the security setting.

WEP key

Enter the WEP key to use. Confirm the key with the system administrator. When "Infrastructure mode" is set for "Communication mode", enter the same WEP key as the access point. When "Ad hoc mode" is set, enter the same WEP key as the communicator.

• WPA key

Enter the WPA key to use. Confirm the key with the system administrator. When "Infrastructure mode" is set for "Communication mode", enter the same WPA key as the access point. When "Ad hoc mode" is set, enter the same WPA key as the communicator.

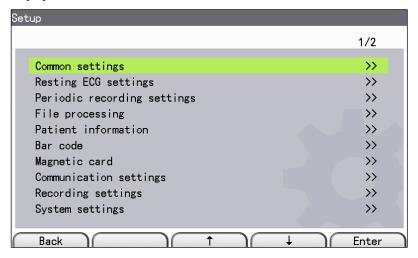
NOTE: The entered WPA key can be overwritten, but cannot be deleted.

Setting the IP Address, Subnet Mask and Default Gateway on the Electrocardiograph

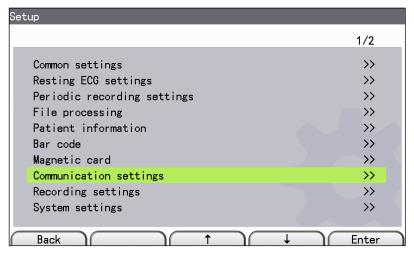
Each device in the network has an unique IP address for data communication. Duplicate IP addresses must not be present in the same network. The IP address takes the form of 4 numbers separated by dots, for example: 192.168.1.10.

Set the electrocardiograph IP address on the "Communication settings" in the <Setup> screen.

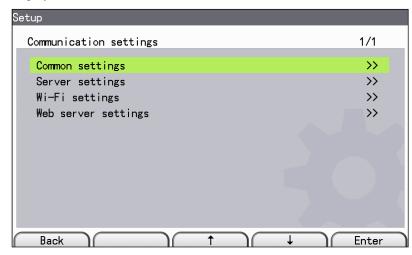
- 1 Before setting the IP address on the electrocardiograph, check the IP address, subnet mask and default gateway on each device in the network.
- When the power is turned on, the <Resting ECG> recording screen appears. If another screen is displayed, press the **FUNCTION** key to display the <FUNCTION> screen.
- **3** Press the [↑] or [↓] function key to select "Setup". The <Setup> screen is displayed.



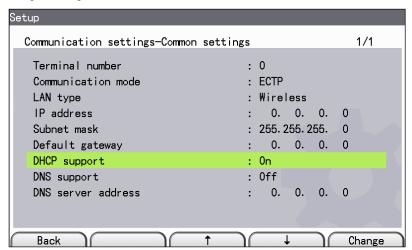
4 Press the [↑] or [↓] function key to select the "Communication settings" on the <Setup> screen.



5 Press the [Enter] function key. The <Communication settings> screen is displayed.



- Press the [Enter] function key. Edit the Terminal number, LAN type, IP address, Subnet mask, Default gateway and DHCP support.
 - i) Press the "↑" or "↓" function key to select the desired item.
 - ii) Edit the "Terminal number", "LAN type", "IP address", "Subnet mask", "Default gateway" and "DHCP support" with the keyboard on the operation panel.



- iii) Press the [Back] function key. The address is set and the <Communication settings> screen is displayed.
- **7** Repeat step 6 to change other settings.
- Press the FUNCTION key. The "Do you want to save your changes?" message is displayed. Select "1. Continue".

Synchronizing the Date and Time with the External Server

The data and time can be synchronized with the external server.

Synchronizing Time with the External Server

When the "Synchronize clock with server" is set to "On", the date and time of the device are synchronized to those of the server when normal mode is started. The time synchronization icon appears at the right side of the date and time.

NOTE: Set the date and time on the device when it cannot be synchronized over the network.

If the "Date and time is synchronized" message does not appear at power on, the date and time at which are set on the device is displayed. The followings are possible cause of sync failure.

- IP address of the device is incorrect.
- IP address of the external server is incorrect.
- External server is down.
- · Network cable is damaged.

Network Icon

| Name | Condition | | |
|----------------------|----------------|---|------------|
| | Ordering sever | address and File server address are not be set. | None |
| | Wired | Connection confirmation in progress. | 2 |
| | | Connecting. | |
| | | Network has already connected. | |
| | | Network connection error. | |
| | | Network is disconnected. | |
| Network display area | | File sending. | |
| | Wireless | Network connection error. | |
| | | Connecting. | |
| | | Network is disconnected. | ₽ X |
| | | Network has already connected. | |
| | | File sending. | |

3

Changing Settings Before Measurement

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General

You can change settings of the electrocardiograph through System Setup by the following steps:

- 1 Press the **FUNCTION** key on the operation panel and select "Setup" to access the <Setup> screen.
- Press the [↑] or [↓] function key to select the desired item then press the [Enter] function key to access the setting item.

To exit setup, press the [Back] function key.

Press the **FUNCTION** key after changing the settings, the message "Do you want to save your changes? 1.Continue 2.Cancel" is displayed on the screen.

3 Press the number key 1 to save the settings.

The following settings are available in the <Setup> screen:

- · Common settings
- · Resting ECG settings
- Periodic recording settings
- File processing
- · Patient information
- · Bar code
- · Magnetic card
- · Communication settings
- · Recording settings
- · System settings
- Save/Load/Print system settings

3

List of Settings

The factory default settings are underlined.

Common settings

Operation

| Item | Description | Settings |
|---------------------|------------------------------------|-------------------|
| Paperless | Select if recording with no paper. | On |
| | | Off |
| Lead mode selection | Select the ECG lead mode. | Standard 12 leads |
| | | Cabrera leads |

Filter settings

| Item | Description | Settings |
|---------------------------------|---|---------------|
| High cut filter | Select high cut filter frequency. | 75 Hz |
| | | <u>100 Hz</u> |
| | | 150 Hz |
| EMG suppression frequency | Select EMG suppression frequency. | 25 Hz |
| | | <u>35 Hz</u> |
| Default EMG suppression setting | Select "Off" to suppress EMG during recording. | On |
| | | Off |
| AC filter | , , , , , , , , , , , , , , , , , , , | <u>50 Hz</u> |
| | frequency. | 60 Hz |
| | | Off |
| baseline from drifting by | Baseline drift suppression prevents the | Strong |
| | baseline from drifting by locking it into one position at the start of recording. | Weak |
| | position at the start of recording. | Off |

Analysis format and settings

| Item | Description | Settings |
|--------------------------------|--|------------------------|
| Analysis mode | Select the analysis mode. | Standard |
| | | Standard (screening) |
| | | Advanced |
| | | Advanced (screening) |
| Measurement/analysis selection | Select whether to print the measurement | Measurement + analysis |
| | values and analysis result with the ECG waveforms. | Measurement only |
| | | None |

3. CHANGING SETTINGS BEFORE MEASUREMENT

| Item | Description | Settings |
|------------------------|--|---------------------|
| QTc calculation method | Select the method to calculate QTc. | <u>ECAPS</u> |
| | | Bazett |
| | | ECAPS + Fridericia |
| | | Bazett + Fridericia |
| Lead check | Select "On" to indicate when the electrode | <u>On</u> |
| | attachment position is incorrect. | Off |

Auto recording

Recording method

| Item | Description | Settings |
|------------------|--|---------------------------------|
| Auto gain output | Select the auto gain control function. | Auto gain |
| | | Auto gain + setting gain |
| | | Setting gain |
| | | Setting gain + auto gain |
| Auto position | Select the auto position control function. | <u>On</u> |
| | | Off |
| Time | Select the total recording time. | 10sec to 24sec (<u>10sec</u>) |

Recording format

| Item | Description | Settings |
|------------------------------|---|------------------|
| Auto recording channels | Set the number of automatic recording | 1 ch |
| | channels. | <u>3 ch</u> |
| | | Average + rhythm |
| Result printing format | Select analysis result recording printing | Result + average |
| | format. | Result only |
| Include findings criteria | Select "On" to print the criteria for the | On |
| fi | finding. | Off |
| Pacing detection sensitivity | Select the pacing detection sensitivity. | <u>High</u> |
| | | Low |

Manual recording

| Item | Description | Settings |
|---------------------------|--|---------------|
| Manual recording channels | Set the number of manual recording | 1 ch |
| | channels. | <u>3 ch</u> |
| | | 1 ch + rhythm |
| Auto position | Select the auto position control function. | <u>On</u> |
| | | Off |

Rhythm recording

| Item | Description | Settings |
|------------------|---|---|
| Rhythm lead ch 1 | Select the rhythm lead for channel 1 in | Standard 12 leads: |
| | rhythm lead recording. | I, <u>II</u> , III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6 |
| | | Cabrera leads: |
| | | aVL, I, - aVR, <u>II</u> , aVF, III, V1, V2, V3, V4, V5, V6 |

Sound output

| Item | Description | Settings |
|---------------------------|---------------------------------------|-----------------------|
| QRS sync sound volume | Select the QRS sync sound volume. | 0, <u>1</u> - 4 (max) |
| Notification sound volume | Select the notification sound volume. | 0, <u>1</u> - 4 (max) |
| Chime volume | Select the chime volume. | 0, <u>1</u> - 4 (max) |

Image format

Auto recording

| Item | Description | Settings |
|--------------------|---------------------------------------|-------------|
| Recording channels | Set the number of recording channels. | 3 ch |
| | | <u>6 ch</u> |

Resting ECG settings

| Item | Description | Settings |
|--------------------|---|--------------------------|
| Auto start | Select "On" to automatically start recording. | On |
| | | Off |
| Extended recording | Select the extended recording type. | On: rhythm (full page) |
| | | On: sequence (full page) |
| | | Off |
| Preview | Select "On" to show the <preview> screen.</preview> | On |
| | | Off |

Periodic recording settings

3. CHANGING SETTINGS BEFORE MEASUREMENT

| Item | Description | Settings |
|---------------------------------|---|------------------------|
| Starting leads | Set the starting leads. | Limb |
| | | Chest |
| Periodic recording type | Set periodic recording type. | Fixed time |
| | | Interval |
| | | Off |
| Fixed recording time 30 s | | On |
| | | Off |
| Fixed recording time 1 min | | On |
| | | Off |
| Fixed recording time 2 min | | <u>On</u> |
| | | Off |
| Fixed recording time 3 min | | <u>On</u> |
| | | Off |
| Fixed recording time 4 min | | On |
| | | Off |
| Fixed recording time 5 min | | On |
| | | Off |
| Fixed recording time 6 min | | On |
| | | Off |
| Fixed recording time 7 min | | On |
| | Select "On" to acquire the ECG waveform | Off |
| Fixed recording time 8 min | after the specified time when "Periodic recording type" is set to "Fixed time". | On |
| | | Off |
| Fixed recording time 9 min | | <u>On</u> |
| | | Off |
| Fixed recording time 10 min | | On |
| | | Off |
| Fixed recording time 11 min | | On |
| | | Off |
| Fixed recording time 12 min | | On |
| | | Off |
| Fixed recording time 13 min | | On |
| | | Off |
| Fixed recording time 14 min | | On |
| | | Off |
| Fixed recording time 15 min | | On |
| | | Off |
| Interval (min) | Select the interval when "Periodic recording type" is set to "Interval". | 1 to 60 (<u>5</u>) |
| Interval recording repetitions | Select time to acquire the ECG waveform. | 1 to 999 (<u>10</u>) |
| Additional slow speed recording | Select "On" to add slow paper speed | <u>On</u> |
| | recording. | Off |

File processing

| ltem | Description | Settings |
|-------------------------------|--|-----------------|
| Auto processing | Select the file processing type. | Save |
| | | Send |
| | | Save + Send |
| | | Off |
| Media | Select the media to save ECG data files. | USB flash disk |
| | | Internal memory |
| Data compression type | Select the type to save the file: type 1 for | Type 1 |
| | normal or type 2 for compressed. | Type 2 |
| File auto delete | Select "On" to automatically delete the | On |
| | oldest file when the media is full. | Off |
| Show media free space warning | When "Show media free space warning" is set to "On" and there is less than 10 % free | |
| | space in the media, the "Not enough free | <u>On</u> |
| | space. Delete unnecessary files." message appears when the power is turned on. | Off |
| Save as PDF | When "Save as PDF" is set to "On" on the | |
| 5470 45 1 51 | "File processing" of the <setup> screen:</setup> | |
| | - Recording time can be set from 10 s to 24 s. | |
| | - Media is fixed to "USB flash disk". | On |
| | - File auto delete is not available. | Off |
| | - The waveform's sensitivity which is saved | |
| | in a PDF file is same as the sensitivity | |
| | displayed on screen when saving the file. | |
| Preview | Select "On" to show the preview screen. | <u>On</u> |
| | | Off |

Patient information

Input settings

| Item | Description | Settings |
|-------------|---|-----------|
| ID | Select "On" to enable ID entry on the | <u>On</u> |
| | <patient information=""> screen.</patient> | Off |
| Sex | Select "On" to enable gender entry on the | <u>On</u> |
| | <patient information=""> screen.</patient> | Off |
| Default sex | Select the default gender when the power is | <u>M</u> |
| | turned on. | F |
| | | Blank |
| Age | Select whether to display age on the <patient< td=""><td>age</td></patient<> | age |
| | information> screen. When displaying age, select whether to display age. | Off |
| ID digits | Select the number of digits in ID. To change the number of digits in ID, the internal | 12 |
| | memory must be formatted. | 20 |

Query settings

| Item | Description | Settings |
|------------------------------------|--|---|
| Show confirmation for searched | Select "On" to display the Patient confirmation screen after entering the data from bar code or magnetic card and search the data. | On Off |
| Patient server | Select "On" to search patient information on the server. | On Off |
| Data search location on the server | Select the external server to search the data. | Scheduled patients today All patient database |
| Automatic search | Select "On" to automatically search the data when the ID is entered from bar code or magnetic card. | On Off |

Bar code

Common settings

| Item | Description | Settings |
|------------|-------------------------------------|--|
| Vendor ID | Set the bar code reader vendor ID. | Up to 4 alphanumeric characters (05E0) |
| Product ID | Set the bar code reader product ID. | Up to 4 alphanumeric characters (1200) |

Code settings

| Item | Description | Settings |
|-------------|----------------------|-------------------------------------|
| Male code | Set the male code. | Up to 8 alphanumeric characters (1) |
| Female code | Set the female code. | Up to 8 alphanumeric characters (2) |

Position settings

| Item | Description | Settings |
|---------------------|------------------------|--------------------|
| ID start address | Set the start address. | 0-99 (1) |
| end address | Set the end address. | 0-99 (<u>12</u>) |
| Name start address | Set the start address. | 0-99 (<u>0</u>) |
| end address | Set the end address. | 0-99 (<u>0</u>) |
| Sex start address | Set the start address. | 0-99 (<u>13</u>) |
| end address | Set the end address. | 0-99 (<u>13</u>) |
| Year start address | Set the start address. | 0-99 (<u>14</u>) |
| end address | Set the end address. | 0-99 (<u>17</u>) |
| Month start address | Set the start address. | 0-99 (<u>18</u>) |
| end address | Set the end address. | 0-99 (<u>19</u>) |
| Day start address | Set the start address. | 0-99 (20) |
| end address | Set the end address. | 0-99 (21) |

^{*} When the position settings are set to "0", the settings are invalid.

3

Magnetic card

Common settings

| Item | Description | Settings |
|-------------------------|---|---|
| Vendor ID | Set the bar code reader vendor ID. | Up to 4 alphanumeric characters (<u>0804</u>) |
| Product ID | Set the bar code reader product ID. | Up to 4 alphanumeric characters (<u>0040</u>) |
| Card reader type | Select the card reader type. | 1 |
| | | 3 |
| Valid data track number | Select the valid data track number when | 1 |
| | "Card reader type" is set to 3 track. | 2 |
| | | 3 |

Code settings

| Item | Description | Settings |
|-------------|----------------------|--|
| Male code | Set the male code. | Up to 8 alphanumeric characters (M) |
| Female code | Set the female code. | Up to 8 alphanumeric characters (<u>F</u>) |

Position settings

| Item | Description | Settings |
|---------------------|------------------------|--------------------|
| ID start address | Set the start address. | 0-99 (<u>1</u>) |
| end address | Set the end address. | 0-99 (<u>9</u>) |
| Name start address | Set the start address. | 0-99 (11) |
| end address | Set the end address. | 0-99 (<u>30</u>) |
| Sex start address | Set the start address. | 0-99 (<u>32</u>) |
| end address | Set the end address. | 0-99 (<u>32</u>) |
| Year start address | Set the start address. | 0-99 (<u>0</u>) |
| end address | Set the end address. | 0-99 (<u>0</u>) |
| Month start address | Set the start address. | 0-99 (<u>0</u>) |
| end address | Set the end address. | 0-99 (<u>0</u>) |
| Day start address | Set the start address. | 0-99 (<u>0</u>) |
| end address | Set the end address. | 0-99 (<u>0</u>) |

^{*} When the position settings are set to "0", the settings are invalid.

Communication settings

Common settings

| Item | Description | Settings |
|--------------------|--|--------------------------------|
| Terminal number | Enter the terminal number. | 0 to 9999 (<u>0</u>) |
| Communication mode | Select the communication mode. When this setting is set to "DICOM", the following applies: - Recording time can be set from 10 s to 24 s. - The waveform's sensitivity which is saved in a DICOM file is same as the sensitivity displayed on screen when saving the file. | DICOM ECTP |
| LAN type | Select the type of LAN. | Wired Wireless |
| IP address | Set the IP address of the electrocardiograph. | xxx.xxx.xxx (<u>0.0.0.0</u>) |
| Subnet mask | Set the subnet mask address of the electrocardiograph. | xxx.xxx.xxx (255.255.255.0) |
| Default gateway | Set the default gateway address. | xxx.xxx.xxx (<u>0.0.0.0</u>) |
| DHCP support | Select "On" to enable DHCP (Dynamic Host Configuration Protocol). | On Off |
| DNS support | Select "On" to enable DNS (Domain Name System). | On Off |
| DNS server address | Set the DNS server address. | xxx.xxx.xxx (<u>0.0.0.0</u>) |

Server settings

ECTP settings

| Item | Description | Settings |
|----------------------------|--|--|
| Communication timeout (ms) | Set the time out period for communication. | 0 - 9999 (<u>3000</u>) |
| Ordering server address | Set the ordering server address. | xxx.xxx.xxx (<u>0.0.0.0</u>) |
| Ordering server host name | Set the ordering server host name. | Up to 64 alphanumeric characters |
| Ordering server port | Set the ordering server port. | 0 - 65535 (30003) |
| File server address | Set the file server address. | xxx.xxx.xxx (<u>0.0.0.0</u>) |
| File server host name | Set the file server host name. | Up to 64 alphanumeric characters |
| File server port | Set the file server port number. | 0 - 65535 (30003) |
| File server user name | Set the file server user name. | Up to 128 alphanumeric characters (<u>CEX</u>) |
| File server password | Set the file server password. | Up to 128 alphanumeric characters (CEX) |
| FTP server port | Set the FTP server port number. | 0 - 65535 (21) |
| File server send folder | Set the folder of the other instruments to send the ECG data files. | Up to 128 alphanumeric characters (/) |
| File server receive folder | Set the folder to receive the ECG data files from other instruments. | Up to 128 alphanumeric characters (/) |

DICOM settings

| Item | Description | Settings |
|----------------------------|--|---|
| Communication timeout (ms) | Set the time out period for communication. | 0 - 9999 (3000) |
| Local AE title | Set the local AE title. | Up to 16 alphanumeric characters |
| MWM server AE title | Set the MWM server AE title. | Up to 16 alphanumeric characters |
| MWM server address | Set MWM server address. | xxx.xxx.xxx (<u>0.0.0.0</u>) |
| MWM server host name | Set MWM server host name. | Up to 64 alphanumeric characters |
| MWM server port | Set MWM server port number. | 0 - 65535 (0) |
| Modality code | Set Modality code. | Up to 16 alphanumeric characters (<u>ECG</u>) |
| Storage server AE title | Set the storage server AE title. | Up to 16 alphanumeric characters |
| Storage server address | Set the storage server address. | xxx.xxx.xxx (<u>0.0.0.0</u>) |
| Storage server host name | Set the storage server host name. | Up to 64 alphanumeric characters |
| Storage server port | Set the storage server port. | 0 - 65535 (0) |

External printer settings

| Item | Description | Settings |
|----------------------------|--|----------------------------------|
| Communication timeout (ms) | Set the time out period for communication. | 0-9999 (3000) |
| Printer server address | Set the printer server address. | xxx.xxx.xxx (<u>0.0.0.0</u>) |
| Printer host name | Set the printer host name. | Up to 64 alphanumeric characters |
| Printer server port | Set the printer server port. | 0 - 65535 (9100) |

Wi-Fi setting

| Item | Description | Settings |
|---------------------|--|----------------------------------|
| SSID | Set the SSID (Service Set Identifier). | Up to 32 alphanumeric characters |
| Authentication mode | Select how the electrocardiograph attempts | Shared |
| | to authenticate to the access point. | Open |
| | | WPA-PSK |
| | | WPA2-PSK |
| Encryption | Select the encryption type. | WEP |
| | | WPA-TKIP |
| | | <u>WPA-AES</u> |
| | | Off |
| WEP key | Set the WEP key. | Up to 26 alphanumeric characters |
| WPA key | Set the WPA key. | Up to 63 alphanumeric characters |

Web server settings

| Item | Description | Settings |
|----------------------------|---|----------------------------------|
| Web server | Select "On" to enable Web server. | On |
| | | Off |
| Login user name | Set the login user name. To access a webserver, the setting parameters of "Login user name" and "Login password" must be set. | Up to 20 alphanumeric characters |
| Login password | Set the login password. To access a webserver, the setting parameters of "Login user name" and "Login password" must be set. | Up to 20 alphanumeric characters |
| Communication timeout (ms) | Set the time out period for communication. | 0 - 9999 (3000) |
| Session timeout (min) | Set the time out period for session. | 0 - 30 (5) |
| Web server port | Set the web server port. | 0 - 65535 (<u>80</u>) |

Recording settings

| Item | Description | Settings |
|---------------------|--|------------------|
| High speed printing | Select whether to turn on fast recording. | On |
| | | Off |
| Default paper speed | Select the default paper speed. | 25 mm/s |
| | | 50 mm/s |
| Recorder | Select the recorder. When this setting is set to | |
| | "External printer", the following applies: | |
| | - Recording time can be set from 10 s to 24 s. | External printer |
| | - The waveform's sensitivity which is printed | Internal printer |
| | by an external printer is same as the current | |
| | sensitivity setting. | |

System settings

| Item | Description | Settings |
|----------|--|------------------------------|
| Language | Select the language for display and recording. | Select your target language. |

Date/Time settings

| Item | Description | Settings |
|---------------------|---|--------------------------|
| Date and time | Set the date and time. (the year effective range: 2000 to 2079) | format: YYYY/MM/DD HH:mm |
| Date display format | Select the date display format. | M-D-Y |
| | | D-M-Y |
| | | Y-M-D |
| | | Y/M/D |
| Time display format | Select the time display format. | 12 hour day |
| | | 24 hour day |

| Item | Description | Settings |
|-------------------------------|--|-----------|
| Synchronize clock with server | Select "On" to automatically adjust the clock to the time of server. When the "Setup-Communication settings-Common settings-Communication mode" is set to "DICOM", the clock cannot be synchronized with server. | On Off |

Power management

| Item | Description | Settings |
|--------------------|---|------------------|
| Backlight auto off | The backlight is turned off automatically when the "Fail" message (the limb electrodes detachment) is displayed on the screen and there is no key operation for approximately 3 minutes. | On <u>Off</u> |
| Auto power off | The electrocardiograph power is turned off automatically when it is not operated for more than 3 minutes in battery pack operation due to limb electrodes detachment as shown in test screen. | On Off |

| Item | Description | Settings |
|--------------------------|--|----------------------------|
| Hospital | Enter the hospital name. | 40 alphanumeric characters |
| Password bypass | When the "Password bypass" is set to "Off", enter the login password when you enter the <resting ecg=""> recording screen.</resting> | On Off |
| Password | Set the password for entering the <resting ecg=""> recording screen.</resting> | 0 - 9999 (1234) |
| Settings password bypass | When the "Settings password bypass" is set to "Off", enter the password when you enter <setup> screen.</setup> | On Off |
| Settings password | Set the password for entering <setup> screen.</setup> | 0 - 9999 (<u>1234</u>) |

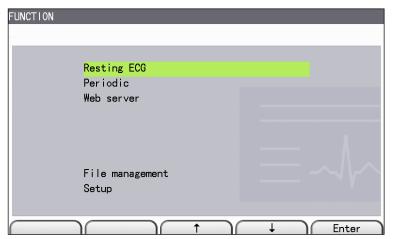
Save/Load/Print system settings

| Item | Description |
|----------------------------|--|
| Save system settings | Saves all system settings on an USB flash disk. |
| Load system settings | Loads system settings from an USB flash disk. |
| Print system settings | Prints all system settings. |
| Initialize system settings | Initializes the system settings to the factory default values. |
| Save hospital name | Saves the hospital name to a USB flash disk. |
| Load hospital name | Loads the hospital name from a USB flash disk. |

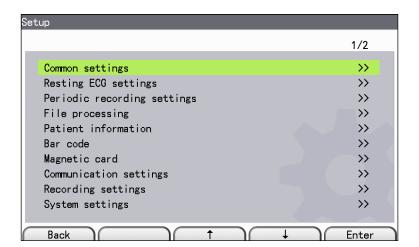
Changing the System Setup Settings

Displaying the System Setup Screen

1 Press the **FUNCTION** key to display the <**FUNCTION**> screen.



Press the [↑] or [↓] function key to select "Setup". And press the [Enter] function key. The <Setup> screen is displayed.



Changing Settings

- 1 Display the <Setup> screen. (To display the <Setup> screen, refer to Displaying the System Setup Screen in this section)
- Press the [↑] or [↓] function key to select the desired item on the <Setup> screen.
- 3 Press the [Enter] function key. The <Setup> screen for that item is displayed.
- Press the [↑] or [↓] function key to select the desired item on the selected item screen.
- 5 Press the [Change] function key to select the desired setting.
- Repeat steps 3 and 4 to change other settings.
- Press the FUNCTION key. The "Do you want to save your changes?"

 message is displayed. Select "1. Continue" The changed settings are saved ECG-3150 Operator's Manual

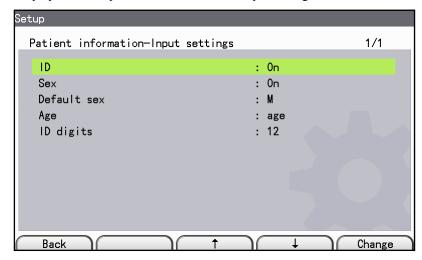
3

Changing the Number of Digits in ID

⚠ CAUTION

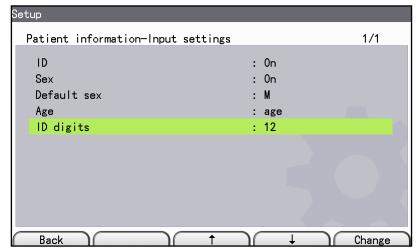
Changing the number of digits in ID will delete all ECG data in the internal memory. Back up the necessary data before changing the number of digits in ID.

1 Display the <Setup - Patient information - Input settings> screen.

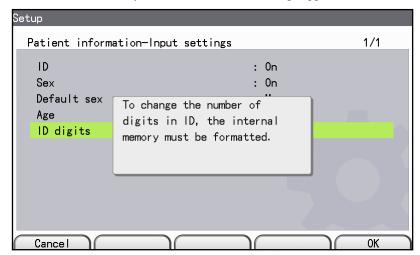


Press the [↑] or [↓] function key to select ID digits.

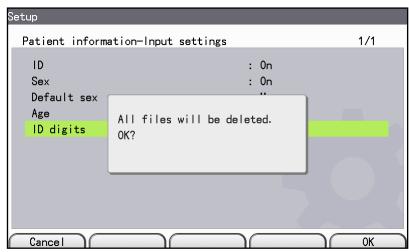
The number of digits in ID can be changed from 12 to 20 and vice versa.



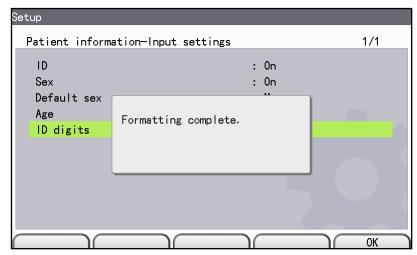
3 Press the [Change] function key. The "To change the number of digits in ID, the internal memory must be formatted." message appears.



4 Press the [OK] function key. The "All files will be deleted. OK?" message appears.

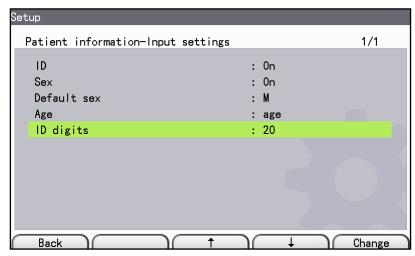


5 Press the [OK] function key. When formatting is complete, the "Formatting complete." message appears.



3

6 Press the [OK] function key. The number of digits in ID has been changed.



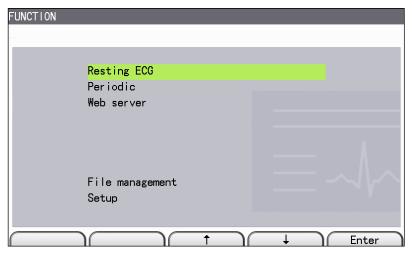
Press the FUNCTION key. The "Do you want to save your changes?" message appears. Select "1. Continue" to save the changed setting.

Saving, Loading and Printing the System Settings

Saving the System Setup Settings

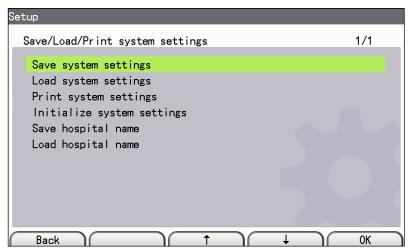
You can save all settings to the USB flash disk.

1 Insert the USB flash disk into the USB flash disk connector before saving the system settings.



- 2 Display the <Setup> screen. To display the <Setup> screen, refer to Displaying the System Setup Screen in this section.
- Press the [↑] or [↓] function key to select "Save/Load/Print system settings". Press the [Enter] function key.

The <Setup-Save/Load/Print system settings> screen is displayed.



4 Select "Save system settings" and press the [OK] function key.

Loading the System Setup Settings

You can load previously <Setup> screen settings from a USB flash disk.

- Insert the USB flash disk in the USB flash disk connector before loading the system settings.
- **2** Display the <Setup> screen. To display the <Setup> screen, refer to *Displaying the System Setup Screen* in this section.
- 3 Press the [↑] or [↓] function key to select "Save/Load/Print system settings" Press the [Enter] function key.
- 4 Select "Load system settings." When the "Continue?" message appears, press the [OK] function key.

Printing the List of System Setup Settings

- 1 Display the <Setup> screen. To display the <Setup> screen, refer to Displaying the System Setup Screen in this section.
- Press the [↑] or [↓] function key to select "Save/Load/Print system settings". Press the [Enter] function key.
- Select "Print system settings" and press the [OK] function key.Then printing starts.To stop printing, press the [Stop] function key.

Initializing the System Settings

- 1 Display the <Setup> screen. To display the <Setup> screen, refer to Displaying the System Setup Screen in this section.
- Press the [↑] or [↓] function key to select "Save/Load/Print system settings". Press the [Enter] function key.
- 3 Select "Initialize system settings." When the "Continue?" message appears, press the [OK] function key to reset all settings to the factory defaults.

Saving the Hospital to a USB Flash Disk

You can save the registered hospital names in the USB flash disk. Before saving, insert the USB flash disk to the USB flash disk connector on the rear of electrocardiograph.

- 1 Display the <Setup> screen. To display the <Setup> screen, refer to Displaying the System Setup Screen in this section.
- Press the [↑] or [↓] function key to select "Save/Load/Print system settings", and press the [Enter] function key to display <Setup-Save/Load/Print system settings> screen.
- 3 Select "Save hospital name" and press the [OK] function key to save it to the USB flash disk.

Loading the Hospital from a USB Flash Disk

You can load the hospital names which were previously registered on the electrocardiograph.

This procedure overwrites the current system settings.

If the current settings are needed, save them to another USB flash disk before loading new settings.

- 1 Display the <Setup> screen. To display the <Setup> screen, refer to Displaying the System Setup Screen in this section.
- Press the [↑] or [↓] function key to select "Save/Load/Print system settings", and press the [Enter] function key to display the <Setup-Save/Load/Print system settings> screen.
- 3 Select "Load hospital name". When the "Continue?" message appears, press the [OK] function key. The hospital names are loaded from the USB flash disk.



Attaching the Electrodes and Entering Patient Information

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General

MARNING

Do not connect the tip of the electrode lead to anything other than an electrode. Connect all the tips to the corresponding electrodes and attach them to the patient. If unconnected tips or electrodes contact an item which is non-equipotential, the patient may receive electrical shock. Also, noise may superimpose on the ECG waveforms and measurement data may be incorrect.

A CAUTION

- Do not use new and old electrodes together, or re-usable and disposable electrodes together (such as clip electrodes, suction electrodes and disposable electrodes). If different types are used together, it may cause a high polarization voltage and prevent displaying and recording of the ECG waveforms.
- Always replace all the electrodes with new ones at the same time.
- When using an ESU and defibrillator with the electrocardiograph, use silver chloride disposable electrodes.
- Only use clean and undamaged electrodes with no scratches on the surface. Electrodes with a deteriorated surface may cause high contact impedance and distorted ECG waveforms.
- The parts of electrodes and other connectors should not contact other conductive parts including earth.

Attaching the ECG Electrodes

Attaching the Limb Electrodes

Attach four limb electrodes to muscular, not bony areas on the extremities.

- 1 Clean the skin with a cotton moistened with alcohol to remove oil.
- 2 Apply a thin layer of electrolyte cream (CardioCream) on the cleaned electrode sites.

R: Right arm

L: Left arm

RF: Right leg

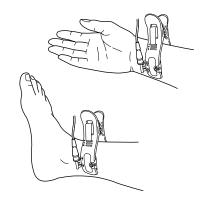
F:Left leg

- 3 Apply a small amount of electrolyte cream on the contact surface of the electrodes.
- ⚠ When limb electrodes are used

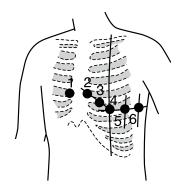
Attach the limb electrodes to the cleaned skin site.

When the ECG clip-on electrodes are used

Clip the electrode site with the ECG clip-on electrode.



Attaching the Chest Electrodes



- 1 Clean the skin with a cotton moistened with alcohol to remove oil.
- 2 Apply a thin layer of electrolyte cream (CardioCream) on the cleaned skin sites.
- 3 Attach the six electrodes to the cleaned skin site. Do not let the electrodes touch each other.
- 4 Apply a thin layer of Cardio Cream on the electrode surface.
- **5** Put the electrode on the site and squeeze the rubber ball to attach the electrode by suction.
 - C1 (V1): Fourth intercostal space at the right border of the sternum
 - C2 (V2): Fourth intercostal space at the left border of the sternum
 - C3 (V3): Halfway between C2 (V2) and C4 (V4)
 - C4 (V4): Fifth intercostal space on left midclavicular line
 - C5 (V5): Left anterior axial line at the horizontal level of C4
 - C6 (V6): Left midaxillary line at the horizontal level of C4 (V4)

Electrode and Patient Cable Tip Color Coding

BJ-961D. BJ-901D (IEC standard, tip: 3 mm diameter)

BJ-962D, BJ-902D (IEC/DIN standard, tip: 4 mm diameter)

BJ-903D (IEC standard, clip)



| Symbol in lead | Color (tip, clip/lead) | |
|----------------|------------------------|--|
| R | Red/Brown | |
| L | Yellow/Brown | |
| F | Green/Brown | |
| N (RF) | Black/Brown | |
| C1 | Red/White | |
| C2 | Yellow/White | |
| C3 | Green/White | |
| C4 | Brown/White | |
| C5 | Black/White | |
| C6 | Violet/White | |

BA-901D (AHA requirement, tip: 3 mm diameter)

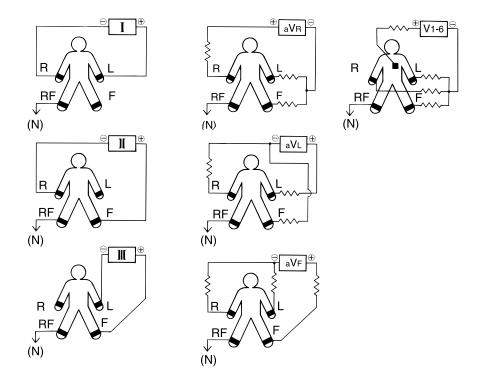
| Symbol in lead | Color (tip, clip/lead) |
|----------------|------------------------|
| RA | White/Brown |
| LA | Black/Brown |
| RL | Green/Brown |
| LL | Red/Brown |
| V1 | Red/White |
| V2 | Yellow/White |
| V3 | Green/White |
| V4 | Blue/White |
| V5 | Orange/White |
| V6 | Violet/White |

4

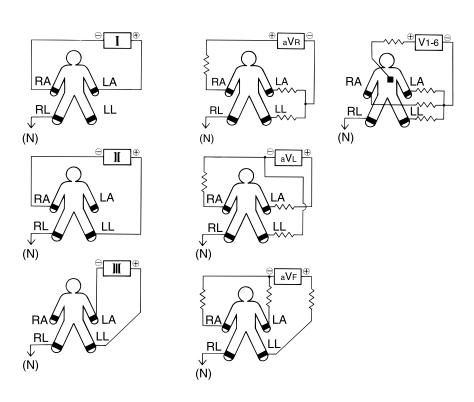
Lead Connection

Standard 12 Leads and Cabrera Leads

IEC Standard



AHA Requirement



Electrode Attachment Status Indication

Screen Message

The electrocardiograph continuously checks electrode attachment status. When electrode detachment or large polarization voltage is detected, a message is displayed.

| Screen message | Possible cause |
|--------------------------|--|
| Fail R, L, F (lead name) | The indicated limb electrode is detached. |
| Fail limb | • Two or more limb electrodes from the R, L or F electrode are detached. |
| | • The RF electrode is detached. |
| | • No electrode is attached to the patient. |
| | ECG input signal overload (the voltage or leakage current exceeds the limits of the device). |
| Fail 1, 2, 3, 4, 5 or 6 | The indicated chest electrode is detached. |
| Noise | Noise or artifact is detected. |

- NOTE If a limb electrode is detached, the chest electrode detachment message is not displayed. Check the chest electrode attachment after removing the cause of the error message.
 - The ECG waveforms can be displayed and recorded if the message due to a large polarization voltage is displayed. If recording starts, the analysis result may be incorrect and the ECG waveforms cannot be saved. Remove the cause of the error message before starting measurement.
 - A flat baseline is recorded for leads with a detached electrode.
 - When using the electrocardiograph with an ESU, noise from the ESU may be superimposed on the ECG waveforms.
 - When the screen shows "Fail:Limb", check the patient cable, otherwise it affects safe use.
 - If the "Fail:Limb" message is still displayed after replacing the electrode or connecting the patient cable, the electrocardiograph may be faulty. Contact your Nihon Kohden representative.

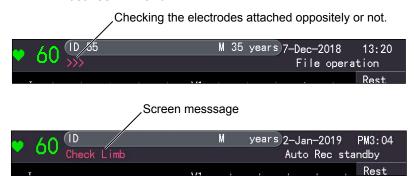
Lead check

When "Lead check" is set to "on" in "Setup-Common settings-Analysis format and settings", the electrocardiograph can indicate when the electrode attachment position is incorrect.

When starting recording, the ">" mark is displayed on the screen.

When electrode detachment or large polarization voltage is detected, one of the following messages will be displayed.

- NOTE The actual electrodes attachment can not be detected only from the ECG waveform. So regardless of the "Lead check" setting, make sure the electrodes are attached correctly.
 - This function is available only when two electrodes attached oppositely (such as "R" and "L"). If more than two electrodes are attached oppositely, this function is invalid.
 - For Dextrocardia or pacemaker use, "Check Lead" function is invalid. If the waveform above is detected by the electrocardiograph, but cannot detected within 20 beats by the influence of noise or arhythmia, the message "****** will display on the screen.
 - The ECG waveform generated from the electrodes attached oppositely between "L" and "RF", the situations above are similar to the ECG waveforms when the electrodes are connected correctly.
 - This function is unrelated to the analysis result. Therefore, there are some differences to the results of analysis result recording.
 - (1) Not related to the setting of "lead check", if the electrodes attached oppositely, the message will be displayed.
 - (2) In addition, The target waveform is not the simultaneous waveform, so the analysis result is different from "Lead check".
 - (3) The analysis result can only indicate the electrodes opposite between "R" and "L".



| Screen message | Possible cause |
|----------------|--|
| Check limb | The indicated limb electrode is attached in an opposite position. Press the HELP key to display Operation guide screen to check it. |
| Check chest | The indicated chest electrode is attached in an opposite position. Press the HELP key to display Operation guide screen to check it. |

Indications on the Paper

| During recording, the following lines are recorded on the paper when an electrode detachment or artifact is detected. | |
|---|-------|
| | |
| Electrode Detachment | Noise |

Countermeasure

Electrode Detachment

Check for detached electrodes corresponding to the message and the electrode lead. Reattach the electrode and connect the electrode lead.

Large Polarization Voltage

If the message is still displayed after reattaching the electrode, it is probably due to a large popularization voltage.

A large polarization voltage can have the following causes:

- New and old electrodes together or re-usable and disposable electrodes are
 used together (such as clip electrodes, suction electrodes and disposable
 electrodes). If different types are used together, it may cause a large
 polarization voltage and prevent displaying and recording of the ECG
 waveforms.
- Improper skin preparation. Use a cotton moistened with alcohol to clean the skin where the electrode is attached and apply the electrolyte cream (Cardio Cream) on the clean skin site. Reattach the electrode.
- After defibrillation, the ECG waveforms become unstable. Wait at least 5 seconds until the ECG waveforms are stable before recording the ECG waveforms.

When the cause of the message cannot be found, the electrode lead may be faulty. If any abnormality is found, refer to *Troubleshooting and Error Messages* in Section 9 to take proper action. If there is any damage or the electrocardiography is suspected to be faulty as a result of checking, attach an "Unusable" or "Require request" label to the electrocardiograph and contact your Nihon Kohden representative.

1

Entering the Patient Information

General

The available patient data can be selected in the "Patient information" settings.

Select "On" for all items of "Setup-Patient information-Input settings". Press the [ID] function key, then enter the following patient information in the <Patient information> screen.

You can enter the patient information by using the key board, reading from a bar code or magnetic card, or searching on the server.

⚠ CAUTION

When the patient sex and age is not entered, ECG analysis is performed with the patient as male and 35 years old.

NOTE: Add an ID to the patient information to prevent the ECG data from being mistaken for a different patient's ECG data.

Available patient data

ID: Up to 20 alphanumeric characters

Sex: Male, female, blank

Age (years): Up to 3 numeric characters

Entering the Patient Information Directly on the Device

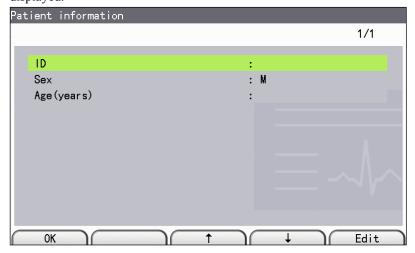
Manually Entering the Patient Information

NOTE: If you change the "ID", "Sex" returns to the default setting. If you change the ID when "Data auto delete" is set to "Off", the corresponding patient information won't be changed.

Screen Operation



1 Press the **ID** key, the Patient information search condition screen is displayed.



- Press the Edit key to enter the patient ID with the keyboard on the operation panel. And then press the Enter key to display the Patient information.
- When all items are entered, press the **ID** key to display the <Resting ECG> recording screen. You can start recording soon after the patient information is entered.

Entering the Patient Information Using a Bar Code Reader or Magnetic Card Reader

You can enter the patient information using a bar code reader or magnetic card on the <Resting ECG> recording screen, <Patient information> screen or Patient information search condition window.

NOTE: Initialize the bar code reader before use. Refer to the operator's manual of the bar code reader.

Set the bar code or magnetic card reader settings on "Bar code" or "Magnetic card" of the system settings.

When "Patient server" is set to "Off" on the <Setup> screen

Read the patient information with the bar code or magnetic card reader. The Patient information screen appears with the information of the bar code or magnetic card.

When "Patient server" is set to "On" on the <Setup> screen

Read the patient information with the bar code or magnetic card reader.

When "Automatic search" is set to "On" on the <Setup> screen

• When there is only one data:

When the "Show confirmation for searched" is set to "On" on the system settings, the <Patient information> screen appears with the information of the server displayed.

When the "Show confirmation for searched" is set to "Off" on the system settings, the <Resting ECG> recording screen is displayed. The patient information of the server is entered but not displayed.

• When there are two or more data:

The data list of the entered ID is displayed. Select the data and press the [OK] function key.

When "Show confirmation for searched" is set to "On" on the system settings, the <Patient information> screen appears with the information of the server displayed.

When "Show confirmation for searched" is set to "Off" on the system settings, the <Resting ECG> recording screen is displayed. The patient information of the server is entered but not displayed.

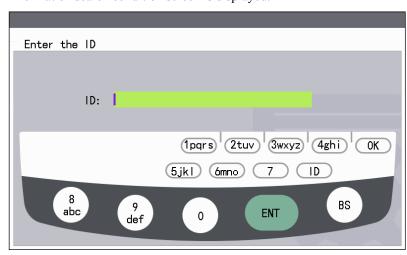
When "Automatic search" is set to "Off" on the system settings. The Patient information search condition window is displayed. Refer to *Entering the Patient Information by Searching on the Server*.

- NOTE If there is no data for the entered ID, the "Corresponding patient is not registered" message appears and the Patient information search condition screen is displayed.
 - Patient information, except for an ID, in the bar code or magnetic card is entered. Press the [Enter] function key to display the patient information screen and add or change the patient information manually.

Entering the Patient Information by Searching on the Server

You can enter the patient information by using data on the server on the Patient information search condition screen. Set "Patient server" to "On" on the "Setup-Patient information-Query settings" before starting the operation.

Press the **ID** key on the <Resting ECG> recording screen or read patient information using a bar code or magnetic card reader. The Patient information search condition screen is displayed.



- 2 Enter the ID and press the [Search] function key.
 - When there is only one data:

When "Show confirmation for searched" is set to "On" on the system settings, the <Patient information> screen appears with the information of the server displayed.

When "Show confirmation for searched" is set to "Off" on the system settings, the <Resting ECG> recording screen is displayed. The patient information of the server is entered but not displayed.

• When there are two or more data:

The data list of the entered ID is displayed. Select the data and press the [OK] function key.

When "Show confirmation for searched" is set to "On" on the system settings, the <Patient information> screen appears with the information of the server.

When "Show confirmation for searched" is set to "Off" on the system settings, the <Resting ECG> recording screen is displayed. The patient information of the server is entered but not displayed.

To cancel searching and to enter the information manually, press the [Enter] function key. The <Patient information> screen is displayed.

Press the [Cancel] function key to return to the previous screen.





Recording Resting ECG Waveforms

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General

You can record the resting ECG waveforms automatically or manually. When the power is turned on, automatic recording mode is the default selection.

In automatic recording mode, ECG analysis is automatically performed. After ECG waveforms are recorded, the ECG analysis result is automatically printed*.

There are two automatic recording modes, real time and review recording mode.

In review recording mode, you can verify the ECG waveform displayed on the screen before starting recording. This lets you confirm clear ECG recording and accurate ECG analysis.

In real time recording mode, when fluctuation of 20 % of R-R interval is detected, the electrocardiograph can automatically extend recording of the lead group for the preset interval.

* When "Paperless" in "Setup-Common settings-Operation" is set to "On", the waveforms are not printed.

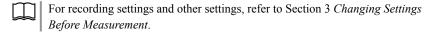
After recording, you can save the 12 lead ECG waveforms (including extended sequence recording), analysis result and patient information as an ECG data file in the media.

You can make one or more copies of the recording results until the next recording is started.

In manual recording mode, you can manually change the recording settings (paper speed, sensitivity, and EMG filter on/off) during recording.

You can also annotate the ECG waveforms with an event mark by pressing the **FEED/MARK** key.

Before or after automatic or manual ECG recording, you can record 1 minute of the rhythm lead. You can set the "Recording format" on "Setup-Common settings-Rhythm recording" in <Setup> screen.



Caution when the ECG waveform has artifact

⚠ CAUTION

During recording, if artifact superimposes on the ECG waveform, immediately stop the recording and remove the cause of the artifact. Refer to Troubleshooting in Section 9. Failure to follow this instruction causes overheating and damage to the electrocardiograph.

If the ECG recording is continued in this condition, the power unit in the electrocardiograph generates high frequency noise which causes the electrocardiograph to heat up. The recording cannot be performed until the electrocardiograph cools down.

5

Flow of Resting ECG Waveform Recording

Following is the basic procedure for recording resting ECG waveforms.

- 1 Turn the power on.
- 2 Select automatic or manual recording mode.

Lamp on: Automatic recording

Lamp off: Manual recording

Automatic recording:

- 1) Enter the patient information for ECG analysis.
- 2) Select the review recording mode with the [Review] function key if necessary.
- 3) Press the START/STOP key.

To print a copy of the recording results, press the COPY/1mV key.

When "Auto processing" on "File processing" of the <Setup> screen is set to "Save", after automatic recording the analysis result and patient information are automatically saved as an ECG data file in a USB flash disk.

When "Auto processing" on the "Setup-File processing" is set to "Save + Send" or "Send", the analysis result and patient information are automatically sent from a media to a personal computer.

Manual recording:

- 1) Press the START/STOP key.
- 2) Press the [F4] or [F5] function key to select the next lead group.
- 3) Repeat step 2) to record all lead groups.
- 4) Press the START/STOP key to stop recording.

Rhythm recording:

Press the **RHYTHM** key. When 1 minute of ECG waveforms are acquired, rhythm lead recording starts automatically.

Notes for Accurate Measurement

Before Starting Recording

- 1 Before pressing the **START/STOP** key, confirm the following to acquire correct heart rate and accurate analysis result.
 - The heart rate displayed on the screen is stable.
 - The electrode detachment or noise message does not appear.
 - The QRS sync mark displayed on the screen blinks.
- Wait at least 10 seconds for stable ECG waveforms. Immediately after electrodes are attached, the ECG waveforms may be unstable because of polarization voltage.

Detecting QRS Waves

The electrocardiograph detects the QRS wave from leads II, V1 and V5. To assure QRS detection accuracy, take care to minimize superimposed artifact on these leads. Take care that QRS wave detection accuracy is not reduced by artifact superimposed on these leads. Also when the amplitude of these QRS waves is too small (less than 0.5 mV), the electrocardiograph cannot detect the ORS wave.

NOTE: If low amplitude QRS wave is displayed on the screen and the QRS sync mark does not blink, the electrocardiograph does not analyze the ECG waveform. The "CANNOT ANALYZE ECG" message is printed on the ECG analysis result.

Counting the Heart Rate

The electrocardiograph counts the heart rate by averaging the latest 5 QRS waves and prints the heart rate together with the ECG waveforms.

Using the ECG/High-cut Filter

When using the EMG filter, the quality of ECG recording may be reduced. However, the EMG filter and high-cut filter do not affect the ECG analysis.

ECG Analysis

The electrocardiograph acquires and analyzes the 12-lead ECG waveforms simultaneously.

NOTE: When an electrode detachment or noise mark is printed on the paper, stop recording, check the ECG lead, and after taking care of electrode detachment or noise, re-record the ECG waveform to ensure the accuracy of ECG analysis.

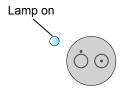
Modes and Functions

* Automatic recording is the default mode.

| | Automatic recording | | Manual | Rhythm | |
|-----------------------------------|---|-----------------------|--|---|--------------------|
| | Real time recording | Review recording | recording | recording | Сору |
| Recording type | Auto | matic | Manual | - | _ |
| Start recording | | [Review] function key | | [Rhythm] function key | ♦/1mV |
| End recording | Automatic | | | Automatic | |
| Stop recording | | | _ | The data is printed while it is reading and the file is processing. Press the [Cancel] function key to stop reading data. The data will not be printed or saved. | |
| Extended recording | Extended recording (Manual) [External] function key or | Cannot | _ | Cannot | _ |
| Contents of recording | Waveforms (change the l * Refer to page 5-10 for real time recording and re Analysis result (Recording time ≥ 10 s) | | Waveforms (Change the lead mode manually) | 1 ch, 3 ch (Select settings on the <setup> screen)</setup> | |
| Channels | 1 ch, 3 ch, 1 ch + rhythm, (Select settings on the <setup> screen)</setup> | | 1 ch, 3 ch, 1 ch + rhythm (Select settings on the <setup> screen)</setup> | 1 lead, 1 min (Select settings on the <setup> screen)</setup> | |
| Sensitivity | 5 mm/mV, 10 mm/mV, 20 mm/mV to adjust sensitivity automatically (Select settings on the <setup> screen)</setup> | | 5 mm/ | /mV, 10 mm/mV, 20 m | nm/mV |
| Speed | 25 mm/s c | or 50 mm/s | Default paper speed: 25 mm/s, 50 mm/s | 25mm/s | 25 mm/s or 50 mm/s |
| Analysis Data saving and sending | Recording time ≥ 10 s | Recording time ≥ 10 s | Cannot | nnot Available | _ |

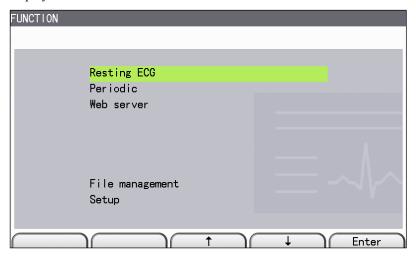
Resting ECG Recording Screen

Displaying the Resting 12 Lead Screen





1 When the power is turned on, the <Resting ECG> recording screen appears. If another screen is displayed, press the **FUNCTION** key to display the <FUNCTION> screen.

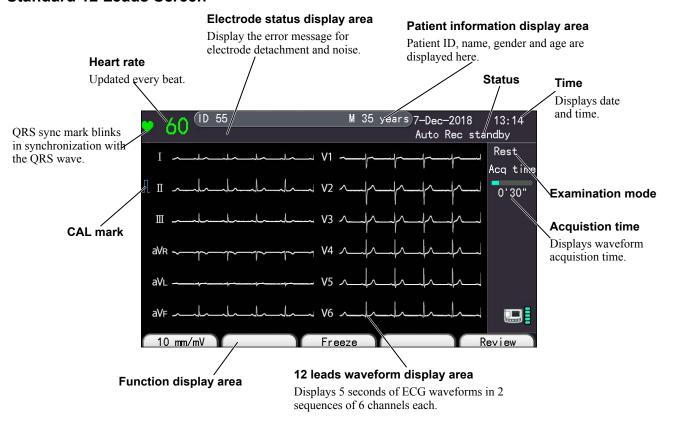


2 Select "Resting ECG" on the <FUNCTION> screen.

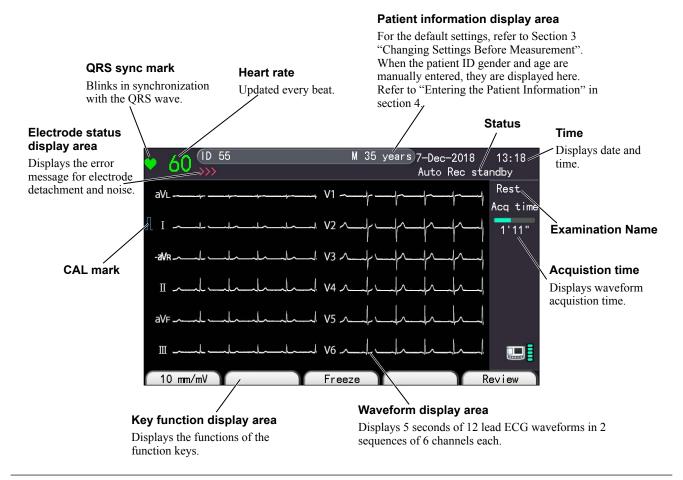
The <Auto Rec standby> screen is displayed.

Explanation of the Resting 12 Leads Screen

Standard 12 Leads Screen



Cabrera Lead Screen



Automatic Recording

General

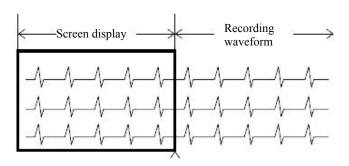
The electrocardiograph automatically records the ECG waveforms and calibration waveforms by switching the lead groups in the settings selected in the Setup mode when the **START/STOP** key is pressed.

There are two recording modes:

Real Time Recording

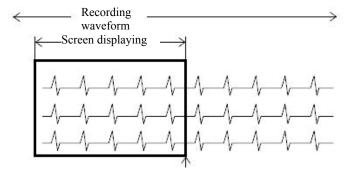


When you press the **START/ STOP** key, the electrocardiograph starts recording real time ECG waveforms.



Review Recording

When the **REVIEW** key is pressed, the electrocardiograph starts recording the saved waveforms from 10 seconds before the **REVIEW** key is pressed. If it is less than 10 seconds from acquisition of ECG waveforms, the recording starts from the earliest acquired waveforms.



Auto Gain and Auto Position

The recording sensitivity and position are automatically adjusted so that the ECG waveforms of each channel do not overlap. However, waveforms may overlap where there is noise or change of waveform.

During recording, if any ECG waveform exceeds the maximum recording width, the waveform amplitude is automatically reduced to 1/2 (minimum to 1/8) and the waveforms are repositioned so that the entire waveforms can be recorded on the recording paper. The auto gain waveform amplitude is based on the sensitivity settings before recording.

5

Preparation for Automatic Recording

Change the following settings if necessary. Refer to Section 3 *Changing Settings Before Measurement*. The factory default settings are underlined.

To print out the current settings, refer to *Saving, Loading and Printing the System Settings* in Section 3.

Common Settings

Operation

• Lead mode selection (Standard 12 leads, Cabrera leads)

Standard 12 leads: I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6
Cabrera leads: aVL, I, -aVR, II, aVF, III, V1, V2, V3, V4, V5, V6

A CAUTION

Take care when interpreting the ECG recording because the EMG filter may cause distortion of P waves and QRS waves depending on the waveform shape.

Filter Settings

High cut filter (75 Hz, 100 Hz, 150 Hz)
 This is active only when the EMG filter is turned off.

- EMG suppression frequency (25 Hz, <u>35 Hz</u>)
- Drift suppression (Strong, Weak, Off)

Baseline drift suppression prevents the baseline from drifting by locking it into one position at the start of recording.

⚠ CAUTION

When baseline drift suppression is set to "Strong", distortion may occur in the ST segment with a decrease of heart rate when heart rate is less than 50. For bradycardia, set this item to "Weak". The "Weak" setting has characteristics conforming to the AHA recommendations.

Auto Recording

Auto gain output

(Auto gain + setting gain, <u>Auto gain</u>, Setting gain + auto gain, Setting gain)

Select the auto gain and auto position control function. When "Setting gain + auto gain" or "Setting gain" is selected, the sensitivity can be changed by pressing the [Sensitivity] function key (F1) "5 mm/mV", "10 mm/mV" or "20 mm/mV".

• Time

Select the total recording time, $(\underline{10} \text{ s to } 24 \text{ s})$

· Auto recording channels

1 ch: 12 lead ECG waveforms are recorded as 1 channel in 12

sequences.

3 ch: 12 lead ECG waveforms are recorded as 3 channels in 4

sequences.

Average + rhythm: 1 channel of rhythm leads are recorded.

1 channel of 12 averaged waveforms for each of 12 lead

ECG waveforms are also recorded.

· Result printing format

Select the analysis result printing format.

Result + average: Prints the analysis result on 1 page.

Result only: Prints the analysis result only.

• Include findings criteria (On, Off)

Prints the criteria for the findings when this item is set to "On".

• Pacing detection sensitivity (High, Low)

Select the pacing detection sensitivity.

Resting ECG Settings

Auto start (On, Off)

When "Auto start" is set to "On", the real time recording is automatically started according to the format set on "Auto recording channel" when all the following conditions are satisfied:

- Automatic recording is not started.
- No electrode detachment is detected for 2 seconds or more.
- Five or more QRS waves are detected.
- Artifact and high frequency noise are not detected.

NOTE: After recording, this function is available only when the electrodes are reattached to the same patient or when attaching the electrodes for the next patient.

Extended recording

On: Rhythm (full page):

When an arrhythmia is detected during automatic recording, the rhythm recording starts after automatic recording ends. The format is set in "Setup-Resting ECG Settings."

When the setting parameter of "Resting ECG settings-Extended recording" is set to "On: Rhythm", the preview function of a resting ECG waveform which is with the extended recording (rhythm) will be invalid, even if the parameter of "Resting ECG settings-Preview" is set to "On".

On: sequence (full page):

When an arrhythmia is detected during automatic recording, the rhythm recording starts after automatic recording ends. The format is set in "Setup-Resting ECG Settings."

When fluctuation of 20 % of R-R interval is detected during automatic recording, the recording of the lead group is extended. The extend recording time is set in the "Time" setting.

NOTE: It is available only when "Auto recording channels" is set to "3 ch" in "Setup - Common settings - Auto recording - Recording format".

Off: Not recorded.

5

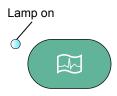
Automatic Recording Procedure

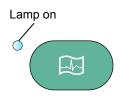
A CAUTION

- When the patient age is not entered, ECG analysis is performed with the patient as 35 years old.
- Do not turn the power off during saving or sending ECG data file, otherwise the data may be lost.
- 1 Check the following before starting recording.
 - The patient is relaxed.
 - The electrodes (especially chest electrodes) are not in electrical contact with each other and they are properly attached and there is no artifact.
- 2 Check that the AUTO/MANUAL lamp is lit. If it is not lit, press the AUTO/MANUAL key.
- **3** Enter the patient information. Refer to *Entering the Patient Information* in Section 4.
- 4 If necessary, press the **FILTER** key to turn the EMG filter on.
- 5 Select the real time or review recording mode by pressing the **START**/ **STOP** key (real time recording) or [Review] function key (review recording). The electrocardiograph automatically records the ECG waveforms with switching the lead groups.









Recording Suspending

To suspend recording, press START/STOP key during recording.

Printing Another Copy of the Recording Results

NOTE: When you tear off the recording paper, tear along the perforation. Otherwise, the paper may get jammed in the recorder.

You can print copies of the recording results after recording and before the following operations:

- · New automatic recording.
- Pressing the **FUNCTION** key to switch checking items.
- Pressing the **ID** key to change the patient.
- * Copies are marked with "Copy" at the top left side of the recording paper.



Copy recording is available when COPY/1 mV lamp lights.

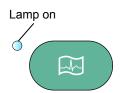


After automatic recording, the COPY/1 mV lamp lights. Press the COPY/1 mV key to print a copy. "COPY" is printed on the top left side of recording paper to distinguish the copy and the original printing.



Starting Copy Printing

Press COPY/1 mV key to start printing the copy.



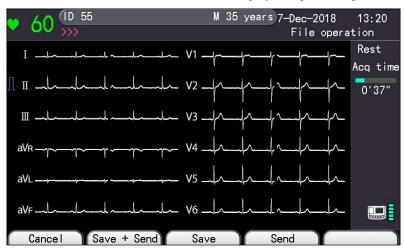
Stopping Copy Printing

Press START/STOP key during printing to stop the copy.

Saving and Sending

Saving and Sending the ECG Data File

Press the [File] function key after completion of automatic recording. The screen displays the processing information.



Press the [Cancel] function key to cancel file processing.

Press the [Save + Send] function key to save and then send the ECG data file.

Press the [Save] function key to save ECG data file.

Press the [Send] function key to send the ECG data file.

After saving or sending, the electrocardiograph returns to resting automatic recording standby.

The Saving media can be set to "USB flash disk" or "Internal memory" in "Setup-File processing-Media".

The electrocardiograph (internal memory) can save 800 ECG data files.

When "Setup - File processing - Save as PDF" is set to "On", the media is fixed to "USB flash disk" and an "NKPDF" folder is created in the USB flash disk. To help identify the saved PDF files, they are automatically named as follow:

NKPDF\creation date\creation time.pdf

For example:

NKPDF\20140311\102315.pdf

- 2014 Year when the PDF was created.
- 03 Month when the PDF was created.
- 11 Day when the PDF was created.
- 10 Hour when the PDF was created (in 24 hour format)
- 23 Minute when the PDF was created.
- 15 Second when the PDF was created.

File Processing

ECG data files processing is unavailable after the following operations:

- · Starting new recording.
- Pressing the **FUNCTION** key
- Pressing the **ID** key

Press the **FUNCTION** key to access the <FUNCTION> screen, then select "File management" to manage ECG data files.

Direct Connection Print

After acquiring and analyzing the ECG waveforms, you can choose to print the ECG waveforms by connecting an external printer directly to the electrocardiograph.

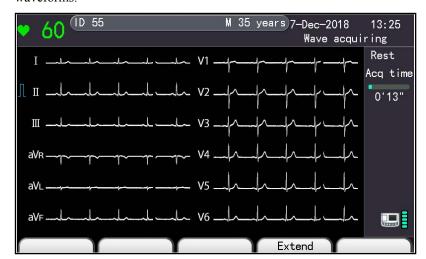
⚠ WARNING

Install the laser printer which is connected to the electrocardiograph outside the patient environment (IEC 60601-1). If the laser printer is installed inside the patient environment, the patient or operator may receive electrical shock or injury. For installation, contact your Nihon Kohden representative.

NOTE: Use the HP LaserJet 400 M401dn / HP LaserJet Enterprise M605dn(E6B70A) / HP LaserJet Enterprise M506dn which supports HP PCL 5 and HP PCL 6 as specified by Shanghai Kohden.

To print the ECG waveforms through an external printer, set the following settings correctly.

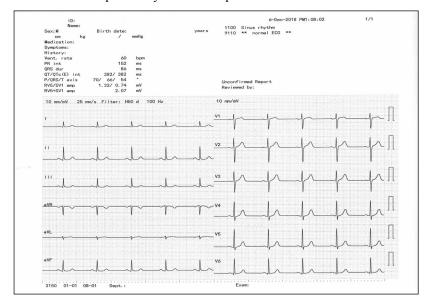
- Set the "Setup-Common settings-Operation-Paperless" to "Off".
- Set the "Setup-Recording settings-Recorder" to "External printer".
- NOTE Check the settings in the "Setup-Communication settings-Common settings" and ensure the electrocardiograph and the external printer are connected to a same network.
 - Make sure both the "Printer server address" and "Printer server port" in the "Setup-Communication settings-Server settings-External printer settings" are consistent with these on the external printer.
- 1 Display the <Resting ECG> recording screen.
- **2** Press the **START/STOP** key or [Review] function key to acquire the ECG waveforms.



3 After acquiring and analyzing, the "Printing. Please wait a moment" message appears.

NOTE: If a printing error message is displayed at the top right of the screen, check the external printer.

4 The ECG data is printed by an external printer.



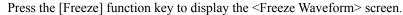
Freeze Waveform Screen

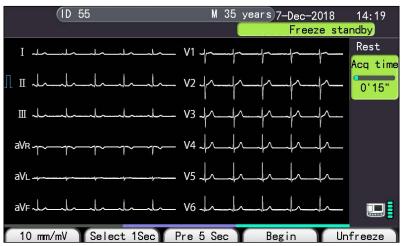
General

After waveforms collection, the [Freeze] function key is valid and press the [Freeze] function key to access the <Freeze Waveform> screen. Manual recording mode in a frozen state is switched to automatic recording mode immediately.

On the <Freeze Waveform> screen, select waveforms for recording from the past frozen waveforms.

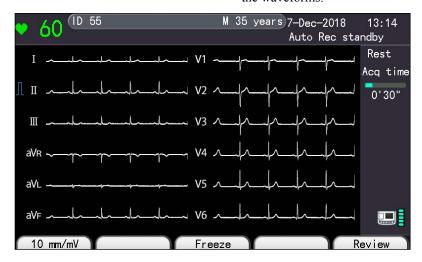
Calling Up the Freeze Waveform Screen



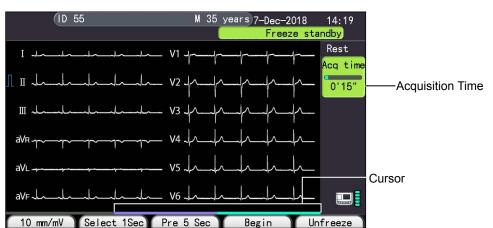


Ending the Freeze Condition

Press the [Unfreeze] function key on the <Freeze Waveform> screen to refresh the waveforms.



Explanation of the Freeze Waveform Screen



Name Description

Acquisition time:

Displays frozen waveform acquisition time of up to 3 minutes.

Cursor:

The width of the waveform display area acquisition time and the width of the cursor is the recording waveform. The width of the cursor in green means the displayed waveform on the screen.

10 mm/mV, 20 mm/mV, 5 mm/mV: (F1 function key)

Press the F1 function key to change the Sensitivity.

Select 1Sec or Select 5Sec (F2 function key)

Press "Select 1Sec", (F3) function key "Pre 5 sec" changes to "Pre 1 Sec". Press "Select 5Sec", (F3) function key "Pre 1 Sec" changes to "Pre 5 sec".

Pre 5 Sec or Pre 1 Sec or End (F3 function key):

Displays the previous 5 seconds (or previous second) of the displayed waveform. When the waveform on the screen is displayed from the start time, the [Pre 5 Sec] function key changes to [End].

Begin or Next 5 Sec or Next 1 Sec (F4 function key):

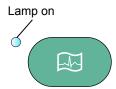
Displays the next 5 seconds (or next second) of the displayed waveform. When the last 5 seconds waveform is displayed on the screen, the [Next 5 Sec] function key changes to [Begin].

Unfreeze:

Cancels the <Freeze Waveform> screen.

Selecting Waveforms for Recording from Freeze Waveform Screen

- 1 Press the [Pre 5 Sec] function key and [Next 5 Sec] function key to select waveforms.
- **2** Press the **START/STOP** key to record and analyze waveforms.
- 3 Press the **START/STOP** key again to end recording and return to <Freeze Waveform> screen.

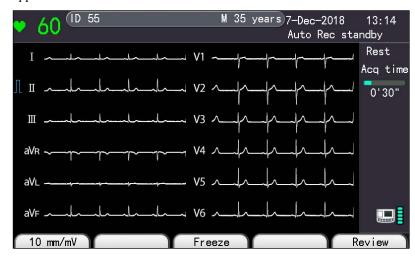


Preview Screen

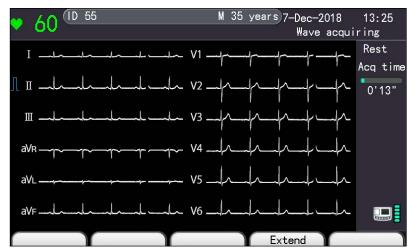
You can confirm the waveform and the analysis result before recording with the preview function.

To enable the preview function, set the "Setup - Resting ECG settings - Preview" to "On".

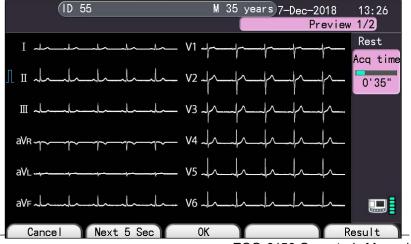
1 When the power is turned on, the <Resting ECG> recording screen appears.

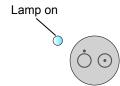


Press the START/STOP key or [Review] function key to acquire the wave.



3 After acquiring, the <Preview> screen is displayed.





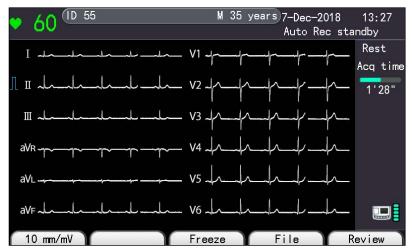
Press the [Result] function key to display the analysis result.



4 Press the **START/STOP** key or [OK] function key to record the waveform and analysis result. The <Recording> screen is displayed.

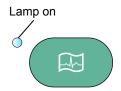
When "Paperless" is set to "On" in the "Setup - Common setting - Operation". It returns to the <Auto Rec standby> screen.

When recording finishes or the **START/STOP** key is pressed, the <Auto Rec standby> screen is displayed.



Manual Recording

General



It is manual mode when the AUTO/ MANUAL lamp is off. Press the **START/STOP** key to start manual recording of ECG waveforms. If the patient state changes (such as chest pain or noise) during manual recording, you can add a mark ECG waveforms. During manual recording, you can change the sensitivity, speed and lead group manually. No ECG analysis is conducted during manual recording mode.

Manual Recording Procedure



NOTE: When you tear off the recording paper, tear along the perforation.

Otherwise, the paper may get jammed in the recorder.

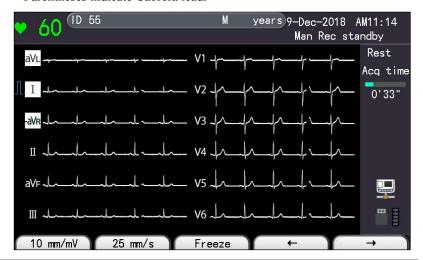
- 1 Check the following before starting recording.
 - The patient is relaxed.
 - AUTO/ MANUAL lamp is off (lamp on indicates Auto mode).
 - The electrodes (especially chest electrodes) are not in electrical contact with each other, they are properly attached and there is no artifact.
- 2 Confirm that no abnormal message is displayed in the 12 leads ECG screen.
- 3 Press the [F4] or [F5] function key to select the lead group.
 The lead groups are switched according to the following sequence.
- "Setup Common settings Manual recording Manual recording channels" is set to "1 ch" or "1 ch + rhythm".

$$| \rightarrow | | \rightarrow | | | \rightarrow aVR \rightarrow aVL \rightarrow aVF \rightarrow V1 \rightarrow V2 \rightarrow V3 \rightarrow V4 \rightarrow V5 \rightarrow V6 \rightarrow (aVL \rightarrow | \rightarrow -aVR \rightarrow | | \rightarrow aVF \rightarrow | | | |)$$

 "Setup – Common settings – Manual recording – Manual recording channels" is set to "3 ch".

$$\rightarrow$$
I, II, III \rightarrow aVR, aVL, aVF \rightarrow V1, V2, V3 \rightarrow V4, V5, V6 \rightarrow *(aVL, I, –aVR) (II, aVF, III)

* Parentheses indicate Cabrera lead.





- 4 To change recording condition.
- To add event marks

In case of chest pain, during recording, add event mark, press the **FEED/ MARK** key, and record event mark continuously during key pressing.



Event mark

· To change the sensitivity

Press the [Sensitivity] function key (F1), the sensitivity can be selected to "5 mm/mV", "10 mm/mV" or "20 mm/mV".

• To change paper speed

Press the [SPEED] function key (F2), the paper speed can be selected to "25 mm/s" or "50 mm/s".



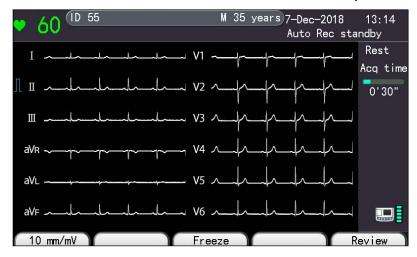
To turn on the EMG filter, press the **FILTER** key.

- 5 Press the **START/STOP** key to start recording.
- 6 Press the [F4] or [F5] function key to select the next lead group.
- **7** Repeat steps 4 to 6 to record all lead groups.
- **8** After recording all lead groups, press the **START/STOP** key to stop recording.

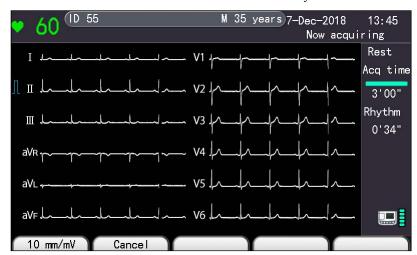
Rhythm Recording

General

You can record the rhythm lead in automatic or manual mode.

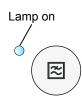


Press the **RHYTHM** key to start acquiring ECG data. Recording starts automatically 1 minute later.



5

Rhythm Recording Operation



- 1 Confirm that there is no message such as an electrode detachment and noise interference.
- **2** Press the **FILTER** key to set the EMG filter.
- **3** Press the [Sensitivity] function key (F1).

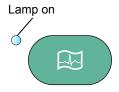
The recording starts after any noise and electrode detachment are taken care of.

Press the **RHYTHM** key to start acquiring ECG data. The "Rhythm time" and rhythm waveform acquisition time (00:00) are displayed at the right side of the screen. After 1 minute acquired, rhythm waveforms are recorded automatically. You can press the **START/STOP** key to start rhythm waveform recording before 1 minute of ECG data is collected.

Stopping Recording

You can stop rhythm recording.

Before 1 minute of ECG data is collected, press the [Cancel] function key to stop the collecting in case of electrode detachment or body movement, etc.



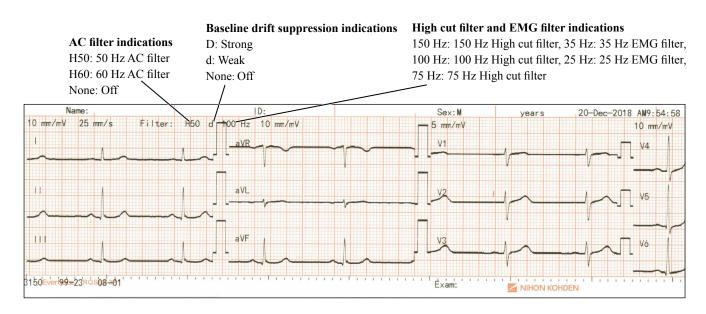
Stop the recording paper:

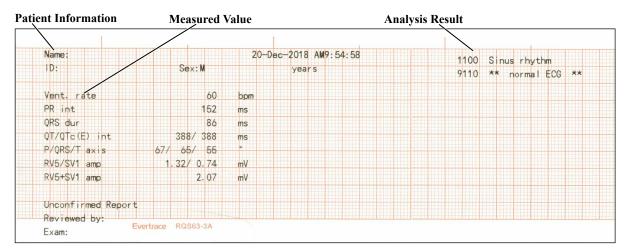
Press START/STOP key to stop recording.

Recording Examples

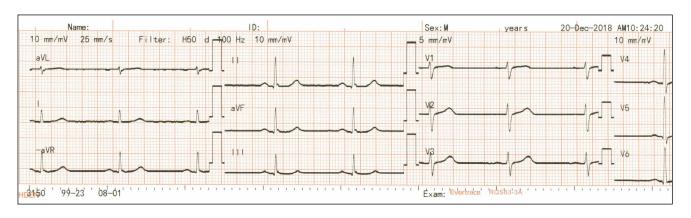
Auto Recording Examples

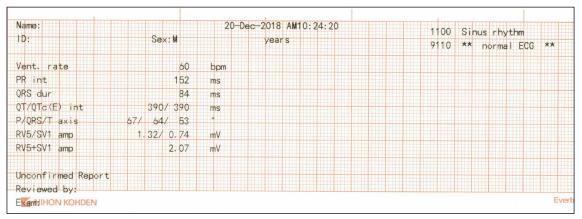
Standard 12 lead ECG





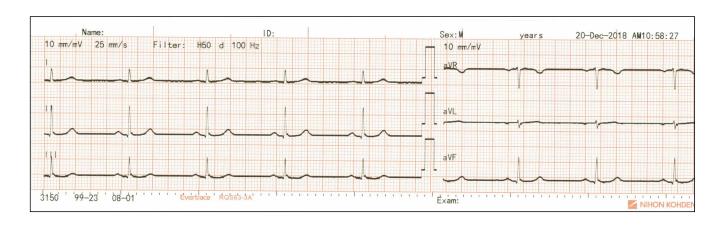
Cabrera Lead ECG



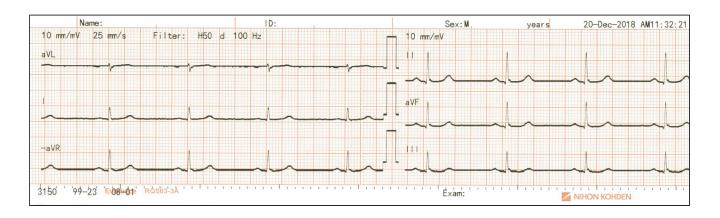


Manual Recording Examples

Standard 12 Lead ECG

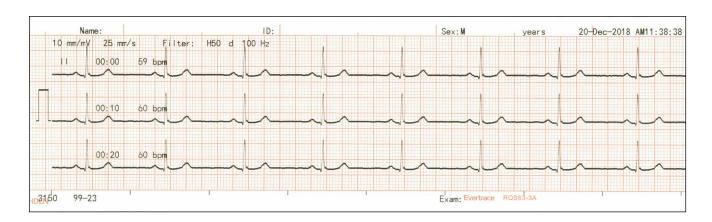


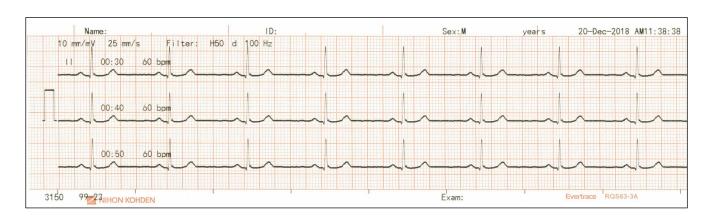
Cabrera Lead ECG



Rhythm Recording Examples

1 ch, 1 min







Periodic ECG Recording

| General | 6-2 |
|--|-----|
| System Settings for Periodic Recording | 6-2 |
| Periodic ECG Recording Screen | 6-3 |
| Displaying the Periodic ECG Recording | 6-3 |
| Explanation of the Periodic ECG Recording Screen | 6-4 |
| Printing Periodic Recording Waveform | 6-5 |
| Starting the Periodic ECG Recording | 6-5 |
| Interval Recording | 6-5 |
| Additional Slow Speed Recording | 6-5 |
| Stopping Recording | 6-5 |
| Auto | 6-5 |
| Manual | 6-6 |
| Stopping the Periodic Recording | 6-6 |
| Recording Examples | 6-6 |

General

The electrocardiograph can automatically perform automatic recording a periodic intervals. The selected leads can be recorded at slow speed. For automatic recording, refer to Section 5 *Recording Resting ECG Waveforms*. You can also perform automatic and manual recording during periodic ECG recording.

System Settings for Periodic Recording

Periodic Recording settings can be changed in "Setup-Periodic recording settings".

The factory default settings are underlined. Record format is same with the Resting ECG recording.

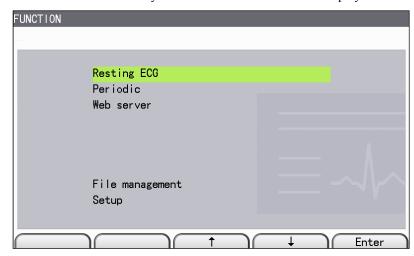
| Item | Settings |
|---------------------------------|---|
| Control 1 | Limb |
| Starting leads | Chest |
| | Fixed time |
| Periodic recording type | Interval |
| | Off |
| Fixed recording time | 30 s, 1 min to 15 min (unit: 1 minute) either can be set to "On" or "Off" (1 min, 2 min, 3 min, 5 min, 7 min, 9 min are defaulted to be On) |
| Interval (min) | 1 to 60 (<u>5</u>) |
| Interval recording repetitions | 1 to 999 (<u>10</u>) |
| Additional slow speed recording | On Off |

Periodic ECG Recording Screen

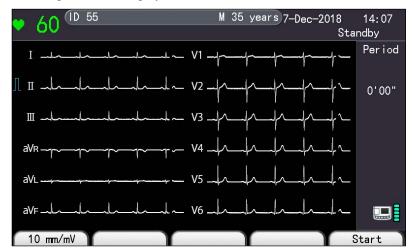
Displaying the Periodic ECG Recording

1 Display the <FUNCTION> screen.

Press the **FUNCTION** key. The <FUNCTION> screen is displayed.



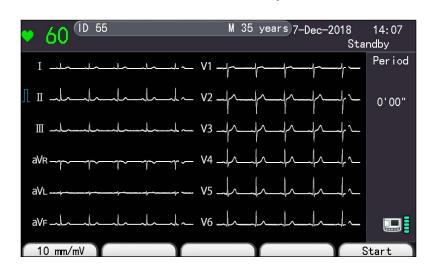
Press the [↑] or [↓] function key to select "Periodic". The <Periodic ECG recording> screen is displayed.

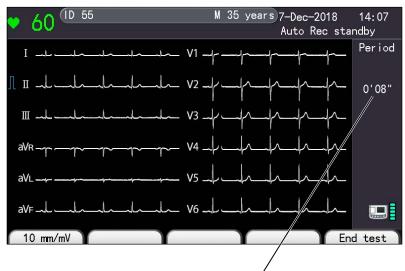


Explanation of the Periodic ECG Recording Screen

The periodic ECG recording screen is the same as the <Resting ECG> recording screen except for the elapsed time in periodic ECG recording.

For more about the screen displayed and the functions, refer to Section 5.





6

Printing Periodic Recording Waveform

Starting the Periodic ECG Recording

- 1 Attach the electrode, check noise and electrode detachment messages at the top left of the screen.
- 2 Press the [Start] function key or **START/STOP** key to start the elapsed time counting of the periodic ECG recording.
- 3 Refer to the following instructions.

Interval Recording

Periodic recording starts according to the settings in "Setup - Periodic recording settings - Interval recording repetitions."

Recording format is same as Resting ECG Recording.

Additional Slow Speed Recording

Select "On" in "Setup - Periodic recording settings - Additional slow speed recording" to use slow paper speed when recording until the next periodic recording starts. The number of recording channels and leads for the additional slow speed recording are as follows.

| Channels | Leads |
|---------------------|-------------|
| 1 ch | II |
| 1 ch + rhythm, 3 ch | II, aVF, V5 |

Recording speed is set in "Setup-Recording settings - Default paper speed". Additional slow speed recording is not done if the periodic recording is interrupted. Press the **START/STOP** key to stop additional slow speed recording.

Stopping Recording

Press the **START/STOP** key to stop recording, for example, if electrodes are detached. Recording resumes at the next set interval time even if recording is stopped this time.

Press the **START/STOP** key to restart recording.

Auto

Auto recording in periodic recording is the same as that of Resting recording.

NOTE: Interval recording is not done when the Auto recording operation coincides with the set interval time.

- 1 Confirm that the Auto/ Manual lamp is on.
- Press the START/STOP key to start recording.
- Recording stops automatically.

Manual

Manual recording in periodic recording is same as that of Resting recording.

NOTE: Interval recording is not done when the manual recording operation coincides with the set interval time.

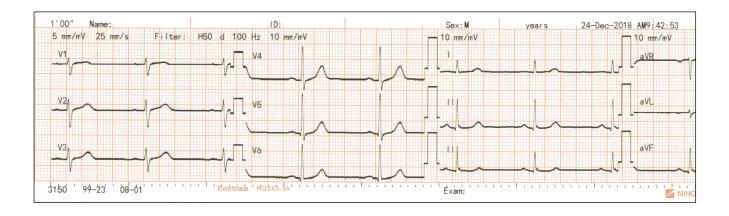
- 1 Confirm that the Auto/ Manual lamp is off.
- **2** Press the **START/STOP** key to start recording.
- 3 Printing stops automatically.

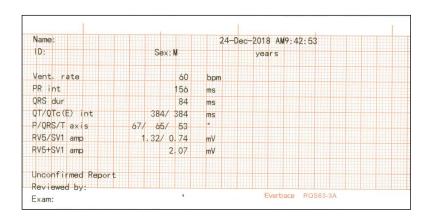
Stopping the Periodic Recording

You can switch the screen from periodic recording to resting recording.

Press the [End test] function key to return to the <Resting ECG> recording screen.

Recording Examples





Web Server

| Connecting to a Web server | 7-2 |
|-----------------------------------|-----|
| Connecting to a Web server | 7-2 |
| Displaying the Browser Terminal | 7-3 |
| Displaying the File List Screen | 7-4 |
| Displaying the PDF Display Screen | 7-5 |
| Failed to Acquire File List | 7-5 |

Connecting to a Web server

Set "On" to "Web server" on "Setup-Communication settings-Web server settings" to enable Web server. And only one client-side can be connected.

A CAUTION

Information can be browsed through web client only when a medical institution is compliant with ISMS(Information Security Management System). Accessing the information from a global network environment is not allowed.

Connecting to a Web server

1 Press the **FUNCTION** key to display the <Main Menu> screen.



NOTE: If Setting "Off" to "Web server" on "Setup-Communication settings-Web server settings". "Web server" will not display in <FUNCTION> screen.

Press the [↑] or [↓] function key to select "Web server". The screen of "Web Server is running...." is displayed.

The IP address here is just an example.



Displaying the Browser Terminal

You can display the browser terminal screen with a web browser of a PC connected to the network.

Defaulted Web Browsers

| Name | Version | Copyright Owner |
|----------------|---------|------------------|
| Google Chrome | 70 | 2018 Google Inc. |
| Microsoft Edge | 17 | 2018 Microsofte |

And also recommended the operating system: Windows 10 64bit



When there are some displaying format problems on the web page, it may be improved by trying the full-screen display.

- 1 Start the web browser on the PC.
- 2 Enter "http://172.31.132.199" into the address input of the web browser.

NOTE: The IP address here is just an example. Please enter the actual IP address which is displayed in your electrocardiograph.

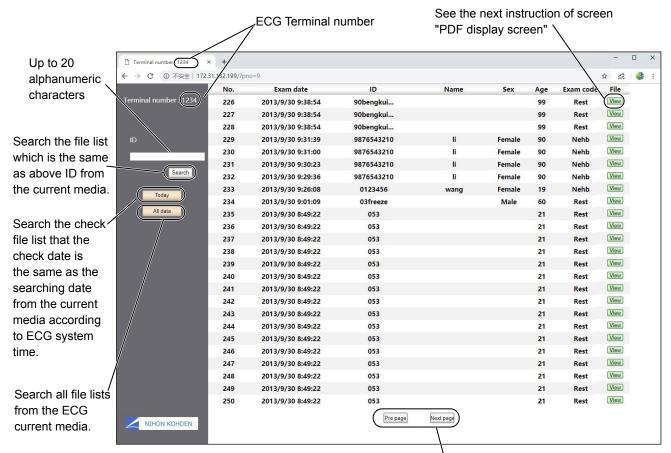


The IP address here is just an example.

3 The login screen appears when Authentication is enabled in the system settings. Input the "Login user name" and "Login password" with the keybord.

Click [Login] on the lower right side of screen.

Displaying the File List Screen



"Next page" or "Pre page" is displayed.
Clicking it will change to Next or Previous page of file list.

• Change to next page failed:

The message "Unable to round-trip http request to upstream: dial tcp 172.31.132.199:80: connectex: No connection could be made because the target machine actively refused it." will display on the screen.

Displaying the PDF Display Screen

Click "View" to display PDF display screen.

Default value:

the current ECG value

Switch to:

1.25 mm/mV,

Default value:

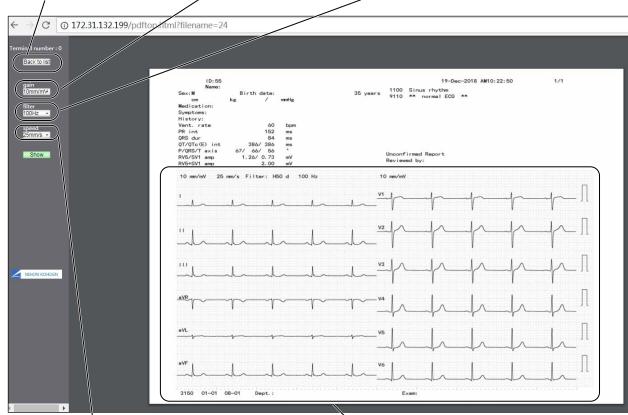
2.5 mm/mV,

the current ECG value Switch to: 25Hz, 35Hz,

5 mm/mV, 10 mm/mV, 20 mm/mV

75Hz, 100Hz, 150Hz

Back to File List screen



Default value: the current ECG value Switch to: 25mm/s, 50mm/s

Set the waveform format on "Setup - Common settings - Image format - Auto recording - Recoding channels" .

Failed to Acquire File List

If acquiring file list fails, it has four error types:

- · USB flash disk isn't inserted
- USB/Nand flash error
- ID length is over 12, but the setting of "ID digits" is set to "12".
- · Read error



File Management

| General | 8-2 |
|---|------|
| List for File Management Functions Displaying the File Management Screen Media for Saving Files and Storage | 8-3 |
| Sending ECG Data Files | 8-4 |
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| Sending All ECG Data Files | 8-4 |
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| Printing ECG Waveforms from a USB Flash Disk or Internal Memory | 8-8 |
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| Formatting the Media | 8-16 |
| Printing a File List | 8-17 |
| Copying Files in the Internal Memory to a USB Flash | l |
| Disk | |

General

NOTE: Only use Shanghai Kohden specified Media. On the <File management> screen, you can do operations as send/delete/print ECG data, change ID, print the ECG data file list, etc.

When the setting parameter of "File processing-Preview" is set to "On", you can preview a resting ECG waveform which is saved in a file. But the preview function cannot be available when the file saves a rhythm waveform or a resting ECG waveform which is with the extended recording (rhythm).

List for File Management Functions

File Management

Send

- 1. All files
- 2. Unsent file
- 3. Selected ID
- 4. Selected date

Print

Print server file

Edit ID

Delete

- 1. All files
- 2. Sent files
- 3. Selected ID
- 4. Selected date

Format

Print file list

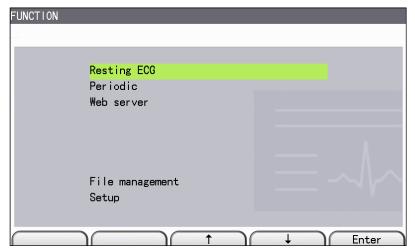
Copy internal memory files to a USB flash disk

NOTE • File management is not available for PDF files.

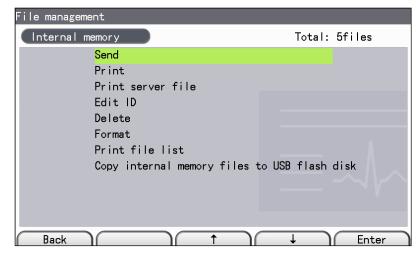
 The "Do not turn off power" message is displayed while processing the file. Do not turn off the power or remove the USB flash disk while files are processing. Otherwise, data will be lost.

Displaying the File Management Screen

1 Press the **FUNCTION** key. The <**FUNCTION**> screen is displayed.



Press the [↑] or [↓] function key to select "File management". The <File management> screen is displayed. The number of ECG data files which are saved in the media is displayed at the upper right of the screen.



To select the desired item, press the number of the item with the keyboard on the operation panel. The screen of the selected item is displayed. To close the <File management> screen, press the **FUNCTION** key. The <FUNCTION> screen is displayed.

Media for Saving Files and Storage

Files can be saved in internal memory or a USB flash disk, the number of files that can be stored is shown below.

NOTE: Depending on the ECG waveform quality and patient information content, the number of files that can be stored may be less than the following numbers.

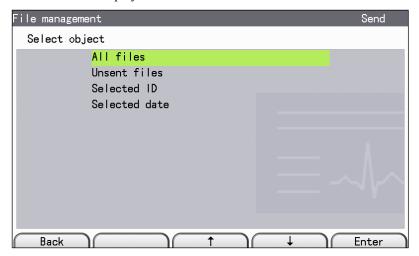
| | Standard 12 lead ECG data file | |
|-----------------|--------------------------------|--------|
| | Resting/periodic recording | |
| | Type 1 | Type 2 |
| Internal memory | 800 | 800 |
| USB flash disk | 780 | 3000 |

Sending ECG Data Files

You can send all ECG data files or unsent ECG data files to a PC.

Displaying the Send Screen

- 1 Display the <File management> screen. Refer to the *Displaying the File Management Screen* in the previous page.
- Press the [↑] or [↓] function key to select "Send". The <File management Send> screen is displayed.

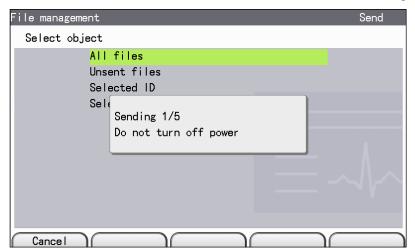


Press the [Back] function key to return to the <File management> screen.

Sending All ECG Data Files

Do this procedure to send all the ECG data files.

Select "All files". The "Sending. Do not turn off power" message appears.



To cancel sending the ECG data files, press the [Cancel] function key. After the current ECG data file is sent, sending the remaining files is canceled and the message disappears. When ECG files are being sent, the "Sending. Do not turn off power" message disappears.

Sending Unsent ECG Data Files

Do this procedure to send only the unsent ECG data files.

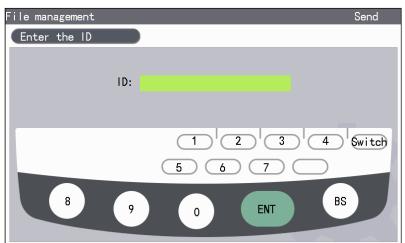
- 1 Display the <File management Send> screen.
- 2 Select "Unsent file". The "Sending ECG file. Do not turn the power off" message appears. To cancel sending while sending the ECG data files, press the [Cancel] function key. After the current ECG data file is sent, sending of the remaining files is canceled, and the "Sending. Do not turn the power off" message disappears.

When all files are sent, the "Sending. Do not turn off power" message disappears.

Sending ECG Data Files of a Selected ID

You can send the ECG data files of a selected ID to a PC.

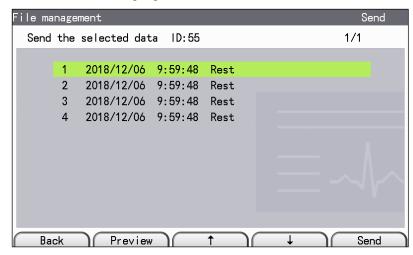
- 1 Display the <File management Send> screen.
- Press the [↑] or [↓] function key to select "Selected ID". The "Enter the ID" message appears.



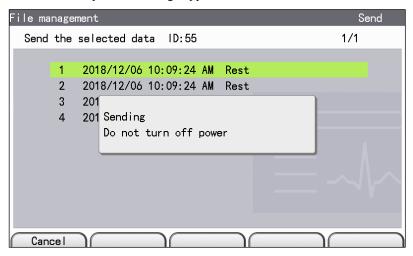
- Press the [Edit] function key to enter the ID.
 Press the [Back] function key to return to the <Send> screen.
- 4 Press the [Search] function key. The files of the selected ID are displayed.

5 Press the $[\uparrow]$ or $[\downarrow]$ function key, or enter the number with the keyboard to select the data.

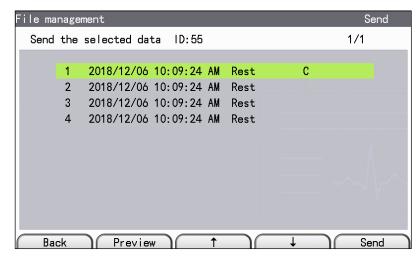
The selected item is highlighted.



Press the [Send] function key. The selected files are sent and the "Sending. Do not turn off power" message appears.



When all files are sent, the message disappears. "C" is displayed beside the sent ECG data files.

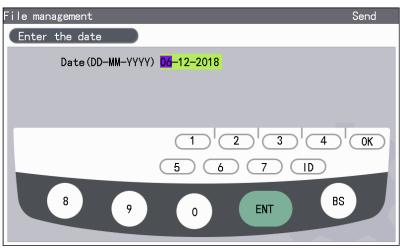


After the operation, press the [Back] function key on the screen, and press the **FUNCTION** key to <FUNCTION> screen.

Sending ECG Data Files of a Selected Date

You can send all ECG data files of the selected date to a personal computer.

- 1 Display the <File management Send> screen.
- 2 Select "Selected date". The "Enter the date" message appears.



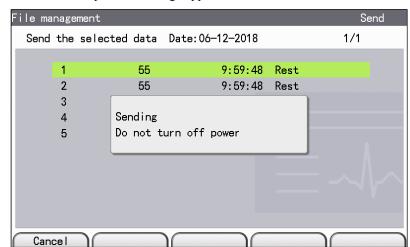
3 Press the [Edit] function key to enter the date.

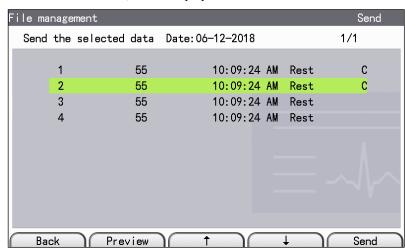
Press the [Back] function key to return to the \leq Send \geq screen.

4 Press the [Search] function key. The "Searching. Do not turn the power off." message appears, then the screen for selecting files is displayed after searching.

To cancel searching, press the [Cancel] function key.

- Press the [↑] or [↓] function key or enter the number with the keyboard to select the data. The selected item is highlighted.
- 6 Press the [Send] function key. The selected files are sent and the "Sending. Do not turn off power" message appears.





When all files are sent, "C" is displayed beside the sent ECG data files.

After the operation, press the [Back] function key to return to the previous screen, and press the **FUNCTION** key to the <**FUNCTION**> screen.

Printing ECG Waveforms from a USB Flash Disk or Internal Memory

You can print the ECG waveforms of the selected ID in a media (internal memory or a USB flash disk).

- **1** Select "Print" on the <File management> screen.
- Press "Edit" to enter the ID of the file to be printed.
 Press the [Back] function key to return to the <File management> screen.
- Press the [Search] function key. The "Searching. Do not turn off power." message is displayed, and the searched files are displayed.
 - To cancel searching ECG data files, press the [Cancel] function key.
- Press the [↑] or [↓] function key or enter the number with the keyboard to select the data.
 - The selected item is highlighted.
- Press the [Print] function key. The ECG data of the selected file is printed and the "Printing. Do not turn off power." message is displayed.
 - To stop printing, press the [Cancel] function key. Printing is stopped.
- After the operation, press the [Back] function key to return to the previous screen then press the **FUNCTION** key to display the <FUNCTION> screen.

Printing ECG Waveforms In the Server

When the device is connected to the server, you can print the ECG waveforms of the selected ID in the server.

1 Press the [↑] or [↓] function key to select "Print server file" in the <File management> screen.

The "Enter the ID" message is displayed.

? Press "Edit" to enter the ID.

Press the [Back] function key to return to FUNCTION screen.

- **3** Press the [Search] function key. The file list of the entered ID is displayed. To cancel searching, press the [Cancel] function key.
- 4 Press the $[\uparrow]$ or $[\downarrow]$ function key or enter the number with the keyboard to select the data.

The selected item is highlighted.

Press the [Cancel] function key to return to the <Send Selected File With ID> screen.

Press the [Print] function key. The ECG data of the selected files is printed and the "Printing. Do not turn off power." message is displayed.

To cancel printing, press the [Cancel] function key or the **START/STOP** key.

The "Printing. Do not turn off power." message is displayed.

The message disappears when the file printing is finished.

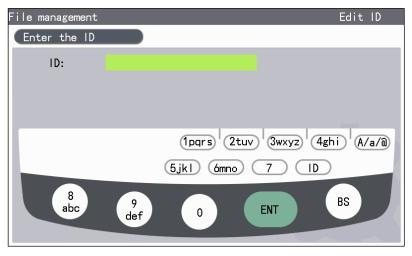
After the operation, press the [Cancel] function key to return to the <Send Selected File With ID> screen, and press the **FUNCTION** key to display the <FUNCTION> screen.

Editing ID

You can edit the ID after recording ECG waveforms.

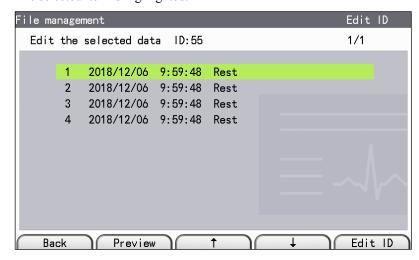
1 Display the <File management> screen.

Press the $[\uparrow]$ or $[\downarrow]$ function key to select "Edit ID". The "Enter the ID" message appears.



- Enter the desired ID numbers with the keyboard.
 Press the [Back] function key to return to the <File management> screen.
- 3 Press the [Search] function key. The file list is displayed.
 To interrupt searching ECG data files, press the [Cancel] function key.
- Press the [↑] or [↓] function key or enter the number with the keyboard to select the data.

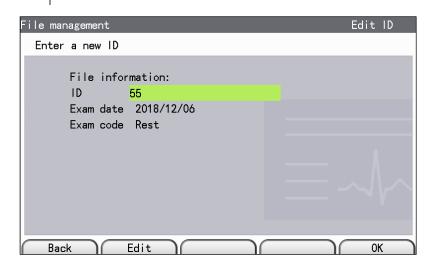
The selected item is highlighted.



5 Press the [Edit ID] function key. The "Change the ID" message appears. Enter the new ID.



To cancel editing ID, press the [Back] function key to return to the searched file list screen.



6 Press the [OK] function key. The "Changing ID. Do not turn off power." message is displayed.

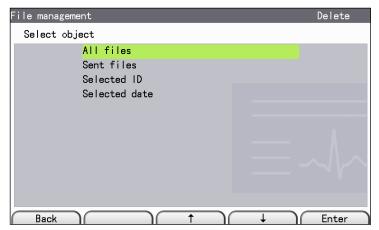
The message disappears after the ID is changed and the screen returns to the searched file list screen.

Deleting ECG Data Files

You can delete all ECG data files, ECG data files of the selected date or ECG data files of the selected ID in the media.

Displaying the Delete Screen

- **1** Display the <File management> screen.
- Press the [↑] or [↓] function key to select "Delete". The <File management
 Delete> screen is displayed.

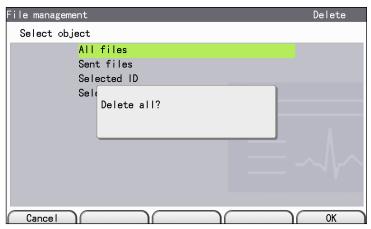


To return to the <File management> screen, press the [Back] function key.

Deleting All ECG Data Files

Do this procedure to delete all ECG data files from the media.

- 1 Display the <File management Delete> screen.
- 2 To cancel deleting the ECG data files, press the [Cancel] function key. The message "Delete all?" is displayed.



3 After the current ECG data file is deleted, deleting of the remaining files is canceled and the "Deleting ECG file. Do not turn off power" message disappears.

After all files are deleted, the "Deleting ECG files. Do not turn the power off" message disappears.

8

Deleting the Sent ECG Data Files

Do this procedure to delete only the sent ECG data files from the media.

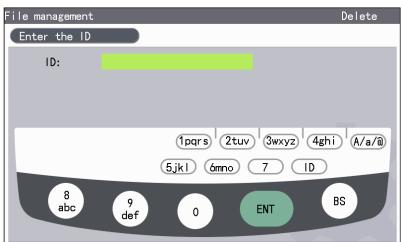
- 1 Display the <File management Delete> screen.
- Press the [↑] or [↓] function key to select "Sent files". The "Deleting ECG file. Do not turn the power off "message appears. To cancel deleting the ECG data files, press the [Cancel] function key. After the current ECG data file is deleted, deleting of the remaining files is canceled and the "Deleting ECG file. Do not turn the power off" message disappears.

After the files are deleted, the "Deleting ECG files. Do not turn the power off" message disappears.

Deleting ECG Data Files of the Selected ID

Do this procedure to delete all ECG data files of the selected ID from the media.

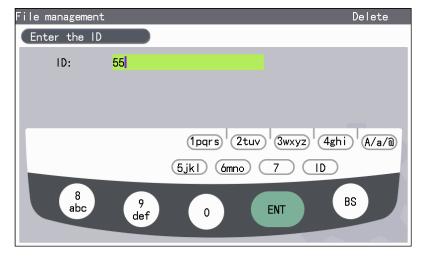
- 1 Display the <File management Delete> screen.
- Press the [↑] or [↓] function key to select "Selected ID". The "Enter the ID" message appears.



Enter the ID.

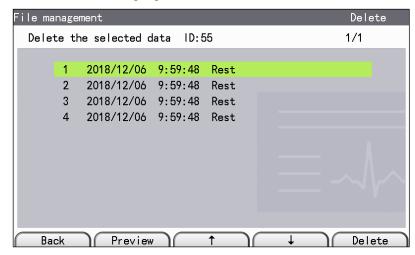
Press the [Back] function key to return to the <Delete File> screen.

4 Press the [Search] function key. The file list of the selected ID is displayed.



Press the [↑] or [↓] function key, or enter the number with the keyboard to select the data.

The selected item is highlighted.



6 Press the [Delete] function key. The "Deleting ECG file. Do not turn off power" message appears.

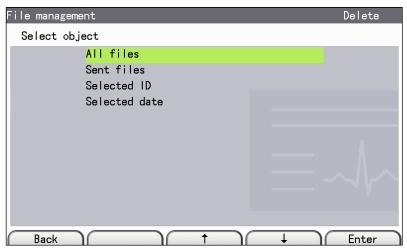
After the files are deleted, the "Deleting ECG files. Do not turn off power" message disappears.

After the operation, it returns to the <Enter the ID> screen and press the **FUNCTION** key to display the <FUNCTION> screen.

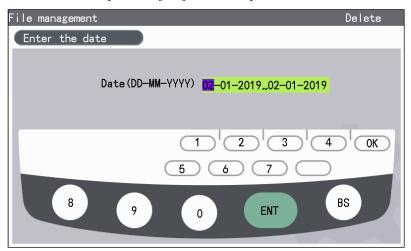
Deleting ECG Data Files of the Selected Date

Do this procedure to delete all ECG data files of the selected date from the media.

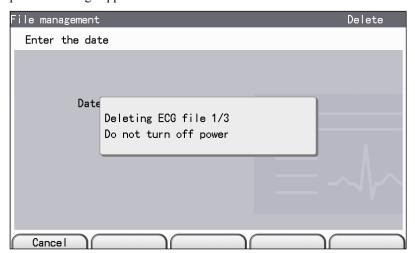
1 Display the <File management - Delete> screen. Press the [↑] or [↓] function key to select "Selected date".



2 Enter the date and press the [OK] function key.



Press the [Delete] function key. The "Deleting ECG file. Do not turn off power" message appears and the files are deleted.



4 After the selected files are deleted, press the [Back] function key to switch to the <File management> screen.

Formatting the Media

You can format a media in the electrocardiograph.

⚠ CAUTION

- · Format the USB flash disk before the first use.
- Format the USB flash disk only in an ECG-3150 electrocardiograph.
 The USB flash disk formatted in other ECG models cannot be used in this electrocardiograph.

NOTE: Formatting deletes all data in the media. Back up the necessary data before formatting.

Select the media to format, when the "Media" is selected to "USB flash disk" in "Setup - File processing", you can follow the steps as below.

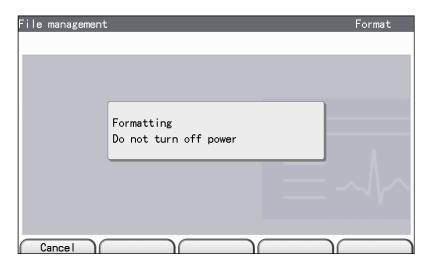
- 1 Turn the electrocardiograph power off.
- 2 Insert the USB flash disk straight into the USB flash disk connector.

 To format the internal memory skip the above 2 steps.
- **3** Display the <File management> screen. Refer to the *Displaying the File Management Screen*.
- 4 Press the [↑] or [↓] function key to select "Format". The <File management Format> screen is displayed.



To cancel formatting, press the [Cancel] function key. The <File management> screen is displayed.

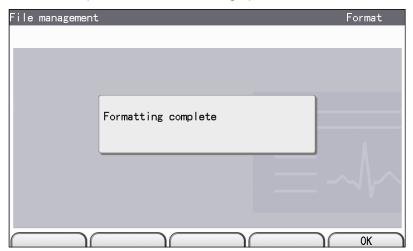
5 Press the [OK] function key. The "Formatting. Do not turn off power" message appears.



When formatting is complete, the "Formatting complete" message appears.

Press the [OK] function key. The <File management> screen is displayed.

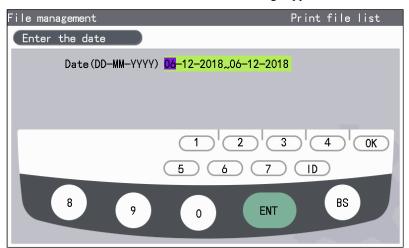
NOTE: Do not turn off the electrocardiograph power while the <File management - Format> screen is displayed and do not give an impact to the electrocardiograph.



Printing a File List

You can print a list of all ECG files saved in the media.

1 Display the <File management> screen. Press the [↑] or [↓] function key to select "Print file list". The "Enter the date" message appears.

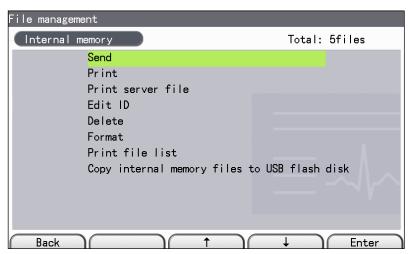


- **2** Enter the date interval.
 - Press the [Back] function key to return to the <File management> screen.
- 3 Press the [Print] function key. The "Printing. Do not turn off power" message is displayed.
- To cancel printing, press the [Cancel] function key or the **START/STOP** key, the "Printing. Do not turn off power" message disappears.
- After all files are printed, the message disappears.

Copying Files in the Internal Memory to a USB Flash Disk

You can copy the ECG data files saved in the internal memory to the USB flash disk.

Press the [↑] or [↓] function key to select "Copy internal memory files to USB flash disk".



The "Copy files to the USB flash disk?" message appears.



Press the [OK] function key to copy the files. A "Copying. Do not turn power off" message appears.

After all files are copied, the message disappears.



Troubleshooting and Error Messages

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Troubleshooting

When trouble occurs, take quick action referring to the table below. If there is any damage or the electrocardiograph is suspected to be faulty as a result of checking, turn the power off, attach an "Unusable" or "Repair request" label to the electrocardiograph and contact your Nihon Kohden representative.

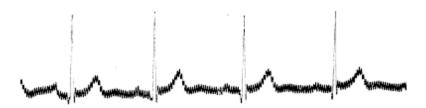
| Trouble | Action | |
|--|--|--|
| When the POWER key is pressed, the electrocardiograph does not operate on AC power. | Check that the power cord is firmly connected to the power socket. | |
| When the POWER key is pressed, the electrocardiograph does not operate on | 1. Check whether the SB-301DC battery pack is inserted in the electrocardiograph correctly. | |
| battery pack power. | 2. Check the battery pack. If it is almost discharged, operate the electrocardiograph on Ac power in emergency circumstances or recharge the battery pack. | |
| The power shuts off suddenly. | 1. Test the memory unit. If it is "abnormal", contact your Nihon Kohden representative. | |
| | 2. Test the memory unit. If it is "normal", electrostatic interference is considered as the cause. Remove the electrostatic source (such as a curtain which does not have anti-static treatment, etc.). | |
| The power shuts off soon after starting operation on battery pack power. | The power is turned off automatically to save the battery pack power if the electrocardiograph is not operated for more than 3 minutes. Refer to Section 3 <i>Changing Settings Before Measurement</i> . Press the POWER key to restore operation. | |
| The screen turns black soon after starting operation on AC power. | When "Backlight auto off" is set to "On" in the system settings, the LCD screen automatically turns off to save power if the electrocardiograph is not operated for more than 3 minutes. Press the POWER key to turn the screen on again. | |
| Power failure during recording in battery pack operation. | 1. Check the battery pack. If the battery pack is almost discharged, recharge it or operate on AC power for emergency use. | |
| | 2. Load the battery pack correctly. | |
| | 3. Replace the battery pack if it has been used for more than 1 year. Contact your Nihon Kohden representative. | |
| Electrodes are attached correctly, but | 1. Start "Electrode Input test" in "System test" to test the patient cable. | |
| ECG waveforms cannot be recorded. | 2. Check whether the electrodes are clean. Dirty electrodes can cause poor contact between the skin and electrodes. Clean the electrodes to remove dirt. | |
| | 3. Clean the skin and apply a layer of electrolyte cream on the position where electrodes are attached to reduce the impedance. | |
| | 4. Using new and used or different electrodes together or using disposable electrodes more than once will cause high polarization voltage and prevent recording of ECG waveforms. | |
| Unable to record all leads | Do not start recording from the middle lead group. Press the LEAD key to select the initial lead group. | |
| Recording without analysis result | 1. Recording must be more than 10 seconds. | |
| | 2. If the II, V1, V5 lead R wave is too small, heart rate cannot be detected and analyzed. Before recording starts, confirm whether that counting of heart rate in the screen is normal. If the counting is displayed as "***", it's impossible to count and measure the heart rate. | |
| Recording does not work. | 1. Check the recording paper, and set the recording paper after hearing clicks. | |
| | 2. Close the paper magazine cover tightly until it is locked. | |
| | 3. Confirm that the START/STOP lamp lights after the START/STOP key is pressed. | |
| | 4. Confirm that the setting of "Setup-Common settings-Operation-Paperless" is set to "Off". | |
| Recording paper is not recognized. | Clean the paper empty sensor. | |

| Trouble | Action | |
|---|--|--|
| Recording is light, faint or defective. | Clean the thermal head with the thermal head cleaner pen. Avoid touching the thermal head with your hand when setting the recording paper. | |
| | 2. Touching recording paper with your hand stained with electrolyte cream and chloride such as normal saline solution, will stain the thermal head. | |
| | 3. Excessive noise during recording prevents recording of the electrocardiograph or triggers ink-saving mode (for protecting thermal head). Check whether there is noise superimposition in the screen, and eliminate noise before restarting recording. | |
| Paper skews as it feeds. | 1. Check if the specified recording paper is used. | |
| | 2. Set the recording paper straight by aligning it with the paper guide. | |
| | 3. If the thermal head is dirty, clean it. | |
| Paper gets jammed in the recorder. | Set the recording paper as specified in <i>Setting the Recording Paper</i> in Section 2. When tearing off the recording paper, tear it along the perforation. | |
| Recording date and time are not correct. | 1. Set the date and time in "Setup-System settings-Date/Time settings". | |
| | 2. If the device setup is synchronized with the server setting, it may be due to server error. Contact your server administrator. | |
| | 3. If the default date before delivery is displayed after the electrocardiograph is started, the built-in lithium cell is in failure. Replace the built-in lithium cell. The expiration date of the built-in lithium cell is about 6 years. | |
| Keys on the operation panel do not work. | It is possibly due to static influence. Press the POWER key for more than 10 seconds to shut down the electrocardiograph. Turn the power on again. | |
| The power is not turned off by pressing the POWER key. | It is possibly due to static influence. Press the POWER key for more than 10 seconds to shut down the electrocardiograph. Turn the power on again. | |
| Cannot read patient information from a bar code or magnetic card. | Check that the bar code reader or the magnetic card reader is firmly connected to the USB connector. If the problem is not solved, contact your Nihon Kohden representative. | |
| | 2. Check that the bar code and the magnetic card settings are correct. Refer to Section 3 <i>Changing Settings Before Measurement</i> to change the settings. If the problem is not solved, contact your Nihon Kohden representative. | |
| Display 'Fail:Limb' (To improve the test | 1. Replace the electrode and check if it returns to normal or not. | |
| environment and still shows) | 2. Replace the patient cable and check if it returns to normal or not. | |
| | 3. If it does not return to normal after the above operation, the electrocardiograph may have failed. Immediately stop using it and contact the maintenance personnel or authorized agents. | |
| | NOTE: The screen displaying 'Fail:Limb' indicates that the patient cable is disconnected or ECG input signal overload (voltage and leakage current exceed the limits specified in the device). | |

ECG Wave Interference Identification and Prevention

AC Interference

AC interference appears as noise over the entire waveforms as shown below. It may also appear together with EMG interference.

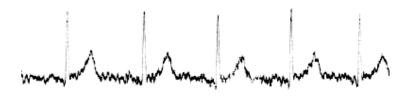


Cause:

- Poor grounding of the device.
- Poor grounding of metal bed, etc.
- The patient contacts surrounding walls or metal parts of bed.
- Other persons contact the patient.
- Poor electrode attachment or patient cable contact.
- Patient cable tip or electrode is stained or eroded.
- The patient or physician contacts the electrodes during recording.
- Interference of nearby electric and lighting equipment, or hidden lines in walls or underground.

EMG Interference

Irregular voltage appears on ECG baseline. It is similar to AC interference or appears together with AC interference.



Cause:

- The patient is not relaxed.
- The patient quivers.
- The bed is too narrow or short and the patient cannot relax the limbs.
- Limb electrodes are too tight.
- If it does not work even after the above causes are eliminated, press the **FILTER** key to set the "EMG filter" to "On".

9

Baseline Drift

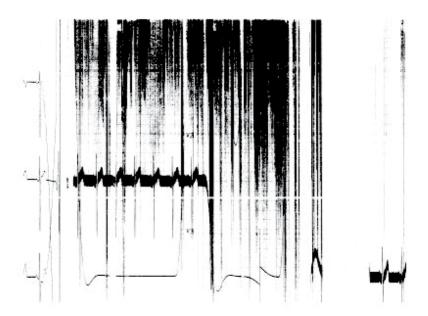
ECG baseline fluctuates up and down.



Cause:

- · Electrodes are dirty or eroded.
- Electrodes get loose or are in poor contact with patient cable.
- Insufficient or dry electrolyte cream.
- Electrodes have oil or the electrodes are attached to bony areas on the extremities.
- Body movement or chest movement caused by breathing.

Recording Abnormality



Waveforms displayed in the screen are normal, but the recording is faint or even defective.

Cause:

• Noise interference:

Remove the main causes such as poor electrode attachment, etc.

 Waveform superimposition appears at multiple positions between upper and lower sections in the recording paper, especially QRS wave. Reduce the recording sensitivity or change the number of recording channels, etc. to remove wave crest superimposition between upper and lower sections.

Excessively noise will cause recording confusion or waveform superimposition. The device limits the current automatically (ink-saving recording) to protect the thermal head and this can cause the recording to be faint or defective.

Others

- Some electrodes are not attached yet.
- High-frequency electrical surgical unit is used together with the ECG.
- ECG turns to be a straight line instantaneously during defibrillation.
- Interference from power supply
- Electrostatic electricity will induce the following peak noise, which may be mixed with QRS and pacemaker peak.



Electrostatic interference

NOTE: The baseline becomes flat for a while after defibrillation to protect the electrocardiograph.

Error Messages

When an error message is displayed on the screen, take quick action referring to the table below.

Common Check

| Error message | Possible cause | Action |
|--|--|--|
| Fail | The indicated electrode is detached and the corresponding lead name is displayed. If two or more limb electrodes are disconnected or the RF electrode is disconnected, Limb is displayed. | Check the electrode attachment of the indicated position. |
| Noise | Noise is superimposed on the indicated electrode waveform. The corresponding lead name is displayed. | Check the electrode attachment of the indicated position. |
| Clock BAT voltage is low Change the battery | The lithium battery with built-in RTC is almost discharged. | Contact your Nihon Kohden representative. |
| Internal temperature is abnormal. | Internal temperature error. | Contact your Nihon Kohden representative. |
| The battery pack is not enough Please switch to AC power | The remaining battery pack power is insufficient. | Use AC power to operate the electrocardiograph or recharge the battery pack. |
| Check the recording paper | The paper magazine is not closed tight or there is no recording paper. | Close the paper magazine and set the recording paper correctly. |
| Invalid entry | The entered data is out of range. | Enter correct values. |

File Common (Communication)

| Error message | Possible cause | Action |
|-----------------------|--|---|
| Error code 2001(1600) | | Check the server or communication path. |
| | F : "C | Check communication path. |
| Error code 2001(1601) | Error in "Setup-Communication settings-Server settings". | Check the file server settings of "Setup-Communication settings-Server settings". |
| Error code 2001(1603) | Network connection is incorrect. | Check the connection of network cable or USB wireless adapter. |
| Error code 2001(1604) | Network connection is incorrect. | Check the connection of network cable or USB wireless adapter. |
| | | Turn the receiver power on. |
| Error code 2001(1605) | The receiver system has something | Contact your system administrator. |
| | wrong. | Check the action of receiver system. |
| Error code 2001(1606) | The data cannot be sent correctly. | Send again or send another file to check network connection. |
| F | Database login failed. | Contact your system administrator. |
| Error code 2002(1410) | | Check the action of receiver system. |
| Error code 2002(1413) | | Contact your system administrator. |
| | | Check the action of receiver system. |
| Error code 2002(1501) | | Check the server settings of "Setup-Communication settings". |

9. TROUBLESHOOTING AND ERROR MESSAGES

| Error message | Possible cause | Action |
|---|--|--|
| | Terminal number of logining receiver | Check communication path. |
| Error code 2002(1502) | system is incorrect. | Check the terminal settings of "Setup-Communication settings". |
| Error code 2002(1510) | Database open error. | Contact your system administrator. |
| Enoi code 2002(1310) | Database open enoi. | Check the action of receiver system. |
| Error code 2003(0452) | There might not be enough space on the destination server. | Check the free space of server. |
| | Network connection is incorrect. | Contact years avatam administrator |
| Error code 2003(0500) | The receiver power is off. | Contact your system administrator. |
| Error code 2003(0530) Error code 2003(0550) | Error in "Setup-Communication settings-Server settings". | Check the server and the file server settings of "Setup-Communication settings-Server settings". |

File Common (Media)

| Error message | Possible cause | Action |
|--|--|---|
| USB flash disk isn't inserted | USB flash disk is not inserted. | Insert the specified USB flash disk or replace the media. |
| Insufficient space on the USB flash disk | There is not enough free space on the USB flash disk. | Delete unnecessary files or replace the media. |
| Invalid USB flash disk | The USB flash disk is invalid. | Replace a new USB flash disk or replace the media. |
| Insufficient space on the memory | There is not enough free space on the internal memory. | Delete unnecessary files or replace the media. |

Resting ECG Recording

| Error message | Possible cause | Action |
|--|--|---|
| Same ID as previous test. | The ID is the same as the previous test. The instrument judges that the patient may be changed when the "Fail:Limb" message appears for more than 5 seconds after recording (including analysis). After solving the problem and recording of the same patient starts, this message appears. | Touch one of the following keys: [Start rec.]: Starts the measurement and overwrites the previous measurement data. [Edit ID]: Displays the <patient information=""> window. Edit the ID and start the measurement. [Cancel]: Cancels the measurement.</patient> |
| Not enough free space Delete unnecessary files | Not enough space on the media. | Delete unnecessary files. |
| File processing Do not turn off power | You tried to turn off the power during file processing. | Turn off the power after file processing is completed. |

9

Periodic Recording

| Error message | Possible cause | Action |
|-------------------------------|---|-----------------------------|
| Can't execute periodic record | During fixed recording time of periodic, another type of recording is being executed. | |
| | Recording mode is manual mode. | Change Manual mode to Auto. |

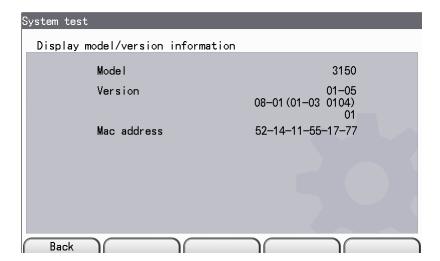
File Management

| Error message | Possible cause | Action |
|---------------------------------|-------------------------------------|--|
| Check the entered ID. | There is no corresponding data. | Check the search condition. |
| Check the entered Date. | There is no corresponding data. | Check the search condition. |
| No ECG file | No files match the search criteria. | Change the search criteria and retry or enter the new search criteria. |
| This file type is not supported | An Unsupported file type was read. | |
| Check sum is not correct | File error. | Contact your Nihon Kohden representative. |

Checking the Software Version

Check the model and software version when upgrading the electrocardiograph. Select [System test] > [Display model/version information] to perform the test.

- 1 Select [System test] > [Display model/version information] and touch the [OK] function key.
- **2** The model, software version, and MAC address are displayed on the window.



3 After checking the results, press the [Back] function key to return to the System test window.

Maintenance and System Test

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Maintenance

Checking Items After Turning the Power Off

After use, check the following items for the next use.

Overview:

- Electrocardiograph is not dirty, damaged or in contact with liquid.
- No peeling or tear in the operation panel.
- No key or button is broken.
- Power cord and AC adapter is not damaged.
- Electrodes are clean and not damaged.
- · Paper magazine is not damaged.

Accessories:

- Enough electrodes and patient cable
- No crack in the rubber of chest electrodes
- Normal clipping force of four limb electrodes
- · Patient cable is not damaged.
- Enough disinfected or sterilized dry electrodes
- Enough electrolyte cream
- · Enough recording paper

Storage:

- Electrodes are washed.
- The battery pack is fully recharged.
- The thermal head is clean.
- The transducer is clean.
- The power is turned off.
- No chemicals or liquid are near the electrocardiograph.
- · Acceptable storage temperature and humidity

10

Periodic Replacement

To maintain the performance of the electrocardiograph, the following parts must be periodically replaced by qualified service personnel.

Battery pack

1 year

The battery pack deteriorates with the use or time. Replace the battery pack with a new one if the operation time is less than 30 minutes after 3 hours charging.

For inspection and replacement of the above parts, consult Nihon Kohden or its agents.

Cleaning and Disinfecting the Electrocardiograph

⚠ CAUTION

- Do not use volatile liquids such as thinner or benzine, because these will cause the materials to melt or crack.
- Before maintenance, cleaning or disinfection, turn the electrocardiograph power off and disconnect the AC adapter.
 Failure to follow this instruction may result in electrical shock and electrocardiograph malfunction.
- After cleaning, make sure that the electrocardiograph is completely dried.
- Never sterilize the electrocardiograph because the materials may deform, crack or discolor.
- The "CAUTION LABEL" contains important information for operating the electrocardiograph. Clean the label if it is dirty. If the label is damaged or difficult to read, contact local agents to replace it with a new one.

Cleaning the Surface of the Electrocardiograph

Clean the outside surface of the electrocardiograph with a soft cloth moistened with water, neutral soap or alcohol (76.9 vol % to 81.4 vol %) and wrung out.

Use a dry cloth when you wipe the connector of the electrocardiograph, input box or operation panel. Otherwise, water gets inside the electrocardiograph and causes malfunction.

Cleaning the Display of the Electrocardiograph

⚠ CAUTION

- · Do not use a rough cloth.
- Do not use acidic, alkaline detergents, or alcohol other than ethanol or isopropyl.

Clean the display using a dry soft cloth or a cloth which is moistened with neutral soap and wrung out.

Disinfecting the Surface of the Electrocardiograph

⚠ CAUTION

- Wipe the electrocardiograph thoroughly after disinfecting it with spray.
- Do not sterilize or disinfect the electrocardiograph with ultraviolet light or ozone.
- · Do not use hypochlorous acid for disinfecting.

To disinfect the outside surface of the electrocardiograph, wipe it with a soft cloth moistened with any of the disinfectants listed below. Use the recommended concentration.

| <u>Disinfectant</u> | Concentration (%) |
|--|-------------------|
| Glutaraldehyde solution | 2.0 |
| Chlorhexidine gluconate solution | 0.5 |
| Benzalkonium chloride solution | 0.2 |
| Benzethonium chloride solution | 0.2 |
| Alkyldiaminoethylglycine hydrochloride | 0.5 |

Using a dry soft cloth or a cloth which is moistened with neutral soap and wrung out.

Cleaning the Thermal Head

A CAUTION

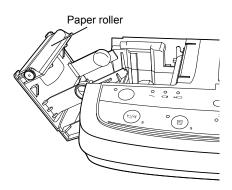
- Do not clean the thermal head immediately after recording because the head is still hot.
- Only clean the head with the provided thermal head cleaner pen.
 Otherwise the thermal head may be damaged.



To protect the thermal head from abrasion or damage and assure optimum performance and long service life, clean the surface of the head with the provided thermal head cleaning pen after every 10 sets of recording paper.

- 1 Turn off the electrocardiograph before cleaning the thermal head.
- 2 Open the paper magazine.
- 3 Clean the gray colored part of the thermal head with the thermal head cleaner pen.

Cleaning the Paper Roller

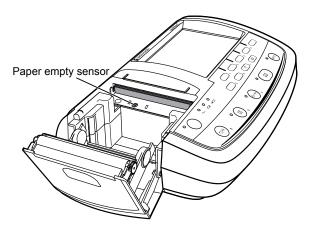


If the paper roller is dirty, clean the paper roller surface with gauze moistened with alcohol.

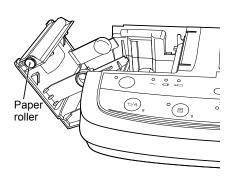
Cleaning the Sensor

The paper empty sensor is located as shown left.

Clean the sensor surfaces with a cotton swab moistened with alcohol.



Cleaning the Wheel Gear



If the wheel gear is dirty, clean the wheel gear surface with a cotton swab moistened with alcohol.

Cleaning and Disinfecting the Patient Cable

Cleaning

A CAUTION

- Do not immerse the connector in liquid.
- Do not use volatile liquids such as thinner or benzine, because these will cause the materials to melt or crack.

Clean the patient cable using a soft cloth or a cloth moistened with neutral soap or water and wipe with a dry cloth. Make sure that the patient cable is completely dried after cleaning.

If you leave electrolyte cream (CardioCream) on the patient cable surface and leave the tip wet, it may cause inaccurate ECG recording due to high skin electrode contact impedance.

Disinfecting

A CAUTION

- · Do not use hypochlorous acid for disinfecting.
- · Wipe the patient cable thoroughly after disinfecting it with spray.

To disinfect the patient cable, wipe it with a soft cloth moistened with any of the disinfectants listed below. Use the recommended concentration.

| Disinfectant | Concentration (%) |
|--|-------------------|
| Glutaraldehyde solution | 2.0 |
| Chlorhexidine gluconate solution | 0.5 |
| Benzalkonium chloride solution | 0.2 |
| Benzethonium chloride solution | 0.2 |
| Alkyldiaminoethylglycine hydrochloride | 0.5 |

10

Cleaning and Disinfecting Electrodes

Cleaning

⚠ CAUTION

Do not use volatile liquids such as thinner or benzine, because these will cause the materials to melt or crack.

Wipe the electrode using a gauze moistened with 35 °C (95 °F) warm water and neutral soap or invert soap or, cotton moistened with alcohol. Make sure that the electrode is completely dried after cleaning.

If you leave electrolyte cream (CardioCream) on the electrode surface or leave the metal part wet, it may cause inaccurate ECG recording due to high skin electrode contact impedance.

Disinfecting

⚠ CAUTION

Do not sterilize electrodes by boiling. It may damage the electrode.

To disinfect the electrode, wipe it with a soft cloth moistened with any of the disinfectants listed below. Use the recommended concentration.

<u>Disinfectant</u> <u>Concentration (%)</u>

Ethanol 76.9 vol % to 81.4 vol %

Benzalkonium chloride 0.2
Benzethonium chloride solution 0.2

Cleaning and Disinfecting Other Options

Refer to the operator's manual of each option.

Waste Disposal

Disposal of waste products according to the relevant regulations and rules of Shanghai Kohden.

Clock Accuracy

At an operating temperature (25 $^{\circ}$ C), the accuracy of the clock IC of this device is about -48 s to +15 s per month.

At storage temperature (-20 °C to +65 °C), the accuracy of the clock IC of this device is about -(6 min 9 s) to +(1 min 41 s) per month.

Periodically check that the date and time on the printing result is correct.

Regular Check

Check the following items regularly to keep your electrocardiograph in optimal condition.

Overview:

- Electrocardiograph is not dirty, damaged or rusty.
- Magazine release button is not broken.

Input circuit:

- Electrode lead is not cut or broken.
- Sensitivity and time constant are correct.
- AC filter and high-cut filter operate correctly.
- Patient cable is not dirty or damaged.
- Patient cable is not broken.

Screen:

- Contrast and backlight brightness are correct.
- Waveform display and other screen display are correct.

Recorder:

- Specified recording paper is used.
- · Paper feeds properly.
- No missing dots on printing.
- Paper entry sensor and mark sensor operate correctly.

Power:

- Power cord is not broken.
- Supplied voltage is correct.

Operation:

- Electrocardiograph passes all check items in the System test screen.
- QRS synchronization sound and notification sound are correct.
- System settings are correct and are saved correctly.
- · Date and time are correct.

Safety:

• Leakage current (earth leakage current, enclosure leakage current and patient leakage current) is not over the range which is specified in IEC 60601-1.

USB and accessories:

- USB operates correctly.
- · Enough accessories.
- NOTE Essential performance refers to IEC 60601-2-25:2011 Table 201.101 ESSENTIAL PERFORMANCE REQUIREMENTS.
 - If essential performance below is not met, please contact Shanghai Kohden or its authorized agents.
 - Defibrillation protection
 - ESSENTIAL PERFORMANCE of ME EQUIPMENT
 - FILTERS (including line frequency interference FILTERS)
 - Electrostatic discharge
 - Electric fast transients and bursts
 - Conducted disturbances
 - Electrosurgery interference

Repair Parts Availability Policy

Shanghai Kohden shall stock repair parts (parts necessary to maintain the performance of the device) for a period of 8 years from the date of delivery. In that period, Shanghai Kohden or the authorized agents will repair the device. This period may be shorter than 8 years if the board or part necessary for the faulty section is not available.

NOTE: The maintenance personnel must be Shanghai Kohden technical personnel or authorized agents.

MARNING

- Replacement of a component could result in an unacceptable risk, cause electric shock or discard the device.
- Only promise that the service personnel can replace the component.
- NOTE All information necessary to safely replace the component is described in the Service Manual.
 - Technical information such as circuit diagrams, component part lists, descriptions, calibration instructions or other information is available for SERVICE PERSONNEL upon request from your Nihon Kohden representative.

System Test

This section provides brief explanations of each test or function and explains how to display the <System test> screen.

Press and hold the FEED/MARK key, then press the POWER key to access the <System test> screen.

Test items are shown below:

• Demonstration mode: This is used to demonstrate the electrocardiograph. Demonstration 12 lead ECG

waveforms are displayed.

• Recorder test: This is used to check the recorder by printing a test pattern and adjusting the recorder

based on the printout.

• Key test: This is used to check the keys on the operation panel. The name of the pressed key is

displayed on the screen.

• LCD/LED test: The LCD displays 3 test patterns. Then the LEDs on the operation panel light up one by

one.

• Electrode Input test: This is used to check if the input analog signal processing circuit detects the lead off

condition correctly using the input check jig. If a lead is not connected, the "Error"

message is displayed on the screen.

• ECG input and output circuit test: In this test, the input analog signal processing circuit generates 1 mV rectangular

waveforms that are printed.

• USB test: This is used to check the external communication input/output line of the

electrocardiograph and display the test results on the screen.

• Display internal information: This displays the internal temperature and power voltage of the electrocardiograph.

• Display model/version information: This displays the model name, software version and MAC address of the

electrocardiograph.

• LAN Test: Display the <System test> screen, move the cursor to "LAN Test", then press the [Enter]

function key to access the <LAN Test> screen. Enter the applicable device IP address, subnet mask, and server address, move the cursor to "PING Server", then press the

[TEST] function key. The [TEST] function key changes to [Testing].

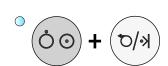
"Ping success!!" appears if the above mentioned settings are correct.

"Ping failed!!" appears if the above mentioned settings are wrong.

• Machine information: This displays the machine information of the electrocardiograph, such as "Distance of

paper recording", "Usage time of motor", "Usage time of lithium battery", etg.

Displaying the System Test Screen



- 1 Turn the power off.
- 2 Press the **POWER** key while pressing the **FEED/MARK** key.

The <System test> screen is displayed.

- Select the desired item with the $[\uparrow]$ or $[\downarrow]$ function key.
- 4 Press the [OK] function key to execute the item.

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Specifications

ECG Input

Input impedance: $\geq 50 \text{ M}\Omega \text{ (at } 0.67 \text{ Hz)}$

Electrode offset tolerance: ±550 mV

Defibrillation-proof: Isolated and defibrillator protected only when the following specified patient cable is connected.

Patient cable: BJ-961D, BJ-962D, BJ-901D, BJ-902D, BJ-903D, BA-901D

Recovery time: < 5 s

NOTE: Complies with IEC 60601-2-25:2011.

Common mode rejection ratio: $\geq 105 \text{ dB (at } 10 \text{ V)}$

Input circuit current: $\leq 0.05 \,\mu\text{A}$

Standard sensitivity: 10 mm/mV, not more than $\pm 2 \%$

Internal noise: $\leq 20 \,\mu\text{Vp-v}$ Interference between channels: $\leq -40 \,\text{dB}$

Frequency response: With 10 Hz as benchmark, 0.05 Hz to 150 Hz (+0.4 dB /-3.0 dB)

150 Hz (≥ 71 %, high-cut filter: 150 Hz)

Sample rate: 8000 samples/s

Waveform Data Processor

Sampling and amplitude quantisation during data

acquisition:

 $500 \; samples/s, \, 1.25 \; \mu v/LSB$

Response to minimum signal: 20 μVp-v

EMG suppression: 25 Hz filter is on: Not less than 70 % for 20 Hz, and not more than 70 % for 30 Hz;

35 Hz filter is on: Not less than 70 % for 30 Hz, and not more than 70 % for 40 Hz;

High-cut filter: When the filter is set to 75 Hz, 100 Hz, 150 Hz, the attenuation for 75 Hz, 100 Hz, 150 Hz is not

more than 3 dB.

AC line filter: $50 \text{ Hz} \pm 0.05 \% \ge 20 \text{ dB}$

 $60~Hz\pm0.05~\%\geq20~dB$

Baseline drift suppression: Weak: -20 dB (0.1 Hz); Strong: -34 dB (0.1 Hz)

Time constant: $\geq 3.2 \text{ s}$

Sensitivity: 5 mm/mV, not more than $\pm 5 \%$.

10 mm/mV, not more than $\pm 2 \%$ 20 mm/mV, not more than $\pm 5 \%$

Recorder

Recording speed accuracy: $\pm 5 \%$

Printing density: 200 dpi (8 dots/mm); 320 dot/mm² (25 mm/s)

Scanning line density: 1 ms

Number of recording channels: 1, 1+rhythm, 3
Paper speed: 25 mm/s, 50 mm/s

Recording paper: 63 mm width, 30 m roll paper Mechanical noise: ≤ 48 dB at paper speed 25 mm/s

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Printed data: ECG waveform, heart rate, lead name, version, date and time, program type, paper speed,

sensitivity, filter, patient information (ID number, sex, age), event mark, electrode detachment,

noise.

Wireless Communication

Wireless Communication

IEEE 802.11a/b/g/n/ac

Standard

EN 300 328 V2.2.2 EN 301 893 V2.1.1 EN 62311:2008

Channel/Frequency Band

IEEE 802.11b/g/n

1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13 (2412 MHz to 2472 MHz)

IEEE 802.11a/n/ac

36, 40, 44, 48 (5180 MHz to 5240 MHz) 52, 56, 60, 64 (5260 MHz to 5320 MHz)

100, 104, 108, 112, 116, 120, 124, 128, 132, 136, 140 (5500 MHz to 5720 MHz)

149, 153, 157, 161, 165 (5745 MHz to 5825 MHz)

IEEE 802.11n: The channel bandwidth of 40 MHz is also available.

IEEE 802.11ac: The channel bandwidths of 40 MHz and 80 MHz are also available.

NOTE: • Channels above are of limited use in each country for compliance with each country's regulations.

• Indoor use only in the frequency band 5150 MHz to 5350 MHz.

Maximum Output Power

100 mW or less (20 dBm or less)

Authentication

Open System

Shared Key

WPA/WPA2-PSK

Encryption

WEP (64 bit / 128 bit)

TKIP

AES (CCMP)

Power Requirements

Line voltage: $100 \text{ V AC to } 240 \text{ V AC} \pm 10 \%$

Line frequency: 50 Hz, 60 Hz Power input: \leq 45 VA

Battery pack: 8.4V, 1600 mAh

Battery pack operation time: More than 180 minutes (auto recording once each 3 minutes with a new battery, at 25 °C)

About 60 minutes (continuous recording with a new battery, at 25 °C)

NOTE: Recording condition: 3-channel recording, input 1 mV 10 Hz sine wave;

paper speed 25 mm/s

Color LCD (with Backlight)

Display size: $W \times H: 108 \text{ mm} \times 64.8 \text{ mm}, 5 \text{ inch}$

Display type: TFT, $800 \text{ dots} \times 480 \text{ dots}$

Display data: Waveform, patient information, recording settings, operation mode, heart rate, QRS sync mark,

error message, electrode detachment, noise.

Connector and Port

USB A type \times 2 LAN port \times 1

Dimensions and Weight

Dimensions: $(W \times H \times D)$: $(260 \text{ mm} \times 75 \text{ mm} \times 172 \text{ mm}) \pm 10\%$

Weight: $1.1 \text{ kg} \pm 10\%$ (without battery pack, recording paper and AC power adapter)

Environment

Operating environment

Temperature: $5 \,^{\circ}\text{C}$ to $40 \,^{\circ}\text{C}$ ($41 \,^{\circ}\text{F}$ to $104 \,^{\circ}\text{F}$)

Relative Humidity: ECG-3150: 25 % to 95 % (noncondensing)

Battery Pack: 40 % to 85 % (noncondensing)

Transport storage environment

Temperature: ECG-3150: -20 °C to +65 °C (-4 °F to +149 °F)

Recording Paper: 0 °C to +45 °C (32 °F to +113 °F)

Battery Pack: The storage environment affects the performance and lifetime of the battery pack. Please store the battery pack under proper environmental conditions depending on the storage

period.

-20 °C to +65 °C (Less than 1 week) -20 °C to +55 °C (Less than 1 month) -20 °C to +45 °C (Less than 6 months) -20 °C to +35 °C (Less than 1 year)

Relative Humidity: ECG-3150: 10 % to 95 % (noncondensing)

Recording Paper: 40 % to 80 % (noncondensing)

Battery Pack (within 2 months): 10 % to 95 % (noncondensing)

Battery Pack (over 2 months and within 1 year): 45 % to 85 % (noncondensing)

Atmospheric pressure: 700 hPa to 1060 hPa altitude: < 3000 m

Overvoltage category: II
Pollution degree: 2

Electromagnetic Compatibility

IEC 60601-1-2: 2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance Collateral standard: Electromagnetic compatibility Requirements and tests.

Safety Specification Classification

IEC 60601-1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

IEC 60601-2-25:2011 Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs

Type of protection against electrical shock: Class I EQUIPMENT (AC powered)

INTERNAL POWER EQUIPMENT (battery pack power)

Degree of protection against electrical shock: Defibrillation-proof type CF applied parts when patient cable BJ-961D,

BJ-962D or BJ-901D, BJ-902D, BJ-903D, BA-901D is used.

Degree of protection against harmful ingress of water: IPX0 (non-protected)

Degree of safety of application in the presence of FLAMMABLE ANAESTHETIC MIXTURE WITH AIR, OR WITH OXYGEN OR NITROUS OXIDE:

Equipment not suitable for use in the presence of FLAMMABLE ANAESTHETIC MIXTURE WITH AIR, OR WITH OXYGEN OR

NITROUS OXIDE.

Operation Mode Continuous operation

Lifetime

6 years

(Self certified based on our data; only when the specified yearly inspection is performed.)

Electromagnetic Emissions

The ECG-3150 essential performance in EMC standard satisfies the following criteria.

This Model ECG-3150 is intended for use in the electromagnetic environment specified below.

The customer or the user of the ECG-3150 should assure that it is used in such an environment.

| Emissions test | Compliance | Electromagnetic environment - guidance |
|--|------------|---|
| Conducted and radiated RF EMISSIONS | Group 1 | The ECG-3150 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. |
| | Clara D | TI - FOC 2150 in a 2411 for an in all available areas in all fine |
| RF emissions | Class B | The ECG-3150 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low- |
| CISPR 11 | | voltage power supply network that supplies buildings used for domestic |
| Harmonic distortion | Class A | purposes. |
| IEC 61000-3-2 | | |
| Voltage fluctuations and | Complies | |
| flicker | | |
| IEC 61000-3-3 | | |

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

Electromagnetic Immunity

The ECG-3150 essential performances in EMC standard satisfies the following criteria. This Model ECG-3150 is intended for use in the electromagnetic environment specified below. The customer or the user of the ECG-3150 should assure that it is used in such an environment.

| Phenomenon | IMMUNITY TEST | Commission on Issuela | Floring and the continuous and continuous |
|---|--|--|---|
| Basic EMC standard | LEVELS | Compliance levels | Electromagnetic environment - guidance |
| ELECTROSTATIC | ±8 kV contact | ±8 kV contact | Floors should be wood, concrete or ceramic tiles. |
| DISCHARGE | ±2 kV, ±4 kV, ±8 kV, | ±2 kV, ±4 kV, ±8 kV, | If floors are covered with synthetic material, the relative humidity should be at least 30%. |
| IEC 61000-4-2 | ±15 kV air | ±15 kV air | |
| Electrical fast transient/ burst | ±2 kV, 100 kHz for power supply lines | ±2 kV, 100 kHz for power supply lines | Mains power quality should be that of a typical commercial or hospital environment. |
| IEC 61000-4-4 | | | |
| Surge | ±1 kV Line-to-line | ±1 kV Line-to-line | Mains power quality should be that of a typical |
| IEC 61000-4-5 | ±2 kV Line-to-ground | ±2 kV Line-to-ground | commercial or hospital environment. |
| Voltage dips | 0 % U _T ; 0.5 cycle | 0 % U _T ; 0.5 cycle | Mains power quality should be that of a typical commercial or hospital environment. |
| IEC 61000-4-11 | At 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° | At 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° | If the user of the ECG-3150 requires continued |
| | $0\% U_{\mathrm{T}}; 1 \text{ cycle}$ | 0 % U _T ; 1 cycle | operation during power mains interruptions, it is recommended that the ECG-3150 be powered from |
| | and | and | an uninterruptible power supply or a battery. |
| | 70 % U _T ; 25/30 cycles | 70 % U _T ; 25/30 cycles | |
| | Single-phase: at 0° | Single-phase: at 0° | |
| Voltage interruptions | 0 % U _T ; | 0% U _T ; | |
| IEC 61000-4-11 | 250/300 cycle | 250/300 cycles | |
| Power frequency | 30 A/m | 30 A/m | Power frequency magnetic fields should be at |
| (50/60 Hz) | | | levels characteristic of a typical location in a typical commercial or hospital environment. |
| Magnetic field | | | , p |
| IEC 61000-4-8 | | | |
| NOTE: U_T is the AC r | nains voltage prior to a | pplication of the test le | vel. |
| Conducted disturbances induced by RF fields IEC 61000-4-6 | 3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands | 3 Vrms 6 Vrms | Portable and mobile RF communications equipment should be used no closer to any part of the ECG-3150 including cables than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. |
| | between 150 kHz and 80 MHz*a | | Recommended separation distance $d = 1.2\sqrt{P}$ $d = 0.6\sqrt{P}$ |

| Phenomenon Basic EMC standard | IMMUNITY TEST LEVELS | Compliance levels | Electromagnetic environment - guidance |
|--------------------------------|-------------------------|-------------------|---|
| Radiated RF EM fields | 3 V/m | 3 V/m | $d = 1.2\sqrt{P} 80 \text{ MHz to } 800 \text{ MHz}$ |
| IEC 61000-4-3 | 80 MHz to 2.7 GHz | | $d = 2.3\sqrt{P} 800 \text{ MHz to } 2.7 \text{ GHz}$ |
| | | | where <i>P</i> 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*b, should be less than the compliance level in each frequency range*c. |
| | | | Interference may occur in the vicinity of equipment marked with the following symbol: |
| | | | ((<u>`</u> `)) |

- NOTE At 80 MHz and 800 MHz, the higher frequency range applies.
 - These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
- *a The ISM (industrial, scientific and medical) bands between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.
- *b Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy.
 - To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ECG-3150 is used exceeds the applicable RF compliance level above, the ECG-3150 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ECG-3150.
- *c Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances between Portable and Mobile RF Communications Equipment

The ECG-3150 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ECG-3150 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ECG-3150 as recommended below, according to the maximum output power of the transmitter.

| Rated maximum output | Separation dist | Separation distance according to frequency of transmitter (m) | | | | |
|----------------------|-------------------|---|-------------------|--|--|--|
| power of transmitter | 150 kHz to 80 MHz | 150 kHz to 80 MHz 80 MHz to 800 MHz | | | | |
| (W) | $d = 1.2\sqrt{P}$ | $d = 1.2\sqrt{P}$ | $d = 2.3\sqrt{P}$ | | | |
| 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 estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

- NOTE At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
 - These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment

⚠ WARNING

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ECG-3150, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

| Test frequency (MHz) | Band (MHz) | Service | Modulation | Maximum power (W) | Distance (m) | IMMUNITY TEST LEVEL (V/m) |
|-------------------------|-------------|-----------------------------------|--------------------------------------|----------------------|-----------------|------------------------------|
| 385 | 380 ~ 390 | TETRA 400 | Pulse modulation 18 Hz | 1.8 | 0.3 | 27 |
| 450 | 430 ~ 470 | GMRS 460, FRS 460 | FM ±5 kHz deviation 1 kHz sine | 2 | 0.3 | 28 |
| 710 | | | Pulse modulation | | | |
| 745 | 704 ~ 787 | LTE Band 13, 17 | | 0.2 | 0.3 | 9 |
| 780 | | | 217 Hz | | | |
| 810 | | GSM 800/900, TETRA 800, iDEN | Pulse modulation | | | |
| 870 | 800 ~ 960 | 820, CDMA 850, | 18 Hz | 2 | 0.3 | 28 |
| 930 | | LTE Band 5 | 10 112 | | | |
| 1435.4 | 1427.9 ~ | LTE Band 11, 21; | Pulse modulation | 2 | 0.3 | 28 |
| 1452.9 | 1510.9 | UMTS | 217 Hz | 2 | 0.3 | 28 |
| 1720 | 1-00 1000 | GSM 1800, CDMA 1900, GSM 1900, | Pulse modulation | | | • |
| 1845 | 1700 ~ 1990 | DECT, LTE Band | 217 Hz | 2 | 2 0.3 | 28 |
| 1970 | | 1, 3, 4, 25; UMTS | | | | |

| Test frequency (MHz) | Band (MHz) | Service | Modulation | Maximum power (W) | Distance (m) | IMMUNITY TEST LEVEL (V/m) |
|-------------------------|------------------|--|----------------------|----------------------|-----------------|------------------------------|
| 2450 | 2400 ~ 2570 | Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7 | i disc illoddiadioli | 2 | 0.3 | 28 |
| 5240 | | | Pulse modulation | | | |
| 5500 | $5100 \sim 5800$ | WLAN 802.11 a/n | | 0.2 | 0.3 | 9 |
| 5785 | | | 217 Hz | | | |

Essential Performance

- The electrocardiograph is intended for medical facalities to process the electrical signals acquired by the electrodes, to display the waveforms and/or to record these electrical signals.
- IEC 60601-1 Edition 3.1:2012
- IEC 60601-2-25:2011

| Tested Requirements | Sub-clause of IEC 60601-2-25:2011 |
|---|-----------------------------------|
| Defibrillation protection | 201.8.5.5.1 |
| ESSENTIAL PERFORMANCE of ME EQUIPMENT | 201.12.1.101 |
| FILTERS (including line frequency interference FILTERS) | 201.12.4.105.3 |
| Electrostatic discharge | 202.6.2.2.1 |
| Electric fast transients and bursts | 202.6.2.4.1 |
| Conducted disturbances | 202.6.2.6.1 |
| Electrosurgery interference | 202.6.2.101 |

System Composition for EMC Test

The ECG-3150 is tested to comply with IEC 60601-1-2: 2014, with the following composition. If any part which is not specified by Shanghai Kohden is used, the EMC specifications may not comply.

| Unit | Cable length |
|--|--------------|
| ECG-3150 electrocardiograph | _ |
| Battery pack, SB-301DC | _ |
| Patient cable, BJ-961D | 3.4 m |
| Magnetic card reader, CRF-200U-5101-00 | _ |
| Bar code reader, LS2208 | _ |
| LAN cable | 2 m |
| Ground lead | 4 m |

Member States in Which this Instrument is Intended for Use

Europe

As of April 2016, Shanghai Kohden Corporation has notified the intended use of this instrument to the authority of the following member states based on Radio Equipment Directive (2014/53/EU).

| • Austria | • Belgium | Bulgaria | Croatia | Cyprus | Czech Republic |
|------------------------------|----------------------------|------------------------------|---------------------------------|--------------------------------|------------------------------------|
| Denmark | • Estonia | Finland | • France | Germany | • Greece |
| Hungary | • Iceland | Ireland | • Italy | • Latvia | • Liechtenstein |
| • Lithuania | • Luxembourg | • Malta | Montenegro | Netherland | • Northern Ireland |
| • North Macedonia | Norway | Poland | Portugal | • Romania | Slovakia |
| Slovenia | • Spain | • Sweden | Switzerland | • Turkey | |

This instrument complies with International Standard IEC 60601-1-2: 2014 which requires CISPR11, Group 1, Class A. Class A EQUIPMENT is instrument suitable for use in all establishments, excluding domestic establishments or in establishments directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.

NOTE: Indoor use only within the band 5150 MHz to 5350 MHz.

| Tímto Shanghai Kohden prohlašuje, že ECG-3150 je v souladu se směrnicí 2014/53/EU. Úplné znění EU prohlášení o shodě je k dispozici na této internetové adrese: https://www.nihonkohden.com/ |
|---|
| |
| Hermed erklærer Shanghai Kohden, at ECG-3150 er i overensstemmelse med direktiv 2014/53/EU. EU- overensstemmelseserklæringens fulde tekst kan findes på følgende internetadresse: https://www.nihonkohden.com/ |
| |
| Hiermit erklärt Shanghai Kohden, dass der ECG-3150 der Richtlinie 2014/53/EU entspricht. Der vollständige Text der EU-Konformitätserklärung ist unter der folgenden Internetadresse verfügbar: https://www.nihonkohden.com/ |
| Käesolevaga deklareerib Shanghai Kohden, et ECG-3150 vastab direktiivi 2014/53/EL nõuetele. ELi |
| vastavusdeklaratsiooni täielik tekst on kättesaadav järgmisel internetiaadressil: |
| https://www.nihonkohden.com/ |
| Hereby, Shanghai Kohden declares that the ECG-3150 is in compliance with Directive 2014/53/EU. The full text of the EU declaration of conformity is available at the following internet address: |
| https://www.nihonkohden.com/ |
| Por la presente, Shanghai Kohden declara que el ECG-3150 es conforme con la Directiva 2014/53/UE. El texto completo de la declaración UE de conformidad está disponible en la dirección Internet siguiente: |
| https://www.nihonkohden.com/ |
| Με την παρούσα ο/η Shanghai Kohden, δηλώνει ότι ο ECG-3150 πληροί την οδηγία 2014/53/ΕΕ. Το πλήρες κείμενο της δήλωσης συμμόρφωσης ΕΕ διατίθεται στην ακόλουθη ιστοσελίδα στο διαδίκτυο: |
| https://www.nihonkohden.com/ |
| Le soussigné, Shanghai Kohden, déclare que le ECG-3150 est conforme à la directive 2014/53/UE. Le texte complet de la déclaration UE de conformité est disponible à l'adresse internet suivante: |
| https://www.nihonkohden.com/ |
| Il fabbricante, Shanghai Kohden, dichiara che il ECG-3150 è conforme alla direttiva 2014/53/UE. Il testo completo della dichiarazione di conformità UE è disponibile al seguente indirizzo Internet: |
| https://www.nihonkohden.com/ |
| Ar šo Shanghai Kohden deklarē, ka ECG-3150 atbilst Direktīvai 2014/53/ES. Pilns ES atbilstības deklarācijas teksts ir pieejams šādā interneta vietnē: |
| https://www.nihonkohden.com/ |
| Aš, Shanghai Kohden, patvirtinu, kad ECG-3150 atitinka Direktyvą 2014/53/ES. Visas ES atitikties deklaracijos |
| tekstas prieinamas šiuo interneto adresu: https://www.nihonkohden.com/ |
| Hierbij verklaar ik, Shanghai Kohden, dat het ECG-3150 conform is met Richtlijn 2014/53/EU. De volledige tekst van de EU-conformiteitsverklaring kan worden geraadpleegd op het volgende internetadres: https://www. |
| nihonkohden.com/ |
| B'dan, Shanghai Kohden, niddikjara li dan it-tip ta' taghmir tar-radju ECG-3150 huwa konformi mad-Direttiva 2014/53/UE. It-test kollu tad-dikjarazzjoni ta' konformità tal-UE huwa disponibbli f'dan l-indirizz tal-Internet li |
| gej: https://www.nihonkohden.com/ |
| |

| hu Magyar [Hungarian] | Shanghai Kohden igazolja, hogy a ECG-3150 megfelel a 2014/53/EU irányelvnek. Az EU-megfelelőségi nyilatkozat teljes szövege elérhető a következő internetes címen: https://www.nihonkohden.com/ | | | | |
|-------------------------------|---|--|--|--|--|
| pl | Shanghai Kohden niniejszym oświadcza, że typ urządzenia radiowego ECG-3150 jest zgodny z dyrektywą 2014/53/UE. Pełny tekst deklaracji zgodności UE jest dostępny pod następującym adresem internetowym: https:// | | | | |
| Polski [Polish] | www.nihonkohden.com/ | | | | |
| pt | O(a) abaixo assinado(a) Shanghai Kohden declara que o presente ECG-3150 está em conformidade com a Diretiva 2014/53/UE. O texto integral da declaração de conformidade está disponível no seguinte endereço de Internet: | | | | |
| Português [Portuguese] | https://www.nihonkohden.com/ | | | | |
| sl Slovensko [Slovenian] | Shanghai Kohden potrjuje, da je ECG-3150 skladen z Direktivo 2014/53/EU. Celotno besedilo izjave EU o skladnosti je na voljo na naslednjem spletnem naslovu: https://www.nihonkohden.com/ | | | | |
| sk Slovenský [Slovak] | Shanghai Kohden týmto vyhlasuje, že ECG-3150 je v súlade so smernicou 2014/53/EÚ. Úplné EÚ vyhlásenie o zhode je k dispozícii na tejto internetovej adrese: https://www.nihonkohden.com/ | | | | |
| fi | Shanghai Kohden vakuuttaa, että ECG-3150 on direktiivin 2014/53/EU mukainen. EU-vaatimustenmukaisuusvakuutuksen täysimittainen teksti on saatavilla seuraavassa internetosoitteessa: https:// | | | | |
| Suomi [Finnish] | www.nihonkohden.com/ | | | | |
| sv Svenska [Swedish] | Härmed försäkrar Shanghai Kohden att denna typ av radioutrustning ECG-3150 överensstämmer med direktiv 2014/53/EU. Den fullständiga texten till EU-försäkran om överensstämmelse finns på följande webbadress: https://www.nihonkohden.com/ | | | | |
| is Íslenska [Icelandic] | Hér með lýsir Shanghai Kohden því yfir að ECG-3150 er í samræmi við tilskipun 2014/53/EU. Heildartexti EB-samræmisyfirlýsingarinnar er fáanlegur á eftirfarandi veffangi: https://www.nihonkohden.com/ | | | | |
| no | Shanghai Kohden erklærer herved at ECG-3150 er i samsvar med direktiv 2014/53/EU. Hele samsvarserklæringsteksten er tilgjengelig på følgende Internett-adresse: https://www.nihonkohden.com/ | | | | |
| Norsk [Norwegian] | same various ingrenous of vingjongong participants maintain various. Imperior various accounts of | | | | |
| bg | С настоящото Shanghai Kohden декларира, че този ECG-3150 е в съответствие с Директива 2014/53/EC. | | | | |
| български език [Bulgarian] | Цялостният текст на EC декларацията за съответствие може да се намери на следния интернет адрес: https://www.nihonkohden.com/ | | | | |
| ro | Prin prezenta, Shanghai Kohden declară că ECG-3150 este în conformitate cu Directiva 2014/53/UE. Textul integral al declarației UE de conformitate este disponibil la următoarea adresă internet: | | | | |
| Română [Romanian] | https://www.nihonkohden.com/ | | | | |
| hr | Shanghai Kohden ovime izjavljuje da je ECG-3150 u skladu s Direktivom 2014/53/EU. Cjeloviti tekst EU izjave o sukladnosti dostupan je na sljedećoj internetskoj adresi: https://www.nihonkohden.com/ | | | | |
| Hrvatski [Croatian] | Sukuditosa dosapan je na sijedecoj memetikog udresi. https://www.mnonkonden.com/ | | | | |

General Requirements for Connecting Medical Electrical Systems

When more than one electrical instrument is used, there may be electrical potential difference between the instruments. Potential difference between instruments may cause current to flow to the patient connected to the instruments, resulting in electrical shock (micro shock). Therefore, electrical instruments must be appropriately installed as specified in IEC 60601-1: 2012.

The following is an extract from IEC 60601-1 "Medical electrical equipment Part 1: General requirements for basic safety and essential performance". For details, refer to IEC 60601-1 and consult with a biomedical engineer.

Examples of Practical Medically used room Nonpossible causes means of Inside the Outside the medically Situation No. compliance for exceeding **PATIENT PATIENT** used room **LEAKAGE** Apply 16.5 in **ENVIRONMENT ENVIROMENT CURRENT Limits** all situations Multiplied Verify total 1a Items A and APPLIED PARTS PATIENT B are Me type can cause the LEAKAGE Mains **EQUIPMENT** total PATIENT **CURRENT** IEC 60601 | IEC 60601 LEAKAGE CURRENT to exceed limits See Note1. Additional 1b Items A and PROTECTIVE B are ME EARTH **EQUIPMENT** Earth conductor CONNECTION of the MULTIPLE IEC 60601 IEC 60601 powered via (for A or B) or, SOCKET-OUTLET a MULTIPLE is broken SOCKET-See also 1a. Separating OUTLET MULTIPLE SOCKET-OUTLET transformer Additional 1c Item A is ME PROTECTIVE **EQUIPMENT** 1 **EARTH** and B is Non-CONNECTION (for B) or, Due to high TOUCH **EQUIPMENT** IEC 60601 ☐IEC ×× CURRENT of B Separating transformer (for B) Additional 1d Item A is ME **PROTECTIVE EQUIPMENT** The earth conductor **EARTH** and B is of the MULTIPLE CONNECTION non-ME IEC 60601 IEC ××× SOCKET-OUTLET (for A or B) or, **EQUIPMENT** is broken powered via Separating a MULTIPLE Due to high TOUCH MULTIPLE SOCKET-OUTLET transformer SOCKET-CURRENT of B OUTLET

Table I.1 - Some examples of ME SYSTEMS for illustration

Table I.1 (continued)

| | Medically used room | | | Examples of | Practical | |
|---|--|--------------------------------|--------------------------------|--------------------------------|--|--|
| | Situation No. | Inside the PATIENT ENVIRONMENT | Outside the PATIENT ENVIROMENT | Non- medically used room | possible causes for exceeding LEAKAGE CURRENT Limits | means of compliance Apply 16.5 in all situations |
| | 1e Item A is ME EQUIPMENT powered from specified power supply in item B | A Mains Plug B IEC ××××× | | | | - Additional PROTECTIVE EARTH CONNECTION (for B) or, |
| 1 | 1f Item A is ME EQUIPMENT powered from NON-ME EQUIPMENT power supply in B | A B Plug IEC 60601 DC/AC | | | Due to high TOUCH CURRENT of B | - Separating transformer (for B) |
| | 2a Items A and B are Me EQUIPMENT | Mains Plug A IEC 60601 | B IEC 60601 | | No causes of exceeding LEAKAGE CURRENT | No further measures are necessary |
| | 2b Items A and item B are ME EQUIPMENT powered via a MULTIPLE SOCKET- OUTLET | A IEC 60601 MULTIPLE SOCKET | B IEC 60601 OUTLET | | Earth conductor of the MULTIPLE SOCKET-OUTLET is broken | - Additional PROTECTIVE EARTH CONNECTION (for A or B) or, - Separating transformer |
| 2 | 2c Item A is ME EQUIPMENT and item B is non-ME EQUIPMENT | Mains Plug A IEC 60601 | B IEC ×××× | | Due to high TOUCH CURRENT of B See rationale for 16.5. | Do not use metal connector housing or,SEPARATION DEVICE |
| | 2d Item A is ME EQUIPMENT and item B is non-ME EQUIPMENT powered via a MULTIPLE SOCKET- OUTLET | A IEC 60601 MULTIPLE SOCKET- | B IEC ××××× | | The earth conductor of the MULTIPLE SOCKET-OUTLET is broken | - Additional PROTECTIVE EARTH CONNECTION (for A or B) or, - Separating transformer |

Table I.1 (continued)

| | | Medically used | room | Non- | Examples of | Practical |
|---|---|---|----------------------|---|--|--|
| ; | Situation No. | Inside the Outside the medically PATIENT PATIENT used room ENVIRONMENT ENVIROMENT | | possible causes for exceeding LEAKAGE CURRENT Limits | means of compliance Apply 16.5 in all situations | |
| | 3a Items A and B are ME EQUIPMENT | Mains Plug A IEC 60601 Comm | on protective earth | Mains Plug B IEC 60601 | No causes of exceeding LEAKAGE CURRENT | - No further measures are necessary |
| | 3b Item A is ME EQUIPMENT and item B is non-ME EQUIPMENT | Mains Plug A IEC 60601 Comn | non protective earth | B Plug | Due to high TOUCH CURRENT of B See rationale for 16.5 | - Do not use metal connector housing for SIGNAL INPUT/ OUTPUT PART or, - SEPARATION DEVICE |
| 3 | 3c Item A is ME EQUIPMENT and item B in is ME EQUIPMENT or non-ME EQUIPMENT | Mains Plug A IEC 60601 Common | protective earth | B IEC 60601 or IEC ××××× Protective earth with potentinal difference | a) Potential difference between PROTECTIVE EARTH CONNECTIONS of A and B b) Due to high TOUCH CURRENT of B See rationale for 16.5 | - Additional PROTECTIVE EARTH CONNECTION for (A), or - SEPARATION DEVICE, or - Do not use metal connector housing in the PATIENT ENVIRONMENT |

- NOTE 1 No causes of TOUCH CURRENT or EARTH LEAKAGE CURRENT exceeding limits.
- NOTE 2 IEC 60601: MEDICAL ELECTRICAL EQUIPMENT in compliance with IEC 60601.
- NOTE 3 IEC xxxxx: Non-medical equipment in compliance with relevant IEC safety standards.
- NOTE 4 Separating transformer: see 16.9.2.1.
- NOTE 5 If equipment "B" is outside the PATIENT ENVIRONMENT and if equipment "A" is a CLASS II equipment and has accessible conductive parts connected to the PROTECTIVE EARTH CONNECTION of equipment "B" then additional safety measures could be necessary, for example: additional protective earth for "B" or separating transformer or SEPARATION DEVICE.

Standard, Options and Consumables

- NOTE: Only use Shanghai Kohden specified parts and accessories to assure maximum performance from your device.
 - When ordering the following accessories/consumables, specify the supply code number. When the supply code number is not provided with the accessory, specify the model or code number.

Common Accessories (Standard)

| No. | Description | Q'ty | Model | Supply Code/Code No. |
|-----|----------------------|------|--------------|----------------------|
| 1 | AC Adapter | 1 | FSP065-DGBM1 | 6104-900343* |
| 2 | Recording paper | 1 | RQS63-3A | A129 |
| 3 | Thermal head cleaner | 1 | _ | Y011 |
| 4 | Input check jig | 1 | _ | 6114-936101* |
| 5 | Operator's Manual | 1 | _ | 0614-907818* |
| 6 | Service Manual CD | 1 | _ | 0634-901099* |
| 7 | ECAPS12C CD | 1 | _ | 0640-900075* |

YD-311D

| No. | Description | Q'ty | Model | Supply Code/Code No. |
|-----|---|------|-------------|----------------------|
| 1 | IEC 3 mm diameter tip, thick cable | 1 | BJ-961D | 9000-062128* |
| 2 | Clip-on limb electrode, 3 mm diameter tip, 4 pcs/set, Fast clip | 1 | NC-143E | H068A |
| 3 | Chest electrode, 3 mm diameter tip, for adult,3 pcs/set | 2 | 6144-011825 | H041A |
| 4 | Power cord | 1 | 365+705 | 6104-900344 |

YD-312D

| No. | Description | Q'ty | Model | Supply Code/Code No. |
|-----|---|------|-------------|----------------------|
| 1 | IEC 3 mm diameter tip, thick cable | 1 | BJ-961D | 9000-062128* |
| 2 | Clip-on limb electrode, 3 mm diameter tip, 4 pcs/set, Fast clip | 1 | NC-143E | H068A |
| 3 | Chest electrode, 3 mm diameter tip, for adult,3 pcs/set | 2 | 6144-011825 | H041A |
| 4 | Power cord | 1 | 31+705 | 6104-900345 |

YD-313D

| No. | Description | Q'ty | Model | Supply Code/Code No. |
|-----|---|------|-------------|----------------------|
| 1 | AHA 3 mm diameter tip | 1 | BA-901D | K019 |
| 2 | Clip-on limb electrode, 3 mm diameter tip, 4 pcs/set, Fast clip | 1 | NC-143E | H068A |
| 3 | Chest electrode, 3 mm diameter tip, for adult,3 pcs/set | 2 | 6144-011825 | H041A |
| 4 | Power cord | 1 | 31+705 | 6104-900345 |

YD-314D

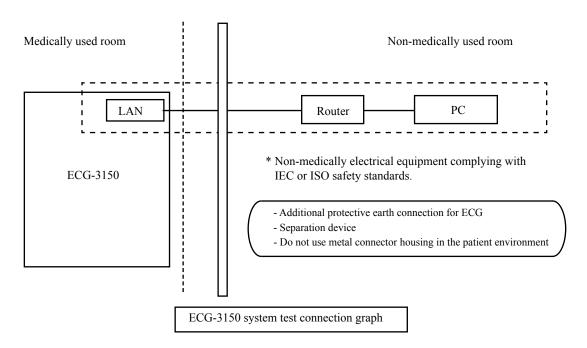
| No. | Description | Q'ty | Model | Supply Code/Code No. |
|-----|---|------|-------------|----------------------|
| 1 | IEC 4 mm diameter tip, thick cable | 1 | BJ-962D | 9000-062130* |
| 2 | Clip-on limb electrode, 4 mm diameter tip, 4 pcs/set, Fast clip | 1 | NC-144E | H068B |
| 3 | Chest electrode, 4 mm diameter tip, for adult, 3 pcs/set | 2 | 6144-011852 | H043A |
| 4 | Power cord | 1 | 365+705 | 6104-900344 |

11. REFERENCE

Options for Electrocardiograph

| Description | Q'ty | Model | Supply Code/Code No. |
|--|------|-----------------|----------------------|
| Battery pack | 1 | SB-301DC | SB-301DC |
| cardioCream, 100 g | 1 | Z-101BC | F010 |
| Ground lead | 1 | OEM-V1125A | 6104-900045* |
| Software kit | 1 | QS-315E | |
| Cart | | | |
| $(W \times H \times D)$: 348 ± 20mm × 855 ± 20mm × 648 ± 20mm | 1 | KD-105D | |
| $(W \times H \times D)$: 348 ± 20mm × 955 ± 20mm × 648 ± 20mm | 1 | KD-105E | |
| $(W \times H \times D)$: $442 \pm 45 \text{mm} \times 850 \pm 85 \text{mm} \times 655 \pm 65 \text{mm}$ | 1 | KD-108D | |
| $(W \times H \times D)$: $442 \pm 45 \text{mm} \times 950 \pm 95 \text{mm} \times 655 \pm 65 \text{mm}$ | 1 | KD-108E | _ |
| Patient cable hanger | 1 | KH-100D/KH-200D | _ |
| Patient cable | | | |
| AHA 3 mm diameter tip | 1 | BA-901D | K019 |
| IEC 3 mm diameter tip, thin cable | 1 | BJ-901D | K079 |
| IEC 4 mm diameter tip, thick cable | 1 | BJ-902D | K081 |
| IEC /DIN clip | 1 | BJ-903D | K082 |
| Electrode | | | |
| Chest electrode, 3 mm diameter tip, for adult,3 pcs/set | 2 | _ | H041A |
| Chest electrode, 4 mm diameter tip, for adult,3 pcs/set | 2 | _ | K043A |
| Clip-on limb electrode, 3 mm diameter tip, 4 pcs/set, Fast clip | 1 | _ | H068A |
| Clip-on limb electrode, 4 mm diameter tip, 4pcs/set, Fast clip | 1 | _ | H068B |
| Wireless LAN module | 1 | QI-330D | _ |

System Connection Diagram



It consists of ECG-3150, router (Buffalo WCR-GN or equivalent) and PC (Think pad E420S or equivalent).

- NOTE: The non-medical equipment which router and PC must in compliance with relevant IEC safety standards.
 - The non-medical equipment which router and PC must be the Shanghai Kohden specified.

System specification

- 1. ECG-3150: See the operator's manual.
- 2. Router (Buffalo WCR-GN): See it's manual.
- 3. PC (Think pad E420S): See it's manual.

System installation, assembly, preventive maintenance and modification

The system installation, assembly, preventive maintenance and modification personnel must be Shanghai Kohden technical personnel or the authorized agents.

System cleaning and disinfecting

System cleaning: see the manual for each item.

For ECG-3150 disinfecting, see the operator's manual. The other devices do not need disinfection.

Conditions of use for the system including conditions for transport and storage

See the manual for each item.

MARNING

- The multiple socket-outlet, when provided as a separate item must not be placed on the floor. This may
 cause electric shock.
- Additional multiple socket-outlets or extension cords must not be connected to the system.
- Connect only items that have been specified as part of the system or specified as being compatible with the system.
- Transport only under conditions described in instructions for use or marked on ME EQUIPMENT with an indication of RESIDUAL RISK if ME EQUIPMENT or its parts overbalances.
- NOTE Non-medical equipment must be installed only in the external environment of patients.
 - When installs system, do not use the ECG-3150 if the electrode or patient cable cannot connected to the patient. This may cause electric shock.
 - Assembly of ME SYSTEMS and modifications during the actual service life require evaluation to the requirements of the IEC 60601-1:2012.
 - · Information, including test data, documentation, must comply with local regulations.
 - Information storage must comply with local regulations and requires backup.
 - If there is failure of any equipment in the system, you must stop using the system immediately. The operator should not contact the ECG-3150, patients and non-medical equipment in the meanwhile, this may cause electric shock.
 - The system needs regular cleaning according to the manual for each item to prevent mechanical failure caused by dust.

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Contact information is accurate as of September 2019. Visit https://www.nihonkohden.com/ for the latest information.

The model and serial number of your device are identified on the rear or bottom of the unit.

Write the model and serial number in the spaces provided below. Whenever you call your representative concerning this device, mention these two pieces of information for quick and accurate service.

| Model | Serial Number |
|---------------------|---------------|
| | |
| Your Representative | |
| | |
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| | |

Note for users in the territory of the EEA and Switzerland:

Any serious incident that has occurred in relation to the device should be reported to the European Representative designated by the manufacturer and the Competent Authority of the Member State of the EEA and Switzerland in which the user and/or patient is established



制造商

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