

Electrocardiograph ECG-2250

General

The Shanghai Kohden ECG-2250 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-2250 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.

Safety Information

A DANGER:	A danger alerts the user to a hazardous situation which causes death or serious injury.
A 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.

Pay attention to all safety information in the Operator's Manual or Installation Guide.

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.

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.

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.

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.

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.

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.

No modification of this equipment is allowed.

This device is used for diagnosis only. Do NOT use for monitoring in ICU/CCU or emergency room.

A WARNING

Connect only the specified devices 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 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.

Additional equipment connected to the medical electrical equipment must comply with the respective IEC or ISO standards (e.g. IEC60950 for data processing equipment). Furthermore all configurations shall comply with the requirements for medical electrical systems (see IEC 60601-1-1). 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.

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.

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

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.

When external device doesn't comply with IEC 60601-1, connect a market-sold medical isolation transformer between the external device and AC power socket.

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.

Install the laser printer which is connected to the electrocardiograph outside the patient environment (IEC 60601-1-1). 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.

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

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

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

Never use a local purchase multiple portable socket outlet. Failure to follow this warning may cause electrical shock to the patient and operator.

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.

A WARNING

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.

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 AC 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.

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

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

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

- 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.

- 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.
- Do not use a battery pack which is damaged or dropped. There is a gas release valve inside the battery, and if the valve is damaged due to dropping, etc. the gas won't be released during operation, and this will induce explosion.

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.

Only use the SB-901DC battery pack.

- 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.

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.

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.

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

🗥 WARNING

- 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.

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.

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

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.

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.

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.

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 60601-1-1). 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.

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.

\land WARNING

Only use the BJ-901D/BJ-902D/BJ-903D/BJ-961D/BJ-962D or BA-901D/BA-903D patient cables when using with a defibrillator. When the specified patient cable is connected, the electrocardiograph is type CF defibrillationproof 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.

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-2250, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

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.

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

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

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

- 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.

When connecting an external device to the EXT-IN 1 or 2 connector, ensure that the external device complies with the IEC 60601-1 safety standard for medical equipment or CISPR 11 Section Edition 1990-09, Group 1 and Class B standard. When the external device does not comply with either of these standards, use a local purchase medical use isolation transformer unit between the external device and the AC socket.

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

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

Do not use the electrocardiograph with its side panel down. Failure to follow this instruction may cause the electrocardiograph to fall over or cause battery pack liquid leakage.

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.

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.

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 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.

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.

If the battery pack operation time is less than 15 minutes, the battery pack may be deteriorated. Do not charge a deteriorated battery pack. Charging a deteriorated battery pack may cause the electrocardiograph to fail to operate in both battery pack and AC power.

The SB-901DC 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.

The battery pack must be replaced by qualified service personnel.

Keep the battery pack away from patients and out of the reach of children.

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.

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

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.

When the battery pack is not used for more than 90 days, store the battery pack at temperatures between -20 °C to +30 °C (-4 °F to +86 °F) in a dry place to prevent rusting and leakage.

Charge the battery pack at surrounding 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 $40 \,^{\circ}$ F, the battery pack may leak or heat up. This may damage the battery pack.

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

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

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.

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.

- Only use the Shanghai Kohden specified 110 mm recording paper. When a narrower recording paper is used, 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.

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.

Organic solvents, plasticizers, and office supplies containing these ingredients 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 included. Examples of color-fading materials containing plastics: Erasers, adhesive tapes, and some fluorescent pens.

- 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.
- Clean the thermal head with the thermal head cleaner after every 100 m printing. A dirty thermal head will degrade the printing quality.

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

- Put the SD memory card in the case when the SD memory card is removed from the electrocardiograph. Store it where patients cannot accidently swallow the SD memory card.
- Do not expose the SD memory card 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 SD memory card in a corrosive gas environment.

Do not use recording paper which is contaminated with ECG electrolyte cream 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 apply high pressure to the recording paper. Rubbing or scratching the surface with a hard object discolors it.
- Do not touch the thermal head with your fingers. If accidentally touched, clean the thermal head with the thermal head cleaner pen.

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

The network must be managed by the network administrator. Only the network administrator can change the network settings on the ECG-2250 electrocardiograph and connect the electrocardiograph to the network. Incorrect settings or connection may cause failure of the network system and device.

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

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.

Only use the KD105D/KD-105E cart for this electrocardiograph. If another cart is used, it may tip over or the electrocardiograph may fall off.

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

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.

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.

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.

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.

Use the electrocardiograph in a securely managed environment.

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.

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.

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.

Do not remove the SD memory card or turn the power off while formatting or data is being written to or read from the SD memory card. This may damage the SD memory card or saved data.

Only use a Shanghai Kohden specified SD memory card. Otherwise, the card might not operate.

Only format or write data to the SD memory card in the specified device. Otherwise, the SD memory card may become unusable.

Do not leave the SD memory card near patients or in reach of children.

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

- Insert only a Shanghai Kohden specified SD memory card in the SD card slot.
- Insert or remove the SD memory card straight into or out of the SD card slot.

- · Format the SD memory card before the first use.
- Format the SD memory card only in an ECG-2250 electrocardiograph. SD memory cards formatted in other ECG models cannot be used in this electrocardiograph.

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.

A CAUTION

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

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

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

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.

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.

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.

- 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.

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

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

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

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.

- 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.

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

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

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

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

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

- 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.

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

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

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

This Safety and Performance Information is an extract from the general and safety information sections of the most recent edition of Operator's Manual or Installation Guide. Therefore, the contents of your Operator's Manual or Installation Guide may differ from those of this Safety and Performance Information. For detailed operating procedures, follow the instructions of your Operator's Manual or Installation Guide.

Manufacturer

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