

Electrocardiograph

ECG-3350

General

The Shanghai Kohden ECG-3350 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-3350 is intended to be used by qualified medical personnel within a medical facility, such as hospital or clinic and neonates, children and adults can be diagnosed with this electrocardiograph.

Safety Information

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

⚠ WARNING

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.

⚠ WARNING

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

⚠ WARNING

When the electrocardiograph is used with an electrosurgical unit (ESU), firmly attach the entire area of the ESU return plate to the patient. 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.

⚠ WARNING

Before discharging energy to the patient using the defibrillator, all persons must keep clear of 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.

⚠ WARNING

Before discharging energy to the patient using the defibrillator, remove everything including electrodes, patches and any gel, cream or medicine from the patient. If the paddles contacts these foreign substances, the discharged energy may be insufficient and may cause skin burn to the patient.

⚠ WARNING

When performing an MR examination, remove all electrodes and transducers from the patient which are connected to this electrocardiograph. Failure to follow this warning may cause skin burn on the patient. For details, refer to the MR equipment manual.

⚠ WARNING

Do not bring the electrocardiograph (including components and accessories) into an MR examination room. It may cause the electrocardiograph to stick to MR equipment, malfunction and damage to the MR equipment and skin burn on the patient. For details, follow the instruction in the manual for the MR equipment.

⚠ WARNING

Do not diagnose a patient based only on data acquired by the electrocardiograph. Overall judgement must be performed by a physician who understands the features, limitations and characteristics of the electrocardiograph and by reading the biomedical signals acquired by other devices.

⚠ WARNING

The electrocardiograph handles personal information (patient information). Install the electrocardiograph in an appropriate location where unauthorized persons cannot access the personal information easily.

⚠ WARNING

Do not disassemble or modify the electrocardiograph.

⚠ WARNING

Do not connect the tip of the patient cable to anything other than an electrode. If unconnected cable 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.

⚠ WARNING

Use only the specified patient cables. Otherwise, energy discharged during defibrillation may cause skin burn on the patient or damage to the electrocardiograph.

⚠ WARNING

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

⚠ 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-3350, including cables specified by the manufacturer. If the distance is closer than 30 cm (12 inches), the performance of the ECG-3350 may decrease.

⚠ WARNING

Use of this electrocardiograph adjacent to or stacked with other equipment could result in improper operation. If adjacent or stacked use is necessary, observe the electrocardiograph and the other equipment to verify that they are operating normally.

⚠ WARNING

When the device and/or system is used in an unspecified system configuration different from the configuration used for EMC testing, it may cause increased electromagnetic emissions or decreased electromagnetic immunity.

⚠ WARNING

Do not leave the parts and accessories near the patient or in reach of children. This may lead to an accident such as the patient or child swallowing the parts or accessories.

⚠ WARNING

Do not do the following to the battery pack. It may cause leakage, overheating, explosion and fire.

- Short-circuit the + and – terminals on the battery pack.
- Put the battery pack into fire or heat the battery pack.
- Disassemble or modify the battery pack.
- Give strong impact to or deform the battery pack.
- Use the battery pack on unspecified devices.
- Charge the battery pack on unspecified devices.
- Install the battery pack with the wrong polarity.
- Leave the battery pack in the reach of patients.

⚠ WARNING

If the liquid inside the battery pack contacts the eyes, mouth or skin, do not rub the eyes, mouth or skin. Wash with clean water and see a physician immediately.

⚠ WARNING

The following may cause overheating and leakage of the battery pack.

- Leaving the battery pack unused for a long period (about 1 year)
- Immersing the battery pack in water or sea water or getting it wet

⚠ WARNING

Remove the battery pack from the electrocardiograph when it is not used for more than 1 month. Otherwise the battery pack may leak.

⚠ WARNING

Only use the specified power cord and connect it to a 3-prong AC outlet which is properly grounded. When the specified power cord cannot be used or when equipotential grounding is doubtful (such as in a poorly grounded facility), operate the electrocardiograph on battery power. Otherwise, the patient and operator may receive electrical shock or injury and performance of the electrocardiograph cannot be ensured.

⚠ WARNING

Connect the AC power cord to the AC outlet on the wall. Connecting the AC power cord to a multiple portable socket outlet, extension cord or other device may cause leakage current to flow and the operator or patient may receive electrical shock or injury.

⚠ WARNING

Do not use a USB hub. The patient and operator may receive electrical shock or injury.

⚠ WARNING

Do not use a multiple portable socket outlet. The patient and operator may receive electrical shock or injury.

⚠ WARNING

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

⚠ WARNING

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

⚠ WARNING

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 instruments to a multiple portable socket outlet in the system. Failure to follow this warning may cause leakage current to increase and the patient and operator may receive electrical shock or injury.

⚠ WARNING

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. Otherwise, the patient and operator may receive electrical shock from leakage current from the external device.

⚠ WARNING

Install the non-medical equipment outside the patient environment. If non medical equipment is installed inside the patient environment, the patient or operator may receive electrical shock or injury. Use the specified isolation transformer to supply power to the non-medical equipment if installation inside the patient environment is necessary.

⚠ WARNING

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

⚠ WARNING

Comply with all relevant IEC and ISO standards (e.g. IEC 60950 or IEC 60601-1) when connecting external devices to the electrocardiograph.

⚠ WARNING

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

⚠ WARNING

Install all network devices, including PC and hubs, outside the patient environment. If non medical equipment is installed inside the patient environment, the patient or operator may receive electrical shock or injury. For installation, contact your Nihon Kohden representative.

⚠ WARNING

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

⚠ WARNING

Do not use a wireless LAN network near medical equipment or in a place such as the CCU where radio frequency interference is strictly prohibited. Interference from the wireless LAN network may cause other equipment to malfunction.

⚠ WARNING

Do not install the electrocardiograph near RF devices, such as a microwave oven, bluetooth device, cordless phone, RFID tag, high frequency heating machine, or hyperthermia and microwave surgical device. The electromagnetic radiation from the devices may interfere with the radio communication of the electrocardiograph.

⚠ CAUTION

- The electrocardiograph automatically analyzes ECG. The automatic ECG interpretation is performed for acquired ECG waveforms only and does not reflect the patient's overall condition. 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 confirmation, the analysis results should be signed or initialed by the physician.

⚠ 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.

⚠ CAUTION

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 format, make sure to enter the patient information in the Patient information window.

⚠ CAUTION

Do not use the output signal from the external signal input/output socket of the electrocardiograph as 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 for another device, always consider this time delay.

⚠ CAUTION

To save data to a server, use a system which meets your local regulations and requirements.

⚠ CAUTION

The filter, auto gain and layout of DICOM and PDF data output from the electrocardiograph is different from those on the recording paper.

⚠ CAUTION

The paper cutter in the paper magazine is sharp. When setting the recording paper, be careful not to cut your finger. Set the recording paper as specified in the Operator's Manual.

⚠ CAUTION

Only use a KD-107D/E cart with the electrocardiograph. If another cart is used, it may tip over or the electrocardiograph may fall off.

⚠ CAUTION

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

- Do not ride on the cart.
- Do not lean on the handle or put your weight on the cart.
- Periodically check that the casters rotate smoothly and that the handle, frame and screws are not loose.
- Always lock the casters so that the cart does not move accidentally.

⚠ CAUTION

- Release the wheel stoppers when moving the cart. Do not move the cart with the stoppers locked. The cart may tip over.
- When moving the cart, hold the handle only.
- When moving the cart with a patient cable hanger mounted, fold the upper and lower arms together and fasten the knob nuts so that the arms do not bump into surrounding objects.

⚠ 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.

⚠ CAUTION

Dispose of the electrocardiograph (including the battery pack) according to your local laws and your facility's guidelines for waste disposal. Otherwise, it may affect the environment. If there is a possibility that the product may have been contaminated with infection, dispose of it as medical waste according to your local laws and your facility's guidelines for medical waste. Otherwise, it may cause infection.

⚠ CAUTION

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.

⚠ CAUTION

Do not use or leave the battery pack in direct sunlight or high temperatures such as in a car in hot weather or in front of a stove. It may cause leakage of the battery pack and degrade the performance and lifetime of the battery pack.

⚠ CAUTION

Only use a Shanghai Kohden specified NKB-301V battery pack.

⚠ CAUTION

The battery pack must be replaced by qualified service personnel.

⚠ CAUTION

Do not charge a deteriorated battery pack. Charging a deteriorated battery pack may cause the electrocardiograph to fail to operate on either battery and AC power.

⚠ CAUTION

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, data may be lost or the device may malfunction.

⚠ CAUTION

The network must be managed by the network administrator. Only the network administrator can change the network settings on the electrocardiograph and connect the electrocardiograph to the network. Incorrect settings or connection may cause failure of devices and systems connected to the network.

⚠ CAUTION

Only use the specified wireless LAN module for network connection. Otherwise, test data cannot be transferred correctly.

⚠ CAUTION

To save data to a server, use a system which meets your local regulations and requirements.

⚠ CAUTION

The electrocardiograph communicates with specified systems via the hospital network. Only connect the electrocardiograph to the network in the medical facility.

⚠ CAUTION

To ensure the security of information stored, transmitted or handled by the electrocardiograph, implement the following security measures on any network which the electrocardiograph is connected to.

1. Set up packet filtering of transmissions to and from the network (LS-NET, HIS, LIS etc.) on a firewall or router.
2. Configure the network so that devices connected to the network (LS-NET, HIS, LIS, etc.) can only communicate with external networks, including the Internet, with the permission and under the supervision of an information security manager at your facility.

⚠ CAUTION

Certain data, settings and operations on the electrocardiograph may only be accessed, changed or performed by an administrator with the appropriate authority. Manage the password allocated to the administrator carefully to prevent unauthorized access. Set a password that is difficult to guess and change it regularly.

⚠ 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.

⚠ 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.

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.



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