

Electroencephalograph

EEG-1200K

General

The EEG-1200K electroencephalograph records electroencephalogram and related vital signals and displays the electroencephalogram and vital signals as waveforms.

Safety Information

⚠ 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 instrument 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 instrument in a hyperbaric oxygen chamber. Failure to follow this warning may cause explosion or fire.

WARNING

When the electroencephalograph 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 electroencephalograph, causing electrical burn where the electrodes are attached. For details, refer to the ESU manual.

WARNING

While using an ESU, intracranial electrodes must not be used for monitoring unless no other alternatives are available. If intracranial electrodes are used, whenever possible, disconnect the electrode leads from the amplifier unit or disconnect the cable of the amplifier unit from the mini electrode junction box while using the ESU. Otherwise, current from the ESU might cause skin burn where the electrodes are attached.

WARNING

When using an ESU, do the following. Otherwise, current from the ESU flows into the electrodes and causes skin burn.

- Ensure that there is enough distance between the electrodes and the ESU tip or return plate.
- Ensure that no electrodes are attached near the high frequency current path between the ESU tip and return plate. If the electrodes are too close to the high frequency current path between the ESU tip and the return plate,
 - Disconnect the electrode leads from the amplifier unit.
 - Disconnect the cable of the amplifier unit from the mini electrode junction box.
- During long term monitoring, periodically check that the electrodes are attached properly.

WARNING

Before discharging energy to the patient using the defibrillator, remove from the patient all electrodes and sensors connected to the amplifier unit. If you cannot remove electrodes from the patient, disconnect the electrode leads from the amplifier unit or disconnect the connection cable from the mini electrode junction box. Failure to follow this warning may result in electrical shock to the operator, and cause instrument malfunction.

WARNING

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

WARNING

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

WARNING

Only use the provided power cord and connect it to a 3-pin AC outlet which is properly grounded. Otherwise, it may result in electrical shock or injury to the patient and operator.

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

Do not leave the electrodes which are not attached to the patient connected to the amplifier unit or mini junction box. If the electrode touches metal or a conductive object, the patient may receive electrical shock.

WARNING

Never disconnect the mini electrode junction box cable from the amplifier unit while using the mini electrode junction box. If the connector touches another electrically conductive object, the patient or operator may get electrical shock or injury.

WARNING

Connect only the specified instrument to the electroencephalograph 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.

WARNING

Before connecting or disconnecting the DC input cable to the DC input connector on the amplifier unit, make sure that the power of the external instrument is turned off and DC signal is not output from the external instrument. Otherwise, the patient or operator may receive electrical shock or injury.

WARNING

Always connect the flash lamp assembly cable to the PHOTIC LAMP connector on the photic stimulator control unit. When you do not use the flash lamp assembly or it is disconnected from the photic stimulator control unit, attach the PHOTIC LAMP connector cap to the PHOTIC LAMP connector. When the instrument power is on, about 560 V is present at the PHOTIC LAMP connector on the photic stimulator control unit. Touching the PHOTIC LAMP connector causes electrical shock.

WARNING

When not monitoring SpO₂, disconnect the SpO₂ adapter cable from the amplifier unit. Otherwise, noise from the probe sensor may interfere and incorrect data is displayed on the screen.

WARNING

Connect the electroencephalograph 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

Use external instruments which satisfy the safety standards specified by IEC 60601-1 or IEC 62368-1. Otherwise, the patient or operator may receive electrical shock or injury.

WARNING

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

WARNING

Do not install the QP-0051 system program into a personal computer other than the PC unit of the electroencephalograph.

- If the personal computer does not satisfy the performance specifications and safety standards which are required by Nihon Kohden, the patient and operator may receive electrical shock.
- Nihon Kohden has no responsibility if hardware or software becomes defective after installation.

WARNING

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

WARNING

To use non-medical equipment that requires an isolation transformer, only connect it to a specified isolation unit. 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

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.

WARNING

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 instrument malfunction and electrical shock to the patient and operator.

WARNING

During acquisition, do not touch a connector which is not connected to an electrode. Failure to follow this warning may result in electrical shock or injury to the patient and operator if the other instrument connected to the patient malfunctions.

WARNING

When a mini junction box is not used, make sure that the cover is firmly attached to the multiple connector on the amplifier unit. If the multiple connector is touched by conductive material, the patient or operator may receive electrical shock.

WARNING

Do not perform hyperventilation activation when the patient has serious heart disease, acute cerebrovascular disease or respiratory insufficiency. The action of humoral regulation due to the extremely low CO₂ and high O₂ concentration in the arterial blood causes vasoconstriction and may result in reduced blood flow.

WARNING

- When using with an MRI, use the disk electrodes for MRI and refer to the accompanying document of the disk electrodes for attachment and connection. Otherwise, local heating caused by induced electromotive force may cause skin burn to the patient.
- When using with an MRI, also refer to the MRI manual and follow the instructions

WARNING

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

WARNING

Confirm that the patient is not connected to the instruments when using the neuro checker to check the electroencephalograph. Failure to follow this warning may result in electrical shock or injury to the patient.

WARNING

Do not spill water or chemical solutions on the electroencephalograph while using it. The patient or operator may receive electrical shock or injury. If fluids are accidentally spilled into the electroencephalograph, stop using or inspecting it and contact your Nihon Kohden representative. The electroencephalograph must be disassembled, cleaned, dried and tested for safety, function and performance.

WARNING

Do not use damaged cables. When the damaged part is touched, the patient or operator may receive electrical shock or injury.

WARNING

If an electrode is removed from the patient after attaching electrodes to the patient and connecting them to the amplifier unit or mini electrode junction box, do not touch the metal part of the electrode with bare hands or let a metal part of the electrode contact a metal part of a bed or any other conductive parts. Failure to follow this warning may cause electrical shock or injury to the patient.

CAUTION

Release the caster locks when moving the cart. Do not move the cart with the casters locked. The cart may tip over.

CAUTION

Before connecting or disconnecting instruments, make sure that each instrument is turned off and the power cord is disconnected from the AC outlet. Otherwise it could cause electrical shock or injury to the patient or operator, loss of data, malfunction or instrument failure.

CAUTION

Never check the skin-electrode impedance with the intracranial electrode inserted in the patient. Failure to follow this caution causes electrical burn where electrodes are inserted.

CAUTION

Do not use the flash lamp assembly continuously over 5 minutes. After 5 minutes of continuous use, the flash lamp assembly gets very hot and causes burn if touched.

CAUTION

During photic stimulation and for 30 minutes after the photic stimulation, do not touch the glass of the flash lamp assembly. The glass gets very hot and causes burn if touched.

CAUTION

Before maintenance, cleaning or disinfection, turn the electroencephalograph power off, disconnect the power cord from the AC socket and then remove the electrodes, sensors and probes connected to the electroencephalograph from the patient. Failure to follow this instruction may result in electrical shock and electroencephalograph malfunction.

CAUTION

Only use Nihon Kohden specified options and consumables such as electrodes, sensors, probes and transducers. Otherwise, the maximum performance from the electroencephalograph cannot be guaranteed.

CAUTION

All activation testing must be applied under the supervision of a physician.

CAUTION

Only use the optional LS-120A photic stimulator control unit (maximum light level of 1.28 J) for the electroencephalograph. If you use other instruments, intended examination might not be performed.

CAUTION

Only use the specified cart for the electroencephalograph. If another cart is used, it may tip over or the electroencephalograph may fall off and cause injury.

CAUTION

Never disassemble or repair the electroencephalograph. If there is any problem with the electroencephalograph, contact your Nihon Kohden representative.

CAUTION

When the "CO₂ sensor not working" or "CO₂ adapter abnormality" message is displayed, check the CO₂ sensor kit and replace it if necessary. CO₂ cannot be monitored while the message is displayed.

CAUTION

Do not sit or lean on the cart. It may tip over.

CAUTION

Periodically check that the casters rotate smoothly and that no screws or knob bolt are loose. Otherwise the cart may tip over or the electroencephalograph may fall off.

CAUTION

Consult an ophthalmologist before performing photic stimulation using the visual stimulator adapter on the following patients. An ophthalmic disorder of the patient may become worse.

- Patients with an acute ophthalmic disorder, including postoperative patients after surgery for retinal detachment or glaucoma
- Patients with photophobia or ocular pain

CAUTION

Only install the specified software in the system. Unspecified software may cause the system to malfunction. Nihon Kohden has no responsibility for any problem caused by unspecified software.

CAUTION

Do not sit or put your weight on the keyboard table. If weight is placed on the table, it may break or the cart may tip over, causing injury.

CAUTION

Be careful not to pinch your fingers between the PC unit, control unit, isolation unit and cart.

CAUTION

When the probe is attached on an appropriate site with sufficient circulation and an error message about probe attachment repeatedly appears, the probe may be deteriorated. Replace it with a new one.

CAUTION

When using a mini electrode junction box or headcap EEG electrode kit with the electroencephalograph, do not connect electrode leads to the amplifier unit. This may cause problems such as distorted waveforms.

CAUTION

When using the instrument for brain death diagnosis, before examination, check and adjust the date and time of the system. The date and time on the screen and recording result are part of important information for the medical record.

CAUTION

Do not connect unspecified USB devices such as USB memory to this instrument because the device may have a computer virus.

CAUTION

Dispose of Nihon Kohden products 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

Create a security policy for the facility to manage the electroencephalograph in accordance with the laws and regulations of the country in which the facility is located. Use the electroencephalograph in an environment in which personal data is securely protected.

CAUTION

Observe all terms and conditions of the information security policy for the electroencephalograph. To protect personal information and device functionality from external and internal threats, the facility where the electroencephalograph is installed is required to implement a comprehensive and multi-layered security strategy (including policies, procedures and technologies).

CAUTION

Some data and operations on the electroencephalograph can be set, changed or managed only by a user with administrator privileges. When using the electroencephalograph for the first time, change the default administrator password to a password that is difficult to guess and store it securely to prevent security breaches.

CAUTION

After the cart is installed, lock the casters and do not move the cart. Otherwise, the cart may tip over or the devices mounted on the cart may fall off.

CAUTION

- If a photoparoxysmal response occurred, stop the stimulation immediately to avoid induction of paroxysm. Especially a patient with photosensitive seizure may react to the low brightness photic stimulation sensitively when using the visual stimulator adapter.
- A patient with photomyoclonic response may feel severely uncomfortable with photic stimulation. Interrupt or stop the stimulation in that case.

CAUTION

Do not use the electroencephalograph for monitoring a patient or life support. The electroencephalograph does not have an alarm function. If the electroencephalograph is used for monitoring, the patient condition might not be diagnosed correctly. For monitoring a patient, use monitoring equipment such as a bedside monitor.

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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