

EEG Amplifier Unit

JE-940A

General

The JE-940A EEG amplifier unit connects to an electroencephalograph for use in general EEG examinations, long term EEG recording (epilepsy EEG monitoring) and PSG testing.

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.

⚠ DANGER

If the liquid leaked from the battery pack contacts the eyes, mouth, or skin, do not rub. Flush with plenty of clean water and see a physician immediately.

⚠ WARNING

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

⚠ WARNING

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

⚠ 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 EEG amplifier unit.
 - Disconnect the electrode junction box cable 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 this EEG amplifier unit. If you cannot remove electrodes from the patient, disconnect the electrode leads from the EEG 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 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

Do not bring the EEG amplifier unit (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

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 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

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

⚠ WARNING

Never disconnect the mini electrode junction box cable from the EEG 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

Do not touch the patient while touching the sockets of the USB conversion adapter or LAN conversion adapter. The patient and operator may receive an electrical shock or injury.

⚠ WARNING

If an electrode is removed from the patient after attaching electrodes to the patient and connecting them to the EEG 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.

⚠ WARNING

Do not touch the metal parts of the electrodes and sensors with bare hands or let the metal parts of the electrodes and sensors contact the metal parts of the bed or any other conductive parts while the EEG amplifier unit is operating. Failure to follow this warning may cause electrical shock or injury to the patient.

⚠ WARNING

Connect only the specified instruments to the EEG amplifier unit and follow the specified procedure. Failure to follow this warning may result in electrical shock or injury to the patient and operator.

⚠ WARNING

- When using the finger probe, do not fasten the probe and cable to the finger by wrapping with tape. This may cause burn, congestion or skin problems from poor blood circulation.
- When using probes other than the finger probe, to avoid poor circulation, do not wrap the tape too tight. Check the blood circulation condition by observing the skin color and congestion at the skin peripheral to the probe attachment site. Even for short-term monitoring, there may be burn or skin problems from poor blood circulation, especially on neonates or low birth weight infants whose skin is delicate. Accurate measurement cannot be performed on a site with poor peripheral circulation.

⚠ WARNING

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

⚠ WARNING

Before connecting or disconnecting the DC input cable to the DC input socket on the EEG 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

Failure to follow the warnings below may cause overheating, explosion or leakage.

- Do not mix old (or used) and new batteries.
- Do not mix different brands or types of batteries.
- Replace the four batteries at the same time.

⚠ WARNING

Install the batteries with the correct polarity. Otherwise measurements cannot be performed during battery operation. Installing the batteries incorrectly may also cause leakage, overheating, explosion or fire.

⚠ WARNING

Do not handle the batteries with wet hands. If a wet battery is installed, it may cause overheating, fire or leakage.

⚠ WARNING

Do not use damaged batteries. The patient or operator may get skin burn or injury due to short-circuit, overheating or leakage.

⚠ WARNING

Use alkaline batteries or NiMH batteries. If unspecified batteries are used, the batteries may overheat and the patient or operator may receive skin burn.

⚠ WARNING

Only use Nihon Kohden specified options such as electrodes, sensors and probes and use the options in the method specified by Nihon Kohden. If unspecified options are used or Nihon Kohden specified options are used in unspecified ways, maximum safety and performance from the EEG amplifier unit might not be achieved.

⚠ WARNING

Do not modify the EEG amplifier unit. Modification may cause heat, fire, skin burn or electrical shock.

⚠ WARNING

Check the circulation condition by observing the skin color at the measurement site and pulse waveform. Change the measurement site every 8 hours for disposable probes and every 4 hours for reusable probes. The skin temperature may increase at the attached site by 2 or 3°C (4 or 5°F) and cause a burn or skin problems. When using the probe on the following patients, take extreme care and change the measurement site more frequently according to symptoms and degree.

- Elderly patient
- Unconscious patient
- Patient with a fever
- Patient with insufficient peripheral circulation
- Neonate or low birth weight infant

⚠ WARNING

When monitoring SpO₂ of a patient who is receiving photodynamic therapy, the light from the probe sensor may cause a burn where the probe is attached. Photodynamic therapy uses a photosensitizing agent that may cause photosensitive side effects.

⚠ WARNING

SpO₂ measurement may be incorrect in the following cases.

- When the patient's carboxyhemoglobin or methemoglobin increases abnormally.
- When dye is injected in the blood.
- When using an electrosurgical unit.
- During CPR.
- When measuring at a site with venous pulse.
- When there is body movement.
- When the pulse wave is small (insufficient peripheral circulation).

⚠ WARNING

When not measuring SpO₂, disconnect the SpO₂ connection cord from the EEG amplifier unit. Otherwise, noise may interfere with measurement and cause an incorrect result to be displayed.

⚠ WARNING

Remove the batteries from the EEG amplifier unit when it is not going to be used for a long time. Otherwise the battery may leak.

⚠ 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 spill water or chemical solutions on the EEG amplifier unit while using it. The patient or operator may receive electrical shock or injury. If fluids are accidentally spilled into the EEG amplifier unit, stop using or inspecting it and contact your Nihon Kohden representative. The EEG amplifier unit must be disassembled, cleaned, dried and tested for safety, function and performance.

⚠ 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 damaged cables. When the damaged part is touched, the patient or operator may receive electrical shock or injury.

⚠ WARNING

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

⚠ WARNING

Close the battery cover when using the EEG amplifier unit. If the EEG amplifier unit is used with the battery cover open, the patient may receive an electrical shock or injury.

⚠ WARNING

Do not use a multiple portable socket outlet or extension cord. This may cause leakage current to flow and the operator or patient may receive electrical shock or injury.

⚠ WARNING

If the EEG amplifier unit is damaged, stop using it and do not touch it. The patient or operator may receive electrical shock.

⚠ WARNING

When carrying the EEG amplifier unit during measurement, attach the strap provided with the battery unit to the EEG amplifier unit. Otherwise the EEG amplifier unit may fall off and the patient may get injured, or the EEG amplifier unit may malfunction.

⚠ WARNING

When carrying the EEG amplifier unit with no main cable connected, attach the cover to the JUNCTION BOX socket on the EEG amplifier unit. If the JUNCTION BOX socket is touched by conductive material, the patient may receive electrical shock or injury.

⚠ WARNING

Connecting or disconnecting the main cable or DC input cable must be done by an operator. If a patient touches the connectors, the patient may receive an electrical shock or injury.

⚠ WARNING

When a mini electrode junction box is not used, attach the cover to the JUNCTION BOX socket on the EEG amplifier unit. If the JUNCTION BOX socket is touched by conductive material, the patient may receive electrical shock or injury.

⚠ 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

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

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

⚠ WARNING

- When using with an MR equipment, use disk electrodes for MR equipment 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 MR equipment, also refer to the MR equipment manual and follow the instructions.

⚠ WARNING

Do not cover the EEG amplifier unit with a blanket. This causes the EEG amplifier unit to heat up and it may cause skin burn on the patient.

⚠ CAUTION

Do not use a probe which is deteriorated by aging. Accurate measurement cannot be performed. Replace the probe approximately 1 year after the date of first use.

⚠ CAUTION

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

⚠ CAUTION

Use alkaline batteries or NiMH batteries. If small capacity batteries or high voltage batteries are used, maximum safety and performance from the EEG amplifier unit might not be achieved. Also they may cause the EEG amplifier unit to malfunction.

⚠ CAUTION

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

⚠ CAUTION

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

⚠ CAUTION

If the attachment site is dirty with blood or bodily fluids, clean the attachment site before attaching the probe. If there is nail polish on the attachment site, remove the polish. Otherwise, the amount of transmitted light decreases, and measured value may be incorrect or measurement cannot be performed.

⚠ CAUTION

When measuring SpO₂ under strong light such as surgical light or sunlight, cover the measuring site with a blanket to block the light. Otherwise measurement accuracy may be affected.

⚠ CAUTION

When measuring SpO₂ for a long period of time, use the TL-271T, TL-272T, TL-273T or TL-274T SpO₂ probe.

⚠ CAUTION

Only use the provided or specified screws to fasten devices. Make sure that the screws are securely tightened. If screws are loose, devices may fall off and the patient or operator may get injured.

⚠ CAUTION

Install the EEG amplifier unit securely as specified by Nihon Kohden. Otherwise the EEG amplifier unit may fall off and the patient or operator may get injured or the EEG amplifier unit may malfunction.

⚠ CAUTION

Do not use the provided JE holder to hold any device other than a JE-940A EEG amplifier unit. The device may fall off and cause injury.

⚠ 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

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

⚠ CAUTION

To prevent the cart from tipping over or the EEG amplifier unit falling off the cart:

- Do not put or hook anything on the pole.
- Do not ride on the cart.
- Do not lean on the pole or put your weight on the cart.
- Make sure that the cart is on a flat surface which is not sloped.
- Always lock the casters so that the cart does not move accidentally.

⚠ CAUTION

Do not put heavy objects in the tray or basket. The cart may tip over or the tray or basket may be damaged or fall off.

⚠ CAUTION

Periodically check that the casters rotate smoothly and that no screw or knob bolt is loose. Otherwise the cart may tip over or the EEG amplifier unit 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

- 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

If photo-paroxysmal response appears during photic stimulation, immediately stop the stimulation to prevent evoking seizure in the patient.

⚠ CAUTION

Do not attach the probe to the same limb that is used for NIBP measurement or an IBP catheter. The SpO₂ measurement may be incorrect.

⚠ CAUTION

When adding an EEG amplifier unit to an already operating network, set the IP address immediately. Otherwise, the default setting is used and the patient may be incorrectly identified.

⚠ 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 the probe is off or not attached to the patient properly, a message other than "CHECK PROBE" may appear and an incorrect measurement value may be displayed.

⚠ CAUTION

Do not get the SpO₂ adapter wet with water or chemical solution. Do not use the EEG amplifier unit when the SpO₂ adapter is wet. Correct measurement data might not be obtained. If there is a possibility that the SpO₂ adapter may come into contact with a chemical solution, install the EEG amplifier unit so that the SpO₂ socket of the unit in a vertical and downward position.

⚠ CAUTION

If the SpO₂ adapter is wet, dry it thoroughly before using it. If fluids are accidentally spilled into the EEG amplifier unit, stop using or inspecting it and contact your Nihon Kohden representative.

⚠ CAUTION

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

⚠ CAUTION

- Use the specified holder and cart and install the EEG amplifier unit on the cart securely as specified by Nihon Kohden. Otherwise the EEG amplifier unit may fall off and the patient or operator may get injured, or the EEG amplifier unit may malfunction.
- If the specified cart is not used, install the EEG amplifier unit where it cannot fall on the patient or operator. Otherwise the EEG amplifier unit may fall off and the patient or operator may get injured, or the EEG amplifier unit may malfunction.

⚠ CAUTION

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

⚠ CAUTION

Keep the patient away from the cable as much as possible. Otherwise the patient may get tangled in the cable and get injured. If the cable coils around the patient, remove the cable promptly.

⚠ 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

For handling and precautions on options and consumables such as electrodes, sensors and probes, refer to the manual of the option or consumable.

⚠ CAUTION

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

⚠ CAUTION

Observe all terms and conditions of the information security policy for the EEG amplifier unit. To protect personal information and device functionality from external and internal threats, the facility where the unit 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 EEG amplifier unit can be set, changed or managed only by a user with administrator privileges. During initial setup, a window may appear requiring the default password to be changed. Set a password for the administrator that is difficult to guess and store it securely to prevent security breaches.

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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