SAFETY AND PERFORMANCE INFORMATION

NIHON KOHDEN

Wireless Input Unit
WEE-1200

General

The WEE-1200 wireless input unit is a system that can be used in routine EEG testing, epilepsy monitoring, or PSG testing to send the measured EEG waves, ECG waves, EMG waves, and respiration waves from the electrodes to the electroencephalograph by wired or wireless LAN. The electrodes are connected to a mini junction box which is connected to the telemetry unit which is worn by the patient or placed near the patient.

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

⚠ DANGER

Failure to observe any of the following may cause battery pack malfunction, overheating, explosion or fire.

- Do not immerse the battery pack in liquid or get it wet.
- Do not leave the battery pack near a heat source such as a stove.
- Do not charge the battery pack on unspecified instruments.
- Do not charge the battery pack in conditions outside the specified environment (over 35°C (95°F)).
- Do not put the battery pack into fire or heat it.
- Do not short-circuit the + and – terminals on the battery pack.
- Do not give strong impact to or deform the battery pack.
- Do not install the battery pack in unspecified instruments.
- Do not disassemble or modify the battery pack.
- Do not charge the battery pack in a high temperature place such as near a stove or in sun-heated cars.

⚠ WARNING

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

⚠ WARNING

When the wireless input unit is used with an ESU, firmly attach the entire area of the ESU return plate. Otherwise, the current from the ESU flows into the electrodes of the wireless input 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 electrode junction box.
- During long term monitoring, periodically check that the electrodes are attached properly.

⚠ WARNING

While using an ESU, needle electrodes, silver ball electrodes and intracranial electrodes must not be used for monitoring unless no other alternatives are available. If needle electrodes, silver ball electrodes and intracranial electrodes are used, whenever possible, disconnect cables of the breakout boxes from the amp unit while using the ESU. Otherwise, current from the ESU might cause skin burn where the electrodes are attached.

⚠ WARNING

Before defibrillation, remove all electrodes and transducers from the patient. If you cannot remove electrodes from the patient, disconnect the electrode leads from the electrode junction box or disconnect the mini flat junction box cable from the electrode junction box. Failure to follow this warning may result in electrical shock to the operator, and cause instrument malfunction.

⚠ WARNING

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.

⚠ WARNING

Before defibrillation, 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

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 electrode junction box. If the electrode touches metal or a conductive object, the patient may receive electrical shock.

⚠ WARNING

Never disconnect the cables from the wireless input unit while the wireless input unit is operating or touch the connector pins with bare hands while the wireless input unit is connected to the patient. If the connector touches another electrically conductive object, the patient and operator may receive electrical shock.

⚠ WARNING

After attaching the electrodes to the patient and connecting the cables to the electrode junction box, check that the electrodes are attached to the patient and check that the cable is connected to the electrode juction box properly. When the electrodes are removed from the patient, do not touch the metal part of the electrode with bare hands or let the metal part of the electrode contact the metal part of the bed or any other conductive parts. Failure to follow this warning may cause electrical shock or injury to the patient by discharged energy.

⚠ WARNING

Do not touch the metal part of the electrode with bare hands or let the metal part of the electrode contact the metal part of the bed or any other conductive parts while the wireless input unit is operating. Failure to follow this warning may cause electrical shock or injury to the patient by discharged energy.

⚠ WARNING

Connect only the specified instrument to the wireless input unit 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

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 and 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 and the power cord is disconnected from the AC socket. Otherwise, the patient or operator may receive electrical shock. Also, it may cause malfunction or instrument failure.

⚠ WARNING

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

⚠ WARNING

Only use Nihon Kohden specified options such as electrodes, sensors, probes and transducers and follow the specified procedure. Otherwise, maximum performance from the wireless input unit cannot be satisfied and the patient or operator may receive electrical shock.

⚠ WARNING

Do not use the wireless input unit near RF devices, such as a microwave oven, bluetooth device, cordless phone, RF-ID tag, high frequency heating machine, or hyperthermia and microwave surgical equipment. The electromagnetic radiation from the devices may interfere with the radio communication of the wireless input unit.

⚠ 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 pressure necrosis. When using the probe on the following patients, take extreme care and change the measurement site more frequently according to symptoms and degree.

- Patient with a fever
- Patient with insufficient peripheral circulation
- Neonate or low birth weight infant with delicate skin

⚠ WARNING

When monitoring SpO_2 of a patient who is receiving photodynamic therapy, the light from the finger probe sensor may cause a burn. Photodynamic therapy uses a photosensitizing agent that has a side effect of photosensitivity.

⚠ WARNING

SpO_2 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 monitoring SpO_2, disconnect the SpO_2 adapter from the telemetry unit. Otherwise, noise from the probe sensor may interfere and cause incorrect data to be displayed on the telemetry unit LCD display or electroencephalograph screen.

⚠ WARNING

Connect all the DIN connectors of the electrodes to the electrode junction box. Failure to follow this warning may result in electrical shock or injury to the patient and operator because the electroconductive part of unconnected DIN connectors is exposed.

⚠ WARNING

Remove the batteries from the telemetry unit and extension unit if they will not be used for three months or more. Otherwise the batteries may leak.

⚠ WARNING

Connect the wireless input unit to 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 the wireless LAN access point outside the patient environment. If it is installed inside the patient environment, the patient and operator may receive electrical shock or injury. For installation, contact your Nihon Kohden representative.

⚠ WARNING

Install all network devices, including printer and hubs, outside the patient environment. 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

Use external instruments which satisfies the safety standards specified by IEC 60601-1. When using external instruments which do not satisfy the safety standards, install the instruments outside the patient environment. If they are installed inside the patient environment, the patient or operator may receive electrical shock or injury.

⚠ WARNING

Install the peripheral devices (options) outside the patient environment. If they are installed inside the patient environment, the patient or operator may receive electrical shock or injury.

⚠ WARNING

Do not directly connect the wireless LAN access point to the medical instrument. If the wireless LAN access point is directly connected, the patient and operator may receive electrical shock or injury.

⚠ WARNING

If fluids are accidentally spilled into the wireless input unit, take the wireless input unit out of service and contact your Nihon Kohden representative. The wireless input unit must be disassembled, cleaned, dried and tested for safety and function.

⚠ WARNING

Do not install the wireless input unit where it will be exposed to water or chemical solutions. The patient or operator may receive electrical shock.

⚠ 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 use a damaged telemetry unit connection cable. The patient or operator may receive electrical shock when the damaged part is touched.

⚠ WARNING

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

⚠ WARNING

To operate the wireless LAN system, assign a system administrator. The system must be used under the supervision of the system administrator according to the hospital protocol.

⚠ 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

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 or damaged or contacts liquid, it may cause instrument malfunction and electrical shock to the patient and operator.

⚠ WARNING

If the case of the instrument is damaged, stop using it and contact your Nihon Kohden representative for repair. Failure to follow this caution may cause electrical shock or injury to the patient and operator.

⚠ WARNING

Check the software version number of the wireless input unit before connecting it to the network. Different software versions have different communication methods. More than one communication method in a network may cause communication failure.

⚠ 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 another instrument connected to the patient malfunctions.

⚠ 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 take the wireless input unit into an MRI test room. The wireless input unit is not designed to be used during MRI tests.

⚠ WARNING

Before disposing of the wireless input unit, remove the batteries from the telemetry unit and extension unit. Otherwise, the person who disposes of the wireless input unit may receive an electric shock.

⚠ WARNING

When uninterrupted monitoring of a patient at the electroencephalograph is required, use a wired LAN instrument to monitor the patient. Wireless LAN can be interrupted by various causes and is less reliable than wired LAN.

⚠ WARNING

When attaching the wireless input unit to the patient during measurement, always put the telemetry unit and electrode junction box into the pouch provided with the wireless input unit. Otherwise, the wireless input unit may fall off and cause electrical shock to the patient or operator.

⚠ WARNING

Cables and connectors must only be connected and removed by the operator. Do not touch the connectors during measurement. Otherwise, the patient or operator may receive electrical shock or injury.

⚠ WARNING

When using the telemetry unit in wireless connection mode, close the cover of the main unit/extension unit socket on the telemetry unit. If the socket is touched by a conductive material, the patient or operator may receive electrical shock.

⚠ WARNING

Connect the main unit to an uninterruptible power supply or the emergency power supply of the hospital.

⚠ WARNING

When using the wireless input unit on patients with pacemakers, ICDs, cochlea implants, neurostimulators or other active implanted devices, observe the following precautions.

- Do not conduct impedance checks using the wireless input unit on patients with active implanted devices. The current used by the wireless input unit for impedance checks is very small but it may cause implanted devices to malfunction due to electromagnetic interference.
- Keep the wireless input unit as far as possible from the implanted devices. The transmission RF power of the wireless input unit is lower than that of a mobile phone but it may cause implanted devices to malfunction due to electromagnetic interference.
- Check the accompanying documentation of the implanted devices before using the wireless input unit, to determine whether any conditions exist which prevent the wireless input unit from being used with those devices.

⚠ CAUTION

Never disassemble or repair the wireless input unit. If there is any problem with the wireless input 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 the measured value may be incorrect or measurement cannot be performed.

⚠ CAUTION

Normal external light does not affect measuring accuracy but strong light such as a surgical light or sunlight may affect measuring accuracy. If affected, cover the measuring site with a blanket.

⚠ CAUTION

Connect only the specified instrument to the wireless input unit and follow the specified procedure. Failure to follow this instruction may result in the device malfunction, skin burn on the patient or data loss.

⚠ CAUTION

If the battery pack is damaged and the substance inside the battery pack contacts the skin or cloth, wash immediately with clear water. The skin may get irritated.

⚠ CAUTION

Keep the battery packs away from patients.

⚠ CAUTION

Keep the battery packs away from patients.

⚠ CAUTION

Do not use sub-dermal straight needle electrodes for more than one hour as a measurement electrode for EEG or evoked potential measurement. When measuring EEG or evoked potential for over one hour, use EEG disk electrodes.

⚠ CAUTION

Never check the skin-electrode impedance while a needle electrode or intracranial electrode is inserted in the patient. Failure to follow this caution causes burn at the electrode site, deterioration of the electrodes, or an electrode breaking and remaining in the body.

⚠ CAUTION

Turn off the power of mobile phones, small wireless devices and other devices which produce strong electromagnetic interference around a patient (except for devices allowed by the hospital administrator). Radio waves from devices such as mobile phones or small wireless devices may be mistaken as pulse waves and the displayed data may be incorrect.

⚠ CAUTION

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

⚠ CAUTION

Install the wireless input unit as specified. The wireless input unit may fall off and the patient or operator may get injured.

⚠ CAUTION

Use the YS-004A9 tool set and a flat-blade screwdriver for cart assembly.

⚠ CAUTION

After mounting the wireless input unit on the cart, confirm that the wireless input unit is securely locked. If the wireless input unit is not locked, it may fall off.

⚠ CAUTION

When moving the cart:

- Release the caster locks. Do not move the cart with the casters locked. The cart may tip over.
- Hold the handle only.

⚠ CAUTION

To prevent the cart from tipping over or the wireless input unit falling off the cart:

- Do not put or hook anything on the handle or pole.
- Do not ride on the cart.
- Do not lean on the handle 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 basket. The cart may tip over and the basket may fall off.

⚠ CAUTION

Periodically check that the caster rotates smoothly and that no screw or knob bolt is loose. Otherwise the cart may tip over or the wireless input unit may fall off.

⚠ CAUTION

Do not measure SpO_2 with the probe attached to a finger or toe where there is an NIBP cuff or an IBP catheter on the arm or leg. Otherwise, the blood circulation at the probe attachment site is affected and measurement may be inaccurate. Attach the probe to the part such as a finger or toe where there is no change in peripheral blood circulation.

⚠ CAUTION

The network must be managed by the network administrator. Make sure that each instrument in the network has a different IP address. Otherwise, data communication cannot be performed properly.

⚠ CAUTION

Do not get the SpO_2 adapter wet with water or chemical solution. Do not use the wireless input unit when connectors are wet. Correct measurement data might not be obtained.

⚠ CAUTION

- Use the specified cart for installing the wireless input unit. Follow the procedure in the cart manual.
- If a specified cart is not used, install the wireless input unit where it cannot fall on the patient or operator. Otherwise the patient or operator may be injured.

⚠ CAUTION

When the wireless input unit is connected to the existing network, immediately change the IP address and SSID on the telemetry unit. Otherwise, the default settings are used for the IP address and SSID, and the patient may be incorrectly identified on the electroencephalograph.

⚠ CAUTION

Do not use a damaged, disassembled, modified or faulty probe. It causes incorrect measurement and may injure the patient.

⚠ CAUTION

The network must be managed by the network administrator. Only the network administrator can change the network settings on the wireless input unit and connect the wireless input unit to the network. Incorrect settings or connection may cause failure of the network system and instrument.

⚠ CAUTION

Do not leave the battery pack in direct sunlight or high temperatures such as in a sun-heated car. This may cause leakage of the battery pack, degrade its performance and make it unusable.

⚠ CAUTION

Do not use the wireless input unit for monitoring a patient or life support. The wireless input unit does not have an alarm function. If the wireless input 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

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

⚠ 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

While a patient is on medication which causes vasodilation, the pulse waveform may change and in rare cases the SpO_2 value might not be displayed.

⚠ CAUTION

To prevent the patient from touching the telemetry unit and electrode junction box, when attaching the wireless input unit to the patient during measurement, always put the telemetry unit and electrode junction box into the pouch provided with the wireless input unit. The temperature of the units increases during measurement and may cause skin burns if they directly touch the patient. Also, if the units are not inside the pouch, they may fall off and injure the patient.

⚠ 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

When using a wireless LAN system, be aware that signal loss and artifact may occur because of multipath cancellation or frequency interference caused by the same frequency signals of other wireless LAN devices.

⚠ CAUTION

When monitoring SpO_2 only, detection of arrhythmia and asystole is not available and arrhythmia alarms such as ASYSTOLE, VF or VT are not available. If the patient requires ECG monitoring, monitor the ECG.

⚠ CAUTION

If the patient requires respiration monitoring, monitor the respiration. Oxygen saturation (SpO_2) is measured by pulse oximetry which cannot be used for respiration monitoring.

⚠ CAUTION

Some data and operations on the wireless input 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.

⚠ CAUTION

Observe all terms and conditions of the information security policy for the wireless input 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

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

⚠ CAUTION

Charge the extension unit outside the patient environment. The extension unit becomes hot during charging and may cause skin burn on the patient if it is directly touched.

⚠ CAUTION

Do not touch the main unit while it is operating. This may cause skin burn on the patient or operator because the main unit temperature increases during use.

⚠ CAUTION

Do not cover the telemetry unit and extension unit with a blanket or cloth. The temperature of the units may increase and cause skin burn on the patient.

⚠ CAUTION

Use the wireless input unit in a place that satisfies the operating environment conditions. The temperature of the wireless input unit increases during measurement. Touching it may cause skin burn on the patient.

⚠ CAUTION

- Only use the specified holder and follow the specified procedure.
- Only use the provided or specified screws to fasten the holder. Make sure that the screws are securely tightened. If screws are loose, the instrument may fall off and the patient or operator may get injured.
- Periodically check that no screws are loose. Otherwise the instrument may fall off.
- Attach the holder to the following sizes of rails or boards.
  - Round rail: 18 to 40 mm in diameter
  - Square rail: 25 to 40 (H) × 10 (D) mm
  - Board (head board, desk, etc.): 18 to 40 mm in thickness

  Otherwise, the instrument may fall off.

⚠ CAUTION

Do not let the holder or knob touch the patient's head when attaching the holder to a bed rail or other equipment. The patient may get injured.

⚠ CAUTION

- Do not mount a device other than the WEE-1200 wireless input unit onto the DH-120A holder.
- Do not lean on or put weight on the holder. The holder may be damaged or fall off and cause injury to the patient or operator.

⚠ CAUTION

Do not let the SpO_2 adapter touch the patient skin while using the adapter. The adapter temperature rises 1 to 7°C (4 to 13°F) during use and may cause burn to the patient.

⚠ CAUTION

When using more than one access point, set the access points so the channels do not interfere with each other.

⚠ CAUTION

When using a DFS supported channel, fully understand the access point operation when the access point detects radar waves and construct the wireless LAN system accordingly. Otherwise, the wireless communication may be interrupted when radar waves are detected.

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
NIHON KOHDEN CORPORATION
1-31-4 Nishiochiai, Shinjuku-ku,
Tokyo 161-8560, Japan
Phone +81 3-5996-8041
https://www.nihonkohden.com/

EC REP European Representative
NIHON KOHDEN EUROPE GmbH
Raiffeisenstrasse 10, 61191 Rosbach, Germany
Phone +49 6003-827-0 Fax +49 6003-827-599

1st Edition: 02 Jul 2026

CE 2797