OPERATOR'S MANUAL

WIRELESS INPUT UNIT

WEE-1000A

Contents

GENERAL HANDLING PRECAUTIONS

This device is intended for use only by qualified medical personnel.
Use only Nihon Kohden approved products with this device. Use of non-approved products or in a non-approved manner may affect the performance specifications of the device. This includes, but is not limited to, batteries, recording paper, pens, extension cables, electrode leads, input boxes and AC power.

Please read these precautions thoroughly before attempting to operate the instrument.

1. **To safely and effectively use the instrument, its operation must be fully understood.**

2. **When installing or storing the instrument, take the following precautions:**
   (1) Avoid moisture or contact with water, dust, extreme atmospheric pressure, excessive humidity and temperatures, poorly ventilated areas, and saline or sulphuric air.
   (2) Place the instrument on an even, level floor. Avoid vibration and mechanical shock, even during transport.
   (3) Avoid placing in an area where chemicals are stored or where there is danger of gas leakage.
   (4) The power line source to be applied to the instrument must correspond in frequency and voltage to product specifications, and have sufficient current capacity.
   (5) Choose a room where a proper grounding facility is available.

3. **Before Operation**
   (1) Check that the instrument is in perfect operating order.
   (2) Check that the instrument is grounded properly.
   (3) Check that all cords are connected properly.
   (4) Pay extra attention when the instrument is in combination with other instruments to avoid misdiagnosis or other problems.
   (5) All circuitry used for direct patient connection must be doubly checked.
   (6) Check that battery level is acceptable and battery condition is good when using battery-operated models.

4. **During Operation**
   (1) Both the instrument and the patient must receive continual, careful attention.
   (2) Turn power off or remove electrodes and/or transducers when necessary to assure the patient's safety.
   (3) Avoid direct contact between the instrument housing and the patient.

5. **To Shutdown After Use**
   (1) Turn power off with all controls returned to their original positions.
   (2) Remove the cords gently; do not use force to remove them.
   (3) Clean the instrument together with all accessories for their next use.

6. **The instrument must receive expert, professional attention for maintenance and repairs. When the instrument is not functioning properly, it should be clearly marked to avoid operation while it is out of order.**

7. **The instrument must not be altered or modified in any way.**

8. **Maintenance and Inspection:**
   (1) The instrument and parts must undergo regular maintenance inspection at least every 6 months.
   (2) If stored for extended periods without being used, make sure prior to operation that the instrument is in perfect operating condition.

(3) Technical information such as parts list, descriptions, calibration instructions or other information is available for qualified user technical personnel upon request from your Nihon Kohden distributor.

9. **When the instrument is used with an electrosurgical instrument, pay careful attention to the application and/or location of electrodes and/or transducers to avoid possible burn to the patient.**

10. **When the instrument is used with a defibrillator, make sure that the instrument is protected against defibrillator discharge. If not, remove patient cables and/or transducers from the instrument to avoid possible damage.**

WARRANTY POLICY

Nihon Kohden Corporation (NKC) shall warrant its products against all defects in materials and workmanship for one year from the date of delivery. However, consumable materials such as recording paper, ink, stylus and battery are excluded from the warranty.

NKC or its authorized agents will repair or replace any products which prove to be defective during the warranty period, provided these products are used as prescribed by the operating instructions given in the operator's and service manuals.

No other party is authorized to make any warranty or assume liability for NKC's products. NKC will not recognize any other warranty, either implied or in writing. In addition, service, technical modification or any other product change performed by someone other than NKC or its authorized agents without prior consent of NKC may be cause for voiding this warranty.

Defective products or parts must be returned to NKC or its authorized agents, along with an explanation of the failure. Shipping costs must be pre-paid.

This warranty does not apply to products that have been modified, disassembled, reinstalled or repaired without Nihon Kohden approval or which have been subjected to neglect or accident, damage due to accident, fire, lightning, vandalism, water or other casualty, improper installation or application, or on which the original identification marks have been removed.

In the USA and Canada other warranty policies may apply.

CAUTION

United States law restricts this device to sale by or on the order of a physician.

FCC Part 15 Subpart B Class B

NOTICE

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.
This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- **Reorient or relocate the receiving antenna.**
- **Increase the separation between the equipment and the receiver.**
- **Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.**
- **Consult the dealer or an experienced radio/TV technician for help.**

FCC WARNING

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Properly shielded an grounded cables and connectors must be used for connection to host computer and/or peripherals in order to meet FCC emission limits.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:
(1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

FCC Radiation Exposure Statement

Telemetry Unit (ZB-101AA):

The available scientific evidence does not show that any health problems are associated with using low power wireless devices. There is no proof, however, that these low power wireless devices are absolutely safe. Low power Wireless devices emit low levels of radio frequency energy (RF) in the microwave range while being used. Whereas high levels of RF can produce health effects (by heating tissue), exposure to low level RF that does not produce heating effects causes no known adverse health effects. Many studies of low level RF exposures have not found any biological effects. Some studies have suggested that some biological effects might occur, but such findings have not been confirmed by additional research. The Telemetry Unit (ZB-101AA) has been tested and found to comply with the Federal Communications Commission (FCC) guidelines on radio frequency energy (RF) exposures. The maximum SAR levels tested for the Telemetry Unit (ZB-101AA) has been shown to be 0.736 W/kg at Body.
Use of other installation may not ensure compliance with FCC RF exposure guidelines.

Access Point (ZR-101AA):

CAUTION

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment.
This equipment should be installed and operated with minimum distance 20cm between the radiator and body (excluding extremities: hands, wrists and feet) and must not be co-located or operated with any antenna or transmitter.

EMC RELATED CAUTION

This equipment and/or system complies with the International Standard IEC 60601-1-2 for electromagnetic compatibility for medical electrical equipment and/or system. However, an electromagnetic environment that exceeds the limits or levels stipulated in the IEC 60601-1-2, can cause harmful interference to the equipment and/or system or cause the equipment and/or system to fail to perform its intended function or degrade its intended performance. Therefore, during the operation of the equipment and/or system, if there is any undesired deviation from its intended operational performance, you must avoid, identify and resolve the adverse electromagnetic effect before continuing to use the equipment and/or system.

The following describes some common interference sources and remedial actions:

1.Strong electromagnetic interference from a nearby emitter source such as an authorized radio station or cellular phone:
Install the equipment and/or system at another location if it is interfered with by an emitter source such as an authorized radio station. Keep the emitter source such as cellular phone away from the equipment and/or system.

2.Radio-frequency interference from other equipment through the AC power supply of the equipment and/or system:
Identify the cause of this interference and if possible remove this interference source. If this is not possible, use a different power supply.

3.Effect of direct or indirect electrostatic discharge:
Make sure all users and patients in contact with the equipment and/or system are free from direct or indirect electrostatic energy before using it.

4.Electromagnetic interference with any radio wave receiver such as radio or television:
If the equipment and/or system interferes with any radio wave receiver, locate the equipment and/or system as far as possible from the radio wave receiver.

If the above suggested remedial actions do not solve the problem, consult your Nihon Kohden Corporation subsidiary or distributor for additional suggestions.

Conventions Used in this Manual and Instrument

Dangers, Warnings, Cautions and Notes

Warnings, cautions and notes are used in this manual to alert or signal the reader to specific information.

DANGER

A danger is used to alert the user to a hazardous situation which will cause 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.

NOTE

A note provides specific information, in the form of recommendations, prerequirements, alternative methods or supplemental information.

Precautions for Input Jack Use

NOTE

Do not perform EEG measurement without the Z, C3, C4, A1 and A2 electrodes.

Use of input jack Z

Connect the lead from the electrode (Z electrode) attached on the patient's nasion to the input jack Z on the electrode junction box. The purpose of this input jack is to eliminate AC interference positively.

NOTE

The input jack Z is also used for checking electrode impedance.

Use of input jacks C3 and C4

Connect the leads from the electrodes attached on the positions C3 and C4 to the input jacks C3 and C4 respectively.

NOTE

- **The C3 and C4 electrodes are the system reference electrodes for EEG measurement.**
- **The input jacks C3 and C4 must be attached for EEG measurement even when the C3 and C4 are not programmed in any montage.**

Use of input jacks A1 and A2, C3 and C4 during skin-electrode impedance check

When checking each electrode impedance, connect the leads from the electrode attached on the positions A1, A2, C3 and C4 to the input jacks A1, A2, C3 and C4 respectively.

NOTE

- **The A1 and A2 electrodes are the reference electrodes for skin-electrode impedance check.**
- **The input jacks A1 and A2 in addition to the Z, C3 and C4 must be attached for the electrode impedance check.**

Checking electrode potentials for all active electrodes

Check the original electrode potential for all active electrodes by programming a montage with the system reference electrode (Use the pattern VA (factory default setting) or select the 0 V button for reference electrode on the Montage dialog box). Refer to "Programming Patterns" in Section 4 of the operator's manual of the electroencephalograph. The digital EEG displays the EEG waveform in each channel by subtracting two electrode potentials selected to a montage. The subtracted result will be incorrect, if the electrode attachment is not correct, the original electrode potential is flat or unstable, or artifact is superimposed on the original electrode potential. Omit the measurement result if the displayed EEG waveform is incorrect.

Section 1 General

Introduction

The WEE-1000A Wireless Input Unit lets you compose a wireless EEG/PSG measuring system with an EEG-1100/9100/9200 Series Electroencephalograph. The wireless input unit consists of an electrode junction box, telemetry unit, access point and isolator. The telemetry unit measures EEG waveforms, ECG waveforms, EMG waveforms, respiration waveforms, SpO_2 and other parameters and transmits them to the access point by wireless transmission (IEEE 802.11b compliant) or by cable transmission through the isolator. The access point is connected to the electroencephalograph by LAN. The electroencephalograph displays and saves the measurement data.

Features

- Compact and lightweight electrode junction box/telemetry unit
  The telemetry unit can be worn by the patient in a pochette and electrode junction box is contained in the shoulder strap so that the patient is free from an electroencephalograph and examination room.

- Up to 32 channels of waveforms can be measured.
  JE-011A Electrode Junction Box and ZB-101AA Telemetry Unit:
  30 channels of EEG waveforms or 22 channels of EEG waveforms, 8 channels of bipolar signals and 2 channels of DC input signals

- SpO_2 measurement
  An optional SpO_2 probe can directly be connected to the telemetry unit with the JL-101A SpO_2 Adapter (option).

- JE-012A Electrode Junction Box for polysomnogram (PSG) measurement

- Battery operation
  The telemetry unit can operate on battery power for 24 hours or more on a lithium-ion rechargeable battery.

- Backup of transmitted data
  The transmitted data is backed up in the telemetry unit to guard against accidental signal loss

- Communication with the Electroencephalograph
  The access point communicates with the electroencephalograph through LAN (10/100Base T). The measurement data from the telemetry unit can be transferred to a distant electroencephalograph by LAN.

- Direct connection with the SC-101A Isolator.
  The telemetry unit can also be directly connected to the access point with an SC-101A Isolator. The isolator is useful when there is a lot of radio frequency interference or to save battery power when the patient is sleeping. DC power is supplied to the telemetry unit from the access point through the isolator.

- Easy skin-electrode contact impedance check
  The skin-electrode contact impedance check can be performed on both the telemetry unit and electroencephalograph. The impedance check result is displayed on the LCD display on the telemetry unit or on the screen on the electroencephalograph.

- LCD display
  The LCD display on the telemetry unit displays the operation status, communication status and remaining battery power.

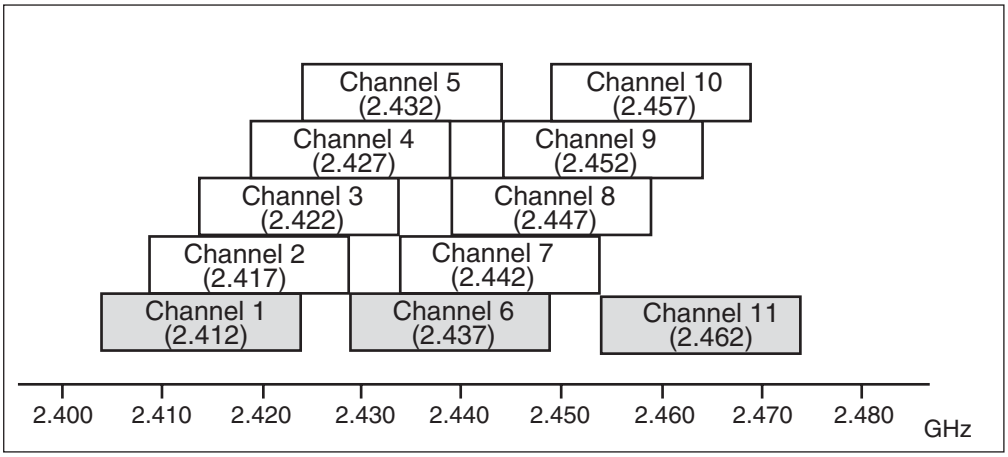
- Pochette
  The pochette contains the telemetry unit, electrode junction box and isolator for stable measurement. It reduces the patient burden and during measurement, the patient can freely move around while wearing the telemetry unit.

NOTE

Use only Nihon Kohden recommended parts and accessories to assure maximum performance from your instrument.

Frequency Band and Channels

The WEE-1000A Wireless Input Unit is a radio wave transmission method used in small wireless devices such as a PHS or cellular telephone. It uses the 2.4 GHz radio frequency band and transmits data up to 11 Mbps. This band is internationally assigned for wireless LAN IEEE 802.11b standard. The frequency band is divided into 11 channels every 5 MHz. Each channel uses about 22 MHz frequency bandwidth. However, all channels cannot be used at the same time because overlapping channels interfere each other.



( ): Center frequency

The WEE-1000 Wireless Input Unit covers channels 1 to 11 and uses up to three non-overlapping channels (for example, channel 1, channel 6 and channel 11) at the same time.

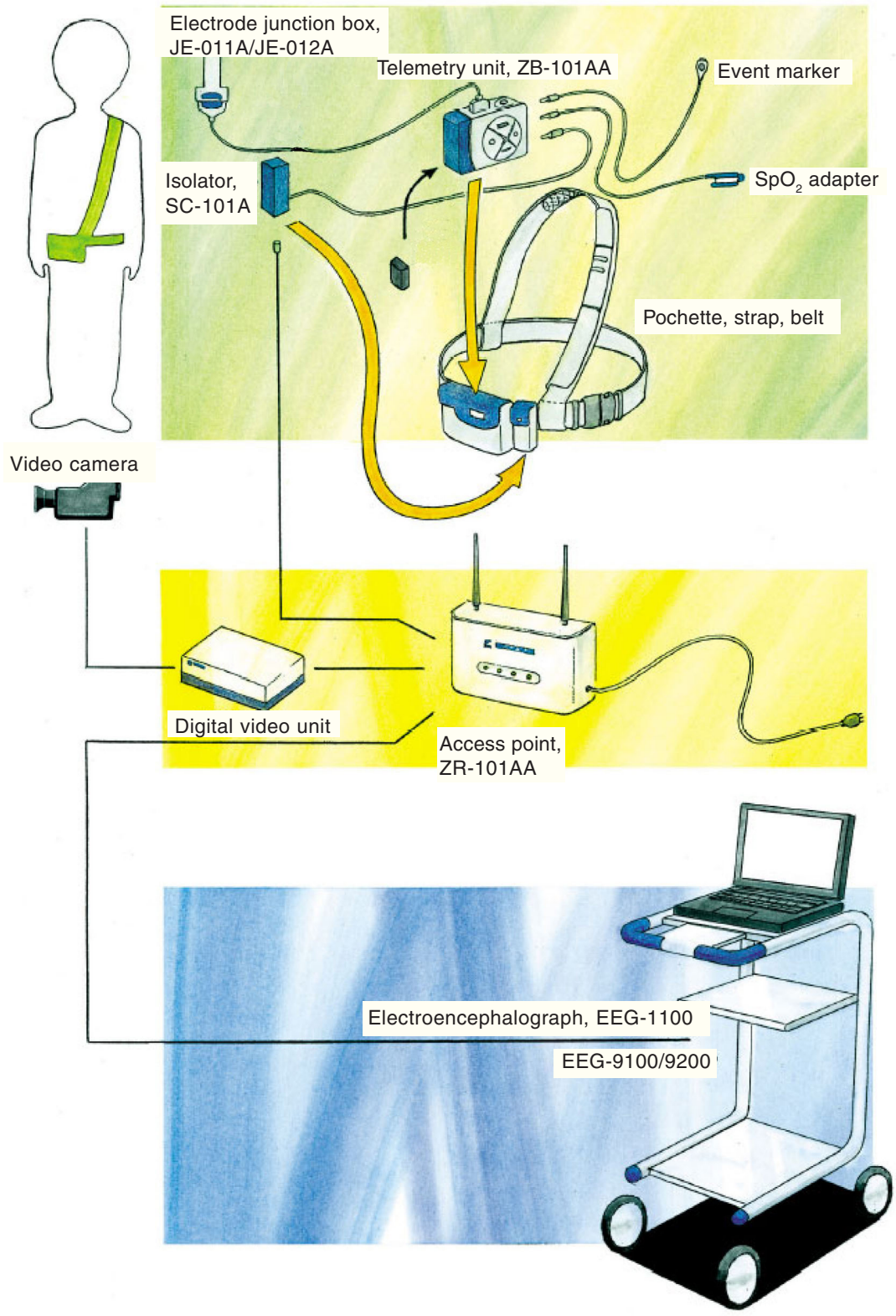
The 2.4 GHz frequency band, which is called ISM (Industry Science Medical), is used for medical devices, ham radio and microwave ovens in addition to wireless LAN. To prevent radio interference, the wireless input unit uses a spread spectrum technology.

WARNING

The wireless input unit complies with radio frequency standards.

- **Do not disassemble, repair or modify the wireless input unit.**
- **Do not peel off the radio frequency standard certification label. If the label is peeled off, this may result in illegal modification.**

Composition



General Safety information

DANGER

- **Never use the wireless input unit in a flammable atmosphere (i.e. areas with flammable anesthetics, concentrated oxygen, hyperbaric oxygen) or in an environment in which an electrical arc could ignite an explosion. Otherwise, the unit will explode or catch fire.**
- **Never use the wireless input unit in a high-pressure oxygen medical care tank. Otherwise, the unit will explode or catch fire.**

WARNING

Using with an electrical surgical unit (ESU)

- **Never use the wireless input unity near the ESU. The unit may malfunction due to high-frequency noise from the ESU.**
- **When using wireless input unit with an ESU, refer to the instruction manual for the ESU. Before measurement, check that the return plate is correctly attached to the patient and that the unit operates correctly when using with the ESU. If the return plate is not attached correctly, it may burn the patient's skin where the electrodes are attached.**
- **Before using the ESU, remove all needle electrodes and silver ball electrodes from the patient. Failure to follow this warning may cause burn on the patient.**

MRI examination

- **Do not install the wireless input unit in an MRI examination room. The unit may not operate properly due to high-frequency magnetic noise from the MRI.**
- **When performing MRI tests, remove all electrodes and transducers from the patient which are connected to the electrode junction box and telemetry unit. Failure to follow this warning may cause serious electrical burn on the patient due to local heating caused by dielectric electromotive force. For details, refer to the instruction manual for the MRI.**

When performing defibrillation

- **Before defibrillation, remove from the patient all electrodes and transducers which are connected to connectors that do not have a "⏦" or "⏦" mark. Otherwise, the discharged energy may cause serious electrical burn or shock to the operator.**
- **Before defibrillation, remove all electrodes, transducers medical agents from the patient. If the defibrillator paddle directly contacts these materials or medical agents, the discharged energy may cause serious electrical burn to the patient.**

Warning - continued

- **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 serious electrical burn, shock or other injury.**

Installation

WARNING

- **Do not install the EEG System Program into a personal computer which is not specified by Nihon Kohden and connect it to the access point.**
  - **If the personal computer does not satisfy the performance specifications and safety standards which are required by Nihon Kohden, the patient and operator may get electrical shock.**
  - **Nihon Kohden does not warrant if hardware and/or software becomes defective after installation.**

- **Only use the provided power cords. If different power cord is used, it may cause electrical shock.**

- **For electrical safety, equipotential grounding is required. Consult a qualified biomedical engineer.**

- **Connect only the specified instruments to the connectors or socket marked with ⚠ , by following the specified procedure. Otherwise, electrical leakage current may harm the patient and operator.**

- **Do not install the access point near a microwave oven. The microwaves from the microwave oven may interfere with the radio wave communication between the telemetry unit and access point.**

Connecting to a Local Area Network

- **When connecting the access point and electroencephalograph with a local area network, connect the access point and electroencephalograph so that the access point and electroencephalograph are electrically separated from the local area network according to the IEC 60601-1-1 "Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems". Failure to follow this warning may cause electrical shock to the patient and operator.**
- **Check that there is no damage on the surface of the network cable. If it is damaged, it may cause electrical shock to the patient and operator.**

CAUTION

- **When connecting the cables, make sure that all components of the wireless input unit turned off.**
- **Only install the specified software in the electroencephalograph. Otherwise the electroencephalograph may malfunction.**
- **Do not install the telemetry unit and access point in a place where is blocked by metal or concrete, or do not install the access point with its antenna bent. Decreased radio wave causes frequent signal loss between the telemetry unit and access point.**
- **Do not give impact to the antenna. This may damage the access point or cause access point malfunction.**
- **Use the provided ZR adapter when installing the access point. Otherwise, the access point may fall off and cause injury.**
- **After installing the telemetry unit and access point, check that the communication between the telemetry unit and access point is correctly performed without any interference.**

Battery

WARNING

- **Keep the battery away from fire. Do not heat the battery. Otherwise, the battery explodes.**
- **Do not immerse the battery in water or seawater. The battery heats up and rusts and the battery liquid leaks out.**
- **Never use a battery which is damaged, discolored or has leakage. A damaged battery explodes if used. If the battery is damaged and the battery liquid contacts the eyes or skin, wash immediately and thoroughly with water and see your physician. Never rub your eyes, otherwise you may lose your eyesight.**
- **Never disassemble, modify or give impact to the battery. The battery short-circuits and the battery liquid leaks out.**
- **Never short-circuit the + and – terminals on the battery with a wire.**
- **Do not leave the battery where patients can reach it. If a battery is swallowed, see your physician immediately.**

Warning - continued

- **Do not expose the battery to direct sunlight or leave it in a high temperature place. The lifetime of the battery may be shortened, the performance of the battery may be degraded and the battery liquid may leak out.**

- **Only charge the CGR-B/242 rechargeable lithium-ion battery with the provided DE-158UA Battery Charger.**

- **Charge the rechargeable lithium-ion battery at the surrounding temperatures of 10 to 40°C (50 to 104°F). If the battery is charged below 10°C or over 40°C, it may leak or heat up. This may damage the battery.**

CAUTION

- **Battery replacement should only be done by the operator. During measurement, when replacing the battery, be careful not to touch the patient.**

- **Do not charge a deteriorated battery. Otherwise, the instrument cannot operate on battery power.**

- **Before turning the telemetry unit on, make sure that the battery holder is firmly attached to the telemetry unit. If any static electricity enters the telemetry unit, it may cause malfunction.**

- **When the telemetry unit is not used, remove the battery from the telemetry unit.**

- **When replacing the battery, while the telemetry unit is connected to the access point with the isolator, do not touch the metal part of the connector. Otherwise the telemetry unit may malfunction due to electrostatic energy.**

- **Before disposing of the battery, check with your local solid waste officials for details in your area for recycling options or proper disposal. The battery is recyclable. At the end of its useful life, under various state and local laws, it may be illegal to dispose of this battery into the municipal waste stream.**

The lithium-ion rechargeable battery can be used for approximately 300 full charging cycles. When the battery is charged more than 300 times, the battery operation time may be reduced.

Electrode Attachment/ Cable Connection

WARNING

- **Do not connect the Z electrode lead plug on the electrode junction box to a ground or equipotential ground. Otherwise, leakage current from another instrument cause electrical shock to the patient.**

- **Only connect a BF type instrument to the DC connector on the telemetry unit. Otherwise, leakage current from the other instrument causes electrical shock to the patient.**

- **Before disconnecting or connecting the cable from/to a connecter on the telemetry unit, while the telemetry unit is turned on, discharge electrostatic charge from your body. Otherwise, the telemetry unit may malfunction due to electrostatic energy.**

- **When connecting the electrode junction box cable to the electrode junction box, align the ▼ marks on the electrode junction box cable connector and electrode junction box. Otherwise, leakage current may cause electrical shock to the patient.**

CAUTION

Using a collodion electrode or EEG paste

- **If rash, redness or itch appears on the patient skin from the use of collodion or EEG paste, immediately remove the collodion or EEG paste from the skin and perform medical treatment.**
- **Never allow collodion or acetone to get in the patient's eyes. If collodion or acetone accidentally gets in the eyes, immediately and thoroughly wash eyes with clean water and perform medical treatment immediately.**
- **If chemical solution is swallowed, have the person drink water and vomit the chemical solution. Perform medical treatment immediately.**
- **Collodion is a volatile solvent. Both patients and medical staff must take extreme care not to inhale collodion. When using collodion, make sure there is adequate ventilation. If too much collodion is inhaled, have the person lie quietly and keep warm in fresh air. Perform medical treatment immediately.**

Operation

WARNING

When using the NE-224S Sub-dermal Straight Needle Electrode

- **Do not use the NE-224S sub-dermal straight needle electrode as a measurement electrode for the EEG or evoked potential measurement for any longer than one hour. When measuring the EEG or evoked potential for over one hour, use the EEG disk electrode.**
- **Do not check the skin-electrode impedance when using a needle electrode or intracranial electrode. Failure to follow this warning injures the patient because these electrodes will be damaged by electrolyzation inside the body.**

- **When measuring the patient with the implantable pacemaker, leave the instrument (telemetry unit and access point) more than 22 cm from the patient. Otherwise, the radio wave from the telemetry unit or access point may interfere with the pacemaker.**

- **Do not delete any system file in the hard disk of the electroencephalograph. Otherwise the electroencephalograph may malfunction.**

- **Periodically back up the EEG data files to prevent loss of data if the hard disk or MO disk is damaged.**

CAUTION

- **Do not use a device which uses Bluetooth® wireless technology and wireless LAN device which complies with IEEE 802.11b near the wireless input unit at the same time. If they are used together, the radio waves interfere with each other. This may prevent the communication between the telemetry unit and access point by reducing transmission speed and transmission distance.**

- **Do not give impact to the telemetry unit. Spike noise may be superimposed on the waveform.**

- **Use the provided pochette to hold the telemetry unit, electrode junction box and/or isolator when they are attached to the patient.**

- **When moving the patient, make sure that the cable connected between the isolator and access point is disconnected. Otherwise, the patient may fall over the cable, or the cable may be broken.**

- **Do not shake or swing the telemetry unit holding the cable connected to the telemetry unit. The telemetry unit may come off and it may injure somebody or damage surrounding instruments.**

Caution - continued

- **Do not shake or swing the electrode junction box holding the cable or EEG lead connected to the electrode junction box. The electrode junction box may come off and it may injure somebody or damage surrounding instruments.**

SpO_2 Measurement

WARNING

- **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 electrical surgery unit**
  - **During CPR**
  - **When there is body movement**
  - **When there is vibration**
  - **When measuring at a site with venous pulse**
  - **When the pulse wave is small (insufficient peripheral circulation)**
  - **When using an IABP (intra-aortic balloon pump)**

- **When the SpO_2 probe is used on a neonate, low birth weight infant or patient with a fever or peripheral circulation insufficiency, a slight burn may result from the probe increasing the skin temperature at the attached site by 2 or 3°C (4 or 5°F). Periodically check the attached state of the probe and change the attachment site.**

- **To avoid poor circulation, do not wrap the tape too tight when fixing the probe with surgical tape. 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 pressure necrosis from poor blood circulation.**

- **When using the probe on the following patients, take extreme care and change the measurement site more frequently according to symptoms and degree.**
  - **A patient with a fever**
  - **A patient with a peripheral circulation insufficiency**
  - **Neonate or low birth weight infant with delicate skin**

  For a patient with a peripheral circulation insufficiency, the measurement result may be incorrect.

- **When not measuring SpO_2, disconnect the SpO_2 adapter cable from the telemetry unit. Otherwise, noise from the probe sensor may interfere and incorrect data is displayed on the screen.**

CAUTION

- **Only use the specified probes and JL-101A SpO_2 Adapter. Otherwise SpO_2 cannot be monitored properly and instrument performance may be degraded.**
- **Do not use a probe which is past the expiration date on the package.**
- **Do not use a damaged or disassembled probe.**
- **Disposable probes are not sterilized.**
- **Use the disposable probe only once and for one patient only. Do not reuse the disposable probe for another patient. It will cause cross infection.**
- **When the attachment site is wet with blood or when the patient has nail polish on, remove the dirt and nail polish before attaching the probe. The transmitted light may decrease due to the blood or nail polish and the measurement data may be incorrect.**
- **Turn off the power of cellular telephones, small wireless devices and other devices which produce strong electromagnetic interference. Otherwise, the waveforms and measurements are affected by interference and the displayed data may be incorrect.**
- **Under normal conditions, normal light has negligible effect on this probe. However, when measuring under strong light (surgical light, bilirubin light, sunlight, etc.), cover the probe with a blanket or cloth. Otherwise, the measurement result may be incorrect.**
- **If the skin gets irritated or redness appears on the skin by the probe, change the attachment site or stop using the probe.**
- **For long term monitoring, check the circulation condition by observing the skin color of the measuring site. To avoid circulation insufficiency and skin burn, change the measurement site every specified number of hours. Refer to the operator's manual of the probe.**
- **Do not pull or bend the probe cable, and do not let caster feet run over the probe cable. Do not immerse the probe cable in chemical solutions or water. Failure to follow these cautions may cause cable discontinuity, short circuit, skin burn on the patient and incorrect measurement data. Replace any broken probe with a new one.**
- **When removing a probe that is taped to the skin, do not pull the cable part of the probe because this can damage the probe's cable connection.**

Caution - continued

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

Disinfecting or Sterilizing

CAUTION

Before cleaning or disinfecting, turn off the power of the telemetry unit and access point, remove the battery from the telemetry unit and disconnect the AC power cord from the access point. Otherwise you may get an electrical shock or the instrument may malfunction.

Maintenance

WARNING

The wireless input unit complies with radio frequency standards.

- **Do not disassemble, repair or modify the wireless input unit. If there is any damage or the unit is suspected to be faulty, attach an "Unusable" or "Repair request" label to the unit and contact your Nihon Kohden distributor or representative.**
- **Do not peel off the radio frequency standard certification label. If the label is peeled off, this may result in illegal modification.**

CAUTION

When upgrading the system program, contact your NK distributor or representative. When the upgrading fails, the electroencephalograph may malfunction.

Disposing

CAUTION

Before disposing of a component of the wireless input unit, check with your local solid waste officials for details in your area for recycling options or proper disposal. When disposing of the telemetry unit, remove the battery from the telemetry unit.

NOTE

- **If any static electricity enters the electrode junction box, spike noise may be superimposed on the waveform.**

Floppy Disk/CD-ROM Disk Handling and Storing

WARNING

The EEG System Program is protected by copyright law and international treaties. Unauthorized reproduction or distribution of this software, or any portion of it, may result in severe civil and criminal penalties, and will be prosecuted to the maximum extent possible under law.

CAUTION

- **Keep floppy disks away from strong magnetic objects such as a magnet, TV set or speaker. Otherwise, data in the disk may be lost.**
- **During measurement, do not insert or remove a CD-R or CD-RW disk into or from the CD-RW drive. Otherwise, the Acquisition program may malfunction.**
- **Do not touch the disk surface of the recorded side (CD-ROM: opposite side of the label side). If the surface of the disk becomes contaminated with any foreign substances such as fingerprints, reading data may be impossible.**
- **Keep the disk away from direct sunlight and high temperature. Otherwise, the disk may become deformed.**
- **Do not handle the disk while smoking or eating.**
- **Do not get the disk wet.**
- **Do not put a label on top of another label. Remove the old label before applying a new label.**
- **Do not write on the label after the label is attached on the disk. Otherwise, the disk may be damaged and reading may be impossible.**
- **Do not bend the disk, put heavy material on the disk, or give a strong impact to the disk.**
- **Clean the disk with a disk cleaner. Do not use organic solvents such as acetone.**
- **This CD–ROM is not an audio CD and cannot be played with an audio CD player.**

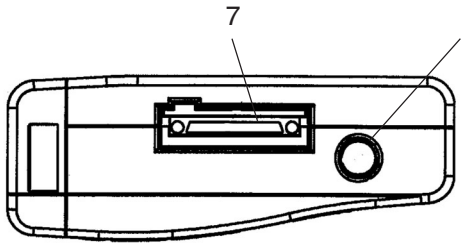
Panel Descriptions

ZB-101AA Telemetry Unit

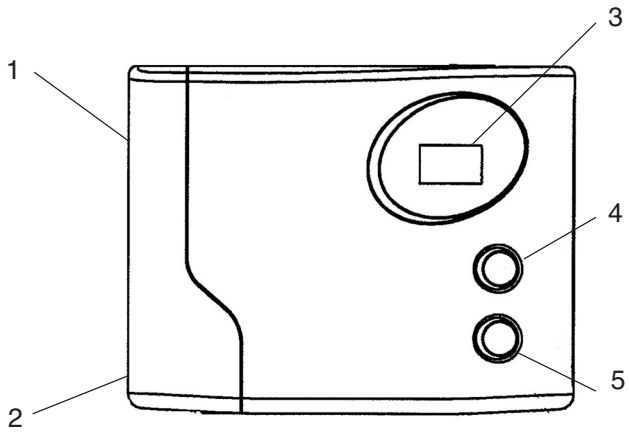
WARNING

Connect only the specified instruments to the connectors or socket marked with ⚠ , by following the specified procedure. Otherwise, electrical leakage current may harm the patient and operator.

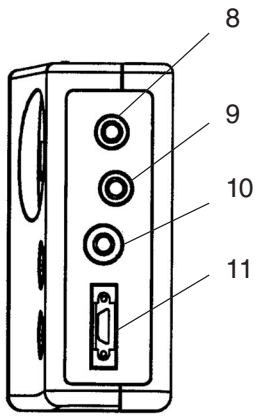
Top panel



Front panel



Right side panel



Name	Functions
1. Battery holder	Contains the battery. Two types of battery holder are provided. One is for the 9 V lithium-ion rechargeable battery, the other is for the 9 V 006P lithium battery and alkaline battery. When setting the battery, make sure that the battery is in the same direction shown by the figure on the holder.
2. Battery holder release lever	Releases the battery holder.
3. LCD display	Displays the operation status, communication status and remaining battery power. Battery mark: Displayed in battery operation. When the isolator is connected, the battery mark goes off. SpO_2 mark: Displays the SpO_2 mark when the JL-101A SpO_2 Adapter is connected. Status display: Displays the result of the selected operation or function and the supplemental information for each function.
4. FUNCTION key	Selects the operation item.

Name	Functions
5. START/OK key	The START/OK key works as follow. • Turns on the power of the telemetry unit when the power is off. • Performs the operation selected by the FUNCTION key.
6. MARK/kΩ key	Adds event marks or changes the impedance threshold • While acquiring the EEG waveforms, adds event marks (annotations) on the waveforms. • When checking the skin-electrode contact impedance, changes the impedance threshold.
7. Electrode junction box connector	Connects to the electrode junction box.
8. DC connector	Inputs analog signals from an external instrument.

WARNING

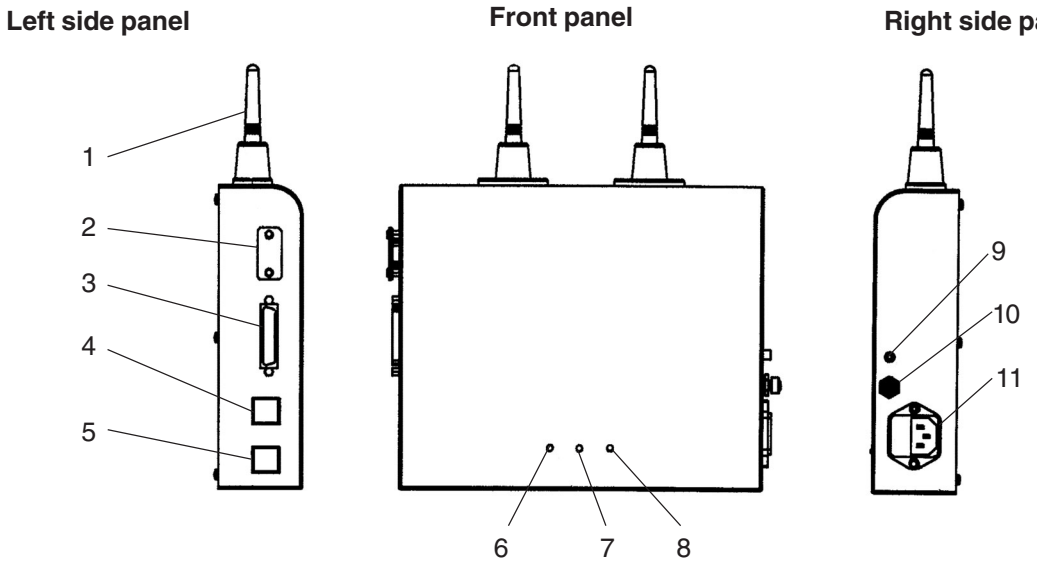
Only connect a BF type instrument to the DC connector on the telemetry unit. Otherwise, leakage current from the other instrument causes electrical shock to the patient.

9. MARK connector	Connects the event marker.
10. SpO_2 connector	Connects an SpO_2 probe by way of the optional JL-101A SpO_2 Adapter.
11. ISOL connector	Connects to the access point by way of the SC-101A Isolator for direct wired connection.

ZR-101AA Access Point

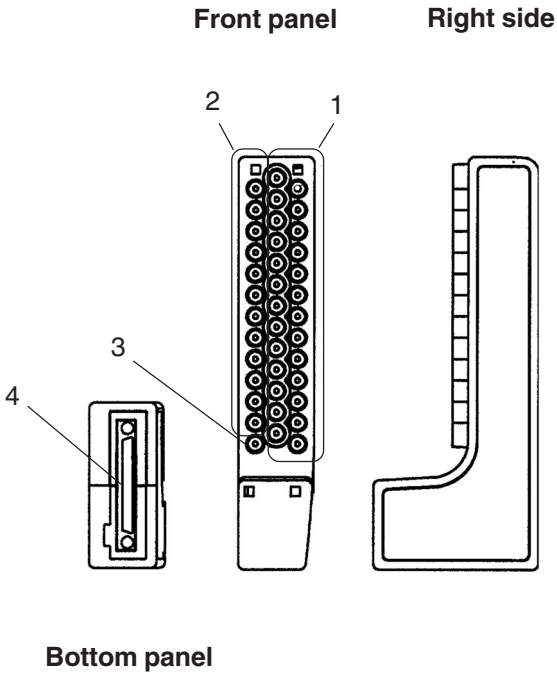
WARNING

Connect only the specified instruments to the connectors or socket marked with ⚠ , by following the specified procedure. Otherwise, electrical leakage current may harm the patient and operator.



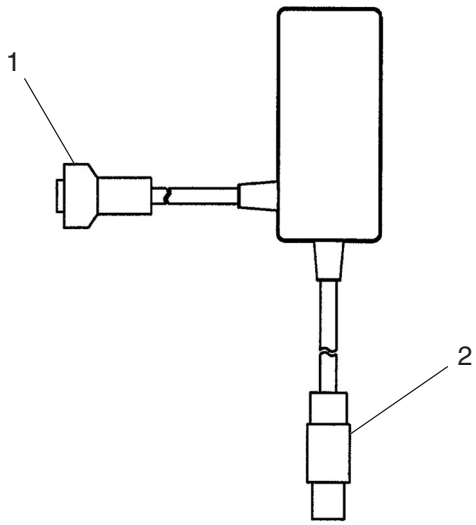
Name	Functions
1. Antenna	Diversity antenna
2. PHOTO UNIT connector	Connects to the optional LS-901A Photo Control Unit.
3. ISOLATOR connector	Connects to the telemetry unit by way of the SC-101A Isolator for direct wired connection. DC power is supplied to the telemetry unit through the isolator.
4. DV UNIT connector	Connects to the optional DV-101A Digital Video Unit through wired LAN.
5. PC connector	Connects to the electroencephalograph through wired LAN.
6. POWER lamp	Lights while AC power is supplied to the access point.
7. TX lamp	Lights while in contact with the telemetry unit.
8. RX lamp	Lights while receiving the data from the telemetry unit.
9. Protective ground terminal	Use this terminal when protective grounding is required.
10. Equipotential ground terminal	Connects this terminal to the equipotential ground terminal on the wall with the ground lead when the equipotential grounding is required to ensure electrical safety.
11. AC SOURCE socket	Connects the power cord to supply AC power to the access point. When AC power is supplied, the access point is turns on and the POWER lamp lights.

JE-011A/JE-012A Electrode Junction Box



Name	Function
1. Electrode jack (DIN type)	Connects the EEG disk electrode.
2. Extra jack (DIN type)	Inputs biological signals other than EEG waveforms. The following extra jacks can be used as bipolar jacks. To select extra jack or bipolar jack, refer to the System Programs. • JE-011A Electrode Junction Box: X2 to X9 • JE-012A Electrode Junction Box: X17 to X24
3. Z jack (DIN type)	Reduces the artifact when the electrode for Z on the patient is connected to the Z jack. Be sure to attach the Z electrode to the patient during measurement
4. Electrode junction box connector	Connects to the telemetry unit.

SC-101A Isolator



Name	Function
1. ISOL connector	Connects the telemetry unit.
2. Access point connector	Connects to the access point with the connection cable.

Section 2 Installation/Preparation

System Location

This wireless input unit measures very small electrical potential changes (5 to 200 μV). Ideally the instrument should be installed in a shielded room which provides constant environmental conditions. Select the examination locations as follows and also refer to "GENERAL HANDLING PRECAUTIONS".

DANGER

- **Never use the system in a flammable atmosphere (i.e. areas with flammable anesthetics, concentrated oxygen, hyperbaric oxygen) or in an environment in which an electrical arc could ignite an explosion. Otherwise, the system will explode or catch fire.**
- **Never use the system in a high-pressure oxygen medical care tank. Otherwise, the system will explode or catch fire.**

WARNING

- **Do not install the EEG System Program into a personal computer which is not specified by Nihon Kohden and connect it to the system.**
  - **If the personal computer does not satisfy the performance specifications and safety standards which are required by Nihon Kohden, the patient and operator may get electrical shock.**
  - **Nihon Kohden does not warrant if hardware and/or software becomes defective after installation.**
- **Only use the provided power cords. If another power cord is used, it may cause electrical shock or other injury.**
- **For electrical safety, equipotential grounding is required. Consult a qualified biomedical engineer.**
- **Connect only the specified instruments to the connectors or socket marked with ⚠ , by following the specified procedure. Otherwise, electrical leakage current may harm the patient and operator.**

Connecting to a Local Area Network

- **When connecting the access point and electroencephalograph with a local area network, connect the access point and electroencephalograph so that the access point and electroencephalograph are electrically separated from the local area network according to the IEC 60601-1-1 "Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems". Failure to follow this warning may cause electrical shock to the patient and operator.**
- **Check that there is no damage on the surface of the network cable. If it is damaged, it may cause electrical shock to the patient and operator.**

CAUTION

- **Select a room with a 3-prong outlet with a ground third contact.**
- **Do not install the system near equipment with a high power consumption, such as large X-ray equipment.**
- **Do not install the system near a power line, dynamo or motor which has electromagnetic induction.**
- **Do not install the wireless input unit near an electrosurgical unit or RF therapeutic equipment.**
- **Select a room with no excessive noise, vibration, sunlight, high humidity or water splashes.**
- **When connecting the cables, make sure that each instrument is turned off.**
- **Only install the specified software in the electroencephalograph. Otherwise the electroencephalograph may malfunction.**
- **Make sure that there is no influence from a cellular phone.**
- **Avoid locations where the wireless input unit may receive strong electromagnetic interference such as radio or TV stations, cellular phones or mobile two-way radios.**
- **A sudden loss of power or extreme power surge can damage data. To assure an uninterrupted power supply, use an uninterruptable power supply (UPS)**.
- **Do not install the wireless input unit where it will be exposed to water or chemical solutions. Avoid direct sprinkling, spray or moist air from the nebulizer or humidifier. These cause malfunction and shorten the life of the unit.**
- **After installing the telemetry unit and access point, check that the communication between the telemetry unit and access point is correctly performed without any interference.**

For external instrument connection and local area network connection, refer to "General Requirements for Connecting Medical Electrical Systems" in this section.

NOTE

- **Do not place blankets or cloth over the access point.**
- **Do not install the wireless input unit in dusty area.**
- **Connect the power cable to an AC outlet which can supply enough AC current to the access point. The access point cannot function properly with low current.**

For electroencephalograph installation, refer to the operator's manual for the electroencephalograph.

Installation Flowchart

1. Install the access point.
2. Connect the access point to the electroencephalograph.
3. Turn on the access point and electroencephalograph.
4. Upgrade the EEG system program to version 05-10 or later.
5. Prepare the telemetry unit.

   The network configuration settings of the telemetry unit and access point can be set on the Acquisition screen.

Installing the Access point

WARNING

- **When attaching the access point to a wall or rack, you must have a qualified builder attach the access point. Show the builder this manual.**
- **Attach the access point securely enough to withstand external force or vibration caused by an earthquake.**
- **Tell the builder the size and weight of the access point. Both size and weight of the access point affect safety.**
  Dimensions and weight: 240 (W) × 55 (D) × 200 (H) mm, 1.5 kg (without antenna).
- **Do not install the access point near a microwave oven. The microwaves from the microwave oven may interfere with the radio wave communication between the telemetry unit and access point.**

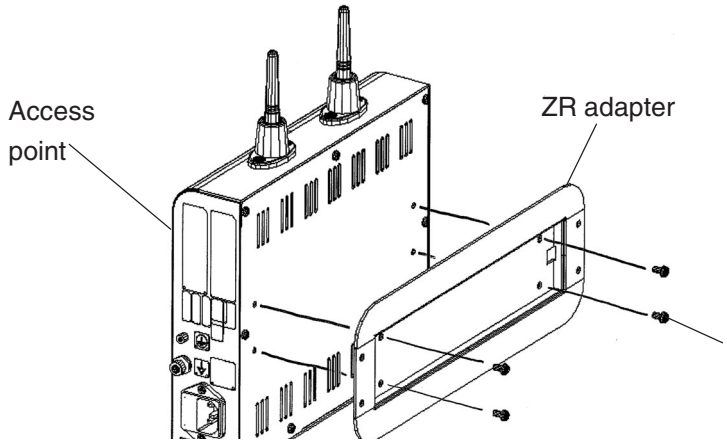
CAUTION

- **Use the provided ZR adapter when installing the access point. Otherwise, the access point may fall off and cause injury.**
- **Use appropriate screws according to the material and structure of the wall or rack.**
- **Make sure that there is enough space between the access point and the wall for adequate ventilation. Leave more than 1 cm of space between the wall and vent holes on the rear panel of the access point. Otherwise the internal temperature of the access point rises, which leads to inaccurate operation and shortens the access point life.**
- **Install the access point at least 20 cm away from the operator.**
- **Do not install the telemetry unit and access point in a place where is blocked by metal or concrete, or do not install the access point with its antenna bent. Decreased radio wave causes frequent signal loss between the telemetry unit and access point.**
- **Do not install the access point and telemetry unit near a device which uses Bluetooth® wireless technology or wireless LAN device which complies with IEEE 802.11b near the wireless input unit at the same time. If they are used together, the radio waves interfere with each other. This may prevent the communication between the telemetry unit and access point by reducing transmission speed and transmission distance.**
- **Do not give impact to the antenna. This may damage the access point or cause access point malfunction.**

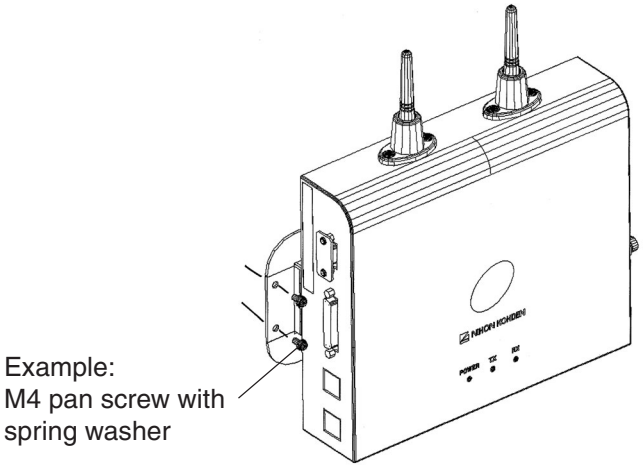
NOTE

Select a place where the POWER lamp, TX lamp and RX lamp can be checked.

Attaching the Access Point to the Wall

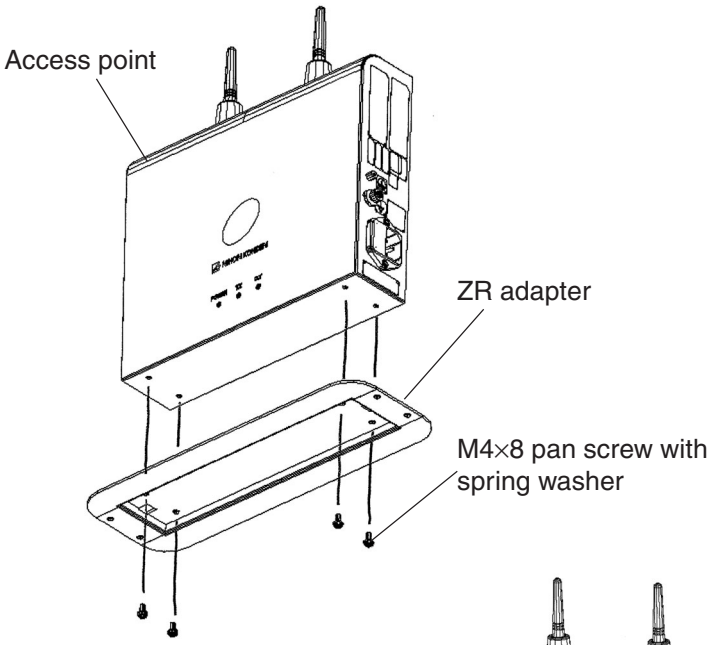


1. Attach the ZR adapter to the rear of the access point and secure it with four M4×8 pan screws with spring washers.

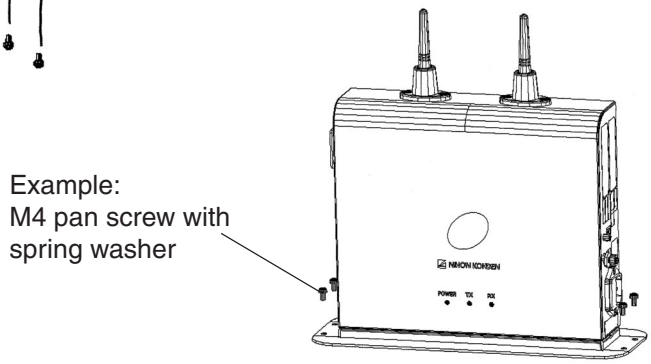


2. Attach the ZR adapter to the wall and secure the ZR adapter with the four pan screws with spring washers.

Attaching the Access Point to the Rack



1. Attach the ZR adapter to the bottom of the access point and secure it with four M4×8 pan screws with spring washers.



2. Attach the ZR adapter to the rack and secure the ZR adapter with the four pan screws with spring washers.

Cable Connection

WARNING

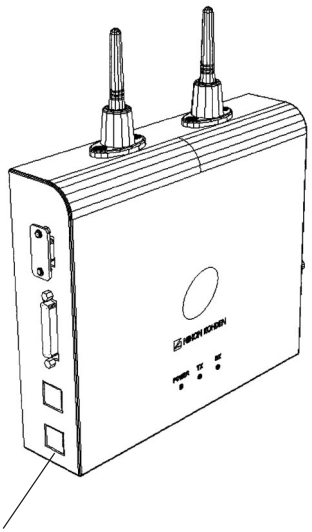
- **When connecting the cables, make sure that all components of the wireless input unit are turned off.**
- **Connect only the specified instruments to the connectors or socket marked with ⚠ , by following the specified procedure. Otherwise, electrical leakage current may harm the patient and operator.**

Connecting to a Local Area Network

- **When connecting the access point and electroencephalograph with a local area network, connect the access point and electroencephalograph so that the access point and electroencephalograph are electrically separated from the local area network according to the IEC 60601-1-1 "Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems". Failure to follow this warning may cause electrical shock to the patient and operator.**
- **Check that there is no damage on the surface of the network cable. If it is damaged, it may cause electrical shock to the patient and operator.**

Connecting the Access point and Electroencephalograph

1. Connect the provided network cable to the PC connector on the left side panel of the access point.



PC connector

2. Connect the other side of the network cable to the network connector on the PC unit of the electroencephalograph.

Connecting the Power Cord

Connecting the Power Cord

Connect the provided power cord to the AC SOURCE socket on the right side panel of the access point and plug the cord into a 3-prong AC outlet.

CAUTION

Only use the provided power cords. If another power cord is used, it may cause electrical shock.

Equipotential Grounding

WARNING

For patient safety, equipotential grounding may be required. Consult with a qualified biomedical engineer.

When more than one electrical instrument is used, there may be electrical potential difference between the instruments. Potential difference between instruments may cause current to flow to the patient connected to the instruments, resulting in electrical shock (micro shock). Never use any medical equipment in patient treatment without proper grounding.

Always perform equipotential grounding when required. It is often required in the operating room, ICU room, CCU room, cardiac catheterization room and X-ray room. Consult with a biomedical engineer to determine if it is required.

When Equipotential Grounding is Required

Connect the equipotential ground terminal on the right side panel of the access point to the equipotential ground terminal on the wall with the ground lead.

Upgrading the EEG System Program

NOTE

When the system program version of the electroencephalograph is 05-01 or earlier, the access point can not be connected. Upgrade the system program with the provided system disk.

1. Insert the EEG system program CD-ROM into the CD-ROM drive.

2. From the Start menu, select Run. The Run dialog opens.

3. Type **X:\Software\Setup.exe** in the Open text box and click the OK button (X is the CD-ROM drive). The EEG setup program starts copying the files.

4. Follow the instructions on the screen.

5. When the setup is complete, restart the computer.

Preparing the Telemetry Unit

General

The telemetry unit communicates with the access point by wireless transmission (IEEE 802.11b compliant). The telemetry unit can also be directly connected to the access point with an SC-101A Isolator. The isolator is useful when there is a lot of radio frequency interference or to save battery power when the patient is sleeping.

Using a Battery

The telemetry unit can operate on battery power with the following batteries

- CGR-B/242 lithium-ion (LiON) rechargeable battery ×1 (option)
- 006P 9V lithium battery ×1 (U9VL: recommended)
- 006P 9V alkaline battery ×1

Battery operation time (at surrounding temperature: 25°C (77°F))

- Lithium- ion rechargeable battery: 24 hours or more (10 seconds intermittent transmission)
- 9V lithium battery: About 12 hours
- 9V alkaline battery: About 5 hours

The lithium-ion rechargeable battery can be used for approximately 300 full charging cycles. When the battery is charged more than 300 times, the battery operation time may be reduced.

WARNING

- **Keep the battery away from fire. Do not heat the battery. Otherwise, the battery explodes.**
- **Do not immerse the battery in water or seawater. The battery heats up and rusts and the battery liquid leaks out.**
- **Never use a battery which is damaged, discolored or has leakage. A damaged battery explodes if used. If the battery is damaged and the battery liquid contacts the eyes or skin, wash immediately and thoroughly with water and see your physician. Never rub your eyes, otherwise you may lose your eyesight.**
- **Never disassemble, modify or give impact to the battery. The battery short-circuits and the battery liquid leaks out.**
- **Never short-circuit the + and – terminals on the battery with a wire.**
- **Do not leave the battery where patients can reach it. If a battery is swallowed, see your physician immediately.**
- **Do not expose the battery to direct sunlight or leave it in a high temperature place. The lifetime of the battery may be shortened, the performance of the battery may be degraded and the battery liquid may leak out.**
- **Only charge the CGR-B/242 rechargeable lithium-ion battery with the provided DE-158UA Battery Charger.**
- **Charge the battery at the surrounding temperatures of 10 to 40°C (50 to 104°F). If the battery is charged below 10°C or over 40°C, it may leak or heat up. This may damage the battery.**

CAUTION

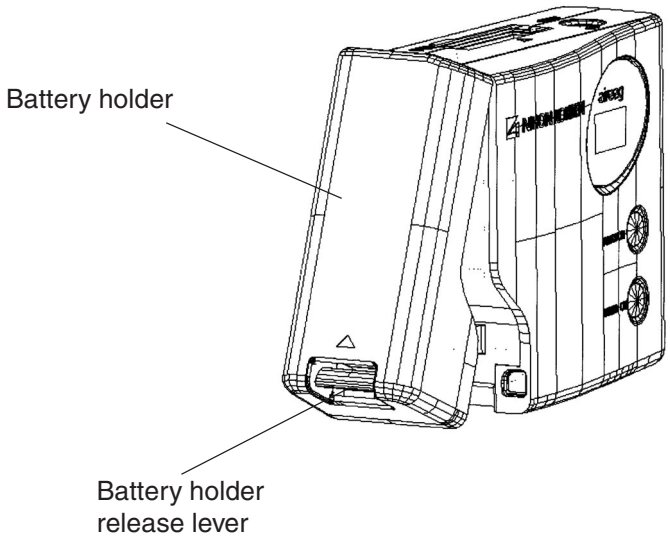
- **Battery replacement should only be done by the operator. During measurement, when replacing the battery, be careful not to touch the patient.**
- **Do not charge a deteriorated battery. Otherwise, the instrument cannot operate on battery power.**
- **Before turning the telemetry unit on, make sure that the battery holder is firmly attached to the telemetry unit. If any static electricity enters the telemetry unit, it may cause malfunction.**
- **When the telemetry unit is not used, remove the battery from the telemetry unit.**
- **When replacing the battery, while the telemetry unit is connected to the access point with the isolator, do not touch the metal part of the connector. Otherwise the telemetry unit may malfunction due to electrostatic energy.**
- **Before disposing of the battery, check with your local solid waste officials for details in your area for recycling options or proper disposal. The battery is recyclable. At the end of its useful life, under various state and local laws, it may be illegal to dispose of this battery into the municipal waste stream.**

NOTE

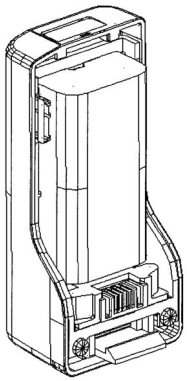
Use a fully charged lithium-ion rechargeable battery, a new 006P 9V lithium battery or new 006P 9V alkaline battery for every measurement.

Inserting the Battery

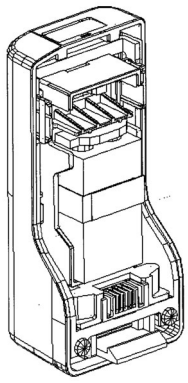
1. Press the battery holder release lever and remove the battery holder from the telemetry unit.



2. Insert the battery into the battery holder. Two types of battery holder are provided. One is for the lithium-ion rechargeable battery, the other is for the 9V 006P lithium battery and alkaline battery. Use the appropriate battery holder according to the battery. When setting the battery, make sure that the battery is in the same direction shown by the figure on the holder.



Battery holder for
lithium-ion battery



Battery holder for 006P lithium
battery and alkaline battery

3. Attach the battery holder to the telemetry unit.

Charging the Lithium-ion Rechargeable Battery

The lithium-ion rechargeable battery can be used for approximately 300 full charging cycles with the DE-158UA Battery Charger. When the battery is charged more than 300 times, the battery operation time may be reduced.

WARNING

- **Only charge the CGR-B/242 Lithium-ion rechargeable battery with the provided DE-158UA Battery Charger.**

CAUTION

- **Battery replacement should only be done by the operator. During measurement, when replacing the battery, be careful not to touch the patient.**
- **When replacing the battery, while the telemetry unit is connected to the access point with the isolator, do not touch the metal part of the connector. Otherwise the telemetry unit may malfunction due to electrostatic energy.**
- **Do not charge the battery inside the patient environment (IEC 60601-1-1 2.204*)**

* Patient environment
Any area in which intentional or unintentional contact between PATIENT and parts of SYSTEM or some other persons touching of the SYSTEM can occur.

The two rechargeable batteries can be set in the battery charger at the same time but the charging is performed for only one battery.

- When the second battery is set in the charger, while a battery is being charged, the second battery is charged after the first battery charging is complete.
- When two batteries are set in the battery charger before AC power is supplied, the battery which is set in the channel 1 is charged first.

1. Connect the battery charger to the AC outlet and turn the power on. The power lamp lights in red.

2. Set the rechargeable battery in the battery charger. Make sure that the battery is set in the direction shown by the ▼ mark. When the batteries is correctly set in the battery charger, charging starts.

   The battery charge lamp (green) indicates the battery charging status:

Lit :	The battery is being charged
Blinking:	The battery is fully charged.
Off:	The battery is too hot (After while, if the battery charge lamp does not light or blink, the battery may be damaged.

   The rechargeable battery can be fully charged in about 100 minutes.

Remaining Battery Power

During battery operation, the battery mark appears on the LCD display. You can check the remaining battery power on the LCD.

1. When the battery is inserted in to the battery holder, press the START/OK key. The telemetry unit is turned on and the version information is displayed on the LCD display.

2. Check the battery operation power by pressing the FUNCTION key. The battery operation power is displayed on the status display.

   The battery voltage is shown as follows.
   BH: The battery voltage is about 7 V or more.
   BL: The battery voltage is less than about 7 V.
   Eb: The battery voltage is less than about 6 V

   Replace the battery when “BL” or “Eb” is displayed on the LCD display. When the battery voltage becomes less than 6 V, the beep sounds and a message to replace the battery is displayed on the Acquisition screen of the electroencephalograph.

   To turn the power off, select “OF” by pressing the FUNCTION key and press the START/OK key.

   Turn the power off, when you detach the battery holder.

Connecting the Telemetry unit to the Access point with the Isolator

The telemetry unit can also be directly connected to the access point with an SC-101A Isolator. DC power is supplied to the telemetry unit from the access point through the isolator.

CAUTION

- **When connecting the isolator to the telemetry unit, make sure that telemetry unit is turned off.**
- **When using the isolator, do not remove the battery holder. Otherwise, the telemetry unit may malfunction due to static energy.**
- **When moving the patient, make sure that the cable connected between the isolator and access point is disconnected. Otherwise, the patient may fall over the cable, or the cable may get broken.**
- **When connecting or disconnecting the connection cable to/from the isolator, hold the connectors. If you hold the cable, the cable may get broken.**

1. Disconnect the connection cable from the isolator which connects the isolator and access point.

2. Connect the cable from the isolator to the telemetry unit and secure the connector with the two screws. Use the provided flat-blade screwdriver to secure the connector.

3. Connect the connection cable to the access point and secure the connector with the two screws.

4. Connect the AC power cord of the access point to the AC outlet.

5. Connect the other side of the connection cable to the isolator. DC power is supplied to the telemetry unit and the telemetry unit is turned on. The LCD display displays the version information, then displays “CL”.

   To turn off the telemetry unit, disconnect the connection cable from the isolator. When the battery is set in the battery holder, the telemetry unit continues to operate on battery power.

Power On/Off Procedure

Power On Procedure

CAUTION

- **When connecting the isolator to the telemetry unit, make sure that telemetry unit is turned off.**
- **When using the isolator, do not remove the battery holder. Otherwise, the telemetry unit may malfunction due to static energy.**

1. Before turning the power on, check the following items. If there is any damage or the instrument is suspected to be faulty as a result of checking, attach an "Unusable" or "Repair required" label to the instrument and contact your NK distributor or representative.

   Check items before turning the power on

   Overview:
   - Telemetry unit, access point and isolator are not dirty, damaged or in contact with liquid.
   - Power cord is not damaged.
   - No key on the telemetry unit is broken.
   - No electrode is dirty or damaged.
   - No electrode lead is frayed or damaged.
   - No connection cable is frayed or damaged.

   Connection and Setting:

   Telemetry unit
   - Fully charged lithium-ion battery, a new lithium battery or a new alkaline battery is inserted.
   - Battery is inserted in the correct direction.
   - Battery holder is attached to the telemetry unit firmly.
   - Isolator is firmly connect to the telemetry unit.
   - Electrode junction box is properly connected to the telemetry unit.

   Access point
   - Power cord and ground lead are properly connected to the access point.
   - Access point is properly connected to the electroencephalograph with the network cable.

   Environment
   - There is no obstruction between the telemetry unit and access point.
   - Bluetooth device or other wireless LAN device is not used near the wireless input unit.

Accessories:

- Enough electrodes.
- Enough EEG paste.
- A second battery.

2. Turn the power on

   Wireless communication:

   1) Connect the AC power cord of the access point to the AC outlet.
   2) Press the START/OK key on the telemetry unit.

   Wired communication:

   1) Connect the telemetry unit and access point with the isolator.
   2) Connect the AC power cord of the access point to the AC outlet.

3. After turning the power on, check the following items.

Check items after turning the power on

Overview:

- No fire, smoke or smell.
- No electrical shock when touching the telemetry unit or access point.
- Telemetry unit and access point are not too hot.
- Telemetry unit and access point do not affect surrounding equipment.

Telemetry unit

- No beep sounds.
- No error code is displayed on the LCD screen.
- All keys operate correctly.

Access point

- The power lamp lights.
- TX and RX lamps blinks
- All operation indicators light.

Electroencephalograph

- The communication between the telemetry unit and access point is established with or without the isolator.
- The message to replace the battery of the telemetry unit is not displayed.
- There is no error message on the screen or malfunction.
- The screen display is correct.
- The time and date display is correct.
- All programs operate correctly.
- All settings (such as montage and amplifier settings) are correct.
- Calibration waveform is properly displayed.
- No noise on the calibration waveform.
- Amplitude of the calibration waveform is correct.

Power Off Procedure

1. Check the following before turning the power off.

Check items before turning the power off

- All necessary files are saved.
- All programs are closed.

2. Turn the power off.
   1) On the telemetry unit, select “OF” by pressing the FUNCTION key, then press the START/OK key.
   2) Disconnect the AC power cord of the access point from the AC outlet.

Check the following items for the next use

- Power of all external instruments are turned off.
- Telemetry unit and access point is not dirty, damaged or in contact with liquid.
- Power cord is not damaged.
- Telemetry unit is turned off
- No key on the telemetry unit is broken.
- Battery is removed from the battery holder.
- Lithium battery or alkaline battery is correctly disposed of.

- No electrode is dirty or damaged.
- No electrode lead is frayed or damaged.
- No connection cable is frayed or damaged.
- Electrodes and leads are cleaned and disinfected.

- Enough electrodes.
- Enough EEG paste.

General Requirements for Connecting in Medical Electrical Systems

When more than one electrical instrument is used, there may be electrical potential difference between the instruments. Potential difference between instruments may cause current to flow to the patient connected to the instruments, resulting in electrical shock (micro shock). Therefore, electrical instruments must be appropriately installed as specified in IEC 60601-1-1.

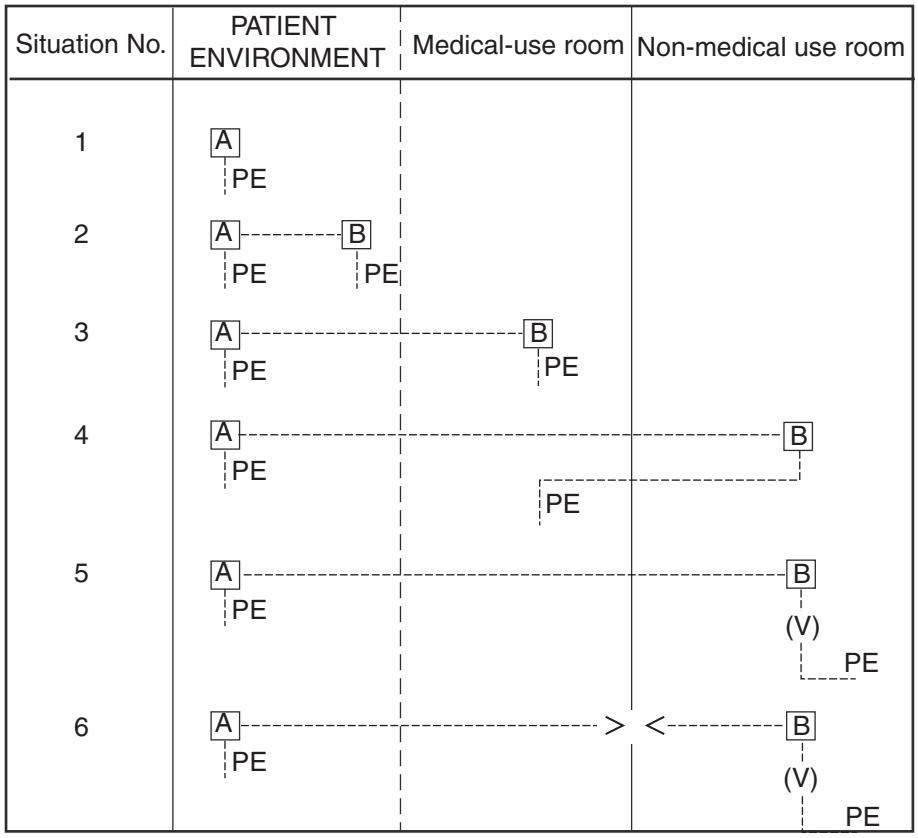
The following is an excerpt from IEC 60601-1-1 "Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems". For details, refer to IEC 60601-1-1 and consult with a biomedical engineer.

Examples of combinations of MEDICAL ELECTRICAL EQUIPMENT and non-medical electrical equipment

Situation No.	Equipment A	Equipment B	Solution
1	IEC 60601/X		OK
1a	IEC XXXXX		OK, if ENCLOSURE LEAKAGE CURRENT is less than 0.5 mA. If the ENCLOSURE LEAKAGE CURRENT is more than 0.5 mA: Solution Q (separating transformers).
2a	IEC 60601/X	IEC 60601/B	OK
2b	IEC 60601/F	IEC XXXXX	for B any one of P, Q, R
2c	IEC 60601/B	IEC XXXXX	for A solution P for B any one of P, Q, R
3a	IEC 60601/X	IEC 60601/B	OK
3b	IEC 60601/F	IEC XXXXX	OK
3c	IEC 60601/B	IEC XXXXX	for A solution P
4	see 3a, 3b, 3c		
5a	IEC 60601/X	IEC 60601/B	for A solution P or S (groundloop possible)
5b	IEC 60601/X	IEC XXXXX	for A solution P or S (groundloop possible)
6a	IEC 60601/X	IEC 60601/X	OK (with S)
6b	IEC 60601/X	IEC XXXXX	OK (with S)

IEC 60601/B = IEC 60601-1 EQUIPMENT of TYPE B **with** PATIENT connection
IEC 60601/F = IEC 60601-1 EQUIPMENT of TYPE BF or TYPE CF (or TYPE B **without** PATIENT connection)
IEC 60601/X = IEC 60601-1 EQUIPMENT of TYPE B or TYPE BF or TYPE CF
IEC XXXXX = Equipment complying with, e.g. IEC 348, IEC 950 etc.

P: additional protective earth
Q: additional separating transformer
R: floating power supply
S: separation



Legend:

(V) = Potential difference between different localities

>< = SEPARATION DEVICE

PE = Protective earth