SAFETY AND PERFORMANCE INFORMATION

NIHON KOHDEN

Bedside Monitor
SVM-7500 Series

General

The SVM-7500 series bedside monitor is installed near a patient and displays the patient's vital signs such as ECG, NIBP, SpO_2, respiration, temperature, IBP and CO_2, and generates alarms. The monitor is designed so the operator can directly touch the screen from the operator position.

EMC RELATED CAUTION

This equipment and/or system complies with IEC 60601-1-2 International Standard for electromagnetic compatibility for medical electrical equipment and/or system. However, an electromagnetic environment that exceeds the limits or level stipulated in 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. Keep the emitter source such as cellular phone away from the equipment and/or system, or turn off the cellular phone.

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. A humid room can help lessen this problem.

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.

5. Interference of lightning:

   When lightning occurs near the location where the equipment and/or system is installed, it may induce an excessive voltage in the equipment and/or system. In such a case, disconnect the AC power cord from the equipment and/or system and operate the equipment and/or system by battery power, or use an uninterruptible power supply.

6. Use with other equipment:

   When the equipment and/or system is adjacent to stacked with other equipment, the equipment and/or system may affect the other equipment. Before using, check that the equipment and/or system operates normally with the other equipment.

7. Use of unspecified accessory, transducer and/or cable:

   When an unspecified accessory, transducer and/or cable is connected to this equipment and/or system, it may cause increased electromagnetic emission or decreased electromagnetic immunity. The specified configuration of this equipment and/or system complies with the electromagnetic requirements with the specified configuration. Only use this equipment and/or system with the specified configuration.

8. Use of unspecified configuration:

   When the equipment and/or system is used with the unspecified system configuration different than the configuration of EMC testing, it may cause increased electromagnetic emission or decreased electromagnetic immunity. Only use this equipment and/or system with the specified configuration.

9. Measurement with excessive sensitivity:

   The equipment and/or system is designed to measure bioelectrical signals with a specified sensitivity. If the equipment and/or system is used with excessive sensitivity, artifact may appear by electromagnetic interference and this may cause mis-diagnosis. When unexpected artifact appears, inspect the surrounding electromagnetic conditions and remove this artifact source.

If the above suggested remedial actions do not solve the problem, consult your Nihon Kohden representative for additional suggestions.

Safety Information

⚠ DANGER:	A danger alerts the user to a hazardous situation which causes death or serious injury.
⚠ WARNING:	A warning alerts the user to possible injury or death associated with the use or misuse of the instrument.
⚠ CAUTION:	A caution alerts the user to possible injury or problems with the instrument associated with its use or misuse such as instrument malfunction, instrument failure, damage to the instrument, or damage to other property.

Pay attention to all safety information in the Operator's Manual or Installation Guide.

⚠ WARNING

Interaction between Minute Ventilation Rate-Adaptive Pacemakers and Cardiac Monitoring and Diagnostic Equipment

The bioelectric impedance measurement sensor of a minute ventilation rate-adaptive implantable pacemaker may be affected by cardiac monitoring and diagnostic equipment which is connected to the same patient. If this occurs, the pacemaker may pace at its maximum rate and give incorrect data to the monitor or diagnostic equipment. If this occurs, disconnect the monitor or diagnostic equipment from the patient or change the setting on the pacemaker by referring to the pacemaker's manual. For more details, contact your pacemaker representative or Nihon Kohden representative.

⚠ WARNING

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

⚠ WARNING

When the monitor is used with an electrosurgical unit (ESU), firmly attach the entire area of the ESU return plate. Otherwise, the current from the ESU flows into the electrodes of the monitor, causing electrical burn where the electrodes are attached. For details, refer to the ESU manual.

⚠ WARNING

When performing defibrillation, discharge as far as possible from electrodes, patches and any gel, cream or medicine on the chest of the patient. If there is a possibility that the defibrillator paddle could touch these materials, remove them from the patient. If the defibrillator paddle directly contacts these materials, the discharged energy may cause skin burn to the patient.

⚠ WARNING

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

⚠ WARNING

Do not perform defibrillation when the cables are located between the defibrillator paddles. The discharged energy may be insufficient.

⚠ WARNING

Do not allow the conductive part of the connector which is connected to the patient to contact other conductive parts including earth. This causes leakage current and incorrect measurement value and leads to wrong diagnosis.

⚠ WARNING

When performing MRI test, remove all electrodes and transducers from the patient which are connected to this instrument. Failure to follow this warning may cause skin burn on the patient. For details, refer to the MRI manual.

⚠ WARNING

After attaching electrodes, probes and sensors on the patient and connecting cables to the bedside monitor, check that there is no error messages and the waveforms and numeric data are appropriately displayed on the screen. If there is an error message, or waveform or numeric data is not appropriate, check the electrodes, probes and sensor attachment, patient condition and settings on the bedside monitor and remove the cause.

⚠ WARNING

Do not use the same monitor on more than one patient at the same time. Do not connect different sensors on different patients to the same monitor.

⚠ WARNING

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

⚠ WARNING

Only use the provided power cord. Using other power cords may result in electrical shock or injury to the patient and operator. To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth. Connect the provided power cord to the AC power cord socket on the rear panel of the bedside monitor and plug the cord into a 3-prong AC socket.

⚠ 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

Connect only the specified instrument to the monitor 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

- Do not install the monitor above the patient.
- Only use the specified tools or equipment when installing the monitor. Failure to follow this warning may result in the monitor or unit falling and injuring the patient.

⚠ WARNING

Install all network devices, including printer and hubs, outside the patient environment (IEC 60601-1-1). 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

Check the software version number of the monitor 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. For details, refer to the network and system installation guide.

⚠ WARNING

Connect the monitor 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

In a network where this monitor is connected, connect only the specified instruments. Unspecified instruments may cause electrical shock or injury to the patient and operator or cause instrument malfunction, instrument stop, or data loss.

⚠ 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 do the following to the battery pack. It may cause leakage, overheating, explosion and fire.

- Short-circuit the + and – terminals on the battery pack.
- Put the battery pack into fire or heat the battery pack.
- Disassemble or alter the battery pack.
- Give strong impact to or deform the battery pack.
- Use the battery pack on unspecified instruments.
- Charge the battery pack on unspecified instruments.
- Install the battery pack with the wrong polarity.
- Leave the battery pack in the reach of patients.
- Connect the wire or cable in a wrong way.

⚠ WARNING

If the battery pack is damaged and the substance inside the battery contacts the eyes, skin or clothes, wash immediately and thoroughly with water and see a physician. Never rub your eyes, or you may lose your eyesight.

⚠ WARNING

- Do not immerse the battery pack in water. The battery may heat up and rust and the substance inside the battery may leak.
- Do not leave the battery pack unused for more than about two years. The battery may leak.

⚠ WARNING

Do not use deformed battery. It may cause overheating, rupture or fire.

⚠ WARNING

When the <EXIT SLEEP MODE ON CRISIS ALARM> check box on the ALARM page of the SYSTEM SETUP window is OFF, the bedside monitor alarm cannot be seen or heard on the bedside monitor during sleep mode. In this case, monitor the bedside monitor alarms on the central monitor. Otherwise, bedside monitor alarms may be overlooked.

⚠ WARNING

Check the alarm settings when admitting a new patient and whenever the patient condition changes and change the alarm settings if necessary. The alarm settings return to the alarm master settings on the SYSTEM SETUP window when:

- A patient is discharged and all data is deleted on the ADMIT window.
- <ADMIT MODE> in the SYSTEM SETUP window is set to AUTO and the monitor power is off for more than 30 mins.
- “PATIENT TYPE” is changed on the ADMIT window.

⚠ WARNING

When an alarm occurs:

- Check the patient first and take necessary measure to ensure patient’s safety.
- Remove the cause of the alarm.
- Check the alarm settings on the bedside monitor and change the alarm settings if necessary.

⚠ WARNING

If more than one medical device is used together in the same facility, make sure all devices have the same alarm default settings (alarm master). If the medical devices have different alarm default settings, when the settings are returned to the alarm master settings, the alarm settings of each device may be different so alarms cannot be managed appropriately in the facility. If using different alarm default settings according to areas or wings in the facility, manage the alarms appropriately.

⚠ WARNING

Please set the appropriate alarm sound according to the operating environment. When the alarm sound is lower than the environment sound, frequently check the patient and device's conditions visually. Otherwise, important alarms may be missed and the condition of the patient and device may be overlooked.

⚠ WARNING

A physician must be within the range where he/she can hear the alarm sound of the bedside monitor while monitoring a patient on the bedside monitor. If the physician cannot hear the alarm sound, critical changes in the patient may be overlooked.

⚠ WARNING

Do not diagnose a patient based on only the alarm information of the bedside monitor. An alarm might not be indicated due to alarm level or alarm on/off setting and critical changes in the patient may be overlooked.

⚠ WARNING

During alarm suspension ("SUSPEND ALARMS", "ALL ALARMS OFF" or "ALARM RESET" message displayed), all alarms are turned off. Be careful when you suspend the alarm.

⚠ WARNING

Do not turn all alarms off with the [ALL ALARMS OFF] key when there is no medical staff around the patient or when the patient is connected to a ventilator.

⚠ WARNING

For arrhythmia monitoring, set <ARRHYTHMIA ANALYSIS> on the ECG page of the PARAMETERS window on the SYSTEM SETUP window to ON. Otherwise, there is no sound or indication for arrhythmia alarms (except for ASYSTOLE).

⚠ WARNING

Do not monitor a patient's vital signs only by the interbed function. The patient must be monitored on the interbed bed or a central monitor.

⚠ WARNING

After attaching the electrode to the patient and connecting the cable to the monitor, check that electrodes are attached to the patient and check that the cable is connected to the monitor 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

When using a defibrillator together with the monitor, use Ag/AgCl electrodes. Other types of electrodes, stainless steel in particular, will adversely affect the ECG waveform by slowing the baseline recovery on the monitor and result in no monitoring immediately following defibrillation.

⚠ WARNING

When performing defibrillation, only the patient cables of BJ-753P, BJ-753PA, BJ-755P and BJ-755PA which are specified by Shanghai Kohden can be used.

⚠ WARNING

When using the monitor with an ESU, locate the monitor and ESU and ground the instruments properly. Check the ECG and value on the monitor. Otherwise noise from the ESU may interfere with the ECG and the heart rate and arrhythmia analysis may be incorrect.

⚠ WARNING

Turn the pacing pulse detection* to ON when monitoring a pacemaker patient. Otherwise the pacemaker pulse is not rejected. However, even when the pacing pulse detection is set to ON, the pacemaker pulse might not be rejected. When the pacemaker pulse is not rejected, the pacemaker pulse is detected as QRS and false heart rate may be indicated or critical arrhythmia such as asystole may be overlooked. Keep pacemaker patients under close observation.

⚠ WARNING

Even when the pacing pulse detection is set to ON, the pacemaker pulse can be overlooked or detected as QRS. You cannot confirm the pacemaker operation only from the detected pacemaker pulse.

⚠ WARNING

When using the airway adapter or nasal adapter on a patient with low ventilatory volume, the CO_2 may mix in the inspiration due to the airway adapter's dead space volume, resulting in inaccurate measured values or difficulty in detecting apnea. Perform ventilation taking into consideration the dead space volume.

⚠ WARNING

The only oxygen cannula that can be used with YG-122T is manufactured by HUDSON RCI®. Do not use any other oxygen cannula. Other oxygen cannulas cannot be attached and oxygen cannot be delivered to the patient through the nostrils.

⚠ WARNING

- When you use YG-122T together with an oxygen cannula, check that the oxygen cannula is correctly attached on the patient by referring to other parameters and by observing the patient periodically.
- If arterial oxygen partial pressure does not increase, immediately stop using the oxygen cannula with the CO_2 sensor kit and select another way to supply oxygen.

⚠ WARNING

Check that the oxygen cannula tube is not bent, broken, or blocked by the nasal tube. If the ends of the oxygen cannula tube turn too far up or down, it causes insufficient O_2 supply or the CO_2 value may be incorrect.

⚠ 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

Check the circulation condition by observing the skin color at the measurement site and pulse waveform. Change the measurement site every 8 h for disposable probes and every 4 h 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.

⚠ WARNING

- When using the TL-201T finger probe, do not fasten the probe and cable to the finger by wrapping with tape. This may cause burn, congestion or pressure necrosis from poor blood circulation.
- When using probes other than the TL-201T finger probe, to avoid poor circulation, do not wrap the tape too tight. Check the blood circulation condition by observing the skin color and congestion at the skin peripheral to the probe attachment site. Even for short-term monitoring, there may be burn or pressure necrosis 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

When not monitoring SpO_2, disconnect the SpO_2 connection cord from the SpO_2 socket. Otherwise, noise from the probe sensor may interfere and incorrect data is displayed on the screen.

⚠ 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

As this medical device uses an alternative small-bore connector design different from those specified in the ISO 80369 series, there is a possibility that a misconnection can occur between this medical device and a medical device using a different alternative small-bore connector, which can result in a hazardous situation causing harm to the patient. Special measures need be taken by the user to mitigate these reasonable foreseeable risks.

⚠ WARNING

Be careful when measuring NIBP on a patient with known bleeding disorders or coagulation. After NIBP measurement, there may be dot hemorrhage, or circulatory disorder by thrombus where the cuff is attached.

⚠ WARNING

Do not attach the NIBP cuff on a wounded area. It may make the wound worse.

⚠ WARNING

Do not attach the NIBP cuff on a limb which is being used for intravascular access or therapy, or an arterio-venous (A-V) shunt. It may cause reflux of blood or medicinal solution or block injection of medicinal solution due to poor blood circulation.

⚠ WARNING

NIBP measuring can not be used with pregnant, including pre-eclamptic patients. NIBP measurement may be incorrect in the following cases.

- When using an electrosurgical unit
- When there is body movement
- When the pulse wave is small (insufficient peripheral circulation)
- Too many arrhythmias
- When there is vibration
- When there is a rapid blood pressure change
- During CPR
- When the pulse is too late
- When blood pressure is too low
- When the cuff is wrapped too tight or too loose
- When the size of the cuff is not proper
- When the cuff is wrapped over thick cloth
- When the cuff is deteriorated
- When using with pregnant, including pre-eclamptic patients

⚠ WARNING

Do not attach the NIBP cuff on an arm which is the same side as a mastectomy or lymph node clearance. It may cause circulatory disorder such as swelling from poor blood circulation.

⚠ WARNING

While measuring NIBP, if the NIBP cuff and other medical equipment are attached to the same limb, the medical equipment might not function temporarily.

⚠ WARNING

When performing long term measurement at intervals less than 2.5 mins, perform measurements while observing the state of the patient, blood vessels and limb to ensure adequate circulation. Congestion may occur at the measurement site. When performing periodic measurement for a long time, periodically check the circulation condition.

⚠ WARNING

All parts, except for transducers, must be non-conductive. Otherwise, the discharged energy may cause electrical shock to the operator during defibrillation.

⚠ WARNING

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the SVM-7500, including cables specified by the manufacturer. Otherwise, degradaion of the performance of this equipment could result.

⚠ CAUTION

Only use Shanghai Kohden specified electrodes, probes and sensors. Otherwise, the maximum performance from the monitor cannot be guaranteed.

⚠ CAUTION

Do not reuse disposable parts and accessories.

⚠ CAUTION

Make sure that the electrodes and cords attached to the patient are properly connected to the monitor. Otherwise, incorrect data may be displayed and lead to wrong diagnosis.

⚠ CAUTION

After the monitor power is turned on, parameter-related alarms do not function until the parameters are monitored.

⚠ 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

When admitting a new patient, first delete all data of the previous patient. Otherwise, the data of the previous patient and new patient will be mixed together.

⚠ CAUTION

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

⚠ CAUTION

When the “CONNECTOR OFF” message appears on the screen, check that the connection cords are connected to the sockets properly. The patient cannot be monitored and the alarm does not function while this message is displayed.

⚠ CAUTION

Before start monitoring, check that the patient type setting (ADULT/CHILD/NEONATE) is correct. If the patient type setting is incorrect, NIBP value or heart rate may be incorrect, and noise and P wave may be incorrectly interpreted as a QRS wave. Moreover, the NIBP initial cuff pressure may also be incorrect.

⚠ CAUTION

Do not lift the monitor by the power cord or patient cable; use only the handle on the monitor.

⚠ Caution

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 or injury.

⚠ Caution

Only use the specified equipment for installing the monitor and instruments. Using non-specified equipment may result in the instruments falling and causing injury.

⚠ CAUTION

When the monitor is connected to a central monitor network, set the Bed Name (Bed ID) and Group Name on the monitor. Otherwise, the default settings are used for the bed name and group name and the bed may be incorrectly identified on the central monitor.

⚠ CAUTION

The network must be managed by the network administrator. Make sure that each monitor in the network has a different IP address. Otherwise, data communication cannot be performed properly. When adding a monitor to an already operating network, set the IP address on the monitor before connecting the monitor to the network.

⚠ CAUTION

Do not touch the thermal head inside the recorder module. The thermal head may be damaged by static electricity or become dirty and cause printing failure.

⚠ CAUTION

Do not pull out the battery connector forcibly. Otherwise, the battery connector may break and battery pack may not be used.

⚠ CAUTION

The battery connection cable must be on the right side. Do not insert the battery pack in the wrong direction.

⚠ CAUTION

Use the bedside monitor in a securely managed environment.

⚠ CAUTION

Personal information stored on the bedside monitor, or the PC, is vulnerable to unauthorized access. Follow the provisions of the user agreement for the bedside monitor related to information security.

⚠ CAUTION

Do not leave the battery pack near the patient or in reach of children.

⚠ CAUTION

To ensure the cybersecurity of the bedside monitor, implement the following security measures in the network environment to which the product is connected.

1. All communication (incoming and outgoing) between the bedside monitor and the local area network (LS-NET, HIS, etc.) is subject to packet filtering by a firewall or router.
2. When the bedside monitor is connected to the local area network (LS-NET, HIS, etc.), all communication with the internet or other external networks is restricted to essential transmissions under the supervision of the appropriate personnel with responsibility for information security of medical equipment.

⚠ CAUTION

Some data and operations on the bedside monitor can be set, changed or managed only by a user with administrator privileges. Set a password for the administrator that is difficult to guess. Change the password at regular intervals and store it securely to prevent security breaches.

⚠ CAUTION

When the monitor is turned on, check that one “bong” sounds and the red, yellow and green alarm indicator lamps blink once to show that the alarm functions properly.

⚠ CAUTION

Do not subject the battery pack to a strong mechanical impact.

⚠ CAUTION

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

⚠ CAUTION

Use the battery pack between 10 °C (50 °F) and 40 °C (104 °F). Temperatures out of this range affect the working of the battery.

⚠ CAUTION

Before disposing of the battery pack, 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.

⚠ CAUTION

Do not use a battery pack which is past the expiration date written on the label.

⚠ CAUTION

When charging the battery pack, keep the ambient temperature at approximately 20 °C to maintain the optimal battery operation time. If the battery pack is charged at less than 10 °C (50 °F) or more than 30 °C (86 °F), the maximum battery operation time will be 20 % to 30 % less than the optimal operation time.

⚠ CAUTION

Follow the specified procedure to turn off the bedside monitor. Otherwise, patient data will be deleted and the storage device and data in the storage device may be damaged.

⚠ CAUTION

When admitting a new patient, first delete all data of the previous patient. Otherwise, the data of the previous patient and new patient will be mixed together.

⚠ CAUTION

Setting ALARM LIMITS to extreme values can render the ALARM SYSTEM useless.

⚠ CAUTION

When the alarm limit is set to OFF, there will be no alarm for that limit. Depending on the setting, the alarm off mark might not be displayed on the screen. Be careful when you set the alarm limit to OFF.

⚠ CAUTION

When the alarm is turned OFF for an arrhythmia, there will be no alarm for that arrhythmia type. There is no message or mark to indicate that a certain arrhythmia alarm is turned off. Therefore, be careful when you turn off an arrhythmia alarm.

⚠ CAUTION

When the monitor is turned on with alarms silenced, there will be no alarms until alarm silence time ends.

⚠ CAUTION

The interbed window only appears on the home screen when an interbed alarm occurs and <AUTO INTERBED DISPLAY> is set to ON.

⚠ CAUTION

At the start of ECG monitoring, check that the dominant QRS is appropriate. Otherwise arrhythmia monitoring may be inaccurate.

⚠ CAUTION

Only use Shanghai Kohden products and specified parts and accessories. When other electrodes are used, the “CHECK ELECTRODES” message may appear and monitoring may stop.

⚠ CAUTION

When the “CHECK ELECTRODES” message is displayed, ECG is not monitored properly and the ECG alarm does not function. Check the electrode, the electrode leads and connection cord, and if necessary, replace with new ones.

⚠ CAUTION

When the “NOISE” or “CANNOT ANALYZE” message is displayed, ECG data and alarm are not reliable. Remove the cause by checking the electrodes, electrode leads, patient’s body movement, EMG and peripheral instruments grounding. Also make sure that an electric blanket is not used.

⚠ CAUTION

- Only use Shanghai Kohden specified electrodes. If other electrodes are used, the electrode lead might not be properly connected and ECG monitoring may be unstable.
- Do not use electrodes of different metals. ECG monitoring may be unstable if electrodes of different metals are used.

⚠ CAUTION

During NIBP cuff inflation, heart rate counting accuracy is not guaranteed by noise interference.

⚠ CAUTION

If there is any doubt about the arrhythmia analysis, make the monitor relearn the patient’s ECG and check that the dominant QRS is appropriate. Otherwise, an important arrhythmia may be overlooked.

⚠ CAUTION

At the start of ECG monitoring, check that the correct patient type is set for <PATIENT TYPE> on the ADMIT window. If an inappropriate patient type is set, heart rate cannot be counted accurately and noise or P waves may be counted as QRS and cardiac arrest may be overlooked.

⚠ CAUTION

When the ECG measurement is OFF, ECG alarms do not occur even if each ECG alarm item is set to ON.

⚠ CAUTION

Measurement might not be performed correctly in environments with rapid temperature change and much condensation.

⚠ CAUTION

The TG-901T4 and TG-921T4 CO_2 sensor kits do not adjust the measurement value to compensate for different atmospheric pressure. Be careful of reading the value when using the CO_2 sensor kit at high altitudes because the measurement value may be inaccurate.

⚠ CAUTION

With the TG-921T4 CO_2 sensor kit, measurements are based on the assumption of no CO_2 gas in the inspiration. The CO_2 concentration in the respiration is calculated by taking the CO_2 concentration in the inspiration as 0 mmHg (0 kPa). Therefore, measuring CO_2 of a patient with an oxygen mask where CO_2 gas may be present in the inspiration gas may result in the acquired data being lower than the actual value.

⚠ CAUTION

With the TG-971T4/TG-981T4 CO_2 sensor kit, measured value may be incorrect when the operating temperature changes greatly. In this case, wait for about 30 mins to acquire correct measurement.

⚠ CAUTION

Only use the specified probes. Otherwise, SpO_2 cannot be monitored.

⚠ CAUTION

When the “CHANGE ADAPTER” or “SENSOR ERROR” message is displayed, check the CO_2 sensor kit and replace it if necessary. CO_2 cannot be monitored while the message is displayed.

⚠ CAUTION

Select the airway adapter or nasal adapter taking into consideration the patient weight and ventilation volume. If an inappropriate airway adapter or nasal adapter is used, the resistance in the respiration circuit increases and it causes incorrect measurement value.

⚠ CAUTION

The CO_2 data may be inaccurate when monitoring a patient with an extremely high respiration rate or irregular respiration. Read the measured values carefully.

⚠ CAUTION

When monitoring CO_2, make sure that the gas composition is entered. Otherwise the measurement result may be inaccurate.

⚠ CAUTION

When using an anesthetic instrument with a volatile anesthetic agent, the CO_2 measurement may be inaccurate.

⚠ CAUTION

When using the YG-121T/YG-122T nasal adapter on a patient with bleeding disorder, poor general medical condition or malnutrition, observe the patient condition all the time. The mouth guide touches the mouth and may cause pressure sores.

⚠ 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

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

⚠ 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

If the skin gets irritated or redness appears on the skin from the probe, change the attachment site or stop using the probe. Take extreme care for the patients with delicate skin.

⚠ CAUTION

When monitoring SpO_2 only (without ECG monitoring), turn on both the upper and lower limit alarms for PR and SpO_2. If the patient’s pulse is not detected during asystole or other condition, a “CANNOT DETECT PULSE” or “CHECK PROBE” alarm occurs instead of an SpO_2 limit alarm. Furthermore, if the patient has no pulse, noise from probe movement could be misjudged as a pulse and cause an incorrect PR or SpO_2 value to be displayed.

⚠ 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

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

⚠ CAUTION

When a message indicates a faulty probe or faulty SpO_2 connection cord, stop monitoring and replace the probe or SpO_2 connection cord with a new one.

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

⚠ **CAUTION**
Do not pull or bend the probe cable, and do not put caster feet on the probe cable. Do not immerse the probe cable in chemical solutions or water. Failure to follow these instructions may cause cable discontinuity, short circuit, skin burn on the patient and incorrect measurement data. Replace any broken probe with a new one.

⚠ **CAUTION**
When removing a probe that is taped to the skin, do not pull the probe cable because this can damage the cable.

⚠ **CAUTION**
Neonatal skin is delicate. Remove the probe (and tape) carefully and slowly.

⚠ **CAUTION**
Do not use a damaged or disassembled probe. It causes incorrect measurement and may injure the patient.

⚠ **CAUTION**
Firmly connect the air hose to the NIBP socket on the monitor until it clicks. At the start of NIBP measurement, check if the cuff type corresponds to the type displayed on the monitoring screen.

⚠ **CAUTION**
Do not wrap the cuff too tight. It may cause poor blood circulation and congestion. If the cuff is wrapped too loosely, the NIBP value may increase.

⚠ **CAUTION**
Do not wrap the cuff on an arm or thigh which is used for injection. NIBP measurement on an arm or thigh which is used for injection may cause reflux of blood and stop injection.

⚠ **CAUTION**
Only connect the air hose to the cuff and NIBP socket on the monitor. Do not connect the air hose, especially the air hose for neonate, to other parts, such as an infusion line. It may cause thrombus.

⚠ **CAUTION**
Measuring mode of Neonate/Child/Adult can not be changed automatically. It should be set in PATIENT TYPE of ADMIT window.

⚠ **CAUTION**
Please select appropriate cuff according to patient. If inappropriate cuff is used, the measuring value may be incorrect.

⚠ **CAUTION**
An air hose for adult cannot be inserted into the cuff for neonate. The cuff for neonate can only be connected to the air hose for neonate.

⚠ **CAUTION**
When too much pressure is applied to the cuff, or the hose is bent or squeezed, the “NIBP SAFETY CIRCUIT RUNNING” message appears on the screen and NIBP monitoring may be stopped. Remove the cause, wait 40 s, check that the message disappears, then measure again.

⚠ **CAUTION**
Before starting STAT or SIM mode measurement, check the measurement setting (measurement intervals).

⚠ **CAUTION**
For safety during lumbar anesthesia, NIBP SIM mode measurement is recommended by medical policy in Japan and the factory default settings are the recommended settings. When changing these initial settings, make sure that the changed setting is appropriate for the patient by referring to the manual of the anesthetic agent.

⚠ **CAUTION**
Do not perform a venous puncture on the same arm where NIBP is measured. This may cause an infusion backflow or internal hemorrhage at the puncture.

⚠ **CAUTION**
Select the appropriate probe for the patient. Using adult probes on premature infants and children may injure the mucous membrane.

⚠ **CAUTION**
The insulation pad may irritate the skin. In long term monitoring, change the attachment site to prevent irritation.

⚠ **CAUTION**
Before maintenance, cleaning or disinfection, turn the bedside monitor power off and disconnect the power cord from the AC socket. Failure to follow this instruction may result in electrical shock and bedside monitor malfunction.

⚠ CAUTION

No modification of this equipment is allowed. If there is any problem with the monitor, contact your Nihon Kohden representative.

⚠ CAUTION

Dispose of the monitor and accessories according to your local laws and your facility's guidelines for waste disposal. Otherwise, they may affect the environment. If there is a possibility that the monitor and accessories may have been contaminated with infection, dispose of them as medical waste according to your local laws and your facility's guidelines for medical waste. Otherwise, it may cause infection.

⚠ CAUTION

- Do not use volatile liquids such as thinner or benzine, because these will cause the materials to melt or crack.
- Be careful not to let any water get inside the bedside monitor.
- Never sterilize the bedside monitor because the materials may deform, crack or discolor.
- When using a flammable solvent such as ethanol for cleaning and disinfecting, do so in an open apace, and ventilate the room adequately.

⚠ CAUTION

- Do not touch the recording head with any hard object. When the head is tapped with hard object, the head may crack and the heater element wire may break.
- Clean the head surface with the provided head cleaner pen before loading new paper. After a period of usage, paper dust may accumulate between the paper and the head surface and good printing cannot be obtained.
- Be careful not to cut yourself on the paper cutter in the recorder.

⚠ CAUTION

With the TG-901T4 CO_2 sensor kit, measurements are based on the assumption of noCO_2 gas in the inspiration. The CO_2 concentration in the respiration is calculated by taking the CO_2 concentration in the inspiration as 0 mmHg. Therefore, measuring CO_2 by connecting the CO_2 sensor kit to a Jackson Rees circuit, Mapleson D circuit or any other respiration circuit where CO_2 gas may be present during inspiration may result in the acquired data being lower than the actual value.

⚠ CAUTION

The CO_2 sensor kit cannot correctly measure the $ETCO_2$ value and respiration rate during high frequency oscillation (HFO). Do not diagnose the patient from the $ETCO_2$ Value and respiration rate.

This Safety and Performance Information is an extract from the general and safety information sections of the most recent edition of Operator's Manual or Installation Guide. Therefore, the contents of your Operator's Manual or Installation Guide may differ from those of this Safety and Performance Information. For detailed operating procedures, follow the instructions of your Operator's Manual or Installation Guide.

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