SAFETY AND PERFORMANCE INFORMATION

NIHON KOHDEN

Bedside Monitor
BSM-2500 series

General

This bedside monitor is for one patient and has a color display.

This bedside monitor is used to monitor the patient's electrocardiogram (ECG) (including ST, QT/QTc, arrhythmia, 12-lead ECG analysis), respiration (RESP), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), temperature (TEMP), blood oxygen saturation (SpO_2), pulse rate (PR), carbon dioxide (CO_2) and non-invasive continuous cardiac output (esCCO), and provides visual and auditory alarm functions.

This bedside monitor should be used in medical institutions by professionally trained clinical staff and can be used in operating rooms, intensive care units, post-anesthesia recovery rooms, examination departments, cardiac care, emergency care, respiratory care, neurological care, dialysis care, obstetrical care, neonatal care, geriatric care, internal-medicine and surgical care.

The target patients for monitoring are adults, children and neonates.

It is installed near the patient and displays the patient's vital signs (such as ECG, respiration, SpO_2, temperature, NIBP, IBP [1], CO_2 [1], esCCO) on the screen and generates alarms.[2] The bedside monitor also detects apnea and monitors arrhythmia.

[1] BSM-2535 and BSM-2565, or BSM-2530, BSM-2532, BSM-2560, BSM-2562 installed with multi sockets module AA-252P.

[2] Essential performance of the bedside monitor.

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

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 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 cable 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

The product is not designed to use in MRI. Do not bring it into the MRI room. Before performing MRI test, remove all electrodes and transducers which are connected to this instrument from the patient. Failure to follow this warning may cause skin burn on the patient. For details, refer to the MRI manual.

⚠ WARNING

Do not modify the monitor. It might cause skin burn, fire, electrical shock or injury.

⚠ 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 monitor. Overall judgement must be performed by a physician who understands the features, limitations and characteristics of the monitor and by reading the biomedical signals acquired by other instruments.

⚠ WARNING

After attaching electrodes, probes and sensors to 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 appropriately displayed, check the electrodes, probes and sensor attachment, patient condition and settings on the bedside monitor and remove the cause.

⚠ 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.

⚠ CAUTION

If fluids are accidentally spilled into the monitor, stop using it and contact your Nihon Kohden representative. The monitor must be disassembled, cleaned, dried and tested for safety, function and performance.

⚠ DANGER

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

- Do not immerse the battery pack in liquid or get it wet.
- Do not put the battery pack into fire or heat it. The battery pack should be far away from a heat source such as fire and the stove.
- Do not charge the battery pack on unspecified instruments.
- Do not charge the battery pack in conditions outside the specified environment such as a place near the stove or sun-heated cars.
- Do not short-circuit the + and – terminals on the battery pack.
- Do not give strong impact to or deform the battery pack.
- Do not disassemble, modify, or damage the battery pack, or weld the shell directly.

⚠ DANGER

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

⚠ WARNING

Remove the battery pack from the monitor when it is not used for a long time. Otherwise the battery pack may leak.

⚠ WARNING

If a battery pack is not installed in the monitor, connect the monitor to an uninterruptible power supply which meets IEC 60601-1 requirements or to the emergency power system in the hospital.

⚠ CAUTION

Do not leave the battery pack within reach of the patient.

⚠ CAUTION

Do not expose the battery pack to direct sunlight or leave it 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

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

⚠ CAUTION

If the battery pack is installed, check that no error messages related to the battery are displayed and the bedside monitor operates normally. If the battery pack is deteriorated, data in the bedside monitor might not be backed up when there is a sudden power failure.

⚠ 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

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

⚠ WARNING

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. In this case, set the impedance measurement to Off on the monitor. When respiration monitoring is turned off, there will be no respiration alarm even if the respiration alarm is set to On.

⚠ 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

When using the output signal from the monitor as the synchronization signal for other equipment such as an IABP (intra-aortic balloon pump) or defibrillator:

- Set the timing of the IABP by checking the waveform on the IABP screen.
- Always check that there is no noise on the waveforms.
- Set the “Filters” setting to “Diag” so that the output waveforms and the waveforms on the bedside monitor are the same.
- Check that the delay time of the output signal is within the range of the connected equipment.

⚠ CAUTION

Only a Nihon Kohden defibrillator can use the output signal from the monitor as a synchronization signal. Check that the delay time of the output signal (heart rate trigger 20 ms maximum) is within the range of the connected defibrillator.

⚠ WARNING

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

⚠ WARNING

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

⚠ WARNING

When an alarm is generated, check the patient condition and secure the patient safety. Depending on the generated alarm, perform appropriate treatment and remove the cause of alarm. If there is a problem on the alarm setting, change it to an appropriate setting.

⚠ 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 different alarm default settings are used according to areas or wings in the facility, manage the alarms appropriately.

⚠ 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
- the patiet type is changed
- “Show Admit Confirmation Window” in the System Setup window is set to Off and 30 minutes elapse after the monitor power is turned off.

⚠ 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" setting to ON on the [ECG] page of the [Parameters] window on the [setup] window. Otherwise, there is no sound or indication for arrhythmia alarms (except for "Asystole").

⚠ WARNING

ST, CO_2 and RESPIRATION settings only affect the individual bedside monitor, not on all monitors connected to the network. The unit settings must be the same on all bedside monitors and central monitors in the network. Otherwise, the different measurement values and alarms will be displayed on different monitors depending on the unit settings on each monitor.

⚠ WARNING

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

⚠ WARNING

The EWS results and the recommendations provided are for reference only. It is not a tool for comprehensive clinical judgement and should not be used directly as a basis for clinical treatment. Nor should it replace the clinician's assessment of the patient's condition or be used as an indicator to predict the progression and make a prognosis of the patient's condition.

⚠ 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. Be careful when you set the alarm limit to Off.

⚠ CAUTION

When the alarm is turned OFF for some type of 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 respiration measurement is Off, respiration alarms do not occur even if each respiration alarm item is set to On.

⚠ CAUTION

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

⚠ 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 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.

⚠ WARNING

When using sleep function, monitor the patient on the central monitor or telemetry system. Otherwise, the bedside monitor alarm may be overlooked. When the "Exit Sleep Mode on Crisis Alarm" check box on the System Setup window is not On, bedside monitor alarms and sync sound appear on the central monitor but do not appear on the bedside monitor during sleep mode.

⚠ CAUTION

All parameters may not be displayed on the screen when too many parameters are monitored. At the start of monitoring, check which parameters are displayed and which parameters are not displayed on the screen. When an alarm occurs on the measured parameter, the alarm is displayed regardless of whether the parameter is displayed or not displayed.

⚠ WARNING

Only use Shanghai Kohden specified options such as electrodes, sensors, probes, cuffs and air hoses. If unspecified options are used, maximum performance from the monitor cannot be satisfied and the patient or operator may receive electrical shock when defibrillation is performed.

⚠ WARNING

After attaching electrodes, probes and sensors to 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 appropriately displayed, check the electrodes, probes and sensor attachment, patient condition and settings on the bedside monitor and remove the cause.

⚠ WARNING

Do not reuse disposable parts and accessories.

⚠ CAUTION

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

⚠ WARNING

For arrhythmia monitoring, set "Arrhythmia Analysis" setting to ON on the [ECG] page of the [Parameters] window on the [setup] window. Otherwise, there is no sound or indication for arrhythmia alarms (except for "Asystole").

⚠ 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

It is not possible to obtain 100 % accurate detection of every arrhythmia.

⚠ WARNING

Do not use A-Fib detection for children or neonates. The monitor might not correctly detect A-Fib in children or neonates.

⚠ WARNING

The monitor requires a minimum of two minutes of continuous analysis before A-Fib can be detected. Detection may take up to 2.5 minutes.

⚠ WARNING

When monitoring children or neonates, QTc interval and QRS width cannot be measured correctly.

⚠ WARNING

Do not use 12-lead ECG interpretation results and measured values from the Mason-Likar modification for diagnosis because the limb electrode placement is not the same as the standard 12-lead ECG. This may cause wrong diagnosis since 12-lead ECG interpretation of this monitor is based on the standard 12-lead ECG.

⚠ CAUTION

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

⚠ CAUTION

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

⚠ CAUTION

At the start of ECG monitoring, check that the correct patient type is set for QRS Detection Type. 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

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

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

- The 12-lead ECG interpretation is performed for acquired ECG waveforms only and does not reflect all conditions of the patient. The results of the analysis might not correspond to the judgement of a physician.
- Overall judgement must be performed by the physician, referring to the analysis result, clinical findings and other examination results. After the physician's overall judgement, the analysis results should be signed or initialed by the physician.

⚠ CAUTION

Enter the age and gender when performing the 12-lead ECG interpretation. Otherwise:

- gender is male.
- age is 35 years old.

⚠ 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

After use, clean the reusable SpO_2 probe. Failure to follow this warning may cause cross infection.

⚠ WARNING

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

⚠ WARNING

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

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

⚠ WARNING

When not monitoring SpO_2, disconnect the SpO_2 connection cord from the bedside monitor. 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.

⚠ 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

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

⚠ 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 have deteriorated. Replace it with a new one.

⚠ CAUTION

When a message indicates a faulty probe or faulty SpO_2 connection cord, stop using the monitor 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

When only SpO_2 is monitored, detection of arrhythmia and asystole is not available and arrhythmia alarms for Asystole, V Fib or V Tachy and so on are not available. If the patient needs ECG monitoring, monitor the ECG.

⚠ CAUTION

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

⚠ 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 or nasal adapter's dead space, resulting in inaccurate measured values or difficulty in detecting no breath. Perform ventilation taking into consideration the dead space of the adapters. If that dead space is too much for this patient, appropriate ventilation might be impossible.

⚠ 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

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 respiratory circuit may increase and it may cause incorrect measurement value.

⚠ CAUTION

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

⚠ CAUTION

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

⚠ CAUTION

Follow the CAUTION label on the CO_2 gas cylinder.

⚠ CAUTION

When a "CO_2 Sensor Error" or "CO_2 Change Adapter" 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

The measured value may be incorrect when the operating temperature changes greatly.

⚠ WARNING

After use, clean the thermistor probe. Failure to follow this warning may cause cross infection.

⚠ CAUTION

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

⚠ CAUTION

Use of the insulated cover may occasionally cause symptoms such as rash or inflammation of the skin. Change the measurement site when conducting several measurements in succession.

⚠ CAUTION

After changing the temperature label, do not change the probe. This may cause an incorrect label display and lead to misjudgement.

⚠ CAUTION

The measured value may be incorrect when the operating temperature changes greatly.

⚠ WARNING

NIBP value may be affected by measurement conditions, measurement site, exercise, or physiological conditions of the patient. NIBP measurement may be incorrect in the following situations.

- When using an ESU
- Body movement
- Small pulse wave
- Too many arrhythmias
- Shaking from an external source
- Rapid blood pressure change
- During CPR
- Slow pulse
- Low blood pressure
- Small pulse pressure
- Cuff is too tight or too loose
- Cuff does not fit the arm
- Cuff is wrapped over thick clothing
- Cuff is deteriorated

⚠ WARNING

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

⚠ WARNING

When performing long-term measurement at intervals less than 2.5 minutes, 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 long-term measurement periodically, also check the circulation condition periodically.

⚠ WARNING

When measuring NIBP in Inflate Mode, use a cuff specified by Shanghai Kohden. If an unspecified cuff is used, correct NIBP measurement might not be performed.

⚠ WARNING

During NIBP measurement, check the cuff attachment site and confirm that the cuff does not affect the blood circulation of the patient.

⚠ 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 an arm 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

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 arm, the medical equipment might not function temporarily.

⚠ WARNING

Do not bend the cuff tube during measurement. This may cause the cuff to interfere with circulation and cause congestion. If the cuff keeps receiving pressure, skin problems may occur at the measurement site.

⚠ CAUTION

Firmly connect the air hose to the NIBP socket on the monitor until it clicks. If not connected properly, the cuff type cannot be identified. At the start of NIBP measurement, check if the cuff type corresponds to the type displayed on the monitoring screen.

⚠ 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

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 around an arm or thigh which is used for infusion. NIBP measurement on an arm or thigh which is used for infusion may cause reflux of blood and stop infusion.

⚠ 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 stop. Remove the cause, wait 40 s, check that the message disappears, and then measure again.

⚠ CAUTION

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

⚠ CAUTION

The NIBP SIM mode measurement is recommended by medical policy in Japan for safety during lumbar anesthesia 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

Nihon Kohden disposable cuffs are not sterilized. Sterilizing the cuffs is not recommended. For details, refer to the operator's manual provided with the disposable cuffs.

⚠ CAUTION

Do not perform a venous puncture on the same arm where NIBP is measured. This may cause reflux of medicinal solution or internal hemorrhage at the puncture.

⚠ CAUTION

PWTT trigger measurement does not completely capture all changes in the circulation dynamics. Do not rely solely on PWTT trigger measurement as the basis for extending the interval of normal NIBP measurement.

⚠ CAUTION

In the following situations, PWTT may not trigger any NIBP measurements or trigger too many measurements. Check the patient condition. If necessary, set the PWTT to Off.

- Patient has an implanted pacemaker
- Rapid blood pressure change with vasoreflex due to vasoactive drugs, such as phenylephrine and nicardipine
- Unstable pulse wave due to poor peripheral circulation
- Too many arrhythmias
- Patient movement or change of body position
- Noise on ECG due to ESU
- SpO_2 measurement on the foot of a child
- When NIBP and SpO_2 are measured on the same limb for reasons such as surgery on other limbs

⚠ CAUTION

Do not locate the air hose connector (bedside monitor side) near a magnetic card or magnetic recording media. The data on the magnetic card or magnetic recording media may be damaged by magnetic interference from the air hose connector.

⚠ CAUTION

Do not replace any parts on the cuff. If parts are replaced with other parts, correct NIBP measurement cannot be performed.

⚠ WARNING

All parts, except for transducers, must be non-conductive. Otherwise, the discharged energy may cause electrical shock to the operator when using an ESU or performing defibrillation.

⚠ CAUTION

When displaying the target area on the target graphs, set the appropriate scale of the target area based on the patient condition.

⚠ CAUTION

esCCO monitoring has not been validated on neonates and patients with high blood pressure caused by obesity, arteriosclerosis, or other reason.

⚠ CAUTION

Do not attach the SpO_2 probe to the patient's foot when measuring esCCO. esCCO cannot be correctly measured when the probe is attached to the patient's foot.

⚠ CAUTION

When calibrating the esCCO value using CO automatically calculated from the patient information, always obtain the decision of a doctor that the automatically calculated CO value is appropriate. If the automatically calculated value is not appropriate, enter the CO measurements manually.
Also, check after calibration that the automatically calculated CO value is still appropriate.

⚠ CAUTION

When using previously measured CO values to calibrate esCCO, use CO values that a doctor has determined to be appropriate values obtained using an instrument that has been determined by medical professional to be reliable for medical use. The CAL CO value used for calibration influences the initial esCCO value and the amount of variation. For example, if a CAL CO value is input that is twice the actual cardiac output of the patient, not only the initial esCCO value displayed, but all subsequent measurements, will be twice the actual value.When a CAL CO value is input that diverges significantly from the actual cardiac output, fluctuations in the patients cardiac output will be magnified in the esCCO values. For this reason, do not use an incorrect CAL CO value for esCCO calibration. If used, do not make clinical decisions based on the resulting measurements.

⚠ CAUTION

Obtain the decision of a doctor that the calibrated parameters are appropriate values obtained during 10 minutes of stable cardiac output. Otherwise correct esCCO measurement cannot be guaranteed.

⚠ CAUTION

When NIBP is measured at a short interval, PWTT changes greatly which might not be correctly applied to the esCCO calibration.

⚠ CAUTION

Because PWTT cannot be measured correctly in the following conditions, the esCCO value may not be correctly displayed in those cases. Also, the esCCO value is not displayed correctly when SQI is 2. Measure esCCO when SQI is 3 or greater.

- When a stable pulse cannot be obtained because of peripheral circulatory failure
- Bodily movement
- Intereference by noise from an electrosurgical unit or other device
- Hypoperfusion
- Hemodynamic instability
- During or immediately after a shift in the patient's body position

⚠ CAUTION

Because PWTT cannot be correctly measured for the following patients, the esCCO value may not be correctly displayed in those cases.

- Patients suffering from atrial fibrillation, atrial flutter, sinus arrhythmia or other condition causing unstable superventricular rhythm.
- Patients with bigeminy or trigeminy
- Patients with a type II or type III AV block
- Patients with an implanted pacemaker
- Patients connected to a heart lung machine
- Patients undergoing off-pump coronary artery bypass surgery (OPCAB)
- Patients undergoing an aortic cross clamping procedure
- Patients with cardiac tamponade
- Patients suffering from displacement of the heart
- Patients with an intra-aortic balloon pump (IABP)

⚠ CAUTION

The esCCO value may not be correctly obtained when an NIBP cuff and SpO_2 probe is attached to the same arm, because PWTT cannot be correctly measured in this case. Attach the NIBP cuff and SpO_2 probe to different arms and measure esCCO again.

⚠ CAUTION

In the following cases, calibrate again because correct esCCO cannot be obtained.

- ECG monitoring lead is changed
- Electrode attachment site is changed
- SpO_2 probe attachment site is changed
- Monitor power is turned off and on
- Patient is admitted or discharged
- Data is deleted
- After patient movement or body position change

⚠ CAUTION

When the cardiac output fluctuates heavily over a short period, the esCCO value may vary significantly from other measures of cardiac output. When this occurs, use the esCCO value in combination with other vital sign data such as heart rate to make clinical decisions.

⚠ 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.

⚠ CAUTION

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

⚠ WARNING

The data output from the serial communication socket of this bedside monitor is not monitoring information for diagnosing a patient's medical condition. Do not use this data to monitor the patient on an external device. Always use a bedside monitor for monitoring.
Shanghai Kohden accepts no responsibility for any harm caused by use of output data in unspecified ways.

⚠ CAUTION

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

⚠ CAUTION

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

⚠ CAUTION

Dispose of Shanghai Kohden products according to your local laws and your facility’s guidelines for waste disposal. Otherwise, it may affect the environment. If there is a possibility that the product may have been contaminated with infection, dispose of it as medical waste according to your local laws and your facility’s guidelines for medical waste. Otherwise, it may cause infection.

⚠ WARNING

When the monitor is used with an electrosurgical unit (ESU), firmly attach the entire area of the ESU return plate to the patient. 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.

⚠ CAUTION

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

⚠ WARNING

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

⚠ WARNING

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

⚠ CAUTION

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

⚠ CAUTION

Keep the cable out of the way by running it along the floor or wall. Otherwise people may trip over it, causing the instrument to fall and injure 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

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.

⚠ CAUTION

When using the output signal from the monitor as the synchronization signal for other equipment such as an IABP (intra-aortic balloon pump) or defibrillator:

- Set the timing of the IABP by checking the waveform on the IABP screen.
- Always check that there is no noise on the waveforms.
- Set the “Filters” setting to “Diag” so that the output waveforms and the waveforms on the bedside monitor are the same.
- Check that the delay time of the output signal is within the range of the connected equipment.

⚠ CAUTION

Only a Nihon Kohden defibrillator can use the output signal from the monitor as a synchronization signal. Check that the delay time of the output signal (heart rate trigger 20 ms maximum) is within the range of the connected defibrillator.

⚠ 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

Install all network devices, including print server, laser printer, data recorder and hubs, outside the patient environment. If they are installed inside the patient environment, the patient or operator may receive electrical shock or injury. For installation, contact your Nihon Kohden representative.

⚠ WARNING

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

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

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

⚠ 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

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 monitor communicates with specified systems by using the HL7 protocol via the hospital network. Only connect the monitor to the network in the medical facility.

⚠ CAUTION

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

⚠ CAUTION

Observe all terms and conditions of the information security policy for the bedside monitor. Otherwise, there is a risk that personal information and other data stored on the bedside monitor, or on computers on which the optional software is installed, may be leaked or misused. In order to protect the security of personal information and maintain the essential functionality of the bedside monitor, it is necessary to implement a comprehensive, multi-layered security strategy (including policies, processes and security controls) to protect against internal and external cybersecurity threats.

⚠ CAUTION

Some data and operations on the 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.

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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CE 2797

1st Edition: 18 Apr. 2023