SAFETY AND PERFORMANCE INFORMATION

NIHON KOHDEN

Bedside Monitor

BSM-5732, BSM-5735, BSM-5752, BSM-5755, BSM-5762, BSM-5765

General

The BSM-5732, BSM-5735, BSM-5752, BSM-5755, BSM-5762 and BSM-5765 bedside monitors have a color display and are for one patient. The bedside monitor can be reused by other patients any number of times.

The bedside monitor is to be installed near the patient. The patient's vital signs such as ECG, IBP, NIBP, temperature, SpO_2, respiration and CO_2 are displayed on the bedside monitor and alarms are generated from the bedside monitor. Apnea and arrhythmia can also be monitored.

Safety Information

⚠ CONTRAINDICATION
A contraindication alerts the user to a situation in which the device should not be used because the risks of using it are clearly greater than the expected benefits.

⚠ WARNING
- A warning alerts the user to a hazardous situation which causes death or serious injury. (Double outline with thick and thin lines)
- A warning alerts the user to possible injury or death associated with the use or misuse of the instrument (Single thick outline).

⚠ 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.

⚠ CONTRAINDICATION

Never use the bedside monitor in the presence of any flammable anesthetic gas or high concentration oxygen atmosphere. Failure to follow this warning may cause explosion or fire.

⚠ CONTRAINDICATION

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

⚠ CONTRAINDICATION

Do not bring the bedside monitor (including components and accessories) into an MR examination room. It may cause stick, malfunction and damage to the MR equipment and skin burn on the patient. For details, follow the instruction in the manual for the MR equipment.

⚠ WARNING

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

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 leave the battery pack near a heat source such as a stove.
- Do not charge the battery pack on unspecified instruments.
- Do not charge the battery pack in conditions outside the specified environment. (Over 45°C (104°F))
- Do not put the battery pack into fire or heat it.
- Do not short-circuit the + and – terminals on the battery pack.
- Do not give strong impact to or deform the battery pack.
- Do not disassemble or modify the battery pack.
- Do not charge the battery pack in a high temperature place such as near a stove or in sun-heated cars. (Over 80°C (176°F))

⚠ WARNING

When the bedside 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 bedside monitor, causing electrical burn where the electrodes are attached. For details, refer to the ESU manual.

⚠ WARNING

When using an ESU, do the following. Otherwise, current from the ESU flows into the electrodes and causes skin burn.

- Ensure that there is enough distance between the electrodes and the ESU tip or return plate.
- Ensure that no electrodes are attached near the high frequency current path between the ESU tip and return plate. If the electrodes are too close to the high frequency current path between the ESU tip and the return plate, remove the electrode from the main cable.
- During long term monitoring, periodically check that the electrodes are attached properly.

⚠ WARNING

When discharging energy to the patient using the defibrillator, discharge the energy as far as possible from electrodes, patches and any gel, cream or medicine on the patient. If there is a possibility that the paddle could touch these foreign substances, remove them from the patient. If the paddle directly contacts these foreign substances, the discharged energy may be insufficient and may cause skin burn to the patient.

⚠ WARNING

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

⚠ WARNING

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

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

⚠ WARNING

When several medical instruments are used together, ground all instruments to the same one-point ground. Any potential difference between instruments may cause electrical shock to the patient and operator.

⚠ WARNING

When using the NMT module or neuromuscular transmission monitor, put the insulation cover to the metal parts such as electrodes. If a metal part is touched with bare hands or a metal part contacts a metal part of the bed or any other conductive parts, the patient may receive electrical shock or injury by discharged energy.

⚠ WARNING

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

Connect only the specified instrument to the bedside 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 using the 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 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

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

- Never short-circuit the + and – terminals on the battery. It may cause overheating and fire.
- Keep the batteries away from fire. They may explode.
- Do not damage, disassemble, drop or give impact to the battery. If the battery is damaged and substance inside the battery contacts the skin or clothes, wash immediately and thoroughly with water.
- Keep the batteries away from patients.

⚠ WARNING

Do not discharge energy to the patient using the defibrillator when the cables are located between the defibrillator paddles. The discharged energy may be insufficient.

⚠ WARNING

During stimulation, do not touch the electrodes. The patient or operator may receive electrical shock.

⚠ WARNING

Only use Nihon Kohden specified options such as electrodes, sensors, probes, cuffs and air hoses. If unspecified options are used, maximum safety and performance from the bedside monitor might not be achieved and the patient or operator may receive electrical shock when discharging energy to the patient.

⚠ WARNING

Only use the Nihon Kohden specified probes. If an unspecified probe is used, maximum safety and performance from the bedside monitor might not be achieved.

⚠ WARNING

Only use Nihon Kohden specified options such as electrodes, sensors, probes, cuffs and air hoses, and use the options in the method specified by Nihon Kohden. If unspecified options are used or Nihon Kohden specified options are used in unspecified ways, maximum safety and performance from the bedside monitor might not be achieved and the patient or operator may receive electrical shock when discharging energy to the patient.

⚠ WARNING

Only use the Nihon Kohden specified probes and connection cords and use the probes and connection cords in the method specified by Nihon Kohden. If unspecified probes or connection cords are used or Nihon Kohden specified probes and connection cords are used in unspecified ways, maximum safety and performance from the bedside monitor might not be achieved.

⚠ 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.

⚠ WARNING

The only oxygen cannula that can be used with YG-122T is #1103 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

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

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

⚠ WARNING

- Insert or remove the catheter from the pulmonary artery as quickly as possible. If it takes longer than about 10 seconds, pulmonary infarction, pulmonary hemorrhage or pulmonary artery perforation may occur.
- When inserting or removing the catheter, check the blood pressure waveform on the bedside monitor, X-ray unit images, and other equipment. Do not depend on the insertion or removal messages displayed on the monitor.

⚠ WARNING

- Insert or remove the catheter from the pulmonary artery as quickly as possible. If it takes longer than about 10 seconds, pulmonary infarction, pulmonary hemorrhage or pulmonary artery perforation may occur.
- When inserting or removing the catheter, check the blood pressure waveform on the bedside monitor, X-ray unit images, and other equipment.

⚠ WARNING

Do not reuse disposable parts and accessories.

⚠ 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

Do not attach the NIBP cuff on an arm which is on the same side of the body as a mastectomy or axillary lymph node dissection. It may cause circulatory disorders, such as swelling caused by poor blood circulation.

⚠ WARNING

During NIBP measurement, other medical devices attached to the same limb as the cuff might stop measuring 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.

⚠ 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

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 periodic measurement for a long time, periodically check the circulation condition.

⚠ 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

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

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

⚠ WARNING

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

⚠ WARNING

SpO_2 measurement may be incorrect in the following cases.

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

⚠ WARNING

When 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.

⚠ WARNING

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

⚠ WARNING

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

⚠ WARNING

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

⚠ 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

Do not place the BIS monitor, BISx or BISx module NK above the patient. Use the clip on the back of the BIS monitor, BISx or BISx module NK to attach it to a bed rail or pole securely. If the BIS monitor, BISx or BISx module NK is not attached to a rail or pole, install it where it cannot fall or tip over. Otherwise, it may cause injury to the patient.

⚠ WARNING

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

⚠ WARNING

During alarm suspension ("Alarm Paused" or "All Alarms Off" message displayed), all alarms are turned off. Be careful when you suspend alarms.

⚠ WARNING

Observe the following when using the NMT module or neuromuscular transmission monitor on a patient with a pacemaker.

- Read the manual for the pacemaker before starting examination and follow its instructions during examination.
- Always monitor the pulse rate and heart's function during examination.
- Check that the pacemaker operates normally after examination. Also, keep eyes on the pacemaker operation for a sufficient period of time after the examination.

⚠ WARNING

When not measuring SpO_2, disconnect the SpO_2 connection cord from the bedside monitor. Otherwise, noise may interfere with measurement and cause an incorrect result to be displayed.

⚠ WARNING

Do not turn all alarms off with the All Alarms Off or Bypass key when there is no medical staff around the patient or when the patient is connected to a ventilator.

⚠ WARNING

When using sleep function, monitor the patient on the central monitor or telemetry system. Otherwise, the bedside monitor alarm may be overlooked. When [Exit Sleep Mode on Crisis Alarm] on the ALARM page of the System Setup window is [Off], bedside monitor alarms and sync sound appear on the central monitor but do not appear on the bedside monitor during sleep mode.

⚠ 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 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.

⚠ WARNING

Disconnect all unused electrode from the EEG connection cord. If the unused electrode or electrode lead touches a metal object or any other conductive parts, the patient may receive electrical shock.

⚠ WARNING

When abnormal waveforms appear (flat waveform or a lot of AC interference) on the monitoring screen, remove all electrodes from the patient and stop using the neuro unit. Otherwise, it may cause skin burn where the electrodes are attached.

⚠ WARNING

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

⚠ WARNING

Never use a battery pack which is damaged, discolored or has leakage. It may cause overheating, explosion or fire.

⚠ WARNING

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

⚠ WARNING

In a network where this bedside 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

Connect the bedside 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 printer and hubs, outside the patient environment. If they are installed inside the patient environment, the patient or operator may receive electrical shock or injury. For installation, contact your Nihon Kohden representative.

⚠ WARNING

Check that the cables are not damaged before using the NMT module or neuromuscular transmission monitor. Using damaged cables may cause the patient or operator to receive electrical shock.

⚠ WARNING

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

⚠ WARNING

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

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 discharging energy to the patient.

⚠ WARNING

When performing defibrillation during cardiac output measurement, never touch the CO connection cord. The discharged energy may cause electrical shock or injury.

⚠ 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

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

When connecting an external instrument using an interface or communication cable to the bedside monitor, some alarms and messages from the external instrument might not be displayed on the bedside monitor. When the waveform or data is abnormal, check the alarm and message on the external instrument.

⚠ WARNING

Change the anesthetic alarm settings by referring to anesthetic agent reference information.

⚠ WARNING

All medical electrical equipment used together in the same facility must have the same default alarm settings (alarm master). Otherwise, equipment with different alarm masters will have different alarm settings after initialization, and alarms in the facility cannot be appropriately managed. If different areas or wings in the facility use different alarm masters, be careful to thoroughly understand the differences so that alarms can be managed appropriately.

⚠ 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 on the patient may be overlooked.

⚠ WARNING

If the alarm sound volume is quieter than the surrounding sound, frequently check the patient and bedside monitor. Otherwise, the alarm sound might not be heard and changes in the patient and bedside monitor may be overlooked. Set the appropriate alarm sound volume according environment where the bedside monitor is used.

⚠ WARNING

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

⚠ WARNING

For arrhythmia monitoring, set [Arrhythmia Analysis] on the ECG window to [On]. Otherwise, there is no sound or indication for arrhythmia alarms (except for Asystole).

⚠ 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

The hypnotic state of a patient undergoing surgery is influenced by the intensity of stimulation that is applied. During the course of a surgical procedure, the balance between the intensity of stimulation and sensory suppression may be constantly changing. Read the BIS value carefully.

⚠ WARNING

Do not use the output data from the serial socket on the bedside monitor as monitoring information to diagnose the patient condition. The patient must be monitored on a bedside monitor. Nihon Kohden is not responsible for consequences from use of output data from the bedside monitor.

⚠ WARNING

It is reported that BIS monitoring is not appropriate when an analgesic anesthetic agent, such as ketamin, fentanyl, morphine, or only a muscle relaxant is used.

⚠ WARNING

Due to limited clinical experience in the following applications, BIS values should be interpreted cautiously in patients with known neurological disorders such as epilepsy, patients taking other psychoactive medications, patients with cerebral infarction and in children below the age of 18.

⚠ WARNING

Reliance on the BIS alone for intraoperative anesthetic management is not recommended. Clinical judgement (patient face color, patient reaction, heart rate, blood pressure and other vital sign data) should always be used. BIS has been studied with the anesthetic agents listed in the “Drugs that have been Studied for Use with the BIS” section in the BIS reference guide, but the studied data are relative values and do not indicate the absolute value of the hypnotic level.

⚠ 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

The conductive parts of BIS sensor and connectors should not contact other conductive parts, including earth.

⚠ WARNING

Do not perform defibrillation with the BIS sensor placed between the defibrillator pads. This may cause skin burn or skin problems where the BIS sensor is affixed to the patient.

⚠ 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:

- After discharge operation
- After the patient type is changed
- 30 minutes after power off and “Show Admit Confirmation Window” is set to [No]

⚠ WARNING

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

⚠ 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

The following information are given by Masimo Corporation.

- A pulse oximeter should NOT be used as an apnea monitor.
- Pulse rate measurement is based on the optical detection of a peripheral flow pulse and therefore may not detect certain arrhythmias. The pulse oximeter should not be used as a replacement or substitute for ECG based arrhythmia analysis.
- A pulse oximeter is an early warning device. Use lab co-oximeter to completely understand the patient's condition.

⚠ WARNING

Do not use additional tape to secure the probe to patient.

⚠ 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

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

⚠ WARNING

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

⚠ WARNING

After use, clean the reusable SpO_2 probe to prevent the patient from cross infection.

⚠ WARNING

After use, clean the temperature probe to prevent the patient from cross infection.

⚠ WARNING

Set the alarm sound volume according to the place where the bedside monitor is used. If the alarm sound is too quiet, keep the patient under close observation and periodically check the bedside monitor. Otherwise, the alarm sound might not be heard and critical changes on the patient or problems in the bedside monitor may be overlooked.

⚠ WARNING

When performing defibrillation during TOF monitoring, never touch the NMT module or neuromuscular transmission monitor cables. The discharged energy may cause electrical shock or injury to the operator.

⚠ WARNING

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

⚠ WARNING

The bedside monitor requires a minimum of 2 minutes of continuous analysis before A-Fib can be detected. Detection may take up to 2.5 minutes.

⚠ CAUTION

Do not use an expired BIS sensor.

⚠ CAUTION

Before connecting or disconnecting instruments, make sure that each instrument is turned off and the power cord is disconnected from the AC outlet. Otherwise, the patient or operator may receive electrical shock or injury.

⚠ CAUTION

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

⚠ 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 use the needle electrodes for more than one hour as a measurement electrode for the EEG measurement. When measuring the EEG for over one hour, use the EEG disk electrode.

⚠ CAUTION

Never check the skin-electrode impedance with the needle electrode inserted in the patient. Failure to follow this caution causes electrical burn where electrodes are inserted.

⚠ CAUTION

When the “Check Electrodes” message is displayed, ECG is not monitored properly and the ECG alarm does not function. Check the electrode, 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

When the “BIS Connector Off” message is displayed, check that the BISx or BISx module NK is firmly connected to the connection cable and connection cable is firmly connected to the bedside monitor. The BIS cannot be monitored and the alarm does not function while this message is 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.

⚠ CAUTION

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

⚠ CAUTION

The thermal insulation cover may irritate the skin. In long term monitoring, change the attachment site to prevent irritation.

⚠ CAUTION

Only use Nihon Kohden specified options such as electrodes, sensors, probes and transducers. If unspecified options are used, maximum safety and performance from the bedside monitor might not be achieved.

⚠ CAUTION

Only use the specified cable and BIS sensor. If unspecified items are used, maximum safety and performance from the bedside monitor might not be achieved.

⚠ CAUTION

- The ECG automatic 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

Only use the specified equipment for installing the bedside monitor on a cart or wall mount. Using non-specified equipment may result in the bedside monitor falling and causing injury.

⚠ CAUTION

The TG-900P and TG-920P CO_2 sensor kits do not adjust the measurement value to compensate for different atmospheric pressure. Be careful when reading the value from the CO_2 sensor kit at high altitudes because the measurement value may be inaccurate.

⚠ CAUTION

Supply adequate oxygen when measuring CO_2 partial pressure of a patient connected to a Jackson Rees, Mapleson D or any other respiration circuit where CO_2 gas may be present during inspiration. The semi-quantitative method measures CO_2 partial pressure based on the assumption of no CO_2 gas in the inspired air; it measures the CO_2 partial pressure of the expiration of every respiration. If the inspired air contains CO_2 gas, the displayed CO_2 value is lower than the actual value.

⚠ CAUTION

When measuring CO_2 partial pressure of a patient with an oxygen mask, set the oxygen supply to 5 L/min or more. If CO_2 gas remains in the oxygen mask and mixes with the inspired air, the measured value may be lower than the actual value.

⚠ CAUTION

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

⚠ CAUTION

Only use Nihon Kohden specified electrodes and electrode leads. If other type of electrodes or electrode leads are used, the “Check Electrodes” message may appear and ECG monitoring may stop.

⚠ CAUTION

- The BIS sensor is single use only. Do not reuse it.
- Do not reuse the BIS sensor for another patient. There are a lot of fine projections on the BIS sensor. Reusing the BIS sensor for another patient may cause infection to another patient by bacteria adhering to the BIS sensor.
- Do not use the BIS sensor for more than 24 hours. It affects monitoring accuracy.

⚠ CAUTION

Do not measure the cardiac output repeatedly at short intervals. Frequently injecting the injectate affects the measuring accuracy.

⚠ CAUTION

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

⚠ CAUTION

Select an appropriate probe according to the patient and measurement site. If an adult temperature probe is used on a neonate or child, it may injure the mucous membrane.

⚠ CAUTION

When the “Sensor Error” or “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

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

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

⚠ 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

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 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

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

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

⚠ CAUTION

When measuring SpO_2 under strong light such as surgical light or sunlight, cover the measuring site with a blanket to block the light. Otherwise measurement accuracy may be affected.

⚠ CAUTION

Do not use wireless devices, such as LF RFID systems or transmitters, with frequencies of 150 kHz or lower near the bedside monitor.
It could display wrong measurement data, and the normal monitoring of the patient cannot be performed.

⚠ 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

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

When using the output signal from the bedside 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.
- Constantly check the measurement status of the bedside monitor. The output signal may be unstable for one of a number of reasons.
- Check that the delay time of the output signal is within the range of the connected equipment.

⚠ 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.

⚠ CAUTION

- Set the remote control channel on the bedside monitor to prevent the remote control from operating a different bedside monitor.
- When several monitors are installed close together, check that the remote control operates only the desired bedside monitor. If the remote control operates a different bedside monitor, recheck the channel setting.

⚠ 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 turning on the power or periodically, check that one "bong" sounds and the alarm indicator blinks in red, yellow and cyan.

⚠ 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 let the BISx or BISx module NK remain continuously in contact with the patient's body. The BISx or BISx module NK heats up during operation and it may cause a low temperature burn to the patient.

⚠ CAUTION

Only use the provided or specified screws to fasten the holder. Make sure that the screws are securely tightened. If screws are loose, the device may tip over or fall off and the patient or operator may be injured.

⚠ 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

The DH-570P unit holder is an option for mounting the AA-174P multi amp unit or AP-170P hemodynamic unit on the BSM-5700 series bedside monitor. Do not attach any unspecified devices. The bedside monitor may tip over or the unit may fall off and cause injury.

⚠ CAUTION

Periodically check that no screws or knob bolts are loose. Otherwise the bedside monitor may tip over or the multi amp unit or hemodynamic unit may fall off and cause injury.

⚠ CAUTION

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

⚠ CAUTION

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

⚠ CAUTION

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

⚠ CAUTION

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

⚠ 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

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

⚠ CAUTION

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

⚠ CAUTION

When transmitting CO_2 data through a ZS-600P transmitter to a receiving monitor, if the transmitted CO_2 data is out of the range of the receiving monitor, the maximum value of the receiving monitor is displayed instead. Be careful when reading the value.

⚠ CAUTION

When inserting the temperature probe into the patient rectum, lubricate the insertion site with a lubricant such as vaseline or water soluble lubricating gel.

⚠ CAUTION

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

⚠ CAUTION

When using the bedside monitor with an ESU, locate the bedside 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.

⚠ 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

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

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

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 seconds, check that the message disappears, then measure again.

⚠ CAUTION

The CO_2 sensor kit cannot measure the $ETCO_2$ value and respiration rate during high frequency oscillation (HFO).

⚠ 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 the bedside monitor is connected to a central monitor network, set the Bed Name (Bed ID) and Group Name on the bedside 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

When two probes are attached too close to each other, the light from the probes interferes with each other and SpO_2 cannot be monitored properly. Make sure that there is no light interference when attaching two probes.

⚠ CAUTION

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

⚠ CAUTION

Do not autoclave the BIS monitor. The BIS monitor may be damaged.

⚠ CAUTION

Select an airway adapter or nasal adapter that is appropriate for 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

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

⚠ 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

The bedside monitor CPU may be reset when there is considerable static electricity or noise and monitoring stops for about two minutes. If this occurs, the alarm indicator blinks in red and there is “pip” alarm sound for about 3 seconds. Observe the patient carefully during this interruption. After the monitor is reset, check that it is working properly.

⚠ 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 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 respiration measurement is [Off], respiration alarms do not occur even if each respiration alarm item is set to [On].

⚠ CAUTION

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

⚠ CAUTION

When the monitoring value is not appropriate, check the measuring accuracy.

⚠ CAUTION

When performing electroconvulsive therapy (ECT), attach the BIS sensor as far as possible from the electrodes that are used for electrical shock. Otherwise noise from the electrodes may interfere and incorrect data is displayed on the screen.

⚠ CAUTION

- The following physiological factors and external factors must be considered in BIS monitoring.
  1. Ischemia or hypoxia, when severe enough to cause global EEG slowing or outright suppression, results in a decrease in the BIS value. It is important to bear in mind that the frontal montage used for BIS monitoring usually will not detect episodes of focal ischemia caused by embolic events.
  2. Hypothermia will generally result in a corresponding decrease in BIS levels as brain processes slow. More profound hypothermia used during cardiac bypass procedures will cause suppression of the EEG and, consequently, a very low BIS.
  3. Artifacts and signal of poor quality cause the BIS to be unreliable. Such artifacts are caused by poor contact of sensor to skin, muscle activity or rigidity, head or body movement, eye movement, inappropriate sensor attachment and other electrical interference. Some examples are given below.
     a) Hum noise: Usually there is no hum interference, but when the hum filter is turned off and a signal larger than 100 μV is superimposed on the EEG waveform on the screen, BIS may increase.
     b) ESU (unipolar): The noise generated by unipolar ESU is so large that it saturates the EEG signal so that EEG waveforms cannot be acquired. BIS value first blinks (SQI decreases) and then disappears. After stopping the use of the ESU, BIS value is displayed again.
     c) ESU (bipolar): Bipolar ESU causes low amplitude high frequency wave signals which may be mistaken as EEG and thus cause an increase in BIS value. If there is unexpected increase in BIS, monitor EEG carefully and read the BIS value carefully.
     d) ECG: The BISx or BISx module NK has a filter for detecting ECG, but large ECG may be mistaken as EEG. If ECG artifact is seen on the EEG, read the BIS value carefully.
     e) Pulse wave: There may be an interference caused by the pulse wave when the BIS sensor is attached near an artery. Reattach the BIS sensor to the appropriate site.

f) Pacemaker: If pacing spikes can be seen on the EEG, the BIS may be affected. Read the BIS value carefully.
g) EMG: EMG is a signal of high frequency wave of more than 500 µV (generally more than 30 Hz). There is an increase in EMG as the patient is emerging from anesthesia. Muscle activity is seen during surgery. The BISx or BISx module NK has a filter for detecting EMG, but the increase in EMG causes an increase in the BIS value. Shivering in a patient who is emerging from anesthesia may increase EMG and artifact on EEG, resulting in an increase in BIS value.

- Check the BIS sensor attachment when there is an unexpected EMG increase and SQI decrease. If EMG still increases after having checked the sensor attachment, there may be an electromagnetic interference. Check the surrounding equipment and power supply.

⚠ CAUTION

To minimize the risk of patient strangulation, the PIC Plus patient interface cable must be carefully placed and secured.

⚠ CAUTION

Do not let the electrodes touch other devices during examination. The NMT module may malfunction and provide incorrect measurement results.

⚠ CAUTION

Turn off the automatic impedance check if the impedance check signal (1 nA, 128 Hz) interferes with other equipment.

⚠ CAUTION

When attaching the BIS sensor to the patient, press each electrode on the sensor for 5 seconds to reduce impedance between the electrode and skin.

⚠ CAUTION

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

⚠ 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

When using the YG-121T or YG-122T nasal adapter on the patient, observe the patient condition all the time. The mouth guide touches the mouth and may cause pressure sores.

⚠ CAUTION

When the Screen Layout is set to “Auto”, not all parameters can be displayed on the screen when too many parameters are monitored. When the Screen Layout is set to “Fixed”, only the assigned parameters are displayed on the screen regardless of whether the parameter is measured or not. 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.

⚠ 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.

⚠ CAUTION

Even when Auto Interbed Display is set to [On], the interbed window only appears when the home window is displayed and an interbed alarm occurs.

⚠ CAUTION

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

⚠ CAUTION

At the start of ECG monitoring, check that the correct QRS Detection Type (Adult, Child or Neonate) is displayed on the bedside monitor screen. 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

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

⚠ CAUTION

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

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

⚠ CAUTION

SpO_2 and pulse rate readings may be inaccurate for a short time after defibrillation when using Masimo probes.

⚠ CAUTION

- Do not reuse adhesive probes for another patients because it causes cross infection.
- Do not use the probe over its stated lifetime. Otherwise the SpO_2 measurement accuracy cannot be guaranteed.
- Do not immerse the Masimo probe in water or any other solutions. The probe, cable and connectors are not waterproof.
- Do not sterilize the probe by irradiation, steam or ethylene oxide. Refer to the probe manual.

⚠ CAUTION

Only use the OxiMAX™ series sensor probes on this monitor.

⚠ 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

Be careful when using a bedside monitor to measure SpO_2 without measuring ECG. Because arrhythmia is not analyzed when ECG is not measured, arrhythmia alarms such as Asystole, VF or VT are not generated. Also, SpO_2 upper and lower limit alarms are not generated when the patient's pulse cannot be detected because of asystole or other condition. If the patient requires ECG monitoring, measure the ECG.

⚠ CAUTION

- When using a bedside monitor to measure SpO_2 without measuring ECG, turn on the upper and lower limit alarms for PR and SpO_2. Even when the limit alarms are turned on, SpO_2 upper and lower limit alarms are not generated if the patient has no pulse. In that case, a technical alarm ("Cannot Detect Pulse" or "Check Probe") occurs instead of an SpO_2 limit alarm.
- Noise from probe movement may be misjudged as a pulse and cause an incorrect PR or SpO_2 value to be displayed.

⚠ CAUTION

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

⚠ CAUTION

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

⚠ 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

Correct measurement may not be able to be performed on a patient with neurological disorder with the NMT module because there may be less reaction to stimulation if stimulation is applied to such patient.

⚠ CAUTION

If the body surface temperature at the monitoring site is dropped abnormally, muscle relaxation of the patient cannot be monitored correctly.

⚠ CAUTION

Correct measurement may not be able to be performed on a patient with neurological disorder with the NMT module or neuromuscular transmission monitor because there may be less reaction to stimulation if stimulation is applied to such patient.

⚠ CAUTION

Do not let the electrodes to touch other devices during examination. The NMT module or neuromuscular transmission monitor may malfunctions or measurement result may become incorrect.

⚠ 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

Some data and operations on the bedside monitor can be set, changed or managed only by a user with administrator privileges. When using the bedside monitor for the first time, a window appears requesting the user to change the default administrator password. Set a password for the administrator that is difficult to guess and store it securely to prevent security breaches.

⚠ CAUTION

Keep the cable out of the way by running it along the floor or ceiling and hooking it onto the cable hanger. Otherwise people may trip over it, causing the cable to break and injure the patient and operator.

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

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

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

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