SAFETY AND PERFORMANCE INFORMATION

NIHON KOHDEN

Vital Signs Monitor
SVM-7100 Series

General

The SVM-7100 series monitors can be used as vital signs monitors, and are intended to be used by clinicians, doctors, nurses and medically qualified personnel for measuring non-invasive blood pressure (NIBP), non-invasive functional oxygen saturation of arteriolar hemoglobin (SpO_2), body temperature (TEMP) of one patient at a time, and can be used for several patients and generate alarms.*

* Essential performance of the vital signs monitor

Meanwhile, the monitors are used in the specialized health care environment like hospital, clinics, special medical facility, independent surgery center, multi-therapy facility and ward.

EMC RELATED CAUTION

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

The following describes some common interference sources and remedial actions:

1. Strong electromagnetic interference from a nearby emitter source such as an authorized radio station or cellular phone:

   Install the equipment and/or system at another location. Keep the emitter source such as cellular phone away from the equipment and/or system, or turn off the cellular phone.

2. Radio-frequency interference from other equipment through the AC power supply of the equipment and/or system:

   Identify the cause of this interference and if possible remove this interference source. If this is not possible, use a different power supply.

3. Effect of direct or indirect electrostatic discharge:
   Make sure all users and patients in contact with the equipment and/or system are free from direct or indirect electrostatic energy before using it. A humid room can help lessen this problem.

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

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

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

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

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

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

10. Use with radiation therapy equipment:
    When the equipment and/or system is used in a radiotherapy room, it may cause failure or malfunction. When you bring the equipment and/or system into a radiotherapy room, constantly observe the operation. Prepare countermeasures in case of failure or malfunction.

11. ME equipment or ME systems may still be subject to interference from other equipment, even if such other equipment meets the emission requirements of the relevant national standards.

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

Safety Information

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

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

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

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

⚠ WARNING
Do not 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
After attaching probes and sensors on the patient and connecting cables to the vital signs 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 probes and sensor attachment, patient condition and settings on the vital signs monitor and remove the cause.

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

⚠ WARNING
When performing MRI test, remove all 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
Do not use the same monitor on more than one patients at the same time. Do not connect different sensors on different patients to the same monitor.

⚠ WARNING

Do not place the multiple socket-outlet on the floor when using it as a separate item. This may result in electric shock.

⚠ WARNING

Do not connect multiple outlets in series with extension cords to the system.

⚠ WARNING

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

⚠ WARNING

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

⚠ WARNING

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

⚠ WARNING

Connect only the specified instrument to the monitor and follow the specified procedure. Failure to follow this warning may result in electrical shock or injury to the patient and operator, and cause fire or instrument malfunction.

⚠ WARNING

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

⚠ WARNING

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

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

⚠ WARNING

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

⚠ WARNING

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

⚠ WARNING

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

⚠ WARNING

Keep the battery pack out of the reach of children. If they are swallowed, consult a physician immediately.

⚠ WARNING

When the monitor will not be used for a long time, remove the battery pack. If a charged or discharged battery is left inside the monitor with the power cord unplugged, the battery self-discharges and deteriorates.

⚠ 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

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

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

⚠ 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 alarm settings when admitting a new patient or 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 new patient is added and Patient Type is input.
- When admitting a new patient in Continuous Mode, first delete all data of the previous patient. Otherwise, the data of the previous patient and new patient will be mixed together.

⚠ WARNING

When the <Exit Sleep Mode on Crisis Alarm> check box on <System Setup - Alarm> window is set to "Off", the vital signs alarm cannot be seen or heard on the vital signs monitor during sleep mode. In this case, monitor the vital signs alarms on the central monitor. Otherwise, vital signs monitor alarms may be overlooked.

⚠ WARNING

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

⚠ WARNING

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

⚠ WARNING

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

⚠ WARNING

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

⚠ WARNING

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

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

⚠ WARNING

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

⚠ WARNING

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

⚠ WARNING

Continuous CUFF pressure due to connection tubing kinking can cause blood flow interference and result harmful injury to the Patient.

⚠ WARNING

Too frequent measurements can cause injury to the Patient due to blood flow interference.

⚠ WARNING

Check (for example, by observation of the limb concerned) that operation of the AUTOMATED SPHYGMOMANOMETER does not result in prolonged impairment of the circulation of the blood of the Patient.

⚠ 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

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

SpO_2 measurement may be incorrect in the following cases.

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

⚠ WARNING

Check the circulation condition by observing the skin color at the measurement site and pulse waveform. Change the measurement site every 8 hours for disposable probes and every 4 hours for reusable probes. The skin temperature may increase at the attached site by 2 or 3 ºC (4 or 5 ℉) and cause a burn or pressure necrosis.

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

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

⚠ WARNING

- When using the TL-201T finger probe, do not fasten the probe and cable to the finger by wrapping with tape. This may cause burn, congestion or pressure necrosis from poor blood circulation.
- When using probes other than the TL-201T finger probe, to avoid poor circulation, do not wrap the tape too tight. Check the blood circulation condition by observing the skin color and congestion at the skin peripheral to the probe attachment site. Even for shortterm monitoring, there may be burn or pressure necrosis from poor blood circulation, especially on neonates or low birth weight infants whose skin is delicate. Accurate measurement cannot be performed on a site with poor peripheral circulation.

⚠ WARNING

Only use the Shanghai Kohden specified probes. If an unspecified probe is used, maximum performance from the monitor cannot be satisfied.

⚠ WARNING

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

⚠ WARNING

Operator needs to verify the compatibility of the monitor, probe, and cable before use. Otherwise, it may cause injury to the patient.

⚠ WARNING

The misapplication of a PULSE OXIMETER PROBE with excessive pressure for prolonged periods can induce pressure injury.

WARNING

As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.
Do not place the pulse oximeter or accessories in any position that might cause it to fall on the patient.
Do not start or operate the pulse oximeter unless the setup was verified to be correct.
Do not use the pulse oximeter during magnetic resonance imaging (MRI) or in an MRI environment.
Do not use the pulse oximeter if it appears or is suspected to be damaged.
Explosion hazard: Do not use the pulse oximeter in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.
To ensure safety, avoid stacking multiple devices or placing anything on the device during operation.
To protect against injury, follow the directions below:

- Avoid placing the device on surfaces with visible liquid spills.
- Do not soak or immerse the device in liquids.
- Do not attempt to sterilize the device.
- Use cleaning solutions only as instructed in this operator's manual.
- Do not attempt to clean the device while monitoring a patient. To protect from electric shock, always remove the sensor and completely disconnect the pulse oximeter before bathing the patient. If any measurement seems questionable, first check the patient's vital signs by alternate means and then check the pulse oximeter for proper functioning. Inaccurate SpO_2 readings may be caused by:
- Improper sensor application and placement
- Elevated levels of COHb or MetHb: High levels of COHb or MetHb may occur with a seemingly normal SpO_2. When elevated levels of COHb or MetHb are suspected, laboratory analysis (CO-Oximetry) of a blood sample should be performed.
- Elevated levels of bilirubin
- Elevated levels of dyshemoglobin
- Vasospastic disease, such as Raynaud's, and peripheral vascular disease
- Hemoglobinopathies and synthesis disorders such as thalassemias, Hb s, Hb c, sickle cell, etc.
- Hypocapnic or hypercapnic conditions
- Severe anemia
- Very low arterial perfusion
- Extreme motion artifact
- Abnormal venous pulsation or venous constriction
- Severe vasoconstriction or hypothermia
- Arterial catheters and intra-aortic balloon
- Intravascular dyes, such as indocyanine green or methylene blue
- Externally applied coloring and texture, such as nail polish, acrylic nails, glitter, etc.
- Birthmark(s), tattoos, skin discolorations, moisture on skin, deformed or abnormal fingers. etc.
- Skin color disorders

Interfering Substances: Dyes or any substance containing dyes that change usual blood pigmentation may cause erroneous readings.
The pulse oximeter should not be used as the sole basis for medical decisions. It must be used in conjunction with clinical signs and symptoms.
The pulse oximeter is not an apnea monitor.
The pulse oximeter may be used during defibrillation, but this may affect the accuracy or availability of the parameters and measurements.
The pulse oximeter may be used during electrocautery, but this may affect the accuracy or availability of the parameters and measurements.
The pulse oximeter should not be used for arrhythmia analysis.
SpO_2 is empirically calibrated in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb).
Do not adjust, repair, open, disassemble, or modify the pulse oximeter or accessories. Injury to personnel or equipment damage could occur. Return the pulse oximeter for servicing if necessary.

⚠ WARNING

Do not take temperature over scar tissue, open sores or abrasions.

⚠ WARNING

Always store this thermometer in a clean, dry place where it will not become excessively cold (-20 ºC / -4 ºF), or hot (50 ºC / 122 ºF) or humid (max RH 93% non-condensing, at 50 kPa to 106 kPa).

⚠ WARNING

The thermometer is not shockproof. Do not drop it or expose it to electrical shocks. Do not autoclave.

⚠ WARNING

Do not use this thermometer if it is not working properly, if it has been exposed to temperature extremes, damaged, been subject to electrical shocks or immersed in water.

⚠ WARNING

The device must stay in stable ambient (room) temperature for 15 minutes before operating.

⚠ WARNING

Before the measurement, please stay in a stable environment for 5 minutes and avoid the exercise, bath for 30 minutes.

⚠ 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 vital sign monitor and change the alarm settings if necessary.

⚠ WARNING

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

⚠ WARNING

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

⚠ WARNING

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

⚠ WARNING

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

⚠ WARNING

During alarm suspension ("Suspend Alarms" or "All Alarms Off" 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

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 new patient is added and Patient Type is input.
- When admitting a new patient in Continuous Mode, first delete all data of the previous patient. Otherwise, the data of the previous patient and new patient will be mixed together.

⚠ WARNING

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

⚠ WARNING*

This equipment is not entitled to protection against harmful interference and may not cause interference to duly authorized systems.
This product is not suitable for use in a domestic environment as it may cause electromagnetic interference that forces the user to take necessary measures to minimize such interference.

⚠ WARNING

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the SVM-7100, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

⚠ 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.

⚠ WARNING

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

⚠ CAUTION

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

⚠ CAUTION

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

⚠ CAUTION

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

⚠ CAUTION

Before start monitoring, check that the patient type setting (Adult/Child/Neonate) is correct. If the patient type setting is incorrect, NIBP value may be incorrect, and the NIBP initial cuff pressure may also be incorrect.

⚠ CAUTION

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

⚠ CAUTION

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

⚠ CAUTION

Do not reuse disposable parts and accessories.

⚠ 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

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

⚠ CAUTION

- For more information about connecting external devices and monitors, please contact Nihon Kohden representative.
- The leakage current will increase when the monitor is connected to multiple medical devices.

⚠ CAUTION

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

⚠ CAUTION

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

⚠ CAUTION

When not using the specified cart, carefully set the monitor to prevent it from falling off or tipping over.

⚠ 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 subject the battery pack to a strong mechanical impact.

⚠ CAUTION

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

⚠ CAUTION

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

⚠ CAUTION

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

⚠ CAUTION

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

⚠ CAUTION

Only use the KC-170P cart for the SVM-7100 series monitor. Do not mount any other instruments which are not specified. The cart may tip over or the instrument may fall off and cause injury.

⚠ CAUTION

Assemble the cart and mount the SVM-7100 series monitor by referring to the installation guide of the cart. If the cart is not properly assembled or the monitor is not firmly secured to the cart, the monitor may fall off and the patient or operator may get injured.

⚠ CAUTION

Do not put heavy materials in the basket. The basket may fall off.

⚠ CAUTION

To prevent the cart from tipping over or the monitor falling off the cart:

- Do not put or hook anything on the handle or pole.
- Do not ride on the cart.
- Do not lean on the handle or put your weight on the cart.
- Make sure that the cart is on a flat surface which is not sloped.
- Always lock the casters so that the cart does not move accidentally.

⚠ CAUTION

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

⚠ CAUTION

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

⚠ CAUTION

The SVM-7100 series monitor use the Patient ID to manage patient information. The patient ID cannot be changed from central monitor.

⚠ CAUTION

The TEMP measurement of SVM-7100 series monitor is different from the existing other monitors. The TEMP parameter cannot be shown on the inter-bed screen.

⚠ CAUTION

Use the vital signs monitor in a securely managed environment.

⚠ CAUTION

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

⚠ CAUTION

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

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

⚠ CAUTION

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

⚠ CAUTION

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

⚠ CAUTION

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

⚠ CAUTION

Make sure the vital signs displayed on the Save window are all correct. The information displayed on the “Save window” is not synchronized with actual time. The setting changes, environment changes or design changes of external system (HIS etc.) maybe not be synchronized.

⚠ CAUTION

If the alarm goes off while there are some other sounds existing, the volume of sounds other than the alarm may turn down. In this case, please check the patient and deal with the causes of alarm. Once the alarm is all clear, the volume of sounds will return to the current setting volume.

⚠ CAUTION

Do not change any sound settings while the alarm is sounding.

⚠ CAUTION

Only use Shanghai Kohden products and specified parts and accessories to ensure the optimum performance.

⚠ CAUTION

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

⚠ CAUTION

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

⚠ CAUTION

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

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

⚠ CAUTION

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

⚠ CAUTION

Measuring mode of Neonate/Child/Adult can not be changed automatically. It should be set in Patient Type of New Patient window or Patient Info window.

⚠ CAUTION

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

⚠ CAUTION

Before start monitoring, confirm that the patient type (Adult/ Child/ Neonate) is right set. If the patient type is not right, NIBP value may be incorrect. Moreover, the NIBP initial cuff pressure may also be incorrect.

⚠ CAUTION

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

⚠ CAUTION

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

⚠ CAUTION

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

⚠ CAUTION

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

⚠ CAUTION

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

⚠ 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

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

⚠ CAUTION

When monitoring SpO_2 only, detection of arrhythmia and asystole is not available. If the patient requires ECG monitoring, use an instrument other than the pulse oximeter to monitor ECG.

⚠ 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

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 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

Do not use the probe over its stated lifetime. Otherwise the SpO_2 measurement accuracy cannot be guaranteed.

⚠ CAUTION

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

⚠ CAUTION

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

⚠ CAUTION

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

⚠ CAUTION

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

⚠ CAUTION

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

⚠ CAUTION

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

⚠ CAUTION

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

⚠ CAUTION

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

CAUTION

Do not place the pulse oximeter where the controls can be changed by the patient.
Electrical shock and flammability hazard: Before cleaning, always turn off the device and disconnect from any power source.
When patients are undergoing photodynamic therapy they may be sensitive to light sources. Pulse oximetry may be used only under careful clinical supervision for short time periods to minimize interference with photodynamic therapy.
Do not place the pulse oximeter on electrical equipment that may affect the device, preventing it from working properly.
If SpO_2 values indicate hypoxemia, a laboratory blood sample should be taken to confirm the patient's condition.
If the Low Perfusion message is frequently displayed, find a better perfused monitoring site. In the interim, assess the patient and, if indicated, verify oxygenation status through other means.
Change the application site or replace the sensor and/or patient cable when a "Replace sensor" and/or "Replace patient cable", or a persistent poor signal quality message (such as "Low SIQ") is displayed on the host monitor. These messages may indicate that patient monitoring time is exhausted on the patient cable or sensor.
If using pulse oximetry during full body irradiation, keep the sensor out of the radiation field. If the sensor is exposed to the radiation, the reading might be inaccurate or the device might read zero for the duration of the active irradiation period.
To ensure that alarm limits are appropriate for the patient being monitored, check the limits each time the pulse oximeter is used.
Variation in measurements may be profound and may be affected by sampling technique as well as the patient's physiological conditions. Any results exhibiting inconsistency with the patient's clinical status should be repeated and/or supplemented with additional test data. Blood samples should be analyzed by laboratory instruments prior to clinical decision making to completely understand the patient's condition.
Do not submerge the pulse oximeter in any cleaning solution or attempt to sterilize by autoclave, irradiation, steam, gas, ethylene oxide or any other method. This will seriously damage the pulse oximeter.
Electrical Shock Hazard: Carry out periodic tests to verify that leakage currents of patient-applied circuits and the system are within acceptable limits as specified by the applicable safety standards. The summation of leakage currents must be checked and in compliance with IEC 60601-1 and UL 60601-1. The system leakage current must be checked when connecting external equipment to the system. When an event such as a component drop of approximately 1 meter or greater or a spillage of blood or other liquids occurs, retest before further use. Injury to personnel could occur.
Electrical Shock Hazard: Carry out periodic tests to verify that leakage currents of patient-applied circuits and the system are within acceptable limits as specified by the applicable safety standards. The summation of leakage currents must be checked and in compliance with IEC 60601-1 and UL 60601-1. The system leakage current must be checked when connecting external equipment to the system. When an event such as a component drop of approximately 1 meter or greater or a spillage of blood or other liquids occurs, retest before further use. Injury to personnel could occur.
Disposal of product - Comply with local laws in the disposal of the device and/or its accessories.

To minimize radio interference, other electrical equipment that emits radio frequency transmissions should not be in close proximity to the pulse oximeter.
Replace the cable or sensor when a replace sensor or when a low SIQ message is consistently displayed while monitoring consecutive patients after completing troubleshooting steps listed in this manual.
Do not immerse the Masimo probe in water or any other solutions. The probe, cable and connectors are not waterproof.

⚠ CAUTION

If your thermometer is not used regularly, remove the battery to prevent possible damage due to chemical leakage.

⚠ CAUTION

Not suitable for use in the presence of flammable anesthetic mixtures.

⚠ CAUTION

It is recommended that you measure the same ear for 3 times. If the 3 measurements are different, select the highest one.

⚠ CAUTION

The thermometer has been designed for practical use. It's not meant to replace a visit to the doctor. Please also remember to compare the measurement result to your regular body temperature. Please consult with doctor if you have health concerns.

⚠ CAUTION

Use only Filac™ 3000 Thermometer Probe Covers with this device. Use of any other probe cover will result in erroneous temperature readings.

⚠ CAUTION

Disposal of used probe covers must be performed in accordance with current medical practices and local regulations regarding disposal of infectious, biological medical waste.

⚠ CAUTION

Setting Alarm Limits to extreme values will render the Alarm System useless.

⚠ CAUTION

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

⚠ CAUTION

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

⚠ CAUTION

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

⚠ CAUTION

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

⚠ CAUTION

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

⚠ CAUTION

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

⚠ CAUTION

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

⚠ CAUTION

Do not submerse the thermometer in any cleaning solution.

⚠ CAUTION

Sterilization is not recommended for cabled versions of the Temporal Scanner.

⚠ CAUTION

Do not use bleach or other cleaning solutions on the sensor lens.

⚠ CAUTION

Holding the thermometer too long may cause a higher ambient temperature reading of the probe. This could make the body temperature measurement lower than usual.

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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