NIHON KOHDEN

Interface
QF-751P

General

QF-751P is intended for transferring SpO_2 data from Masimo probes to SVM-7500 or SVM-7600 series bedside monitors.

This interface can be used with SVM-7500 or SVM-7600 series bedside monitor and JL-639P SpO_2 adapter.

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
Do not use a damaged or disassembled interface. It causes incorrect measurement and may cause electrical shock or skin burn.

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

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

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

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

⚠ WARNING
Do not diagnose patients based on only the data from the connected instrument. Overall judgement must be performed by a physician who understands the features, limitations and characteristics of the connected instrument by reading this operator's manual thoroughly and the biomedical signals acquired by other instruments.

⚠ WARNING
Before monitoring SpO_2 through the interface, confirm that the operator's manual of the instrument to which the interface is connected allows the use of the Interface. The safety of the attachment section (including the SpO_2 adapter and the probe) depends on the specifications of the connected instrument. If the interface is used with an unspecified instrument or attachment section (including the SpO_2 adapter and the SpO_2 probe), the instrument does not function. The patient and operator may receive an electrical shock.

⚠ WARNING
The following information is 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.

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

⚠ CAUTION
For handling and precautions on options and consumables such as adapter and probes, refer to the manual of the option or consumable.

⚠ 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 cause the incorrect data to be displayed.

⚠ **CAUTION**

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

⚠ **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.

Maintenance and Inspection

⚠ **CAUTION**

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

⚠ **CAUTION**

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

SpO_2 Measurement

⚠ **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 performing MRI test, remove the SpO_2 adapter and probe from the patient. Failure to follow this warning may cause skin burn on the patient. For details, refer to the MRI manual.

⚠ **WARNING**

Do not fasten the probe and cable to the finger by wrapping with tape. This may cause burn, congestion or skin problems from poor blood circulation.

⚠ **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**

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

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

⚠ **WARNING**

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 and 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.

⚠ **CAUTION**

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

⚠ **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**

Keep the patient away from the cable as much as possible. Otherwise the patient may get tangled in the cable and get injured. If the cable coils around the patient, remove the cable promptly.

⚠ **CAUTION**

When monitoring SpO_2 only, detection of arrhythmia and asystole is not available. If the patient requires ECG monitoring, monitor the ECG.

⚠ CAUTION

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

⚠ 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

Attach the probe to the part such as a finger or toe where there is no change in peripheral blood circulation. If the probe is attached to a finger or toe where there is an NIBP cuff or an IBP catheter on the arm or leg, the blood circulation at the probe attachment site is affected and measurement may be inaccurate.

Disposal

⚠ CAUTION

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

The following information are given by Masimo Corporation.

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.

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.

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.

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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