Pulse Oximeter
OLV-4201, OLV-4202

General

The pulse oximeter is a compact monitor with a 7-inch display and is designed for touchscreen operation at the patient's side.

The pulse oximeter is installed near the patient to display the patient's vital signs (SpO_2, pulse rate, etc.) on the display and generate alarms.

Safety Information

⚠ 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.

> ### ⚠ 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 40°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.
> • Install the battery with the correct polarity.

> ### ⚠ 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
> Never use the pulse oximeter 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 pulse oximeter 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 pulse oximeter, causing electrical burn where the probes are attached. For details, refer to the ESU manual.

> ### ⚠ WARNING
> Do not use the pulse oximeter near an ESU. High frequency energy from the ESU may cause the pulse oximeter to malfunction and correct measurement values cannot be displayed.

> ### ⚠ WARNING
> Do not bring the pulse oximeter (including components and accessories) into an MRI room. It may cause stick, malfunction and damage to the MRI machine and skin burn on the patient. For details, follow the instruction in the manual for the MRI machine.

> ### ⚠ 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

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

⚠ WARNING

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

⚠ 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

Only use the provided power cord. When the provided power cord cannot be used or when equipotential grounding is doubtful (such as in poor grounding facility), operate the pulse oximeter on battery power. Otherwise, the patient and operator may receive electrical shock or injury.

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

Connect only the specified instrument to the pulse oximeter 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

After attaching probes on the patient and connecting cables to the pulse oximeter, check that there are no error messages and that 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 attachment, patient condition and settings on the pulse oximeter and remove the cause.

⚠ WARNING

Only use Nihon Kohden specified probes. Otherwise, the maximum performance from the pulse oximeter cannot be guaranteed.

⚠ 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 (every 8 hours for TL-630T3/TL-631T3 probe). 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 insufficient peripheral circulation
- Neonate or low birth weight infant with delicate skin

⚠ 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

Do not diagnose a patient based on only the alarm information of the pulse oximeter. 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 is generated, check the patient condition and secure the patient safety. Depending on the generated alarm, perform appropriate treatment and remove the cause of alarm. If there is a problem on the alarm setting, change it to an appropriate setting.

⚠ WARNING

Only use the specified probe and connection cord and follow the specified procedure. Otherwise, correct monitoring cannot be performed.

⚠ WARNING

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

⚠ WARNING

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

⚠ WARNING

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

⚠ 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

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.

⚠ WARNING

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

⚠ WARNING

When the "ALL ALARMS OFF" or "ALARMS SUSPENDED" message is 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

While using sleep mode, monitor the patient on the central monitor or telemetry system. Otherwise, the pulse oximeter alarm may be missed. When EXIT ON CRISIS ALARM is not selected for the EXIT SLEEP MODE setting of the SYSTEM SETUP window, the alarm sound and sync sound of pulse do not appear on the pulse oximeter during sleep mode.

⚠ WARNING

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

⚠ WARNING

Remove the battery pack from the pulse oximeter when it will not be not used for a long time. Otherwise the battery pack may leak.

⚠ WARNING

After using the reusable probes, disinfect and sterilize it. Failure to follow this instruction causes cross infection.

⚠ **WARNING**

Install all network devices, including a 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 pulse oximeter 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**

Use external instruments which satisfy the safty standards specified by IEC-60950 or IEC 60601-1. When using external instruments which do not satisfy the safety standards, install the instruments outside the patient environment. If they are installed inside the patient environment, the patient or operator may receive electrical shock or injury.

⚠ **WARNING**

Do not leave the SD card near the patient or in reach of children. This may lead to an accident such as the patient or child swallowing the SD card.

⚠ **WARNING**

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

⚠ **WARNING**

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

⚠ **WARNING**

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

⚠ **WARNING**

If more than one medical equipment is used together in the same facility, make sure all equipments have the same alarm default settings (alarm master). If the medical equipments have different alarm default settings and when initialized, the alarm settings differ with the other equipments and alarm 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**

Check the software version number of the pulse oximeter 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**

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 in the following cases.
• Network mode:
  - The patient is admitted or discharged
  - Another alarm master is selected
  - SHOW ADMIT CONFIRMATION WINDOW on the SYSTEM CONFIGURATION screen is set to OFF and 30 minutes elapse after the pulse oximeter power is turned off
• Standalone mode
  - Another alarm master is selected

⚠ **WARNING**

Do not use the pulse oximeter with the MRI device. Failure to follow this instruction may cause skin burn on the patient. For details, refer to the MRI manual.

⚠ **WARNING**

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

⚠ WARNING

If a message indicating the current measurement condition remains displayed for 30 seconds, the pulse oximeter judges that the patient pulse wave is not detected and generates a "CHECK PROBE" alarm.

⚠ WARNING

In Standalone mode, the pulse oximeter exits from sleep mode when a CRISIS, WARNING or ADVISORY alarm occurs.

⚠ WARNING

Set the alarm to an adequate volume according to the surrounding environment. If you need to set the alarm volume low, keep the patient under close observation because the alarm sounds may not be heard. If an alarm cannot be heard, critical changes in the patient condition may be overlooked.

⚠ WARNING

Do not use the output signal of the pulse oximeter as the synchronous signal for an external device such as a ventilator. This may cause the device to operate incorrectly and result in improper medical treatment.

⚠ CAUTION

There is a time delay between the input signal and output signal of the pulse oximeter. When using the output signal from the pulse oximeter for the synchronization signal on other instrument, always consider this time delay.

⚠ 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, data may be lost or the instrument may malfunction.

⚠ CAUTION

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

⚠ CAUTION

Keep the battery pack away from patients.

⚠ 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

The battery pack must be replaced by qualified service personnel.

⚠ CAUTION

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

⚠ CAUTION

Do not reuse disposable parts and accessories.

⚠ CAUTION

Before maintenance, cleaning or disinfection, turn the pulse oximeter power off, disconnect the power cord from the AC socket and then remove the battery from the pulse oximeter. Failure to follow this instruction may result in electrical shock and pulse oximeter malfunction.

⚠ CAUTION

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

⚠ CAUTION

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

⚠ 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

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

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.

⚠ 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

Install the pulse oximeter as specified. The pulse oximeter may fall off and the patient or operator may get injured.

⚠ CAUTION

To prevent the cart from tipping over or the pulse oximeter 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 pulse oximeter is turned on and periodically, 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

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

Do not attach the probe to the same limb that is used for NIBP measurement or an IBP catheter. The SpO_2 measurement may be incorrect. Attach the probe to a finger on a limb which blood flowis stable.

⚠ CAUTION

If 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

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

⚠ CAUTION

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

⚠ CAUTION

When the 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

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

⚠ CAUTION

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

⚠ CAUTION

When using a ZS-600P or ZS-900P transmitter, the measurement values and displayed waveform on the pulse oximeter and receiving monitor may differ due to timing delay of the display and other factors. Be careful when reading the value and waveform.

⚠ CAUTION

When the pulse oximeter is connected to a central monitor network, set the Bed Name (Bed ID) and Group Name on the pulse oximeter. 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

If 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 more than one probe.

⚠ CAUTION

Do not leave the battery pack in direct sunlight or high temperatures such as in a sun-heated car. This may cause leakage of the battery pack, degrade its performance and make it unusable.

⚠ CAUTION

When a ZS-600P or ZS-900P transmitter is attached to the pulse oximeter, check the alarm and monitoring settings on the central monitor or telemetry system. The transmitter does not transmit the alarm and monitoring setting information.

⚠ 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

Keep the battery pack away from patients.

⚠ CAUTION

When monitoring the patient only with this instrument, turn on the alarm limits 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

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

The INTERBED window is not automatically displayed on interbed alarm occurrence when interbed alarms are turned off or a window other than the HOME screen or INTERBED window is displayed on the pulse oximeter.

⚠ 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 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

The ZS-600P or ZS-900P transmitter does not tranmit the SpO_2-2 and ΔSpO_2 data. When using a ZS-600P or ZS-900P transmitter to transmit pulse oximeter data to another monitor, only one channel SpO_2 data can be sent to the monitor.

⚠ CAUTION

Do not diagnose a patient based on data (e.g., pulse wave and SpO_2) which is exported from the pulse oximeter to a USB flash drive using one of the TREND page functions. The exported data does not contain patient information and therefore you cannot accurately identify the patient condition from the exported data.

⚠ CAUTION

The pulse oximeter communicates with specified systems using the HL7 protocol via the hospital network.

When transmitting medical information containing personal information from the pulse oximeter to an external facility over a network using the HL7 protocol, security measures such as encryption must be used to prevent leakage of confidential information or alteration of data. In addition, security measures must be employed to protect the route between the institutions exchanging data, such as using a closed IP network or other closed network.

When using the HL7 protocol for data communication, use the pulse oximeter in a securely managed environment.

⚠ CAUTION

Use the pulse oximeter in a securely managed environment.

⚠ CAUTION

To ensure the cybersecurity of the pulse oximeter, implement the following security measures in the network environment to which the product is connected.
1. All communication (incoming and outgoing) between the pulse oximeter and the local area network (LS-NET, HIS, etc.) is subject to packet filtering by a firewall or router.
2. When the pulse oximeter 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 pulse oximeter 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

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