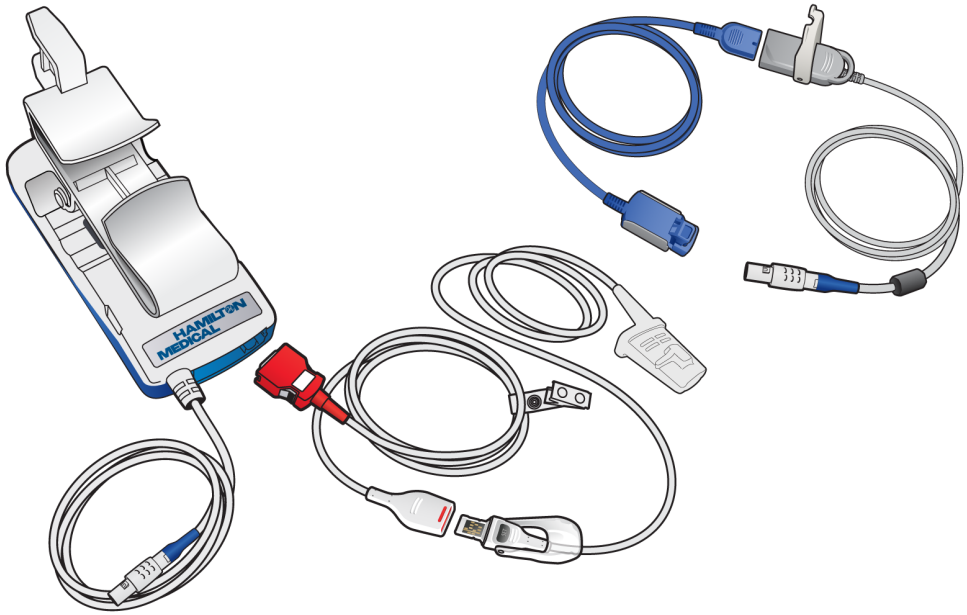

Pulse oximetry

Instructions for use

HAMILTON-C6

REF 282010, 10109010, 10109010BA

Software version 1.2.x

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HAMILTON MEDICAL

Instructions for use

Pulse oximetry

2021-07-01

624963/03

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Table of Contents

About this guide

When a supported pulse oximeter is connected to the device, the ventilator provides integrated monitoring and data display of functional oxygen saturation of arterial hemoglobin (SpO2) and related pulse oximetry data.

This guide provides information about the use and configuration of SpO2 sensors and data. It is designed for use together with your ventilator *Operator's Manual*, and refers to information provided therein.

Conventions used in this guide

In this manual:

- The SpO2 sensors and cables shown in this manual may not exactly match what you see in your environment.
- Button and tab names are shown in a **bold** font.
- The notation **XX** > **XX** shows the sequence of buttons/tabs to touch to open the associated window.

  For example, the text "Touch **System** > **Settings**" means touch the **System** button, then touch the **Settings** tab.
- Window names are shown using the sequence of buttons/tabs used to open them.

  For example, "Alarms > Limits 2 window" means the window is accessed by touching the **Alarms** button, then the **Limits 2** tab.
- Pressure is indicated in cmH2O, length in cm, and temperature in degrees Celsius (°C). 1 cmH2O equals 0.981 mbar, which equals 0.981 hPa.
- A green check mark ✓ or button XXX indicates a selected item or feature.
- The graphics shown in this manual may not exactly match what you see in your environment.
- Some figures use callouts in a white circle with a blue border.

  ① These figures may have an associated legend table, or may provide the legend in the figures title, if a single item. Callouts may be numeric or alphabetic. Callouts are *unrelated* to any nearby procedures and refer only to the figures themselves and their associated legend.
- Some figures use small dark blue callouts.

  ❶ These callouts show the sequence of steps. Note that any numbering is *not* directly related to the numbering of any associated procedure.
- Not all features or products are available in all markets.
- Product description and order number may differ depending on region.
- Pulse oximeter technologies offered with this device are provided by Masimo and Nihon Kohden.
- The pulse oximeter is also referred to as a pulse *CO-oximeter/SpO2 adapter*, and the sensor is also referred to as a *probe*. The terms as used in this manual are synonymous.
- In general, warnings, cautions, and notes related to CO-oximetry are specific to Masimo technology only.

- Phrases referring to an SpO2 adapter are specific to the enclosure containing the optional oximetry or CO-oximetry solution that allows connection to either standard pulse oximetry sensors (Masimo or Nihon Kohden), or pulse CO-oximetry sensors (Masimo only).
- The Masimo **rainbow SET** option is only available with a Masimo SET pulse oximeter.
- The **PI** and **PVI** monitored parameters are only available with a Masimo SET pulse oximeter.

Safety messages are displayed as follows:

⚠ WARNING

Alerts the user to the possibility of injury, death, or other serious adverse reactions associated with the use or misuse of the device.

⚠ CAUTION

Alerts the user to the possibility of a problem with the device associated with its use or misuse, such as device malfunction, device failure, damage to the device, or damage to other property.

NOTICE

Emphasizes information of particular importance.

In tables, safety messages are indicated as follows:

⚠ WARNING!

⚠ CAUTION!

NOTICE!

1
Safety information

1.1 General safety information

The pulse oximeter is to be operated by, or under the supervision of, qualified personnel only. Review the manual, accessories, directions for use, all precautionary information, and specifications before using the pulse oximetry system.

Safety information is organized by general area of application:

- General safety
- Safety related to pulse oximetry measurements
- Sensor safety
- Maintenance (see Chapter 3)

⚠ WARNING

- *Explosion/Fire hazard.* Never use the SpO2 adapter in a hyperbaric oxygen chamber. Failure to comply with this warning can cause explosion or fire.
- *Explosion/Fire hazard.* Never use the SpO2 adapter in the presence of any flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide. Failure to comply with this warning can cause explosion or fire.
- The pulse oximeter is intended only as an adjunct device in patient assessment. Do not use it as the sole basis for diagnosis or therapy decisions. It must be used in conjunction with clinical signs and symptoms. Overall judgment must be made by a physician who understands the limitations and characteristics of the pulse oximeter and can read the biomedical signals acquired by other instruments.
- Additional ventilator-independent patient monitoring (bedside vital sign monitoring or arterial blood gas (ABG) measurement) must be used during automatic or guided ventilation. Check PaCO2 against displayed PetCO2 and SaO2 against displayed SpO2.
- Verify the compatibility of the adapter, sensor, and cables before use. Use of incompatible components can result in patient injury.
- Do *not* use the pulse oximeter if it appears, or is suspected to be, damaged.
- Do *not* place the SpO2 adapter or accessories in any position that might cause them to fall on the patient.
- Do *not* use the pulse oximeter unless the setup has been verified to be correct.
- The pulse oximeter is *not* an apnea monitor.
- To ensure safety, avoid stacking multiple devices or placing anything on the instrument during operation.
- Only use the SpO2 adapter and SpO2 sensors that are listed as compatible with Hamilton Medical ventilators. The safety of the attachment section (including the SpO2 adapter and the sensor) depends on the specifications of the connected instrument. If the SpO2 adapter is used with an instrument or SpO2 sensor other than those specified, the patient and operator can get an electrical shock and the SpO2 adapter can become hot.
- SpO2 is empirically calibrated in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb).

- To ensure patient electrical isolation, connect only to other equipment with electrically isolated circuits.
- Do *not* use the pulse oximeter during magnetic resonance imaging (MRI) scanning or in an MR environment.
- Do *not* use SpO2 measurement and **PEEP/Oxygen** adjustment with patients suffering from carbon monoxide intoxication.
- Do *not* permit the operation of mobile phones, small wireless devices and other devices that 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 can cause the display of incorrect data.
- The pulse oximeter should *not* be used for arrhythmia analysis.

⚠ CAUTION

- *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 unit might read zero for the duration of the active irradiation period.*
- *Never disassemble or repair the SpO2 adapter. Disassembly and repair must be performed by qualified service personnel.*
- *The instrument must be configured to match your local power line frequency to allow for the cancellation of noise introduced by fluorescent lights and other sources.*
- *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 instrument, preventing it from working properly.*
- *To minimize radio interference, other electrical equipment that emits radio frequency transmissions should NOT be in close proximity to the pulse oximeter.*
- *Avoid permanent direct contact of the SpO2 sensor with the body. It can burn the skin as the sensor may reach a temperature of 41°C (105.8°F).*

NOTICE

- (USA only) Federal law restricts this device to sale by or on the order of a physician.
- Only use components specified by Hamilton Medical.
- *Not* all SpO2-related devices are protected against the effect of the discharge of a cardiac defibrillator.
- A functional tester *cannot* be used to assess the accuracy of the pulse CO-oximeter.
- Do *not* shake or swing the SpO2 adapter or sensor while holding the cable. This can break the SpO2 adapter, sensor (probe), or cable.
- Ensure that the accessories used during transport are adequately protected against water ingress.

- The Masimo SET pulse oximetry equipment has been tested and found to comply with the Class B limits for medical devices according to the EN 60601-1-2, Medical Device Directive 93/42/EEC. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

1.2 Pulse oximetry measurements safety information

⚠ WARNING

- If any measurement seems questionable, first check the patient's vital signs by alternate means and then check the pulse oximeter for proper function.
- Inaccurate pulse rate measurements may be caused by:
  - Improper sensor application
  - Low arterial perfusion
  - Motion artifact
  - Low arterial oxygen saturation
  - Excessive ambient or environmental noise
- Inaccurate SpO2 readings may be caused by:
  - Improper sensor application
  - Elevated levels of carboxyhemoglobin (COHb) or methemoglobin (MetHb). High levels of COHb or MetHb may occur with a seemingly normal SpO2. When elevated levels are suspected, perform a laboratory analysis of a blood sample.
  - Dye injected into the blood, such as indocyanine green or methylene blue
  - Externally applied coloring and texture, such as nail polish, acrylic nails, glitter, and so on
  - Birthmarks, tattoos, skin discolorations, moisture on skin, deformed or abnormal fingers, and so on
  - Skin color disorders
  - 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, and so on
  - Hypocapnic or hypercapnic conditions
  - An electrosurgical unit is used
  - During CPR
  - Measuring at a site with a venous pulse
  - Low arterial perfusion
  - Severe anemia
  - The pulse wave is small (the patient has insufficient peripheral circulation)
  - Motion artifact
- Interfering substances: Dyes or any substance containing dyes that change usual blood pigmentation may cause erroneous readings.
- SpO2 measurement for patients with carbon monoxide poisoning can be incorrect.
- In case of anemia and blood loss, the SpO2 sensor is unable to detect tissue hypoxia.
- Loss of pulse signal can occur when:
  - The sensor is too tight
  - The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia

– There is arterial occlusion proximal to the sensor

– The patient is in cardiac arrest or in shock

- The pulsations from intra-aortic balloon support can be additive to the pulse rate on the oximeter pulse rate display. Verify the patient's pulse rate against the ECG heart rate.
- When not measuring **SpO2**, disconnect the Nihon Kohden adapter from the ventilator. Otherwise, noise from the sensor may interfere and incorrect data may be displayed.

⚠ CAUTION

- *Verify **SpO2** periodically by comparing measured **SpO2** against the patient's **SaO2** with an arterial blood gas (ABG) measurement.*
- *If **SpO2** values indicate hypoxemia, a laboratory blood sample should be taken to confirm the patient's condition.*
- *Skin pigmentation can affect the **SpO2** value. Periodically verify the **SpO2** value by checking the plethysmographic waveform and the quality index of the measured **SpO2** value.*
- *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.*
- *To ensure that alarm limits are appropriate for the patient being monitored, check the limits each time the pulse oximeter is used.*
- *Variation in hemoglobin 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.*

NOTICE

- When static electricity affects the measurement, take necessary remedial actions, such as sufficiently discharging static electricity from the patient and operator, and increasing humidity in the room.
- When a parameter shows dashes (---) or no value, it is not used in any calculations.
- When **SpO2** cannot be measured on a patient with insufficient peripheral circulation or IABP, check the **SpO2 Sensitivity** mode setting on the ventilator. The configuration of the **Sensitivity** mode may affect whether **SpO2** can be measured.
- In the following cases, an **SpO2** value may appear on the ventilator display even when the sensor is detached from the patient:

  – The adapter is connected to a ventilator without a defined **Sensitivity** mode for **SpO2** monitoring.

  – The adapter is connected to a ventilator where the **Sensitivity** mode is set to its highest setting. For details on the settings, see Chapter 6.

1.3 Sensor safety information

⚠ WARNING

- If the SpO2 adapter is used with SpO2 sensors other than those specified, the patient and operator can receive an electric shock and the SpO2 adapter can become hot.
- Avoid permanent contact of the SpO2 sensor and the body.
- If a sensor or cable is damaged in any way, discontinue use immediately. Do *not* use a sensor or patient cable with exposed optical or electrical components.
- Keep the patient away from the cable as much as possible. If the cable coils around the patient by their body movement, the patient can get injured. If this happens, remove the cable promptly.
- As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.
- The sensor cable must face away from the patient. Safely secure the sensor cable out of the way by attaching the sensor cable holding clips to the airway tubing, and connecting the sensor cable to the clips.
- Use disposable sensors only once. They cannot be sterilized and can cause cross contamination.
- To avoid cross contamination, only use single-use sensors on the same patient.
- When using Masimo reusable sensors, the site must be checked at least every four (4) hours to ensure adequate adhesion, circulation, skin integrity, and correct optical alignment. For adhesive sensors, check every eight (8) hours, or more frequently when perfusion is poor. If the circulatory condition or skin integrity has deteriorated, the sensor should be applied to a different site.
- When using Nihon Kohden sensors, change the SpO2 sensor measurement site regularly: every eight (8) hours for disposable and every four (4) hours for reusable sensors. The skin temperature may increase at the attached site by 2°C or 3°C degrees and cause a burn or pressure necrosis.
- Check the circulation condition by observing the skin color peripheral to and at the sensor measurement site and the pulse waveform.
- Do *not* use tape to secure the sensor to the site; this can restrict blood flow and cause inaccurate readings.
- Tissue damage can be caused by incorrect application or use of a sensor, for example, by wrapping the sensor too tightly.
  Inspect the sensor site as directed in the sensor's *Directions for use* to ensure skin integrity and correct positioning and adhesion of the sensor.
- Venous congestion may cause underreading of actual arterial oxygen saturation. Therefore, assure proper venous outflow from the monitored site. The sensor should *not* be below heart level (for example, sensor on hand of a patient in bed with arm dangling to the floor).

- Misapplied sensors or sensors that become partially dislodged may cause either over or under reading of actual arterial oxygen saturation.
- Avoid placing the sensor on any extremity with an arterial catheter, blood pressure cuff, or intravascular line to avoid potential inaccurate measurements or loss of pulse signal.
- Detach the SpO2 sensor before defibrillation.
- To protect from shock, always remove the sensor from the patient and completely disconnect the SpO2 adapter before bathing the patient.

⚠ CAUTION

- *Under normal conditions, the probe is almost unaffected by light. However, when measuring under strong light (surgical light, sunlight), cover the probe with an ambient light shield made of opaque material. Otherwise, measurement accuracy is affected.*
- *Do NOT pull, twist, turn, or bend the sensor cable, and do not let caster feet run over the sensor cable. Failure to follow these cautions may cause cable discontinuity, short circuit, skin burn on the patient, and incorrect measurement data, and can permanently damage the sensor. Replace any broken sensor with a new one.*
- *Redness or skin irritation may appear at the attachment site. Take extreme care of patients with weak skin. In case of redness or skin irritation, change the attachment site or stop using the sensor.*
- *Routinely check circulation distal to the sensor site.*
- *If the sensor is wrapped too tightly or supplemental tape is used, venous congestion/pulsations may occur causing erroneous readings and/or pressure injuries.*
- *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
- *If the probe is attached to the same limb that is used for NIBP measurement or an IABP catheter, the blood circulation at the attachment site is affected and the measurement might not be correct. Attach the probe to a limb where the blood circulation is not affected.*
- *To avoid poor circulation, do not secure the sensor too tightly. 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 can 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.*

NOTICE

- Read all of the safety information before using the sensor.
- Before use, carefully read the sensor's *Directions for use*.
- With Masimo SET pulse oximetry, use only Masimo sensors for SpO2 measurements.
- Do *not* loop the patient cabling into a tight coil or wrap around the device, as this can damage the cable.
- High-intensity extreme lights (such as pulsating strobe lights) directed on the sensor may not permit the pulse oximeter to obtain vital sign readings.
- When using the Maximum Sensitivity setting, performance of "Sensor Off" detection may be compromised. If the instrument is in this setting and the sensor becomes dislodged from the patient, the potential for false readings may occur due to environmental noise such as light, vibration, and excessive air movement.
- Masimo cables and sensors are provided with X-Cal technology to minimize the risk of inaccurate readings and unanticipated loss of patient monitoring. Refer to the manufacturer's *Directions for use* for sensor and cable lifetime specifications.

This guide includes several descriptions, warnings, and specifications for the pulse oximetry adapter and sensors.

Not all of the information is included here.

- For detailed information about Masimo adapters and patient sensors, see the Masimo Starter Kit documentation, sensor inserts, and the manufacturer's *Directions for use*. Additional information may also be available at the manufacturers' website: *www.masimo.com*.

  Note that possession or purchase of this device does not convey any express or implied license to use the device with unauthorized sensors or cables which would, alone or in combination with this device, fall within the scope of one or more of the patents relating to this device.

  For information on Masimo patents, see *www.masimo.com/patents*

- For detailed information about Nihon Kohden adapters and patient sensors, see the manufacturer's *Directions for use*.

Be sure to also read the safety information for the ventilator, provided in the ventilator *Operator's Manual*.

2
SpO2 monitoring

2.1 Overview

The supports **SpO2** pulse oximeters from two manufacturers: Nihon Kohden and Masimo. The pulse oximeter comprises a sensor, cables, and adapter.

The sensor takes continuous measurements to provide accurate, reliable data for various pulse oximetry parameters, together with a signal quality indicator. Working with the adapter, the sensor sends this information to the ventilator.

These parameters are available:

- In the Monitoring window
- As main monitoring parameters (MMPs)
- As secondary monitoring parameters (SMPs)
- In the Dynamic Lung
- As trends

They are subject to applicable alarms, all of which are controlled at the ventilator. You can configure an alarm delay for the **SpO2** high/low alarms that specifies a short waiting period after an alarm condition occurs before the system sounds an audible alarm.

Support for pulse oximetry is available with installation and activation of the SpO2 option and related hardware. For ordering details, see the ventilator product catalog.

Table 2-1 describes the options available with each oximeter. Details on each option[1] are provided in this chapter.

Table 2-1. SpO2 pulse oximeter options

Options, Measurements	Nihon Kohden	Masimo SET	Masimo rainbow SET
SpO2	X	X	X
Pulse	X	X	X
Plethysmogram	X	X	X
Alarm delay	X	X	X
Perfusion index (PI)		X	X
Pleth variability index (PVI)[2]		X	X
SpCO (carboxyhemoglobin)			X
SpMet (methemoglobin)			X
SpHb (total hemoglobin)			X
SpOC (oxygen content)			X

[1] Masimo rainbow SET measurements are purchasable options for the Masimo pulse oximeter. They require the use of the Masimo SpO2 pulse oximeter. For details, see the Masimo rainbow SET *Instructions for Use*. Not available in all markets.

[2] The **PVI** parameter must be enabled on the adapter firmware and in the ventilator software. For details about Masimo rainbow SET parameters, contact your Hamilton Medical technical representative or Masimo area sales representative.

2.1.1 About the Nihon Kohden pulse oximeter

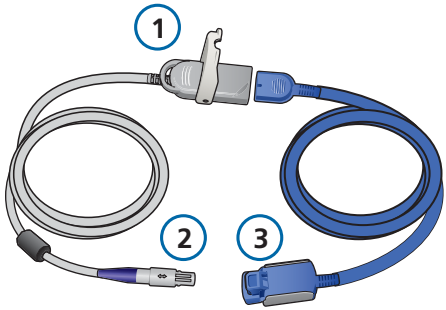
The Nihon Kohden pulse oximeter comprises a sensor and adapter, with integrated cable and locking cover.

The sensor takes continuous measurements to provide accurate, reliable data for SpO2, oxygen saturation index (OSI), and pulse, together with a signal quality indicator. Working with the adapter, the sensor sends this information to the ventilator.

Figure 2-1 shows the Nihon Kohden system components[3].

For connection information, see Section 2.4.1. For configuration details, see Chapter 6.

Figure 2-1. Nihon Kohden pulse oximeter components



1	SpO2 adapter main unit with locking cover (part of cable to ventilator)	3	Sensor and cable
2	Adapter cable to ventilator		

2.1.2 About the Masimo SET pulse oximeter

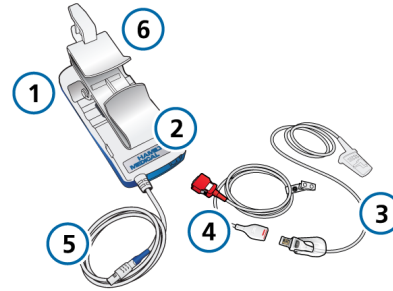
The Masimo SET pulse oximeter comprises a sensor, cables, and adapter.

The sensor takes continuous measurements to provide accurate, reliable data for SpO2, oxygen saturation index (OSI), pulse, perfusion index (PI), and pleth variability index (PVI), together with a signal quality indicator. Working with the adapter, the sensor sends this information to the ventilator.

Figure 2-2 shows the Masimo SET system components[3].

For connection information, see Section 2.4.2. For configuration details, see Chapter 6.

Figure 2-2. Masimo SET components



1	Adapter	4	RD Series patient cable
2	Connection ports	5	Adapter cable to ventilator
3	RD Series sensor	6	Sensor cable holder

[3] The SpO2 connection on the ventilator is not shown.

2.2 Getting started

Getting up and running involves just a few steps.

Table 2-2. Configuration and set up

For technical personnel	See ...
These one-time initial configuration tasks are completed by technical personnel.	
Installing and enabling the communication board	See the board documentation or the ventilator *Installation Guide*
Configuring sensor settings	Chapter 6

For medical caregivers	See ...
The following tasks are performed by medical personnel caring for patients.	
Enabling SpO2 monitoring in the ventilator **System** window	Section 2.3
Connecting the components	Section 2.4
Verifying measurements	Section 2.5
Setting alarm limits	Section 2.6.1
Monitoring the patient data	Section 2.7
Cleaning and maintenance	Chapter 3

2.3 Enabling SpO2 monitoring

Sensor data is integrated with the ventilator monitoring system.

To enable SpO2 monitoring

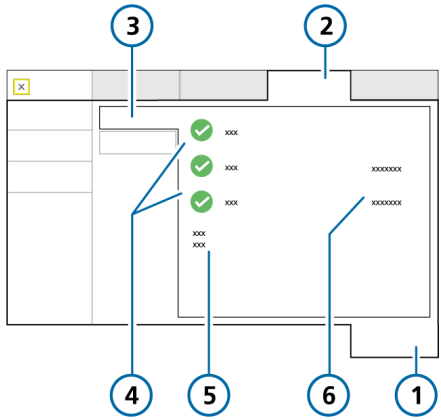
1. Touch **System** > **Sensors**.
2. Touch the **On/Off** button on the left, if not already selected.
3. Touch the **SpO2 sensor** checkbox.

   The status text **active** appears next to the checkbox as long as the adapter is connected to the ventilator.

   If the status area is empty, the adapter is not connected.

You can also specify sensor acquisition settings, if needed. See Sections 6.4 and 6.5.

Figure 2-3. Enabling SpO2 monitoring



1	System	4	Sensor options (O2, CO2, SpO2)
2	Sensors	5	Sensor and cable status (*Masimo only*)
3	On/Off	6	Sensor type (Nihon Kohden or Masimo)

2.4 Connecting the components

Before connecting the patient, carefully read the warnings and cautions at the beginning of this guide.

For additional details about setting up the sensor cable holder, see the *SpO2 Sensor Cable Holder User Guide*.

See the following sections depending on your pulse oximeter:

- For Nihon Kohden, see Section 2.4.1.
- For Masimo, see Section 2.4.2.

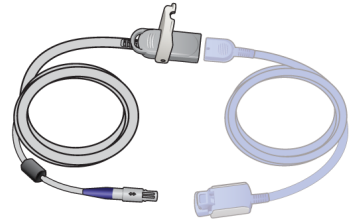
2.4.1 Connecting the Nihon Kohden pulse oximeter

Connecting the components comprises the following steps:

1. Connect the cables to the sensor and to the ventilator.
2. Attach the sensor to the patient.

Once connected, verify the sensor measurements on the ventilator display. See Section 2.5.

Figure 2-4. Connecting the Nihon Kohden adapter cable to the ventilator



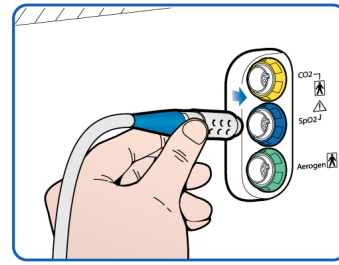
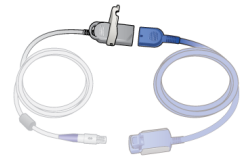
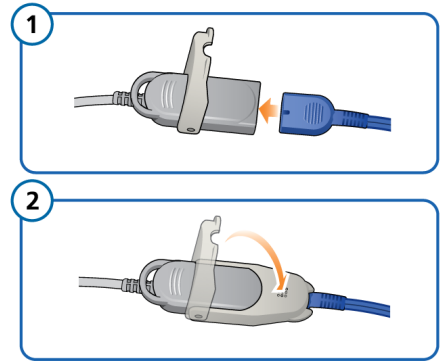


Figure 2-5. Connecting the sensor cable to Nihon Kohden adapter



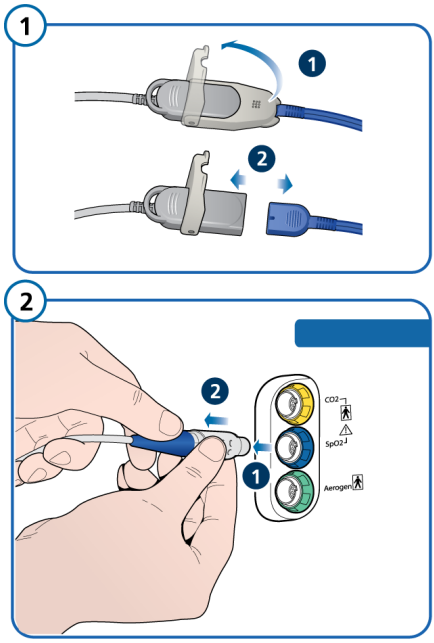


2.4.1.1 Disconnecting Nihon Kohden components

To disconnect the components

1. Remove the sensor from the patient.
2. Open the adapter cover and disconnect the sensor cable.
3. Disconnect the adapter cable from the communication board on the ventilator by gently pulling back the connector and pulling it out from the connection port.
4. Cover the port with the attached rubber cover.

Figure 2-6. Disconnecting the Nihon Kohden pulse oximeter components



2.4.2 Connecting the Masimo pulse oximeter

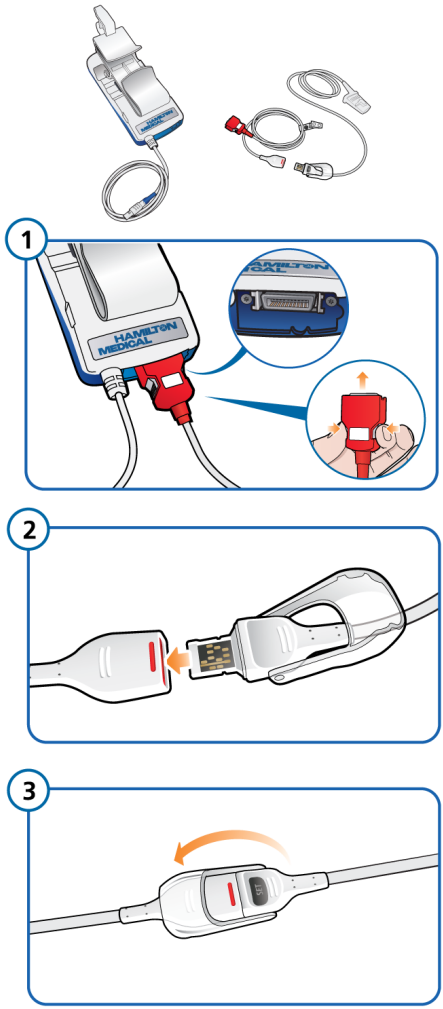
Refer to the sensor *Directions for use* for connection and disconnection details.

Connecting the components comprises the following steps:

1. Attach the adapter where desired, ensuring the adapter handle clicks into place and is securely attached. For detailed instructions, see the *Sensor Cable Holder User Guide* (PN 627167).
2. Connect the cables.
3. Attach the sensor to the patient.

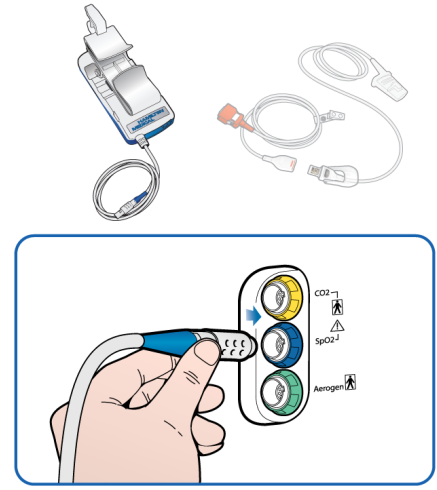
The following illustrations show connecting the RD Series sensor cables.

Figure 2-7. Connecting the Masimo components



Once connected, attach the sensor to the patient, and verify the sensor measurements on the ventilator display. See Section 2.5.

Figure 2-8. Connecting Masimo adapter to the ventilator



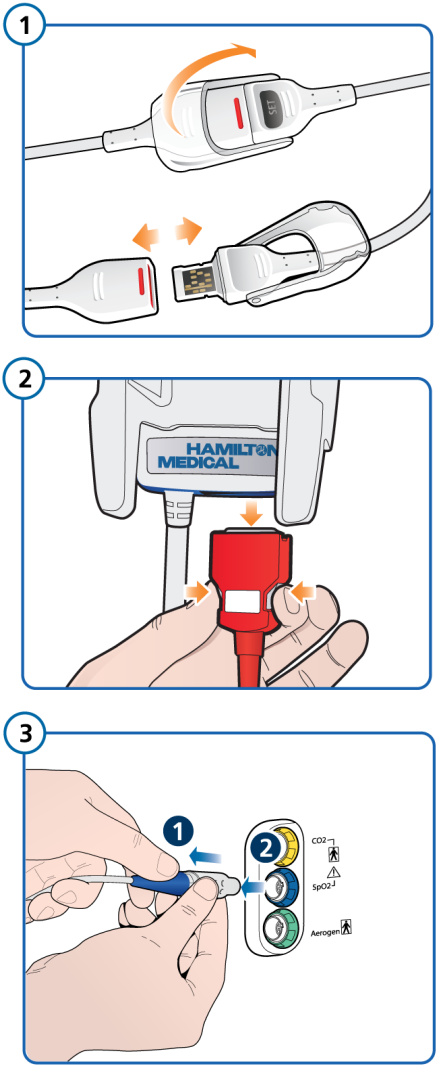
2.4.2.1 Disconnecting the Masimo components

Refer to the sensor *Directions for use* for connection and disconnection details.

To disconnect the components

1. Remove the sensor from the patient.
2. Open the adapter cover and disconnect the sensor cable.
3. Disconnect the patient cable from the adapter.
4. Disconnect the adapter cable from the communication board on the ventilator by gently pulling back the connector and pulling it out from the connection port.
5. Cover the port with the attached rubber cover.
6. Remove the adapter from the rail, if needed.

Figure 2-9. Disconnecting Masimo components



2.5 Verifying sensor measurements

When SpO2 monitoring is enabled on the ventilator and the sensor is connected to the ventilator and to the patient, measurements recorded by the pulse oximeter are displayed in the Monitoring > SpO2 window.

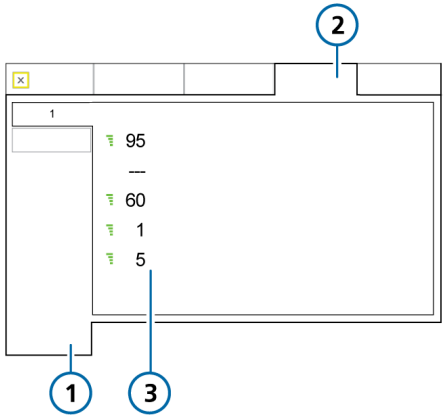
During active ventilation, if the device does not detect a pulse for 30 seconds, the ventilator generates a patient disconnection alarm.

To verify that measurements are being recorded

1. Start ventilating the patient.
2. On the ventilator, touch **Monitoring** > **SpO2** (Figure 2-10).

The SpO2 value is displayed approximately 10 seconds after placing the sensor. Note that the values may take up to 30 seconds to be displayed.

Figure 2-10. Pulse oximetry data, Monitoring window



1	Monitoring	3	Monitored pulse oximetry parameter values and quality index
2	SpO2		

If you do not see any oximeter-related measurements, ensure that the SpO2 sensor is enabled in the **System > Sensors > On/Off** window. See Section 2.3.

You can configure sensor acquisition settings as appropriate for the patient during ventilation. See Sections 6.4 and 6.5.

2.5.1 Reviewing the Masimo sensor and cable status

Masimo sensors and cables incorporate a specified lifetime. When this lifetime expires, the affected sensor or cable no longer functions and must be replaced.

Use the **System > Sensors** window to monitor the sensor and cable lifetime and operation status.

Hamilton Medical recommends that you check the sensor and cable status before each patient use.

To review Masimo sensor and cable status

- Touch **System** > **Sensors** > **On/Off** (Figure 2-3).

The sensor and cable status are listed below the **SpO2** checkbox.

Table 2-3. Masimo sensor and cable operation status

Status message	Description
Ok	The device is operational.
Near expiration	The device is approaching its intended maximum usage. Be sure to change the affected component before the next patient use.
Expired	The device is expired and no longer operational. An **SpO2 sensor error** message is generated. Replace the device.

2.6 Working with alarms

You can specify alarm limits for several pulse oximetry parameters. In addition, default ranges can be defined in configuration.

During an active **SpO2** alarm, the **SpO2** parameter is displayed in the color corresponding to the associated alarm priority, together with a colored bar to the right of the **SpO2** parameter. For the list of alarms, see Section 2.6.3.

See the ventilator *Operator's Manual* for details about reviewing and working with alarms.

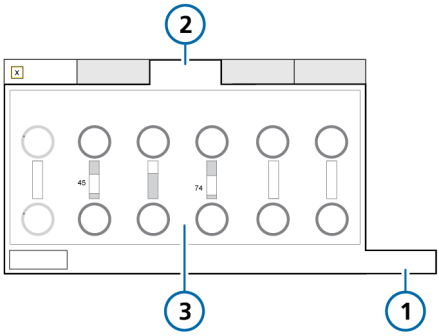
2.6.1 Setting alarm limits

NOTICE

The ventilator **Auto** alarm function does not apply to pulse-oximetry alarms.

Pulse-oximetry-related alarms are displayed in the **Alarms > Limits 2** window[4].

Figure 2-11. Pulse oximetry alarms



1 Alarms

2 Limits 2

3 Pulse oximetry alarms

The PVI alarm limits are available only when the option is enabled.

The high and low **SpO2** alarm limits are a special case: you can set a short alarm delay as described in Section 2.6.2.

2.6.2 SpO2 alarm delay

Oxygen saturation levels can be relatively variable but the changes are transient, and as such, do not generally require clinical intervention.

To reduce the number of alarms that are not actionable (that is, nuisance alarms), a short delay of up to 15 seconds can be configured after a **Low SpO2** or **High SpO2** alarm condition occurs *before* the system displays the message and sounds the alarm.

The alarm delay is set in the **System > Sensors > SpO2** window. See the appropriate section for Nihon Kohden or Masimo in Chapter 6.

[4] Additional ventilator alarm settings are available in the **Alarms > Limits 1** window. When the Masimo rainbow SET option is enabled, related alarm settings are available in the **Alarms > Limits 3** window.

2.6.3 Pulse-oximetry-related alarms

The following table lists the pulse-oximetry-related alarms.

Table 2-4. SpO2 alarms, priority, and corrective actions

Alarm/Priority	Definition/Corrective action
SpO2: Adapter missing *Medium priority.*	SpO2 adapter is disconnected from ventilator. **To resolve** • Connect an adapter. • Replace adapter.
SpO2: Light interference *Medium priority.*	Light interference with the sensor. **To resolve** • Check sensor for visible contamination, clean sensor windows. • Cover sensor or change attachment site. • Verify line frequency setting (**Configuration**). • Replace sensor.
SpO2: Low perfusion index *Medium priority.*	*Masimo only.* Perfusion index was too low for at least 30 seconds. **To resolve** Move sensor to a better perfused site.
SpO2: Poor signal *Medium priority.*	*Nihon Kohden only.* Pulse from SpO2 sensor was not found. Sensor may be detached from patient or secured too tightly, preventing circulation. **To resolve** • Check patient condition. • Change attachment site. • Reattach sensor less tightly.
SpO2: Probe missing *Medium priority.*	Sensor disconnected from adapter or cable is defective. **To resolve** • Connect sensor to adapter. • Replace adapter, patient cable, and/or sensor.

Alarm/Priority	Definition/Corrective action
SpO2: Patient disconnected *Medium priority.*	Sensor is disconnected from patient or not properly attached to patient, or sensor is faulty. **To resolve** • Check sensor attachment to patient. • Replace sensor.
SpO2: Sensor error *Medium priority.*	Any of the following: • Hardware problem with sensor or connected sensor is incompatible. • Sensor/cable has expired (Masimo only). **To resolve** Replace adapter, patient cable, and/or sensor.
High PI *Medium priority.*	*Masimo only.* Peripheral perfusion exceeds the set limit. **To resolve** • Check patient condition. • Check settings, including alarms.
Low PI *Medium priority.*	*Masimo only.* Peripheral perfusion is below the set limit. **To resolve** • Check patient condition. • Move sensor to a better perfused site.
High PVI *Medium priority.*	*Masimo only.* Pleth perfusion variability exceeds the set limit. **To resolve** • Check patient condition. • Check settings, including alarms.
Low PVI *Medium priority.*	*Masimo only.* Pleth perfusion variability is below the set limit. **To resolve** • Check patient condition. • Move sensor to better perfused site.

Alarm/Priority	Definition/Corrective action
High pulse *Medium priority.*	Pulse rate exceeds the set limit. **To resolve** • Check patient condition. • Check settings, including alarms.
Low pulse *Medium priority.*	Pulse rate is below the set limit. **To resolve** • Check patient condition. • Check settings, including alarms.
High SpO2 *Low priority.*	SpO2 exceeds the set limit. **To resolve** • Check patient condition. • Check settings, including alarms.
Low SpO2 *High priority or medium priority.*	The **Low SpO2** alarm has two levels of priority, depending on how much below the limit the measured value is. *Medium priority.* SpO2 meets all of the following conditions: • Below the set limit. • Above 85%. • Above *(limit - 2% of set limit).* *High priority.* SpO2 is either of the following: • Lower than *(limit - 2% of set limit)* even if above 85%. • Below 85%. **To resolve** • Check patient condition. • Check settings, including alarms.

2.7 Viewing pulse oximetry data

Sensor data is updated every second.

Pulse oximeter data is readily available as follows:

View SpO2-related data ...	See ...
In the **Monitoring** window	Section 2.7.2
On the main display	Section 2.7.3
In the **Dynamic Lung** panel	Section 2.7.4
In a **Plethysmogram**	Section 2.7.5
As a **Trend** graph	Section 2.7.6
As an SMP	Section 2.7.7

Basic sensor information is displayed in the **System > Sensors** window. Additional sensor data is available in **Configuration** (Chapter 6).

2.7.1 Monitored parameters

The following tables provide an alphabetical list of the pulse-oximetry-related monitored parameters.

This data is displayed in the **Monitoring > SpO2** window. The measured **SpO2** value is also displayed under the MMP list at the bottom left of the display.

- Section 2.7.1.1 describes parameters supported with Nihon Kohden.
- Section 2.7.1.2 describes parameters supported with Masimo.

2.7.1.1 Parameters supported with Nihon Kohden

For parameter ranges and accuracy information, see Chapter 4.

Table 2-5. Nihon Kohden SpO2 parameters

Setting	Description
Oxygen saturation index (OSI)	Calculated approximation of the Oxygenation index (**OI**) when SpO2 is 97% or lower[5]. Calculated as: *Pmean*FiO2*100 / SpO2* For details, see Section 2.10.
Pulse rate (bpm) *(displayed on device as 1/min)*	Pulse
SpO2 (%)	Arterial oxygen saturation in blood
SpO2/FiO2 (%)	Calculated approximation of **PaO2/FiO2** when **SpO2** is 97% or lower[5]. Calculated as: *100*SpO2 / Oxygen* For details, see Section 2.9.

[5] When **SpO2** exceeds 97%, the **SpO2/FiO2** ratio and **OSI** are not calculated; the display shows dashes (---).

2.7.1.2 Parameters supported with Masimo SET

For parameter ranges and accuracy information, see Chapter 5.

Table 2-6. Masimo SET SpO2 parameters

Settings	Description
Oxygen saturation index (OSI)	Calculated approximation of the Oxygenation index (OI) when SpO2 is 97% or lower[6]. Calculated as: *Pmean*FiO2*100 / SpO2* For details, see Section 2.10.
Perfusion index (PI) (%)	Pulse strength.
Pleth variability index (PVI) (%)	Measure of peripheral perfusion changes. For details, see Section 2.7.1.3.
Pulse rate (bpm) *(displayed as 1/min)*	Pulse.
SpO2 (%)	Arterial oxygen saturation in blood.
SpO2/FiO2 (%)	Calculated approximation of PaO2/FiO2 when SpO2 is 97% or lower[6]. Calculated as: *100*SpO2 / Oxygen* For details, see Section 2.9.

2.7.1.3 About the Pleth Variability Index (PVI)

PVI[7] is only supported with use of a Masimo SET pulse oximeter. This parameter must be enabled on the adapter firmware.

PVI is a measure of the dynamic changes in the perfusion index (PI) that occur during the respiratory cycle. It can be closely related to intrathoracic pressure changes.

This index can be used as an early indicator by the clinician to help determine whether to administer fluids to the patient.

PVI is displayed in the Monitoring window, as well as in the Dynamic Lung panel.

You can set high and low alarm limits.

You can check whether the option is available in the **Configuration > Sensors > Upgrade** window. For details, contact your Hamilton Medical technical representative.

For additional information about the PVI parameter, see the following:

- Chapter 5 of this guide
- Masimo SET product documentation

[6] When SpO2 exceeds 97%, the SpO2/FiO2 ratio and OSI are not calculated; the display shows dashes (---).
[7] The PVI parameter must be enabled on the adapter firmware and in the ventilator software. For details about Masimo rainbow SET parameters, contact your Hamilton Medical technical representative or Masimo area sales representative.

2.7.2 Viewing data in the Monitoring window

The **Monitoring > SpO2** window provides access to the pulse oximetry data. See Section 2.5.

The quality index shows the sensor's evaluation of the signal quality. A low quality index indicates a poor signal due to interference from excessive motion or other cause.

For troubleshooting information when the quality index is poor, see Section 2.8.

Table 2-7. Quality index display

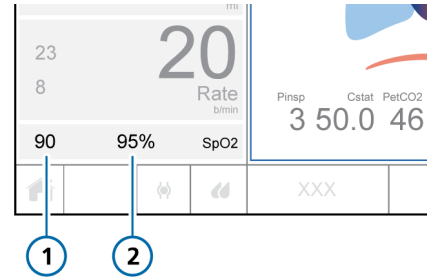
Quality indicator	Confidence value
4 gray (or blue) bars, no data 	OFF (no information).
1 red bar, poor quality 	The data from the sensor is not usable or the parameter measurement is still initializing.
2 orange bars, medium quality 	The data from the sensor is acceptable for most uses. An alarm may be active that could affect how accurately this parameter is currently measured.
3 green bars, good quality 	The data from the sensor is reliable.
4 green bars, best quality 	The data from the sensor is highly stable and reliable.

2.7.3 Viewing data on the main display

As with other parameters, any of the monitored pulse oximetry parameters can be configured as a main monitoring parameter (MMP). For configuration details, see your ventilator *Operator's Manual*.

When **SpO2** monitoring is enabled, the **low SpO2** alarm limit and measured **SpO2** value are always displayed under the MMP list, as shown in Figure 2-12.

Figure 2-12. SpO2 data in main display



1 Low SpO2 alarm limit

2 Measured SpO2 value

2.7.4 Viewing data in the Dynamic Lung panel

NOTICE

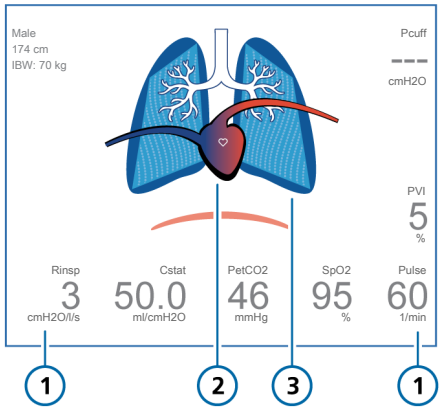
If the large heart is not displayed, the SpO2 option is disabled or not installed.

When the SpO2 option is enabled, the Dynamic Lung panel is expanded to show the circulation of blood through the heart, superimposed on the breathing of the lungs. See your ventilator *Operator's Manual* for details.

The **Dynamic Lung** panel displays the following data: **Rinsp**, **Cstat**, **PetCO2**, **SpO2**, **Pulse**, **PVI** *(Masimo only)*, **Pcuff**.

During an active **SpO2** alarm, the **SpO2** parameter is displayed in the color corresponding to the associated alarm priority. For details, see your ventilator *Operator's Manual*.

Figure 2-13. Dynamic Lung panel



1 Parameter values[8]

2 Real-time heart and pulse display

3 Real-time lung display

The heart and pulse display varies as described next.

Table 2-8. Heart and pulse display

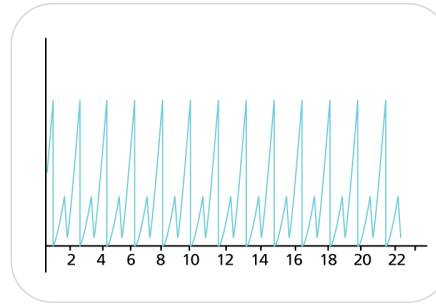
	The data from the SpO2 sensor is not usable or the parameter measurement is still initializing.
	The small white heart pulsates in time with the patient's pulse. SpO2 is being measured.

For additional details about the Dynamic Lung panel, including how to display it, see your ventilator *Operator's Manual*.

2.7.5 Reviewing the plethysmogram

A **plethysmogram** is a waveform that represents the pulsating blood volume; it is generated by the pulse oximeter.

Figure 2-14. Plethysmogram waveform (adult)



The time scale displayed is the same as for other waveforms. For details, see your ventilator *Operator's Manual*.

[8] The PVI parameter is displayed only with Masimo sensors.

With Masimo sensors, the graph also shows the currently selected sensor sensitivity setting when set to **Maximum** or **APOD** (see Section 6.5.2). No text is displayed when the setting is **Normal**.

To display the plethysmogram

1. Touch the area of the display where you wish to show the plethysmogram as described in your ventilator *Operator's Manual*.

   The graphics selection window appears.

2. Touch the **Waveforms** tab, and then the **Plethysmogram** button.

The plethysmogram is displayed.

2.7.6 Viewing data as trends

You can view trend data for the following pulse oximetry-related parameters: **SpO2**, **Pulse**, **OSI**, **SpO2/FiO2**, **PI** *(Masimo only)*, **PVI** *(Masimo only)*, and **QI-SpO2**

For details, see your ventilator *Operator's Manual*.

2.7.7 Viewing data as an SMP

In **Configuration**, you can select the pulse oximetry data to display in the **Monitoring** window. For details, see the ventilator *Operator's Manual*.

2.8 Troubleshooting

Table 2-9 describes how to address some potential pulse oximeter issues. Be sure to also check the information provided in Section 2.6.3.

Note that one of the most common reasons for a poor or absent signal is having one or more bent pin(s) in the connector head.

Table 2-9. Troubleshooting issues

Message/Issue	Details	Actions
No **SpO2** tab or disabled **SpO2** tab in Monitoring window	SpO2 monitoring is not enabled.	When no **SpO2** tab is visible, the SpO2 hardware is not enabled. Check Configuration. Ensure the SpO2 checkbox is selected in the System > Sensors > On/Off window.
No pulse oximetry data is displayed in the Monitoring > SpO2 window	• A component is damaged: for example, pins may be bent in the connector head. • An unsupported sensor is connected.	Replace adapter, patient cable, or sensor, as appropriate.
The Monitoring > SpO2 window shows values as dashes	• A component is disconnected or damaged. • A sensor/adapter- or disconnection-related alarm is generated.	• Check the connection from the adapter to the ventilator. • Check the patient cable connection to the adapter. • Check the connection between the sensor and the patient cable.
No pulse oximetry data in Configuration > Sensors > Upgrade window	The communication board is not installed.	Have the communication board installed.
No reading for a patient with an intra-aortic balloon pump (IABP) or insufficient peripheral circulation	Sufficient blood perfusion is required to generate a valid SpO2 signal.	Check the SpO2 real-time waveform and the quality indicator. If the quality is poor, do the following: • Reattach the probe to a different site. • Reconnect the pulse oximeter components. • Replace the probe.

Message/Issue	Details	Actions
An SpO2 value is displayed on the ventilator when the sensor is detached from, or not attached to, the patient.	The system may also display no signal, poor signal, no sensor, or patient disconnected message.	Check the SpO2 real-time waveform and the quality indicator. If the quality is poor, do the following: • Reattach the probe to a different site. • Reconnect the pulse oximeter components. • Replace the probe.

2.9 About the SpO2/FiO2 ratio

For the diagnosis of acute respiratory distress syndrome (ARDS) and acute lung injury (ALI), the PaO2/FiO2 ratio index is used. PaO2 is the partial pressure of oxygen in the arterial blood measured by an arterial blood gas test, and FiO2 is the fraction of inspired oxygen (Oxygen control) set on the ventilator. PaO2/FiO2 is used as a measure of blood hypoxia.

The SpO2/FiO2 ratio (%) is an approximation of the PaO2/FiO2 ratio, which, in contrast to PaO2/FiO2, can be calculated noninvasively and continuously.

The SpO2/FiO2 ratio is a useful monitoring value for bedside assessment of a patient's oxygenation status. It can also be helpful for ALI and ARDS diagnoses and patient follow up.

The ventilator calculates and displays the SpO2/FiO2 ratio when the measured SpO2 is 97% or lower.

When SpO2 exceeds 97%, the SpO2/FiO2 ratio is not calculated; the display shows dashes (---). At these higher oxygen saturation levels, the correlation between SpO2 and PaO2 is poor (the oxygen-hemoglobin curve flattens out), so SpO2/FiO2 is no longer a good approximation of PaO2/FiO2.

2.10 About the Oxygen saturation index (OSI)

The Oxygenation index (OI) is useful for diagnosing pediatric acute respiratory distress syndrome (PARDS). The Oxygen saturation index (OSI) provides an alternative to OI, which in contrast, can be calculated noninvasively and continuously.

OSI is calculated as follows:

OSI = Pmean * FiO2 *100 / SpO2

where:

- Pmean is the mean airway pressure measured by the ventilator.
- SpO2 is the monitored arterial oxygen saturation in the blood.
- FiO2 is the fraction of inspired oxygen (Oxygen control) set on the ventilator.

OI is calculated using the partial pressure of oxygen in the arterial blood (PaO2) measured by an arterial blood gas test. Since OSI is calculated using the measured SpO2 value, it can be used in cases where blood gas test data is not available.

At higher oxygen saturation levels, the correlation between SpO2 and PaO2 is poor (the oxygen-hemoglobin curve flattens out), and OSI does not provide a good alternative to OI.

When SpO2 exceeds 97%, or if the calculated OSI is below 0.21 or above 50, the display shows dashes (---).

3 Maintenance

3.1 Safety information

Maintenance safety information

⚠ WARNING

- *Electric shock hazard.* Only a qualified operator may perform maintenance procedures specifically described in this manual.
- 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 these *Instructions for use*.

  – Do *not* attempt to clean the device while monitoring the patient.
- 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

- ***Electrical shock and flammability hazard**. Before cleaning, always turn off the instrument and disconnect from any power source.*
- ***Electric shock hazard**. Before maintenance or cleaning, disconnect the SpO2 adapter from the device. Failure to comply with this instruction can result in electrical shock and **SpO2** malfunction or both.*
- ***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 UL60601-1. 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.*
- *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.*
- *Do NOT immerse the SpO2 adapter in any chemical solution or water. Do NOT use a wet SpO2 adapter; correct measurement may not be possible. If the adapter is immersed, wipe off liquid with a dry cloth and thoroughly dry the adapter.*
- *Before maintenance or cleaning, disconnect the SpO2 adapter from the ventilator. Failure to do so may result in electrical shock and SpO2 adapter error.*
- *Do NOT modify, alter, or repair the sensor and/or adapter in any way. Alterations or modification may affect performance and/or accuracy, as well as the manufacturer's warranty.*
- *After cleaning and before use, wipe liquid off with a dry cloth and thoroughly dry the adapter.*

- *If there is a possibility that the SpO2 adapter may come into contact with a chemical solution, use the SpO2 adapter with the sensor connector in a vertical and downward position.*
- *If fluid is spilled into the SpO2 adapter, stop using it and contact the manufacturer.*
- *Do NOT disinfect and sterilize the SpO2 adapter. Doing so will damage the adapter.*
- *Disposal of product: Comply with local laws in the disposal of the instrument and/or its accessories.*

3.2 Cleaning the adapter and sensor

To clean the adapter

1. Periodically clean the SpO2 adapter by wiping it with a soft cloth moistened with ethanol (15°C (59°F), 76.9% to 81.4% by volume).
2. Dry the adapter completely after cleaning.

To clean a reusable sensor

1. Remove the sensor from the patient.
2. Disconnect the sensor and the patient cable from the adapter.
3. *Nihon Kohden*: Wipe the components with a soft cloth moistened with a 2.0% glutaraldehyde solution or 0.5% alkyldiaminoethylglycine hydrochloride.

   Masimo: Wipe the components with a soft cloth moistened with a 70% isopropyl solution.
4. Allow to air dry before reuse.

3.3 Replacing the adapter, cables, or sensor

When an SpO2 adapter, cable, or sensor is broken, cracked, or visibly damaged, immediately stop using it and replace it with a new one.

3.4 Disposing of the adapter, cables, and sensor

Follow your local laws for environmental protection when disposing of an SpO2 adapter, cables, and/or sensors. For detailed information, contact your Hamilton Medical technical representative.

4
Specifications: Nihon Kohden

4.1 Parameter specifications

Table 4-1. Pulse oximetry parameters, ranges, and resolution

Parameter (units)	Range	Resolution
Oxygen saturation index (OSI)[9, 10]	0.21 to 50	0.01
Pulse (bpm) *(displayed as 1/min)*	0 to 240	1
SpO2 (%)	0 to 100	1
SpO2/FiO2[10] (%)	0 to 500	1

4.1.1 Accuracy of measurements

Table 4-2. Nihon Kohden SpO2 parameters, accuracy[11]

Parameter		Accuracy
SpO2 accuracy guaranteed at temperatures between 18°C and 40°C (64.4°F and 104°F)		
SpO2, no motion	70% to 100%	±3%[12]
Pulse rate (bpm)		±3%, ±1 bpm

Table 4-3. Nihon Kohden SpO2 sensor accuracy: Sensor SpO2 values compared to functional SaO2 measured by a CO-oximeter (see Notes below)

SpO2 sensor	PN 281951, 281952, 281953, 281954	PN 281947	PN 281948, 281949
70% to 79.9%	2.03%	1.62%	2.79%
80% to 89.9%	1.57%	1.16%	1.87%
90% to 100%	1.23%	1.01%	1.07%

[9] When the calculated OSI is out of range, the display shows dashes (---).
[10] When SpO2 exceeds 97%, the SpO2/FiO2 ratio and OSI are not calculated; the display shows dashes (---).
[11] Accuracy calculated using the root mean square (rms).
[12] For SpO2 measurements from 80% to 100% the accuracy is ±2%.

Neonatal use

Clinical functionality has been demonstrated on a population of hospitalized neonate patients. The observed SpO2 accuracy measured by the sensor was within 2.6% of the measured SaO2 value by a CO-oximeter in a study of 55 patients weighing between 447 and 2,458 grams. 368 observations were made spanning a range of 70% to 100% SaO2.

Notes

The following information relates to accuracy of Nihon Kohden pulse oximetry measurements.

- The SpO2 accuracy was tested using the TL-201T, TL-260T, TL-271T, TL-631T, TL-051S, and TL-535U SpO2 probes. The testing was performed during induced hypoxia on healthy volunteers (Ethnicity: 10 Caucasians, 2 Africans, 4 Asians, 1 Haitian, 3 Hispanics, 2 Hispanics/Caucasians, 6 Indians; Skin: 7 Light, 4 Light/Medium, 10 Medium, 1 Med/Dark, 6 Dark; Age: 21 to 30; Gender: 17 men and 11 women) under the condition of no motion.
  Arterial blood was sampled and measured by a CO-oximeter. The difference between SpO2 measured by the SpO2 probe and functional SaO2 measured by a CO-oximeter was calculated using the root-mean-square (rms) according to ISO 80601-2-61:2017. This measurement accuracy figure represents two-thirds of all test measurements.
- A pulse oximeter tester that generates simulated signals can be used to check the difference from the design specification, but it cannot be used as a replacement for human signals for testing accuracy.
- In the first two graphs that follow, response time is selectable. Options are Slow, Normal, Fast, and Extra Fast.

Figure 4-1. Response time, SpO2 changes 0.6%/s, 70 bpm

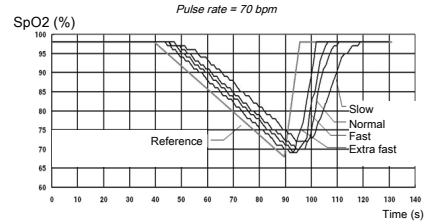


Figure 4-2. Response time, SpO2 changes 0.6%/s, 140 bpm

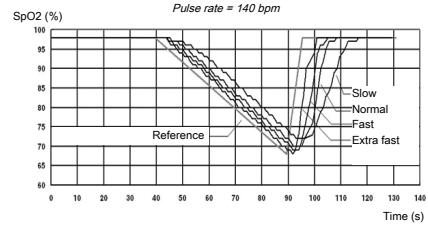
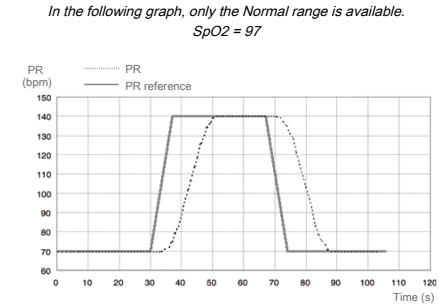


Figure 4-3. Response time, pulse rate changes 10 bpm/s



4.2 Alarm specifications

Table 4-4. Adjustable alarm ranges, default settings, and resolution

Alarm (units)	Range: Adult/ped/neo	Default: Adult/ped	Default: Neo	Resolution
Beats per minute (bpm) are displayed as 1/min.				
Pulse low (bpm)	30 to 230	50	100	5
Pulse high (bpm)	35 to 235	140	180	5
SpO2 low (%)	70 to 99	90	90	1
	When **SpO2** monitoring is enabled, the low **SpO2** alarm limit and measured **SpO2** value are always displayed below the MMP list.			
SpO2 high (%)	71 to 100/OFF	OFF	95	1

4.3 Technical specifications

Table 4-5. Nihon Kohden adapter specifications

Feature	Specifications
For sensor and other additional specifications, refer to the device Operator's Manual and the Nihon Kohden product documentation.	
Dimensions (mm)	34 W x 18 H x 117 D
Cable length	2.5 m
Weight	95 g ±10% (including cable and connector)
Degree of protection (solid particle and liquid ingress)	IPX2 Protected against dripping water when the device is tilted to a maximum of 15 degrees
Mode of operation	Continuous
Wavelength[13]	Nihon Koden pulse oximeters have two wavelengths with peaks in the range of 650 and 950 nm
Maximum light intensity	< 5.5 mW/sr
Applied part classification (per IEC 60601-1)	Type BF

[13] The wavelength range can provide especially useful information to clinicians.

Feature	Specifications
Operating requirements	
Operating temperature	10°C to 40°C (50°F to 104°F)
Operating humidity	30% to 85% relative humidity, noncondensing
Operating pressure	700 to 1060 hPa
Storage requirements	
Storage temperature	-20°C to 65°C (-4°F to 149°F)
Storage humidity	10% to 95% relative humidity, noncondensing
Storage pressure	700 to 1060 hPa
Configuration settings	
For details about the configuration settings, see Table 6-3.	
SpO2 alarm delay (s)	0, 5 (default), 10, 15
SpO2 response	Slow, Normal (default), Fast, Extra fast
Pulse detection sensitivity	Low, Normal (default), High
Sensitivity mode	Maximum, Normal (default)
Alarms	
Out of limit alarms: SpO2, Pulse rate	High/low alarms
Sensor condition alarm	No Sensor, Sensor Off, Sensor defect, Sensor error

5
Specifications: Masimo SET

5.1 Parameter specifications

Table 5-1. Pulse oximetry parameters, range, and resolution

Parameter (units)	Display range	Resolution
Oxygen saturation index (OSI)[14, 15]	0.21 to 50	0.01
Perfusion index (PI) (%)	0 to 20	0.01 if value < 1 0.1 if value ≥ 1
Pleth variability index (PVI) (%)	0 to 100	1
Pulse (bpm) *(displayed as 1/min)*	0 to 240	1
SpO2 (%)	0 to 100	1
SpO2/FiO2[15] (%)	0 to 500	1

5.1.1 Accuracy of measurements

Table 5-2. Masimo RD Series SpO2 parameters, accuracy

Parameter	Accuracy
See the notes after the table for additional details about the accuracy testing. For more information, see the Masimo SET product documentation.	
SpO2, no motion, 70% to 100%	±2% adults/ pediatrics
SpO2, motion, 70% to 100%	±3%, adults/ pediatrics
SpO2, low perfusion, 70% to 100%	±2%, adults/ pediatrics
Pulse rate, no motion, 25 to 240 bpm	±3 bpm, adults/ pediatrics
Pulse rate, motion, 25 to 240 bpm	±5 bpm, adults/ pediatrics
Pulse rate, low perfusion, 25 to 240 bpm	±3 bpm, adults/ pediatrics

[14] When the calculated OSI is out of range, the display shows dashes (---).
[15] When **SpO2** exceeds 97%, the **SpO2/FiO2** ratio and **OSI** are not calculated; the display shows dashes (---).

Notes

The following information relates to accuracy of Masimo SET pulse oximetry measurements.

- Sensor accuracy is specified when used with Masimo technology using a Masimo patient cable for RD SET sensors. Numbers represent A_{rms} (RMS error compared to the reference). Because pulse oximeter measurements are statistically distributed, only about two-thirds of the measurements can be expected to fall within a range of $\pm A_{rms}$ compared to the reference value. Unless otherwise noted, SpO2 accuracy is specified from 70% to 100%. Pulse Rate accuracy is specified from 25 to 240 bpm.
- Masimo RD SET sensor types have the same optical and electrical properties and may differ only in application type (adhesive/non-adhesive/hook & loop), cable lengths, optical component locations (top or bottom of sensor as aligned with cable), adhesive material type/size, and connector type (RD 15 pin modular plug). All sensor accuracy information and sensor application instructions are provided with the associated sensor *Directions for use*.
- The Masimo sensors have been validated for no-motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies in the range of 70% to 100% SpO2 against a laboratory CO-oximeter and ECG monitor. This variation equals plus or minus one standard deviation, which encompasses 68% of the population.
- The Masimo sensors have been validated for motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies in the range of 70% to 100% SpO2 against a laboratory CO-oximeter and ECG monitor. This variation equals plus or minus one standard deviation, which encompasses 68% of the population.
- The Masimo SET technology has been validated for low-perfusion accuracy in bench-top testing against a Biotek Index 2 simulator and Masimo's simulator with signal strengths of greater than 0.02% and transmission of greater than 5% for saturations ranging from 70% to 100%. This variation equals plus or minus one standard deviation, which encompasses 68% of the population.
- The Masimo sensors have been validated for pulse-rate accuracy for the range of 25 to 240 bpm in bench-top testing against a Biotek Index 2 simulator. This variation equals plus or minus one standard deviation, which encompasses 68% of the population.

- The following substances may interfere with pulse CO-oximetry measurements:
  - Elevated levels of methemoglobin (**MetHb**) may lead to inaccurate **SpO2** measurements.
  - Elevated levels of carboxyhemoglobin (**COHb**) may lead to inaccurate **SpO2** measurements.
  - Severe anaemia may cause erroneous **SpO2** measurements.
  - Dyes or any substance containing dyes that change usual blood pigmentation may cause erroneous readings.
  - Elevated levels of total bilirubin may lead to inaccurate **SpO2** measurements.

A_{RMS} values measured with Masimo RD SET sensors

The following tables and graphs show A_{RMS} values measured with Masimo RD SET sensors in a clinical study.

Figure 5-1. A_{RMS} values, Masimo RD SET DCI & DCI-P sensors

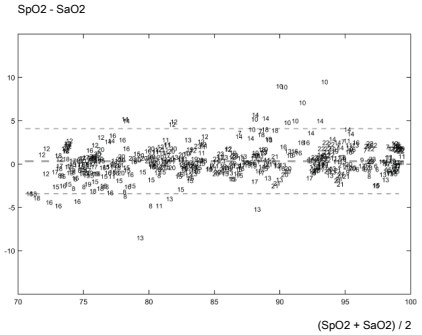


Table 5-3. A_{RMS} values, Masimo RD SET DCI & DCI-P sensors

Range	Measured A_{RMS}
90% to 100%	1.44%
80% to 90%	2.30%
70% to 80%	1.84%
Overall claimed accuracy value	
70% to 100%	1.90%

Figure 5-2. A_{RMS} values, Masimo RD SET DBI sensors

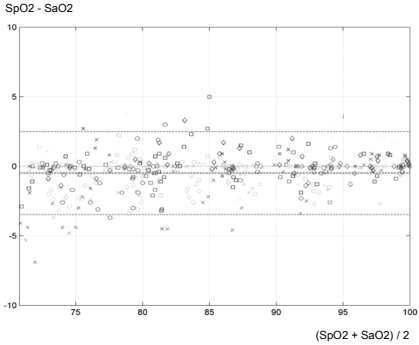


Figure 5-3. A_{RMS} values, Masimo RD SET TC-I sensors

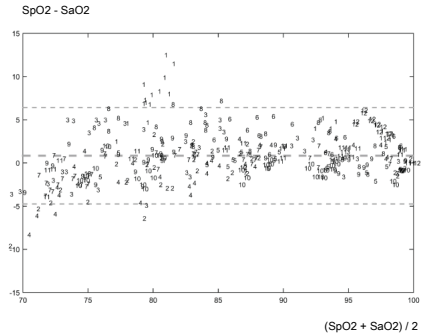


Table 5-4. A_{RMS} values, Masimo RD SET DBI sensors

Range	Measured A_{RMS}
90% to 100%	1.01%
80% to 90%	1.54%
70% to 80%	2.06%
Overall claimed accuracy value	
70% to 100%	1.60%

Table 5-5. A_{RMS} values, Masimo RD SET TC-I sensors

Range	Measured A_{RMS}
90% to 100%	2.16%
80% to 90%	2.54%
70% to 80%	3.97%
Overall claimed accuracy value	
70% to 100%	3.02%

5.2 Alarm specifications

Table 5-6. Adjustable alarms

Alarm (units)	Range: Adult/ped/neo	Default: Adult/ped	Default: Neo	Resolution
Beats per minute (bpm) are displayed on the device as 1/min.				
PI low (%)	OFF / 0.03 to 18.00	OFF	OFF	0.01 < 1 0.10 ≥ 1
PI high (%)	0.04 to 19.00 / OFF	OFF	OFF	0.01 < 1 0.10 ≥ 1
PVI low (%)	OFF / 1 to 99	OFF	OFF	1
PVI high (%)	2 to 100 / OFF	OFF	OFF	1
Pulse low (bpm)	30 to 230	50	100	5
Pulse high (bpm)	35 to 235	140	180	5
SpO2 low (%)	70 to 99	90	90	1
	When **SpO2** monitoring is enabled, the low **SpO2** alarm limit and measured **SpO2** value are always displayed below the MMP list.			
SpO2 high (%)	71 to 100/OFF	OFF	95	1

5.3 Technical specifications

Table 5-7. Masimo SET pulse oximeter specifications

Feature	Specification
For additional specifications, refer to the device Operator's Manual and the Masimo SET product documentation.	
Mechanical	
Material	Polycarbonate/ABS blend
Circuitry	Microprocessor controlled Automatic self-test when powered on Automatic setting of default parameters Automatic alarm messages Trend data output
Firmware	MX board/circuitry
Environmental	
Operating temperature	0 to 50°C (32°F to 122°F)
Storage temperature	-40°C to 70°C (-40°F to 158°F)
Relative storage humidity	10% to 95%, noncondensing
Operating altitude	*Pressure:* 500 to 1060 hPa *Altitude:* -304.5 to 5486 m (-1000 to 18,000 ft)
Configuration settings	
For details about the configuration settings, see Table 6-4.	
SpO2 alarm delay (s)	0, 5 (default), 10, 15
SpO2 averaging time (s)	2, 4, 8 (default), 10, 12, 14, 16 When operating in INTELLiVENT-ASV mode with an active PEEP and/or Oxygen controller, this parameter is always set to 16 seconds.
Sensitivity mode	APOD, Normal (default), Maximum
PVI averaging mode	Normal (default), Fast
FastSat	On, off (default)

Feature	Specification
Line frequency (Hz)	50 (default), 60
Alarms	
Out of limit alarms: SpO2, Pulse rate, PI , PVI	High/low alarms
Sensor condition alarm	No Sensor, Sensor Off, Sensor defect, Sensor error
Compliance	
EMC compliance	EN 60601-1-2:2007/AC:2014
Electrical safety	IEC 60601-1:2006/A1:2012 ANSI/AAMI ES60601-1:2005/(R)2012
Applied part classification (per IEC 60601-1) (patient cable)	Type BF
Degree of protection (solid particle and liquid ingress)	IP22 Protected against dripping water when the device is tilted to a maximum of 15 degrees
Mode of operation	Continuous

Table 5-8. Radiant power specifications for Masimo SpO2 sensors

Radiant power of light, RD SET sensors, at 50 mA, pulsed
≤ 15 mW

Table 5-9. Nominal wavelength specifications for SpO2 sensors[16]

Sensor	LED	Wavelength
RD SET sensors	Red	660 nm
	Infrared	905 nm

[16] The wavelength range can provide especially useful information to clinicians.

6 Configuration

6.1 Overview

You can access **Configuration** mode settings when the ventilator is in **Standby**. Access requires a configuration code; contact your administrator.

Configuration tasks for setting up a pulse oximeter with your ventilator fall into two categories:

- One-time settings that are specified in **Configuration** mode (Table 6-1)
- Sensor acquisition settings that can be specified during ventilation (Table 6-2)

Table 6-1. Configuring the ventilator for pulse oximetry, Configuration mode

To ...	See ...
Install the communication board	Documentation provided with the communication board or your ventilator *Operator's Manual*
Activate the **SpO2** hardware option	Section 6.2
Select the sensor type	Section 6.3

Table 6-2. Configuring sensor acquisition settings during ventilation

To ...	See ...
Select SpO2 sensor data options	
Nihon Kohden	Section 6.4
Masimo SET	Section 6.5

6.2 Activating the SpO2 hardware option

Before you begin, ensure the SpO2 communication board is installed.

To enable the board

1. In the **Configuration** window, touch **Options** > **HW options**.
2. Select the **SpO2** checkbox.

   The **Sensors** button appears on the left side of the main **Configuration** window.

You can now select your sensor type.

6.3 Selecting the sensor type

The **SpO2** communication board must be enabled for the **Sensors** button to be available (Section 6.2).

To select the sensor type

1. In the **Configuration** window, touch **Sensors**.
2. Touch the **Sensor type** tab, if not already selected.
3. Touch the appropriate button for your pulse oximeter: **Nihon Kohden** or **Masimo**.

You can now set the sensor acquisition settings appropriate for your device.

6.4 Configuring Nihon Kohden sensor settings

Before proceeding, ensure that:

- The SpO2 hardware option is activated and the sensor type is selected in Configuration.
- SpO2 monitoring is enabled (Section 2.3).

Sensor settings are persistent; they remain active until manually changed.

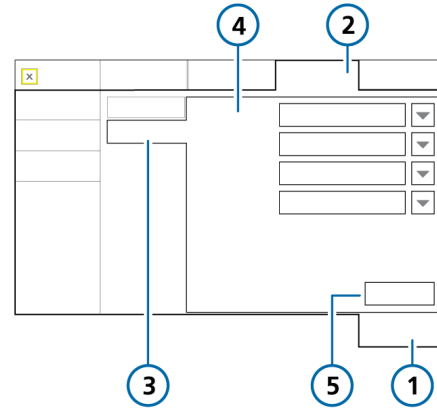
You specify sensor settings in the System > Sensors > SpO2 window.

To specify sensor data acquisition options

1. Touch **System** > **Sensors**.
2. Touch **SpO2**.
3. Specify the desired settings, as appropriate (Table 6-3).
4. To reset any of these options to the factory settings, touch **Defaults** (available only in Standby).

Configuration is now complete.

Figure 6-1. Sensor data acquisition settings, Nihon Kohden



1	System	4	Data acquisition settings
2	Sensors	5	Defaults
3	SpO2		

Table 6-3. SpO2 sensor data settings for Nihon Kohden

Parameter	Description
SpO2 alarm delay (s)	Set in the **System > Sensors > SpO2** window. Specifies the length of time, in seconds, that the measured **SpO2** value must be outside the set alarm limits before the system generates the alarm. For details, see Section 2.6.2. Options are: 0, 5 (default), 10, 15
SpO2 response	Set in the **System > Sensors > SpO2** window. Specifies the speed at which the sensor sends data to the system. Choose options as follows, if other than **Normal** (the default): • **Normal** (default) • **Slow**: Increase response time to prevent frequent alarms • **Fast**: Decrease response time to be alerted to alarm conditions quickly • **Extra fast**: Minimize the response time (this option most closely tracks the reference oxygen saturation)
Pulse detection sensitivity	Set in the **System > Sensors > SpO2** window. Specifies the sensitivity level of the sensor to detect the pulse. Options are: • **Normal** (default) • **Low**: Used to lower sensitivity when the pulse oximeter double counts the pulse wave • **High**: Used to increase sensitivity when the pulse wave amplitude is unstable, for example, due to arrhythmia
Sensitivity mode[17]	Set in the **System > Sensors > SpO2** window. Specifies the sensor sensitivity, which can be tailored to different patient conditions. Options are: • **Normal** (default) • **Maximum**: Used when it is difficult to detect a pulse, for example, with patients with insufficient peripheral circulation or when an intra-aortic balloon pump is used.

[17] If your Nihon Kohden sensor was manufactured prior to 2011, the **Sensitivity mode** setting may not be displayed.

6.5 Configuring Masimo SET sensor settings

Before proceeding, ensure that:

- The SpO2 hardware option is activated and the sensor type is selected in Configuration.
- SpO2 monitoring is enabled (Section 2.3).
- For upgrade information, contact your Hamilton Medical technical representative.

The power line frequency (50 or 60 Hz) for the sensor is specified during device configuration. Additional acquisition settings, such as alarm delay and sensitivity mode, can be changed during ventilation.

Sensor settings are persistent; they remain active until manually changed, with one exception: **Sensitivity** mode set to **Maximum**. For details, see Section 6.5.3.

Sensor settings are configured in two places: **Configuration** mode and in the **System > Sensors > SpO2** window.

6.5.1 Specifying sensor settings in Configuration mode

To specify line frequency in Configuration

1. In the **Configuration > Sensors > SpO2** window, touch the **Settings** tab.
2. Set the desired power line frequency: 50 or 60 Hz.

   The rest of the sensor settings are specified outside of **Configuration**, in the **System > Sensors** window.
3. Touch **Back** to return to the main **Configuration** window.

6.5.2 Specifying sensor settings during ventilation

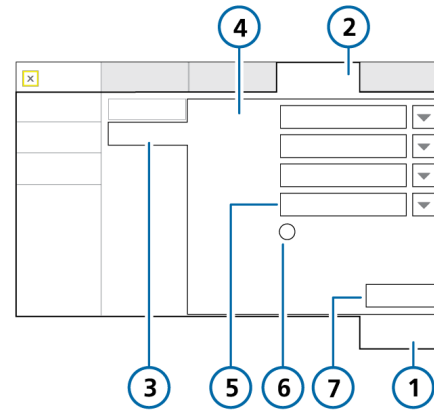
You specify sensor settings in the **System > Sensors > SpO2** window.

To configure sensor data acquisition settings

1. Touch **System** > **Sensors**.
2. Touch **SpO2**.
3. Specify the desired settings, as appropriate. See Table 6-4.
4. To reset any of these options to the factory settings, touch **Defaults** (available only in **Standby**).

Configuration is complete and the system is ready for use.

Figure 6-2. Sensor data acquisition settings, Masimo SET



1	System	5	PVI averaging mode[18]
2	Sensors	6	FastSat
3	SpO2	7	Defaults
4	Data acquisition settings		

[18] The **PVI averaging mode** setting is only displayed if the **PVI** parameter is enabled in the SpO2 adapter. Contact your Hamilton Medical technical representative for details.

Table 6-4. SpO2 sensor data settings for Masimo

Parameter	Description
SpO2 alarm delay (s)	Set in the **System > Sensors > SpO2** window. Specifies the length of time, in seconds, that the measured **SpO2** value must be outside the set alarm limits before the system generates the alarm. For details, see Section 2.6.2. Options are: 0, 5 (default), 10, 15
SpO2 averaging time (s)	Set in the **System > Sensors > SpO2** window. Defines how many **SpO2** readings will be used to calculate the final value to display. A higher averaging time provides a more accurate value, but takes longer. Options are: 2, 4, 8 (default), 10, 12, 14, 16 When operating in **INTELLiVENT-ASV** mode with an active **PEEP** and/or **Oxygen** controller, this parameter is always set to 16 seconds.
Sensitivity mode	Set in the **System > Sensors > SpO2** window. Specifies the sensor sensitivity, which can be tailored to different patient conditions. Options are: • **Normal (default).** Appropriate for most patients, provides an optimal combination of measurement sensitivity and responsiveness to a detached sensor. • **Maximum.** Recommended for patients with low perfusion for use during procedures, or in high acuity settings where there is frequent clinician/patient contact. Unlike other settings, this option is not persistent. For details, see Section 6.5.3. • **APOD (adaptive probe off detection).** Protects against incorrect pulse rate and **SpO2** readings due to a detached sensor. Not appropriate for patients with low perfusion.
PVI averaging mode	Set in the **System > Sensors > SpO2** window[19]. Specifies the time period over which the **PVI** measurement is averaged. Options are: • **Normal (default).** A longer period provides more stable readings over time. • **Fast.** A shorter period reduces the response time of the device, with higher variability in the measurements.

[19] The **PVI averaging mode** setting is only displayed if the **PVI** parameter is enabled in the SpO2 adapter. Contact your Hamilton Medical technical representative for details.

Parameter	Description
FastSat	Set in the **System > Sensors > SpO2** window. Provides quicker **SpO2** sampling and display. May show more changes in rate, as it is not an averaged value. Options are: On, Off (default)
Line frequency (Hz)	Set in the **Configuration > Sensors > SpO2 > Settings** window. Power line frequency. Options are: 50 (default), 60

6.5.3 About the Maximum Sensitivity mode setting

Unlike other sensor data settings, when the **Sensitivity** mode is set to **Maximum**, the setting is not persistent, and may change depending on how the ventilator is set up for a new patient.

When **Maximum** is already selected, and you start a new patient session:

- If you choose the **Last patient** option in the **Standby** window, the **Sensitivity** mode setting stays at **Maximum**.
- If you choose a new patient option (**Adult/Ped**, **Neonatal**), depending on ventilator model and options), the **Sensitivity** mode setting changes to the default, **Normal**, after ventilation is started.

6.5.4 Reviewing configured options

Once enabled, Masimo SET pulse oximeter configuration data is displayed in the **Configuration > Sensors > Sensor type** and **Upgrade** windows.[20]

The **Sensor type** window shows version number and sensor codes. Note the following:

- If the window shows only dashes (---) for all of the data, an adapter is not connected.
- If a parameter is listed as **Off**, it is not enabled on the adapter.

[20] The **PVI** parameter status is displayed in the Upgrade window, as well as Masimo rainbow SET parameters, if enabled.

bpm
Beats per minute; also shown as 1/min

CPR
Cardiopulmonary resuscitation

Dynamic Lung
Intelligent panel that graphically represents tidal volume, lung compliance, patient triggering, and resistance in real time

ECG
Electrocardiogram

IABP
Intra-aortic balloon pump

NIBP
Non-Invasive blood pressure

Plethysmogram
The waveform that visualizes the pulsating blood volume; it is delivered by the pulse oximeter

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