Operator's Manual

LifeSense® II
Model LS1

Capnography/Pulse Oximetry Monitor

CE 0123

English

℞ Only **CAUTION:** Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner.

Follow Instructions for Use.

Nonin makes no claim for use of the product other than those uses specified herein and disclaims any liability resulting from other uses. Observe all warnings, cautions, and notes.

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Indications for Use

The LifeSense II, Model LS1, capnography/pulse oximetry monitor is indicated for use in simultaneously measuring, displaying, monitoring, and recording functional oxygen saturation of arterial hemoglobin (SpO_2), end tidal carbon dioxide ($EtCO_2$), respiration, and pulse rate of well or poorly perfused adult, pediatric, and infant patients. It is intended for use in environments where patients require continuous, non-invasive monitoring of these parameters by a healthcare professional, including hospitals, long-term care, medical facilities, sleep laboratories, home healthcare, subacute environments, and Emergency Medical Services (EMS), including patient transport.

Contraindications

Do not use the monitor in an MR environment or in the presence of flammable anesthetics or gases.
This system is not intended to be used simultaneously on multiple patients.
Refer to the applicable sensor instructions for use for additional contraindications, warnings, and cautions.

Warnings

This device is intended only as an adjunct device in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.
The monitor is not classified as an apnea monitor.
This monitor is not intended for use with inhalation halogenated agents.
Verify all alarm settings and limits during system start-up to ensure that they are set as intended.
Before each use, it is the operator's responsibility to verify that the alarm limits are appropriate for the patient being monitored.
Ensure that all alarm volumes are audible in all situations. Do not cover or obstruct any speaker openings.
When turning on the monitor, verify that a beep is heard. If a beep is not heard, do not use the device. The speaker may not be functioning properly.
Atmospheric pressure compensation occurs during system startup. - An increase in the surrounding environment's atmospheric pressure may cause the system to display incorrect readings until the system stabilizes. - A decrease in the surrounding environment's atmospheric pressure may cause the system to not detect an occlusion when the condition exists.
A hazard can exist if different presets are used on multiple LifeSense II monitors in one care area.
To prevent improper performance and/or patient injury, verify compatibility of the monitor, sensor, and accessories before use.
No modifications to this device are allowed as it may affect device performance.
Never allow liquids to enter into or to be spilled onto the monitor. If liquid has penetrated into the monitor, it must be checked by Nonin Technical Service.
To avoid patient injury, only use Nonin-specified power supplies, cables, and accessories (see *Accessories*).

Warnings (Continued)

To avoid patient injury, use only Nonin-branded PureLight® pulse oximeter sensors. These sensors are manufactured to meet the accuracy specifications of Nonin pulse oximeters. Using other manufacturers' sensors can result in improper pulse oximeter performance.
Inspect the pulse oximeter sensor application site at least every 6 to 8 hours to ensure correct sensor alignment and skin integrity. Patient sensitivity to sensors and/or adhesive strips may vary due to medical status or skin condition.
Avoid excessive pressure to the sensor application site as this may cause damage to the skin beneath the sensor.
When selecting a sensor application site, use an extremity without a catheter, blood pressure cuff, or intravascular infusion line.
Do not use a damaged sensor. If the sensor is damaged in any way, discontinue use immediately and replace the sensor.
Misuse or improper handling of the pulse oximeter sensor could damage the sensor or the cable, which may lead to inaccurate readings. Never alter or modify the sensor since this may affect the performance or accuracy.
The monitor displays a flashing yellow battery indicator (low battery) when it has approximately 60 minutes of use remaining before it shuts itself off.
This device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed carefully to verify normal operation.
Prior to connecting the monitor to the power supply and a power outlet, be sure to verify the voltage and frequency rating on the power supply are the same as the outlet. If this is not the case, do not connect the monitor and power supply to the outlet.
The use of accessories other than those specified in this manual may result in increased electromagnetic emission and/or decreased immunity of this device.
As with all medical equipment, carefully route cables and cannula to reduce the possibility of entanglement, strangulation, or tripping.
Refer to the applicable sensor instructions for use for additional contraindications, warnings, and cautions.

⚠ *Cautions*

LifeSense II should only be operated by trained licensed practitioners.
To prevent damage to the monitor, operate and store the monitor in an upright position.
Visually inspect the monitor for damage before each use. Do not use a damaged monitor or system.
Verify display functionality before each use.
Setting alarm limits to extremes can render the alarm system useless.
Each time the system is turned on, audible alarms are silenced for 2 minutes unless the operator presses the Audio Pause button.
When an alarm is acknowledged and audible alarms are paused, new alarms will have visual indicators, but not an audible indicator.
Capnography alarms are not active until the first breath is detected.
Oximetry alarms are not active until the first pulse is detected.

⚠ *Cautions (Continued)*

To ensure the longevity and safety of the monitor, the carrying case must be used when operating the monitor in an emergency medical services (EMS) environment.
Do not mount the monitor directly above the patient. If the monitor is mounted, be sure to check that the adjustable mounting clamp is securely affixed.
When mounting the monitor to a mobile pole, mounting the monitor higher than 1.5 meters (5 feet) or mounting more than 2 kilograms (4.5 pounds) of equipment onto the pole may result in tipping, damage to the equipment, or injury.
Do not use cables longer than 3 meters (10 feet).
Do not place the device in liquid or clean it with agents containing ammonium chloride or bleach.
Do not sterilize or autoclave the monitor or accessories. Do not immerse in liquids.
Always turn off the monitor prior to cleaning the monitor.
Do not simultaneously touch the accessible connector pins and the patient.
After exposing the monitor to an environment outside of normal room temperature/humidity conditions, always replace the moisture trap and filter before each use.
The sample line, moisture trap, filter, and Nafion tubing are single-patient use, disposable components. Do not reuse disposable accessories. Accessories marked “single-use” must be used on one patient only and be disposed of after usage. Dispose of all components in accordance with your local, state or national regulations regarding waste management.
Set or adjust alarm parameters one at a time.
The oximeter sensor might not work on cold extremities due to reduced circulation. Warm or rub the finger to increase circulation, or reposition the sensor.
This device is designed to determine the percentage of arterial oxygen saturation of functional hemoglobin. Factors that may degrade pulse oximeter performance or affect the accuracy of the measurement include the following: - excessive ambient light - excessive motion - blood flow restrictors (arterial catheters, blood pressure cuffs, infusion lines, etc.) - moisture in the sensor - improperly applied sensor - incorrect sensor type - inadequate signal - venous pulsations - anemia or low hemoglobin concentrations - cardiogreen and other intravascular dyes - carboxyhemoglobin - methemoglobin - dysfunctional hemoglobin - artificial nails or fingernail polish
Ear Clip and Reflectance SpO_2 sensors are not recommended for pediatric or infant use. The accuracy of these sensors has not been established for pediatric or infant use.
Always clean the Nonin PureLight reusable sensor after each patient use. Before cleaning, unplug it from the monitor.
The patient’s nasal passage may dry out if continuous monitoring is required. Check patient hourly for nasal comfort.
When using sample lines that also deliver oxygen to the patient, it is important to be aware that the $EtCO_2$ value may be diluted when used in combination with supplemental oxygen. To obtain a true $EtCO_2$ reading, it is recommended that the supplemental oxygen be disconnected for a few seconds to establish a baseline.
If the $EtCO_2$ value is out of normal range (4.4 – 5.7 Vol%/kPa or 33 – 43 mmHg) an internal air leak is possible (see *Troubleshooting*). Replace the single-use, disposable moisture trap and perform the calibration procedure. If the problem persists, contact Nonin Technical Service.

⚠ Cautions (Continued)

In order to prevent damage to the equipment, always charge the battery to full capacity before storing the monitor.
Avoid rapid temperature change or extreme temperatures. This can cause malfunction.
Never store or transport the monitor where condensation can occur. If condensation does occur, wait until all condensation has evaporated before using the monitor.
The temperature of the monitor may exceed 41 °C, but will not exceed 48 °C when operating at high ambient temperatures (40 °C). Limit skin contact to less than 10 minutes and inspect the contact area often. Patient sensitivity may vary due to medical status or skin condition.
Do not attempt to replace the battery inside the monitor. The battery is not field replaceable and cannot be replaced by the operator. Use only Nonin-specified components. Use of another battery may present a risk of fire or explosion. Contact Nonin Technical Service when the battery needs replacing. Battery replacement by inadequately trained personnel could result in a hazardous situation.
Do not charge Li-Ion batteries at a temperature of 0 °C (32 °F) or less as this may result in significantly reduced battery life.
Do not use the power supply if the integrity of the AC cord conductors or the outlet is in doubt.
This device is a precision electronic instrument and must be repaired by qualified technical professionals. Field repair of the device is not possible. Do not attempt to open the case or repair the electronics. Opening the case may damage the device and void the warranty.
In compliance with the European Directive on Waste Electrical and Electronic Equipment (WEEE) 2002/96/EC, do not dispose of this product as unsorted municipal waste. This device contains WEEE materials; please contact your distributor regarding take back or recycling of the device. If you are unsure how to reach your distributor, please call Nonin for your distributor's contact information.
When using the monitor in the home, avoid exposing the monitor to lint and dust.
When using the monitor around small children and pets, avoid leaving the monitor unattended. Cables and cannulas pose a risk of injury, including strangulation.
Be careful not to drop the monitor on the floor or strike it against hard surfaces. If such an incident happens, do not use the monitor until a functional test has been carried out.
The monitor is equipped with automatic barometric pressure compensation. End tidal pCO_2 values displayed are calculated based on an atmospheric pressure of 760 mmHg and pH_2O of 47 mmHg (example: 760 – 47 = 713, 713 x 5% = 36 mmHg).
Water or other liquid in the sample line may cause erroneous $EtCO_2$ readings or an occlusion.
Ensure that all connections are tight, leak-free, and properly attached.
If the Nafion tubing becomes contaminated or damaged during use, discard it and replace it with a new one.
A functional tester cannot be used to assess the accuracy of a pulse oximeter monitor or sensor.
Portable and mobile RF communications equipment can affect medical electrical equipment.
Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast towers and TV broadcast towers may affect accuracy.

⚠ *Cautions (Continued)*

This equipment complies with IEC 60601-1-2 for electromagnetic compatibility for medical electrical equipment and/or systems. This standard is designed to provide reasonable protection against harmful interference in a typical medical installation. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in healthcare and other environments, it is possible that high levels of such interference due to close proximity or strength of a source might disrupt the performance of this device. Medical electrical equipment needs special precautions regarding EMC, and all equipment must be installed and put into service according to the EMC information specified in this manual.
All parts and accessories connected to the USB port of this device must be certified according to at least IEC Standard EN 60950, IEC 62368-1, or UL 1950 for data-processing equipment.
Failure of a network data coupling (USB cable/connectors) will result in loss of data transfer.
If the entire memory is filled, portions of the oldest record will be overwritten when new data is written.
Refer to the applicable sensor instructions for use for additional contraindications, warnings, and cautions.

Guide to Symbols

This chapter describes the symbols that are found on the system components and packaging.

Table 1. Symbols

Symbol	Description/Function
	CAUTION!
	Follow Instructions for Use.
	CE Marking indicating conformance to EC Directive No. 93/42/EEC concerning medical devices.
	Authorized representative in the European Community.
	Indicates separate collection for electrical and electronic equipment (WEEE).
	Class II, double insulated
	Type BF-Applied Part
IP22	Protected against vertically falling water drops when enclosure is tilted up to 15 degrees and against access to hazardous parts with a finger per IEC 60529.
	Green charging indicator (LED)
	On/Standby button
	Audio Pause button
	Power supply input
	USB port
***NONIN* SpO_2**	Sensor input
	Luer lock connector for sample line, Nafion tubing, or cannula
	Do not reuse (moisture trap)
$\mathbb{R}_{x}$ Only	Medical prescription required
	Manufacturer
REF	Catalogue number
SN	Serial number

Table 1. Symbols (Continued)

Symbol	Description/Function
	Quantity
	Temperature limitation for storage/shipping
	RoHS compliant (China)
	Date of manufacture
	Country of manufacture

Introduction

About LifeSense II

LifeSense II allows healthcare professionals to non-invasively monitor pulse oximetry and capnometry on either intubated or spontaneously breathing patients.

When measuring $EtCO_2$, the patient is attached to the monitor by a sample line that can be an airway adapter for an endotracheal tube, a nasal cannula, or a nasal cannula with supplemental oxygen delivery. A variety of sample lines can be used and connected to a specially designed moisture trap, which is easily snapped into the monitor. The sample lines can be used with or without Nafion® tubing. Pulse rate and SpO_2 are measured by a Nonin-branded PureLight pulse oximetry sensor, provided with the system. Use only those accessories recommended by Nonin. Refer to the *Accessories* section for more information.

The monitor has a touch screen display where settings and adjustments are made. The only buttons on the monitor, On/Standby (off) and Audio Pause, are located on the upper right corner of the front panel. Next to these buttons there is a small indicator that turns green when the monitor is connected to a power outlet. The monitor operates on a fully-charged battery for approximately 5 hours.

About Capnometry

The monitor uses sidestream non-dispersive infrared (NDIR) spectroscopy to continuously measure the amount of CO_2 present at the end of exhalation ($EtCO_2$), and respiratory rate (RR). Capnometry has been proven to be a reliable method for detecting esophageal intubation, hypoventilation, and disengagement of the endotracheal tube during mechanical ventilation.

> ⚠ **CAUTION:** When using sample lines that also deliver oxygen to the patient, it is important to be aware that the $EtCO_2$ value may be diluted when used in combination with supplemental oxygen. To obtain a true $EtCO_2$ reading, it is recommended that the supplemental oxygen be disconnected for a few seconds to establish a baseline.

About Pulse Oximetry

Pulse oximetry is a non-invasive method that passes red and infrared light through perfused tissue and detects the fluctuating signals caused by arterial pulses. Well-oxygenated blood is bright red, while poorly oxygenated blood is dark red. The pulse oximeter determines functional oxygen saturation of arterial hemoglobin (SpO_2) from this color difference by measuring the ratio of absorbed red and infrared light as the volume fluctuates with each pulse.

Operator Requirements

Each operator should read this manual before using the monitor. LifeSense II should only be operated by licensed practitioners.

System Components

Carefully remove the monitor and accessories from the shipping carton. Save the packaging materials in case the monitor or accessories must be returned. Compare the packing list with the accessories received to make sure the shipment is complete.

The standard system configuration includes these non-sterile components:

- LifeSense II monitor
- Power supply and plug
- Nonin PureLight reusable pulse oximetry sensor
- Single-use, disposable moisture trap with filter
- Single-use, disposable filters (qty 3)
- Adult nasal cannula (qty 3)
- Sample line
- T-connector
- Operator’s manual (CD)

See *Accessories* for information on optional accessories.

After unpacking the monitor and accessories, connect the monitor to the power supply and a power outlet and ensure the green LED charge indicator is lit.

Before using the monitor, charge it for at least 6 hours.

LifeSense II Monitor

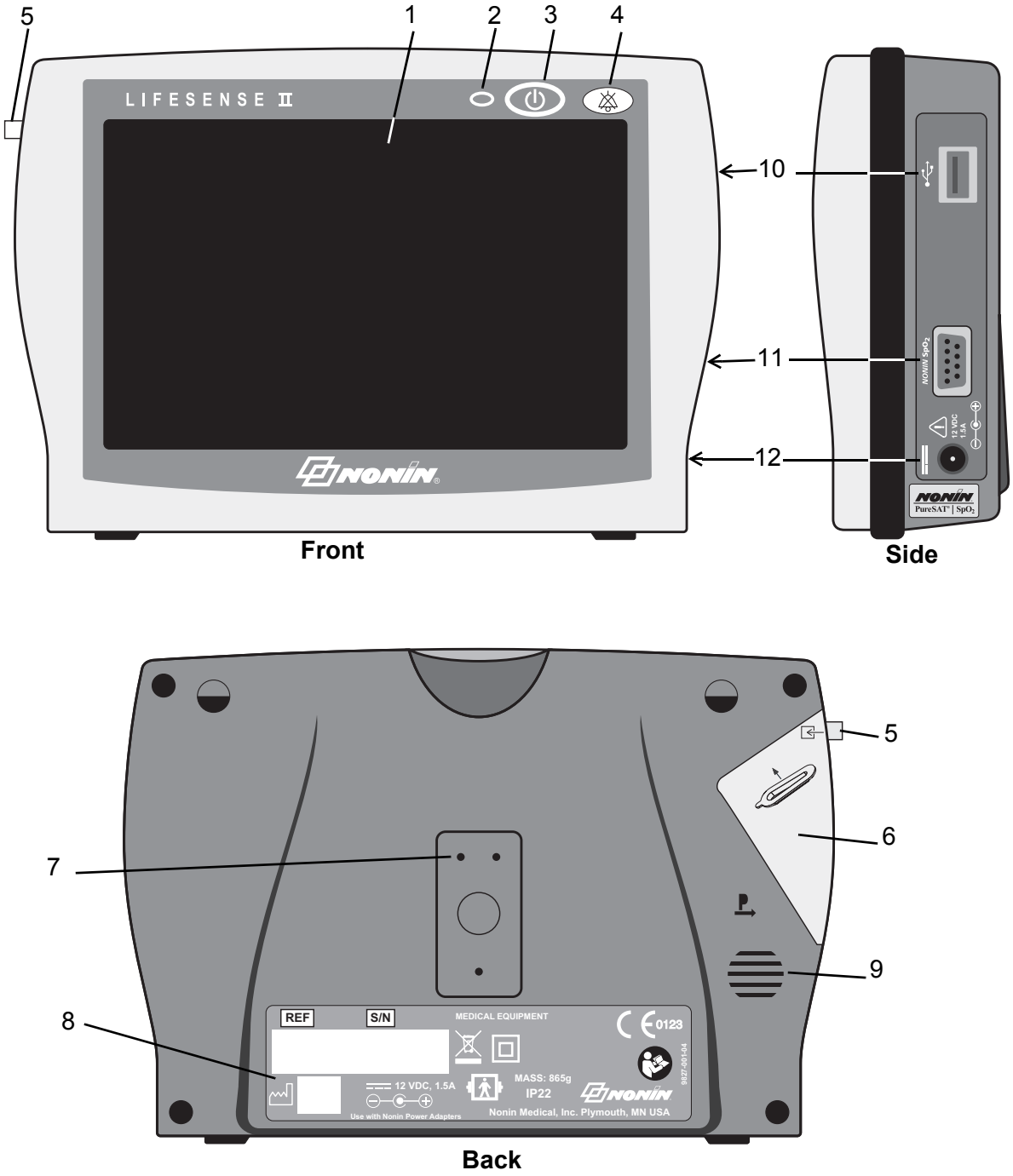


Figure 1. Monitor Features

Table 2. Monitor Features

No.	Symbol/Name	Description
1	Touch Screen Display	The monitor's LCD displays parameters, graphs, menus, and other information.The display is a touch screen from which all operator-defined settings are made. See *Display Screens* section for additional screen information and descriptions.
2		**Charging Indicator** The LED indicator is green whenever the power supply is connected and the battery is charging. **NOTE:** When the external power supply is disconnected, the device automatically switches to battery power without loss of functionality.

3		**On/Standby Button**
		• ***On*** – Pressing this button once turns on the monitor.
		• ***Standby (off)*** – When the monitor is on, pressing this button for at least 3 seconds shuts down the monitor, putting it into Standby mode. In Standby mode, all device functions are shut off, with the following exceptions:
		  • The charging indicator is lit whenever the device is plugged in.
		  • Batteries are charged whenever the device is plugged in.
		See *Shut Down Modes* for information about Standby and Deep Sleep modes.

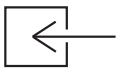
4		**Audio Pause Button** Pressing the Audio Pause button temporarily silences audible alarms for 2 minutes. The operator can reactivate the alarms before the 2 minutes are up by pressing the button again.
5		**Luer Lock Connector** For attaching the sample line, Nafion tubing, or cannula.
6	Moisture Trap with Filter (Single-Use, Disposable)	The moisture trap and filter are single-use, disposable components and should be replaced after each patient. The filter fits into the moisture trap and protects the monitor from moisture. See *Replacing the Moisture Trap/Filter* for more information.
7	Attachment Holes	Dedicated holes for attaching a mounting bracket. See *Accessories* if a mounting bracket is required. See *Using the Mounting Bracket* for more information.
8	Label	See the *Guide to Symbols* section for descriptions of the label symbols. Every device has a unique serial number for identification.

Table 2. Monitor Features (Continued)

No.	Symbol/Name	Description
9		**Speaker** **WARNING: Ensure that all alarm volumes are audible in all situations. Do not cover or obstruct any speaker openings.**
10		**USB Port** Connects a USB flash drive, PSG DAC cable, or Capno RTC cable to the monitor. **CAUTION:** All parts and accessories connected to the USB port of this device must be certified according to at least IEC Standard EN 60950, IEC 62368-1, or UL 1950 for data processing equipment.
11	***NONIN* SpO_2**	**Sensor Input** Connects the SpO_2 sensor to the monitor. See the *Accessories* section for a complete list of compatible sensors. No other sensors may be used. **WARNING: To avoid patient injury, use only Nonin-branded PureLight pulse oximeter sensors. These sensors are manufactured to meet the accuracy specifications of Nonin pulse oximeters. Using other manufacturers' sensors can result in improper pulse oximeter performance.**
12		**Power Supply Input** Connects the power supply to the monitor. Only use Nonin-specified power supplies.

Battery

The monitor is designed to operate continuously when connected to a power outlet or for approximately 5 hours on a fully-charged battery.

- A flashing yellow battery indicator (low battery) displays when the battery is almost depleted. This gives the operator approximately 60 minutes of use, or time to plug in the monitor before it switches itself off.
- A flashing red battery indicator (critical battery) displays when 10 minutes of power is left before the monitor switches itself off.

For more information, see the Internal Power section of the *System Specifications*.

Charging the Battery

⚠ **CAUTION:** Do not charge Li-Ion batteries at a temperature of 0 °C (32 °F) or less as this may result in significantly reduced battery life.

WARNING: To avoid patient injury, only use Nonin-specified power supplies, cables, and accessories (see *Accessories*).

The battery is rechargeable and charges itself whenever the monitor is connected to a power outlet, even when the monitor is turned off. Always connect the monitor to an outlet whenever it is not in use. Recharging a fully depleted battery takes approximately 9 hours when using a Nonin-specified power supply.

Battery Replacement

The battery, made of Lithium Ion (Li-Ion) rechargeable cells, is integral to the device and cannot be replaced by anyone other Nonin Technical Service. The life expectancy of the battery is approximately 1 year.

⚠ **CAUTION:** Do not attempt to replace the battery inside the monitor. The battery is not field replaceable and cannot be replaced by the operator. Use only Nonin-specified components. Use of another battery may present a risk of fire or explosion. Contact Nonin Technical Service when the battery needs replacing. Battery replacement by inadequately trained personnel could result in a hazardous situation.

For optimal performance, the battery should be replaced once per year to limit the amount of Li build up if the battery is charged in a cold environment.

SpO_2 Sensors

See the *Accessories* section for a complete list of compatible sensors. Detailed information regarding specific sensor use (e.g., patient population, body/tissue, application) can be found in the respective sensor instructions for use.

WARNING: When selecting a sensor application site, use an extremity without a catheter, blood pressure cuff, or intravascular infusion line.

WARNING: Do not use a damaged sensor. If the sensor is damaged in any way, discontinue use immediately and replace the sensor.

WARNING: Misuse or improper handling of the pulse oximeter sensor could damage the sensor or the cable, which may lead to inaccurate readings. Never alter or modify the sensor since this may affect the performance or accuracy.

WARNING: Inspect the pulse oximeter sensor application site at least every 6 to 8 hours to ensure correct sensor alignment and skin integrity. Patient sensitivity to sensors and/or adhesive strips may vary due to medical status or skin condition.

⚠ **CAUTION:** The presence of ambient light may affect the accuracy of the pulse oximeter sensor.

Sample Line

Intended Use

The sample line is used to measure the content of carbon dioxide in exhaled air ($EtCO_2$). It is single-use, disposable tubing that connects to the monitor's moisture trap with a Luer lock connector. One sample line is included in the standard kit. The monitor can be fitted with several types of sample lines to best suit the patient (see *Accessories*).

The following instructions refer to the nasal cannula supplied in the standard system configuration. Other sample lines have separate instructions included in their packaging.

Applying the Sample Line

1. Insert the cannula into the patient's nostrils.
2. Place the tubing behind each ear.
3. Connect the Luer lock fitting to the moisture trap and twist to tighten.

WARNING: To avoid patient injury, only use Nonin-specified power supplies, cables, and accessories (see *Accessories*).

CAUTION: The sample line, moisture trap, filter, and Nafion tubing are single-patient use, disposable components. Do not reuse disposable accessories. Accessories marked “single-use” must be used on one patient only and be disposed of after usage. Dispose of all components in accordance with your local, state or national regulations regarding waste management.

CAUTION: The patient’s nasal passage may dry out if continuous monitoring is required. Check patient hourly for nasal comfort.

Nafion Tubing

The Nafion tubing is a single-use, disposable component designed to be placed between the moisture trap and the nasal cannula or sample line to remove water vapor.

Attaching the Nafion Tubing

1. Connect male end of the Nafion tubing to the moisture trap. Turn clockwise to tighten.
2. Connect female end of the Nafion tubing to the sample line or cannula. Turn clockwise to tighten.
3. Ensure that the Nafion tubing is firmly attached.

CAUTION: Water or other liquid in the sample line may cause erroneous $EtCO_2$ readings or an occlusion.

CAUTION: Ensure that all connections are tight, leak-free, and properly attached.

CAUTION: If the Nafion tubing becomes contaminated or damaged during use, discard it and replace it with a new one.

Single-Patient Use, Disposable Moisture Trap and Filter

The moisture trap and filter are single-patient use, disposable components. During long-term monitoring of a patient, the moisture trap fills up with liquid (condensed moisture from breathing). Check the moisture trap frequently and replace when necessary.

Make sure to keep a sufficient supply of new moisture traps and filters within easy reach.

When the moisture trap is removed, guide marks (numbered 1 and 2) and arrows, are visible on the back of the monitor. These guide marks help the operator insert the moisture trap.

Replacing the Moisture Trap/Filter

> ⚠ **CAUTION:** The sample line, moisture trap, filter, and Nafion tubing are single-patient use, disposable components. Do not reuse disposable accessories. Accessories marked “single-use” must be used on one patient only and be disposed of after usage. Dispose of all components in accordance with your local, state or national regulations regarding waste management.

> ⚠ **CAUTION:** After exposing the monitor to an environment outside of normal room temperature/humidity conditions, always replace the moisture trap and filter before each use.

1. Place the filter in the moisture trap so the silicone gasket faces up and hydrophobic material fits inside the moisture trap opening (figure 2-A).
2. Using the guide marks on the back of the monitor, align the groove at the top of the moisture trap with the ridge at the top of the trap housing on the monitor (figure 2-B).
3. The trap is tilted in top first, then bottom. Press the moisture trap into position using the tab (figure 2-C). There should be a tactile click and the moisture trap should be flush with the side and back of the monitor.
4. To remove the moisture trap and replace the filter, use the tab to pull the moisture trap away from the monitor. Remove the filter from the moisture trap. If the filter is not in the moisture trap, check to see if it is still attached to the monitor.

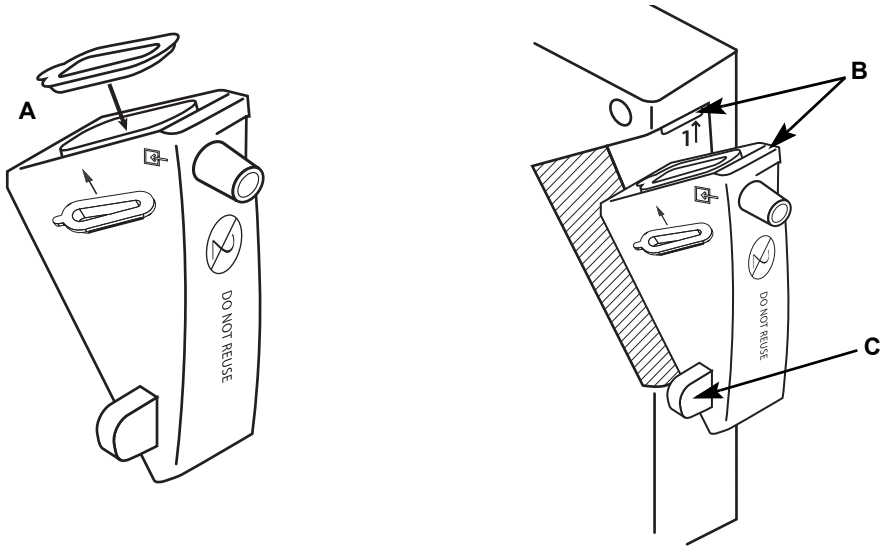


Figure 2. Replacing the Moisture Trap/Filter

PSG DAC Cables

Nonin's PSG DAC (Polysomnography Digital-to-Analog Converter) cables connect the monitor to a polysomnograph to record data ($EtCO_2$, respiratory rate, SpO_2, and CO_2).

Refer to the individual PSG DAC cable instructions for use for more information.

Capno RTC Cable

Nonin's Capno RTC digital USB cable transmits real-time data from the monitor to another device (e.g., computer).

Refer to the Capno RTC instructions for use for more information.

Display Screens

The following section describes the icons and their functions on the select alarm group, operating, and trend screens.

Select Alarm Group Screen

NOTE: This screen does not display if the monitor has locked alarm limits (see *Alarm Lock Mode Screen* section).

The select alarm group screen (figure 3) displays after the start-up screen. On this screen, the operator may select alarm limits for a patient under 30 kg, over 30 kg, or select the last used alarm settings.

If a selection is not made within approximately 8 seconds, the monitor defaults to the over 30 kg alarm limits.

Figure 3. Select Alarm Group Screen

Table 3. Select Alarm Group Screen – Display Descriptions

No.	Symbol	Description
1		**Alarm Limits ≤30kg / 66lbs** Pressing this icon selects the default alarm limits for patients weighing 30 kg (66 lbs) or less. • If the Responsible Organization Settings have not been set, the alarm limits will be the factory default settings (see table 6). • If the Responsible Organization Settings are set, the alarm limits may be restricted by the Responsible Organization alarm limits.
2		**Alarm Limits >30kg / 66lbs** Pressing this icon selects the default alarm limits for patients weighing more than 30 kg (66 lbs). • If the Responsible Organization Settings have not been set, the alarm limits will be the factory default settings (see table 6). • If the Responsible Organization Settings are set, the alarm limits may be restricted by the Responsible Organization alarm limits.
3		**Last Used Alarm Setting** Pressing this button selects the last used alarm settings and alarm volume.

Operating Screen

The main operating screen (figure 4) displays parameters, graphs, and other information.

NOTE: If a pop-up window displays while monitoring, the icons and alarm limit up/down arrows cannot be used until the pop-up window is closed.

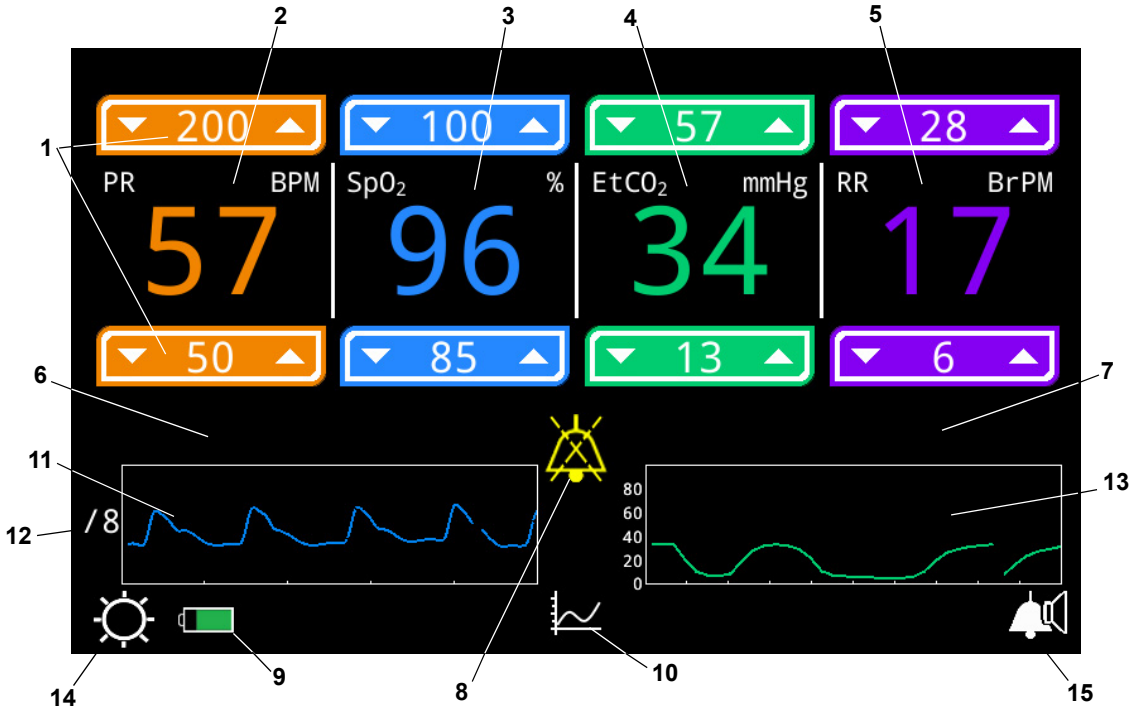


Figure 4. Operating Screen

Table 4. Operating Screen – Display Descriptions

No.	Symbol/Name	Description
1		**Alarm Limits** The high alarm limit is always located above the displayed value, and the low alarm limit is always located below the displayed value. When the parameter readings fall between the low and high settings, they are treated as normal values. Values outside these limits activate both audible and visual alarms. The limit that triggered the alarm flashes on the display. See *Alarm Limits* for more information.
2	**PR BPM**	Displays the pulse rate as beats per minute (BPM).

Table 4. Operating Screen – Display Descriptions (Continued)

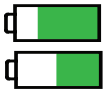
No.	Symbol/Name	Description
3	**SpO_2 %**	Displays percent (%) oxygen saturation (%SpO_2).
4	**$EtCO_2$ mmHg** or **$EtCO_2$ kPa**	Displays the volume of end tidal CO_2 in exhaled air. $EtCO_2$ is shown as mmHg or kPa.
5	**RR BrPM**	Displays the respiration rate in breaths per minute.
6	SpO_2 Messages Example: 	Shows pulse oximeter alarm messages. See *Alarms* for more information.
7	$EtCO_2$ Messages Example:	Shows capnometer alarm messages. See *Alarms* for more information.
8		**Audible Alarm** No symbol means audible alarms are enabled. A bell with dashed lines indicates that audible alarms are paused. A bell with solid lines indicates that audible alarms are off.
9	**Full**  **Partial**  **Low**  **Critical**  **Charging** 	**Battery** The battery indicator shows the approximate percentage of battery life remaining. • ***Full/Partial*** – Battery indicator is green. • ***Low*** – Battery indicator flashes yellow. • ***Critical*** – Battery indicator flashes red. • ***Charging*** – Battery indicator displays a lightning bolt when the monitor is connected to the power supply and a power outlet. **NOTE:** When the monitor reaches a low or critical battery condition, an audible alarm sounds if the audible alarm is on. To clear the alarm, connect the monitor to the power supply and a power outlet.
10		**Trend** Touch this icon to display the trend screen. The trend screen automatically closes after 1 minute or if an alarm activates. **NOTE:** When an alarm is active or when a parameter is not being monitored, this icon does not display on the monitor and the trend screen cannot be accessed.

Table 4. Operating Screen – Display Descriptions (Continued)

No.	Symbol/Name	Description
11	Pulse Oximetry Plethysmograph	Displays a graph of the oximetry signal (plethysmograph). The signal displays 75 samples per second.
12	**/1, /2, /4, or /8**	**Plethysmogram Scale Factor** Scale factor will be either /1, /2, /4, or /8 and is automatically set by the monitor.
13	Respiration Graph	Displays a graph of the CO_2 in exhaled air (capnograph).
14		**Brightness** Allows the operator to change the brightness of the display. Options are maximum (default), medium, and low.
15	 **Medium**  **Maximum (default)**  **Off**	**Audible Alarm Volume** Allows the operator to change the audible alarm volume. The minimum alarm value is set on the Responsible Organization Settings screen. To set the volume to Off, the operator must press **OK** in the “Audible Alarms Off” pop-up window. The audible alarm may only be shut off if allowed by the Responsible Organization Settings.

Trend Screen

The trend screen displays up to 4 hours of trending data for pulse rate, SpO_2, $EtCO_2$, and respiration rate. The scale of the graphs is automatically set and cannot be adjusted. The 4-hour timescale is divided into 30-minute segments.

To access the trend screen (figure 5), press the Trend icon on the operating screen.

NOTE: When an alarm is active, the trend icon does not display on the monitor and the trend screen cannot be accessed.

NOTE: If an alarm activates while the trend screen is displayed, the trend screen closes and the display returns to the operating screen so the alarm condition is visible.

The trend screen automatically closes after 1 minute. To manually exit the trend screen, press **Close**.

All trend data clears when the device is turned off.

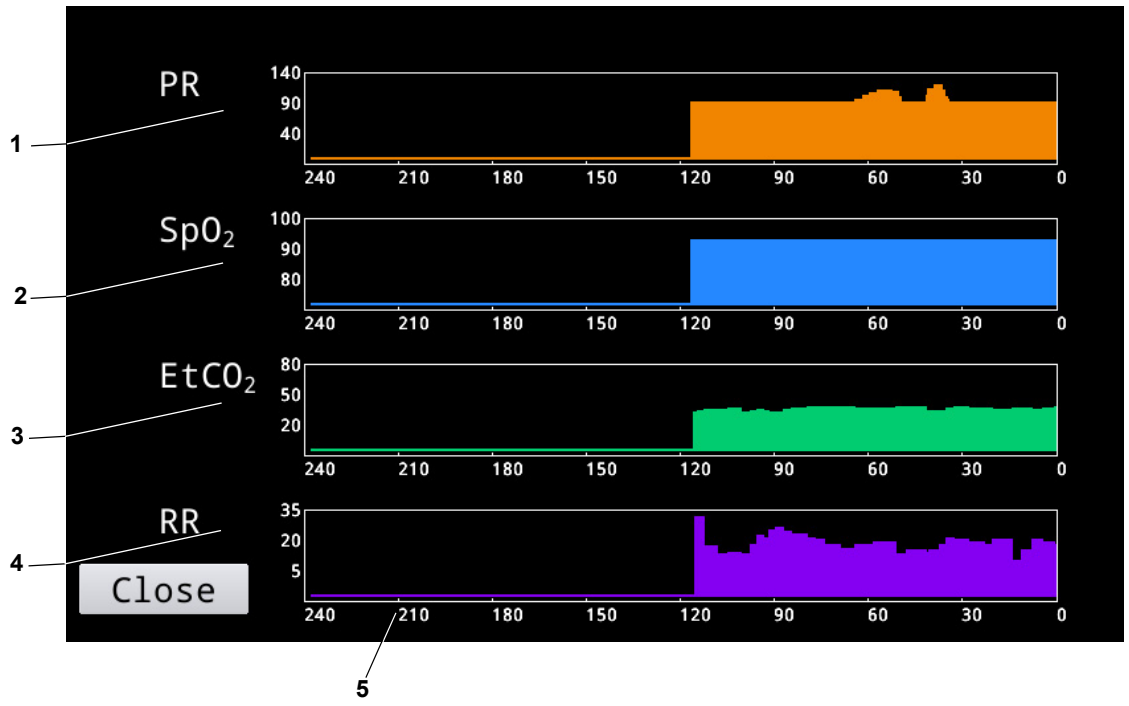


Figure 5. Trend Screen

Table 5. Trend Screen – Display Descriptions

No.	Description
1	**PR Trend Graph** Scale is 40 – 140 BPM. This scale is fixed and cannot be changed.
2	**SpO_2 Trend Graph** Scale is 80 – 100%. This scale is fixed and cannot be changed.

Table 5. Trend Screen – Display Descriptions (Continued)

No.	Description
3	**$EtCO_2$ Trend Graph** Scale is 20 – 80 mmHg (2.7 – 10.7 kPa). This scale is fixed and cannot be changed.
4	**RR Trend Graph** Scale is 5 – 35 BrPM. This scale is fixed and cannot be changed.
5	**Trend Timescale** Timescale is presented in half-hour segments and cannot be changed.

Using the LifeSense II Monitor

Before use, ensure the battery is fully charged by viewing the battery indicator on the display.

> **CAUTION:** To ensure the longevity and safety of the monitor, the carrying case must be used when operating the monitor in an emergency medical services (EMS) environment.

> **CAUTION:** To prevent damage to the monitor, operate and store the monitor in an upright position.

Start-up Sequence

Each time the monitor is turned on, it performs a brief start-up sequence.

1. Press and hold **On/Standby** until the LCD lights up and displays “Please Wait....”
2. An audible beep sounds.
3. The Loading screen displays.

NOTE: A green screen may briefly display while screens transition.

4. The Nonin logo start-up screen (figure 6) displays with the monitor name. The lower left corner of the screen shows the monitor’s software revision.

Figure 6. Start-up Screen

Verify each of the above items occur on initialization. If any do not occur, contact Nonin Technical Service for assistance.

If the clock is not set, the message “System Time is Not Set” displays above the software revision.

If the warning “Settings File CRC Error, Restoring Factory Default Settings” pop-up displays, all settings but the clock revert back to the factory defaults.

NOTE: The Responsible Organization Settings screen is accessed through the start-up screen. See the *Responsible Organization Settings Screen* section for more information.

Shut Down Modes

To conserve battery life, the monitor has two shut down modes – Standby mode and Deep Sleep mode. Start-up from Standby mode is slightly faster than start-up from Deep Sleep mode.

Standby Mode

The monitor enters Standby mode if the battery indicator at shut down is green or if the monitor is connected to a power supply.

Deep Sleep Mode

If the monitor is not plugged in and has been in Standby mode for more than an hour, it enters Deep Sleep mode.

The monitor immediately enters Deep Sleep mode if the battery level at shut down is either low (yellow battery indicator) or critical (red battery indicator).

Using the Mounting Bracket

The monitor can be equipped with a mounting bracket and adjustable mounting clamp, which fits most vertical poles (see *Accessories*). The mounting bracket is screwed onto the back of the monitor.

After attaching the mounting bracket to the monitor, securely clamp the monitor to the pole.

> ⚠ **CAUTION:** When mounting the monitor to a mobile pole, mounting the monitor higher than 1.5 meters (5 feet) or mounting more than 2 kilograms (4.5 pounds) of equipment onto the pole may result in tipping, damage to the equipment, or injury.

> ⚠ **CAUTION:** Do not mount the monitor directly above the patient. If the monitor is mounted, be sure to check that the adjustable mounting clamp is securely affixed.

System Setup

1. Place the monitor in a position so the display can be clearly seen.
   - If using the monitor portably or in an environment without power, the monitor can operate for approximately 5 hours on a fully-charged battery. The battery indicator on the display shows the battery capacity.
   - If using the monitor while connected to the power supply and a power outlet, the green charging indicator is lit. The battery indicator on the display shows a lightning bolt to indicate the battery is charging.
2. Visually inspect the monitor and make sure it has no visible signs of damage.
3. Examine the sensor for obvious defects. Ensure the sensor is clean if it has been previously used.
4. Connect the sensor to the SpO_2 port located on the side of the monitor.
5. Replace the single-use, disposable moisture trap and filter before each use. Refer to *Single-Patient Use, Disposable Moisture Trap and Filter* for instructions on how to replace the moisture trap and filter.

> ⚠ **CAUTION:** After exposing the monitor to an environment outside of normal room temperature/humidity conditions, always replace the moisture trap and filter before each use.

6. Connect the sample line to the connector on the moisture trap and secure it by turning the Luer lock connector clockwise. Only use sample lines recommended by Nonin (see *Accessories*).
7. See *Monitoring a Patient*.

WARNING: Prior to connecting the monitor to the power supply and a power outlet, be sure to verify the voltage and frequency rating on the power supply are the same as the outlet. If this is not the case, do not connect the monitor and power supply to the outlet.

WARNING: The monitor displays a flashing yellow battery indicator (low battery) when it has approximately 60 minutes of use remaining before it shuts itself off.

Monitoring a Patient

CAUTION: To avoid patient injury, use only Nonin-branded PureLight pulse oximeter sensors. These sensors are manufactured to meet the accuracy specifications of Nonin pulse oximeters. Using other manufacturers' sensors can result in improper pulse oximeter performance.

1. Verify the system has been set up (see *System Setup*).
2. Apply the sensor to the patient. Detailed information regarding specific sensor use (e.g., patient population, body/tissue, application) can be found in the respective sensor instructions for use.
3. Attach the sample line to the patient, as described in *Applying the Sample Line*, or refer to the individual sample line instructions for use.
4. Press **On/Standby** to turn the monitor on.

WARNING: When turning on the monitor, verify that a beep is heard. If a beep is not heard, do not use the device. The speaker may not be functioning properly.

5. Monitor runs a self-test (see *Start-up Sequence*).
6. Select alarm limits. If alarm limits are locked, this screen does not display.

CAUTION: Each time the system is turned on, audible alarms are silenced for 2 minutes unless the operator presses the Audio Pause button.

CAUTION: Capnography alarms are not active until the first breath is detected.

CAUTION: Oximetry alarms are not active until the first pulse is detected.

7. Verify the graphs and alarm limits display on the touch screen display.
8. If allowed, adjust the alarm limits for the patient. Refer to *Alarm Limit Settings* for instructions on how to change alarm limits.
9. The audible alarm function activates approximately 2 minutes after start-up. The operator can activate the audible alarm before the 2 minutes are up by pressing the Audio Pause button.
10. The monitor is ready to use. The patient can stay connected to the monitor for as long as needed.

WARNING: Inspect the pulse oximeter sensor application site at least every 6 to 8 hours to ensure correct sensor alignment and skin integrity. Patient sensitivity to sensors and/or adhesive strips may vary due to medical status or skin condition.

CAUTION: The patient's nasal passage may dry out if continuous monitoring is required. Check patient hourly for nasal comfort.

CAUTION: Set or adjust only one parameter at a time.

WARNING: The device is intended only as an adjunct device in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.

11. When done monitoring, press **On/Standby** for 3 seconds to turn off the monitor.
12. Disconnect the patient.

NOTE: If the monitor is on and the patient is no longer connected, the alarm will activate.

Adjusting Display Brightness

The display brightness can be adjusted while monitoring. The default brightness is maximum.

1. In the lower left corner of the operating screen, press the brightness icon ☼.
2. With each press of the icon, the screen brightness changes from maximum to medium to low.

Adjusting Audible Alarm Volume

The alarm volume can be adjusted while monitoring. The default volume is maximum.

1. In the lower right corner of the operating screen, press the audible alarm volume icon .
2. With each press of the icon, the audible alarm volume changes from off to medium to maximum (if allowed by the Responsible Organization Settings).

NOTES:

- Configure the alarm volume options using the Responsible Organization Settings screen (see the *Minimum Alarm Volume* and *Default Alarm Volume* sections).
- Audible alarms cannot be shut off if the Minimum Alarm Volume field is set to Medium or Maximum.
- The default alarm volume is either the saved Default Alarm Volume or the last used volume (if Last Used Alarm Setting is selected at start-up).

Configuration Menu

The Configuration Menu allows the operator to:

- Change the display language and units of measurement (mmHg or kPa)
- Configure the Responsible Organization Settings
- Set the date and time
- Lock the alarm limits
- Calibrate the device

Access the Configuration Menu

1. Press **On/Standby** to turn the monitor on.
2. Start-up sequence begins.
3. When the Nonin logo start-up screen displays, press the Nonin logo twice (double-tap). In figure 7, the Nonin logo is highlighted with a white box.
4. Configuration Menu (figure 8) displays.
5. After configuring the monitor, click **OK** to close the Configuration Menu and begin monitoring.

Figure 7. Access Configuration Menu (Nonin Logo)

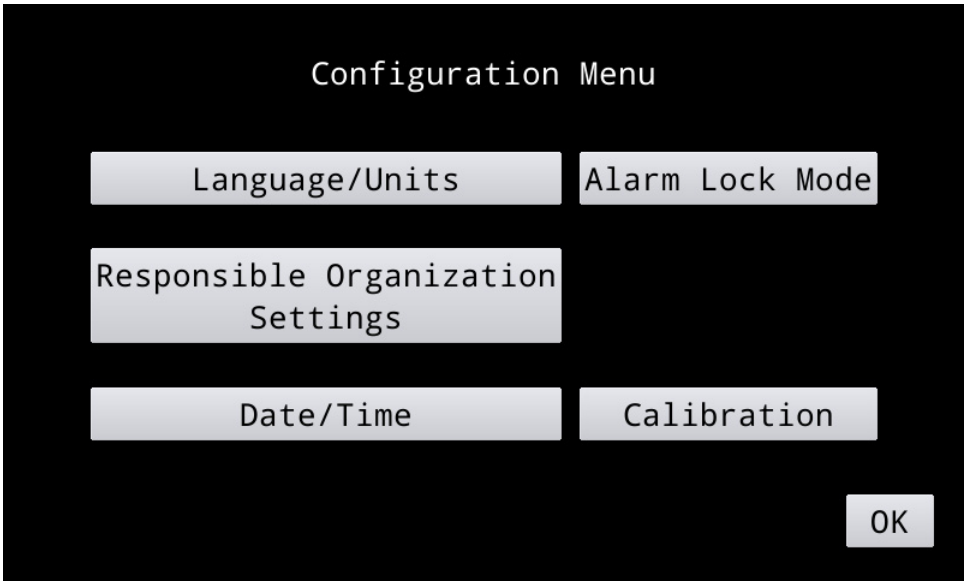


Figure 8. Configuration Menu

Language/Units Screen

This screen allows the operator to change the display language and the $EtCO_2$ unit of measurement.

This screen is accessed through the Configuration Menu (see *Access the Configuration Menu*).

Defaults are English and mmHg. The available languages are:

Dansk (Danish)	English (default)
Deutsch (German)	Nederlands (Dutch)
Ελληνικά (Greek)	Polski (Polish)
Español (Spanish)	Português (Portuguese)
Français (French)	Русский (Russian)
Italiano (Italian)	Svenska (Swedish)
	Türkçe (Turkish)

Set Language and/or Units of Measurement

NOTE: When the Units of Measurement are changed, the Responsible Organization Settings revert to the factory defaults.

1. On the Configuration Menu, press **Language/Units**. Language/Units screen (figure 9) displays.
2. Press desired language. A check mark displays to the left of the selection.
3. Press desired units of measure. A check mark displays to the left of the selection.
4. When finished, press **Save** to save the changes, close the screen, and return to the Configuration Menu. To exit without saving changes, press **Cancel**.

Figure 9. Language/Units Screen

Responsible Organization Settings Screen

This screen allows the operator to establish institution default high and low limits for pulse rate, SpO_2, $EtCO_2$, and respiration rate.

This screen is accessed through the Configuration Menu (see *Access the Configuration Menu*).

NOTES:

- The operator is required to enter a new 4-digit PIN the first time the Responsible Organization Settings screen is accessed or after restoring factory defaults.
- The Responsible Organization Settings are populated with factory default settings until changed by the organization.
- Once a PIN is saved, the alarm limits become restricted to the high and low limits on the Responsible Organization Settings screen.

1. On the Configuration Menu, press **Responsible Organization Settings**.
2. Enter the responsible organization PIN and press **OK**. Responsible Organization Settings screen displays (figure 10).
3. From this screen, the operator may:
   - Set the minimum alarm volume
   - Set the default alarm volume
   - Set the responsible organization's alarm limits: pulse rate (PR), SpO_2, $EtCO_2$, and respiration rate (RR)
   - Reset the device to the factory defaults
   - Change the 4-digit PIN
4. Press **Save** when all changes to the Responsible Organization Settings are complete. To exit without saving changes, press **Cancel**.

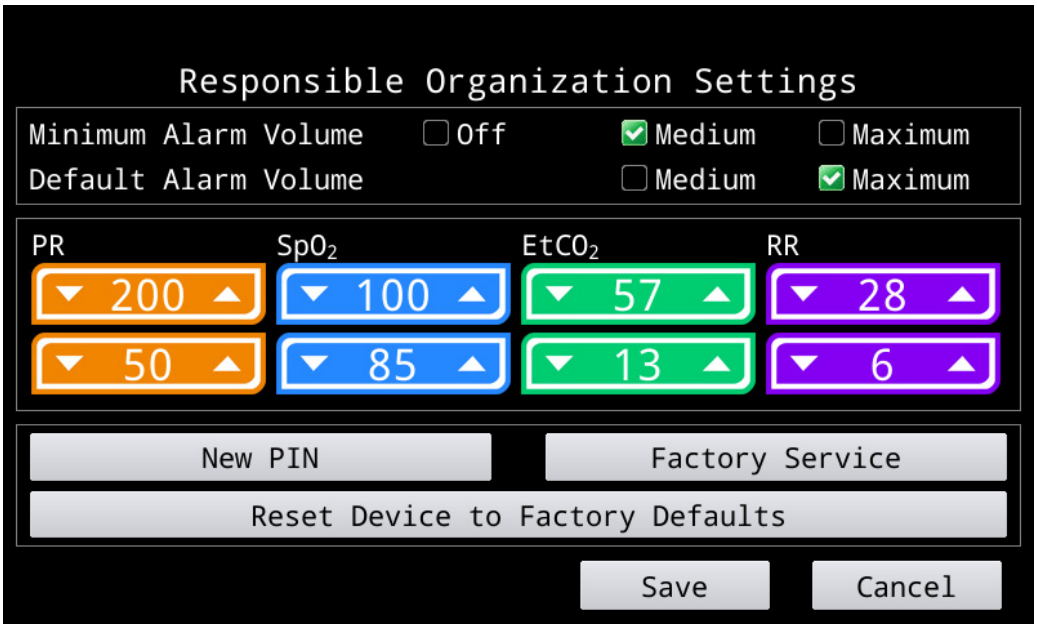


Figure 10. Responsible Organization Settings Screen

Minimum Alarm Volume

This setting controls the monitor's available audible alarm volume levels.

The default minimum alarm volume is Medium.

Set the Minimum Alarm Volume

1. Access the Responsible Organizations Settings screen.
2. In the Minimum Alarm Volume field, press one of the options. Options include Off, Medium (default), and Maximum. A check mark displays to the left of the selection.
   - Off – all options are available when monitoring, including shutting audible alarms off.
   - Medium – both medium and maximum alarm volumes are available when monitoring.
   - Maximum – only the maximum alarm volume is available when monitoring.

Default Alarm Volume

The default alarm volume is Maximum.

Set the Default Alarm Volume

1. Access the Responsible Organizations Settings screen.
2. In the Default Alarm Volume field, press one of the volume options. Options include Medium and Maximum (default). A check mark displays to the left of the selection.

Alarm Limits – PR, SpO_2, $EtCO_2$, RR

The alarm limit settings allow the Responsible Organization to restrict upper and lower alarm limits.

Use the up/down arrows to adjust the high and low alarm limits to the desired values.

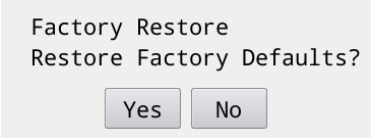
Set the Responsible Organization Alarm Limits

1. Access the Responsible Organizations Settings screen.
2. In the PR (pulse rate) field, use the up/down arrows to adjust the high and low alarm limits to the desired values.
3. Repeat, as needed, for each parameter.

Reset Device to Factory Defaults

This setting discards all user settings and returns the monitor to the factory default settings and alarm limits.

Restore Factory Defaults



1. Access the Responsible Organizations Settings screen.
2. Press **Reset Device to Factory Defaults**.
3. In the “Factory Restore” pop-up window:
   - Press **Yes** to restore the factory defaults. The monitor:
     - Reverts to the factory default minimum alarm volume, default alarm volume, and alarm limits (see table 6).
     - Deletes the PIN.
     - Removes the Responsible Organization Settings limit restrictions.
   - Press **No** to cancel.

New PIN

NOTE: The operator is required to enter a new 4-digit PIN the first time the Responsible Organization Settings screen is accessed or after restoring factory defaults.

The PIN, which may be set to any 4-digit number, is used to unlock parameter settings on the Responsible Organization Settings screen.

Change the PIN

1. Access the Responsible Organizations Settings screen.
2. Press **New PIN**.
3. In the “Enter New PIN” pop-up window, enter a 4-digit PIN.

NOTE: If the PIN is less than four digits, the “Invalid PIN Entered” pop-up window displays. Press **OK** to acknowledge and press **New PIN** again.

4. Press **OK** to save the new PIN. To exit without saving changes, press **Cancel**.
5. Display returns to the Responsible Organization Settings screen.

Factory Service

This feature is only used by Nonin Medical, Inc.

Date/Time Screen

This screen allows the operator to set the monitor's date and time (24-hour clock). The date/time is used in the file name when downloading data. If the operator will not be downloading data, setting the date/time is not required.

This screen is accessed through the Configuration Menu (see *Access the Configuration Menu*).

1. On the Configuration Menu, press **Date/Time**. Date/Time screen (figure 11) displays.
2. To select a field, press the up or down arrow for that field. The field highlights.
3. Tap the up arrow to increase the value; tap the down arrow to decrease the value. Steadily press the arrow to scroll through the values.
4. When finished, press **Save** to save the date and time, close the screen, and return to the Configuration Menu. To exit without saving changes, press **Cancel**.

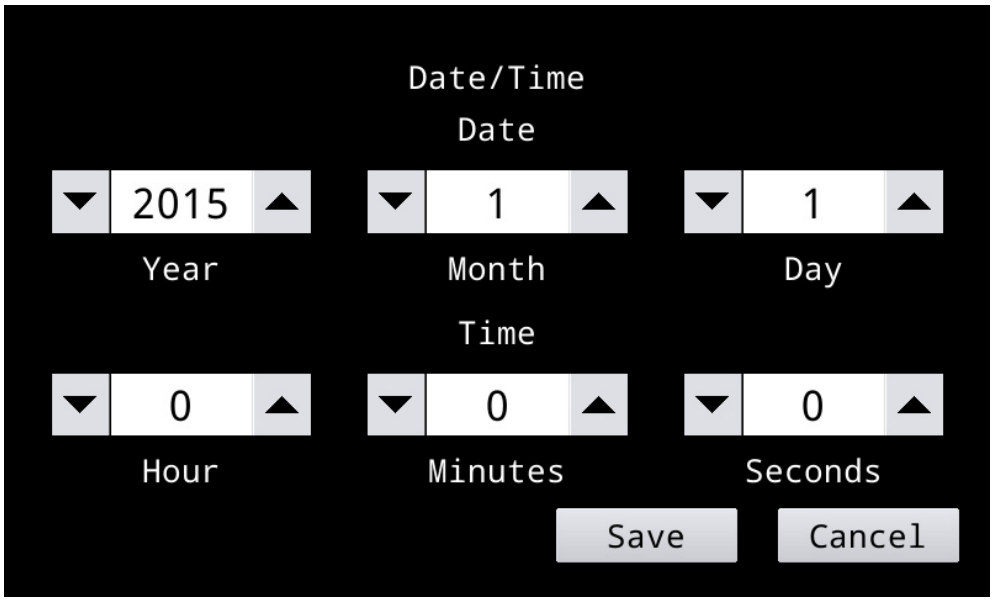


Figure 11. Date/Time Screen

NOTE: If the monitor shuts off because of a critical battery, the date recorded in patient data files reverts to 1970:01:01 and the time begins counting from 00:00:00.

Alarm Lock Mode Screen

This screen allows the operator to set and lock the monitor's alarm limits.

NOTES:

- The locked alarm limits cannot be set to limits outside of the Responsible Organization limits.
- When alarm limits are locked, limits cannot be adjusted when monitoring.

This screen is accessed through the Configuration Menu (see *Access the Configuration Menu*).

1. On the Configuration Menu, press **Alarm Lock Mode**. Alarm Lock Mode screen (figure 12) displays.
2. To lock the alarm limits, press **On**. A check mark displays to the left of the selection.
3. Use each parameter's up/down arrows to adjust the high and low alarm limits.
4. When finished, press **Save** to save the changes, close the screen, and return to the Configuration Menu. To exit without saving changes, press **Cancel**.

Figure 12. Alarm Lock Mode Screen

Calibration Screen

This screen is accessed through the Configuration Menu (see *Access the Configuration Menu*).

Calibration Procedure

The monitor has a built-in zero-point calibration function for CO_2. Perform the calibration procedure at least every 6 months, or if the baseline of the CO_2 graph is elevated.

The calibration apparatus (see *Accessories*) is reusable for approximately 100 times. When the pellets start to turn purple they cannot absorb any more CO_2 and the calibration apparatus must be replaced. Dispose of the calibration apparatus in accordance with your local, state, or national regulations concerning waste materials.

1. Attach a calibration apparatus to the moisture trap.
2. Press **On/Standby** to turn on the monitor.
3. Access the Configuration Menu.
4. Press **Calibration**. Calibration screen (figure 13) displays.

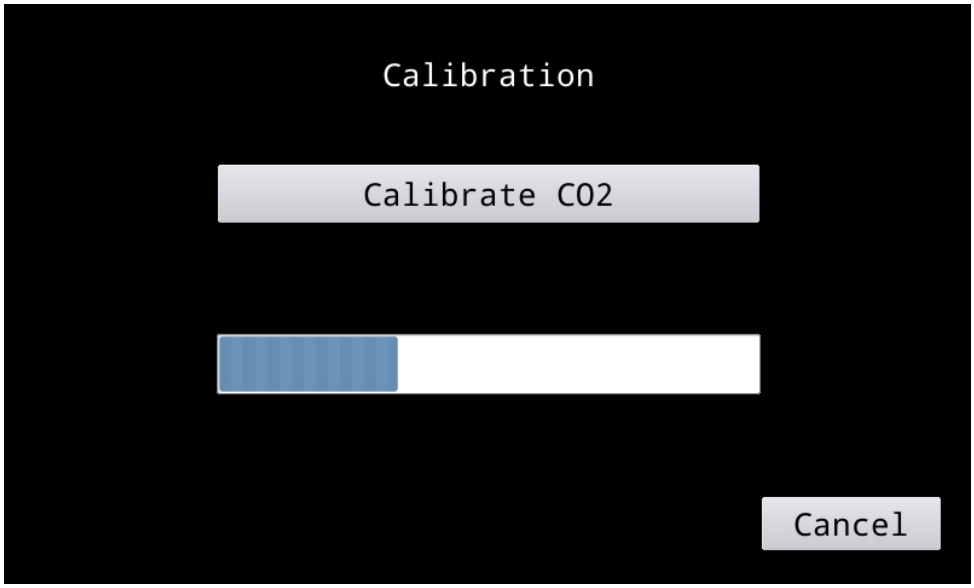


Figure 13. Calibration Screen

5. Press **Calibrate CO2**. The monitor starts the calibration procedure.
6. Calibration takes 15 minutes to complete. When calibration is finished, the monitor returns to the Configuration Menu.
7. Press **OK** to exit the Configuration Menu.
8. Disconnect the calibration apparatus.
9. Verify calibration:
   a. Connect the gas valve, which is already equipped with a T-connector, to a gas bottle containing 5 Vol% of CO_2 (verifying gas) and the monitor.
   b. Verify that the gas valve needle is in the green zone of the dial indicator. If the gas valve needle is in the red zone, the CO_2 tank is empty and should be replaced.

c. Release gas for 1 – 3 seconds (until the ball rises to the top of the column) and then turn off the gas valve. This equals one exhale. The ball should return to the bottom of the column when the gas valve is turned off. Repeat 2 – 3 times.

d. Verify the $EtCO_2$ reading on the display. A reading of 33 – 43 mmHg (4.4 – 5.7 kPa) is considered normal. This should agree with the device accuracy claims found in the *Capnography Specifications* section.

⚠ **CAUTION:** If the $EtCO_2$ value is out of normal range (4.4 – 5.7 Vol%/kPa or 33 – 43 mmHg) an internal air leak is possible. Replace the single-use, disposable moisture trap and perform the calibration procedure. If the problem persists, contact Nonin Technical Service.

Alarm Limit Settings

If not locked, the operator can increase or decrease the alarm limit settings for individual patients. The alarm limit settings may be restricted by the Responsible Organization Settings.

- Press the up arrow ▲ to increase an alarm limit.
- Press the down arrow ▼ to decrease an alarm limit.
- Each time the arrow is pressed, it increases or decreases the alarm limit by a single digit until the maximum or minimum is reached. Steadily press the arrow to scroll through the values.

The high alarm limit is always located above the displayed value, and the low alarm limit is always located below the displayed value.

Alarm Limits

⚠ **CAUTION:** Set or adjust only one parameter at a time.

During start-up, the operator can select from two different default settings or the last used alarm limits.

All parameters have built-in limits that cannot be exceeded.

Table 6. Alarm Limit Settings

Alarm Limit	Adjustment Options	Adjustment Increments	> 30kg / 66lbs Patient (Defaults)	≤ 30kg / 66lbs Patient (Defaults)
PR high	75 – 275 BPM	5 BPM	200 beats per minute (BPM)	200 BPM
PR low	30 – 110 BPM	5 BPM	50 BPM	80 BPM
SpO_2 high	80 – 100%	1%	100%	95%
SpO_2 low	50 – 95%	1%	85%	85%
$EtCO_2$ high	0 – 99 mmHg (0 – 13.2 kPa)	1 mmHg (0.1 kPa)	57 mmHg (7.6 kPa)	57 mmHg (7.6 kPa)
$EtCO_2$ low	0 – 99 mmHg (0 – 13.2 kPa)	1 mmHg (0.1 kPa)	13 mmHg (1.7 kPa)	13 mmHg (1.7 kPa)
RR high	3 – 60 breaths per minute (BrPM)	1 BrPM	28 BrPM	60 BrPM
RR low	3 – 60 BrPM	1 BrPM	6 BrPM	20 BrPM

WARNING: Verify all alarm settings and limits during system startup to ensure that they are set as intended.

WARNING: Before each use, it is the operator's responsibility to verify the alarm limits are appropriate for the patient being monitored.

WARNING: Ensure that all alarm volumes are audible in all situations. Do not cover or obstruct any speaker openings.

⚠ **CAUTION:** Setting alarm limits to extremes can render the alarm system useless.

⚠ **CAUTION:** The monitor is equipped with automatic barometric pressure compensation. End tidal pCO_2 values displayed are calculated based on an atmospheric pressure of 760 mmHg and pH_2O of 47 mmHg (example: 760 – 47 = 713, 713 x 5% = 36 mmHg).

Alarms

The monitor has audible and visual alarm indicators to alert the operator in case immediate patient attention is required or an equipment alarm occurs (figure 14). An audible or visual alarm remains active until the condition is no longer present. Each parameter can only have one high or low limit alarm at a time.

The Audio Pause button temporarily silences audible alarms for 2 minutes. The operator can reactivate the audible alarm before the 2 minutes are up by pressing the button again.

NOTE: If an alarm activates while the trend screen is displayed, the trend screen closes and the display returns to the operating screen so the alarm condition is visible.

The intended operator's position for correctly perceiving a visual alarm signal and its priority is 1 meter (3.3 feet).

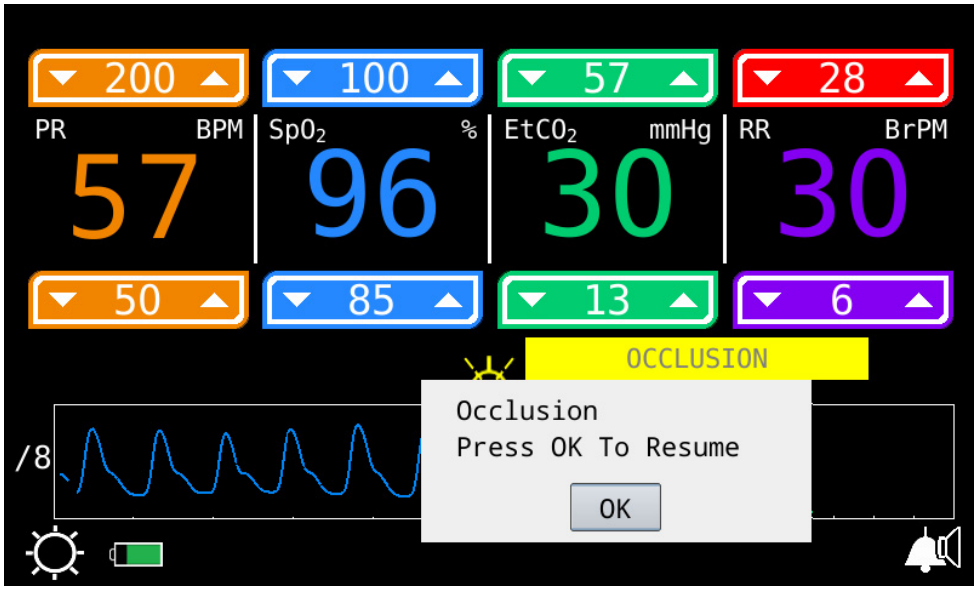


Figure 14. Operating Screen with Alarms

High Priority Alarms

High priority alarms require immediate attention to the patient. An alarm (table 7) occurs if any of the parameters are outside the defined limits.

High priority alarms are both audible and visual.

Table 7. High Priority Alarms

Alarm	Visual Indicator	Audible Indicator
PR High Limit – displays when pulse rate is above the high alarm limit	PR high limit flashes red 2 times per second.	3 beeps, pause, 2 beeps, pause, 3 beeps, pause, 2 beeps, and a 6-second pause. This cycle repeats until silenced or the alarm condition is cleared.
PR Low Limit – displays when pulse rate is below the low alarm limit	PR low limit flashes red 2 times per second.	
SpO_2 High Limit – displays when SpO_2 is above the high alarm limit	SpO_2 high limit flashes red 2 times per second.	
SpO_2 Low Limit – displays when SpO_2 is below the low alarm limit	SpO_2 low limit flashes red 2 times per second.	
$EtCO_2$ High Limit – displays when $EtCO_2$ is above the high alarm limit	$EtCO_2$ high limit flashes red 2 times per second.	
$EtCO_2$ Low Limit – displays when $EtCO_2$ is below the low alarm limit	$EtCO_2$ low limit flashes red 2 times per second.	
RR High Limit – displays when respiration rate is above the high alarm limit	RR high limit flashes red 2 times per second.	
RR Low Limit – displays when respiration rate is below the low alarm limit	RR low limit flashes red 2 times per second.	
No breath is detected for approximately 30 seconds	“NO BREATH” displays with a red background that flashes 2 times per second.	
Critical Low Battery	Battery indicator flashes red 2 times per second.	

Medium Priority Alarms

A medium priority alarm indicates that an equipment fault has occurred and the device is unable to provide a measurement value. See table 8 for medium priority alarms.

Medium priority alarms are both audible and visual.

Table 8. Medium Priority Alarms

Alarm	Visual Indicator	Audible Indicator
Low battery	Battery indicator flashes yellow once every 2 seconds.	3 beeps followed by a 20-second pause. This cycle repeats until silenced or the alarm condition is cleared.
Sensor fault: • Sensor is not connected to the monitor. • Sensor is not connected to the finger.	The  indicator flashes yellow once every 2 seconds.	
Poor signal quality. Hard to detect pulse.	The  indicator flashes yellow once every 2 seconds.	
Occlusion: • Low or no flow from sample line or cannula • Clogged filter in the moisture trap • Kinked sample line or cannula • Full trap	“OCCLUSION” displays with a yellow background that flashes once every 2 seconds. To prevent damage to the pump, the pump stops after 10 seconds of occlusion and then displays a pop-up window: “Occlusion Press OK To Resume”	

Inoperable Alarms

Inoperable alarms (table 9) are medium priority alarms. To correct the condition, perform these steps:

1. Turn the monitor off and then back on again to remove the error message.
2. If the error persists, note the error code and contact Nonin Technical Service at (800) 356-8874 (USA and Canada), +1 (763) 553-9968, or +31 (0)13 - 79 99 040 (Europe).

Table 9. Inoperable Alarms

Message/Error Code	Probable Cause
NO OXIMETER E03	No communication from the pulse oximetry unit.
NO CAPNO E04	No communication from capnography unit.
SPEAKER FAULT E05	Speaker is not working properly.
SYSTEM FAILURE E06	General system error.
BUTTON FAILURE E07	Audio Pause button is damaged.
MEMORY CORRUPT E08	Error detected in memory structure.

Low Priority Alarms

Low priority alarms do not have an audible alarm.

Table 10. Low Priority Alarms

Alarm	Visual Indicator
Low perfusion.	“LOW PERFUSION” displays with a cyan background.
A poor pulse signal was detected.	The cyan ⃠ indicator displays.
Incompatible USB flash drive has been connected to the monitor.	“Incompatible USB” pop-up window displays.

Data Output and Software

Device Memory

The monitor can collect and store a minimum of 36 hours of patient data, including 8 hours of waveform. To store data in memory, the monitoring duration must be at least 2 minutes.

Data may be downloaded from the monitor using a USB flash drive. Memory may be cleared once data is downloaded.

Patient data are sampled every second.

- Oxygen saturation values are stored in 1% increments in the range of 0 – 100%.
- Pulse rate values are stored in 1 BPM increments in the range of 18 – 321 BPM.
- $EtCO_2$ values are stored in 1 mmHg (0.1 kPa) increments in the range of 0 – 99 mmHg (0 – 13.2 kPa).
- Respiration rate values are stored in 1 BrPM increments in the range of 0 – 99 BrPM.

Patient data are retained even when both external and battery power are lost.

The memory in the device functions much like an “endless loop” tape. When the memory is full, the monitor begins overwriting the oldest data with new data.

> ⚠ **CAUTION:** If the entire memory is filled, portions of the oldest record will be overwritten when new data is written.

Download Patient Data

USB Drive Requirements

- Formatted with FAT32 file system
- Compatible with USB 2.0 or 2.1
- More than 1 GB available space
- 100 mA maximum current draw

Recommended SanDisk® USB Flash Drives

Nonin has tested these flash drives with the monitor:

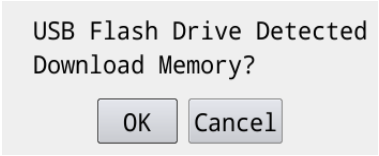
Name	Size	SanDisk P/N
Cruzer Glide™	8 GB	SDCZ60-008G-A46 (see *Accessories* section)
Cruzer Edge™	8 GB	SDCZ51-008G-A11
Cruzer Force™	8 GB	SDCZ71-008G-A46
Cruzer Blade™	4 GB	SDCZ50-004G-A46

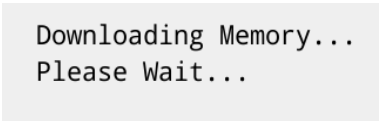
NOTE: If USB flash drive performance issues occur, see the *Troubleshooting* section for more information before contacting Nonin. Nonin cannot guarantee USB flash drive performance if a recommended flash drive is not used.

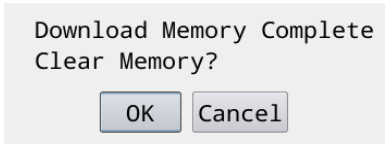
Download Data from the Monitor

NOTE: Data cannot be downloaded if there is a medium or high priority alarm.

1. With the monitor on, but not connected to a patient, connect a USB flash drive to the monitor.
2. In the “USB Flash Drive Detected” pop-up window, *Download Memory?* displays.
3. Press **OK** to download data. Press **Cancel** to return to the operating screen.
4. Once the data download is complete, the “Download Memory Complete” pop-up window displays. See *Clear Memory*.





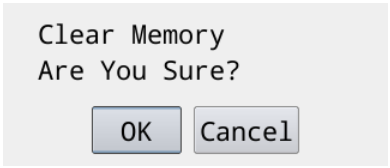


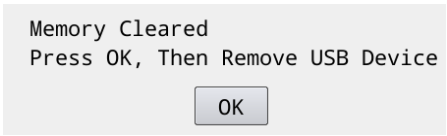
If the USB drive is disconnecting during the download, the “USB Drive Failure” pop-up displays.

Clear Memory

This procedure deletes patient data recordings from the monitor.

1. In the “Download Memory Complete” pop-up window, *Clear Memory?* displays.
2. Press **OK** to clear memory.
3. In the “Clear Memory” pop-up window, *Are you sure?* displays.
4. Press **Yes**.
5. *Memory Cleared* displays.
6. Press **OK** and remove USB flash drive.
7. Operating screen displays.





Data Format

The download directory name is the monitor's serial number (XXXXXXXXX) followed by the current date and time.

Example: XXXXXXXXX_YYYY_MM_dd_hh_mm_ss

NOTE: 1970 will display in the YYYY field if the date/time is not set.

Within the directory, patient data records are downloaded using a comma separated values (.csv) format. The file names are automatically generated using the record number (XXXX), the start date and time of the record, and the data type (zz).

Example: XXXX_ YYYY_MM_DD_hh_mm_ss_zz.csv

The data type ("_zz" in example) options are _gd (patient readings, alarm limits, and volume), _cw (capnography waveform data), and _pt (pulse timing data).

NOTE: The patient data and capnography waveform data files are read and displayed using the Capno Report Converter software (see *Accessories*). The pulse timing data file is reserved for future use (contact Nonin for more information).

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S
1	Date	Time	SpO2	PR	EtCO2 (mmHg)	RR	PulseOx_Status	Capno_Status	Sys_Status	LAL_SpO2	UAL_SpO2	LAL_PR	UAL_PR	LAL_ETCO2	UAL_ETCO2	LAL_RR	UAL_RR	Alarm_Volume	CRC
2	8/17/2015	10:20:37	98	80	12	10	0	0	0	85	100	50	200	13	57	6	28	Medium	46865
3	8/17/2015	10:20:38	98	80	12	10	0	0	0										30908
4	8/17/2015	10:20:39	98	80	12	10	0	0	0										34906
5	8/17/2015	10:20:40	98	80	12	10	0	0	0										45110

Figure 15. Sample Patient Data (_gd.csv File)

	A	B	C	D
1	Date	Time	CO2	CRC
2	8/17/2015	20:37.0	5	57309
3	8/17/2015	20:37.2	3	43556
4	8/17/2015	20:37.5	4	17011
5	8/17/2015	20:37.7	3	4783
6	8/17/2015	20:38.0	3	65426
7	8/17/2015	20:38.2	3	29152
8	8/17/2015	20:38.5	3	34275
9	8/17/2015	20:38.8	3	49119
10	8/17/2015	20:39.0	2	13810
11	8/17/2015	20:39.2	3	39084
12	8/17/2015	20:39.5	8	13718
13	8/17/2015	20:39.7	9	38602
14	8/17/2015	20:39.9	7	59834
15	8/17/2015	20:40.2	7	59793
16	8/17/2015	20:40.2	5	63815
17	8/17/2015	20:40.5	4	60059
18	8/17/2015	20:40.7	4	52920
19	8/17/2015	20:41.0	4	27067

Figure 16. Sample Capnography Waveform Data (_cw.csv File)

Date: month, day, year

Time:

Hour, minutes, seconds (_gd.csv files)

Minutes, seconds, 1/10 second (_cw.csv files)

SpO_2, PR, $EtCO_2$, and RR are the current values (_gd.csv files). CO_2 is the current value (_cw.csv files). Blank if data is missing [dashes on display].

PulseOx_Status, Capno_Status, and Sys_Status Bits:

Bit	PulseOx_Status Description
23	Reserved
22	Sensor Disconnect Bit
21	Artifact Bit
20	Out of Track Bit
19	Sensor Alarm Bit
18 17	Perfusion Bits ‘10’ – red perfusion ‘01” – green perfusion ‘11’ – yellow perfusion
16	Reserved
15	Reserved
14	Reserved
13	Reserved
12	Reserved
11	No SpO_2
10	Reserved
9	Reserved
8	Reserved
7	PR High Alarm Active
6	PR Low Alarm Active
5	SpO_2 High Alarm Active
4	SpO_2 Low Alarm Active
3	Reserved
2	Reserved
1	Reserved
0	Reserved

Bit	Capno_Status Description
23	Reserved
22	Reserved
21	Reserved
20	Reserved
19	Reserved
18	Reserved
17	No Breath
16	No CO_2
15	Reserved
14	Reserved
13	Reserved
12	Reserved
11	Occlusion – Pump Off
10	Reserved
9	No Breath Alarm
8	Occlusion
7	$EtCO_2$ High Alarm Active
6	$EtCO_2$ Low Alarm Active
5	RR High Alarm Active
4	RR Low Alarm Active
3	Reserved
2	Reserved
1	Reserved
0	Reserved

Bit	Sys_Status Description
7	Alarm Silence
6	Low Batt
5	Reserved
4	Reserved
3	Reserved
2	Reserved
1	Reserved
0	Reserved

UAL is the current upper alarm limit value for each parameter.

LAL is the current lower alarm limit value for each parameter.

Alarm volume is Off, Medium or Maximum.

CRC is a 16-bit CCITT for the entire row.

Monitor Software

Visit nonin.com for more information about the monitor’s software, including the latest monitor software revision.

Connecting the Device into a Medical System

Incorporating the device into a medical system requires the integrator to identify, analyze, and evaluate the risks to patient, operators, and third parties. Subsequent changes to the medical system after device integration could introduce new risks and will require additional analysis. Changes to the medical system that must be evaluated include:

- Changing the system configuration
- Adding devices to or disconnecting devices from the system
- Updating or upgrading equipment connected to the system

Issues resulting from user-initiated system changes may include corruption or loss of data.

NOTES:

- Use of a multiple-socket outlet with multiple devices results in a Medical Electrical System.
- When using the USB port to connect the device to other equipment, follow each device's cleaning instructions.
- Verify all equipment connected to the device is suitable for the patient's environment.

⚠ **CAUTION:** Failure of a network data coupling (USB cable/connectors) will result in loss of data transfer.

Maintenance and Inspection

Maintenance

Ensuring Optimal Performance

In order to ensure safety and optimal performance of the monitor, Nonin recommends a yearly inspection and functional check be performed on the monitor (see *Recommended Inspections and Functional Check*). The inspection and functional check may be performed by Nonin Technical Services or at your facility.

Perform the calibration procedure at least every 6 months, or if the baseline of the CO_2 graph is elevated (see *Calibration Procedure*). After calibration, the monitor should be verified using 5% CO_2 gas. The calibration apparatus, gas valve, and 5% CO_2 verification gas are available from Nonin (see *Accessories*).

Please contact Nonin Technical Service if monitor maintenance cannot be performed at your facility.

The Oxitest^{Plus7} (software rev. 2.5 or greater) by Datrend Systems, Inc. can be used to verify operation of the pulse oximeter.

Cleaning the Sensor

Refer to individual sensor Instructions for Use for details.

Cleaning the Monitor

1. Clean the monitor with a soft cloth moistened with isopropyl alcohol. Do not use any cleaning solution other than what is recommended here, as permanent damage could result.
2. Dry with a soft cloth, or allow to air dry.

> ⚠ **CAUTION:** Do not place the device in liquid or clean it with agents containing ammonium chloride or bleach.

> ⚠ **CAUTION:** Always turn off the monitor prior to cleaning the monitor.

> ⚠ **CAUTION:** Do not sterilize or autoclave the monitor or accessories. Do not immerse in liquids.

Recommended Inspections and Functional Check

1. Before each use, verify the equipment is clean and in optimal operating condition. See *Cleaning the Monitor*.
2. Verify the single-use, disposable sample line or cannula is free of bends and kinks for optimal performance.
3. Verify the single-use, disposable moisture trap and filter are in position.

> ⚠ **CAUTION:** After exposing the monitor to an environment outside of normal room temperature/humidity conditions, always replace the moisture trap and filter before each use.

4. Verify the reusable sensor is clean, if previously used. Visually examine the accessories for defects prior to use.
5. Press **On/Standby** to turn the monitor on.
6. Verify battery capacity. If the battery indicator is yellow or red, connect the monitor to the power supply and a power outlet.

NOTE: To ensure the monitor is always ready to use, always connect the monitor to an outlet whenever it is not in use.

7. Verify all parameters display correctly and, if allowed, adjust any alarm limits according to the patient.
8. Verify alarm function/status by simulating alarm situations for all parameters.
9. Visually verify the zero-point of the CO_2 graph is not elevated.

WARNING: If the monitor fails to respond as described, discontinue use and contact Nonin Technical Service.

⚠ **CAUTION:** LifeSense II should only be operated by trained licensed practitioners.

WARNING: Never allow liquids to enter into or to be spilled onto the monitor. If liquid has penetrated into the monitor it must be checked by Nonin Technical Service.

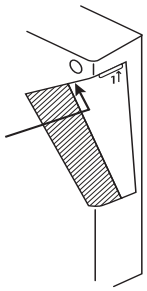
⚠ **CAUTION:** Be careful not to drop the monitor on the floor or strike it against hard surfaces. If such an incident happens, do not use the monitor until a functional test has been carried out.

⚠ **CAUTION:** This device is a precision electronic instrument and must be repaired by qualified technical professionals. Field repair of the device is not possible. Do not attempt to open the case or repair the electronics. Opening the case may damage the device and void the warranty.

Troubleshooting

Detected fault conditions messages display on the operating screen. The fault conditions are either operator- or system-generated. The table below lists common messages, descriptions, and actions to take.

If these solutions do not correct the problem, please contact Nonin Technical Service at (800) 356-8874 (USA and Canada), +1 (763) 553-9968, or +31 (0)13 - 79 99 040 (Europe).

Message/Problem	Possible Cause	Possible Solution
No $EtCO_2$ value or waveform displays after monitor start-up.	Patient is not connected to monitor.	Verify sample line or cannula are properly connected to the patient and the moisture trap.
	Filter is incorrectly inserted into moisture trap or is missing.	Remove the moisture trap from the monitor to verify filter is properly inserted into the moisture trap.
	Moisture trap is not properly seated in the monitor.	Verify the moisture trap and filter are properly inserted in the monitor by creating an occlusion: 1. Using a finger, cover the Luer lock connector inlet. After 10 seconds, the pump shuts off and the “Occlusion” pop-up window displays. 2. Remove the finger and press **OK** to resume. 3. If there is still no value or waveform, the moisture trap is not inserted properly. 4. Remove and reinsert the moisture trap in the monitor. 5. Repeat occlusion test.
	The monitor has an internal air leak.	Verify that there is not an internal leak to the pump by creating an occlusion: 1. Remove the moisture trap from the monitor. 2. Using a finger, cover the small hole in the recessed area of the monitor (see arrow in figure at right). 3. After 10 seconds, the pump shuts off and the “Occlusion” pop-up window displays. 4. Remove the finger and press **OK** to resume. 5. If there is still no value or waveform, contact Nonin Technical Service. 

Message/Problem	Possible Cause	Possible Solution
"OCCLUSION" displays in the $EtCO_2$ message area. **To prevent damage to the pump, the pump stops after 10 seconds of occlusion and then displays a pop-up window:** **"Occlusion Press OK to Resume"**	Sample line or cannula occlusion.	Check the sample line or cannula for kinks or occlusions. Replace the sample line or cannula. Press **OK** to resume monitoring. If occlusion reoccurs, check filter.
	Clogged filter.	Replace the filter. Press **OK** to resume monitoring. If occlusion reoccurs, check moisture trap.
	Full moisture trap.	If full, replace the moisture trap.
Monitor pump has shut off.	Occlusion.	To prevent damage to the pump, the pump stops after 10 seconds of occlusion. See above for "OCCLUSION" message solutions. If the problem persists, contact Nonin Technical Service.
Monitor has shut off.	To avoid overheating, the monitor shuts off if there is an occlusion for 15 minutes.	See above for "OCCLUSION" message solutions. If the problem persists, contact Nonin Technical Service.
	The battery is depleted.	Charge the monitor. Connect the monitor to the power supply and the power supply to an outlet.
"NO BREATH" displays in the $EtCO_2$ message area.	The patient has stopped breathing for 30 seconds or longer.	Check the patient.
	Sample line is not properly applied to the patient.	Verify sample line placement.
	Sample line or Nafion tubing is not connected to the moisture trap.	Verify connection to moisture trap is tight.
	Moisture trap is not properly seated in the monitor.	Verify the moisture trap and filter are properly inserted in the monitor by creating an occlusion: 1. Using a finger, cover the Luer lock connector inlet. After 10 seconds, the pump shuts off and the "Occlusion" pop-up window displays. 2. Remove the finger and press **OK** to resume. 3. If "NO BREATH" still displays, the moisture trap is not inserted properly. 4. Remove and reinsert the moisture trap in the monitor. 5. Repeat occlusion test.
The indicator displays in the SpO_2 message area.	The sensor is not connected to the monitor.	Check all sensor connections between patient and the monitor.
	The sensor is not connected to the patient, or the sensor is damaged.	Check sensor application site.

Message/Problem	Possible Cause	Possible Solution
The ⎍ indicator displays in the SpO_2 message area.	The pulse is hard to detect.	Verify perfusion status at the sensor application site, minimize motion, and verify that there is not excessive ambient light.
The ⃠ indicator displays in the SpO_2 message area.	Poor pulse signal.	If condition persists, check the sensor application site. Reapply sensor to another site if necessary.
"LOW PERFUSION" displays in the SpO_2 message area.	The system detects low perfusion at the SpO_2 sensor site.	Warm or rub the finger, or re-position the sensor. If condition persists, check the sensor application site. Reapply sensor to another site if necessary.
Battery indicator flashes yellow.	Battery is low. Monitor will run for approximately 60 minutes.	Charge the monitor. Connect the monitor to the power supply and the power supply to an outlet. If the monitor continues to show the low or critical battery indicator after recharging, contact Nonin Technical Service as the battery may need replacement. The battery is integral to the device and cannot be replaced by the operator.
Battery indicator flashes red.	Battery is critically low. Monitor will shut off in 10 minutes.	
The alarm continuously sounds.	The monitor is not functioning. This indicates that a problem has occurred, possibly due to interference or software issues.	Turn off the monitor and then turn on again. Charge the monitor. Connect the monitor to the power supply and the power supply to an outlet. If the problem persists, contact Nonin Technical Service.
Low $EtCO_2$ alarm even though the patient's $EtCO_2$ is suspected to be normal.	All alarms for low $EtCO_2$ require the operator to check the patient's status. It is also possible to get a low reading if an air leakage has occurred in the sample line, Nafion tubing, moisture trap, or internally.	Check patient status. Verify the moisture trap and filter are properly installed. Replace the moisture trap and filter if necessary. Check sample line connector and visually inspect the sample line for signs of damage. Check Nafion tubing connection. If the problem persists, contact Nonin Technical Service.
An error code appears in the display area.	The monitor encountered an error.	Turn the monitor off and then back on again to remove the error code. If the error persists, note the error code and contact Nonin Technical Service.
Monitor will not turn on.	The monitor has no power.	Plug in the power supply and verify the charging indicator is lit. If the problem persists, contact Nonin Technical Service.
Monitor will not operate on battery power.	The battery pack is not charged.	Charge the monitor. Connect the monitor to the power supply and the power supply to an outlet.
	The battery pack is inoperable.	Contact Nonin Technical Service.

Message/Problem	Possible Cause	Possible Solution
Charging indicator is not lit when the power supply is connected to the monitor and the power outlet.	The system may be damaged.	Contact Nonin Technical Service.
Pressing the alarm limit up/down arrows does not adjust the alarm limits.	The monitor may be in Alarm Lock Mode.	Verify display functionality by pressing the brightness icon. If the brightness changes, the alarm limits are locked. Contact the individual responsible for configuring your organization's devices.
	The alarm limit settings may be restricted by the Responsible Organization Settings.	Access the Responsible Organization Settings screen and adjust the high and low alarm limits. Contact the individual responsible for configuring your organization's devices.
	A pop-up window displays on the monitor screen.	Address the pop-up window and then try adjusting the alarm limits again.
	The display may not be functioning.	Verify display functionality by pressing the brightness icon. If the brightness does not change, contact Nonin Technical Service.
"Incompatible USB" or "USB Device Failure" error displays.	USB flash drive is full.	Delete unnecessary data from the flash drive. or Replace the USB flash drive with a Nonin-recommended USB flash drive.
	USB flash drive does not have enough available space.	Replace the USB flash drive with a Nonin-recommended USB flash drive.
	USB flash drive has an incorrect format.	
"Settings File CRC Error" warning pop-up displays.	Settings file is corrupted or missing.	System reverts to factory defaults. Contact the individual responsible for configuring your organization's devices.
"Invalid PIN Entered" pop-up message displays.	When entering a new PIN, the PIN is not the correct length.	Enter a PIN that is four digits.
	The PIN entered does not match the Factory PIN or the Responsible Organization PIN.	Enter the default PIN (0000). If 0000 is not the correct PIN, contact Nonin Technical Service.

Accessories

LifeSense II is designed to be used with Nonin-recommended accessories only. Use of other brands will compromise the function and performance. For more information about Nonin parts and accessories:

- Contact your distributor or Nonin at (800) 356-8874 (USA and Canada), +1 (763) 533-9968, or +31 (0)13 - 79 99 040 (Europe)
- Visit www.nonin.com

Nonin may update the accessories list at any time. It is the purchaser's responsibility to always ask for the current list, by model number, when ordering accessories.

Monitor Accessories

Item	Description
Power Supply	Approximately 100 – 240 VAC, 50 – 60 Hz
PSG DAC	Digital-to-analog USB cable that connects the monitor to a polysomnograph to record data. Several versions are available; contact Nonin or your distributor for more information.
Capno RTC (Real Time Cable)	Digital USB cable that transmits real-time data from the monitor to another device (e.g., computer). Requires USB driver and USB port with 2.0 or greater.
USB Flash Drive	SanDisk Cruzer Glide™ 8 GB USB flash drive (SanDisk P/N SDCZ60-008G-A46)
Capno Report Converter	Patient data management software for LifeSense II and RespSense II.
Monitor Mounting Bracket	Connector that enables adjustable mounting and hospital standard mounting. Delivered with 3 screws for connecting to the back of the monitor.
Adjustable Mounting Clamp	Allows mounting on poles. Fits on poles up to 50 mm (2.0 in.) in diameter.
Carrying Case	Protective carrying case in which the monitor can be fully connected without removing the bag.
Nasal CO_2 Cannula	Single-use, disposable, cannula with a male Luer lock connector. Adult (Salter Labs® Ref. 4000) Pediatric (Salter Ref. 4100) Infant (Salter Ref. 4200)
Oxygen Delivery CO_2 Nasal Cannula	Single-use, disposable O_2 delivery nasal cannula with male Luer lock connector. Adult (Salter Ref. 4707) Pediatric (Salter Ref. 4703) Infant (Salter Ref. 4700)
CO_2 Sample Line	Single-use, disposable, straight sample line with male Luer lock connectors on both ends (Salter Ref. 4507).

Item	Description
Straight T-Connector	Single-use, disposable gas adapter, 15 and 22 mm connector ends.
Nafion Tubing	Single-use, disposable Perma Pure Nafion tubing to remove water vapor from the sample line.
Verification Gas	Verification gas and tubing. Contains 5 Vol% of CO_2 (equals 38 mmHg or 5.3 kPa). To be used with a gas valve.
Gas Valve for Verification Gas	Reusable gas valve and tubing for controlling the flow from the verification gas.
Calibration Apparatus	Used for 0-point calibration.
Moisture Trap with Filter	10 packages, each containing 1 single-use, disposable moisture trap and 1 single-use, disposable filter.
Filters	Available in 25 or 100 pack.

PureLight Sensors

Model Number	Description
	Finger Clip Sensor, Reusable
8000AA	Adult (>30 kg; >66 lb)
8000AP	Pediatric (8 – 30 kg; 18 – 66 lb)
	Soft Sensor for Fingers / Toes, Reusable
8000SS	Small (Digit thickness 7.5 – 12.5 mm; 0.3 and 0.5 in.)
8000SM	Medium (Digit thickness 10 – 19 mm; 0.4 and 0.75 in.)
8000SL	Large (Digit thickness 12.5 – 25.5 mm; 0.5 and 1.0 in.)
	Reflectance Sensor for Middle Forehead, Reusable
8000R	Adult (>30 kg; >66 lb)
8000H	Sensor holder (10 pack with 20 adhesive collars)
	Flex Sensor (Reusable) with Single-Use FlexiWrap®
8000J	Adult Flex Sensor (>20 kg; >44 lb)
8008J	Infant Flex Sensor (2 – 20 kg; 4.4 – 44 lb)
8000JFW	Adult FlexiWrap (Pack of 25)
8008JFW	Infant FlexiWrap (Pack of 25)
	6000C Cloth Series, Single-Use
6000CA	Adult (>30 kg; >66 lb)
6000CP	Pediatric (>10 kg; >22 lb)
6000CI	Infant (>2 kg; >4 lb)
	7000 Flexi-Form® III Series, Single-Use
7000A	Adult (>30 kg; >66 lb)
7000P	Pediatric (>10 kg; >22 lb)
7000I	Infant (>2 kg; >4 lb)

Model Number	Description
8000Q2	**Ear Clip Pulse Oximeter Sensor** Patients weighing more than 40 kilograms (88 pounds)
6500MA **6500SA**	**6500 Durafoam Series, Single-Patient Use** Adult and pediatric (>30 kg; >66 lb)

Service, Support, and Warranty

A return authorization number is required before returning any product to Nonin. To obtain this return authorization number, contact Nonin Technical Service:

Nonin Medical, Inc.
13700 1st Avenue North
Plymouth, Minnesota 55441-5443 USA

(800) 356-8874 (USA and Canada)
+1 (763) 553-9968 (outside USA and Canada)
Fax: +1 (763) 553-7807
E-mail: technicalservice@nonin.com

Nonin Medical B.V.
Prins Hendriklaan 26
1075 BD Amsterdam, Netherlands

+31 (0)13 - 79 99 040 (Europe)
Fax: +31 (0)13 - 79 99 042
E-mail: technicalserviceintl@nonin.com

nonin.com

Warranty

NONIN MEDICAL, INCORPORATED, (Nonin) warrants to the purchaser, for a period of 1 year from the date of purchase, each battery and touch panel display screen. Nonin warrants the LifeSense II monitor for a period of 3 years from the date of purchase. Extended warranties are available on most Nonin devices. Please consult your local Nonin distributor for additional information. The device’s expected service life is 5 years.

Nonin shall repair or replace any LifeSense II found to be defective in accordance with this warranty, free of charge, for which Nonin has been notified by the purchaser by serial number that there is a defect, provided said notification occurs within the applicable warranty period. This warranty shall be the sole and exclusive remedy by the purchaser hereunder for any LifeSense II delivered to the purchaser which is found to be defective in any manner, whether such remedies be in contract, tort, or by law.

This warranty excludes cost of delivery to and from Nonin. All repaired units shall be received by the purchaser at Nonin's place of business. Nonin reserves the right to charge a fee for a warranty repair request on any LifeSense II that is found to be within specifications.

The LifeSense II is a precision electronic instrument and must be repaired by knowledgeable and specially trained Nonin personnel only.

Accordingly, any sign or evidence of opening the LifeSense II, field service by non-Nonin personnel, tampering, or any kind of misuse or abuse of the LifeSense II, shall void the warranty in its entirety. All non-warranty work shall be done according to Nonin standard rates and charges in effect at the time of delivery to Nonin.

DISCLAIMER/EXCLUSIVITY OF WARRANTY:

THE EXPRESS WARRANTIES SET FORTH IN THIS MANUAL ARE EXCLUSIVE AND NO OTHER WARRANTIES OF ANY KIND, WHETHER STATUTORY, WRITTEN, ORAL, OR IMPLIED, INCLUDING WARRANTIES OF FITNESS FOR A PARTICULAR PURPOSE OR MERCHANTABILITY, SHALL APPLY.

Technical Information

NOTE: This product complies with ISO 10993-1, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing.

CAUTION: All parts and accessories connected to the USB port of this device must be certified according to at least IEC Standard EN 60950, IEC 62368-1, or UL 1950 for data-processing equipment.

CAUTION: Portable and mobile RF communications equipment can affect medical electrical equipment.

Operating Environment

The equipment must only be used in situations that meet the system's specified environmental conditions. Refer to *System Specifications* in this section.

Storage Environment

Refer to *System Specifications* in this section for the system's specified storage conditions.

CAUTION: In order to prevent damage to the equipment, always charge the battery to full capacity before storing the monitor.

Power Requirements

Power Ratings	Unit
Rated supply voltages or voltage ranges for the power supply	100 – 240 VAC 50 – 60 Hz
Input voltage from the power supply	12 VDC, 1.5 A

WARNING: To avoid patient injury, only use Nonin-specified power supplies, cables, and accessories (see *Accessories*).

Manufacturer's Declaration

See the following tables for specific information regarding this device's compliance to IEC 60601-1-2.

Table 11. Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment—Guidance
This device is intended for use in the electromagnetic environment specified below. The user of this device should ensure that it is used in such an environment.		
RF Emissions CISPR 11	Group 1	This device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	This device is suitable for use in all establishments, including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Pass	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Pass	

Table 12. Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
This device is intended for use in the electromagnetic environment specified below. The user of this device should ensure that it is used in such an environment.			
Electrostatic Discharge (ESD) IEC 61000-4-2	3rd edition: ±6 kV contact ±8 kV air	3rd edition: ±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 500V for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV for common mode	± 1 kV differential mode ± 2 kV for common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	± 5% U_T (>95% dip in U_T) for 0.5 cycle ± 40% U_T (60% dip in U_T) for 5 cycles ± 70% U_T (30% dip in U_T) for 25 cycles ± 5% U_T (>95% dip in U_T) for 5 cycles	± 5% U_T (>95% dip in U_T) for 0.5 cycle ± 40% U_T (60% dip in U_T) for 5 cycles ± 70% U_T (30% dip in U_T) for 25 cycles ± 5% U_T (>95% dip in U_T) for 5 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or battery pack.
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the AC mains voltage before application of the test level.			

Table 13. Guidance and Manufacturer's Declaration—Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
This device is intended for use in the electromagnetic environment specified below. The user of this device should ensure that it is used in such an environment.			
Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.			
			Recommended Separation Distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	$d = 1.17\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m	80 MHz to 800 MHz $d = 1.17\sqrt{P}$ 800 MHz to 2.7 GHz $d = 2.33\sqrt{P}$ where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	Professional Transport 20 V/m 80% AM 1 kHz modulation 80 MHz to 2.7 GHz	20 V/m	
NOTES: • At 80 MHz and 800 MHz, the higher frequency range applies. • These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 14. Recommended Separation Distances

This device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. Customers or users of this device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the device as recommended below, according to maximum output power of the communications equipment.

	Separation Distance According to Frequency of Transmitter		
Rated Maximum Output Power of Transmitter W	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.7 GHz $d = 2.33\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Notes:

- At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Equipment Response Time

If the signal from the sensor is inadequate, the last measured SpO_2 and pulse rate values freeze for 10 seconds and are then replaced with dashes.

SpO_2 Values	Average	Latency
Standard/Fast Averaged SpO_2	4 beat exponential	2 beats

Pulse Rate Values	Average	Latency
Standard/Fast Averaged Pulse Rate	4 beat exponential	2 beats

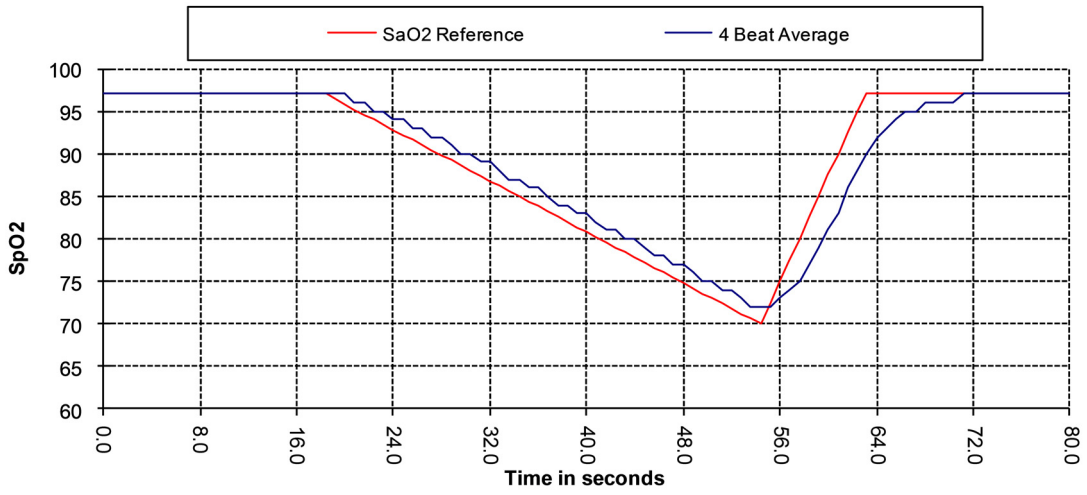
Equipment Delays	Delays
Display Update Delay	2 – 5 seconds
Alarm Signal Generation Delay*	0 – 5 seconds

*After adjusting the limits, it may take up to 5 seconds for the new limits to take effect.

Example: SpO_2 Exponential Averaging

SpO_2 decreases 0.75% per second (7.5% over 10 seconds)

Pulse Rate = 75 BPM



Specific to this example, the response of the 4 beat-average is 1.5 seconds.

CAUTION: A functional tester cannot be used to assess the accuracy of a pulse oximeter monitor or sensor.

Testing Summary

SpO_2 accuracy and low perfusion testing were conducted by Nonin Medical, Inc., as described below:

SpO_2 Accuracy Testing

SpO_2 accuracy testing is conducted during induced hypoxia studies on healthy, non-smoking, light-to-dark-skinned subjects during motion and no-motion conditions in an independent research laboratory. The measured arterial hemoglobin saturation value (SpO_2) of the sensors is compared to arterial hemoglobin oxygen (SaO_2) value, determined from blood samples with a laboratory co-oximeter. The accuracy of the sensors in comparison to the co-oximeter samples measured over the SpO_2 range of 70 – 100%. Accuracy data is calculated using the root-mean-squared (A_{rms} value) for all subjects, per ISO 80601-2-61, Standard Specification for Pulse Oximeters for Accuracy.

Pulse Rate Accuracy Testing

This test measured pulse rate oximeter accuracy with and without motion artifact simulation introduced by a pulse oximeter tester. This test determines whether the oximeter meets the criteria of ISO 80601-2-61 for pulse rate during simulated movement, tremor, and spike motions.

Low Perfusion Accuracy Testing

This test uses an SpO_2 Simulator to provide a simulated pulse rate, with adjustable amplitude settings at various SpO_2 levels for the oximeter to read. The oximeter must maintain accuracy in accordance with ISO 80601-2-61 for pulse rate and SpO_2 at the lowest obtainable pulse amplitude (0.3% modulation).

System Specifications

Power Requirements:		
	Power Supply:	100 – 240 VAC 50 – 60 Hz
	Power Consumption:	3.6 W with battery operation
		9 W with power supply
	Input:	12 VDC, 720 mA
Internal Battery:		
	Type:	Lithium Ion (Li-Ion) internal battery, non-field replaceable, rechargeable
	Battery Capacity:	Approximately 5 hours
	Charging Time:	Approximately 9 hours
Dimensions:		200 x 135 x 50 mm (7.9 x 5.3 x 2 in.)
Weight:		865 grams (1.9 pounds)

Temperature:	
Operating:	0 °C to 40 °C (32 °F to 104 °F)
Storage/Transportation:	-40 °C to 70 °C (-40 °F to 158 °F)
Time (from storage) for monitor to be ready for its intended use:	10 minutes to warm from -40 °C to ambient temperature of 20 °C
	19 minutes to cool from 70 °C to ambient temperature of 20 °C
Applied part temperature will not exceed 41°C as measured during a controlled environment test.	
Humidity:	
Operating:	15% to 93% noncondensing
Storage/Transportation:	Up to 93% noncondensing
Altitude:	
Operating:	Up to 2,740 meters (9,000 feet)
Atmospheric Pressure:	720 to 1060 hPa (540 to 795 mmHg)
Pump:	
Pump Flow:	75 ml/min
Flow Accuracy:	±15 ml/min
High and Medium Priority Alarms (at 1 m):	
Sound Pressure Level:	74.6 to 75.5 dB
Classification per ANSI/AAMI ES60601-1 and CSA C22.2 No. 60601.2:	
Type of Protection:	Internally powered class II (with power supply)
Degree of Protection:	Type BF-Applied Part
Mode of Operation:	Continuous
Enclosure Degree of Ingress Protection:	IP22

Pulse Oximeter Specifications

Oxygen Saturation Display Range:	0 to 100% SpO_2
Pulse Rate Display Range:	18 to 321 beats per minute (BPM)
Measurement Wavelengths*:	
Infrared:	660 nanometers @ 0.8 mW max. average
Red:	910 nanometers @ 1.2 mW max. average
Accuracy - Sensors:	Declared accuracy data for compatible sensors can be found in Nonin's Sensor Accuracy document.

*This information is especially useful for clinicians performing photodynamic therapy.

Capnography Specifications

Respiration Range:	0 to 99 respirations/minute
Respiration Accuracy:	3 to 50 respirations/minute ±2 51 to 60 respirations/minute ±3
$EtCO_2/CO_2$ Range:	0 to 99 mmHg (0 to 13.2 kPa)
$EtCO_2/CO_2$ Accuracy:	±0.2 kPa / ±2 mmHg, +8% of reading* 540 – 795 mmHg (720 – 1060 hPA) ($EtCO_2/CO_2$ reading reaches its steady state accuracy within 10 minutes after power up. From maximum storage temperature, monitor reaches steady state accuracy 19 minutes after power up.)
Calculated Update Frequency:	Once every breath (“NO BREATH” alarm after 30 seconds)
Sampling Rate:	4 Hz (4 times per second)
Total System Response Time:	<6 seconds (includes delay time and rise time)
Drift of Measurement:	Within CO_2 accuracy specifications for 6 hours of continuous monitoring
Measurement:	Automatic barometric pressure compensation and CO_2 temperature compensation

* Presented concentration of CO_2 and $EtCO_2$ can be false, indicating a high presence of nitrous oxide and other interfering gases.

The table below shows the CO_2 and $EtCO_2$ concentration corrections. Only use agents listed in the table below.

Agent Concentration	Correction of Presented CO_2 to Real Concentration
50 – 70% N_2O	Presented CO_2 x 0.75 = Actual CO_2
30 – 50% N_2O	Presented CO_2 x 0.85 = Actual CO_2
0 – 30% N_2O	No correction