Operator's Manual

LifeSense® LS1-9R

Vital Signs Monitor
Capnography/Pulse Oximeter

CE 0123

English

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


Consult 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® Model LS1-9R Capnography/Pulse Oximeter monitor is indicated for use in simultaneously measuring and displaying 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 (e.g., hospitals, medical facilities, post-operative care, within facility patient transport, home use, or any Emergency Medical Service (EMS) environments).

Contraindications

Do not use LifeSense in an MR environment or in the presence of flammable anesthetics or gases.
Do not use LifeSense during defibrillation.

Warnings

LifeSense is intended only as an adjunct in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.
LifeSense is not intended to be used as a primary diagnostic apnea monitor.
Verify all alarm settings and limits during system start up to ensure that they are set as intended.
A hazard can exist if different presets are used on multiple LifeSense monitors in one care area.
To prevent improper performance and/or patient injury, verify compatibility of the monitor, sensor(s), and accessories before use.
No modifications to the device are allowed as it may affect device 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.
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.
Accessories marked “single-use” must be used on one patient only and be disposed of after usage.
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.
Only use power supplies that either are supplied with LifeSense or specified by Nonin (see “Accessories”).
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.

Warnings (Continued)

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.
If the LifeSense fails to respond as described, discontinue use and contact Nonin Technical Service.
Use only Nonin recommended accessories and replacement parts (see “Accessories”).
LifeSense displays a BATT LOW message when it has approximately 20 minutes of use remaining before it shuts itself off.
$EtCO_2$ value will be diluted when used in combination with supplemental oxygen. To get a true $EtCO_2$ reading it is recommended that the supplemental oxygen is disconnected for a few seconds.
Oximeter readings may be affected by the use of an electrosurgical unit (ESU).
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 LifeSense to the power supply and the power outlet, be sure to verify the voltage and frequency rating on the power supply are the same as the power outlet. If this is not the case, do not connect the monitor and power supply to the power outlet.
Ensure that all alarm volumes are audible in all situations. Do not cover or obstruct any speaker openings.
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 patient cables and connections to reduce the possibility of entanglement, strangulation, or injury to the patient.
When turning on the monitor, verify that a beep is heard each time a button is pressed. If a beep is not heard, do not use the device. The speaker may not be functioning properly.

Cautions

LifeSense should only be operated by trained licensed practitioners.
To prevent damage to the monitor, operate and store the monitor in an upright position.
Setting alarm limits to extremes can render the alarm system useless.
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.
Secure LifeSense with mounting hardware if used in transport vehicles.
Do not mount LifeSense 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.
Always turn off the monitor prior to cleaning the monitor or changing the pulse oximeter sensor or moisture trap and/or filter.

Cautions (Continued)

Portable and mobile RF communications equipment can affect medical electrical equipment.
The sample line, moisture trap, and filter are single-use disposable components. Do not disassemble the plastic parts of the single-use disposable moisture trap. Dispose all components in accordance with your local, state or national regulations regarding waste management.
Ear Clip and Reflectance SpO_2 sensors are not recommended for pediatric or infant/neonatal use. The accuracy of these sensors has not been established for pediatric or infant/neonatal use.
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.
Set or adjust alarm parameters one at a time.
Do not cover or block speaker opening. This may significantly reduce the sound volume.
Before each use, it is the operator's responsibility to verify that the alarm limits are appropriate for the patient being monitored.
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 on a regular basis for nasal comfort.
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 repeat the calibration procedure. If the problem persists, contact Nonin Technical Service.
If LifeSense is intended to be stored for longer periods of time, always charge the battery to full capacity before storing it in order to prevent damage to the equipment.
Avoid rapid temperature change or extreme temperatures. This can cause malfunction.
Never store or transport LifeSense where condensation can occur. However, if this has occurred, wait until all condensation has evaporated before using LifeSense.
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. 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.
The sample line, moisture trap, Nafion tubing, filter, and T-connector are single-patient use, disposable components. Dispose all components in accordance with your local, state, or national regulations regarding waste management.
Do not sterilize or autoclave the monitor or sensors. Do not immerse in liquids. Do not disassemble the plastic parts of the single-use disposable moisture trap.

Cautions (Continued)

Never open the monitor housing/case. By opening the case you render your warranty invalid.
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.
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.
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 - electrosurgical interference - 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
Each time the system is turned on, all audible alarms are disabled for 2 minutes unless the operator presses the Audible Alarm Pause/Resume button.
Capnography alarms are not active until the first breath is detected.
Oximetry alarms are not active until the first pulse is detected.
A functional tester cannot be used to assess the accuracy of a pulse oximeter monitor or sensor.
Be careful not to drop LifeSense on the floor or strike it against hard surfaces. If such an incident happens, do not use LifeSense until a functional test has been carried out.
All parts and accessories connected to the serial port of this device must be certified according to at least IEC Standard EN 60950 or UL 1950 for data-processing equipment.
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 sampling tube may cause erroneous CO_2 readings.
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.
Radios and cell phones or similar devices may affect the LifeSense and should be kept at least 2.5 meters (8 feet) away from the device. 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.
Failure of a network data coupling (serial cable/connectors) will result in loss of data transfer.

Guide to Symbols

This table describes the symbols found on the LifeSense monitor and in this manual.

Symbol	Meaning
	CAUTION!
	Consult Instructions for Use
	Follow Instructions for Use
	CE Marking indicating conformance to EC Directive No. 93/42/EEC concerning medical devices.
	Authorized representative in the European Community.
	Type BF-Applied Part
	Indicates separate collection for electrical and electronic equipment (WEEE).
	Model/article number
	Serial number
	Protected against vertically falling water drops when enclosure is tilted up to 15 degrees per IEC 60529.
	UL Mark for Canada and the United States with respect to electric shock, fire, and mechanical hazards only in accordance with UL 60601-1 and CAN/CSA C22.2 No. 601.1.
	Manufacturer
	ON/OFF
	Audible Alarm Pause/Resume
	Charging indicator. This indicator is green when the monitor is connected to a power outlet.
	DC input. Used for connecting the power supply.
IOIOI	Serial interface for use with either TrendSense™ data memory module or NC1, Nurse Call Accessory.
NONIN SpO_2	Input used for connecting a Nonin-branded PureLight SpO_2 sensor.
	Indoor use only
	Class II, double insulated
	Date of manufacture

Introduction

About LifeSense

LifeSense allows healthcare professionals to non-invasively monitor pulse oximetry and capnometry on either intubated or spontaneously breathing patients. This very useful combination serves as a reliable indication of the patient's respiratory and ventilation status.

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 slot on the left side of the monitor. The sampling lines or cannulas can be used with or without Nafion® tubing. Pulse rate and SpO_2 are measured by a Nonin-branded PureLight® finger clip sensor, provided with the system. Use only those accessories and replacement parts recommended by Nonin. Refer to the "Accessories" section for more information.

LifeSense has visual and audible alarms when limit readings are outside the predefined limits. Limits can easily be adjusted using the touch panel display. The operator can pause or resume the alarm by pressing the Audible Alarm Pause/Resume button.

LifeSense has a touch panel display where settings and adjustments are made. The touch panel display also shows battery status and fault messages. The only buttons on the monitor, ON/OFF and Audible Alarm Pause/Resume, 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. LifeSense operates on battery power for approximately 8 hours.

About Capnometry

The monitor uses sidestream non-dispersive infrared (NDIR) spectroscopy to continuously measure the amount of carbon dioxide (CO_2) during every breath, 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 will 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.

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

The LifeSense monitor is easy to operate. Each operator should read this manual before using the monitor. LifeSense should only be operated by licensed practitioners.

Displays and Controls

A standard LifeSense set-up consists of a monitor, single-use disposable moisture trap with filters, Nonin-branded PureLight finger clip sensor (Model 8000AA), nasal cannula, and power supply. See “Accessories” for information on optional accessories.

All operator settings are adjusted using the touch panel display on the monitor.

Monitor Front View

When the monitor is turned on, it displays the start-up screens (figure 1 and table 1) and then the operating (figure 2 and table 2) and trend (figure 3 and table 3) screens. The following section describes the icons on these screens as well as their functions.

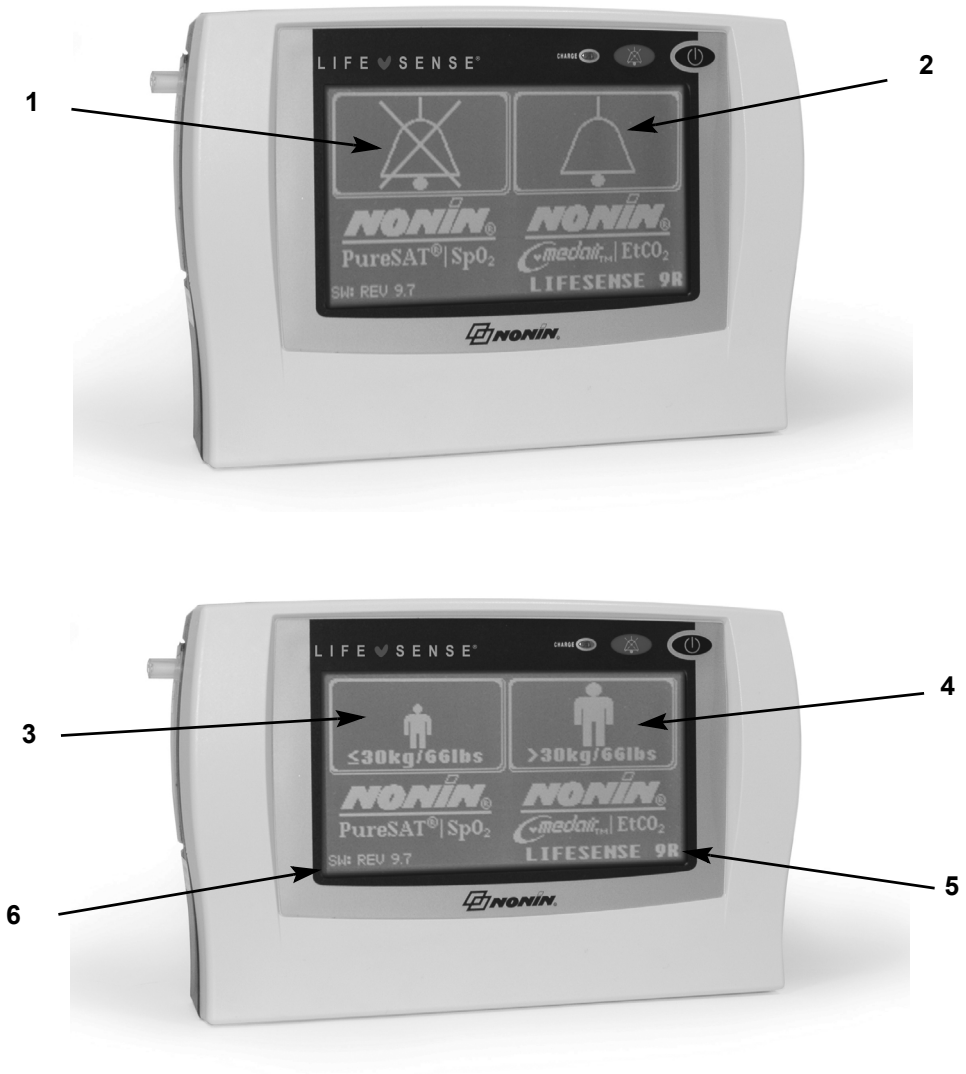


Figure 1: Start-up Screens

Table 1: Start-up Screen Icons and Display Descriptions

No.	Name	Description
1.	Audible Alarm Disable 	Pressing this icon turns the audible alarms off. It disables the audible alarms by setting all lower limits to 0.
2.	Audible Alarm Enable 	Pressing this icon turns the audible alarms on. Default if no icon is chosen.
3.	≤30kg/66lbs 	Pressing this icon selects the default alarm limits for patients weighing 30 kg (66 lbs) or less. Only available if Audible Alarm Enable icon is chosen on previous screen.
4.	>30kg/66lbs 	Pressing this icon selects the default alarm limits for patients weighing more than 30 kg (66 lbs). Only available if Audible Alarm Enable icon is chosen on previous screen.
5.	LifeSense Version	Shows LifeSense version. If an error occurs during start-up, an error number displays here and an alarm activates.
6.	Software Revision Level **SW: REV**	Shows the software revision level installed on the LifeSense monitor.

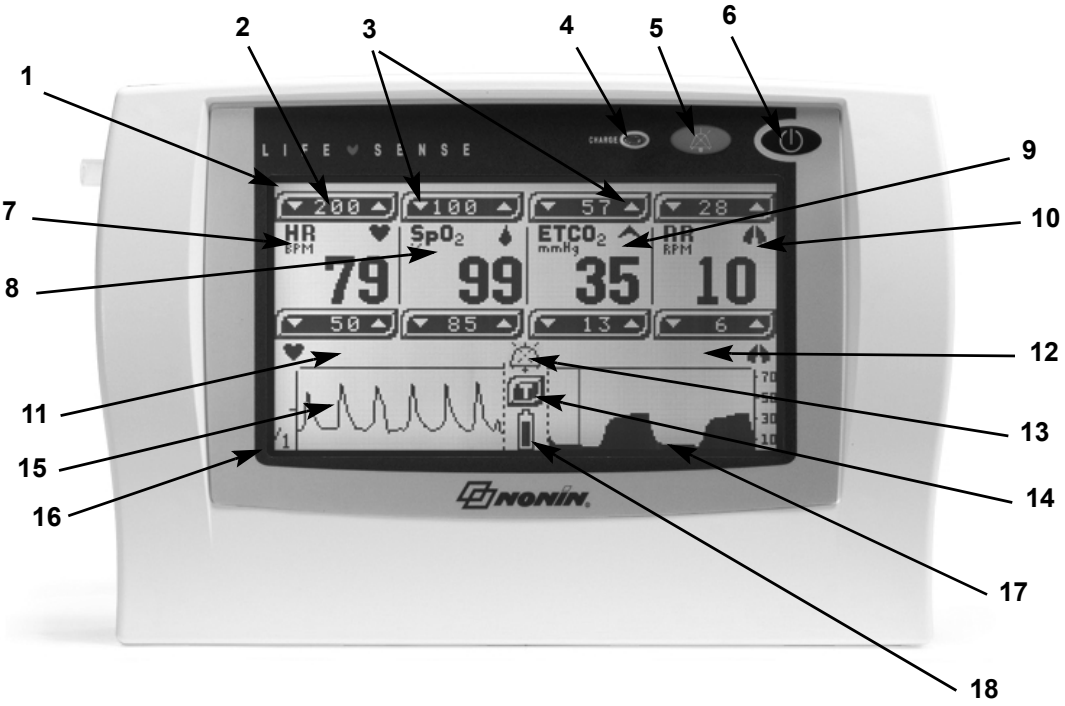


Figure 2: Operating Screen

Table 2: Device and Operating Screen Icons and Display Descriptions

No.	Name	Description
1.	LCD Display	The LCD monitor displays parameters, graphs, menus, and other information. It is also a touch panel from which all the operator-defined settings are made.
2.	Limit Settings	The upper figures represent the highest value set by the operator. The lower figures represent the lowest value set. 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.
3.	Up/Down Bar 	Control buttons for increasing or decreasing an alarm limit.

Table 2: Device and Operating Screen Icons and Display Descriptions (Continued)

No.	Name	Description
4.	Charge Indicator 	This 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
5.	Audible Alarm Pause/Resume 	Audible alarms alert the operator when readings are outside the preset limits. The operator can temporarily disable one or more active audible alarms by pressing this button. The audible alarms will remain inactive until one of the following occurs: • 2 minutes elapses. • Operator presses the Audible Alarm Pause/Resume button again. • New SpO_2, capnography, or system audible alarm begins (see “Alarm Silence” section). If there are no active audible alarms, pushing this button temporarily disables all audible alarms for 2 minutes, unless the operator presses the button again. This button does not disable the visual alarms. The current alarm status displays on the LCD (see #13 below).
6.	ON/OFF 	This button turns the monitor ON or OFF. Press the button for more than 1 second to turn the monitor off. Briefly pressing this button will also enable or disable the audible pulse beep function. **NOTE:** When enabled, the audible pulse beep (tone) increases as the pulse rate increases or decreases as the pulse rate decreases. The default setting is OFF.
7.	HR	Displays the pulse rate as beats per minute. The pulse rate is updated on the display each second.
8.	SpO_2	Displays percent (%) oxygen saturation (%SpO_2). The SpO_2 value is updated on the display every 1.5 seconds.
9.	$ETCO_2$	Displays the volume of end tidal CO_2 in expired air. $EtCO_2$ is shown as mmHg or kPa. The value is updated after each breath without averaging.

Table 2: Device and Operating Screen Icons and Display Descriptions (Continued)

No.	Name	Description
10.	RR	Displays the respiratory rate in breaths per minute. The value is the mean of four breaths.
11.	Status Text	Shows alarm messages for the pulse oximeter and battery. See “Alarms” section for more information.
12.	Status Text	Shows alarm messages for the capnometer. See “Alarms” section for more information.
13.	Alarm Symbol 	Space for alarm symbol. No symbol means audible alarms are enabled. A bell with broken lines indicates one or more audible alarms are paused. A bell with solid lines indicates that audible alarms are disabled.
14.	Trend Icon 	Touch this icon to display the trend screen. The trend screen remains visible until an alarm activates or until the operator touches the screen. **NOTE:** When an alarm is active, this icon does not display on the monitor and the trend screen cannot be accessed.
15.	Pulse Oximetry Plethysmograph	Displays a graph giving information on the oximetry signal (plethysmograph). The signal displays 25 samples per second.
16.	Plethysmograph Scale Factor	Displays a scale factor for the plethysmogram. Scale factor will be either /1, /2, /4, or /8 and is automatically set.
17.	Respiration Graph	Displays a graph of the CO_2 in expired air (capnograph).
18.	Battery Indicator	Displays the battery status. See “Checking Battery Capacity” for more information.

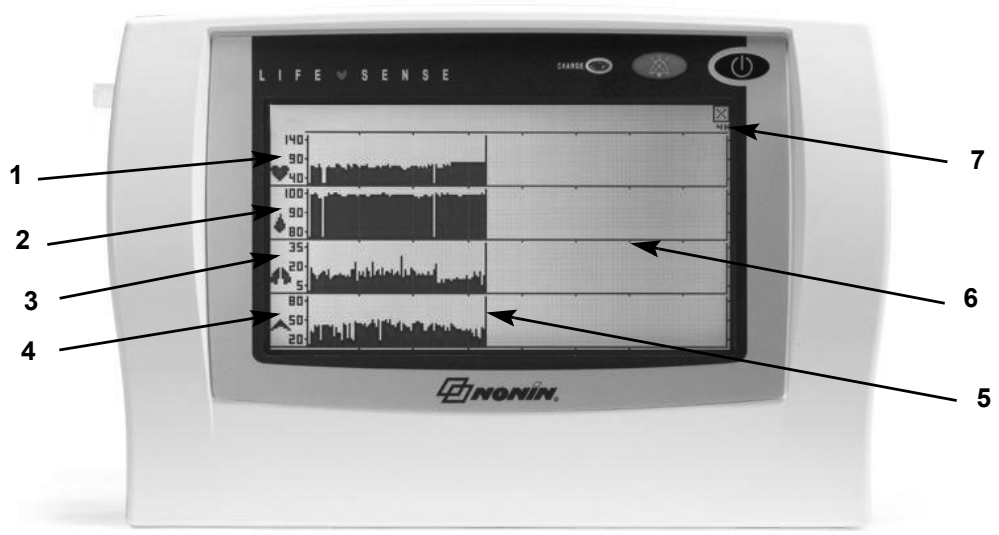


Figure 3: Trend Screen

Table 3: Trend Screen Icons and Display Descriptions

No.	Name	Description
1.	Trend HR	Displays a trend graph of the pulse rate. This scale is fixed and cannot be changed.
2.	Trend SpO_2	Displays a trend graph of the SpO_2 values. This scale is fixed and cannot be changed.
3.	Trend RR	Displays a trend graph of the respiration rate. This scale is fixed and cannot be changed.
4.	Trend $ETCO_2$	Displays a trend graph of the $EtCO_2$ values. This scale is fixed and cannot be changed.
5.	Trend Cursor	A trend cursor points out where the actual sample is in the time interval.
6.	Trend Timescale	Timescale is presented in half-hour segments.
7.	Trend Time	The total trend time is approximately 4 hours of volatile internal memory. Data can be collected using the TrendSense memory module for download to a PC.

Monitor Rear View

The moisture trap, filter, and equipment label are located on the back of the LifeSense (figure 4). Names and descriptions of each component are listed in table 4.



Figure 4: Rear View of Monitor

Table 4: Rear View Features and Descriptions

No.	Name	Description
1.	Single-Use, Disposable Moisture Trap with Filter	The filter is a single-use disposable component and should be replaced after each patient use or cleaning. It fits into the moisture trap and protects the monitor from moisture. The moisture trap clicks into position from the left hand side of the monitor. 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 user insert the moisture trap. 1. Slide the moisture trap into position. 2. Press it down. Push tab out to remove.
2.	Attachment Holes	Dedicated holes for attaching a mounting bracket. See “Accessories” if a mounting bracket is required. 2 mm screws can be used if there is a need to attach the monitor in a fixed position.
3.	Luer Lock	Luer lock connector for attaching sample line, Nafion tubing, or cannula.
4.	Equipment Label	The label contains the model number, serial number, manufacturing date, manufacturer, UL mark, CE mark, and other applicable symbols. See the “Guide to Symbols” section for descriptions of the different symbols. Every LifeSense device has a unique serial number for identification.

Monitor Right Side View

Outputs and connections are located on the right hand side of the monitor as shown in figure 5. Names and descriptions of each component are listed in table 5.

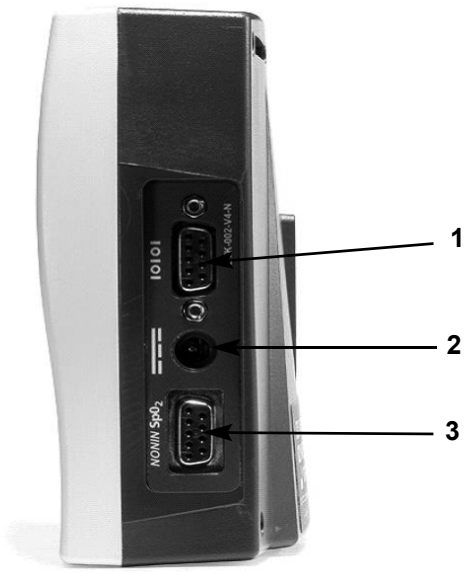


Figure 5: Right Side of Monitor

Table 5: Right Side Components and Descriptions

No.	Name	Description
1.	Serial Interface IOIOI	Serial interface works with either: • TrendSense, to transfer data to a PC. • NC1, Nurse Call Accessory, to add nurse call functionality.
2.	DC Input ⎓	Used to connect the power supply to the monitor. Only use Nonin-specified power supplies.
3.	SpO_2 Connector *NONIN* $Sp0_2$	Used to connect the PureLight pulse oximeter sensor to the monitor. See “Accessories” for a list of pulse oximeter 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.

Using the LifeSense Monitor

After unpacking the monitor and accessories, LifeSense is ready for use. Ensure the LifeSense battery is fully charged by viewing the status of the battery indicator on the display panel after the power supply is connected to the monitor and the power outlet.

> ⚠ **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.

Stationary Operation

1. Place the monitor in a position so the display can be clearly seen.
2. Connect the power supply to the monitor and to a power outlet. The green indicator on the front panel will light up as soon as the monitor is connected to the outlet.
3. Turn LifeSense monitor on by pressing the ON/OFF button until you hear a beep.

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

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

Battery Operation

Whenever the monitor is to be used portably or in an environment where there is no power, it can operate on battery power. This is only possible if the battery has been charged. Always plug in the power supply as soon as it is possible for the monitor to be connected to a power outlet.

1. Place the monitor in a position so the display can be clearly seen.
2. Turn LifeSense monitor on by pressing the ON/OFF button until you hear a beep. The battery symbol on the touch panel display shows the battery capacity.
3. Plug the LifeSense power supply into the power outlet as soon as there is no need for battery operation.

WARNING: LifeSense displays a BATT LOW message when it has approximately 20 minutes of use remaining before it shuts itself off.

Mounting

LifeSense can be equipped with a mounting bracket and adjustable mounting clamp, intended to fit most hospital rails, poles, and table edges. The mounting bracket is screwed onto the back side of the LifeSense monitor.

After attaching the mounting bracket to the monitor, securely clamp the monitor to the hospital rail, pole or table edge. If the pole is mobile, do not attach the monitor to the pole higher than 1.5 meters (5 feet) and do not exceed a total of 2 kilograms (4.5 pounds) of equipment on the pole.

Contact Nonin Customer Support to order a mounting bracket and adjustable mounting clamp.

⚠ **CAUTION:** Secure LifeSense with mounting bracket if used in transport vehicles.

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

⚠ **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 of onto the pole may result in tipping, damage to the equipment, or injury.

Pulse Oximeter Sensor

Intended Use

Nonin-branded PureLight oximeter sensors are designed to non-invasively measure oxygen saturation (%SpO_2), pulse rate, and plethysmographic pulse waves.

Applying the Sensor

The following instructions refer to the sensor supplied in the LifeSense standard kit. Other sensors have separate instructions included in their packaging.



1. Choose the appropriate sensor for the patient that will be monitored.
2. Remove nail polish or artificial fingernails, if applicable.
3. Insert a finger into the sensor until the end of the finger reaches the finger stop. Keep the fingernail facing the sensor top. Ensure long fingernails do not interfere with proper finger position.
4. Position the sensor so the cable lies on top of the hand. This places the light source on the fingernail side and the detector on the underside of the finger.

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.

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 expired air ($EtCO_2$). It is single-use disposable tubing that attaches into the patient's nose and connects to the monitor's moisture trap with a Luer lock connector. One sample line is included in the standard kit. LifeSense can be fitted with several types of sample lines to best suit the patient (see "Accessories" section).

The following instructions refer to the sample line supplied in the LifeSense standard kit. Other sample lines have separate instructions included in their packaging.

WARNING: Use only Nonin-recommended accessories and replacement parts.

CAUTION: The sample line is a single-use, disposable component. Use a new sample line for each patient. Dispose the sample line 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.

Applying the Sample Line

1. Insert the cannula into each nostril.
2. Place the tubing behind each ear.
3. Connect the Luer lock fitting to the moisture trap, twist to tighten.

Nafion Tubing

The Nafion tubing is a single-use disposable component designed to be placed between the moisture trap and the nasal cannula or sampling tubing to remove water vapor. It is intended for use only with Nonin's LifeSense and RespSense monitors.

CAUTION: Water or other liquid in the sampling tube may cause erroneous CO_2 readings.

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.

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 sampling line or cannula. Turn clockwise to tighten.
3. Ensure that the Nafion tubing is firmly attached.

Single-Patient Use, Disposable Moisture Trap and Filters

The moisture trap and filters are single-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, Nafion tubing, filter, and T-connector are single-patient use, disposable components. Do not disassemble the plastic parts of the single-use disposable moisture trap*.* Dispose all components in accordance with your local, state, or national regulations regarding waste management.

1. Place the filter in the moisture trap as shown in figure 6 (1).
2. Slide the moisture trap into position (figure 6, 2) using the guide marks on the back of the monitor.
3. Press the moisture trap into position using the tab (figure 6, 3).

4. To remove the moisture trap and replace the filter, reverse the three steps above.

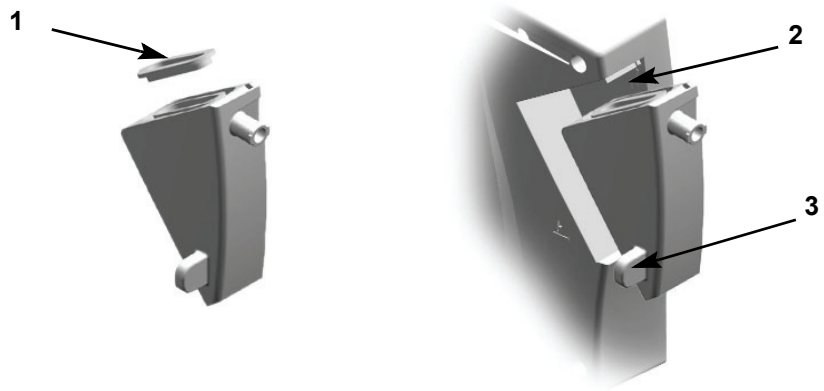


Figure 6: Replacing the Moisture Trap/Filter

Trend Screen

The trend screen displays up to 4 hours of trending data for pulse rate, SpO_2, respiration, and $EtCO_2$. 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 3), 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.

To exit the trend screen manually, press anywhere on the touch panel display.

All trend data clears when the device is turned off.

Getting Started

Preparations

Visually inspect the monitor and make sure it has no visible signs of damage. Examine the SpO_2 sensor for obvious defects. Ensure the sensor is clean if it has been previously used.

Connect the pulse oximeter sensor to the SpO_2 port located on the right side of the monitor. Use only Nonin-branded PureLight pulse oximeter sensors (see “Accessories”). These sensors are manufactured to meet the accuracy specifications of Nonin pulse oximeters. Using other manufacturers’ sensors can result in improper pulse oximeter performance.

Replace the single-use disposable moisture trap and filter on the back of the monitor before each use. The moisture trap slides into place and is pressed into position. To remove, pull the plastic tab on the back of the moisture trap to snap it out of position. Refer to “Single-Patient Use, Disposable Moisture Trap and Filters” for instructions on how to handle and maintain the moisture trap and filter.

Connect the sample line to the adjacent connector on the monitor's side and secure it by turning the Luer lock connector clockwise. Only use sample lines recommended by Nonin (see “Accessories”).

Connect the Patient

Apply the pulse oximeter sensor to the patient, as described in “Applying the Sensor,” or refer to the individual sensor Instructions for Use.

Attach the sample line to the patient, as described in “Applying the Sample Line,” or refer to the individual sample line Instructions for Use.

Turn on the Monitor

Turn on the monitor by pressing the ON/OFF ⏻ button until you hear a beep.

The monitor starts by running a self-test (this only takes a few seconds) before the graphs and settings are displayed. See “Monitor Front Views” and “Changing Settings” for more information on disabling alarms and setting alarm limits.

Verify the graphs and settings display on the touch panel screen.

⚠ **CAUTION:** Each time the system is turned on, all audible alarms are disabled for 2 minutes unless the operator presses the Audible Alarm Pause/Resume 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.

Check the Alarm Limits

Adjust alarm limits for each patient. If appropriate, use the factory default settings that are programmed at start-up. All settings are adjusted using the touch panel display. Refer to “Settings and Alarms” for instructions on how to change alarm limits.

The audible alarm function activates approximately 2 minutes after start up, unless activated by the operator before then. The monitor is now ready for use. The patient can stay connected to the monitor for as long as needed.

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

Contraindication: Do not use LifeSense during defibrillation.

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

Disconnect the Patient

Turn off the monitor using the ON/OFF ⏻ button and disconnect the patient.

NOTE: If the monitor is ON and there is no patient connected, the alarm will activate.

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 serial 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 (serial cable/connectors) will result in loss of data transfer.

Settings and Alarms

Touch Panel Display

All adjustments and settings are made using the LifeSense touch panel display. Each specific parameter is adjusted by using the up/down arrows on the display bar .

Factory Default Settings

LifeSense recalls and displays the factory default settings (table 6) upon start-up. At the start-up screen, the operator can select from two different default settings (only if alarms are activated on the first start-up screen). Adjust settings according to each patient's needs.

Table 6: Factory Default Settings

Parameter	> 30kg / 66lbs Patient Selected	≤ 30kg / 66lbs Patient Selected
HR upper limit	200 beats per minute (BPM)	200 BPM
HR lower limit	50 BPM	80 BPM
SpO_2 upper limit	100 %	95 %
SpO_2 lower limit	85 %	85 %
$ETCO_2$ upper limit	7.5 kPa or 57 mmHg	7.5 kPa or 57 mmHg
$ETCO_2$ lower limit	1.5 kPa or 13 mmHg	1.5 kPa or 13 mmHg
RR upper limit	28 respirations per minute (RPM)	80 RPM
RR lower limit	6 RPM	20 RPM

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

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

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

⚠ **CAUTION:** Do not cover or block speaker opening. This may significantly reduce the sound volume.

⚠ **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).

Alarm Limits

All parameters have built in limits that cannot be exceeded.

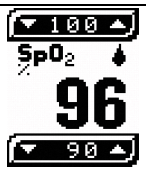
Pulse Limits



– Upper limit: 255 BPM

– Lower limit: 0 BPM

SpO_2 Limits



– Upper limit: 100 %

– Lower limit: 0 %

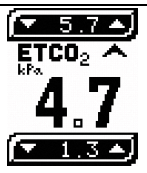
Respiration Limits



– Upper limit: 99 RPM

– Lower limit: 0 RPM

$EtCO_2$ Limits



– Upper limit: 9.9 kPa or 99 mmHg

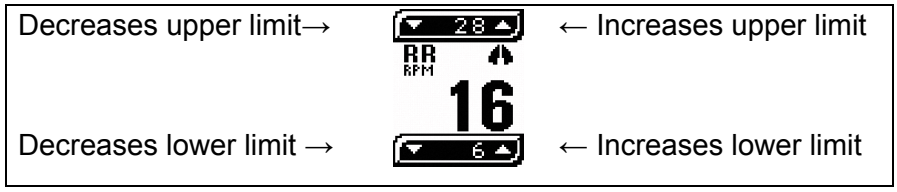
– Lower limit: 0 kPa or mmHg

Changing Settings

All settings follow the same procedure to increase or decrease an alarm limit.

- The up arrow ▲ on the right side of a displayed parameter bar is used to increase an alarm limit.
- The down arrow ▼ on the left side of a displayed parameter bar is used 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. The display scrolls through the values if the arrow is steadily pressed.

The upper alarm limit is always located above the displayed value, and the lower limit is always located below the displayed value.



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

NOTE: The monitor will always reset the alarm limits to the factory default settings once it is turned off and turned on again.

Alarms

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

Alarm Function

An alarm activates under certain conditions, such as if an alarm limit is outside the set limits, if the patient is not connected, or if an equipment fault occurs. The alarm is both visual (a blinking parameter, limit, or a message) and audible (beeping tones at different intervals).

If an alarm activates when the trend screen is displayed, the monitor returns to the operating screen. When an alarm is active, the trend screen cannot be accessed.

Alarm Silence

There are three categories of LifeSense alarms: pulse oximetry, capnography, and system.

Pulse Oximetry Alarms	Capnography Alarms	System Alarms
SpO_2 (high and low)	$EtCO_2$ (high and low)	BATT LOW
Pulse rate (high and low)	Respiration rate (high and low)	DISP ERROR
NO PROBE	NO BREATH	NO OXIMET
NO FINGER	OCCLUSION	NO CAPNO
ARTIFACT	TRAP FULL? / PUSH ALARM	
SIGNAL LOW		

Audible alarms can be temporarily disabled using the Audible Alarm Pause/Resume button.

- If audible alarms are active, pressing this button temporarily disables all of the active audible alarms in one or more categories for 2 minutes. Alarms will reactivate if the operator presses the Audible Alarm Pause/Resume button again during those 2 minutes or if an alarm from a different category begins.

Example: Patient experiences a high pulse rate (i.e., pulse oximetry alarm) and the audible alarm sounds. Operator presses the Audible Alarm Pause/Resume button to silence the pulse oximetry alarms for 2 minutes. If a new capnography or system alarm triggers during those 2 minutes, audible alarms are reactivated.

- If there are no active audible alarms, pressing this button temporarily disables all audible alarms for 2 minutes. The operator can reactivate the alarms before the 2 minutes are up by pressing the button again.

The visual alarms remain active until the condition is corrected.

The operator can increase ▲ or decrease ▼ the alarm limit settings for individual patients. If lower alarm limits are set to 0 for the capnograph and for the pulse oximeter, alarms are disabled until the limits are set higher. The Alarm Disabled icon appears on the touch panel display.

High Priority Alarm

A high priority alarm calls for immediate action from the operator. An alarm (table 7) occurs if any of the parameters are outside the operator-defined limits (or default alarm limits if operator-defined limits have not been set).

High priority alarms are both audible and visual:

- Audible alarms beep faster in a high priority situation than in a low priority situation.
- The value and the exceeded alarm parameter setting(s) flash on the monitor display.

Table 7: High Priority Alarm Parameters and Causes

Parameter	Cause of Alarm
Pulse	Outside the high limit setting
Pulse	Below the low limit setting
SpO_2	Outside the high limit setting
SpO_2	Below the low limit setting
$EtCO_2$	Outside the high limit setting
$EtCO_2$	Below the low limit setting
RR	Outside the high limit setting
RR	Below the low limit setting
NO BREATH	No breath is detected for approximately 25 seconds

Low Priority Alarm

A low priority alarm indicates that an equipment fault has occurred and the device is unable to provide a measurement value. See table 8 for parameters, fault messages, and possible cause.

Low priority alarms are both audible and visual:

- Audible alarms beep slower in a low priority situation than in a high priority situation.
- The fault message displays on the monitor.

Table 8: Low Priority Alarm Parameters and Causes

Parameter	Message	Possible Cause
Pulse oximetry	NO PROBE	Sensor is not connected to the monitor.
Pulse oximetry	NO FINGER	Sensor is not connected to the finger.
Pulse oximetry	ARTIFACT	A questionable pulse was detected
Pulse oximetry	SIGNAL LOW	Hard to detect a pulse. Verify perfusion status at the sensor application site, minimize motion, and verify that there is not excessive ambient light.
Capnometry	OCCLUSION*	Low or no flow from sample line tubing or cannula.
Capnometry	TRAP FULL? PUSH ALARM	There has been an occlusion for several seconds, possibly due to moisture in the moisture trap. Replace it and then press the Audible Alarm Pause/Resume button.
System	BATT LOW	Battery is almost depleted.
System	DISP ERROR	Touch panel display is not working properly.
System	NO OXIMET	No communication from the pulse oximetry unit.
System	NO CAPNO	No communication from capnometry unit.

*A full moisture trap or a kinked sampling line or cannula may trigger the occlusion alarm. To prevent the monitor from damage by liquid, the pump will stop after 10 seconds of occlusion and the message “TRAP FULL? / PUSH ALARM” displays. Check the moisture trap and replace it if necessary. Check the sampling line or cannula for kinks or occlusions and replace if necessary. Press the Audible Alarm Pause/Resume button to continue.

Disable Alarms

It is possible to disable the audible alarms either by selecting Audible Alarm Disable on the start-up screen or by decreasing all lower limit settings to 0. When audible alarms are disabled, the Alarm Disabled icon displays on the touch panel display.

Maintenance and Inspection

Battery Operation

LifeSense is designed to operate continuously when connected to a power outlet or on battery power for approximately 8 hours. When LifeSense is disconnected from the outlet and is ON, it automatically runs on battery.

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.

The battery is rechargeable and charges itself whenever the monitor is connected to a power outlet, even when the monitor is turned off. The green indicator on the front panel of the monitor indicates the battery is charging.

Always connect LifeSense to an outlet whenever it is not in use. Recharging a fully depleted battery takes approximately 17 hours. To maximize battery capacity for monitoring, you can use this rule: 1 hour of monitoring needs approximately 2 hours of charging time.

Checking Battery Capacity

The touch panel display shows a battery symbol indicating battery capacity. Approximate battery capacity is defined by the battery symbols below:

 A filled battery symbol indicates the monitor can be used for approximately 8 hours.

 A depleted battery symbol indicates the battery has run out of power and needs recharging immediately.

To check the battery's capacity, time how long a fully charged battery is able to power the device. When a fully charged battery only provides approximately 4 hours of operation, it needs to be replaced. Contact Nonin Technical Service for battery replacement.

Battery Message

LifeSense displays **BATT LOW** when the battery is almost depleted. This gives the operator approximately 20 minutes of use, or time to plug in the monitor before it switches itself off.

Battery Care

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.

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.

Maintenance

Ensuring Optimal Performance

In order to ensure safety and optimal performance of LifeSense, Nonin recommends a yearly inspection and functional check be performed on the monitor (see Recommended Inspections and Functional Check section). This inspection and functional check may be performed by Nonin Technical Services or at your facility. Additionally, the LifeSense monitor should be calibrated (see Calibration section), and the calibration should be verified using 5% CO_2 gas (a calibration apparatus, gas valve, and 5% CO_2 verification gas are available from Nonin [see Accessories]).

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

> ⚠ **CAUTION:** Always turn off the monitor prior to cleaning the monitor or changing the pulse oximeter sensor or moisture trap and/or filter.

Cleaning the Sensor

Refer to individual sensor Instructions for Use for details.

Cleaning the Monitor

Clean the monitor with a soft cloth moistened with isopropyl alcohol. Allow the monitor to dry completely after cleaning.

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

Calibration

LifeSense 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.

Calibration Procedure

1. Attach a calibration apparatus to the moisture trap (see “Accessories”).
2. Turn the monitor ON by pressing the ON/OFF ⏻ button.
3. While the Nonin logo displays, press and hold the Audible Alarm Pause/Resume 🔕 button. After approximately 15 seconds, the message HOLD ALARM PAUSE BUTTON AND PRESS POWER TO CALIBRATE displays on the monitor. Do not release the Audible Alarm Pause/Resume 🔕 button.

4. While continuing to press the Audible Alarm Pause/Resume button, press the ON/OFF button.
5. LifeSense starts the calibration procedure and displays the following message: CALIBRATING...
6. Release both buttons.
7. Calibration takes 15 minutes to complete. When calibration is finished, LifeSense returns to normal operating mode.
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 LifeSense. **NOTE**: Older versions of the gas valve do not have a pre-attached T-connector. For this configuration, connect a T-connector and gas sampling tube before connecting the gas valve to the gas bottle and LifeSense. The T-connector allows excess flow to exit into the room.
   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 4 – 5 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 reading of $EtCO_2$ on the touch panel 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.

NOTE: If the reading is out of range, an internal air leak is possible. Replace the moisture trap and repeat the calibration procedure. If the out of range reading continues, contact Nonin Technical Service.

Recommended Inspections and Functional Check

1. Before each use, verify the equipment is clean and in optimal operating condition. See “Cleaning the Monitor” section.

> **CAUTION:** Always turn off the monitor prior to cleaning the monitor or changing the pulse oximeter sensor or moisture trap and/or filter.

2. Verify battery capacity by turning on the monitor.
3. Verify the single-use disposable sample line or cannula is free of bends and kinks for optimal performance.
4. Verify the moisture trap and filter are in position.
5. Verify the reusable PureLight finger clip sensor is clean, if previously used. Visually examine the accessories for defects prior to use.
6. Turn on the monitor by pressing the ON/OFF button until you hear a beep.
7. Verify all parameters display correctly and 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 LifeSense fails to respond as described, discontinue use and contact Nonin Technical Service.

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

⚠ **CAUTION:** Never open the monitor housing/case. By opening the case you render your warranty invalid.

Troubleshooting

Fault Messages

LifeSense has built-in self-diagnostics for detection of fault conditions. Detected fault conditions are presented as messages on the touch panel display. The fault conditions are either operator- or system-generated. The table below lists common messages, descriptions, and advice on actions to take.

If the problem persists, contact Nonin Technical Service.

Message	Description	Action
OCCLUSION	Sample line or cannula occlusion.	Remove obstruction. Replace the sample line or cannula.
	Incorrect placement of the moisture trap.	Reposition the moisture trap.
	Clogged filter.	Replace the filter.
	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.
NO PROBE	The sensor is not connected to the monitor.	Check all sensor connections between patient and the monitor.
NO FINGER	The sensor is not connected to the patient, or the sensor is damaged.	Check sensor application site.
ARTIFACT	A detected pulse beat did not match the detected pulse interval.	Check the sensor application site. Reapply sensor to another site, if necessary.
BATT LOW	Battery is low. Monitor will run for approximately 20 minutes.	Plug the power supply into a power outlet and charge the monitor. If the monitor continues to show BATT LOW message 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.
DISP ERROR	The display is not showing any parameters.	Turn off the monitor and then turn on again. If the problem persists, contact Nonin Technical Service.

Troubleshooting

Problem	Possible Cause	Possible Solution
Continuous beeping sound	The alarm beeps continuously. The monitor is not functioning. This indicates that a problem has occurred, possibly due to interference or loss of power.	Turn off the monitor and then turn on again. Recharge the monitor with the power supply. 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. Check the moisture trap and filter. 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.
WARM UP with alarms	All abnormal readings have to be checked with respect to the patient's condition. Should the readings be out of range one may also suspect an equipment fault.	Verify the filter is in place. Replace as needed Perform calibration and gas verification to assure performance of the device.

Accessories

LifeSense is designed to be used with Nonin-recommended accessories only. Use of other brands will compromise the function and performance. The following list of accessories can be ordered from Nonin or your distributor. 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
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 to 20 – 50 mm (0.8 – 2.0 in.) diameter poles.
TrendSense/ TrendSense W	Data memory modules. Dimensions 38x32x17mm. The module does not contain a battery; it draws power from the host. PC software and cable included. • TrendSense logs $EtCO_2$, respiration rate, pulse and oxygen saturation once per second for more than 72 hours. • TrendSense W logs $EtCO_2$, respiration rate, pulse and oxygen saturation four times per second for up to 36 hours and can generate capnograms in Excel charts. **Note:** A TrendSense module cannot be used at the same time as the NC1, Nurse Call Accessory.
NC1 Sens Nurse Call Accessory Cable	Designed for Nonin LifeSense monitoring device to remotely connect to healthcare facility Nurse Call system. Default setting is Continuous Normally Open. **Note:** NC1, Nurse Call Accessory cannot be used at the same time as TrendSense.
Carrying Case	Protective carrying case in which the monitor can be fully connected without removing the bag.

Pulse Oximeter Accessories

Model Number	Description
	PureLight Finger Clip Sensor, Reusable For spot-checking and short-term monitoring. Minimizes motion artifact. Comfortable, self-aligning grip. Durable and easy to clean.
8000AA **8000AP**	Adults (>30 kg; >66 lb) Pediatric / Infants (10 – 40 kg; 22 – 88 lb)
	PureLight Reusable Soft Sensor for Fingers / Toes Quick and easy spot-checking and continuous monitoring. Durable and easy to clean. Universal sensor for many medical settings.
8000SS **8000SM** **8000SL**	Small (Digit thickness 7.5 – 12.5 mm; .3 and .5 in.) Medium (Digit thickness 10 – 19 mm; .4 and .75 in.) Large (Digit thickness 12.5 – 25.5 mm; .5 and 1 in.)
	PureLight Reflectance Reusable Sensor for Middle Forehead Provides convenient site for stress testing and continuous monitoring when an alternative site is needed.
8000R **8000H**	Adults (>30 kg; >66 lb) Sensor holder (10 pack with 20 adhesive collars)
	PureLight Reusable Flex Sensor with Single-Use FlexiWrap® Replaceable adhesive FlexiWrap. Optimal performance in motion situations. Comfortable for extended monitoring. Durable and easy to clean.
8000J **8008J** **8000JFW** **8008JFW**	Adult Flex Sensor (>20 kg; >44 lb, for fingers) Infant Flex Sensor (2 – 20 kg; 4.4 – 44 lb) Adult FlexiWrap (Pack of 25, for index, middle, or ring finger) Infant FlexiWrap (Pack of 25, for toe, thumb, hand)
	PureLight Value Line Sensor, Single-Use Ideal for extended monitoring. Microfoam material for comfort. Repositionable tape. Adult and pediatric sensor for index-, middle- or ring finger. Infant sensor for fingers or large toe. Boxes of 24 disposable sensors.
6000CA **6000CP** **6000CI**	Adults (>30 kg; >66 lb) Pediatric (10 – 50 kg; 22 – 110 lb) Infants (1 – 20 kg; 2.2 – 44 lb)
	PureLight Flexi-Form® III Sensor, Single-Use For extended monitoring; minimizes motion artifact; self-adhesive. Adult and pediatric sensor for index, middle, or ring finger. Infant sensor for large toe. Boxes of 10 disposable sensors.
7000A **7000P** **7000I**	Adults (>30 kg; >66 lb) Pediatric (10 – 40 kg; 22 – 88 lb) Infants (2 – 20 kg; 4 – 44 lb)
8000Q2	**Ear Clip Pulse Oximeter Sensor** For use on patients weighing more than 40 kilograms (88 pounds) when fingertip monitoring is impractical. Sensor for ear lobe application.

Capnography Accessories

Item	Description
Nasal CO_2 Sample Line	Single-use, disposable, universal sample line with male luer lock connectors at both ends. 2.1 m. Adult Pediatric Infant
Oxygen Delivery CO_2 Sampling Nasal Cannula	Single-use, disposable O_2 delivery sample line with male luer lock connector. Infant Pediatric (22 mm ID x 6 mm OD adapter included) Adult (22 mm ID x 6 mm OD adapter included)
CO_2 Sample Line	Single-use, disposable 2.1 m. Universal sample line with male luer lock connectors on both ends.
Straight T-Connector	Single-use, disposable gas sampling port, 15 and 22 mm connector ends. For use with CO_2 sample line to connect monitor to a main stream.
PermaPure Nafion Tubing	Single-use, disposable 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 containing 1 single-use disposable moisture trap and 1 single-use disposable filter each.
Filters	Available in 25 or 100 pack.

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 serial port of this device must be certified according to at least IEC Standard EN 60950 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: If LifeSense is intended to be stored for longer periods of time, always charge the battery to full capacity before storing it in order to prevent damage to the equipment.

Power Requirements

Power Ratings	Unit
Rated supply voltages or voltage ranges for the power supply	100 – 240 VAC 50 – 60 Hz
Input voltage to LifeSense from the power supply	12 VDC, 720mA

WARNING: Only use power supplies that either are supplied with LifeSense or specified by Nonin (see "Accessories").

System Specifications

Power Data	
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
Battery Data	
Type:	Lithium Ion (Li-Ion) internal battery, non-field replaceable, rechargeable
Battery Capacity:	Approximately 8 hours
Charging Time:	Approximately 17 hours, or 2 hours for each hour of use
Physical Data	
Dimensions:	200 x 135 x 50 mm (7.9 x 5.3 x 2 in.)
Weight:	800 grams (1.8 pounds)
Operation	
Working Temperature:	23 °F to 104 °F (-5 °C to 40 °C)
Device temperature will not exceed 41°C as measured during a controlled environment test.	
Humidity:	10 % to 90 % (non-condensing)
Atmospheric Pressure:	720 to 1060 hPa (540 to 795 mmHg)
Altitude:	Up to 9,000 ft (2,740 m)
Storage	
Temperature:	-40 °F to 158 °F (-40 °C to 70 °C)
Humidity:	10 % to 90 % (non-condensing)
Pump	
Pump Flow:	75 ml/min
Flow Accuracy:	±15 ml/min
Alarms	
Sound Pressure Level:	65 dBa maximum at 1 meter in front of monitor
Classification per IEC 60601-1 / CAN/CSA-C22.2 No. 601.1 / UL 60601-1:	
Type of Protection:	Internally powered class II (with battery charger)
Degree of Protection:	Type BF-Applied Part
Mode of Operation:	Continuous
Enclosure Degree of Ingress Protection:	IPX2

Pulse Oximeter Specifications

Displayed Oxygen Saturation Range (SpO_2)	0 to 100 %
Displayed Pulse Rate Range	18 to 255 BPM
Measurement Wavelengths*	Red: 660 nanometers @ 0.8 mW max. average Infrared: 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.

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.

Capnography Specifications

Respiration Range:	3 to 60 respirations/minute
Update Frequency:	Once every breath (No Breath alarm after 25 seconds)
Respiration Accuracy:	3 to 50 respirations/minute ±2
	51 to 60 respirations/minute ±3
$EtCO_2/CO_2$ Range:	0 to 9.9 kPa or 0 to 99 mmHg
$EtCO_2/CO_2$ Accuracy:	±0.2 kPa / ±2 mmHg +8% of reading† 540 – 795 mmHg ($EtCO_2/CO_2$ reading reaches its steady state accuracy 10 minutes after power up)
Update Frequency:	Once every breath (No Breath alarm after 25 seconds)
Sampling Rate:	4 Hz (4 times per second)
Total System Response Time:	4 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
0 – 5% Isoflurane	No correction
0 – 4% Halothane	Presented CO_2 x 0.98 = Actual CO_2

Manufacturer's Declaration

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

Table 9: 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 10: 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	±6 kV contact ±8 kV air	±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	3 A/m	3 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 11: 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 2.5 GHz	3 V/m	80 MHz to 800 MHz $d = 1.17\sqrt{P}$ 800 MHz to 2.5 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 2.5 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 12: 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 2.5 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.			

Pulse Oximeter 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

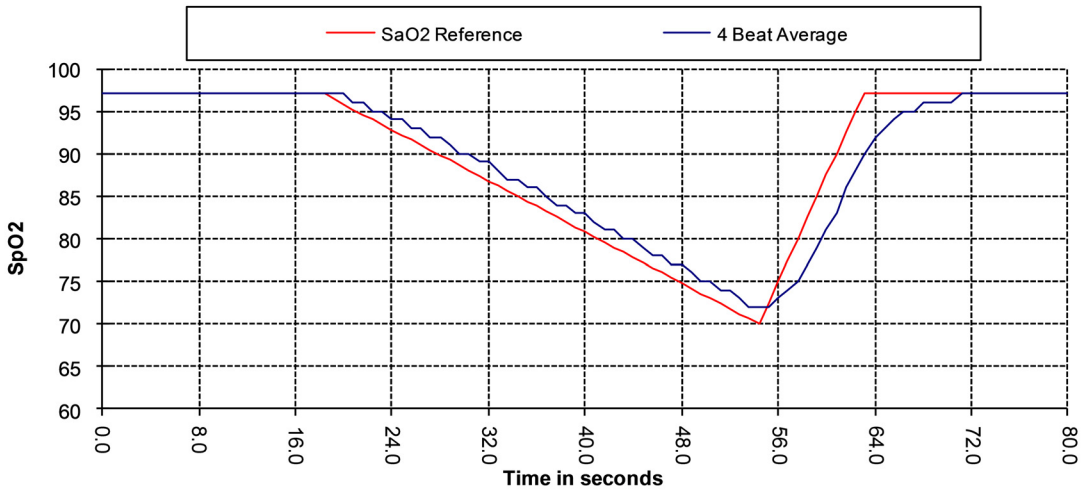
Pulse Rate Values	Average	Latency
Standard/Fast Averaged Pulse Rate	4 beat exponential	2 beats

Equipment Delays	Delays
Display Update Delay	1.5 seconds
Alarm Signal Generation Delay	0 seconds

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.

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 LifeSense battery and touch panel display screen. Nonin warrants the LifeSense monitor for a period of 3 years from the date of purchase. Extended warranties are available on most Nonin pulse oximeter models. 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 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 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 that is found to be within specifications.

The LifeSense 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, field service by non-Nonin personnel, tampering, or any kind of misuse or abuse of the LifeSense, 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.