

# Operator's Manual

*Vital Signs Monitor*

*Capnography/Pulse Oximeter*



## LifeSense LS1-9R

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



**Consult Instructions for Use**

**LifeSense®** is a registered trademark of MedAir AB, a NONIN® Medical, Inc. company.

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

Unauthorized use, copying, or distribution of this manual is prohibited without written consent from NONIN Medical, Inc.

NONIN Medical, Inc  
13700 1<sup>st</sup> Avenue North  
Plymouth, MN 55441-5443  
USA

+1 (763) 553-9968  
(800) 356-8874 (USA and Canada)  
Fax +1 (763) 553-7807  
[mail@NONIN.com](mailto:mail@NONIN.com)  
[www.NONIN.com](http://www.NONIN.com)

References to "NONIN" in this manual shall imply NONIN Medical, Inc. NONIN, Flexi-Form, FlexiWrap and PureLight are registered trademarks of NONIN Medical, Inc. TrendSense is a Nonin trademark.

© 2007 NONIN Medical, Inc.

5843-001-01

# Content

## *Chapter 1 – General Information*

### **Introduction**

Indications for Use, Contraindications, Warnings .....	1
Warnings .....	2
Cautions .....	3
Equipment Symbols .....	6

### **General information**

About LifeSense .....	7
-----------------------	---

## *Chapter 2 – Description of Components*

### **Description of Components**

Monitor Front View .....	9
Start-Up Screen .....	9
Operating Screen .....	10
Trend Page Screen .....	10
Screen Icon and Display Descriptions .....	11
Monitor Rear View .....	13
Monitor Right Side View .....	14
Replacing Single-Use Disposable Moisture Trap / Filter .....	15

## *Chapter 3 – Installation*

### **Installation**

Unpacking .....	16
Standard Kit .....	16
Stationary Use .....	16
Battery Operation .....	17
Mounting .....	17

## *Chapter 4 – Set-Up*

### **Pulse Oximeter Sensor**

Intended Use .....	18
Applying the Sensor .....	18

### **Sample Line**

Intended Use .....	19
Applying the Sample Line .....	19

### **Getting started**

Preparations .....	20
--------------------	----

### **Patient hook up**

Connect the Patient .....	20
Turn on the Monitor .....	20
Check the Alarm Limits .....	20
Up and Running .....	21

### **End of procedure**

Disconnect the Patient .....	21
------------------------------	----

## Chapter 5 – Settings and Alarms

### Settings

Touch Panel Display .....	22
Factory Default Settings.....	22

### Alarm Limits

Pulse Limits .....	23
SpO <sub>2</sub> Limits .....	23
Respiration Limits.....	23
ETCO <sub>2</sub> Limits.....	23

### Changing Settings

Procedure.....	24
----------------	----

### Alarms

Alarm Function .....	25
Alarm Silence .....	25
High Priority Alarm .....	25
Low Priority Alarm .....	26
Disable Alarm.....	26

## Chapter 6 – Maintenance and Inspection

### Battery

Battery Operation .....	27
Charging the Battery .....	27
Checking Battery Capacity.....	27
Battery Message .....	27
Battery Care .....	27

### Maintenance

Ensuring Optimal Performance.....	28
Single-Use, Disposable Moisture Trap .....	28
Cleaning the Sensor .....	28
Cleaning the Monitor .....	28

### Calibration

Calibration Procedure .....	29
-----------------------------	----

### Recommended Inspections

Functional Check .....	30
Yearly Inspection.....	31

### Troubleshooting

Fault Messages.....	32
---------------------	----

### Accessories

List of Accessories .....	34
Capnography Accessories .....	34
Pulse Oximeter Accessories .....	35
Monitor Accessories.....	36

## Chapter 7 – Environmental Requirements

### **Environmental Requirements**

Working Environment.....	37
Storage Environment .....	37
Power Requirements .....	37

### **System Specifications**

Power Data .....	38
Battery Data .....	38
Physical Data .....	38
Operation .....	38
Storage.....	38
Pump .....	38
Alarms .....	38
Classification .....	38
Pulse Oximeter Specifications .....	39
SpO <sub>2</sub> Accuracy Testing .....	39
Capnography Specifications .....	40

### **Manufacturer’s Declaration**

Manufacturer’s Declaration .....	41
----------------------------------	----

### **Pulse Oximeter Response Time**

Pulse Oximeter Response Time .....	44
------------------------------------	----

### **Service, Support, Warranty**

Service, Support, Warranty .....	45
----------------------------------	----

### **Quick step with LifeSense LS1-9R**

To start .....	46
Alarm .....	46
Battery .....	46
When finished .....	46

# CHAPTER 1

## **Indications for Use**

The LifeSense® Model LS1-9R Capnography/Pulse Oximeter monitor indicated for use in simultaneously measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO<sub>2</sub>), end tidal carbon dioxide (ETCO<sub>2</sub>), 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, patient transport, home-use, or any emergency medical services and environments.

## Safety Messages

### **Contraindications**

**Do not use LifeSense in an MR environment.**

**Do not use LifeSense during defibrillation.**

**Do not use LifeSense in an explosive atmosphere or in the presence of flammable anaesthetics or gases.**

### **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.

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 a NONIN Technical Service.

Accessories marked "Single-Use" must be used on one patient only and be disposed of after usage.

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 battery chargers that either are supplied with **LifeSense** or specified by NONIN. See the Accessories List in Chapter 6.

**Warnings, continued**

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.

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 the Accessories List in Chapter 6.

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

ETCO<sub>2</sub> value will be diluted when used in combination with supplemental oxygen. To get a true ETCO<sub>2</sub> 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 battery charger and the power outlet be sure to check that the voltage and frequency rating on the battery charger are the same as the power outlet. If this is not the case, do not connect the monitor and battery charger to the power outlet.

To comply with relevant product safety standards, ensure that all alarm volumes are set appropriately and are audible in all situations. Do not cover or obstruct any speaker openings.



## Cautions

**LifeSense** should only be operated by trained licenced practitioners.

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 it is secured.

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

Portable and mobile RF communications equipment may interfere with medical electrical equipment.

Do not reuse the moisture trap. Do not disassemble the plastic parts of the single-use, disposable moisture trap.

Ear Clip and Reflectance SpO<sub>2</sub> 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 60601-1-2:2001 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, not simultaneously.

Do not cover or block speaker opening; this may significantly reduce the sound volume.

Always store and ship the device in its case to avoid accidental damage.

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 double-backed adhesive strips may vary due to medical status or skin condition.



## Cautions

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 finger clip sensor after each patient use; before cleaning, remove it from the monitor.

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

If the ETCO<sub>2</sub> value is out of normal range (4.7-6.0 Vol%/KPa or 35-45 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.

Prior to connecting **LifeSense** to the battery charger and the power outlet, be sure to verify the voltage and frequency rating on the battery charger are compatible with the outlet. If this is not the case, do not connect the monitor and battery charger to the outlet.

Do not attempt to replace the battery inside the monitor. The battery is hard wired to the circuit board and cannot be replaced by the operator. Contact NONIN Technical Service when the battery needs replacing.

Do not operate **LifeSense** while charging a depleted battery. This may cause permanent damage to the monitor. Charge the battery prior to operating the monitor.

The sample line, moisture trap and filters are "Single-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.

Never open the monitor housing/case. By opening the case you render your warranty invalid.

***Cautions, continued***

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.

Significant levels of dysfunctional hemoglobin may affect SpO<sub>2</sub> measurement accuracy.

Fluctuating or very bright light, moisture, blood pressure cuffs, infusion lines, venous pulsations, insufficient pulse signals, anemia, arterial catheters, nail polish, and/or artificial nails may degrade the SpO<sub>2</sub> device's performance.

Cardiogreen and other intravascular dyes may affect the accuracy of the SpO<sub>2</sub> measurement.












The presence of ambient light may affect the accuracy of the pulse oximeter sensor.

Each time the system is turned on, a breath must be detected to activate the no-breath alarm.

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

## Equipment Symbols

This table describes the symbols that are found on the **LifeSense** monitor.

Symbol	Meaning
	Consult Instructions for Use
	Type BF applied part.
	Indicates separate collection for electrical and electronic equipment (WEEE).
	Model / article number.
	Serial number.
	Date of manufacture.
IPX1	Protected against a uniform flow of water drops over the whole area of the enclosure. Per IEC 60529, clause 14.2.1.
	<b>UL Mark for Canada and the United States</b> with respect to electric shock, fire, and mechanical hazards only in accordance with UL 60601-1 and CAN/CSA C22.2 No. 601.1.
	Indicates the ON/OFF switch on the device.
	Audible alarm pause button.
	Charging indicator. When the monitor is connected to the power outlet the charge indicator will be green. This also means that the batteries are charging.
	DC input. Connection of battery charger.
I O I O I	Serial port for use with TrendSense data memory module only.
SpO <sub>2</sub>	Connection for NONIN-branded PureLight® SpO <sub>2</sub> sensor.

## About LifeSense

**LifeSense** offers the healthcare professional the ability to non-invasively monitor pulse oximetry and capnometry on either intubated or spontaneous breathing patients. This very useful combination serves as a reliable indication of the patient's respiratory status.

When measuring ETCO<sub>2</sub> the patient is attached to the monitor by a sample line that can be an airway adapter for 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 single-use disposable moisture trap which is easily snapped into the slot on the left side of the monitor. Pulse rate and SpO<sub>2</sub> are measured by a NONIN-branded PureLight® finger clip sensor, provided with the system. It is essential to only use the accessories and replacement parts recommended by NONIN. Refer to the Accessories List in Chapter 6 for further information.

**LifeSense** alarms both audibly and visually when predefined limits are exceeded. Limits can easily be adjusted using the touch panel display. The operator can pause or resume the alarm by activating the audible alarm pause button.

**LifeSense** is equipped with a touch panel display where all settings and adjustments are made. The touch panel display also shows battery status and fault messages. The only actual buttons on the monitor are placed on the right hand side of the front panel and are the On/Off button and the audible alarm pause button. Next to these buttons there is a small charging indicator that will turn green as soon as the monitor is connected to the power outlet. **LifeSense** can be operated on battery for approximately 8 hours, without being plugged into a power outlet.

## About Capnometry

The monitor uses sidestream non-dispersive infrared (NDIR) spectroscopy to continuously measure the amount of carbon dioxide (CO<sub>2</sub>) during every breath, the amount of CO<sub>2</sub> present at the end of exhalation (ETCO<sub>2</sub>), 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<sub>2</sub> value will be diluted when used in combination with supplemental oxygen. To obtain a true ETCO<sub>2</sub> 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<sub>2</sub>) from this color difference by measuring the ratio of absorbed red and infrared light as the volume fluctuates with each pulse.

## ***Operator Requirements***

The concept of **LifeSense** is simplicity in combination with accurate measurements. Even though the **LifeSense** monitor is easy to operate it is necessary for each operator to read this manual before using the monitor. **LifeSense** should only be operated by licenced practitioners.

# Chapter 2

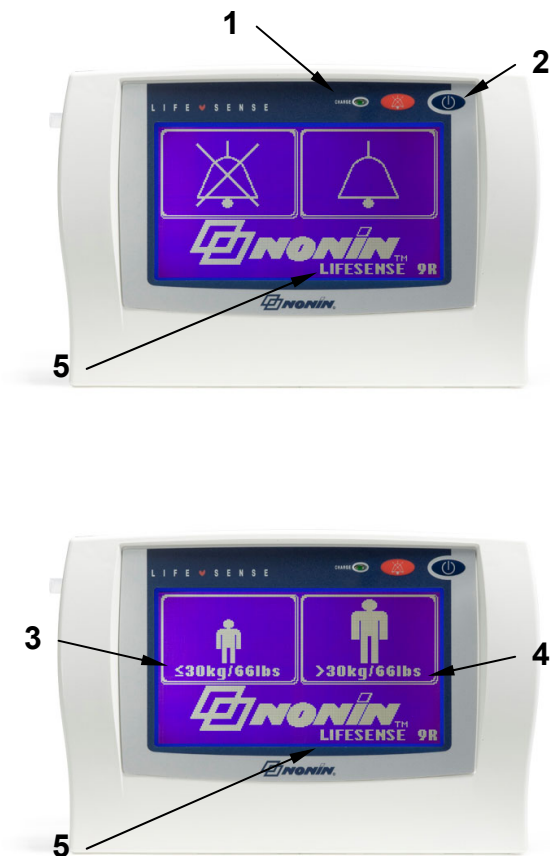
## Description of Components

A standard **LifeSense** set-up consists of a monitor, single-use, disposable moisture trap with filters, NONIN-branded PureLight® finger clip sensor (8000AA), nasal cannula (Ref 5814-001), and battery charger (5783-000). It is shipped in a specially designed case. See the Accessories List in Chapter 6 for information on optional accessories.

### Monitor Front View

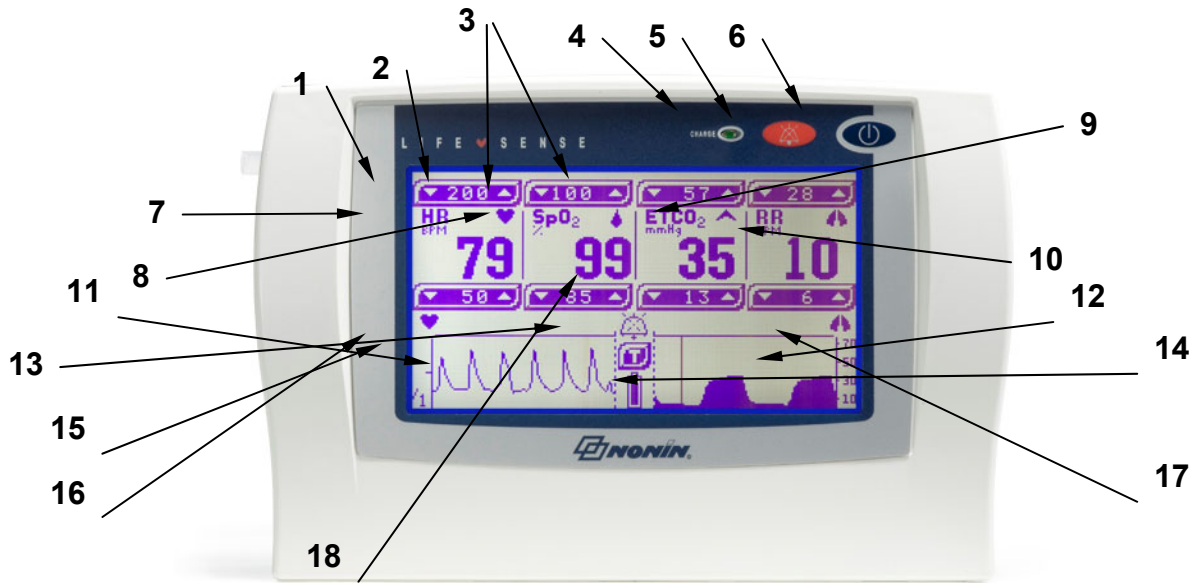
All operator settings are made using the touch panel display on the monitor. The components and functions used and displayed on the front panel of the monitor are shown in the figures below. Names and descriptions of each component are listed in the table below.

#### 1) Start-up Screens

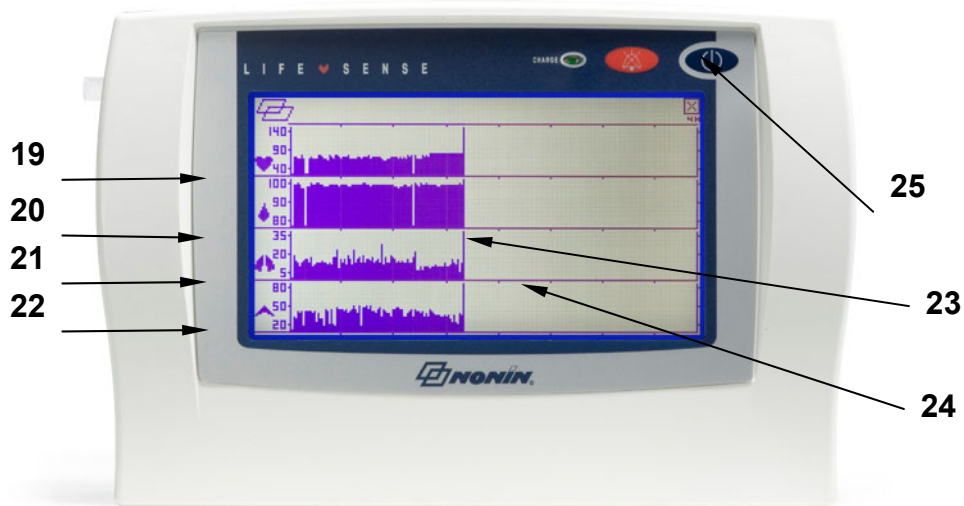


No	Name	Description
1.	Audible Alarm silence Icon	Icon for selecting alarms off (disables audible alarms by setting all lower limits to 0)
2.	Alarms on Icon	Icon for selecting alarms on. Default if no icon is chosen.
3.	≤ 30kg or ≤ 66 lbs. Icon	Icon for selecting default alarm limits for patients weighing ≤ 30kg or ≤ 66 lbs. Only available if alarms on icon is chosen on previous screen.
4.	> 30kg or >66lbs. Icon	Icon for selecting default alarm limits for patients weighing >30kg or >66lbs. Only available if alarms on icon is chosen on previous screen.
5.	LifeSense version	Shows <b>LifeSense</b> version. If error occurs during start-up, an error number will be shown here and the monitor will alarm.





### 2) Operating Screen




### 3) Trend Page Screen



## **Screen Icons and Display Descriptions**

No	Name	Description
1.	LCD Display	The LCD monitor displays parameters, graphs, menus and other information. It also functions as 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 is within the range of low and high setting they are treated as normal values. Values exceeding these limits activate alarm function, which is both audible and visual. The exceeded limit is also displayed as inverted blue and white figures if the alarm is silenced.
3.	Up/Down Bar 	Control buttons for increasing or decreasing an alarm limit.
4.	 Charge Indicator	The charge indicator is green whenever the battery charger is connected between the power outlet and <b>LifeSense</b> . This also indicates that the battery is charging. When there is no outlet power connected the indicator will remain off.
5.	Audible Alarm Pause Button 	Audible alarm function alerts the operator when preset limits are exceeded. The operator can temporarily disable the audible alarm by pushing the audible alarm pause button. Alarms are still indicated visually on the display when limits are exceeded, and on the status texts. If the alarm is paused it will remain inactive for approximately 2 minutes before it will reactivate again. The current alarm status is indicated visually on the LCD (See No 13; Alarm symbols in this table).
6.	 ON/OFF Button	This button turns the monitor ON or OFF. This button will also enable or disable the audible pulse beep function by depressing the ON/OFF button briefly.  <b>Note:</b> depressing this button > 1 second will turn the monitor off. When enabled the audible pulse beep (tone) increases as the SpO <sub>2</sub> rate increases or decreases as the SpO <sub>2</sub> 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 <sub>2</sub>	Displays percent (%) oxygen saturation (% SpO <sub>2</sub> ). The SpO <sub>2</sub> value is updated on the display every 1.5 seconds.

No	Name	Description
9.	ETCO <sub>2</sub>	Displays the volume of end tidal CO <sub>2</sub> in expired air. ETCO <sub>2</sub> is shown as mmHg or kPa. The value is updated after each breath without averaging.
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 under Chapter 5 for more information.
12.	Status Text	Shows alarm messages for the capnometer. See alarms under Chapter 5 for more information.
13.	Alarm Symbols 	Space for alarm symbols. No symbol means audible alarms are active. A bell with a cross of broken lines indicates that audible alarm is paused. A bell with a cross of solid lines indicates that audible alarm is disabled.
14.	Trend Icon	Push the icon for displaying a trend page. The trend page will remain visible until the operator touches the screen.
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 can be either /1, /2, /4 or /8
17.	Respiration Graph	Displays a graph of the CO <sub>2</sub> in expired air (capnograph).
18.	Battery Indicator	Displays the battery status. See Chapter 6 for more information.
19.	Trend HR	Displays a trend graph of the pulse rate.
20.	Trend SpO <sub>2</sub>	Displays a trend graph of the SpO <sub>2</sub> values.
21.	Trend RR	Displays a trend graph of the respiration rate.
22.	Trend ETCO <sub>2</sub>	Displays a trend graph of the ETCO <sub>2</sub> values.
23.	Trend Cursor	A trend cursor points out where the actual sample is in the time interval.
24.	Trend Time Scale	Timescale is presented in half hour segments.
25.	Trend Time	The total trend time is approximately 4 hours of volatile internal memory. Real time data can be collected using the TrendSense memory module for download to a PC.

## Monitor Rear View

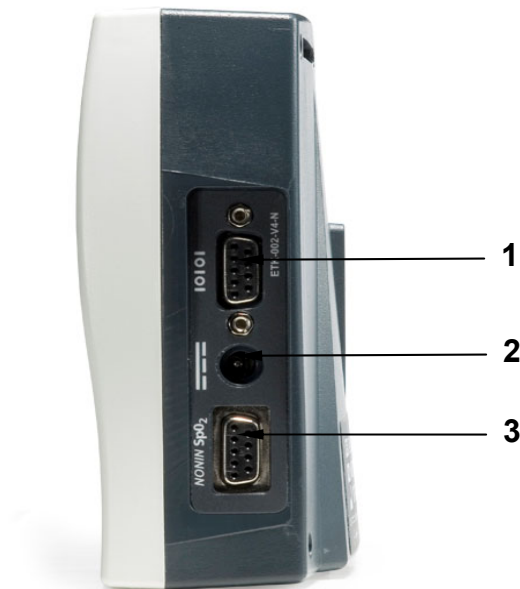
The moisture trap, filter and equipment label are located on the rear side of **LifeSense**. The items on the rear side of the monitor are shown in the figure below. Names and descriptions of each component are listed in the table below.



No	Name	Description
1.	Single-use, Disposable Moisture Trap and Filter	<p>The moisture trap located on the back of the monitor, clicks into position as illustrated above. Numbers 1 and 2 act as guide marks.</p> <p>1.) Slide the moisture trap into position. 2.) Push it down. Push tab out to remove.</p> <p>The moisture trap and filter are single-use, disposable components and should be replaced after each patient use. The filter fits into the moisture trap and protects the monitor from moisture.</p>
2.	Attachment Holes	Dedicated holes for attachment of a mounting bracket. See the Accessories List in Chapter 6 for part number if a mounting fitting 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.
4.	Equipment Label	The label contains model number, serial number, manufacturing date, manufacturer, UL-mark, "Read operator's manual" symbol and the Applied Part symbol. Every <b>LifeSense</b> device has a unique serial number for identification. See Chapter 1, Equipment Symbols for description of the different symbols.

## Monitor Right Side View

Outputs and connections are located on the right hand side of the monitor as shown in the figure below. Detailed specification of connections is listed in Chapter 7, “Specification”. Names and descriptions of each component are listed in the table below.



No	Name	Description
1.	TrendSense Serial Interface Output	For patient data transfer from <b>LifeSense</b> to a PC. <b>NOTE:</b> Use only TrendSense with LifeSense Capnography/Pulse Oximeter Systems.
2.	Power Inlet	Power inlet for the battery charger that is connected to the power outlet. Only use NONIN specified chargers.
3.	SpO <sub>2</sub> Connector	PureLight® pulse oximeter sensor connection for measuring oxygen saturation. Pulse oximeter sensors to be used with the device are specified under “Accessories” in Chapter 6. No other sensors may be used.
<b>WARNING</b>		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.

## Replacing the Single-Use, Disposable Moisture Trap and Filter



**Caution:** The moisture trap and filters are Single-use, disposable components and a new one must be used for each patient and be disposed of after use.



**Caution:** Do not reuse the moisture trap. Do not disassemble the plastic parts of the single-use, disposable moisture trap.

- Place the filter in the moisture trap as shown in arrow 1.
- Connect the moisture trap into position as shown by arrow 2.
- Then press the moisture trap into position, by pushing the tab, as shown by arrow 3.
- To remove the moisture trap and replace the filter, reverse the three steps as described above.



# Chapter 3

## Installation

### ***Unpacking***

**LifeSense** is shipped in a shockproof case designed to protect the equipment. The case has an inner compartment which the device fits. It is recommended that the equipment be stored in its case whenever it is not in use.

### ***Standard Kit***



If you have ordered a standard kit your delivery should contain the following:

- 1 **LifeSense** LS1-9R monitor with single-use, disposable moisture trap and filter
- 3 extra filters
- 1 AC/DC battery charger
- 1 NONIN-branded PureLight® finger clip sensor
- 1 CO<sub>2</sub> Sample line
- 1 Operator's Manual
- 1 Hard case
- 1 Straight T-Connector
- 3 CO<sub>2</sub> sampling nasal cannulas


Unpack all accessories and check that everything is included in your shipment. Read the individual instructions for use provided with each accessory prior to use. Contact NONIN if anything is missing or seems to be defective. Dispose of all waste material in accordance with the local, state, or national environmental regulations that apply.

After unpacking the monitor and accessories the **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 battery charger is connected to the monitor and the power outlet.

### ***Stationary Use***


- Place the monitor in a position so that you can see the display clearly.
- Connect the battery charger to the monitor by putting the small plug into the power inlet marked with  on the right hand side of the monitor. Plug in the other end of the power cable into a power outlet. The green charging indicator  located on the front panel will light up as soon as the monitor is connected to the power outlet.

<b>Warning</b>	Prior to connecting <b>LifeSense</b> to the battery charger and the power outlet be sure to check that the voltage and frequency rating on the battery charger are the same as the power outlet. If this is not the case, do not connect the monitor and battery charger to the power outlet.
----------------	---

Turn on **LifeSense** by pressing the ON/OFF  button on the monitor and keep it pressed until you hear a beep.


## ***Battery Operation***


Whenever there is a need for the monitor to be used portably, or if it is needed in environments where there is no power, the monitor can operate on battery; this will only be possible if the battery has been charged. Always plug in the battery charger as soon as possible for the monitor to be connected to a power outlet.

- Turn on **LifeSense** by pressing the ON/OFF  button on the monitor until you hear a beep. The battery symbol on the touch panel display shows the remaining battery capacity. Also, the charging indicator on the top right hand side of the monitor will not light up if the battery charger is not connected.
- Plug the **LifeSense** battery charger into the power outlet as soon as there is no need for battery operation.

## ***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. Contact NONIN customer support to order a mounting bracket and adjustable mounting clamp. Order number can be found in the Accessories List in Chapter 6.

	<b>Caution:</b> Secure <b>LifeSense</b> with mounting bracket if used in transport vehicles.
---	--

	<b>Caution:</b> Do not mount <b>LifeSense</b> directly above the patient. If the monitor is mounted be sure to check that the adjustable mounting clamp is securely affixed.
---	--

# Chapter 4

## Set-Up

### **Intended Use**

The NONIN-branded PureLight® oximeter sensors are designed to non-invasively measure oxygen saturation (%SpO<sub>2</sub>), pulse rate and plethysmographic pulse waves.

### **Applying the Sensor**



Choose the appropriate sensor for the patient that will be monitored.

Remove nail polish or artificial fingernails.

Insert a finger into the Adult Articulated Finger Clip Sensor (Figure 1) until the end of the finger reaches the finger stop; keep the fingernail facing the sensor top. Ensure that long fingernails do not interfere with proper finger position.



Position the sensor so that 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.

<b>Warning</b>	When selecting a sensor application site use an extremity without a catheter, blood pressure cuff or intravascular infusion line.
<b>Warning</b>	Do not use a damaged sensor.
<b>Warning</b>	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.
	<b>Caution:</b> 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 double-backed adhesive strips may vary due to medical status or skin condition.
	<b>Caution:</b> 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<sub>2</sub>). It is a Single-Use, Disposable tubing that attaches into the patient's nose and connects to the monitor's moisture trap with a luer lock connector. In the standard kit one sample line is included. **LifeSense** can be fitted with several types of sample lines to best suit the patient. Refer to the Accessories List in Chapter 6. The instructions below refer to the sample line supplied with **LifeSense** as a standard kit. Other sample lines have separate instructions included in their packing.

## ***Applying the Sample Line***

Insert the cannula into each nostril.

Place the tubing behind each ear.

Connect the luer lock fitting to the moisture trap, twist to tighten.



<b>Warning</b>	Use only NONIN recommended accessories and replacement parts.
----------------	---

	<b>Caution:</b> 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.
--	--

	<b>Caution:</b> The patient's nasal passage may dry out if continuous monitoring is required. Check patient hourly for nasal comfort.
--	---

# Getting Started

## **Preparations**

Visually inspect the monitor and make sure it has no visual signs of damage. Examine the PureLight® SpO<sub>2</sub> sensor for obvious defects. Ensure the sensor is clean if it has been previously used.

Connect the pulse oximeter sensor to the port located on the side of the monitor with the SpO<sub>2</sub> symbol. 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. See the Accessories List in Chapter 6.

Replace the single-use, disposable moisture trap and filter on the back of the monitor before each patient use. The moisture trap snaps into position by pushing it firmly into position. For removal just pull the plastic tab placed on the back of the moisture trap and it will snap out of position. Refer to Chapter 6 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 clock-wise. Only use sample lines recommended by NONIN. See the Accessories List in Chapter 6.

## Patient Hook Up

### **Connect the Patient**

Apply the pulse oximeter sensor to the patient, as described in the previous section or refer to the individual sensor Instructions for Use.

Attach the sample line to the patient, as described in the previous section refer to the individual sample line Instructions for Use.

### **Turn on the Monitor**

Turn on the monitor by pressing the ON/OFF  button and keep it pressed 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 view, Start-up screen* in Chapter 2 for more information on disabling alarms and setting alarm limits.

Verify that the graphs and settings are displayed on the touch panel screen.



**Caution:** Each time the system is turned on, a breath must be detected to activate the no-breath alarm.

## 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 directly on the touch panel display. Refer to Chapter 5 for instructions on how to change alarm limits.

<b>Note</b>	The audible alarm is paused for approximately 2 minutes, unless activated by the operator. This gives the operator a chance to verify and adjust the connections and alarm limits.
-------------	--

## Up and Running

The audible alarm function activates approximately 2 minutes after start up, which means that the monitor is now ready for use. The patient can stay connected to the monitor for as long as needed.

<b>Contraindication</b>	Do not use <b>LifeSense</b> during defibrillation.
-------------------------	--

<b>Warning</b>	<b>LifeSense</b> is intended only as an adjunct in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms
----------------	---

## End of procedure

### Disconnect the Patient


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

<b>NOTE:</b>	If the monitor is ON and there is no patient connected, the alarm will be activated.
--------------	--

# Chapter 5

## Settings and Alarms

### Touch Panel Display

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

### Factory Default Settings

**LifeSense** always recalls and displays the factory default settings upon start-up. At the start-up screen the operator can select from 2 different default settings (only if alarms are activated on first start-up screen). Adjust settings according to each patient's needs. The factory settings are:

Parameter	> 30kg / 66lbs. patient selected (default)	≤ 30kg / 66lbs. patient selected (default)
HR upper limit	200 beats per minute (BPM)	200 beats per minute (BPM)
HR lower limit	50 beats per minute (BPM)	80 beats per minute (BPM)
SpO2 upper limit	100 %	95%
SpO2 lower limit	85 %	85 %
ETCO <sub>2</sub> upper limit	7.5 kPa or 57 mmHg	7.5 kPa or 57 mmHg
ETCO <sub>2</sub> lower limit	1.5 kPa or 13 mmHg	1.5 kPa or 13 mmHg
RR upper limit	28 respirations per minute (RPM)	80 respirations per minute (RPM)
RR lower limit	6 respirations per minute (RPM)	20 respirations per minute (RPM)



**Caution:** Before each use, it is the operator's responsibility to verify that 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.


## Alarm Limits

All parameters have built in limits that cannot be exceeded.


### *Pulse limits*

 <p>HR BPM 75 110 40</p>	<p>– Upper limit range: 255 (beats per minute)</p> <p>– Lower limit range: 0 (beats per minute)</p>
---	---


### *SpO<sub>2</sub> limits*

 <p>SpO<sub>2</sub> 96 100 90</p>	<p>– Upper limit range: 100 (%)</p> <p>– Lower limit range: 0 (%)</p>
--	---



### *Respiration limits*

 <p>RR RPM 16 28 6</p>	<p>– Upper limit range: 99 (respirations per minute)</p> <p>– Lower limit range: 0 (respirations per minute)</p>
---	--


### *ETCO<sub>2</sub> limits*

 <p>ETCO<sub>2</sub> kPa 4.7 5.7 1.3</p>	<p>– Upper limit range: 9.9 (kPa) or 99 (mmHg)</p> <p>– Lower limit range: 0 (kPa or mmHg)</p>
---	--


## Changing Settings

All settings follow the same procedure to increase or decrease an alarm limit. The arrow  located on the right side of a displayed parameter bar allows the alarm limits to be increased and the arrow  on the left side of the displayed parameter bar allows the alarm limit to be decreased. The upper alarm limit is always located above the displayed value, and the lower limit is displayed below.

### Procedure

Decreases upper limit →		← Increases upper limit
Decreases lower limit →		← Increases lower limit

Each time the arrow is pressed it will increase or decrease the alarm limit in single digits.

	<b>Caution:</b> Set or adjust only one parameter at a time, not simultaneously.
<b>Note</b>	The monitor will always reset the alarm limits to the factory default settings once it is turned off and turned on again.





# Alarms

## Alarm Function

The alarm is activated under certain conditions, such as if an alarm limit is exceeded, if there is no patient connected or if an equipment fault has occurred.

The alarm is both visual (a blinking parameter, digit, or a message) and audible (beeper tones at different intervals).

## Alarm Silence

The operator can silence the audible alarm by pressing the audible alarm pause button . The audible alarms will stay deactivated for approximately 2 minutes but the visual alarms will remain active until the condition is corrected. The operator can increase  or decrease  the alarm limit settings for individual patients. If alarm limits are set to zero for the capnograph and for the pulse oximeter, alarms will be disabled until alarm limits are set higher. The alarm off icon () will appear on the touch panel display.

## High Priority Alarm

A high priority alarm calls for immediate action from the operator. The alarm will occur if any of the parameters exceed operator defined or default alarm limits. High priority alarms are both audible and visually indicated. The audible alarm beeps faster in high priority situation than in low priority situation. A flashing alarm value indicates the alarm parameter has been exceeded

The following table shows the high priority alarm parameter and their causes.


Parameter	Cause of alarm
Pulse	Exceeds the high limit setting
Pulse	Outside the low limit setting
SpO <sub>2</sub>	Exceeds the high limit setting
SpO <sub>2</sub>	Outside the low limit setting
ETCO <sub>2</sub>	Exceeds the high limit setting
ETCO <sub>2</sub>	Outside the low limit setting
RR	Exceeds the high limit setting
RR	Outside 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 is unable to provide a measurement value. See the table below for parameters, fault messages and possible cause.

Low priority alarms are also both audible and visible with a slower beep frequency and the monitor will display a fault message. The table below shows possible fault messages and possible causes.

Parameter	Message	Possible Cause
Pulse oximetry	NO PROBE	The sensor is not connected to the monitor.
Pulse oximetry	NO FINGER	The sensor is not connected to the finger.
Pulse oximetry	ARTIFACT	A questionable pulse was detected
Pulse oximetry	NO OXIMET	No communication from the pulse oximetry unit. Possibly due to a sensor error.
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.
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 button.
Capnometry	NO CAPNO	No communication from capnometry unit.
Capnometry	WARM UP	Warm up delay and stabilizing measurements.
System	BATT LOW	Battery is almost depleted.
System	DISP ERROR	The touch panel display is not working properly.

\*A full or a kinked sampling line may trigger the occlusion alarm. To prevent the monitor from damage by liquid, the pump will stop after 10 seconds of occlusion. The message “Trap full? / Press alarm” will be displayed. Check the moisture trap and replace if necessary. Check the sampling line for kinks or occlusions and replace if necessary. Press the audible alarm pause  button to continue.

## Disable Alarm

It is possible to disable the audible alarms either by selecting the alarm off icon  on the start-up screen or by decreasing all lower limit settings to 0. When audible alarms are disabled, this will be visually indicated on the display screen by the alarm off icon .


# Chapter 6

## Maintenance and Inspection


### **Battery Operation**



**LifeSense** is designed to operate continuously using a power outlet or on battery for approximately 8 hours. As soon as **LifeSense** is disconnected from the outlet, and is ON, it automatically runs on battery.

### **Charging the Battery**

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 light  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 depleted battery takes approximately 17 hours. To maximize battery capacity for monitoring you can use this rule: one hour of monitoring needs approximately two 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 that the monitor can be used for approximately 8 hours.
-  A depleted symbol indicates that the battery has run out of power and needs recharging immediately.

### **Battery Message**

**LifeSense** displays a **LOW BATTERY** message 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 is made of Lithium Ion (Lilon) rechargeable cells and requires no maintenance. The battery is integral to the device and cannot be replaced by anyone other than NONIN Technical Service. Check the remaining capacity of the battery by running a fully charged battery down to depletion.


<b>Note</b>	When a fully charged battery allows for 3 to 5 hours of operation it needs to be replaced. Contact NONIN Technical Service for battery replacement.
-------------	---

# Maintenance

## ***Ensuring Optimal Performance***

In order to ensure safety and optimal performance of **LifeSense** it is necessary to carry out recommended maintenance and inspections. See the section on recommended inspections in this chapter.

	<b>Caution:</b> Always turn off the monitor prior to changing the oximeter sensor or moisture trap and/or filter.
---	---

	<b>Caution:</b> Always store or ship the device in its case to avoid accidental damage.
---	---

## ***Single-Use, Disposable Moisture Trap***

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, replace when necessary.


Make sure to keep a sufficient supply of new moisture traps and filters within easy reach. For instructions on how to replace the moisture trap, see Chapter 2.

## ***Cleaning the Sensor***

Clean the NONIN PureLight® reusable sensor with a soft cloth moistened with isopropyl alcohol, or a mild soap solution. Allow the sensor to dry completely after cleaning. Refer to individual sensor Instructions for Use for details.

## ***Cleaning the Monitor***

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



	<b>Caution:</b> Do not sterilize or autoclave the <b>LifeSense</b> monitor or sensors. Do not immerse in liquids.
---	---


# Calibration

## Calibration Procedure

**LifeSense** has a built-in zero-point calibration function for CO<sub>2</sub>, performed by following steps; the procedure can be performed as often as needed. It is recommended that you carry out the calibration procedure at least once a year along with the yearly inspection (refer to “Recommended inspections” below), or if the baseline of the CO<sub>2</sub> graph is elevated.

Attach a calibration apparatus to the moisture trap (see the Accessories List in this chapter for the correct item number).

Turn on the monitor by pressing the ON/OFF  button. While the NONIN logotype is displayed press and hold down the audible alarm pause  button for 15 seconds. Keep it pressed until the following message is displayed on the touch panel screen: HOLD AUDIBLE ALARM PAUSE BUTTON AND PRESS POWER TO CALIBRATE.

Simultaneously press the ON/OFF  button.

**LifeSense** then starts the calibration procedure and the following message is displayed: CALIBRATING

Release both buttons. The procedure takes 15 minutes and when the calibration is finished **LifeSense** returns to its normal operating mode. Disconnect the calibration apparatus. The calibration apparatus is reusable for approximately 100 times. When the pellets start to turn purple they can not absorb any more CO<sub>2</sub> and the calibration apparatus must be replaced. Dispose of the calibration apparatus in accordance with your local, state, or national regulations concerning waste materials.

Verify calibration following these steps.

Connect a gas sampling tube to a gas bottle containing 5 Vol% of CO<sub>2</sub> (verifying gas) and **LifeSense**. Release approx. 200 ml of gas for 4-5 seconds and then turn off the gas valve (equals one exhale). Verify the reading of ETCO<sub>2</sub> on the touch panel display. A reading of (4.7-6.0 kPa or 35 – 45 mmHg) is considered normal.




**Caution:** 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

### Functional Check

Before each use verify the equipment is clean and in optimal operating condition, if needed, wipe the surface of the monitor with isopropyl alcohol.

	<p><b>Caution:</b> Always turn off the monitor prior to cleaning the monitor or changing the pulse oximeter sensor or moisture trap and/or filter.</p>
---	--

Verify battery capacity by turning on the monitor.

	<p><b>Caution:</b> Do not operate LifeSense while charging a depleted battery. This may cause permanent damage to the monitor. Charge the battery prior to operating the monitor.</p>
---	---

For optimal performance, verify the single-use, disposable sample line is free of bends and kinks.

Verify the moisture trap and filter are in position.

Always verify the reusable PureLight® finger clip sensor is clean, if previously used. Visually examine the accessories for defects prior to use.


Turn on the monitor by pressing the ON/OFF  button and keep it pressed until you hear a beep.

Verify that all parameters are displayed correctly and adjust any alarm limits according to the patient.


Verify alarm function/status by simulating alarm situations for all parameters.

Visually verify that the zero-point of the CO<sub>2</sub>-graph is not elevated.

<p><b>Warning</b></p>	<p>If the <b>LifeSense</b> fails to respond as described, discontinue use and contact NONIN Technical Service.</p>
-----------------------	--

	<p><b>Caution:</b> LifeSense should only be operated by trained licenced practitioner</p>
---	---

<p><b>Warning</b></p>	<p>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.</p>
-----------------------	--

	<p><b>Caution:</b> Be careful not to drop <b>LifeSense</b> on the floor or strike it against hard surfaces. If such an incident happens do not use <b>LifeSense</b> until a functional test has been carried out.</p>
---	---

## ***Yearly Inspection***

A comprehensive inspection should be carried out annually by NONIN Technical Service to ensure optimal performance of **LifeSense**. Contact NONIN Technical Service for return authorization instructions.



**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	Possible Cause: Action
OCCLUSION	<p>Sample Line occlusion.</p> <p>Incorrect placement of the moisture trap</p> <p>Clogged filter</p> <p>The sample line is not properly applied to the patient:</p> <p>Sample line is not connected to the moisture trap:</p>	<p><b>Remove</b> obstruction or replace the sample line.</p> <p><b>Reposition</b> the moisture trap.</p> <p><b>Replace</b> the filter.</p> <p><b>Verify</b> sample line placement.</p> <p><b>Verify</b> connection to moisture trap.</p>
NO PROBE	The sensor is not connected to the monitor.	<b>Check</b> all sensor connections between patient and the monitor.
NO FINGER	The sensor is not connected to the patient, or the sensor is damaged.	<b>Check</b> sensor application site.
ARTIFACT	A detected pulse beat did not match the detected pulse interval.	<b>Check</b> the sensor application site; reapply sensor to another site, if necessary.
BATT LOW	The monitor will run for approximately 20 minutes.	<b>Plug</b> the power cable into a power outlet and charge the batteries for 17 hours. If the monitor continues to show BATT LOW message after recharging, <b>contact</b> NONIN Technical Service, as the battery may need replacement. The battery is integral to the device and cannot be replaced by the operator itself.

Message	Description	Remedy
DISP ERROR	The display is not showing any parameters.	<b>Turn off</b> the monitor and then <b>turn on</b> again. If the problem persists contact NONIN Technical Service.
Continuous beeping sound	The alarm beeps continuously.  The monitor is non-functioning in this state. This indicates that a problem has occurred, possibly due to interference or loss of power.	<b>Turn off</b> the monitor and then <b>turn on</b> again.  <b>Recharge</b> the monitor with the battery charger.  If the problem persists, <b>contact</b> NONIN Technical Service.
Low ETCO <sub>2</sub> alarm even though the patient's ETCO <sub>2</sub> is suspected to be normal.	All alarms for low ETCO <sub>2</sub> 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, moisture trap, or internally.	<b>Check</b> patient status, <b>Check</b> the moisture trap and filter. <b>Replace</b> the moisture trap and filter if necessary <b>Check</b> sample line connector and visually inspect the sample line for signs of damage.  If the problem persists, <b>contact</b> 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.	<b>Verify</b> the filter is in place; <b>replace</b> as needed <b>Perform</b> calibration and gas verification to assure performance of the device.
FLASH CHECKSUM ERROR on the display screen	An internal memory fault has occurred	<b>Contact</b> NONIN Technical Service.



# Accessories

## List of 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.



## Capnography Accessories

Item	Description	Order no
	<b>Nasal CO<sub>2</sub> sample line, Single-use, disposable</b> Single-use, disposable, 2.1 m. Sample Line, with male luer lock connector.  <b>Adult</b> <b>Pediatric</b> <b>Infant</b>	<b>5814-001</b> <b>5814-002</b> <b>5814-003</b>
	<b>Oxygen delivery CO<sub>2</sub> sampling nasal cannula, Single-use, disposable</b> Single-use, disposable O <sub>2</sub> Delivery Sample Line with male luer lock connector.  <b>Infant</b> <b>Pediatric</b> (22 mm ID x 6 mm OD adapter included) <b>Adult</b> (22 mm ID x 6 mm OD adapter included)	<b>5820-001</b> <b>5820-002</b> <b>5820-003</b>
	<b>CO<sub>2</sub> Sample Line, Single-use, Disposable</b> Single-use, disposable 2.1 m. Universal Sample Line with male luer lock connectors on both ends.	<b>5821-000</b>
	<b>Straight T-connector, Single-use, Disposable</b> Single-use, disposable Gas Sampling Port, 15 and 22 mm connector ends, for use with CO <sub>2</sub> sample line to connect monitor to a main stream.	<b>5777-000</b>
	<b>PermaPure Nafion Tubing, Single-use, Disposable</b> Single-use, disposable Nafion Tubing to remove water vapor from the Sample Line.	<b>5778-000</b>
	<b>Verification Gas</b> Verification gas and tubing; contains 5 Vol% of CO <sub>2</sub> (equals 38 mmHg or 5, 3 kPa); must be used with a gas valve, 5780-000.	<b>Contact Nonin Customer Support</b>
	<b>Gas Valve for Verification Gas</b> Reusable gas valve and tubing for controlling the flow from the verification gas.	<b>5780-000</b>



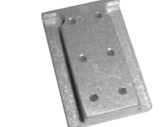
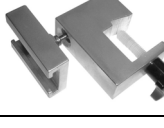

Item	Description	Order no
	<b>Calibration Apparatus</b> For 0-point calibration.	<b>5781-000</b>
	<b>Single-Use, Disposable Moisture Trap, with Filters – 10 Pack</b> 10 packages containing one single-use disposable moisture trap and 3 single-use disposable filters each.	<b>6024-000</b>

### Pulse Oximeter Accessories

Item	Description	Order no
	<b>PureLight® Finger Clip Sensor, Reusable</b> For spot-checking and short-term monitoring. Minimizes motion artifact. Comfortable, self-aligning grip. Durable & easy to clean. <b>Adults:</b> (>30 kg; >66 lbs) <b>Pediatric / Infants:</b> (10 – 40 kg; 22 – 88 lbs)	<b>8000AA</b> <b>8000AP</b>
	<b>PureLight® Soft Sensor for Fingers / Toes, Reusable</b> Quick and easy spot-checking and continuous monitoring. Durable and easy to clean. Universal sensor for many medical settings. <b>Small</b> (Digit thickness 7.5 – 12.5 mm; .3 and .5 in) <b>Medium</b> (Digit thickness 10 – 19 mm; .4 and .75 in) <b>Large</b> (Digit thickness 12.5 – 25.5 mm; .5 and 1in)	<b>8000SS</b> <b>8000SM</b> <b>8000SL</b>
	<b>PureLight® Reflectance Sensor for middle forehead, reusable</b> Provides convenient site for stress testing & continuous monitoring when an alternative site is needed. <b>Adults:</b> (>30 kg; >66 lbs) <b>Sensor holder:</b> (10 pack with 20 adhesive collars)	<b>8000R</b> <b>8000H</b>
	<b>PureLight® Reusable Flex Sensor, with FlexiWrap®, Single-Use</b> Replaceable adhesive FlexiWrap®. Optimal performance in motion situations. Comfortable for extended monitoring. Durable and easy to clean. <b>Adult Flex Sensor</b> (>20 kg; >44 lbs, for fingers) <b>Infant Flex Sensor</b> (2 – 20 kg; 4.4 – 44 lbs) <b>Adult FlexiWrap®</b> Pack of 25, for index-, middle- or ring finger <b>Infant FlexiWrap®</b> Pack of 25, for toe, thumb, hand	<b>8000J</b> <b>8008J</b> <b>8000JFW</b> <b>8008JFW</b>

Item	Description	Order no
	<p><b>PureLight® Value Line Sensor, Single-Use</b></p> <p>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.</p> <p><b>Adults:</b> (&gt;30 kg; &gt;66 lbs)  <b>Pediatric:</b> (10 – 50 kg; 22 – 110 lbs)  <b>Infants:</b> (1 – 20 kg; 2.2 – 44 lbs)</p>	<p><b>6000A</b>  <b>6000P</b>  <b>6000I</b></p>
	<p><b>PureLight® Flexi-Form® II Sensor, Single-Use</b></p> <p>For extended monitoring; minimizes motion artifact; self-adhesive</p> <p>Adult and pediatric sensor for index-, middle- or ring finger. Infant sensor for large toe. Boxes of 10 disposable sensors.</p> <p><b>Adults:</b> (&gt;30 kg; &gt;66 lbs)  <b>Pediatric:</b> (10 – 40 kg; 22 – 88 lbs)  <b>Infants:</b> (2 – 20 kg; 4 – 44 lbs)</p>	<p><b>7000A</b>  <b>7000P</b>  <b>7000I</b></p>

## Monitor Accessories

Item	Description	Order no
	<p><b>Battery charger</b></p> <p>approximately 120 VAC, 60 Hz (USA)</p>	<p><b>5783-000</b></p>
	<p><b>Emergency Bag</b></p> <p>Protective emergency bag in which the monitor still can be fully connected without removing the bag. Perfect for ambulance-, field- and portable use where the monitor might be needed instantly.</p>	<p><b>5784-000</b></p>
	<p><b>Monitor Mounting Bracket</b></p> <p>Connector that enables adjustable mounting and hospital standard mounting. Delivered with 6 screws for connection on the backside of the monitor.</p>	<p><b>5785-000</b></p>
	<p><b>Adjustable Mounting Clamp</b></p> <p>Mounting for hospital rails, 10 – 30 mm diameter poles (as beds, IV-poles and transport vehicles) and table edges.</p>	<p><b>5786-000</b></p>
	<p><b>TrendSense</b></p> <p>Data memory module. It logs ETCO<sub>2</sub>, respiration rate, pulse and oxygen saturation once per second for more than 72 hours. Dimensions 38x32x17mm. No battery, it draws the necessary power from the host. PC software and cable included.</p>	<p><b>5787-000</b></p>

# Chapter 7

## Environmental Requirements

### ***LifeSense Operation***

**LifeSense** must only be used when the specified environmental conditions are met. Refer to device specification in this chapter.

### ***LifeSense Storage***

When **LifeSense** is stored or not used for a long period of time it can be stored safely in its original shipping case. The same applies if it needs to be shipped or sent for service. Refer to device specification in this chapter.



**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***

<b>Power Ratings</b>	<b>Unit</b>
Rated supply voltages or voltage ranges for the battery charger US / Canada	120 VAC / 60 Hz
Input voltage to <b>LifeSense</b> from the battery charger	12 VDC, 800mA

<b>Warning</b>	Only use battery chargers that either are supplied with <b>LifeSense</b> or specified by NONIN. See the Accessories List in Chapter 6.
----------------	--

## System Specifications

<b>Power Data</b>	Battery charger:	120 VAC, 60 Hz for USA / Canada
	Power consumption:	3.6 W at battery operation 12 W with battery charger
	Input:	12 VDC, 800mA
<b>Battery Data</b>	Type:	Lithium Ion (Lilon) internal battery, non- field replaceable, rechargeable
	Battery capacity:	8 hours approximately
	Charging time:	17 hours approximately, or 2 hours for each hour of use
<b>Physical Data</b>	Dimensions:	200 x 135 x 50 mm (7.9 x 5.3 x 2 inches)
	Weight:	800 gram (1.8 lbs)
<b>Operation</b>	Working temperature:	23° – 104°F (-5° – +40°C)
	Humidity:	10 – 95% (non-condensing)
	Atmospheric pressure:	860 – 1060 hPa
<b>Storage</b>	Storage temperature:	-4° – +122°F (-20° – +50°C)
	Humidity:	10 – 90% (non-condensing)
	Atmospheric pressure:	up to 4 atmosphere (110 - 4050 hPa)
<b>Pump</b>	Pump flow:	75ml/min
	Flow accuracy:	±15ml/min
<b>Alarms</b>	Sound pressure level:	65 dBa maximum at 1m in front of monitor

### **Classification** per IEC 60601-1/CSA601.1/UL60601-1:

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: IPX1

## **Pulse Oximeter Specifications**

<b>Displayed Oxygen Saturation Range (SpO<sub>2</sub>)</b>	0 to 100%	
<b>Displayed Pulse Rate Range</b>	18 to 255 beats per minute (BPM)	
<b>Measurement Wavelengths*</b>	Red: 660 nanometers @ 0.8 mW max. average Infrared: 910 nanometers @ 1.2 mW max. average	
<b>Saturation Accuracy (A<sub>rms</sub>) **</b>	70-100%	
	<b>Adult / Pediatric</b>	<b>Infant</b>
REUSABLE:		
Finger Clip, Soft Sensor (8000 Series):	± 2 digits	± 3 digits
Flex:	±2 digits	± 3 digits
Reflectance:	±2 digits Adults Only	N/A
DISPOSABLE:		
6000 Series	±2 digits	± 3 digits
7000 Series	± 3 digits	± 4 digits
<b>Pulse Rate Accuracy</b>	8 to 255 beats per minute (BPM)	
	<b>Adult / Pediatric</b>	<b>Infant</b>
REUSABLE		
Finger Clip, Soft Sensor (8000 Series):	± 3 digits	± 3 digits
Flex:	± 3 digits	± 3 digit
Reflectance:	± 3 digits Adults Only	N/A
DISPOSABLE		
6000 Series	± 3 digits	± 3 digits
7000 Series	± 3 digits	± 3 digits
<b>Low Perfusion Pulse Rate Accuracy</b>	40 to 240 beats per minute (BPM)	
	<b>Adult / Pediatric</b>	<b>Infant</b>
REUSABLE:		
Finger Clip, Soft Sensor (8000 Series):	± 3 digits	± 3 digits
Flex	± 3 digits	± 3 digits
Reflectance:	± 3 digits Adults Only	N/A
DISPOSABLE		
6000 Series	± 3 digits	± 3 digits
7000 Series	± 3 digits	± 3 digits

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

\*\* ±1 A<sub>rms</sub> represents approximately 68% of measurements

## **SpO<sub>2</sub> Accuracy Testing**

SpO<sub>2</sub> 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<sub>2</sub>) of the sensors is compared to arterial hemoglobin oxygen (SaO<sub>2</sub>) 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<sub>2</sub> range of 70 – 100%. Accuracy data is calculated using the root-mean-squared (A<sub>rms</sub> value) for all subjects, per ISO 9919:2005, Standard Specification for Pulse Oximeters for Accuracy.

## Capnography Specifications

Respiration range:	3 – 80 respirations/min
Update frequency:	Once every breath (No breath after 25 seconds)
Respiration accuracy:	3 – 50 respirations/min $\pm$ 2 51 – 80 respirations/min $\pm$ 5
ETCO <sub>2</sub> /CO <sub>2</sub> range:	0 – 9.9 kPa, or 0 – 99 mmHg
ETCO <sub>2</sub> /CO <sub>2</sub> accuracy:	$\pm$ 0.2 kPa / $\pm$ 2 mmHg, +6% of reading <sup>†</sup> (ETCO <sub>2</sub> /CO <sub>2</sub> reading reaches its steady state accuracy 10 minutes after power up)
Update frequency:	Once every breath (No breath after 25 seconds)
Sampling rate:	4 Hz
Total system response time:	4 seconds (includes delay time and rise time)
Drift of measurement:	Within CO <sub>2</sub> accuracy specifications for 6 hours of continuous monitoring
Measurement:	BTPS (Body Temperature and Pressure Saturated) Automatic barometric pressure compensation and temperature compensation

<sup>†</sup>Presented concentration of CO<sub>2</sub> and ETCO<sub>2</sub> can be false, indicating a high presence of Nitrous Oxide and Desflurane.

The table below shows the CO<sub>2</sub> and ETCO<sub>2</sub> concentration corrections; any agents not listed do not require correction.

Agent concentration	Correction of Presented CO <sub>2</sub> to real concentration
60-80% N <sub>2</sub> O	Presented CO <sub>2</sub> *0.90=Actual CO <sub>2</sub>
40-60% N <sub>2</sub> O	Presented CO <sub>2</sub> *0.94=Actual CO <sub>2</sub>
0-40% N <sub>2</sub> O	No correction
10-15% Desflurane	Presented CO <sub>2</sub> *0.90=Actual CO <sub>2</sub>
5-10 % Desflurane	Presented CO <sub>2</sub> *0.94=Actual CO <sub>2</sub>
0-5% Desflurane	No correction

The formula used for compensations is:

CO<sub>2</sub> presented = CO<sub>2</sub> measured  $\times$  (1 + K<sub>T</sub>  $\times$  T)  $\times$  (1-K<sub>p</sub>  $\times$   $\Delta$ P), where:

K<sub>T</sub>= Temperature dependency constant defined during production

T = Temperature

K<sub>p</sub> = Pressure dependency constant defined during production


$\Delta$ P = Change of pressure from absolute atmospheric pressure to actual pressure

## Manufacturer's Declaration

See the following tables for specific information regarding this device's compliance to IEC 60601-1-2:2001.

<b>Table 1: Electromagnetic Emissions</b>			
<b>Emissions Test</b>	<b>Compliance</b>	<b>Electromagnetic Environment—Guidance</b>	
<i>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.</i>			
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		
<b>Table 2: Electromagnetic Immunity</b>			
<b>Immunity Test</b>	<b>IEC 60601 Test Level</b>	<b>Compliance Level</b>	<b>Electromagnetic Environment—Guidance</b>
<i>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.</i>			
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.
<b>Note:</b> $U_T$ is the AC mains voltage before application of the test level.			

**Table 3: Guidance and Manufacturer’s Declaration—Electromagnetic Immunity**

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
<p><i>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.</i></p>			
<p>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.</p>			
<p>Conducted RF IEC 61000-4-6</p>	<p>3 Vrms 150 kHz to 80 MHz</p>	<p>3 V</p>	<p><b>Recommended Separation Distance</b>  <math>d = 1.17 \sqrt{P}</math></p> <p><math>d = 1.17 \sqrt{P}</math> 80 MHz to 800MHz  <math>d = 2.33 \sqrt{P}</math> 800MHz to 2.5 GHz</p> <p>where <math>P</math> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <math>d</math> is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,<sup>a</sup> should be less than the compliance level in each frequency range.<sup>b</sup></p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>Radiated RF IEC 61000-4-3</p>	<p>3 V/m 80 MHz to 2.5 GHz</p>	<p>3 V/m</p>	This content is merged into the previous cell for better readability
<p><b>Notes:</b></p> <ul style="list-style-type: none"> <li>At 80 MHz and 800MHz, the higher frequency range applies.</li> <li>These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.</li> </ul> <p>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.</p> <p>b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [3] V/m.</p>			

**Table 4: 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.*

Rated Maximum Output Power of Transmitter W	Separation Distance According to Frequency of Transmitter		
	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 800MHz, 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.

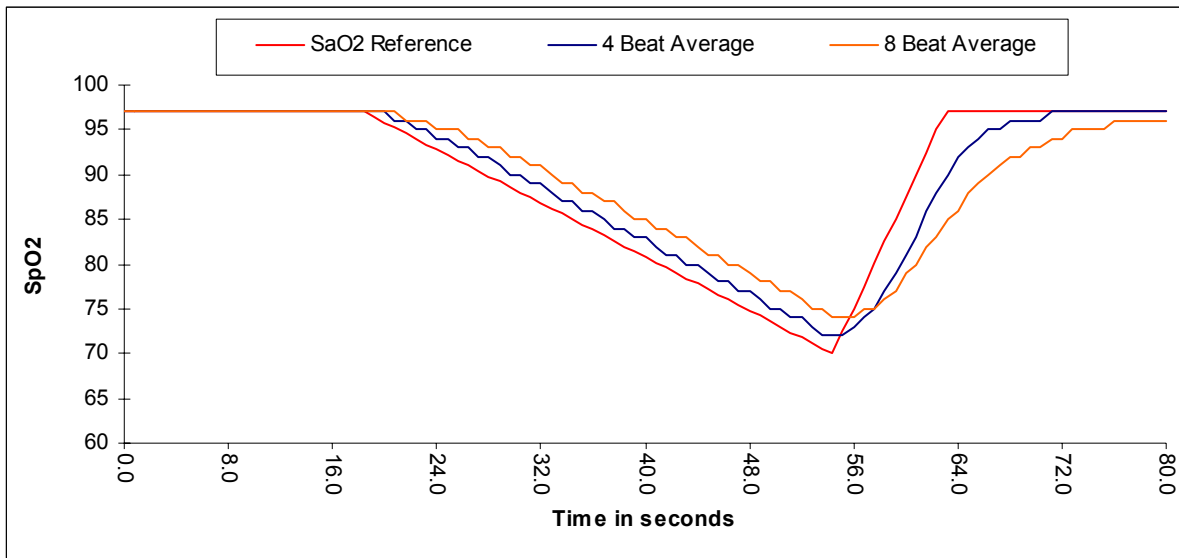
### Pulse Oximeter Response Time

SpO2 Values	Average	Latency
Standard/Fast Averaged SpO2	4 beat exponential	2 beats


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

#### EXAMPLE: SpO2 Exponential Averaging

SpO2 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.

	<p><b>Caution:</b> A functional tester cannot be used to assess the accuracy of a pulse oximeter module or sensor.</p>
---	--

## 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 & Canada)  
Fax +1 (763) 553-7807  
E-mail: [mail@nonin.com](mailto:mail@nonin.com)[www.nonin.com](http://www.nonin.com)

### Warranty

NONIN MEDICAL, INCORPORATED, (NONIN) warrants to the purchaser, for a period of one year from the date of purchase, each LifeSense battery and touch panel display screen. NONIN warrants the LifeSense monitor for a period of three 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.

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.

## QUICK STEP with LifeSense LS1-9R



### To start

1. Visually inspect the monitor, pulse oximeter sensor and sample line to make sure it has no visual signs of damage. Make sure that the NONIN-branded PureLight® reusable finger clip sensor is clean, if previously used.
2. Use a new sample line, moisture trap and filter for each patient.
3. For AC power, plug the **LifeSense** battery charger into a power outlet.
4. Connect the pulse oximeter sensor to the connector on the monitor's side with the SpO2 symbol.
5. Replace the moisture trap and filter after each patient use. Connect the sample line to the luer lock connector on the moisture trap.
6. Place the patient in a resting position; apply the NONIN-branded PureLight® finger clip sensor and the sample line to the patient.
7. Turn on the monitor with the ON/OFF  button. Keep it pressed until you hear a beep.
8. Verify that all parameters are displayed. Adjust alarm limits according to the patient.


### Alarm

-  Change Settings - Increase alarm limits with ; decrease with .
- Sound alarm - Check the patient status and take necessary medical action.
-  Audible alarm pause button – Pause/activate the audible alarm. It will stay turned off for approximately 2 minutes.

### Battery

-  Indicates remaining battery capacity.
- **LifeSense** can run on battery for approximately 8 hours, when fully charged.
- The green light indicator  comes on as soon as the monitor is connected to the power outlet and also indicates that the battery is being charged.

### When finished

1. Turn off the monitor with the ON/OFF  button.
2. Disconnect the pulse oximeter sensor and sample line from the patient. Properly dispose the sample line and filter after each patient use.
3. Plug the **LifeSense** into a power outlet to charge the battery.



Prior to using **LifeSense** it is necessary for each user to read the Operator's Manual.