Operator's Manual

RespSense™ LS1R-9R

Capnography Monitor

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

RespSense is a lightweight, portable, battery-operated monitor that measures and displays carbon dioxide in expired air ($EtCO_2$), and respiration rate of 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 RespSense in an MR environment or in the presence of flammable anesthetics or gases.
Do not use RespSense during defibrillation.

Warnings

RespSense is intended only as an adjunct in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.
RespSense 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 RespSense monitors in one care area.
To prevent improper performance and/or injury to the patient, verify compatibility of the monitor and accessories before use.
No modifications to this device are allowed as it may affect device performance.
Never allow liquids to enter into or to be spilled onto the monitor. If liquid has penetrated into the monitor, it must be checked by Nonin Technical Service.
Accessories marked “single-use” must be used on one patient only and be disposed of after usage.
Use only power supplies that either are supplied with RespSense or specified by Nonin (see “Accessories”).
If RespSense fails to respond as described, discontinue use and contact Nonin Technical Service.
Use only Nonin-recommended accessories and replacement parts.
RespSense 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.
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.
Ensure that all alarm volumes are audible in all situations. Do not cover or obstruct any speaker openings.

Warnings

Prior to connecting RespSense 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 outlet. If this is not the case, do not connect the monitor and power supply to the outlet.
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

RespSense 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 RespSense with mounting hardware if used in transport vehicles.
Do not mount RespSense 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 moisture trap and/or filter.
Portable and mobile RF communications equipment can affect medical electrical equipment.
Do not sterilize or autoclave the monitor or accessories. Do not immerse in liquids.
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.
Each time the system is turned on, alarms are silenced for 2 minutes unless the operator presses the Audible Alarm Pause/Resume button.
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 the alarm limits are appropriate for the patient being monitored.
The patient’s nasal passage may dry out if continuous monitoring is required. Check patient hourly for nasal comfort.

Cautions (Continued)

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 moisture trap and repeat the calibration procedure. If the problem persists, contact Nonin Technical Service.
If RespSense 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 RespSense where condensation can occur. However, if this has occurred, wait until all condensation has evaporated before using RespSense.
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, 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.
Be careful not to drop RespSense on the floor or strike it against hard surfaces. If such an incident happens, do not use RespSense until a functional test has been carried out.
Never open the monitor housing/case. By opening the case you render your warranty invalid.
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.
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 RespSense 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 RespSense monitor.

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.
	Serial interface. Used with either TrendSense™ data memory module or NC1, Nurse Call Accessory.
	Indoor use only
	Class II, double insulated
	Date of manufacture

Introduction

About RespSense

RespSense allows healthcare professionals to non-invasively monitor capnometry on either intubated or spontaneously breathing patients.

When measuring $EtCO_2$, the patient is attached to the monitor by a sample line that can be an airway adapter for an endotracheal tube, a nasal cannula, or a nasal cannula with supplemental oxygen delivery. A variety of sample lines can be used and connected to a specially designed moisture trap, which is easily snapped into the slot on the left side of the monitor. The sampling lines or cannulas can be used with or without Nafion® tubing. Use only those accessories and replacement parts recommended by Nonin. Refer to the “Accessories” section for more information.

RespSense 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.

RespSense 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. RespSense 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.

Operator Requirements

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

Displays and Controls

A standard RespSense set-up consists of a monitor, moisture trap with filters, 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 Views

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

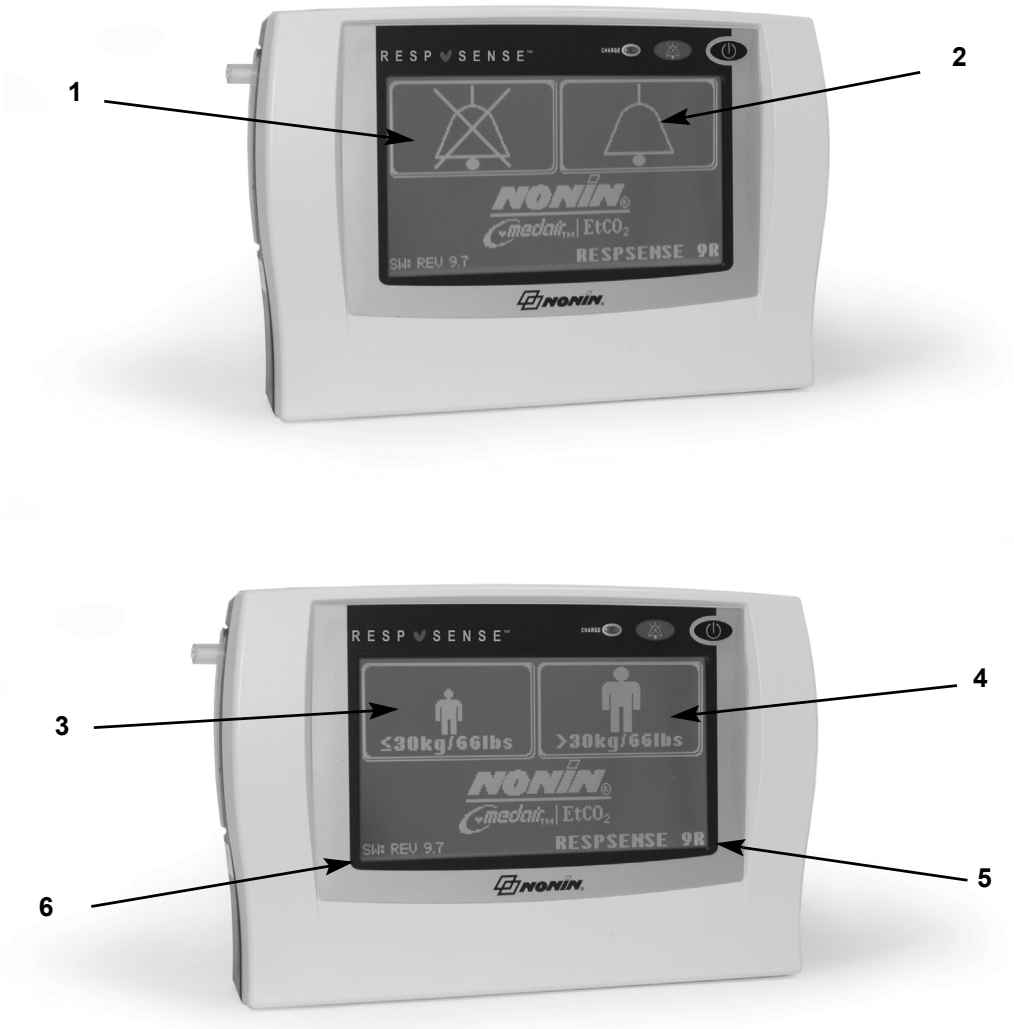


Figure 1: Start-up Screens

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	RespSense Version	Shows RespSense 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 RespSense monitor.

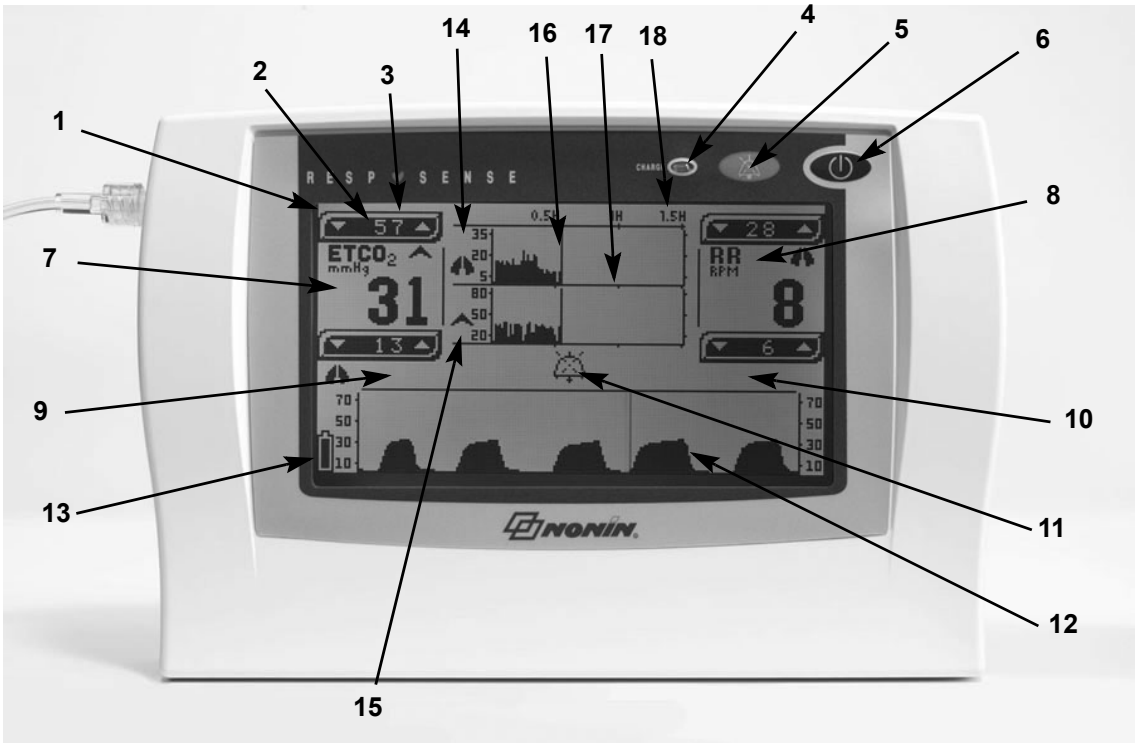


Figure 2: Operating and Trend Screen

Table 2: Device 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 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 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 the audible alarm by pushing the Audible Alarm Pause/Resume button. Alarms will be inactive for approximately 2 minutes or until the operator presses the Audible Alarm Pause/Resume button again. This button does not disable the visual alarms. The current alarm status displays on the LCD (see #11 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.
7	$ETCO_2$	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.
8	RR	Displays the respiratory rate in breaths per minute. The value is the mean of four breaths.
9	Status Text	Shows alarm messages for the battery. See “Alarms” section for more information.
10	Status Text	Shows alarm messages for the capnometer. See “Alarms” section for more information.
11	Alarm Symbol 	Space for alarm symbol. No symbol means audible alarms are enabled. A bell with broken lines indicates that audible alarms are paused. A bell with solid lines indicates that audible alarms are disabled.
12	Respiration Graph	Displays a graph of the CO_2 in expired air (capnograph).
13	Battery Indicator	Displays the battery status. See “Checking Battery Capacity” for more information.
14	Trend RR	Displays a trend graph of the respiration rate. This scale is fixed and cannot be changed.

Table 2: Device Icons and Display Descriptions (Continued)

No.	Name	Description
15	Trend $ETCO_2$	Displays a trend graph of the $ETCO_2$ values. This scale is fixed and cannot be changed.
16	Trend Cursor	A trend cursor points out where the actual sample is in the time interval.
17	Trend Timescale	Timescale is presented in half-hour segments.
18	Trend Time	The total trend time is approximately 1.5 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 RespSense (figure 3). Names and descriptions of each component are listed in table 3.

Figure 3: Rear View of Monitor

Table 3: 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 RespSense 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 4. Names and descriptions of each component are listed in table 4.

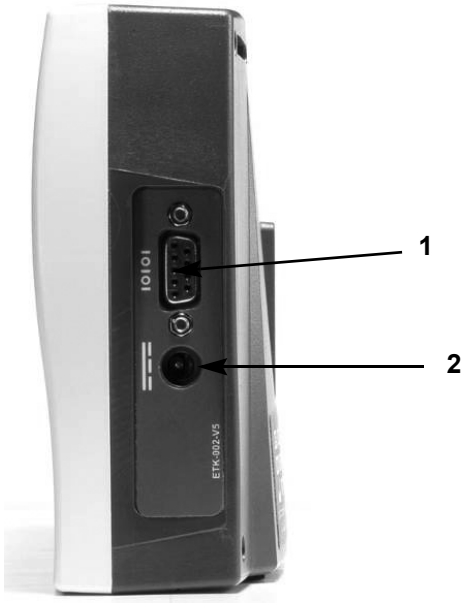


Figure 4: Right Side of Monitor

Table 4: 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.

Using the RespSense Monitor

After unpacking the monitor and accessories, RespSense is ready for use. Ensure the RespSense 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 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 RespSense monitor on by pressing the ON/OFF ⏻ button until you hear a beep.

WARNING: Prior to connecting RespSense 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 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 RespSense 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 RespSense power supply into the power outlet as soon as there is no need for battery operation.

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

Mounting

RespSense 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 RespSense 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 RespSense with mounting bracket if used in transport vehicles.

CAUTION: Do not mount RespSense 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 onto the pole may result in tipping, damage to the equipment, or injury.

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. RespSense 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 RespSense 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, moisture trap, Nafion tubing, and filter are single-use disposable components. Dispose all components in accordance with your local, state, or national regulations regarding waste management.

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

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, 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.

1. Place the filter in the moisture trap as shown in figure 5 (1).
2. Slide the moisture trap into position (figure 5, 2) using the guide marks on the back of the monitor.
3. Press the moisture trap into position using the tab (figure 5, 3).
4. To remove the moisture trap and replace the filter, reverse the three steps above.

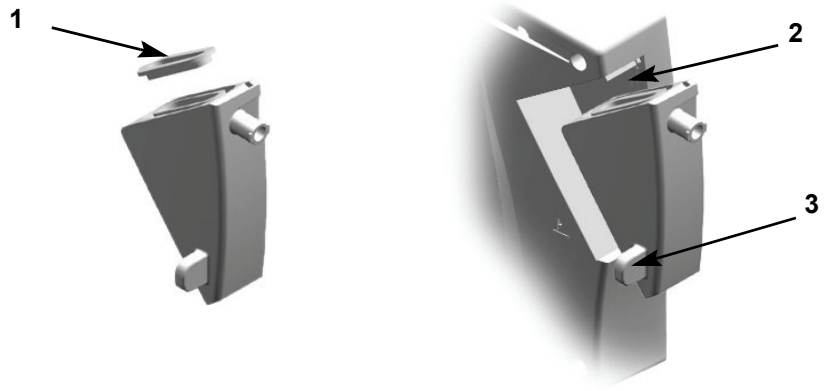


Figure 5: Replacing the Moisture Trap/Filter

Getting Started

Preparations

Visually inspect the monitor and make sure it has no visible signs of damage. 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

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, alarms are silenced for 2 minutes unless the operator presses the Audible Alarm Pause/Resume button.

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. The monitor is now ready for use. The patient can stay connected to the monitor for as long as needed.

⚠ **CAUTION:** Set or adjust alarm parameters one at a time.

Contraindication: Do not use RespSense during defibrillation.

WARNING: RespSense 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 RespSense touch panel display. Each specific parameter is adjusted by using the up/down arrows on the display bar  .

Factory Default Settings

RespSense recalls and displays the factory default settings (table 5) 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 5: Factory Default Settings

Parameter	> 30kg / 66lbs Patient Selected	≤ 30kg / 66lbs Patient Selected
$ETCO_2$ 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

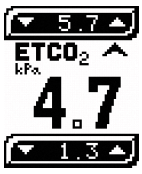
All parameters have built in limits that cannot be exceeded.

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.

Decreases upper limit→ ← Increases upper limit

Decreases lower limit → ← Increases lower limit

⚠ **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 limit, 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).

Alarm Silence

The operator can silence the audible alarm by pressing the Audible Alarm Pause/Resume button . The audible alarms stay deactivated for approximately 2 minutes, unless the operator presses the Audible Alarm Pause/Resume button again during those 2 minutes. 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, 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 6) 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 6: High Priority Alarm Parameters and Causes

Parameter	Cause of Alarm
$ETCO_2$	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 7 for parameters, fault messages, and possible causes.

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 7: Low Priority Alarm Parameters and Causes

Parameter	Message	Possible Cause
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.
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	Touch panel display is not working properly.

*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

RespSense is designed to operate continuously when connected to a power outlet or on battery power for approximately 8 hours. When RespSense 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 RespSense 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.

Low Battery Message

RespSense 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 (LiIon) 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 RespSense, 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 RespSense 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 moisture trap and/or filter.

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 accessories. Do not immerse in liquids.

Calibration

RespSense 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. RespSense 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, RespSense 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 RespSense. **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 RespSense. 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 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. 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 RespSense fails to respond as described, discontinue use and contact Nonin Technical Service.

> ⚠ **CAUTION:** RespSense 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 RespSense on the floor or strike it against hard surfaces. If such an incident happens, do not use RespSense 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

RespSense 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.
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. If the readings are 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

RespSense 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 module. Dimensions 38x32x17mm. TrendSense does not contain a battery; it draws power from the host. PC software and cable included. • TrendSense logs $EtCO_2$ and respiration rate once per second for more than 72 hours. • TrendSense W logs $EtCO_2$ and respiration rate 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 RespSense 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.

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 RespSense 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 RespSense from the power supply	12 VDC, 720 mA

WARNING: Only use power supplies that either are supplied with RespSense 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:	32 °F to 104 °F (0 to 40 °C)
Humidity:	10% to 90% (non-condensing)
Atmospheric Pressure:	720 to 1060 hPa (540 – 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 m in front of monitor
Classification per IEC 60601-1 / CAN/CSA-C22.2 No. 601.1 / UL60601-1:	
Type of Protection:	Internally powered class II (with power supply)
Degree of Protection:	Type BF-Applied Part
Mode of Operation:	Continuous
Enclosure Degree of Ingress Protection:	IPX2

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/min ± 2 51 to 60 respirations/min ± 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 8: 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 9: 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 10: 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 11: 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.			

Equipment Response Time

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

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

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 RespSense battery and touch panel display screen. Nonin warrants the RespSense 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 RespSense 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 RespSense 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 RespSense that is found to be within specifications.

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

Accordingly, any sign or evidence of opening RespSense, field service by non-Nonin personnel, tampering, or any kind of misuse or abuse of RespSense, 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.