Operator's Manual

Model 7600

4-Channel Regional Oximeter with Equanox™ Technology and Bluetooth® Wireless Technology

For Display Software

Revision 11 and Higher

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® reserves the right to make changes and improvements to this manual and the products it describes at any time, without notice or obligation.

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References to “NONIN” in this manual shall imply Nonin Medical, Inc.

7839-001-01

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Indications for Use

Nonin's non-invasive Model 7600 4-Channel Regional Oximeter system is intended for use as an absolute real-time adjunct monitor of regional hemoglobin oxygen saturation of blood underneath the sensor. It is intended for spot-checking or continuous monitoring of adult or pediatric patients weighing greater than 40 kilograms (88 pounds). It is intended for use in environments including the operating room, surgical recovery, critical care, emergency room, long-term care, and mobile environments.

Contraindications

Do not use this device in an MR environment.
Explosion Hazard: Do not use in an explosive atmosphere or in the presence of flammable anesthetics or gasses.

Warnings

This device is intended only as an adjunct device in patient assessment. It should not be used as the sole basis for diagnosis or therapy decisions. It must be used in conjunction with other methods of assessing clinical signs and symptoms.
Use only Nonin-branded oximeter pods, sensors, and accessories. These sensors are manufactured to meet the accuracy specifications for Nonin oximeters. Using other manufacturers' sensors can result in improper oximeter performance.
Always inspect the device before use. Do not use a damaged device or sensor. Before using any sensor, carefully read the sensor Instructions for Use, which contains sensor application information for each sensor.
Protect from exposure to water or any other liquid, with or without AC power.
Use the Model 7600 only with power adapters supplied by Nonin Medical.
As with all medical equipment, carefully route patient cables and connections to reduce the possibility of entanglement or strangulation.
Use the Model 7600 Monitor only within its designated range (approximately 100 meters (300 feet) spherical radius from 7600 monitor to remote location). Moving outside this range may cause missing or lost data at the remote monitoring location.
Memory is cleared if error code E06 appears on the display screen.
This device turns off after approximately 30 minutes when in low battery condition.

Warnings (Continued)

If this device is used adjacent to or stacked with other equipment, the device should be observed carefully to verify normal operation.
The battery pack must be installed at all times while the device is operating—even when operating on AC power. Do NOT use the device without batteries.
The use of pods, sensors, accessories, and cables other than those listed in this manual may result in increased electromagnetic emission and/or decreased immunity of this device.
The device Nurse Call and Bluetooth features should not be used as the primary source of alarm notification.
The user must verify the device Bluetooth pairing to ensure the correct patient is remotely monitored.
Ensure all alarm volumes are set appropriately and are audible in all situations. Do not cover or otherwise block any speaker openings.
This device is a precision electronic instrument and must be repaired by qualified technical professionals. Field repair of the device is not possible. Do not attempt to open the case or repair the electronics. Opening the case may damage the device and void the warranty.

⚠ Cautions

The value of data from the system has not been demonstrated in specific disease states.
When using this device in an operating room, it must remain outside the sterile field.
This equipment complies with IEC 60601-1-2 for electromagnetic compatibility (EMC) 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.

⚠ Cautions (Continued)

Exposure to Radio Frequency Radiation. The radiated output power of the display device is far below FCC radio frequency exposure limits. Nevertheless, the device must be used in such a way that the potential for human contact during normal operation is minimized. To avoid the possibility of exceeding FCC radio frequency exposure limits, remain at least 20 cm (8 in.) away from the display unit's internal antenna during normal operation. The monitor has been tested and meets allowed limits for exposure.
Portable and mobile RF communications equipment can affect medical electrical equipment.
Radios and cell phones or similar devices can affect the equipment and must be kept at least 2 meters (6.5 feet) away from the equipment.
Readings of this device may be affected by the use of an electrosurgical unit (ESU). Keep electrosurgical/electrocautery instruments away from the sensors and oximetry pod, as they may cause damage or result in erroneous readings.
This device is designed to determine regional hemoglobin oxygen saturation of blood underneath the sensor. Factors that may degrade performance or affect the accuracy of the measurement include the following: - excessive ambient light or direct sunlight - excessive motion - electrosurgical interference - metal plate or other foreign object in sensor path - moisture on the skin - improperly applied sensor - incorrect sensor type - anemia or low hemoglobin concentrations - cardiogreen and other intravascular dyes - methemoglobin and other dyshemoglobins - hemoglobinopathies - performance has not been verified in the presence of elevated carboxyhemoglobin or bilirubin - non-normocapnic conditions or other conditions that affect blood volume
Batteries are a fire hazard if damaged. Do not damage, mishandle, or disassemble.
Inspect the sensor application sites at least every 2 to 4 hours to ensure correct sensor alignment and skin integrity. Patient sensitivity to the sensor's adhesive may vary due to medical status or skin condition.
Do not autoclave, sterilize, or immerse this device in liquid or use caustic or abrasive cleaning agents. Do not use cleaning agents or cleaning products that contain ammonium chloride.

⚠ Cautions (Continued)

Follow local, state and national governing ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries. Use only Nonin-approved battery packs.
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.
Data is written continuously when the device is on. If the entire memory is filled, portions of the oldest record will be overwritten when a new record begins.
Verify all alarm settings and limits during system startup to ensure that they are set as intended.
A 2-minute alarm silence is automatically engaged at startup.
A functional tester cannot be used to assess the accuracy of the oximeter monitor or sensor.
When running on battery power, pairing must be initiated within 2 minutes of turning the device on or within 2 minutes of pressing the Bluetooth button. After 2 minutes, the Bluetooth portion of the device turns off to conserve power.
If this device fails to respond as described, discontinue use until the situation is corrected by qualified technical professionals.

Declaration of Conformity with FCC and Canadian Ministry of Health Rules for Electromagnetic Compatibility

- Nonin Medical, Inc., of 13700 1st Avenue North, Plymouth, Minnesota, 55441, declares under its sole responsibility that the Model 7600, to which this declaration relates, comply with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

- Ministry of Health (Canada), Safety Code 6: standards include a substantial safety margin designed to ensure the safety of all persons, regardless of age and health. The exposure standard for wireless mobile phones employs a unit of measurement known as the Specific Absorption Rate, or SAR. The SAR limit set by the FCC is 1.6W/kg.

Federal Communications Commission (FCC) Notice

This equipment has been tested and found to comply with the limits for a class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy. If not installed and used in accordance with the instructions, it may cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on. The user is encouraged to try to correct the interference by one or more of the following measures: (1) Reorient or relocate the receiving antenna, (2) Increase the distance between the equipment and the receiver, (3) Connect the equipment to an outlet on a circuit different from the outlet where the receiver is connected, or (4) Consult the dealer or an experienced radio/TV technician for assistance.

The Model 7600 is designed and manufactured not to exceed the emission limits for exposure to radio frequency (RF) energy set by the Federal Communications Commission of the U.S. Government. These limits are part of comprehensive guidelines and establish permitted levels of RF energy for the general population. The guidelines are based on the safety standards previously set by both U.S. and international standards bodies. This EUT has been shown to be capable of compliance for localized specific absorption rate (SAR) for uncontrolled environment/ general population exposure limits specified in ANSI/IEEE Std. C95.1-2005.

The FCC requires the user to be notified that any changes or modifications to this device that are not expressly approved by Nonin Medical, Inc. may void the user's authority to operate the equipment.

NOTE: No modifications to this device are allowed that in any way affect or alter its antenna or antenna configuration.

Guide to Symbols

This chapter describes the symbols that are found on the Model 7600 system or packaging. Detailed information about functional symbols can be found in “Displays, Indicators, and Controls.”

Table 1: Labeling Icons

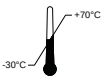
Symbol	Description
	**Caution!**
	Consult instructions for use.
	Defibrillation-Proof Type BF Applied Part (Patient isolation from electrical shock).
	UL Mark for Canada and the United States with respect to electric shock, fire, and mechanical hazards only in accordance with UL 60601-1 30EM and CAN/CSA C22.2 No. 601.1.
	Non-ionizing electromagnetic radiation. Equipment includes RF transmitters; interference may occur in the vicinity of equipment marked with this symbol.
CE 0123	CE Marking indicating conformance to all applicable directives, including EC Directive No. 93/42/EEC concerning medical devices.
SN	Serial Number
LOT	Lot Number
	Indicates separate collection for waste electrical and electronic equipment (WEEE).
EC REP	Authorized Representative in the European Community.
IP32	Protected against vertically falling water drops when enclosure is tilted up to 15 degrees, per IEC 60529.
	Storage/shipping temperature range of -30 °C to 70 °C (-22 °F to 158 °F).

Table 2: Display Icons

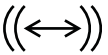
Symbol	Description
$\%rSO_2$	Regional Hemoglobin Oxygen Saturation
HbI	Hemoglobin Index
AUC	Cumulative Saturation Below Reference (Area Under the Curve)
	Sensor Alarm
	AC Power Adapter LED
	Poor Signal
	Pod Communication Lost
	Alarm Silence
	Low Battery
	Adjustable Upper Limit
	Adjustable Lower Limit
	Reference
	Trend
	Alarm Volume
	Brightness

Table 2: Display Icons (Continued)

Symbol	Description
	Clear Memory
	Factory Defaults
	User Defaults
	Nurse Call

Table 3: Button Icons

Symbol	Description
	ON/STANDBY
	Alarm Silence

Table 4: Soft Button Icons

Symbol	Description
	Limits Menu
	Menu
	Event Mark
	Bluetooth
	Plus
	Minus
	Next
	Save

Introduction to the Model 7600

Benefits of the Model 7600 Regional Oximetry System

The Model 7600 Regional Oximetry System with Equanox™ Technology is a fully integrated, digital, Bluetooth-enabled system for measuring regional hemoglobin oxygen saturation (rSO_2) underneath the sensor. It can be used in virtually any common clinical environment where rSO_2 measurements might improve patient outcomes. The following features and user-defined parameters allow the clinical team to adjust the system for the needs of the operating environment.

- 4.5-meter (15-foot) trunk cable and monitor mounting features allow the system to be conveniently located for viewing without interfering with surgical and anesthesiology operations.
- Weighing only 1 kg (2 lbs), this highly mobile system has a 3-hour battery life and 69 hours of memory, which allows for operational flexibility.
- Trend graph timescale is adjustable from 7.5 minutes to 24 hours, making it ideal for virtually all clinical application timeframes, and allowing the clinical team to track relative saturation changes from baseline.
- Saturation value trends can be read from across the room, and reflect the actual percentage of oxygen saturation at that moment.
- Saturation event markers identify critical deviations from acceptable rSO_2 trends and include alphabetical sequencing of events and associated saturation values.
- Area Under the Curve (AUC) displays the integrated, cumulative time and saturation value below a channel's reference setpoint.
- Display brightness adjusts for the lighting conditions in each potential clinical environment.
- Alarm thresholds and volumes are also adjustable to signal intervention at the clinician's discretion, and to compensate for ambient noise in each unique clinical operating environment.
- The Nurse Call feature integrates into standard hospital systems.
- RS-232 serial data port allows the 7600 to connect to a PC or an external monitoring system via a serial cable.

Setting Up the Model 7600 Monitor

Carefully remove the monitor and accessories from the shipping carton. Save the packaging materials in case the monitor or accessories must be returned. Compare the packing list with the accessories received to make sure the shipment is complete. The monitor includes these non-sterile components:

- 7600, Regional Oximeter Monitor (figure 1)
- 7600TC-1, Two-Channel Trunk Cable
- 7600B or 7600PA, Regional Oximeter Pods (qty 2)
- Operator's Manual
- 7800 PS, Power Supply, 25W
- eVision Patient Data Management Software

The Four-Channel Accessory Kit includes these components:

- 7600TC-2, Four-Channel Trunk Cable
- 7600B or 7600PA, Regional Oximeter Pods (qty 2)

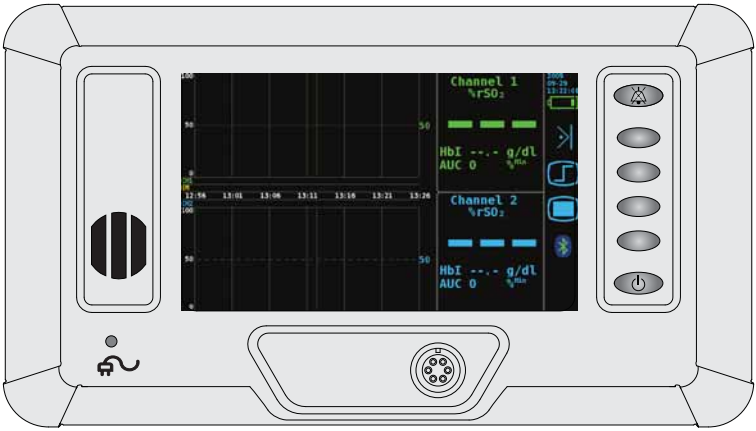


Figure 1: Model 7600 Regional Oximeter Monitor

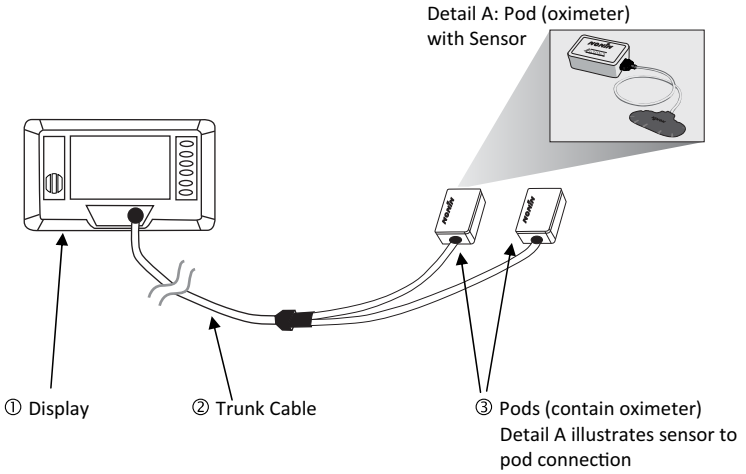


Figure 2: Setting Up the Monitor (Two-Channel Trunk Cable Shown)

Sensor Application

Refer to the sensor Instructions for Use (IFU) for proper sensor application sites, and sensor application cautions and warnings.

WARNING: This device is intended only as an adjunct device in patient assessment. It should not be used as the sole basis for diagnosis or therapy decisions. It must be used in conjunction with other methods of assessing clinical signs and symptoms.

WARNING: As with all medical equipment, carefully route patient cables and connections to reduce the possibility of entanglement or strangulation.

Bluetooth Technology

Bluetooth allows wireless connections between electronic communications and computing devices. The technology is based on a radio link that offers fast and reliable data transmissions. Bluetooth uses a license-free, globally available frequency range in the ISM band—intended to ensure communication compatibility worldwide.

Nonin's use of Bluetooth wireless technology allows regional oxygen saturation information to be transmitted through a Bluetooth radio to a compatible Bluetooth-enabled device. Nonin's wireless system removes the connection from the monitor to a remote monitor location, giving increased ability to move the monitor freely. Nonin's 7600 monitor uses an automatically switchable class I/class II Bluetooth radio with a maximum range of about 100 meters (328 feet) (spherical radius).

The Model 7600 features point-to-point communications, allowing one master device (the remote monitor) to be paired to one slave device (the 7600 monitor). Once connected, the 7600 monitor will not connect with any other Bluetooth-enabled device.

Battery

Battery capacity: 7.2 V Li-ion battery pack, 2.4 Ah when charged with the Model 7600

Operating life (fully charged battery): 3 hours minimum

Storage life: 20 day minimum

Recharge time to 90% capacity: 2.5 hours maximum

CAUTIONS:

- Follow local, state and national governing ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.
- Use only Nonin-approved battery packs.
- Batteries are a fire hazard if damaged. Do not damage, mishandle, or disassemble.

Displays, Indicators, and Controls

This chapter describes the displays, indicators, and controls for the Model 7600.

Figure 3 shows operation when pods are only connected to channels 1 and/or 2. If pods are connected to channels 3 and/or 4, the system will automatically display all four channels (figure 4) (four-channel accessory kit required).

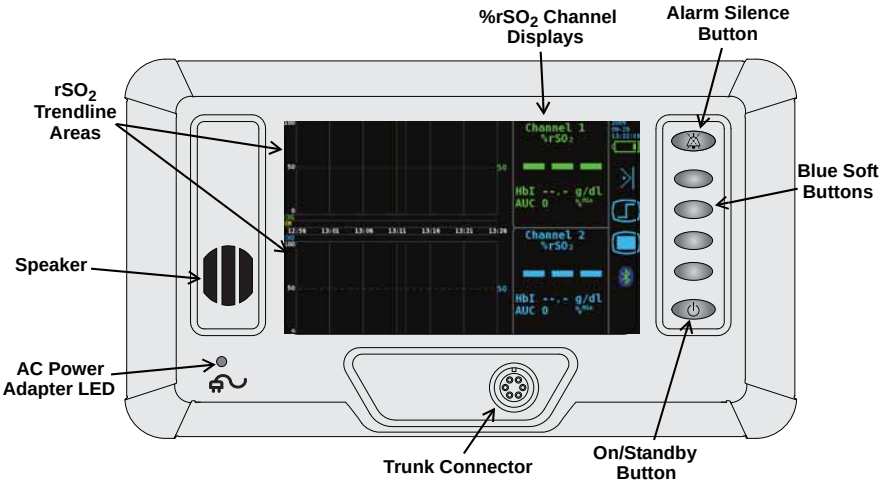


Figure 3: Model 7600 Controls and Indicators with Two-Channel Display

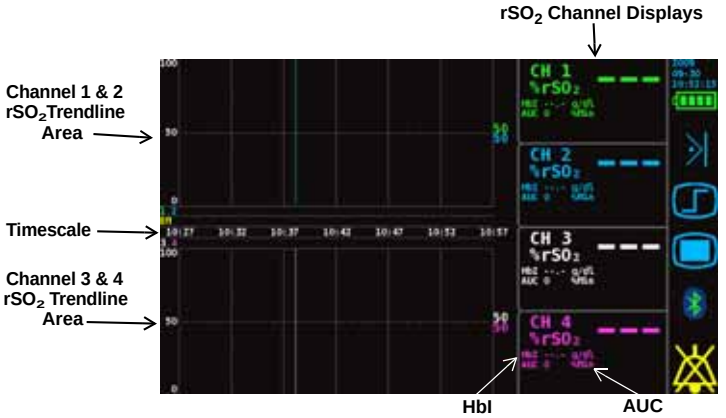


Figure 4: Four-Channel Display

Displays

%rSO_2 Displays

The rSO_2 displays, located on the right side of the 7600 monitor front panel, show %rSO_2 blood oxygen saturation from 0 to 100%. The device continually displays an rSO_2 trendline for each monitored channel. The numeric display flashes:

- YELLOW during medium priority alarm conditions (rSO_2 values less than 5% above the rSO_2 low alarm limit).
- RED during high priority rSO_2 alarm conditions (set by the high and low rSO_2 alarm limits).

Hemoglobin Index (HbI) Display

The Hemoglobin index is displayed under the %rSO_2 for each monitored channel. Local hemoglobin measurements display in units of grams per deciliter. There are no alarms for HbI.

NOTE: Hemoglobin index is not available for all sensors.

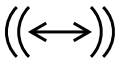
Cumulative Saturation Below Reference Display (AUC)

NOTE: In order for the AUC display to match the Society of Thoracic Surgeons (STS) database definition, the reference values for each channel must be set to 75% of the patient's baseline.

The saturation values below the reference setpoint for each channel are integrated together and displayed as the cumulative saturation below reference, also known as AUC (Area Under the Curve). The value is expressed in units of % minute (%Min). When a reference value is changed, the AUC resets to 0 and begins integrating only the data after that point. A dashed vertical line on the trendline display indicates when a reference was changed.

Indicators and Controls

Table 5: Display Indicators and Icons

Symbol	Description
	**Sensor Fault** This yellow indicator flashes when a sensor is disconnected, has failed, or is not compatible with the monitor.
	**Poor Signal** This yellow indicator flashes when there has been a sustained period of poor patient signals from the sensor. Check the sensor site and reposition or replace the sensor if necessary.
	**Pod Communication Lost** This yellow indicator flashes when the respective pod has stopped communicating with the display. Check the pod connections or replace the pod to correct the issue.
	**Alarm Silence** This yellow indicator flashes once every 2 seconds when the audible alarm is silenced for 2 minutes. When the audible alarm volume setting is “4” or less, the indicator is solidly lit.
	**AC Power Adapter LED** This light-emitting diode (LED) indicator is lit when an external power supply is providing power to the Model 7600. It is YELLOW when the battery pack is charging and GREEN when the battery pack is fully charged.
	**Battery** The battery indicator shows the approximate percentage of battery life remaining. When AC power is connected, the battery indicator fills up repeatedly to indicate the battery is charging. The indicator stops filling when the battery is fully charged.

NOTE: When the 7600 reaches a critical battery condition, a medium priority alarm will sound. To clear the alarm, charge the battery. Also, during critical battery the display blanks unless there was an alarm active when the device went into critical battery. When that is the case, the display(s) that had the alarm conditions show dashes in critical battery mode.

Table 6: Front Panel Buttons

Symbol	Description
	**ON/STANDBY** Pressing this button once turns on the Model 7600. When on, pressing this button for at least 1 second shuts down the 7600, putting it into Standby mode. In Standby mode, all device functions are shut off, with the following exceptions: • The AC Power Adapter LED is lit whenever the device is plugged in. • Batteries are charged whenever the device is plugged in.
	**Alarm Silence** This button toggles alarms between silenced and audible. Pressing the Alarm Silence button silences the alarm for 2 minutes. Pressing it again (while alarms are silenced) returns the alarms to their audible mode.

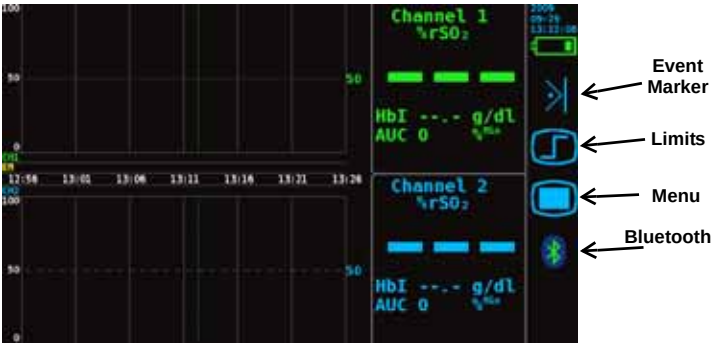


Figure 5: Model 7600 Main Menu Screen Buttons

Table 7: Main Menu Buttons

Symbol	Description
	**Event Marker** Pressing this button marks an event in memory and on the trendline. Events are denoted by increasing alphabetic letters.
	**Limits** This button allows the user to display or change the upper and lower limits for alarm indications for rSO_2 measurements. It also allows a user to set a reference value for each channel.
	**Menu** Pressing the Menu button allows users to access advanced menu options, including trendline timescale, memory clear, number of displayed trendlines, brightness, alarm volume, date/time, and the USER Menu. All adjustments can be made using the Plus (+) and Minus (-) buttons.
	**Bluetooth** The Bluetooth button activates the internal Bluetooth module for pairing with host devices. It also displays pairing information for the device. The Bluetooth symbol is green when Bluetooth is connected to a host, white when it is enabled but not connected, and gray when it is disabled.

Figure 6: Model 7600 Limits Menu Screen Buttons

Table 8: Limits Menu Buttons

Symbol	Description
+ −	**Plus (+) and Minus (-)** These buttons adjust values for time, date, volume, and upper and lower alarm limits.
↵	**Next** Use this button to move to the next option.
💾	**Save** Press this button to exit a menu. It saves the changed settings within each menu while the device is on. If the device is turned off and then back on, the active default settings (User-Defined Defaults or Factory Defaults) are used for limits and settings.

Using the Model 7600 Regional Oximeter Monitor

NOTES:

- Before using the Model 7600, please review all contraindications, warnings, and cautions.
- Before using the Model 7600 for the first time, the battery should be charged for 4 hours.

Verifying System Operation

Press **ON/STANDBY** ⏻. Each time the unit is turned on, the 7600 performs a brief initialization sequence:

1. The LCD display lights up and displays the Nonin logo.
2. An audible tone sounds.
3. Software revisions for all microcontrollers, including connected oximeter pods, display on the LCD.
4. The default alarm limits display on the LCD.

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

Connecting Devices with Bluetooth

The Bluetooth screen (figure 7) is used to connect (pair) the display device with output devices via Bluetooth.

Figure 7: Bluetooth Screen

How to Determine the Bluetooth Information for the Model 7600

1. To enter the Bluetooth screen, press the **Bluetooth** soft button.
2. Note the Bluetooth address on the screen. This address must be chosen at the host computer.
3. The Bluetooth symbol is green when Bluetooth is connected to a host, white when it is enabled but not connected, and gray when it is disabled.

CAUTION: When running on battery power, pairing must be initiated within 2 minutes of turning the device on or within 2 minutes of pressing the Bluetooth button. After 2 minutes, the Bluetooth portion of the device turns off to conserve power.

WARNING: The user must verify the device Bluetooth pairing to ensure the correct patient is remotely monitored.

Event Mark

The Event Mark button is used to place a mark on the displayed trendline, in the memory, and in the real time serial data output. Events are marked with increasing alphabetic letters. When Z is reached, the letters start over at A.

How to Mark an Event

1. Press **Event Mark** .
2. The letter and rSO_2 value at that time appear on the screen and are stored in memory.

NOTE: It may take up to 4 seconds for the event mark to appear on the display.

Operating Modes and Defaults

The Model 7600 features Limits mode, Menu mode, User-Defined Defaults, and Factory Defaults.

Limits Mode

In Limits mode, users can adjust alarm limits and review limits settings.

Pressing the Limits button activates Limits mode. All adjustments can be made using the blue soft buttons: Plus (+), Minus (-), Next , and Save .

Limits mode is available when the device is operating. The device saves any changed settings and returns to the monitoring screen after 10 seconds if the user does not press any buttons.

Figure 8: Model 7600 Limits Screen

NOTE: Alarm limits reset to currently active default values each time the unit is powered up.

Reviewing, Setting, or Changing Alarm Limits

How to Set Limits

1. Press **Limits** .
2. Press **Next** to move through the limits to the limit setting to be changed.
3. Use **Plus** (+) and **Minus** (-) to adjust the limit setting.
4. Use **Next** to move through the limits to the next setting to be changed.
5. Repeat steps 3 and 4 as needed.
6. When all limits have been set appropriately, press **Save** to save the settings and return to the monitoring screen.

Table 9: Alarm Limit Setting Options

Alarm Limit	Factory Default	Adjustment Options	Increment
rSO_2 High	Off	Off, 20-95%	1%
rSO_2 Low	50%	Off, 15-90%	1%

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

rSO_2 Reference

A rSO_2 reference can be set so subsequent rSO_2 changes are measured relative to this reference. The display shows a reference line on the trend graph equal to the set reference value. A reference value may be set as a User-Defined Default and it willbe recalled when the device is turned off and back on again. There are no audible or visual alarms specific to this reference value. Alarm values may be set as described in the “How to Set Limits” section above.

As soon as rSO_2 numbers appear on the screen, the device begins plotting trend data on the screen. At this point, if the patient condition is stable, an awake reference reading can be set for each channel in use. For example, in surgical patients, a reference value may be set prior to induction. The reference value may be set to the rSO_2 value displayed by the monitor or to another value against which the operator prefers to measure the saturation change.

Reference lines for channels 2 and 4 are dashed (- - - -); reference lines for channels 1 and 3 are dotted (. . . .). The value of each reference line displays to the right of the trendline area in a color matching the channel's display.

How to Set Reference

1. Press **Limits** .
2. Press **Next** to select “Reference” for the desired channel.
3. Adjust the reference value using **Plus** (+) and **Minus** (-).
4. Repeat steps 2 and 3 to set the reference for the other channels as needed.
5. When the reference values have been set appropriately, press **Save** to save the settings and return to the monitoring screen.

Menu Mode

In Menu Mode, the user may change the trendline selection, timescale, alarm volume, screen brightness, date and time and clear the memory.

Figure 9: Model 7600 Menu Mode Screen

How to Change Trendline Selection

Changing trendline selection allows users to show and hide trendlines for past rSO_2 on the display. It does not affect the data in the device memory, and the absolute rSO_2 numbers still appear on the display for all connected oximeter pods.

1. Press **Menu** .
2. Press **Next** to move through the settings and select the appropriate channel under “Trendlines.”
3. Press **Plus** (+) or **Minus** (-) to change the Trendline to either “On” or “Off.”
4. When all settings have been set appropriately, press **Save** to save the settings and return to the monitoring screen.

How to Change Display Timescale

Display Timescale is the range of data time displayed on the screen. This setting does not affect stored data.

1. Press **Menu** .
2. Press **Next** to move through the settings and select "Timescale."
3. Press **Plus** (+) or **Minus** (-) to change the Timescale to the desired setting. Available settings are 7.5 minutes, 15 minutes, 30 minutes, 1 hour, 2 hours, 4 hours, 8 hours, 12 hours, and 24 hours.
4. When all settings have been set appropriately, press **Save** to save the settings and return to the monitoring screen.

How to Change Alarm Volume

1. Press **Menu** .
2. Press **Next** to move through the settings and select "Alarm Volume."
3. Press **Plus** (+) or **Minus** (-) to adjust the Alarm Volume.
4. When all settings have been set appropriately, press **Save** to save the settings and return to the monitoring screen.

WARNING: Ensure all alarm volumes are set appropriately and are audible in all situations. Keep speaker openings clear of all obstructions.

How to Change Screen Brightness

1. Press **Menu** .
2. Press **Next** to move through the settings and select "Brightness."
3. Press **Plus** (+) or **Minus** (-) to adjust the Brightness setting.
4. When all settings have been set appropriately, press **Save** to save the settings and return to the monitoring screen.

How to Change the Date and Time

1. Press **Menu** .
2. Press **Next** to move through the settings and select the time and date setting.
3. Press **Plus** (+) or **Minus** (-) to change the time and date. Use **Next** to move through the time and date options.
4. When all settings have been set appropriately, press **Save** to save the settings and return to the monitoring screen.

How to Clear Memory

1. Press **Menu** .
2. Press **Next** to move through the settings and select “Clear Memory.”
3. Default setting is NO. Press **Plus** (+) or **Minus** (-) to select YES.
4. Press **Save** .
5. Device asks “Clearing memory. Are you sure?” Press **Plus** (+) or **Minus** (-) to select YES.
6. Press **Save** to delete.
7. Device will confirm deletion by displaying “Clearing Memory.”

USER Menu Mode

The USER Menu mode is used to select the User Mode (factory or user-defined defaults), nurse call settings, and language options.

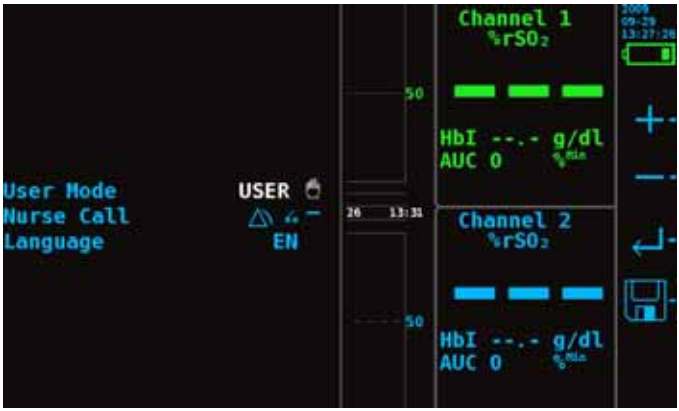


Figure 10: USER Menu Mode Options

How to Enter USER Menu Mode

1. Press **Menu** .
2. Press **Next** to move through the settings and select “USER Menu.”
3. Monitor displays “Press Special Keys.” Press **Plus** (+) and **Minus** (-) at the same time to enter the USER Menu. If Plus and Minus are not pressed at the same time, the device will not enter the USER Menu. This is intended to keep unauthorized operators from changing settings.

4. Use **Plus** (+), **Minus** (-), and **Next** ↵ to change USER Menu settings.
5. When all settings have been set appropriately, press **Save** to save the settings and return to the monitoring screen.

> ⚠ **CAUTION:** Verify all alarm settings and limits during system startup to ensure that they are set as intended.

Factory Defaults

In Factory Defaults, alarm limits are set as indicated in table 10. These are the Model 7600's default operating settings.

The Model 7600 is shipped with factory defaults active.

NOTE: User-Defined Default values are lost when Factory Defaults are set active.

Table 10: Factory Default Alarm Limit Settings

Alarm Limit	Factory Default
rSO_2 High	Off
rSO_2 Low	50%

Default alarm and volume settings are automatically used each time the device is turned on.

How to Restore Factory Defaults

1. Press **Menu** .
2. Press **Next** ↵ to move through the settings and select "USER Menu."
3. Monitor displays "Press Special Keys." Press **Plus** (+) and **Minus** (-) at the same time to enter the USER Menu.
4. Press **Next** ↵ to move through the settings and select "User Mode."
5. Press **Plus** (+) or **Minus** (-) to select "FAC" (Factory Default option).
6. Press **Save** to restore the factory defaults and return to the monitoring screen.

User-Defined Defaults

The Model 7600 recalls User-Defined Default settings at startup whenever this option is selected. Once they are activated, these settings have priority over Factory Defaults. In User-Defined Defaults, default alarm limit and volume settings may be set to any value.

The User-Defined Defaults are rSO_2 high and low alarm limits, rSO_2 reference values, alarm volume, display trendlines, timescale, and brightness.

How to Set User-Defined Defaults

1. Adjust settings to desired User-Default values using the limits and menu modes.
2. Press **Menu** ( ).
3. Press **Next** ↵ to move through the settings and select "USER Menu."
4. Monitor displays "Press Special Keys." Press **Plus** (+) and **Minus** (-) at the same time to enter the USER Menu.
5. Press **Next** ↵ to move through the settings and select "User Mode."
6. Press **Plus** (+) or **Minus** (-) to select "USER" (User Default option).
7. Press **Save** ( ) to set the current settings as the User-Defined Defaults and return to the monitoring screen.

> ⚠ **CAUTION:** Verify all alarm settings and limits during system startup to ensure that they are set as intended.

NOTE: All User-Defined Default settings are retained even when both external and battery power are lost.

NOTE: If the user changes the settings while the User-Defined Defaults are active and then wants to make the new settings the User-Defined Defaults, the user should follow the "How to Set User-Defined Defaults" procedure.

Nurse Call Feature

The Model 7600 Nurse Call feature allows alarm notification at a central monitoring location. The Nurse Call feature functions on AC or battery power. The facility determines the alarm condition as audible, visual, or both.

NOTE: The Nurse Call feature overrides silenced alarms.

NOTE: It is the user's responsibility to implement the interface between the Nurse Call system and the Model 7600, and to adequately test the interface between the Model 7600 and the Nurse Call system to ensure operation.

WARNING: The device Nurse Call and Bluetooth features should not be used as the primary source of alarm notification.

How to Set Up Nurse Call Feature

1. Press **Menu** .
2. Press **Next** to move through the settings and select "USER Menu."
3. Monitor displays "Press Special Keys." Press **Plus** (+) and **Minus** (-) at the same time to enter the USER Menu.
4. Press **Next** to move through the settings and select **"**Nurse Call." Nurse Call can be setup multiple ways to meet a facility's Nurse Call system requirements (see setup options in table 11).
5. Press **Save** to save the Nurse Call setting.

Table 11: Nurse Call Setup Options

Symbol	Description
	Signifies the Nurse Call contact is normally open and the Nurse Call contact is closed during alarm conditions.
	Signifies the Nurse Call contact is normally closed and the Nurse Call contact is open during alarm conditions.
	Signifies a momentary Nurse Call signal. The Nurse Call contact temporarily changes state at the onset of an alarm condition.
	Signifies a continuous Nurse Call signal. The Nurse Call contact continuously changes state during an alarm condition. It only reverts to the original non-alarm state when the alarm condition is cleared.

Language Options

This feature allows the user to change the language displayed on the monitor. Language options are:

- EN - English
- FR - French
- DE - German
- NL - Dutch
- IT - Italian
- SV - Swedish
- ES - Spanish
- PT - Portuguese
- EL - Greek

How To Change the Displayed Language

1. Press **Menu** .
2. Press **Next** to move through the settings and select “USER Menu.”
3. Monitor displays “Press Special Keys.” Press **Plus** (+) and **Minus** (-) at the same time to enter the USER Menu.
4. Press **Next** to move through the settings and select “Language.”
5. Press **Plus** (+) or **Minus** (-) to scroll through the language selections and select the desired language for the display.
6. Press **Save** to save the language selection. The monitor displays in the selected language each time the device is used.

Alarms

The Model 7600 has audio and visual alarm indicators to alert the operator in case immediate patient attention is required or an equipment alarm occurs.

High Priority Alarms

High priority alarms require immediate attention to the patient. They include high and low rSO_2 alarms. On the Model 7600, the high priority alarm is as follows:

Alarm	Visual Indicator	Audible Indicator
rSO_2 Limit (rSO_2 equal to or above high alarm limit or rSO_2 equal to or below low alarm limit)	rSO_2 background flashes in RED at 2 times per second.	3 beeps, pause, 2 beeps, and a 10-second pause. This cycle repeats until silenced.

Medium Priority Alarms

Medium priority alarms signal potential problems with the equipment or other non-life-threatening situations. They include rSO_2 warning, low battery, critical low battery, and rSO_2 sensor fault.

Medium priority alarms sound as 3 beeps followed by a 25-second pause. This cycle repeats until silenced. On the Model 7600, medium priority alarms are visually indicated as follows:

Alarm	Visual Indicator
rSO_2 Warning (rSO_2 5% or less above low rSO_2 alarm limit)	rSO_2 background flashes YELLOW once every 2 seconds.
Low Battery	Battery indicator flashes YELLOW once every 2 seconds.
Critical Low Battery	Battery indicator flashes RED once every 2 seconds, parameters with alarms show dashes.
rSO_2 Sensor Alarm	Sensor alarm indicator flashes YELLOW once every 2 seconds.
Pod Communication Error	Pod Communication indicator flashes YELLOW once every 2 seconds.
Poor Signal	Poor Signal indicator flashes YELLOW once every 2 seconds.

Silencing Alarms

Press **Alarm Silence** to silence alarms for 2 minutes. Audible alarms may be reactivated before the 2 minute silence period is over by pressing Alarm Silence again. All silenced audible alarms are automatically reactivated when a new physiological alarm goes off.

The yellow Alarm Silence icon blinks while alarms are temporarily silenced.

The yellow Alarm Silence icon is lit solidly when the alarm volume setting is “4” or less. Audible indicators can be turned off in the Limits menu by selecting “0” in the Alarm Volume menu option.

Error Codes

This device includes error codes that indicate problems with the unit. When an error occurs, the device emits a loud, two-tone, steadily beeping signal and an error code displays on the monitor screen. Error codes are indicated by the letter “E” and a two-letter code (table 12).

To correct error conditions, perform these steps:

1. Turn the unit off and then back on again to remove the error code.
2. If the error persists, note the error code and contact Nonin Technical Service at (800) 356-8874 (USA and Canada) or +1 (763) 553-9968.

Table 12: Error Codes

Error	Visual Indicator
Stuck Key	E01
Sound Module Fault	E02
Sound Module Communications Fault	E03
Oximeter Communications Fault	E04
Memory Alarm **WARNING: Memory is cleared if error E06 appears on the display screen.**	E06
Critical Battery	E08

Memory and Data Output Features

The Model 7600 provides real-time patient data output for rSO_2. The device may be connected to a PC via a Bluetooth connection or using the RS-232 serial data port on the back of the 7600 monitor (figure 11).

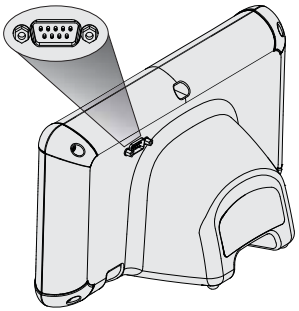


Figure 11: RS-232 Serial Data Port

NOTE: Use only a null modem serial cable to connect the Model 7600 to a PC.

NOTE: Verify Bluetooth status as follows: The Bluetooth symbol is green when Bluetooth is connected to a host, white when it is enabled but not connected, and gray when it is disabled. To enable the Bluetooth module for 2 minutes when running on battery, press the Bluetooth button.

Patient Data Output

This device features real-time data output capabilities. The data format includes an ASCII header containing model number, time, and date information.

Data from the device are sent once per second in the following format:

Ch1=XXX Ch2=XXX Ch3=XXX Ch4=XXX 1234&$*|
yyyy-mm-ddThh:mm:ss|rSO2=xxx,xxx,xxx,xxx|HbI=xx.x,xx.x,xx.x,xx.x|
AUC=xxxx,xxxx,xxxx,xxxx|REF=xxx,xxx,xxx,xxx|HI_LIM=xxx,xxx,xxx,xxx|
LOW_LIM=xxx,xxx,xxx,xxx|ALM=xxx,xxx,xxx,xxx|SIG_QUAL_ALM=x,x,x,x|
POD_COMM_ALM=x,x,x,x|SNS_FLT=x,x,x,x\LCD_FLT=x\
LOW_BATT=x\CRIT_BATT=x\BATT_FLT=x\STK_KEY=x\SND_FLT=x\
SND_ERR=x\EXT_MEM_ERR=x\CKSUM=xxxx<CR><LF>

Table 13: Data Output Format

Parameter	Value	Following Delimiter
Ch1=XXX	Channel 1 regional oximeter value. Leading zeros blank; --- if no value available.	space
Ch2=XXX	Channel 2 regional oximeter value. Leading zeros blank; --- if no value available.	space
Ch3=XXX	Channel 3 regional oximeter value. Leading zeros blank; --- if no value available.	space
Ch4=XXX	Channel 4 regional oximeter value. Leading zeros blank; --- if no value available.	space
1234	Patient alarm indication for channel 1,2,3,4. Appears only if a channel's patient alarm is active. If not active, number does not appear (e.g., 14 means channel 1 and 4 patient alarms are active).	none
&	Appears if an equipment alarm is active.	none
$	Appears if the critical battery state is detected.	none
*	Appears if the event is marked.	|
yyyy-mm-ddThh:mm:ss	International date and time format: year, month, day, hour, minutes, seconds.	|
rSO2=xxx,xxx,xxx,xxx	Regional oximetry values for channels 1,2,3,4 in %. Leading zeros blank; --- if no value available.	|
HbI=xx.x,xx.x,xx.x,xx.x	Hemoglobin index values for channels 1,2,3,4 in grams per deciliter. Leading zeros blank; --- if no value available.	|
AUC=xxxx,xxxx,xxxx,xxxx	Area under curve for channels 1,2,3,4. Leading zeros blank.	|
REF=xxx,xxx,xxx,xxx	Reference line values for channels 1,2,3,4. Used to calculate AUC. Leading zeros blank.	|
HI_LIM=xxx,xxx,xxx,xxx	High limit alarm setting for channels 1,2,3,4. Leading zeros blank.	|
LOW_LIM=xxx,xxx,xxx,xxx	Low limit alarm setting for channels 1,2,3,4. Leading zeros blank.	|
ALM=xxx,xxx,xxx,xxx	Active alarm indication for channels 1,2,3,4. Valid values: HI, MAR (marginal), LOW, OFF.	|
SIG_QUAL_ALM=x,x,x,x	Signal quality alarm indication for channels 1,2,3,4. 0 = no active alarm; 1 = active alarm.	|

Parameter	Value	Following Delimiter
POD_COMM_ALM=x,x,x,x	Pod communication alarm indication for channels 1,2,3,4. 0 = no active alarm; 1 = active alarm.	|
SNS_FLT=x,x,x,x	Sensor fault indication for channels 1,2,3,4. 0 = no active alarm; 1 = active alarm.	|
LCD_FLT=x	Display fault indicator. 0 = no fault active; 1 = fault active.	\
LOW_BATT=x	Low battery indicator. 0 = no low battery state; 1 = low battery state.	\
CRIT_BATT=x	Critical battery indicator. 0 = no critical battery state. 1 = critical battery state.	\
BATT_FLT=x	Battery fault indicator. 0 = no battery fault; 1 = battery fault active.	\
STK_KEY=x	Stuck key fault indicator. 0 = no stuck key fault active. 1 = stuck key fault active.	\
SND_FLT=x	Sound fault indicator. 0 = no sound fault active. 1 = sound fault active.	\
SND_ERR=x	Sound error indicator. 0 = no sound error active. 1 = sound error active.	\
EXT_MEM_ERR=x	External memory error indicator. 0 = no external memory error active. 1 = external memory error active.	\
CKSUM=xxxx	Hexadecimal representation of all parameters and values beginning with the “C” in “Ch1=” and ending with the value of “EXT_MEM_ERR.” Leading zeros if appropriate. The checksum is calculated using the CRC16-CCITT algorithm.	<CR><LF>

Memory Features

The Model 7600 can collect and store 69 hours of continuous rSO_2 information.

The memory in the Model 7600 functions much like an “endless loop” tape. When the memory is full, the unit begins overwriting the oldest data with new data.

> **CAUTION:** Data is written continuously when the device is on. If the entire memory is filled, portions of the oldest record will be overwritten when a new record begins.

Each time the Model 7600 is turned on, the current time/date information (if the clock is set properly) is stored in memory, starting a new recording session. Only recording sessions greater than 1 minute in length are stored in memory.

rSO_2 is sampled and recorded in memory once every second. Oxygen saturation values are stored in 1% increments in the range of 0 to 100%.

Patient data is retained even when power is lost.

To clear patient memory, refer to “How to Clear Memory.”

Data Management Software

The Model 7600 Regional Oximetry System has comprehensive data management capability. Confidential patient data is extracted from the system via Bluetooth or the RS-232 serial port using eVision Patient Data Management Software. During memory download, DATAXFR displays on the 7600 monitor.

Each data record in the Model 7600 system is identified by date and time. On a host computer, files are identified by this data, extracted, and stored as either raw data or as a .pdf. The files comply with standards defined in the STS National Adult Cardiac Surgery Database.

For instructions on installing the software and using the data management feature, please see the eVision CD included with the device.

Care and Maintenance

The advanced digital circuitry within the Model 7600 requires **no calibration** or periodic maintenance other than battery replacement by qualified technical professionals.

Field repair of the Model 7600 is not possible. Do not attempt to open the Model 7600 case or repair the electronics. Opening the case may damage the Model 7600 and void the warranty. If the Model 7600 is not functioning properly, see “Troubleshooting.”

CAUTIONS:
- Follow local, state and national governing ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.
- Use only Nonin-approved battery packs.
- Batteries are a fire hazard if damaged. Do not damage, mishandle, or disassemble.

Cleaning the Model 7600 and 7600B/7600PA

Wipe the device with a soft cloth dampened with a mild detergent or a 10% bleach solution. Do not use undiluted bleach or any cleaning solution other than those recommended here, as permanent damage could result. Dry with a soft cloth or allow to air dry.

WARNING: Protect from exposure to water or any other liquid, with or without AC power.

CAUTION: Do not place the Model 7600 in liquid or clean it with agents containing ammonium chloride, isopropyl alcohol, or products that are not listed in this User’s Guide.

Parts and Accessories

The following Nonin accessories function with the Model 7600. Detailed information regarding specified sensor use (patient population and application) can be found in the respective sensor instructions.

Model Number	Description
7800 PS	Power supply, 25W
7600 Manual	Operator's Manual for the Model 7600
7600B	Regional oximeter pod
7600PA	Regional oximeter pod
7600TC-1	Two-channel trunk cable
7600TC-2	Four-channel trunk cable
7600-4	Four-channel accessory kit (includes four-channel trunk cable [7600TC-2] and 2 regional oximeter pods [7600B or 7600PA]).
Regional Oximeter Sensors	
8000CA	Large regional sensor
8004CA	Large absolute regional sensor
Contact your distributor or Nonin for other options.	
Other Accessories	
7800 NC	Nurse call cable
Avant RS	Rolling stand, available in standard or deluxe
7800C	Carrying case, 7600
Avant PC	Pole mount clamp
eVision	eVision patient data management software
6819-000	International power supply plug kit
Philips VueLink Accessories (order from Philips)	
M1032A #K6C (Philips P/N M1032-61699)	VueLink Open Interface cable with 9-pin connector
M1032A #A05 (Philips P/N M1032-60605)	Philips VueLink Interface Module Auxiliary Plus (Type B) with Digital Open Interface Driver
M1032A-9000D	Philips M1032A VueLink Module Handbook

For more information about Nonin parts and accessories, contact your distributor, or contact Nonin at (800) 356-8874 (USA and Canada) or +1 (763) 553-9968. This information is also available on Nonin's website: www.nonin.com.

WARNING: Use the Model 7600 only with power adapters supplied by Nonin Medical.
WARNING: The use of accessories, sensors, and cables other than those listed in this manual may result in increased electromagnetic emission and/or decreased immunity of this device.
WARNING: Use only Nonin-branded oximeter sensors. These sensors are manufactured to meet the accuracy specifications for Nonin oximeters. Using other manufacturers' sensors can result in improper oximeter performance.

Troubleshooting

Problem	Possible Cause	Possible Solution
Model 7600 will not activate.	The unit has no power.	Plug in the AC adapter.
Model 7600 will not operate on batteries.	The battery pack is not charged.	Plug in the Model 7600 AC Adapter to charge the battery pack.
	The battery pack is inoperable.	Contact Nonin Technical Service for repair or replacement.
Dashes (---) appear in the rSO_2 display.	Sensor or pod is disconnected.	Check the connections between the sensor and the pod and between the pod and the 7600 monitor. Ensure all connections are secure.
	The signal from the sensor is inadequate.	Reposition sensor. Position sensor at different site.
	The sensor is damaged.	Remove the sensor from the patient and observe the sensor emitters while the system is on. If both emitters do not flash red, replace the sensor. Ensure both emitters flash red on new sensor.
	The 7600B/7600PA is damaged.	Turn the 7600 off and then back on again. Observe the start up screen where the software revisions display. Verify a number (1 - 4) appears for the channel that the sensor is connected to. If a number does not appear, the 7600B/ 7600PA is not communicating to the display device. Contact Nonin Technical Service.
	The Model 7600 display is not functioning.	Contact Nonin Technical Service.
An error code appears in the display area.	The Model 7600 encountered an error.	Turn the unit off and then back on again to remove the error code. If the error persists, note the error code and contact Nonin Technical Service.

Problem	Possible Cause	Possible Solution
The unit is in Alarm mode, but no audible alarms can be heard.	The 2-minute Alarm Silence button is activated.	Press Alarm Silence to re-engage alarm volume, or wait 2 minutes. After 2 minutes, alarm tones automatically re-engage.
	Audible volume set to “0” in alarm limits.	Adjust volume through setup mode.
Sensor LED is not lit.	Pod initialization error.	Disconnect the pod. Wait 5 seconds and reconnect pod. If problem continues, contact Nonin Technical Service.
Bluetooth symbol is red.	Fault within the Bluetooth module.	Contact Nonin Technical Service.
The 7600 monitor does not establish communciations with the Philips multi-parameter monitor.	The 7600 monitor is not communicating with the Philips VueLink Module.	Disconnect the 7600 from the Philips VueLink Module for several seconds and then reconnect, **or** power down the 7600 for several seconds and then turn on again, **or** power down the Philips monitor for several seconds and turn on again. If problem persists, contact Nonin Technical Service.

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

Service, Support, and Warranty

Service and Support

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
www.nonin.com

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

Warranty

NONIN MEDICAL, INCORPORATED, (NONIN) warrants to the purchaser, for a period of 1 year from the date of purchase, each Model 7600 battery pack. NONIN warrants the regional oximeter monitor, oximeter pods, and trunk cable for a period of 3 years from the date of purchase. Extended warranties are available on most NONIN oximeter models. Please consult your local NONIN distributor for additional information.

NONIN shall repair or replace any Model 7600 or 7600B/7600PA 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 Model 7600 or 7600B/7600PA 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 device that is found to be within specifications.

The Model 7600 is a precision electronic instrument and must be repaired by qualified technical professionals. Accordingly, any sign or evidence of opening the device, field service by non-authorized personnel, tampering, or any kind of misuse or abuse of the device, shall void the warranty in its entirety. All non-warranty work shall be done according to NONIN standard rates and charges in effect at the time of delivery to NONIN.

DISCLAIMER/EXCLUSIVITY OF WARRANTY:

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

Technical Information

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

⚠ **CAUTION:** A functional tester cannot be used to assess the accuracy of the oximeter monitor or sensor.
⚠ **CAUTION:** Portable and mobile RF communications equipment can affect medical electrical equipment.
⚠ **CAUTION:** Radios and cell phones or similar devices can affect the equipment and must be kept at least 2 meters (6.5 feet) away from the equipment.

Manufacturer's Declaration

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

Table 14: 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 2	This device must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF Emissions CISPR 11	Class A	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	N/A	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	N/A	

Table 15: 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 ±1 kV 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 common mode	±1 kV differential mode ±2 kV 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 sec.	±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 sec.	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 16: 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	$d = 1.17\sqrt{P}$ 80 MHz to 800 MHz $d = 2.33\sqrt{P}$ 800 MHz to 2.5 GHz 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: 
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 17: Recommended Separation Distances

This table details the recommended separation distances between portable and mobile RF communications equipment and this device.

This device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. 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 allsituations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Testing Summary

Principles of Operation

Model 7600 oximeter pod uses calculations based on the Beer-Lambert law or Beer's law, to determine regional oxygenation. The Beer-Lambert law relates the absorption of light to the properties of the material through which the light is traveling. The law states that there is a logarithmic relationship between the concentration of compounds and the transmission of light through it. By utilizing wavelengths of light that are absorbed by the compounds to be measured, the concentration of the compounds can be determined. For regional oximetry, the compounds of interest are hemoglobin, deoxygenated hemoglobin, and tissue.

The oximetry sensors use a proprietary, patented arrangement of light emitters (LEDs) and light detectors (photodiodes). This arrangement effectively provides a "deep tissue" absorption measurement focused on the cerebrum. The absorption measurement is largely unaffected by surface or near-surface features, irregularities, or substances.

rSO_2 Accuracy Testing

rSO_2 accuracy testing was conducted by Nonin Medical, Inc., as described below:

rSO_2 accuracy testing is conducted during induced hypoxia studies on healthy, non-smoking, light- to dark-skinned subjects in an independent research laboratory. The measured regional hemoglobin saturation value (rSO_2) of the sensors is compared to arterial / venous hemoglobin oxygen ($SavO_2$) value, determined from venous and arterial blood samples. The model used for blood in the brain is 70% venous and 30% arterial. The accuracy of the sensors in comparison to the blood gas analyzer samples measured over the rSO_2 range of 45–100%. Accuracy data is calculated using the root-mean-squared (A_{rms} value) for all subjects, per ISO 9919:2005, Medical Electrical Equipment—Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use.

Specifications

Oxygen Saturation Display Range:	0 to 100% rSO_2	
rSO_2 Accuracy (A_{rms})[a]:	Refer to sensor Instructions for Use (IFU) for accuracy specifications.	
Inter/Intra Sensor Repeatability Accuracy (A_{rms})[a]: ± 2 digits		
Alarm Volume (at 1 m):	15:	75 dBA
	8:	61 dBA
Informational Tone Volume (at 1 m):		67 dBA
Measurement Wavelengths and Output Power[b]: Refer to sensor IFU for details.		
Memory:	69 hours (assuming continuous operation)	
Temperature:		
Operating:	-5 ºC to +40 ºC (23 ºF to 104 ºF)	
Storage/Transportation:	-30 ºC to +70 ºC (-22 ºF to 158 ºF)	
Humidity:		
Operating:	10 % to 90 % noncondensing	
Storage/Transportation:	10 % to 95 % noncondensing	
Altitude (Operating):	Up to 3,657 meters (12,000 feet)	
Power Requirements (Mains):	100–240 VAC 50–60 Hz	
Internal Power:		
Battery:	7.2 volt Li-ion battery pack, 2.4 Ah when charged with the Model 7600.	
Operating Life (fully charged battery):	3 hours minimum	
Storage Life:	20 days minimum	
Recharge Time to 90% Capacity:	2.5 hours maximum	
Dimensions:		
7600:	Approximately 305 mm (12.0 in.) W x 180 mm (7.2 in.) H x 130 mm (5.0 in.) D	
7600B / 7600PA:	Approximately 85 mm (3.25 in.) W x 30 mm (1.25 in.) H x 60 mm (2.25 in.) D	
Weight:		
7600:	Approximately 900 grams (2 pounds)	
7600B / 7600PA:	Approximately 80 grams (2.8 ounces)	
Warranty:	3 years	
Classification per IEC 60601-1 / CAN/CSA-C22.2 No. 601.1 / UL60601-1:		
Type of Protection:	Internally powered (on battery power). Class II with AC adapter.	
Degree of Protection:	Type BF-Applied Part	
Mode of Operation:	Continuous	
Enclosure Degree of Ingress Protection:	IP32	

a. ±1 A_{rms} represents approximately 68% of measurements.

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

Transmitter

Bluetooth Compliance:	Version 2.0
Operating Frequency:	2.4 to 2.4835 GHz
Output Power:	< 20 dBm
Operating Range:	100-meter (328-feet) radius indoors (line of sight when connected to a class I device)
Network Topology:	Star
Operation:	Bluetooth Slave
Antenna Type:	Internal
Modulation Type:	Gaussian Frequency Shift Keying
Band Width:	1 MHz

External Monitor Installation Instructions

Philips VueLink

Components

- Nonin Model 7600 4-Channel Regional Oximeter with RS-232 Serial Data Port
- Philips IntelliVue™ Patient Monitoring System (MP40/50/60/70/90, MX800)
- Philips M1032A#A05 VueLink Interface Module Auxiliary Plus (Type B) with Digital Open Interface Driver (Philips P/N M1032-60605)
- VueLink Open Interface Cable with 9-Pin Connector (Philips P/N M1032-61699)

Connection Specifications

Baud Rate (7600 Communication to VueLink Module): 19200

Word Length: 8 Bit

Start Bit: 1

Stop Bit: 1

Parity: None

NOTE: To support VueLink communication, the 7600 monitor must have display software revision 011 or higher (DPY = 011, as shown on the initial screen).

Connecting the 7600 to the Philips Monitor

The Model 7600 4-Channel Regional Oximeter communicates with the Philips Patient Monitoring System using a VueLink Interface Module Auxiliary Plus (Type B) and a connection cable (figure 12). See “Setting up the Connection” for detailed steps.

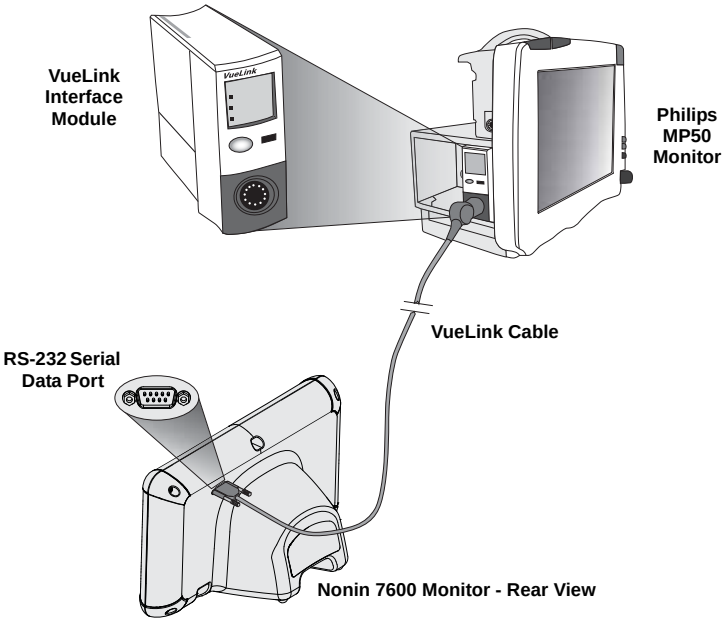


Figure 12: 7600 Connection to Philips Monitor

Once the connection between the 7600 and the Philips monitor is established, the 7600 transfers all patient numerics (rSO_2, Hbl, and AUC), as well as patient and equipment alarms, to the Philips monitor. The Philips monitor can display up to 6 numerics at a time.

The connection procedure only needs to be completed once. When complete, the 7600 and Philips monitor should communicate even after disconnecting/reconnecting the 7600 or after power off/on.

NOTES:

- The VueLink Open Interface Protocol is unidirectional. The Philips monitor can display data received from the 7600, but cannot remotely control the 7600.
- Due to the specific features of the VueLink Open Interface Protocol, the data transmission from the 7600 to a Philips monitor may be delayed by several seconds.

7600 Configuration

The Model 7600 is a plug and play device. It does not require any configuration to be used with the Philips monitor. The 7600 detects the VueLink connection and begins communicating automatically.

NOTE: If the 7600 display language is changed during operation, the language display on the Philips monitor will not update until the 7600 monitor is powered off and then on again.

VueLink Interface Module Installation and Configuration

A Philips-authorized technician installs the VueLink Interface Module. During installation, the technician activates the module so it will operate with any external device that supports the VueLink Open Interface.

Setting Up the Connection

NOTE: The instructions below refer to the Philips IntelliVue MP50 patient monitor. The procedure to set up the connection may vary slightly for other Philips IntelliVue models.

To connect the 7600 to a Philips monitor:

1. Switch the Philips monitor OFF.
2. Verify the VueLink Interface Module has been inserted in the module rack of the Philips monitor (done by a Philips authorized technician).
3. Connect the VueLink connection cable to the VueLink Interface Module (see figure 12).
4. Connect the VueLink connection cable to the RS-232 serial data port on the back of the 7600. Use the screws to secure the cable to the serial data port.

NOTE: RS-232 extension cables should not be used.

5. Turn on the 7600 monitor.
6. Turn on the Philips monitor. Ensure the Open Interface LED on the VueLink Interface Module is lit. This indicates the module has correctly been identified and configured by the Philips monitor (contact a Philips authorized technician if the VueLink Interface Module has not been configured).

7. Communication between the 7600 and Philips monitor should be established within approximately 45 seconds. Once established, PHILIPS displays on the right side of the 7600 LCD (figure 13).

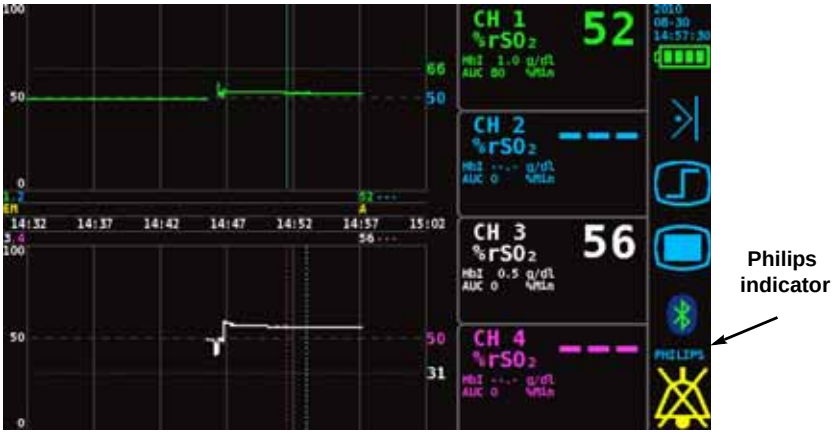


Figure 13: Philips Indicator on Model 7600 Display

Philips Monitor Display Configuration

Nonin's 7600 rSO_2, Hbl, and AUC real-time numeric data are transmitted to the Philips monitor through the VueLink Interface Module. Up to 12 numerics are transmitted at a time, and up to 6 of the patient numerics can be displayed on the Philips monitor.

The default numerics are rSO_2, HbI, and AUC for channels 1 and 2. The trendline does not display.

NOTE: A Philips monitor may accommodate several VueLink interface modules at once. They are identified as AUXILIARY PLUS 1, AUXILIARY PLUS 2, etc. Be sure to select the proper identifier.

Setup Philips Monitor to Display 7600 Numerics

1. Connect the 7600 to the Philips monitor (see the “Setting up the Connection” section).
2. Verify the 7600 and Philips monitors are on.
3. On the Philips monitor, enter Configuration Mode by selecting **Main Setup** key.
4. Select **Operating Modes**.
5. Select **Config**.
6. Enter the 5-digit Configuration Password and press **Enter**. The password can be found in the Philips M1032A VueLink Module Handbook (Philips P/N M1032-9000D).
7. Philips monitor enters Config Mode.
8. Select **Main Setup**.
9. Select **Measurements**.
10. Select **NONIN 7600** (see note below). Setup NONIN 7600 window opens.

NOTE: If communications between the 7600 and Philips monitor have not been established, VueLink X (where X is the VueLink module number) will appear in the Measurements menu instead of NONIN 7600. Select VueLink X.

NOTE: After NONIN 7600 is selected, the Philips monitor pauses while VueLink re-synchronizes with the 7600. Wait for values to appear.

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11. Select a **Numeric #** to update.
    a. Drop down list, which show the available and in-use numerics, displays to right of the numerics. NOTE: The 7600 channel number appears at the end of the numeric (e.g., AUC 1, HbI 2, rSO_2-3).
    b. Select available Numeric. If a numeric is in use, it is grayed out.
    c. Repeat as needed until up to 6 numerics have been assigned.
12. User may also setup Device Alarms (options include Accepted or Ignored) and Default Color. The 7600 numerics will display in the color chosen.
13. When setup is complete, select **Store to Module** to save settings to the VueLink module. Other options include Restore from Module and Recall Mod. Def. (Module Defaults).
14. In the Please Confirm task bar, user is asked to select Confirm to store new settings. Select **Confirm**.

15. Philips monitor stores active values as user defaults.
16. Close Setup NONIN 7600 window.
17. Close Measurements window.
18. Close Main Setup window.
19. To place a numeric on the Philips monitor:
    a. Select the appropriate screen configuration for the Philips monitor (see Philips Intellivue Patient Monitor Instructions for Use [Philips P/N M8000-9001K] for screen configuration information).
    b. Using either the touch screen or the Navigation Point knob, select a numeric location on the Philips monitor. White box displays on monitor.
    c. Select the white box to open the Change Numeric window.

NOTE: If the Change Numeric window does not open, that location is not available for 7600 numerics.

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    d. Scroll up to see the 6 numerics.
    e. Choose a numeric to display on the Philips monitor.
    f. Repeat until up to 6 numerics display.
20. Exit Config Mode by shutting off the Philips monitor.
21. Turn the Philips monitor back on. Monitor is ready to use.

Alerts

The VueLink Open Interface Protocol recognizes two types of alerts: patient alarms and equipment alarms (also known as inops or inoperable conditions).

Only one alert message text of each alert type can be displayed at the Philips monitor at the same time. Therefore, a priority is assigned to each alarm and inop. All other functions related to alerts (e.g., flashing value, replacing a numeric with a “?”) of two or more active alerts may occur simultaneously.

NOTES:

- By default, alerts are deactivated in VueLink. Activation requires access to the configuration mode of the monitor and can only be done by technical staff.
- The VueLink interface does not allow the Philips monitor to generate audible signals at the bedside for alarms and inops generated by the 7600.

Patient Alarms

The VueLink Open Interface Protocol defines two types of patient alarms:

- **Red alarms**: Indicate potentially life-threatening situations that require an immediate response.
- **Yellow alarms**: Indicate less critical situations. A response is required, but is of less critical importance.

Alarm Messages

On Philips IntelliVue patient monitors, red alarm messages may display in the upper right corner of the monitor screen. Yellow alarm messages may display at the top of the monitor screen in the middle. For more information on Philips monitor alarm messages, see the specific monitor's documentation.

Alarm Indicators

The Philips IntelliVue patient monitor may have alarm indicators at the top, left side of the monitor. For more information on Philips monitor alarm indicators, see the specific monitor's documentation.

Table 18: Philips Monitor Patient Alarms

7600 Alarm	Alarm Priority	Effect on Philips Display
rSO_2 Limit Low	Red	• Numeric flashes • ***rSO_2 LOW displays • Alarm indicator flashes red
rSO_2 Limit High	Red	• Numeric flashes • ***rSO_2 HIGH displays • Alarm indicator flashes red
rSO_2 Low Limit Warning	Yellow	• Numeric flashes • **rSO_2 LOW WARN displays • Alarm indicator flashes yellow

NOTE: For more information on 7600 alarms, see the "Alarms" chapter.

Equipment Alarms

VueLink displays equipment alarms as “inops” or “inoperatives.” Each inop carries information either on the validity of all related measurements (general inop) or on the validity of a specific numeric. Depending on this information, the numeric may display differently on the Philips IntelliVue monitor (e.g., it may blink or be replaced with “-?-”).

On the Philips IntelliVue patient monitor, inop messages may display in the upper left corner of the monitor screen. Inop messages are green. For more information on Philips monitor equipment alarms, see the specific monitor’s documentation.

Table 19: Philips Monitor Equipment Alarms

7600 Alarm (Medium Priority)	Effect on Philips Display
Pod Communication Error	• -?- replaces numeric data • rSO_2 POD COMM ERROR displays
Sensor Fault	• -?- replaces numeric data • rSO_2 SENSOR FAULT displays
Sensor Alarm (Signal Quality Alarm)	• ? displays next to numeric label • rSO_2 SENSOR ALARM displays
Sensor Alarm (rSO_2 Data Unavailable)	• -?- replaces numeric data • rSO_2 UNAVAILABLE displays
Low Battery	• EQUANOX LOW BATT displays
Critical Battery	• -?- replaces all numeric data • EQUANOX CRIT BATT displays
Error Codes	• -?- replaces all numeric data • EQUANOX ERROR displays