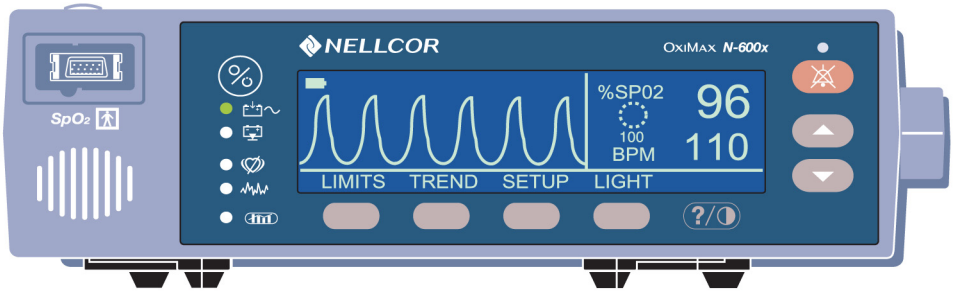
COVIDIEN

Operator's Manual

Nellcor™

OxiMax N-600x
Pulse Oximeter



OxiMax™ Technology

To obtain information about a warranty, if any, contact Covidien Technical Services at 1.800.635.5267 or your local representative.

Purchase of this instrument confers no express or implied license under any Covidien patent to use the instrument with any pulse oximeter that is not manufactured or licensed by Covidien.

Contents

Safety Information

Safety Warnings

Warnings are identified by the WARNING symbol shown above.

Warnings alert you to potential serious outcomes (death, injury, or adverse events) to the patient or user.

WARNING: The sensor extrapolates from the date and time provided by the N-600x when recording the sensor event record to the sensor. The accuracy of the date/time is determined by the date/time setting of the N-600x. It is recommended that the N-600x user set the time/date to the correct value before a sensor event record-enabled sensor is connected, and that this date/time not be changed while the sensor remains connected. Since a sensor with sensor event record data can be transported from one monitor to another, having discrepancies in the date/time between monitors and the sensor event record data will affect the order the sensor event record data appears. To eliminate this possible problem, all monitors within an institution should be set to the same time.

WARNING: Explosion hazard. Do not use the N-600x pulse oximeter in the presence of flammable anesthetics or gases.

WARNING: Chemicals from a broken LCD display panel are toxic when ingested. Use caution when handling a pulse oximeter with a broken display panel.

WARNING: Pulse oximetry readings and pulse signals can be affected by certain environmental conditions, *OxiMax* sensor application errors, and certain patient conditions. See the appropriate sections of this manual for specific safety information.

WARNING: The use of accessories, sensors, and cables other than those specified may result in increased emission and/or decreased immunity and inaccurate readings of the N-600x pulse oximeter.

WARNING: Failure to cover the *OxiMax* sensor site with opaque material in high ambient light conditions may result in inaccurate measurements.

Safety Cautions

Cautions are identified by the CAUTION symbol shown above.

Cautions alert you to exercise care necessary for the safe and effective use of the N-600x pulse oximeter.

Caution: When connecting the N-600x to any instrument, verify proper operation before clinical use. Both the N-600x and the instrument connected to it must be connected to a grounded outlet. Accessory equipment connected to the

pulse oximeter's data interface must be certified according to IEC Standard 60950 for data-processing equipment or IEC Standard 60601-1 for electromedical equipment. All combinations of equipment must be in compliance with IEC Standard 60601-1-1 systems requirements. Anyone who connects additional equipment to the signal input port or signal output port (N-600x data port connector) configures a medical system and is therefore responsible for ensuring that the system complies with the requirements of system standard IEC Standard 60601-1-1 and the electromagnetic compatibility system standard IEC Standard 60601-1-2. The N-600x accuracy may degrade if it is connected to secondary I/O devices when the instrument is not connected to earth reference.

Caution: Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

Caution: Dispose of battery in accordance with local requirements and regulations.

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Introduction

WARNING: The N-600x is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.

Intended Use

The Nellcor N-600x Pulse Oximetry System with N-600X Pulse Oximeter and Nellcor Sensors and Cables with *OxiMax* technology is indicated for prescription use only for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate. The N-600x Pulse Oximeter is intended for use with neonatal, pediatric, and adult patients during both no motion and motion conditions and for patients who are either well or poorly perfused, in hospitals, hospital-type facilities, intra-hospital transport, and home environments.

Note:Hospital use typically covers such areas as general care floors, operating rooms, special procedure areas, intensive and critical care areas, within the hospital plus hospital-type facilities. Hospital-type facilities include physician office based facilities, sleep labs, skilled nursing facilities, surgicenters, and sub-acute centers.

Intra-hospital transport includes transport of a patient within the hospital or hospital-type facility.

Note: Home Care use is defined as managed or used by a lay person (parent or other similar noncritical caregiver) in the home environment.

Use with any particular patient requires the selection of an appropriate oxygen *OxiMax* sensor as described in this manual.

How to Use this Manual

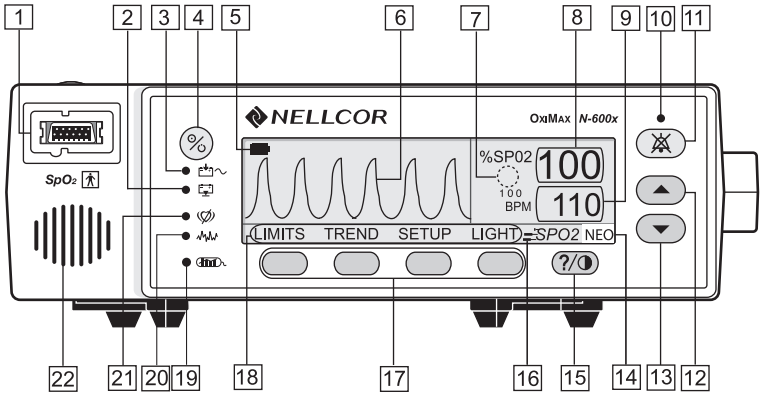
All users should read this manual thoroughly. More experienced users of the N-600x can directly go to the topics for the information they require.

This manual is available on the Internet at:

www.covidien.com/rms

Symbols, Controls, Displays and Indicators

About the Front Panel



1. SpO2 *OxiMax* Sensor Port, page 26.	12. ADJUST UP Button, page 10.
2. Low Battery Indicator, page 15.	13. ADJUST DOWN Button, page 10.
3. AC Power Indicator, page 15.	14. Neonate Mode Indicator, page 17.
4. ON/STANDBY Button, page 10.	15. HELP/CONTRAST Button, page 10.
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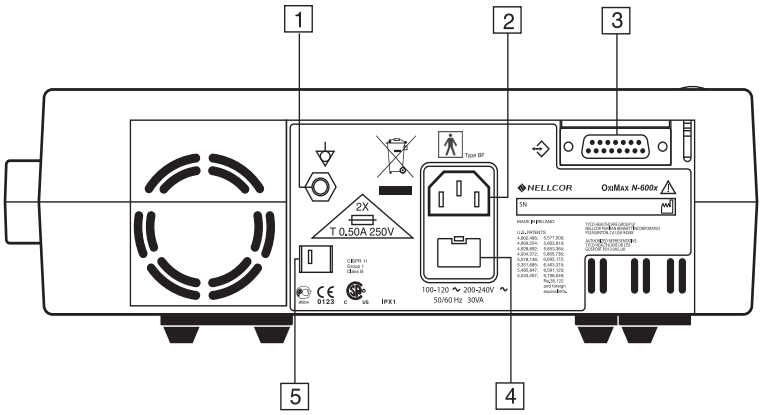
6. Waveform Display, page 11.	17. Softkeys, page 11.
7. *SatSeconds*™ Indicator, page 17.	18. Menu Bar, page 11.
8. %SpO2 Display, page 15.	19. Data In-Sensor Indicator, page 17.
9. Pulse Rate Display, page 15.	20. Interference Indicator, page 16.
10. Alarm Silence Indicator, page 16.	21. Pulse Search Indicator, page 16.
11. ALARM SILENCE Button, page 10.	22. Monitor Speaker.

Figure 1: Front Panel Buttons and Symbols

About the Rear Panel



1. Equipotential Terminal (Ground).
2. AC Power Connector, page 23.
3. Data Port Connector, page 105.
4. Fuse Holder.
5. Supply Voltage Selector Switch, page 24.

Figure 2: Rear Panel Components

About the Symbols

The symbols, located on the rear panel of the N-600x, are as follows.

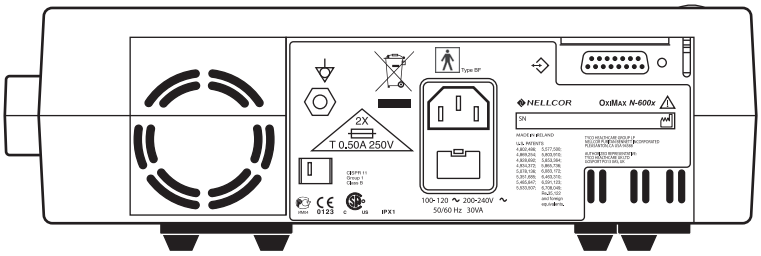
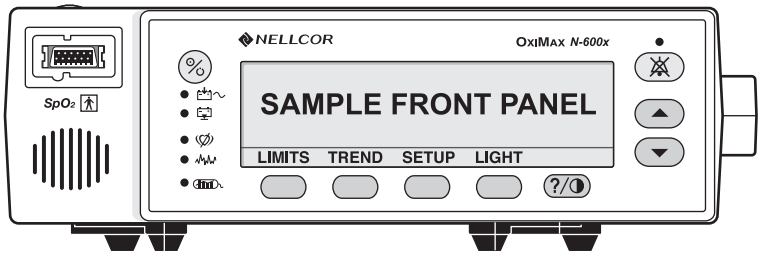


Table 1: Symbols and Descriptions

Symbol	Description
	See Instructions for Use
	Fuse Replacement
	Equipotential Terminal (ground)
	Date of Manufacture
	Data Interface
	Type BF Applied Part - Not defibrillator proof

About the Controls



ON/STANDBY Button
Turns the monitor on and off.

Note: Pressing a button, except the ON/STANDBY button, should result in either a valid or an invalid key tone (refer to Table 3). If the key pressed fails to emit a tone, contact qualified service personnel.

ALARM SILENCE Button
Silences current alarms for the alarm silence duration period. When an alarm has been silenced, pressing the button again reactivates, or "unsilences" the alarm. It is also used to view and adjust alarm silence duration and alarm volume. The ALARM SILENCE button clears "SENSOR OFF," "LOW BATTERY," and "SENSOR DISCONNECT" messages from the display.

ADJUST UP Button
Increases variable parameters of the monitor.

ADJUST DOWN Button
Decreases variable parameters in the monitor.

HELP/CONTRAST Button
Enables you to access the on-screen help and adjust the monitor screen contrast.

- Pressing and releasing the HELP/CONTRAST button launches the on-screen help.

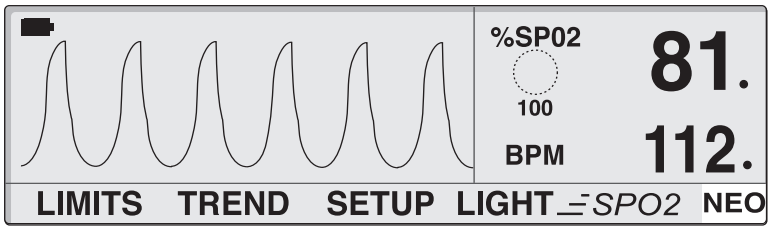
- Pressing and holding the HELP/CONTRAST button while simultaneously pressing the ADJUST UP and ADJUST DOWN buttons lightens or darkens the display screen.

Softkey Menu Bar
Displays the current functions for each of the four softkey buttons.

About the Displays

Pleth Display

The pleth display is user selectable. Refer to *Selecting the Pleth View* on page 50.



The pleth display includes a "wiper bar" plethysmographic waveform, menu bar, and current measured %SpO_2 and pulse rate. If *SatSeconds* are enabled, the pleth display includes the *SatSeconds* indicator and *SatSeconds* setting. A decimal point after the %SpO_2 or pulse rate indicates the respective limits have been changed from the power on defaults (*Overview* on page 69). Plethysmographic waveforms with peak to peak amplitudes less than ten PAUs are associated.

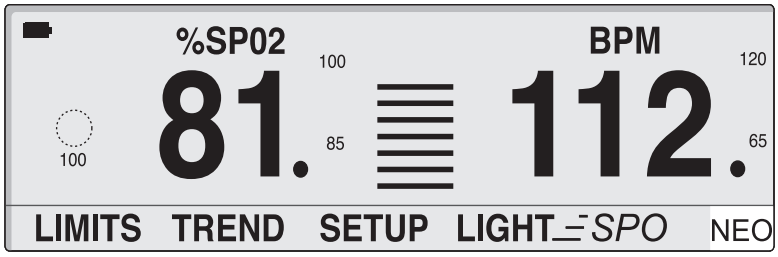
Caution: Verify the movement of the blip bar or plethysmographic waveform or beating heart before accepting any displayed data as a current measurement.

When the monitor is powered by the internal battery, the pleth display includes a horizontal battery fuel gauge positioned in the upper left corner which shows the remaining charge (operating hours) on the battery. If a monitor reporting low battery is connected to an AC power source, the battery fuel gauge displays the charging progress. The battery fuel gauge is cleared from the display once the monitor can provide at least 15 minutes of operating time.

Blip Display

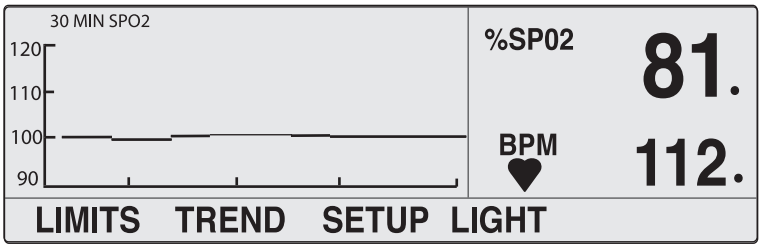
The blip display includes a pulse amplitude blip bar, current measured %SpO_2 and pulse rate, and current upper and lower %SpO_2 and pulse rate limits. If *SatSeconds* are enabled, the blip display includes the *SatSeconds* indicator and *SatSeconds* setting. Decimal points after the %SpO_2 or pulse rate indicate that the respective limits have been changed from the power-on defaults.

When the monitor is powered by internal battery, the blip display includes a horizontal battery fuel gauge positioned in the upper left corner that shows the remaining charge (operating hours) on battery. If a monitor reporting a low battery is connected to AC power, the battery fuel gauge shows the charging progress. The battery fuel gauge is cleared from the display once the monitor can provide at least 15 minutes of operating time on battery.



Real-Time Trend Display

The real-time trend display includes %SpO2 and/or pulse rate trend data plots and current measured %SpO2 and pulse rates. The trend data plots are automatically updated as each new trend point is calculated, where the interval between calculations is based on the display time scale selected. If *SatSeconds* is enabled, the real-time trend display includes the *SatSeconds* indicator. Decimal points after the displayed %SpO2 or pulse rate indicate that the respective limits have been changed from the power-on defaults. Each time a pulse is detected by the oximeter, a heart icon flashes.



SpO2 and Pulse Rates

There are various matrixes within the *N-600x* algorithm. Some of these are used to assess the severity of conditions presented to the N-600x in measuring SpO_2 and pulse rate on a patient. These individual matrices or combinations of these matrices are used to drive the LED indicators on the N-600x front panel.

The *N-600x* algorithm automatically extends the amount of data required for measuring SpO_2 and pulse rate depending on the measurement conditions. During normal measurement conditions the averaging time is 6 to 7 seconds. During conditions such as those caused by low perfusion, interference (e.g., external interference such as ambient light or patient movement), or a combination of these, the *N-600x* algorithm automatically extends the amount of data required beyond 7 seconds. If the resulting dynamic averaging time exceeds 20 seconds, the pulse

search indicator is lit solid and SpO_2 and Pulse Rate will continue to be updated every second. As these conditions extend, the amount of data required continues to increase. If the dynamic averaging time reaches 40 seconds, the pulse search indicator begins flashing, the SpO_2 and pulse rate displays flash zeros indicating a loss-of-pulse condition.

WARNING: Failure to cover the *OxiMax* sensor site with opaque material in high ambient light conditions may result in inaccurate measurements.

About the Visual Indicators

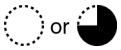
Table 2: Visual Indicators

Indicator	Description
%SpO2 Display %SP02 **81**	Shows the hemoglobin oxygen saturation level. The display value flashes zeros during loss-of-pulse alarms and flashes the SpO2 value when the SpO2 is outside the alarm limits. During Pulse Search, the monitor continues to update the display. If alarm limits have been changed from their power-on defaults, a decimal point (.) is displayed after the SpO2 value (81.).
Pulse Amplitude Indicator (blip bar) 	Indicates pulse beat and shows the relative (non-normalized) pulse amplitude. As the detected pulse becomes stronger, more bars light with each pulse. This indicator is available only in the blip view.
Plethysmographic Waveform Display 	Displays a non-normalized waveform in real-time sensor signals. The relative pulsatile strength and quality of the incoming signals can be observed.
Pulse Rate Display BPM **112**	Displays the pulse rate in beats per minute. It flashes during loss-of-pulse alarms and when the pulse rate is outside of the alarm limits. During Pulse Search, the monitor continues to update the display. Pulse rates outside of the pulse rate range of 20 to 250 bpm are displayed as 0 and 250, respectively. If alarm limits have been changed from their power-on defaults, a decimal point (.) is displayed after the BPM value (112.).
AC Power Indicator • 	Lights continuously when the N-600x is connected to an AC power source. The indicator shows that the battery is charging. It is off when the monitor is being powered by internal battery.
Low Battery Indicator • 	Lights continuously when 15 or fewer minutes of battery capacity remain. Flashes when the battery capacity reaches a critically low condition.

Table 2: Visual Indicators

Indicator	Description
Battery Fuel Gauge Indicator 	Displays the battery charge remaining on the monitor. The battery fuel gauge consists of four bars, each corresponding to approximately 1.5 hours of operating time. All four bars are lit when the battery is fully charged. No bars are lit when a low battery condition exists. See *Battery Fuel Gauge Indicator* on page 34.
Alarm Silence Indicator 	Lights continuously when an audible alarm has been silenced. It flashes when the alarm silence duration has been set to Off.
Interference Indicator 	Lights whenever the *N-600x* algorithm detects the incoming signal quality is degraded. **Note:** Degradation can be caused by ambient light, electrical noise, electro-surgical interference, patient movement, or other causes. An intermittently lit Interference Indicator is common during patient monitoring, and indicates the *N-600x* algorithm is dynamically adjusting the amount of data required for measuring SpO_2 and Pulse Rate. When lit continuously, the *N-600x* algorithm has extended the amount of data required for measuring SpO_2 and Pulse Rate and consequently fidelity in tracking rapid changes in these values may be reduced.
Pulse Search Indicator 	Lights continuously prior to initial acquisition of a pulse signal and during prolonged and challenging monitoring conditions. The pulse search indicator flashes during a loss-of-pulse signal.

Table 2: Visual Indicators

Indicator	Description
Data In-Sensor Indicator 	Lights to indicate that the attached *OxiMax* sensor contains a patient sensor event record. The sensor event record information may be viewed or printed.
SatSeconds Indicator 	Fills in clockwise as the *SatSeconds* alarm management system detects a %SpO_2 reading outside of the limit setting. Empties in counterclockwise direction when %SpO_2 reading is within limits. When the indicator is full, a medium priority alarm sounds.
Fast Response Mode Indicator 	Determines the response time (2 to 4 seconds in fast mode and 5 to 7 seconds in normal mode) applied by the *OxiMax* algorithm in its calculation of SpO_2. The *OxiMax* algorithm's calculation of pulse rate is unaffected by the response mode setting. The trending interval (2 seconds or 4 seconds) updated automatically by the monitor to roughly correspond with the SpO_2 calculation response time.
Neonate Alarm Limits Indicator 	Displays when the alarm limits are set to neonate. No symbol displays when the monitor is set to adult limits.

About the Audible Indicators

Table 3: Audible Indicators

Function	Description
Alarm Silence Reminder	Three beeps sound approximately every three minutes when alarms are silenced with the alarm silence duration set to OFF and the alarm silence reminder function is enabled.
Confirmation Tone	Three beeps sound to indicate default settings have been saved or reset to factory defaults or trend data has been deleted.

Table 3: Audible Indicators

Function	Description
Invalid Button Press	Short, low-pitched tone indicating a button has been pressed that is inappropriate for the current state of the monitor.
Valid Button Press	Short, medium-pitched tone indicating an appropriate button has been pressed.
High Priority Alarm	High-pitched, fast-pulsing tone indicating loss-of-pulse. **Note:** If a High Priority Alarm is not silenced within 30 seconds by pressing the ALARM SILENCE Key, the monitor increases the urgency level of the audible alarm signal by alternating a piezo tone with the primary alarm tone. See *Piezo Tone* on page 18.
Medium Priority Alarm	Medium-pitched, pulsing tone indicating an SpO_2 or pulse rate limit violation. **Note:** If a Medium Priority Alarm is not silenced within 2 minutes by pressing the ALARM SILENCE Key, the monitor increases the urgency level of the audible alarm signal by alternating a piezo tone with the primary alarm tone. See *Piezo Tone* on page 18.
Low Priority Alarm	Low-pitched, slow-pulsing tone indicating an *OxiMax* sensor disconnect, low battery, or monitor failure. **Note:** If a Low Priority Alarm is not silenced within 2 minutes by pressing the ALARM SILENCE Key, the monitor increases the urgency level of the audible alarm signal by alternating a piezo tone with the primary alarm tone. See *Piezo Tone* on page 18.
Piezo Tone	A high-pitched piezo tone is sounded if there is no user response to an audible alarm, or if the monitor detects a failure of the primary speaker. See High, Medium, and Low Priority Alarms in Table 3.
Power-On Self-Test Pass	One-second tone indicating the monitor has been turned on and has successfully completed the power-on self-test.

Table 3: Audible Indicators

Function	Description
Pulse Beep	Single beep sounds for each detected pulse. The pitch of the pulse beep signal changes with a point-by-point rise or fall in the saturation level.
Volume Setting Tone	Continuous tone used when adjusting the alarm volume.

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Setting Up the Monitor

WARNING: To ensure patient safety, do not place the pulse oximeter in any position that might cause it to fall on the patient.

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

WARNING: Ensure that the speaker is clear of any obstruction. Failure to do so could result in an inaudible alarm tone.

WARNING: Disconnect the N-600x and Nellcor *OxiMax* sensor from the patient during magnetic resonance imaging (MRI) scanning. Objects containing metal can become dangerous projectiles when subjected to the strong magnetic fields created by MRI equipment. Also, induced currents could potentially cause burns.

WARNING: To ensure accurate performance and prevent device failure, do not subject the N-600x to extreme moisture, such as direct exposure to rain. Such exposure may cause inaccurate performance or device failure.

WARNING: Do not use an N-600x pulse oximeter, *OxiMax* sensor, cables, or connectors that appear damaged.

WARNING: Do not lift the pulse oximeter by the pulse oximetry cable or power cord because the cable or cord could disconnect from the pulse oximeter, causing the pulse oximeter to drop on the patient.

WARNING: The N-600x is not defibrillator-proof. However, it may remain attached to the patient during defibrillation or while an electrosurgical unit is in use, but the readings may be inaccurate during the defibrillation and shortly thereafter.

WARNING: In the USA, do not connect the pulse oximeter to an electrical outlet controlled by a wall switch, because the pulse oximeter may be accidentally turned off.

WARNING: Use only the Nellcor pulse oximetry cable DOC-10 with the N-600x pulse oximeter. Use of another pulse oximetry cable will have an adverse effect on performance. Do not attach any cable that is intended for computer use to the *OxiMax* sensor port. Do not connect any device other than a Nellcor-approved *OxiMax* sensor to the *OxiMax* sensor connector.

WARNING: The N-600x should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the N-600x should be observed to verify normal operation in the configuration it is to be used.

Note: The monitor incorporates watchdog timers which reset the monitor in the event of software errors.

List of Components

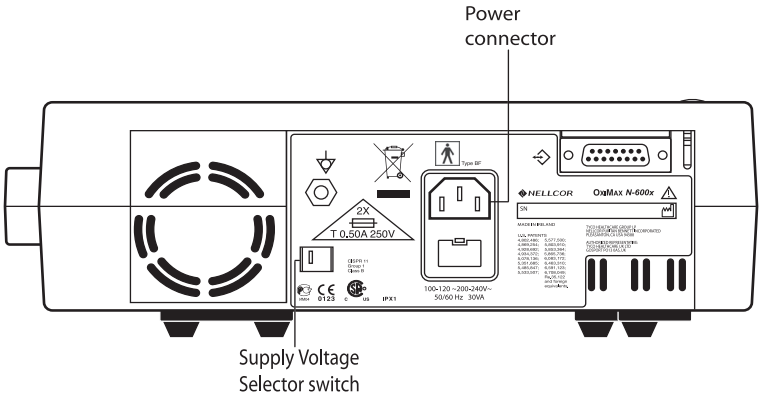
Quantity	Item
1	N-600x Pulse Oximeter
1	Nellcor *OxiMax* Sensor or Assortment Pack
1	DOC-10 Pulse Oximetry Cable
1	N-600x Operator's Manual (applicable to country of sale) and/or compact disc
1	Power Cord (applicable to country of sale)
2	Fuses, 0.5 A, 250 volts, slow-blow, IEC (5 x 20 mm)
1	Quick Guide

Connecting to an AC Power Source

WARNING: In the USA, do not connect the pulse oximeter to an electrical outlet controlled by a wall switch, because the pulse oximeter may be accidentally turned off.

Caution: The Supply Voltage Selector switch must be set to the correct voltage (115 or 230) to avoid equipment damage and ensure battery charging.

Caution: Use only the hospital-grade power cord provided by Nellcor.



1. Set the Supply Voltage Selector switch to the applicable voltage.

2. Plug the female connector end of the power cord into the power connector on the rear of the monitor.

3. Plug the male connector of the power cord into a properly grounded AC outlet.

Caution: Ensure the pulse oximeter is properly grounded when operating on AC power. If you are uncertain whether the AC outlet is properly grounded, disconnect the pulse oximeter from the outlet and use the battery power. Contact a qualified electrician to examine the outlet for ground connections.

- 4. Verify the monitor's AC power indicator is lit.

Note:If the AC power indicator is not lit, check the:

- power cord
- supply voltage selector switch
- user-accessible fuses
- AC power outlet

Note: The monitor can be operated with a depleted battery when connected to an AC power outlet. A warning message displays and must be cleared by pressing the ALARM SILENCE button before the monitor can be used for patient monitoring.

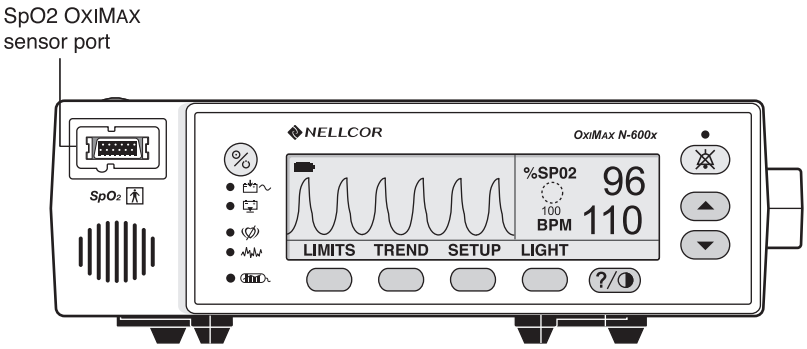
Connecting an *OxiMax* Sensor

The *OxiMax* sensor type is shown at the bottom of the display when an *OxiMax* sensor is connected to the N-600x or when the monitor completes POST with an *OxiMax* sensor attached.

Note: Sensor LED light emissions fall within Class 1 level, according to IEC 60825-1:2001.

Caution: Use only Nellcor-approved *OxiMax* sensors and pulse oximetry cables.

Note:Physiological conditions, medical procedures, or external agents that may interfere with the monitor's ability to detect and display measurements include dysfunctional hemoglobin, arterial dyes, low perfusion, dark pigment, and externally applied coloring agents, such as nail polish, dye, or pigmented cream.



1. Firmly connect a DOC-10 pulse oximetry cable to the SpO_2 *OXIMAX* Sensor Port of the monitor.

2. Connect a Nellcor *OXIMAX* SpO_2 sensor to the opposite end of the DOC-10 pulse oximetry cable.

Operating the Battery

WARNING: Dispose of battery in accordance with local requirements and regulations.

Operating on Battery Power

The N-600x monitor has an internal battery that can be used to power the monitor during transport or when AC power is not available. A new, fully charged battery provides at least 7 hours of monitoring time under the following conditions:

- No audible alarms sound
- No analog or serial output devices are attached to the N-600x
- Default display brightness setting

The monitor cannot be used when the battery is depleted unless the monitor is connected to an AC power source. A warning message displays and must be cleared by pressing the ALARM SILENCE button before the monitor can be used for patient monitoring.

The pleth and blip displays include a battery fuel gauge indicator that shows the remaining charge (operating hours). When the monitor is fully charged, all four bars are lit on the indicator.

Caution: If the N-600x monitor is stored for a period of three months or longer, notify service personnel to place the monitor in "Shelf-mode" prior to storage. The monitor can be placed in "Shelf-mode" by qualified service personnel using the procedures indicated in the *N-600x*

***Service Manual*. Recharge the battery when it has not been charged for three or more months.**

Caution: Replace the battery if fewer than four bars are lit after fully charging the battery. To charge a low or fully depleted battery, connect the monitor to AC power outlet. A full charge of a fully depleted battery takes 8 hours to charge while the monitor is turned off. A full charge of a fully depleted battery takes 12 hours while the monitor is in the normal operating mode.

Caution: If the monitor is operated on an AC power source with a depleted battery and the AC power is subsequently lost, the monitor will shut down immediately.

When all of the following conditions are present for 15 minutes, the N-600x automatically shuts down:

- Monitor is running on battery power
- No buttons have been pressed
- No pulse has been detected (for example, when a patient is not connected to the *OxiMax* sensor or the *OxiMax* sensor is disconnected from the monitor)
- No alarms are present (other than low battery or a non-correctable error)

Note:Whenever the monitor is connected to AC power source, the battery is being charged. We recommend the monitor remain connected to an AC power source when not in use. This ensures a fully-charged battery when the monitor is needed.

Low Battery Indicator

The Low Battery Indicator lights and a low priority alarm begins to sound when approximately 15 minutes of monitoring time is

available on the existing battery charge. Refer to Table 4 for a description of the low and critical battery conditions.

A low battery audible alarm can be cancelled by pressing the ALARM SILENCE button. The low battery indicator and display screen message continues to display. Connecting the monitor to an AC power source silences the audible alarm, but the low battery indicator remains lit as long as the battery is in the low voltage condition. After the 15-minute period of low battery condition, a high priority alarm sounds for about 10 seconds before the monitor shuts off.

If the monitor backlight is turned off during a low battery condition, the backlight cannot be turned back on.

Nellcor recommends that a qualified service personnel replace the internal battery every 24 months. Replaced batteries should be disposed of in accordance with local ordinances.

Caution: The pulse oximeter default settings will return to factory default setting if the battery becomes fully discharged or is replaced. Qualified service personnel will have to reset the institutional defaults, following the instructions in the *N-600x Service Manual*.

Note: If the AC voltage selector switch on the monitor rear panel does not match your AC voltage source, the monitor may run on battery power, even though it is connected to an AC power source, which eventually results in a low priority alarm and a lighted low battery indicator. Ensure that the switch setting matches your AC voltage.

Note: As the battery is used and recharged over time, the amount of time between the onset of the low battery alarm and the instrument shut-off may become shorter.

Description of Low and Critical Battery Conditions

Table 4: Low and Critical Battery Conditions

State	Critical Battery	Low Battery	AC Power	Operation
1	No	No	Yes	SpO_2-normal AC/Battery charge LED-on LOW BATTERY LED-off LOW BATTERY message-off Audible alarm-off Error code-none Effect of ALARM SILENCE key-normal Shutdown-N/A
2	No	No	No	SpO_2-normal AC/Battery charge LED-off LOW BATTERY LED-off LOW BATTERY message-off Audible alarm-off Error code-none Effect of ALARM SILENCE key-normal Shutdown- N/A

State	Critical Battery	Low Battery	AC Power	Operation
3	No	Yes	No	SpO_2-normal AC/Battery charge LED-off LOW BATTERY LED-on LOW BATTERY message-on Audible alarm-low priority Error code-logged Effect of ALARM SILENCE key-First press silences audio alarm, second press cancels LOW BATTERY message (LED) stays on until Low Battery Condition is corrected. Shutdown-Imminent
4	No	Yes	Yes	SpO_2-normal AC/Battery charge LED-on LOW BATTERY LED-on LOW BATTERY message-off Audible alarm-off Error code-logged Effect of ALARM SILENCE key-N/A (LED stays on) Shutdown-N/A **Note**: Connecting AC functions the same as ALARM SILENCE key in state 3.

State	Critical Battery	Low Battery	AC Power	Operation
5	Not used			
6	Yes	Yes	No	SpO_2-not displayed AC/Battery charge LED-off LOW BATTERY LED-on (flashing) LOW BATTERY message-on Audible alarm-high priority Error code-displayed and logged Effect of ALARM SILENCE key-none Shutdown-after 10 seconds

State	Critical Battery	Low Battery	AC Power	Operation
7	Yes	Yes	Yes	SpO2 - displayed. AC/Battery Charge LED - on LOW BATTERY LED-on (flashing) LOW BATTERY message - on The Battery Fuel Gauge Indicator shows a fully depleted battery (no bars lit). Warning message in the pleth window: UNIT WILL SHUT DOWN IF AC POWER LOST Audio alarm - low priority Error code - logged Affect of Silence key - One press silences the audible alarm. Pressing the Affect Silence key twice cancels the LOW BATTERY message, removes the warning message and restores default Pleth (or Blip) display (LED continues to FLASH until Low Battery condition is not true, Battery Fuel Gauge Indicator shows charging progress) Shutdown - N/A

Battery Fuel Gauge Indicator

The N-600x has a battery fuel gauge indicator which displays the battery power remaining on the monitor. The indicator appears on the the pleth and blip display screens. When the monitor is fully charged, all four bars are lit on the battery fuel gauge indicator. The battery fuel gauge indicator capacities are described below.

Table 5: Battery Fuel Gauge Indicator Levels

Level	Description
	Indicates 100% battery capacity remaining.
	Indicates 75% battery capacity remaining.
	Indicates 50% battery capacity remaining.
	Indicates 25% battery capacity remaining.
	Indicates 0% battery capacity remaining.

Note: The levels in Table 5 are based on a brand new battery. As a battery is used and recharged over time, it may provide only 75% of the capacity of brand new battery. For example, a battery that is two-years old may provide only 75% (3 bars) of the capacity of a new battery.

Caution: If the battery is fully depleted, and the AC power is lost, the monitor will shut down.

Using the Monitor

Overview

This section describes menu navigation, power on/off and display options, parameter ranges, *OxiMax* sensor attachments, and configuring default settings suitable for your environment.

Menu Description

The N-600x is outlined below. You can choose the type of trend data to view by selecting either Monitor trend or Sensor trend data in the Trend menu. Sensor sub-menu choices differ depending on what type of in-sensor data is stored in the sensor chip, such as, event or loop.

The menu structure includes BACK softkey options that enable you to move back to the previous menu level without exiting the Trend menu entirely. Trend data must be compiled on entry/reentry to the Trends menu. When the softkeys are available, both BACK and EXIT options are available. The BACK softkey goes to the previous level and the EXIT softkey goes to the main menu. If only one space is available the BACK softkey is included, this may require going back one or two levels to get to an EXIT softkey.

The BACK and EXIT softkeys are positioned on the right-most softkeys, respectively. The below menu structure identifies:

- **BOLDFACE TYPE** — softkey title as displayed on the monitor
- Underlined Text — description of the softkey menu item

- *Italicized Text* — the destination of the BACK and EXIT softkeys

Menu Structure

Main Menu
LIMITS (Limits Menu)
- **SELECT**
- **NEO**
- **ADULT**

EXIT *(to Main menu)*
TREND (Trend Menu)
- **MON** (Monitor Menu**)**
- - **VIEW** (Monitor Trend View Menu)
- - - **DUAL**
- - - **SPO2**
- - - **PULSE**
- - - **NEXT** (History/Amplitude Menu)
- - - - **HIST** (Delete/Print2 Menu)
- - - - - **DELETE** *(Delete Trends)*
- - - - - - "DELETE TRENDS"
- - - - - - - **YES** *(return to Main menu)*
- - - - - - - **NO** *(back to Delete/Print menu)*
- - - - - **PRINT**
- - - - - **BACK** *(back to Hist/Amp menu)*
- - - - - **EXIT** *(to Main menu)*
- - - - **AMP** (Amplitude Menu)
- - - - - **BACK** *(back to Hist/Amp menu)*
- - - - - **EXIT** *(to Main menu)*
- - - - **BACK** *(back to Monitor Trend View menu)*
- - - - **EXIT** *(to Main menu)*
- - **ZOOM** (Monitor Trend Zoom Menu)
- - - **TIME** *(Cycle through 48h, 36h, 24h, 12h, 8h, 4h, 2h, 1h, 30m, 15m, 40s, 20s for current view)*

Menu Structure
(continued...)

- - - **SCALE** *(Cycle through ±5, ±10, ±15, ±20, ±25, ±30, ±35, ±40 and ±50 (units of BPM or %SpO2, depending on the data displayed) of the max and min. values under the cursor, default to 10 to 100 for SAT trend graph and 5-250 for Pulse trend graph if there is no data point under the cursor for current view)*
- - - **AUTO** *(Based on all of the graphed trend data: maximum value, rounded up to nearest multiple of 10, minimum value, rounded down to nearest multiple of 10 minus 10)*
- - - **BACK** *(back to Monitor menu)*
- - **NEXT** (Delete/Print1 Menu)
- - - **DELETE**
- - - - "DELETE TRENDS?"
- - - - - **YES** *(to Main menu)*
- - - - - **NO** *(back to Delete/Print1 menu)*
- - - **PRINT**
- - - **BACK** *(back to Monitor menu)*
- - - **EXIT** *(to Main menu)*
- - **BACK** *(back to Trend menu)*
- **SENSOR** (Sensor/Event Menu)
(if Event data is in the sensor, the following menu, the Screen will remain in the appropriate state until the next menu selection is made)
- - **GRAPH** (Graph Menu) *(display events #1-N, in inverse chronological order; up/down also scroll through events in order)*
- - - *< (show previous graph, only available when there is a previous graph)*
- - - *> (show next graph, only available when there is a next graph)*
- - - **PRINT**
- - - **BACK** *(back to Sensor menu)*

Menu Structure (continued...)

- - **TABLE** (Table Menu)
- - - ^ *(show previous table, only available when there is a previous graph; bottom/top line repeats in new table)*
- - - *v (show next table, only available when there is a next graph; bottom/top line repeats in new table)*
- - - **PRINT**
- - - **BACK** *(back to Sensor menu)*
- - **BACK** *(back to Trend menu)*
- - - **EXIT** *(to Main menu)*

(Sensor/Loop Menu) *(If continuous-Loop data is in the sensor, the following will be displayed)*

- - **VIEW** (Sensor Trend View Menu)
- - - **DUAL** *(shows SPO2+BPM)*
- - - **SPO2**
- - - **PULSE**
- - **ZOOM** *(cycle through 2h, 1h, 30m, and 15m for current view)*
- - **PRINT**
- - **BACK** *(to Trend menu)*
- **EXIT** *(to Main menu)*

SETUP (Setup Monitor Menu)

- **VIEW** *(Setup View Menu)*
- - **PLETH**
- - **BLIP**
- - **TREND**
- - - **VIEW** (RT Trend View Menu)
- - - - **DUAL**
- - - - **SPO2**
- - - - **PULSE**
- - - - **BACK**
- - - **ZOOM** (RT Trend View Menu)
- - - - **TIME**
- - - - **SCALE**
- - - - **AUTO**
- - - - **BACK**
- - **BACK** *(back to Setup menu)*
- - **EXIT** *(to Main menu)*
- - - **SENSOR** (Setup Sensor Menu)

Menu Structure (continued...)

- - **DATA** *(On-screen options for SENSOR-R (Write-once Sensor) sensor are: "SPO2, SPO2+BPM, DEFAULT." On-screen options for SENSOR-RW (rewritable sensor) are: "SPO2, SPO2+BPM, DEFAULT." SELECT toggles SENSOR-R or SENSOR-RW sensor type; up/down keys scroll through options in order.) The SENSOR-R feature supports all of the current OxiMax sensors.*
- - - **SELECT**
- - - **BACK** *(back to Setup Sensor menu)*
- - - **EXIT** *(to Main menu)*
- - **MSG** (Sensor Set Message Menu)
- - - **BACK** *(back to Setup Sensor menu)*
- - - **EXIT** *(to Main menu)*
- **NEXT** (Clock/Language Menu)
- - **CLOCK** (Clock Menu)
- - - **SET** (Clock Set Menu)
- - - - **SELECT** *(press select to toggle through hours, minutes, seconds, month, day, year; use up/down buttons to set each selection)*
- - - - **BACK** *(back to Clock/Language menu)*
- - - - **EXIT** *(to Main menu)*
- - - **BACK** *(back to Clock/Language menu)*
- - - **EXIT** *(to Main menu)*
- - **LANG** (Language Setup Menu) *(use up/down buttons to toggle though languages)*
- - - **BACK** *(back to Clock/Language menu)*
- - **NEXT** (Communication/Nurse Call Menu)
- - - **COMM** (Communication Port Configuration Menu)
- - - - **SELECT**
- - - - **BACK** *(back to Communication/Language menu)*
- - - - **EXIT** *(to Main menu)*
- - - **NCALL** (Nurse Call Menu)
- - - - **NORM +**
- - - - **NORM -**
- - - - **BACK** *(back to Communication/Nurse Call menu)*
- - - - **EXIT** *(to Main menu)*

Menu Structure (continued...)

- - - **NEXT** (Analog/Mode Menu)
- - - - **ANALOG** (Analog Voltage Select Menu)
- - - - - **0 VOLT**
- - - - - **1 VOLT**
- - - - - **STEP**
- - - - - **BACK** *(back to Analog/Mode menu)*
- - - - **MODE** (Mode Menu)
- - - - - **BACK** *(back to Analog/Mode menu)*
- - - - - **EXIT** *(to Main menu)*
- - - - **BACK** *(back to Communication/Nurse Call menu)*
- - - - **EXIT** *(to Main menu)*
- - - **BACK** *(back to Clock/Language menu)*
- - **BACK** *(back to Setup menu)*
- **EXIT** *(to Main menu)*

LIGHT (Light Menu)

- **OFF** (Turns display backlight off)
- **EXIT** *(to Main menu)*

Parameter Ranges

The parameters of the N-600x monitor are preset to factory default settings. See *Factory Default Settings* on page 157. The factory default parameters may be changed to institutional default parameters by following the procedures in the *N-600x Service Manual*.

Table 6 lists the parameters, ranges available, and the factory default setting. The parameters may be set on an individual basis,

by the clinician, and these settings remain in effect until the monitor is turned off.

Table 6: Parameter Ranges

Parameter	Ranges/ Selections	Factory Adult Defaults	Factory Neonate Defaults
%SpO_2 Upper Alarm Limit	Lower Alarm Limit plus 1 to 100%	100%	95%
%SpO_2 Lower Alarm Limit	20% to Upper Alarm Limit minus 1	85%	85%
Pulse Rate Upper Alarm Limit	Lower Alarm Limit plus 1 to 250 bpm	170 bpm	190 bpm
Pulse Rate Lower Alarm Limit	30 bpm to Upper Alarm Limit minus 1	40 bpm	90 bpm
Alarm Silence Duration	Alarms 30, 60, 90, 120 seconds	60	60
Alarm Volume	1 to 10	7	7
Alarms	Allow Off - Yes/No	No	No
	Off Reminder - Yes/No	Yes	Yes
Backlight Brightness	0 to 10		
Data Port Baud Rate	2400, 9600, 19200	9600	9600

Table 6: Parameter Ranges

Parameter	Ranges/ Selections	Factory Adult Defaults	Factory Neonate Defaults
Data Port Mode	ASCII, GRAPH, OXINET, CLINICAL, PHILIPS, SPACELBS, MARQ (GE Marquette), DATEX (Datex-Ohmeda)	ASCII	ASCII
Default Display Format	Pleth, Blip Real-Time Trend	Pleth	Pleth
Display Contrast	Low to high	Medium	Medium
Language	English, Danish, Dutch, Finnish, French, German, Norwegian, Portuguese, Spanish, Italian, Swedish	English	English
Limits	Adult, Neonate	Adult	Neonate
On AC Power		10	10
On Battery Power		8	8
Pulse Beep Volume	0 to 10	4	4
Pulse Rate Lower Alarm Limit	30 bpm to Upper Alarm Limit minus 1	40 bpm	90 bpm
Pulse Rate Upper Alarm Limit	Lower Alarm Limit plus 1 to 250 bpm	170 bpm	190 bpm
Real-Time Trend Display	Saturation, Dual, Pulse Rate	Saturation	Saturation

Table 6: Parameter Ranges

Parameter	Ranges/ Selections	Factory Adult Defaults	Factory Neonate Defaults
Real-Time Trend Scale	48, 36, 24, 12, 8, 4, 2, 1 hours, 30 minutes	30 minutes	30 minutes
Response Mode	Normal or Fast	Normal	Normal
RS-232 Level Nurse Call Polarity	Normally High, Normally Low	Normally Low	Normally Low
SatSeconds	Off, 10, 25, 50, 100	Off	Off
Allow *SatSeconds*	Yes/No	Yes	Yes
Sensor Event Date Format (SENSOR-R and SENSOR-RW	SpO_2, SpO_2+Pulse Rate, Default (default is factory default)	Default	Default
Sensor Messages Enabled	Yes/No	Yes	Yes
Trend Display	Dual, %SpO_2, Pulse, Histogram, Amplitude	%SpO_2	%SpO_2
Trend Scale	48, 36, 24, 12, 8, 4, 2, 1 hours, 30, 15 minutes, 40, 20 seconds	2 hours	2 hours

Turning On the Monitor

Before using the monitor in a clinical setting, verify the monitor is safe and working properly. Proper working condition is verified

each time the N-600x is turned on as described in the following procedure.

Caution: If any indicator or display element does not light when the pulse oximeter is turned on, do not use the pulse oximeter. Instead, contact qualified service personnel, your local Nellcor representative, or Nellcor's Technical Services Department.

Note: Physiological conditions, medical procedures, or external agents that may interfere with the monitor's ability to detect and display measurements, include dysfunctional hemoglobin, arterial dyes, low perfusion, dark pigment, and externally applied coloring agents such as nail polish, dye, or pigmented cream.

Note: The monitor automatically launches the Power-On Self-Test (POST), which tests the monitor circuitry and functions.

Caution: During POST (immediately after power-up), confirm that all indicators light, all display segments turn on, and the pulse oximeter speaker sounds a sequence of three ascending tones. After the POST process complete, verify that a single one-second tone sounds.

1. Turn on the monitor by pressing the ON/STANDBY button.

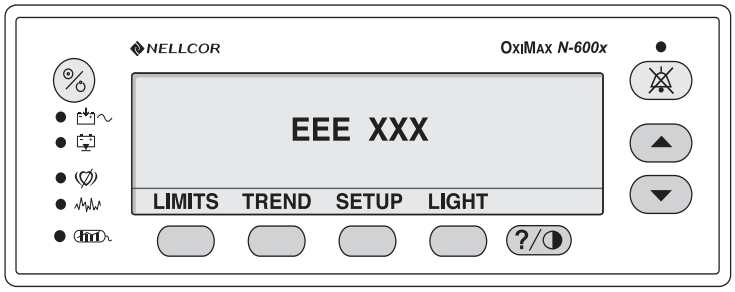
2. Ensure all of the front panel indicators illuminate.

3. Once the display test portion of POST completes, the software version displays for approximately five seconds and a sequence of three ascending tones sound.

Note:The software version shown above is only a sample. Check your monitor for the current software version installed.

The software version is often needed when calling Nellcor's Technical Services Department or your local Nellcor representative for technical assistance. Record the software version number and have it available prior to contacting technical assistance.

4. If the monitor detects an internal problem during the POST process, an error tone sounds and the monitor displays an error code (EEE) and the corresponding number (see *Troubleshooting* on page 131).



5. Upon successful completion of the POST, the monitor sounds a one-second tone indicating the monitor has passed the test.

WARNING: If you do not hear the POST pass tone, do not use the pulse oximeter.

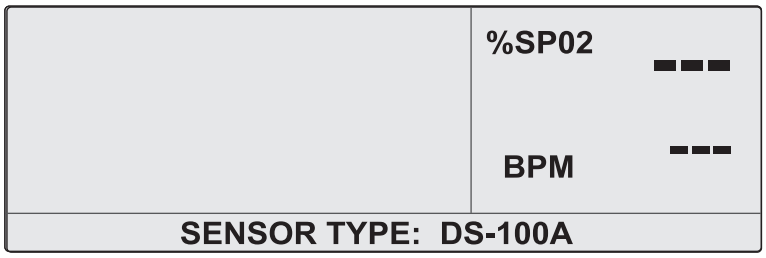
WARNING: Ensure the speaker is clear of any obstructions. Failure to do so could result in an inaudible alarm tone.

Note:In addition to serving as the POST pass verification, the POST pass tone also functions as an audible confirmation that the speaker is performing properly. If the speaker does not function, the alarm warning sounds cannot be heard.

OxiMax Sensor Attached

WARNING: Do not use any other cables to extend the length of the DOC-10 Pulse Oximetry Cable. Increasing the length of the DOC-10 cable will degrade signal quality and may lead to inaccurate measurements.

When an *OxiMax* sensor is connected to the monitor, a "SENSOR TYPE: . . ." message is displayed 4 to 6 seconds at the bottom of the monitor display. The message identifies the type (model) of *OxiMax* sensor connected to the monitor. The type is used to determine the action messages in the *OxiMax* sensor message(s) function. This display is the first message displayed when an *OxiMax* sensor is connected to the monitor.

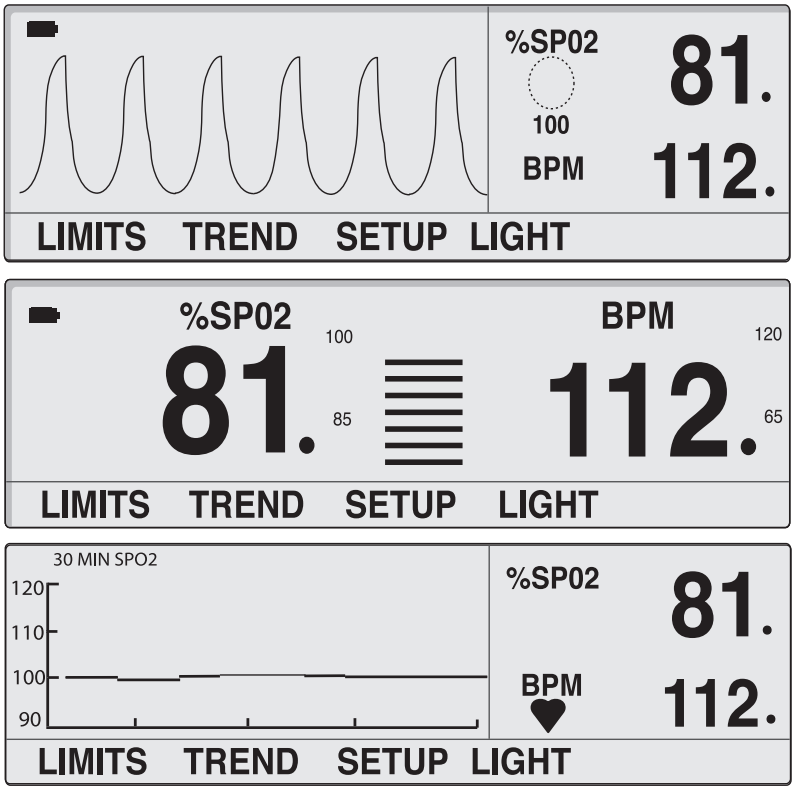


For a sensor containing data, the message identifies the sensor data type. For a blank sensor, the message identifies the monitor's current data type setting used to write data to the sensor. The data type settings are SpO_2 and SPO_2+BPM.

Note:The type of data recorded is only displayed when data is present in the *OxiMax* sensor.

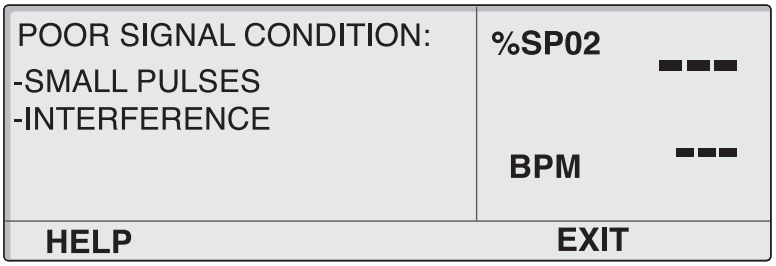
The monitor displays zeros in the %SpO_2 and Pulse Rate displays while the N-600x is searching for a valid pulse. For optimal performance, allow the monitor to search and lock onto a pulse for approximately 5 to 10 seconds.

When a valid pulse is detected, the monitor enters the Monitoring Mode and displays patient parameters.



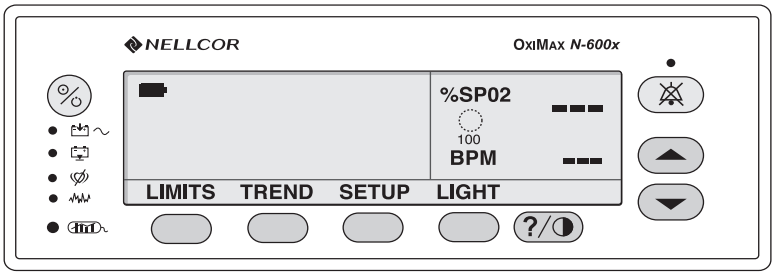
Notice the movement of the blip bar or plethysmographic waveform or beating heart indicating the monitor is displaying real-time data. Listen for the pulse beep tone. If the pulse beep tone does not sound with each pulse, it is an indication the pulse beep volume is set to zero, the speaker is malfunctioning, or the signal is corrupt.

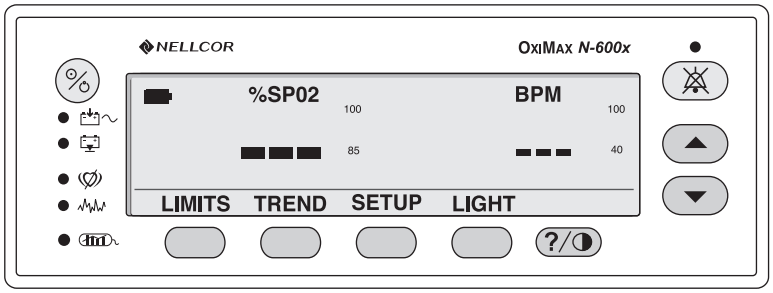
When an *OxiMax* sensor is attached to the monitor and applied to a patient, the monitor may lose a pulse signal. If a pulse signal is lost, an alarm sounds and a poor signal condition message displays on the monitor screen. At this point, the monitor displays [**--- / ---**]
(3 dashes / 3 dashes) and remains in the Pulse Search Mode for five seconds before displaying the poor signal condition screen. The poor signal condition screen is part of the N-600x's Sensor Messages feature. For more information about *OxiMax* Sensor Messages, refer to *OXIMAX Sensor Messages* on page 66.



No *OxiMax* Sensor Attached

Upon successful completion of the POST process, the monitor sounds a one-second tone indicating that the monitor has passed the POST.





The monitor displays dashes [**- - -**] and the Pulse Search indicator is not lit, indicating the monitor failed to detect an *OxiMax* sensor.

Turning the Backlight On or Off

You can turn off the backlight by pressing the LIGHT softkey and then pressing OFF.

Note: Any of the following conditions turn on the backlight:

- pressing any of the softkeys
- pressing and holding the HELP/CONTRAST button

- pressing the ALARM SILENCE button
- any alarm

Adjusting the Screen Contrast

1. With the monitor in the normal monitoring mode, press and hold the HELP/CONTRAST button while pressing the ADJUST UP or ADJUST DOWN button until the desired contrast is obtained.

2. Press the HELP/CONTRAST button to return to the normal monitoring mode.

Adjusting the Backlight Brightness

1. With the monitor in the normal monitoring mode, press the LIGHT softkey.

2. Press the ADJUST UP or ADJUST DOWN button until the desired backlight brightness is obtained.

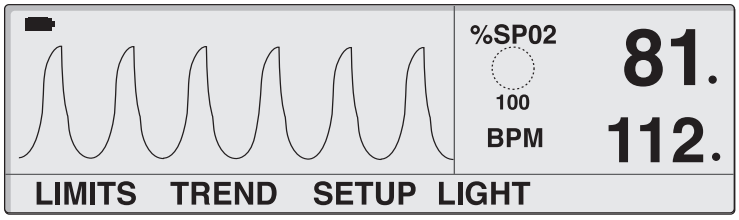
Selecting the Pleth View

The pleth view displays the pleth waveform, %SpO_2, and pulse rate data. Refer to *Principles of Operation* on page 161, for a description of the pleth waveform.

1. With the monitor in the normal monitoring mode, press the SETUP softkey.

2. Press the VIEW softkey.

3. Press the PLETH softkey. The pleth view displays.



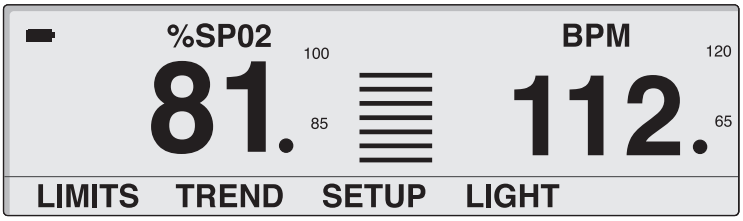
Selecting the Blip View

The blip view displays the SpO_2, pulse rate, blip bar, and limits in a larger format for easier viewing.

1. With the monitor in the normal monitoring mode, press the SETUP softkey.

2. Press the VIEW softkey.

3. Press the BLIP softkey. The blip view displays.

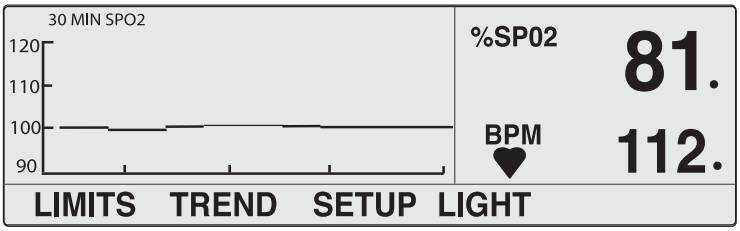


Selecting the Real-Time Trend View

The real-time trend view displays the %SpO_2 and/or pulse rate trend data. The real-time trend submenu enables you to:

- select the trend data display,
- set the trend time scale display, and
- set the trend amplitude scale display.

1. With the monitor in the normal monitoring mode, press the SETUP softkey.
2. Press the VIEW softkey.
3. Press the TREND softkey. The real-time trend view displays.



Selecting the Trend Data Display

1. Press the SETUP softkey.
2. Press the VIEW softkey.

3. Press the TREND softkey.

4. Press the VIEW softkey.

5. Press any of the trend softkeys (DUAL, SPO2, or PULSE).

Setting the Trend Time Scale Display

1. Press the SETUP softkey.

2. Press the VIEW softkey.

3. Press the TREND softkey.

4. Press the ZOOM softkey.

5. Press the TIME softkey to cycle the displayed trend time scale through 48 hours, 36 hours, 24 hours, 12 hours, 8 hours, 4 hours, 2 hours, 1 hour, and 30 minutes.

Setting the Trend Amplitude Scale Display

1. Press the SETUP softkey.

2. Press the VIEW softkey.

3. Press the TREND softkey.

4. Press the ZOOM softkey.

5. Press the SCALE softkey to cycle the trend amplitude scale display through ±5 points, ±10 points, ±15 points, ±20 points, ±25 points, ±30 points, ±35 points, ±40 points and ±50 points above and below the newest - rightmost - trend data point.

Note: You can set the trend amplitude scale to AUTO by pressing the AUTO softkey. The maximum trend data point is rounded up to the nearest multiple of 10, shown at the top of the graph display. The minimum trend data point is rounded down to the next multiple of 10. 10 is then subtracted from the rounded down number. This value is located at the bottom of the trend graph.

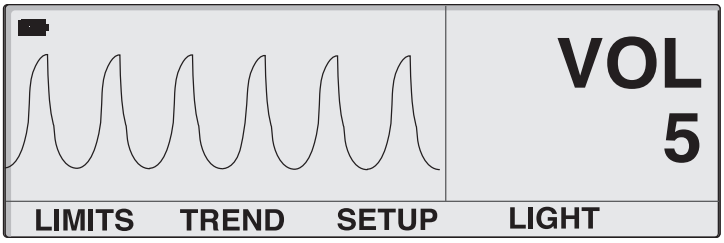
Setting the Pulse Beep Volume

With the monitor in the normal monitoring mode, press and hold the ADJUST UP or ADJUST DOWN button to increase or decrease the pulse beep volume.

Setting the Alarm Volume

The Alarm Volume display enables you to adjust the volume of alarm tones.

1. With the monitor in the normal monitoring mode, press the ALARM SILENCE button until the alarm volume level displays and sounds on the monitor.



2. While continuing to press the ALARM SILENCE button, press and hold the ADJUST UP or ADJUST DOWN button to increase or decrease the volume.

Setting the Date and Time

WARNING: The sensor extrapolates from the date and time provided by the N-600x when recording the sensor event record to the sensor. The accuracy of the date/time is the responsibility of the N-600x. It is recommended that the N-600x user set the time/date to the correct value before a sensor event record-enabled sensor is connected, and that this date/time not be changed while the sensor remains connected. Since a sensor with sensor event record data can be transported from one monitor to another, having discrepancies in the date/time between monitors and the sensor event record data will affect the order the sensor event record data appears. To eliminate this possible problem, all monitors within an institution should be set to the same time.

1. With the monitor in the normal monitoring mode, press the SETUP softkey.

2. Press the NEXT softkey.

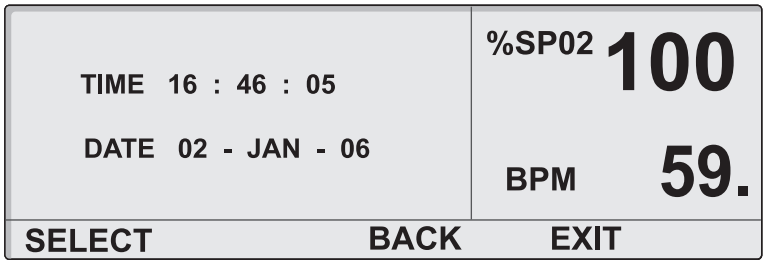
3. Press the CLOCK softkey.

4. Press the SET softkey.

5. Press the SELECT softkey to select the TIME and DATE fields as shown in the graphic below.

   TIME HOURS : MINUTES : SECONDS (16 : 46 : 05)

   DATE DAY - MONTH - YEAR (02 - JAN - 06)



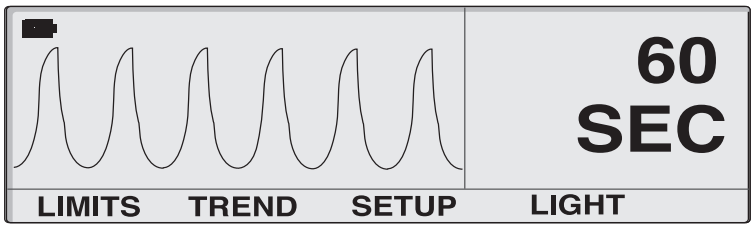
6. Use the ADJUST UP or ADJUST DOWN buttons to change the selected value.

7. Press the EXIT softkey.

Setting the Alarm Silence Duration

The Alarm Silence Duration display enables you to adjust the alarm silence duration.

1. With the monitor in the normal monitoring mode, press the ALARM SILENCE button until the alarm silence duration setting displays. The alarm silence durations available are 30, 60, 90, and 120 seconds.



2. Press and hold the ALARM SILENCE button and the ADJUST UP button to increase the alarm silence duration setting.

3. Press and hold the ALARM SILENCE button and the ADJUST DOWN button to decrease the alarm silence duration setting.

Note: Releasing the ADJUST UP or ADJUST DOWN button sets the alarm silence duration.

Disabling Audible Alarms

Setting the alarm silence duration to OFF disables all audible alarms.

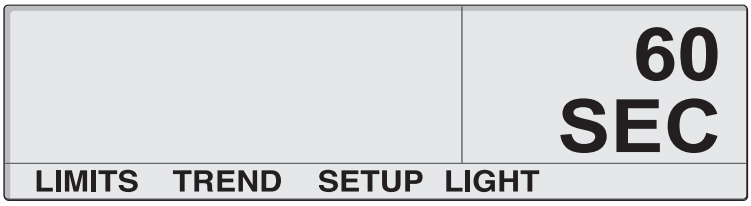
Note: The ability to set the alarm silence duration to OFF can be enabled or disabled by qualified service personnel as described in the *N-600x Service Manual*.

The *N-600x Service Manual* is available on the Internet at:

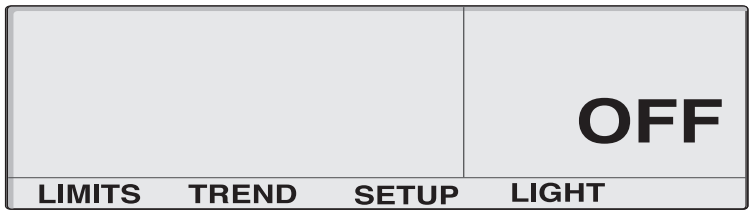
www.covidien.com/rms

WARNING: Do not disable the audible alarm function or decrease the audible alarm volume if the patient's safety could be compromised.

1. With the monitor in the normal monitoring mode, press the ALARM SILENCE button until the alarm silence duration setting displays.



2. While pressing the ALARM SILENCE button, press and hold the ADJUST UP button until OFF displays. Release the buttons.



Selecting the Standby Mode

The standby mode enables the monitor to retain the alarm limit settings that are in effect while monitoring a patient. The monitor must be connected to an AC power source to enter the standby mode.

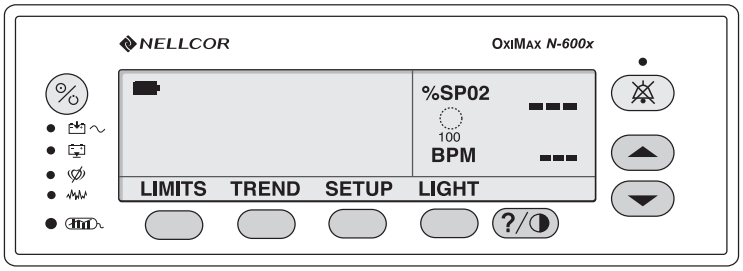
Normally, the standby mode setting is used when a patient has to temporarily leave the monitor.

1. Verify the N-600x is monitoring a patient and the alarm limits are configured to the patient being monitored.

2. Disconnect the sensor from the monitor.

3. Press the ALARM SILENCE button to silence the audible alarms.

4. Press the ALARM SILENCE button to disable the alarm messages.



The monitor is now in the standby mode. Reconnect the sensor to the monitor and the patient to return to normal monitoring.

Adult-Pediatric or Neonatal Settings

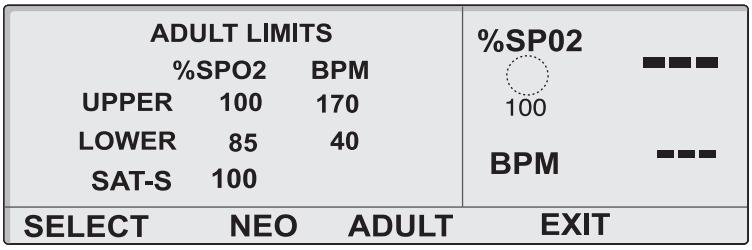
The clinician can set the monitor's operating mode to adult-pediatric or neonatal by using the LIMITS softkey. This setting remains active until the monitor is turned OFF. The factory default power-on setting is for adult-pediatric patients. This default setting can be changed to neonatal by qualified service personnel using the procedures indicated in the *N-600x Service Manual*.

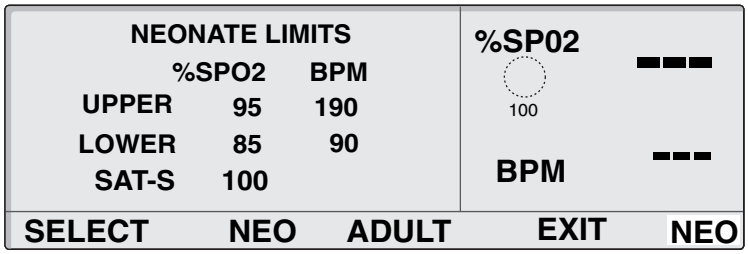
Refer to Table 15, for neonate factory default limit settings. Refer to Table 16, for adult factory default limit settings.

WARNING: Each time the pulse oximeter is used, check alarm limits to ensure that they are appropriate for the patient being monitored.

Setting Patient Adult-Pediatric or Neonatal Modes

1. With the monitor in the normal monitoring mode, press the LIMITS softkey. The monitor displays the ADULT LIMITS or NEONATE LIMITS screen, depending on the patient setting used.

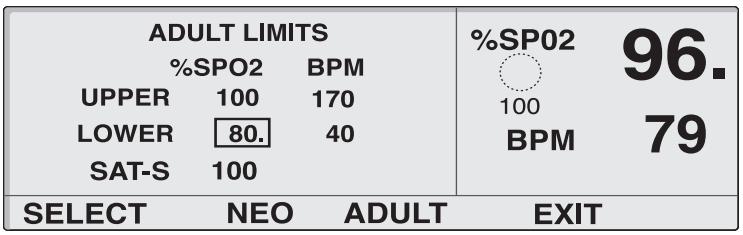




2. Press the NEO or ADULT softkey to select ADULT LIMITS or NEONATE LIMITS depending on the patient being monitored.

Alarm Limit Changed Indicator

Alarm limits that have been changed from the institution or factory default settings are identified by a decimal point (.) after the displayed reading (%SpO2 or BPM). The changed parameter is also identified by a decimal point on the alarm limits screen.



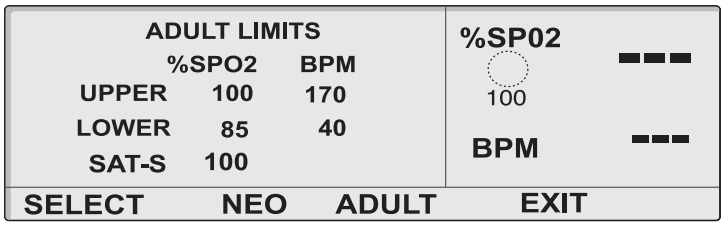
Setting Alarm Limits

The Alarm Limit display enables you to adjust the upper and lower saturation and pulse rate limits. It also enables you to adjust the *SatSeconds* limit.

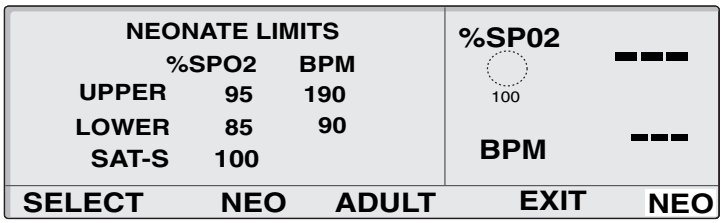
The Alarm Limit display is accessed by pressing the LIMITS softkey on the main menu.

The Alarm Limit display includes the alarm limit table and current measured %SpO2 and pulse rate. The title of the alarm limit table indicates whether the instrument is in Adult or Neonate monitoring mode. If *SatSeconds* are enabled, the Alarm Limit display also includes the *SatSeconds* indicator. Decimal points after the displayed %SpO2 or pulse rate indicate that the respective limits have been changed from the power-on defaults.

1. Press the LIMITS softkey. The current alarm limits display.



OR



2. Press the ADULT or NEO softkey to select the Adult-Pediatric or Neonatal alarm limits screen.

3. Press the SELECT softkey to select the parameter to be adjusted.

4. Use the ADJUST UP or ADJUST DOWN buttons to increase or decrease the selected limit parameter.

5. Repeat steps 2, 3, and 4 as necessary to complete the alarm limits setup.

6. Wait for the display to time-out to accept the changes or press the EXIT softkey to close the display and return to the normal monitoring mode.

Note: Limit changes are in effect as long as the monitor remains turned on. When the monitor is turned off, the institutional default limits are restored. When the monitor is turned on, the

institutional default limits are effected. Factory or institutional defaults are selected by qualified service personnel by following the procedures outlined in the *N-600x Service Manual*.

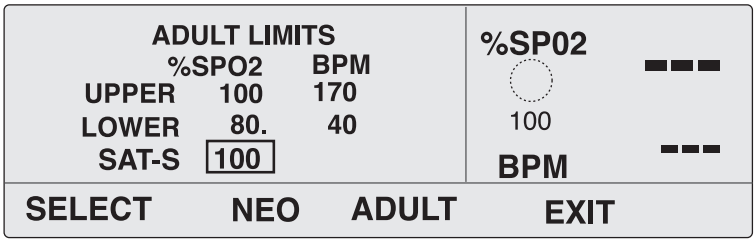
Setting *SatSeconds* Alarm Limit

Refer to *Using SatSeconds* on page 153, for more information on the *SatSeconds* feature.

Note: The ability to adjust the *SatSeconds* Alarm limit can be enabled or disabled by a qualified service personnel as described in the *N-600x Service Manual*.

1. With the monitor in the normal monitoring mode, press the LIMITS softkey. The current alarm limits display.

2. Press the SELECT softkey twice to select %SpO_2 SAT-S.



3. Use the ADJUST UP or ADJUST DOWN buttons to select the limit. The choices are 10, 25, 50, 100 seconds or OFF.

4. Press the EXIT softkey to save your selection.

Setting Monitor Response Mode

The purpose of the response mode is to set the response time of the *N-600x* algorithm calculation of the SpO_2 (the response mode does not affect the *N-600x* algorithm's calculation of pulse rate). The trending interval (2- or 4-seconds) is updated automatically by the monitor to roughly correspond with the SpO_2 calculation response time.

The response mode automatically programs the *N-600x* algorithm to record and display monitor trend information at 2-second intervals (Fast Mode) up to 24 hours or 4-second intervals (Normal Mode) up to 48 hours.

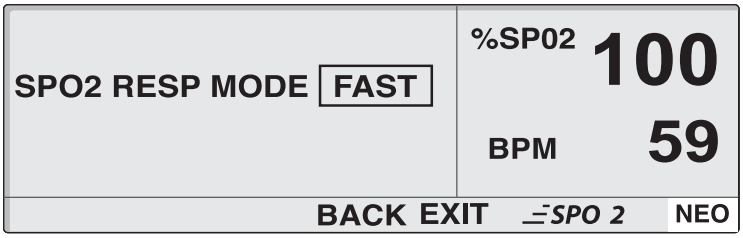
The response mode display screen includes the current SpO_2 response mode setting and the current measured %SpO_2 and pulse rate. When in the fast mode, the screen displays the fast mode symbol.

1. With the monitor in the normal monitoring mode, press the SETUP softkey.

2. Press the NEXT softkey three times.

3. Press the MODE softkey.

Note: When the monitor is in the fast response mode, the monitor may produce more SpO_2 and pulse rate alarms than you are accustomed to experiencing.



4. Use the ADJUST UP or ADJUST DOWN buttons to select the desired response mode.

5. Press the EXIT softkey.

Selecting the Display Language

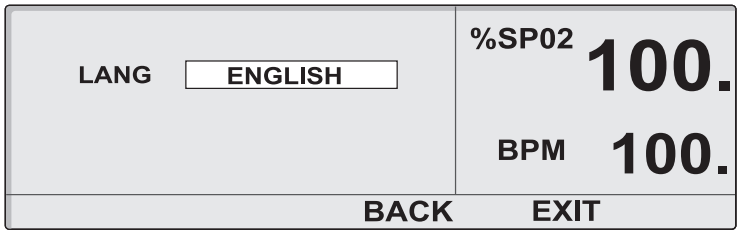
The N-600x can be programmed to display the information in various languages. The languages available are:

ENGLISH
DANSK (Danish)
DEUTSCH (German)
ESPAÑOL (Spanish)
FRANCAIS (French)
ITALIANO (Italian)
NEDERLANDS (Dutch)
NORSK (Norwegian)
PORTUG (Portuguese)
SUOMI (Finnish)
SVERIGE (Swedish)

1. With the monitor in the normal monitoring mode, press the SETUP softkey.

2. Press the NEXT softkey.

3. Press the LANG softkey.



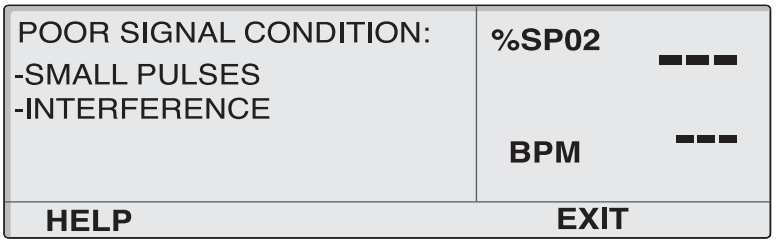
4. Use the ADJUST UP or ADJUST DOWN buttons to select the desired language.

5. Press the EXIT softkey.

Note: The selected language displays until the monitor is turned OFF. The selected language can be set as a default by qualified service personnel by following the procedures outlined in the *N-600x Service Manual*.

OxiMax Sensor Messages

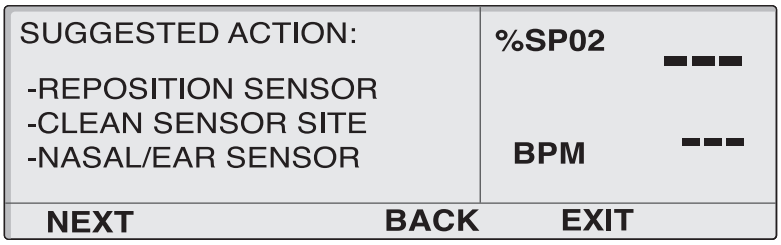
OxiMax sensor messages consist of sensor adjust condition messages and sensor adjust messages which, when enabled, are displayed when the monitor is not able to display saturation. When *OxiMax* sensor messages are displayed, it is an indication that the *OxiMax* sensor is functioning properly, but the site to which the *OxiMax* sensor applies or the application method is not optimal for calculating %SpO_2. Condition messages are followed by action messages. Up to three condition messages may be displayed on the "POOR SIGNAL CONDITION" display in priority order, highest on top. The condition display may be dismissed by using the EXIT softkey. Once closed, the *OxiMax* sensor message screen will not return until a new condition occurs.



If the HELP softkey is pressed from the Condition message display, the action messages are displayed. Action messages are linked to the sensor type; action messages will be displayed for the type of *OxiMax* sensor connected to the monitor. Up to five action messages may be displayed. Multiple screens may be required to

display all of the messages. When multiple screens are required, navigation between screens can be accomplished by using the NEXT, BACK, and EXIT softkeys.

OxiMax sensor messages may be disabled. Refer to *OXIMAX Sensor Messages* on page 66 for selecting the *OxiMax* Sensor Messages, Enable/Disable function.



OxiMax Sensor Adjust Condition Messages

- Condition — SENSOR OFF?
- Condition — SMALL PULSES
- Condition — WEAK SIGNAL
- Condition — INTERFERENCE
- Condition — EXCESS INFRARED LIGHT
- Condition — INTERFERENCE
- Condition — HIGH PULSE AMPLITUDE

OxiMax Sensor Adjust Messages

- Message — ALTERNATE SITE?
- Message — COVER SENSOR SITE?

- Message — EAR/FOREHEAD SENSOR?
- Message — NASAL/EAR SENSOR?
- Message — *OxiMax* ADHESIVE SENSOR
- Message — SECURE CABLE
- Message — HEADBAND
- Message — WARM SITE
- Message — BANDAGE ASSEMBLY
- Message — NAIL POLISH
- Message — SENSOR TOO TIGHT?
- Message — REPOSITION SENSOR
- Message — ISOLATE INTERFERENCE SOURCE
- Message — CLEAN SENSOR SITE

Using Monitor Trend Data

Overview

The trend displays enable you to view trend data. Two types of trend data can be viewed:

- Monitor trend data stored in the monitor
- Patient event data stored in the *OxiMax* sensor (single-patient-use *OxiMax* sensors only) and can be used with the sensor event record feature.

Monitor trend data can be viewed anytime patient trend is stored in the monitor. Monitor trend displays are accessed by pressing the TREND softkey on the main menu and selecting the MONITR softkey option. The monitor trend submenu enables you to choose which trend data are displayed:

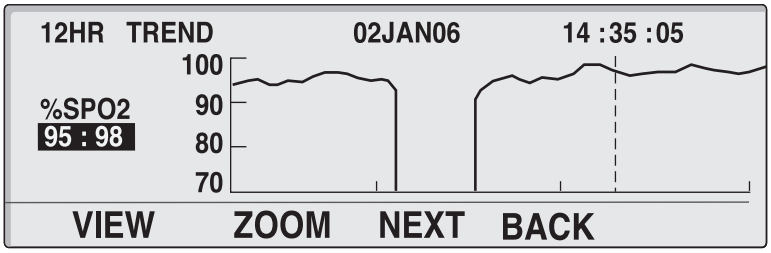
- Saturation and pulse rate (Dual)
- Saturation
- Pulse rate
- Pulse amplitude
- Histogram

The N-600x can graphically display trend data for SpO_2, pulse rate, or both. Trend data is stored at 2- or 4-second intervals and linked to the response mode. When the TREND softkey is pressed, "READING TRENDS" displays at the bottom of the N-600x screen, indicating that the monitor is formatting the trend data to be displayed.

The monitor stores up to 48 hours of 4-second trend data or 24 hours of 2-second trend data. The amount of trend data displayed on the screen is determined by using the ZOOM softkey. The settings available are 20 and 40 seconds, 15 or 30 minutes, and 1, 2, 4, 8, 12, 24, 36, or 48 hours. All trend data are displayed in a graphical format except the 20 and 40 second trend displays, which are shown in tabular format.

The trend display can be viewed throughout the 48 hours of trend data. Selecting the 1-hour trend display allows you to view one hour of trend information. By using the scrolling feature, any one hour of trend data can be viewed up the 48 hours of trend information. The ADJUST DOWN button scrolls the display to the left and the ADJUST UP button scrolls the display to the right.

When the data displays, the most recent readings are on the right side of the graph. The numbers below %SpO_2 indicate the highest and lowest parameter values at the cursor position (vertical dotted line on the display). See Table 7.



Trend data is further explained in *Specifications* on page 167.

Trend data information may be retrieved through the N-600x data port or cleared using options available in a display menu.

Caution: Monitor trend data will be lost if the main battery fails or is removed.

Storing Trend Data

Whenever the N-600x is turned on, it stores the monitor %SpO2 and pulse rate readings in memory every 2- or 4-seconds (regardless of whether the N-600x is monitoring a patient or not). The N-600x can store up to 48 hours of 4-second trend data or 24 hours of 2-second trend data. The 48/24 hours of stored trend data can be downloaded to a printer or a portable computer. Up to 50 alarm limit changes can be stored in the trend data. If more than 50 alarm limit changes occur during the 48/24 hours of trend data collection, the additional alarm limit changes will take space reserved for trend data.

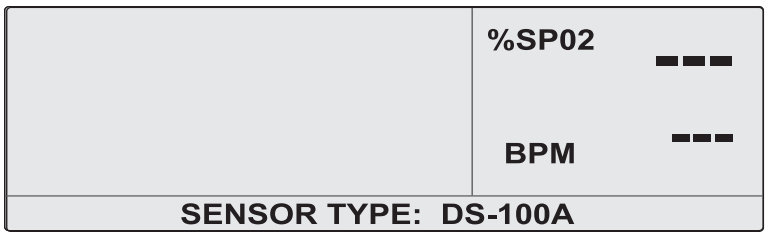
Caution: Changing alarm limit settings uses up trend memory space. Change alarm limits only as needed.

Note: Trend memory always contains the most recent 48 hours of data, with newly collected data overwriting the oldest data on a rolling basis. The N-600x continues to record data points as long as the monitor is powered on, with "blank" data points collected if no *OxiMax* sensor is connected to the monitor or patient. "Blank" data overwrites older patient data if the memory becomes full. Therefore, if you want to save old patient data, it is important that you turn your monitor off when you are not monitoring a patient, and that you download the trend memory before it fills up and overwrites the old data with new data (or "blank" data).

OxiMax Sensor Type

When an *OxiMax* sensor is connected to the monitor, a "SENSOR TYPE:..." message is displayed for 4 to 6 seconds at the bottom of the display. The message identifies the type (model) of *OxiMax* sensor connected to the monitor. Type is used in the determination of action messages in the *OxiMax* sensor

message(s) function. This display is the first message displayed when an *OxiMax* sensor is connected to the monitor.



Selecting the Trend Data Display Scale

The trend scale is the amount of trend data displayed on the screen.

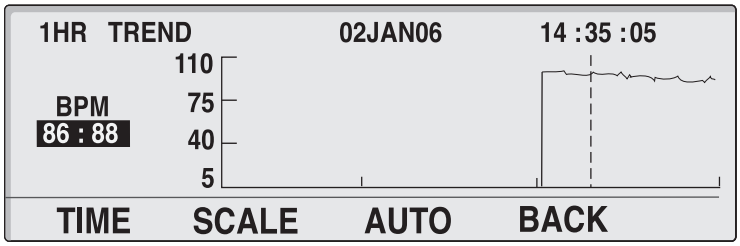
1. With the monitor in the normal monitoring mode, press the TREND softkey.

2. Press the MONITR softkey.

3. Press the VIEW softkey.

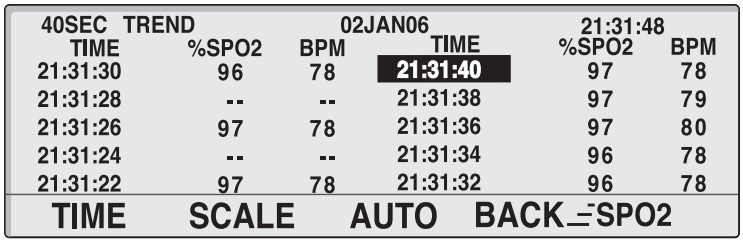
4. Press any of the trend softkeys (DUAL, SPO2, or PULSE). To select HIST (histogram) or AMP (amplitude), press the NEXT softkey and then the HIST or AMP softkeys.

5. Press the ZOOM softkey. The Zoom menu displays.



Pressing the TIME softkey cycles the displayed trend time scale through 48 hours, 36 hours, 12 hours, 8 hours, 4 hours, 2 hours, 1 hour, 30 minutes, 15 minutes, 40 seconds and 20 seconds.

Note: The 20-second and 40-second trend displays are in tabular format. The display below begins in the normal response mode (left side of the display) and switches to the fast response mode.



Pressing the SCALE softkey cycles the displayed trend amplitude scale through ±5 points, ±10 points, ±15 points, ±20 points, ±25 points, ±30 points, ±35 points, ±40 points and ±50 points above and below the data point under the cursor. The saturation graphical monitor trend display vertical scale default setting is from 10 to 100 if there is no data under the cursor. The pulse rate graphical monitor trend display vertical scale is from 5 to 250 if there is no data under the cursor.

Pressing the AUTO softkey presets the amplitude of the graphed trend data. The maximum trend data point is rounded up to the nearest multiple of 10, this value is the top of the graph display. The minimum trend data point is rounded down to the next multiple of 10. Then 10 is subtracted from the rounded down number, this value is the bottom of the trend graph.

Pressing the BACK softkey returns the monitor to the Monitor menu.

Reading the Trend Data Display

The following table identifies the components of the trend data display.

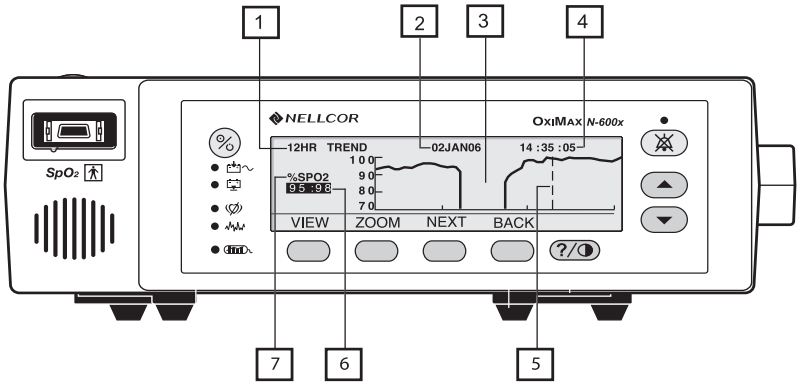


Table 7: Reading Trend Display

Item	Description
1	Amount of trend data displayed on the screen. Settings available are 20 and 40 seconds, 15 and 30 minutes, 1, 2, 4, 8, 12, 24, 36, and 48 hours.
2	Date represented by the cursor (item 5).
3	No trend data recorded during this time.
4	Time represented by the cursor (item 5).
5	Cursor - can be moved left or right using the ADJUST UP (right) or ADJUST DOWN (left) buttons.
6	Highest and lowest reading at the cursor position.
7	Trend data that is being displayed (%SPO2, BPM, or PAU [pulse amplitude units]).

Dual Trend Data Display

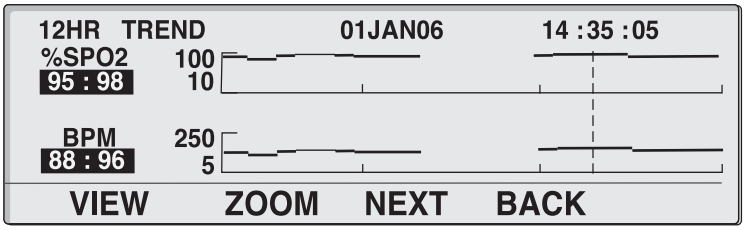
The dual trend data display shows both oxygen saturation (%SpO_2) levels and pulse rate (bpm) trend data.

1. With the monitor in the normal monitoring mode, press the TREND softkey.

2. Press the MONITR softkey.

3. Press the VIEW softkey.

4. Press the DUAL softkey. The dual trend (%SpO_2 and Pulse Rate) displays.



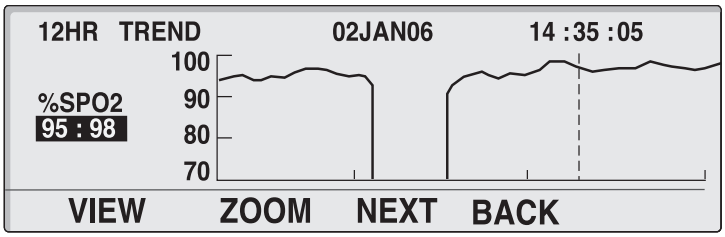
SpO_2 Trend Display

1. With the monitor in the normal monitoring mode, press the TREND softkey.

2. Press the MONITR softkey.

3. Press the VIEW softkey.

4. Press the SPO2 softkey. SpO2 trend data displays.



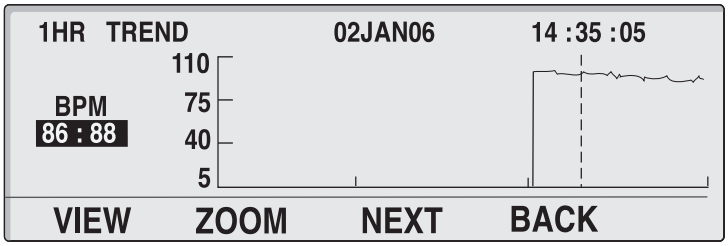
Pulse Rate Trend Display

1. With the monitor in the normal monitoring mode, press the TREND softkey.

2. Press the MONITR softkey.

3. Press the VIEW softkey.

4. Press the PULSE softkey. The pulse rate trend data displays.



Histogram Trend Data Display

The histogram displays trend data for the percent of oxygen blood saturation (SpO2) and pulse rate (bpm). The data displayed represents the trend data stored over the period of time indicated

on the display. Refer to *OXIMAX Sensor Type* on page 71, to set up the desired trend data scale. Pulse amplitude cannot be displayed on the histogram display.

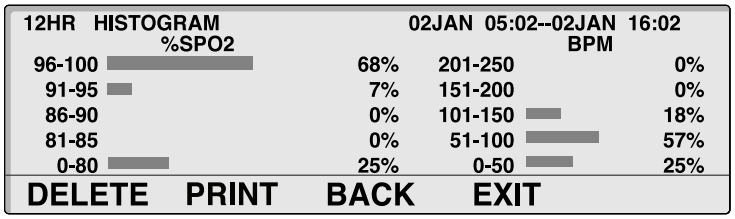
1. With the monitor in the normal monitoring mode, press the TREND softkey.

2. Press the MONITR softkey.

3. Press the VIEW softkey.

4. Press the NEXT softkey.

5. Press the HIST softkey. The histogram trend data displays.



Pulse Amplitude Trend Data Display

The pulse amplitude trend data display shows the amplitude of the patient's pulse rate over the period of time indicated on the display. Refer to *OXIMAX Sensor Type* on page 71 to setup the desired trend data scale.

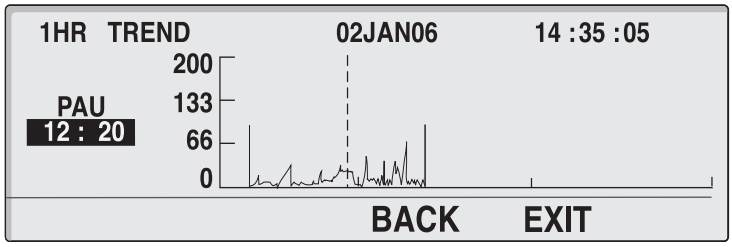
1. With the monitor in the normal monitoring mode, press the TREND softkey.

2. Press the MONITR softkey.

3. Press the VIEW softkey.

4. Press the NEXT softkey.

5. Press the AMP softkey. The pulse amplitude units (PAU) trend data displays.



The PAU reading (12 : 20) indicates the pulse amplitude units (upper and lower) at the cursor position (dashed line). The cursor moves right or left using the ADJUST UP (right) and ADJUST DOWN (left) buttons.

Clearing Trend Information

1. With the monitor in the normal monitoring mode, press the TREND softkey.

2. Press the MONITR softkey.

3. Press the NEXT softkey.

4. Press the DELETE softkey.

Note: Press NO and then EXIT to close this function without deleting the trend data.

5. Press the YES softkey.

All the trend data clears and the monitor sounds three beeps.

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Using OxiMax Sensor Event Records

Overview

WARNING: The sensor extrapolates from the date and time provided by the N-600x when recording the sensor event record to the sensor. The accuracy of the date/time is determinated by the date/time of the N-600x. It is recommended that the N-600x user set the time/date to the correct value before a sensor event record-enabled sensor is connected, and that this date/time not be changed while the sensor remains connected. Since a sensor with sensor event record data can be transported from one monitor to another, having discrepancies in the date/time between monitors and the sensor event record data will affect the order the sensor event record data appears. To eliminate this possible problem, all monitors within an institution should be set to the same time.

The adhesive *OxiMax* sensors are capable of storing patient alarm event data. A sensor event record allows alarm event history to travel with the patient on the sensor's memory chip for quick assessment at every point of care where *OxiMax* monitors are used.

Patient (alarm event) data is stored on the memory chip of adhesive *OxiMax* sensors (single-patient-use *OxiMax* sensors only). The alarm event data is stored (recorded) with the limit/threshold settings that were active at the time of the event on the recording monitor. These events can be viewed on the next *OxiMax* sensor monitor when the patient moves to a new point of care.

An event occurs when the %SpO_2 value exceeds either the upper or lower alarm limit for at least 15 seconds. Alarm events are grouped and recorded to the memory chip every 5 minutes. The

maximum number of events that can be stored in an *OxiMax* sensor is typically 100.

Event records can only be viewed after an *OxiMax* sensor containing patient alarm data (event records) has been connected to an *OxiMax* monitor with SENSOR enabled. Event records are designed to view patient events from prior areas of care or transport (history) while monitor trend should be used to view data or events from a patient currently being monitored.

The monitor's SENSOR EVENT RECORD indicator lights when an *OxiMax* sensor containing event data is connected to the *OxiMax* monitor.

Patient alarm event data is accessed by pressing the TREND softkey on the main menu and selecting the SENSOR softkey option. Sensor event record can be viewed in graphical form (GRAPH) or in a summary table (TABLE).

Note: Once the *OxiMax* sensor event record type is setup in the *OxiMax* sensor and event data is stored in the *OxiMax* sensor, the *OxiMax* sensor event record type cannot be reset. The monitor's type set up can be changed at any time.

Recording and viewing of *OxiMax* sensor event record is only available on *OxiMax* compatible monitors with SENSOR enabled. The *OxiMax* sensors may function on older technology monitors but the *OxiMax* sensor event record feature is not available.

Refer to the *N-600x Service Manual* for specific instruction on how to disable the storage of the sensor event recorded in an *OxiMax* sensor.

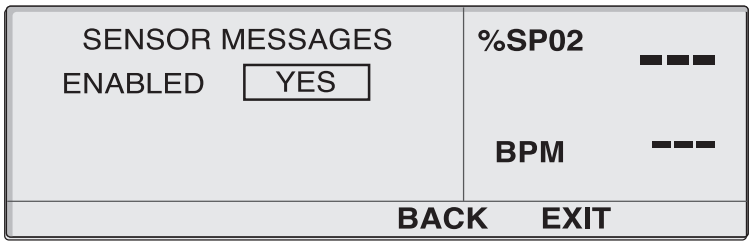
Setting up *OxiMax* Sensor Messages

The *OxiMax* sensor message setup display allows you to enable or disable the *OxiMax* sensor message feature. When disabled, neither the "SENSOR NOT POSTING" nor the "RECOMMENDED ACTION" messages display.

1. With the monitor in the normal monitoring mode, press the SETUP softkey.

2. Press the SENSOR softkey.

3. Press the MSG softkey.



4. Press the ADJUST UP or ADJUST DOWN button to toggle the ENABLE message.

5. Press the EXIT softkey.

Setting In-Sensor Data Type

The In-Sensor Data Type display enables you to adjust the type of patient alarm event trend data to be recorded in an *OxiMax* sensor. *OxiMax* sensors can be set to record either SpO_2 or SpO_2+BPM.

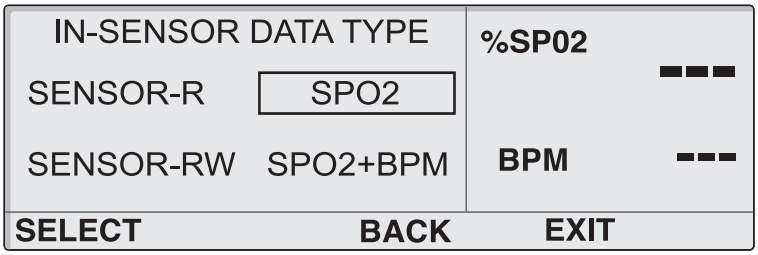
Note: The *OxiMax* sensor data type can only be set when an *OxiMax* sensor is not connected to the monitor.

1. With the monitor turned on and no cables attached to the SpO_2 *OxiMax* sensor port, press the SETUP softkey.

2. Press the SENSOR softkey.

3. Press the DATA softkey.

Note: *OxiMax* sensor data type settings are displayed on the monitor as shown in the figure below (in-sensor data type). If no sensor is connected, both sensor types and the full set of options for each are displayed. If a sensor is connected, only the sensor data type for that sensor displays.



Note: The SENSOR-R feature supports all the current *OxiMax* sensors. The SENSOR-RW feature is only applicable to *OxiMax* sensors with a read/write chip installed.

4. Use the SELECT softkey to toggle between SENSOR-R and SENSOR-RW.

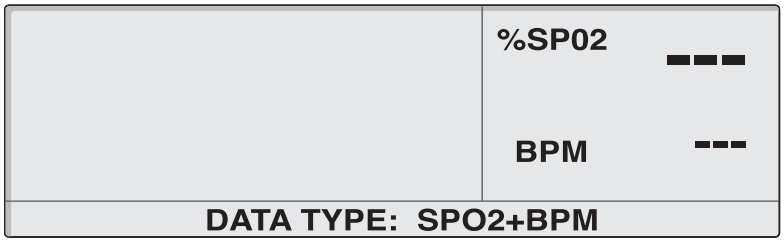
5. Use the ADJUST UP or ADJUST DOWN button to select the *OxiMax* sensor data type. SENSOR-R and SENSOR-RW selections are:

   - SpO_2
   - SpO_2+BPM
   - DEFAULT

6. Press the EXIT softkey to set the *OxiMax* sensor type.

OxiMax Sensor Data Type

When an *OxiMax* sensor with no previously recorded patient data is connected to the *OxiMax* monitor, a "DATA TYPE: . . ." message is displayed briefly at the bottom of the display after the *OxiMax* sensor type message. The message identifies the monitor's current data type setting that will be used to write data to the *OxiMax* sensor. The data type setting options are EVENT/ SPO_2 and EVENT/SPO_2+BPM.

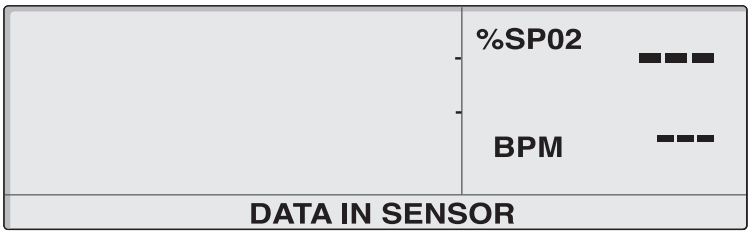


You can change the setting by referring to *Setting up OXIMAX Sensor Messages* on page 82. The *OxiMax* sensor event record type must be set prior to connecting the *OxiMax* sensor to the monitor.

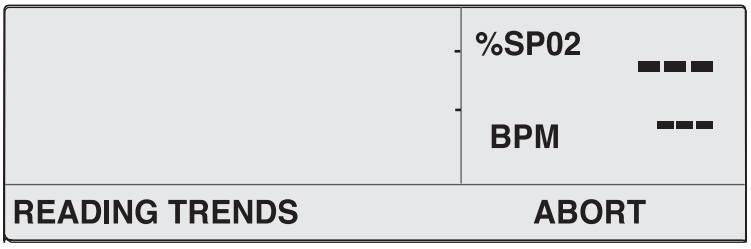
OxiMax Sensor Event Record Data Available

When an *OxiMax* sensor containing patient alarm data (single-patient-use *OxiMax* sensors only) is connected to the monitor, the Sensor Event Record indicator on the monitor front panel blinks at a medium priority flash rate to indicate that the *OxiMax* sensor attached to the monitor contains patient event data. The LED blinks for approximately 60 seconds or until the *OxiMax* sensor is disconnected or until the sensor trend data is displayed by pressing TREND, then SENSOR.

A corresponding "DATA IN SENSOR" message is also displayed at the bottom of the display. After 4 to 6 seconds, if all the data has been read from the *OxiMax* sensor, the message is replaced with the main menu.



If data is still being read from the *OxiMax* sensor after 4 to 6 seconds, the DATA IN SENSOR message is replaced with a READING TRENDS message which includes an ABORT option.



Selecting the ABORT softkey stops the recording, accessing or viewing of additional data into the *OxiMax* sensor.

Sensor event records can be viewed by accessing the TREND/SENSOR menu.

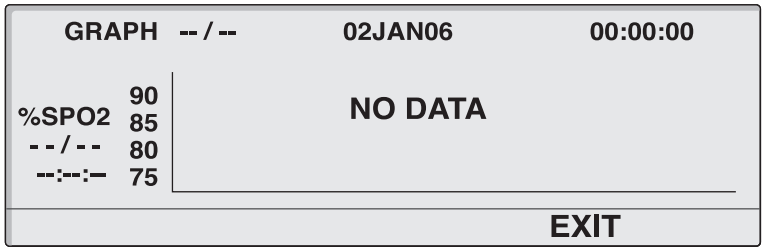
The SENSOR EVENT RECORD LED comes on steady when *OxiMax* sensor memory is full and stays on until the *OxiMax* sensor is disconnected.

OxiMax Sensor Event Record Not Available

If you select the TREND/SENSOR option when a connected *OxiMax* sensor (single-patient-use *OxiMax* sensors only) does not contain data, because no events were recorded to the *OxiMax*

sensor memory chip in the prior monitoring situation, a TREND/ SENSOR option is unavailable.

A sample event display without data is shown below. The message clears when the graph or summary closes.



OxiMax Sensor Event Record Graphical Data

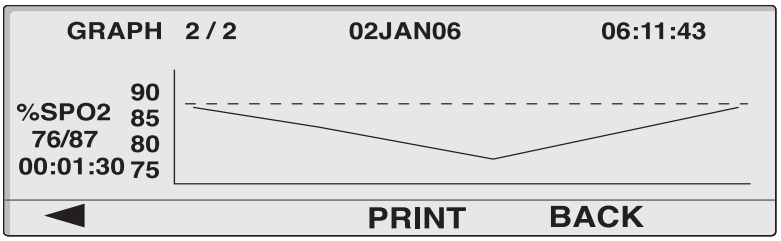
Graphical representations of patient event history is only available on single-patient-use *OxiMax* sensors. Graphed data points are the minimum or maximum %SpO_2 value for each 30-second interval throughout the duration of an event (%SpO_2 continuously below alarm threshold for at least 15 seconds) and continuing every 30 seconds until the actual %SpO_2 value equals or exceeds the alarm threshold.

The duration of an event is determined by the number of data points in the event. Each data point is stored at 30-second intervals.

Events end due to one of the following reasons:

- %SpO_2 returns to or above the alarm limit
- Loss of pulse

- *OxiMax* sensor is disconnected
- *OxiMax* sensor is removed from the patient



The graph title shows the data type (EVENT GRAPH) in the upper left corner. The number of the displayed event and the total number of events recorded in the *OxiMax* sensor are shown to the right of the title (example, 2/2). The date and time of the displayed event are shown in the upper center and upper right corner.

The type of data displayed in the graph is indicated to the left of the vertical axis (%SpO_2). Below this is the range of values (min./max.) during the event. The duration of the event is shown below the range value. The vertical axis of the graph is labeled to show the magnitude scale of the graphed data. The horizontal axis is not labeled but automatically scales to accommodate the number of 30-second intervals during the event. The alarm threshold (lower than %SpO_2 alarm limit) is represented by a horizontal dotted line across the graph. The first data point is the alarm threshold.

Events are displayed one at a time and one per graph. Graphs are displayed in chronological sequence, with the most recent event shown first when accessing the graphical *OxiMax* sensor event display. The user can move between events by using the two left-most softkeys which are labeled with left- and right-facing arrow icons, respectively. At the beginning of an event sequence, event 1 of 2 events, the left-arrow softkey is blank; at the end of a sequence, event 2 of 2 events, the right-arrow softkey is blank.

The ADJUST UP and ADJUST DOWN buttons on the monitor panel can also be used to move through events.

The PRINT softkey enables you to print the displayed event graph. The BACK softkey returns to the previous TREND/SENSOR submenu level.

Viewing and Printing *OxiMax* Sensor Event History Data

With the monitor in the normal monitoring mode, you can connect a printer, capable of printing graphs, to the monitor data port connector in order to print *OxiMax* sensor event history data.

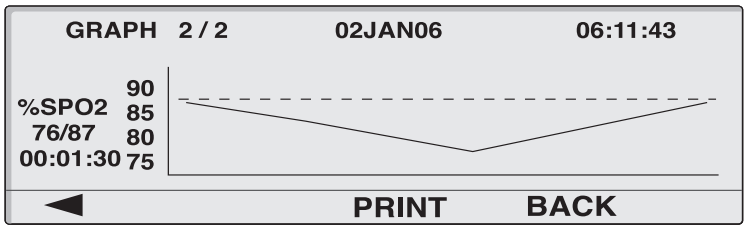
The monitor protocol must be set to GRAPH to print the in-sensor event history data. Refer to *Printing Monitor Trend Data* on page 93.

1. Connect an *OxiMax* sensor containing patient data to the SPO2 *OxiMax* sensor port of the monitor.

2. Press the TREND softkey.

3. Press the SENSOR softkey.

4. Press the GRAPH softkey.

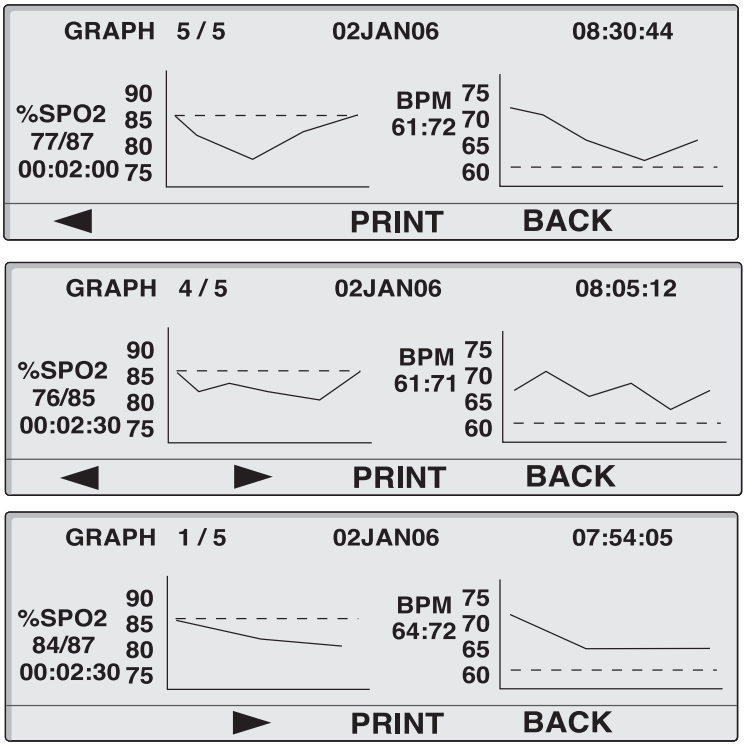


Note: Use the left and right arrow softkeys to scroll through the pages of the event graph.

5. Press the PRINT softkey to print the displayed screen.

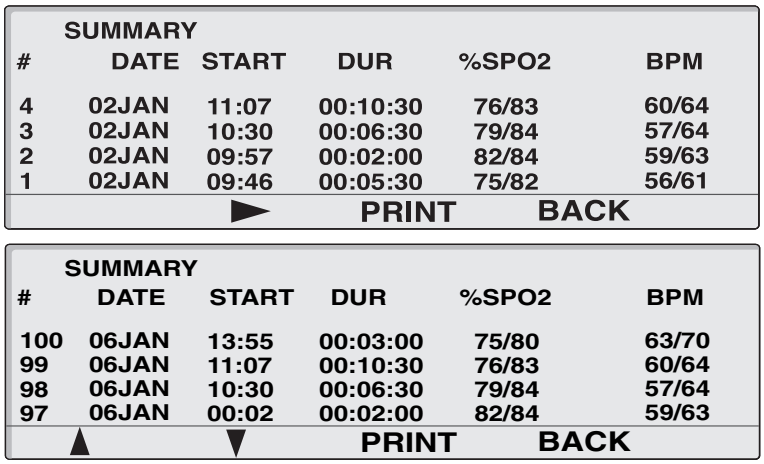
6. Press the EXIT softkey.

A sequence of %SpO2 + BPM (saturation plus pulse rate) "dual-view" event graphs are shown below. The dual-view graph is the same as a single graphical event history graphs, except the graphs are compressed horizontally to allow both %SpO2 and pulse rate graphs to be shown for the same event.



OxiMax Sensor Tabular Event Data

The *OxiMax* sensor tabular event data is a listing of all events recorded on the *OxiMax* sensor's memory chip.



The table title is located in the upper left corner. Below the table title is a six-column table with left-to-right column headings of event number (#), date (DATE), event start time (START), event duration (DUR), %SPO_2 minimum and maximum values during the event (%SPO_2), and pulse rate minimum and maximum values during the event (BPM).

Event data are listed in chronological order with the most recent event shown first, at the top of the list, when the tabular Event Summary display is first accessed. Four events can be displayed simultaneously; the table must be scrolled to view additional events. You can move to the next screen view of the table, the next three events (the previously displayed bottom or top event is retained as the fourth event for context when a table is scrolled), using the two left-most softkeys that are labeled with left- and right-facing arrow icons, respectively. At the beginning of an event sequence, Event 1 of 5 events, the left-arrow softkey is blank; at the end of a sequence, Event 5 of 5 events, the right-arrow soft key is blank, indicating the beginning or end of the table.

The ADJUST UP and ADJUST DOWN buttons on the monitor panel are used to move through the Event Summary table line by line.

The PRINT softkey enables you to print the displayed event graph.

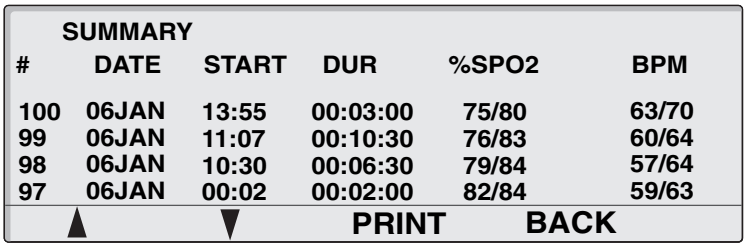
The BACK softkey returns to the previous TREND/SENSOR submenu level.

Viewing and Printing In-Sensor Tabular Event History Data

1. With the monitor in the normal monitoring mode, press the TREND softkey.

2. Press the SENSOR softkey.

3. Press the TABLE softkey to view the data.



4. Press the PRINT softkey to print the data.

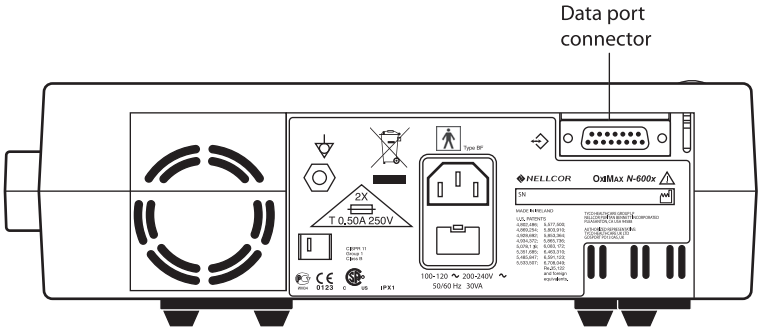
5. Press the BACK softkey.

Printing Monitor Trend Data

Overview

Trend information (monitor and in-sensor event history) can be sent to a personal computer or to a serial printer.

Note: The protocol settings must be set to ASCII MODE for printing text data or GRAPH MODE for printing graphical data.



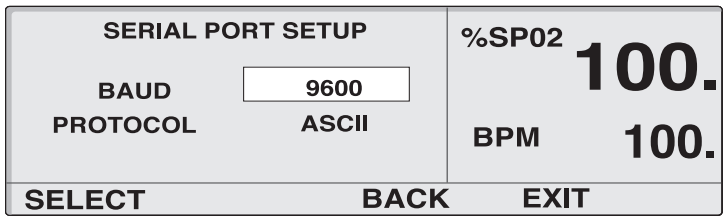
Printing

1. With the monitor in the normal monitoring mode, connect the serial printer to the monitor's Data port connector, using Nellcor printer cable part number 036341.

2. Turn on the printer.

3. Press the SETUP softkey on the monitor, and then press the NEXT softkey.

4. Press the COMM softkey.



5. Set the BAUD rate to the appropriate number using the ADJUST UP button.

6. Press the SELECT softkey to select PROTOCOL.

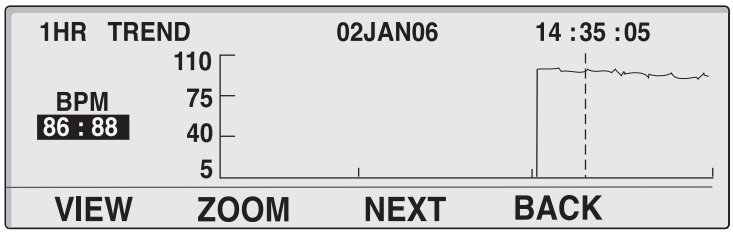
7. Set the PROTOCOL to ASCII for text printing or GRAPH for graph printing using the ADJUST UP button.

8. Press the EXIT softkey.

9. Press the TREND softkey.

10. Press the MONITR softkey for monitor trend printing or press the SENSOR softkey for in-sensor event history data printing.

11. Press the NEXT softkey.



12. Press the PRINT softkey.

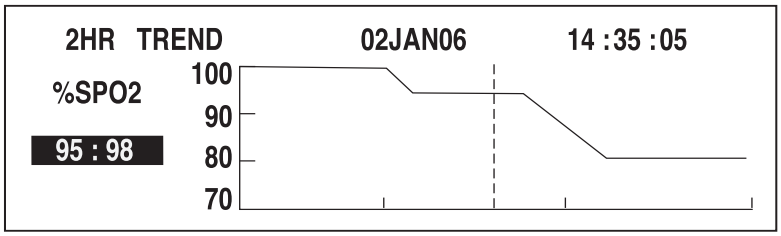
ASCII printout:

N-600x VERSION 4.0.0.0 TREND SpO2 Limit: 85-100% PR Limit: 40-170BPM
ADULT 0SAT-S SPO2 RESP MODE: NORMAL

TIME	%SpO2	BPM	PA	STATUS
02-JAN-06 14:00:05	100	120	150	
02-JAN-06 14:00:09	100	121	154	
02-JAN-06 14:00:13	100	120	150	

Output Complete

GRAPH printout:



Monitor Trend Data in ASCII Mode

Refer to *Printing Monitor Trend Data* on page 93 for the procedure to print trend information.

The format of data displayed when a trend printout is shown in Figure 3. “TREND” is displayed in the top row.

Readings are displayed in 2 or 4 second intervals depending on the response mode selected. The values on each row are an average of the response mode selected period.

At the end of the printout, an “Output Complete” line indicates the transmission was successful. If the “Output Complete” line is

not present, a corruption of the data may have been detected and the data should be ignored.

```
N-600x  VERSION 4.0.0.0  TREND      SpO2 Limit:  85-100%   PR Limit:  40-170BPM
              ADULT      0SAT-S     SPO2 RESP MODE: NORMAL
TIME                     %SpO2   BPM   PA        STATUS
02-JAN-06  14:00:05      100     120   150
02-JAN-06  14:00:09      100     121   154
02-JAN-06  14:00:13      100     120   150
Output Complete
```

Figure 3: ASCII Mode Printout

Note: Once trend printing has begun, printing can only be aborted by turning off the N-600x or the printer.

Trend Data in Graph Mode

Refer to *Printing Monitor Trend Data* on page 93 for the procedure to print trend information. See Figure 4.

The graph mode disables all printout functions except trend data. Graph mode trend printouts are formatted for a Seiko DPU-414 and Okidata 320 serial printer.

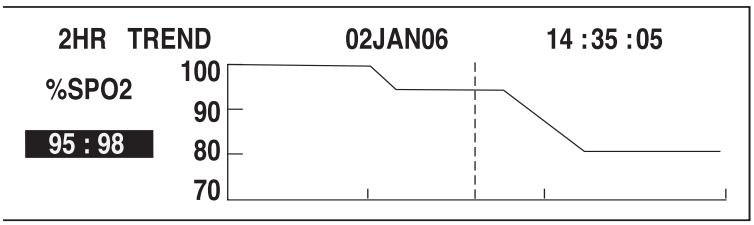


Figure 4: Graph Mode Printout

Real-Time Display/Printout Format

Real-time data is continuously sent to the data port on the back of the N-600x. Patient data can be obtained through the data port by connecting the monitor data port to a PC or serial printer.

When a real-time printout or display is being transmitted to a printer or PC, a new line of data is displayed every 2 seconds. Column headings are displayed or printed after every 25 lines, or if one of the values in the column heading changes. Readings are displayed at 4-second intervals if the SpO_2 response mode is set to normal and at 2-second intervals when the SpO2 response mode is set to fast.

Data cannot be obtained if the N-600x is operating on battery power.

Note: If the data output stops transmitting, turn the power off and back on again or, if the monitor is connected to a PC, send an XON (Ctrl-q) command to reset the monitor.

An example of real-time data output is shown in Figure 5.

N-600x VERSION 4.0.0.0 CRC: XXXX SpO2 Limit: 85-100% PR Limit: 40-170BPM
ADULT 0SAT-S SPO2 RESP MODE: NORMAL

TIME		%SpO2	BPM	PA	Status			
02-JAN-06	14:00:05	100	120	50				
02-JAN-06	14:00:07	100	124	50				
02-JAN-06	14:00:09	100	190*	52			PH	
02-JAN-06	14:00:11	100	190*	50			PH	
02-JAN-06	14:00:13	100	190*	51			PH	
02-JAN-06	14:00:15	100	190*	50			PH	
02-JAN-06	14:00:17	100	190*	50			PH	
02-JAN-06	14:00:19	100	190*	51			PH	
02-JAN-06	14:00:21	100	190*	53			PH	LB
02-JAN-06	14:00:23	100	190*	50			PH	LB
02-JAN-06	14:00:25	100	090*	50			PH	LB
02-JAN-06	14:00:27	—	—	—	SD			LB
02-JAN-06	14:00:29	—	—	—	SD			LB
02-JAN-06	14:00:31	—	—	—	SD			
02-JAN-06	14:00:33	—	—	—	SD			
02-JAN-06	14:00:35	—	—	—	SD			
02-JAN-06	14:00:37	—	—	—	SD			
02-JAN-06	14:00:39	—	—	—	SD			
02-JAN-06	14:00:41	—	—	—	SD			
02-JAN-06	14:00:43	—	—	—	SD			
02-JAN-06	14:00:45	—	—	—	SD			
02-JAN-06	14:00:47	—	—	—	SD			
02-JAN-06	14:00:49	—	—	—	SD			

N-600x VERSION 4.0.0.0 CRC: XXXX SpO2 Limit: 85-100% PR Limit: 40-170BPM
ADULT 0SAT-S SPO2 RESP MODE: NORMAL

TIME		%SpO2	BPM	PA	Status
02-JAN-06	14:00:51	—	—	—	SD

N-600x VERSION 4.0.0.0 CRC: XXXX SpO2 Limit: 80-100% PR Limit: 40-170BPM
ADULT 0SAT-S SPO2 RESP MODE: NORMAL

TIME		%SpO2	BPM	PA	Status			
02-JAN-06	14:00:53	79*	59	50		SL	PL	LB
02-JAN-06	14:00:55	79*	59	50	PS	SL	PL	LB

Figure 5: Real-Time Printout

Column Headings

Every 25th line of the data output consists of a column heading.

N-600x VERSION 4.0.0.0 CRC: XXXX SpO2 Limit: 85-100% PR Limit: 40-170BPM				
	ADULT	0SAT-S	SPO2 RESP MODE: NORMAL	
TIME	%SpO2	BPM	PA	Status

A column heading is displayed whenever the value within a column heading changes. There are three column-heading lines shown in the printout. Using the top row as the starting point there are 25 lines before the second row of column headings is printed. The third row of column headings is displayed when the operator changes the SpO_2 lower alarm limit from 85 percent to 80 percent.

Data Source

N-600x VERSION 4.0.0.0 CRC: XXXX SpO2 Limit: 85-100% PR Limit: 40-170BPM				
	ADULT	0SAT-S	SPO2 RESP MODE: NORMAL	
TIME	%SpO2	BPM	PA	Status

Data in the highlighted box above represents the model number of the monitor, in this case the N-600x monitor.

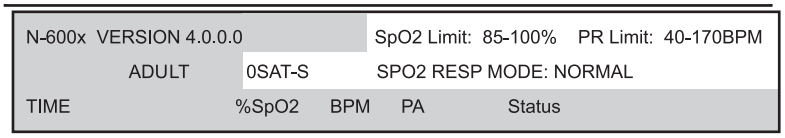
Software Version

N-600x VERSION 4.0.0.0 CRC: XXXX SpO2 Limit: 85-100% PR Limit: 40-170BPM				
	ADULT	0SAT-S	SPO2 RESP MODE: NORMAL	
TIME	%SpO2	BPM	PA	Status

The next data field displays the software level (Version 4.0.0.0) and a software verification number (CRC: XXXX). Neither of these numbers should change during normal operation.

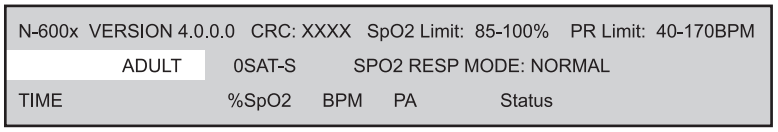
Note: The numbers may change if the monitor is serviced and receives a software upgrade.

Alarm Limits



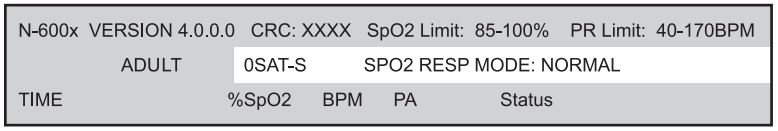
The last data field in the top line indicates the upper and the lower alarm limits for %SpO_2 and for the pulse rate (PR). In the example above the lower alarm limit for SpO_2 is 85% and the upper alarm limit is 100%. Pulse Rate alarm limits are 40 and 170 bpm. The *SatSeconds* alarm limit (0SAT-S) displays the *SatSeconds* alarm setting. In this example *SatSeconds* is set to off.

Monitor Mode



The monitor mode (ADULT or NEONATE) is identified on the printout.

Response Mode



The response mode (NORMAL or FAST) is identified on the printout.

Data Column Headings

N-600x VERSION 4.0.0.0 CRC: XXXX SpO2 Limit: 85-100% PR Limit: 40-170BPM				
ADULT	0SAT-S	SPO2 RESP MODE: NORMAL		
TIME	%SpO2	BPM	PA	Status

Actual column headings are in the second row of the column heading line. Patient data presented in the chart, from left to right, is the:

- time the patient data was recorded
- current %SpO_2 value
- current Pulse Rate (BPM)
- current Pulse Amplitude (PA)
- operating status of the N-600x.

Time

TIME	%SpO2	BPM	PA	Status
02-JAN-06 14:00:05	100	190*	50	

The Time column displays the value of the N-600x real-time clock.

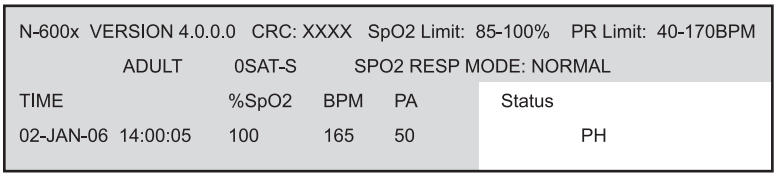
Patient Data

N-600x VERSION 4.0.0.0 CRC: XXXX SpO2 Limit: 85-100% PR Limit: 40-170BPM				
ADULT	0SAT-S	SPO2 RESP MODE: NORMAL		
TIME	%SpO2	BPM	PA	Status
02-JAN-06 14:00:05	100	190*	50	

Patient information is highlighted in the display above. Parameter values are displayed directly beneath the heading for each parameter. In this example, the %SpO_2 is 100 and the pulse rate is 190 beats per minute. The "*" next to the 190 indicates that 190 beats per minute is outside of the alarm limits, indicated in the top row, for pulse rate. If no data for a parameter is available, three dashes [- - -] display.

PA represents the pulse amplitude value, in which the number can range from 0 to 254. There are no alarm parameters for this value. It can be used for trending information as an indication of a change in pulse volume, relative pulse strength, or circulation.

Operating Status



The Status column indicates alarm conditions and operating status of the N-600x. In this example, "PH" indicates the pulse rate upper alarm limit (Pulse High) has been exceeded. A complete listing of the status codes is listed below. As many as four codes can be displayed at one time in the Status column.

Code	Definition
AO	Alarm Off
AS	Alarm Silence
LB	Low Battery
LM	Loss of Pulse with Interference
LP	Loss of Pulse

Code	Definition
MO	Patient **Mo**tion
PH	Pulse Rate Upper Limit Alarm
PL	Pulse Rate Lower Limit Alarm
PS	Pulse Search
SH	Saturation Upper Limit Alarm
SL	Saturation Lower Limit Alarm
SD	Sensor Disconnect
SO	Sensor Off

Note: An *OxiMax* sensor disconnect causes three dashes [- - -] to be displayed in the patient data section of the display or printout.

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Using the Data Port

Overview

Patient data can be output through the data port on the back of the N-600x by connecting it to a PC or serial printer.

When connecting the N-600x to a printer or PC, verify proper operation prior to clinical use. Both the N-600x and the printer or PC must be connected to a grounded AC power outlet. The N-600x protocol setting must be ASCII.

Any printer or PC connected to the monitor's data port must be certified according to IEC Standard 950. All combinations of equipment must be in compliance with IEC Standard 60601-1-1 systems requirements. Anyone who connects a printer or PC to the data output port configures a medical system and is therefore responsible for ensuring the system complies with the requirements of system standard IEC Standard 60601-1-1 and the electromagnetic compatibility system standard IEC Standard 60601-1-2.

Connecting to the Data Port

The N-600x data port may be connected to a serial printer or PC by using a cable terminated with:

- an AMP connector (AMP part number 747538-1),
- ferrule (AMP part number 1-747579-2), and
- compatible pins (AMP part number 66570-2).

The cable should not exceed 25 feet (7.6 meters) in length. The external ITE (Information Technology Equipment) device must be

certified to UL-1950 or IEC-60950. The cable used must have a braided shield that provides 100% coverage, such as a Belden cable (Belden part number 9609) or equivalent. The shield must have a 360-degree connection to the metal shell on the N-600x's DB-15 connector and to the connector on the PC or serial printer.

Caution: Do not create sharp bends in the cable, as this may tear or break the shielding.

No hardware flow control is used. However, in ASCII mode, XON/XOFF flow control is supported.

Data Port Pinouts

The pinouts for the data port are listed in Table 8.

Table 8: Data Port Pinouts

Pin	Signal Name
1	RXD+ (RS-422 [+] input)
2	RXD_232 (RS-232 input)
3	TXD_(RS-232 output)
4	TXD+ (RS-422 [+] output)
5	Signal Ground (isolated from Earth Ground)
6	AN_SpO2 (analog saturation output)
7	NC_NO (relay closure nurse call, normally open)
8	NC_NC (relay closure nurse call, normally closed)
9	RxD- (RS_422 [-] input)
10	Signal Ground (isolated from Earth Ground)
11	Nurse Call (RS-232-level-output)
12	TxD- (RS-422 [-] output)
13	AN_PULSE (analog pulse rate output)

Table 8: Data Port Pinouts

Pin	Signal Name
14	AN_PLETH (analog pleth waveform output)
15	NC_COM (relay closure nurse call, common lead)

TxD represents the Transmit Data line, and RxD is the Receive Data line.

The pin layouts (as viewed from the rear panel of the N-600x) are illustrated in Figure 6. The conductive shell is connected to earth ground when connected to a PC or printer.

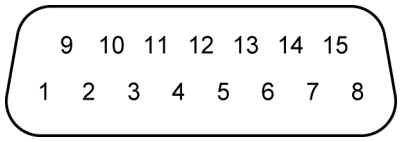


Figure 6: Data Port Pin Layout

Pins 2, 3, and 5 provide data in RS-232 format.

Pins 1, 4, 9, and 12 provide data in RS-422 format. TxD+ and TxD- are the differential transmit data pair. RxD+ and RxD- are the differential receive data pair.

WARNING: If the serial port, analog outputs, or nurse call lines are shorted, remote communication may be lost.

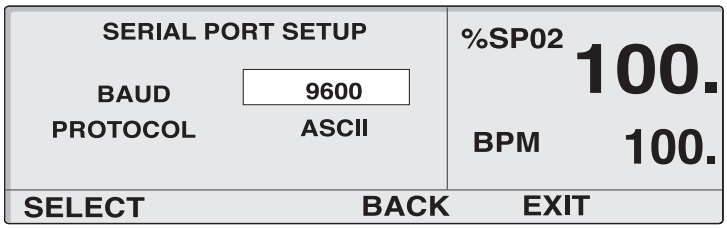
Data Port Setup

Use the Data Port Setup display to set the baud rate and the protocol of the data port on the N-600x.

The Data Port Setup display is accessed by pressing the COMM softkey on the Setup menu.

1. With the monitor in the normal monitoring mode, press the SETUP softkey.

2. Press the NEXT softkey twice and then press the COMM softkey.



3. Press the ADJUST UP or ADJUST DOWN buttons to select the desired baud rate.

4. Press the SELECT softkey.

5. Press the ADJUST UP or ADJUST DOWN buttons to select the desired protocol. The available protocols are:

    - ASCII
    - CLINICAL

- GRAPH
- OXINET
- PHILIPS
- SPACELBS (Spacelabs)
- MARQ (GE Marquette)
- DATEX (Datex-Ohmeda)

6. Press the EXIT softkey.

Using the Nurse Call Interface

WARNING: The nurse call feature should not be used as the primary source of alarm notification. The audible and visual alarms of the pulse oximeter, used in conjunction with clinical signs and symptoms, are the primary sources for notifying medical personnel that an alarm condition exists.

WARNING: The nurse call feature is not functional whenever the pulse oximeter alarms are silenced.The nurse call feature of the N-600x monitor is operational when the monitor is powered by AC power or battery power.

The nurse call feature of the N-600x works in conjunction with the nurse call system of your institution when the monitor sounds an audible alarm. It is accessed through the data port pins 7, 8, 10, 11, or 15 as indicated in Table 8.

The N-600x provides two different types of nurse call interfaces: an RS-232 level and relay closure. The RS-232 level nurse call function operates when the monitor is connected to AC power or

on battery. The relay-based nurse call function is available when the monitor is operating either on AC power or on battery power.

The remote location is signaled anytime there is an audible alarm. If the audible alarm has been turned off or silenced, the nurse call function is also turned off.

Pin 11 on the data port is the RS-232 level nurse call signal and pin 5 or 10 is ground (see Table 8). When there is no alarm condition, the voltage between pins 10 and 11 is -5 to -12 VDC. Whenever the monitor is in an alarm condition, the output between pins 10 and 11 is +5 to +12 VDC.

Pins 7 and 15 provide a relay that closes when an alarm is sounding on the monitor. Pins 8 and 15 provide a relay that opens when an alarm is sounding. Pin 15 is a common lead for both relays.

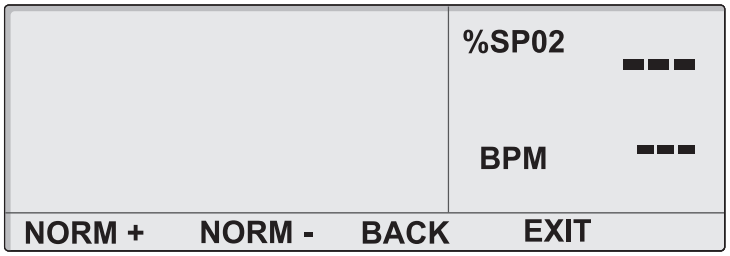
The nurse call function needs to be tested after it has been set up in your facility. The nurse call feature should be tested whenever setting up the N-600x pulse oximeter in a location that uses nurse call. If an attached *OxiMax* sensor is not connected to a patient, the monitor display reads zeros and the monitor remains in the Pulse Search Mode for 5 seconds, then the monitor displays [**- - -**] (3 dashes) in the %SpO_2 and pulse rate display. One way to test the nurse call function is to create an alarm condition (for example, sensor disconnect) and verify that your facility's nurse call system is activated.

Setting Nurse Call RS-232 Polarity

The nurse call polarity can be set to a positive signal (NORM +) on a monitor alarm condition or a negative signal (NORM -) on a monitor alarm condition.

1. With the monitor in the normal monitoring mode, press the SETUP softkey.

2. Press the NEXT softkey twice and then press the NCALL softkey.



3. Press the NORM + softkey OR press the NORM - softkey.

4. Press the EXIT softkey.

Setting Nurse Call Relays Normally Open/Closed

Data port pins 7 and 15 provide a relay that closes when an alarm is sounding on the monitor. Pins 8 and 15 provide a relay that opens when an alarm is sounding. Pin 15 is a common lead for both relays. The relay operates whether the monitor is operating on AC power or battery.

Calculating the Analog Voltage Output

The N-600x data port provides analog voltage outputs between pins 6, 13, 14, and ground (pin 10), which can be used to calibrate instruments such as a chart recorder. The voltage represents a specific measured parameter's current value. The voltage differential varies proportionally from 0 to 1 volt as the

pin's parameter varies over its full range of values, as indicated in Table 9.

Table 9: Analog Pinouts

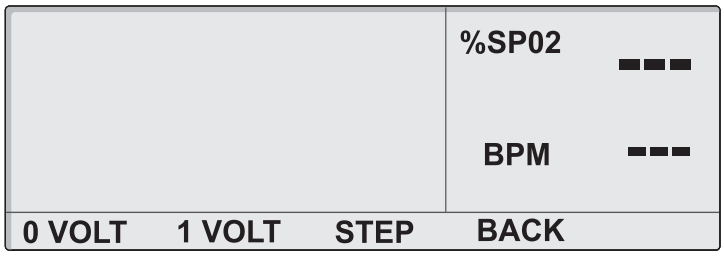
Pin	Parameter	Parameter Range
6	%SpO2	0 - 100%
13	Pulse Rate	0 - 250 bpm
14	Pleth Waveform	0 - 255

For example, as the current value of %SpO_2 varies from 0 to 100%, the voltage from pin 6 to ground (pin 10) varies from 0 to 1 volt. A voltage of 0.94 volts indicates a current %SpO_2 value of 94.

1. Press the SETUP softkey.

2. Press the NEXT softkey three times.

3. Press the ANALOG softkey.



Selecting the 0 VOLT or 1 VOLT softkey causes that voltage to appear at pins 6, 13, or 14 as referenced to ground pins 5 and 10.

Selecting the STEP softkey causes the voltage to increase from 0 to 1 volt at 1/10th-volt increments, with each step lasting at least 1 second.

Nellcor recommends that a qualified service personnel perform the calibration of the attached device as described in the *N-600x Service Manual*.

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OxiMax Sensors and Accessories

WARNING: The sensor extrapolates from the date and time provided by the N-600x when recording the sensor event record to the sensor. The accuracy of the date/time is determined by the date/time of the N-600x. It is recommended that the N-600x user set the time/date to the correct value before a sensor event record-enabled sensor is connected, and that this date/time not be changed while the sensor remains connected. Since a sensor with sensor event record data can be transported from one monitor to another, having discrepancies in the date/time between monitors and the sensor event record data will affect the order the sensor event record data appears. To eliminate this possible problem, all monitors within an institution should be set to the same time.

Overview

The N-600x records a patient's *OxiMax* sensor %SpO2 event history from the *OxiMax* sensor's memory chip, allowing a patient's event history to travel with the patient as the patient moves throughout the hospital. This allows caregivers to assess whether the patient had a bad event during transport or in the previous area of care. This feature is only available with adhesive single-patient-use *OxiMax* sensors. Single-patient-use *OxiMax* sensors are intended for single-patient use only; recorded %SpO2 event history data does not distinguish between events that have been collected from multiple patients.

Selecting an *OxiMax* Sensor

WARNING: Before use, carefully read the *OxiMax* sensor directions for use, including all warnings, cautions, and instructions.

WARNING: Do not use a damaged *OxiMax* sensor or pulse oximetry cable. Do not use an *OxiMax* sensor with exposed optical components.

WARNING: Use only Nellcor-approved *OxiMax* sensors and pulse oximetry cables with this pulse oximeter. Other sensors or pulse oximetry cables may cause improper N-600x performance.

WARNING: Do not attach any cable to the *OxiMax* sensor port connector that is intended for computer use.

WARNING: Tissue damage can be caused by incorrect application or duration of use of an SpO_2 *OxiMax* sensor. Inspect the *OxiMax* sensor site periodically as directed in the *OxiMax* sensor directions for use.

WARNING: Do not lift the pulse oximeter by the pulse oximetry cable or power cord because the cable or cord could disconnect from the pulse oximeter, causing the pulse oximeter to drop on the patient.

WARNING: Pulse oximetry readings and pulse signal can be affected by certain ambient environmental conditions,

OxiMax **sensor application errors, and certain patient conditions.**

WARNING: Do not immerse or wet the *OxiMax* sensor.

Caution: The *OxiMax* sensor disconnect error message and associated alarm indicate that the *OxiMax* sensor is either disconnected or the wiring is faulty. Check the *OxiMax* sensor connection and, if necessary, replace the *OxiMax* sensor, pulse oximetry cable, or both.

Caution: Adhesive *OxiMax* sensors are intended for single-patient use only. Do not transfer an adhesive sensor containing sensor trend data from one patient to a second patient. Doing so may result in data from the first patient being used to evaluate the second patient.

Note: Physiological conditions, medical procedures, or external agents that may interfere with the pulse oximeter's ability to detect and display measurements include dysfunctional hemoglobin, arterial dyes, low perfusion, dark pigment, and externally applied coloring agents such as nail polish, dye, or pigmented cream.

A Sensor Accuracy Grid listing all of the *OxiMax* sensors used with the N-600x is available on the Internet at:

www.covidien.com/rms

When selecting an *OxiMax* sensor, consider the patient's weight and activity level, the adequacy of perfusion, and the available *OxiMax* sensor sites, the need for sterility, and the anticipated duration of monitoring. For more information refer to Table 10 or contact your local Nellcor representative. Refer to *OxiMax Sensor*

Performance Considerations on page 127, for more information on *OxiMax* sensor performance.

Table 10: Nellcor *OxiMax* Sensor Models and Patient Sizes

***OxiMax* Sensor**	**Model**	**Patient Size**
OxiMax MAX-FAST adhesive reflectance oxygen sensor	MAX-FAST	>10 kg
OxiMax oxygen sensor (Sterile, single-use only)	MAX-N	<3 or >40 kg
	MAX-I	3 to 20 kg
	MAX-P	10 to 50 kg
	MAX-A	>30 kg
	MAX-AL	>30 kg
	MAX-R	>50 kg
OxiMax Durasensor® oxygen sensor (Reusable, nonsterile)	DS-100A	>40 kg
OxiMax Oxiband® oxygen sensor (Reusable with adhesive nonsterile)	OXI-A/N	<3 or >40 kg
	OXI-P/I	3 to 40 kg
OxiMax OxiCliq® oxygen sensors (Sterile, single-use only)	P	10 to 50 kg
	N	<3 or >40 kg
	I	3 to 20 kg
	A	> 30 kg
OxiMax Dura-Y® multisite oxygen sensor (Reusable, nonsterile)	D-YS	>1 kg
	D-YSE	>30 kg
For use with the Dura-Y sensor:	D-YSPD	3 to 40 kg
Ear clip (Reusable, nonsterile)		
Pedi-Check™ pediatric spot-check clip (Reusable, nonsterile)		

Table 10: Nellcor *OxiMax* Sensor Models and Patient Sizes

OxiMax Sensor	Model	Patient Size
OxiMax Softcare nonadhesive sensor, single-patient-use, preterm infant	SC-PR	<1.5 kg
OxiMax Softcare nonadhesive sensor, single-patient-use, neonate	SC-NEO	1.5 to 5 kg
OxiMax Softcare nonadhesive sensor, single-patient-use, adult	SC-A	>40 kg

The pulse oximetry cable DOC-10 connects the N-600x pulse oximeter with the patient *OxiMax* sensor.

OxiMax Sensor Features

OxiMax sensor features are different for *OxiMax* sensors at a different revision level and by *OxiMax* sensor type (adhesive, recycled, and reusable). The revision level of an *OxiMax* sensor is located on the *OxiMax* sensor plug. Refer to Table 11.

Table 11: *OxiMax* Sensor Features

Feature	Adhesive Sensors	Recycled Sensors	Reusable Sensors	
	Revision B	Revision B	Revision A	Revision B
OxiMax Sensor Event Record	Yes	No	No	No
Sensor Messages	Yes	Yes	No	Yes
Sensor ID Message	Yes	Yes	Yes	Yes

Biocompatibility Testing

Biocompatibility testing has been conducted on Nellcor *OxiMax* sensors in compliance with ISO 10993-1, Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing. The *OxiMax* sensors have passed the recommended biocompatibility testing and are therefore in compliance with ISO 10993-1.

Optional Accessories

Several mounting configurations, a carrying case, and a utility basket are offered with the N-600x. Contact Nellcor's Technical Services Department or your local Nellcor representative for information about these accessories.

- GCX Mounting Plate. See Figure 7 on page 121
- GCX Vertical Wall Mount Arm. See Figure 8 on page 122.
- GCX Roll Stand. See Figure 9 on page 123.
- Soft-Sided Carrying Case. See Figure 10 on page 124.

Accessories for the N-600x are also listed on the Internet at:

www.covidien.com/rms

GCX Mounting Plate

An optional mounting plate is available for the N-600x. This mounting plate fits standard, commercially available GCX mount brackets, and is used to securely mount the N-600x to a wall bracket or a roll stand.

The mounting plate attaches to the bottom of the N-600x as shown in Figure 7. For further instructions regarding connecting the mounting plate to GCX brackets, refer to the illustrated directions for use included with the GCX mounting plate.

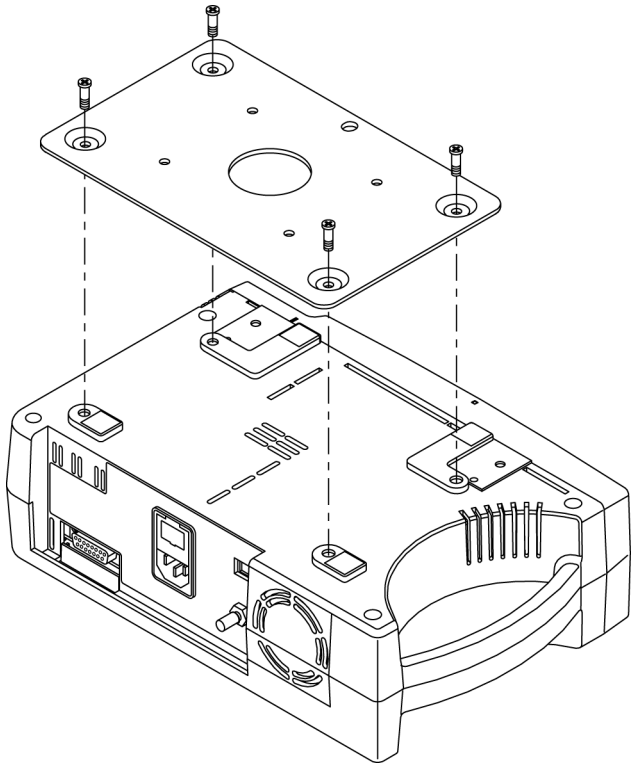

Figure 7: GCX Mounting Plate

GCX Vertical Wall Mount Arm

An optional vertical wall mount arm and 19-inch channel are available and can be ordered separately for the N-600x.

The vertical wall mount arm attaches to the N-600x GCX mounting plate as in Figure 8. For further instructions regarding connecting the vertical wall mount arm, refer to the illustrated directions for use included with the vertical wall mount arm.

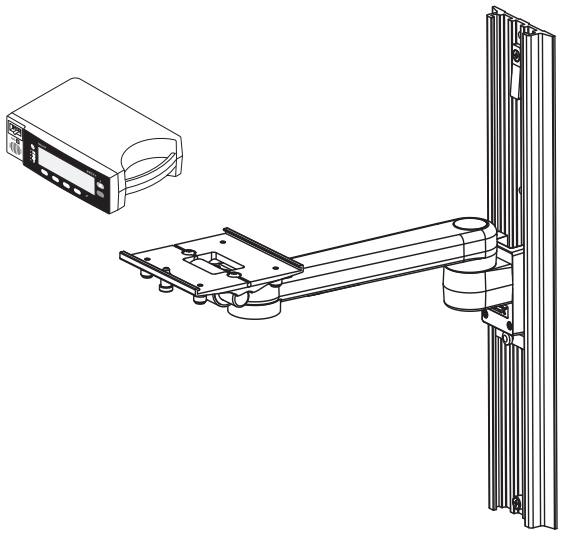

Figure 8: GCX Vertical Wall Mount Arm

GCX Roll Stand

An optional GCX roll stand with utility basket with an attached handle is available from Nellcor for the N-600x.

The GCX roll stand attaches to the N-600x GCX mounting plate as shown in Figure 9. For further instructions regarding

connecting the GCX roll stand, refer to the illustrated directions for use included with the GCX roll stand.

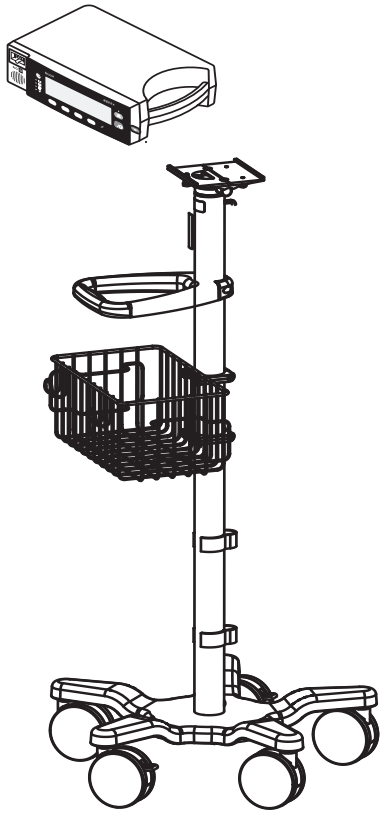

Figure 9: GCX Roll Stand

Soft-Sided Carrying Case

An optional soft-sided carrying case is available from Nellcor for the N-600x. See Figure 10. The padded carrying case protects the N-600x while transporting the monitor. The carrying case

contains two pockets for *OxiMax* sensors, cables, and Operator's Manual. You can order the carrying case directly from Nellcor.

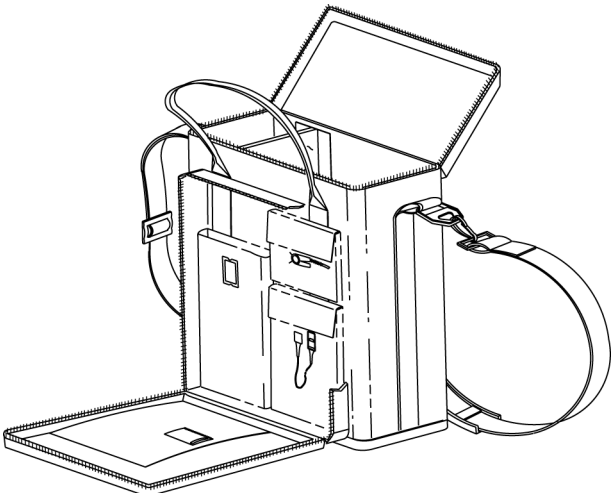

Figure 10: Soft-Sided Carrying Case

Performance Considerations

WARNING: Pulse oximetry readings and pulse signals can be affected by certain ambient environmental conditions, *OxiMax* sensor application errors, and certain patient conditions. See the appropriate sections of the manual for specific safety information:

- *Safety Information* on page 1
- *OXIMAX Sensors and Accessories* on page 115
- *Performance Considerations* on page 125

Overview

The performance of the N-600x is verified by following the procedures outlined in the Performance Verification section of the *N-600x Service Manual*. Qualified service personnel should perform these procedures before initially using the monitor in a clinical setting.

Performance Considerations

Certain patient conditions can affect the measurements of the N-600x and cause the loss of the pulse signal.

Inaccurate measurements can be caused by:

- incorrect sensor application
- failure to cover the sensor with opaque material in high ambient light conditions

- dysfunctional hemoglobins
- poor peripheral perfusion
- excessive patient movement
- venous pulsations
- intravascular dyes, such as indocyanine green or methylene blue
- externally applied coloring agents (nail polish, dye, pigmented cream)
- defibrillation

Dysfunctional Hemoglobins

Dysfunctional hemoglobins such as carboxyhemoglobin, methemoglobin, and sulphemoglobin are unable to carry oxygen. SpO_2 readings may appear normal; however, a patient may be hypoxic because less hemoglobin is available to carry oxygen. Further assessment beyond pulse oximetry is recommended.

Anemia

Anemia causes decreased arterial oxygen content. Although SpO_2 readings may appear normal, an anemic patient may be hypoxic. Correcting anemia can improve arterial oxygen content. The monitor may fail to provide an SpO_2 if hemoglobin levels fall below 5 gm/dl.

Saturation

The N-600x displays saturation levels between 1 and 100%.

Pulse Rates

The N-600x only displays pulse rates between 20 and 250 bpm. Detected pulse rates above 250 bpm are displayed as 250. Detected pulse rates below 20 are displayed as 0.

OxiMax Sensor Performance Considerations

WARNING: Pulse oximetry readings and pulse signal can be affected by certain ambient conditions, *OxiMax* sensor application errors, and certain patient conditions.

WARNING: Tissue damage can be caused by incorrect application or inappropriate duration of use of an SpO_2 *OxiMax* sensor. Inspect the *OxiMax* sensor site as directed in the *OxiMax* sensor directions for use.

WARNING: Use only Nellcor-approved *OxiMax* sensors and pulse oximetry cables.

Inaccurate measurements can be caused by:

- incorrect application of the *OxiMax* sensor
- placement of the *OxiMax* sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line
- ambient light
- excessive patient movement
- intravascular dyes or externally applied coloring, such as nail polish or pigmented cream

- failure to cover the *OxiMax* sensor site with opaque material in high ambient light conditions

Loss-of-pulse signal can occur for the following reasons:

- the *OxiMax* sensor is applied too tightly
- a blood pressure cuff is inflated on the same extremity as the one with the *OxiMax* sensor attached
- there is arterial occlusion proximal to the *OxiMax* sensor
- poor peripheral profusion

Select an appropriate *OxiMax* sensor, apply it as directed, and observe all warnings and cautions presented in the directions for use accompanying the *OxiMax* sensor. Clean and remove any substances such as nail polish from the application site. Periodically check to ensure that the *OxiMax* sensor remains properly positioned on the patient.

High ambient light sources such as surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight can interfere with the performance of an SpO_2 *OxiMax* sensor. To prevent interference from ambient light, ensure that the sensor is properly applied, and cover the *OxiMax* sensor site with opaque material.

WARNING: Failure to cover the *OxiMax* sensor site with opaque material in high ambient light conditions may result in inaccurate measurements.

If patient movement presents a problem, try one or more of the following remedies to correct the problem.

- verify the *OxiMax* sensor is properly and securely applied
- move the *OxiMax* sensor to a less active site

- use an adhesive *OxiMax* sensor that improves patient skin contact
- use a new *OxiMax* sensor with fresh adhesive backing
- keep the patient still, if possible

If poor perfusion affects performance, consider using the MAX-R *OxiMax* sensor; it obtains measurements from the nasal septal anterior ethmoid artery, an artery supplied by the internal carotid. This *OxiMax* sensor may obtain measurements when peripheral perfusion is relatively poor.

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Troubleshooting

Overview

This section describes how to troubleshoot common problems while using your N-600x pulse oximeter. This chapter includes information about the on-screen help function, error code messages, and how to obtain technical help and support.

WARNING: If you are uncertain about the accuracy of any measurement, check the patient's vital signs by alternate means; then make sure the pulse oximeter is functioning correctly.

WARNING: The cover should be removed only by qualified service personnel. There are no user-serviceable parts inside.

Caution: Do not spray, pour, or spill any liquid on the N-600x, its accessories, connectors, switches, or openings in the chassis.

On-Screen Help

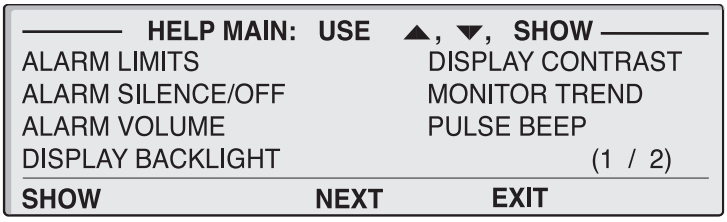
The N-600x monitor is equipped with an on-screen help system which enables you to browse and navigate through multiple help topics. Follow the steps outlined below to access and utilize the on-screen help.

Accessing Multiple Topics

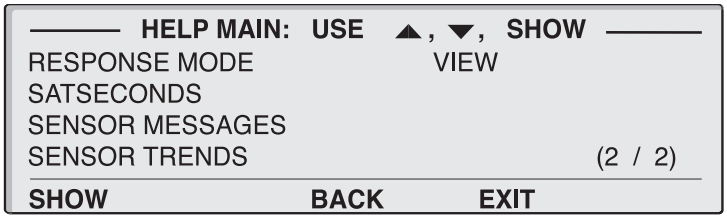
You can access multiple on-screen help topics and select a specific topic to view.

Follow the example described below to access the *SatSeconds* help topic.

1. From the Main menu, press the HELP/CONTRAST button. The HELP MAIN window appears.

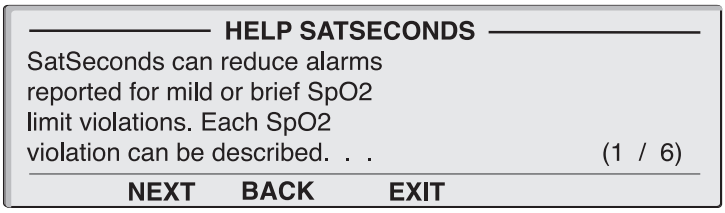


2. Press the ADJUST UP or ADJUST DOWN button to scroll through the available help topics or press NEXT to access page (2 / 2). Page (2 / 2) of the HELP MAIN window appears.

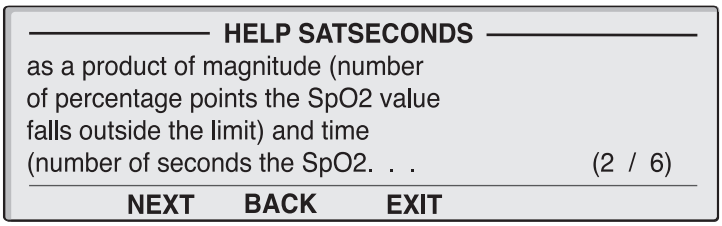


3. From page (2 / 2) of the HELP MAIN window, press ADJUST DOWN to select SATSECONDS and then press SHOW. The HELP SATSECONDS window appears.

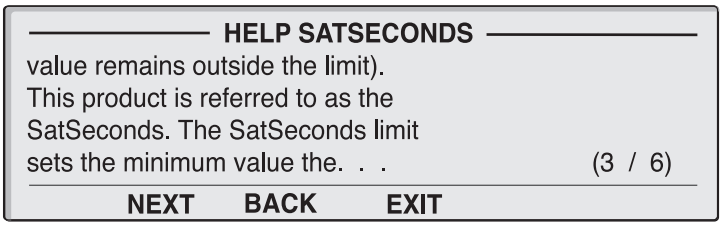
The *SatSeconds* help topic contains a total of six consecutive help windows.



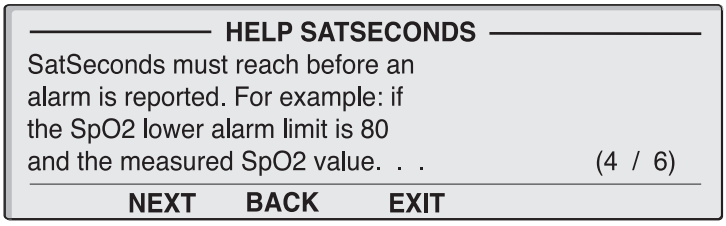
4. Press the NEXT softkey to scroll through each window of the selected help topic.



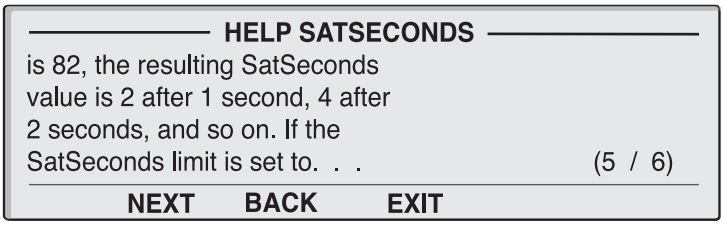
5. Press NEXT.



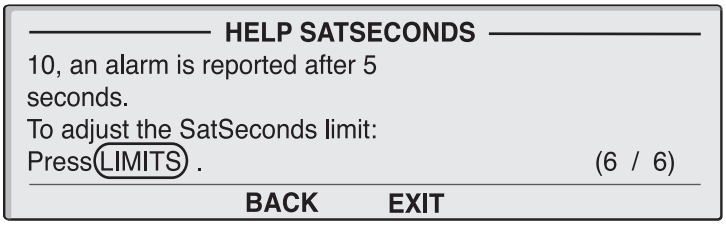
6. Press NEXT.



7. Press NEXT.



8. Press NEXT.



9. Press BACK to view the previous windows. Continue to press BACK to return to the HELP MAIN window.

10. Press EXIT to return to the monitor's Main menu.

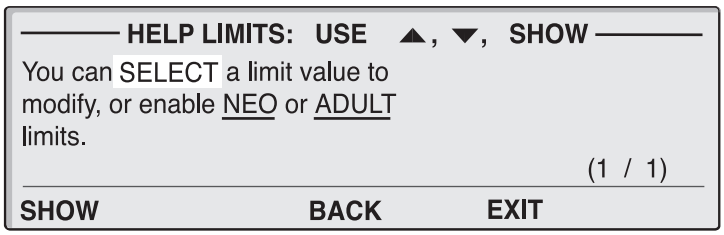
Accessing Single Topics

The on-screen help enables you to access single topics by pressing the HELP/CONTRAST button from a monitor submenu.

Follow the example described below to access the *SatSeconds* help topic.

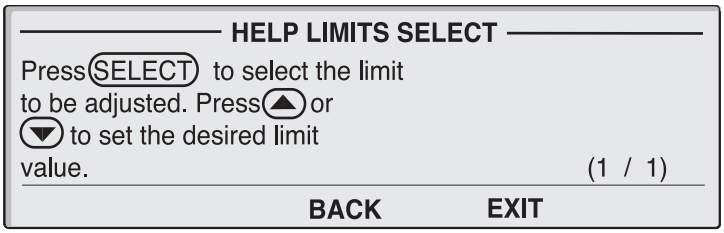
1. Press LIMITS on the monitor Main menu and then SELECT to highlight SAT-S (*SatSeconds*).

2. Press the HELP/CONTRAST button. The HELP LIMITS window appears.



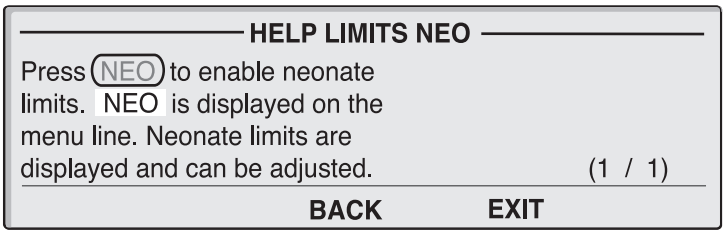
3. Press ADJUST UP or ADJUST DOWN to highlight an available help topic (SELECT, NEO and ADULT). For this example, hightlight SELECT.

4. Press SHOW. The HELP LIMITS SELECT window appears.



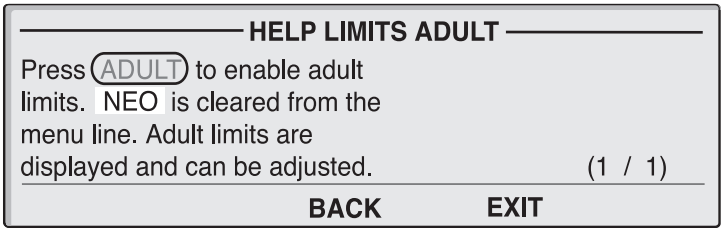
5. Press BACK.

6. Press ADJUST DOWN to highlight NEO and then press SHOW. The HELP LIMITS NEO window appears.



7. Press BACK.

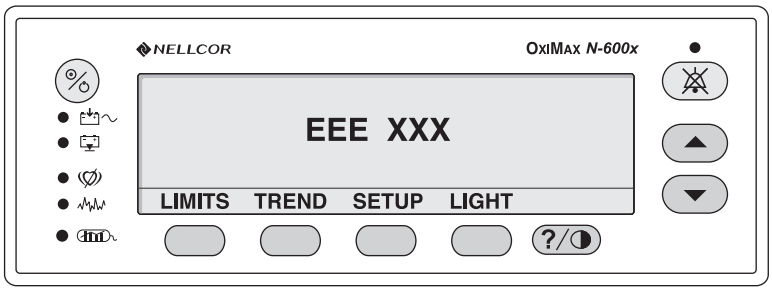
8. Press ADJUST DOWN to highlight ADULT and the press SHOW. The HELP LIMITS ADULT window appears.



9. Press EXIT to return to the LIMITS display.

Error Codes

When the N-600x detects an error condition, it may display "EEE" followed by an error code.



Note:The "XXX" indicates the error code number may contain up to three digits.

When an error code (other than the ones listed in Table 12) is displayed, turn the instrument off and back on again. If the error code reappears, record it and notify service personnel. Below Table 12 lists the error codes and possible causes. When this occurs, the unit will stop monitoring, remove all information from

the screen and display the message "EEE XXX," and sound a low priority alarm. Cycling the power clears these errors.

Table 12: Error Codes

Error Code	Error Message	Action
80	DEFAULTS LOST	The current power-on default settings have been lost and returned to factory defaults. Qualified service personnel can use the *N-600x Service Manual* to restore the desired power-on default settings.
81	SETTINGS LOST	The current settings (for example, alarm limits, alarm and pulse beep volumes, alarm silence duration) have been lost and returned to power-on defaults. Turn the monitor off and back on again. If it is necessary to have settings different from the power-on default settings, turn the monitor off and back on again, and reenter the desired settings.
82	CLOCK SETTING LOST	The date and time settings have been lost. Reenter the date and time. Recharge or replace the battery.
515, 518, 534, 535, 569	N-600x Boot Version x.x.x.x	The application software is missing or corrupt. Notify a qualified service personnel.
529, 729	LOW BATTERY	The battery is discharged to a critically low level. The monitor will shutdown after 10 seconds. Verify the SUPPLY VOLTAGE SELECTOR switch on the rear panel is set to the proper voltage. Connect the monitor to AC power and turn back on. A warning message is displayed and a low priority audible alarm sounded. These must be acknowledged (by pressing the alarm silence key twice) before the monitor can be used for patient monitoring.

Table 12: Error Codes

Error Code	Error Message	Action
575	TRENDS LOST	Monitor trends are corrupted and will be cleared. Turn off the monitor, and then back on again.
701-716, 720-724, 732-740, 576-582	POWER SUPPLY FAILURE	The monitor power supply has detected an error. The monitor will shutdown after 10 seconds. Verify the monitor is being operated within specified environmental conditions. Notify a qualified service technician.
717, 718	BATTERY FAILURE	The monitor has detected a battery open or short condition. The monitor will shutdown after 10 seconds. Battery should be replaced. Notify a qualified service technician.
725-728, 730	REPLACE BATTERY	The battery is not charging properly. The monitor will shutdown after 10 seconds. Battery should be replaced. Notify a qualified service technician.

Prompts and Error Messages

Prompt/Error Messages are displayed in the menu area. Prompt messages alert you for a response while error messages provide information.The two figures below show examples of a prompt and an error message.

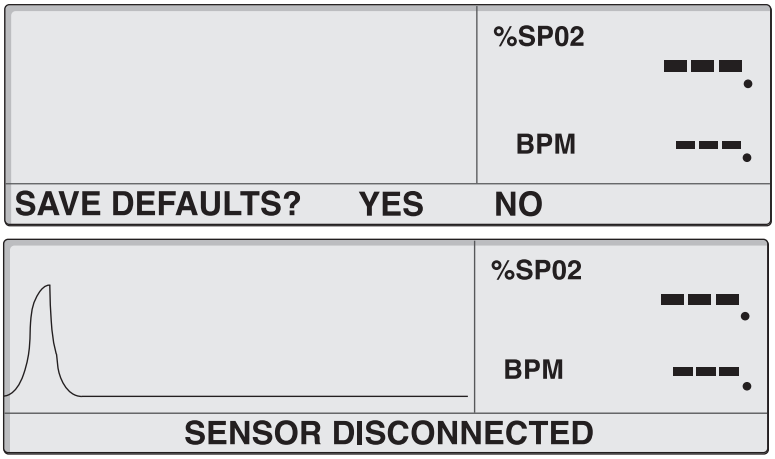


Table 13 describes the N-600x prompt/error messages. Time-out is the maximum time that the message remains displayed. If Time-out is None, the message remains displayed until the condition is corrected or until an exit event occurs. Some messages close when the ALARM and/or ALARM SILENCE buttons are pressed. Messages are prioritized so that high priority messages overwrite low priority messages. Messages of the same priority are displayed in order of occurrence. For multiple messages, lower priority messages will be displayed when higher priority conditions are cleared. The highest priority is 1 and the lowest is 3.

Advisory messages are centered on the display. Prompts are those messages requiring a response (yes or no) and will be left justified.

Table 13: Prompt/Error Messages

Message	Time-out (seconds)	Exit on Alarm	Exit on Alarm Silence	Displayed	Resolution
CLOCK SETTING LOST	None	No	No	If the N-600x detects that the real-time clock has stopped running and both battery and AC power are lost.	After the monitor is power-cycled. Recharge or replace the battery.
DATA IN SENSOR	5	No	Yes	When a sensor containing data is connected to the monitor.	On time-out, sensor disconnect, or pressing the ALARM SILENCE button, whichever comes first.
DATA TYPE SPO2+BPM	5	No	Yes	When a blank event sensor is connected to a monitor with event data type set to SPO2+BPM.	On time-out, sensor disconnect, or pressing the ALARM SILENCE button, whichever comes first.
DATA TYPE: SPO2	5	No	Yes	When a blank event sensor is connected to a monitor with the event data type set to SPO2.	On time-out, sensor disconnect, or pressing the ALARM SILENCE button, whichever comes first.

Table 13: Prompt/Error Messages

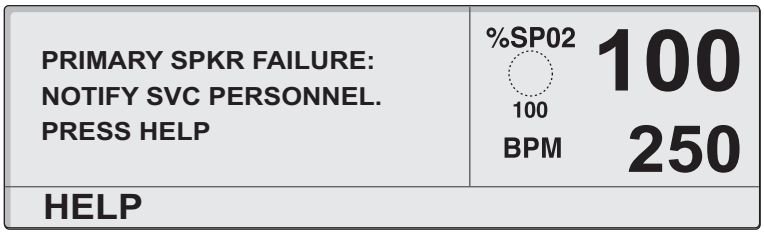
Message	Time-out (seconds)	Exit on Alarm	Exit on Alarm Silence	Displayed	Resolution
DEFAULTS LOST	None	No	No	If the N-600x detects that power-on settings have been lost.	After the monitor is power-cycled.
DELETE TRENDS?	10	Yes	Yes	When attempting to delete trend data from memory by pressing the DELETE softkey.	After responding to the prompt.
LOW BATTERY	None	No	Yes [1]	When the monitor is on battery power and the battery charge is low.	When the monitor is connected to AC power or when the low battery is acknowledged by pressing the ALARM SILENCE button.
[1] Pressing the ALARM SILENCE button silences any audible tone and the second press clears the message.					
READING TRENDS ...	None	Yes	Yes	When the N-600x needs more than 4 to 6 seconds to retrieve trend data from memory.	When sensor data is completely retrieved or ABORT is selected.
SENSOR DISCONNECTED	None	No	Yes (1)	When the sensor is disconnected from the monitor.	When the sensor is reconnected or when the sensor disconnection is acknowledged by pressing the ALARM SILENCE button.

Table 13: Prompt/Error Messages

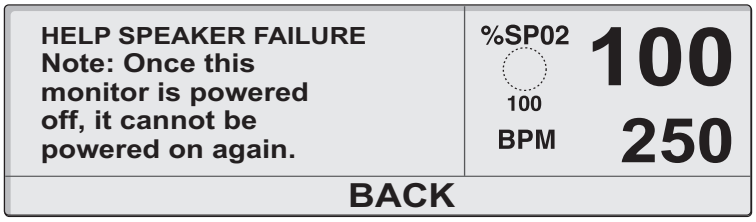
Message	Time-out (seconds)	Exit on Alarm	Exit on Alarm Silence	Displayed	Resolution
SENSOR TYPE	5	No	No	First message displayed when a sensor is connected to the monitor.	Time-out

Primary Speaker Failure

The N-600x may detect a failure of the primary speaker and sound a high-pitched, slow-pulsing piezo tone. A primary speaker failure message displays as shown below.



1. Press HELP to continue. The following message displays.



2. Press BACK to display the speaker failure message again. The message cannot be cleared.

3. Press the ALARM SILENCE button to silence the slow-pulsing piezo tone.

Note: Once the monitor is silenced, the N-600x sounds a piezo tone every three minutes as a reminder of the primary speaker failure condition. The N-600x also sounds the piezo tone to annunciate low, medium and high priority alarms during this time. If an N-600x monitor is reporting a primary speaker failure is powered off, it cannot be powered on again.

WARNING: If an N-600x reports a primary speaker failure, do not use the monitor longer than necessary to ensure patient safety. Contact a qualified service personnel, your local Nellcor representative, or Nellcor's Technical Services Department for assistance.

Help and Support

If you experience a problem while using the N-600x and are unable to correct it, contact qualified service personnel or your local Nellcor representative. The *N-600x Service Manual*, which is for use by qualified service personnel, provides additional troubleshooting information.

The *N-600x Service Manual* is available on the Internet at:

www.covidien.com/rms

The following is a list of possible errors and suggestions.

Table 14: Common Problems and Resolutions

Problem	Resolution
There is no response when I press the ON/STANDBY button.	• Ensure the supply voltage selector switch is set to the proper voltage. • A fuse may be malfunctioning. Notify a qualified service technician to check and, if necessary, replace the fuse. • If operating on battery power, the battery may be missing or discharged. If the battery is discharged, charge the battery, see *Operating on Battery Power* on page 27. If the battery does not charge, notify a service personnel to replace the battery.
One or more display elements or indicators do not light during the power-on self-test (POST).	Do not use the N-600x pulse oximeter; contact qualified service personnel or your local Nellcor representative.
The monitor is operating on battery power, even though it is connected to an AC power source.	• Ensure the supply voltage selector switch is set to the proper voltage. • Ensure the power cord is properly connected to the N-600x. • Check to see if power is available to other equipment on the same AC circuit.

Table 14: Common Problems and Resolutions

Problem	Resolution
The Pulse Search Indicator is lit for more than 10 seconds (before any measurements are taken).	• Check the *OxiMax* sensor directions for use to determine if an appropriate *OxiMax* sensor is being used and if it is applied properly. Check *OxiMax* sensor and pulse oximetry cable connections. Test the *OxiMax* sensor on another patient and/or try another *OxiMax* sensor or pulse oximetry cable. • Perfusion may be too low for the N-600x to track the pulse. Check the patient. Test the instrument on someone else. Change the *OxiMax* sensor site. Try another type of *OxiMax* sensor. • Interference may be preventing the N-600x from tracking the pulse. Keep the patient still, if possible. Verify that the *OxiMax* sensor is securely applied and replace it if necessary. Change the *OxiMax* sensor site. Electromagnetic interference may be preventing the N-600x from tracking the pulse. Remove the source of interference and/or try to stabilize the environment. • Use a type of *OxiMax* sensor that tolerates more patient movement; for example, an adhesive *OxiMax* sensor. • The *OxiMax* sensor may be too tight, there may be excessive ambient light, or the *OxiMax* sensor may be on an extremity with a blood pressure cuff, arterial catheter, or intravascular line. Reposition the *OxiMax* sensor, as necessary.

Table 14: Common Problems and Resolutions

Problem	Resolution
The Pulse Search Indicator illuminates after successful measurements have been made.	• Check the status of your patient. • Perfusion may be too low for the monitor to track the pulse. Test the instrument on another patient. Change the *OxiMax* sensor site and/or try another type of *OxiMax* sensor. • Interference may be preventing the N-600x from tracking the pulse. Verify the *OxiMax* sensor is securely applied and replace it if necessary. Change the *OxiMax* sensor site. Use a type of *OxiMax* sensor that tolerates more patient movement; for example, an adhesive *OxiMax* sensor. Electromagnetic interference may be preventing the N-600x from tracking the pulse. Remove the source of interference and/or try to stabilize the environment. • The *OxiMax* sensor may be too tight, there may be excessive ambient light, or the *OxiMax* sensor may be on an extremity with a blood pressure cuff, arterial catheter, or intravascular line. Reposition the *OxiMax* sensor, as necessary.

Table 14: Common Problems and Resolutions

Problem	Resolution
Error Code: "EEE XXX" followed by a number appears.	• Press the ON/STANDBY button and allow the monitor to shut off completely. Then press the button again to turn the monitor back on. If the error code persists, record the number and provide this information to a qualified service personnel, or your local Nellcor representative. • Error Code "EEE 529 or 729" displays when the battery discharges to a critically low level. Ensure the SUPPLY VOLTAGE SELECTOR switch on the rear panel is set to the proper voltage based on your location. • Press the ON/STANDBY button and allow the monitor to shut off completely. Allow the battery to charge for about 10 minutes and then turn the unit back on. If the error code is still present, turn the unit off and allow it to continue to charge. If the monitor has been charged for 30 minutes and the error code persists, notify a qualified service personnel, or your local Nellcor representative.

EMI (Electromagnetic Interference)

Caution: This device has been tested and found to comply with the limits for medical devices to the IEC 60601-1-1-2 (second edition), EN60601-1-2, and the Medical Device

Directive 93/42/EEC. These limits are 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 health care environments (for example, electrosurgical units, cellular phones, mobile two-way radios, electrical appliances, and high-definition television), it is possible that high levels of such interference due to close proximity or strength of a source may result in disruption of performance of this device.

The N-600x is designed for use in environments in which the pulse can be obscured by electromagnetic interference. During such interference, measurements may seem inappropriate or the monitor may not seem to operate correctly.

Disruption may be evidenced by erratic readings, cessation of operation, or other incorrect functioning. If this occurs, the site of use should be surveyed to determine the source of this disruption, and the following actions taken to eliminate the source:

- Turn equipment in the vicinity off and on to isolate the offending equipment.
- Reorient or relocate the interfering equipment.
- Increase the separation between the interfering equipment and this equipment.

The N-600x generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with these instructions, may cause harmful interference with other devices in the vicinity.

If assistance is required, contact Nellcor's Technical Services Department, 1.800.635.5267 select option 3, or your local Nellcor representative.

Obtaining Technical Assistance

For technical information and assistance, or to order parts or a *N-600x Service Manual*, contact Nellcor's Technical Services Department, 1.800.635.5267 select option 3, or your local Nellcor representative. The *N-600x Service Manual* includes block diagrams and a parts list required by qualified personnel when servicing the N-600x.

When calling Nellcor's Technical Services Department, 1.800.635.5267, or your local Nellcor representative, you may be asked to tell the representative the software version number of your N-600x.

The software version appears in the monitor display each time the monitor successfully completes the power-on self-test. Write the number down and have it available whenever requesting technical assistance.

Returning your Monitor

Contact Nellcor's Technical Services Department, 1.800.635.5267 select option 3, or your local Nellcor representative for shipping instructions including a Returned Goods Authorization (RGA) number. Unless otherwise instructed by Nellcor's Technical Services Department, it is not necessary to return the *OxiMax* sensor or other accessory items with the monitor. Pack the monitor in its original shipping carton. If the original carton is not available, use a suitable carton with the appropriate packing material to protect it during shipping.

Return the N-600x by any shipping method that provides proof of delivery.

The *N-600x Operator's* and *Service Manuals* are available on the Internet at:

www.covidien.com/rms

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Maintenance

Overview

This section describes the steps required to maintain, service, and properly clean your N-600x pulse oximeter. Follow local governing ordinance and recycling instructions regarding the disposal or recycling of the N-600x and accessories.

Service

WARNING: The cover should be removed only by qualified service personnel. There are no user-serviceable parts inside.

The N-600x requires no calibration.

The battery should be replaced at least every 24 months. Refer to the *N-600x Service Manual* for the battery changing procedure.

If service is necessary, contact qualified service personnel or your local Nellcor representative.

Periodic Safety Checks

It is recommended the following checks be performed every 24 months.

- Inspect the equipment for mechanical and functional damage.
- Inspect the safety relevant labels for legibility.

Cleaning

Caution: Do not spray, pour, or spill any liquid on the N-600x, its accessories, connectors, switches, or openings in the chassis.

For *surface-cleaning* and *disinfecting* the monitor, follow your institution's procedures or:

- The N-600x may be *surface-cleaned* by using a soft cloth dampened with either a commercial, nonabrasive cleaner or a solution of 70% alcohol in water, and lightly wiping the surfaces of the monitor.
- The N-600x may be *disinfected* using a soft cloth saturated with a solution of 10% chlorine bleach in tap water.

Before attempting to clean a SpO_2 *OxiMax* sensor, read the directions for use enclosed with the *OxiMax* sensor. Each *OxiMax* sensor model has cleaning instructions specific to that *OxiMax* sensor.

Follow the *OxiMax* sensor cleaning and disinfecting procedures in the particular *OxiMax* sensor's directions for use.

Using SatSeconds

Overview

With traditional alarm management, upper and lower alarm limits are set for monitoring oxygen saturation. During monitoring, as soon as an alarm limit is violated by as little as one percentage point, an audible alarm immediately sounds. When the %SpO_2 level fluctuates near an alarm limit, the alarm sounds each time the limit is violated. Such frequent alarms can be distracting.

The N-600x pulse oximeter utilizes Nellcor *SatSeconds* alarm management technique. With the *SatSeconds* technique, upper and lower alarm limits are set in the same way as with traditional alarm management. The clinician also sets a *SatSeconds* limit that allows the monitoring of %SpO_2 below the selected low alarm limit for a period of time before an audible alarm sounds.

The *SatSeconds* limit controls the time that the %SpO_2 level may fall outside the alarm before an audible alarm sounds.

The method of calculation is as follows:

The number of percentage points that the %SpO_2 falls outside of the alarm limit is multiplied by the number of seconds that the %SpO_2 level remains outside that limit. This can be stated as an equation:

Points x Seconds = *SatSeconds*

Where:

Points = %SpO_2 percentage points outside of the limit

Seconds = number of seconds the %SpO_2 remains at that point outside of the limit

The alarm response time, assuming a *SatSeconds* limit set at 50 and a lower alarm limit set at 90, is described and illustrated below.

In this example, the %SpO_2 level drops to 88 (2 points) and remains there for a period of 2 seconds (2 points x 2 seconds = 4 *SatSeconds*). The %SpO_2 then drops to 86 for 3 seconds and then to 84 for 6 seconds. The resulting *SatSeconds* are:

%SpO_2	**Seconds**	***SatSeconds***
2 x	2 =	4
4 x	3 =	12
6 x	6 =	36
Total *SatSeconds* =		52

After approximately 10.9 seconds the *SatSeconds* alarm would sound, because 50 *SatSeconds* had been exceeded. See the arrow (↑) in Figure 11.

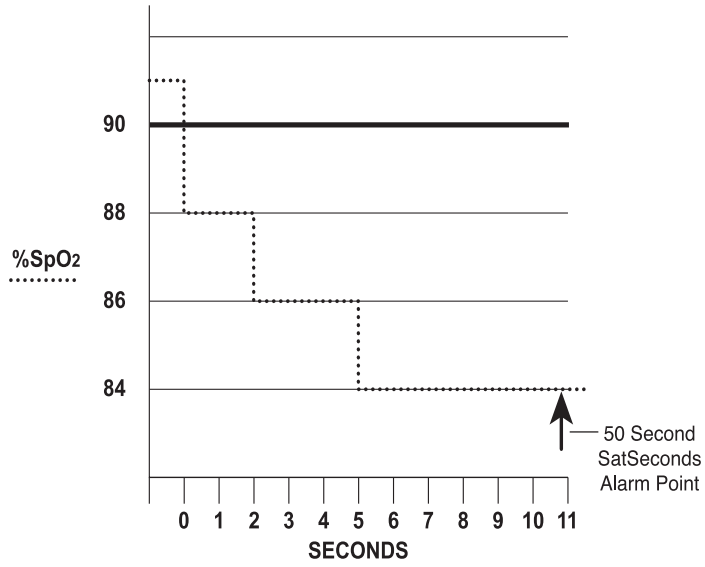


Figure 11: Alarm Response with *SatSeconds*

Saturation levels may fluctuate rather than remain steady for a period of several seconds. Often, the %SpO_2 levels may fluctuate above and below the alarm limit, reentering the non-alarm range several times.

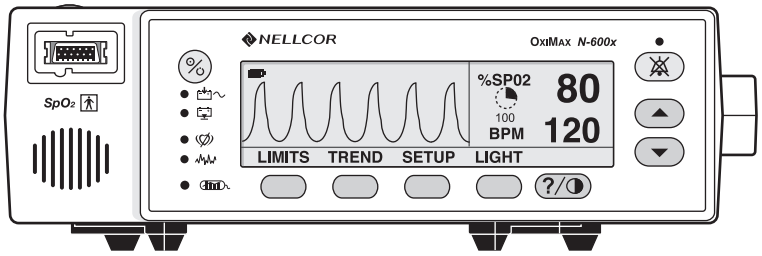
During such fluctuations, the N-600x pulse oximeter integrates the number of %SpO_2 points, both positive and negative, until either the *SatSeconds* limit (*SatSeconds* time setting) is reached, or the %SpO_2 level returns to within a normal range and remains there.

SatSeconds "Safety Net"

The *SatSeconds* "Safety Net" is for patients with saturation levels having frequent excursions below the limit, but not staying below the limit long enough for the *SatSeconds* time setting to be reached. When 3 or more limit violations occur within 60 seconds, an alarm sounds even if the *SatSeconds* time setting has not been reached.

SatSeconds Display

When the N-600x *SatSeconds* technology detects an SpO_2 value outside the alarm limit, the *SatSeconds* indicator (the circular graph located on the right side of the display, adjacent to the SpO_2 reading) begins to "fill" clockwise. When the SpO_2 value is within the set limits, the *SatSeconds* indicator empties counterclockwise.



When the indicator is filled, indicating that the *SatSeconds* setting has been reached, an audible alarm sounds and the displayed %SpO_2 rate flashes. As with traditional alarm management, the audible alarm may be silenced by pressing the ALARM SILENCE button.

Factory Default Settings

Overview

The N-600x is shipped with factory default settings. Authorized technical personnel using the procedures described in the *N-600x Service Manual* can change default settings.

Neonate Default Settings

Table 15: Neonate Factory Defaults

Parameter	Setting
Monitoring Mode	Neo
%SpO2 Lower Alarm Limit	85%
%SpO2 Upper Alarm Limit	95%
Allow silence duration to be set to OFF	No
Alarm Silence Duration	60 Seconds
Alarm Silence Reminder	Enabled
Alarm Volume	7 of 10
Backlight Brightness	8 (Battery Power) 10 (AC Power)
Data Port Baud Rate	9600
Data Port Protocol	ASCII
Display Contrast	Midrange
Display Format	Pleth

Table 15: Neonate Factory Defaults

Parameter	Setting
Language	English
Nurse Call Polarity	Normally Low
Pulse Beep Volume	4 of 10
Pulse Rate Lower Alarm Limit	90 bpm
Pulse Rate Upper Alarm Limit	190 bpm
Real-Time Trend Display	%SpO2
Real-Time Trend Scale	30 Minutes
Response Mode	Normal
SatSeconds	Off
Allow *SatSeconds*	Yes
Trend Display	%SpO2
Trend Scale	2 Hours

Adult Default Settings

Table 16: Adult Factory Defaults

Parameter	Setting
Monitoring Mode	Adult
%SpO2 Lower Alarm Limit	85%
%SpO2 Upper Alarm Limit	100%
Allow silence duration to be set to OFF	No
Alarm Silence Duration	60 Seconds
Alarm Silence Reminder	Enabled

Table 16: Adult Factory Defaults

Parameter	Setting
Alarm Volume	7 of 10
Backlight Brightness	8 (Battery Power) 10 (AC Power)
Data Port Baud Rate	9600
Data Port Protocol	ASCII
Display Contrast	Midrange
Display Format	Pleth
Language	English
Nurse Call Polarity	Normally Low
Pulse Beep Volume	5 of 6
Pulse Rate Lower Alarm Limit	40 bpm
Pulse Rate Upper Alarm Limit	170 bpm
Real-Time Trend Display	%SpO_2
Real-Time Trend Scale	30 Minutes
Response Mode	Normal
SatSeconds	Off
Allow *SatSeconds*	Yes
Trend Display	%SpO_2
Trend Scale	2 Hours

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Principles of Operation

Overview

The N-600x uses pulse oximetry to measure functional oxygen saturation in the blood. Pulse oximetry works by applying an *OxiMax* sensor to a pulsating arteriolar vascular bed, such as a finger or toe. The *OxiMax* sensor contains a dual light source and a photo detector.

Bone, tissue, pigmentation, and venous vessels normally absorb a constant amount of light over time. The arteriolar bed normally pulsates and absorbs variable amounts of light during the pulsations. The ratio of light absorbed is translated into a measurement of functional oxygen saturation (SpO_2).

Because a measurement of SpO_2 is dependent upon light from the *OxiMax* sensor, excessive ambient light can interfere with this measurement.

Specific information about ambient conditions, *OxiMax* sensor application, and patient conditions is contained throughout this manual.

Pulse oximetry is based on two principles: that oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (spectrophotometry), and that the volume of arterial blood in tissue (and hence, light absorption by that blood) changes during the pulse (plethysmography). A pulse oximeter determines SpO_2 by passing red and infrared light into an arteriolar bed and measuring changes in light absorption during the pulsatile cycle. Red and infrared low-voltage light-emitting diodes (LED) in the oximetry *OxiMax* sensor serve as light sources; a photo diode serves as the photo detector.

Because oxyhemoglobin and deoxyhemoglobin differ in light absorption, the amount of red and infrared light absorbed by blood is related to hemoglobin oxygen saturation.

The monitor uses the pulsatile nature of arterial flow to identify the oxygen saturation of arterial hemoglobin. During systole, a new pulse of arterial blood enters the vascular bed, and blood volume and light absorption increase. During diastole, blood volume and light absorption reach their lowest point. The pulse oximeter bases its SpO_2 measurements on the difference between maximum and minimum absorption (measurements at systole and diastole). By doing so, it focuses on light absorption by pulsatile arterial blood, eliminating the effects of nonpulsatile absorbers such as tissue, bone, and venous blood.

Automatic Calibration

Because light absorption by hemoglobin is wavelength dependent and because the mean wavelength of LEDs varies, an oximeter must know the mean wavelength of the *OxiMax* sensor's red LED to accurately measure SpO_2.

During monitoring, the instrument's software selects coefficients that are appropriate for the wavelength of that individual *OxiMax* sensor's red LED; these coefficients are then used to determine SpO_2.

Additionally, to compensate for differences in tissue thickness, the light intensity of the *OxiMax* sensor's LEDs is adjusted automatically.

Note: During certain automatic calibration functions, the N-600x may briefly display a flat line on the plethysmographic waveform. This is a normal operation and does not require any user intervention.

Functional versus Fractional Saturation

This pulse oximeter measures functional saturation – oxygenated hemoglobin expressed as a percentage of the hemoglobin that can transport oxygen. It does not detect significant amounts of dysfunctional hemoglobin, such as carboxyhemoglobin or methemoglobin. In contrast, hemoximeters such as the IL482 report fractional saturation – oxygenated hemoglobin expressed as a percentage of all measured hemoglobin, including measured dysfunctional hemoglobins. To compare functional saturation measurements to those from an instrument that measures fractional saturation, fractional measurements must be converted as follows:

$$\text{functional saturation} = \frac{\text{fractional saturation}}{100 - (\%\text{carboxyhemoglobin} + \%\text{methemoglobin})} \times 100$$

Measured versus Calculated Saturation

When saturation is calculated from a blood gas partial pressure of oxygen (PO_2), the calculated value may differ from the SpO_2 measurement of a pulse oximeter. This usually occurs because the calculated saturation was not properly corrected for the effects of variables that shift the relationship between PO_2 and pH,

temperature, the partial pressure of carbon dioxide (PCO_2), 2,3-DPG, and fetal hemoglobin. See Figure 12.

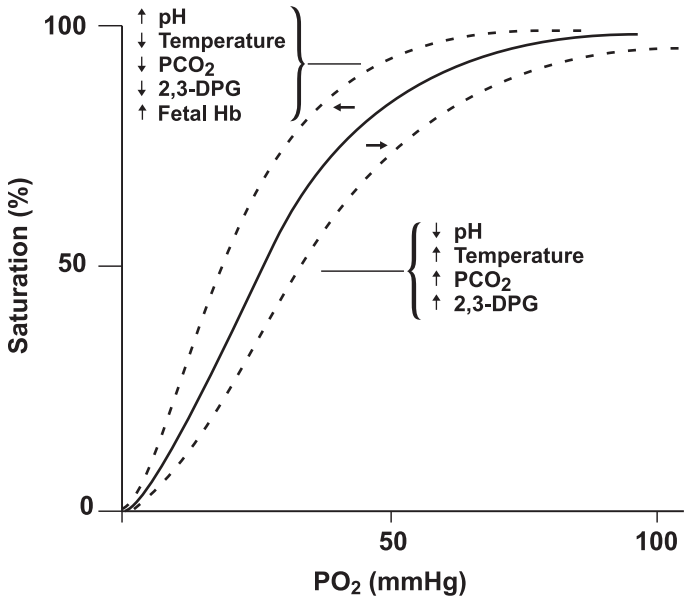

Figure 12: Oxyhemoglobin Dissociation Curve

OxiMax Technology

The N-600x pulse oximeter is designed to use Nellcor *OxiMax* brand sensors, which integrate the *OxiMax* technology. These *OxiMax* sensors can be identified by their deep lavender/blue plug color. All *OxiMax* sensors contain a memory chip carrying information about the *OxiMax* sensor, which the oximeter needs for correct operation, including the *OxiMax* sensor's calibration data, model type, troubleshooting codes, and error detection data. This unique oximetry architecture enables development of new sensors as well as several new features with the *OxiMax* sensor N-600x.

When an *OxiMax* sensor is connected to the N-600x, the pulse oximeter will first reads the information in the *OxiMax* sensor memory chip, checks it to make sure that there are no errors, and

then loads the data to begin monitoring. As the pulse oximeter reads the information, it displays the *OxiMax* sensor model number. This process only takes a couple of seconds. The *OxiMax* sensor model number disappears after 5 seconds.

Pulse oximeters containing *OxiMax* technology, including the N-600x, use calibration data contained in the *OxiMax* sensor in calculating the patient's SpO_2. Consult the *OxiMax* sensor accuracy grid card included with the pulse oximeter for specific accuracy information for the N-600x with different Nellcor *OxiMax* sensors.

The N-600x uses the information in the *OxiMax* sensor to tailor troubleshooting messages for the clinician. The *OxiMax* sensor contains coding that tells the pulse oximeter what kind of *OxiMax* sensor is being used. When deciding what messages to display, the pulse oximeter takes into account the *OxiMax* sensor type and recommended patient site for that model.

Functional Testers and Patient Simulators

Some models of commercially available bench top functional testers and patient simulators can be used to verify the proper functionality of Nellcor pulse oximeter sensors, cables and monitors. See the individual testing device's operator's manual for the procedures specific to the model of tester being used.

While such devices may be useful for verifying that the pulse oximeter sensor, cabling, and monitor are functional, they are incapable of providing the data required to properly evaluate the accuracy of a system's SpO_2 measurements. Fully evaluating the accuracy of the SpO_2 measurements requires, at a minimum, accommodating the wavelength characteristics of the sensor and reproducing the complex optical interaction of the sensor and the patient's tissue. These capabilities are beyond the scope of known bench top testers. SpO_2 measurement accuracy can only be evaluated in vivo by comparing pulse oximeter readings with SaO_2 measurements obtained from simultaneously sampled arterial blood made using a laboratory CO-oximeter.

Many functional testers and patient simulators have been designed to interface with the pulse oximeter's expected calibration curves and may be suitable for use with Nellcor monitors and/or sensors. Not all such devices, however, are adapted for use with the Nellcor *OxiMax* digital calibration system. While this will not affect use of the simulator for verifying system functionality, displayed SpO_2 measurement values may differ from the setting of the test device. For a properly functioning monitor, this difference will be reproducible over time and from monitor to monitor within the performance specifications of the test device.

Specifications

Performance

Measurement Range

SpO_2	1% to 100%
Pulse Rate	20 to 250 beats per minute (bpm)
Perfusion Range	0.03% to 20%

Accuracy[1]

Saturation	
Adult[2, 3]	70 to 100% ±2 digits
Adult and Neonate Low Sat[2, 3, 4]	60 to 80% ±3 digits
Neonate[4, 5]	70 to 100% ±2 digits
Low Perfusion[6]	70 to 100% ±2 digits
Adult and Neonate with Motion[2, 7]	70 to 100% ±3 digits
Pulse Rate	
Adult and Neonate[2, 3, 4]	20 to 250 bpm ±3 digits
Low Perfusion[6]	20 to 250 bpm ±3 digits
Adult and Neonate with Motion[2, 7]	20 to 250 bpm ±5 digits

Accuracy[1]

[1]Saturation accuracy varies by sensor type. Refer to the Sensor Accuracy Grid at www.covidien.com/rms.

[2]Accuracy specifications were validated using measurements of healthy non-smoking adult volunteers during controlled hypoxia studies spanning the specified saturation ranges. Subjects were recruited from the local population and comprised both men and women ranging in age from 18-50 years old, and spanned a range of skin pigmentations. Pulse oximeter SpO_2 readings were compared to SaO_2 values of drawn blood samples measured by hemoximetry. All accuracies are expressed as ±1 SD. Because pulse oximeter equipment measurements are statistically distributed, about two-thirds of the measurements can be expected to fall in this accuracy (ARMS) range (refer to the Sensor Accuracy Grid for more details).

[3]Adult specifications are shown for *OxiMax* MAX-A and MAX-N sensors with the N-600x.

[4]Neonate specifications are shown for *OxiMax* MAX-N sensors with the N-600x.

[5]Clinical functionality of the MAX-N sensor has been demonstrated on a population of hospitalized neonate patients. The observed SpO_2 accuracy was 2.5% in a study of 42 patients with ages of 1 to 23 days, weight from 750 to 4,100 grams, and 63 observations made spanning a range of 85% to 99% SaO_2.

[6]Specification applies to N-600x oximeter performance. Reading accuracy in the presence of low perfusion (detected IR pulse modulation amplitude 0.03% - 1.5%) was validated using signals supplied by a patient simulator. SpO_2 and pulse rate values were varied across the monitoring range over a range of weak signal conditions and compared to the known true saturation and pulse rate of the input signals.

[7]Motion performance was validated during a controlled hypoxia blood study over an SaO_2 span of 70% to 98% and a convenience-sample heart rate range of 47-102 bpm. Subjects performed rubbing and tapping movements 1-2 cm in amplitude with aperiodic intervals (randomly changing) with a random variation in frequency between 1-4 Hz. The average percent modulation during quiescent periods was 4.27, during motion 6.91. Motion performance over the entire specified pulse rate range was validated using synthetic signals from a patient simulator that comprised representative cardiac and signal artifact components. Applicability: *OxiMax* MAX-A, MAX-AL, MAX-P, MAX-I, and MAX-N sensors.

Display Update Interval
1 second

Electrical

Instrument	
Power Requirements	Rated at 100 to 120 volts AC (nominal 120 VAC) or 220 to 240 volts AC (nominal 230 VAC), 20 volt/amps to be compliant with IEC 60601-1 sub-clause 10.2.2.
Fuses	Quantity 2, 0.5 A, 250 volts, slow-blow, IEC (5 x 20 mm).

Battery	
The battery provides at least 7 hours of battery life when new and fully charged with no alarms, no serial data, no analog output, no nurse call output, with backlight on while using an SRC-MAX set at 200 bpm, high light and low modulation.	
Type	Lead acid
Voltage	6 Volts DC
Recharge	• 8 hours with N-600x turned off • 12 hours with N-600x turned on

Battery	
Shelf Life	• 4 months, new fully-charged battery (when monitor is placed in "Shelf-mode" by qualified service personnel using the procedures indicated in the *N-600x Service Manual*) • After 4 months storage in "Shelf-mode", the N-600x will run for 33% of stated battery life
Complies With	91/157/EEC

OxiMax **Sensors**	
Wavelength and Power	Nellcor pulse oximetry sensors contain LEDs that emit red light at a wavelength of approximately 660 nm and infrared light at a wavelength of approximately 900 nm. The total optical output power of the sensor LEDs is less than 15 mW. This information may be useful to clinicians, such as those performing photodynamic therapy.

Environmental Conditions

Operation	
Temperature	5 °C to 40 °C (41 °F to 104 °F)

Operation

Altitude	-390 m to 3,012 m (-1,254 ft. to 9,882 ft.)
Atmospheric Pressure	70 kPa to 106 kPa (20.6 in. Hg to 31.3 in. Hg)
Relative Humidity	15% to 95% non-condensing to be compliant with IEC 60601-1, sub-clause 44.5

Transport and Storage (not in shipping container)

Temperature	-20 °C to 60 °C (-4 °F to 140 °F)
Altitude	-390 m to 5,574 m (-1,280 ft. to 18,288 ft.)
Atmospheric Pressure	50 kPa to 106 kPa (14.7 in. Hg to 31.3 in. Hg)
Relative Humidity	15% to 95% non-condensing

Transport and Storage (in shipping container)

Temperature	-20 °C to 70 °C (-4 °F to 158 °F)
Altitude	-390 m to 5,574 m (-1,280 ft. to 18,288 ft.)
Atmospheric Pressure	50 kPa to 106 kPa (14.7 in. Hg to 31.3 in. Hg)
Relative Humidity	15% to 95% non-condensing

OxiMax Sensor Power Dissipation

Sensor	Dissipation
OxiMax MAX-N	52.5 mW
OxiMax MAX-I	52.5 mW
OxiMax MAX-P	52.5 mW
OxiMax MAX-A	52.5 mW
OxiMax MAX-AL	52.5 mW
OxiMax MAX-R	52.5 mW
OxiMax Oxiband OXI-A/N	52.5 mW
OxiMax Oxiband OXI-P/I	52.5 mW
OxiMax Durasensor DS-100A	52.5 mW
OxiMax OxiCliq P	52.5 mW
OxiMax OxiCliq N	52.5 mW
OxiMax OxiCliq I	52.5 mW
OxiMax OxiCliq A	52.5 mW
OxiMax Dura-Y D-YS	52.5 mW
OxiMax MAX-FAST	52.5 mW

Physical Characteristics

Weight	5.8 lbs. (2.6 kg)
Dimensions	3.3 in. x 10.4 in. x 6.8 in. (8.4 cm x 26.4 cm x 17.3 cm)

Compliance

Item	Compliant With
Equipment classification	Safety Standards: IEC 60601-1 (same as EN60601-1), CSA 601.1, UL 60601-1, EN865, EN/IEC 60601-1-2 (second edition)
Type of protection	Class I (on AC power) Internally powered (on battery power)
Degree of protection	Type BF - Applied part
Mode of operation	Continuous
N-600x resistant to liquid ingress	IEC 60601-1, sub-clause 44.6 for class IPX1 Drip-Proof equipment
Degree of Safety in presence of a flammable anaesthetic	UL 60601-1, sub-clause 5.5, Not suitable
Applied sensor label to indicate Type BF applied part	IEC 60601-1 Symbol 2 of Table D of Appendix D
N-600x exterior markings	IEC 60601-1, sub-clause 6.1, 6.3, and 6.4; EN 865, clause 6
Front panel and case labeling	IEC 60878, EN 980, ISO 7000, EN 60417-1, EN 60417-2
N-600x button spacing	ISO 7250
Year of manufacture symbol	EN 980
Operation during physical shock	IEC 60068-2-27 at 100 g
Operation during vibration	IEC 60068-2-6 and IEC 60068-2-34
Electromagnetic Compatibility	IEC 60601-1, sub clause 36, IEC/EN 60601-1-2 (second edition)

Item	Compliant With
Radiated and conducted emissions	EN 55011, Group 1, Class B
Operation with electrical line voltage variations	FDA Reviewer's Guide
Magnetic field susceptibility	RS 101 in MIL-STD-461E

Manufacturer's Declaration

WARNING: The use of accessories, sensors, and cables other than those specified may result in increased emission and/or decreased immunity of the N-600x pulse oximeter.

Table 17: Electromagnetic Emissions

The N-600x is suitable for use in the specified electromagnetic environment. The customer and/or user of the N-600x should assure that it is used in an electromagnetic environment as described below:

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emission CISPR 11	Group 1	The N-600x uses RF only for its internal function.
RF emissions CISPR 11	Class B	The N-600x is suitable for use in all establishments.
Harmonic emissions IEC 61000-3-2	Complies	
Voltage fluctuations/ flicker emission IEC 61000-3-3	Complies	

Table 18: Electromagnetic Immunity

The N-600x is suitable for use in the specified electromagnetic environment. The customer and/or user of the N-600x should assure that it is used in an electromagnetic environment as described below.

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floor should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electric 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 and/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 and/or hospital environment.

Note: UT is the AC mains voltage prior to application of the test level.

Table 18: Electromagnetic Immunity

The N-600x is suitable for use in the specified electromagnetic environment. The customer and/or user of the N-600x should assure that it is used in an electromagnetic environment as described below.

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Voltage dips, short interruptions and voltage variations on power supply IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle	<5 % U_T (>95 % dip in U_T) for 0.5 cycle	Mains power quality should be that of a typical commercial and/or hospital environment. While using the N-600x requires continued operation during power mains interruption, it is recommended that the N-600x be powered from an uninterruptible power supply or battery.
	40 % U_T (60 % dip in U_T) for 5 cycles	40 % U_T (60 % dip in U_T) for 5 cycles	
	70 % U_T (30 % dip in U_T) for 25 cycles	70 % U_T (30 % dip in U_T) for 25 cycles	
	<5 % U_T (95 % dip in U_T) for 5 seconds	<5 % U_T (95 % dip in U_T) for 5 seconds	

Note: UT is the AC mains voltage prior to application of the test level.

Table 18: Electromagnetic Immunity

The N-600x is suitable for use in the specified electromagnetic environment. The customer and/or user of the N-600x should assure that it is used in an electromagnetic environment as described below.

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	It may be necessary to position the N-600x further from the sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.

Note: UT is the AC mains voltage prior to application of the test level.

Table 19: Electromagnetic Immunity, RF Portable Equipment

For portable and mobile communication equipment. The N-600x is suitable for use in the specified electromagnetic environment. The customer and/or user of the N-600x should assure that it is used in an electromagnetic environment as described below:

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Portable and mobile RF communications equipment should be used no closer to any part of the N-600x, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter.			
			Recommended Separation Distance
Note: 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 survey 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 N-600x is used exceeds the applicable RF compliance level above, the N-600x should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the N-600x. **Note**: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
Interference may occur in the vicinity of equipment marked with the following symbol: 			

Table 19: Electromagnetic Immunity, RF Portable Equipment

For portable and mobile communication equipment. The N-600x is suitable for use in the specified electromagnetic environment. The customer and/or user of the N-600x should assure that it is used in an electromagnetic environment as described below:

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Radiated RF IEC 61000-4-3	3 V/m 80 MHz 800 MHz	3 V/m	*distance* = 1.2√ *Power* 80 MHz to 800 MHz
	3 V/m 800 MHz 2.5 GHz	3 V/m	*distance* = 2.3√ *Power* 800 MHz to 2.5 GHz

Note: 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 survey 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 N-600x is used exceeds the applicable RF compliance level above, the N-600x should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the N-600x.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Interference may occur in the vicinity of equipment marked with the following symbol:

Table 19: Electromagnetic Immunity, RF Portable Equipment

For portable and mobile communication equipment. The N-600x is suitable for use in the specified electromagnetic environment. The customer and/or user of the N-600x should assure that it is used in an electromagnetic environment as described below:

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz 80 MHz	3 Vrms	*distance* = 1.2√ *Power* 150 kHz to 80 MHz

Note: 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 survey 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 N-600x is used exceeds the applicable RF compliance level above, the N-600x should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the N-600x.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Interference may occur in the vicinity of equipment marked with the following symbol:

Table 20: Recommended Separation Distances

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the N-600x (IEC 60601-1-2)

Frequency of Transmitter	150 KHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
Equation	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
Rated Maximum Output Power of Transmitter in Watts	Separation Distance in Meters	Separation Distance in Meters	Separation Distance in Meters
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the separation distance can be estimated using the equation in the corresponding column, where P is the maximum output [power rating of the transmitter in watts (W)] according to the transmitter manufacturer.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Table 21: Cables

Cables and *OxiMax* Sensors	Maximum Length	Complies With
DOC-10 pulse oximetry cable	10.0 ft. (3 m)	• RF emissions, CISPR 11, Class B/Group 1 • Harmonic emissions, IEC 61000-3-2 • Voltage fluctuations/flicker emission, IEC 61000-3-3 • Electrostatic discharge (ESD), IEC 61000-4-2 • Electric fast transient/burst, IEC 61000-4-4 • Surge, IEC 61000-4-5 • Conducted RF IEC 61000-4-6 • Radiated RF, IEC 61000-4-3
Software download cable, RS-232 serial, 15 to 9 pin "D"	10.0 ft. (3 m)	
Non-terminated cable, RS-232/ Analog, 15 pin "D"	3.3 ft. (1 m)	
Oxinet hardwire cable	10.0 ft. (3 m)	
Printer cable, RS-232, 15 to 9 pin "D"	3.3 ft. (1 m)	
Philips interface cable	3.3 ft. (1 m)	
GE Marquette interface cable	3.3 ft. (1 m)	
Datex--Ohmeda interface cable	3.3 ft. (1 m)	
Oxinet® Data Cable	10.0 ft. (3 m)	
HP Agilent interface cable	10.0 ft. (3 m)	

Table 21: Cables

Cables and *OxiMax* Sensors	Maximum Length	Complies With
OxiMax sensors:		• RF emissions, CISPR 11, Class B/Group 1 • Harmonic emissions, IEC 61000-3-2 • Voltage fluctuations/flicker emission, IEC 61000-3-3 • Electrostatic discharge (ESD), IEC 61000-4-2 • Electric fast transient/burst, IEC 61000-4-4 • Surge, IEC 61000-4-5 • Conducted RF IEC 61000-4-6 • Radiated RF, IEC 61000-4-3
MAX-A	1.5 ft. (0.5 m)	
MAX-AL	3.0 ft. (0.9 m)	
MAX-I	1.5 ft. (0.5 m)	
MAX-N	1.5 ft. (0.5 m)	
MAX-P	1.5 ft. (0.5 m)	
MAX-R	1.5 ft. (0.5 m)	
OxiMax Oxiband sensors:	3.0 ft. (0.9 m)	
OXI-A/N		
OXI-P/I		

Table 21: Cables

Cables and *OxiMax* Sensors	Maximum Length	Complies With
OxiMax Durasensor sensor DS-100A	3.0 ft. (0.9 m)	• RF emissions, CISPR 11, Class B/Group 1 • Harmonic emissions, IEC 61000-3-2 • Voltage fluctuations/flicker emission, IEC 61000-3-3 • Electrostatic discharge (ESD), IEC 61000-4-2 • Electric fast transient/burst, IEC 61000-4-4 • Surge, IEC 61000-4-5 • Conducted RF IEC 61000-4-6 • Radiated RF, IEC 61000-4-3

Table 21: Cables

Cables and *OxiMax* Sensors	Maximum Length	Complies With
OxiMax *OxiCliq* sensors: P N I A	OC-3 cable 3.0 ft. (0.9 m)	• RF emissions, CISPR 11, Class B/Group 1 • Harmonic emissions, IEC 61000-3-2 • Voltage fluctuations/flicker emission, IEC 61000-3-3 • Electrostatic discharge (ESD), IEC 61000-4-2 • Electric fast transient/burst, IEC 61000-4-4 • Surge, IEC 61000-4-5 • Conducted RF IEC 61000-4-6 • Radiated RF, IEC 61000-4-3
OxiMax *Dura-Y* sensors: D-YS D-YSE D-YSPD	4.0 ft. (1.2 m)	

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Clinical Study

Overview

This section contains data from the clinical study conducted for the Nellcor™ sensors used with the Nellcor™ N-600X Pulse Oximeter.

One (1) prospective, controlled hypoxia clinical study was conducted to demonstrate the accuracy of Nellcor™ sensors when used in conjunction with the Nellcor™ N-600X Pulse Oximeter. The study was performed with healthy volunteers at a single clinical laboratory. Accuracy was established by comparison to CO-oximetry.

Methods

Data from 11 healthy volunteers were included in the analysis. Sensors were rotated on digits and brow to provide a balanced study design. SpO_2 values were continuously recorded from each instrument while inspired oxygen was controlled to produce five steady state plateaus at target saturations of approximately 98, 90, 80, 70 and 60%. Six arterial samples were taken 20 seconds apart at each plateau resulting in a total of approximately 30 samples per subject. Each arterial sample was drawn over two (2) respiratory cycles (approximately 10 seconds) while SpO_2 data were simultaneously collected and marked for direct comparison to CO_2. Each arterial sample was analyzed by at least two of the three IL CO-oximeters and a mean SaO_2 was calculated for each sample. End tidal CO_2, respiratory rate, and respiratory pattern were continuously monitored throughout the study.

Study Population

Table 22: Demographic Data

Type	Class	Total
Gender	Male	5
	Female	6
Race	Caucasian	8
	Hispanic	2
	African American	1
	Asian	0
Age	--	19-48
Weight	--	108-250
Skin pigment	Very light	2
	Olive	5
	Dark olive/Medium black	3
	Extremely dark/Blue black	1

Study Results

Accuracy was calculated using the root mean square difference (RMSD).

Table 23: SpO_2 Accuracy for Nellcor™ Sensors vs. CO-oximeters

SpO_2 Decade	MAX-A		MAX-N		MAX-FAST	
	Data Points	Arms	Data Points	Arms	Data Points	Arms
60-70	71	3.05	71	2.89	71	2.22
70-80	55	2.35	55	2.32	55	1.28
80-90	48	1.84	48	1.73	48	1.48
90-100	117	1.23	117	1.68	117	0.98

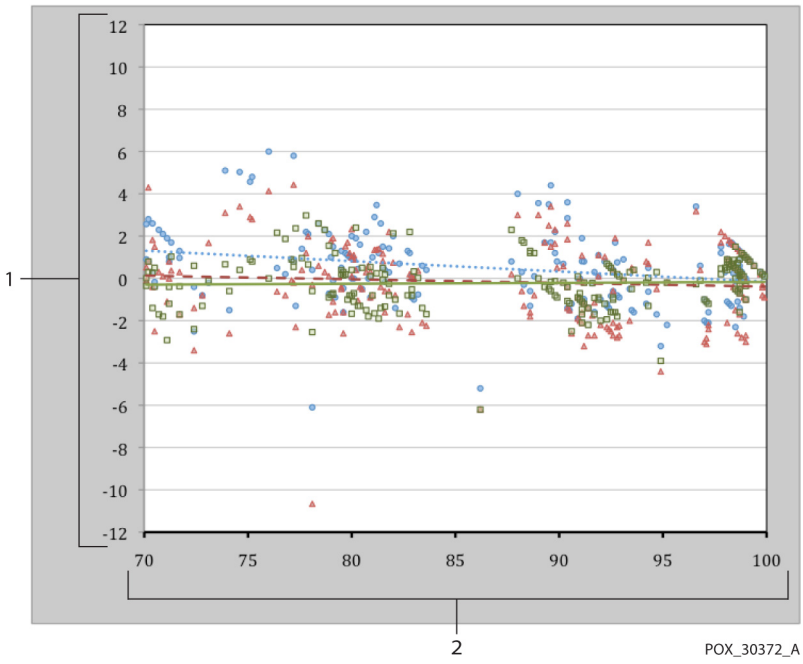

Figure 13: Modified Bland-Altman Plot

1	Test Sensor; Avg CO-oximeter value 70-100% SpO2	2	Avg CO-oximeter value 70-100% SpO2
●	Oximetry board with MAX-A sensor	·····	Trendline of MAX-A sensor
▲	Oximetry board with MAX-N sensor	- - -	Trendline of MAX-N sensor
▫	Oximetry board with MAX-FAST sensor	———	Trendline of MAX-FAST sensor

Adverse Events or Deviations

The study was conducted as expected with no adverse events and no deviations from the protocol.

Conclusion

The pooled results indicate that for a saturation range of 60-80% for SpO_2, the acceptance criterion was met for the monitoring system when tested with MAX-A, MAX-N and MAX-FAST sensors. The pooled results indicate that for a saturation range of 70-100% for SpO_2, the acceptance criterion was met.

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