NELLCOR PURITAN BENNETT™

OPERATOR'S MANUAL

Nellcor Symphony®
N-3000 Pulse Oximeter

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

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To obtain information about a warranty, if any, for this product, contact Nellcor Puritan Bennett Technical Services or your local Nellcor Puritan Bennett representative.

Purchase of this instrument confers no express or implied license under any Nellcor Puritan Bennett patent to use the instrument with any sensor that is not manufactured or licensed by Nellcor Puritan Bennett.

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Covered by one or more of the following U.S. Patents and foreign equivalents: 4,621,643; 4,700,708; 4,770,179; 4,653,498; 5,078,136; 5,351,685; 4,869,254; and 5,368,026.

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SAFETY INFORMATION

General Safety Information

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GENERAL SAFETY INFORMATION

This section contains important safety information related to the general use of the *Nellcor Symphony* N-3000 Pulse Oximeter. Other important safety information appears throughout in sections that relate specifically to the precautionary information. Read all text surrounding all precautionary information.

Important! Before use, carefully read this manual, accessory directions for use, all precautionary information in boldface type, and specifications.

WARNING: Explosion hazard. Do not use the N-3000 pulse oximeter in the presence of flammable anesthetics or gases.

WARNING: The N-3000 is to be operated by qualified personnel only. Before use, carefully read this manual, accessory directions for use, all precautionary information, and specifications.

WARNING: Pulse oximetry readings and pulse rate signals can be affected by certain ambient environmental conditions, sensor application errors, and certain patient conditions.

CAUTION: When connecting the N-3000 to any instrument, verify proper operation before clinical use. Both the N-3000 and the instrument connected to it must be connected to a grounded outlet. Accessory equipment connected to the monitor's data interface must be certified according to IEC Standard 950 for data-processing equipment or IEC Standard 601-1 for electromedical equipment. All combinations of equipment must be in compliance with IEC Standard 601-1-1 system requirements. Anyone who connects additional equipment to the signal input port or signal output port configures a medical system and is therefore responsible that the system complies with the requirements of system standard IEC Standard 601-1-1.

Nellcor Puritan Bennett's oxygen transducers (sensors) can be categorized as surface devices contacting skin for a limited duration of time. Biocompatibility testing has been conducted on Nellcor Puritan Bennett's sensors in compliance with ISO 10993-1, which suggests cytotoxicity, sensitization and irritation or intracutaneous reactivity testing be performed on devices falling into this category. The sensors have passed the recommended biocompatibility testing and are therefore in compliance with ISO 10993-1.

Measurements

If the accuracy of any measurement does not seem reasonable, first check the patient's vital signs by alternate means and then check the N-3000 for proper functioning.

Inaccurate measurements may be caused by:

- **incorrect sensor application or use**
- **significant levels of dysfunctional hemoglobins (such as carboxyhemoglobin or methemoglobin)**
- **intravascular dyes such as indocyanine green or methylene blue**
- **exposure to excessive illumination, such as surgical lamps (especially ones with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, or direct sunlight**
- **excessive patient movement**
- **venous pulsations**
- **placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line**

You can continue to use the N-3000 on a patient during defibrillation, but the readings may be inaccurate for a short time.

Loss of pulse signal can occur in any of the following situations:

- **the sensor is too tight**
- **there is excessive illumination from light sources such as a surgical lamp, a bilirubin lamp, or sunlight**
- **a blood pressure cuff is inflated on the same extremity as one to which an SpO_2 sensor is attached**
- **the patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia**
- **there is arterial occlusion proximal to the sensor**
- **the patient is in cardiac arrest or is in shock**

N-3000 and Other Equipment

When connecting the N-3000 to any instrument, verify proper operation before clinical use. Refer to the other device's manual for full instructions. Accessory equipment connected to the monitor's data interface must be certified according to IEC Standard 950 for data-processing equipment or IEC Standard 601-1 for electromedical equipment. All combinations of equipment must be in compliance with IEC Standard 601-1-1 systems requirements. Anyone who connects additional equipment to the signal input port or signal output port configures a medical system and is therefore responsible that the system complies with the requirements of system standard IEC Standard 601-1-1. If in doubt, consult Nellcor Puritan Bennett's Technical Services Department or your local Nellcor Puritan Bennett representative.

Noninvasive blood pressure monitors may interrupt N-3000 pulse rate measurements, creating false alarms. A stacked N-3100 *Nellcor Symphony* blood pressure monitor informs the N-3000 of an inflation in progress, reducing the likelihood of false alarms. It is recommended that only a stacked N-3100 blood pressure monitor be used with the N-3000.

INTRODUCTION

INTENDED USE

The purpose and function of the *Nellcor Symphony* N-3000 pulse oximeter is to continuously and noninvasively measure functional arterial oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 sensor).

The monitor is intended for use on adult, pediatric, and neonatal patients in all hospital areas, hospital-type facilities, and home environments. It may be used during intra-hospital transport when powered by its internal battery.

The N-3000 can operate as a standalone monitor or it can be connected to (stacked with) other *Nellcor Symphony* instruments, such as the N-3100 blood pressure monitor and N-3200 display/printer. When used with the N-3200 display/printer, the instruments can display and print out plethysmographic waveforms and SpO_2 and pulse rate tabular data.

WARNING: The N-3000 is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.

ABOUT THIS MANUAL

This manual explains how to set up and use the N-3000 pulse oximeter. Important safety information relating to general use of the N-3000 appears before this introduction. Other important safety information is located throughout the text where appropriate. **Read the entire *Safety Information* section before you operate the monitor**.

In addition to the safety section, this manual includes the following sections:

- *Controls, Indicators, and Symbols* shows the monitor, locates all controls, indicators, and symbols, and explains their functionality.

- *Setup* explains how to set up the monitor and connect it to other *Nellcor Symphony* instruments and accessories.

- *Sensors and Accessories* describes Nellcor Puritan Bennett sensors and accessories used with the monitor.

- *Start-up and Use* explains how to operate the monitor.

- *Troubleshooting and Maintenance* provides information about servicing the monitor and obtaining technical assistance.

- *Specifications* lists technical specifications for the monitor, default alarm limit settings, and performance ranges.

- *Appendix: Principles of Oximetry* presents a clinical explanation of the how pulse oximetry works.

CONTROLS, INDICATORS, AND SYMBOLS

English

DISPLAYS, CONTROLS, INDICATORS, AND CONNECTORS

Figures 1 through 5 show the front, rear, side, and top views of the N-3000 and identify displays, controls, and connectors.

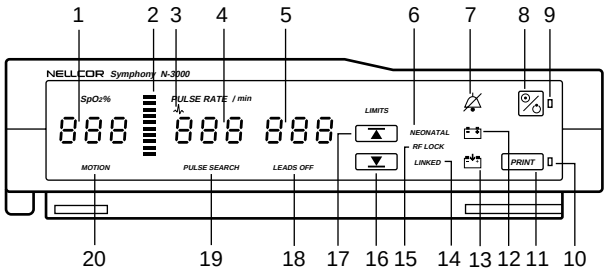


Figure 1: N-3000 Front Panel (North American)

1	SpO2% Display	11	Print Button
2	Pulse Amplitude Indicator	12	Battery in Use/Battery Low Indicator
3	ECG Heart Rate Indicator *	13	Battery Charging Indicator
4	Pulse Rate Display	14	Linked Indicator
5	Auxiliary Display	15	RF Lock Indicator *
6	Neonatal Mode Indicator	16	Lower Alarm Limit Button
7	Audible Alarm Off Indicator	17	Upper Alarm Limit Button
8	On/Standby Button	18	Leads Off Indicator *
9	Power On Indicator	19	Pulse Search Indicator
10	Stacked Indicator	20	Patient Motion Indicator

* Not used on this model

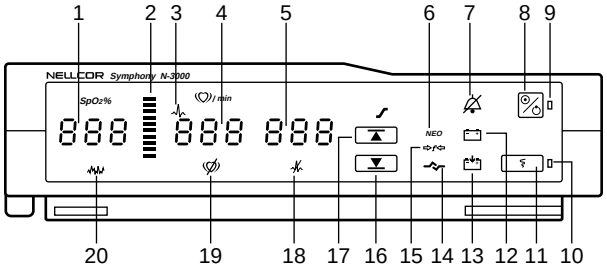


Figure 2: N-3000 Front Panel (International)

1	SpO_2% Display	11	Print Button
2	Pulse Amplitude Indicator	12	Battery in Use/Battery Low Indicator
3	ECG Heart Rate Indicator *	13	Battery Charging Indicator
4	Pulse Rate Display	14	Linked Indicator
5	Auxiliary Display	15	RF Lock Indicator*
q		16	Lower Alarm Limit Button
7	Audible Alarm Off Indicator	17	Upper Alarm Limit Button
8	On/Standby Button	18	Leads Off Indicator *
9	Power On Indicator	19	Pulse Search Indicator
10	Stacked Indicator	20	Patient Motion Indicator

* Not used on this model

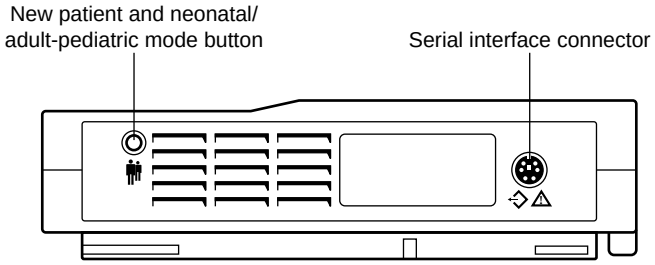


Figure 3: N-3000 Rear Panel

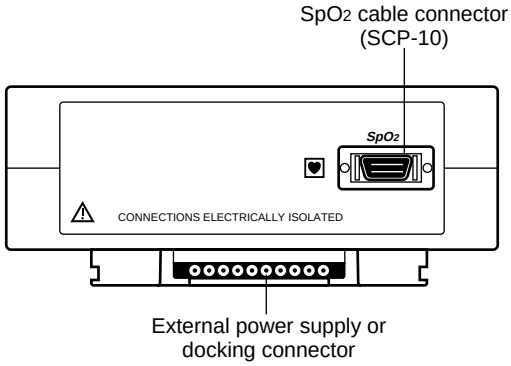


Figure 4: N-3000 Right Side Panel (North American)

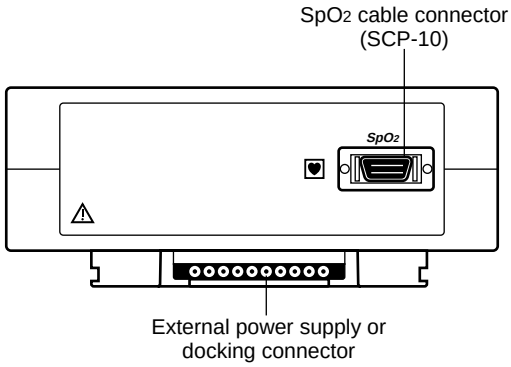


Figure 5: N-3000 Right Side Panel (International)

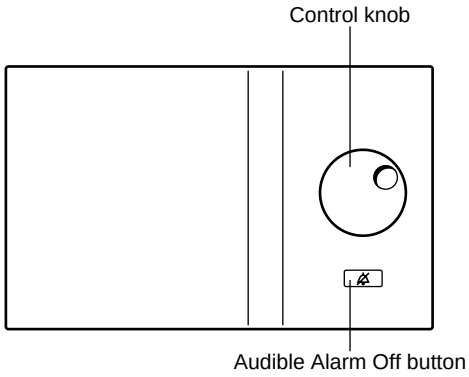


Figure 6: N-3000 Top Panel

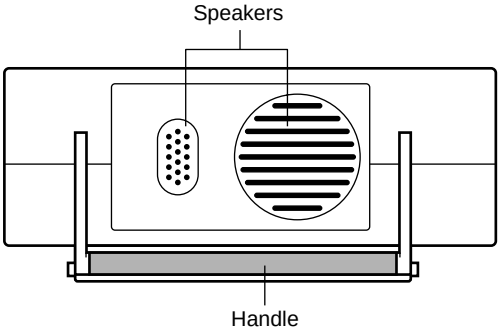


Figure 7: N-3000 Left Side Panel

N-3000 SYMBOLS

Rear Panel


New Patient/Neonatal Button


Data Interface


Attention: Refer to Manual

English

Right Side Panel

SpO2	SpO2 Cable Input
	Type CF Equipment

SPS EXTERNAL POWER SUPPLY SYMBOLS

	Input Voltage
	Output Voltage
	Equipotential (Ground) Terminal
	Caution: Shock Hazard
	Power Available Indicator

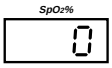
DESCRIPTION OF CONTROLS

	The ON/STANDBY button is used to turn the N-3000 on or off. Three consecutively higher-pitched beeps sound when turning the N-3000 on, and three consecutively lower-pitched beeps sound when turning the N-3000 off.
	The NEW PATIENT/NEONATAL button on the rear panel is used to clear stored patient data or to switch between adult-pediatric and neonatal modes.
	The AUDIBLE ALARM OFF button is used to silence current audible alarms for the selected alarm silence duration period.
PRINT or 	The PRINT button is used when the N-3000 and the N-3200 display/printer are stacked to cause the N-3200 to begin printing current N-3000 data.
	The UPPER ALARM LIMIT button is used to view and set upper alarm limits.

The LOWER ALARM LIMIT button is used to view and set lower alarm limits.

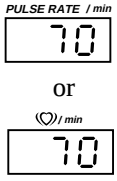
When used by itself, the knob adjusts pulse beep volume on the N-3000. It is also used with other controls to adjust alarm limits, audible alarm silence duration, and alarm volume.

DESCRIPTION OF VISIBLE INDICATORS AND DISPLAYS



The SpO2% display shows patient arterial hemoglobin oxygen saturation level. It is updated with each pulse. The SpO2% display flashes and an alarm sounds when SpO2% is outside the alarm limits. During Pulse Search, the display will alternate between dashed lines and the last qualified oxygen saturation measurement.

The PULSE AMPLITUDE indicator is a 10-segment display that shows the relative pulse amplitude. The bottom segment remains lit as long as an SpO2 cable and SpO2 sensor are connected to the N-3000. As the detected pulse becomes stronger, more contiguous segments light with each pulse.



The PULSE RATE display shows the pulse rate in beats per minute. It is updated with each pulse. It flashes and an alarm sounds when the pulse rate is outside the alarm limits. During pulse search, the display alternates between dashed lines and the last detected pulse rate. If the detected pulse is lost, a flashing zero is displayed and an alarm sounds.

PULSE SEARCH

or

The PULSE SEARCH indicator lights during power-up, prior to initial acquisition of a pulse signal and during pulse search mode.

MOTION

or

The MOTION indicator lights when patient motion is detected by the N-3000.

NEONATAL

or

NEO

The NEONATAL indicator lights when the N-3000 is in neonatal mode.

LINKED

or

The LINKED indicator lights when data is being transmitted from the N-3000 to a remote monitoring station.

The POWER ON indicator to the right of the ON/STANDBY button lights continuously while the N-3000 is on.

The AUDIBLE ALARM OFF indicator lights steadily to signify that the current audible alarm has been temporarily silenced. If the alarm condition ceases prior to the end of the alarm silence duration, the light goes out.

While the condition exists, the indicator remains lit for the selected duration or until a higher priority alarm condition arises, in which case the AUDIBLE ALARM OFF indicator is no longer illuminated and an alarm sounds. The indicator flashes when the audible alarm silence duration is set to “OFF”.

When the N-3000 (or an attached N-3100) has the audible alarm silence duration set to “OFF” during an alarm condition, the AUDIBLE ALARM OFF indicator flashes and the audible alarm off reminder will sound at 3-minute intervals. The latter occurs only if the N-3000 (or any attached N-3100) has had the audible alarm off reminder enabled (using the service mode as described in the N-3000 service manual).

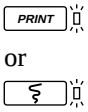
The BATTERY IN USE/BATTERY LOW indicator lights continuously when the battery is in use. When 15 minutes or less battery capacity remains, the indicator flashes and a medium priority alarm sounds.

WARNING: If the unit is turned off while the BATTERY IN USE/BATTERY LOW indicator is flashing and then turned on again without recharging, the indicator may take up to 30 seconds to begin flashing, even though the battery has less than 15 minutes of use left. Always recharge the battery after turning off an N-3000 with a flashing BATTERY IN USE/BATTERY LOW indicator.

The BATTERY CHARGING indicator is always lit when the N-3000 is connected to AC power and turned on. When the N-3000 is connected to AC power and the monitor is turned *off*, the BATTERY CHARGING indicator will remain lit for approximately 14 hours and then turns off. If there are any power interruptions, the 14-hour charging period begins again when power is restored.

An illuminated BATTERY CHARGING indicator is not necessarily an indication that the battery contains less than a full charge. It is merely used as a timer to indicate that the battery has been continuously charging for less than 14 hours.

The N-3000 may be used with a less than fully charged battery but with a corresponding decrease in operating time from that charge.



The STACKED indicator lights when the N-3000 is stacked with the N-3100, the N-3200, or both and communication between the instruments is established.

DESCRIPTION OF AUDIBLE INDICATORS

Audible indicators listed previously in this section have symbols associated with them. The following list represents tones for which there is no accompanying symbol or button.

Valid keypress	1 high-pitched beep
Invalid keypress	1 low-pitched beep
Power-on self-tests passed	1 one-second medium-pitched beep
"*Smart*" Pulse Rate Alarm Limits Set	3 medium-pitched beeps
Pulse "beep"	Beeps that are synchronous with each measured pulse

SETUP

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

WARNING: Do not subject the N-3000 to extreme moisture, such as direct exposure to rain. Such exposure may cause inaccurate performance or device failure

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

WARNING: The N-3000 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 use and shortly thereafter.

WARNING: Disconnect the N-3000 and Nellcor sensor during magnetic resonance imaging (MRI) scanning. Use during MRI could cause burns or adversely affect the MRI image or the monitors accuracy. Also, to avoid burns, remove the N-3000 sensor from the patient before conducting MRI.

WARNING: Do not lift the monitor by the sensor cable, lead, or power cord because the cable, lead, or cord could disconnect from the monitor, causing the monitor to drop on the patient.

PERFORMANCE VERIFICATION

The N-3000 performance can be verified by following the procedures outlined in the *Performance Verification* section of the N-3000 service manual. Qualified service personnel should perform this procedure before using the monitor for the first time in a clinical setting.

CONNECTING TO AN EXTERNAL POWER SUPPLY

The N-3000 may be used alone or stacked with the N-3100 blood pressure monitor, the N-3200 display/printer, or both. If connected to the N-3200, it is not necessary to connect to an external power supply.

If transporting the monitor, or if AC power is not available, you may operate the N-3000 on battery power for a limited amount of time. In that case, it is not necessary to connect to an external power supply.

CONNECTING THE N-3000 TO THE SPS POWER SUPPLY

1. Place the N-3000 on a flat surface near the patient. With an optional mounting adapter such as the *Nellcor Symphony* DB-1 mounting kit, the N-3000 may be attached to an IV pole, bed rail, wall mount, or headboard.

2. Place the SPS power supply on a flat surface near the N-3000 so the power supply cable will reach the N-3000.

Caution: For AC operation, use only the *Nellcor Symphony* SPS-N1 (North America), SPS-I1 (international), PSS-1 (North America) or PSS-1I (international) external power supplies. Use of other power supplies may result in damage to or improper operation of the N-3000.

3. Plug the SPS power supply cable into the socket on the right side of the N-3000. The connector will engage only one way, with the cable toward the rear of the monitor as illustrated in Figure 8.

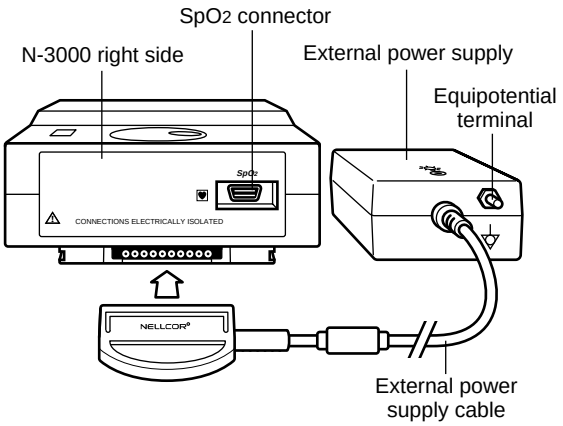


Figure 8: Connecting to the SPS External Power Supply

4. Connect the Nellcor Puritan Bennett power cord to the external power supply as shown in Figure 9.

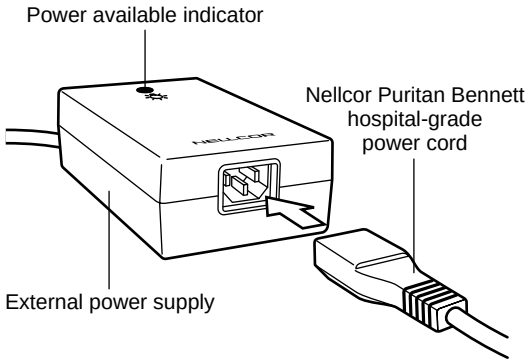


Figure 9: Connecting Power Cord

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

5. Plug the power cord into a properly grounded AC outlet.

6. Use only the original hospital-grade AC power cord provided by Nellcor Puritan Bennett. Ensure that the power available indicator on the external power supply lights.

CONNECTING THE N-3000 TO THE PSS POWER SUPPLY

1. Place the PSS on a flat surface near the patient.

2. Connect the PSS to the N-3000 as shown in Figure 10.

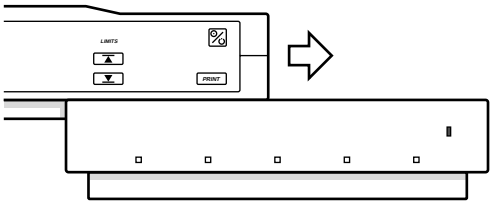


Figure 10: Connecting to the PSS External Power Supply

3. Slide the monitor onto the PSS until the docking connectors firmly engage and you hear a “click”.

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

4. Plug the PSS into an AC outlet.

5. Using the PSS rear-panel rocker switch, turn the power supply on. Ensure that the green LED on the front of the PSS is lit.

BATTERY OPERATION

In case of loss of external power, the N-3000 operates on its internal battery that provides at least 4 hours of operation from a new, fully charged battery when operating independently of the N-3100 and N-3200. When operating in the stacked configuration with the N-3200, either the N-3000 battery or N-3200 battery provides power to the stack, depending on which battery has the higher charge voltage. When stacked with the N-3100, battery life varies, depending primarily on the frequency of N-3100 blood pressure measurements.

Recharge the N-3000 after extensive battery use or after the BATTERY IN USE/BATTERY LOW indicator has been flashing. If the monitor is not recharged, the monitor may fail to operate or stop operating suddenly.

When the N-3000 is connected to an external power supply or is stacked with an N-3200 connected to AC power, or stacked with an N-3100 connected to an active SPS or PSS external power supply, the self-contained battery automatically recharges, whether the N-3000 is on or off. A complete recharge of a fully drained battery requires 14 hours.

STACKING WITH THE N-3100 OR N-3200

If you wish to operate in the stacked configuration, use the following instructions to connect the N-3000 to the N-3100 or N-3200. These procedures assume that you have read the appropriate N-3100 or N-3200 operator's manual.
When operating stacked with the N-3100, ensure that both instruments are in the same operating mode (neonatal or adult-pediatric) and check all configurable settings.

If the active instruments in the stack are in different operating modes when power is turned on, press the NEW PATIENT/ NEONATAL button on any of the active instruments twice (two presses within 2 seconds) as needed to place all active instruments in the same operating mode.

CONNECTING THE N-3000 TO THE N-3100 OR N-3200

The N-3000 must be the top unit in the stack.

1. Connect the external power supply and power cable to the N-3100, as indicated in the N-3100 operator's manual. If stacking with the N-3200, plug the power cord directly into the power input connector on the rear panel of the N-3200.

2. Press the docking release button on the rear of the N-3100 or N-3200 to remove the top cover and expose the docking connector (N-3100 illustrated in Figure 11).

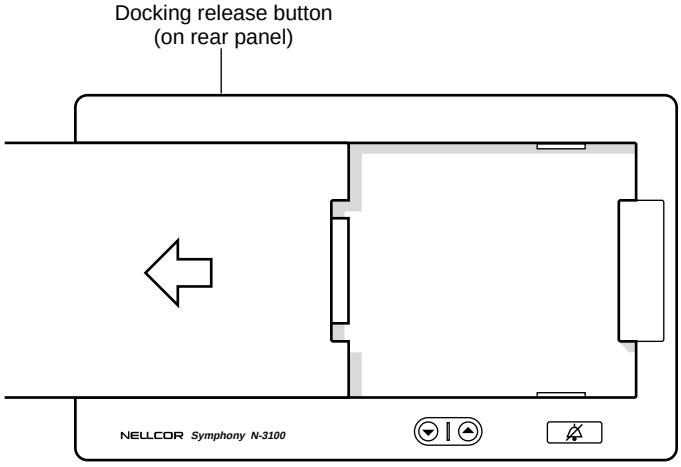


Figure 11: Removing the N-3100 Top Cover

3. Slide the N-3000 onto the N-3100 or N-3200 until the docking connectors firmly engage and you hear a "click." See Figure 12.

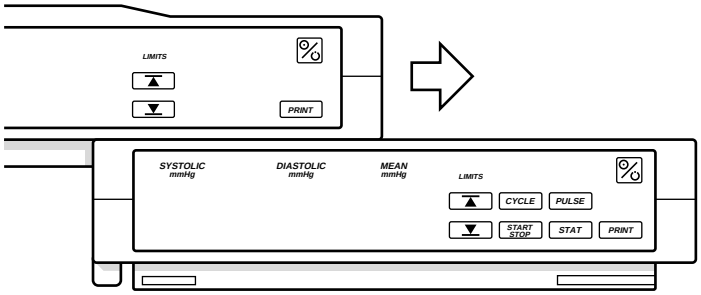


Figure 12: Connecting to the N-3100

4. Operate the N-3000 as indicated in the *Start-up and Use* section of this manual.

Note: The STACKED indicators on the N-3000, the N-3100, and N-3200 in a stack will light while the instruments are stacked, communicating, and power is turned on. If the STACKED indicator does not light, refer to the *Troubleshooting and Maintenance* section.

Read the N-3100 or N-3200 operator's manual before using the stacked configuration.

REMOVING THE N-3000 FROM THE N-3100 OR N-3200

Note: When operating on battery power, you may remove the N-3000 from the N-3100 while the N-3000 is ON. However, the N-3100 must be off prior to removal from the stack in order to avoid a power-failure alarm. If a power-failure alarm occurs, press the N-3100 AUDIBLE ALARM OFF button to silence the alarm.

To remove a *Nellcor Symphony* instrument from the stack, press the docking release button on the rear panel of the bottom instrument and slide the top instrument off the bottom instrument.

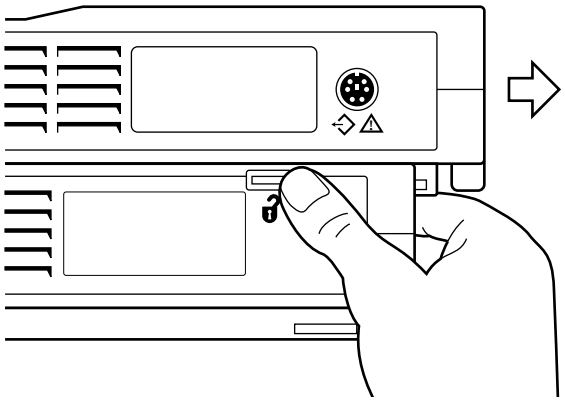


Figure 13: Removing the N-3000 From the N-3100

SERIAL INTERFACE

WARNING: To ensure patient electrical isolation, connect only to other equipment with electrically isolated circuits.

The N-3000 serial interface provides patient data output using EIA-232 or RS-422 signal levels and is located on the rear panel. When data is requested by a computer connected to the serial interface port, requested data is checked to ensure integrity and then sent out through the port in a proprietary format.

The serial port is functional only when the N-3000 is operating on AC power. Use of the port by a qualified programmer requires an EIA-232 Nellcor Puritan Bennett cable (purchased separately) to connect the N-3000 with the computer as illustrated in Figure 14. The cable and directions for use are available by contacting Nellcor Puritan Bennett Technical Services or your local Nellcor Puritan Bennett representative.

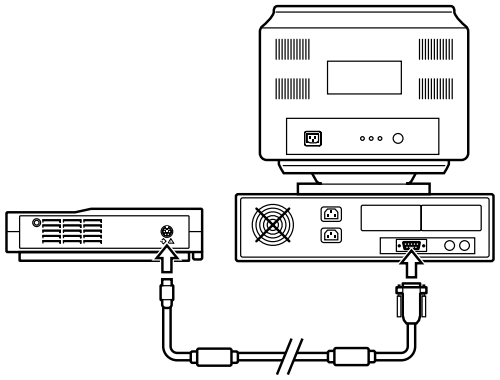


Figure 14: Serial Port Interface

This output port can also be configured to provide an alarm active function instead of serial data.

Note: When the N-3000 is configured for the alarm active function, the serial data interface connector is dedicated to the alarm active function and patient data will not be available. Refer to the N-3000 service manual.

The alarm active function, also located in the serial port connector, may be used to monitor N-3000 alarms from a remote location. The alarm active function remains active whether the monitor is operating from an AC source or the internal battery. The alarm active function allows use of a "nurse call" light. Alarm monitoring also applies to an attached, active N-3100 or N-3200. Refer to the N-3000 service manual for information concerning the required serial port configuration to activate the alarm active function.

WARNING: The alarm active function will not be activated by alarms from other stacked instruments unless all instruments are communicating with each other. For proper operation, verify that the STACKED indicator on each stacked instrument is on.

WARNING: The nurse call feature should not be used as the primary source of alarm notification. The audible and visual alarms of the N-3000 monitor, used in conjunction with clinical signs and symptoms, are the primary sources for notifying medical personnel that an alarm condition exists.

SENSORS AND ACCESSORIES

WARNING: Use only one extension cable to increase the length of the sensor. Use of more than one sensor extension cable may have an adverse effect on performance. Do not attach to the sensor port any cable that is intended for computer use.

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

WARNING: Do not use a damaged sensor such as one with exposed optical components.

WARNING: Use only Nellcor Puritan Bennett sensors and sensor cables with this monitor. Other sensors or sensor cables may cause improper N-3000 performance.

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

WARNING: Pulse oximetry readings and pulse rate signals can be affected by certain ambient environmental conditions, sensor application errors, and certain patient conditions.

SELECTING A NELLCOR PURITAN BENNETT SENSOR

When selecting a sensor, consider the patient's weight and activity, the adequacy of perfusion, the available sensor sites, the need for sterility, and the anticipated duration of monitoring. For more information, refer to Table 1 or contact your local Nellcor Puritan Bennett representative.

Table 1: Compatible Nellcor Puritan Bennett Sensors

Oxygen Transducer	Model	Patient Size
Oxisensor® *II* oxygen transducer (sterile, single use)	N-25 I-20 D-20 D-25(L) R-15	<3 or >40 kg 3 to 20 kg 10 to 50 kg >30 kg >50 kg
Oxiband® oxygen transducer (reusable with disposable non sterile adhesive)	OXI-A/N OXI-P/I	<3 or >40 kg 3-40 kg
Durasensor® oxygen transducer (reusable, non sterile)	DS-100A	>40 kg
Nellcor Puritan Bennett reflectance oxygen transducer (reusable/non sterile)	RS-10	>40 kg
Dura-Y® multisite oxygen transducer(non sterile, reusable) For use with Dura-Y sensors: Ear clip (reusable, non sterile) *Pedi-Check*™ pediatric spot-check clip (reusable, non sterile)	D-YS D-YSE D-YSPD	>1 kg >30 kg 3-40 kg
OxiClip® oxygen transducers (sterile, single-use only)	P N I A	10 to 50 kg <3 or >20 kg 3 to 40 kg >30 kg

BIOCOMPATIBILITY TESTING

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

CONNECTING SPO_2 SENSORS

Use only notched Nellcor Puritan Bennett sensors, such as those indicated in Table 1, which are compatible with the SCP-10 cable.

Connect the sensor to the SCP-10 cable, locking it into place as illustrated in Figure 15. Notice that the sensor connector and SCP-10 connector are shaped to fit together only one way, with the NELLCOR name on the upper side of the connector.

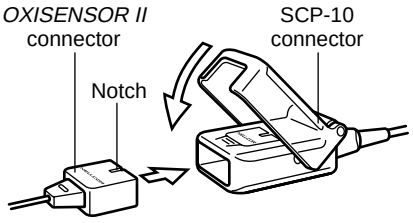


Figure 15: Connecting SpO_2 Sensor to SCP-10 Cable

PERFORMANCE CONSIDERATIONS

WARNING: Pulse oximetry readings and pulse rate signals can be affected by certain ambient environmental conditions, sensor application errors, and certain patient conditions.

Use only Nellcor Puritan Bennett sensors and sensor cables. Select an appropriate sensor, apply sensor as directed, and observe all warnings and cautions presented in the directions for use accompanying the sensor.

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 sensor. To prevent interference from ambient light, cover the sensor site with opaque material. Failure to take this action 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 that the sensor is properly and securely applied
- Move the sensor to a less active site
- Use an adhesive sensor that tolerates some patient motion
- Use a new sensor with fresh adhesive backing

START-UP AND USE

WARNING: The N-3000 is to be operated by qualified personnel only (for non-prescription device). Before use, carefully read this manual, accessory directions for use, all precautionary information, and specifications.

WARNING: The N-3000 is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.

WARNING: Pulse oximetry readings and pulse rate signals can be affected by certain ambient environmental conditions, sensor application errors, and certain patient conditions.

WARNING: For pacemaker patients, the N-3000 may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely upon N-300 alarms. Keep pacemaker patients under close surveillance.

WARNING: Do not silence the audible alarm or decrease its volume if patient safety could be compromised.

POWER-ON AND SELF-TEST

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

Automatic Self-Tests

When the N-3000 is turned on, it performs automatic self-tests. A 1-second beep indicates that self-tests were performed successfully.

While in use, the N-3000 performs self-tests every 4 to 5 minutes without interrupting normal operation. If these self-tests are successful, you will see no changes in the operation of the N-3000. If a failure occurs, the N-3000 will display an error code as indicated in the *Troubleshooting and Maintenance* section.

N-3000 Turn On Procedure

The safe and proper working condition of the N-3000 can be verified through the completion of the power-on self-test in the following procedure.

1. Ensure that the SpO_2 cable with sensor is connected to the N-3000. Press the ON/STANDBY button. You will hear three consecutively higher-pitched beeps, and the POWER ON indicator will light.

2. All indicators light for a few seconds.

Caution: If any indicator or display element does not light, do not use the monitor. Instead, contact qualified service personnel, your local Nellcor Puritan Bennett representative, or the Nellcor Puritan Bennett's Technical Services Department.

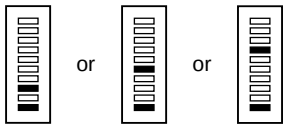
   If segments of the digital displays or other indicators do not light, notify service personnel and do not use the N-3000.

3. Digital displays individually light in a scanning test pattern. Following a successful self-test, you will hear a 1-second tone and all indicators will light while the tone sounds.

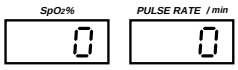
   If a self-test fails, you will hear an alarm and you may see an error code in the digital display. If this occurs, press the ON/STANDBY button to turn the unit off. Attempt to restart. If the unit again fails the self-test, refer to the *Troubleshooting and Maintenance* section.

Note: The bottom segment of the pulse amplitude indicator remains lit as long as the N-3000 is powered on and connected to a sensor cable and SpO2 sensor. Other segments may light briefly.

While the SpO2 cable with sensor is attached to the monitor, or any time the N-3000 is attempting to acquire a pulse signal, the first and third, first and fifth, or first and seventh segments of the pulse amplitude indicator may light *briefly* as shown below.



If the SpO2 cable with sensor is attached to the monitor but *not* attached to the patient when you first power-up the N-3000, the SpO2% and PULSE RATE displays indicate “0”.



Note: Other combinations (for example, the SpO2 cable without sensor) will result in different initial displays.

CLEARING DATA

Caution: Pressing and holding the NEW PATIENT/NEONATAL button 3 seconds or more until three beeps sound, clears all previously stored patient data.

If the N-3000 is being applied to a new patient, press and hold the NEW PATIENT/NEONATAL button for 3 seconds until you hear three beeps to indicate that stored patient data is cleared. Alarm limits are not affected.

NEONATAL MODE

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

The default power-on mode set at the factory is the adult-pediatric mode. To change the N-3000 from the adult-pediatric mode to the neonatal mode, press the NEW PATIENT/ NEONATAL button twice within 2 seconds.

When the N-3000 is in neonatal mode, the NEONATAL MODE indicator lights; the indicator does not light when the N-3000 is in the adult-pediatric mode. To change back to adult-pediatric mode, press the NEW PATIENT/ NEONATAL button twice within 2 seconds. The NEONATAL MODE indicator should no longer be lit

Note: The default power-on operating mode can be changed to the neonatal mode by qualified service personnel using the configuration mode described in the N-3000 service manual.

When you change operating modes (adult-pediatric to neonatal, or vice versa), alarm limits return to power-on defaults for the respective modes and previous patient data is cleared from the displays.

When the N-3000 is stacked with the N-3100, the initial power-on default operating mode may be different for the two instruments. Both instruments in the stack should be in the same operating mode (neonatal or adult-pediatric).

If active instruments in the stack are in different operating modes when power is turned on, press the NEW PATIENT/NEONATAL button twice (2 presses within 2 seconds) on the active instrument that is in the incorrect mode as needed to place all active instruments in the same operating mode.

Note: The default power-on operating mode can be changed by technically qualified service personnel using the configuration mode described in the service manual for the instrument needing to be changed.

To adjust neonatal alarm limits, switch to neonatal mode, then follow the procedures in the “Adjusting Alarm Limits” paragraph.

PATIENT TREND DATA

N-3000 patient trend data is available to be displayed as waveforms or in a tabular format on a stacked and active N-3200. Refer to the N-3200 operator's manual to display and print N-3000 trend data. Additionally, the data is available for viewing on a PC attached to the N-3000 serial port. Contact Nellcor Puritan Bennett's Technical Services Department or your local Nellcor Puritan Bennett representative for serial port protocol information.

Data stored includes SpO_2 percent, pulse rate, pulse amplitude, and alarm status. The N-3000 uses one of three selectable formats to record samples of parameters of patient data. Format 1 is the default format. The configuration mode, as detailed in the N-3000 service manual, can be used by qualified service personnel to change the default format setting.

Format 1

Patient data is sampled for 10 seconds and the average of the measurements during that period is recorded. Trend data is available for the last 24 hours of actual monitoring during the previous 5 days. If an alarm occurs anytime during that period, it is recorded.

Format 2

Patient data is sampled for 20 seconds and the maximum and minimum values during that period are recorded. Trend data is available for the last 32 hours of actual monitoring during the previous 5 days. If an alarm occurs anytime during that period, it is recorded.

Format 3

Patient data is sampled for 5 seconds and the last measurement during that period is recorded. Trend data is available for the last 12 hours of actual monitoring during the previous 5 days. An alarm is recorded only if the alarm was active during the last measurement.

The sample period for all three formats does not necessarily have to be continuous. When the N-3000 is removed from the patient, the sample period is stopped and then continued when the N-3000 is again applied to the patient. For all three formats however, any sample data that is over 5 days old is discarded.

Note: Only the data from the last format used is available. For example, if format 1 was used continuously for an hour, then format 2 was used for 2 hours, only the 2 hours of format 2 data is available.

DESCRIPTION OF ALARMS

Management of Loss-of-Pulse Alarm

Nellcor Symphony® N-3000 *Oxismart* ™ signal processing is designed to reduce the adverse effects of normal interference associated with motion, low patient perfusion, and spurious electrical or optical signals. Figure 16 illustrates monitor response in sporadic or lost pulse situations with and without continuous motion.

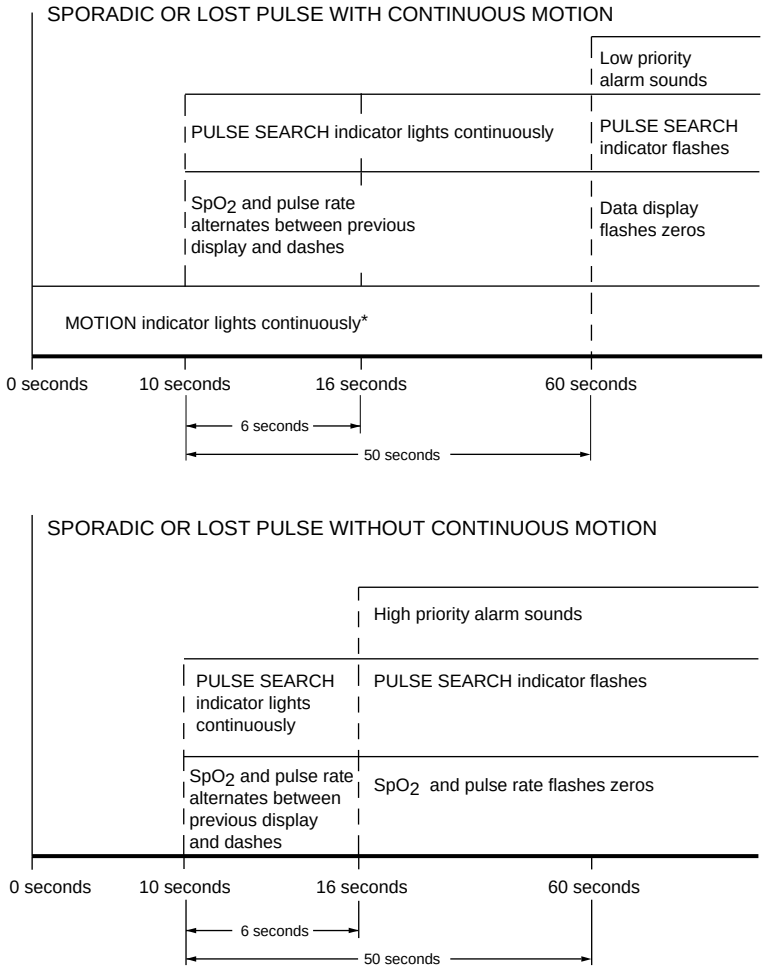
Loss of pulse presents an alarm-management challenge for any oximeter—sometimes it is caused by a clinical emergency, sometimes by signal distortion. When the pulse is lost because of deteriorating patient condition, the oximeter should alarm quickly.

However, normal interference can obscure the pulsatile signal. If interference is short-lived, no alarm should sound. Such alarms are distracting and potentially time-consuming. However, if interference persists, an alarm should notify the attendant.

The N-3000 loss-of-pulse alarm is designed for use in environments in which the pulse can be obscured by interference. Most loss-of-pulse alarms are attributable to interference from patient motion which typically is brief.

When the pulsatile signal is lost, the N-3000's ability to identify interference from motion becomes particularly important because the response of the monitor is determined by the presence or absence of interference from patient motion.

Because a spontaneously moving patient can be assumed to have a pulse, as long as continuous motion is detected, the N-3000 continues to search for the pulse.



*If during motion the N-3000 detects a qualified pulse, the values on the display are updated.

If motion stops at any time during the pulse search mode, and no qualified pulse is detected, the high priority alarm will immediately sound after 6 seconds.

Figure 16: Monitoring Conditions and Alarm Responses

When an N-3000 is stacked with an N-3100 blood pressure monitor and the N-3100 begins a blood pressure measurement, the N-3000 is notified. Blood perfusion at the SpO_2 sensor on the same limb as an N-3100 blood pressure cuff will be momentarily interrupted during a blood pressure measurement.

Therefore, an N-3000 stacked with an N-3100 will be inhibited from producing a loss-of-pulse alarm when the N-3100 begins a blood pressure measurement. This happens even if the N-3000 SpO_2 sensor and the N-3100 blood pressure cuff are on different extremities. The N-3000 will resume monitoring for loss-of-pulse after the N-3100 has completed its measurement, including any needed measurement re-attempts.

The N-3000 manages loss-of-pulse alarms as follows, and as illustrated in Figure 16. If the N-3000 fails to detect at least one qualified pulse during any 10-second period, it enters pulse search mode, the PULSE SEARCH indicator lights, the displays alternate between data and dashes, and the data evaluation period starts.

During the 50-second data evaluation period:

- If the patient is *not* moving (for example, because of cardiac arrest, shock, paralysis, anesthesia) and has no qualified pulse for 6 seconds, a high-priority alarm immediately sounds, the PULSE SEARCH indicator flashes, and the data displays flash zeroes.

- If the patient *is* constantly moving, the N-3000 searches for qualified pulses for up to 50 seconds. Each time a qualified pulse is detected, even during motion, the data displays are updated.

  The N-3000 returns to normal operation as soon as it detects one of the following: three consecutive qualified pulses (when there is no motion), five consecutive qualified pulses (when there *is* motion), or a total of 10 qualified pulses. Otherwise, at the end of the data evaluation period, the data displays flash zeroes and, if motion is still present, a low-priority alarm sounds; if there is no motion, a high-priority alarm sounds.

  If, during the 50-second data evaluation period, motion stops and no qualified pulse is found for 6 seconds, a high-priority alarm sounds immediately.

N-3000 loss-of-pulse alarm management can therefore be considered a three-tier system:

- Normal mode, during which qualified pulses are being detected and the data display is routinely updated.
- Pulse-search mode, during which the PULSE SEARCH indicator lights, the data display alternates between data and dashes, and the data evaluation period is ongoing. The data display is updated when a qualified pulse is detected.
- Loss-of-pulse mode, during which an alarm sounds, the PULSE SEARCH indicator flashes, and the data displays flash zeroes.

Alarm Descriptions

The N-3000 has five levels of audible alarms.

1. *High-priority alarm*: Indicated by a high-rate, high-pitched, pulsing tone. A high-priority alarm sounds after loss of pulse is detected (refer to the "Management of the Loss-of-Pulse Alarm" paragraph in this section).

2. *Medium-priority alarm*: Indicated by a medium-rate, medium-pitched, pulsing tone. A medium-priority alarm sounds and the corresponding parameter display flashes when any measured patient parameter moves outside the set alarm limits. A medium-priority alarm also sounds during battery operation, when 15 minutes or less battery capacity remains.

3. *Low-priority alarm*: Indicated by a low-rate, low-pitched, pulsing tone. A low-priority alarm sounds during the following conditions:

    - When an SpO_2 cable has disconnected (this alarm function is inactive from the time the N-3000 is turned on until the cable is connected)
    - 50 seconds after loss of pulse is detected in the presence of continuous motion

4. *Microprocessor-failure alarm*: Indicated by a shrill, continuous tone. A microprocessor alarm sounds when the microprocessor has failed.

5. *Power-failure alarm*: Indicated by a shrill, pulsing tone. A power-failure alarm sounds when the N-3000 loses power for any reason (other than when the ON/STANDBY button is pressed).

As shown in the "Alarm Summary" paragraph later in this section, alarm pitch, time between beeps, and the type of visual indication depend on the alarm condition.

Note: Beeps that indicate valid and invalid keypresses, pulse beep, patient data cleared, and selection on "*Smart*" pulse rate alarm limits will also be heard during audible alarms.

There will be no upper/lower alarm limit, loss-of-pulse, or sensor/cable disconnect alarms if the N-3000 is turned on before the cable or SpO_2 sensor is attached. These alarms sound only after a pulse has been monitored.

Press the AUDIBLE ALARM OFF button once to silence an alarm. The alarm will be turned off for an amount of time as described in Table 2.

Table 2: Audible Alarm Off Duration

Alarm	**When AUDIBLE ALARM OFF button is pressed, alarm will remain off until:**
High priority	1. Alarm silence duration setting expires
Parameter outside of set alarm limits 50 sec. after loss of pulse with continuous motion	1. Alarm silence duration setting expires, or 2. A higher priority alarm occurs
SpO_2 cable/sensor disconnect; Low battery, or microprocessor/ power failure	1. The situation is corrected, then recurs, or 2. A higher priority alarm occurs

If the alarm condition ceases prior to the end of the alarm silence duration, the AUDIBLE ALARM OFF indicator is extinguished. While the condition exists, the indicator remains lit for the duration of the selected alarm silence period or until a higher priority alarm condition arises, in which case the AUDIBLE ALARM OFF indicator goes out and an alarm sounds.

If the audible alarm silence duration is set to OFF, the AUDIBLE ALARM OFF indicator flashes and no audible alarms will occur (except those for low battery, power or microprocessor failure, and sensor or sensor cable disconnect). Silence duration selection, including OFF, does not affect low battery, power or microprocessor-failure, or sensor or sensor cable disconnect alarms.

All Alarm Silence

The all alarm silence feature is available only in models with a software version of 3.4.3 or later. Qualified service personnel can determine the software version using the procedures in the configuration mode section of the service manual.

Press the AUDIBLE ALARM OFF button twice within 2 seconds to silence *all* alarms for the alarm silence duration, whether an alarm is currently sounding or not. Three beeps indicate that this feature has been activated and the AUDIBLE ALARM OFF indicator lights continuously until the end of the alarm silence duration. The all alarm silence mode is automatically exited at the end of the alarm silence duration.

To deactivate the feature before the alarm silence duration has expired, press the AUDIBLE ALARM OFF button twice within 2 seconds. Again, three beeps indicate that this feature has been deactivated. The AUDIBLE ALARM OFF indicator is extinguished.

While in the all alarm silence mode, no alarms will sound during the alarm silence duration, including those of a higher priority. The appropriate parameter displays or indicators, however, will flash. Similarly, if any alarm condition is corrected and then recurs during the alarm silence duration, no alarms will sound, but the appropriate parameter displays or indicators will flash.

Latching Alarm Option

Qualified service personnel can configure your system to have latching alarms. The factory default is non-latching alarms.

Latching alarms
The parameter display flashes and an audible alarm sounds even *after* the alarm condition no longer exists, until you press the AUDIBLE ALARM OFF button.

Note: If the N-3000 is configured for latching alarms and the AUDIBLE ALARM OFF button is pressed during a high- or medium-priority alarm, the parameter display will stop flashing when the alarm condition is no longer present.

Non-latching alarms
The parameter display flashes only until the alarm condition no longer exists. The audible alarm sounds until the condition no longer exists or until you press the AUDIBLE ALARM OFF button.

Alarm Summary

1. AUDIBLE ALARM OFF button has *not* been pressed after alarm occurs.

- Alarm condition present
  - Audible alarm
  - Flashing display
- Alarm condition ceases to exist (non-latching option)
  - Audible alarm stops
  - Display stops flashing
- Alarm condition ceases to exist (latching option)
  - Audible alarm and
  - Flashing display continues until AUDIBLE ALARM OFF button is pressed

2. AUDIBLE ALARM OFF button *has* been pressed after alarm occurs.

- Alarm condition still present
  - No audible alarm for silence duration
  - AUDIBLE ALARM OFF indicator lights
  - Flashing display continues
- Alarm condition ceases to exist
  - No audible alarm
  - No flashing display
  - No AUDIBLE ALARM OFF indicator

3. Audible alarm silence duration set to OFF.

- No alarm condition is present
  - No audible alarm
  - Audible alarm off reminder at 3-minute intervals
  - AUDIBLE ALARM OFF indicator flashes
- Alarm condition occurs
  - No audible alarm
  - Audible alarm off reminder at 3-minute intervals
  - AUDIBLE ALARM OFF indicator flashes
  - Display flashes continuously for out-of-limit parameter

ADJUSTING ALARM LIMITS

Overview

When the N-3000 is first turned on, alarm limits will be set to their power-on default values. Power-on default alarm limits can be changed by qualified personnel with the N-3000 in the configuration mode described in the N-3000 service manual. You can change alarm limits from default values if necessary, as described below. Changes you make will remain in effect until you change them again or turn the N-3000 off.

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

When monitored patient values appear in the digital displays or dashes are displayed before a measurement is taken, the N-3000 is in normal (patient-monitoring) mode.

When either the UPPER or the LOWER ALARM LIMIT button is pressed, the N-3000 is in view/adjust alarm limits mode.

While in the view/adjust alarm limits mode, current alarm limits will be displayed, but patient parameter values will not be displayed.

The N-3000 automatically returns from view/adjust alarm limits mode to normal mode if you do not press a limit button or adjust a setting within 3 seconds. It also returns to normal mode if you press the AUDIBLE ALARM OFF, or NEW PATIENT/NEONATAL button. Any alarm limit changes made will take effect.

Selecting Alarm Limit to be Adjusted

To select an upper alarm limit to view or adjust, press the UPPER ALARM LIMIT button. When the UPPER ALARM LIMIT button is pressed, the upper alarm limit for SpO_2 is displayed. Subsequent pressing of the UPPER ALARM LIMIT button will cycle through the displays showing upper alarm limit for pulse rate and back again to the SpO_2 display. The display of an upper alarm limit is indicated by dashes in the upper portion of the displays that are not selected. An example of a pulse rate upper alarm limit is shown below.

To select a lower alarm limit, press the LOWER ALARM LIMIT button. When the LOWER ALARM LIMIT button is pressed, the lower alarm limit for SpO_2 is displayed.

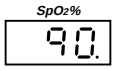
Pressing of the LOWER ALARM LIMIT button again while in the view/adjust alarm limits mode will display the lower alarm limit for pulse rate and back to the SpO_2 display when pressed again. The display of a lower alarm limit is indicated by dashes in the lower portion of the displays that are not selected. An example of a pulse rate lower alarm limit is shown below.

If the LOWER ALARM LIMIT button is pressed while an upper alarm limit is displayed, the lower alarm limit for that parameter will then be displayed.

While the upper alarm limit or the lower alarm limit is displayed and before 3 seconds have elapsed, turn the knob on the top of the N-3000 to adjust the displayed alarm limit.

Note: If the SpO_2 limits are set to their minimum (20%) or maximum (100%) values, the SpO_2 alarm is *disabled* and will not sound. However, if the pulse rate limits are set to their maximum (250 bpm) or minimum (30 bpm), the alarms are enabled and will alarm normally.

Alarm Limits Changed Indicator



If alarm limits have been changed from the N-3000's power-on defaults, a decimal point will appear after the displayed parameter value during patient monitoring or when alarm limits are viewed. The decimal point remains until you change modes (adult or neonatal), turn the N-3000 off, or until the value is adjusted back to the default value.

SELECTING "*SMART*" PULSE RATE ALARM LIMITS

The "*Smart*" feature automatically sets pulse rate alarm limits as follows:

- Lower Alarm Limit = 75% of the patient's current pulse rate (at time of setting) or 30 bpm, whichever is larger.
- Upper Alarm Limit = 150% of the patient's current pulse rate or 250 bpm, whichever is smaller.

For example, if the patient's pulse rate is 80 bpm when you select the *Smart* feature, the upper alarm limit would be set at 120 bpm, and the lower limit would be set at 60 bpm.

Note: *Smart* pulse rate alarm limits can be set only when the N-3000 is displaying a pulse rate value other than zero.

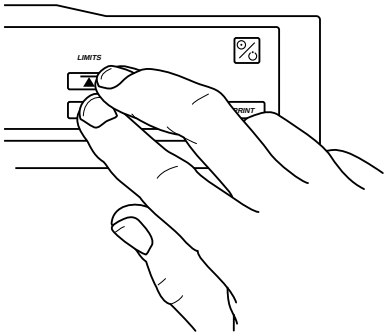


Figure 17: Selecting *Smart* Pulse Rate Alarm Limits

To select *Smart* pulse rate alarm limits, press and hold the UPPER and LOWER ALARM LIMIT buttons simultaneously for 3 seconds as shown in Figure 15. Three beeps indicate that the new limits are set, based on a valid pulse. A single, "invalid keypress" beep (after the 3 seconds) indicates that *Smart* pulse rate alarm limits were not set for lack of a qualified pulse.

Once *Smart* pulse rate alarm limits are activated, alarm limits will not change unless one of the following occurs:

- You turn the instrument off and then back on where limits revert to power-on defaults
- You use standard alarm setting procedures to select new pulse rate alarm limits
- You reactivate the *Smart* pulse rate alarm limits setting as described above
- You see an error code displayed indicating current limits have been lost

ADJUSTING AUDIBLE ALARM SILENCE DURATION

WARNING: Do not silence an audible alarm or decrease its volume if patient safety could be compromised.

Alarms can be silenced for a preset period called the *audible alarm silence duration*. The audible alarm silence duration starts when you press the AUDIBLE ALARM OFF button.

If an alarm of the same or lower priority occurs during the audible alarm silence duration, it will not be heard until the end of the duration. If the alarm condition is still present or a new alarm occurs after the audible alarm silence duration has elapsed, an audible alarm will sound.

An alarm with a higher priority will sound regardless of whether the duration has ended. Also, if alarm condition ceases to exist before the audible alarm silence duration has ended, any alarm condition will cause an alarm to sound.

The power-on default audible alarm silence duration setting is in effect unless it is changed. The power-on default set at the factory is 60 seconds. The power-on default setting can be adjusted by service personnel using the configuration mode as indicated in the N-3000 service manual. The setting OFF can not be selected as a power-on default setting.

To view the current audible alarm silence duration, press and hold the AUDIBLE ALARM OFF button for less than 3 seconds. The setting is displayed similarly to that shown below.

WARNING: If an alarm condition (except those for low battery, power-failure and microprocessor-failure) occurs while the audible alarm silence period is set to OFF, the only alarm indication will be visual displays related to the alarm condition.

You can set the audible alarm silence period to 30, 60, 90, or 120 seconds or to OFF. To adjust the audible alarm silence period, press and hold the AUDIBLE ALARM OFF button. Within 3 seconds, after pressing the AUDIBLE ALARM OFF button, turn the control knob until you see the desired alarm silence duration in the PULSE RATE display. The displayed setting takes effect when you release the AUDIBLE ALARM OFF button.

When operating in the stacked configuration, setting the audible alarm silence period for one instrument causes any other active instrument in the stack to be set to the same period.

Shortcut to Select OFF for Audible Alarm Silence Duration

To quickly select OFF for the N-3000 audible alarm silence period, simultaneously press the AUDIBLE ALARM OFF button and the UPPER ALARM LIMIT button as shown in Figure 16.

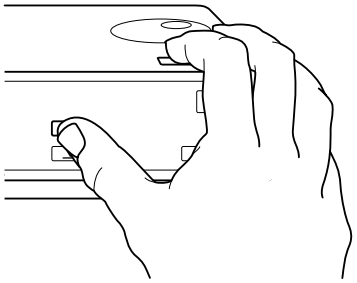


Figure 18: Setting Audible Alarm Silence Duration to Off

When operating in the stacked configuration, using the shortcut method to set the N-3000 audible alarm silence duration to OFF does *not* affect the audible alarm silence duration of other instruments in the stack.

To return to the previous alarm silence duration selection (or to the power-on default if no change was made), simultaneously press the AUDIBLE ALARM OFF button and the LOWER ALARM LIMIT button.

ADJUSTING AUDIBLE ALARM VOLUME

To adjust the audible alarm volume, for alarms other than microprocessor and power failure, press and hold the AUDIBLE ALARM OFF button for at least 3 seconds, without turning the knob or pressing any other buttons, until you hear a tone. Observe the audible alarm volume range, expressed in a value from 1 to 10 in the AUXILIARY display. A “1” represents the lowest volume, and a “10” represents the highest volume setting. Turn the control knob to adjust the volume.

When operating in the stacked configuration, the audible alarm volume level setting for each instrument remains as it was before being stacked.
Setting the audible alarm volume on one active instrument in a stack, sets the audible alarm volume on any other active instrument in the stack to the same level.

Audible Alarm Off Reminder

An audible alarm off reminder sounds three beeps at 3-minute intervals when the audible alarm silence duration has been set to OFF. The AUDIBLE ALARM OFF indicator continues to flash until the silence duration is changed. The volume of the audible alarm off reminder is equal to the alarm volume setting or, if stacked with another instrument, equal to the highest current audible alarm volume setting for any active instrument in the stack.

Note: The audible alarm off reminder may be disabled using the service mode as indicated in the N-3000 service manual.

ADJUSTING PULSE "BEEP" VOLUME

The N-3000 "beeps" with each detected pulse. The beep pitch varies proportionately with percentage of saturation, rising as SpO_2% increases toward 100%, and falling as it decreases.

While in normal (patient monitoring) mode, turn the knob to adjust pulse beep volume. When the N-3000 is turned off and back on again, the pulse beep returns to its power-on default volume. Pulse beeps will continue during an audible alarm.

TECHNICAL STAFF ADJUSTABLE FEATURES

When the N-3000 is placed in the configuration mode by qualified service personnel, they may adjust power-on default values of N-3000 features.

Instructions for activating the configuration and service modes and making these adjustments are found in the N-3000 service manual. Power-on default values that can be adjusted or set in the configuration mode include the following:

- Operating mode (adult or neonatal)
- SpO_2% upper and lower limits
- Pulse rate upper and lower limits
- Audible alarm volume
- Audible alarm silence duration
- Pulse beep volume
- Serial port baud rate
- Trend format

Values that can be adjusted in the service mode include the following:

- Alarm silence reminder
- Alarm latching

NELLCOR SYMPHONY INSTRUMENTS IN STACK

When *Nellcor Symphony* N-3000 and N-3100 or N-3200 instruments are connected together or "stacked," certain functions are shared. Active instruments are those that are connected together and are on.

- The AUDIBLE ALARM OFF button on any active instrument silences the current audible alarm on all active instruments in the stack. However, only the AUDIBLE ALARM OFF button on the N-3000 is accessible when the instruments are stacked.

- Changing the audible alarm silence period and alarm volume on one instrument in the stack will affect all active instruments in the stack (unless using the shortcut method described previously in this section).

- When an instrument is added to a stack of instruments, it will retain its audible alarm silence period and alarm volume settings until manually changed.

- During operation, when the operating mode (neonatal or adult-pediatric) is adjusted on one instrument, all active instruments in the stack are automatically set to that mode.
- The knob on the N-3000 may be used to perform adjustments on the N-3100 or N-3200 when a knob-related function is activated.

- One Nellcor Puritan Bennett external power supply connected to AC power can supply power to the N-3000 and N-3100. If the N-3200 is used, it can be directly connected to AC power and provide power to any combination of stacked instruments.

- Pressing the NEW PATIENT/NEONATAL button for 3 seconds on either the N-3000 or N-3100 clears data for both active instruments in the stack.

- When the N-3100 is connected to the N-3000, it informs the N-3000 of blood pressure cuff inflation. The N-3000 may then correctly process pulse signals affected by cuff inflation to prevent a nuisance alarm. N-3000 SpO_2 alarms will be silenced for the entire time the N-3100 is taking a blood pressure measurement.

- When the N-3000 is connected to the N-3200, the N-3000 provides data for plethysmographic waveforms. The N-3000 also provides SpO_2 percentage, pulse rate, and pulse amplitude for display in a tabular format on the N-3200.

- When the N-3000 is connected to the N-3100, the initial power-on default operating mode may be different for the two instruments. Both instruments in the stack should be in the same operating mode (neonatal or adult-pediatric). If the active instruments in the stack are in different operating modes when power is turned on, press the NEW PATIENT/NEONATAL button twice (2 presses within 2 seconds) on the active instrument that is in the incorrect mode as needed to place all active instruments in the same operating mode.

  Note: The power-on default operating mode can be changed by qualified service personnel using the configuration mode described in the service manual for the instrument needing to be changed.

BATTERY OPERATION

In case of loss of external power, the N-3000 operates on its internal battery that provides at least 4 hours of operation from a new, fully charged battery when operating independently of the N-3100 and N-3200. When operating in the stacked configuration with the N-3200, either the N-3000 battery or N-3200 battery provides power to the stack, depending on which battery has the higher charge voltage. When stacked with the N-3100, battery life varies, depending primarily on the frequency of N-3100 blood pressure measurements.

Recharge the N-3000 after extensive battery use or after the BATTERY IN USE/BATTERY LOW indicator has been flashing. If the monitor is not recharged, the monitor may fail to operate or stop operating suddenly.

When the N-3000 is connected to an external power supply or is stacked with an N-3200 connected to AC power, or stacked with an N-3100 connected to an active SPS or PSS external power supply, the self-contained battery automatically recharges, whether the N-3000 is on or off. A complete recharge of a fully drained battery requires 14 hours.

Caution: If the N-3000 is to be stored for a period of 24 months or longer, notify service personnel to remove the battery from the monitor prior to storage. Recharge the battery when it has not been charged for 6 months or more.

Caution: Follow local government ordinances and recycling instructions regarding disposal or recycling of device components, including batteries.

TROUBLESHOOTING AND MAINTENANCE

English

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

WARNING: Do not spray, pour, or spill any liquid on the N-3000 its accessories, connectors, switches, or openings in the chassis.

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

TROUBLESHOOTING

Error Codes

When the N-3000 detects an error condition, it displays an error code similar to the illustration below.

If the number is other than one of those listed below, turn the instrument off and back on again. If the error code reappears, record it, press the AUDIBLE ALARM OFF button to silence the alarm, if present, and notify your service personnel.

Error codes that begin with a "0" are user-correctable. The following N-3000 error codes are user-correctable.

EEE 055

SpO2 alarm limits and other settings may have returned to power-on defaults due to an internal instrument reset.

Turn the instrument off and back on again. Check and, if necessary, readjust alarm limits. Notify service personnel if it is necessary to reconfigure power-on defaults.

EEE 058

Alarm and beep volume, audible alarm silence duration, and operating mode may have returned to power-on defaults due to an internal instrument reset.

Turn the instrument off and back on again. Check and, if necessary, readjust alarm and pulsatile beep volume setting, audible alarm silence duration, and operating mode.

Notify service personnel if it is necessary to reconfigure power-on defaults.

EEE 081

The N-3000 is unable to interface with the sensor.

Check the sensor and SCP-10 cables and the connections. To clear the error, disconnect and reconnect the sensor.

If the error code remains, replace the sensor and/or the cable. If the error code still persists, notify service personnel.

Error Conditions

1. **A pulsing, shrill alarm sounds and the N-3000 does not start up.**

   - There is no power available to the N-3000. Press the AUDIBLE ALARM OFF button to stop the alarm. The battery has discharged below the shutdown point, and either AC power is not available or the external power supply has failed. Notify your service personnel.

   - The ON/STANDBY button may be inoperable, in which case the N-3000 may attempt to restart until the battery is discharged or removed.

2. BATTERY-IN-USE indicator lights steadily while the N-3000 is connected to its external power supply and AC outlet.

- Make sure that the external power supply is properly connected to the N-3000 and to the hospital-grade power cord.
- Confirm that the Power Available indicator on the external power supply is on. If it is not, and connections are good, the external power supply may be defective. Notify your service personnel.
- Check to see if power is available to other equipment on the same AC circuit.

3. The PULSE AMPLITUDE indicator seems to indicate a pulse, but the digital displays show zeroes.

- *Check the patient.*
- Excessive patient motion may be making it impossible for the N-3000 to acquire a good pulse signal. If possible, keep the patient still. Check whether the sensor is applied securely and properly and replace if necessary, or move the sensor to a new site.
- The sensor or cable may be damaged; replace it.
- The signal may be too low to allow the N-3000 to measure oxygen saturation and pulse rate.

4. SpO_2 or pulse rate values change rapidly; pulse amplitude indicator is erratic.

- *Check the patient.*
- Excessive patient motion may be making it impossible for the N-3000 to acquire a good pulse signal. If possible, keep the patient still. Check whether the sensor is applied securely and properly and replace if necessary, or move the sensor leads to a new site.
- The sensor may be damp or may have been reused too many times; replace it.
- An electrosurgical unit (ESU) may be interfering with performance:
  - Move the N-3000, cables and sensor as far from the ESU as possible.
  - Plug the N-3000 power supply and the ESU into different AC circuits.
  - Move the ESU ground pad as close to the surgical site as possible and as far away from the sensor as possible.

5. Displayed SpO_2 pulse rate does not correlate with that of an ECG monitor connected to the patient.

- The patient may have a dysrhythmia. All beats counted by the ECG monitor may not be perfused.
- Excessive patient motion may be making it impossible for the N-3000 to acquire a good pulse signal. If possible:
  - keep the patient still
  - check whether the sensor is applied securely and properly and replace if necessary
  - move the sensor to a new site
- The patient may have a pronounced dicrotic notch, which could cause the pulse rate measurement to double. Try another sensor site.

- An ESU may be interfering with performance. Refer to the discussion above.

- Interference, artifact, or patient motion may be affecting the accuracy of the ECG monitor.

6. Oxygen saturation (SpO_2) measurement does not correlate with the value calculated from a blood gas determination.

- Calculated saturation values are inherently and slightly different from pulse oximeter measurements.

- Accuracy can be affected by:

  – incorrect sensor application and use

  – significant levels of dysfunctional hemoglobins, intradermal or intravenous dyes, bright light, excessive patient movement, venous pulsations, electrosurgical interference

  – placement of a sensor on an extremity that has a blood pressure cuff, arterial catheter, or intravascular line

- Observe all instructions, warnings, and cautions in this manual and in the sensor directions for use.

EMI INTERFERENCE

The N-3000 has been tested and found to comply with the limits for medical devices to the EN60601-1-2:1993, EN60601-1-2;1994, Medical Device Directive 93/42/EEC. These limits are designed to provide reasonable protection against harmful electromagnetic interference (EMI) in a typical medical installation. In addition, the device contains alarms which notify the user when EMI is detected (although detection cannot be assured in all cases).

Because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in the health-care environment (for example, cellular phones, mobile two-way radios, electrical appliances), it is possible that high levels of EMI interference due to close proximity or strength of a source, may result in disruption of performance of the N-3000.

The N-3000 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.

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

- Turn equipment in the vicinity off and on to isolate the source of interference.
- Reorient or relocate the N-3000 or the receiving device.
- Increase the distance between the N-3000 and the other equipment.
- Select alternative power receptacle (A/C power outlet).

If assistance is required, contact Nellcor Puritan Bennett's Technical Services Department or your local Nellcor Puritan Bennett representative.

COMPLIANCE WITH TEST LIMITS FOR A CLASS B DIGITAL DEVICE

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15.103 of the FCC Rules (and CISPR II, Class B). These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation,. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

PERIODIC SAFETY CHECKS

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

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

SERVICE

The N-3000 requires no routine maintenance other than cleaning, battery maintenance and that which is mandated by your institution.

If the monitor has been visibly damaged or subjected to mechanical shock (for example, when dropped), qualified service personnel should perform the procedure in the *Performance Verification* section of the service manual.

If problems cannot be corrected by your service personnel, the N-3000 should be returned to Nellcor Puritan Bennett for service. Contact Nellcor Puritan Bennett's Technical Services Department or your local representative for return instructions.

CLEANING

WARNING: Do not spray, pour, or spill any liquid on the N-3000 its accessories, connectors, switches, or openings in the chassis.

To clean the N-3000, dampen a cloth with a commercial, non-abrasive cleaner and wipe the top, bottom, and front surfaces lightly. Wipe the sensor extension cable with a damp cloth. For sensors, follow cleaning instructions in the directions for use accompanying the sensor.

If liquid is accidentally spilled on the N-3000, clean and dry thoroughly before reuse.

BATTERY MAINTENANCE

Caution: If the N-3000 is to be stored for a period of 24 months or longer, notify service personnel to remove the battery from the monitor prior to storage. Recharge the battery when it has not been charged for 6 months or more.

If the N-3000 has not been used for a long period of time, the battery will need charging. To charge the battery, connect the N-3000 to an SPS or PSS external power supply (or an N-3200) which is connected to an AC outlet (refer to the *Setup* section). It may be necessary to briefly turn on the N-3000 to start battery charging.

Note: Storing the N-3000 for a long period without charging the battery may degrade the battery capacity. A complete battery recharge requires 14 hours.

Nellcor Puritan Bennett recommends that the N-3000 battery be replaced at 2-year intervals. Refer to the N-3000 service manual for battery replacement and general service instructions.

OBTAINING TECHNICAL ASSISTANCE

For technical information and assistance, or to order a service manual, contact Nellcor Puritan Bennett's Technical Services Department or your local Nellcor Puritan Bennett representative. The service manual includes information required by qualified service personnel when servicing the N-3000.

RETURNING SYSTEM COMPONENTS

If it is necessary to return the N-3000 or the external power supply for service, call Nellcor Puritan Bennett's Technical Services Department or your local representative for shipping instructions. Have all equipment serial numbers available when calling.

To pack the N-3000 for return, disconnect the sensor, sensor cable, and external power supply. It is not necessary to return the sensor. To pack the SPS power supply, disconnect the power cord. Pack items to be returned in their original shipping carton if available. If not, use a suitable carton with appropriate packing material to protect the item or items during shipping.

SPECIFICATIONS

GENERAL

Designed to meet safety requirements of:

UL 2601-1, CSA-C22.2 No. 601-1-M90, EN60601-1:1995, ISO 9919, EMC per EN60601-1-2:1993, ISO 10993-1 (Sensors).

Sensors

Nellcor Puritan Bennett's oxygen transducers (sensors) can be categorized as surface devices contacting skin for a limited duration of time. Biocompatibility testing has been conducted on NPB's sensors in compliance with ISO 10993-1, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing, which suggests cytotoxicity, sensitization and irritation or intracutaneous reactivity testing be performed on devices falling into this category. The sensors have passed the recommended biocompatibility testing and are therefore in compliance with ISO 10993-1.

ELECTRICAL CLASSIFICATION (IEC 601-1)

Protection Class

Class I: per I.E 601-1, clause 2.2.4

Degree of Protection

Type CF: per I.E 601-1, clause 2.2.26

Enclosure Degree of Protection

Ordinary (IPX0)

Mode of Operation

Continuous

Emissions Compliance

EN55011 Emissions Classification
CISPR II, Group I, Class B

Battery

Type
Rechargeable, sealed lead-acid internal battery

Operating Time
4 hours minimum from a new, fully charged battery in stand-alone configuration; age and usage affect battery performance.

Recharge Period
14 hours for full charge; 6 hours for 1 hour operating time

Expected Battery Life
Age and usage patterns will affect the capacity of the N-3000 battery. If the monitor is operated primarily from auxiliary power supplies, its battery will maintain nominal capacity for at least two years.

In situations of intensive battery use, (where the monitor is operated frequently in portable applications, for example) battery life can be as short as six months.

In these applications it is recommended that the battery operating time be tested every six months and the battery replaced if the capacity is less than two hours of operating time.

Avoiding deep discharge and operating from auxiliary power supplies where possible will prolong battery life and preserve capacity.

N-3000 Input Voltage

15 V ⎓ (DC)

External Power Supplies

Input Voltage/Current
Model SPS-N or N1: 100–120 VAC, 500 mA (max), 50/60 Hz
Model SPS-I or I1: 100–240 VAC, 1.3 amps, 50/60 Hz
Model PSS-1 or 1I: 100–240 VAC, 1.3 amps, 50/60 Hz

Output Voltage
15 V ⎓ (DC)

PHYSICAL CHARACTERISTICS

Dimensions

Height (when used standalone)	6.8 cm (2.68 in.)
Height (excluding docking pedestal)	5.4 cm (2.13 in.)
Width	23.9 cm (9.41 in.)
Depth	14.7 cm (5.79 in.)

Weight

1.8 kg (4.0 lb.)

FACTORY SETTINGS

Factory Alarm Default Settings

	Adult/Pediatric	**Neonate**
SpO_2 Upper Alarm Limit:	100%	95%
SpO_2 Lower Alarm Limit:	85%	80%
Pulse Rate Upper Alarm Limit:	170 bpm	190 bpm
Pulse Rate Lower Alarm Limit:	40 bpm	90 bpm

Factory General Default Settings

Operating Mode:	Adult-Pediatric
Pulse Beep Volume:	57.5 dB(A) at 1 meter (volume setting of 4)
Audible Alarm Volume:	62.5 dB(A) at 1 meter (volume setting of 5)
Audible Alarm Silence Duration:	60 seconds
Alarm Silence Reminder:	On
Latching Alarms:	Off
Serial Port Baud Rate:	19,200 bits per second
Trend Format:	10-second averaged (format 1)

PERFORMANCE

Measurement Range

SpO_2
0–100%

Pulse Rate
20–250 bpm

Pulse Rate Display Update Frequency

The PULSE RATE display updates in less than 2.5 seconds with a 1-second change in SpO_2-derived pulse rate from 30 pulses per minute (ppm) to 200 ppm.

Alarm Limit Range - Adult/Pediatric and Neonate

SpO_2 Upper Alarm Limit:	20–100%
SpO_2 Lower Alarm Limit:	20–100%
Pulse Rate Upper Alarm Limit:	30–250 bpm
Pulse Rate Lower Alarm Limit:	30–250 bpm

Alarm Characteristics

Audible Characteristics

Alarm Priority	Pitch (± 30 Hz)	Pulse Width (± 20 msec)	Pulse Repetition Interval (± 20 msec)
High	932 Hz	255 msec	320 msec
Medium	752 Hz	400 msec	700 msec
Low	500 Hz	400 msec	3600 msec

Rise/fall time for pulses is 16 milliseconds ± 3 milliseconds.

Flashing Display Characteristics

During high or medium priority alarms, the .5-inch, red, front-panel display with a parameter outside the alarm limits, flashes at the following rates:

High priority - 300 milliseconds ON, 150 milliseconds OFF
Medium priority - 750 milliseconds ON, 600 milliseconds OFF

Accuracy

SpO_2

Adults	70–100%	±2 digits
	0–69%	unspecified
Neonatal	70–100%	±3 digits
	0–69%	unspecified

Accuracies are expressed as plus or minus “X” digits (saturation percentage points) between saturations of 70–100%. This variation equals plus or minus one standard deviation (1SD), which encompasses 68% of the population. All accuracy specifications are based on testing the subject monitor on healthy adult volunteers in induced hypoxia studies across the specified range. Adult accuracy is determined with *Oxisensor II* D-25 sensors. Neonatal accuracy is determined with *Oxisensor II* N-25 sensors. In addition, the neonatal accuracy specification is adjusted to take into account the theoretical effect of neonatal blood on oximetry measurements.

Pulse Rate

20–250 bpm	±3 bpm

ENVIRONMENTAL CONDITIONS

Transport and Storage (in shipping container)

Temperature
-40° C to +70° C (-40° F to +158° F)

Altitude/Barometric Pressure
-390 m to +6,096 m (-1,280 ft. to +20,000 ft.)
+1,060 hPa to + 500 hPa (+31.3 in. Hg to +14 in. Hg)

Relative Humidity
15% relative humidity to 95% relative humidity (noncondensing)

Transport and Storage (not in shipping container)

Temperature
-20° C to +60° C (-4° F to +140° F)

Altitude/Barometric Pressure
-390 m to +6,096 m (-1,280 ft. to +20,000 ft.)
+1,060 hPa to + 500 hPa (+31.3 in. Hg to +14 in. Hg)

Relative Humidity
15% relative humidity to 95% relative humidity (noncondensing)

Operation

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

Altitude/Barometric Pressure
-390 m to +3,048 m (-1,280 ft. to +10,000 ft.)
+1,060 hPa to +700 hPa (+31.3 in. Hg to +20.6 in. Hg)

Relative Humidity
15% relative humidity to 95% relative humidity (noncondensing)

APPENDIX: PRINCIPLES OF OXIMETRY

PULSE OXIMETRY OVERVIEW

The N-3000 uses pulse oximetry based on two principles: that oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (i.e., spectrophotometry), and that the volume of arterial blood in tissue (and hence, light absorption by that blood) changes during the pulse (i.e., 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 (LEDs) in the oximetry 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. To identify the oxygen saturation of *arterial* hemoglobin, the monitor uses the pulsatile nature of arterial flow. During systole, a new pulse of arterial blood enters the arteriolar bed, and blood volume and light absorption increase. During diastole, blood volume and light absorption reach their lowest point. The monitor bases its SpO_2 measurements on the difference between maximum and minimum absorption (i.e., 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 sensor's red LED to accurately measure SpO_2. During manufacturing, the mean wavelength of the red LED is encoded in a resistor in the sensor.

During monitoring, the instrument's software reads this resistor and selects coefficients that are appropriate for the wavelength of that sensor's red LED; these coefficients are then used to determine SpO_2. This resistor is read when the monitor is turned on, periodically thereafter, and each time a new sensor is connected.

Additionally, to compensate for differences in tissue thickness, the intensity of the sensor's LEDs are adjusted automatically.

FUNCTIONAL VERSUS FRACTIONAL SATURATION

This monitor 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, CO-oximeters 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 arterial saturation (SpO_2) 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 (derived from a blood gas analyzer) was not appropriately corrected for the effects of variables that shift the relationship between PO_2 and saturation (Figure A-1): pH, temperature, the partial pressure of carbon dioxide (PCO_2), 2,3-DPG, and fetal hemoglobin.

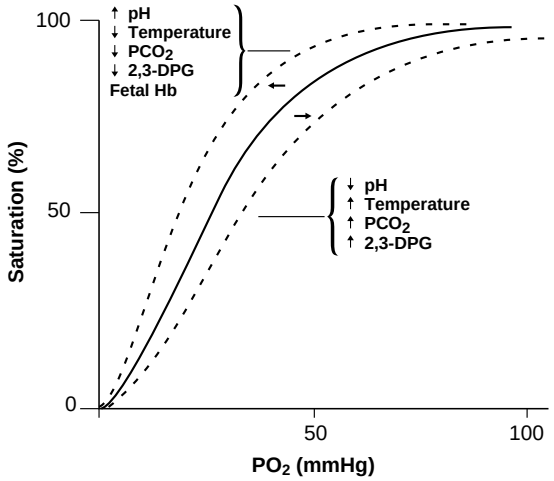


Figure A-1: Oxyhemoglobin Dissociation Curve