

NELLCOR

N-180 Pulse Oximeter

**Operator's Manual
1992**

NEL-14

OPERATOR'S MANUAL

NELLCOR® N-180 Pulse Oximeter

NELLCOR®

Nellcor Incorporated
25495 Whitesell Street
Hayward, California 94545
U.S.A.

Nellcor Europe B.V.
Hambakenwetering 1
5231 DD 's-Hertogenbosch
The Netherlands
31.73.426565

To contact Nellcor's representative: in the United States, call 1-800-NELLCOR or 510 887-5858; outside of the United States, call Nellcor's local representative.

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



TABLE OF CONTENTS

	Symbols	v
	Safety Information	vii
	Quick Guide to Operation	Q-1
I	Features of the N-180	1
II	Principles of Operation	3
III	N-180 Setup	5
	Unpacking and Inspection	5
	Testing	5
	Components	5
IV	NELLCOR Sensors	7
V	Guide to Operations	9
	Basic Operation	9
	Pulse Oximetry Subsystem Features	10
VI	Connecting to Other Instruments	15
	Overview	15
	RS-232 Communication Protocol	15
VII	Maintenance	17
	Service	17
	Cleaning Instructions	17
	Battery Testing	17
	Determining Software Version	17
	Technical Assistance	17
	Returning the N-180	19
VIII	Troubleshooting	20
	Status Messages	23
	Troubleshooting	22
IX	Specifications	23
	Configuration	23
	Performance	23
	Environmental Requirements	26
	Electrical Characteristics	26
	Physical Characteristics	26
	Warranty—For Replacement or Repair	27

LIST OF TABLES

1	Default Alarm Settings	11
2	SERIAL COMM Connector Pin Assignments	15
3	Output Format Switch Settings	16
4	Baud Rate Switch Settings	16

LIST OF FIGURES










1	Oxyhemoglobin Dissociation Curve	4
2	N-180 Front Panel	5
3	N-180 Rear Panel	6

The following are trademarks of Nellcor Incorporated: *NELLCOR*, which is registered in the United States and other countries; *DURASENSOR*, and *OXIBAND*, which are registered in the United States; and *OXISENSOR*, and the Nellcor knob.

Covered by one or more of the following patents and corresponding foreign patents: U.S. patent numbers 4,621,643; 4,653,498; 4,700,708; 4,770,179; 4,802,486; 4,869,254; 4,928,692; 4,934,372.

SYMBOLS

N-180 SYMBOLS

I/O	Power on/off switch
	Dangerous voltage.
	Equipotential (ground) terminal
	Caution: refer to manual
~	Alternating current
	Fuse replacement symbol
	Patient electrically isolated (Type BF equipment)
I / 	On/standby switch
 SpO ₂	High saturation limit
SpO ₂ 	Low saturation limit
	High heart rate limit

SYMBOLS

N-180 SYMBOLS (continued)



Low heart rate limit



Audible alarm off



Battery in use



Low battery



Pulse search indicator

SAFETY INFORMATION

WARNINGS

DANGER! Explosion hazard. Do not use in the presence of flammable anesthetics.

Carefully read this operator's manual, accessory directions for use, all precautionary information (which is set in boldface type), and specifications before application and use of the equipment.

The N-180 is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.

Shock hazard. Cover to be removed only by qualified service personnel. There are no user-serviceable parts inside.

Do not silence the audible alarm if patient safety could be compromised.

Tissue damage can be caused by incorrect application or use of a sensor (e.g., wrapping the sensor too tightly, applying supplemental tape, or failing to inspect the sensor site periodically).

Loss of pulse signal can occur if:

- the sensor is too tight;
- there is excessive illumination: e.g., a surgical or bilirubin lamp or sunlight;
- the sensor is placed on an extremity with a blood pressure cuff, arterial catheter, or intravascular line;
- the patient is in shock, has hypotension, severe vasoconstriction or anemia, hypothermia, arterial occlusion proximal to the sensor, or cardiac arrest.

Inaccurate measurements may be caused by:

- incorrect application or use of a sensor;
- significant levels of dysfunctional hemoglobins, such as carboxyhemoglobin or methemoglobin;
- significant levels of indocyanine green, methylene blue or other intravascular dyes;
- 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;
- electrosurgical interference;
- placement of the sensor on an extremity that has a blood pressure cuff, arterial catheter, or intravascular line.

Do not use the N-180 or oximetry sensors during MRI scanning. Conducted current may cause burns. Also, the N-180 may affect the MRI image, and the MRI unit may affect the accuracy of oximetry measurements.

Do not use a damaged sensor or one with exposed electrical contacts. Do not immerse in liquids. Do not sterilize by irradiation, steam or ethylene oxide.



QUICK GUIDE TO OPERATION

BASIC OPERATION

WARNING: The N-180 is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.

WARNING: Carefully read this operator's manual, accessory directions for use, and all precautionary information (which is set in boldface type) before use.

1. Select appropriate *NELLCOR* sensor and apply to patient, following sensor directions for use. Connect sensor to N-180 (see page 9). If required, use a *NELLCOR* EC-4 or EC-8 sensor extension cable.
2. Turn on system: switch N-180's rear-panel power switch to **I** (on) position and switch front-panel ON/STDBY switch to ON position (see page 11).

When rear panel switch is in the "I" position, the light in the switch indicates power is on and battery is being charged.

Alternatively, operate the N-180 on its internal battery for up to 6 hours.

3. Check alarm limits. If necessary, adjust them to suit patient's needs (see page 11).

For a quick guide to the N-180's alarm functions, refer to the following information.

ALARM FUNCTIONS

Check alarm limits (see page 10)	Press appropriate alarm button (HIGH SAT, LOW SAT, HIGH RATE, or LOW RATE).
Adjust alarm limits (see page 10)	Press appropriate alarm button (HIGH SAT, LOW SAT, HIGH RATE, or LOW RATE), then turn control knob until desired setting appears.
Adjust alarm volume (see page 11)	Press LOW SAT and HIGH SAT buttons at the same time. Turn control knob until desired setting appears in OXYGEN SATURATION display. Turning knob activates audible alarm to indicate volume.
Silence alarm temporarily (see page 12)	Press AUDIO ALARM OFF button. ALARM OFF indicator lights steadily during the alarm-off period.
Adjust alarm silence period (see page 12)	Press AUDIO ALARM OFF button and turn control knob until desired setting (30-120 seconds) appears in OXYGEN SATURATION display.

QUICK GUIDE TO OPERATION

Disable audio alarm
(see page 12)

Press AUDIO ALARM OFF button and
turn control knob clockwise until "OFF"
appears in OXYGEN SATURATION
display. AUDIO ALARM OFF flashes.

OVERVIEW

WARNING: The N-180 is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.

WARNING: Carefully read this operator's manual, accessory directions for use, and all precautionary information (which is set in boldface type) before use.

The **NELLCOR** N-180 pulse oximeter measures functional oxygen saturation of arterial hemoglobin (SpO₂), and pulse rate. The N-180 monitors SpO₂ and pulse rate continuously and noninvasively, with measurements updated at each pulse beat. An internal AC power supply provides isolated power for operating the monitor and charging its internal batteries. In addition, the N-180 provides a digital output for external data recording devices.

Automatic Self-Test and Start-Up

The N-180 provides immediate use after power-up, without need for operator calibration or configuration. It offers:

- Automatic self-test and error messages.
- Automatic oximetry calibration.
- Visible and audible oximetry displays.
- Early warning system that provides an audible indicator for both SpO₂ and pulse rate: a tone signals each pulse and its pitch varies with changes in SpO₂.
- Operator-configured audible oximetry alarms, with default alarm limits preset for adults or neonates. Pulse rate and oxygen saturation displays change from green to red during an alarm condition.
- Battery operation up to 6 hours.

Operator Configurable

The N-180 provides the operator with the capability to tailor the system for specific clinical applications. Capabilities include:

- Audible alarms that can be silenced temporarily or disabled; the alarm tone has adjustable volume.
- Three oximetry operating modes that change measurement averaging time to suit varied clinical applications.



**PULSE OXIMETRY
SUBSYSTEM**

The N-180 is based on the principles of spectrophotometry and plethysmography. It includes an electro-optical sensor and a microprocessor-based monitor. The sensor has two low-voltage light-emitting diodes (LEDs) as light sources and one photodiode as a photodetector. One LED emits red light (nominal 660 nm) and the other emits infrared (nominal 920 nm). When the light from the LEDs passes through the sensor site, part of it is absorbed. The photodetector measures the light that passes through, which indicates red and infrared absorption.

With each heartbeat, a pulse of oxygenated arterial blood flows to the sensor site. Oxygenated hemoglobin differs from deoxygenated hemoglobin in its relative red and infrared absorption, and the N-180 measures red and infrared absorption to determine the percentage of functional hemoglobin that is saturated with oxygen.

Light absorption that is measured when pulsatile blood is not present reflects absorption by tissue and nonpulsatile blood—absorption that does not change substantially during the pulse. This is analogous to the reference measurement of a spectrophotometer. Absorption is also measured when pulsatile, arterial blood is in the tissue. The N-180 then corrects this measurement for absorption when the pulsatile blood is not present. The ratio of the corrected absorption at each wavelength determines arterial oxygen saturation (SpO₂).

Automatic Calibration

The oximetry subsystem incorporates automatic calibration mechanisms. It is automatically calibrated each time it is turned on, at periodic intervals thereafter, and whenever a new sensor is connected. Also, the intensity of the sensor's LEDs is adjusted automatically to compensate for differences in tissue thickness.

Each sensor is calibrated when manufactured: the effective mean wavelength of the red LED is determined and encoded into a calibration resistor in the sensor plug. The instrument's software reads this calibration resistor to determine the appropriate calibration coefficients for the measurements obtained by that sensor.

**Functional versus
Fractional Saturation**

Because the N-180 measures functional SpO₂, it may produce measurements that differ from those of instruments that measure fractional SpO₂. Functional SpO₂ is oxygenated hemoglobin expressed as a percentage of the hemoglobin that is capable of transporting oxygen. Because the N-180 uses two wavelengths, it measures oxygenated and deoxygenated hemoglobin, yielding functional SpO₂. It does not detect dysfunctional hemoglobin, such as carboxyhemoglobin or methemoglobin.

In contrast, some laboratory instruments such as the Instrumentation Laboratory 282 CO-Oximeter report fractional SpO₂—oxygenated hemoglobin expressed as a percentage of all measured hemoglobin, whether or not that hemoglobin is available for oxygen transport. Measured dysfunctional hemoglobins are included.

Section II

PRINCIPLES OF OPERATION

Functional versus Fractional Saturation (continued)

Consequently, to compare N-180 measurements directly with those of another instrument, that other instrument must measure functional SpO₂. If it measures fractional SpO₂, those measurements can be converted using the following equation:

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

Measured versus Calculated Saturation

When SpO₂ is calculated from a blood gas measurement of the partial pressure of arterial oxygen (PaO₂), the calculated value may differ from the N-180 SpO₂ measurement. This is because the calculated SpO₂ may not have been corrected for the effects of variables that shift the relationship between PaO₂ and SpO₂ (see Figure 1): temperature, pH, the partial pressure of carbon dioxide (PaCO₂), and the concentrations of 2,3-DPG and fetal hemoglobin.

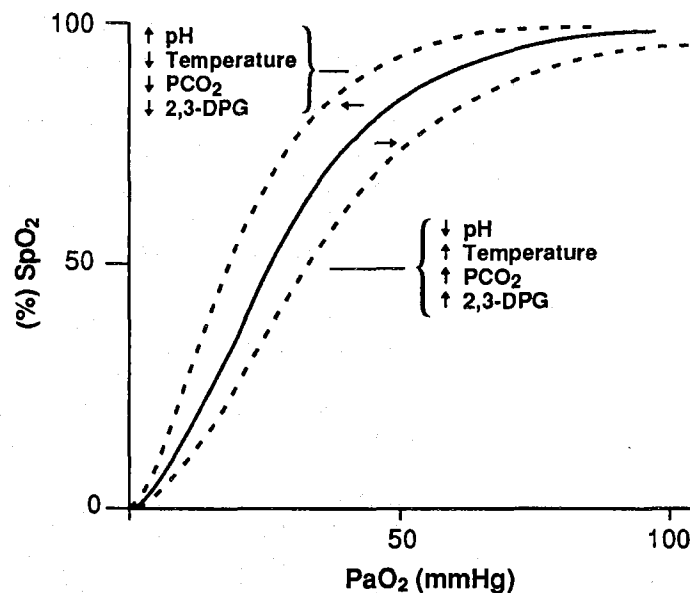


Figure 1: Oxyhemoglobin Dissociation Curve

Section III

N-180 SETUP

UNPACKING AND INSPECTION

WARNING: Carefully read the operating instructions and all precautionary information (which is set in boldface type) before use.

Notify the carrier immediately if the N-180 shipping carton is damaged. Carefully unpack the instrument and its accessories. Confirm that the items in the list of components packed with the unit are included.

Inspect each component. If any component is missing or damaged, contact Nellcor's Customer Service Department or Nellcor's representative.

TESTING

Verify all functions as described in Section V, "Guide to Operations." If a difficulty occurs, refer to Section VIII, "Troubleshooting." If that does not resolve the difficulty, contact qualified service personnel or Nellcor's representative.

COMPONENTS

N-180 Front Panel

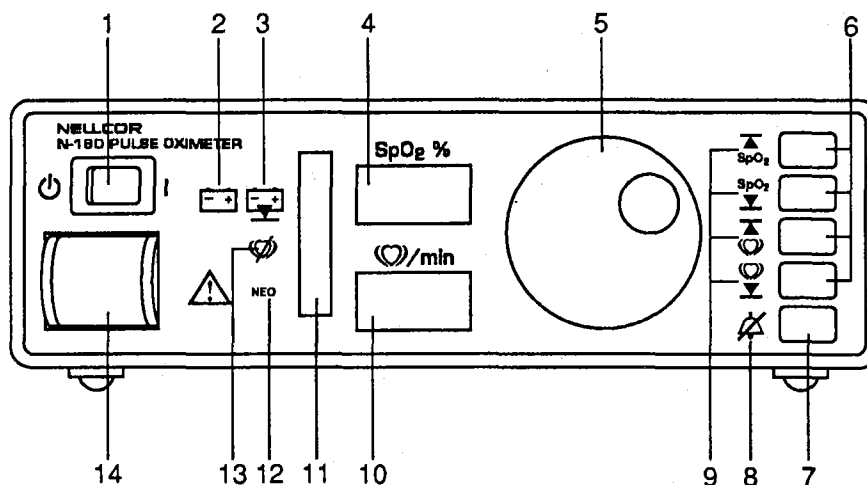


Figure 2: N-180 Front Panel

1. On/Standby switch
2. Battery in Use indicator
3. Low Battery indicator: Flashes when five or fewer minutes of battery power remain.
4. Oxygen Saturation (SpO₂) display
5. Control knob: Changes instrument functions and sets values.
6. High Saturation, Low Saturation, High Rate, Low Rate buttons: Change alarm functions.
7. Audio Alarm Off button: Changes alarm functions and other instrument functions.

Section III

N-180 SETUP

N-180 Front Panel (continued)

8. **Audio Alarm OFF indicator:** Lights steadily when audio alarm has been temporarily silenced; flashes when audio alarm has been disabled.
9. **High Saturation, Low Saturation, High Rate, Low Rate indicators:** Flash during an alarm state.
10. **Pulse Rate display**
11. **Pulse amplitude indicator:** Vertical column of light bars that qualitatively indicates pulse amplitude.
12. **NEO indicator:** Lights when neonatal alarm limits are in effect.
13. **Pulse Search indicator:** Flashes when the N-180 is attempting to locate the patient's pulse.
14. **Sensor or sensor extension cable connector and lock.**

Note: The sensor extension cable connection is electrically isolated.

N-180 Rear Panel

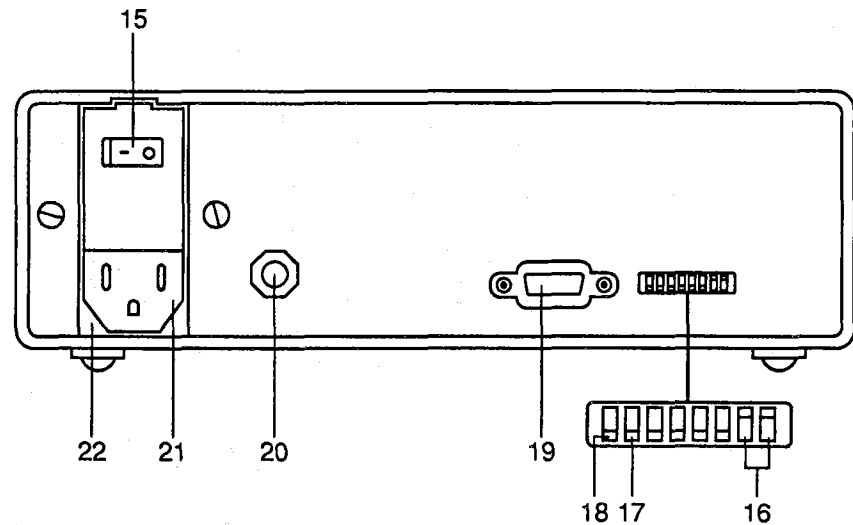


Figure 3: N-180 Rear Panel

15. **Power on/off switch.**
16. **Baud rate switches.**
17. **RS-232 mode switch.**
18. **Adult/neonatal limit setting switch.**
19. **SERIAL COMM connector.**
20. **Ground (equipotential) terminal**
21. **AC mains inlet.**
22. **Fuse compartment.**

OVERVIEW

WARNING: Use only *NELLCOR* oxygen transducers. Use of other oxygen transducers may cause improper oximeter performance.

WARNING: Tissue damage or inaccurate measurements may be caused by incorrect sensor application or use, such as wrapping it too tightly, applying supplemental tape, failing to inspect the sensor site periodically, or failing to position it appropriately. Carefully read the sensor directions for use, the N-180 operating instructions, and all precautionary information (which is set in boldface type) before use.

WARNING: Excessive ambient light may cause inaccurate measurements. Cover the sensor site with opaque material.

Nellcor provides a family of sensors suitable for a wide variety of clinical settings and patients. Specific sensors have been developed for neonates, infants, children, and adults. *OXISENSOR* oxygen transducers are sterile adhesive sensors with optical components mounted on adhesive tape. *OXIBAND* oxygen transducers are reusable sensors that are applied with disposable adhesive. The *DURASENSOR* DS-100A adult digit oxygen transducer is a reusable sensor with its optical components mounted in a plastic casing. The *NELLCOR* RS-10 reflectance oxygen transducer is an adhesive sensor for application to forehead or temple.

SELECTING A SENSOR

Sensors are designed for specific sites on patients within designated weight ranges. To select the appropriate sensor, consider the patient's weight, level of activity, adequacy of perfusion, which sensor sites are available, whether sterility is required, and the anticipated duration of monitoring.

CLEANING AND REUSE

Do not immerse any *OXISENSOR*, *DURASENSOR*, or *OXIBAND* oxygen transducer, the *NELLCOR* RS-10 oxygen transducer, or any Nellcor adhesive in water or cleaning solution. Clean *DURASENSOR*, *OXIBAND*, and the *NELLCOR* RS-10 oxygen transducer by wiping with a disinfectant such as 70% alcohol. Do not sterilize by irradiation, steam, or ethylene oxide. Use a new *OXIBAND* adhesive wrap for each patient. Do not resterilize *OXISENSOR* oxygen transducers.

PERFORMANCE
CONSIDERATIONS

To ensure optimal performance, use an appropriate sensor, apply it as directed, and observe all warnings and cautions.

If excessive ambient light is present, cover the sensor site with opaque material. Failure to do so may result in inaccurate measurements. Light sources that can affect performance include surgical lights, especially those with a xenon light source, bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight.

**PERFORMANCE
CONSIDERATIONS
(CONTINUED)**

If poor perfusion affects instrument performance, and the patient weighs more than 50 kg, consider using the *OXISENSOR* R-15 adult nasal oxygen transducer. Because the R-15 obtains its measurements from the nasal septal anterior ethmoid artery, an artery supplied by the internal carotid, this sensor may obtain measurements when peripheral perfusion is relatively poor. For low peripheral perfusion, consider using the *NELLCOR* RS-10 reflectance oxygen transducer, which is applied to the forehead or temple.

If patient movement presents a problem:

- Verify that the sensor is properly and securely applied.
- Use a new sensor with fresh adhesive backing.
- Move the sensor to a less active site.
- Use a type of sensor that tolerates some patient motion, such as the *OXISENSOR* D-25, D-20, N-25, or I-20 oxygen transducer.

BASIC OPERATION

WARNING: Improper use could present a hazard to the patient. Carefully read the operating instructions and all precautionary information (which is set in boldface type) before use.

WARNING: Inaccurate measurements may be caused by incorrect sensor application or use; significant levels of dysfunctional hemoglobins, (e.g., carboxyhemoglobin or methemoglobin); or 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; electrosurgical interference; and placement of a sensor on an extremity that has a blood pressure cuff, arterial catheter, or intravascular line.

1. Plug the power cord into the N-180 power inlet to a 220–240 V ~ outlet. Use only an outlet that has a grounding connection and the original hospital-grade plug and cord or an equivalent hospital-grade plug and cord. If in doubt about the integrity of the grounding of the mains supply connection, the unit must be operated from its internal battery. The N-180 can operate for up to 6 hours on battery power.
2. Switch the power on/off switch to the on position.
3. Apply an appropriate *NELLCOR* sensor in accordance with its directions for use. Plug the sensor into the N-180 sensor connector. Close the sensor lock over the plug. If required, use a *NELLCOR* EC-4 or EC-8 sensor extension cable.
4. Turn the N-180 on using the ON/STDBY switch. After a few seconds, following successful completion of the self-test, the monitor displays measurements and the pulse amplitude bar graph indicator rises and falls with each pulse beat.

A "beep" signals each pulse beat, and its pitch increases and decreases to reflect changes in SpO₂.

Note: When the N-180 is turned off and back on, all operator-adjustable features return to their default state.

5. Check the alarm limits each time the N-180 is used by pressing the HIGH SAT, LOW SAT, HIGH RATE, and LOW RATE buttons in sequence.
6. Adjust the alarm limits if necessary. Press the appropriate alarm button, and then turn the control knob until the desired value is displayed.

**PULSE OXIMETRY
SUBSYSTEM FEATURES**

This portion of the N-180 measures and displays SpO₂ and pulse rate, and provides data for alarms and for the digital output.

Alarm Functions**Introduction**

If the oxygen saturation level or pulse rate moves beyond the alarm limits, the corresponding alarm indicator flashes and the indicator color changes from green to red. The appropriate display flashes, and an audio alarm sounds (unless or until it has been turned off).

If the alarms activate because the pulse signal is lost, the OXYGEN SATURATION and PULSE RATE displays flash "0," the PULSE SEARCH indicator flashes, and an audio alarm sounds (unless or until it has been turned off).

The audio alarm function can be altered in several ways: it can be silenced temporarily, it can be disabled, and its volume can be adjusted. The visible alarm cannot be turned off.

Checking Alarm Limits

Check the alarm limits each time the N-180 is used, by sequentially pressing the HIGH SAT, LOW SAT, HIGH RATE, and LOW RATE buttons. The unit displays each limit in turn.

Adjusting Alarm Limits

To adjust the alarm limits to meet a specific patient's needs, press the appropriate button (HIGH SAT, LOW SAT, HIGH RATE, or LOW RATE), and then turn the control knob until the display shows the desired value. Oxygen saturation alarm limits may be set for any value from 20% to 100%, and the pulse rate alarm limits may be set for any value from 20 to 250 beats per minute. The upper limit must be higher than the lower limit.

Note: When the operator turns the N-180 off and back on again, alarm limits return to default values.

Default Alarm Limits

Default alarm limits are in effect when the N-180 is turned on. There are two sets of default alarm limits, one for adults and one for neonates (see Table 1).

Alarm Functions
(continued)

Table 1: Default Alarm Settings

Alarm Limit	Adult Setting	Neonatal Setting
high oxygen saturation	100%	95%
low oxygen saturation	85%	80%
high pulse rate	140 bpm	200 bpm
low pulse rate	55 bpm	100 bpm

Changing From Adult to Neonatal Alarm Limits

To change the adult/neonatal setting, move the adult/neonatal alarm switch (switch section 1) up to change the setting to adult default limits; down for neonatal default limits.

Audio Alarm Functions

WARNING: Do not set the alarm volume too low to be heard.

Adjusting Audio Alarm Volume: To adjust audio alarm volume, press the HIGH SAT and LOW SAT buttons at the same time, and then turn the control knob clockwise to increase the volume or counterclockwise to decrease it.

WARNING: In normal operation, the AUDIO ALARM OFF button silences the audio alarm temporarily. While it is possible to disable the audio alarm by following the instructions in this section, this must not be done if patient safety could be compromised.

WARNING: When the AUDIO ALARM OFF button has been pressed and the red AUDIO ALARM OFF indicator is lighted, no audio alarm sounds in the event of adverse patient condition. The AUDIO ALARM OFF button must not be used in situations in which patient safety could be compromised.

**Alarm Functions
(continued)**

Silencing the Audio Alarm Temporarily: To silence the audio alarm for 60 seconds, press the AUDIO ALARM OFF button once. The AUDIO ALARM OFF indicator lights steadily to show that the audio alarm has been silenced temporarily. After 60 seconds, the alarm sounds again if the alarm state continues.

Note: The alarm resumes at the end of alarm silence period only if a pulse was detected at the time the alarm was silenced.

Adjusting the Temporary Silence Period: To change the period during which the audio alarm is silenced temporarily, hold the AUDIO ALARM OFF button down, and turn the control knob until the desired period appears in the OXYGEN SATURATION display. Release the button. This period can be set for any value between 30 and 120 seconds.

Note: When the operator turns the N-180 off and back on again, the audio alarm returns to the default volume.

Disabling the Audio Alarm: To disable the audio alarm, hold the AUDIO ALARM OFF button down, and turn the control knob clockwise until "OFF" appears on the OXYGEN SATURATION display. The audio alarm can be reactivated by pressing the AUDIO ALARM OFF button again.

Pulse Tone**Description**

When a *NELLCOR* sensor is connected to the N-180 and a patient, the pulse beat is signaled by a "beep" that varies in pitch to reflect changes in oxygen saturation, rising as saturation increases and falling as it decreases.

Changing Pulse Tone Volume

Turn the control knob to adjust pulse tone volume. When the N-180 is turned off and back on again, the pulse tone returns to its default volume.

Oxlmety Operating Modes

The N-180's three operating modes enable it to make accurate measurements despite differing levels of patient activity. In all three modes, the N-180 updates its measurements with every pulse beat. Data from the most recent beat replace data from the earliest beat, and new averages are determined and displayed.

Mode 1, the default operating mode, uses a 5- to 7-second averaging time and is useful in situations in which the patient is relatively inactive.

Mode 2 uses a 2- to 3-second averaging time and therefore is more affected by patient motion. It is useful for special applications that require a fast response time, such as sleep studies.

Mode 3 uses a 10- to 15-second averaging time and consequently is least affected by patient motion. In this mode, pulse rate is not displayed and there is no pulse tone.

**Oximetry Operating Modes
(continued)****Changing Operating Mode**

Press the HIGH RATE and LOW RATE buttons at the same time. Turn the control knob until the desired mode appears in the PULSE RATE display.

Battery Operation

If AC power is lost or disconnected, the N-180 operates on its internal battery for up to 6 hours. When the battery level is too low to power the instrument reliably, an internal switch turns off the N-180 automatically.

The battery recharges whenever the instrument is plugged into AC power and the mains switch is on. A minimum of 14 hours is required to recharge the battery fully.

Serial Data Output**Overview**

Serial data output from the N-180 can be in two forms: conversation, where the N-180 responds to inputs from an external ASCII device, or computer, where the N-180 provides a periodic data string reporting saturation and rate data, alarm conditions, and monitor status. The following paragraphs describe each output mode.

Conversation Mode

In this mode, the N-180 responds to an input character. Set switch section 2 down. Connect a computer or ASCII terminal ready to receive data to the serial communications connector.

Transmit a character (see list below); the N-180 responds by transmitting an alphanumeric string containing a data identifier and numeric data (nnn is a numeric value between 000 and 255).

Character Transmitted**String Received**

R (pulse rate)

Rnnn

S (oxygen saturation)

Snnn

P (unused message)

P000

L (low rate alarm limit)

Lnnn

H (high rate alarm limit)

Hnnn

O (low saturation alarm limit)

Onnn

A (alarm status in ASCII-coded decimal;
logic "1" = alarm condition)

Bit 0 = high rate

Bit 1 = low rate

Bit 2 = high sat

Bit 3 = low sat

M monitor status (in ASCII-coded decimal);

Bit 0 = pulse search

status; 1 = locked, 0 = search

Bit 1 = sensor status;

1 = attached, 0 = off

Bit 2 = audio alarm status;

1 = enabled, 0 = disabled

Bit 3 = always 1

Bits 4 through 7 not used

T (unused message)

T000000

Q (high saturation alarm limit)

Qnnn

**Serial Data Output
(continued)****Computer Mode**

In this mode the N-180 transmits a data string every 10 seconds, or when a parameter has changed, whichever is sooner. Set switch section 2 up.

The string transmitted from the N-180 has the format shown below.

```
<STX>RnnnSnnnP000LnnnHnnnOnnnAnnnMnnnT000000Qnnn<CR>  
<LF><checksum><ETX>
```

OVERVIEW

WARNING: Carefully read the operating instructions and all precautionary information (which is set in boldface type) before use.

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

WARNING: When connecting this monitor 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 analog or digital outputs must be certified according to the respective standards, i.e., IEC 950 for data-processing equipment or IEC 601.1 for electromedical equipment. The accessory equipment must be powered from separate wall outlets to avoid possible summation of earth leakage currents. If in doubt, contact Nellcor's Technical Services Department or your local Nellcor representative.

RS-232 COMMUNICATION
PROTOCOL

This section contains information to allow the user to provide serial communications between the N-180 and external digital devices.

Serial Data Connector Pin
Assignments

Table 2 lists pin assignments on the serial communications connector and the corresponding pin assignments for a 25-pin RS-232 connector.

Table 2: Serial Communications Connector Pin Assignments

Connector Pin	Signal	Direction	Output Device Pin	Output Device Signal
1	not used	none	none	none
2	Rx data	←	2	Tx data
3	Tx data	→	3	Rx data
4	DTR	→	6	DSR
5	Signal Ground	↔	7	Signal Ground
6	DSR	←	4	RTS
7	RTS	→	5	CTS
8	CTS	←	20	DTR
9	not used			

**Communications
Formats**

The RS-232 format switches are used to set the communication port format, as shown in Table 3. The serial communication format of the N-180 is eight data bits, no parity bit, and one stop bit.

Table 3: Output Format Switch Settings

Format	Description	Switch Section 2
Conversation	Request for parameter	Down
Computer	ASCII string containing single identifier characters plus values	Up

Setting Baud Rate

Identify the baud rate required by the device that is to be connected, and set the N-180 baud rate using the rear-panel baud rate switches (switch sections 7 and 8). Refer to Table 4.

Table 4: Baud Rate Switch Settings

Baud Rate	Switch Sections	
	7	8
2400	Down	Down
4800	Up	Down
9600	Down	Up
19200	Up	Up

Section VII

MAINTENANCE

SERVICE

WARNING: Carefully read the operating instructions and all precautionary information (which is set in boldface type) before use.

WARNING: For continued protection against fire, replace fuses only with those of the same type and rating.

WARNING: Shock hazard. Cover to be removed only by qualified service personnel. There are no user-serviceable parts inside.

The N-180 requires no routine service other than that which is mandated by the operator's institution. Section VIII, "Troubleshooting," discusses potential difficulties, their possible causes, and suggestions for resolving them. Complete service instructions, including preventive maintenance checks, are contained in the *NELLCOR N-180 service manual*.

CLEANING INSTRUCTIONS

Caution: Do not immerse the N-180 in liquid or use caustic or abrasive cleaners.

To clean the N-180's surfaces, dampen a cloth with a commercial, nonabrasive cleaner and wipe the top, bottom, and front surfaces lightly. Do not spray or pour any liquid directly on the N-180 or its accessories. Do not allow any liquid to come in contact with power connector, fuse holder, or switches. Do not allow any liquid to penetrate connectors or openings in the chassis.

BATTERY TESTING

The battery should be tested by qualified service personnel every two years, using the procedures given in the N-180 service manual.

DETERMINING SOFTWARE VERSION

To determine the N-180 software version, press the HIGH SAT and AUDIO ALARM OFF buttons at the same time. Turn the control knob until a "0" appears in the OXYGEN SATURATION display. The units digit of the software version appears in the PULSE RATE display. Turn the control knob until a "1" appears in the OXYGEN SATURATION display. The tenths digit of the software version appears in PULSE RATE display. For example, version 1.0 should show as a "1" in the PULSE RATE display with "0" showing in the OXYGEN SATURATION display and "0" showing in the PULSE RATE display with "1" showing in the OXYGEN SATURATION display.

TECHNICAL ASSISTANCE

For technical information and assistance, contact Nellcor's Technical Services Department or Nellcor's local representative. To order parts or a service manual, contact Nellcor's Customer Service Department or Nellcor's local representative. The service manual includes circuit diagrams and parts lists required by qualified personnel when servicing the N-180.

RETURNING THE N-180

If it is necessary to return the monitor to Nellcor, call Nellcor's Technical Services Department for shipping instructions.

To repack the N-180, disconnect the sensor. It is not necessary to return sensors. Pack in the original shipping carton. If the carton is not available, wrap the unit in air bubble cushioning material. Locate a corrugated cardboard carton with at least 200 psi (1,400 kPa) bursting strength. Fill the bottom of the carton with at least 2 in. (5 cm) of polystyrene packing material. Place the unit on the layer of packing material and fill the box completely. Seal the carton with packing tape.

STATUS MESSAGES

WARNING: For continued protection against fire, replace the fuses only with those of the same type and rating.

WARNING: Shock hazard. Do not remove cover. There are no user-serviceable parts inside. Contact qualified service personnel.

WARNING: Carefully read the operating instructions and all precautionary information (which is set in boldface type) before use.

This section lists status messages, along with the actions that the operator should take. If the recommended actions do not cause the message to disappear, contact qualified service personnel or Nellcor's representative. The service manual describes additional suggested actions for use by qualified service personnel.

N-180 Status Messages

The following messages are displayed in the N-180's OXYGEN SATURATION and PULSE RATE displays.

Err 1

Defective data memory. Contact qualified service personnel.

Err 2

Defective program memory. Contact qualified service personnel.

Err 3

WARNING: Continue to use the N-180 only in an urgent situation with an "Err 3" message and only if the defective segment(s) has been identified. If a defective segment cannot be identified, do not continue to use the N-180.

Defective display or indicator, or possibly a circuit malfunction. Contact qualified service personnel.

Note: The N-180 may operate if any button is pressed while "Err 3" is showing. However, if any numeric display segment or indicator is missing, the display or warning indicators may be incorrect.

TROUBLESHOOTING

This section discusses potential difficulties and suggestions for resolving them. If the difficulty persists, contact qualified service personnel or Nellcor's representative. The service manual provides additional troubleshooting information, which is for use by qualified service personnel.

This section is divided into two troubleshooting categories:

- Items 1 and 2 describe general system problems.
 - Items 3 through 8 describe general oximetry subsystem problems.
1. **N-180 does not turn on.**
 - Check AC connections. Check that monitor is connected properly to the AC supply.
 - Check battery operation. If battery is discharged, connect N-180 to an appropriate AC outlet and turn on the mains switch. The N-180 requires a minimum of 14 hours to recharge the battery completely.
 - Check AC fuses.
 2. **N-180 operates on AC power but not on battery.**
 - The battery may be discharged. To recharge the battery, connect the N-180 to an appropriate AC power outlet. Turn on the power on/off switch and confirm that the BATT IN USE indicator is off. A minimum of 14 hours is required to recharge the battery completely.
 - The battery pack or battery charger circuit may be defective, or the battery fuse may be open.
 3. **PULSE SEARCH indicator is on; SpO₂ and pulse rate not displayed.**
 - *Check the patient.* The patient may be experiencing shock, hypotension, severe vasoconstriction, severe anemia, hypothermia, arterial occlusion proximal to the sensor, or cardiac arrest.
 - The sensor may be improperly applied (e.g., too tight) or it may not be plugged in.
 - There may be excessive ambient light; cover the sensor site with opaque material.
 - The sensor may be placed on an extremity with a blood pressure cuff, arterial catheter, or intravascular line.
 - The patient's perfusion may be too low for the N-180 to detect an acceptable pulse.
 - Test the N-180 on someone else; try another sensor site; or try another sensor (see Section IV, "NELLCOR Sensors," for suggestions).
 - The sensor may be damaged; replace it.
 - Evaluate performance using a NELLCOR PT-2500 pocket tester. The saturation reading should be 81 ± 1 digit; the pulse rate reading should be 40 ± 1 digit. If incorrect readings result, contact qualified service personnel.
-

4. **The pulse amplitude indicator tracks a pulse, but there is no oxygen saturation or pulse rate.**
- *Check the patient.*
 - Excessive patient motion may be making it impossible for the N-180 to find a pulse pattern. 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; use a sensor that tolerates more motion; or set the N-180 for Mode 3.
 - The sensor may be damaged; replace it.
 - The patient's perfusion may be too low to allow the N-180 to measure saturation and pulse rate.
5. **SpO₂ or pulse rate change rapidly; pulse amplitude indicator is erratic.**
- *Check the patient.*
 - Excessive patient motion may be making it impossible for the N-180 to find a pulse pattern. If possible, keep the patient still; check whether the sensor is applied securely and properly, and replace it if necessary; move the sensor to a new site; use a sensor that tolerates more motion; or set the N-180 for Mode 3.
 - An electrosurgical unit (ESU) may be interfering with performance:
 - Move the N-180 and the cables as far from the electrosurgical unit as possible.
 - Plug the N-180 and the electrosurgical unit into different AC circuits.
 - Move the electrosurgical unit ground pad as close to the surgical site as possible.
 - The sensor may be damp or may have been reused too often. Replace it.
 - If using a sensor extension cable, remove it and connect the sensor directly to the N-180.
 - If the patient weighs less than 3 kg or more than 40 kg, apply an OXISENSOR N-25 oxygen transducer to an appropriate site. This sensor has added insulation against electrosurgical interference.
6. **Displayed pulse rate does not correlate with that of ECG monitor.**
- Excessive patient motion may be making it impossible for the N-180 to find a pulse pattern. 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; use a sensor that tolerates more motion; or set the N-180 for Mode 3.
 - The patient may have a pronounced dicrotic notch, which causes the pulse rate measurement to double. Try another sensor site.
 - An ESU may be interfering. Refer to discussion under item 5.
-

7. Oxygen saturation measurement does not correlate with the value calculated from a blood gas determination.

- The SpO₂ calculation may not have been correctly adjusted for the effects of pH, temperature, PaCO₂, 2,3-DPG, or fetal hemoglobin. Check whether calculations have been corrected appropriately for relevant variables. (See Section II, "Principles of Operation," for more information.) In general, calculated saturation values are not as reliable as direct CO-Oximeter measurements.
- Accuracy can be affected by incorrect sensor application or use, significant levels of dysfunctional hemoglobins, intravascular dyes, bright light, excessive patient movement, venous pulsations, electrosurgical interference, and 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's directions for use.
- Evaluate performance using a *NELLCOR* PT-2500 pocket tester. The saturation reading should be 81 ± 1 digit; the pulse rate reading should be 40 ± 1 digit. If incorrect readings result, contact qualified service personnel.

8. Oxygen saturation does not correlate with laboratory CO-Oximeter

- Fractional measurements may not have been converted to functional measurements before the comparison was made. The N-180, as well as other two-wavelength oximeters, measure functional saturation. Multi-wavelength oximeters, such as the Instrumentation Laboratory 282 CO-Oximeter and Corning CO-oximeters, measure fractional saturation. Fractional measurements must be converted to functional measurements for comparison. Refer to the equation for this conversion in Section II, "Principles of Operation."
- Close correlation requires simultaneous blood sampling and pulse oximeter measurements from the same arterial supply.
- Evaluate performance using a *NELLCOR* PT-2500 pocket tester. The saturation reading should be 81 ± 1 digit; the pulse rate reading should be 40 ± 1 digit. If incorrect readings result, contact qualified service personnel.

Section IX**SPECIFICATIONS**

CONFIGURATION**Components**

Oximeter unit, hospital-grade power cord, and *NELLCOR* EC-8 eight-foot sensor extension cable.

Readout

Two three-digit green and red displays for oxygen saturation and pulse rate. Sixteen-segment display for pulse amplitude indicator (pulse amplitude). Annunciators for LOW BATT, PULSE SEARCH, HIGH SAT, LOW SAT, HIGH RATE, and LOW RATE alarms, and AUDIO ALARM OFF. Annunciators for LOW BATT, BATT IN USE and NEONATAL alarm limits.

Controls

Control knob to adjust volume and set alarm limits, and five buttons to select alarm limits and disable audio alarm.

Rear-panel switches for mains power on/off, adult/neonatal alarm settings, RS-232 format, and baud rate.

PERFORMANCE**Range**

Saturation: 0-100%

Pulse Rate: 20-250 bpm (beats per minute)

Accuracy

Saturation (%SpO₂ ±1 standard deviation)

SpO ₂		Accuracy*
Adults	70-100 %	±2 digits
	50-69 %	±3 digits
	0-49 %	unspecified
Neonates:	70-95 %	±3 digits

Pulse Rate	Accuracy
20-250 bpm	±3 bpm

Note: The N-180 pulse oximeter is calibrated to read oxyhemoglobin saturation (%SpO₂) of functional hemoglobin as compared to an Instrumentation Laboratory 282 CO-Oximeter. Significant levels of dysfunctional hemoglobins (e.g., carboxyhemoglobin, methemoglobin) may affect the accuracy of the instrument. Indocyanine green, methylene blue, and other intra-vascular dyes, depending upon their concentrations, may interfere with the accuracy of the instrument. Instrument performance may also be compromised by excessive patient movement, electrosurgical interference, or intense environmental illumination.

*Accuracy is based on testing with an *OXISENSOR* D-25; 68% of the measurements across the population will be within ±1 standard deviation.

Testing to verify specifications is done against *NELLCOR* N-100 pulse oximeters with D-25 sensors previously validated for accuracy against an Instrumentation Laboratory CO-Oximeter. For specification of accuracy with other *NELLCOR* sensors, refer to the sensor's directions for use.

Section IX**SPECIFICATIONS****Sensors**

- Type:** Compatible with *NELLCOR* sensors including *OXISENSOR*, *OXIBAND*, Reflectance, and *DURASENSOR* oxygen transducers.
- Wavelengths:** 660 nm (red, nominal), 920 nm (infrared, nominal)
- Heating:** Sensor power dissipation; less than 50 mW total heat dissipation by LEDs (typically less than 1°C temperature rise).
- Patient Size:** Nellcor provides a range of oxygen transducers. Each sensor has a recommended weight range.

Sensor	Model	Patient Size
<i>OXISENSOR</i>	N-25	< 3 or > 40 kg
	I-20	1-20 kg
	D-20	10-50 kg
	D-25, D-25L	> 30 kg
	R-15	> 50 kg
<i>OXIBAND</i>	OXI-A/N	< 3 or > 50 kg
	OXI-P/I	3-40 kg
<i>DURASENSOR</i>	DS-100A	> 40 kg
Reflectance	RS-10	> 40 kg

Alarms

Audio and visual alarms for high and low oxygen saturation, high and low pulse rate, and loss of pulse. Audio alarms are interrupted briefly for detected pulses and the volume is adjustable. Audio alarms can be disabled for a 60-second period with the AUDIO ALARM OFF button; disable period can be changed to 30-120 seconds, or the disable timer can be turned off (for permanent disable) with a visual warning to alert the user that the audible alarm is disabled.

Section IX

SPECIFICATIONS

Alarms (continued)

The initial default alarm settings that are in effect when the N-180 leaves Nellcor are as follows. High and low alarm limits cannot overlap.

Adult Mode:

High Sat:	100%	(adjustable 20-100)
Low Sat:	85%	(adjustable 20-100)
High Rate:	140 bpm	(adjustable 20-250)
Low Rate:	55 bpm	(adjustable 20-250)

Neonatal Mode:

High Sat:	95%	(adjustable 20-100)
Low Sat:	80%	(adjustable 20-100)
High Rate:	200 bpm	(adjustable 20-250)
Low Rate:	100 bpm	(adjustable 20-250)

Audio Pulse

When a sensor-derived signal is present, an audio beep sounds with each detected pulse; volume is adjustable with control knob; pitch is proportional to oxygen saturation.

Modes

Three response modes, selected by the control knob and LOW RATE/HIGH RATE buttons.

- Mode 1: normal response (5-7 seconds)
- Mode 2: fast response (2-3 seconds)
- Mode 3: slow response (10-15 seconds, pulse rate not displayed, no pulse tone)

Switches

Eight for digital output, adult/neonatal alarm limits.

Switch Section	Function
1	Adult/neonatal alarm settings
2	RS-232 format
3, 4, 5, 6	not used
7, 8	Baud rate select

Data Output

Digital:

- Type: RS-232
- Connector: 9-pin D-type, sub-miniature, female
- Baud Rate: Switch-selectable, 2400, 4800, 9600, and 19,200
- Formats: Conversation and computer

Section IX**SPECIFICATIONS**

**ENVIRONMENTAL
REQUIREMENTS**

Temperature	N-180:	50-104 °F (10-40 °C) operating 32-122 °F (0-50 °C) storage
	Sensor:	Within physiologic range 82.4-107.6 °F (28-42 °C) for accurate measurement.
Atmospheric Pressure		700-1060 mbar operating 500-1060 mbar storage
Humidity		0-90% operating without condensation.
Altitude		3,048 m

**ELECTRICAL
CHARACTERISTICS**

Protective Class	Class I	
Equipment Type	Type BF: patient electrically isolated	
Voltage	220–240 V ~ , 50 Hz	
Power Consumption	Maximum rating: 25 VA	
Battery	Type:	Lead-acid battery pack, 1.9 AH
	Battery Life:	6 hours minimum on full charge
	Recharge Period:	14 hours minimum

**PHYSICAL
CHARACTERISTICS**

Dimensions	2.9 in. high x 8.5 in. wide x 9.5 in. deep (74 x 216 x 241 mm)
Weight	6.6 lb (3 kg)

WARRANTY—FOR REPLACEMENT OR REPAIR

WARRANTY

Nellcor warrants to the initial purchaser ("Purchaser") that each new *NELLCOR* N-180 pulse oximeter (the "Warranted Product") purchased from Nellcor or a Nellcor-authorized distributor will be free from defects in workmanship and materials for one year from the date of its initial shipment to the Purchaser. Repair or replacement of Products under this warranty does not extend the warranty period. (Products which are not new are subject to warranties expressly provided in connection with the sale of such products.)

Nellcor's only obligations under this warranty are (1) to repair or replace any Warranted Product (or part thereof) that Nellcor reasonably determines to be covered by this warranty and to be defective in workmanship or materials and (2) to provide loaner equipment in the circumstances set forth below.

To request repair or replacement under this warranty, Purchaser must contact Nellcor or a Nellcor-authorized distributor as follows to request a returned goods authorization:

Outside the U.S., contact the local Nellcor office or Nellcor-authorized distributor. Nellcor offices outside the United States are:

Nellcor Europe B.V.
's-Hertogenbosch,
The Netherlands
Tel. 31.73.426565

Nellcor GmbH
Idstein,
Germany
Tel. 49.6126.5930

Nellcor S.a.r.l.
Jouy-en-Josas,
France
Tel. 33.1.39.46.96.58

Nellcor Limited
Kowloon,
Hong Kong
Tel. 852.7355618

Nellcor (U.K.) Ltd.
Coventry, West Midlands
United Kingdom
Tel. 44.203.690220

If, on the basis of the information provided by Purchaser, Nellcor reasonably believes that the defect is covered by this warranty, Nellcor will authorize Purchaser to return the Warranted Product (or part thereof) to Nellcor. For countries where Nellcor has a direct sales office or an authorized distributor: if the Warranted Product is to be repaired rather than replaced, Nellcor will ship a comparable loaner product for use by Purchaser during the period that the Warranted Product or part is at Nellcor's facility for service. Nellcor shall determine whether to repair or replace Products and parts covered by this warranty and all Products or parts replaced shall become Nellcor's property. In the course of warranty service, Nellcor may, but shall not be required to, make engineering improvements to the Warranted Product or part thereof.

WARRANTY—FOR REPLACEMENT OR REPAIR

Loaner Policy

Purchaser is responsible for any damage to or loss of any loaner equipment while it is at Purchaser's location. Purchaser must return loaner equipment within 10 days after receiving the repaired or replaced Product or receiving notice from Nellcor that the Product returned by Purchaser is not covered by the warranty. If Purchaser does not return loaner equipment within 20 days after the return due date, then Purchaser agrees to pay Nellcor the reasonable value of the loaner equipment or a reasonable daily rental fee, whichever Nellcor selects.

SHIPPING PROCEDURES

If Nellcor reasonably determines that a repair or replacement is covered by the warranty, Nellcor shall bear the costs of shipping the loaner Product and the repaired or replacement Product to Purchaser. All other shipping costs shall be paid by Purchaser. Risk of loss or damage during shipments under this warranty shall be borne by the party shipping the Product.

Products shipped by Purchaser under this warranty shall be suitably packaged to protect the Product. If Purchaser ships a Product to Nellcor in unsuitable packaging, any physical damage present in the Product on receipt by Nellcor (and not previously reported) will be presumed to have occurred in transit and will be the responsibility of Purchaser.

EXCLUSIONS

This warranty does not extend to any Warranted Products or parts thereof that have been subject to misuse, neglect or accident; that have been damaged by causes external to the Warranted Products, including but not limited to failure of or faulty electrical power; that have been used in violation of Nellcor's instructions; that have been affixed to any nonstandard accessory attachment; on which the serial number has been removed or made illegible; or that have been modified or improperly disassembled, serviced, or reassembled by anyone other than Nellcor, unless authorized by Nellcor.

Nellcor makes no warranty (a) with respect to *OXISENSOR* oxygen transducers, any other disposable products or any other products that are not Warranted Products, (b) with respect to any products purchased from a person other than Nellcor or a Nellcor-authorized distributor or (c) with respect to any product sold under a brand name other than Nellcor.

Nellcor will not be responsible for the effect on safety, reliability, and performance of the Product if: (a) assembly operations, extensions, readjustments, modifications, or repairs are carried out by persons other than Nellcor or persons authorized by Nellcor to perform repair service on Nellcor's behalf; or (b) the electrical installation does not comply with the requirements of the applicable national and international standards, including requirements of the IEC; or (c) the Product is not used in accordance with Nellcor's instructions for use.

In the event of a defect in the Product, Nellcor will be liable for injury or death of any actual person, or damage to property, to the extent, but only to the extent, that such liability is mandated under laws applicable to manufacturers in general and to manufacturers of the category of products to which the Product belongs.

WARRANTY—FOR REPLACEMENT OR REPAIR

THIS WARRANTY, TOGETHER WITH ANY OTHER EXPRESS WRITTEN WARRANTY THAT MAY BE ISSUED BY NELLCOR, IS THE SOLE AND EXCLUSIVE WARRANTY AS TO NELLCOR'S PRODUCTS, EXTENDS ONLY TO THE PURCHASER AND IS EXPRESSLY IN LIEU OF ANY ORAL OR IMPLIED WARRANTIES INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. NELLCOR SHALL NOT BE LIABLE FOR ANY INCIDENTAL, SPECIAL OR CONSEQUENTIAL LOSS, DAMAGE OR EXPENSE (INCLUDING WITHOUT LIMITATION LOST PROFITS) DIRECTLY OR INDIRECTLY ARISING FROM THE SALE, INABILITY TO SELL, USE OR LOSS OF USE OF ANY PRODUCT.

