NELLCOR

OxiMax NPB-40

Handheld Pulse Oximeter Operator's Manual

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Warnings

Warnings are identified by the WARNING symbol shown above.

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

WARNING: The sensor uses the date and time provided by the NPB-40 handheld pulse oximeter when the sensor event record is recorded by the sensor. The accuracy of the date/time is dependent on the date/time already set in and provided by the NPB-40."

WARNING: Explosion hazard. Do not use the NPB-40 in the presence of flammable anesthetics mixture with air, oxygen, or nitrous oxide.

WARNING: Chemicals from a broken LCD display panel are toxic when ingested. Use caution when the NPB-40 has a broken display panel.

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

WARNING: The use of accessories, sensors, and cables other than those specified may result in increased emission and/or create invalid readings of the NPB-40.

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

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

WARNING: The NPB-40 is a prescription device to be operated only by trained personnel.

WARNING: Dispose of batteries in accordance with local ordinances and regulations.

Cautions

Cautions are identified by the CAUTION symbol shown above.

Cautions alert the user to exercise care necessary for the safe and effective use of the *OxiMax* NPB-40 handheld pulse oximeter.

Caution: All combinations of equipment must be in compliance with IEC Standard 60601-1-1 systems requirements.

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

Notes

Notes are identified by the NOTE symbol shown above.

Notes provide additional helpful information.

WARNING: Do not make any clinical judgments based solely on the NPB-40. The NPB-40 is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.

Intended Use for the NPB-40

The *OxiMax* NPB-40 handheld pulse oximeter (herein referred to as the NPB-40) is indicated for non-invasive, spot-check measurements of functional arterial oxygen saturation (SpO_2) and pulse rate of adult, pediatric, and neonatal patients. It can be used in hospital, emergency, transport, and mobile environments, as well as in the home care environment.

How to Use this Manual

All users should read this manual thoroughly. More experienced users of the NPB-40 will be able to go to the topics for the information they require.

The current copy of this manual is available on the internet at:

http://www.mallinckrodt.com/respiratory/resp/Serv_Supp/ProductManuals.html

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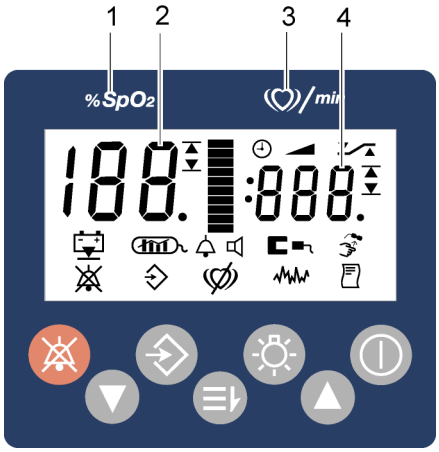
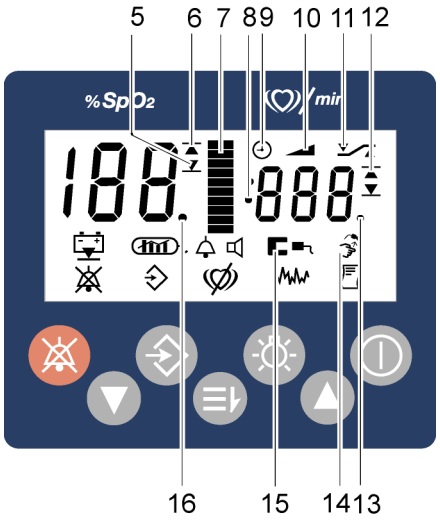
Identification of Front Panel Buttons and Symbols



1 — %SpO2 area of display
2 — Measured %SpO2
3 — Pulse beats per minute (BPM) area of display
4 — Measured BPM



5 — %SpO2 Lower Alarm Limit indicator

6 — %SpO2 Upper Alarm Limit indicator

7 — Pulse Amplitude indicator (Blip bar)

8 — Time Colon time/date field separator

9 — Adjust Time mode indicator

10 — Adjust Volume mode indicator

11 — Set Limit mode indicator

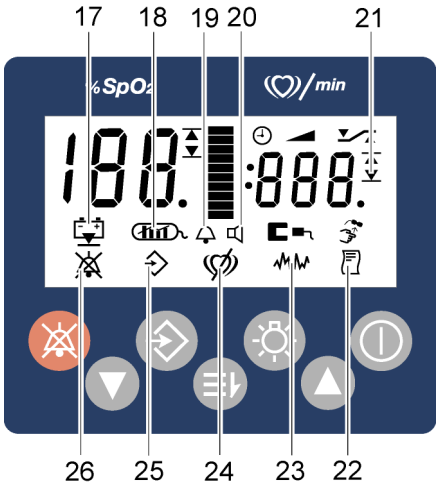
12 — BPM Upper Alarm Limit indicator

13 — BPM Limit Changed indicator

14 — Sensor Off Patient indicator

15 — Sensor Disconnected indicator

16 — %SpO2 Limit Changed indicator



17 — Low Battery indicator

18 — Data In-Sensor indicator

19 — Alarm Volume Adjust indicator

20 — Pulse Beep Tone Volume Adjust indicator

21 — BPM Lower Alarm Limit indicator

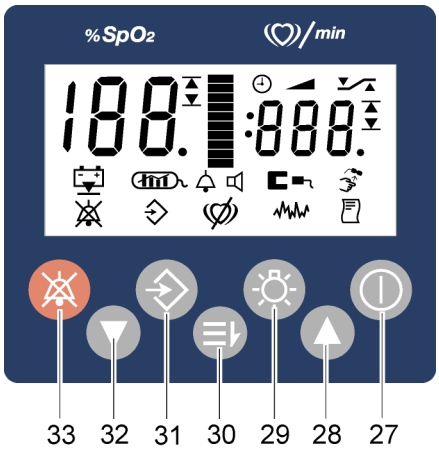
22 — Print indicator

23 — Motion indicator

24 — Pulse Search indicator

25 — Data indicator

26 — Alarm Silenced indicator



27 — Power button

28 — Up Arrow button

29 — Backlight button

30 — Menu button

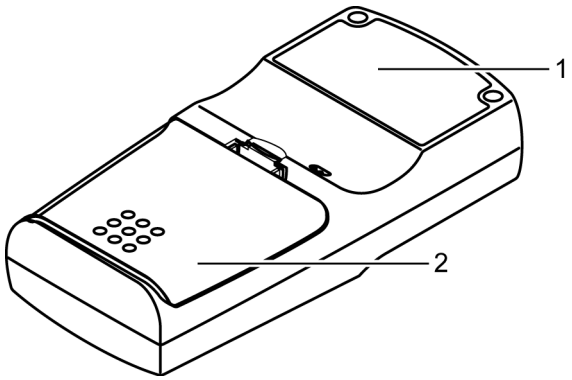
31 — Data (Record/Print) button

32 — Down Arrow button

33 — Alarm Silence button

NPB-40 Symbols

These symbols are located on the rear panel of the NPB-40.



1 — Label

2 — Battery Cover

See Instructions for Use

Type BF Applied Part - Not defibrillator proof

IPX1 Resistant to liquid ingress

Date of Manufacture

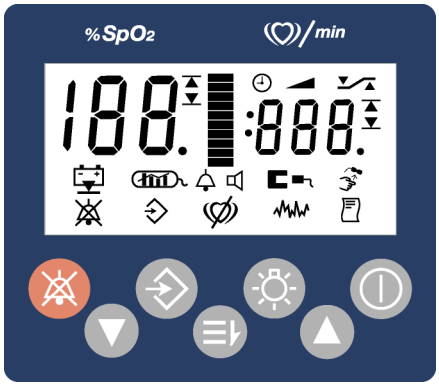
CE 0123 European union approval

Canadian/USA certification mark (electrical safety)

Russian regulatory approval

Serial number

These two symbols are located on the front panel of the NPB-40.



%SpO2 Area of the display that displays the measured percent of oxygen saturation.

/min Area of the display that displays the measured pulse beats per minute.

These symbols are also used on the NPB-40 labels.


Keep away from heat

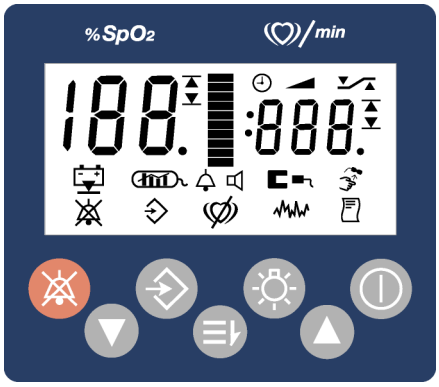
Temperature limitation


Protect from moisture


Fragile


Keep upright

Description of Controls



Note: When the NPB-40 is turned on, a button press, except the Power button, should result in either a valid or an invalid key tone (refer to *Description of Audible Indicators* on page 22). If the key pressed fails to emit a tone, contact qualified service personnel.

The Alarm Silence button. Press the Alarm Silence button to silence audible alarms within 1.5 seconds after the start of the alarm. If the Alarm Silence button is pressed when no audible alarm is active, alarms during the alarm silence duration will be silenced. In all cases, the alarm silence shall time out after the selected alarm silence duration, and auditory alarm capability is reactivated.

Note: Alarms that occur throughout Power-On Self-Test (POST) cannot be silenced.

Press and hold the Alarm Silence button for three seconds to invoke the Alarm Silence Duration menu, which allows the alarm silence interval to be adjusted from 30, 60, 90, or 120 seconds or to OFF (alarms disabled). See *Set Alarm Silence Duration* on page 54.

The Down Arrow button. Press the Down Arrow button to sequentially decrease the parameter under adjustment by one decrement. Press and hold the Down Arrow button for more than three seconds may cause the decrement to repeat.

Press the Down Arrow button during normal operation to decrease the pulse beep volume.

The Data (Record/Print) button. Press the Data button to store the currently shown SpO_2 and BPM values (snap-shot data) to be stored. The stored snap-shot data can be printed. In the print mode (accessed via the Menu button), the Data button starts the print function of single-event report, snap-shot, and/or sensor-event data.

The Menu Button. Press the Menu button repeatedly during normal operation to sequentially display the seven parameter-settable displays, one for each button activation, and then return to the default monitor display. Settable parameters include high and low SpO_2 limits, high and low BPM limits, alarm volume, pulse beep volume, and data print. The NPB-40 will return to normal operation and incorporate the selected parameter value if there are no button presses for 27 to 33 seconds. See *Menu Structure* on page 113.

Alarms and alarm icons (such as, Sensor Disconnected, Pulse Search, Motion, and Low Battery, as well as Alarm Silenced indicator) are enabled when menu-accessed parameter adjustment activities are activated and will display in the event of an alarm condition.

If the Menu button is pressed while Power-On Self-Test (POST) is activated the Time/Date set display is displayed. Repeated activations of the Menu button in this sequence displays five (5) time/date parameter-set displays that allows the user to set Hour, Minute, Day, Month, and Year, and then return to the POST display.

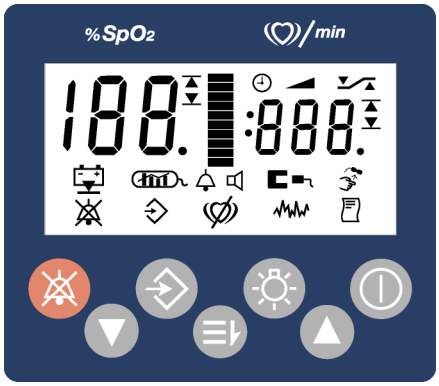
The Backlight button. Press the Backlight button to toggle the backlight ON or OFF. The backlight will remain on for 9.5 to 10.5 minutes. See *Backlight On/Off* on page 44.

The Up Arrow button. Press the Up Arrow button sequentially to increase the parameter under adjustment by one increment. Press and hold the Up Arrow button for more than three seconds to cause the increment to repeat.

Press the Up Arrow button during normal operation to increase the pulse beep volume.

The Power button. Press the Power button to toggle the NPB-40 power ON or OFF. The Power button has a raised protrusion (bump) at its center and a gloss surface finish for tactile differentiation.

Description of the Display and Indicators



The NPB-40 display includes a Pulse Amplitude blip bar, functional icons, and current measured %SpO_2 and pulse rate. A decimal point after the %SpO_2 or pulse rate indicates that the respective limits have been changed from the power on default values (Table 2 on page 35).

Decimal points after the %SpO_2 or pulse rate indicate that the respective limits have been changed from the power-on default values.

There are various matrices within the *OxiMax* algorithm. Some of these are used to assess the severity of conditions presented to the NPB-40 in SpO_2 and pulse rate measurements on a patient. These individual matrices or combinations of these matrices are used to drive the icon indicators on the NPB-40 front panel.

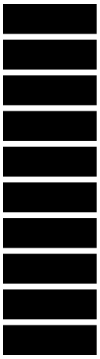
The *OxiMax* algorithm automatically extends the amount of data required for measurements of SpO_2 and pulse rate dependent on the measurement conditions. Throughout normal measurement conditions the, averaging time is six to seven seconds. Throughout challenging measurement conditions that could be caused by low perfusion, motion, external interference like ambient light, or a combination of these, the *OxiMax* algorithm automatically extends the amount of data required beyond seven seconds. If the resulting dynamic averaging time exceeds 20 seconds, the Pulse Search indicator is displayed and SpO_2 and Pulse Rate display is continue to be updated every second. As these conditions become even more challenging, the amount of data required continues to extend. If the dynamic averaging time reaches 40 seconds, the Pulse Search indicator begins to flash, the SpO_2 and pulse rate displays flash zeros to indicate a loss-of-pulse condition.

Selected display elements (icons, numerals, etc.), may flash. There are three flash rates. See Table 1.

Table 1: Flash Rates

Priority	Hertz	Duty Cycle
High	1.4 Hz to 2.8 Hz	20% to 60%
Medium	0.4 Hz to 0.8 Hz	20% to 60%
Low	N/A	Constant on

%SpO2 display. Shows the oxygen saturation level of functional hemoglobin. Displays two dashes throughout Sensor Disconnected and Sensor Off Patient conditions. The display flashes the SpO_2 value when the SpO_2 is outside the alarm limits. If alarm limits have been changed from their power-on defaults, a decimal point (.) is shown after the SpO_2 value (98.).



Pulse Amplitude indicator (blip bar). The Pulse Amplitude indicator indicates the dynamic pulse amplitude and rate. As the detected pulse becomes stronger, more bars light with each pulse.

In the parameter-set menu, the Pulse Amplitude indicator displays with the number of shown elements incremenated/decremented to reflect changes in the volume level for alarms and Pulse Amplitude indicator (blip bar).

PULSE RATE display. Shows the pulse rate in beats per minute. It flashes throughout loss-of-pulse alarms and when the pulse rate is outside of the alarm limits. The PULSE RATE display displays two dashes throughout Sensor Disconnected and Sensor Off Patient conditions. Pulse rates outside of the pulse rate range (0, 20 to 300 bpm) are shown as the closest value within the range. If alarm limits have been changed from their power-on defaults, a decimal point (.) is shown after the BPM value (123.).

Low Battery indicator. The Low Battery indicator flashes when 15 or fewer minutes of battery capacity remain. The Low Battery indicator displays constantly when the battery capacity reaches critical condition, the NPB-40 indicates an error condition and shuts down.

Alarm Silenced indicator. The Alarm Silenced indicator displays when audible alarms have been silenced. It flashes when the audible alarms have been disabled.

Motion indicator. The Motion indicator is displays whenever the *OxiMax* algorithm detects the presence of artifacts[1] independent of its severity or the impact on the SpO_2 or pulse rate values. When the Motion indicator and the Pulse Search indicator are simultaneously displayed, it is an indication that the artifact is significant and/or has been persistent.

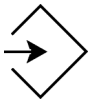
[1] Artifacts are events contained within the in-sensor data.

Pulse Search indicator. The Pulse Search indicator displays before initial acquisition of a pulse signal and throughout prolonged and challenged monitored conditions. The Pulse Search indicator flashes throughout a loss-of-pulse signal.

Data In-Sensor indicator. The Data In-Sensor indicator displays to indicate that the attached *OxiMax* sensor contains sensor-event data or the in-sensor memory is full. The Data In-Sensor indicator flashes when the sensor contains sensor-event data and when sensor-event data is printed. The Data In-Sensor indicator displays when the sensor memory is full.

Upper Alarm Limit indicator. The Upper Alarm Limit indicator indicates that the displayed value is the upper alarm limit for SpO_2 or Pulse Rate.

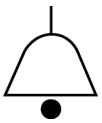
Lower Alarm Limit indicator. The Lower Alarm Limit indicates that the displayed value is the lower alarm limit for SpO_2 or Pulse Rate.



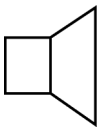
Data indicator. The Data indicator displays when the NPB-40 is in the store snap-shot data or data print mode. The Data indicator flashes when snap-shot data prints.

Print indicator. The Print indicator displays to indicate that the NPB-40 is in the print mode. The Print indicator flashes when the NPB-40 is prints single-event, snap-shot or sensor-event data.

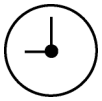
Sensor Disconnected indicator. The Sensor Disconnected indicator displays when the patient sensor is disconnected from the NPB-40.



Alarm Volume Adjust indicator. The Alarm Volume Adjust indicator is displays when the NPB-40 is in the alarm volume adjust mode.



Pulse Beep Tone Volume Adjust indicator. The Pulse Beep Tone Volume Adjust indicator displays when the NPB-40 is in the pulse beep tone volume adjust mode.



Adjust Time indicator. The Adjust Time indicator displays when the NPB-40 is in the time/date set mode.

Set Limit mode indicator. The Set Limit mode indicator displays when the NPB-40 alarm limit values are under adjustment.

Adjust Volume mode indicator. The Adjust Volume mode indicator displays when the NPB-40 volume levels are under adjustment.

Sensor Off Patient indicator. The Sensor Off Patient indicator displays when the patient sensor is attached to the NPB-40 but not attached to the patient.

SNAP-SHOT DATA ID indicator. The SNAP-SHOT DATA ID indicator is an alphanumeric display that indicates the number of the current captured snapshots. The snapshot number is shown in the %SpO_2 area of the display.

Description of Audible Indicators

The NPB-40 generates auditory signals for use as alarms, status indicators, and feedback. A summary of the audible indicators is provided below. See *Audible Indicators* on page 127 for a more detailed definition of the audible indicators.

- Alarm volume tone — one pulse at 752 Hz for 500 msec at 52 dB(A) maximum
- Beep volume tone — one pulse at 1,500 Hz for 500 msec at 52 dB(A) maximum
- POST pass tone — one pulse at 600 Hz for 1,000 msec at 45 dB(A) maximum
- Invalid key press tone — one pulse at 200 Hz for 50 msec at 45 dB(A) maximum
- Confirmation tone — one pulse at 700 Hz for 130 msec at 45 dB(A) maximum
- Valid key press tone — one pulse at 800 Hz for 10 msec at 45 dB(A) maximum
- Pulse beep tone — one pulse at 1,500 Hz for each heart beat for 50 msec at 52 dB(A) maximum

- Alarm silence reminder tone — three pulses at 500 Hz for 130 msec each at 52 dB(A) maximum
- High priority alarm tone — continuous pulses at 1,200 Hz, 250 msec each at 52 dB(A) maximum
- Medium priority alarm tone — continuous pulses at 752 Hz, 400 msec each at 52 dB(A) maximum
- Low priority alarm tone — continuous pulses at 500 Hz, 250 msec each at 52 dB(A) maximum

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WARNING: To ensure patient safety, do not place the NPB-40 in any position that might cause it to fall on the patient.

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

WARNING: Ensure that the speaker is clear of any obstruction and that the speaker holes are not covered. Failure to do so could result in an inaudible alarm tone.

WARNING: Disconnect the NPB-40 and Nellcor *OxiMax* sensor from the patient throughout magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns.

WARNING: To ensure accurate performance and prevent device failure, do not subject the NPB-40 to extreme moisture, such as direct exposure to rain. Such exposure may cause inaccurate performance or device failure.

WARNING: Do not use an NPB-40, *OXIMAX* sensor, or cables that appear damaged.

WARNING: Do not lift the NPB-40 by the sensor or extension cable because the cable could disconnect from the NPB-40 and the NPB-40 may drop on the patient.

WARNING: The NPB-40 is not defibrillator-proof. However, it may remain attached to the patient throughout defibrillation or while an electrosurgical unit is in use, but the measurements may be inaccurate throughout the defibrillation and shortly thereafter.

WARNING: Use only the Nellcor extension cable DEC-4 with the NPB-40. Do not attach any cable that is intended for computer use to the *OXIMAX* sensor port. Do not connect any device other than a Nellcor-approved *OXIMAX* sensor to the *OXIMAX* sensor connector.

WARNING: The NPB-40 should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the NPB-40 should be observed to verify normal operation using the configuration in which it is to be used.

List of Components

Quantity	Item
1	NPB-40 *OXIMAX* handheld pulse oximeter
4	Alkaline “AA” size, 1.5-volt batteries
1	Nellcor *OXIMAX* sensor or sensor assortment pack
1	Compact disk (NPB-40 manuals) and/or operator’s manual (applicable to country of sale)
1	Quick guide adhesive label

Connect *OXIMAX* Sensor to the NPB-40

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

- ***Safety Information* on page 1**
- ***OXIMAX Sensors and Accessories* on page 77**
- ***OXIMAX Sensor Performance Considerations* on page 93**

Caution: Use only Nellcor-approved *OXIMAX* sensors and extension cables.

Note: Physiological conditions, medical procedures, or external agents that may interfere with the NPB-40's ability to detect and display measurements include:

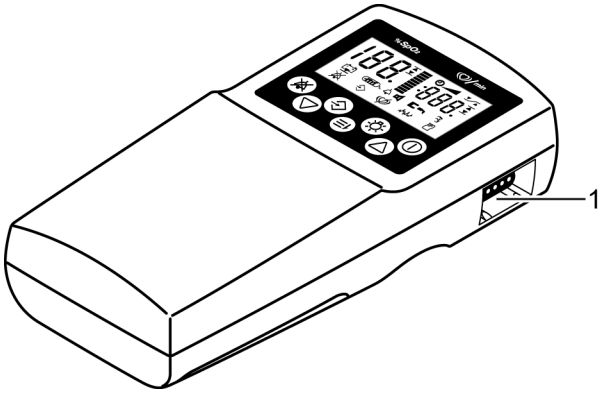
- dysfunctional hemoglobin
- arterial dyes
- low perfusion
- dark pigment
- externally applied coloring agents, such as nail polish, dye, or pigmented cream

Inaccurate measurements can be caused by:

- incorrect application of the *OXIMAX* sensor
- placement of the *OXIMAX* sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line
- ambient light
- prolonged and/or excessive patient movement
- intravascular dyes or externally applied coloring, such as nail polish or pigmented cream
- failure to cover the *OXIMAX* sensor site with opaque material in high ambient light conditions

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

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



1 — **SpO_2 *OxiMax* Sensor Port**

Connect a Nellcor *OxiMax* SpO_2 sensor to the NPB-40 SpO_2 sensor port.

Note: An extension cable may be used to provide more distance between the NPB-40 and the sensor. Use the DEC-4 extension cable available from Nellcor:

- DEC-4, 4 feet (1.2 m)

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

Battery Power

The NPB-40 has internal batteries used to power the NPB-40. A new set of batteries will provide at least 15 hours of operation.

Low Battery Indicator

The Low Battery indicator displays and flashes, and a low priority alarm begins to sound when approximately 15 minutes of operation is available. The batteries should be replaced. See *Battery Installation* on page 33.

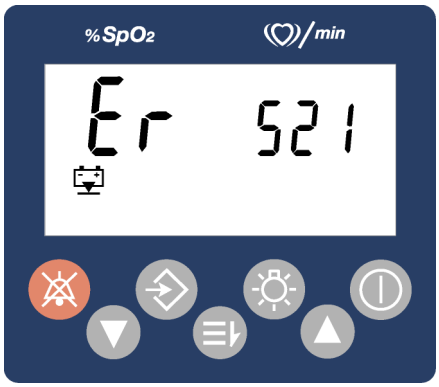
Caution: If the NPB-40 is to be stored for a period of three months or longer, remove the batteries from the NPB-40 before storage.

Critical Battery Indication

When the NPB-40 batteries are critically low, the NPB-40:

- displays an error message (Er 521)
- sounds a high priority alarm
- shuts down

Replace the batteries and restart the NPB-40. See *Battery Installation* on page 33.

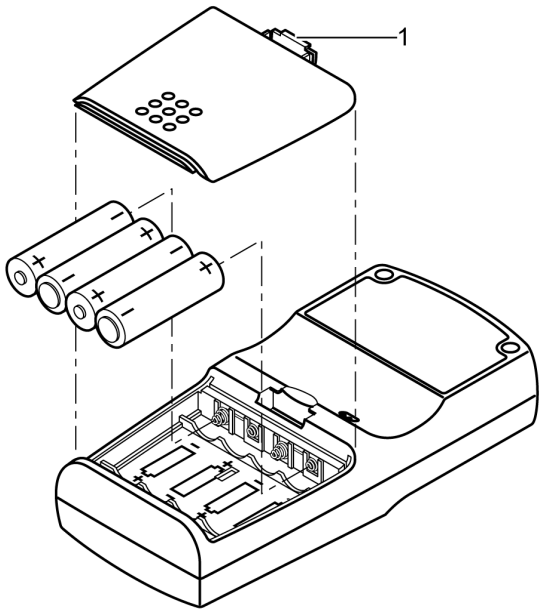


Battery Installation

1. Turn off power. Pull the battery compartment latch downward, toward the bottom of the NPB-40, and remove the battery access door.

2. Install four “AA” size batteries, orientated as shown in Figure 1.

3. Replace the battery access door.



1 — Battery compartment latch

Figure 1: Battery Installation

WARNING: Explosion hazard. Do not use the NPB-40 in the presence of flammable anesthetics mixed with air, oxygen, or nitrous oxide.

WARNING: To ensure patient safety, do not place the NPB-40 in any position that might cause it to fall on the patient.

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

WARNING: To ensure accurate performance and prevent device failure, do not expose the NPB-40 to extreme moisture such as rain.

Introduction

The parameters of the NPB-40 are preset to factory default values. See Table 2.

Table 2 lists the parameters, ranges available, and the factory default values. The parameters may be set on an individual basis, by the clinician, and will remain in effect until the NPB-40 is turned off.

Table 2: Parameter Ranges

Parameter	Ranges/ Selections	Factory Defaults
%SpO_2 Upper Alarm Limit	Lower Alarm Limit plus 1 to 100%	100%
%SpO_2 Lower Alarm Limit	20% to Upper Alarm Limit minus 1	85%
Pulse Rate Upper Alarm Limit	Lower Alarm Limit plus 1 to 250 bpm	170 bpm
Pulse Rate Lower Alarm Limit	30 bpm to Upper Alarm Limit minus 1	40 bpm

Table 2: Parameter Ranges (Continued)

Parameter	Ranges/ Selections	Factory Defaults
Alarm Silence Duration	Alarms 30, 60, 90, 120 seconds	30 sec.
Alarm Volume	1 to 10	10
Pulse Beep Volume	0 to 10	10

Turn On the NPB-40

Discussion

You must verify that the NPB-40 works properly and is safe to use. Proper operation of the NPB-40 is verified each time the NPB-40 is turned on, as described in this procedure. The verification procedure Power-On Self-Test (POST) takes 7 to 13 seconds to complete.

Caution: If any indicator or display element does not display when the NPB-40 is turned on, do not use the NPB-40. Instead, contact qualified service personnel, your local Nellcor representative, or Nellcor's Technical Services Department.

Note: Physiological conditions, medical procedures, or external agents that may interfere with the NPB-40's ability to detect and display measurements, include:

- dysfunctional hemoglobin
- arterial dyes

- low perfusion
- dark pigment
- externally applied coloring agents such as nail polish, dye, or pigmented cream

Note: When the NPB-40 is turned on, POST automatically tests the NPB-40 circuitry and functions.

Caution: During POST (immediately after power-up), confirm that all display segments and icons are shown, and the NPB-40 speaker sounds a one-second tone.

When the NPB-40 is turned on, the backlight remains on, the display cycles through the following sequence as POST takes place:

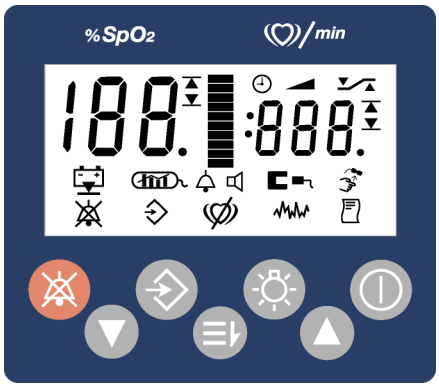
- all display graphics are shown for three seconds, the backlight is turned on at this time
- the display goes blank (all display elements off) for one second
- the version number of the software is shown as a three digit number in the right hand number field (with foremost zeros if the version number is less than 100) and two dashes in the left-hand number field, for three seconds
- the current time of day (24-hour format) is shown for three seconds
- successful completion of POST is announced by a POST pass tone. A failed POST is announced by a high-priority alarm tone

Procedure

1. Press the Power button to turn on the NPB-40.

Note: The backlight will remain on throughout POST.

2. All display numbers and icons are shown for three seconds. The backlight is turned on while all numbers and icons are shown.



3. The display goes blank for one second.

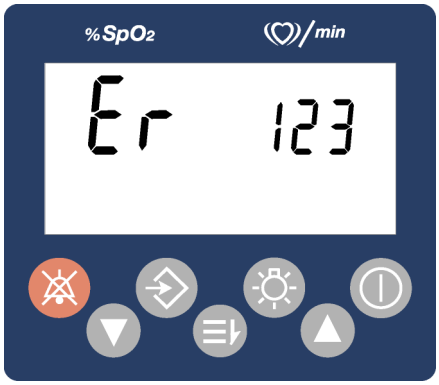
4. The software version number is shown for three seconds. The software version is identified by two dashes in the %SpO2 area of the display. The software version number is shown with foremost zeros for software version numbers less than 100.

Note: The software version shown above is only a sample. Check the NPB-40 for the software version installed.

Note: Software version numbers are often needed when calls are made to Nellcor's Technical Services Department or your local Nellcor representative for technical assistance. Write down the software version number and have it available prior to requests for technical assistance.

5. The current time is shown in a 24-hour format.

6. If the NPB-40 detects a problem, an error tone sounds and the NPB-40 displays an error code (Er) and the error number (see *Troubleshooting* on page 99).



7. Upon successful completion of POST, the NPB-40 sounds a one-second tone to indicate that the NPB-40 has passed the test.

WARNING: If you do not hear the POST pass tone, do not use the NPB-40.

WARNING: Ensure that the speaker is clear of any obstructions and that the speaker holes are not covered. Failure to do so could result in an inaudible alarm tone.

Note: The POST pass tone also functions as an audible confirmation that the speaker performs properly.

OxiMax Sensor Attached

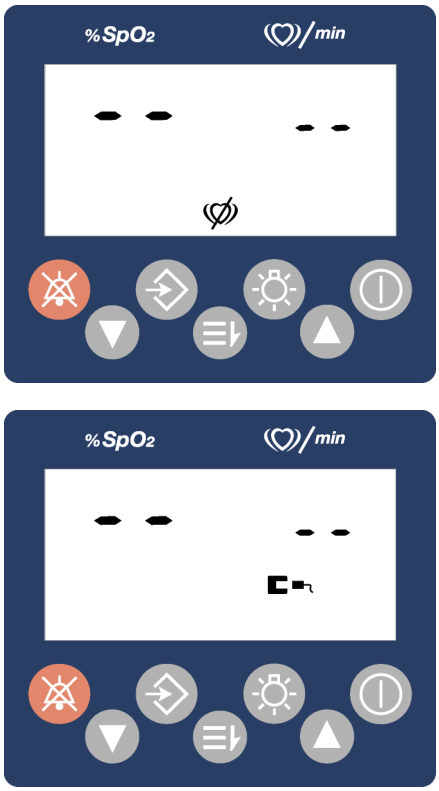
When a sensor contains data and is attached to the NPB-40, the Data In-Sensor indicator is shown.

The NPB-40 displays two dashes in the %SpO_2 and Pulse Rate displays as the NPB-40 searches for a valid pulse. For optimal performance, allow the NPB-40 to search and lock onto a pulse for approximately 10 seconds in non-motion conditions.

When a valid pulse is detected, the NPB-40 enters the normal mode and displays patient parameters.

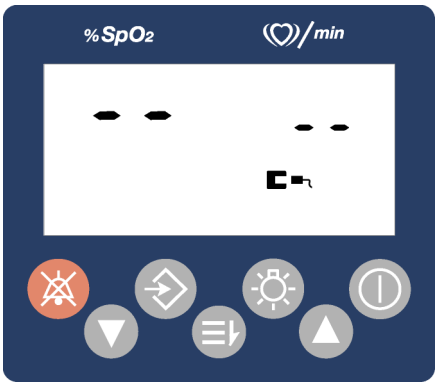
Movement of the blip bar indicates that real-time data is being displayed. Listen for the pulse beep tone. If the pulse beep tone does not sound with each pulse, it is an indication that the pulse beep volume is set to zero, the speaker has malfunctioned, or the signal is corrupted.

When an *OxiMax* sensor is attached to the NPB-40 and is applied to a patient, and the NPB-40 loses the pulse signal, the NPB-40 will display "-- & --" (two dashes and two dashes) and display the Pulse Search icon for five seconds before the Sensor Disconnected icon is displayed.



No *OxiMax* Sensor Attached

Upon successful completion of POST, the NPB-40 sounds a one-second tone that indicates that the NPB-40 has passed POST.



The NPB-40 displays dashes (--) and the Pulse Search indicator is not displayed when the NPB-40 fails to detect an *OxiMax* sensor.

Backlight On/Off

Note: The backlight will automatically turn off after 9.5 seconds to 10.5 seconds.

With the NPB-40 turned on, press the Backlight button to turn the NPB-40 backlight on or off.

Adjust Pulse Beep Volume

Discussion

There are two ways to adjust the pulse beep volume.

- Press the Up Arrow or Down Arrow button during normal operation to increase or decrese the pulse beep volume
- Select pulse beep volume adjust through the menu structure

When the pulse beep volume display is shown, the user is able to adjust the volume of the pulse beep tone. Each activation of an Up Arrow or Down Arrow button increases or decreases the pulse beep volume and increments or decrements by one the number of segments shown on the Pulse Amplitude (blip) bar as a relative indicator of the current volume. The minimum pulse rate volume is none or OFF (no blip bar segments shown), the maximum pulse rate volume is ten (ten segments). Attempted adjustments outside the range generate an invalid key tone.

The default pulse beep volume is 52 dB(A) shown by 10 blip bar segments.

Note: When the NPB-40 times-out (30 seconds) the currently shown parameter is set and the NPB-40 display returns to the normal mode.

Procedure — Normal Operation

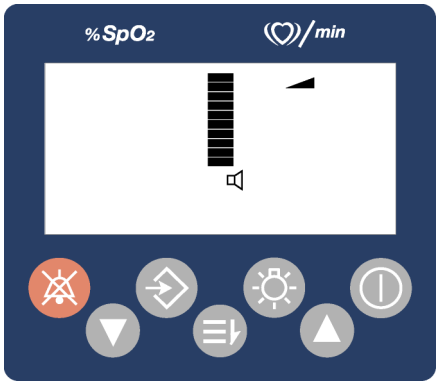
Press the Up Arrow or Down Arrow button during normal operation to increase or decrese the pulse beep volume.

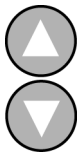
Note: The Beep Tone Volume Adjust indicator flashes when the pulse beep volume is adjusted to zero.

Procedure — Menu Structure

With the NPB-40 in the normal mode:

1. Press the Menu button five times until the pulse beep volume level is shown and sounds on the NPB-40.





2. Press the Up Arrow button or the Down Arrow button until the desired tone level is heard.

3. Press the Menu button three times to set the tone volume and return to normal operation.

Adjust Alarm Volume

Discussion

When the Alarm Volume display is shown, the user is able to adjust the volume of alarm tones. Each activation of an Up Arrow or Down Arrow button increases or decreases the alarm volume and increments or decrements by one the number of segments shown on the Pulse Amplitude (blip) bar as a relative indicator of the current volume. The minimum alarm volume is one (one blip bar segment); the maximum is ten (ten segments). Attempted adjustments outside the range generate an invalid key tone.

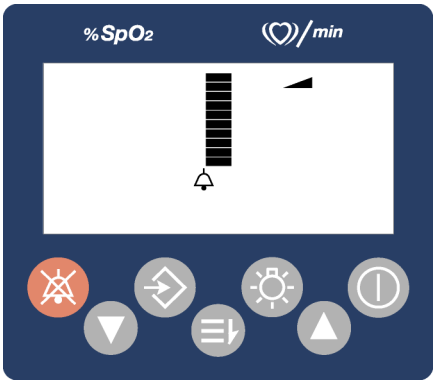
The default alarm volume is at least 52 dB(A) shown by 10 blip bar segments.

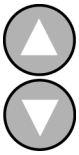
Note: When the NPB-40 times-out (30 seconds) the currently shown parameter is set and the NPB-40 display returns to the normal mode.

Procedure

With the NPB-40 in the normal mode:

1. Press the Menu button six times.





2. Press the Up Arrow or Down Arrow button to increase or decrease alarm volume.

3. Press the Menu button two times to set the alarm level and return to normal mode.

Set Time and Date

Discussion

WARNING: The sensor uses the date and time provided by the NPB-40 handheld pulse oximeter when the sensor event record is recorded by the sensor. The accuracy of the date/time is dependent on the date/time already set in and provided by the NPB-40.

Note: When the NPB-40 times-out (30 seconds) the currently shown parameter and the NPB-40 display returns to the normal mode.

When the month entry is made, the NPB-40 checks the day selection to see if it is correct. If the day selection is not valid for the month selected the menu display returns to the day selection display.

When the year entry is made, the NPB-40 checks the day and month selections to see if they are correct. If the day or month selection is not valid for the year selected the menu display returns to the day selection display.

Some examples of illegal dates are:

- 30 February
- 31 February
- 31 April
- 31 June

- 31 September
- 31 November
- 29 February on a non-leap year

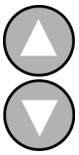
Procedure

With the NPB-40 in the normal mode:

1. Press the Power button to turn the NPB-40 off.

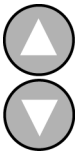
2. Press the Power button to turn the NPB-40 on.

3. Press the Menu button, while the NPB-40 is in the POST mode, until the set hours display is shown. The hours display (13) will flash.



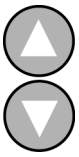
4. Press the Up Arrow button or the Down Arrow button until the desired hours are shown.

5. Press the Menu button to set the hours and display the minutes set display. The minutes display (45) will flash.



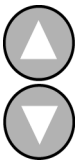
6. Press the Up Arrow button or the Down Arrow button until the desired minutes are shown.

7. Press the Menu button to set the minutes and display the day set display. The day (29) will flash.



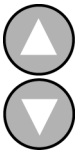
8. Press the Up Arrow button or the Down Arrow button until the desired day is shown.

9. Press the Menu button to set the day and display the month set display. The month (7) will flash.



10. Press the Up Arrow button or the Down Arrow button until the desired month is shown.

11. Press the Menu button to set the month and display the year set display. The year (2004) will flash.



12. Press the Up Arrow button or the Down Arrow button until the desired year is shown.

13. Press the Menu button to set the year and return to normal operation.

Set Alarm Silence Duration

Discussion

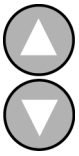
The Alarm Silence Duration display allows the user to adjust the alarm silence duration of the high-, medium-, and low-priority alarms. A low battery low-priority alarm cannot be silenced.

Note: When the NPB-40 times-out (30 seconds), the currently shown parameter is set and the NPB-40 returns to the normal mode.

Procedure

With the NPB-40 in the normal mode:

1. Press the Alarm Silence button until SEC or OFF is displayed on the pulse rate area of the display, then release the button. Alarm silence durations that are available are OFF, 30, 60, 90, and 120 seconds.



2. Press the Up Arrow button or the Down Arrow button until the desired alarm silence duration is shown.

3. Press the Alarm Silence button to set the shown alarm silence duration and return to normal operation.

Disable Audible Alarms

Discussion

When the alarm silence duration is set to OFF the NPB-40 will produce no audible alarms. The Alarm Silence indicator will flash while the alarm silence duration is set to off.

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

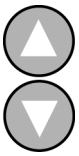
Note: When the NPB-40 times-out (30 seconds), the currently shown parameter is set and the NPB-40 display returns to the normal mode.

Procedure

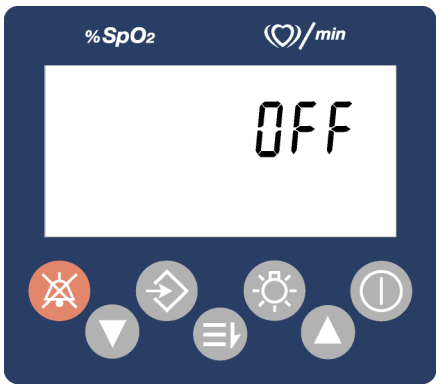
With the NPB-40 in the normal mode:

1. Press the Alarm Silence button until SEC or OFF is displayed in the pulse rate area of the display, then release the button. Alarm silence durations that are available are OFF, 30, 60, 90, and 120 seconds.

or



2. Press the Up Arrow button or the Down Arrow button until OFF is shown.



3. Press the Alarm Silence button to set the alarm silence duration to OFF and return to normal operation.

Note: The Alarm Silenced indicator will flash and an audible reminder sounds every three minutes while the alarm silence duration is set to OFF.

Set Alarm Limits

Discussion

The Alarm Limit display allows the user to adjust the upper and lower saturation and pulse rate limits.

Pressing the Up Arrow or Down Arrow button for three seconds or more causes the increment or decrement to scroll.

The Alarm Limit Changed indicator is displayed anytime an alarm limit is being changed or has been changed. See *Alarm Limit Changed Indicator* on page 63.

Note: When the NPB-40 times-out (30 seconds), the currently shown parameter is set and the NPB-40 display returns to the normal mode.

Procedure

With the NPB-40 in the normal mode:

1. Press the Menu button. The SpO_2 lower alarm limit is shown.

Note: The %SpO2 low alarm limit range is 20% to 99%. The upper value of the %SpO2 low alarm limit is limited to the %SpO2 upper alarm limit. The %SpO2 low alarm limit cannot be set equal to or higher than the %SpO2 upper alarm limit.

2. Press the Up Arrow or Down Arrow buttons to increase or decrease the shown limit parameter.

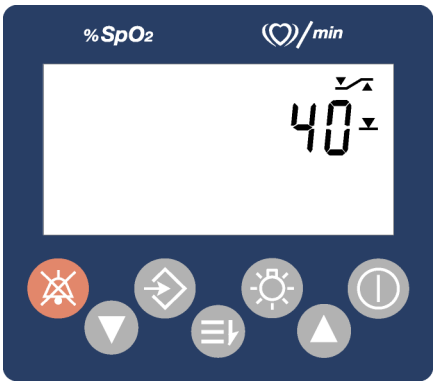
3. Press the Menu button to set the limit value. The SpO2 upper alarm limit is shown.

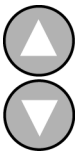
Note: The %SpO2 upper alarm limit range is 21% to 100%. The lower value of the %SpO2 upper alarm limit is limited to the %SpO2 low alarm limit. The %SpO2 upper alarm limit cannot be set equal to or lower than the %SpO2 low alarm limit.

4. Press the Up Arrow or Down Arrow buttons to increase or decrease the shown limit parameter.

5. Press the Menu button to set the limit value. The BPM lower alarm limit is shown.

Note: The pulse rate low alarm limit range is 30 to 249. The upper value of the pulse rate low alarm limit is limited one number lower than the pulse rate upper alarm limit. The pulse rate low alarm limit cannot be set equal to or higher than the pulse rate upper alarm limit.





6. Press the Up Arrow or Down Arrow buttons to increase or decrease the shown limit parameter.

7. Press the Menu button to set the limit value. The BPM upper alarm limit is shown.

Note: The pulse rate upper alarm limit range is 31 to 250. The lower value of the pulse rate upper alarm limit is limited to one number above the pulse rate low alarm limit. The pulse rate upper alarm limit cannot be set equal to or lower than the pulse rate low alarm limit.

8. Press the Up Arrow or Down Arrow buttons to increase or decrease the shown limit parameter.

9. Press the Menu button to set the alarm limit value.

10. Press the Menu button four times to return to normal operation.

Note: Limit changes will only be in effect as long as the NPB-40 remains turned on. When the NPB-40 is turned off, the default limits will be restored in the NPB-40. When the NPB-40 is turned on, the default limits will be in effect.

Alarm Limit Changed Indicator

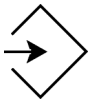
Alarm limits that have been changed from the default values are identified by a decimal point (.) after the shown value (%SpO_2 or BPM).

The Alarm Limit Changed indicator is displayed anytime an alarm limit is being changed or has been changed.

Record Snap-Shot Data

Discussion

The NPB-40 contains an internal memory that can store 50 patient data event records (snap-shots). Data event records can be printed. Events are retained in the NPB-40 memory while the NPB-40 remains on and cleared when the NPB-40 is turned off or powers itself off. If the events are cleared the events will not be available to print. Replacement of the NPB-40 batteries clears event records.

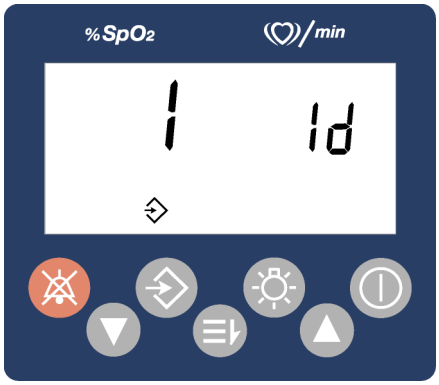


The Data indicator flashes at a medium priority rate when the NPB-40 patient memory is full.

Procedure

With the NPB-40 in the normal mode:

1. Press the Data button to capture a snap-shot of the NPB-40 data. The capture data display will be shown.



Note: The number (1) in the SpO_2 field is the identification (ID) number of captured snap-shots.

Note: When the Data button is pressed and there is no empty event memory location available, the NPB-40:

- displays the last ID number assigned (50)
- the Data icon continues to flash at the medium priority rate
- sounds an invalid key tone
- returns to the normal operating mode immediately

2. The NPB-40 returns to the normal mode after about three seconds.

Print Data

The NPB-40 can print data when used with a Citizen printer, model PD-22T, which is available from Nellcor Customer Services 1.800.635.5267 or your local Nellcor representative.

Caution: Ensure that the printer model number contains a "T". The "T" indicates that the printer has been configured for use with the NPB-40.

Note: Read the entire user's manual for the Citizen printer, model PD-22T prior to operation of the printer with the NPB-40.

Note: The NPB-40 must be IR-linked to a compatible printer in order to print.

When the print data display is shown, press the Data button to start printing. The report always contains a header and footer, and one or more of the following:

- summary report, if currently connected to a patient
- snap-shot report, if any are stored
- sensor data, if a sensor with patient event data is connected to the NPB-40

If the Data button is pressed in the print menu when no data is stored and the device is not connected to a patient, an invalid key tone is sounded, and the NPB-40 transitions to the normal mode.

The Print-mode indicator (page icon) flashes at the medium rate throughout the print mode.

When the print function is complete, the display returns to the normal mode. When NPB-40 times-out before the Data button is pressed, the display returns to the normal mode.

The Menu button is disabled during the print mode.

If there is no communication with the printer for 30 seconds, the print mode is aborted and the display returns to the normal mode.

Summary report data is purged after it is printed or on time-out due to printer communication failure. Printing or time-out due to printer communication failure does not purge snap-shot or sensor-event data; this data is purged from the NPB-40 memory at power off. Sensor-event data is retained in the sensor and loads/reloads to the NPB-40 memory at power on.

Alarm annunciation and patient monitoring is disabled during active printing (when the NPB-40 is communicating with printer).

Printing Data

Discussion

The NPB-40 prints:

- summary report, if available
- stored snap-shot data, if available
- sensor-event data, if available

Press the Menu button while in normal mode to access the parameter set up menu hierarchy. Press the Menu button seven times to access the print data display.

The summary report is displayed if the NPB-40 is currently posting saturation and rate. It then lists snap-shot data stored since the NPB-40 is powered on, and any sensor trend data.

If snap-shot data are stored in the NPB-40 memory, the Data icon is displayed on the print data display. If sensor-event data are stored in sensor memory, the Data In-Sensor icon is displayed on the print data display. If both types of data are stored, both icons are displayed. If no data are stored, neither icon is shown (blank display).

Note: The monitor and sensor does not differentiate between patients; therefore, use caution when reviewing the report as the list of snap-shots may contain data from more than one patient. Also, if a single-use sensor is used more than once, the sensor trend report section can contain data from more than one patient.

Note: The snap-shot list is deleted when the NPB-40 is turned on. When first connecting a single-use sensor, look for the DATA in SENSOR icon.

Procedure

With the NPB-40 in the normal mode:

1. Align the printer and the NPB-40. Place the printer and the NPB-40 on a flat, stable surface.

2. Orientate the printer and NPB-40 as shown in Figure 2. The alignment of the infrared ports of the printer and the NPB-40 must not exceed two feet (61 cm) separation and be within 15 degrees of centerline of each window. The printer and the NPB-40 must not be closer than six inches (15 cm). See Figure 2.

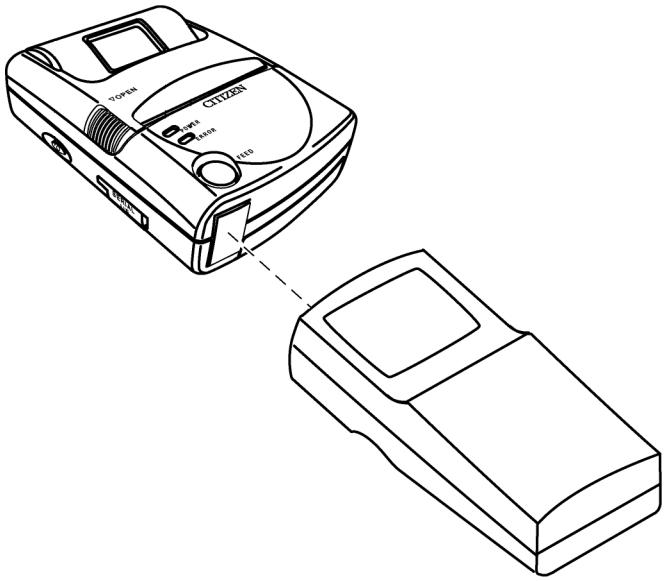
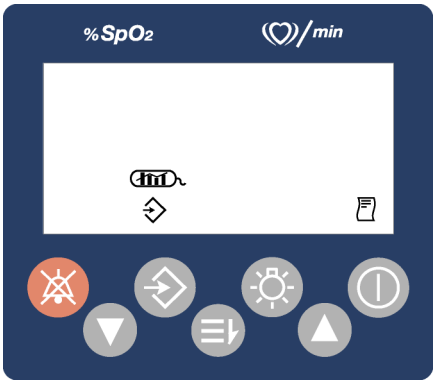


Figure 2: Printer Alignment

3. Press the Menu button seven times. The print display is shown.



4. Press the Data button to start printing. During printing, the stored snap-shot number is display for each snap-shot.

The NPB-40 prints all available data. Figure 3 illustrates all the print information that may be available.

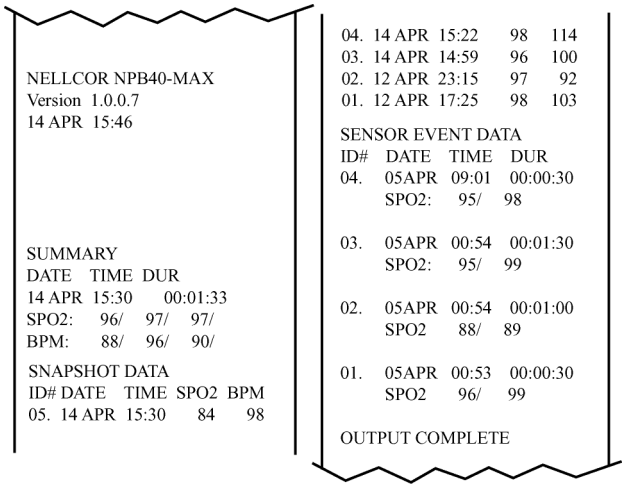


Figure 3: Combined Printed Data

Blank Page

Printer Setup Report

The printer is shipped with a PD-22 Setup Report. See Figure 4 for a copy of the printer setup report. The setup report lists the preset condition of the PD-22T printer.

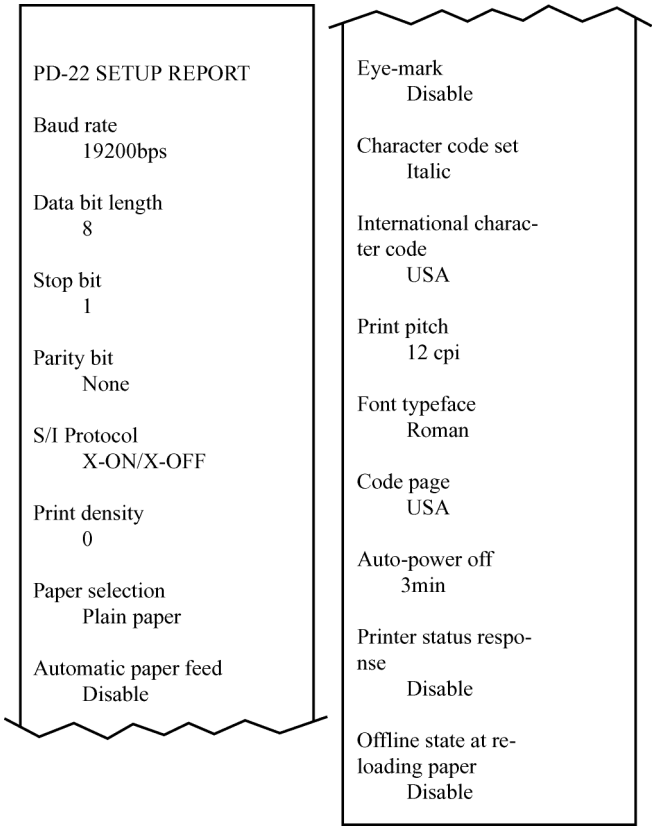


Figure 4: PD-22T Setup Report

Event Records

WARNING: The sensor uses the date and time provided by the NPB-40 handheld pulse oximeter when the sensor event record is recorded by the sensor. The accuracy of the date/time is dependent on the date/time already set in and provided by the NPB-40.

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

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

An event occurs when the %SpO_2 value exceeds either the upper or lower alarm limit for at least 15 seconds. The first *OXIMAX* sensor event record event will be stored in the *OXIMAX* sensor after the *OXIMAX* sensor has been attached to a patient for five minutes and every five minutes thereafter. The maximum number of events that can be stored in an *OXIMAX* sensor is 100.

Event records can only be viewed after an *OxiMax* sensor containing patient data (event records) has been connected to an *OxiMax* monitor capable of displaying sensor event records. The NPB-40 does not support viewing sensor event records, but does support printing sensor event records. Event records are designed to view patient events from prior areas of care or transport (history), while monitor trend should be used to view data or events from a patient currently being monitored. The monitor's Data In-Sensor indicator will light when an *OxiMax* sensor containing sensor-event data is connected to the *OxiMax* monitor.

Recording and viewing of *OxiMax* sensor-event data is only available on *OxiMax* comparable monitors. The *OxiMax* sensors may function on older technology monitors, but the *OxiMax* sensor event record feature is not available.

WARNING: The sensor uses the date and time provided by the NPB-40 handheld pulse oximeter when the sensor event record is recorded by the sensor. The accuracy of the date/time is dependent on the date/time already set in and provided by the NPB-40.

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

OXIMAX Sensor Event Record Data

The NPB-40 records a patient's *OXIMAX* sensor %SpO_2 event history from the *OXIMAX* sensor's memory chip, allowing a patient's event history to travel with the patient as the patient moves throughout the hospital. This allows caregivers to assess whether the patient had a bad event during transport or in the previous area of care. This feature is only available with adhesive single-patient-use *OXIMAX* sensors. Single-patient-use *OXIMAX* sensors are intended for single-patient use only; recorded %SpO_2 event history data does not distinguish between events that have been collected from multiple patients.

Select an *OxiMax* Sensor

WARNING: Before use, carefully read the *OxiMax* sensor Directions For Use, including all warnings, cautions, and instructions.

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

WARNING: Use only Nellcor-approved *OxiMax* sensors and extension cables with the NPB-40. Other sensors or extension cables may cause improper NPB-40 performance.

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

WARNING: Tissue damage can be caused by incorrect application or duration of use of an SpO_2 *OXIMAX* sensor. Inspect the *OXIMAX* sensor site periodically as directed in the *OXIMAX* sensor Directions For Use.

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

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

WARNING: Do not lift the NPB-40 by the sensor or extension cable because the cable could disconnect from the NPB-40, causing the NPB-40 to drop on the patient.

Caution: The *OXIMAX* Sensor Disconnected icon and associated alarm indicate that either the OXIMAX sensor is disconnected or the wiring is faulty. The user should check the *OXIMAX* sensor connection and, if necessary, replace the *OXIMAX* sensor, extension cable, or both.

Note: Physiological conditions, medical procedures, or external agents that may interfere with the NPB-40's ability to detect and display measurements include dysfunctional hemoglobin, arterial dyes, low perfusion, dark pigment, and externally applied coloring agents such as nail polish, dye, or pigmented cream.

For a complete and up-to-date listing of all *OxiMax* sensors applicable to the NPB-40, refer to the latest Sensor Accuracy Grid posted on the Internet at:

http://www.mallinckrodt.com/respiratory/resp/Serv_Supp/ProductManuals.html

When selecting an *OxiMax* sensor, consider the patient's weight and activity level, the adequacy of perfusion, and the available *OxiMax* sensor sites, the need for sterility, and the anticipated duration of monitoring. For more information refer to Table 3 on page 80 or contact your local Nellcor representative. Refer to *Performance Considerations* on page 91, for more information on *OxiMax* sensor performance.

Table 3: Nellcor Oximetry Sensor Models and Patient Weights

OxiMax Sensor	Model	Patient Size > = greater than < = less than
OxiMax MAX-FAST adhesive forehead sensor, single-patient-use	MAX-FAST	>10 kg (22 lbs)
OxiMax Softcare nonadhesive sensor, single-patient-use, preterm infant	SC-PR	<1.5 kg (3.3 lbs)
OxiMax Softcare nonadhesive sensor, single-patient-use, neonate	SC-NEO	1.5 to 5 kg (3.3 to 11 lbs)

Table 3: Nellcor Oximetry Sensor Models and Patient Weights (Continued)

OxiMax Sensor	Model	Patient Size > = greater than < = less than
OxiMax Softcare nonadhesive sensor, single-patient-use, adult	SC-A	>40 kg (88 lbs)
OxiMax adhesive sensor, single-patient-use, adult	MAX-A	>30 kg (66 lbs)
OxiMax adhesive sensor, single-patient-use, adult, longer cable 36 inches (91.44 cm)	MAX-AL	>30 kg (66 lbs)
OxiMax adhesive sensor, single-patient-use, neonatal/adult	MAX-N	<3 kg or >40 kg (<6.6 lbs or >88 lbs)
OxiMax adhesive sensor, single-patient-use, pediatric	MAX-P	10 to 50 kg (22 to 110 lbs)
OxiMax adhesive sensor, single-patient-use, infant	MAX-I	3 to 20 kg (6.6 to 44 lbs)
OxiMax adhesive sensor, single-patient-use, adult nasal	MAX-R	>50 kg (110 lbs)
OxiMax OxiCliq® nonadhesive sensor, single-patient-use, adult, reusable cable	OxiCliq A	>30 kg (66 lbs)
OxiMax OxiCliq nonadhesive sensor, single-patient-use, neonatal/adult, reusable cable	OxiCliq N	<3 kg or >40 kg (<6.6 lbs or >88 lbs)
OxiMax OxiCliq nonadhesive sensor, single-patient-use, pediatric, reusable cable	OxiCliq P	10 to 50 kg (22 to 110 lbs)

Table 3: Nellcor Oximetry Sensor Models and Patient Weights (Continued)

OxiMax Sensor	Model	Patient Size > = greater than < = less than
OxiMax OxiCliq nonadhesive sensor, single-patient-use, infant, reusable cable	OxiCliq I	3 to 20 kg (6.6 to 44 lbs)
OxiMax Durasensor® finger-clip sensor, reusable, adult	DS-100A	>40 kg (88 lbs)
OxiMax Oxiband® sensor, reusable, neonatal/adult	OXI-A/N	<3 kg or >40 kg (<6.6 lbs or >88 lbs)
OxiMax Oxiband sensor, reusable, pediatric/infant	OXI-P/I	3 kg to 40 kg (6.6 lbs to 88 lbs)
OxiMax Dura-Y® multisite sensor, reusable	D-YS	>1 kg (>2.2 lbs)
For use with the Dura-Y sensor: Ear clip (Reusable, nonsterile)	D-YSE	>30 kg (66 lbs)
Pedi-Check™ pediatric spot-check clip (Reusable, nonsterile)	D-YSPD	3 kg to 40 kg (6.6 lbs to 88 lbs)

OxiMax Sensor Features

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

Table 4: *OxiMax* Sensor Features

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

Biocompatibility Test

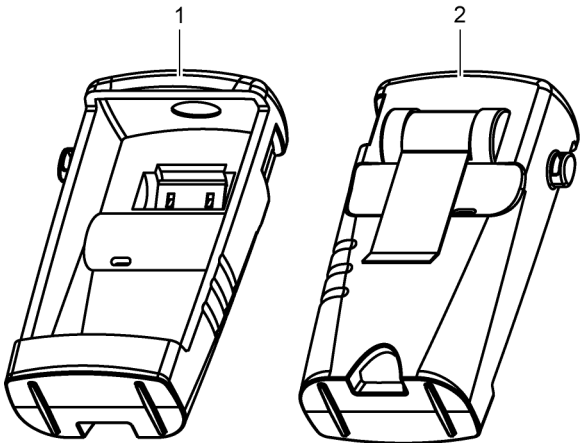
Biocompatibility testing has been conducted on Nellcor *OxiMax* sensors in compliance with ISO 10993-1, Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing. The *OxiMax* sensors have passed the recommended biocompatibility testing and are therefore in compliance with ISO 10993-1.

Optional Accessories

The optional accessories offered with the NPB-40 are:

Boot With Clip

This accessory protects the NPB-40.



1 — Front view	2 — Rear view

Figure 5: NPB-40 Boot with Clip

Carrying Case

The Nylon carrying case is equipped with compartments for the NPB-40, Operator's manual, compact disk containing all manuals, and sensors. The case comes with a carrying strap that is adjustable from 71 cm to 135 cm (28 inches to 53 inches).

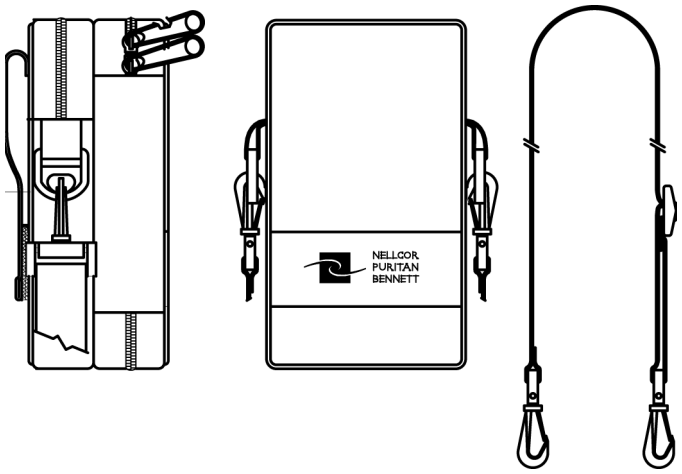


Figure 6: NPB-40 Carrying Case

Water-Resistant Jacket

The water-resistant jacket is made of clear plastic to facilitate use of the NPB-40.

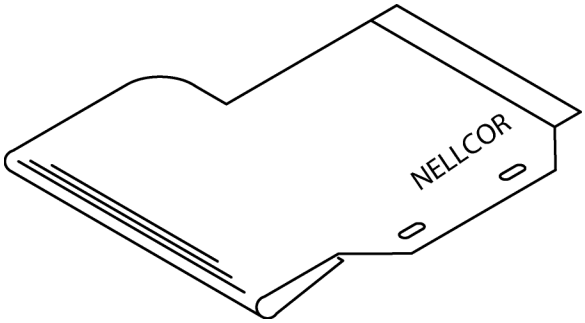


Figure 7: Water-Resistant Jacket

Infrared Printer

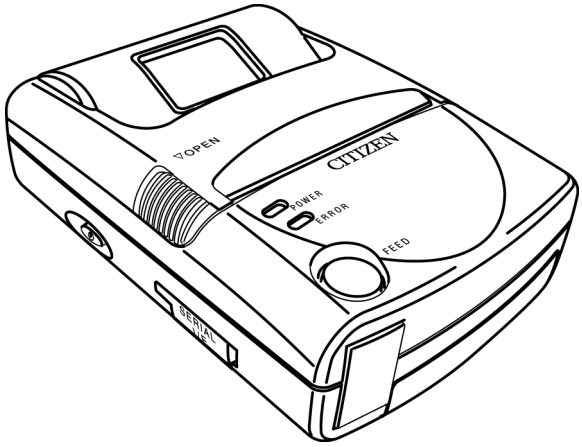


Figure 8: Printer

The Citizen's PD-22T portable printer is used to print selected data from the NPB-40. The NPB-40 uses the printer IrDA infrared interface. Refer to the User's Manual supplied with the printer for details on the PD-22T printer.

Thermal Paper

The thermal paper is for the Citizen PD-22 infrared printer. Refer to the User's Manual supplied with the printer for details on the thermal paper.

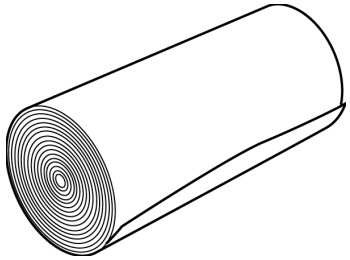
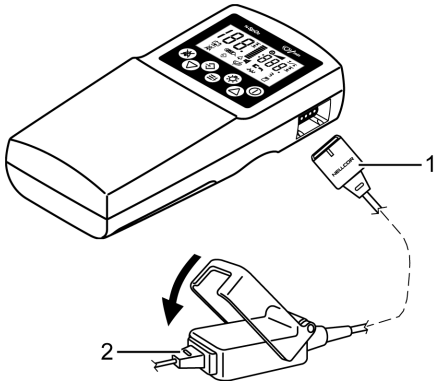


Figure 9: Thermal Paper

DEC-4 extension cable



1 — DEC-4 extension cable

2 — Sensor connector

Figure 10: DEC-4 Extension Cable

The DEC-4 extension cable provides 1.2 m (4 ft.) of cable extension between the NPB-40 and the sensor.

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

- ***Safety Information*** **on page 1**
- ***OXIMAX Sensors and Accessories*** **on page 77**
- ***Performance Considerations*** **on page 91**

Performance Verification

The performance of the NPB-40 is verified by following the procedures outlined in the Performance Verification section of the NPB-40 service manual. Qualified service personnel should perform these procedures before using the NPB-40 for the first time in a clinical setting.

NPB-40 Performance Considerations

Certain patient conditions can affect the measurements of the NPB-40 and cause the loss of the pulse signal.

Inaccurate measurements can be caused by:

- prolonged and/or excessive patient movement
- venous pulsations
- intravascular dyes, such as indocyanine green or methylene blue
- externally applied coloring agents (nail polish, dye, pigmented cream)
- defibrillation

Dysfunctional Hemoglobins

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

Anemia

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

Saturation

The NPB-40 will display saturation levels between 1% and 100%.

Pulse Rates

The NPB-40 displays pulse rates between 20 and 300 beats per minute. The sensor accuracy ranges do not apply to pulse rates above 250 bpm. Detected pulse rates below 20 are shown as 0.

OxiMax Sensor Performance Considerations

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

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

Warning: Use only Nellcor-approved *OxiMax* sensors and extension cables. Do not use cables more than 4 feet in length. Use only the DEC-4 extension cable or only the sensor.

Inaccurate measurements can be caused by:

- incorrect application of the *OxiMax* sensor
- placement of the *OxiMax* sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line
- ambient light
- prolonged and/or excessive patient movement
- intravascular dyes or externally applied coloring, such as nail polish or pigmented cream
- failure to cover the *OxiMax* sensor site with opaque material in high ambient light conditions

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

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

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

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

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

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

- verify that the *OxiMax* sensor is properly and securely applied
- move the *OxiMax* sensor to a less active site
- use an adhesive *OxiMax* sensor that tolerates some patient motion
- use a new *OxiMax* sensor with fresh adhesive backing

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

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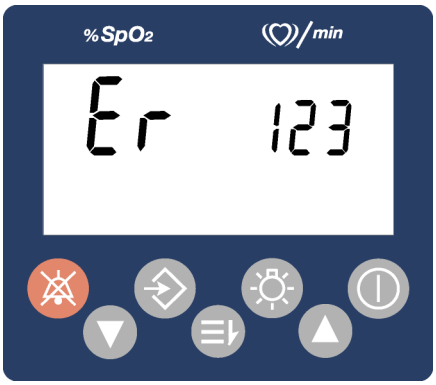
WARNING: If you are uncertain about the accuracy of any measurement, check the patient's vital signs by alternate means; then make sure the NPB-40 is functioning correctly.

WARNING: The cover should only be removed by qualified service personnel. There are no user-serviceable parts inside the NPB-40.

Caution: Do not spray, pour, or spill any liquid on the NPB-40, its accessories, connectors, switches, or openings in the chassis.

Error Codes

When the NPB-40 detects an error condition, it may display “Er” followed by the error code.



Note: The error code number may contain up to three digits.

When an error code (other than the ones listed in Table 5) is shown, turn the NPB-40 off, wait 10 seconds, and turn the NPB-40 on. If the error code reappears, record it and notify service personnel.

Table 5 lists the error codes and corrective actions. When an error occurs, the unit will stop monitoring, remove all information from the display and display message “Er XXX,” and sound a low priority alarm. Turn the NPB-40 off, wait 10 seconds, then turn the NPB-40 on. If the error appears, follow the action(s) listed in Table 5.

Table 5: Error Codes

Error Code	Action
10	Check/replace sensor/extension cable.
11	1 — Replace batteries. 2 — Notify service personnel.
17	Check/replace sensor/extension cable.
19	Check/replace sensor/extension cable.
273	1 — Restart the NPB-40. 2 — Set the time and date. 3 — Notify service personnel.
274	Return NPB-40 for reprogramming.
275	Check/replace sensor/extension cable.
276	Replace with Oximax sensor.
277	Check/replace sensor/extension cable.
280	Check/replace sensor/extension cable.
282	Check/replace sensor/extension cable.
521	Replace batteries.
522	Replace batteries.

Table 5: Error Codes (Continued)

Error Code	Action
523	1 — Restart the NPB-40. 2 — Set the time and date. 3 — Notify service personnel.
525	1 — Restart the NPB-40. 2 — Notify service personnel.
538	Set time and date.
539	1 — Restart the NPB-40. 2 — Notify service personnel.
543	Set the NPB-40 time and date.

Corrective Action

If you experience a problem while using the NPB-40 and are unable to correct it, contact qualified service personnel or your local Nellcor representative. The NPB-40 service manual, which is for use by qualified service personnel, provides additional troubleshooting information.

The current copy of the NPB-40 service manual is available on the Internet at:

http://www.mallinckrodt.com/respiratory/resp/Serv_Supp/ProductManuals.html

Following is a list of possible errors and suggestions for correcting them.

1. **There is no response to the Power button.**

   - Ensure that the Power button is fully depressed.
   - The batteries may be missing, discharged, or oriented incorrectly. Install new batteries. See *Battery Installation* on page 33.

2. **One or more display segments or indicators do not light during the power-on self-test.**

   - Do not use the NPB-40; contact qualified service personnel or your local Nellcor representative.

3. **The Pulse Search indicator is displayed for more than 10 seconds.**

   - Check the sensor directions for use to determine if an appropriate sensor is being used and if it is applied properly. Check sensor and extension cable connections. Test the sensor on another subject. Try another sensor or extension cable.
   - Perfusion may be too low for the NPB-40 to track the pulse. Check the patient. Test the NPB-40 on yourself. Change the sensor site. Try another sensor.
   - Excessive patient motion may be preventing the NPB-40 from tracking the pulse. Keep the patient still, if possible. Verify that the sensor is securely applied, and replace it if necessary. Change the sensor site.

- The sensor may be too tight, there may be excessive ambient light, or the sensor may be on an extremity with a blood pressure cuff, arterial catheter, or intravascular line. Reposition sensor, as necessary.

- Excessive environmental motion or electromagnetic interference may be preventing the NPB-40 from tracking the pulse. Remove the source of interference or try to stabilize the environment, or do both.

4. The Pulse Search indicator lights after successful measurements have been made.

- Check the patient.

- Perfusion may be too low for the NPB-40 to track the pulse. Test the NPB-40 on another subject. Change the sensor site. Try another type of sensor.

- Excessive patient motion may be preventing the NPB-40 from tracking the pulse. Verify that the sensor is securely applied and replace it if necessary. Change the sensor site.

- The sensor may be too tight, there may be excessive ambient light, or the sensor may be on an extremity with a blood pressure cuff, arterial catheter, or intravascular line. Reposition sensor, as necessary.

- Excessive environmental motion or electromagnetic interference may be preventing the NPB-40 from tracking the pulse. Remove the source of interference or try to stabilize the environment, or do both.

5. Er followed by a number appears on the display.

- Disconnect the sensor from the NPB-40. Restart the NPB-40. If error code appears again, record the number and provide that information to qualified service personnel or your local Nellcor representative.

EMI (Electro-magnetic Interference)

Caution: This device has been tested and found to comply with the limits for medical devices to the EN60601-1-2, (second edition), and the Medical Device Directive 93/42/EEC. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in health care environments (for example, electrosurgical units, cellular phones, mobile two-way radios, electrical appliances, and high-definition television), it is possible that high levels of such interference due to close proximity or strength of a source may result in disruption of performance of this device.

The NPB-40 is designed for use in environments in which the pulse can be obscured by electromagnetic interference. During such interference, measurements may seem inappropriate or the NPB-40 may not seem to operate correctly.

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

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

The NPB-40 generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with these instructions, may cause harmful interference with other devices in the vicinity.

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

Obtaining Technical Assistance

For technical information and assistance, or to order parts or a service manual, contact Nellcor's Technical Services Department, 1.800.635.5267, or your local Nellcor representative. The service manual includes block diagrams and a parts list required by qualified personnel when servicing the NPB-40.

When calling Nellcor's Technical Services Department, 1.800.635.5267, or your local Nellcor representative, you may be asked to tell the representative the software version number of the NPB-40.

The software version appears in the NPB-40 display each time the NPB-40 successfully completes the power-on self-test. Write the number down and have it available whenever requesting technical assistance.

The current copy of this manual and the NPB-40 service manual are available on the Internet at:

http://www.mallinckrodt.com/respiratory/resp/Serv_Supp/ProductManuals.html

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Caution: The institution should follow local government regulations and recycling instructions regarding disposal or recycling of the batteries and NPB-40 components or end of life of the NPB-40.

Caution: The NPB-40 will not operate with dead batteries. Install new batteries.

Return the NPB-40

Contact Nellcor's Technical Services Department, 1.800.635.5267, or your local Nellcor representative for shipping instructions including a Returned Goods Authorization (RGA) number. Unless otherwise instructed by Nellcor's Technical Services Department, it is not necessary to return the *OxiMax* sensor or other accessory items with the NPB-40. Pack the NPB-40 in its original shipping carton. If the original carton is not available, use a suitable carton with appropriate packing material to protect it during shipping.

Return the NPB-40 by any shipping method that provides proof of delivery.

Service

WARNING: Only qualified service personnel should remove the cover. There are no user-serviceable parts inside the NPB-40.

The NPB-40 requires no calibration.

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

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.

Cleaning

Caution: Do not spray, pour, or spill any liquid on the NPB-40, its accessories, connectors, switches, or openings in the chassis.

For *surface-cleaning* and *disinfecting* the NPB-40, follow the institution's procedures or:

- The NPB-40 may be *surface-cleaned* by using a soft cloth dampened with either a commercial, nonabrasive cleaner or a solution of 70% alcohol in water, and lightly wiping the surfaces of the NPB-40.

- The NPB-40 may be *disinfected* using a soft cloth saturated with a solution of 10% chlorine bleach in tap water.

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

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

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Introduction

Pressing the Menu button repeatedly during normal operation sequentially displays seven parameter-setting displays, one for each button activation, and then returns to the default monitoring display. Settable parameters include high and low SpO_2 limits, high and low BPM limits, alarm volume, pulse beep volume, and data printing.

Pressing the Menu button during start-up Power-On Self-Test (POST) test to access the Time/Date setting menu. Repeated activations of the Menu button in this menu sequence displays five (5) time/date parameter-setting displays that allows the user to set Hour, Minute, Day, Month, and Year, and then return to the POST display.

Structure

Table 6: Menu Structure

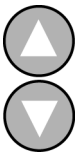
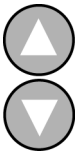
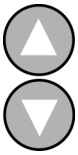
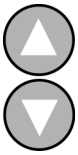
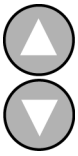
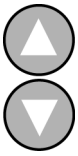
# of Presses	Parameter	Press	Function
1 	%SpO_2 Low Limit		Adjust limit
2 	%SpO_2 High Limit		Adjust limit
3 	BPM Low Limit		Adjust limit
4 	BPM High Limit		Adjust limit
5 	Pulse Beep Volume		Adjust volume. Indications on blip bar.
6 	Alarm Volume		Adjust volume. Indications on blip bar.

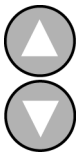
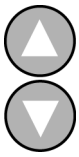
Table 6: Menu Structure (Continued)

# of Presses	Parameter	Press	Function
7	Print Data		Print summary and/or stored snap-shot and sensor-event data.

Table 7: Time Set Menu

# of Presses	Parameter	Press	Function
The must be pressed during the NPB-40 POST.			
1	Hour		Adjust 1 to 23
2	Minute		Adjust 1 to 59
3	Day		Adjust 1 to 31

Table 7: Time Set Menu (Continued)

# of Presses		Parameter	Press	Function
4		Month		Adjust 1 to 12
5		Year		Adjust 2003 to 2099

When the month entry is made, the NPB-40 checks the day selection to see if it is correct. If the day selection is not valid for the month selected the menu display returns to the day selection display.

When the year entry is made, the NPB-40 checks the day and month selections to see if they are correct. If the day or month selection is not valid for the year selected the menu display returns to the day selection display.

Some examples of illegal dates are:

- 30 February
- 31 February
- 31 April
- 31 June
- 31 September

- 31 November
- 29 February on a non-leap year

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Oximetry Overview

The NPB-40 uses pulse oximetry to measure functional oxygen saturation in the blood. Pulse oximetry works by applying an *OxiMax* sensor to a pulsating arteriolar vascular bed, such as a finger or toe. The *OxiMax* sensor contains a dual light source and a photo detector.

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

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

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

Pulse oximetry is based on two principles: that oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (spectrophotometry), and that the volume of arterial blood in tissue (and hence, light absorption by that blood) changes during the pulse (plethysmography). A pulse oximeter determines SpO_2 by passing red and infrared light into an arteriolar bed and measuring changes in light absorption during the

pulsatile cycle. Red and infrared low-voltage light-emitting diodes (LED) in the oximetry *OxiMax* sensor serve as light sources; a photo diode serves as the photo detector.

Because oxyhemoglobin and deoxyhemoglobin differ in light absorption, the amount of red and infrared light absorbed by blood is related to hemoglobin oxygen saturation. 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 vascular bed, and blood volume and light absorption increase. During diastole, blood volume and light absorption reach their lowest point. The pulse oximeter bases its SpO_2 measurements on the difference between maximum and minimum absorption (measurements at systole and diastole). By doing so, it focuses on light absorption by pulsatile arterial blood, eliminating the effects of nonpulsatile absorbers such as tissue, bone, and venous blood.

Automatic Calibration

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

During monitoring, the NPB-40's software selects coefficients that are appropriate for the wavelength of that individual *OxiMax* sensor's red LED; these coefficients are then used to determine SpO_2.

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

Functional versus Fractional Saturation

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

Measured versus Calculated Saturation

When saturation is calculated from a blood gas partial pressure of oxygen (PO_2), the calculated value may differ from the SpO_2 measurement of a pulse oximeter. This usually occurs because the calculated saturation was not appropriately corrected for the effects of variables that shift the relationship between PO_2 and pH, temperature, the partial pressure of carbon dioxide (PCO_2), 2,3-DPG, and fetal hemoglobin. See Figure Figure 11:.

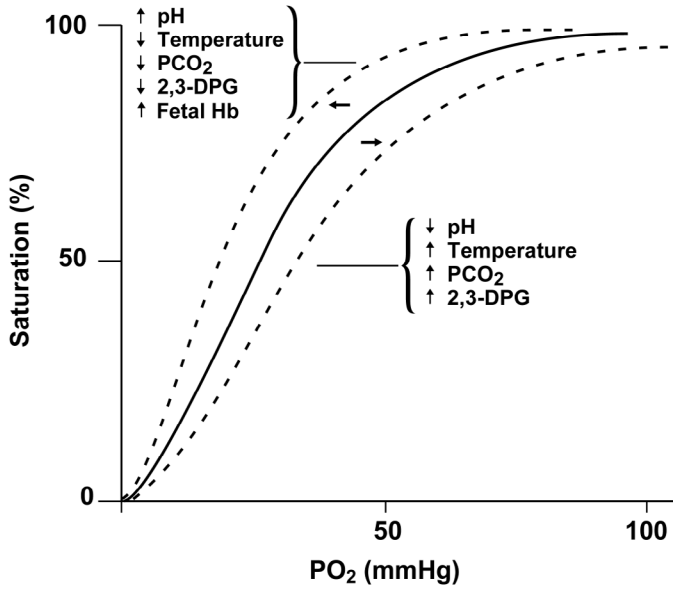

Figure 11: Oxyhemoglobin Dissociation Curve

OxiMax Technology

The NPB-40 is designed to use Nellcor *OxiMax* brand sensors, which integrate the *OxiMax* technology. These *OxiMax* sensors can be identified by their deep lavender/ blue plug color. All *OxiMax* sensors contain a memory chip carrying information about the *OxiMax* sensor, which the oximeter needs for correct operation, including the *OxiMax* sensor's calibration data, model type, troubleshooting codes, and error detection data.

When an *OxiMax* sensor is connected to the NPB-40, the pulse oximeter will first reads the information in the *OxiMax* sensor memory chip, checks it to make sure that there are no errors, and then loads the data to begin

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

Pulse oximeters containing *OxiMax* technology, including the NPB-40, use calibration data contained in the *OxiMax* sensor in calculating the patient's SpO_2. Consult the *OxiMax* sensor accuracy grid card included with the pulse oximeter for specific accuracy information for the NPB-40 with different Nellcor *OxiMax* sensors.

The NPB-40 uses the information in the *OxiMax* sensor to tailor troubleshooting messages for the clinician. The *OxiMax* sensor contains coding that tells the pulse oximeter what kind of *OxiMax* sensor is being used. When deciding what messages to display, the pulse oximeter takes into account the *OxiMax* sensor type and recommended patient site for that model.

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Performance

Measurement Range

SpO_2	1% to 100%
Pulse Rate	0, 20 beats per minute (bpm) to 300 bpm
Perfusion Range	0.03% to 20%

Accuracy and Motion Tolerance

Saturation	
Without Motion [1]	70 to 100% ±2 digits
With Motion [2]	70 to 100% ±3 digits
Low Perfusion[3]	70 to 100% ±2 digits

[1] Saturation accuracy will vary by sensor type. Refer to the Sensor Accuracy Grid. The Sensor Accuracy Grid is shipped with the NPB-40. The latest version of the Sensor Accuracy Grid is available on the Internet at:

http://www.mallinckrodt.com/respiratory/resp/Serv_Supp/ProductManuals.html

[2] Applicability: *OxiMax* MAX-A, MAX-FAST, DS-100A, D-YSE, SC-NEO, and OxiCliq A sensors.

[3] Specification applies to NPB-40 performance.

Accuracy and Motion Tolerance (Continued)

Pulse Rate	
Without Motion [1, 2, 3]	20 to 250 bpm ±3 digits
With Motion [2]	normal physiologic range (55 - 125 bpm) ±5 digits
Low Perfusion [3]	20 to 250 bpm ±3 digits

[1] Saturation accuracy will vary by sensor type. Refer to the Sensor Accuracy Grid. The Sensor Accuracy Grid is shipped with the NPB-40. The latest version of the Sensor Accuracy Grid is available on the Internet at:

http://www.mallinckrodt.com/respiratory/resp/Serv_Supp/ProductManuals.html

[2] Applicability: *OxiMax* MAX-A, MAX-FAST, DS-100A, D-YSE, SC-NEO, and OxiCliq A sensors.

[3] Specification applies to NPB-40 performance.

Display Update Interval

100 millisecond

Audible Indicators

Audible Indicator	Parameter	Value
Alarm Volume Setting	Volume level	Adjustable, 40 to 52 dB(A), at one meter
	Pitch (±30 Hz)	752 Hz
	On pulse width (±20 msec)	500 msec
	Off Interval (±20 msec)	10 msec
	Number of pulses in burst	1
	Repetition Pause (±2 sec.)	N/A
	Priority	1
Beep Volume setting	Volume level	Adjustable, 42 to 52 dB(A), at one meter
	Pitch (±30 Hz)	1500 Hz
	On pulse width (±20 msec)	500 msec
	Off Interval (±20 msec)	10 msec
	Number of pulses in burst	1
	Repetition Pause (±2 sec.)	N/A
	Priority	2

Audible Indicators (Continued)

Audible Indicator	Parameter	Value
POST Pass	Volume level	Fixed at 45 dB(A), at one meter
	Pitch (±30 Hz)	600 Hz
	On pulse width (±20 msec)	1000 msec
	Off Interval (±20 msec)	10 msec
	Number of pulses in burst	1
	Repetition Pause (±2 sec.)	N/A
	Priority	3
Invalid Key Press	Volume level	Fixed at 45 dB(A), at one meter
	Pitch (±30 Hz)	200 Hz
	On pulse width (±20 msec)	50 msec
	Off Interval (±20 msec)	10 msec
	Number of pulses in burst	1
	Repetition Pause (±2 sec.)	N/A
	Priority	4

Audible Indicators (Continued)

Audible Indicator	Parameter	Value
Confirmation	Volume level	Fixed at 45 dB(A), at one meter
	Pitch (±30 Hz)	700 Hz
	On pulse width (±20 msec)	130 msec
	Off Interval (±20 msec)	130 msec
	Number of pulses in burst	3
	Repetition Pause (±2 sec.)	N/A
	Priority	5
Valid Key Press	Volume level	Fixed at 45 dB(A), at one meter
	Pitch (±30 Hz)	800 Hz
	On pulse width (±20 msec)	10 msec
	Off Interval (±20 msec)	10 msec
	Number of pulses in burst	1
	Repetition Pause (±2 sec.)	N/A
	Priority	6

Audible Indicators (Continued)

Audible Indicator	Parameter	Value
Pulse Beep	Volume level	Adjustable, 42 to 52 dB(A), at one meter
	Pitch (±30 Hz)	1500 Hz
	On pulse width (±20 msec)	50 msec
	Off Interval (±20 msec)	10 msec
	Number of pulses in burst	1
	Repetition Pause (±2 sec.)	N/A
	Priority	7
Alarm Silence Reminder	Volume level	Adjustable, 42 to 52 dB(A), at one meter
	Pitch (±30 Hz)	500 Hz
	On pulse width (±20 msec)	130 msec
	Off Interval (±20 msec)	130 msec
	Number of pulses in burst	3
	Repetition Pause (±2 sec.)	179.27 sec.
	Priority	8

Audible Indicators (Continued)

Audible Indicator	Parameter	Value
High Priority Alarm	Volume level	Adjustable, 42 to 52 dB(A), at one meter
	Pitch (±30 Hz)	1200 Hz
	On pulse width (±20 msec)	250 msec
	Off Interval (±20 msec)	80 msec
	Number of pulses in burst	1
	Repetition Pause (±2 sec.)	0 sec.
	Priority	9
Medium Priority Alarm	Volume level	Adjustable, 42 to 52 dB(A), at one meter
	Pitch (±30 Hz)	752 Hz
	On pulse width (±20 msec)	400 msec
	Off Interval (±20 msec)	300 msec
	Number of pulses in burst	1
	Repetition Pause (±2 sec.)	0 sec.
	Priority	10

Audible Indicators (Continued)

Audible Indicator	Parameter	Value
Low priority Alarm	Volume level	Adjustable, 42 to 52 dB(A), at one meter
	Pitch (±30 Hz)	500 Hz
	On pulse width (±20 msec)	400 msec
	Off Interval (±20 msec)	3200 msec
	Number of pulses in burst	1
	Repetition Pause (±2 sec.)	0 sec.
	Priority	11

Electrical

Batteries

The batteries provide at least 15 hours of battery life with no alarms, no printing, and with backlight on while using a pulse simulator set for 200 bpm, high light and low modulation.	
Type	4 AA alkaline
Voltage	1.5 Volts DC (each)

OxiMax Sensors

Wavelength	The wavelength range of the light emitted are near 660 nm and 890 nm.

OxiMax Sensor Power Dissipation

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

Environmental Conditions

Operation

Temperature	5 ºC to 40 ºC (41 ºF to 104 ºF)
Altitude	-390 m to 3,012 m (-1,254 ft. to 9,882 ft.)
Atmospheric Pressure	70 kPa to 106 kPa (20.6 in. Hg to 31.3 in. Hg)
Relative Humidity	15% to 95% non-condensing

Transport and Storage (not in shipping container)

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

Transport and Storage (in shipping container)

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

Physical Characteristics

Weight	0.62 lbs. (0.28 kg)
Dimensions	2.875 in. x 6.25 in. x 1.375 in. (7.3 cm x 15.9 cm x 3.5 cm)

Compliance

Item	Compliant With
Equipment classification	Safety Standards: EN 60601-1: 1990 (A1 + A2), EN 60601-1-2: 2001, UL 60601-1, CAN/CSA C22.2 No. 601.1
Type of protection	Internally powered equipment (on battery power)
Degree of protection	Type BF - Applied part
Mode of operation	Continuous
Front panel and case labeling	IEC 60878, EN 980, ISO 7000, EN 60417-1, EN 60417-2
Button spacing	ISO 7250
Year of manufacture symbol	EN 980
Operation during physical shock	IEC 60068-2-27 at 100 g
Alarm requirements	EN 60601-1-8
Pulse oximeters	EN 865
Operation during vibration	IEC 60068-2-6 and IEC 60068-2-34
Radiated and conducted emissions	EN 55011, Group 1, Class B

Manufacturer’s Declaration

WARNING: The use of accessories, sensors, and cables other than those specified may result in increased emission and/or create invalid readings of the NPB-40.

The NPB-40 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the NPB-40 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the NPB-40 as recommended below, according to the maximum output of the communications equipment.

Table 8: Recommended Separation Distances

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the NPB-40 (IEC 60601-1-2)

Frequency of Transmitter	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
Equation	$d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	$d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	$d = \left[\frac{7}{V_1}\right]\sqrt{P}$
Rated Maximum Output Power of Transmitter in Watts	Separation Distance in Meters	Separation Distance in Meters	Separation Distance in Meters
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

Note: At 80 MHz to 800 MHz, the separation distance for the higher frequency range applies.

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

Table 9: Cable Compliance

Cables Comply With:
• RF emissions, EN 55011, Class B/Group 1 • EN 60601-1-2: 2001

Cables and *OxiMax* Sensors	Maximum Length
OxiCliq-OC-3 cable	3 ft. (0.9 m)
DEC-4 sensor extension cable	4 ft. (1.2 m)
MAX-FAST sensor	30 in. (76.2 cm)
MAX-A sensor	1.5 ft. (0.5 m)
MAX-AL sensor	3 ft. (0.9 m)
MAX-I sensor	1.5 ft. (0.5 m)
MAX-N sensor	1.5 ft. (0.5 m)
MAX-P sensor	1.5 ft. (0.5 m)
MAX-R sensor	1.5 ft. (0.5 m)
SC-PR sensor	3 ft. (0.9 m)
SC-NEO sensor	3 ft. (0.9 m)
SC-A sensor	3 ft. (0.9 m)
DS-100A sensor	3 ft. (0.9 m)
OXI-A/N sensor	3 ft. (0.9 m)
OXI-P/I sensor	3 ft. (0.9 m)
D-YS sensor	4 ft. (1.2 m)
D-YSE sensor	4 ft. (1.2 m)
D-YSPD sensor	4 ft. (1.2 m)

Table 10: Electronic Emissions

The NPB-40 is intended for use in the electromagnetic environment specified below. The customer or user of the NPB-40 should assure that it is used in such an environment.

Emission Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The NPB-40 uses RF energy only for its internal function. Therefore, the RF emissions are very low and not likely to cause interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The NPB-40 is suitable for use in establishments, including diagnostic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Table 11: Electromagnetic Immunity

The NPB-40 is intended for use in the electromagnetic environment specified below. The customer or user of the NPB-40 should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	Complies	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV power supply lines ± 1 kV for input/output lines	Complies	Main power should be that of a typical commercial or hospital environment.
Power Frequency (50/60 Hz) magnetic field	3 A/m	Complies	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Table 12: Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the NPB-40, including the cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 Vrms	
Recommended Separation Distance			
$d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$			where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
$d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	80 MHz to 800 MHz		Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] , should be less than the compliance level in each frequency range.[b]
$d = \left[\frac{7}{V_1}\right]\sqrt{P}$	800 MHz to 2.5 GHz		

Table 12: Electromagnetic Immunity

Interference may occur in the vicinity of equipment marked with this symbol.

Note 1: At 80 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

[a] Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in which the NPB-40 is used exceeds the applicable RF compliance level above, the NPB-40 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the NPB-40.

[b] Over the frequency range 150 kHz to 80 MHz, field strength should be less than [V_1 } V/m.

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