

OPERATOR'S MANUAL

NPB-295 Pulse Oximeter

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

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SAFETY INFORMATION

General Safety Information

GENERAL SAFETY INFORMATION

This section contains important safety information related to general use of the NPB-295 pulse oximeter. Other important safety information appears throughout the manual in sections that relate specifically to the precautionary information. Read all text surrounding all precautionary information.

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

WARNING: Explosion hazard. Do not use the NPB-295 pulse oximeter in the presence of flammable anesthetics or gases.

WARNING: The NPB-295 is a prescription device and is to be operated by qualified personnel only.

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

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

Caution: When connecting the NPB-295 to any instrument, verify proper operation before clinical use. Both the NPB-295 and the instrument connected to it must be connected to a grounded outlet. Accessory equipment connected to the monitor's data interface must be certified according to IEC Standard 950 for data-processing equipment or IEC

Standard 601-1 for electromedical equipment. All combinations of equipment must be in compliance with IEC Standard 601-1-1 systems requirements. Anyone who connects additional equipment to the signal input port or signal output port (NPB-295 data port connector) configures a medical system and is therefore responsible that the system complies with the requirements of system standard IEC Standard 601-1-1 and the electromagnetic compatibility system standard IEC Standard 601-1-2.

To ensure accurate readings, consider the environmental conditions that are present and the condition of the patient. See the appropriate sections of the manual for specific safety information related to these conditions.

INTRODUCTION

Intended Use
General Operating Principles and Conditions

INTENDED USE

The purpose and function of the Nellcor NPB-295 pulse oximeter is to continuously and noninvasively measure functional oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate (measured by an SpO₂ sensor). It is also used to display plethysmographic waveforms. Refer to *Appendix A: Principles of Operation* for a more detailed discussion of oximetry.

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

WARNING: The NPB-295 is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.

GENERAL OPERATING PRINCIPLES AND CONDITIONS

The NPB-295 uses pulse oximetry to measure functional oxygen saturation in the blood. Pulse oximetry works by applying a sensor to a pulsating arteriolar vascular bed, such as a finger or toe. The sensor contains a dual light source and a photodetector.

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 (SpO₂).

Note: For an explanation of functional versus fractional saturation, refer to *Appendix B, Principles of Operation*.

Because a measurement of SpO₂ is dependent upon light from the sensor, excessive ambient light can interfere with this measurement.

Introduction

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

CONTROLS, INDICATORS, AND SYMBOLS

Displays, Controls, Indicators, and Connectors

NPB-295 Symbols

Description of Controls

Description of Displays and Visual Indicators

Description of Audible Indicators

DISPLAYS, CONTROLS, INDICATORS, AND CONNECTORS

Figures 1 and 2 show the front and rear views of the NPB-295 and identify displays, controls, and connectors.

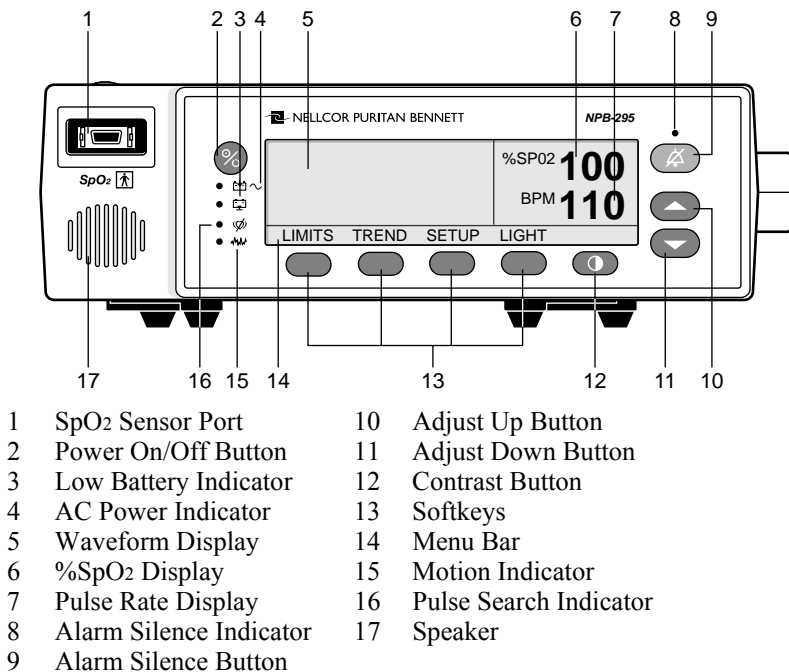
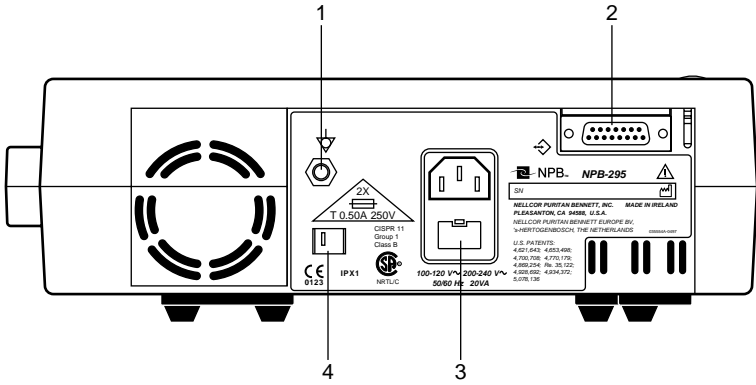








Figure 1: NPB-295 Front Panel Display (Pleth View)



- 1 Equipotential (ground) Terminal
- 2 Data Port Connector
- 3 Fuse Receptacle
- 4 Supply Voltage Selector Switch

Figure 2: NPB-295 Rear Panel

NPB-295 SYMBOLS

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

DESCRIPTION OF CONTROLS

Function Buttons



The Power On/Off Button. Used to turn the NPB-295 monitor on or off.



The Alarm Silence Button. Used to silence current alarms for the alarm silence duration period. When an alarm has been silenced, pressing the button again reactivates, or “unsilences” the alarm. It is also used to view and adjust alarm silence duration and alarm volume.



The Adjust Up Button. Used to increase alarm limit values, alarm silence duration, pulse beep volume, alarm volume, contrast, date and time values, data port baud rate, and to move the cursor to the right (in the trend view).



The Adjust Down Button. Used to decrease alarm limit values, alarm silence duration, pulse beep volume, alarm volume, contrast, date and time values, data port baud rate, and to move the cursor to the left (in the trend view).



The Contrast Button. Used in conjunction with the Adjust Up/Down Buttons to lighten or darken the display screen.



The softkey buttons have multiple uses depending on the label displayed above the button.

DESCRIPTION OF DISPLAYS AND VISUAL INDICATORS

%SP02 100

The %SpO₂ Display. Shows the hemoglobin oxygen saturation level. It flashes during loss-of-pulse alarms and when SpO₂ is outside of the alarm limits. During Pulse Search, the display will alternate between dashed lines and the last oxygen saturation measurement.



The Pulse Amplitude Indicator (blip bar). Indicates pulse beat and shows the relative pulse amplitude. As the detected pulse becomes stronger, more bars light with each pulse. This indicator is available only in the magnified (blip) view.

BPM 86

The digital Pulse Rate Display. Shows the pulse rate in beats per minute. It flashes during loss-of-pulse alarms and when the pulse rate is outside of the alarm limits. During Pulse Search, the display will alternate between dashed lines and the last pulse rate measurement.



The AC Power Indicator. Lights continuously when the NPB-295 is connected to AC power. It also indicates that the battery is charging. It is off when the monitor is being powered by its internal battery.



The Low Battery Indicator. Lights continuously to indicate that 15 or fewer minutes of battery capacity remains.



The Alarm Silence Indicator. Lights continuously when an audible alarm has been silenced. It flashes when the alarm silence duration has been set to OFF and the Alarm Silence Button is pressed.



The Motion Indicator. Lights continuously when the monitor detects motion sufficient enough to affect readings.



The Pulse Search Indicator. Lights continuously prior to initial acquisition of a pulse signal, and during Pulse Search. It flashes during a loss-of-pulse signal.

DESCRIPTION OF AUDIBLE INDICATORS

Following are descriptions of NPB-295 audible indicators.

Power-On Self-Test Pass	A 1-second tone indicating that the NPB-295 has been turned on and successfully completed the power-on self-test
-------------------------	--

Valid Button Press	A short, medium-pitched tone indicating that an appropriate button has been pressed
Invalid Button Press	A short, low-pitched tone indicating that a button has been pressed that is not appropriate for the current state of the monitor
High Priority Alarm	A high-pitched, fast-pulsing tone indicating loss of pulse
Medium Priority Alarm	A medium-pitched, pulsing tone indicating an SpO ₂ or pulse rate limit violation
Low Priority Alarm	A low-pitched, slow-pulsing tone indicating a sensor disconnect, low battery, or monitor failure
Alarm Silence Reminder	Three beeps that sound at least every 3 minutes when alarms are silenced with the alarm silence duration set to OFF
Pulse Beep	A single beep sounds for each detected pulse
Volume Setting Tone	A continuous tone that is used to adjust the alarm volume
Confirmation Tone	Three beeps sound to indicate that default settings have been saved or reset to factory defaults or trend data has been deleted

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SETUP

Unpacking and Inspection
Performance Verification
List of Components
Monitor Setup
Language Selection
Tilt-Stand Supports

UNPACKING AND INSPECTION

Notify the carrier if the shipping carton is damaged. Unpack the NPB-295 and components. If anything is missing or damaged, contact Mallinckrodt's Technical Services Department or your local Mallinckrodt representative.

PERFORMANCE VERIFICATION

Before using the NPB-295 for the first time in a clinical setting, you must verify that the monitor is working properly as described in the Power-on Self-test paragraph of the *Start-up and Use* section. If the monitor does not operate properly, refer to the *Troubleshooting* section. If you cannot resolve the problem, contact qualified service personnel or your local Mallinckrodt representative.

LIST OF COMPONENTS

- 1 Nellcor NPB-295 pulse oximeter
- 1 Hospital-grade power cord
- 1 Nellcor Sensor or ASP-3 assortment pack
- 1 Nellcor pulse oximetry cable, Model MC-10 or SCP-10
- 1 Pair of tilt-stand supports
- 1 Operator's manual
- 2 Fuses, 0.5 Amps, 250 Volts

Optional Accessories

A wall mount plate, as described in the *Sensors and Accessories* section is available from Mallinckrodt for use with this monitor.

MONITOR SETUP

General Warnings

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

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

WARNING: Disconnect the NPB-295 and Nellcor sensor from the patient during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns. The NPB-295 may affect the MRI image; the MRI unit may affect the accuracy of oximetry measurements.

WARNING: To ensure accurate performance and prevent device failure, do not subject the NPB-295 to extreme moisture, such as direct exposure to rain. Such exposure may cause inaccurate performance or device failure.

WARNING: Do not use an NPB-295 monitor, sensor, cable, or connector that appears to be damaged.

WARNING: The NPB-295 is not defibrillator-proof. However, it may remain attached to the patient during defibrillation or while an electrosurgical unit is in use, but the readings may be inaccurate during use and shortly thereafter.

Connecting The NPB-295

The NPB-295 operates on AC power when the hospital-grade power cord is connected to both the monitor and an AC power source (wall outlet).

The supply voltage selector switch allows connection of the monitor to AC power ranging from 100 VAC to 240 VAC. The switch has two positions: one for 100-120 VAC (“115”), and one for 200-240 VAC (“230”). *Ensure that the supply voltage selector switch on the rear panel is set to the proper voltage.*

Operating on a discharged battery

The NPB-295 will not operate when its internal battery is discharged, even when the monitor is connected to AC power. Instead, the error code “EEE 04” will be displayed. This feature prevents the accidental use of the monitor with a dead battery. The monitor is only capable of indicating a loss of AC power if its internal battery is functional.

The battery may discharge during prolonged storage or shipment. If the monitor has been in storage for more than 2 months it is important to plug the monitor into an AC outlet and allow the battery to charge for approximately 30 minutes before attempting to operate the instrument on AC power.

To charge a low battery, connect the monitor to AC power. A full charge of a completely discharged battery takes 14 hours while turned off, or 18 hours during regular use.

If AC power is not available, you may operate the NPB-295 on battery power for a limited amount of time. In that case, skip Steps 2, 3, and 4 below.

1. Place the NPB-295 on a flat surface near the patient. With the optional wall mount plate available from Mallinckrodt, the monitor may be attached to a GCX Poly-mount bracket.
2. Plug the female connector end of the power cord into the rear of the monitor. Use only the hospital-grade power cord provided by Mallinckrodt.

3. Plug the male connector end of the power cord into a properly grounded AC outlet.
4. Verify that the AC Power Indicator is lit. If it is not, ensure that the supply voltage selector switch matches your AC voltage source. If the indicator still does not light, contact qualified service personnel, your local Mallinckrodt representative, or the Mallinckrodt's Technical Services Department.

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

5. Select a Nellcor sensor appropriate for the patient to be monitored (see the *Sensors and Accessories* section of this manual for sensor selection information).

WARNING: Do not use an extension cable with the NPB-295 monitor (other than the MC-10 or SCP-10 sensor cable). Use of another sensor extension cable will have an adverse effect on performance. Do not attach to the sensor port any cable that is intended for computer use.

6. Plug the sensor into the MC-10 or SCP-10 sensor cable, and secure the sensor in place by lowering the plastic sensor lock over the sensor connector until it clicks into place (refer to the MC-10 or SCP-10 directions for use).
7. Plug the MC-10 or SCP-10 cable into the sensor port located on the front of the NPB-295.

LANGUAGE SELECTION

The languages available for display on the screen are English, French, German, Dutch, Portuguese, Spanish, and Italian. The NPB-295 is shipped with the factory default English language displayed.

To select the appropriate language after the unit is powered on, press the SETUP softkey, then the NEXT softkey, then the LANG softkey. Use the Adjust Up and Adjust Down Buttons to

select the desired language. Press the EXIT button to return to the main menu.

Service personnel may set the appropriate language as the power-on default using the procedure described in the NPB-295 service manual.

TILT-STAND SUPPORTS

A pair of tilt-stand supports provide the option of tilting the front of the monitor upward in order to view the display at an angle. When not in use, the supports can be folded flat against the bottom of the monitor.

The supports are attached to the NPB-295 as shown in Figure-3.

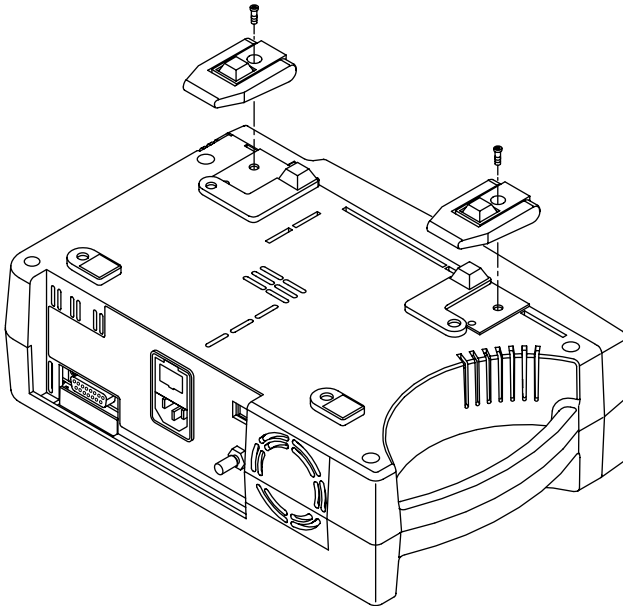


Figure 3: Attaching the Tilt-Stand Supports

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SENSORS AND ACCESSORIES

Selecting a Sensor
Biocompatibility Testing
Performance Considerations
Wall Mount Plate

SELECTING A SENSOR

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

WARNING: Do not use a damaged sensor or sensor cable. Do not use a sensor with exposed optical components.

WARNING: Use only Nellcor sensors and sensor cables with this monitor. Other sensors or sensor cables may cause improper NPB-295 performance.

WARNING: Do not use the NPB-295 or Nellcor sensors during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns. The NPB-295 may affect the MRI image; the MRI unit may affect the accuracy of oximetry measurements.

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

Table 1: Nellcor Sensors

Sensor	Model	Patient Size
<i>Oxisensor</i> [®] II oxygen transducer (sterile, single-use only)	N-25/N-25LF I-20/I-20LF D-20 D-25/D-25L R-15	<3 or >40 kg 3 to 20 kg 10 to 50 kg >30 kg >50 kg
<i>Oxiband</i> [®] oxygen transducer (reusable with disposable nonsterile adhesive)	OXI-A/N OXI-P/I	<3 or >40 kg 3 to 40 kg
<i>Durasensor</i> [®] oxygen transducer (reusable, nonsterile)	DS-100A	>40 kg
Nellcor reflectance oxygen transducer (reusable/nonsterile)	RS-10	>40 kg
<i>Dura-Y</i> [®] multisite oxygen transducer (reusable/nonsterile) For use with Dura-Y sensor: Ear clip (reusable, nonsterile)	D-Y D-YSE	>1 kg >30 kg
<i>Pedi-Check</i> [™] pediatric spot-check clip (reusable, nonsterile)	D-YSPD	3-40 kg
<i>OxiCliq</i> [®] oxygen transducers (sterile, single-use only)	P N I A	10 to 50 kg <3 or >40 kg 3 to 40 kg >30 kg

BIOCOMPATIBILITY TESTING

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

PERFORMANCE CONSIDERATIONS

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

Inaccurate measurements can be caused by:

- incorrect application of the sensor
- placement of the sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line
- ambient light
- excessive patient movement
- venous pulsations
- intravascular dyes, such as indocyanine green or methylene blue
- defibrillation

Other physiological conditions or medical procedures that may interfere with the monitor's measurements include significant levels of dysfunctional hemoglobin, low perfusion, and dark pigment.

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

- the sensor is too tight
- a blood pressure cuff is inflated on the same extremity as the one with the sensor attached
- there is arterial occlusion proximal to the sensor

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

WARNING: Tissue damage can be caused by incorrect application or duration of use of an SpO₂ sensor. Inspect the sensor site as directed in the sensor directions for use.

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 SpO₂ sensor. To prevent interference from ambient light, ensure that the sensor is properly applied, and cover the sensor site with opaque material.

Note: Failure to take this precaution in high ambient light conditions may result in inaccurate measurements.

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

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

If poor perfusion affects performance, consider using the *Oxisensor* R-15 sensor; it obtains measurements from the nasal septal anterior ethmoid artery, an artery supplied by the internal carotid. This sensor may obtain measurements when peripheral perfusion is relatively poor. For low peripheral perfusion, consider using the Nellcor RS-10 sensor, which is applied to the forehead or temple. These are sites that may be spared during peripheral vasoconstriction.

WALL MOUNT PLATE

A wall mount plate is available by contacting Mallinckrodt Technical Services or your local Mallinckrodt representative.

The wall mount plate fits standard, commercially available GCX Poly-mount brackets, and is used to securely mount the monitor to a wall.

The plate attaches to the bottom of the NPB-295 monitor as shown in Figure 4. If the tilt-stand supports are attached, remove them before attaching the mounting plate.

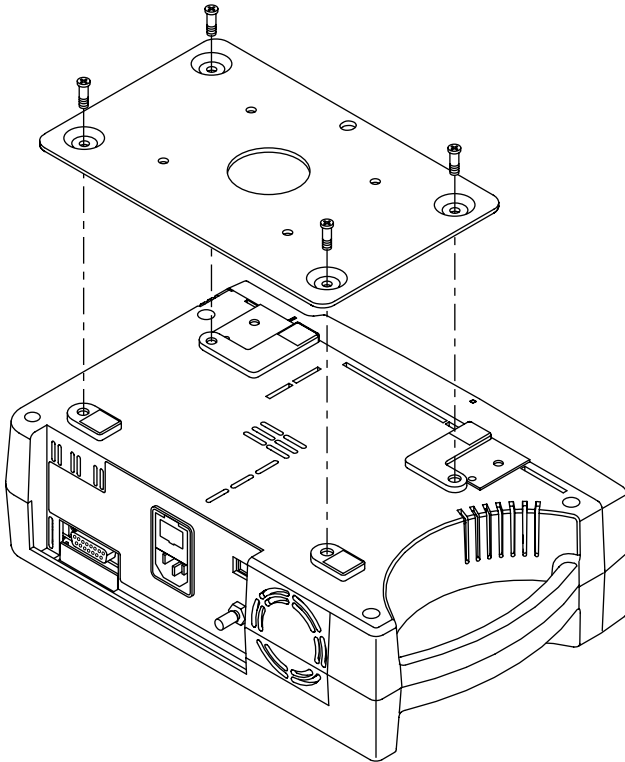


Figure 4: Attaching the Mounting Plate

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START-UP AND USE

Basic Operation
Alarms
Adjustable Settings
Menu
Battery Operation
Disposal of Device Components

BASIC OPERATION

WARNING: The NPB-295 is a prescription device and is to be operated by qualified personnel only.

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

WARNING: The NPB-295 is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.

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

Important! Prior to using the NPB-295, carefully read this manual, accessory directions for use, all precautionary information in boldface type, and all specifications.

Before using the NPB-295 in a clinical setting, you must verify that the monitor is working properly and is safe to use. Proper working condition can be verified by successful completion of the power-on self-test described in the following steps, and by following instructions contained in the “Monitoring Mode” paragraph of this section.

Ensure that the supply voltage selector switch on the rear panel is set to the proper voltage.

Power-On Self-Test (POST)

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

1. Plug an appropriate Nellcor sensor firmly into the MC-10 or SCP-10 and lower the MC-10 or SCP-10 sensor lock over the sensor connector until it clicks into place. Insert the MC-10 or SCP-10 into the NPB-295 sensor port. Apply the sensor to the patient as described in the sensor directions for use.
2. Turn on the NPB-295 by pressing the Power On/Off Button. The monitor automatically starts a power-on self-test (POST), which tests its circuitry.
3. During the POST, the entire display lights and then the Nellcor logo with model number and software version are displayed for approximately 3 seconds. All indicator lights illuminate briefly.

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

4. If the NPB-295 detects an internal problem during POST, an error code or error message may be displayed and a low priority alarm will sound. Depending on the reason for the failure, the screen may be blank or the low priority alarm may not sound. Refer to the *Troubleshooting* section for a list of correctable error messages.
5. Upon successful completion of the POST, the NPB-295 sounds a 1-second tone indicating that the monitor has passed the test.

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

6. If a sensor is connected to the monitor and the patient, the Pulse Search Indicator lights and the NPB-295 displays zeroes in the %SpO₂ and Pulse Rate Displays while it searches for a valid pulse. If a sensor is not attached to the monitor, dashes are displayed and the Pulse Search Indicator is not lit.

When a valid pulse is detected, the NPB-295 enters Monitoring Mode and a display similar to the one indicated in either Figure 5 or Figure 6 is displayed.

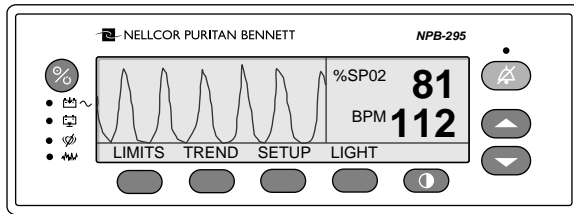


Figure 5: Monitoring Mode Display - Pleth View

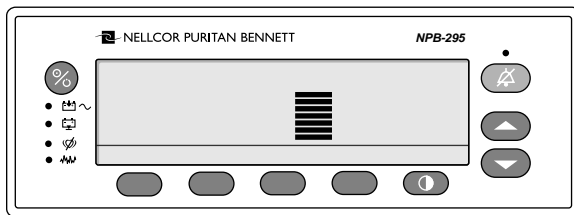


Figure 6: Monitoring Mode Display - Magnified View

Contrast

To adjust the screen contrast, press and hold the Contrast Button. Press the Adjust Up or Adjust Down Button to increase or decrease the contrast. Continue to press and hold the buttons to adjust the value at a faster rate.

Monitoring Mode

In Monitoring Mode - Pleth View (Figure 5), the NPB-295 displays SpO₂ readings, pulse rate readings, and a pleth waveform. In the Monitoring Mode - Magnified (blip) View (Figure 6), the Pulse Amplitude Indicator and a larger %SpO₂ and pulse rate reading are displayed. The pleth waveform is not displayed. How to select one of the two views by using the softkeys will be discussed later in this section.

%SpO₂ is displayed for values between 0% and 100%. Pulse rates are displayed for values from 20 to 250 beats per minute and zero beats per minute. Pulse rates below 20 (except zero) will be displayed as 20, and pulse rates above 250 will be displayed as 250. A pulse rate of zero is used to indicate that the monitor is not monitoring a pulse.

A variable-pitch beep sounds once for each pulse, and the Pulse Amplitude Indicator (in the Magnified View) visually displays relative pulse strength at the sensor site. The pitch of the beep decreases as %SpO₂ decreases.

Note: Verify that indicators, display information, and audible sounds including alarms are operational, indicating that the monitor is functioning. Each valid button push should generate an appropriate audible or visual action. Observe movement of the Pulse Amplitude Indicator or pleth waveform, and listen for pulse beeps to verify that measurements are being made.

If any action does not seem appropriate, do not use the monitor. Instead, contact Mallinckrodt's Technical Services Department or your local Mallinckrodt representative.

In Monitoring Mode, if the acquired pulse is lost, the monitor enters Pulse Search Mode.

Pulse Search

If the acquired pulse is lost during monitoring, the NPB-295 enters Pulse Search. During Pulse Search, the monitor attempts to detect a pulse from which to take a measurement.

Note: Pulse Search is a normal function of the monitor, and entering this mode does not *necessarily* mean that the patient has no pulse.

At Initial Power-Up (*Sensor Attached to Monitor*)

Immediately after POST is completed and the NPB-295 displays its software version number, the monitor enters Pulse Search Mode and the Pulse Search Indicator lights. If an attached sensor is not connected to a patient, the display reads zeroes and the monitor remains in the Pulse Search Mode. If the sensor is connected to the patient, the NPB-295 enters the Monitoring Mode when a pulse is detected.

At Initial Power-Up (*No Sensor Attached to Monitor*)

Immediately after POST is completed and the NPB-295 displays its software version number, the monitor displays dashes. It does not enter the Pulse Search Mode.

After Taking Measurements

If a pulse was previously acquired and then lost, the NPB-295 enters Pulse Search, and the Pulse Search indicator lights. The display flashes the last detected readings while the monitor searches for a valid pulse. When the monitor considers the pulse “lost,” it displays flashing zeroes and a high priority alarm sounds.

When a valid pulse is detected, the NPB-295 exits the Pulse Search Mode and displays the current readings. The Pulse Search indicator goes out.

Refer to the “Management of the Loss-of-Pulse Alarm” paragraph later in this section for a detailed description of Pulse Search, motion, and the loss-of-pulse alarm.

Automatic Shutdown

When all of the following conditions are present for 15 minutes, the NPB-295 automatically shuts down:

- Running on battery power
- No buttons have been pressed
- No pulse has been detected (for example, when no patient is connected to the sensor or the sensor is disconnected)
- No alarms are present (other than low battery or a non-correctable error)

ALARMS

Description of Alarms

The NPB-295 has three levels of audible alarms.

1. *High-priority alarm:* Indicated by a fast-rate, high-pitched, pulsing tone. A high-priority alarm sounds after loss-of-pulse is detected.

Refer to the “Management of the Loss-of-Pulse Alarm” paragraph in this section for a detailed description of the loss-of-pulse alarm.

2. *Medium-priority alarm:* Indicated by a medium-rate, medium-pitched, pulsing tone. A medium-priority alarm sounds when any measured patient parameter moves outside the set alarm limits.

During a medium-priority alarm, the display flashes with the patient parameter that violated the limit (%SpO₂ or Pulse Rate).

3. *Low-priority alarm:* Indicated by a slow, low-pitched, pulsing tone. A low-priority alarm sounds during the following conditions:
 - low battery (while operating on battery power)
 - when an SpO₂ cable has been disconnected
 - monitor failure

- 50 seconds after loss of pulse is detected in the presence of continuous motion

When operating on DC power, during a low battery condition, the Low Battery Indicator illuminates and the alarm tone sounds immediately, even if the alarms are silenced or set to OFF.

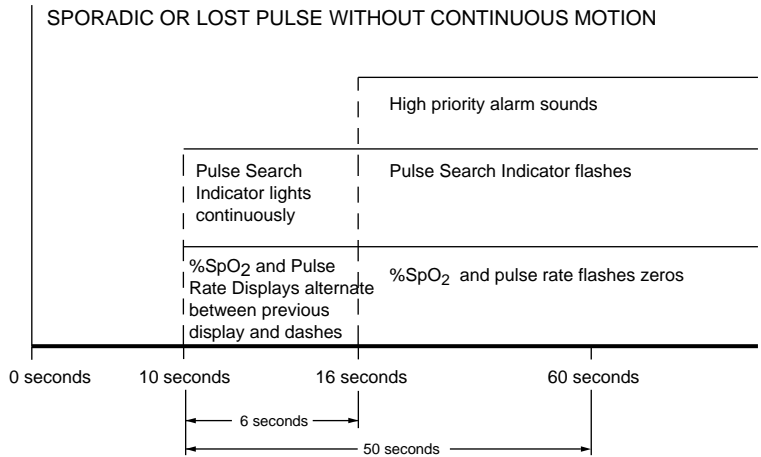
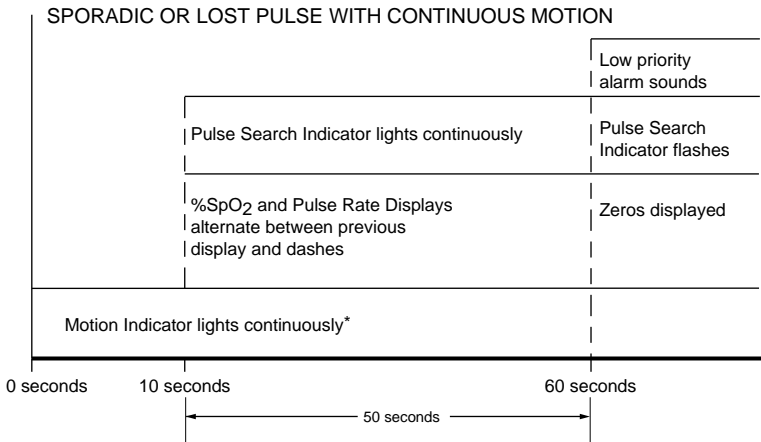
Management of Loss-of-Pulse Alarm

The NPB-295 signal processing is designed to reduce the adverse effects of normal interference associated with motion, low patient perfusion, and spurious electrical or optical signals. Figure 7 illustrates monitor response in sporadic or lost pulse situations with and without continuous motion.

Losing the pulse presents an alarm-management challenge for any oximeter—sometimes it is caused by a clinical emergency, sometimes by signal distortion. When the pulse is lost because of deteriorating patient condition, the oximeter should alarm quickly. However, normal interference can obscure the pulsatile signal. If interference is short-lived, no alarm will sound. Such alarms are distracting and potentially time-consuming. However, if interference persists, an alarm should notify the attendant.

The NPB-295 loss-of-pulse alarm is designed for use in environments in which the pulse can be obscured by interference. Most loss-of-pulse alarms are attributable to interference from patient motion, which typically is brief.

When the pulsatile signal is lost, the NPB-295's ability to identify interference from motion becomes particularly important because the response of the monitor is determined by the presence or absence of interference from patient motion. Because a spontaneously moving patient can be assumed to have a pulse, as long as continuous motion is detected, the NPB-295 continues to search for the pulse.



*If during motion the NPB-295 detects a qualified pulse, the values on the display are updated.

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

Figure 7: Monitoring Conditions and Alarm Responses

The NPB-295 manages loss-of-pulse alarms as follows, and as illustrated in Figure 7. If the NPB-295 fails to detect at least one qualified pulse during any 10-second period, it enters pulse search, the Pulse Search Indicator lights, the displays alternate between data and dashes, and the data evaluation period starts.

During that data evaluation period:

- If the patient is *not* moving (for example, because of cardiac arrest, shock, paralysis, anesthesia) and has no qualified pulse for 6 seconds, a high-priority alarm immediately sounds, the Pulse Search Indicator flashes, and the data displays flash zeroes.
- If the patient *is* constantly moving, the NPB-295 searches for qualified pulses for up to 50 seconds. Each time a qualified pulse is detected, even during motion, the data displays are updated.

The NPB-295 returns to normal operation as soon as it detects one of the following: three consecutive qualified pulses (when there is no motion), five consecutive qualified pulses (when there *is* motion), or a total of 10 qualified pulses. Otherwise, at the end of the data evaluation period, the data displays flash zeroes and, if motion is still present, a low-priority alarm sounds; if there is no motion, a high-priority alarm sounds.

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

NPB-295 alarm management can therefore be considered a three-tier system:

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

ADJUSTABLE SETTINGS

The following adjustments can be made using the Adjust Up/Down and Alarm Silence Buttons.

- Pulse beep volume
- Alarm volume
- Alarm silence duration
- Disabling audible alarms

Pulse Beep Volume

To adjust the pulse beep volume during normal monitoring, press and hold the Adjust Up or Adjust Down Button to change the setting. Pressing and holding the Adjust Down Button will cause the volume to decrease until it is no longer heard.

Alarm Volume

To *view* the current volume of the audible alarm, press and hold the Alarm Silence Button for more than 3 seconds. The current volume level is indicated in the Pulse Rate Display as a value from 1 (lowest) to 10 (highest). A tone at the displayed level sounds.

To *adjust* the volume, press and hold the Alarm Silence Button for more than 3 seconds, then press the Adjust Up or Adjust Down Button to change the setting. The volume cannot be set to zero.

Alarm Silence Duration

Alarms can be silenced for a preset period called the *audible alarm silence duration*. To view the current setting, press and hold the Alarm Silence Button for less than 3 seconds. To adjust the setting, press and hold the Alarm Silence Button (for less than 3 seconds) and use the Adjust Up or Adjust Down Buttons to increase or decrease the value. Possible values are 30, 60, 90, or 120 seconds, or OFF. (The OFF selection is discussed later in this section.)

The audible alarm silence duration begins when the Alarm Silence Button is pressed (for less than 3 seconds) and released.

(If the button is pressed for more than 3 seconds or the duration is changed, the Alarm Silence Button must be pressed again to start the alarm silence duration.)

Subsequently, if any alarm condition (other than a low battery alarm) occurs while the alarm is silenced, the alarm will not sound until the alarm silence duration is ended. Operating on battery power during a low battery alarm condition will cause an alarm to sound, even if the duration time has not elapsed.

If the Alarm Silence Button is pressed during the alarm silence duration, the alarm silence duration is ended and the audible alarms are re-enabled.

Visual indications of an alarm condition cannot be turned off. For example, if the %SpO₂ upper alarm limit is exceeded, the alarm can be silenced for the alarm silence duration, but the %SpO₂ value will continue to flash.

If the alarm condition is still present when the alarm silence duration has elapsed, the alarm will sound.

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

Disabling Audible Alarms

Setting the alarm silence duration to OFF means that no audible alarms will be produced by the monitor.

To set the alarm silence duration to OFF, press and hold the Alarm Silence Button for less than 3 seconds and use the Adjust Up Button to increase the current setting until “OFF” is displayed. The next time the Alarm Silence Button is pressed, the Alarm Silence Indicator flashes, indicating that audible alarms have been disabled. If the Alarm Silence Button is pressed again, the Alarm Silence Indicator stops flashing.

Visual indications of an alarm condition are not affected by disabling the audible alarms.

The ability to set the alarm silence duration to OFF can be enabled or disabled by qualified service personnel as described in the service manual.

The factory default is that the capability of setting the alarm silence duration to OFF is enabled.

Alarm Silence Reminder

The alarm silence reminder (three beeps) will sound at least every 3 minutes while the alarm silence duration is set to OFF and the Alarm Silence Indicator is flashing.

The alarm silence reminder may also be disabled by service personnel using the procedures described in the service manual. The factory default is that the reminder is enabled.

MENU

Menu Structure

The four softkeys on the front panel are used to view or adjust the following NPB-295 settings or functions:

- %SpO₂ and pulse rate alarm limits
- Pleth or magnified view
- Time and date settings
- Data port baud rate settings
- Trend data viewed (%SpO₂, pulse, or both)
- “Zoom” factor of trend data
- Graph of trend data (histogram)
- Delete all trend data
- Print trends
- Language displayed on screen or data port
- Nurse call settings
- Analog output settings

Menu items are selected by pressing and releasing the corresponding softkey directly below the item. Refer to Figure 8 to access menu items.

Note: If, after accessing a submenu, no buttons are pressed for 10 seconds, the display will timeout and return to the main menu. Exceptions to this are the clock and trend

menus, which will timeout in 5 minutes and the analog port calibration menu, which times out in 2 minutes.

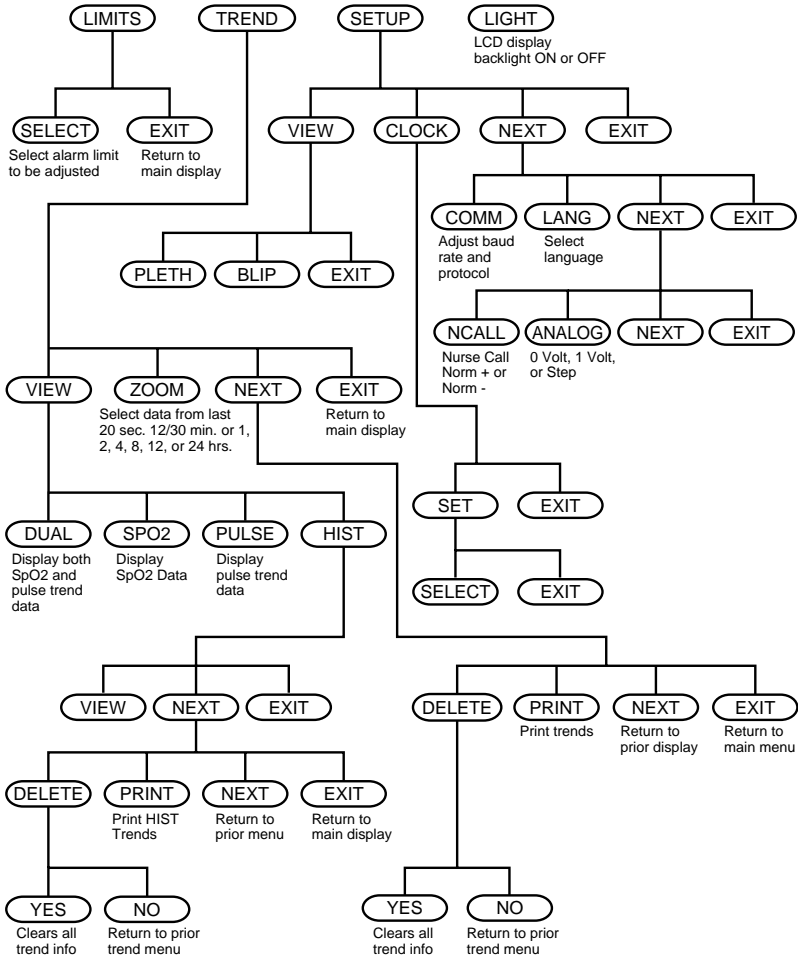


Figure 8: Menu Items

A description of each menu item is included in the following paragraphs.

LIMITS

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

Overview

When the NPB-295 is first turned on, alarm limits are set to their power-on default values. Power-on default alarm limits can be changed by qualified service personnel, using the instructions described in the NPB-295 service manual.

You can temporarily change alarm limits from their power-on default values if necessary, as described below. Changes you make will remain in effect until you change them again, or until you turn off the NPB-295.

Viewing Current Alarm Limits

To view the current alarm limit values from the main menu, press the LIMITS softkey. The current upper and lower alarm limits for %SpO₂ and pulse rate are displayed.

Changing Alarm Limits

Use the SELECT softkey to select the parameter whose value you want to change. Use the Adjust Up/Down Buttons to change the settings. The setting takes effect immediately and remains in effect when the alarm setting menu is exited.

Alarm Limits Changed Indicator

If alarm limits are changed from the NPB-295's power-on defaults, a decimal point appears after the displayed value and in the %SpO₂ and Pulse Rate Display as illustrated in Figure-9. The decimal point remains on the display until the NPB-295 is turned off or the limit is returned to its default value.

ALARM LIMITS		%SP02	96.
%SPO2	BPM		
UPPER	100	BPM	79
LOWER	80.	40	
SELECT		EXIT	

Figure 9: Alarm Limits Selection

TREND

The NPB-295 can graphically display trends for SpO₂, pulse rate. The NPB-295 can store up to 24 hours of trend data. The 24 hours of stored trend data is available for downloading to Score™ software for 45 days. There are no limitations for displaying or printing data.

Trend data is stored at 2-second intervals. When the TREND softkey is pressed, “READING TRENDS . . .” is displayed at the bottom of the screen, indicating that the monitor is collecting the trend data.

The amount of trend data displayed on the screen is determined using the ZOOM softkey. Settings available are 20 seconds, 12 or 30 minutes, and 1, 2, 4, 8, 12, and 24 hours. All data is displayed in a graph format except the 20-second setting, which is shown in tabular format.

When the trends are displayed, the most recent readings are on the right side of the graph. The graph indicates the highest and lowest parameter values during the period of time represented by the width of the cursor (vertical dotted line).

The highest and lowest values of the parameter at the cursor are indicated on the left side of the screen (“95” and “98” in Figure 10). These values are *not* the current patient readings but represent the highest/lowest trend values at the cursor.

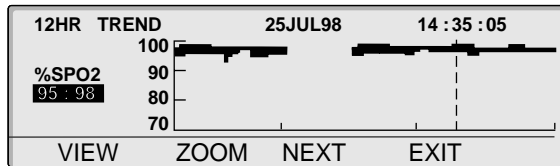


Figure 10: SpO2 Trend

Periods of time when no measurements were acquired are indicated by blank spaces in the graph as shown in Figure 10.

The number of trend hours or minutes currently displayed on the screen is indicated in the upper left corner. The location of the cursor is indicated by the date and time on the top middle and right of the screen.

The cursor is moved right or left by using the Adjust Up/Down Buttons. Each press of the button causes the cursor to move a certain period of time depending on the trend scale, as indicated in Table 2.

Table 2: Trend Scale

Trend Scale	Amount of Time Represented by One Press of the Adjust Up/Down Button
20 seconds	2 seconds
12 minutes	4 seconds
30 minutes	10 seconds
1 hour	20 seconds
2 hours	40 seconds
4 hours	1 minute, 20 seconds
8 hours	2 minutes, 40 seconds
12 hours	4 minutes
24 hours	8 minutes

Scrolling past the limits of the right or left edges of the screen causes the viewing area to jump, relocating the cursor to the middle of the screen if enough trend data is available.

For example, suppose the time represented by the right-hand edge of the screen in Figure 10 is 14:54:05. Scrolling one time period to the right (4 minutes) results in the cursor relocating to the center of the screen at the time period 14:58:05, with 6 hours of data on both sides of the cursor. If no data was available to the right of the screen, an invalid tone would sound. If only 3 hours of data was to the right of the screen, the cursor would relocate to approximately 3/4 of the way to the right of the screen, at the time period 14:58:05.

Note: The screen will return to the monitoring mode if an alarm sounds, the Alarm Silence Button is pressed or a trend or histogram has been displayed for 5 minutes with no button presses.

View

Pressing the VIEW softkey allows you to select the %SpO₂ or pulse rate trend or both (DUAL). You can also select the histogram view as illustrated in Figure 11.

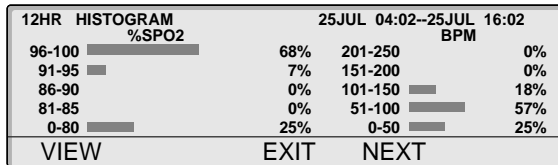


Figure 11: Histogram

Histogram

The histogram graphically illustrates the percentage of time a given range of values has been measured. The period of time covered is given in the upper left corner of the display. Only points with data are included in the histogram.

For example, in Figure 11, the histogram is for the last 12 hours. During those 12 hours, 68% of the %SpO₂ measurements were from 96 to 100, 7% of the measurements were from 91 to 95, and 25% of the measurements were from 0 to 80.

Zoom

Pressing the ZOOM softkey changes the period of time indicated on a trend graph. Selectable times displayed graphically are 24, 12, 8, 4, 2, or 1 hours, and 30 or 12 minutes. The location of the cursor, as indicated by the time in the upper right-hand corner of the screen, remains the same.

A table is used to display 20-second trends.

The ZOOM softkey is not displayed for the histogram trend view.

20-second trends table

The 20-second trends table is available by continuing to press the ZOOM softkey. As indicated in Figure 12, the time indicated on trend graphs by the cursor is displayed in the upper right-hand corner of the screen and is highlighted in the table. Press the Down Arrow button to highlight the time of the trends readings. The readings are in 2-second increments and go back in time as the Down Arrow button is pressed and forward in time as the Up Arrow button is pressed.

20SEC TREND		28JUL98		21:31:48			
TIME	%SPO2	BPM	TIME	%SPO2	BPM		
21:31:38	96	78	21:31:48	97	78		
21:31:36	97	79	21:31:46	97	79		
21:31:34	97	78	21:31:44	97	80		
21:31:32	97	78	21:31:42	96	78		
21:31:30	97	78	21:31:40	96	78		
VIEW		ZOOM		NEXT		EXIT	

Figure 12: 20-Second Trends

When the oldest reading on the screen is highlighted and the Down Arrow button is pressed again, the screen shifts to display an older column of readings. Similarly, if the newest reading on the screen is highlighted and the Up Arrow button is pressed, the screen shifts to display a newer column of readings.

Next

The NEXT softkey gives you access to the DELETE and PRINT softkeys.

Delete

Pressing the DELETE softkey presents two options: YES or NO. YES deletes all trend information from the NPB-295 memory and the display. NO returns you to the previous menu.

Print

Note: The protocol setting must be set to ASCII MODE or GRAPH MODE to transmit text or graphical data. Check this setting using the COMM softkey as indicated in the following paragraphs.

ASCII MODE: Pressing the PRINT softkey begins the transmission of data via the data port to a connected PC or serial printer.

GRAPH MODE: The graph mode disables all printouts except for trend printouts. Pressing the PRINT softkey from the trend menu will print graphical printout of the displayed graphical trend data.

Refer to Appendix C of this manual for more information concerning the data port.

SETUP

The SETUP softkey allows you to select or view the following settings:

- view displayed on the screen (PLETH or BLIP)
- time and date
- data port baud rate and protocol
- language displayed on the screen
- data port nurse call normally high or normally low setting

- data port analog voltage.

Press the SETUP softkey once to display VIEW and CLOCK. Then press NEXT to display COMM and LANG. Press NEXT again to display NCALL and ANALOG.

VIEW

The VIEW softkey allows you to select the view displayed on the screen, PLETH or BLIP (magnified). The pleth view displays the pleth waveform. The BLIP view displays the Pulse Amplitude Indicator and larger numerical values for easier viewing.

CLOCK

The CLOCK softkey allows you to set the time and date.

Press the SET softkey to access the SELECT softkey. Use the SELECT softkey to select the item you wish to change. Use the Adjust Up/Down Buttons to adjust the setting. The date is expressed as DD-MMM-YY. For example, November 29, 1998, would be expressed as 29 - NOV - 98.

Note: The NPB-295 will timeout in 5 minutes when the SET and EXIT softkeys are displayed. However, it will timeout in 10 seconds after the SET button is pressed if there are no further button presses.

Press the EXIT button to accept the new settings. Press EXIT again to return to the previous menu.

COMM

Press the NEXT softkey to access the COMM softkey. The COMM softkey allows you to select the baud rate and the protocol of the data port.

After pressing the COMM softkey, use the Adjust Up/Down Buttons to select a baud rate of 2400, 9600, or 19200. Press Exit to return to the SETUP submenu.

Press the SELECT softkey to highlight the protocol setting. Use the Adjust Up/Down Buttons to select the desired setting. ASCII is used during normal operation and for serial printers. GRAPH is used to print copies of the NPB-295 trend displays when you

have an ESC/P compatible graphical serial printer is attached to the NPB-295 serial port. Select OXINET if you are connecting to an Oxinet® II central station network or Score™ software. Do not use the CLINICAL setting unless instructed to do so by Mallinckrodt customer service personnel. Press Exit to return to the SETUP submenu.

Note: When using Score™ software use the latest version. Contact Mallinckrodt's Technical Services Department or your local Mallinckrodt representative to determine the latest version of Score software.

LANG

The LANG softkey allows you to select the language displayed on the screen.

Press the NEXT softkey to access the LANG softkey. After pressing the LANG softkey, use the Adjust Up/Down Buttons to select Dutch, English, French, German, Italian, Portuguese, or Spanish.

If the language is changed and EXIT is pressed, (or a 10-second timeout occurs), the monitor begins displaying data in the selected language.

NCALL

The NCALL softkey allows you to set the alarm voltage at a normally high (NORM +) or normally low (NORM -). Refer to the "Nurse Call" heading of *Appendix C: Data Port Protocol* for a more thorough explanation of these settings. The nurse call feature is also discussed later in this section.

ANALOG

The ANALOG softkey allows you to calibrate the NPB-295 data port voltages with instruments such as a chart recorder. Refer to the "Analog Outputs" heading of *Appendix C: Data Port Protocol* for a more thorough explanation of these settings.

LIGHT

The LIGHT softkey allows you to turn the backlight on or off.

Default Settings

The NPB-295 is shipped with factory default settings. Default settings can be changed by authorized technical personnel using the procedures described in the NPB-295 service manual.

The factory default settings are as follows:

%SpO2 Upper Alarm Limit:	100%
%SpO2 Lower Alarm Limit:	85%
Pulse Rate Upper Alarm Limit:	170 beats per minute
Pulse Rate Lower Alarm Limit:	40 beats per minute
Alarm Volume:	75 dB(A) peak at 1 meter (volume setting of 5)
Alarm Silence Duration:	60 seconds
Alarm Silence Duration OFF Setting:	Enabled
Alarm Silence Reminder:	Enabled
Pulse Beep Volume:	72 dB(A) at 1 meter (volume setting of 4)
Data Port Baud Rate:	9600
Data Port Protocol:	ASCII
Display Format:	Pleth
Trend Display:	%SpO2
Display Contrast:	Midrange
Language:	English
Nurse Call Polarity:	Normally Low

Nurse Call Feature

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

The nurse call feature of the NPB-295 works in conjunction with the nurse call system of your institution when the monitor sounds an audible alarm. It is accessed through the data port (pins 7, 8, 10, 11, or 15, as indicated in Table 5 in Appendix C).

WARNING: The nurse call feature is not functional whenever the monitor alarms are silenced.

The nurse call feature is available when the NPB-295 is operated on AC power and the monitor has been electronically connected to the hospital's nurse call system. Depending on the method of installation used by the service technicians in your institution, it *may* be available when the monitor is running on its internal battery. Qualified service personnel may refer to the NPB-295 service manual for complete connection instructions.

Prior to using the monitor in a clinical setting, test the nurse call feature by creating an alarm condition, then verifying that the hospital's nurse call system is activated.

BATTERY OPERATION

The NPB-295 has an internal battery that may be used to power the monitor during transport or when AC power is not available. A new, fully charged battery will provide at least 8 hours of monitoring time under the following conditions: no audible alarms, no analog or serial output devices attached, and no backlight.

Note: Whenever the monitor is connected to AC power, the battery is being charged. Therefore, it is recommended that the monitor remain connected to AC power when not in use. This will make available a fully charged battery for use at any time.

Since the monitor cannot operate with a fully discharged battery, before attempting to turn on an NPB-295 whose battery charge has been depleted, first plug the monitor into an AC outlet to allow the battery to charge for a few minutes. The monitor may then be powered on.

To charge a dead battery, connect the monitor to AC power. A full charge takes 14 hours while turned off, or 18 hours during regular use.

When all of the following conditions are present for 15 minutes, the NPB-295 will automatically shutdown:

- Running on battery power
- No buttons have been pressed
- No pulse has been detected (for example, when no patient is connected to the sensor or the sensor is disconnected)
- No alarms are present (other than low battery or a non-correctable error)

Low Battery Indicator

The Low Battery Indicator lights and a low priority alarm begins to sound when approximately 15 minutes of monitoring time is available on the existing battery charge. This alarm cannot be silenced while running on battery power. Connect to AC power to silence the alarm.

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

If the monitor is not connected to AC power within approximately 15 minutes, it will shut down.

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

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

It is recommended that the internal battery be replaced by qualified service personnel every 24 months.

Caution: If the NPB-295 is to be stored for a period of 2 months or longer, notify service personnel to remove the battery from the monitor prior to storage. Recharge the battery when it has not been charged for 2 or more months.

DISPOSAL OF DEVICE COMPONENTS

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

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TROUBLESHOOTING AND MAINTENANCE

Troubleshooting
EMI Interference
Obtaining Technical Assistance
Returning the NPB-295
Maintenance

TROUBLESHOOTING

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

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

Error Codes

When the NPB-295 detects an error condition, it may display the letters "EEE" followed by an error code.

When an error code (other than the ones listed in Table 3) is displayed, turn the instrument off and back on again. If the error code reappears, record it and notify service personnel.

Error messages will be displayed along with the error codes listed in Table 3. If the error codes are encountered, perform the prescribed action as indicated in the table.

Table 3: Error Codes and Messages

Error Code	Error Message	Action
4	LOW BATTERY	The battery is discharged to a critically low level. Check to ensure that the voltage selector switch is set to the proper voltage. Turn the monitor off and let it charge for about 10 minutes and then turn the unit back on. If the error code is still present, turn the unit off and let it continue to charge. If the monitor has been charged for 30 minutes and the error code is still present, notify service personnel.
80	DEFAULTS LOST	The current power-on default settings have been lost and returned to factory defaults. Qualified service personnel can use the service manual to restore the desired power-on default settings.
81	SETTINGS LOST	The current settings (for example, alarm limits, alarm and pulse beep volumes, alarm silence duration) have been lost and returned to power-on defaults. Turn the monitor off and back on again. If it is necessary to have settings different from the power-on default settings, turn the monitor off and back on again, and reenter the desired settings.
82	CLOCK SETTING LOST	The date and time settings have been lost. Reenter the date and time.

Other Messages

In addition to the messages listed in Table 3, the following messages may be encountered:

SENSOR DISCONNECTED - The sensor has disconnected from the cable or the cable has disconnected from the monitor. Press the Alarm Silence Button to silence the alarm. Check the connections. If this does not correct the problem, replace the sensor and/or cable.

DISALLOWED ON BATTERY - An attempt to print or download data port information while operating on battery power has been made. Connect to AC power and retry.

DISALLOWED ON LOW BATTERY - An attempt to turn on the backlight has been made while in a low battery condition. If the backlight is turned off during a low battery condition, it cannot be turned back on.

READING TRENDS - The monitor is gathering trend information for display.

INVALID SILENCE DURATION - An attempt has been made to set the alarm silence duration power-on default to "OFF". The power-on default cannot be set to "OFF".

INVALID SPO2 LIMIT - An attempt has been made to set either the upper or lower alarm limit power-on default below 80. The power-on default cannot be set below 80.

Suggested Corrective Actions

If you experience a problem while using the NPB-295 and are unable to correct it, contact qualified service personnel or your local Mallinckrodt representative. The NPB-295 service manual, which is for use by qualified service personnel, provides additional troubleshooting information.

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

1. There is no response to the Power On/Off Button.

- If operating on AC power, ensure that the supply voltage selector switch is set to the proper voltage.
- If operating on AC power, the fuse may be blown. Notify service personnel to check and, if necessary, replace the fuse.
- If operating on battery power, the battery may be missing or discharged. If the battery is discharged, notify service personnel to charge or replace the battery.

- 2. One or more display elements or indicators do not light during the power-on self-test.**
 - Do *not* use the NPB-295; contact qualified service personnel or your local Mallinckrodt representative.
- 3. The monitor is operating on battery power, even though it is connected to AC.**
 - Ensure that the supply voltage selector switch is set to the proper voltage.
 - Make sure that the power cord is properly connected to the NPB-295.
 - Check to see if power is available to other equipment on the same AC circuit.
- 4. The Pulse Search Indicator is lit for more than 10-seconds (before any measurements are taken).**
 - 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 someone else. Try another sensor or extension cable.
 - Perfusion may be too low for the NPB-295 to track the pulse. Check the patient. Test the instrument on someone else. Change the sensor site. Try another type of sensor.
 - Excessive patient motion may be preventing the NPB-295 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. Use a type of sensor that tolerates more patient movement, for example, an adhesive sensor.
 - 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-295 from tracking the pulse. Remove the source of interference or try to stabilize the environment, or do both.

5. The Pulse Search Indicator lights *after* successful measurements have been made.

- *Check the patient.*
- Perfusion may be too low for the NPB-295 to track the pulse. Test the instrument on someone else. Change the sensor site. Try another type of sensor.
- Excessive patient motion may be preventing the NPB-295 from tracking the pulse. Verify that the sensor is securely applied and replace it if necessary. Change the sensor site. Use a type of sensor that tolerates more patient movement, for example, an adhesive sensor.
- 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-295 from tracking the pulse. Remove the source of interference or try to stabilize the environment, or do both.

Other physiological conditions or medical procedures that may interfere with the monitor's measurements include dysfunctional hemoglobin, arterial dyes, low perfusion, and dark pigment.

EMI INTERFERENCE

Caution: This device has been tested and found to comply with the limits for medical devices to the IEC 601-1-2:1993, EN60601-1-2:1994, 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 healthcare environments (for example, electrosurgical

units, cellular phones, mobile two-way radios, electrical appliances), 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-295 is designed for use in environments in which the pulse can be obscured by electromagnetic interference. During such interference, measurements may seem inappropriate or the monitor may not seem to operate correctly.

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

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

The NPB-295 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 Mallinckrodt's Technical Services Department or your local Mallinckrodt representative.

OBTAINING TECHNICAL ASSISTANCE

For technical information and assistance, or to order parts or a service manual, contact Mallinckrodt's Technical Services Department or your local Mallinckrodt representative. The service manual includes block diagrams and a parts list required by qualified personnel when servicing the NPB-295.

When calling Mallinckrodt's Technical Services Department or your local Mallinckrodt representative, you may be asked to tell the representative the software version number of your NPB-295.

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

RETURNING THE NPB-295

Contact Mallinckrodt's Technical Services Department or your local Mallinckrodt representative for shipping instructions including a Returned Goods Authorization number. It is not necessary to return the sensor. Pack the NPB-295 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-295 by any shipping method that provides proof of delivery.

MAINTENANCE

Service

The NPB-295 requires no calibration.

The battery should be replaced at least every 24 months. Refer to the NPB-295 service manual for the battery changing procedure.

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

Performance Verification

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

Cleaning

WARNING: Do not spray, pour, or spill any liquid on the NPB-295, its accessories, connectors, switches, or openings in the chassis.

To clean the NPB-295, dampen a cloth with a commercial, nonabrasive cleaner or a solution of 70% isopropanol in water, and lightly wipe the surfaces of the monitor. Do not spray or pour liquid on the instrument or accessories.

The NPB-295 may be disinfected using a soft cloth saturated with one of the following solutions:

- 10% chlorine bleach in tap water
- Glutaraldehyde (cidex or equivalent)

Before attempting to clean an SpO₂ sensor, read the directions for use enclosed with the sensor. Each sensor model has cleaning instructions specific to that sensor.

SPECIFICATIONS

Performance
Electrical
Environmental Conditions
Physical Characteristics

PERFORMANCE

Measurement Range

SpO₂

0–100%

Pulse Rate

20–250 beats per minute (bpm)

Accuracy

SpO₂

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

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

Specifications

Pulse Rate

20–250 bpm ± 3 bpm

Note: Pulse Rate accuracy is expressed as ± 3 bpm across the display range. This variation equals \pm one standard deviation (1SD), which encompasses 68% of the population.

Pulse Rate Display Update Frequency

The Pulse Rate Display updates in less than 2.5-seconds with a one-second change in SpO₂-derived pulse rate from 30 pulses per minute (ppm) to 200 ppm.

Radiated Immunity

The NPB-295 is immune to radiated radio-frequency electromagnetic fields of up to 3 volts per meter from 80 MHz to 1 GHz.

Conducted Immunity

The NPB-295 is immune to conducted radio-frequency electromagnetic energy of up to 3 volts from 150 kHz to 80 MHz.

ELECTRICAL

Instrument

Power Requirements

100 - 120 VAC, 200 -240 VAC, 50/60 Hz, 20 VA

Patient Isolation

Type BF

Battery

Type

Lead-Acid

Battery Capacity

A minimum of 8 hours with a new, fully charged battery under the following conditions: no alarms, no analog or serial output devices attached, and no backlight. A completely discharged battery can be fully recharged in approximately 14 hours while turned off or 18 hours while turned on.

Charge/discharge cycles: at least 400

ENVIRONMENTAL CONDITIONS

Transport and Storage (in shipping container)

Temperature

-20°C to 70°C (-4°F to +158°F)

Altitude/Barometric Pressure

-457 m to 4,573 m (-1280 ft. to 15,000 ft.)
1060 hPa to 500 hPa (31.3 in. Hg to +14 in. Hg)

Relative Humidity

15-95% noncondensing

Transport and Storage (not in shipping container)

Temperature

-20°C to +60°C (-4°F to +140°F)

Altitude/Barometric Pressure

-457 m to 4,573 m (-1280 ft. to 15,000 ft.)
1060 hPa to 500 hPa (31.3 in. Hg to +14 in. Hg)

Relative Humidity

15-95% noncondensing over temperature range of -20°C to 60°C
(-4°F to +140°F)

Specifications

Operation

Temperature

+5°C to +40°C (+41°F to +104°F)

Altitude/Barometric Pressure

-390 m to 3,658 m (-1280 ft. to 12,000 ft.)

+1060 hPa to +700 hPa (+31.3 in. Hg to +20.6 in. Hg)

Relative Humidity

15-95% noncondensing

PHYSICAL CHARACTERISTICS

Weight

5.7 lbs.

2.6 kg

Dimensions

3.3 in. x 10.4 in. x 6.8 in.

8.4 cm x 26.4 cm x 17.3 cm

Emissions Compliance

EN55011 Emissions Classification

CISPR 11, Group 1, Class B

Equipment Classification (IEC 601-1 / CSA 601.1 / UL 2601-1)

Type of Protection

Class 1 (on AC power)

Internally powered (on battery power)

Degree of Protection

Type BF - Applied part

Enclosure Degree of Ingress Protection from Solids/Liquid

IPX1

Mode of Operation

Continuous

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APPENDIX A: QUICK GUIDE TO OPERATION

Introduction
Settings Adjustments

INTRODUCTION

This *Quick Guide to Operation* is intended for use by experienced NPB-295 users. First-time users of the monitor should read the entire manual before use.

To turn the monitor on or off press



SETTINGS ADJUSTMENTS

Table 4 contains the procedures necessary to adjust or view the basic NPB-295 settings. In general, press EXIT to return to the main menu.

Table 4: Settings Adjustments






To Adjust	Action	Button
Pulse Beep Volume	Press and hold	 or 
Contrast	Press and hold	
	Press	 or 
Pleth or Magnified (blip) View	Press	SETUP
	Press	VIEW
	Select	PLETH or BLIP
	Press	EXIT

Table 4: Settings Adjustments









To Adjust	Action	Button
Alarm Limits	Press Press (to select parameter) Press Press	LIMITS SELECT  or  EXIT
Alarm Volume	Press and hold (for <i>more</i> than 3 seconds) then, Press	  or 
Alarm Silence Duration	Press and hold (for <i>less</i> than 3 seconds) then, Press	  or 

Table 4: Settings Adjustments





To Adjust	Action	Button
Time and Date Settings	Press Press Press Press (to select setting) Press Press (to return to main menu)	SETUP CLOCK SET SELECT  or  EXIT, EXIT, EXIT
Trends	Press Press Select desired view	TREND VIEW

Table 4: Settings Adjustments

To Adjust	Action	Button
Language	Press	SETUP
	Press	NEXT
	Press	LANG
	Press	 or 
	Press	EXIT

APPENDIX B: PRINCIPLES OF OPERATION

Oximetry Overview

OXIMETRY OVERVIEW

Pulse oximetry is based on two principles: that oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (i.e., spectrophotometry), and that the volume of arterial blood in tissue (and hence, light absorption by that blood) changes during the pulse (i.e., plethysmography). A pulse oximeter determines SpO₂ by passing red and infrared light into an arteriolar bed and measuring changes in light absorption during the pulsatile cycle. Red and infrared low-voltage light-emitting diodes (LEDs) in the oximetry sensor serve as light sources; a photodiode 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 monitor bases its SpO₂ measurements on the difference between maximum and minimum absorption (i.e., measurements at systole and diastole). By doing so, it focuses on light absorption by pulsatile arterial blood, eliminating the effects of nonpulsatile absorbers such as tissue, bone, and venous blood.

Automatic Calibration

Because light absorption by hemoglobin is wavelength dependent and because the mean wavelength of LEDs varies, an oximeter must know the mean wavelength of the sensor's red LED to accurately measure SpO₂. During manufacturing, the mean wavelength of the red LED is encoded in a resistor in the sensor.

During monitoring, the instrument's software reads this resistor and selects coefficients that are appropriate for the wavelength of that sensor's red LED; these coefficients are then used to determine SpO₂. This resistor is read when the monitor is turned on, periodically thereafter, and each time a new sensor is connected.

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

Functional versus Fractional Saturation

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

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

Measured versus Calculated Saturation

When saturation is calculated from a blood gas partial pressure of oxygen (PO₂), the calculated value may differ from the SpO₂ 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 PO₂ and saturation (Figure 13): pH, temperature, the partial pressure of carbon dioxide (PCO₂), 2,3-DPG, and fetal hemoglobin.

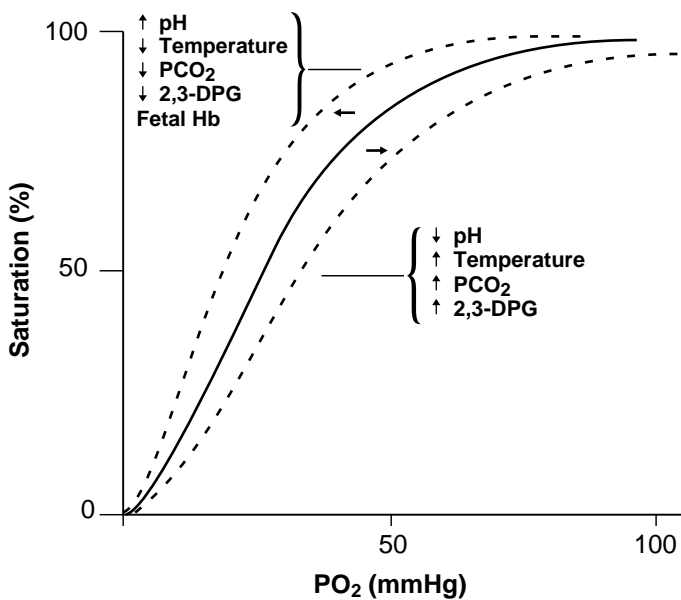


Figure 13: Oxyhemoglobin Dissociation Curve

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APPENDIX C: DATA PORT PROTOCOL

- Overview
- Connecting to the Data Port
- Baud Rate
- Real-Time Display Format
- Trend Data Printout
- Nurse Call
- Analog Outputs

OVERVIEW

Patient data can be obtained through the data port on the back of the NPB-295 by connecting it to an attached PC or serial printer.

When connecting the NPB-295 to a printer or PC, verify proper operation before clinical use. Both the NPB-295 and the printer or PC must be connected to a grounded AC outlet. The NPB-295 protocol setting must be in the ASCII mode as described in the “COMM” paragraph of the *Start-Up and Use* section.

Any printer or PC connected to the monitor’s data port must be certified according to IEC Standard 950. All combinations of equipment must be in compliance with IEC Standard 601-1-1 systems requirements. Anyone who connects a printer or PC to the data output port configures a medical system and is therefore responsible that the system complies with the requirements of system standard IEC Standard 601-1-1 and the electromagnetic compatibility system standard IEC Standard 601-1-2.

CONNECTING TO THE DATA PORT

The NPB-295 data port may be connected to the printer or PC by using a cable terminated with an AMP connector (AMP part number 747538-1), ferrule (AMP part number 1-747579-2), and compatible pins (AMP part number 66570-2). The cable should be no more than 25 feet (7.6 meters) in length.

The cable used must have a braided shield providing 100% coverage, such as a Belden cable (Belden part number 9609) or equivalent. The shield must have a 360-degree connection to the metal shell on the NPB-295's DB-15 connector and to the connector on the PC or serial printer. Do not create sharp bends in the cable, as this may tear or break the shielding.

The pinouts (as illustrated in Figure 14) for the data port are listed in Table 5.

Table 5: Data Port Pinouts

Pin	Signal Name
1	RxD+ (RS-422[+] input)
2	RxD_232 (RS-232 input)
3	TxD_232 (RS-232 output)
4	TxD+ (RS-422[+] output)
5	Signal Ground (isolated from Earth Ground)
6	AN_SPO2 (analog saturation output)
7	NC_NO (relay closure nurse call, normally open)
8	NC_NC (relay closure nurse call, normally closed)
9	RxD- (RS-422 [-] input)
10	Signal Ground (isolated from Earth Ground)
11	Nurse Call (232-level output)
12	TxD- (RS-422 [-] output)
13	AN-PULSE (analog pulse rate output)
14	AN-PLETH (analog pleth wave output)
15	NC-COM (relay closure nurse call common lead)

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

The pin layouts (as viewed from the rear panel of the NPB-295) are illustrated in Figure 14. The conductive shell is connected to earth ground when connected to a PC or printer.

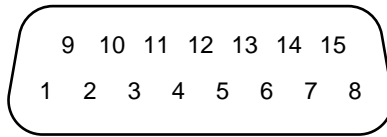


Figure 14: Data Port Pin Layout

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

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

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

BAUD RATE

The baud rate can be changed by pressing the SETUP softkey, the NEXT softkey, and then the COMM softkey. Use the Adjust Up/Down Buttons to select a baud rate of 2400, 9600, or 19200, depending on the capabilities of the attached equipment.

REAL-TIME DISPLAY FORMAT

While on AC power and while the NPB-295 data port protocol setting is set to ASCII (refer to *Start-Up and Use* section), real-time data is continuously sent to the data port on the back of the NPB-295. Patient data can be obtained through the data port by connecting it to an attached PC or serial printer. When a real-time printout or display is being transmitted to a printer or PC, a new line of data is displayed every 2 seconds. Column headings will be displayed or printed after every 25 lines, or if one of the values in the column heading changes.

Data cannot be obtained if the NPB-295 is operating on battery power.

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

An example of a real-time printout is shown in Figure 15.

Appendix C: Data Port Protocol

NPB-295	VERSION 2.0.0.0	CRC: XXXX	SpO2 Limit: 70-100%	PR Limit: 60-160BPM
TIME	%SPO2	BPM	PA	Status
12-NOV-98 14:00:05	100	120	50	
12-NOV-98 14:00:07	100	124	50	
12-NOV-98 14:00:09	100	190*	52	PH
12-NOV-98 14:00:11	100	190*	50	PH
12-NOV-98 14:00:13	100	190*	51	PH
12-NOV-98 14:00:15	100	190*	50	PH
12-NOV-98 14:00:17	100	190*	50	PH
12-NOV-98 14:00:19	100	190*	51	PH
12-NOV-98 14:00:21	100	190*	53	PH LB
12-NOV-98 14:00:23	100	190*	50	PH LB
12-NOV-98 14:00:25	100	190*	50	PH LB
12-NOV-98 14:00:27	---	---	---	SD LB
12-NOV-98 14:00:29	---	---	---	SD LB
12-NOV-98 14:00:31	---	---	---	SD
12-NOV-98 14:00:33	---	---	---	SD
12-NOV-98 14:00:35	---	---	---	SD
12-NOV-98 14:00:37	---	---	---	SD
12-NOV-98 14:00:39	---	---	---	SD
12-NOV-98 14:00:41	---	---	---	SD
12-NOV-98 14:00:43	---	---	---	SD
12-NOV-98 14:00:45	---	---	---	SD
12-NOV-98 14:00:47	---	---	---	SD
12-NOV-98 14:00:49	---	---	---	SD
NPB-295	VERSION 2.0.0.0	CRC: XXXX	SpO2 Limit: 70-100%	PR Limit: 60-160BPM
TIME	%SPO2	BPM	PA	Status
12-NOV-98 14:00:51	---	---	---	SD
NPB-295	VERSION 2.0.0.0	CRC: XXXX	SpO2 Limit: 80-100%	PR Limit: 60-160BPM
TIME	%SPO2	BPM	PA	Status
12-NOV-98 14:00:53	79*	59*	50	SL PL LB
12-NOV-98 14:00:55	79*	59*	52	PS SL PL LB

Figure 15: Real-Time Printout

Column Headings

Every 25th line of the data is a column heading.

NPB-295	VERSION 2.0.0.0	CRC: XXXX	SpO2 Limit: 70-100%	PR Limit: 60-160BPM
TIME	%SPO2	BPM	PA	Status

A column heading is also displayed whenever a value of the column heading is changed. There are three column heading lines shown in Figure 15. Using the top row as the starting point there are 25 lines before the second column heading is printed. The third column heading was displayed because the SpO2 limits changed from 70-100% to 80-100%.

Data Source

NPB-295	VERSION 2.0.0.0	CRC: XXXX	SpO2 Limit: 70-100%	PR Limit: 60-160BPM
TIME	%SPO2	BPM	PA	Status

Data in the highlighted box above represents the model number of the monitor, in this case the NPB-295.

Software Revision Level

NPB-295	VERSION 2.0.0.0	CRC: XXXX	SpO2 Limit: 70-100%	PR Limit: 60-160BPM
TIME	%SPO2	BPM	PA	Status

The next data field tells the user the software level, (Version 2.0.0.0) and a software verification number (CRC: XXXX). Neither of these numbers should change during normal operation. The numbers may change if the monitor is serviced and receives a software upgrade.

Alarm Limits

NPB-295	VERSION 2.0.0.0	CRC: XXXX	SpO2 Limit: 70-100%	PR Limit: 60-160BPM
TIME	%SPO2	BPM	PA	Status

The last data field in the top line indicates the high and the low alarm limits for %SpO2 and for the pulse rate (PR). In the example above the low alarm limit for SpO2 is 70% and the high alarm limit is 100%. Pulse Rate alarm limits are 60 and 160 bpm.

Column Headings

NPB-295	VERSION 2.0.0.0	CRC: XXXX	SpO2 Limit: 70-100%	PR Limit: 60-160BPM
TIME	%SPO2	BPM	PA	Status

Actual column headings are in the second row of the column heading line. Patient data that is presented in the chart, from left to right, is the time that the patient data on the row was obtained, the current %SpO2 value being measured, the current Pulse Rate in beats per minute (BPM), the current Pulse Amplitude (PA), and the operating status of the NPB-295.

Patient Data and Operating Status

Time

TIME	%SPO2	BPM	PA	Status
12-NOV-98 14:00:05	100	120	50	

The Time column represents the NPB-295 real-time clock.

Patient Data

NPB-295	VERSION 2.0.0.0	CRC: XXXX	SpO2 Limit: 70-100%	PR Limit: 60-160BPM
TIME	%SPO2	BPM	PA	Status
12-NOV-98 14:00:05	100	190*	50	

Patient data is highlighted in the display above. Parameter values are displayed directly beneath the heading for each parameter. In this example the %SpO2 is 100, and the pulse rate is 190 beats per minute. The “*” next to the 190 indicates that 190 beats per minute is outside of the alarm limits, indicated in the top row, for pulse rate. If no data for a parameter is available three dashes (- - -) will be displayed.

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

Operating Status

NPB-295	VERSION 2.0.0.0	CRC: XXXX	SpO2 Limit: 70-100%	PR Limit: 60-160BPM
TIME	%SPO2	BPM	PA	Status
12-NOV-98 14:00:11	100	190*	50	PH

The Status column indicates alarm conditions and operating status of the NPB-295. In this example, the PH means that the pulse rate upper alarm limit (Pulse High) has been exceeded. A complete listing of the status codes is listed in Table 6. As many as 4 codes can be displayed at one time in the Status column.

Table 6: Status Codes

Code	Meaning
AO	Alarm Off
AS	Alarm Silence
LB	Low Battery
LP	Loss of Pulse
MO	Patient Motion
PH	Pulse Rate High Limit Alarm
PL	Pulse Rate Low Limit Alarm
PS	Pulse Search

SH	Sat High Limit Alarm
SL	Sat Low Limit Alarm
SD	Sensor Disconnect

Note: A sensor disconnect will also cause three dashes (- - -) to be displayed in the patient data section of the display or printout.

TREND DATA PRINTOUT (ASCII MODE)

The format of data displayed when a trend printout is requested is similar to that of the real-time data. The only differences are that “TREND” is displayed in the top row instead of the “CRC: XXXX” software verification number and there is no “Status” column.

Readings are displayed in 2-second intervals. The values on each row are an average for the 2-second period.

At the end of the printout an “Output Complete” line indicates that the transmission was successful. If the “Output Complete” line is not present, a corruption of the data may have been detected and the data should be ignored.

NPB-295	VERSION 2.0.0.0	TREND	SpO2 Limit: 70-100%	PR Limit: 60-160BPM
TIME	%SPO2	BPM	PA	
22-NOV-98 14:00:05	100	120	150	
22-NOV-98 14:00:07	100	121	154	
22-NOV-98 14:00:09	100	120	150	
Output Complete				

Figure 16: Trend Data Printout (ASCII MODE)

Once a trend printout has begun, the NPB-295 must be turned off and back on again before a new trend printout can begin. A trend printout cannot be aborted without turning off the NPB-295 or the printer.

TREND DATA PRINTOUT (GRAPH MODE)

The graph mode disables all printout functions except trend data. Trend printouts will be graphical if connected to a serial printer.

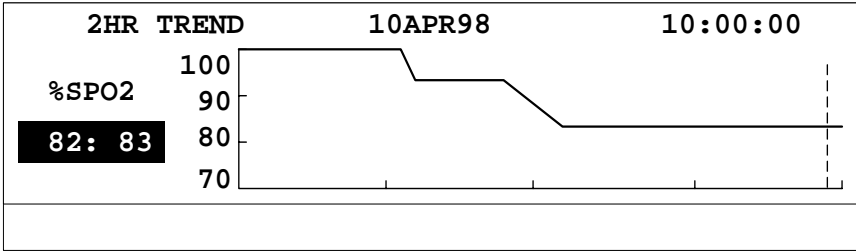


Figure 17: Trend Data Printout (GRAPH MODE)

Trend Data Operation

Whenever the NPB-295 is turned on, it stores a “data point” in memory every 2 seconds (regardless of whether the NPB-295 is monitoring a patient or not). Up to 50 alarm limit changes will also be stored in trend data. The NPB-295 can store up to 24 hours of trend data. . The 24 hours of stored trend data is available for downloading to Score™ software for 45 days. There are no limitations for displaying or printing data.

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

Note: Trend memory always contains the MOST RECENT 24 hours of data, with newly collected data over-writing the oldest data on a rolling basis. The NPB-295 continues to record data points as long as the monitor is powered on, with “blank” data points collected if no sensor is connected to the monitor or patient. “Blank” data will over-write older patient data if the memory becomes full. Therefore, if you want to save old patient data, it is important that you turn your monitor off when you are not monitoring a patient, and that you download the trend memory, using Score software, before it fills up and over-writes the old data with new data (or “blank” data).

Note: When using Score™ software use the latest version. Contact Mallinckrodt’s Technical Services Department or your local Mallinckrodt representative to determine the latest version of Score software.

If battery power is disconnected or depleted, trend data and user settings will be lost. All data is stored with error detection coding. If data stored in memory is found to be corrupted, it is discarded.

NURSE CALL

The NPB-295 provides two different types of nurse call interfaces; an RS-232 level and relay closure. The RS-232 level nurse call function only operates when the monitor is connected to AC power. It will not operate when running on battery. The relay-based nurse call function is available when the monitor is operating either on AC power or when powered by battery.

The remote location will be signaled anytime there is an audible alarm.

Pin 11 on the data port is the RS-232 level nurse call signal and pin 10 is ground (see Table 5). The voltage between these pins is determined by the nurse call polarity setting (normally high or normally low) and whether the monitor is in alarm state. The nurse call polarity setting by using the procedures in the *Start-up and Use* section. To access the nurse call menu from the main menu, press softkeys SETUP, NEXT, NEXT and NCALL.

When the nurse call polarity setting is normally high (NORM +) and there is no alarm condition, the voltage between pins 11 and 5 will be +5 to +12 VDC. Whenever the monitor is in an alarm condition, the output between pins 11 and 5 will be -5 to -12 VDC. When the setting is normally low (NORM -), the readings are opposite, as indicated in Table 7.

These voltages are present only the monitor is operating on AC power.

If the audible alarm has been turned off, or silenced, the nurse call alarm is also silenced.

Table 7: Voltage between pins 10 and 11

Alarm State	Nurse Call Polarity Setting	Voltage from pins 10 to 11
No current alarms	Normally high	+5 to +12 VDC
Alarm condition	Normally high	-5 to -12 VDC
No current alarms	Normally low	-5 to -12 VDC
Alarm condition	Normally low	+5 to +12 VDC

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

ANALOG OUTPUTS

The NPB-295 data port also provides analog voltage outputs between pins 6, 13, 14, and ground (pin 10), which can be used to calibrate the NPB-295 data port voltages with instruments such as a chart recorder. The voltage represents a specific measured parameter's current value. The voltage differential varies proportionally from 0 to 1 volt as the pin's parameter varies over its full range of values, as indicated in Table 8.

Table 8: Analog Pinouts

Pin	Parameter	Parameter Range
6	%SpO ₂	0 - 100%
13	Pulse rate	0 - 250 bpm
14	Pleth wave	0 - 255

For example, as the current value of %SpO₂ varies from 0 to 100%, the voltage from pin 6 to ground (pin 10) would vary from 0 to 1 volt. A voltage of .94 volts indicates a current %SpO₂ value of 94.

The analog function can be accessed from the main menu by pressing SETUP, NEXT, NEXT, ANALOG. Selecting “0 VOLT” or “1 VOLT” causes that voltage to appear at pins 6, 3, or 10. Selecting “STEP” causes the voltage to increase from 0 to 1 volt at 1/10th second increments, with each step lasting at least 1 second.

Calibration of the analog output and the attached device can be performed by qualified service personnel using the procedure described in the NPB-295 service manual.