Nellcor™
OxiCable, USB
305 cm
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1 Introduction

1.1 Overview

This manual provides information for using the Nellcor™ Oxicable, USB (the “monitoring cable”). This manual applies to the following product:

1.2 Safety Information

This section contains important safety information for use of the monitoring cable. Use this information in conjunction with the safety information specified in the host monitoring system documentation.

1.2.1 Safety Symbols

Table 1-1. Safety Symbol Definitions

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>![WARNING]</td>
<td>Warnings alert users to potential serious outcomes (death, injury, or adverse events) to the patient, user, or environment.</td>
</tr>
<tr>
<td>![Caution]</td>
<td>Cautions alert users to exercise appropriate care for safe and effective use of the product.</td>
</tr>
<tr>
<td>![Note]</td>
<td>Notes provide additional guidelines or information.</td>
</tr>
</tbody>
</table>
1.2.2 Patient and Operator Safety - General Use

WARNING:
Shock hazard — Do not immerse or wet the monitoring cable or sensor.

WARNING:
Choking hazard — The monitoring cable contains small detachable parts.

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

WARNING:
Do not use the monitoring cable in the presence of flammable anesthetics. This may cause an explosion or fire.

WARNING:
Do not use a pulse oximetry sensor on the same extremity as a blood pressure cuff or other constricting instrument. Such usage can cause inaccurate pulse oximetry measurements or a loss of signal.

WARNING:
Do not use any monitoring cable, monitoring system, sensor, cable, or connector that has a damaged enclosure or any damaged component. Remove any damaged equipment from service for inspection by a qualified service technician.

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

WARNING:
Ensure that the monitoring cable is carefully positioned to prevent tripping and entanglement.

Caution:
Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.
1.2.3 System Connection, Compliance, and Interference

**WARNING:**
The monitoring cable may cause radio interference or may disrupt the operation of nearby equipment. Mitigation for such disruption may require re-orienting or relocating the monitoring cable or shielding the location.

**WARNING:**
The use of accessories, sensors, and cables other than those specified may result in inaccurate readings and increased EMI emissions of the monitoring cable.

**WARNING:**
EMI disruption can cause erratic readings, cessation of operation, or other incorrect functioning.

**Caution:**
This device has been tested and found to comply with the limits for medical devices related to IEC 60601-1-2: 2007 for Class B Emissions. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

**Caution:**
Anyone who connects the monitoring cable to a host monitoring system is configuring a medical system and, therefore, is responsible for ensuring the system complies with the Requirements for Medical Electrical Systems IEC/EN 60601-1:2005 and electromagnetic compatibility IEC/EN 60601-1-2:2007.

**Caution:**
Do not connect the monitoring cable’s USB connector to anything other than a compatible USB 2.0 host device.

1.2.4 Sensor Use and Performance Considerations

**WARNING:**
Certain physical conditions may affect calculation of SpO₂ and pulse rate. These conditions include, but are not limited to: dysfunctional hemoglobin, intravascular dyes, low perfusion, and darkly pigmented skin. Refer to *Nellcor™ Sensor Performance Considerations*, page 4-1.

**Caution:**
Use only Medtronic-approved sensors when connecting to the sensor port. Connecting any other sensor influences the accuracy of sensor data, which may lead to adverse results.
1.2.5 **Disposal**

**Caution:**
Dispose of the monitoring cable in accordance with local requirements and regulations.

1.3 **Technical Assistance**

1.3.1 **Technical Services**

For technical information and assistance, if unable to correct a problem while using the monitoring cable, or to order parts, contact Medtronic or a local Medtronic representative.

**Medtronic Technical Services: Patient Monitoring**

15 Hampshire Street
Mansfield, MA 02048 USA

1.800.635.5267, 1.925.463.4635 (toll)
or contact a local Medtronic representative

[www.medtronic.com](http://www.medtronic.com)

When calling Medtronic or a local Medtronic representative, have the monitoring cable serial number available.

1.3.2 **Warranty Information**

To obtain information, contact Medtronic or a local Medtronic representative. See *Technical Services*, page 1-4.

Purchase of this instrument confers no express or implied license under any Medtronic patent to use that instrument with any sensor not manufactured or licensed by Medtronic.
2 Product Overview

2.1 Product Description

When used with a host monitoring system, the Nellcor™ oxicable, USB (the “monitoring cable”) provides continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin ($\text{SpO}_2$) and pulse rate, as measured by Nellcor™ pulse oximetry sensors. The monitoring cable relies on unique oximetry technology and design to provide hospitals, clinicians, and caregivers with accurate, timely data.

The monitoring cable provides the following patient data to the host monitoring system:

- **Arterial blood oxygen saturation ($\text{SpO}_2$)** - Functional measure of oxygenated hemoglobin relative to the sum of oxyhemoglobin and deoxyhemoglobin.
- **Pulse rate (PR)** - Detected pulsations per minute.
- **Plethysmographic waveform (Pleth)** - Visual waveform representing detected pulsations. (Non-normalized)
- **Operating status** - Alarm conditions and operational status.

2.2 Indications for Use

The Nellcor™ OxiCable, USB is indicated for prescription use only for spot check or continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin ($\text{SpO}_2$) and pulse rate. It is intended for use with neonatal, pediatric, and adult patients during both no motion and motion conditions and for patients who are either well or poorly perfused, in hospitals and hospital-type facilities.

**Note:**

- Hospital use typically includes such areas as the intensive care unit (ICU), neonatal intensive care unit (NICU), operating room (OR), post-anesthesia care unit (PACU), emergency department, and medical/surgical general care floor (GCF).
- Hospital-type facilities include step-down units and long-term care facilities.

Use with any particular patient requires the selection of an appropriate Nellcor™ sensor. See Nellcor™ Sensor Selection, page 6-1.
2.3 Monitoring Cable Components

Figure 2-1. Monitoring Cable Components

1. Sensor Port (to Nellcor™ Sensor)

2. Sensor Latch

3. Isolation Module

4. USB Connector (to Host Monitoring System)
### 2.4 Labeling Symbols

#### Table 2-1. Labeling Symbols

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Icon" /></td>
<td>Must consult instructions for use</td>
<td><img src="image" alt="Icon" /></td>
<td>Date of manufacture</td>
</tr>
<tr>
<td><img src="image" alt="Icon" /></td>
<td>Universal Serial Bus (USB) connector</td>
<td><img src="image" alt="Icon" /></td>
<td>Proper waste disposal for electrical and electronic equipment</td>
</tr>
<tr>
<td><strong>IP47</strong></td>
<td>Protection against particulate and fluid ingress: Protected against solid objects greater than 1mm. Protected against the effects of submersion in water up to 1 meter deep for up to 30 minutes.</td>
<td><img src="image" alt="Icon" /></td>
<td>Type BF applied part: Nellcor™ sensor and sensor cable Defibrillator proof</td>
</tr>
<tr>
<td><img src="image" alt="Icon" /></td>
<td>Atmospheric pressure limitations (see <em>Environmental Conditions</em>, page 8-1)</td>
<td><img src="image" alt="Icon" /></td>
<td>Keep dry</td>
</tr>
<tr>
<td><img src="image" alt="Icon" /></td>
<td>Temperature limitations (see <em>Environmental Conditions</em>, page 8-1)</td>
<td><img src="image" alt="Icon" /></td>
<td>Catalog number</td>
</tr>
<tr>
<td><img src="image" alt="Icon" /></td>
<td>Humidity limitations (see <em>Environmental Conditions</em>, page 8-1)</td>
<td><img src="image" alt="Icon" /></td>
<td>CSA – Canadian Standards Association certification mark</td>
</tr>
<tr>
<td><strong>SN</strong></td>
<td>Serial number</td>
<td><strong>Rx</strong></td>
<td>Prescription only</td>
</tr>
<tr>
<td><img src="image" alt="Icon" /></td>
<td>Consult instructions for use</td>
<td><img src="image" alt="Icon" /></td>
<td></td>
</tr>
</tbody>
</table>
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3 Connection

3.1 Connection to a Host Monitoring System

To connect the Nellcor™ oxicable, USB (the “monitoring cable”) to a host monitoring system, insert the monitoring cable’s USB connector into a compatible USB port on the host system.

**Figure 3-1.** USB Connector on Monitoring Cable

**Note:**
The monitoring cable derives power from the host monitoring system. The monitoring cable has no power switch. To ensure that power is removed from the monitoring cable, disconnect it from the host monitoring system.

3.2 Connection to a Nellcor™ Sensor

Prior to using a Nellcor™ sensor with the monitoring cable:

- See *Nellcor™ Sensor Selection*, page 6-1 for information about selecting the appropriate sensor for the patient.

- Read the *Instructions for Use* accompanying the sensor.

- See *Nellcor™ Sensor Performance Considerations*, page 4-1 for information about optimizing the performance of the sensor and monitoring cable during patient use.
To connect a Nellcor™ sensor to the monitoring cable:

1. Open the latch at the end of the monitoring cable’s sensor port and firmly insert the sensor connector. The connector is keyed so that it fits correctly in one orientation only.

   **Figure 3-2.** Inserting Sensor Connector

2. Snap the latch over the sensor connector. When the sensor connector is seated properly, the latch should close completely over the connector.

   **Figure 3-3.** Latch Closed over Sensor Connector
4 Performance Considerations

4.1 Nellcor™ Sensor Performance Considerations

A variety of conditions can cause inaccurate sensor measurements or cause the loss of the pulse signal:

- Incorrect application of the recommended sensor
- Sensor applied too tightly
- Placement of the sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line
- Failure to cover the sensor site with material that blocks light when operating under bright light conditions

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

Additional possible patient conditions may also influence measurements:

- Anemia — Anemia causes decreased arterial oxygen content. Although SpO2 readings may appear normal, an anemic patient may be hypoxic. Correcting anemia can improve arterial oxygen content. The monitoring cable may fail to provide an SpO2 reading if hemoglobin levels fall below 5 gm/dl.

- Dysfunctional hemoglobins — Dysfunctional hemoglobins such as carboxyhemoglobin, methemoglobin, and sulfhemoglobin are unable to carry oxygen. SpO2 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.

- Arterial occlusion proximal to the sensor
- Poor peripheral perfusion
- Excessive patient movement
- Venous pulsations
- Dark skin pigment
• Intravascular dyes, such as indocyanine green or methylene blue

• Externally applied coloring agents (nail polish, dye, pigmented cream)

• Defibrillation

4.2 Electromagnetic Interference

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 might result in disruption of monitoring cable performance.

The monitoring cable is designed for use in environments in which electromagnetic interference might obscure the client’s pulse. During such interference, measurements may seem inappropriate or the monitoring cable may not seem to operate correctly. EMI disruption can cause erratic readings, cessation of operation, or other incorrect functioning. If this occurs, survey the site of use to determine the source of this disruption, and take the listed actions to eliminate the source.

• Turn equipment in the vicinity off and on to isolate the interfering equipment.

• Reorient or relocate the interfering equipment.

• Increase the separation between the interfering equipment and the monitoring cable.

The monitoring cable can radiate radio frequency energy and, if not installed and used in accordance with these instructions, may itself cause harmful interference with other susceptible devices in the vicinity.
5 Product Maintenance

5.1 Cleaning

For surface cleaning of the Nellcor™ oxicable, USB (the “monitoring cable”), follow the procedure below.

**Note:**
Before attempting to clean a Nellcor™ sensor, read the *Instructions for Use* enclosed with the sensor. Each sensor model has cleaning instructions specific to that sensor.

**Note:**
For cleaning instructions for the host monitoring system, refer to the host system’s operators manual.

**Materials**
- Paper towels
- Soft, lint-free cloths
- Water (tap water is acceptable)
- Cleaning agent:
  - Isopropyl alcohol, maximum 60% by weight, or
  - Bleach: Mix 10 parts water to 1 part 5.25% bleach to create an 0.5% bleach concentration

**Procedure**

**Note:**
Ensure at least 30 seconds of contact time between the cleaning agent and all surfaces being cleaned.

**To clean the monitoring cable:**
1. Power off the host monitoring system.
2. If a sensor is connected to the monitoring cable, disconnect the sensor.
3. Moisten (but do not saturate) a paper towel with water. Remove excess water as necessary.
4. Starting at the sensor port end of the monitoring cable, use the moistened paper towel to soften and loosen any bulky soils on the exterior of the monitoring cable, then wipe them off.

5. Moisten (but do not saturate) a clean lint-free cloth with one of the cleaning agents listed in Materials, page 5-1.

![Note:](Image)

*Note:* Do not spray the cleaning agent into the sensor port.

![Note:](Image)

*Note:* Do not clean the metal USB connector with the cleaning agent. The cleaning agent can damage the connector.

6. Wipe down all external surfaces of the monitoring cable, removing all visible soil, ensuring not to wipe the USB connector. Begin at the sensor port end of the cable and work toward the opposite end. Pay special attention to the areas shown in the following figure.

![Figure 5-1. Check These Areas for Soil](Image)

7. If there is soil beneath the sensor latch, clean the latch and area under the latch as follows:

![Figure 5-2. Check These Areas for Soil When Latch is Removed](Image)

a. With the sensor latch in the open (up) position, gently pull one side of the latch away from the body of the monitoring cable until the latch disengages from the pegs on both sides.

b. Moisten (but do not saturate) a paper towel with water. Remove excess water as necessary.
c. Use the moistened paper towel to soften and loosen any bulky soils on the latch and in the area under the latch, then wipe them off.

d. Moisten (but do not saturate) a clean lint-free cloth with one of the cleaning agents listed in Materials, page 5-1.

e. Use the moistened cloth to remove all visible soil from the latch and area under the latch, with special attention to the areas shown in Figure 5-2.

f. Rinse the latch in tap water until all residual cleaning agent has been removed.

g. Use a clean lint-free cloth to dry the latch.

h. Wipe the surfaces of the monitoring cable where the latch was attached until all residual cleaning agent has been removed. See Figure 5-3.

**Figure 5-3.** Ensure all of These Areas are Clean When Latch is Removed

i. Use a clean lint-free cloth to dry the area where the latch was attached.

**Note:**
Do not use pressurized air or gas to dry inside the sensor port.

j. If visible soil remains, repeat the cleaning process.

k. Ensure all areas are dry before reattaching the sensor latch.

l. Replace the sensor latch by positioning it directly in front of the sensor port in the closed position. Slide the latch over the sensor port until it snaps into position on the pegs on both sides of the sensor port body. Ensure that the latch opens and closes freely over the sensor port. If the latch is damaged, contact Medtronic (see Technical Services, page 1-4).

8. Moisten a clean lint-free cloth with water and wipe the monitoring cable until all residual cleaning agent has been removed.

9. Use a clean lint-free cloth to dry the monitoring cable.

**Note:**
Do not use excessive drying techniques, such as oven, forced heat, or sun drying.

10. If visible soil remains on the monitoring cable, repeat the cleaning process.
Note:
Ensure that the monitoring cable is completely dry before connecting a sensor and returning it to patient use.

5.2 Service and Calibration

Note:
There are no user-serviceable parts inside the monitoring cable. Users may not modify any components of the monitoring cable.

Periodically verify the functionality of the monitoring cable by following the procedures outlined in the SRC-MAX Pulse Oximetry Functional Tester Technical Manual. Have a qualified service technician perform these procedures prior to initial installation in a clinical setting.

The monitoring cable requires no calibration.
6 Accessories

6.1 Nellcor™ Sensor Selection

When selecting a Nellcor™ 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. Use the recommended sensor’s *Instructions for Use* to guide sensor selection, or contact Medtronic or a local Medtronic representative.

<table>
<thead>
<tr>
<th>Nellcor™ Sensor</th>
<th>SKU</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nellcor™ Preemie SpO₂ Sensor, non-adhesive (Single-patient use)</td>
<td>SC-PR</td>
</tr>
<tr>
<td>Nellcor™ Neonatal SpO₂ Sensor, non-adhesive (Single-patient use)</td>
<td>SC-NEO</td>
</tr>
<tr>
<td>Nellcor™ Adult SpO₂ Sensor, non-adhesive (Single-patient use)</td>
<td>SC-A</td>
</tr>
<tr>
<td>Nellcor™ Adult-Neonatal SpO₂ Sensor with Wraps (Reusable with adhesive)</td>
<td>OXI-A/N</td>
</tr>
<tr>
<td>Nellcor™ Pediatric-Infant SpO₂ Sensor with Wraps (Reusable with adhesive)</td>
<td>OXI-P/I</td>
</tr>
<tr>
<td>Nellcor™ Pediatric SpO₂ Sensor, Two Piece (Sterile, single-use only)</td>
<td>P</td>
</tr>
<tr>
<td>Nellcor™ Neonatal-Adult SpO₂ Sensor, Two Piece (Sterile, single-use only)</td>
<td>N</td>
</tr>
<tr>
<td>Nellcor™ Infant SpO₂ Sensor, Two Piece (Sterile, single-use only)</td>
<td>I</td>
</tr>
<tr>
<td>Nellcor™ Adult SpO₂ Sensor, Two Piece (Sterile, single-use only)</td>
<td>A</td>
</tr>
<tr>
<td>Nellcor™ Neonatal-Adult SpO₂ Sensor (Sterile, single-use only)</td>
<td>MAXN</td>
</tr>
<tr>
<td>Nellcor™ Infant SpO₂ Sensor (Sterile, single-use only)</td>
<td>MAXI</td>
</tr>
<tr>
<td>Nellcor™ Pediatric SpO₂ Sensor (Sterile, single-use only)</td>
<td>MAXP</td>
</tr>
<tr>
<td>Nellcor™ Adult SpO₂ Sensor (Sterile, single-use only)</td>
<td>MAXA</td>
</tr>
<tr>
<td>Nellcor™ Adult SpO₂ Nasal Sensor (Sterile, single-use only)</td>
<td>MAXR</td>
</tr>
<tr>
<td>Nellcor™ Adult XL SpO₂ Sensor (Sterile, single-use only)</td>
<td>MAXAL</td>
</tr>
<tr>
<td>Nellcor™ Forehead SpO₂ Sensor (Sterile, single-use only)</td>
<td>MAXFAST</td>
</tr>
<tr>
<td>Nellcor™ Adult SpO₂ Sensor, Reusable (Nonsterile)</td>
<td>DS100A</td>
</tr>
<tr>
<td>Nellcor™ SpO₂ Sensor, Multi-site Reusable (Nonsterile)</td>
<td>D-YS</td>
</tr>
</tbody>
</table>
Contact Medtronic for sensor accuracy information regarding all applicable Nellcor™ sensors.
7 Theory of Operations

7.1 Theoretical Principles

The Nellcor™ oxicable, USB (the “monitoring cable”) uses pulse oximetry to measure functional oxygen saturation in the blood [1]. Pulse oximetry works by applying a Nellcor™ sensor to tissue regions with rich presence of capillaries and arterioles, such as a finger or toe [2]. The sensor contains a dual light source and a photodetector [2] [3].

Bone, tissue, pigmentation, and venous vessels normally absorb a constant amount of light over time. The vascular 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) [2] [3].

Ambient conditions, sensor application, and patient conditions can influence the ability of the monitoring cable to accurately measure SpO₂ [4].

Pulse oximetry is based on two physical principles: oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (measured using spectrophotometry), and the volume of arterial blood in tissue (and hence, light absorption by that blood) changes during the pulse (registered using plethysmography) [5]. A monitoring system determines SpO₂ by passing red and infrared light into a vascular bed and measuring changes in light absorption during the pulsatile cycle. Red and infrared low-voltage light-emitting diodes (LED) in the sensor serve as light sources; a photo diode serves as the photo detector [2] [3].

Since oxyhemoglobin and deoxyhemoglobin differ in light absorption, the amount of red and infrared light absorbed by blood is related to hemoglobin oxygen saturation [2].

The monitoring cable uses the pulsatile nature of arterial flow to identify the oxygen saturation of arterial hemoglobin. During systole, a new pulse of arterial blood enters the vascular bed, and blood volume and light absorption increase. During diastole, blood volume and light absorption reach their lowest point. The monitoring cable bases its SpO₂ 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 non-pulsatile absorbers such as tissue, bone, and venous blood [2] [6].
7.2 Automatic Calibration

Because light absorption by hemoglobin is wavelength dependent and because the mean wavelength of LEDs varies, a monitoring system must know the mean wavelength of the sensor’s red LED to accurately measure SpO₂ [2].

During monitoring, the monitoring cable’s software selects coefficients that are appropriate for the wavelength of that individual sensor’s red LED; these coefficients are then used to determine SpO₂ [2].

Additionally, to compensate for differences in tissue thickness, the light intensity of the sensor’s LEDs is adjusted automatically [2].

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

7.3 Functional Testers and Patient Simulators

Some models of commercially available bench top functional testers and patient simulators can be used to verify the proper functionality of Medtronic Nellcor™ monitoring systems, sensors, and cables. Reference the individual testing device’s operator’s manual for the procedures specific to the model of tester used. While such devices may be useful for verifying that the sensor, cabling, and monitoring system are functional, they are incapable of providing the data required to properly evaluate the accuracy of a system’s SpO₂ measurements. Fully evaluating the accuracy of the SpO₂ measurements requires, at a minimum, accommodating the wavelength characteristics of the sensor and reproducing the complex optical interaction of the sensor and the patient’s tissue. These capabilities are beyond the scope of known bench top testers. SpO₂ measurement accuracy can only be evaluated in vivo by comparing monitoring system readings with values traceable to SaO₂ measurements obtained from simultaneously sampled arterial blood using a laboratory CO-oximeter [6].

Many functional testers and patient simulators have been designed to interface with the monitoring system’s expected calibration curves and may be suitable for use with monitoring systems and/or sensors. However, not all functional testers and patient simulators are compatible for use with the OxiMax™ digital calibration system [6].

While this will not affect use of the simulator for verifying system functionality, displayed SpO₂ measurement values may differ from the setting of the test device. For a properly functioning monitoring system, this difference will be reproducible over time and from monitoring system to monitoring system within the performance specifications of the test device [6].
7.4 Functional versus Fractional Saturation

This monitoring cable measures functional saturation where oxygenated hemoglobin is 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, report fractional saturation where oxygenated hemoglobin is expressed as a percentage of all measured hemoglobin, including measured dysfunctional hemoglobins. To compare functional saturation measurements to those from a monitoring system that measures fractional saturation, fractional measurements must be converted using the following equation:

\[ \Phi = \frac{\phi}{100} - (\eta + \Lambda) \]

- \( \Phi \) Functional saturation
- \( \eta \) %carboxyhemoglobin
- \( \phi \) Fractional saturation
- \( \Lambda \) %methemoglobin
7.5 Measured versus Calculated Saturation

When calculating saturation from a blood gas partial pressure of oxygen (PO$_2$), the calculated value may differ from the SpO$_2$ measurement of a monitoring system. This usually occurs when saturation calculations exclude corrections for the effects of variables such as pH, temperature, the partial pressure of carbon dioxide (PCO$_2$), and 2,3-DPG, that shift the relationship between PO$_2$ and SpO$_2$ as shown in the following figure.

![Figure 7-1. Oxyhemoglobin Dissociation Curve](image)

7.6 System Features

7.6.1 Nellcor™ Sensor Technology

Nellcor™ sensors are specifically designed for use with particular monitoring systems. Nellcor™ sensors are identified by the Nellcor™ logo on the plug. All Nellcor™ sensors with OxiMax™ technology contain a memory chip carrying information about the sensor which the monitoring cable requires for correct operation, including the sensor’s calibration data, model type, troubleshooting codes, and error detection data [7].

Medtronic's unique oximetry architecture enables several distinctive features. When an OxiMax™ sensor is connected to the monitoring cable, the monitoring cable reads the information from the
sensor’s memory chip, ensures it is error free, and then loads the sensor data prior to monitoring for new information [7].

Any monitoring system containing OxiMax™ technology uses calibration data contained in the sensor to calculate the patient’s SpO₂. With sensor calibration, the accuracy of many sensors is improved over non-calibrated sensors, since the calibration coefficients can be tailored to each sensor [7].

### 7.6.2 Data Update Period, Data Averaging, and Signal Processing

The advanced signal processing of the OxiMax™ algorithm automatically extends the amount of data required for measuring SpO₂ and pulse rate depending on the measurement conditions. The OxiMax™ algorithm automatically extends the dynamic averaging time required beyond seven seconds during degraded or difficult measurement conditions caused by low perfusion, signal artifact, ambient light, electrocautery, other interference, or a combination of these factors, which results in an increase in the dynamic averaging. If the resulting dynamic averaging time exceeds 20 seconds for SpO₂, the monitoring cable reports a pulse search condition to the monitoring system while continuing to update SpO₂ and pulse rate values every second. If the dynamic averaging time exceeds 25 seconds, the monitoring cable reports a low-priority Extended Update alarm condition to the monitoring system.

As such measurement conditions extend, the amount of data required may continue to increase. If the dynamic averaging time reaches 40 seconds for SpO₂, and/or 50 seconds for pulse rate, a high priority alarm state results: the monitoring cable reports a Pulse Timeout alarm condition to the monitoring system and reports a zero saturation indicating a loss-of-pulse condition.

### 7.6.3 Pulse Rate Delay Alarm Management Parameter

**Note:**

This parameter is available via the monitoring cable but may be optionally implemented on the host monitoring system.

The monitoring cable also monitors pulse rate by determining the number of cardiac cycles over a one minute time period. With traditional alarm management, upper and lower alarm limits are set for monitoring pulse rate. When pulse rates fluctuate near an alarm limit, alarms trigger with each violation. Pulse Rate Delay allows a period of threshold violation before the pulse rate alarm sounds. Thus, it helps distinguish clinically significant events from minor and brief pulse rate limit violations that may result in nuisance alarms.
7.6.4 SatSeconds™ Alarm Management Parameter

**Note:**
This parameter is available via the monitoring cable but may be optionally implemented on the host monitoring system.

The monitoring cable monitors the percentage of hemoglobin binding sites saturated with oxygen in the blood. With traditional alarm management, upper and lower alarm limits are set to alarm at specific SpO₂ levels. When the SpO₂ level fluctuates near an alarm limit, the alarm sounds each time it violates the alarm threshold. SatSeconds monitors both degree and duration of desaturation when the SpO₂ level crosses the alarm limits as an index of desaturation severity. When the SatSeconds index crosses a set threshold, the alarm annunciates. Thus, the SatSeconds parameter helps distinguish clinically significant events from minor and brief desaturations that may result in nuisance alarms.

7.7 References


8 Product Specifications

8.1 Physical Characteristics

<table>
<thead>
<tr>
<th>Weight</th>
<th>160 ± 16 g (0.35 ± 0.03 lbs.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length</td>
<td>305 ± 5 cm (10 ± 0.16 ft.)</td>
</tr>
</tbody>
</table>

8.2 Electrical Requirements

<table>
<thead>
<tr>
<th>Power Requirements</th>
<th>USB host power supply: 5.0V ±5% DC power input</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Consumes maximum 250mW (average power) with no fault conditions</td>
</tr>
<tr>
<td></td>
<td>Consumes typical 40mA ±10% current (5V input ±5%)</td>
</tr>
<tr>
<td>USB Standard</td>
<td>USB 2.0 full-speed compliant</td>
</tr>
</tbody>
</table>

8.3 Environmental Conditions

<table>
<thead>
<tr>
<th></th>
<th>Operating</th>
<th>Transport and Storage</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Temperature</strong></td>
<td>5°C to 40°C (41°F to 104°F)</td>
<td>-40°C to 70°C (40°F to 158°F)</td>
</tr>
<tr>
<td><strong>Altitude/Atmospheric Pressure</strong></td>
<td>-500 m to 4,000 m (1075 hPa to 616 hPa)</td>
<td>-500 m to 5,572 m (1075 hPa to 500 hPa)</td>
</tr>
<tr>
<td><strong>Relative Humidity</strong></td>
<td>15% to 95% non-condensing</td>
<td>15% to 95% non-condensing</td>
</tr>
</tbody>
</table>
8.4 **System Accuracy and Ranges**

The monitoring cable has the capability to detect physiological alarm conditions using SpO₂ accuracy, pulse rate accuracy, and alarm limit conditions.

<table>
<thead>
<tr>
<th>Measurement Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>SpO₂ 1% to 100%</td>
</tr>
<tr>
<td>Pulse Rate 20 to 300 beats per minute (bpm)</td>
</tr>
<tr>
<td>Perfusion 0.03% to 20%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Table 8-1. System Measurement Ranges</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Saturation¹</td>
</tr>
<tr>
<td>Adult², ³</td>
</tr>
<tr>
<td>Neonate⁴, ⁵</td>
</tr>
<tr>
<td>Adult and Neonate Low Sat², ³, ⁴</td>
</tr>
<tr>
<td>Low Perfusion⁶</td>
</tr>
<tr>
<td>Adult and Neonate with Motion², ⁷</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pulse Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adult², ³ and Neonate⁴, ⁵</td>
</tr>
<tr>
<td>Low Perfusion⁶</td>
</tr>
<tr>
<td>Adult and Neonate with Motion², ⁷</td>
</tr>
</tbody>
</table>

---

1. Saturation accuracy varies by sensor type. Contact Medtronic for sensor accuracy information.
2. Accuracy specifications were validated using measurements of healthy non-smoking adult volunteers during controlled hypoxia studies spanning the specified saturation ranges. Subjects were recruited from the local population and comprised both men and women ranging in age from 18-50 years old, and spanned a range of skin pigments. Pulse oximeter SpO₂ readings were compared to SaO₂ values of drawn blood samples measured by hemoximetry. All accuracies are expressed as ±1 SD. Because pulse oximeter equipment measurements are statistically distributed, about two-thirds of the measurements can be expected to fall in this accuracy (ARMS) range.
3. Adult specifications are shown for OxiMax™ MAXA and MAXN sensors with the pulse oximeter.
4. Neonate specifications are shown for OxiMax™ MAXN sensors with the pulse oximeter.
5. Clinical functionality has been demonstrated on a population of hospitalized neonate patients. The observed SpO₂ accuracy was 2.5% in a study of 42 patients with ages of 1 to 23 days, weight from 750 to 4,100 grams, and 61 observations made spanning a range of 77% to 98% SaO₂.
6. Specification applies to monitoring cable performance. Reading accuracy in the presence of low perfusion (detected IR pulse modulation amplitude 0.03% - 1.5%) was validated using signals supplied by a patient simulator. SpO₂ and pulse rate values were varied across the monitoring range over a range of weak signal conditions and compared to the known true saturation and pulse rate of the input signals.
7. Motion performance was validated during a controlled hypoxia blood study over an SaO₂ span of 70% to 98.9% and a convenience-sample heart rate range of 41-105 bpm. Subjects performed rubbing and tapping movements 1-2 cm in amplitude with aperiodic intervals (randomly changing) with a random variation in frequency between 1-4 Hz. The average percent modulation during quiescent periods was 3.28, during motion 4.05. Motion performance over the entire specified pulse rate range was validated using synthetic signals from a patient simulator that comprised representative cardiac and signal artifact components. Applicability: OxiMax™ MAXA, MAXAL, MAXP, MAXII, and MAXN sensors.
8.5 Nellcor™ Sensor Optical Specifications

<table>
<thead>
<tr>
<th>LED Wavelength</th>
<th>Maximum Output Power</th>
</tr>
</thead>
<tbody>
<tr>
<td>Red: Approximately 650 to 670 nm</td>
<td>3.0 mW</td>
</tr>
<tr>
<td>Infrared: Approximately 880 to 910 nm</td>
<td>4.0 mW</td>
</tr>
</tbody>
</table>

Power Dissipation

52.5 mW

Wavelength range can be especially useful to clinicians.

8.6 Product Compliance

<table>
<thead>
<tr>
<th>Equipment Classification</th>
<th>USB-Powered Pulse Oximeter</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>IEC CISPR 11, Group 1, Class B</td>
</tr>
<tr>
<td></td>
<td>IEC/EN 80601-2-61:2011</td>
</tr>
<tr>
<td></td>
<td>CAN/CSA-C22.2 No. 60601-1:14</td>
</tr>
<tr>
<td></td>
<td>IEC 60601-1:2005/AMD1:2012</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Patient Isolation</th>
<th>1.5 kV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Degree of Protection Against Electrical Shock</td>
<td>Defibrillation-Proof Type BF Applied Part</td>
</tr>
<tr>
<td>Mode of Operation</td>
<td>Continuous</td>
</tr>
<tr>
<td></td>
<td>IEC 60601-1-2:2014</td>
</tr>
<tr>
<td>Ingress Protection</td>
<td>IP47</td>
</tr>
<tr>
<td>Degree of Safety</td>
<td>Not suitable for use in the presence of flammable anesthetics</td>
</tr>
<tr>
<td>Biocompatibility Testing (Monitoring Cable)</td>
<td>ISO 10993-1, Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing</td>
</tr>
</tbody>
</table>

8.7 Biocompatibility Testing

Biocompatibility testing has been conducted on the monitoring cable in compliance with ISO 10993-1, Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing. The monitoring cable has passed the recommended biocompatibility testing and is therefore in compliance with ISO 10993-1.
8.8 Manufacturer’s Declaration and Guidance

8.8.1 Electromagnetic Compatibility (EMC)

The monitoring cable is suitable for prescription use only in the specified electromagnetic environments, in accordance with the IEC 60601-1-2:2014 standard. The monitoring cable requires special precautions during installation and operation for electromagnetic compatibility. In particular, the use of nearby mobile or portable communications equipment may influence monitoring cable performance.

Electromagnetic Emissions

<table>
<thead>
<tr>
<th>Emissions Test</th>
<th>Compliance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emission</td>
<td>Class B</td>
</tr>
<tr>
<td>CISPR 11</td>
<td></td>
</tr>
<tr>
<td>EN 55011</td>
<td></td>
</tr>
</tbody>
</table>

Electromagnetic Immunity

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC/EN 60601-1-2 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD)</td>
<td>± 8 kV contact</td>
<td>± 8 kV contact</td>
<td>Floor should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td>IEC/EN 61000-4-2</td>
<td>± 15 kV air</td>
<td>± 15 kV air</td>
<td></td>
</tr>
<tr>
<td>Powerfrequency (50/60 Hz) magnetic field</td>
<td>30 A/m</td>
<td>30 A/m</td>
<td>It may be necessary to position further from the sources of power frequency magnetic fields or to install magnetic shielding.</td>
</tr>
<tr>
<td>IEC/EN 61000-4-8</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 8-5. Electromagnetic Immunity Compliance

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC/EN 60601-1-2 Test Level</th>
<th>Compliance Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted RF IEC/EN 61000-4-6</td>
<td>3 Vrms 150 kHz to 80 MHz</td>
<td>3 Vrms 150 kHz to 80 MHz</td>
</tr>
<tr>
<td>Radiated RF IEC/EN 61000-4-3</td>
<td>3 V/m 80 MHz to 2.7 GHz</td>
<td>3 V/m 80 MHz to 2.7 GHz</td>
</tr>
<tr>
<td>Electrical Fast Transient (EFT)</td>
<td>±1kV (100 kHz rep rate) I/O &gt;3 m</td>
<td>±1kV (100 kHz rep rate) I/O &gt;3 m</td>
</tr>
</tbody>
</table>

Table 8-6. Proximity Field Immunity Compliance

<table>
<thead>
<tr>
<th>Test Frequency (MHz)</th>
<th>Band (MHz)</th>
<th>Service</th>
<th>Modulation</th>
<th>Max. Power (W)</th>
<th>Distance (m)</th>
<th>Immunity Compliance Level (V/m)</th>
<th>Immunity Test Level (V/m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>385</td>
<td>380 to 390</td>
<td>TETRA 400</td>
<td>Pulse Modulation 18 Hz</td>
<td>1.8</td>
<td>0.3</td>
<td>27</td>
<td>27</td>
</tr>
<tr>
<td>450</td>
<td>430 to 470</td>
<td>GMRS 460, FRS 460</td>
<td>FM ± 5kHz deviation 1 kHz sine</td>
<td>2</td>
<td>0.3</td>
<td>28</td>
<td>28</td>
</tr>
<tr>
<td>710</td>
<td>704 to 787</td>
<td>LTE Band 13, 17</td>
<td>Pulse Modulation 217 Hz</td>
<td>0.2</td>
<td>0.3</td>
<td>9</td>
<td>9</td>
</tr>
<tr>
<td>745</td>
<td>704 to 787</td>
<td>LTE Band 13, 17</td>
<td>Pulse Modulation 217 Hz</td>
<td>0.2</td>
<td>0.3</td>
<td>9</td>
<td>9</td>
</tr>
<tr>
<td>780</td>
<td>704 to 787</td>
<td>LTE Band 13, 17</td>
<td>Pulse Modulation 217 Hz</td>
<td>0.2</td>
<td>0.3</td>
<td>9</td>
<td>9</td>
</tr>
<tr>
<td>810</td>
<td>800 to 960</td>
<td>GSM 800/900, TETRA 800, IDEN 820, CDMA 850, LTE Band 5</td>
<td>Pulse Modulation 18 Hz</td>
<td>2</td>
<td>0.3</td>
<td>28</td>
<td>28</td>
</tr>
<tr>
<td>870</td>
<td>800 to 960</td>
<td>GSM 800/900, TETRA 800, IDEN 820, CDMA 850, LTE Band 5</td>
<td>Pulse Modulation 18 Hz</td>
<td>2</td>
<td>0.3</td>
<td>28</td>
<td>28</td>
</tr>
<tr>
<td>930</td>
<td>800 to 960</td>
<td>GSM 800/900, TETRA 800, IDEN 820, CDMA 850, LTE Band 5</td>
<td>Pulse Modulation 18 Hz</td>
<td>2</td>
<td>0.3</td>
<td>28</td>
<td>28</td>
</tr>
<tr>
<td>1720</td>
<td>1700 to 1990</td>
<td>GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS</td>
<td>Pulse Modulation 217 Hz</td>
<td>2</td>
<td>0.3</td>
<td>28</td>
<td>28</td>
</tr>
</tbody>
</table>
8.8.2 Safety Tests

The monitoring cable is intended to be used only in combination with an external monitoring system that either operates with AC power isolation conforming with IEC 60601-1 (or equivalent) or operates on battery power. It is the monitoring system manufacturer’s responsibility to conduct the appropriate safety tests required to ensure compliance.

8.9 Host Monitoring System Requirements

The monitoring cable provides oximetry reporting to any host monitoring system that provides the following features:

- USB Standard A female receptacle supporting USB 2.0 Full-Speed
- Operating system compatible with the monitoring cable’s Client-Side Virtual COM Port Driver
- Operating system that allows power saving settings (turning off power to an inactive connected device) to be disabled for the USB port to which the monitoring cable is connected
- User interface software that connects and manages a virtual COM port connection to the USB port hosting the monitoring cable
• User interface software that can update the displayed monitoring cable information without significant delays

• User interface software providing a GUI to display SpO₂ and pulse rate as reported by the monitoring cable

• User interface software that displays physiological and technical system alarms in accordance with appropriate sections of EN 60601-1-8

• User interface software that can produce audible alarms as directed by the monitoring cable in accordance with appropriate sections of EN 60601-1-8

• User interface software providing a GUI that allows a user to send commands to the monitoring cable

8.10 Essential Performance

Per IEC 60601-1-2:2007 and ISO 80601-2-61:2011, the monitoring cable’s essential performance attributes include:

• **SpO₂ and pulse rate accuracy** - See *System Accuracy and Ranges*, page 8-2.

• **Detection of physiological alarm conditions** - The monitoring cable reports physiological alarm conditions to the host monitoring system. The host monitoring system is responsible for prioritizing and notifying the operator of the alarm conditions. Refer to the documentation provided with the host monitoring system.

• **Sensor disconnect/off notification** - The monitoring cable reports sensor off/disconnect conditions to the host monitoring system. The host monitoring system is responsible for providing the appropriate notification to the operator. Refer to the documentation provided with the host monitoring system.

• **Motion, interference, or signal degradation indicator** - The monitoring cable reports motion, interference, or signal degradation conditions to the host monitoring system. The host monitoring system is responsible for providing the appropriate notification to the operator. Refer to the documentation provided with the host monitoring system.
A Clinical Study

A.1 Overview

This appendix contains data from the clinical study conducted for the Nellcor™ sensors used with the Nellcor™ oxicable, USB, PMC10UB305N (the "monitoring cable").

One prospective, controlled hypoxia clinical study was conducted to demonstrate the accuracy of Nellcor™ sensors when used in conjunction with the monitoring cable. The study was performed with healthy volunteers at a single clinical laboratory. Accuracy was established by comparison to CO-oximetry.

A.2 Methods

Data from 12 healthy volunteers were included in the analysis. Sensors were rotated on digits and brow to provide a balanced study design. SpO₂ values were continuously recorded from each instrument while inspired oxygen was controlled to produce five steady state plateaus at target saturations of approximately 98, 90, 80, 70 and 62%. Arterial blood samples are periodically taken from an indwelling arterial catheter at each plateau resulting in a total of approximately 30 samples per subject. Each arterial sample is drawn while SpO₂ data were simultaneously collected and marked for direct comparison to reference-standard measurements of blood SaO₂ by a CO-oximeter. Each arterial sample was analyzed by multiple CO-oximeters and an average SaO₂ value was calculated for each sample. End tidal CO₂, respiratory rate, and respiratory pattern were continuously monitored throughout the study.

A.3 Study Population

A total of 12 subjects completed the study, 6 males (50%) and 6 females (50%) with a mean age of 29.3 ± 5.3 and an age range of 21 to 40 years of age. The mean height was 172.7 ± 9.7 cm and the mean weight was 68.7 ± 11.4 kg.

### Table A-1. Demographic Data

<table>
<thead>
<tr>
<th>Type</th>
<th>Class</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td>Male</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>6</td>
</tr>
</tbody>
</table>
A.4 Study Results

Accuracy was calculated using Accuracy Root Mean Square ($A_{RMS}$).

Table A-2. SpO$_2$ Accuracy for Nellcor$^\text{TM}$ Sensors vs. Co-Oximeters

<table>
<thead>
<tr>
<th>SpO$_2$ Range</th>
<th>100% - 90%</th>
<th>90% - 80%</th>
<th>80% - 70%</th>
<th>70% - 60%</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>588</td>
<td>428</td>
<td>394</td>
<td>378</td>
</tr>
<tr>
<td>MAXA</td>
<td>1.49</td>
<td>1.57</td>
<td>2.50</td>
<td>3.08</td>
</tr>
<tr>
<td>MAXN</td>
<td>1.71</td>
<td>1.51</td>
<td>1.59</td>
<td>2.01</td>
</tr>
<tr>
<td>MAXFAST</td>
<td>1.24</td>
<td>1.26</td>
<td>2.05</td>
<td>3.14</td>
</tr>
<tr>
<td>$A_{RMS}$ (%)</td>
<td>1.56</td>
<td>1.50</td>
<td>2.06</td>
<td>2.68</td>
</tr>
</tbody>
</table>

The following modified Bland-Altman plots show SpO$_2$ data by sensor type. Each individual subject is represented by a unique marker on the plots. Subject identification numbers are indicated in the legend with each plot.
Figure A-1. Modified Bland-Altman for SpO₂ - MAXA Sensor: SaO₂ vs. (SpO₂ - SaO₂)

1. SpO₂ - SaO₂ (%)  
2. SaO₂ (%)  
3. Upper 95% LoA  
4. Mean Bias  
5. Lower 95% LoA

Figure A-2. Modified Bland-Altman for SpO₂ - MAXN Sensor: SaO₂ vs. (SpO₂ - SaO₂)

1. SpO₂ - SaO₂ (%)  
2. SaO₂ (%)  
3. Upper 95% LoA  
4. Mean Bias  
5. Lower 95% LoA
A4.1 Adverse Events or Deviations

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

A5 Conclusion

When using the monitoring cable in conjunction with the MAXA, MAXN, and MAXFAST sensors, during a saturation range of 60% - 80% and non-motion conditions, the system demonstrates expected SpO2 accuracy of 3% ARMS.

When using the monitoring cable in conjunction with the MAXA, MAXN, and MAXFAST sensors, during a saturation range of 70% - 100%, the system passed the expected SpO2 accuracy of 2% ARMS.