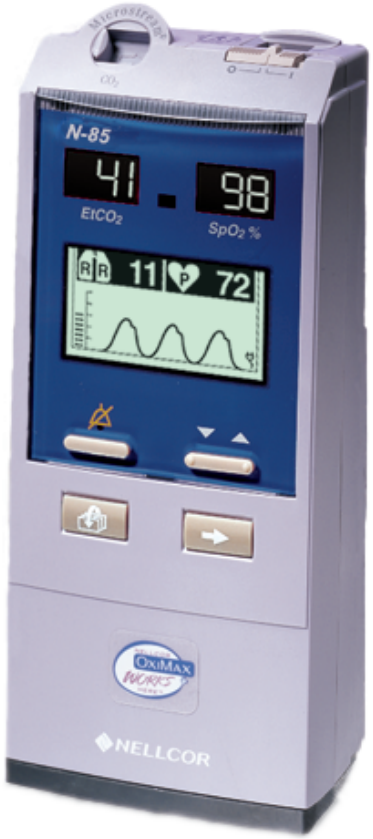
NELLCOR

OxiMax®
N-85™

Operator's Manual
Portable Bedside Capnograph/ Pulse Oximeter



Operator's Manual

Portable Bedside Capnograph/Pulse Oximeter

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Safety Information

Warnings
Symbols

To use the portable capnograph/pulse oximeter monitor correctly and safely, carefully read this operator's manual and the *Directions for Use* for the SpO_2 sensors and Microstream $EtCO_2$ consumables. Use of the monitor requires full understanding and strict observance of these instructions, the precautionary information in boldface type, and the specifications.

Warnings

General

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

WARNING: Carefully route patient cabling (SpO_2 sensor and FilterLine) to reduce the possibility of patient entanglement or strangulation.

WARNING: Do not lift the monitor by the SpO_2 sensor cable or FilterLine as they could disconnect from the monitor, causing the monitor to fall on the patient.

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

WARNING: The use of accessories, transducers, sensors and cables other than those specified may result in increased emission and/or decreased immunity of the equipment and/or system.

WARNING:	CO_2 readings, respiratory rate, pulse oximetry readings, and pulse signal can be affected by certain ambient environmental conditions, sensor application errors, and certain patient conditions.
WARNING:	The monitor is a prescription device and is to be operated by qualified healthcare personnel only.

MRI Scanning

WARNING:	Do not use Nellcor oximetry sensors during magnetic resonance imaging (MRI) scanning. Conducted current could cause burns. The sensors may affect the MRI image and the MRI unit may affect the accuracy of oximetry measurements.
CAUTION:	During MRI scanning, the monitor must be placed outside the MRI suite. When the monitor is used outside the MRI suite, $EtCO_2$ monitoring can be implemented using the FilterLine XL. (Refer to MRI Scanning, page 56.)

Alarms

WARNING:	Do not silence the audible alarm if patient safety may be compromised.
WARNING:	Always respond immediately to a system alarm since the patient may not be monitored during certain alarm conditions.
WARNING:	Before each use, verify that the alarm limits are appropriate for the patient being monitored.
WARNING:	Check the audible alarm silence duration before temporarily silencing the audible alarms.

Fire Hazard

WARNING: When using the monitor with anesthetics, such as high concentrations of oxygen or nitrous oxide, connect the gas outlets to a scavenger system.

WARNING: The monitor is not suitable for use in the presence of flammable anesthetic mixture with air, oxygen or nitrous oxide.

WARNING: The FilterLine may ignite in the presence of O_2 when directly exposed to laser, ESU devices, or high heat. When performing head and neck procedures involving laser, electrosurgical devices or high heat, use with caution to prevent flammability of the FilterLine or surrounding surgical drapes.

Electrical

WARNING: To protect against electric shock hazard, the monitor's cover is to be removed only by qualified service personnel. There are no user-serviceable parts inside.

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

WARNING: Use only the medical grade AC adapter provided by the manufacturer. If in doubt about the integrity of the mains supply connection, operate the monitor from its internal battery pack.

WARNING: Do not connect to a printer or to a PC unless using the Communication Adapter provided by the manufacturer as an optional accessory. The printer and PC (when connected to the patient through the Communication Adapter) must be distanced from the patient environment by at least 1.5 m.

Electro-magnetic Interference

This device has been tested and found to comply with the requirements for medical devices according to the standard EN60601-1-2/2001. These standards are designed to provide reasonable protection against harmful interference in a typical medical installation.

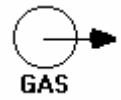
However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in the healthcare environments (for example: cellular phones, mobile two–way radios, electrical appliances), it is possible that high levels of such interference due to close proximity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

WARNING: Operating high frequency electrosurgical equipment in the vicinity of the monitor can produce interference in the monitor and give incorrect measurements.

WARNING: Do not use the monitor with nuclear spin tomography (MRT, NMR, NMT) as the function of the machine may be disturbed.

Symbols

The following symbols appear on the monitor and monitor LCD (liquid crystal display):

Symbol	Description
	See Directions for Use
	Gas Outlet
	Defibrillator–proof Type BF equipment (patient electrically isolated)
	Audible Alarms Off

	Plug Icon
	Battery Icon
$EtCO_2$	End tidal carbon dioxide value
SpO_2 %	Oxygen saturation value
	DC Input
	Refer to manual for connector interface and other information
Pump Off/On	Pump Off

Introduction

This manual provides directions for setup and operation of the monitor.

The monitor is a portable bedside capnograph/pulse oximeter that continuously monitors end tidal carbon dioxide ($EtCO_2$), respiratory rate (RR), fractional inspired carbon dioxide ($FiCO_2$), oxygen saturation (SpO_2), and pulse rate. The unit is indicated for monitoring only and must be used in the continuous presence of a qualified healthcare provider. It is intended for use in any environment where continuous, noninvasive monitoring of these parameters is desired, including hospital and hospital type facilities. The monitor is intended for use on adult, pediatric, and infant/neonatal patients.

Monitor Features

- Combines a capnograph and pulse oximeter in a small, portable, lightweight monitor.
- Measures and displays $EtCO_2$, $FiCO_2$, respiration rate, SpO_2, and pulse rate in one graphic and two digital displays.
- Displays CO_2 and SpO_2 waveforms and trends.
- Utilizes a wide range of Microstream $EtCO_2$ consumables and Nellcor SpO_2 sensors for all applications.
- Operates on mains line power or a rechargeable Nickel Metal Hydride battery pack.
- Employs audible and visual alarm warnings for monitored parameters and instrument malfunctions.
- Provides user selectable language options: English, French, German, Spanish, Italian, Dutch, Swedish, Norwegian and Portuguese.
- Displays $EtCO_2$ and $FiCO_2$ values in mmHg, kPa or Vol%.
- Provides output for printer, PC, and Digital to Analog Converter.

- Provides interface to hospital nurse call systems.

Overview

Principles of Operation
FilterLine
Pulse Oximetry
Displays, Controls and Connectors

The monitor combines Oridion's Microstream capnography technology with Nellcor pulse oximetry technology.

Principles of Operation

Capnography

The monitor uses Microstream non–dispersive infrared (NDIR) spectroscopy to continuously measure the amount of CO_2 during every breath, the amount of CO_2 present at the end of exhalation ($EtCO_2$) and during inhalation ($FiCO_2$), and the Respiratory Rate.

Infrared spectroscopy is used to measure the concentration of molecules that absorb infrared light. Because the absorption is proportional to the concentration of the absorbing molecule, the concentration can be determined by comparing its absorption to that of a known standard.

The Microstream $EtCO_2$ consumables deliver a sample of the inhaled and exhaled gases from the ventilator consumable or directly from the patient (via an oral/nasal cannula) into the monitor for CO_2 measurement. Moisture and patient secretions are extracted from the sample, while maintaining the shape of the CO_2 waveform.

The 50 ml/min. sampling flow rate reduces liquid and secretion accumulation, decreasing the risk of obstruction in the sample pathway in humid ICU environments.

Once inside the Microstream CO_2 sensor, the gas sample goes through a micro-sample cell (15 microliters). This extremely small volume is quickly flushed, allowing for fast rise time and accurate CO_2 readings, even at high respiration rates.

The Micro Beam IR source illuminates the micro-sample cell and the reference cell. This proprietary IR light source generates only the

specific wavelengths characteristic of the CO_2 absorption spectrum. Therefore, no compensations are required when different concentrations of N_2O, O_2, anesthetic agents and water vapor are present in the inhaled and exhaled breath. The IR that passes through the micro-sample cell and the IR that passes through the reference cell are measured by the IR detectors.

The microcomputer in the monitor calculates the CO_2 concentration by comparing the signals from both channels.

Microstream EtCO_2 Consumables

The following products comprise the Microstream EtCO_2 consumables:

Sample Lines and Airway Adapter Sets for Intubated Patients:

- FilterLine Set (for non–humid environments).
- FilterLine H set (for humid environments).

Nasal Cannulas for Non-intubated patients:

- Smart CapnoLine Plus – for use in procedural sedation. Also available with O_2 delivery.
- Smart CapnoLine H Plus – for use in post-op pain management. Also available with O_2 delivery.
- CapnoLine H – for patients receiving hi–flow oxygen by mask , on long term CPAP or Bi-PAP, or post-op pain management. Also available with O_2 delivery.
- NIV Line – for use under oxygen CPAP, Bi–PAP or NPPV mask.
- Smart BiteBloc – for use during upper endoscopy procedures.

Note: Smart products provide oral and nasal sampling. H products are for long term use.

Special Procedure FilterLines

- FilterLine XL – Provides extended length so that the monitor can be used safely during MRI (see page 56).

Note: The generic term FilterLine, used in this manual, is interchangeable with any of the Microstream $EtCO_2$ consumables.

FilterLine

The FilterLine has five active elements that work together to offer a solution to the problems that have previously proved challenging to capnography in ICU, emergency, and intra-transport applications. These elements are:

- Hydrophobic filter

  The hydrophobic filter is located at the end of the sample line that is closest to the capnograph. This filter strips the remaining water vapor from the gas sample while keeping a laminar flow of the gas. This laminar flow minimizes distortion of the CO_2 waveform. This filter is made of a 0.2 µ hydrophobic porous medium.

- Drying element

  The drying element is a tube made of a synthetic material that is extremely chemically stable and has high water absorption. This material allows the water vapor to pass outside the tube, thereby adjusting the humidity inside the FilterLine close to the level of humidity in the ambient air.

- Sample line

  The sample line has low dead space due to its small internal diameter. This provides a sharp waveform and an accurate CO_2 reading at a high breath rate per minute. The sample line is not affected by gases and anesthetic agents in the operating room environment.

- FilterLine Recognition Safeguard

  When the FilterLine is attached to the monitor, the FilterLine Recognition Safeguard (FRS) identifies the FilterLine and activates the pump, thus enabling measuring.

- Airway Adapter

  The airway adapter design provides multiple channels for the sampled air from the airway minimizing the possibility of water

infiltration or line blockage. These multiple channels allow uninterrupted monitoring for all adapter orientations and in all applications. The airway adapter provides optimal performance in all directions and is seldom disabled by secretions or liquids.

Pulse Oximetry

Operating Principles

Pulse oximetry is based on two principles: 1) oxyhemoglobin and deoxyhemoglobin, which differ in their absorption of red and infrared light (spectrophotometry), and 2) changes in the volume of arterial blood in tissue during the pulse cycle (plethysmography), and hence, light absorption by that blood.

A pulse oximeter determines SpO_2 by passing red and infrared light into an arteriolar bed and measures changes in light absorption during the pulsatile cycle. Red and infrared lowpower lightemitting diodes (LEDs) in the oximetry sensor serve as light sources; a photodiode serves as the photodetector.

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 SpO_2 measurements on the difference between maximum and minimum absorption (measurements at systole and diastole). The focus of light absorption by pulsatile arterial blood eliminates the effects of nonpulsatile absorbers such as tissue, bone, and venous blood.

Automatic Calibration

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

During monitoring, the instrument's software selects coefficients that are appropriate for the wavelength of that individual sensor's red LED. These coefficients are then used to determine SpO_2.

Additionally, to compensate for differences in tissue thickness, the light intensity of the sensor's LEDs is 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, laboratory hemoximeters 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 (PO_2), the calculated value may differ from the SpO_2 measurement of a pulse oximeter. This usually occurs because the calculated saturation was not appropriately corrected for the effects of variables that shift the relationship between PO_2 and saturation: pH, temperature, the partial pressure of carbon dioxide (PCO_2), 2,3-DPG, and fetal hemoglobin.

Use of 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 Nellcor pulse oximeter sensors, cables and monitors. See the individual testing device's Operator's Manual for the procedures specific to the model of tester being used.

While such devices may be useful for verifying that the pulse oximeter sensor, cabling and monitor are functional, they are incapable of providing the required data needed to properly evaluate the system's SpO_2 reading accuracy.

Fully evaluating SpO_2 reading accuracy requires, at a minimum, accommodating the wavelength characteristics of the sensor and reproducing the complex optical interaction of the sensor and patient's tissue - capabilities beyond the scope of known bench top testers. SpO_2 accuracy can only be evaluated *in vivo* by comparing pulse oximeter readings with values traceable to SaO_2 measurements obtained from simultaneously sampled arterial blood made using a laboratory CO-oximeter.

Many functional testers and patient simulators have been designed to interface with the pulse oximeter's expected calibration curves and may be suitable for use with Nellcor monitors and/or sensors. Not all, however, are adapted for use with the Nellcor *OxiMax* digital calibration system.

While this will not affect use of the simulator for verifying system functionality, displayed SpO_2 values may differ from the setting of the test device. For a properly functioning monitor, this difference will be reproducible over time and from monitor to monitor within the performance specifications of the test device.

Displays, Controls and Connectors

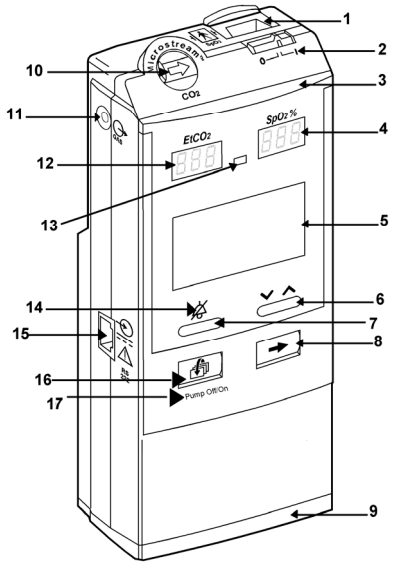


Figure 1: Monitor Front View

The numbered labels in Figure 1 are described below.

Label	Description	Label	Description
1	SpO_2 Connector	9	Battery Pack
2	Off/On Switch	10	FilterLine Input Connector
3	Alarm Bar	11	Gas Outlet
4	Digital Display of SpO_2	12	Digital Display of $EtCO_2$
5	Graphic Display	13	Photo Resistor
6	Contrast/Value Change Button	14	Alarm Silence Indicator
7	Alarm Silence/ Alarm Silence Menu Button	15	Port for AC Adapter or communication adapters
8	Next/Menu Button	16	Event /Home Button
		17	Pump Off/On Adhesive Label

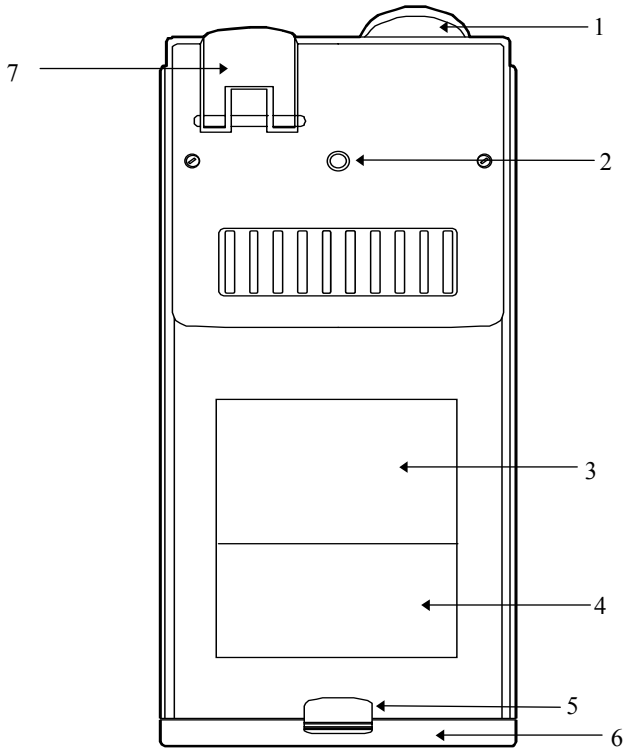


Figure 2: Monitor Rear View

The numbered labels in Figure 2 are described below.

Label	Description	Label	Description
1	FilterLine Input Connector	5	Battery Pack Release Button
2	Clamp Connector	6	Battery Pack
3	Space for Quick Guide Adhesive Label	7	SpO_2 Connector Latch
4	Serial Number Label		

Initial Setup

Power Requirements
Unpacking and Inspection
Start-Up and Self Test
Single Parameter Setup Options
Measuring Mode
Quick Guide

Power Requirements

The monitor operates on batteries or on AC power. It is equipped with a rechargeable Nickel Metal Hydride battery pack. When a power outlet is available, use the medical grade AC adapter provided with the monitor.

Before using the monitor in the field, ensure that the battery pack is fully charged. At the Measuring mode, check that the battery icon at the right side of the graphic display is full.

Note: If the battery is not fully charged, the icon may first show as full and after a short period of time will drop to indicate the real charge level.

A fully charged battery pack provides between four and seven operating hours, depending on power management (refer to Table 7 on page 50 for a description of the power management options).

WARNING: Use only the medical grade AC adapter provided by the manufacturer. If unsure about the integrity of the line connection, operate the monitor from its internal battery pack.

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

Battery and Power Usage

If power is lost when the monitor is operating from AC power, it automatically switches to its internal battery pack.

A plugshaped icon at the bottom right side of the graphic display is displayed when the monitor operates from an external power source and the battery pack is fully charged. A battery-shaped icon is displayed when the monitor operates from the battery pack. The battery icon will show the battery pack's approximate charge level. An advisory message, **Battery↓!**, appears when approximately 40 minutes of battery charge remains. A caution message, **Battery↓!!**, appears when approximately 15 minutes of charge time remains.

While the monitor is connected to AC power, the battery pack can be replaced without interrupting monitoring.

Battery Pack

Before using a new battery pack for the first time, charge and discharge the battery three times to ensure full battery capacity. For charging and discharging, the Microstream Capnograph Battery Charger is recommended (refer to the Microstream Capnograph Battery Charger *Directions for Use*).

Internal Recharge Function

CAUTION: Do not attempt to disassemble the battery pack. It is a sealed unit and has no serviceable parts inside.

When the monitor is connected to an external power source (even if the monitor is turned off), the battery pack charges automatically. If the instrument is on during charging, the battery-shaped icon displays a filling pattern. It takes approximately 4.5 hours to fully charge an empty battery pack. Additional battery packs can be purchased from your local representative.

The recommended temperature for battery charging is between 5ºC and 45ºC.

CAUTION: Important! The following information relates to the safe handling, storage, and disposal of the monitor battery pack.

Battery Testing

The battery pack charge level should be tested before each use by observing the level on the battery icon after Self Test. For a correct reading, wait for the battery charge level to stabilize. Replace or recharge the battery pack when the advisory message **Battery↓!** appears on the graphic display screen (refer to Troubleshooting on page 61).

Handling

- Do not immerse the battery pack in water; it may malfunction.
- Only recharge the battery pack in the monitor or use the Microstream Capnograph Battery Charger, provided by your local representative, to avoid possible overheating, burning or rupture of the battery pack.

Storage

- Short-term storage (one month or less): The battery pack has an automatic discharge feature. You must periodically check the charge level of the battery pack.
- Long-term storage (6 months or more): The battery pack must be stored in a cool, dry area. Its charge decreases over time. To restore the battery pack to full power, charge and discharge it three times before use. Long-term storage, without charging the battery, may degrade the battery capacity.

Disposal

- Do not dispose of the battery pack in fire; it may explode.
- Be sure to follow local governing ordinances and recycling instructions regarding disposal or recycling of batteries.

Unpacking and Inspection

Components

1. Remove the monitor and the accessories from the box carefully.
2. Check that the items listed in the table on the back cover of this manual are included.
3. Inspect each component. If the package is damaged or any component is missing, contact your local representative.

Optional Accessories

The following items are available for use with the monitor:

- Protective Boot
- Carrying Case
- Clamp
- Rechargeable Battery Pack
- Microstream Capnograph Battery Charger
- Battery Pack Carrying Pouch
- 12 Volt Cable
- Communication Adapter Kit
- Calibration Gas Kit
- Service Manual
- Digital to Analog (D/A) Converter
- Seiko DPU 414 Printer
- Nurse Call Interface Kit
- MSM (Microstream Monitor) Interface Kit

Note: For information on operating the monitor with any accessory, refer to the specific accessory's *Directions for Use*.

CAUTION:	To protect the unit, the manufacturer recommends using the carrying case, the clamp, or the protective boot, depending on the type of application.

Start-Up and Self Test

WARNING:	Do not lift the monitor by the SpO_2 sensor cable or the FilterLine as they could disconnect from the monitor, causing it to drop on the patient.
WARNING:	To ensure patient safety, do not place the monitor in any position that might cause it to fall on the patient. Carefully route patient cabling (SpO_2 sensor and FilterLine) to reduce the possibility of patient entanglement or strangulation.
WARNING:	When using the monitor with anesthetics, such as high concentrations of oxygen or nitrous oxide, connect the gas outlets to a scavenger system.
CAUTION:	The monitor is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.
CAUTION:	The monitor is a prescription device and is to be operated by qualified healthcare providers only.
CAUTION:	Only use Microstream $EtCO_2$ consumables and *Nellcor* SpO_2 sensors to ensure that the monitor functions properly.
CAUTION:	Do not connect anything other than an SpO_2 sensor to the sensor port (for example, do not attempt to connect a PC to the monitor at the sensor port).

Preparation

Prior to start-up:

1. Slide open the FilterLine input connector shutter and connect the appropriate FilterLine. Connect the appropriate Nellcor SpO_2 sensor firmly into the sensor port.
2. Connect the FilterLine and Nellcor SpO_2 sensor to the patient as described in the *Directions for Use*. If needed, use a Nellcor SpO_2 sensor extension cable, model DEC-4 or DEC-8.

Note: When the monitor is used in stationary applications, secure it with the clamp (available as an optional accessory).

Initialization

CAUTION: If any monitor response does not seem appropriate, do not use the monitor. Instead, contact your local representative.

CAUTION: Immediately after powerup, confirm that all display segments and icons function.

3. Turn on the monitor by sliding the on/off switch to the on position.
4. Verify that the monitor is working properly. Proper working condition is verified by completing the power on Self Test described below.
5. When turned on, the monitor automatically performs a Self Test. The display and alarm functions are tested activating the LCD, alarm bar, seven segment displays, alarm silence indicator, and buzzer. In this mode all alarms are disabled. The initialization screen displays for 5 seconds (refer to Figure 3).

Figure 3: Initialization Screen

6. As the monitor continues to test its internal subsystems, the Self Test screen appears (refer to Figure 4). During this test, there is an option to choose a single parameter operation. This option is also available from the *Setup* menu (see the *Basic Operation* section of this manual).

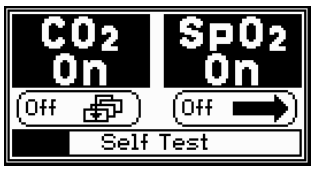


Figure 4: Self Test Screen

During Self Test, the $EtCO_2$ and SpO_2 LEDs show dashes. When the monitor is ready and the FilterLine is connected, the dashes in the $EtCO_2$ LEDs are replaced by numeric values. If one or both, the FilterLine consumable or SpO_2 probe, are not connected to the monitor, dashes will appear on their respective LEDs.

Single Parameter Setup Options

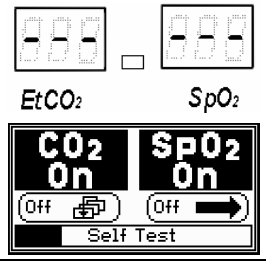
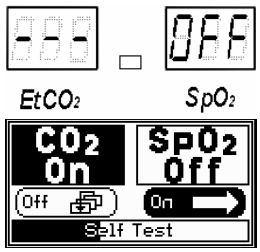
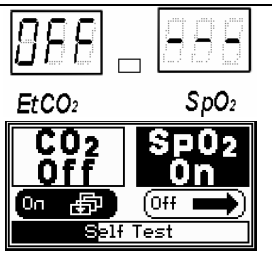
The monitor is preset at the factory to simultaneously measure CO_2 and SpO_2. There is an option to individually measure either CO_2 or SpO_2 as follows:

- CO_2 Accessed during Self Test (Table 1, page 30) or from the *Instrument Setup* menu (see *Basic Operation on page 39*).

- SpO_2 Accessed during Self Test (Table 1, page 30) or from the *Instrument Setup* menu (see *Basic Operation on page 39*).

Note: Every time the monitor is turned on, it automatically reverts to its default setting, measuring both CO_2 and SpO_2.

Table 1: Single Parameter Setup Options

Parameter	Action	Display
Startup measuring both CO_2 and SpO_2: (factory set option)	No action required	
Startup measuring only CO_2	long press (during Self Test)	
Startup measuring only SpO_2	long press (during Self Test)	

Measuring Mode

In measuring mode, the monitor measures, displays, and stores event data, or prints data that has been stored in its memory.

During measuring, the monitor shows $EtCO_2$ and SpO_2 readings on the digital displays. Waveform, respiration rate, pulse rate, and other information (according to the selected screen, see the *Basic Operation* section of this manual) are shown on the graphic display. A beep sounds once for each pulse beat. The tone of the pulse beat varies in proportion to the saturation level. If the saturation level is high, the pitch is higher, if the saturation level is low, the pitch is lower.

The monitor begins measuring after recognizing one breath (after monitor power up or after exiting Standby). The monitor recognizes two breath measurement ranges:

Valid breath: values ≥ 7.5 mmHg (for adult mode) or ≥ 5.0 mmHg (for neonatal mode)

Low readings breath: values < 7.5 mmHg (for adult mode) or < 5.0 mmHg (for neonatal mode)

Note: If the first breath the monitor recognizes is a Low readings breath, the monitor will not display nor emit warning signals and a No Breath message will not appear. If the values go above 7.5 mmHg (for adult mode) or 5.0 mmHg (for neonatal mode), and then fall below these ranges, the monitor will display a No Breath message and emit warning signals (see the Troubleshooting section of this manual).

$EtCO_2$ readings between 3.0–7.0 mmHg (adult mode) or 3.0–5.0 mmHg (neonatal mode) appear as numerical values on the $EtCO_2$ LEDs. Readings < 3.0 mmHg show as 0 (zero) on the LEDs.

The waveform appears on the graphic display for all $EtCO_2$ values.

Battery Pack and AC Operation

1. Connect only Microstream $EtCO_2$ consumables and *Nellcor* SpO_2 sensors to the monitor.
2. **Battery pack operation**: First, switch the monitor on and check that the battery pack is charged (at the Measuring mode, check that the battery icon on the right side of the graphic display is full).

   AC operation: Connect the AC adapter to the monitor and plug the cord into the mains power supply. Switch the monitor on. Check that the battery icon displays a filling pattern or the plug icon appears.

   (Refer to Figure 5: Quick Guide, on page 32, for all button functions.)
3. Adjust the parameters in the *Alarm Limits* menu, *Instrument Setup* menu, and *Alarm Silence* menu to the values appropriate to the patient's condition.

Quick Guide

The Quick Guide adhesive label is included in the monitor packaging. Apply the label to the monitor as shown in Figure 2: Monitor Rear View on page 22.

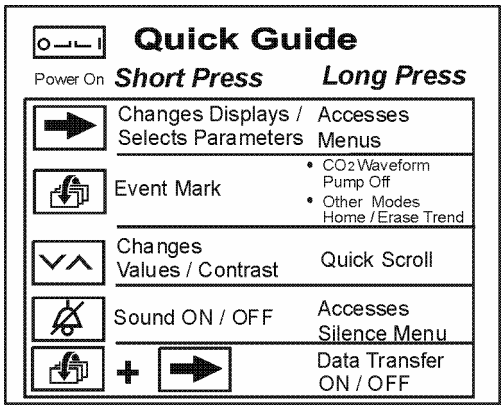


Figure 5: Quick Guide

Accessories

Microstream $EtCO_2$ Consumables
Nellcor SpO_2 Sensors

Microstream $EtCO_2$ Consumables

- FilterLine Set
- FilterLine H Set
- Smart CapnoLine and Smart CapnoLine Plus (available with O_2 delivery)
- Smart CapnoLine H Plus (available with O_2 delivery)
- CapnoLine H (available with O_2 delivery)
- NIV Line
- Smart BiteBloc

(For a description of Microstream $EtCO_2$ consumables see page 16)

CAUTION: Before use, carefully read the Microstream $EtCO_2$ consumables *Directions for Use*.

CAUTION: Only use Microstream $EtCO_2$ consumables to ensure the monitor functions properly.

CAUTION: Microstream $EtCO_2$ consumables are designed for single patient use, and are not to be reprocessed. Do not attempt to disinfect or flush the FilterLine as the monitor can be damaged.

CAUTION: Dispose of Microstream $EtCO_2$ consumables and retired Nellcor pulse oximetry sensors according to standard operating procedures or local regulations for the disposal of contaminated medical waste.

WARNING: The FilterLine may ignite in the presence of O_2 when directly exposed to laser, ESU devices, or high heat. When performing head and neck procedures involving laser, electrosurgical devices or high heat, use with caution to prevent flammability of the FilterLine or surrounding surgical drapes.

Basic Principles

When choosing Microstream $EtCO_2$ consumables, the following should be considered:

- Intubated versus non-intubated
- Whether the patient is on mechanical ventilation
- Duration of use
- Patient's size and weight

For further information, please contact your local representative.

Select the appropriate FilterLine and connect it to the monitor before attaching it to the patient's airway. Be sure to follow Microstream $EtCO_2$ Consumables' *Directions for Use* for proper connection.

Nellcor SpO_2 Sensors

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

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

WARNING: Use only Nellcor sensors for SpO_2 measurements. Other sensors may cause improper monitor performance.

Note: Biocompatibility testing has been performed on the materials used in Nellcor pulse oximetry sensors per ISO 10993–1, and found to be compliant.

Nellcor pulse oximetry sensors contain light emitting diodes (LEDs) that emit red (~660 nm) and infrared (~900 nm) light, with a total optical output power of less than 15 mW.

This information of sensor wavelength range can be especially useful to clinicians, e.g., those performing photodynamic therapy.

Sensor LED light output falls within Class 1 Level per IEC 60825-1:2001 Safety of Laser Products; no special safety precautions are needed.

Selecting Nellcor SpO_2 Sensors

When selecting a sensor, consider the patient's weight and activity, the adequacy of perfusion, the available sensor sites, and the anticipated duration of monitoring. The sensor models are summarized in Table 2. For further information, please contact your local representative.

Table 2: Nellcor SpO_2 Sensors

Oxygen Sensor	Model	Patient Weight
OxiMax® oxygen transducer (single patient use)	MAX-N	<3 kg or >40 kg
	MAX-I	3 to 20 kg
	MAX-P	10 to 50 kg
	MAX-A	>30 kg
	MAX-AL	>30 kg
	MAX-R	>50 kg
	MAX-FAST	>40 kg
OxiMax® OxiCliq® oxygen transducer (single-use only)	P	10 to 50 kg
	N	<3 or >40 kg
	I	3 to 20 kg
	A	>30 kg
OxiMax® Dura-Y® multisite oxygen transducer (Nonsterile, reusable)	D-YS	>1 kg
For use with Dura-Y sensor:		
Ear clip (Reusable, nonsterile)	D-YSE	30 kg
Pedi-Check™ pediatric spot-check clip (Reusable, nonsterile)	D-YSPD	3 to 4 kg
OxiMax® Oxiband® oxygen transducer (Reusable with disposable nonsterile adhesive)	OXI-A/N OXI-P/I	<3 kg or>40 kg 3 to 40 kg
OxiMax® Durasensor® oxygen transducer (Nonsterile, reusable)	DS-100A	>40 kg

Performance Considerations

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

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

WARNING: Use only Nellcor-approved sensors and pulse oximetry cables. Other sensors or oximetry cables may cause improper monitor performance.

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
- prolonged and/or excessive patient movement
- interavascular dyes or externally applied coloring, such as nail polish or pigmented cream
- failure to cover the sensor site with opaque material in high or ambient light conditions

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

- the sensor is applied too tightly
- 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
- poor peripheral profusion

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.

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

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

If patient movement presents a problem, try one or more of the following remedies:

- 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 MAX-R 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.

Basic Operation

Data Display Screens
Displayed Data Options
Alarm Functions
Alarm Limits Menu
Alarm Silence/Standby Menu
Instrument Settings Menus
MRI Scanning
Standby
Pump Off Mode
Pump Off/On Label

Data Display Screens

In Measuring mode, the monitor constantly measures and displays the CO_2 waveform, $EtCO_2$ numerical value, respiratory rate (RR), $FiCO_2$ (user selected), SpO_2, and pulse rate values.

Note: For both neonatal and adult patients, the $EtCO_2$ displayed on the LED Numeric Displays represents the maximum value during the last 15 seconds (updated every 5 seconds). The $EtCO_2$ is displayed from the first breath. The $EtCO_2$ warning is according to the value in the 7-Segment display.

The SpO_2 and $EtCO_2$ values are shown in the digital displays. Waveform or trends, respiratory rate and pulse rate values are shown in the graphic display (Figure 6: Monitor Display Screen and LEDs). If a parameter is turned off, the related screens are skipped and that parameter's value of the display indicates "OFF". Power icons, advisories, warnings, or cautions appear super-imposed over the data display.

At any time during the Measuring mode, the user can mark a special event by a short press of  and a short duration tone sounds. The event is stored in the monitor's memory and will appear on the data printout marked by an asterisk ("*") on the tabular trend printout and as a horizontal line on the graphic trend printout.

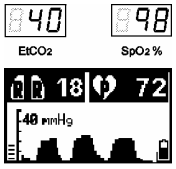


Figure 6: Monitor Display Screen and LEDs

There are seven graphic display screens (refer to Table 3 on page 44):

- CO_2 Waveform
- CO_2 Trend, 30 minutes
- CO_2 Trend, 8 hours
- Meter Mode
- Plethysmograph
- SpO_2 Trend, 30 minutes
- SpO_2 Trend, 8 hours

CO_2 Waveform

The CO_2 waveform screen displays real-time CO_2 waveform, pulse bar, numeric pulse and respiration rates. The end tidal CO_2 and SpO_2 values are shown simultaneously on the digital displays.

CO_2 Time Base

The time base is the period of time captured on the display. The time base default values are:

- 6 seconds for Adult Mode
- 3 seconds for Neonatal Mode

The instrument automatically changes the time base of the CO_2 waveform according to the actual respiration rate as follows:

Current Time Base	Time Base Change Condition	New Time Base
6 seconds	>35 bpm for 10 seconds	3 seconds
3 seconds	<25 bpm for 10 seconds	6 seconds
Any	Initialization, “No Breath” or blockage	6 seconds

During periods of high respiration rates, the display will automatically depict the shorter time base to avoid compression of the waveform.

The time base appears at the top right side of the graphic screen as a Temporary Silent Advisory and is shown for 5 seconds each time the instrument enters the CO_2 waveform screen or after every change of the time base. The instrument also automatically changes the time base when changing from Adult or Neonatal Mode.

CO_2 Trends

The trends graphs represent trend data of the last 30 minutes or 8 hours (15-second or 4-minute resolution respectively). The trends are shown in the CO_2 scale selected by the user. The tabular trend data for 8 hours (5-second resolution) is relevant for the print/PC option only.

During the 8-hour tabular trend period, the data of (up to) the last 100 patients is stored. A new patient is defined each time the monitor is turned off and on or enters Standby.

Note: In the case of "Autoscale," the CO_2 scale is that of the maximum range.

- The $FiCO_2$ value shows as light pixels (a light area) at the bottom of the trends graph.
- When the monitor is turned on, a trend data border will mark the end of the previous trend. The trend data border is a vertical line on the graph. An event will appear on the tabular trend printout marked by an asterisk (*) and as a vertical line on the graphic trend printout.
- When you enter a trend display, a temporary message:
- Press To Erase appears for 3 seconds. You now have the option to erase the old trends of all parameters as follows: Press (the message begins to flash) and hold it until the message disappears. This message will not appear during an alarm.
- The $EtCO_2$ and SpO_2 values are (simultaneously) shown on the real-time digital display. The respiration and pulse rate values are shown on the graphic display.

Meter Mode

The Meter mode screen includes the four numerical parameters for CO_2, SpO_2, respiration rate, and pulse rate. This mode is recommended in the following cases:

- When the power management is Low (see Table 7, page 50).
- When the monitor display is exposed to direct sunlight affecting the digital display reading.

Plethysmograph Waveform Display

The graph shows the changes in the blood's volume at the point of measurement. The pulse rate and respiration rate are also displayed at the top of the graphic display screen. The SpO_2 values show on the digital display.

The display provides the (non-normalized) real-time sensor signal (see the following section on SpO_2 Data Update Period). The relative pulsatile strength and quality of the incoming signal can be observed.

SpO_2 Data Update Period

The advanced signal processing in the algorithms automatically extends the amount of data required for measuring SpO_2 and pulse rate depending on the measuring conditions. During normal measurement conditions, the averaging time is six to seven seconds (approximately three seconds in Fast Mode).

The monitor automatically adjusts the signal processing during degraded conditions such as those caused by low perfusion, interference (e.g. external interference like ambient light, electromagnetic interference, and patient motion), or a combination of these, which results in an increase in the dynamic averaging beyond the minimum as set by monitor.

If the result of the dynamic averaging time exceeds 20 seconds for SpO_2, the PULSE SEARCH indicator is illuminated solid, and the SpO_2 and pulse rate will continue to be updated every second. As these conditions extend, the amount of data required continues to increase. If the dynamic averaging time for SpO_2 reaches 40 seconds, and/or 50

seconds for Pulse Rate, a low priority alarm state results: the pulse search indicator begins flashing, the SpO_2 and pulse rate displays flash zeros indicating a loss of pulse condition and the audible alarm state is activated.

Pulse Bar Amplitude Indicator

The Pulse Bar Amplitude Indicator indicates pulse beat and shows the relative (non-normalized) pulse amplitude. As the detected pulse becomes stronger, more bars light up with each pulse. This indicator is only available in the CO_2 Waveform screen.

SpO_2 Trends

The trends graphs represent data of the last 30 minutes or 8 hours (15-second or 4-minute resolution respectively).

SpO_2 values appear on the digital display. The respiration and pulse rate values are shown on the graphic display.

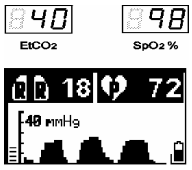
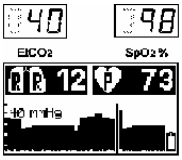
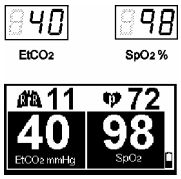
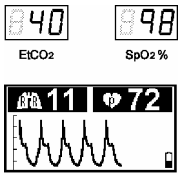
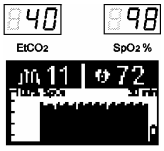
Graphic Display Screen Contrast

The LCD contrast intensity can be adjusted during Measuring mode. To adjust the contrast, press on the contrast button  . Press the right side for a darker contrast and the left side for a lighter contrast.

The photo resistor senses the ambient light intensity and accordingly switches the backlight on or off during Normal power management setting.

Displayed Data Options

Table 3: Display Screens

To View	Press	Result
CO_2 waveform	Appears automatically	
CO_2 Trend – 30 min	1st short press	
CO_2 Trend - 8 hr	2nd short press	
Meter Mode	3rd short press	
Plethysmograph	4 th short press	
SpO_2 Trend – 30 min	5th short press	
SpO_2 Trend - 8 hr	6th short press	
CO_2 waveform	7th short press	

Note: To return to CO_2 waveform from any measuring display screen, long press the button.

Alarm Functions

WARNING: Do not turn off the audible alarm or decrease the audible alarm volume if patient safety could be compromised. Pressing the alarm silence button turns the audible alarms OFF and turns the alarm silence icon LED indicator ON. In this condition there will be no audible alarms in the event of adverse patient conditions.

WARNING: When exiting Standby mode, the monitor reverts to the factory default of "All Alarms On".

The monitor has four levels of alarms. For full details on alarms, see Troubleshooting on page 61.

Alarms

Warnings are the highest level of alarms to alert the user that the patient's condition is beyond predefined limits. Alarms can be set (from the *Alarm Limits* menu – see Table 5 on page 47). The monitor has the following alarms with adjustable level settings:

- No Breath (alerting the user when no valid breath is detected after a predetermined time)
- $EtCO_2$ high and low levels
- Respiration rate (RR) high and low levels
- $FiCO_2$ high level
- SpO_2 high and low levels
- Pulse rate high and low levels

The following alarms alert the user of the instrument's status or malfunction:

- Caution messages (audible and visual)
- Advisory messages (audible and visual)
- Silent advisory messages (visual)
- Pump Off two minute warning (audible and visual)

Factory Default Alarm Range Values

Table 4 lists the default values of the various alarm ranges. These can be changed from the Alarm Limits menu.

CAUTION: Make sure that the monitor default alarm settings are appropriate for the specific patient being monitored.

CAUTION: The monitor will revert to its default alarm limit settings at power on, power interruption, and when changing the patient mode.

Note: The user can have the factory default values of the alarm range permanently changed (see *Institutional Settings on page 55)*. For further information, call your local representative.

The CO_2 values in the table are shown in mmHg. The values in brackets correspond to the kPa and Vol% (at sea level).

Table 4: Factory Default Alarm Range Values

Parameter	Adult Default	Neonate Default	Maximum	Minimum
$EtCO_2$ high	60 [8.0]	60 [8.0]	100 [13.0]	5 [0.5]
$EtCO_2$ low	0	0	99 [12.9]	0 [0.0]
$FiCO_2$ high	8 [1.1]	8 [1.1]	99 [12.9]	2 [0.1]
RR high	150	150	150	1
RR low	3	12	149	0
No Breath delay*	30	20	60	10
SpO_2 high	100	95	100	21
SpO_2 low	85	80	99	20
Pulse rate high	140	200	250	5
Pulse rate low	55	100	245	0

* No Breath appears in the *Alarm Limits* menu as “No Resp.”

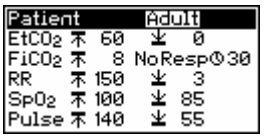
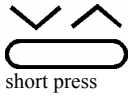
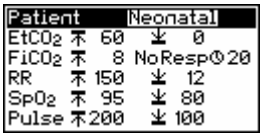
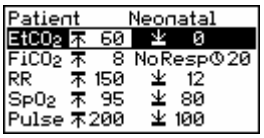
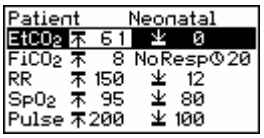
See the *Instrument Settings Menus on page 50* for a list of parameters that are set by the user and stored in the memory.

Alarm Limits Menu

Table 5 explains how to access the *Alarm Limits* menu and to change the parameters and values.

CAUTION: "No Resp" will appear as "No Breath" on the monitor display.

Table 5: Alarm Limits

Objective	Action	Result
To access the Alarm Limits menu from any measuring display.*	 long press	
To change the patient mode.**	 short press	
To access any displayed parameter.	 short press	
To change the selected parameter's value.	 short press***	
To exit and return to Measuring mode (at any point in the Alarm Limits menu).****	 long press	

* If after 15 seconds no action is taken, the display returns to Measuring mode.

** The Neonatal mode is used when a patient's breath rate is >50 breaths per minute. The default lower SpO_2 alarm limit in the Neonatal mode is 80%, however, institutions may reset this limit to a greater value by following the information in the service manual under "Default Alarm Limits".

*** Long press: the value advances quickly.

**** Display does not necessarily return to the wave form shown in the Results column; it returns to the screen active prior to entering the *Alarm Limits* menu.

Alarm Silence

Alarms can be temporarily silenced. A short press of the alarm silence button  will temporarily disable the audible alarm for a pre-set period of time and the alarm silence indicator will be lit. The audible alarm can be reactivated with a short press of the alarm silence button. The default setting is 2 minutes. You can change this setting from the *Alarm Silence/Standby* menu (Table 6 on page 49).

From the *Alarm Silence* menu, you can choose to permanently disable a specific audible alarm or all audible alarms. Whenever an alarm is disabled indefinitely, the alarm silence indicator  will be lit on the front panel and the *Alarm Silence* icon will appear on the right side of the graphic display with the appropriate label.

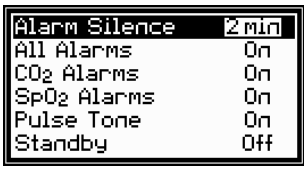
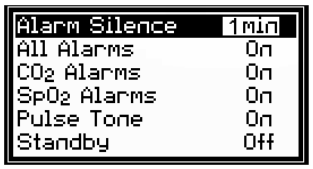
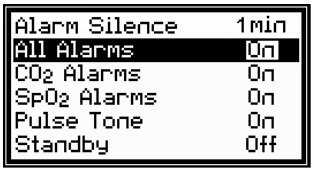
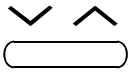
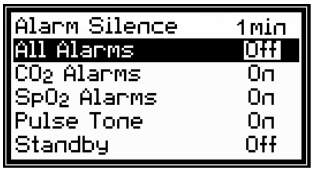
- **ALL -** All the audible alarms are turned off.
- **CO2 -** CO_2 audible alarms (including **No Breath** message) are turned off.
- **SpO2 -** SpO_2 alarms and pulse tone are turned off.
- **PAT. (Patient)** - Both CO_2 (including **No Breath** message) and SpO_2 alarms are turned off.
- **Pulse -** Pulse tone is turned off (and the alarm silence is not lit). (Refer to Institutional Settings on page 55.)

Note: When any alarm is disabled, a single caution burst can sound once every three minutes if this option is selected through Institutional Settings (refer to *Institutional Settings on page 55.)* If an alarm condition occurs when any corresponding alarm is disabled, a message is generated on the monitor display.

Note: If either ALL or CO_2 audible alarms are off and the alarm silence button is pressed, the screen will remove the ALL or CO_2 message next to the alarm icon while all alarms are silenced temporarily. When the time limit for alarm silence is reached, the ALL or CO_2 message returns.

Alarm Silence/Standby Menu

Table 6: Alarm Silence/Standby

Objective	Action	Result
To access the Alarm Silence/Standby menu from any measuring display.*	 long press	
To change the silence period.**	 short press	
To access any displayed parameters.	 short press	
To change the setting of the selected parameter.	 short press	
To exit and return to measuring display (at any point in the Alarm Silence/Standby menu).	 long press	

* If after 15 seconds no action is taken, the display returns to measuring mode.

** Alarm silence limits are from 1-2 minutes.

Instrument Settings Menus

Instrument Settings Menu Parameters

Table 7 below and Table 8 on page 51 explain the user-defined parameters that can be set from the *Instrument Settings* menus.

Table 7: Instrument Settings Parameters (Menu 1)

Parameter	User options
CO_2 units	mmHg, kPa, Vol%
Power Mgmt	Full - Display backlight on and 7 segments LEDs at high intensity. Normal - Display backlight on and 7 LEDs segments at normal intensity. Low - Backlight and 7 LEDs segments off. Note: During AC power, power management appears as Full.
Print	Screen – the current display is printed Graphic Trend - real time trend is printed in graphic form. Trend History - stored trend is printed in graphic and tabular form. Tab. Trend (5s) Real time trend data is printed in tabular form (every 5 seconds). Tab. Trend (1m) Real time trend data is printed in tabular form (every minute) Tab. Trend (8H) - with a resolution of 5 seconds. Stored trend is communicated in tabular form.
Parameter	CO_2 Only, SpO_2 is disabled. SpO_2 Only, CO_2 is disabled. Both: CO_2 and SpO_2 function.
CO_2 scale	-0-50 mmHg (0-7 kPa or Vol%) -0-99 mmHg (0-14 kPa or Vol%) -Autoscale
$FiCO_2$	On: display $FiCO_2$ Off: do not display $FiCO_2$ Default: Off

WARNING: Make sure the patient type and CO_2 scale are appropriate for each patient. An error in the patient type can cause incorrect alarm limits or incorrect CO_2 readings. If the CO_2 scale is not appropriate, the waveform will be either incomplete or small.

CO_2 Scale: Autoscale

When Autoscale is selected, the CO_2 scale changes as follows:

- From lower to higher scale after 12 consecutive breaths with $EtCO_2$ values greater than low level scale limit.
- From higher to lower scale after 12 consecutive breaths with $EtCO_2$ values less than low level scale limit.

Whenever autoscale is selected, the trend scale (and printed graphic scale) will be the high-level scale limit.

The Factory Default CO_2 is 0-50 mmHg. The CO_2 scale option will not return to the Factory Default after being changed by the user. See *User-defined Parameters Stored as Defaults on page 52*.

Table 8: Instrument Settings Parameters (Menu 2)

Parameter	User options
Languages	English, French, German, Spanish, Italian, Dutch, Swedish, Norwegian and Portuguese.
Check Cal.	Off/Start See the CO_2 Calibration Check section, Table 18: CO_2 Calibration Check, Page 75
Factory Default	Off/Start This option will reset the device to the factory default settings.

User-defined Parameters Stored as Defaults

The following parameters will not return to their defaults after being changed by the user. These parameters are stored in the memory of the monitor until the next time they are changed by the user.

- CO_2 Scale
- CO_2 Mode (Patient)
- Language
- CO_2 Units
- Print
- Power Management

Note: When changing any parameter below, wait approximately 10 seconds before turning the monitor off. If you turn off the monitor immediately after changing the parameter, the new setting may not be saved.

Changing Instrument Settings

Table 9 on page 53 and Table 10 on page 54 describe how to change the instrument settings.

Note: If after 15 seconds no action is taken, the display returns to Measuring mode.

Table 9: Changing Instrument Settings (Menu 1)

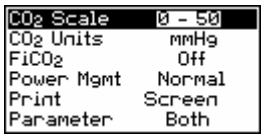
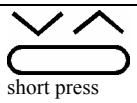
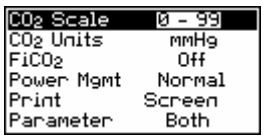
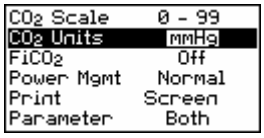
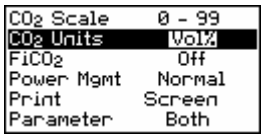
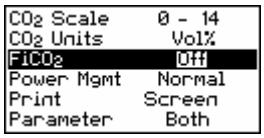
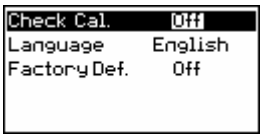
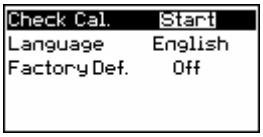
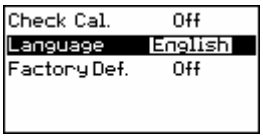
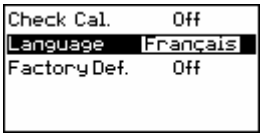
Objective	Action	Result
To access the Instrument Settings menu 1 (From any measuring display, the 1st long press accesses the Alarm Limits menu. The 2nd long press accesses the Instrument Settings menu 1.)	 long press (x2)	
To change a parameter setting.	 short press	
To access the next displayed parameter.	 short press	
To change the parameter's setting.	 short press	
To exit and return to the Measuring mode at any point in the Instrument Settings menu.	 long press	
To exit and return to the Alarm Limits menu.	 long press	

Table 10: Changing Instrument Settings (Menu 2)

Objective	Action	Result
To access the Instrument Settings menu 2. (From any measuring display, the 1st long press accesses the Alarm Limits menu. The 2nd long press accesses the Instrument Settings (menu 1). The 3rd long press accesses the Instrument Settings menu 2.)	 long press (x3)	
To change the check cal. option.	 short press	
To access the language option.	 short press	
To switch languages.	 short press desired language appears.	

Institutional Settings

The factory default parameter settings in Table 11 below can be changed by your local service representative.

Table 11: Institutional Settings

Parameter	Factory Default Setting
Alarm Default Settings*	See Table 4: Factory Default Alarm Range Values on page 46.
3 Min Alert (to remind user that alarms are set to off)	OFF
BTPS (body temperature, pressure, saturation assumed 37°C, 47mmHg)**	ON
Pulse Tone	OFF
Pump Off	15 minutes

* SpO_2 alarm limits can only be permanently changed in the *Institutional Settings* menu between 80-100.

** Calculations are made according to:

$PCO_2 = FCO_2 \times (Pb - 47)$

Where:

FCO_2 is the Fractional concentration of CO_2 in dry gas,
$FCO_2 = \% CO_2/100$
Pb = the ambient pressure
PCO_2 = the partial pressure of CO_2 at BTPS

MRI Scanning

WARNING: Do not use Nellcor oximetry sensors during magnetic resonance imaging (MRI) scanning. Conducted current could cause burns. The sensors may affect the MRI image and the MRI unit may affect the accuracy of oximetry measurements.

WARNING: Do not use the FilterLine H Set Infant/Neonatal consumable during magnetic resonance imaging (MRI) scanning. Using the FilterLine H Set Infant/Neonatal during MRI scanning could harm the patient.

CAUTION: During MRI scanning, the monitor must be placed outside the MRI suite. When the monitor is used outside the MRI suite, $EtCO_2$ monitoring can be implemented by attaching the FilterLine XL, to provide extended length.

Non-invasive $EtCO_2$ monitoring during magnetic resonance imaging (MRI) can be accomplished with the monitor and a FilterLine XL as follows:

1. Place the monitor outside the MRI suite. There must be a hole in the wall of the suite (approximately 10 cm. diameter).

Note: A small hole at the base of the wall does not affect the integrity of the MRI shielding (shielding of a 1.5 Tesla magnet).

2. Connect the FilterLine XL to the monitor and guide the FilterLine XL through the hole in the wall of the MRI suite. Attach the FilterLine XL to the patient.

Note: Due to the extended length of the FilterLine XL, there may be a slower response and a decreased frequency response time.

To purchase the FilterLine XL, contact your local representative.

Standby

The Standby mode is an automatic or selectable function designed to reduce power consumption and to avoid unnecessary alarms.

To set the monitor manually in the Standby mode, choose the Standby **ON** option from the *Alarm Silence/Standby* menu (Table 6 on page 49). The Standby screen appears. A long press of any key restores the Measuring mode. (The *Alarm Limits* menu appears briefly before the Measuring mode but the alarms cannot be changed at this time).

The monitor will automatically enter Standby mode if, after Power **ON**, no signal is registered for 10 minutes.

Note: When exiting Standby mode, the monitor reverts to the Factory default of "All Alarms On."

Note: The *Alarm Limits* settings are not changed (do not revert to defaults) when moving to and from Standby mode.

Pump Off Mode

The Pump Off mode is a selectable function designed to prevent liquids from entering and saturating the filter. During Pump Off mode, pump activity is suspended to facilitate drug delivery, suctioning and equipment changes while avoiding the need to replace the consumable due to blockage.

WARNING: If at any time the device displays the **Blockage!!** message, replace the consumable.

1. From the CO_2 Waveform screen, select Pump Off mode by long pressing once.

Figure 7: Pump Off

Note: During Pump Off mode the CO_2 parameter is dashed and the SpO_2 function operates normally.

Note: Note: The time range for Pump Off is 5–30 minutes. The factory default time for Pump Off mode is 15 minutes. To change the factory default, contact a qualified service technician.

2. Exit Pump Off mode by one long press except during the last two minutes.

3. During the last two minutes an alarm sounds indicating there are two minutes left before the device exits Pump Off mode automatically. This alarm cannot be disabled. One long press resets Pump Off mode to the default time.

   Another long press will exit the Pump Off mode.

Figure 8: Pump Off Additional Time

Pump Off/On Label

The Pump Off adhesive label is included in the monitor packaging. Adhere the label, to the monitor as shown in Figure 1: Monitor Front View on page 21.

Figure 9: Pump Off/On Label

Communication Interface

The monitor can integrate data to the following devices:

- Communication Adapter Kit
- Printer (Seiko DPU-414)
- PC
- Digital to Analog Converter
- Nurse Call Interface Kit
- MSM Interface Kit – (provides remote paging and central station networking to Oxinet III and MSM Bernoulli systems.)

Note: The monitor interfaces to the PC or Printer with the Communication Adapter Kit.

For interface directions to the different devices, refer to the *Directions for Use* of the appropriate devices and/or the *Communication Interface Manual*.

Note: The Digital to Analog converter does not communicate O_2 saturation.

WARNING: When connecting the monitor to another instrument, verify its proper operation before clinical use. Refer to the other device's manual for full instructions. For further questions, contact your local representative.

WARNING: Do not connect the monitor to a printer or to a PC unless using the Communication Adapter Kit provided by the manufacturer as an optional accessory.

WARNING: When using the printer/PC with mains line power, it is recommended to use a medical grade power supply complying with the following standards: EN60601-1, UL 60601-1, CSA C22.2 No. 601.1-M90. If the power supply is not medical grade, the printer must be placed at least 1.5 meters from the patient environment to comply with standard EN60601-1-1.

Troubleshooting

This section lists the alarms and messages and the corresponding actions the operator should take. The *Troubleshooting* section discusses potential problems and suggestions for resolving them. If the problem persists and the message remains, contact a qualified service person or your local representative.

Alarms and Messages

The monitor displays the following four types of alarms and messages in order of priority:

- Warnings
- Cautions
- Advisories
- Silent Advisories

Alarm and Message Priorities

The messages in the following tables (Tables 12-15) are listed in order of priority.

In the event that several problems occur simultaneously, the higher priority will appear first on the display. After each problem is resolved, the next message is displayed in order of priority.

Warnings

WARNING: Always respond immediately to a system alarm since the patient may not be monitored during certain alarm conditions.

Warnings refer to either patient or alarm limit settings problems. They are serious and require immediate operator attention. The message appears on the screen followed by **!!!**, the numerical parameter

associated with the alarm blinks, the alarm bar flashes red, and a special, repetitive warning tone is heard.

If one of the following warning messages appears, first check the patient, then check the ventilation equipment (if used), and then check the alarm limits settings (Table 12).

Table 12: Warning Messages

Message	Possible Causes	Action
No Breath xxx !!!*	No valid breath has been detected for xxx seconds.	First check the patient, then ventilation equipment (if used), and then the alarm settings (refer to Alarm Limits Menu on page 47).
$EtCO_2$ ↑ !!!	The $EtCO_2$ exceeded the $EtCO_2$ high alarm limit.	
$EtCO_2$ ↓ !!!	The $EtCO_2$ fell below the $EtCO_2$ low alarm limit.	
RR ↑ !!!	The RR exceeded the RR high alarm limit.	
RR ↓ !!!	The RR fell below the RR low alarm limit.	
SpO_2 ↑ !!!	The SpO_2 exceeded the SpO_2 high alarm limit.	
SpO_2 ↓ !!!	The SpO_2 fell below the SpO_2 low alarm limit.	
Pulse ↑ !!!	The pulse rate exceeded the pulse rate high alarm limit.	
Pulse ↓ !!!	The pulse rate fell below the pulse rate low alarm limit.	
$FiCO_2$ ↑ !!! = xx**	The $FiCO_2$ exceeded the $FiCO_2$ high alarm limit.	

* xxx = the number of seconds elapsed since the last valid breath has been detected.

** The $FiCO_2$ value is displayed if selected in the Instrument Settings menu 1. See Table 7, page 50.

Cautions

Caution messages appear during Measuring mode and indicate that a problem has occurred requiring the operator's attention. The message appears on the screen followed by **!!**, the alarm bar will flash yellow and a special repetitive caution tone is heard (Table 13).

Table 13: Caution Messages

Message	Possible Causes	Action
Check Unit **!!**	Instrument fault.	Contact authorized service representative.
Check CO_2 **!!**	CO_2 module fault. (SpO_2 module operational.)	Contact authorized service representative.
Check SpO_2 **!!**	SpO_2 module fault. (CO_2 module operational.)	Contact authorized service representative.
Battery ↓ **!!**	Message appears when battery charge level is very low (approximately 15 minutes left).	Prepare to replace or recharge battery or connect monitor to AC power.
FilterLine **!!**	FilterLine is disconnected or not securely connected to monitor.	Connect FilterLine to CO_2 input connector or tighten connection.
SpO_2 Sensor **!!**	Sensor or sensor extension cable may not be connected to monitor.	Connect sensor to monitor socket.
	Sensor off patient or improperly placed.	Place sensor properly on patient.
	Sensor not connected to extension cable.	Connect sensor to extension cable.
	Sensor or sensor extension cable may be damaged.	Replace the sensor or sensor extension cable.

Message	Possible Causes	Action
Blockage **!!**	FilterLine is twisted or clogged. The message appears after 30 seconds of unsuccessful clearing of the FilterLine.	Disconnect and reconnect the FilterLine. Disconnect and replace with a new FilterLine.
	FilterLine airway connection is clogged.	Check the airway adapter and, if necessary, replace the FilterLine.

Advisory Messages

Advisories are informative messages appearing at start-up before any patient input has been detected by the monitor or during operation. The message appears on the screen followed by **!**. The alarm bar will display a yellow light and a special one-time advisory tone is heard (Table 14: Advisory Messages below).

Table 14: Advisory Messages

Message	Possible Causes	Action
Check Unit **!**	Instrument fault.	
Check CO_2 **!**	CO_2 module fault.	Contact authorized service representative.
Check SpO_2 **!**	SpO_2 module fault.	
Battery Empty **!**	Battery pack is discharged.	Replace or recharge the battery, or connect to AC power.
Pump-Off xxx	*The pump is currently off.	Restart pump-off timer by one long press
Battery **!**	Message appears when battery charge level is low (approximately 40 minutes left).	Prepare to replace or recharge the battery, or connect to AC power.

* xxx is the remaining time in seconds until the pump turns back on.

Silent Advisories

Silent Advisories are instrument status messages indicating the operational state of the monitor or accessories. Silent advisories are low priority signals and only a message appears (with no exclamation marks and no other visual or audible indicator). See Table 15: Silent Advisory Messages.

Table 15: Silent Advisory Messages

Message	Possible Causes	Action
Pump-Off	The pump is currently off.	Activate the pump by one long press .
Clearing FilterLine	FilterLine tube twisted or clogged.	Check the FilterLine and, if necessary, untwist or replace it.
FilterLine	FilterLine is not connected to the instrument.	Connect FilterLine to input connector.
Autozero	Monitor automatically performs a zero-point calibration.	No action required.
CO_2 Warm-up	SpO_2 is ready for measurement. CO_2 module is preparing itself for operation.	Wait for "Ready" message before measuring for $EtCO_2$. No action required.
Calibration Required	Monitor requires calibration.	Calibrate Unit.
SpO_2 Sensor	Sensor is not connected to the instrument.	Check sensor and sensor extension cable connection and/or sensor placement on patient.
Demo	User mistakenly activated Demo mode.	Reset the monitor by sliding the on/off switch to the off position and then to the on position.

Message	Possible Causes	Action
BTPS On	BTPS setting is on.	No action required.
Ready	SpO_2 and CO_2 modules are operational but neither pulse nor breath are detected. Note: If BTPS is set to **OFF**, only Ready appears.	
$FiCO_2$ = xx	The $FiCO_2$ value (xx mmHg or x.x Vol% or kPa). Activated by user.	No action required.
CO_2 Off	CO_2 function is temporarily disabled, only SpO_2 is being measured.	For CO_2 measurements, go to Parameter option at Setup menu.
SpO_2 Off	SpO_2 function is temporarily disabled, only CO_2 is being measured.	For SpO_2 measurements go to Parameter option at Setup menu.
6 sec	Patient setting for Adult mode, or respiration rate is low.	No action required.
3 sec	Patient setting for Neonate mode, or respiration rate is high.	No action required.
Press  to erase	Trend screen displayed (CO_2 Trend-8 hrs, SpO_2 Trend -8hrs, CO_2 Trend-30 min, SpO_2 Trend-30 min)	No action required. (To erase trends, press and hold  until message disappears.)

Troubleshooting Guide

Table 16: Troubleshooting Guide below lists potential problems you may experience while using the monitor and suggestions for resolving them. If you are unable to correct the problem, contact qualified service personnel or your local representative.

Table 16: Troubleshooting Guide

Problem	Cause	Action
Monitor does not turn on.	Power cable improperly attached or disconnected, or cable has faulty electrical connection.	Check power cable connection and check that on/off switch is on.
	Battery pack may be discharged.	Replace or recharge the battery pack, or connect to AC power.
	The battery pack may not be inserted properly or missing.	Be sure the battery pack is in the monitor and inserted properly.
Monitor switches on but then switches off automatically	Electrical connection is faulty, or the AC wall outlet has no power.	Check connections and correct problem.
	The battery pack is almost discharged.	Replace or recharge battery pack, or connect to AC power.
	One of the monitor subsystems is out of order.	If previous actions are not effective, contact authorized service representative.
$EtCO_2$ values read erratically.	Mechanically ventilated patient who breathes spontaneously.	No action needed
	A leak in the airway.	Check for connection and line leaks to patient and correct if necessary.

Problem	Cause	Action
$EtCO_2$ values are consistently higher or lower than expected.	Physiological cause.	Check patient.
	Ventilator malfunction.	Check ventilator and patient.
	Improper calibration.	Check calibration. See CO_2 Calibration Check on page 74.
$EtCO_2$ values are consistently higher or lower than expected.	BTPS setting **ON** or **OFF.** Note: When BTPS is on, the correction lowers the $EtCO_2$ reading to compensate for BodyTemperature, Pressure and Saturation.	Check BTPS setting on the graphic display after Power on. Contact your local service representative.
Loss of pulse or SpO_2 signal: Zero display for oxygen saturation and pulse rate.	Sensor is improperly applied to patient.	Check sensor application.
	Patient's perfusion may be too poor.	Check the condition of the patient.
	Sensor or sensor extension cable may be damaged.	Replace sensor or sensor extension cable
	Excessive patient motion or electrosurgical interference.	If possible, keep patient still. Check whether the sensor is secure and properly placed. Replace if necessary, move the sensor to a new site, or use a sensor that tolerates more motion.

Problem	Cause	Action
Inaccurate SpO_2 measurements	Excessive illumination.	Check sensor placement or cover sensor with a dark or opaque material.
	Sensor placement on an extremity that has a blood pressure cuff, arterial catheter or intravascular line, or nail polish.	Check sensor placement.
	Patient's condition.	Check patient.
	Excessive patient movement.	If possible, keep patient still and use a sensor that tolerates more motion.

Maintenance

Periodic Maintenance
Service
Cleaning
Calibration
CO_2 Calibration Check
Returning the Monitor
Technical Assistance

Periodic Maintenance

Periodic maintenance is recommended according to operating hours:

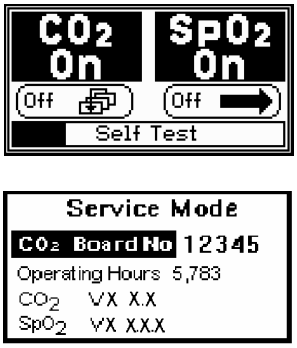
- Pump and Flow System should be replaced every 7,000 operating hours.
- Monitor should be returned to the manufacturer for periodic maintenance every 14,000 operating hours.

As part of routine preventative maintenance, a calibration check should be performed with safety checks as outlined by hospital protocol.

To check the monitor's operating hours, go to the information screen in the Service mode. Table 17 on page 72 describes how to access the information screen in the Service mode.

The battery pack should be replaced once every two years.

Table 17: Accessing the Service Mode

Objective	Action	Result
To access the Service mode	During Self Test, press and hold simultaneously → and	

Note: Contact your local representative to order spare parts, calibration kits, or to answer any questions regarding periodic maintenance.

Service

The monitor requires no routine service other than any performance testing mandated by the operator's institution. The Troubleshooting section on page 61 discusses potential difficulties, their possible causes and suggestions for resolving them. Contact your local representative for service instructions and performance tests and checks.

CAUTION: The monitor must be returned for repair if the "Check Unit" message appears.

Cleaning

To clean the monitor's surfaces, dampen a cloth with a commercial, nonabrasive cleaner and wipe the top, bottom, and front surfaces lightly.

CAUTION: Do not spray or pour any liquid directly on the monitor, accessories or consumables.

CAUTION: Do not use caustic or abrasive cleaners.

CAUTION: Microstream $EtCO_2$ consumables are designed for single patient use and are not to be reprocessed. Do not attempt to disinfect or flush the FilterLine as the monitor can be damaged.

Calibration

Calibrate after 1,400 hours of initial use. After that, the calibration should be performed any time the monitor displays the advisory message **Calibration Required**. Calibration should be performed annually or after 4,000 hours, whichever comes first, by qualified service personnel.

Note: It is recommended that you calibrate the monitor within two weeks of the message appearing on the monitor.

Note: The monitor is calibrated when it leaves the factory.

Note: No calibration of the pulse oximetry portion of the monitor is required.

CO_2 Calibration Check

The process should be performed only after the device has been operating for at least 20 minutes in a normal operating mode and connected to a FilterLine.

The calibration check must be performed with a manufacturer authorized Calibration Kit containing 5% CO_2 gas and the connecting means. A manufacturer approved Calibration Kit can be purchased from Scott Medical (part number 0304653ORFBD) consisting of:

- Calibration Gas containing 5% CO_2, 21% O_2
- Tubing Adapter
- Calibration Line

CAUTION: Do not check CO_2 values from the Measuring mode. This mode corrects the CO_2 value for BTPS (Body, Temperature, Pressure, Saturation) which assumes that alveolar gases are saturated with water vapor. The Calibration Check mode disables this correction.

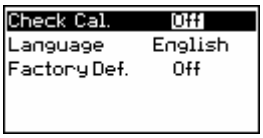
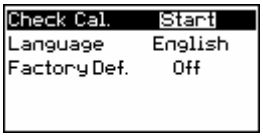
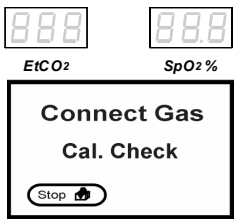
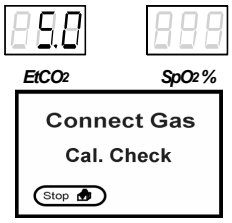
CAUTION: The instrument should not be in *Standby Mode* before beginning the calibration check process. To prevent the device from entering *Standby Mode*, measure at least two breaths. The device will then remain in normal operating mode with an active *Apnea* (for software versions prior to 2.7) or *No Breath* (from software version 2.7) alarm.

Note: If this process is performed while a battery powers the device, make sure that the battery is fully charged.

Note: Prior to calibration, verify that the Calibration Line supplied with the Calibration Kit is firmly attached.

Start the process from the *Setup* menu as described in Table 18.

Table 18: CO_2 Calibration Check

Objective	Action	Result
Access Instrument Settings menu.	→ long press x3 (long press x2 for software versions prior to 2.7)	
Change option to start.	→ ⌄ ⌃ short press	
Start Check Cal. (An Autozero process begins.)	→ short press	
Start Cal. Check process.	Connect the calibration gas via the connecting means.	
Check the measured values (shown in Vol% in the $EtCO_2$ digital display).*	Press the gas valve for 15 seconds until the readings stabilize.	

* Calibration is not required if the measured value is the same as the concentration of the calibration gas (±0.3 Vol% of readings)

Objective	Action	Result
To return to Measuring mode if calibration is not required.	 long press	

If calibration is required, contact your local service representative.

Returning the Monitor

If it is necessary to return the monitor for repairs, call the local representative for shipping instructions.

To repack the monitor, disconnect the accessories from the instrument and wrap each item separately. Pack them in the original shipping carton. If the original carton is unavailable, use a suitable box filled with the appropriate amount of packing material. It is not necessary to return the sensors, Microstream $EtCO_2$ consumables, or power cords.

If the monitor malfunctions, carefully package the monitor with the consumable used at the time of malfunction and return it with the monitor for inspection.

Technical Assistance

For technical information, contact your local representative.

The *Service Manual* includes information that is required by qualified personnel to service the monitor.

Specifications

Physical
Environmental
Safety Standards
Compliance
Manufacturer's Declaration
Performance
Pulse Oximeter
Power Specifications
Electrical
Components and User Interface

Physical

Size

206 mm H x 88 mm W x 52.5 mm D (8.11"H x 3.46" W x 2.06"D)

Weight

850 grams (1.87 lb.) (including battery pack)

Noise Emission

maximum 45 dB(A)

Environmental

Temperature

Parameter	Value
Operating	0°C to 45°C (32°F to 113°F)
Relative Humidity	10 to 95% non-condensing
Storage	-35°C to 70°C (-31°F to 158°F)

Pressure and Altitude (for operating and storage)

Parameter	Value
Pressure	430 mmHg to 795 mmHg
Altitude	-380m to 4,570m (-1,250 ft. to 15,000 ft.)

Transport and Storage

Parameter	Value
Temperature	For Monitor: -35°C to 70°C (-31°F to 158°F) not in shipping container For Microstream Accessories: -20°C to 70°C (-4°F to 158°F) in shipping container
Altitude	-380m to 4,570m (-1,250 ft. to 15,000 ft.)
Atmospheric Pressure	50 kPa to 106 kPa (14.7 in Hg. To 31.3 in. Hg)
Relative Humidity	10% to 95% non-condensing

OxiMax® Sensor Power Dissipation

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

Nellcor pulse oximetry sensors contain light emitting diodes (LEDs) that emit red (~660 nm) and infrared (~900 nm) light, with a total optical output power of less than 15 mW.

This information of sensor wavelength range can be especially useful to clinicians, e.g., those performing photodynamic therapy.

Sensor LED light output falls within Class 1 Level per IEC 60825-1:2001 Safety of Laser Products; no special safety precautions are needed.

Safety Standards

The monitor complies with EN60601-1, UL 60601-1 and CSA C22.2 No. 601.1-M90, ISO 21647 and ISO 9919.

Compliance

ISO 9919:2005 Compliance

When used with Nellcor *OxiMax* sensors and the appropriate Nellcor pulse oximetry cable, the Portable Bedside Handheld Capnograph and Pulse Oximeter is compliant with ISO 9919:2005 with the following exceptions:

Clause 50.101

See SpO_2 Data Update Period information in this document.

Clause 201.5.4.1

See Alarm Functions information in this document.

Item	Compliant With
Equipment classification	Safety Standards: IEC 60601-1 (same as EN60601-1), CSA 601.1, UL 60601-1, ISO 21647, ISO 9919 (Exception of Clause 50.102) and EN/IEC 60601-1-2.
Type of protection	Class I or II (on AC power)
	Internally powered (on battery power)
Degree of protection	Type BF – Applied part
Mode of operation	Continuous
Resistant to liquid ingress	IEC 60601-1, sub-clause 44.6 for class IPX1 Drip-Proof equipment
Degree of safety in presence of a flammable anesthetic	UL 60601-1, sub-clause 5.5, Not suitable
Applied sensor label to indicate Type BF applied part	IEC 60601-1 Symbol 2 of Table DII of Appendix D
Attention symbol, consult accompanying documentation	IEC 60601-1 Symbol 14 of Table DI of Appendix D
External case made with non-conductive plastic	IEC 60601-1, sub-clause 16(a)
No holes in case top	IEC 60601-1, sub-clause 16(b)

Item	Compliant With
Rigid case	IEC 60601-1, sub-clause 21(a)
Case mechanically strong	IEC 60601-1, sub-clause 21(b)
Resistant to rough handling	IEC 60601-1, sub-clause 21.6
Tip/tilt test	IEC 60601-1, sub-clause 24.1
Resistant to liquid ingress due to spills	IEC 60601-1, sub-clause 44.3 as modified by ISO 9919 clause 44.6
Environmental	IEC 60601-1, sub-clause 44.5
Cleaning	IEC 60601-1, sub-clause 44.7
Case surface made of non-toxic materials	IEC 60601-1, sub-clause 48
Case resistant to heat and fire	IEC 60601-1, sub-clause 59.2 (b)
Exterior markings	IEC 60601-1, sub-clause 6.1., 6.3, and 6.4; ISO 9919, clause 6
Front panel and case labeling	IEC 60878, EN 980, ISO 7000, EN 60417-1, EN 60417-2
Button spacing	ISO 7250
Year of manufacture symbol	EN 980
Conductive coating and polymeric materials	UL 60601-1, clause 55
Operation during physical shock	IEC 60068-2-27 at 100 g
Operation during vibration	IEC 60068-2-6 and IEC 60068-2-34
Electromagnetic compatibility	IEC 60601-1, sub clause 36, IEC/EN 60601-1-2 (second edition)
Radiated and conducted emissions	EN 55011, Group 1, Class B
Harmonic emissions	IEC 61000-3-2
Voltage fluctuations/flicker	IEC 61000-3-3

Item	Compliant With
emissions	
Electrostatic discharge immunity	EN 61000-4-2, level 3 table top equipment
Radiated radio-frequency electromagnetic field immunity	IEC 61000-4-3 at 3 V/m
Electrical fast transient/burst immunity	IEC 610004-4-4
Surge immunity	IEC 61000-4-5
Conducted EMI susceptibility	IEC 61000-4-6 at 3 V/m
Power frequency magnetic fields	IEC 61000-4-8 at 3A/m
Laser Safety	The sensor LED light output falls within Class I level, according to 60825-1:2001. No special safety precautions are required.
Operation with line voltage variations	IEC 61000-4-11

Manufacturer's Declaration

WARNING: The use of accessories, transducers, sensors and cables other than those specified may result in increased emission and/or decreased immunity of the equipment and/or system.

Performance

Capnograph

Parameter	Value
Sampling Rate	50 ml/min.
CO_2 Range	0-99 mmHg (0-13.2 kPa and 0-13.0 Vol%) at sea level
Accuracy	
$EtCO_2$ readings	From power up until steady state is reached, the CO_2 reading accuracy is: 0 - 38 mmHg: (± 4 mmHg) 39 - 99 mmHg: (± 12% of reading) The CO_2 reading reaches its steady state accuracy 20 minutes after power up. 0 - 38 mmHg: (± 2 mmHg) 39 - 99 mmHg: (±5% of reading + 0.08% for every 1 mmHg above 40mmHg) Equivalent values for kPa and Vol%
Respiration Rate	0-150 breaths/min.
Warm-up Time	30 seconds (typical)
Frequency Response	$EtCO_2$ accuracy is maintained up to 80 breaths/min (for maintaining accuracy for respiration rate over 60 bpm, use the neonatal mode.) From 81 to 150 bpm, accuracy is ±12%, if the $EtCO_2$ is higher than 18.8 mmHg in neonatal mode.
System Response Time	2.45 seconds (typical), 2.9 seconds maximum (includes delay time and rise time)
Rise Time	
Neonate	190 msec with low dead space endotracheal tube adapter
Adult	240 msec with FilterLine airway adapter
Ambient Pressure	Compensated internally – automatic
Alarms	$EtCO_2$ high, $EtCO_2$ low, RR high, RR low, $FiCO_2$ high, No Breath

Display Update Interval

2 seconds

Pulse Oximeter

Parameter	Value	
SpO_2 Saturation Range	0-100% SpO_2	
Saturation Accuracy	(% SpO_2, $\pm$1 SD)	
OxiMax® oxygen transducer (single patient use)		
MAX-A, MAX-AL	70—100%	+/- 2 digits
	0—69%	Unspecified
MAX-N (Adult)	70—100%	+/- 2 digits
	0—69%	Unspecified
MAX-N (Neonate)	70—100%	+/- 3 digits
	0—69%	Unspecified
MAX-P	70—100%	+/- 2 digits
	0—69%	Unspecified
MAX-I	70—100%	+/- 2 digits
	0—69%	Unspecified
MAX-R	70—100%	+/- 3.5 digits
	0—69%	Unspecified
MAX-FAST	70—100%	+/- 2 digits
	0-69%	Unspecified
OxiCliq® oxygen transducer (single patient use)		
OxiCliq A	70—100%	+/- 2.5 digits
	0—69%	Unspecified
OxiCliq P	70—100%	+/- 2.5 digits
	0—69%	Unspecified

Parameter	Value	
OxiCliq N (Adult)	70—100%	+/- 2.5 digits
	0—69%	Unspecified
OxiCliq N (Neonate)	70—100%	+/- 3.5 digits
	0—69%	Unspecified
OxiCliq I	70—100%	+/- 2.5 digits
	0—69%	Unspecified
Reusable Sensor Models		
D-YS (Infant to Adult)	70—100%	+/- 3 digits
	0—69%	Unspecified
D-YS (Neonate)	70—100%	+/- 4 digits
	0—69%	Unspecified
D-YS & D-YSE	70—100%	+/- 3.5 digits
	0—69%	Unspecified
D-YS & D-YSPD	70—100%	+/- 3.5 digits
	0—69%	Unspecified
DS-100A	70—100%	+/- 3 digits
	0—69%	Unspecified
OXI-A/N (Adult)	70—100%	+/- 3 digits
	0—69%	Unspecified
OXI-A/N (Neonate)	70—100%	+/- 4 digits
	0—69%	Unspecified
OXI-P/I	70—100%	+/- 3 digits
	0—69%	Unspecified

Parameter	Value
Accuracy Specifications: Accuracy specifications are based on controlled hypoxia studies with healthy, non-smoking adult volunteers over the specified saturation SpO_2 range. Pulse oximeter SpO_2 readings were compared to SaO_2 values of drawn blood samples measured by hemoximetry. All accuracies are expressed as ± "X" digits. This variation equals ± one standard deviation (± 1SD), which encompasses 68% of the population.	
Neonatal Accuracy: When sensors are used on neonatal subjects as recommended, the **specified accuracy range is increased by ± 1 digit,** to account for the theoretical effect on Oximeter measurements of fetal hemoglobin in neonatal blood.	
Pulse Rate Range	20-250 beats per minute (bpm)
Perfusion Range	0.03% to 20%
Pulse Rate Accuracy	±3 bpm Note: Pulse rate accuracy is expressed as ± 3 bpm across the display range. This variation equals ±1 standard deviation (1SD), which encompasses 68% of the population.
Alarms	SpO_2 high, SpO_2 low, Pulse high, Pulse low

Parameter	Value

Reading accuracy in the presence of low perfusion (detected IR pulse modulation amplitude < 1.5%) was validated using signals supplied by a patient simulator. SpO_2 and pulse rate values were varied across the monitoring range over a range of weak signal conditions and compared to known true saturation and pulse rate of the input signals.

Reading accuracy in the presence of motion was validated, in part, in studies conducted on healthy adult volunteers under controlled laboratory conditions over the saturation range 70%-100%. Pulse oximeter $Sp0_2$ was compared to SaO_2 measured to blood CO-oximetry, and PR was compared to EKG heart rate. Sensors were fitted on the digits and optically shielded from one another, with subjects instructed to move their fingers with tapping, rubbing and non-repetitive movements, in response to a random noise at 1-4 Hz, and with an amplitude of 1 to 2 cm.

Power Specifications

External Power Source

12V DC Medical Grade Adapter

Internal Power Source

Ni-MH Rechargeable Battery Pack 7.2V 2.1 A/h (intended for continuous operation)

Parameter	Value
Operating Time (fully charged)	Between 4 and 7 hours, depending on power management. These values reflect the performance of a new battery; age and usage will decrease capacity. Note: If the battery pack is stored for 6 months or longer, you must charge and discharge it (leave unit on, not connected to AC power, until battery is empty) three times before use in order to ensure full capacity.
Recharging Period	Approximately 4.5 hours internal recharging
Charger Type	Internal

Electrical

Instrument

Rated 100-250VAC, 50/60HZ, 0,5A

OxiMax® Sensors

Parameter	Value
Wavelength and Power	The wavelength range of the light emitted are near 660 nm and 890 nm with the energy not exceeding 15 mW.

Electromagnetic Emissions

The monitor is suitable for use in the specified electromagnetic environment. The user of the monitor should ensure that it is used in an electromagnetic environment as described below:

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emission CISPR 11	Group 1	The monitor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The monitor is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emission IEC 61000-3-3	Complies	

Electromagnetic Immunity

The monitor is suitable for use in the specified electromagnetic environment. The user of the monitor should assure that it is used in an electromagnetic environment as described below.

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electric fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial and/or hospital environment
Surge IEC 61000-4-5	±1 kV differential mode	±1 kV differential mode	Mains power quality should be that of a typical commercial and/or hospital environment
	±2 kV common mode	±2 kV common mode	

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Voltage dips, short interruptions and voltage variations on power supply input lines. IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles	Mains power quality should be that of a typical commercial and/or hospital environment. If the user of the monitor requires continued operation during power mains interruption, it is recommended that the monitor be powered from an uninterruptible power supply or battery.
	70% U_T (30% dip in U_T) for 25 cycles <5% U_T (95% dip in U_T) for 5 sec.	70% U_T (30% dip in U_T) for 25 cycles <5% U_T (95% dip in U_T) for 5 sec.	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: U_T is the AC mains voltage prior to application of the test level

Electromagnetic Immunity

The monitor is suitable for use in the specified electromagnetic environment. The user of the monitor should assure that it is used in an electromagnetic environment as described below:

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2 \sqrt{P}$

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	d = 1.2√*P* 80 MHz to 800 MHz d = 2.3 √*P* 800 MHz to 2.5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a] should be less than compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol  .

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

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

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

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the monitor (IEC60601-1-2)

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d=1.2\sqrt{P}$	$d=1.2\sqrt{P}$	$d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts(W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

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

Electric and Communication Cables

Cables and *OxiMax*® Sensors	Maximum Length	Complies with:
791001, Power cord North America	10 ft. (3 m)	• RF emissions, CISPR 11, Class B/ Group 1 • Harmonic emissions. IEC 61000-3-2 • Voltage fluctuations/flicker emission. IEC 61000-3-3 • Electrostatic discharge (ESD), IEC 61000-4-2 • Electric fast transient/burst, IEC 61000-4-4 • Surge, IE 61000-4-5 • Conducted RF IEC 61000-4-6 • Radiated RF, IEC 61000-4-3
RJ11 communication cable (contained in 048127 communication adapter kit)	10 ft. (3 m)	
RJ45 communication cable (contained in 048127 communication adapter kit)	1.7 ft. (0.5 m)	
15 pin D-type output connector cable (contained in 063755 D/A Converter kit)	10 ft. (3 m)	
RS232 monitor cable (contained in 063755 D/A Converter kit	1.7 ft. (0.5 m)	
060606, 12 VAC adapter cable	2.3 ft (0.7 m) not extended	

Sensors

Cable/Sensor	Patient Type	Maximum Length	Complies with:
DEC 4	Extension cable	4 ft. (1.2m)	• RF emissions, CISPR 11, Class B/ Group 1 • Harmonic emissions. IEC 61000-3-2 • Voltage fluctuations/flicker emission. IEC 61000-3-3 • Electrostatic discharge (ESD), IEC 61000-4-2 • Electric fast transient/burst, IEC 61000-4-4 • Surge, IE 61000-4-5 • Conducted RF IEC 61000-4-6 • Radiated RF, IEC 61000-4-3
DEC 8	Extension cable	8 ft. (2.4 m)	
OxiMax® Sensors			
MAX-A	Adult	1.5 ft. (0.5 m)	
MAX-AL	Adult, longer cable	3 ft. (0.9m)	
MAX-P	Pediatric	1.5 ft. (0.5 m)	
MAX-I	Infant	1.5 ft. (0.5 m)	
MAX-N	Neonatal/Adult	1.5 ft. (0.5 m)	
MAX-R	Adult, Nasal	1.5 ft. (0.5 m)	
MAX-FAST	Adult, Forehead	2.5 ft. (0.8m)	
OxiMax SoftCare™			
SC-PR	Pre-term infant (< 1.5 kg)	3 ft. (0.9m)	
SC-NEO	Neonatal (1.5 - 5 kg),	3 ft. (0.9m)	
SC-A	Adult (>40 kg)	3 ft. (0.9m)	
OxiMax® Oxiband Sensors			
OXI-A/N	Adult/Neonatal (<3 kg or >40 kg)	1.5 ft. (0.5 m)	
OXI-P/I	Pediatric/Infant Sensor (3 - 40 kg)	3 ft. (0.9m)	
OXIMAX® Durasensor Sensors			
DS-100A	Adult Finger Clip Sensor (>40 kg)	3 ft. (0.9m)	

Cable/Sensor	Patient Type	Maximum Length	Complies With :
OxiMax® OxiCliq Sensors			• RF emissions, CISPR 11, Class B/ Group 1 • Harmonic emissions. IEC 61000-3-2 • Voltage fluctuations/flicker emission. IEC 61000-3-3 • Electrostatic discharge (ESD), IEC 61000-4-2 • Electric fast transient/burst, IEC 61000-4-4 • Surge, IE 61000-4-5 • Conducted RF IEC 61000-4-6 • Radiated RF, IEC 61000-4-3
OC-3	OxiCliq Sensor Cable	3 ft. (0.9m)	
P	Pediatric (10 - 50 kg)	3 ft. (0.9m)	
N	Neonatal/Adult (<3 kg or >40 kg)	3 ft. (0.9m)	
I	Infant (3 - 20 kg)	3 ft. (0.9m)	
A	Adult (>30 kg),	3 ft. (0.9m)	
OXIMAX® Dura-Y Sensors			
D-YS	(>1 kg)	4 ft. (1.2m)	
D-YSE	Ear Clip for Dura-Y Sensor (>30 kg)	4 ft. (1.2m)	
D-YSPD	PediCheck® Pediatric Spot-Check Clip for Dura-Y Sensor (3 - 40 kg)	4 ft. (1.2m)	

Components and User Interface

Displays

Parameter	Value
Graphic LCD display	(128 x 64 dots) with LED backlight dimension 75 mm x 53 mm.
Two numeric fields	3 digits each, using 7-segment LED dimension 22 mm x 14 mm.
Alarm bar	yellow, red

Controls and Indicators

Parameter	Value
Front Panel	On/off switch; Alarm Silence/Alarm Silence Menu button; Contrast/Value change button; Event/Home button; Next/Menu button.

Connections

Parameter	Value
Front Panel	CO_2 Input connector
Top Panel	SpO_2 Input socket
Rear Panel	Clamp connector
Side Panel	Power supply/communication adapter port, gas outlet

Portable Bedside Capnograph/Pulse Oximeter

Package Components

- Capnography/Pulse Oximetry monitor
- $EtCO_2$ Sample Kit
- SpO_2 Sensor Assortment Pack or Reusable Sensor
- Sensor Extension Cable
- Power Cord
- Power Supply
- Operation Manual (English only)
- Operation Manual CD (operation manual in 17 languages)
- Other documentation
- Quick Guide Sticker
- Pump Off Label

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