Capnostream™35 Portable Respiratory Monitor

PM35MN, with Microstream™ $EtCO_2$ and Nellcor™ SPO_2 Technologies

Operator's Manual

CE
0482

PN: PT00039637A

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1. Introduction

1.1. Introduction

Carefully read this operator's manual and the Directions for Use that accompany Microstream™ $etCO_2$ sampling lines (FilterLines™, henceforth referred to as sampling lines) and the SpO_2 sensors, in order to use the Capnostream™35 Portable Respiratory Monitor PM35MN, with Microstream™ $EtCO_2$ and Nellcor™ SPO_2 Technologies (henceforth referred to as Capnostream™35 or the monitor) correctly and safely. Use of the monitor requires full understanding and strict observance of these instructions, the precautionary information, and the specifications.

1.2. Safety Information

1.2.1. General

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

WARNING:
The monitor should not be used as an apnea monitor.

WARNING:
The monitor should be considered an early warning device. As a trend towards patient deoxygenation is indicated,

blood samples should be analyzed by a laboratory co-oximeter to completely understand the patient's condition.

WARNING:

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

WARNING:

Carefully route patient cabling (SpO_2 sensor and sampling line) to reduce the possibility of patient entanglement or strangulation.

WARNING:

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

WARNING:

Do not obstruct the monitor so that the visual alarm indicators cannot be seen or the audio alarm indicators cannot be heard.

WARNING:

The monitor should not be used adjacent to or stacked with other equipment; if adjacent or stacked use is necessary, the monitor shall be observed to verify normal operation in the configuration in which it will be used.

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:

Re-use of single-use accessories could pose a cross-

contamination risk to the patient or damage the functioning of the monitor.

WARNING:

CO_2 readings, respiratory rate, pulse oximetry readings, and pulse signals can be affected by sensor application errors, certain ambient environmental conditions, and certain patient conditions.

WARNING:

The monitor is a prescription device and is to be operated by qualified healthcare personnel only.

WARNING:

No modification of this equipment is allowed.

WARNING:

If calibration does not take place as instructed in the relevant service manual, the monitor may be out of calibration. A monitor that is out of calibration may provide inaccurate results.

WARNING:

Do not use any monitoring system, sensor, cable, connector, or screen that appears damaged. Remove any damaged equipment from service for inspection by a qualified service technician.

WARNING:

Do not perform service or maintenance on the device while it is in use.

Caution:

Storage or transport of the monitor under environmental

conditions beyond those mentioned in the specification will affect monitor performance and damage the monitor.

WARNING:
Do not transport damaged or defective lithium cells and batteries via air transport.

Note:
Temperature sensors will turn the monitor off when it exceeds the permitted temperature.

Devices connected to the monitor must be medical grade only.

The accurate display of the following parameters is required in order to fill the essential performance of the monitor: Carbon dioxide levels in expired and inspired breath (CO_2) and respiration rate when monitoring with capnography, and arterial oxygen saturation of blood (SpO_2) and pulse rate when monitoring with pulse oximetry. If the patient is being monitored with both functions, all of these parameters will be displayed.

1.2.2. MRI Scanning

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

WARNING:
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. Reference *4.10.5 Monitoring CO2 during MRI Scanning* on page 81.

Caution:
Use of a CO$_2$ sampling line with H in its name (indicating that it is for use in humidified environments) during MRI scanning may cause artefacts on the MRI image. The use of non-H sampling lines is advised. For a list of sampling lines, reference *8.1 Microstream EtCO2 Consumables* on page 191.

1.2.3. Alarms

WARNING:
Do not silence the audible alarm if patient safety may be compromised.

WARNING:
Always respond immediately to a device alarm since the patient may not be monitored during certain technical/caution 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.

WARNING:

Do not preset different or inappropriate alarm limits for the same or similar equipment in any single area, since this may compromise patient safety.

1.2.4. Fire Hazard

WARNING:

When using the monitor with anesthetics, nitrous oxide or high concentrations of oxygen, connect the gas outlet 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 sampling line 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 these devices with caution to prevent flammability of the sampling line or surrounding surgical drapes.

1.2.5. 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:
Do not connect the monitor to a power supply other than that supplied with the monitor.

WARNING:
To avoid the risk of electric shock, the monitor must be connected only to a supply mains with protective earth.

WARNING:
Connect the monitor only to a hospital grade receptacle. The plug must be inserted into a properly wired receptacle; if a properly wired receptacle is not available, a qualified electrician must install one in accordance with the governing electrical code. Do not use extension cords or adapters of any type. The power cord and plug must be intact and undamaged.

WARNING:
Do not connect to an electrical outlet controlled by a wall switch or a dimmer.

WARNING:
Measure the monitor's leakage current whenever an external device is connected to the serial port. Leakage current must not exceed 100 microamperes.

Caution:
Any USB device (excluding a flash memory drive) or PC connected to the monitor must be running on a battery, or a IEC 60601-1 compliant power supply (Clause 16, ME

Systems), or a IEC 60601-1 compliant isolation transformer (Clause 16, ME Systems).

Caution:
All signal input and output (I/O) connectors are intended for connection of devices complying with Clause 16, ME Systems, of IEC 60601-1 only. Connecting additional devices to the monitor may increase chassis or patient leakage currents. To maintain operator and patient safety, consider the requirements of Clause 16, ME Systems, of IEC 60601-1. Measure the leakage currents to confirm that no electric shock hazard exists.

Caution:
Electrical installation of the room or the building in which the monitor is to be used must comply with regulations specified by the country in which the equipment is to be used.

Caution:
Keep power cord, plug and socket clear in case an urgent power supply disconnection is required.

1.2.6. Electro-magnetic Interference

This monitor has been tested and found to comply with the requirements for medical devices according to the standard IEC 60601-1-2. This standard is designed to provide reasonable protection against harmful interference in a typical medical installation.

However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in healthcare environments (for example: 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 cause incorrect measurements. Do not use the monitor with nuclear spin tomography (MRT, NMR, NMT) as the function of the monitor may be disturbed.

1.3. Definitions

Note:
A Note is inserted to point out procedures or conditions which may otherwise be misinterpreted or overlooked and to clarify apparently contradictory or confusing situations.

Caution:
A Caution is inserted to call attention to a procedure which, if not followed exactly, can lead to damage or destruction of the equipment.

WARNING:
A Warning is inserted to call attention to dangerous or hazardous conditions inherent to the operation, cleaning, and maintenance of the equipment which may result in personal injury or death of the operator or patient.

1.4. Contacting Technical Support

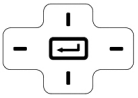
For any technical issue involving the monitor, contact your local Service Center or Covidien Technical Support, as follows:

North America: Tel: 1-888-ORIDION (674-3466), Fax: (781) 453-2722; Outside North America: Tel: + (972) 2-589-9104, Fax: + (972) 2-582-8868; E-mail: Capnographytechnicalsupport@medtronic.com

1.5. Symbols

The following symbols appear on the body of the monitor.

Table 1.Symbols that Appear on the Monitor

Symbol	Description
	**Monitor ON/OFF button**
	**Battery/power indicator**
	**Home button**
	**Back button**
	**Temporarily silence alarms**
	**Enter button with directional arrows**
	**Type BF Defibrillator Proof Protection**
	**Gas inlet**
	**Gas outlet**

	**CO_2 port indicator**
	**Micro SD card port**
	**12VDC**
	**Nellcor SpO_2 connection**
	**USB flash memory connection port**
	**Monitor connection**
	**Federal Communications Commission**
	**For prescription use only**
	**Caution, consult accompanying documents**
	**Follow Instructions for Use (in blue)**
	**Directive on waste from electrical and electronic equipment**
	**Non-ionizing electromagnetic radiation**

	**Wireless regulation (Australia)**
IP54	**IPX rating**
	**ETL Mark**
	**CE Mark**
	**Serial number**
	**Catalog number**
	**Date of manufacture**
	**Manufacturer**

1.6. Who Should Read This Manual

The following persons should read this manual:

- **Health Care Professionals who will be using the monitor.**
- **Equipment managers responsible for ensuring that equipment conforms to institutional policies.**
- **Researchers or laboratory personnel who will be downloading patient data.**
- **Technical experts who will be connecting the monitor to a computer.**

WARNING:
In the United States, federal law restricts this device to sale by or on the order of a physician.

1.7. Warranty and Disclaimers

1.7.1. Warranty

Oridion Medical 1987 Ltd. ("Oridion Medical") - Warranty for Oridion Monitors:

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invoice. Customer shall be solely responsible for the selection, use, efficacy, efficiency and suitability of the Products.

1.7.2. Disclaimers

CUSTOMER MAY USE THE PARAMETERS (INCLUDING ANY AND ALL REFERENCES TO CO_2, SpO_2, CURRENT INTEGRATED PULMONARY INDEX™ AND FUTURE AND RELATED INDICES AND CONFIGURATIONS AND SIGNAL ALARM NOTIFICATIONS) WHICH APPEAR ON ORIDION'S PATIENT MONITORING DEVICES AND/OR ORIDION'S COMMUNICATION PROTOCOL AND/OR ANY OUTPUT IN REPORTS DOWNLOADED FROM ORIDION'S PATIENT MONITORING DEVICES TO PRINTERS OR USB MEMORY STICKS OR APPROVED SYSTEMS ("DATA") SOLELY AND EXCLUSIVELY FOR THE PURPOSE OF PATIENT CARE. CUSTOMER ACKNOWLEDGES THAT DATA TRANSMITTED FROM ORIDION'S PATIENT MONITORING DEVICES MAY NOT BE TRANSFERRED, INTERFACED, EXCHANGED OR OTHERWISE TRANSMITTED AND THAT ORIDION ACCEPTS NO RESPONSIBILITY WHATSOEVER FOR THE ACCURACY OR COMPLETENESS OF DATA THAT HAS BEEN TRANSFERRED, INTERFACED, EXCHANGED OR OTHERWISE TRANSMITTED. CUSTOMER FURTHER ACKNOWLEDGES THAT IT MAY NOT SELL, LICENSE OR OTHERWISE COMMERCIALIZE THE DATA, IN WHOLE OR IN PART. ANY OTHER USE OF THE DATA OR INTERFACE WITH OTHER SYSTEMS, WHETHER BY CUSTOMER OR ANY PARTY ON ITS BEHALF, SHALL BE SUBJECT TO A SEPARATE LICENSING ARRANGEMENT WITH ORIDION, INCORPORATING, BUT NOT LIMITED TO, COMMERCIAL TERMS TO BE NEGOTIATED IN GOOD FAITH.

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2. Product Overview

The Capnostream™35 Operational Check Sheet is provided at the end of this chapter to simplify the installation, setup, and getting started processes. Photocopy the Check Sheet from the manual and check off the steps on the Check Sheet as you set up the monitor.

2.1. Overview

This manual provides directions for setting up and operating the monitor.

The Capnostream™35 Portable Respiratory Monitor PM35MN, with Microstream™ $EtCO_2$ and Nellcor™ SPO_2 Technologies, is a portable bedside monitor that continuously monitors a patient's:

- **End tidal carbon dioxide ($etCO_2$) - level of carbon dioxide in exhaled breath**
- **Respiratory rate (RR)**
- **Oxygen saturation (SpO_2)**
- **Pulse rate (PR)**

The monitor also provides an Integrated Pulmonary Index™ (henceforth referred to as IPI) value, which is a numerical value that integrates four major parameters measured by the monitor in order to provide a simple indication of the patient's ventilatory status. The integrated parameters are $etCO_2$, RR, SpO_2, and PR. Only these four parameters are used to calculate IPI; other parameters are not taken into account.

In addition, the monitor provides Apneas per Hour (A/hr) (also known as ASA, Apnea Saturation Alert) and an Oxygen Desaturation Index (ODI), used to help in the identification and quantification of apnea and oxygen desaturation events for patients over age 22, as follows:

A/hr: a count of the number of pauses in breathing (of at least 10 seconds) which the patient experienced, either over the past hour (on the Home screen) or average pauses per hour over a period of time (on the Apnea and O_2 Desaturation screen).

ODI: the number of times that the SpO_2 value dropped 4% or more from baseline and returned to baseline in 240 seconds or less, either in the last hour (on the home screen) or average drops per hour over a period of time (on the Apnea and O_2 Desaturation screen).

2.2. Intended Use

The Capnostream™35 is a portable capnograph/pulse oximeter, intended to provide professionally trained health care providers with continuous non-invasive monitoring of carbon dioxide concentration of the expired and inspired breath, respiration rate, arterial oxygen saturation (SpO_2) and pulse rate of adult, pediatric, and neonatal patients. The pulse oximeter is intended for use during both no motion and motion conditions and for patients who are well or poorly perfused.

The Capnostream™35 also provides the clinician with integrated pulmonary index (IPI), apnea per hour (A/hr) and oxygen desaturation index (ODI) values. IPI is intended for pediatric and adult patients only. A/hr and ODI are intended for age 22 and up.

The device is intended for use in hospitals, hospital-type facilities, during intra-hospital transport, and out-of-hospital Emergency Medical Service applications that include ground and air transport.

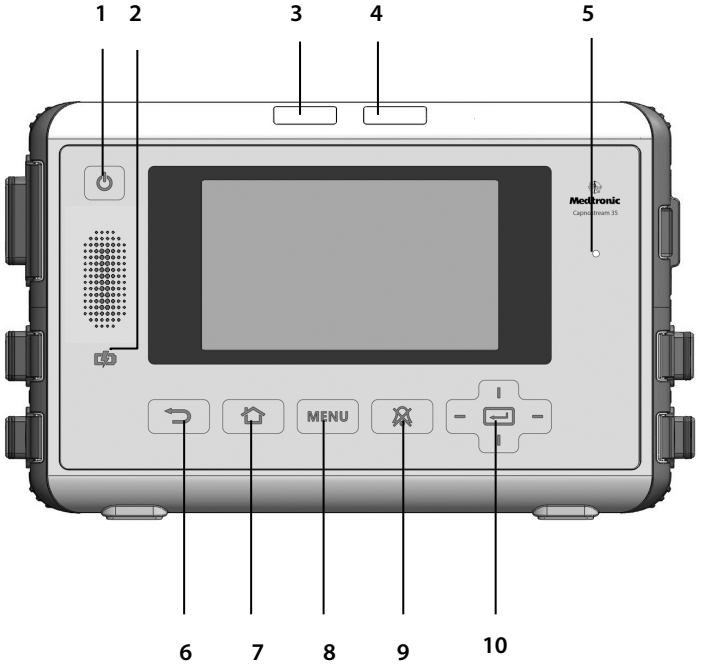
2.3. Buttons, Indicators and Connections

Following are the front, rear, and side views of the monitor showing the display, controls, and external connection points.

2.3.1. Monitor Front Panel

The monitor's front panel controls are described below. Reference *Figure 1. Monitor Front Panel*, below.

Figure 1. Monitor Front Panel

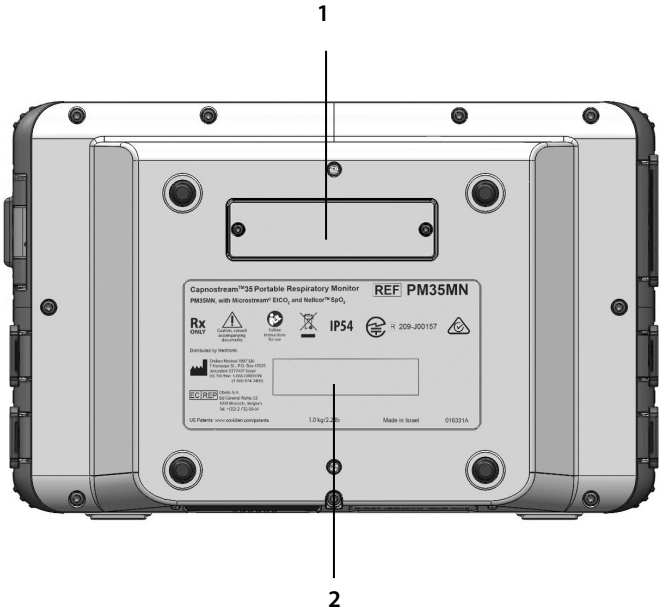


Label	Name	Description	Label	Name	Description

1	On/Off button	Turns the monitor on or off	6	Back button	Returns the user to the previous screen
2	Battery/ power indicator	Indicates battery and power status	7	Home button	Returns the user to the Home screen
3	Medium Priority Alarm LED indicator	Indicates current medium priority alarm status	8	Menu button	Opens the Menu screen so a menu option can be chosen
4	High Priority Alarm LED indicator	Indicates current high priority alarm status	9	Alarm Silence button	Silences the alarms for two minutes
5	Ambient light sensor	Senses level of ambient light and adjusts screen brightness	10	Enter button and directional arrows	Used for navigation and menu selection

2.3.2. Monitor Back Panel

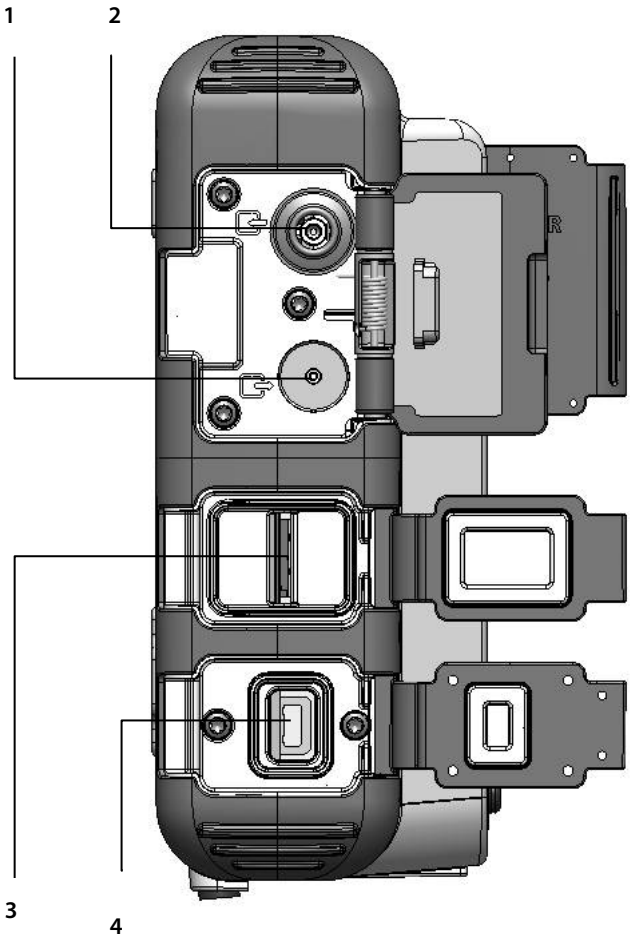
Figure 2. Monitor Back Panel



Label	Function	Description
1	Connector	Connects the monitor with optional accessories
2	Product label	

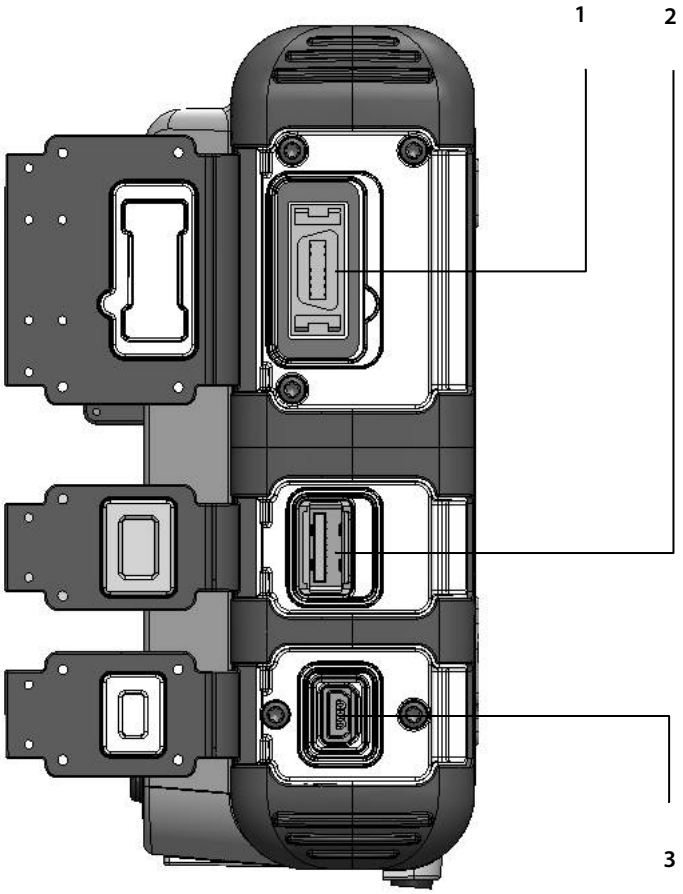
2.3.3. Monitor Right and Left Panels

Figure 3. Monitor Right View



Label	Function	Description
1	CO_2 input connector port	Port for connecting Microstream CO_2 sampling line
2	Gas outlet	To connect to a scavenger system when the monitor is used in the presence of anesthetic gases. The gas output is a barbed style connector intended for 3/32 inch ID tubing.
3	Micro SD port	Port for micro SD card
4	12VDC connector port	To connect to AC adapter

Figure 4. Monitor Left View



Label	Function	Description
1	Nellcor SpO_2 sensor port	Port for connecting Nellcor SpO_2 sensor

2	USB connector port	Port for connecting USB flash drive
3	Mini USB port	Mini USB port; for technical support use

2.3.4. Display Screen Options

The monitor provides a number of options for the display screen, in order to meet needs to different users and institutions.

2.3.5. Monitoring Display Screen Options

The monitor provides a number of monitoring display screen options, as listed below. Default Home Screen Display #1 will appear when the device is turned on for the first time. By default, Home Screen Displays 1, 2, and 3 will be available when the device is turned on for the first time. To toggle between the screen options, press the right or left directional arrows on the Enter button.

A different Home Screen Display option may be selected as a default using the Institutional Defaults option; this is described in *11.1.8 Home Screen Configuration* on page 230.

1. Display Mode Default #1: $EtCO_2$, RR, SpO_2, and PR values with CO_2 and SpO_2 waveforms (this is the factory default for Default Home Screen)

2. Display Mode Default #2: Numeric Home screen without IPI

3. Display Mode Default #3: $EtCO_2$, RR, SpO_2, and PR values with IPI trend graph

4. Display Mode Default #4: $EtCO_2$ and RR values with CO_2 waveform

5. **Display Mode Default #5: EtCO2, RR, SpO_2, and PR values with CO_2 waveform**

6. **Display Mode Default #6: EtCO2, RR, SpO_2, and PR values with SpO2 waveform**

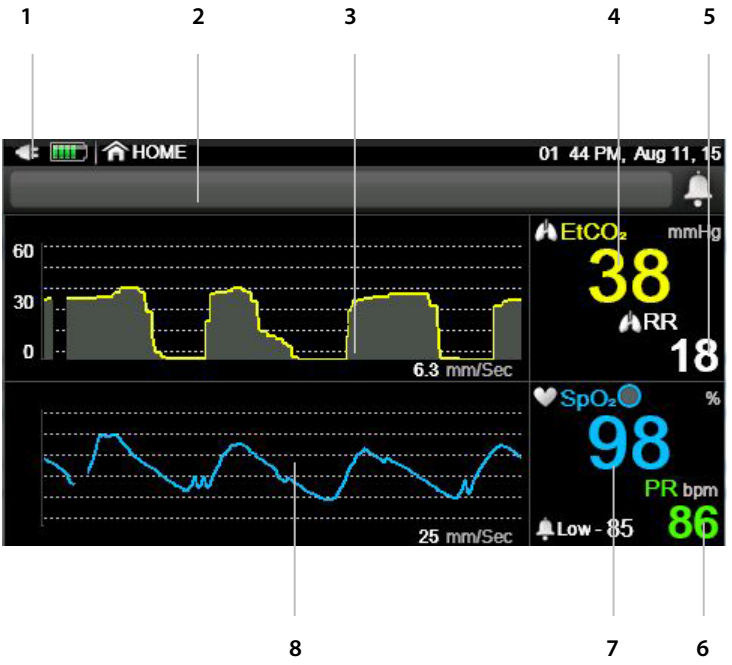
7. **Display Mode Default #7: EtCO2, RR, SpO_2, PR, and IPI values with SpO_2 waveform**

8. **Display Mode Default #8: EtCO2, RR, SpO_2, PR, and IPI values with CO_2 waveform**

9. **Display Mode Default #9: EtCO2, SpO_2, ODI, RR, A/hr, and PR values with IPI trend graph**

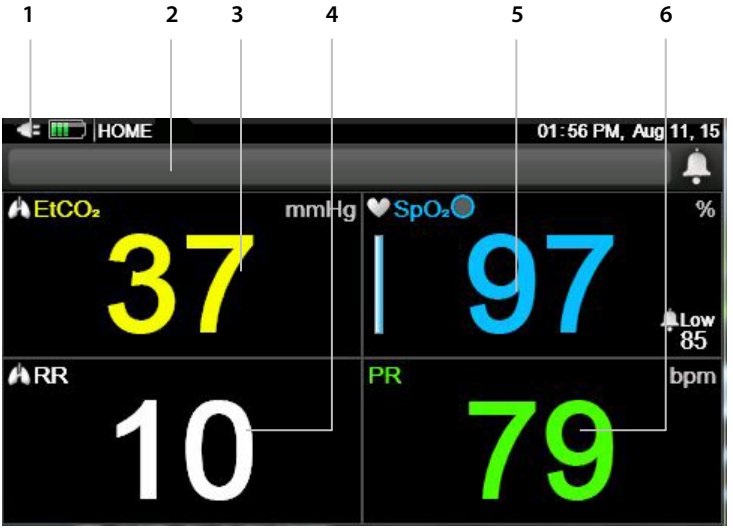
Examples are shown in the screens below.

Figure 5. Home Screen Display #1



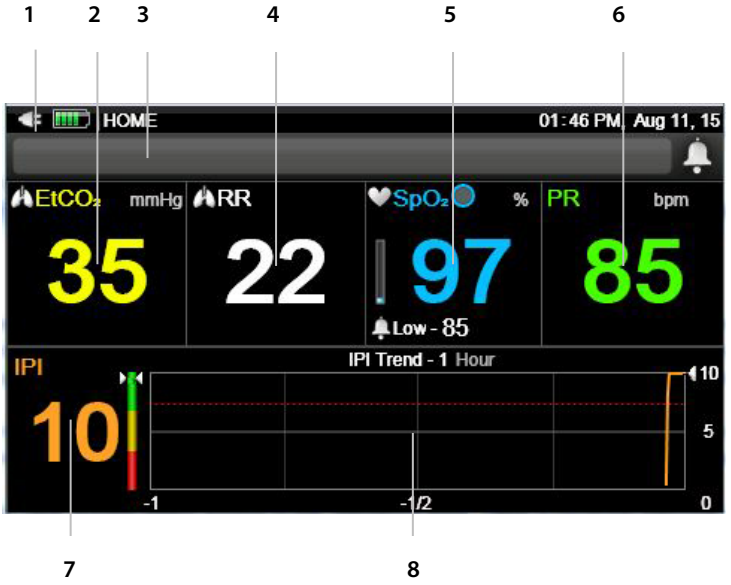
Label	Function	Description
1	Power indicators	Indicates power level of removable battery pack and connections status of power cord
2	Message area	Area in which alarm and other messages appear
3	CO_2 waveform	Display of patient CO_2 values in waveform format
4	$EtCO_2$ patient data	Current patient $etCO_2$ patient data
5	RR patient data	Current patient RR patient data
6	PR patient data	Current patient PR patient data
7	SpO_2 patient data	Current patient SpO_2 patient data
8	SpO_2 (plethysmograph) waveform	Display of patient SpO_2 values in waveform format

Figure 6. Home Screen Display #2



Label	Function	Description
1	Power indicators	Indicates power level of removable battery pack and connections status of power cord
2	Message area	Area in which alarm and other messages appear
3	$EtCO_2$ patient data	Current patient $etCO_2$ patient data
4	RR patient data	Current patient RR patient data
5	SpO_2 patient data	Current patient SpO_2 patient data
6	PR patient data	Current patient PR patient data

Figure 7. Home Screen Display #3



Label	Function	Description
1	Power indicators	Indicates power level of removable battery pack and connections status of power cord
2	$EtCO_2$ patient data	Current patient $etCO_2$ patient data
3	Message area	Area in which alarm and other messages appear
4	RR patient data	Current patient RR patient data
5	SpO_2 patient data	Current patient SpO_2 patient data
6	PR patient data	Current patient PR patient data
7	IPI value	Current patient Integrated Pulmonary Index (IPI) value

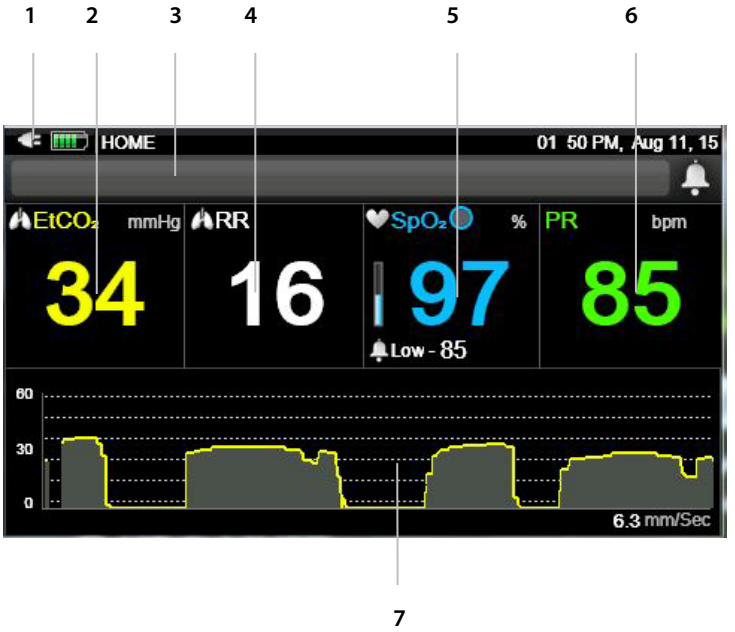
8	IPI trend waveform	IPI for current patient as a trend in waveform format

Figure 8. Home Screen Display #4

Label	Function	Description
1	Power indicators	Indicates power level of removable battery pack and connection status of power cord
2	Message area	Area in which alarm and other messages appear
3	$EtCO_2$ patient data	Current patient $etCO_2$ patient data
4	RR patient data	Current patient RR patient data

5	CO_2 waveform	Display of patient CO_2 values in waveform format

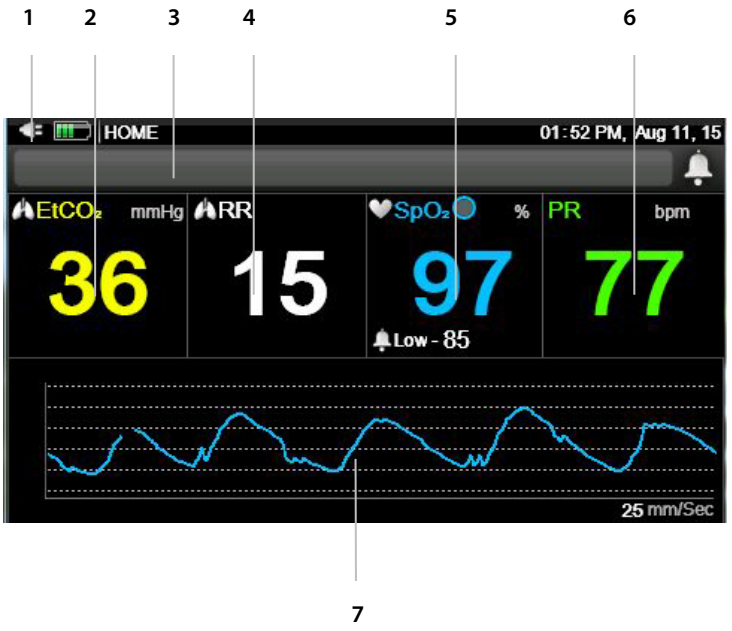
Figure 9. Home Screen Display #5



Label	Function	Description
1	Power indicators	Indicates power level of removable battery pack and connections status of power cord
2	$EtCO_2$ patient data	Current patient $etCO_2$ patient data
3	Message area	Area in which alarm and other messages appear

4	**RR patient data**	**Current patient RR patient data**
5	**SpO_2 patient data**	**Current patient SpO_2 patient data**
6	**PR patient data**	**Current patient PR patient data**
7	**CO_2 waveform**	**Display of patient CO_2 values in waveform format**

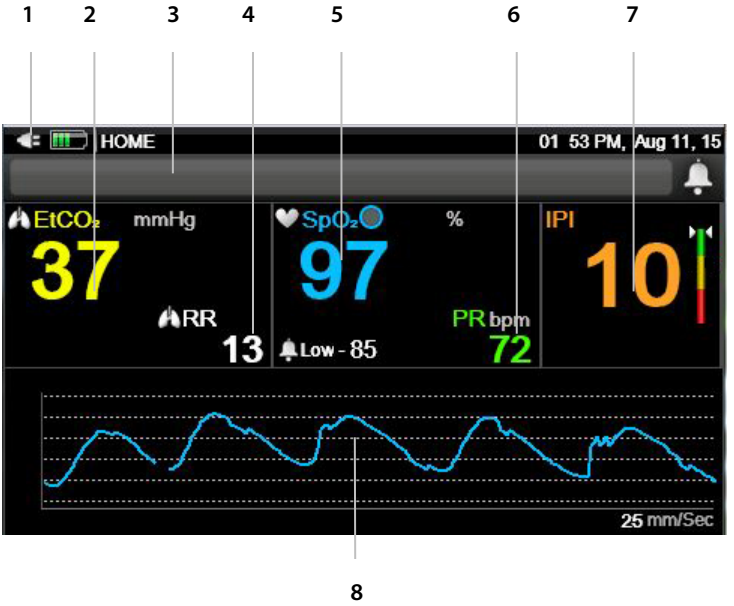
Figure 10. Home Screen Display #6



Label	Function	Description
1	Power indicators	Indicates power level of removable battery pack and connections status of power cord
2	$EtCO_2$ patient data	Current patient $etCO_2$ patient data
3	Message area	Area in which alarm and other messages appear
4	RR patient data	Current patient RR patient data
5	SpO_2 patient data	Current patient SpO_2 patient data

6	PR patient data	Current patient PR patient data
7	SpO_2 (plethysmograph) waveform	Display of patient SpO_2 values in waveform format

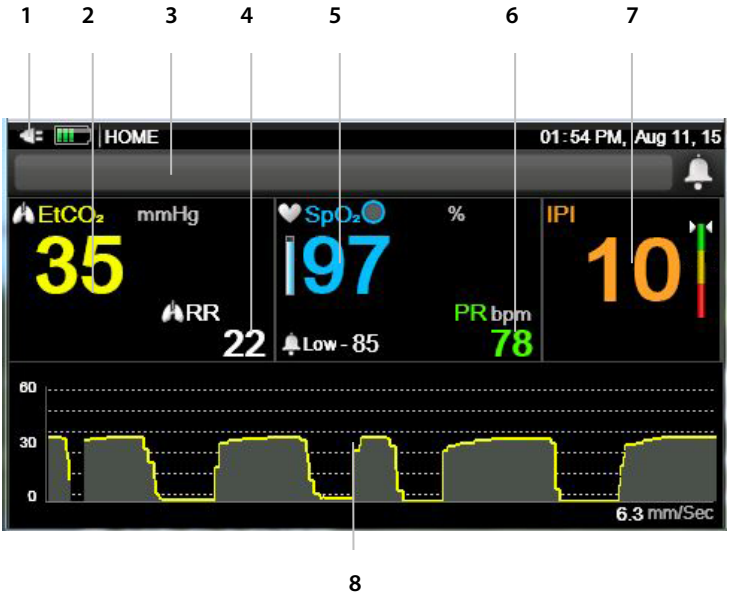
Figure 11. Home Screen Display #7



Label	Function	Description
1	Power indicators	Indicates power level of removable battery pack and connections status of power cord
2	$EtCO_2$ patient data	Current patient $etCO_2$ patient data
3	Message area	Area in which alarm and other messages appear

4	**RR patient data**	**Current patient RR patient data**
5	**SpO_2 patient data**	**Current patient SpO_2 patient data**
6	**PR patient data**	**Current patient PR patient data**
7	**IPI value**	**Integrated Pulmonary Index (IPI) value for current patient**
8	**SpO_2 (plethysmograph) waveform**	**Display of patient SpO_2 values in waveform format**

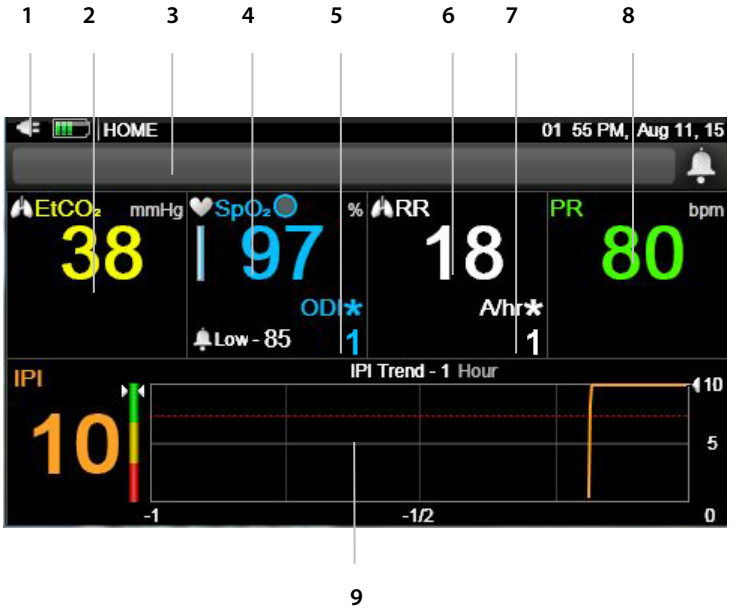
Figure 12. Home Screen Display #8



Label	Function	Description
1	Power indicators	Indicates power level of removable battery pack and connections status of power cord
2	$EtCO_2$ patient data	Current patient $etCO_2$ patient data
3	Message area	Area in which alarm and other messages appear
4	RR patient data	Current patient RR patient data
5	SpO_2 patient data	Current patient SpO_2 patient data
6	PR patient data	Current patient PR patient data
7	IPI value	Current patient Integrated

		Pulmonary Index (IPI) value
8	CO_2 waveform	Display of patient CO_2 values in waveform format

Figure 13. Home Screen Display #9



Label	Function	Description
1	Power indicators	Indicates power level of removable battery pack and connections status of power cord
2	$EtCO_2$ patient data	Current patient $etCO_2$ patient data
3	Message area	Area in which alarm and other messages appear

4	SpO_2 patient data	Current patient SpO_2 patient data
5	ODI patient data	Current patient Oxygen Desaturation Index data
6	RR patient data	Current patient RR patient data
7	A/hr patient data	Current patient Apneas per hour data
8	PR patient data	Current patient PR patient data
9	IPI trend waveform	Integrated Pulmonary Index (IPI) for current patient as a trend in waveform format

The user may change the display screen as follows:

1. **When the device is turned on, the Display Default Home Screen #1 will appear.**

2. **On the Home screen, click the right directional arrow on the Enter button.**

3. **The Default Home Screen #2 will now appear.**

4. **Click the right directional arrow on the Enter button again to cycle through the Home screen options.**

5. **The chosen Home Screen will be displayed until the monitor is turned off. When the monitor is turned on again, the Display Default Home Screen #1 will appear.**

6. **To choose a different Home Screen Display option as a default, so that it remains the default even after the device is turned off, use the Institutional Defaults option;**
   reference *11.1.8 Home Screen Configuration* on page 230.

2.3.6. Monitor Turn-off

To terminate operation of the monitor, take the following steps:

1. Remove the CO_2 sampling line and SpO_2 sensor from the patient and, if using a patient case, close the patient case.

2. Press the **On/Off** button for 2-3 seconds to turn off the monitor.

2.3.7. Screen Navigation

To move around the screen:

1. Use the directional arrows to move around the screen.

2. When the screen shows a choice of options/parameters which may each be adjusted to display a list of choices, a frame will appear around the selected section. Click **Enter** to select the option/parameter for which you want to make changes. You may now use the up and down arrows to make your selection.

Figure 14. Sample Parameters Adjustment Screen

Note the inactive arrows on the left and the active arrows with the shape change on the right.

Letters and numbers may be entered as follows:

1. When the cursor is located in a section of the screen in which letters or numbers may be added, a keyboard will appear on the screen.

2. Navigate within the keyboard using the directional arrows. When you have moved the cursor to the letter/number which you want to input, click **Enter**.

3. When the data input is completed, navigate to **Done** and click **Enter**.

For setting time, date and other changes, reference *2.3.8 Date, Time, Language, and Other Options,* below.

2.3.8. Date, Time, Language, and Other Options

Date and time may be changed as follows:

1. Click the **Menu** button on the front panel.

2. The first option in the menu is **Setup>Alarm Setup**. Click the down arrow on the **Enter/Navigation** button to navigate to **System Setup** and click **Enter**.

3. Use right arrow to navigate to **Date and Time** and click **Enter**.

4. Select the first window you want to update and click **Enter**.

5. Using directional arrows, navigate to the value you want to display and click **Enter**. Make the desired change and click **Enter**.

6. To make additional changes, navigate to the next window you want to update, and repeat.

7. When you are done, navigate to the **Apply** window and click **Enter**.

Languages and other options may be changed as follows:

1. Click the **Menu** button on the front panel.

2. The first option in the menu is **Setup>Alarm Setup**. Click the down arrow on the Enter/Navigation button to navigate to **System Setup** and click **Enter**.

3. Use the right arrow and the down arrow to navigate to the desired window and click **Enter**.

4. Using directional arrows, navigate to the value you want to display and click **Enter**. Make the desired change and click **Enter**.

5. To make additional changes, navigate to the next window you want to update, and repeat.

6. Return to the home screen using the Home button to implement the changes.

Table 2. Display Options Available on System Screen

Parameter	Default	Options
Date and Time	NA	NA
Language	English	English, French, German, Spanish, Italian, Dutch, Swedish, Norwegian, Japanese
Event Marking Mode	Detailed	Quick, Detailed
Graphical Trend Display	4 Hour	1,2,4,8,12, Hour
Tabular Trend Increment Display	30 sec	1,5,15,30 sec, 1,5,15,30 Min, 1 hour
Graphical Trend Display Mode	Recorded	Calendar, Recorded
Nurse Call	Disabled	Disabled, Enabled
Home Trend Display View	1 Hour	1,2,4, Hour

Daylight Savings Time	**Off**	**Off, On**
Brightness Index	**Auto**	**Auto, 7,8,9,10**

2.3.8.1. Keyboard locking

The monitor keyboard may be locked by the user, perhaps to avoid accidental changes by the patient or for another reason. Take the following steps to lock the keyboard:

1. **Press the Enter key for more than two seconds to lock the keyboard. An on-screen message will indicate that the keyboard is locked.**

2. **To unlock the keyboard when it is locked, press the Enter key for more than two seconds. An on-screen message will indicate that the keyboard is unlocked.**

2.3.8.2. Screen timeouts

After one minute of no user interaction, all set-up type screens, except screens in the service mode, will return to the screen that they were on last. If a setup screen times out with a change having been in process, no change is made.

2.3.8.3. Daylight savings time

The monitor provides the option of automatically adjusting the time shown for Daylight Savings Time, based on Windows CE definitions. Automatic Daylight Savings Time adjustment may be set as follows:

1. **Click the Menu button on the front panel.**

2. **The first option in the menu is Setup. Click the right arrow and then the down arrow on the Enter/Navigation button to navigate to System Setup and click Enter.**

3. Navigate to **Daylight Savings Time** and click **Enter**.

4. Select **On** and click **Enter**.

5. Select **Home** to return to the Home Screen.

2.3.9. Capnostream™35 Operational Check Sheet

To get the monitor up and running quickly and smoothly, follow the list of instructions below:

☐ **1. Unpack the monitor**

Remove the monitor and the accessories from the box.

Check that the items on the enclosed packing list are included.

☐ **2. Install the battery pack**

Refer to *3.2.2 Removable Battery Pack Installation* on page 47 for installation instructions.

☐ **3. Turn on the monitor**

Plug an AC adapter into the 12VDC port on the right side panel of the monitor.

Plug the adapter cable into the mains AC supply.

The battery/power indicator at the front of the monitor will turn on.

Press the Power ON/OFF button  **on the front panel to turn on the monitor. The screen will light up, showing that the monitor is turned on.**

☐ **4. Change the date, time or language**

☐ **5. Set the Patient Type and Mode**

☐ **6. To toggle between the home screen options, click the right/left button on the front panel navigational pad.**

☐ **7. Check Alarm Limits (Menu>Setup>Alarm Setup>Select Alarm>Select Limit)**

☐ **8. Open a Patient Case (Menu>Actions>Patient Admit)**

☐ **9. Connect a Sampling Line**

Open the CO_2 input connector shutter on the right side panel of the monitor and connect the appropriate sampling line to the CO_2 input port at the top of this section.

Connect the sampling line to the patient as described in the Directions for Use supplied with the sampling line. The sampling line connecter should be screwed clockwise into the monitor CO_2 port until it can no longer be turned, to ensure that it is connected securely to the monitor. This will assure that there is no leak of gases during measurement at the connection point and that measurement accuracy is not compromised.

☐ **10. Connect a SpO_2 Sensor**

Connect the SpO_2 extension cord firmly to the monitor SpO_2 sensor port on the left side panel of the monitor, and then connect the appropriate SpO_2 sensor to the extension cord.

Connect the SpO_2 sensor to the patient as described in its Directions for Use.

☐ **11. Once either sensor or both sensors are connected to the monitor, it is ready for operation. Patient data should begin appearing on the screen within a few seconds.**

☐ **12. View Trends if desired (Menu>Trend> Graphical Trend or Tabular Trend)**

☐ **13. Set Up Data Transfer as required (if applicable; connectivity accessories must be purchased separately) (reference *5.4 Data Transfer* on page 162).**

3. Installation

This chapter describes the physical components of the monitor and how to set up the monitor so it is ready for use.

3.1. Unpacking and Inspecting the Monitor

Unpack the monitor and check all the components before performing any further procedures.

To unpack and inspect the monitor:

1. **Carefully remove the monitor and the accessories from the box.**

2. **Check that the items on the enclosed packing list are included:**

    a. **Monitor**

    b. **Mains electrical power cord (AC cable)**

    c. **AC adapter with DC cable**

    d. **Removable battery pack**

    e. **Operator's manual**

    f. **Monitor quick guide**

    g. **CD with additional documentation (this manual in additional languages)**

3. Inspect each component.

If any component is damaged or missing, contact your local representative.

When unpacking the monitor, dispose of packaging waste according to local regulations for the disposal of packaging waste.

3.2. Batteries

3.2.1. Batteries

The device includes an internal battery, which is not accessible by the user, and a removable battery pack. Both are lithium-ion batteries.

WARNING:
The unit should always be operated with the removable battery installed in order to provide back-up power in the event of a momentary or temporary power outage.

Caution:
Prolonged storage of the device above 60° C might cause performance degradation of the batteries

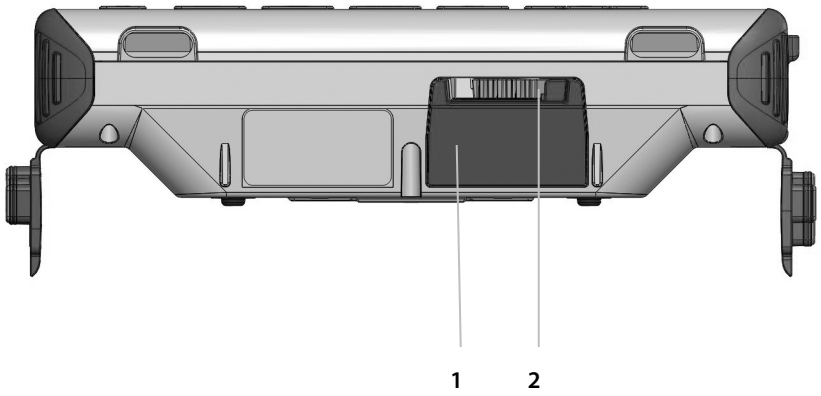
3.2.2. Removable Battery Pack Installation

The battery pack may be installed as follows:

1. Slide the battery pack into the battery pack compartment at the bottom of the monitor, with label facing downwards, towards the back panel of the monitor.

2. Push the battery pack in all the way, until a click is heard. The battery pack is now installed.

Figure 15. Monitor Bottom, with Battery Pack Installed



Label	Function	Description
1	Battery pack	Battery pack installed in monitor
2	Black slider	Black slider used to open the battery pack compartment

3. To remove or switch the battery pack, open the battery pack compartment of the monitor by sliding the black slider to the left.

4. The battery pack will release itself from the compartment. Pull the battery pack out all the way.

Caution:
There should always be a removable battery installed in the device. If the removable battery is not installed, the unit will operate properly on AC power, and will operate on the

internal battery for a very limited period (for battery exchange/hot swap purposes), but if AC power is lost for any reason, the monitor will work only for a limited period, until the internal battery's charge is used up.

Caution:
Only the battery pack provided with this monitor shall be used for the monitor. Other batteries may not operate correctly.

Caution:
The battery pack supplied with this monitor should not be used with other devices.

The battery icon indicates the charge level of the removable battery.

Reference *3.2.5 Battery and AC Connections Indicators* on page 50.

3.2.3. Battery and Power Usage

If power is lost when the monitor is operating from AC power, it automatically switches to the removable battery pack for power. If the removable battery pack is empty, the monitor includes an internal battery which can supply power for a limited period while the user inserts another removable battery pack or attaches the monitor to AC power.

The battery/power indicator at the front of the monitor ( **) indicates the battery/power status, as described *in 3.2.5 Battery and AC Connections Indicators* on page 50.**

The monitor can work using the removable battery pack for approximately 3 hours. The monitor can work using the permanent internal battery for 20 minutes. It is recommended to use the internal battery only for battery switching periods and not for more extended use.

Both batteries will charge when the unit is plugged in. Charging time is up to 5 hours when the unit is turned off, and up to 8 hours when

the unit is turned on. The removable battery may also be charged in the battery charger (see *8.2 Available Accessories* on page 193).

The battery icon will show the battery pack's approximate charge level. An advisory message, BATTERY LOW, appears when approximately 30 minutes of battery charge remains.

3.2.4. Battery Hot Swap

The monitor includes an internal permanent battery pack, to maintain battery power during battery switching while the monitor is turned on but not attached to AC power. Remove the removable battery pack as described above and insert another battery pack.

When the monitor is attached to AC power, both the internal permanent and the external removable battery packs will charge.

3.2.5. Battery and AC Connections Indicators

The battery pack charge level and AC power connections should be confirmed before each use.

Recharge the removable battery pack when the advisory message **BATTERY LOW** appears on the display screen. To recharge the battery, make sure that the monitor is plugged into the AC mains or use the external battery charger.

The battery/power indicator at the front of the monitor () indicates the battery/power status, as follows:

- The indicator is green when the monitor is connected to AC power and both batteries are fully charged.
- The indicator is orange when the monitor is connected to AC power and one or both battery packs are currently being charged.

- The indicator is red when the monitor is connected to AC power and one or both battery packs are not being charged as the result of a malfunction.

- The indicator is off (no light emitted from the indicator) when the monitor is not connected to AC power.

An on-screen indicator () will appear whenever the removable battery is installed, indicating the current status of the battery. This indicator will flicker when the removable battery charge level is low (reference *3.2.3Battery and Power Usage* on page 49).

An on-screen indicator () will appear if the internal battery is not charged. In this case, a hot swap of the removable battery should not take place, and the device should be attached to AC power to charge the internal battery. If the indicator appears even after the device is attached to AC power, the device will need to be serviced; contact Capnographytechnicalsupport@medtronic.com.

For normal operation, always check that the battery/power indicator is green or orange during monitor use. This will ensure the battery is charged during use and the monitor is prepared in case of a power outage. In the case of a patient transfer, the unit can be unplugged and transferred with the patient. Care should be taken to reconnect the monitor to the AC mains following the transfer.

3.2.6. Handling the Battery Pack

Caution:
Do not immerse the removable battery pack in water; it may malfunction.

Caution:
Recharge the removable battery pack only in the monitor or the external battery charger (reference *8.2 Available Accessories* on page 193) to avoid possible heating, burning or rupture of the battery pack.

3.2.7. Storing the Battery

The removable battery should be stored outside the device. The battery pack has an automatic discharge feature. You must periodically check the charge level of the battery pack. The battery may be stored as follows:

The battery pack must be stored in a cold, dry area, not inside the monitor. Its charge decreases over time. To restore the battery pack to full power, recharge the battery before use.

Optimum storage for a removed battery is room temperature. The batteries must be stored at the following temperature ranges:

- **Less than 1 month: -20 to +50°C**
- **1 month to 3 months: -20 to +40°C**
- **3 months to 1 year: -20 to +20°C**

3.2.8. Disposing of the Battery

Caution:
Do not dispose of the battery pack in fire; it may explode.

Follow local governing ordinances and recycling instructions regarding disposal or recycling of batteries.

3.2.9. Internal Battery Pack

The internal battery pack is not removable and should not be handled by the user.

3.2.10. Monitor Mounting Plate

The back of the monitor is designed to fit a 75mm VESA standard mounting plate.

3.2.11. Operation in Helicopter Transport

When installing the device in a helicopter for use during transport, please note the following:

The device shall be mounted using a VESA mount and the monitor mounting plate, positioned so that the bottom of the device is parallel to the floor of the helicopter. The device shall be placed in a position where the controls are easily reached by the caregiver, and the screen may be viewed clearly by the caregiver.

3.3. Periodic Maintenance

If your institution has a periodic maintenance database, log the monitor in this database for its periodic regular maintenance and its calibration procedure.

Regular maintenance is required every 24 months, starting from the installation date.

Calibration is required after the first 1,200 hours of use (or 12 months, whichever comes first) and thereafter every 4,000 hours of use (or 12 months, whichever comes first). The number of hours remaining until calibration will appear on the monitor's Service Screen. For more details about calibration and other maintenance procedures, reference ***6 Preventive Maintenance*** **on page 176.**

4. Operation

4.1. Turning on the Monitor

This section explains how to turn on the monitor.

Caution:
The monitor is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.

Caution:
Use only Microstream™ etCO2 consumables and Nellcor SpO2 sensors, to ensure that the monitor functions properly.

Take the following steps to turn on the monitor:

1. **Attach the AC adapter to the 12VDC connector port on the right side of the monitor.**

2. **Attach the power cord to the AC adapter.**

3. **Plug the power cord into an external power source.**

4. **The battery/power indicator on the front of the monitor should be either green or orange once the monitor is plugged in. If necessary, the monitor can work for a limited period of time on battery power; reference 3.2.3 Battery and Power Usage on page 49 for details.**

5. Press the **On/Off** button ( ) at the front of the monitor. The monitor will turn on and the screen will light up.

Caution:
If the battery/power indicator at the front of the monitor ( ) is red or off, the monitor is running on battery power only and will stop operating when the battery is discharged.

Caution:
If the red and yellow alarm lights do not light up or there is no sound from the speaker, the monitor should not be used and should be sent for servicing.

6. **The default mode for the device is the EMS-enabled mode, in which the monitor will immediately be ready for monitoring, once a CO_2 sampling line and an SpO_2 sensor are attached.**

7. **If EMS mode is disabled on the device, the monitor will display the following on-screen message when turned on:**

Figure 16. Trend Memory Message

8. **In this case, click No to continue monitoring the same patient, or click Yes if you are now monitoring a new patient and want to clear any information regarding the previous**

patient to avoid mix-ups. The monitor is now ready to begin monitoring, once a CO_2 sampling line and an SpO_2 sensor are attached. If you want to enable or disable EMS mode, reference *4.8.3 EMS Mode* on page 70.

4.2. Monitor Preparation for a Patient

Caution:
If any monitor response does not seem appropriate, do not use the monitor. Instead, contact your local Service Center or Capnographytechnicalsupport@medtronic.com.

The following steps describe the procedure for preparing the monitor for a patient.

1. **Connect the sampling line, the SpO_2 sensor, or both to the monitor, following the instructions in this manual. To connect the sampling line and sensor, reference *4.10.2 FilterLine Connection* on page 76 and *4.11.1 Connecting an SpO2 Sensor to the monitor* on page 82.**

2. **Once either or both the SpO_2 sensor and the sampling line are connected to the monitor, it is ready for operation.**

3. **It is possible to use either the Capnography function ($etCO_2$) or the Pulse Oximetry function (SpO_2) individually. If you only want to operate one function, connect ONLY the component for that function, and the monitor will operate normally.**

The monitor is for use with one patient at a time only.

4.2.1. Patient Types

There are five different patient types recognized by the monitor, listed below.

- **Infant/Neonatal: for patients from birth to the age of one year**
- **Pediatric 1-3 yrs: for patients aged one to three years**
- **Pediatric 3-6 yrs: for patients aged three to six years**
- **Pediatric 6-12 yrs: for patients aged six to twelve years.**
- **Adult: for patients aged 12 years and up**

The patient type is displayed at the top left hand corner of the screen.

The original default patient type on the monitor is ADULT; once the patient type has been changed, the default will be the current patient type.

WARNING:
The characteristics of a breath are calculated differently for the different patient types. Setting the correct patient type is therefore very important. Incorrect setting will result in inaccurate monitoring of the patient's respiration, and could lead to incorrect alarm limits or produce incorrect patient IPI data.

To change the patient type:

1. **Click the Menu button on the front panel.**
2. **The first option in the menu is Setup>Alarm Setup.**
3. **On the Setup Menu screen, navigate to the Patient Type Icon using the directional arrows and click Enter to open the drop-down menu.**

Figure 17. Patient Type Drop-down List

4. **Using the directional arrows, select the relevant patient type.**

5. **Select Enter and, if requested, Confirm, using the Enter button. If there is a contradiction between the patient type and patient age, check your patient data and change as required.**

4.3. Patient Cases and Patient ID Numbers

The monitor may be used for one patient at a time. It is recommended that all patients should be recorded as patient cases, as described below.

1. **Click the Menu button on the front panel.**

2. **On the Menu screen, navigate to and select Actions>Patient Admit.**

3. **Change the automatically generated patient ID number (which includes the current date according to the device) to a number that will identify the patient in your system, if desired.**

4. **Input patient data as required. Note that a patient case may be opened even if you do not add patient data.**

5. Navigate to and click the **Start Case** button on the left. A window will notify you that a case has been started, and the text on that button will change to **Stop Case**.

6. To stop a case that has already been started, navigate to the same screen and click the **Stop Case** button.

4.4. Patient Events

When scanning patient history in the monitor, it is often useful to have a record of patient events that could have influenced the recorded readings. Events are added to the patient trend record as follows:

1. Click the **Menu** button on the front panel.

2. On the **Menu** screen, navigate to and select **Actions>Events**. The Event screen will open. Reference *Figure 18. Event Marking Screen* on page 60.

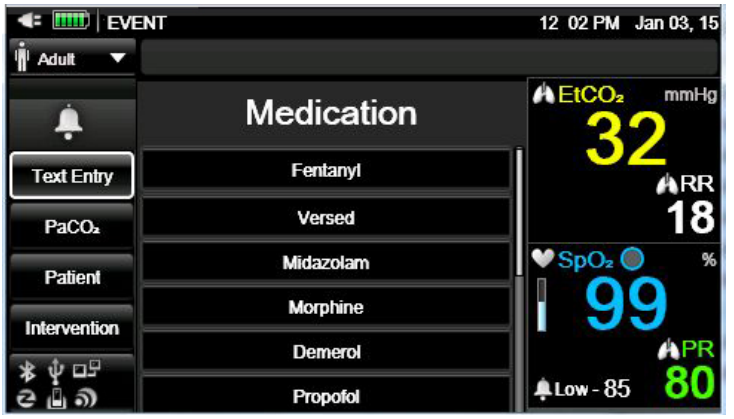
3. The Medication Event list will be seen on the main screen; if you want to add a Medication Event, navigate to the relevant event and click **Enter**. If you want to add a $PaCO_2$, Patient or Intervention Event, navigate to the **$PaCO_2$**, **Patient** or **Intervention** buttons and click **Enter.** For $PaCO_2$, navigate to and set the date, time and number of $PaCO_2$ using the **Enter** button. For a Patient or Intervention Event, navigate to and select the desired event.

4. If you want to add a different event, navigate to and click the **Text Entry** button and add free text, up to 20 characters, and date and time for this event. This date and time may be in the past.

5. Once you have inputted Event data, clicking **Enter** will return you to the Home screen. If you decide not to input Event data, click **Back** or **Home** to return to the Home screen.

Trend recording will continue as before; entering an event does not change the trend recording status.

Figure 18. Event Marking Screen



The default event marking options in the monitor are as follows:

Table 3. Event Markings

MEDICATION	PATIENT	INTERVENTION
Fentanyl	EATING	OXYGEN
Versed	DRINKING	SUCTION
MIDAZOLAM	COUGHING	ADJ AIRWAY
Morphine	AMBULATING	NARCAN
Demerol	CHEST PT	ROMAZICON
Propofol	TURNED	NEB TX
SURFACTANT	SNORING	STIMULATED
Other	OTHER	CO_2 Insufflation
		ABG

		OTHER

New events may be added and any of these event markings may be changed, using Institutional Settings. Reference *11.1.1 Changing Institutional Defaults* on page 92 for more information.

4.5. Alarm and Pulse Volumes and Alarm Delay

The alarm volume can be made louder or softer for patient alarms and pulse tone. The pulse tone can also be turned off using the SpO_2 menu. By default, the pulse tone is turned off.

4.5.1. Alarm Volume

Follow the steps listed below to make the alarm volume louder or softer.

1. Click the **Menu** button on the front panel.

2. Navigate to and select the **Setup>Alarm Volume** screen. Click **Enter** and select the desired volume using the directional arrows. Select **Home** to return to the Home screen while retaining any changes you have made.

3. If the monitor is set to the Alarm Volume default setting, the set volume will remain active when the monitor is turned off.

Other alarm volume options settable in Institutional Defaults are **Maximum** and **Audio Off**. To change the Alarm Volume Institutional Settings, reference *11.1.7.1 Main Monitor settings* on page 228.

4.5.2. Pulse Tone Volume

The pulse tone volume can be turned on or off as follows:

1. Click the **Menu** button on the front panel.

2. Navigate to and select **Setup>SpO_2 Setup** on the Menu Screen.

3. Navigate to **Pulse Tone** and click **Enter** to view options. The default value is **Off**. Navigate to **On** and click **Enter** to turn on the Pulse Tone sound.

4. This will return you to the SpO_2 Setup screen. Select **Home** to return to the Home screen.

The pulse tone volume can be set as follows:

1. When the Pulse Tone has been turned on as described above, click the **Menu** button on the front panel.

2. Navigate to the **Setup >Alarm Volume** screen. Click the down arrow to navigate to the Pulse Volume section of the screen. Click **Enter** and select the desired volume using the directional arrows. Select **Home** to return to the Home screen while retaining any changes you have made.

4.5.3. Alarm Volume Default Options

WARNING:
The Audio off option (which will create permanent alarm silence) should be set in the Institutional Defaults only in a situation in which the caregiver is also monitoring the patient by other means, to avoid the chance of missed alarms.

4.5.4. Alarm Delay

Alarm delay may be set for all patient alarms except for the NO BREATH alarm, using the following steps:

1. Click the **Menu** button on the front panel.

2. Navigate to and select **Setup** on the Menu Screen and **Service** on the Setup Menu Screen.

3. Enter Service password and select **Done**.

4. Navigate to **Institutional Defaults>Alarms>Alarm Delay**.

5. Navigate to and select **Enter** on the relevant alarm.

6. Navigate and select to the desired alarm delay. Click **Enter**.

7. Select **Home** to return to the Home Screen.

8. The device will ask you to save settings and shut down. Shut down and then restart to retain the settings change you have just made.

If SatSeconds is selected and the SatSeconds value triggers an SpO_2 alarm, any SpO_2 delay that has been set will be superseded and the alarm will occur despite the SpO_2 delay.

4.6. Use of Scavenging System

When using the monitor with anesthetics, nitrous oxide or high concentrations of oxygen, connect the gas outlet to a scavenger system. The gas output is a barbed style connector intended for 3/32 inch ID tubing.

The gas outlet may be seen in *Figure 3. Monitor Right View* on page 21.

4.7. Use of Pump Off Mode

Use the Pump Off mode whenever performing suction or lavage. During Pump Off mode, pump activity is suspended to protect the monitor from drawing in liquids which could cause a malfunction.

In the Pump Off mode, the CO_2 module pump is switched *OFF* for a preset time to prevent liquids from entering the monitor.

WARNING:
If at any time the monitor displays the FilterLine Blockage message, replace the sampling line.

Set the pump mode as follows:

1. **The monitor must be currently monitoring CO_2 in order to be placed in Pump Off mode.**

2. **Click the Menu button on the front panel.**

3. **Navigate to and select Actions on the menu screen and Pump Off on the Actions menu screen. Click Enter.**

4. **The monitor will indicate, in the CO_2 area and the message area, the time remaining until the pump will automatically turn back on.**

5. **The standard Pump Off period is 15 minutes. This may be changed in the CO_2 Setup screen (temporarily, until the monitor is turned off; reference *4.10.4 Adjustable CO2 Parameters* on page 79), or in the Institutional defaults screen (permanently; Reference *11.1.1 Changing Institutional Defaults* on page 92.)**

6. **To turn the CO_2 pump back on before the set time period has passed, click the menu button on the front panel and then navigate to and select Pump Off for xx:xx – Exit Now.**

7. **To extend the timer for another Pump Off period, beyond the current period, click the menu button on the front panel and then navigate to and select Extend Timer. Clicking the Extend Timer button will begin another Pump Off period of the same length as the set Pump Off period.**

While the pump is off, CO_2 is not monitored and no breath waveform, $etCO_2$, or respiration rate number values are displayed. SpO_2 and pulse rate monitoring continues.

4.8. Additional Monitor Modes

4.8.1. Demo Mode

Access the Demo Mode as follows:

1. **Click the Menu button on the front panel.**
2. **Navigate to and select Setup on the Menu Screen and Service on the Setup Menu Screen.**
3. **Enter Service password and select Done.**
4. **Navigate to and select Demo Mode. Navigate to and select the desired demo patient type option. Click Enter.**
5. **After a brief waiting period, the monitor will move to Demo Mode. An on-screen message indicating Demo Mode can be seen on the upper right, next to the time and date, in black text on a yellow background.**
6. **To exit Demo Mode, turn off the monitor. When the monitor is restarted, it will no longer be in Demo Mode.**

Note:
No patient monitoring will take place while the monitor is in Demo Mode, even if a sampling line and sensor are attached to the monitor. To return to monitoring, turn off the monitor and restart it.

When a device is in Demo Mode, the trend data in the device will not be erased. However, if trend data is viewed while the device is in

Demo Mode, the trend data displayed will be the Demo data. When the device is turned off and turned on again, the device will show the previous patient's trend data, if the user has not cleared it (by choosing Yes when the devices asks whether to clear trend data). For the period of time during which the Demo mode was viewed on the screen, no data will be available, since no data is recorded while the device is in Demo mode.

4.8.2. Parameter Standby Mode

There is an option of placing the monitor in a separate parameter standby mode for capnography and for pulse oximetry. Once this possibility is enabled, the user can activate Parameter Standby as required. The purpose of this option is to enable a monitor to alarm when a sampling line/sensor is disconnected from the monitor, but permit the user to turn off this option at will.

By default, Parameter Standby Mode is disabled.

In Standard Mode (when Parameter Standby Mode is not enabled), removing a sampling line or SpO_2 sensor/extension cable from the monitor will cause a message to appear on the screen (FilterLine Disconnected or SpO_2 Sensor Disconnected, as relevant) but no alarms will sound. Removing the SpO_2 sensor from the patient will set off an audible alarm and an on-screen message. By default, Parameter Standby mode is disabled.

When Parameter Standby Mode is enabled, after a sampling line (FilterLine) has been connected and then removed from the monitor, a medium priority alarm FilterLine Disconnected will sound. Likewise, after a pulse oximetry sensor/extension cable has been connected and then disconnected from the monitor, a medium priority alarm SpO_2 Sensor Disconnected will sound. The purpose of this alarm is to prevent unauthorized disconnection of a sampling line/SpO_2 sensor from the monitor, perhaps by patients or patients' visitors.

When Parameter Standby Mode is enabled, removing the SpO_2 sensor from patient will set off an audible alarm and an on-screen message, as it does in Standard Mode.

Parameter Standby Mode may be enabled as follows:

1. **Click the Menu button on the front panel.**

2. **Navigate to and select Setup on the Menu Screen and Service on the Setup Menu Screen.**

3. **Enter Service password and select Done.**

4. **Select Institutional Defaults>Monitor.**

5. **Navigate to Parameter Standby Mode and click Enter. Set Parameter Standby Mode to Enabled and click Enter.**

6. **Select Home to return to the Home Screen. The device will ask you to save settings and shut down; do so.**

Once Parameter Standby Mode has been enabled, it may be activated as follows:

1. **Remove the sampling line and/or SpO_2 sensor from the monitor or remove the SpO_2 sensor from the patient.**

2. **Press the alarm silence hard key at the front of the monitor () for more than two seconds to enter the Parameter Standby Mode.**

3. **The monitor will emit the Standby pattern beep when the monitor is successfully placed in Parameter Standby Mode, and the monitor screen will indicate the following messages in the waveform areas (and in the message areas, alternately with other relevant messages): CO_2 Standby, SpO_2 Standby.**

If a CO_2 sampling line is connected to the monitor, the Parameter Standby Mode for CO_2 will not open even if the alarm silence key is pressed as required. Likewise, if an SpO_2 sensor is connected to the monitor and to a patient, the Parameter Standby Mode for SpO_2 will not open even if the alarm silence key is pressed as required. This is to prevent entering this mode while a patient is being monitored. Pressing the alarm silence key will therefore start Parameter Standby Mode for both CO_2 and SpO_2 if both are disconnected, or for one if only one is disconnected.

Please note the following:

- **CO_2 standby will be exited automatically when a CO_2 sampling line is attached to the monitor.**
- **SpO_2 standby will be exited automatically when an SpO_2 sensor is attached to the monitor and to a patient.**

Thus, if the user is unaware that the monitor is in the Parameter Standby mode, simply reattaching a sampling line to the monitor or SpO_2 sensor to the patient will cause the monitor to exit the Parameter Standby mode and monitoring to resume.

During Standby Mode, the current value of any parameter in standby will be displayed as a double dash in the relevant area on the home screen.

Table 4. Message and Alarm Status during Different Parameter Standby Situations

Feature	Status when Parameter Standby mode disabled	Status when Parameter Standby mode enabled but not activated	Status when Parameter Standby mode enabled and Parameter Standby activated

Feature	Status when Parameter Standby mode disabled	Status when Parameter Standby mode enabled but not activated	Status when Parameter Standby mode enabled and Parameter Standby activated
FilterLine disconnected (from monitor) on-screen message / SpO_2 sensor disconnected (from monitor) on-screen message	Yes	Yes	Yes
FilterLine disconnected (from monitor) alarm / SpO_2 sensor disconnected (from monitor) alarm	No	Yes	No
SpO_2 Sensor not on Patient Medium Priority audible alarm	Yes	Yes	No
SpO_2 Sensor not on Patient on-screen message	Yes	Yes	Yes
CO_2 Standby message / SpO_2 Standby message	No	No	Yes

Feature	Status when Parameter Standby mode disabled	Status when Parameter Standby mode enabled but not activated	Status when Parameter Standby mode enabled and Parameter Standby activated
High Priority (patient) alarms	Yes	Yes	No(for the parameter in standby)
Flashing red and yellow LEDs on the front panel during high Priority (patient) alarms	Yes	Yes	No, for the parameter in standby (since high priority [patient] alarms related to the parameter in standby do not exist in this case)
Storage or transfer to remote stations of high priority (patient) alarms	Yes	Yes	No, for the parameter in standby (since high priority [patient] alarms related to the parameter in standby do not exist in this case)

4.8.3. EMS Mode

The monitor provides an option to create a different set of factory defaults, for use of the monitor in the EMS environment.

When the EMS mode is enabled, the following changes will occur in the monitor's functioning:

- **After powerup, the monitor immediately opens the home screen, with no on-screen messages.**

By default, the EMS Mode is enabled.

Disable the EMS Mode as follows:

1. **Click the Menu button on the front panel.**

2. **Navigate to and select Setup on the Menu Screen and Service on the Setup Menu Screen.**

3. **Enter Service password and select Done. Select Institutional Defaults>Monitor>Factory Defaults.**

4. **Navigate to EMS Mode and click Enter.**

5. **Set to EMS Mode to Disabled and click Enter.**

6. **Select Home to return to the Home Screen. The device will ask you to save settings and shut down; do so.**

7. **To enable the EMS mode, follow steps 1, 2, 3, 4 and 5 above. Set EMS Mode to Enabled and click Enter.**

8. **Select Home to return to the Home Screen. The device will ask you to save settings and shut down; do so.**

Any institutional defaults set while the monitor is in EMS-enabled mode will remain relevant only as long as the monitor is in EMS mode. When the EMS mode is disabled on the monitor, defaults will remain factory defaults (if no changes to Institutional Defaults were ever made when EMS was disabled) or defaults set while EMS was disabled on the monitor.

Likewise, if changes are made to defaults while EMS mode is disabled on the monitor, these changes will not be relevant while the monitor is in EMS mode. Thus, if desired, an institution can maintain two sets of Institutional Defaults: one for EMS mode and one for when EMS mode is disabled.

4.8.4. Reminder Signal

When the monitor is set to Audio Off (Permanent Alarm Silence), a reminder signal, which is a single beep, may be provided every two minutes to indicate that the monitor is in a Permanent Alarm Silence state.

By default, this Reminder Signal is Disabled.

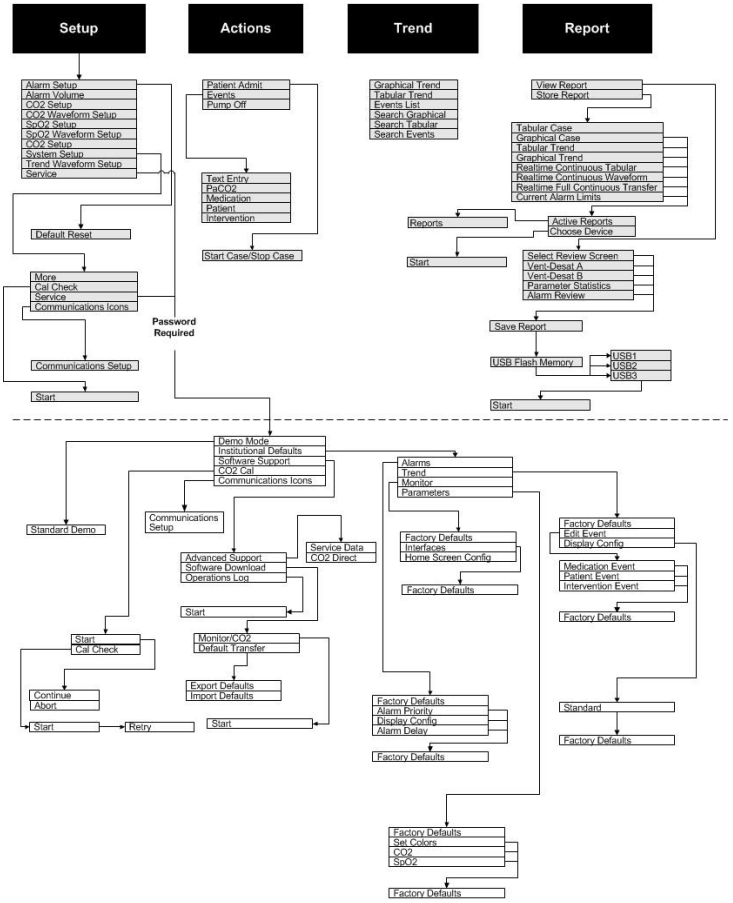
Enable the reminder signal as follows:

1. **Click the Menu button on the front panel.**
2. **Navigate to and select Setup on the Menu Screen and Service on the Setup Menu Screen.**
3. **Enter Service password and select Done.**
4. **Select Institutional Defaults>Monitor.**
5. **Navigate to Reminder Signal and click Enter. Set Reminder Signal to Enabled and click Enter.**
6. **Select Home to return to the Home Screen. The device will ask you to save settings and shut down; do so.**
7. **When you restart, the Reminder Signal wil be enabled.**

4.9. Monitor Screen Menu Reference Chart

The chart below shows the menu flow paths for navigating through the different screens of the monitor.

Figure 19. Monitor Menu Flow



4.10. Capnography with the Monitor

4.10.1. Microstream™ $EtCO_2$ Consumables

Caution:

Before use, carefully read the Microstream™ $etCO_2$ consumables Directions for Use.

Caution:

Use only 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 clean, disinfect or blow out the sampling line as the monitor can be damaged.

Caution:

Dispose of Microstream™ $etCO_2$ consumables according to standard operating procedures or local regulations for the disposal of contaminated medical waste.

WARNING

Loose or damaged connections may compromise ventilation or cause an inaccurate measurement of respiratory gases. Securely connect all components and check connections for leaks according to standard clinical procedures.

WARNING:

If too much moisture enters the sampling line (i.e., from ambient humidity or breathing of unusually humid air), the message Clearing FilterLine will appear in the monitor message area. If the sampling line (FilterLine) cannot be cleared, the message FilterLine Blockage will appear in the CO_2 waveform display section on the Home screen and in the monitor message area. (If there is no waveform display, the message will appear only in the message area.) Replace the sampling line once the FilterLine Blockage message appears.

WARNING:

The sampling line 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 combustion of the sampling line or surrounding surgical drapes.

Note:
When connecting a sampling line to the monitor, screw the sampling line connecter clockwise into the monitor CO_2 port until it can no longer be turned, to ensure that it is connected securely to the monitor. This will assure that there is no leak of gases during measurement at the connection point and that measurement accuracy is not compromised.

Note:

Following connection of the CO_2 sampling line, check that CO_2 values appear on the monitor display.

Microstream™ etCO_2 consumables are available in a number of varieties, depending on the patient size and type and other

considerations. The following considerations should be taken into account when choosing the correct consumable for a patient.

- **Whether the patient is intubated or non-intubated**
- **Whether the patient is on mechanical ventilation**
- **Duration of use**
- **Patient's size and weight**
- **Whether the patient is breathing through his nose, his mouth, or alternating between oral and nasal breathing**

A list of Microstream™ $etCO_2$ consumables appears in *8.1 Microstream EtCO2 Consumables* on page 191. For more information about Microstream FilterLines or additional sizing and packaging options for these products, contact your local representative, or see http://www.covidien.com/rms/pages.aspx?page=OurBrands/Microstream.

Select the appropriate sampling line 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.

Note:
The generic term FilterLine or sampling line, used in this manual, is interchangeable with any of the Microstream™ $etCO_2$ consumables.

4.10.2. FilterLine Connection

Before monitoring a patient with capnography, the appropriate sampling line (FilterLine) must be connected to the monitor and to the patient.

Connect the sampling line as follows:

1. **Slide open the sampling line input connector shutter and connect the appropriate sampling line. Screw the sampling line connector into the monitor clockwise until it can no longer be turned.**

2. **Connect the sampling line to the patient as described in the Directions for Use supplied with the sampling line.**

3. **When the sampling line is connected, the monitor will immediately begin to search for breaths, but it will not indicate a No Breath condition before any valid breaths have occurred.**

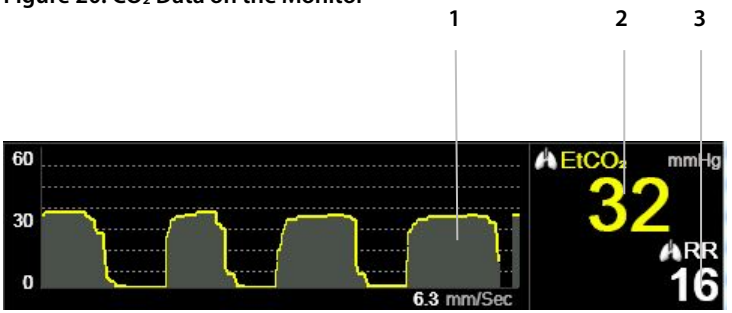
4.10.3. CO_2 Data Displayed by the Monitor

EtCO_2 monitoring is available for adult, pediatric (all types) and neonatal patients.

The monitor Home screen displays real time CO_2 data. The displayed data includes:

- **Real time etCO_2 values along with selected unit(for available units, reference 10.6 Microstream™ Capnography on page 201)**
- **Respiration rate (RR) in breaths per minute, as derived from capnography**
- **CO_2 Waveform (on some screens)**

Figure 20. CO_2 Data on the Monitor



Label	Function
1	CO_2 Waveform
2	$EtCO_2$ value
3	Respiration Rate value

Additionally, the monitor can display CO_2 data in trend form, showing time, date, $etCO_2$, RR, alarms, events, and a CASE START marker. For more information about trend display, reference *4.15 Trends* on page 134.

If the numeric home screen is chosen, the CO_2 waveform will not appear. Instead, CO_2 data will appear in a large font, to enable easy viewing, even at a distance. For the CO_2 section of the numeric home screen, reference *Figure 7. Home Screen Display #3* on page *28*. For other home screen types, reference *2.3.5 Monitoring Display Screen Options* on page 24.

For all types of patients, the $etCO_2$ numeric displayed on the screen is the maximum value of CO_2 over the last 20 seconds, updated once a second. An $etCO_2$ alarm will occur based on the $etCO_2$ value displayed on the screen.

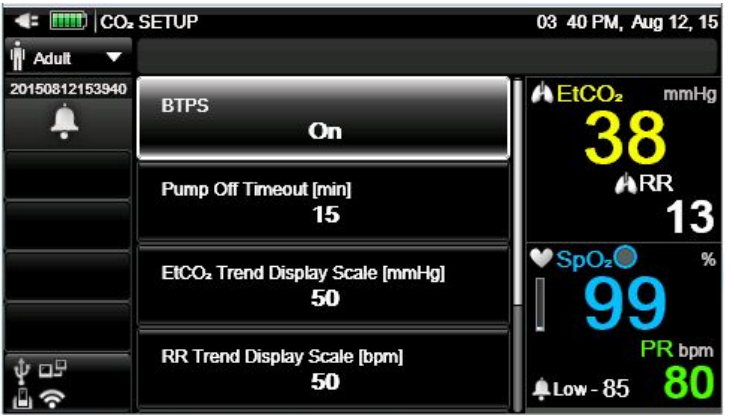
In high-altitude environments, $etCO_2$ values may be lower than values observed at sea level, as described by Dalton's law of partial pressures. When using the monitor in high-altitude environments, it is advisable to consider adjusting $etCO_2$ alarm settings accordingly.

Measuring mode corrects the CO_2 value for BTPS setting (Body Temperature, Pressure, Saturation) which assumes that alveolar gases are saturated with water vapor. BTPS should remain on for patient measurement. For other purposes, it may be turned off in the CO_2 Setup screen.

4.10.4. Adjustable CO_2 Parameters

The monitor provides the option of adjusting some parameter settings used for CO_2 measurement to suit your patients, your institution's requirements, or other needs. To change these settings on a temporary basis, until the monitor is turned off, follow the procedure below. To set changes as institutional defaults so that the settings will remain in effect even after the monitor is turned off, reference *11.1.1 Changing Institutional Defaults* on page 214.

Figure 21. CO_2 Setup Screen



CO_2 parameter settings may be changed as follows:

1. Click the **Menu** button on the front panel.

2. Navigate to and select **Setup** on the Menu Screen and **CO_2 Setup** on the Setup Menu Screen. Click **Enter**.

3. Navigate to the desired parameter and click **Enter**. Select the desired value and click **Enter** to return to the CO_2 Setup screen. Select **Home** to return to the Home screen.

4. To make changes to the CO_2 waveform, select **CO_2 Waveform Setup** on the Setup Menu Screen. Click **Enter**.

5. In either case, navigate to the desired parameter and click **Enter**. Select the desired value and click **Enter** to return to the CO_2 Setup screen. Select **Home** to return to the Home screen.

6. For permanent changes to these parameters, change the parameters in Institutional Defaults. For more information reference *11.1.1 Changing Institutional Defaults* on page 214.

Table 5. CO_2 Parameters

Parameter	Choices	Factory Default
BTPS*	On, Off	On
PumpOff Timeout (min)	5, 10, 15, 30	15
$EtCO_2$ Trend Display Scale (mmHg)	50, 100, 150	50
RR Trend Display Scale (bpm)	50, 100, 150	50
A/hr Visual Alert Level	1-99	10

*** BTPS denotes the standard correction used during measurement for body temperature, pressure, and saturation. BTPS should be set to ON during all measurement procedures. The monitor automatically turns off the BTPS correction during calibration procedures**

and turns it on again following these procedures. There is no need for the user to make any changes to the BTPS setting.

Table 6. CO_2 Waveform Setup Parameters

Parameter	Choices	Factory Default
Sweep Speed Adult/Pediatric (mm/sec)	1,2,3,6.3,12.5,25	6.3
CO_2 Waveform Scale (mmHg)	20, 60, 120, 150, Auto	60

Sweep speed is the speed at which the waveform completes one cycle of the graph to cover the entire display screen once.

4.10.5. Monitoring CO_2 during MRI Scanning

WARNING:
Do not use the FilterLine H Set Infant/Neonatal or the VitaLine H Set Infant/Neonatal during magnetic resonance imaging (MRI) scanning. Using the FilterLine H Set Infant/Neonatal during MRI scanning could cause an artefact on the MRI image.

WARNING:
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.

Caution:
Use of a CO_2 sampling line with H in its name (indicating

that it is for use in humidified environments) during MRI scanning may cause interference. The use of non-H sampling lines is advised. For a list of H sampling lines, reference *8.1 Microstream EtCO2 Consumables* on page 191.

Non-invasive etCO_2 monitoring during magnetic resonance imaging (MRI) can be accomplished with the monitor, a FilterLine XL, and an appropriate CO_2 sampling line.

The monitor may be used during MRI scanning, 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).

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

3. Attach the FilterLine XL to the patient.

Due to the extended length of the FilterLine XL, there may be an increased delay time and thus a slower response time.

To purchase the FilterLine XL, contact your local representative.

4.11. Pulse Oximetry with the monitor

4.11.1. Connecting an SpO_2 Sensor to the monitor

Before monitoring a patient with pulse oximetry, the appropriate SpO_2 sensor must be connected to the monitor and to the patient.

Connection of the SpO_2 Sensor is performed as follows:

1. Connect the SpO_2 extension cord firmly to the monitor SpO_2 sensor port on the left side panel, and then connect the appropriate Nellcor SpO_2 sensor to the extension cord.

2. Connect the Nellcor SpO_2 sensor to the patient as described in its Directions for Use, using a Nellcor SpO_2 sensor extension cable.

3. When the SpO_2 sensor is plugged into the extension cable and connected to the monitor, the monitor will immediately begin to search for a pulse. It will indicate **SpO_2 Sensor Not On Patient** until the time that the sensor is placed on the patient. This is classified as a Medium Priority Alarm, and will generate a triple beep every thirty seconds. To avoid the alarm message and beeping, you can connect the extension cable to the monitor, but wait to connect the SpO_2 sensor to the extension cable until it is time to connect the patient to the monitor.

4. To begin monitoring, place the sensor on the patient as described in the sensor's Instructions for Use.

4.11.2. Nellcor SpO_2 Sensors

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

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

WARNING:
Do not use any monitoring system, sensor, cable, or

connector that appears damaged. Remove any damaged equipment from service for inspection by a qualified service technician.

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

WARNING:
Do not spray, pour, or spill any liquid on the monitor, its accessories, connectors, switches, or openings in the chassis, since this may cause damage to the monitor.

WARNING:
Use only Covidien-approved sensors and interface cables when connecting to the sensor port. Connecting any other cable or sensor influences the accuracy of sensor data, which may lead to adverse results. Verify the compatibility of the pulse oximetry probe, cable and monitor before use to ensure accuracy and safe use.

WARNING
Use only Covidien-approved interface cables with the monitor. Use of another interface cable will adversely impact performance. Do not attach any cable intended for computer use to the sensor port.

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

WARNING:
Tissue damage can be caused by incorrect application or use of a pulse oximetry sensor. Inspect the sensor site as directed in the Instructions for Use. Do not apply the sensor too tightly or by using excessive pressure. Do not wrap the sensor, apply supplemental tape, or leave the sensor too long in one place. If the skin under the sensor becomes irritated, change the location of the sensor.

Caution:
Single-patient use sensors and adhesive sensors are intended for single-patient use only. Do not transfer a single-use sensor or an adhesive sensor from one patient to a second patient.

The sensors used with this monitor can be categorized as surface devices contacting skin for a limited duration of time. The sensors have passed the recommended biocompatibility testing and are therefore in compliance with ISO 10993–1.

4.11.3. Nellcor SpO_2 Sensor Selection

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. Use the recommended sensor's Directions for Use to guide sensor selection or contact Covidien or a local Covidien representative. Reference *Table 7. Nellcor SpO2 Sensor Models and Patient Sizes* on page 86. Sensor length information is included in the Directions for Use for each sensor.

The Nellcor™ interface cable (DOC-10, 10 ft/3m or DEC-4, 4 ft/1.2m) connects the monitoring system with the Nellcor™ sensor. Do not attach any cable to the sensor port that is intended for computer use. Use only Covidien-approved sensors and interface cables when connecting to the sensor port.

Table 7. Nellcor SpO_2 Sensor Models and Patient Sizes

Nellcor™ Sensor	SKU	Patient Size
Nellcor™ Preemie SpO_2 Sensor, non-adhesive (Single-patient use)	SC-PR*	<1.5 kg
Nellcor™ Neonatal SpO_2 Sensor, non-adhesive (Single-patient use)	SC-NEO*	1.5 to 5 kg
Nellcor™ Adult SpO_2 Sensor, non-adhesive (Single-patient use)	SC-A*	>40 kg
Nellcor™ Adult-Neonatal SpO_2 Sensor with Wraps (Reusable with adhesive)	OXI-A/N*	<3 or >40 kg
Nellcor™ Pediatric-Infant SpO_2 Sensor with Wraps (Reusable with adhesive)	OXI-P/I*	3 to 40 kg
Nellcor™ Pediatric SpO_2 Sensor, Two Piece (Sterile, single-use only)	P	10 to 50 kg
Nellcor™ Neonatal-Adult SpO_2 Sensor, Two Piece (Sterile, single-use only)	N	<3 or >40 kg
Nellcor™ Adult SpO_2 Sensor, Two Piece (Sterile, single-use only)	A	> 30 kg
Nellcor™ Neonatal-Adult SpO_2 Sensor (Sterile, single-use only)	MAXN*	<3 or >40 kg
Nellcor™ Infant SpO_2 Sensor (Sterile, single-use only)	MAXI*	3 to 20 kg
Nellcor™ Pediatric SpO_2 Sensor (Sterile, single-use only)	MAXP*	10 to 50 kg
Nellcor™ Adult SpO_2 Sensor (Sterile, single-use only)	MAXA*	>30 kg
Nellcor™ Adult XL SpO_2 Sensor (Sterile, single-use only)	MAXAL*	>30 kg

Nellcor™ Sensor	SKU	Patient Size
Nellcor™ Adult SpO_2 Nasal Sensor (Sterile, single-use only)	MAXR*	>50 kg
Nellcor™ Forehead SpO_2 Sensor (Sterile, single-use only)	MAXFAST*	≥10 kg
Nellcor™ Adult SpO_2 Sensor, Reusable (Nonsterile)	DS-100A*	>40 kg
Nellcor™ SpO_2 Sensor, Multisite Reusable (Nonsterile)	D-YS*	>1 kg
Nellcor™ SpO_2 Ear Clip, Reusable (Nonsterile)	D-YSE*	>30 kg
Nellcor™ Pediatric SpO_2 Clip, Reusable (Nonsterile)	D-YSPD*	3 to 40 kg

***suitable for use in EMS typical environments, refer to Degree of protection against matter and water ingress in 10.11 Compliance on page 207.**

4.11.4. Nellcor™ Sensor Features

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

4.11.4.1. Biocompatibility testing

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

4.11.5. Performance Considerations

This chapter contains information for assisting users to optimize the performance of pulse oximetry in the monitor.

Prior to initial installation in a clinical setting, a qualified service technician should verify the performance of the monitor per the Service Manual.

4.11.5.1. Monitoring system constraints

WARNING:
Do not utilize for measurements outside the display levels listed for the monitor while monitoring patients.

Pulse Rate — The monitoring system only displays pulse rates between 20 and 250 bpm. Detected pulse rates above 250 bpm appear as 250. Detected pulse rates below 20 appear as a zero (0).

Saturation — The monitoring system displays saturation levels between 1% and 100%.

4.11.6. Nellcor™ Sensor Performance Considerations

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

Caution:
Failure to cover the sensor site with opaque material in high

ambient light conditions may result in inaccurate measurements.

4.11.6.1. Inaccurate sensor measurement conditions

A variety of conditions can cause inaccurate sensor measurements.

- **Incorrect application of the recommended sensor**
- **Placement of the recommended sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line**
- **Ambient light**
- **Failure to cover the sensor site with opaque material when operating under high ambient light conditions**
- **Excessive patient activity**
- **Dark skin pigment**
- **Intravascular dyes or externally applied coloring, such as nail polish or pigmented cream**
- **Signal Loss**
- **Loss-of-pulse signal can occur for several reasons.**
    - **Recommended sensor applied too tightly**
    - **Inflation of a blood pressure cuff on the same extremity as the attached sensor**
    - **Arterial occlusion proximal to the recommended sensor**
    - **Poor peripheral perfusion**

4.11.6.2. Recommended usage

Select an appropriate recommended 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.

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.

4.11.6.3. Patient conditions

Application issues and certain patient conditions can affect the measurements of the monitoring system and cause the loss of the pulse signal.

Anemia — Anemia causes decreased arterial oxygen content. Although SpO_2 readings may appear normal, an anemic patient may

be hypoxic. Correcting anemia can improve arterial oxygen content. The monitoring system may fail to provide an SpO_2 reading if hemoglobin levels fall below 5 gm/dl.

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

The following additional possible patient conditions may also influence measurements:

- **Poor peripheral perfusion**
- **Excessive patient activity**
- **Venous pulsations**
- **Dark skin pigment**
- **Intravascular dyes, such as indocyanine green or methylene blue**
- **Externally applied coloring agents (nail polish, dye, pigmented cream)**
- **Defibrillation**

4.11.6.4. Reducing EMI (Electromagnetic Interference) during use

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

WARNING:
The monitoring system is intended for use by healthcare professionals only. It may cause radio interference or may disrupt the operation of nearby equipment. Mitigation for such disruption may require re-orienting or relocating the monitoring system or shielding the location.

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

Because of the proliferation of radio frequency transmitting equipment and other sources of electrical noise in health care environments (for example, electrosurgical units, cellular phones, mobile two-way radios, electrical appliances, and high-definition television), it is possible that high levels of such interference due to close proximity or strength of a source might result in disruption of monitoring system performance. Reference *Table 9. Electromagnetic Immunity Compliance and Guidance, Not Life-Supporting Equipment* on page 99. The monitoring system is designed for use in environments in which electro-magnetic interference might obscure the client's pulse. During such interference, measurements may seem inappropriate or the monitoring system may not seem to operate correctly. EMI disruption can cause erratic readings, cessation of operation, or other incorrect functioning. If this occurs, survey the site of use to determine the source of this disruption, and take the listed actions to eliminate the source.

Turn equipment in the vicinity off and on to isolate the interfering equipment. Reorient or relocate the interfering equipment.

Increase the separation between the interfering equipment and the monitoring system. The monitoring system generates, uses, and can radiate radio frequency energy and, if not installed and used in

accordance with these instructions, may itself cause harmful interference with other susceptible devices in the vicinity.

4.11.7. Nellcor™ Sensor Technology

Use Nellcor™ sensors, which are specifically designed for use with the monitor. Identify Nellcor™ sensors by the Nellcor™ logo on the plug. All Nellcor™ sensors contain a memory chip carrying information about the sensor which the monitor needs for correct operation, including the sensor's calibration data, model type, troubleshooting codes, and error detection data.

Any monitoring system containing OxiMax technology uses calibration data contained in the sensor in calculating the patient's SpO_2. With sensor calibration, the accuracy of many sensors is improved, since the calibration coefficients can be tailored to each sensor.

Contact Covidien or a local Service Center for a Nellcor™ Oxygen Saturation Accuracy Specification Grid listing all of the Nellcor™ sensors used with the monitoring system. A soft copy is available at www.covidien.com.

4.11.7.1. SatSeconds™ alarm management parameter

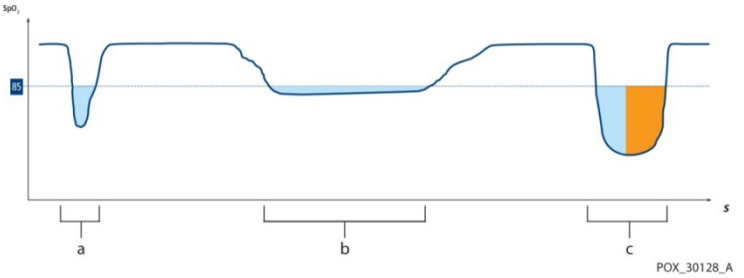
The monitoring system monitors the percentage of hemoglobin binding sites saturated with oxygen in the blood. With traditional alarm management, upper and lower alarm limits are set to alarm at specific SpO_2 levels. When the SpO_2 level fluctuates near an alarm limit, the alarm sounds each time it violates the alarm threshold. SatSeconds monitors both degree and duration of desaturation as an index of desaturation severity. Thus, the SatSeconds parameter helps distinguish clinically significant events from minor and brief desaturations that may result in nuisance alarms.

4.11.7.1.1. SpO_2 events sequence

Consider a series of events leading to a violation of the SatSeconds alarm limit. An adult patient experiences several minor desaturations, then a clinically significant desaturation.

See the sketch below to view a chronological sequence of SpO_2 events and how they will appear on the monitor.

Figure 22. Series of SpO_2 Events

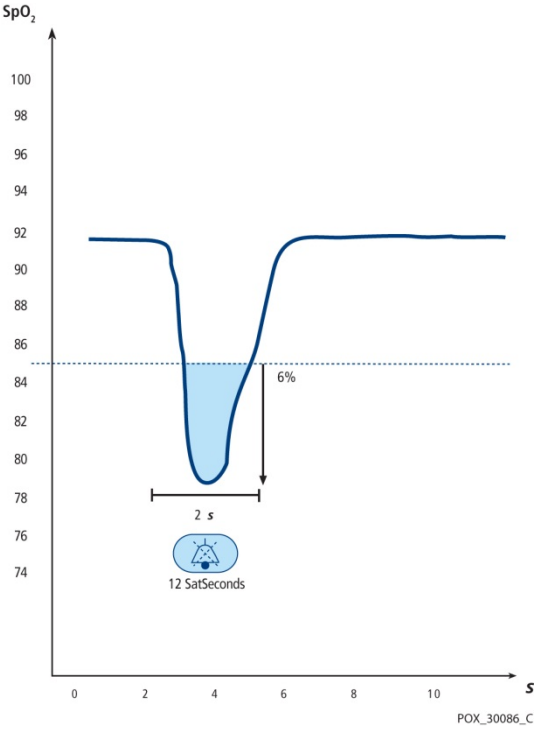


4.11.7.1.2. First SpO_2 event

The SatSeconds value is calculated by multiplying the amount of desaturation below the threshold value by the time (in seconds) of the desaturation. Consider the first event. Suppose the SPO_2 alarm limit is set to 85 and the SatSeconds alarm limit is set to 25. The patient's SpO_2 drops to 79% and the duration of the event is two (2) seconds before saturation again exceeds the lower alarm threshold of 85%. In this scenario, the amount below threshold is 6 (85-79) and the number of SatSeconds is therefore 12 (6x2).

Because the SatSeconds alarm limit is set to 25 and the actual number of Sat-Seconds equals 12, there is no audible alarm.

Figure 23. First SpO_2 Event: No SatSeconds Alarm

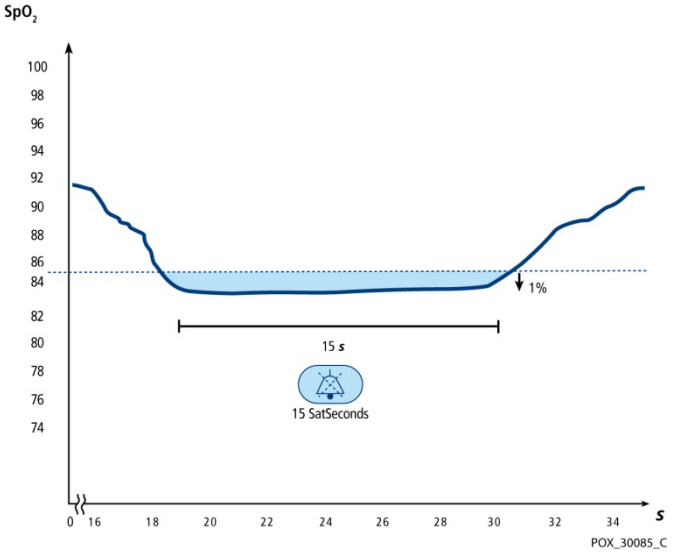


4.11.7.1.3. Second SpO_2 event

Consider the second event. Suppose the SatSeconds alarm limit is still set to 25. The patient's SpO_2 drops to 84% and the duration of the event is 15 seconds before saturation again exceeds the lower alarm threshold of 85%.

Because the SatSeconds alarm limit is set to 25 and the actual number of Sat-Seconds equals 15 (1x15), there is no audible alarm.

Figure 24. Second SpO_2 Event: No SatSeconds Alarm

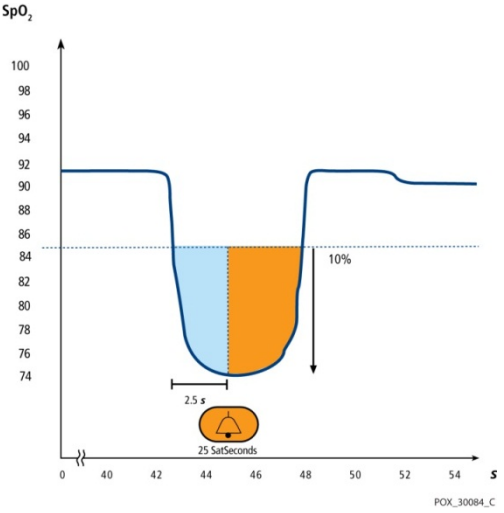


4.11.7.1.4. Third SpO_2 event

Consider the third event. Suppose the SatSeconds alarm limit is still set to 25. During this event, the patient's SpO_2 drops to 75%, which is 10% below the lower alarm threshold of 85%. Since the patient's saturation does not return to a value over the lower alarm threshold within 2.5 seconds, an alarm sounds.

At this level of saturation, the event cannot exceed 2.5 seconds without invoking a SatSeconds alarm.

Figure 25. Third SpO_2 Event: Triggers SatSeconds Alarm



4.11.7.1.5. The SatSeconds Safety Net

The SatSeconds "Safety Net" is for patients with saturation levels frequently below the limit, but not staying below the limit long enough for the SatSeconds time setting to be reached. When three or more limit violations occur within 60 seconds, an alarm sounds even if the SatSeconds time setting has not been reached.

By default, the SatSeconds option is 100 for adult and pediatric patients and OFF for infant/neonatal patients. The SatSeconds option may be changed in Institutional Defaults; reference *11.1.5 Monitor Alarms Settings* on page 217.

4.11.7.1.6. SpO_2 Alarms and SatSeconds

The monitor uses Nellcor's SatSeconds technology to help reduce the number and frequency of false SpO_2 alarms.

A SatSeconds indicator () in the SpO_2 section of the screen indicates the SatSeconds status. When SatSeconds is Off, only the

indicator appears. If SatSeconds is on, its alarm value will appear under the icon. With SatSeconds on, the SatSeconds circle icon fills in the clockwise direction as the alarm management system detects SpO_2 readings outside of the limit setting. The circle icon empties in counterclockwise direction when SpO_2 readings are within limits. When the icon fills completely, the SatSec alarm sounds. For more information about the SatSeconds technology, reference *4.11.7.1 SatSeconds™ alarm management parameter* on page 93. If SatSeconds is selected and the SatSeconds value triggers an SpO_2 alarm, any SpO_2 delay that has been set will be superseded and the alarm will occur despite the SpO_2 delay.

4.11.8. Nellcor Oximax Pulse Oximetry Essential Performance

This monitoring system has the capacity to detect physiological alarm conditions using SpO_2 accuracy, pulse rate accuracy and alarm limit conditions.

Table 8. Pulse Oximetry Performance

Type	Values
Measurement Ranges	
SpO_2 saturation range	1% to 100%
Pulse rate range	20 to 250 beats per minute (bpm)
Perfusion range	0.03% to 20%
Measurement Accuracy	
Pulse rate accuracy	20 to 250 beats per minute (bpm) ±3 digits (including under low perfusion); with motion, 48 to 127 bpm ±5 digits

SpO_2 saturation accuracy	**70% to 100% ±2 to ±3 digits**
Operating Range and Dissipation	
Red Light Wavelength	**Approximately 660 nm**
Infrared Light Wavelength	**Approximately 900 nm**
Optical Output Power	**Less than 15 mW**
Power Dissipation	**52.5 mW**

Table 9. Electromagnetic Immunity Compliance and Guidance, Not Life-Supporting Equipment

Immunity Test	**IEC/EN 60601-1-2 Test Level**	**Compliance Level**	**Electromagnetic Environment Guidance**
	Frequency of Transmitter		**Equation for Separation Distance (d)**
Conducted RF IEC/EN 61000-4-6	**3 Vrms 150 kHz 80 MHz**	**3 Vrms 150 kHz 80 MHz**	**$d = 1.2\sqrt{P}$ 150 kHz to 80 MHz**
Radiated RF IEC/EN 61000-4-3	**3 V/m 80 MHz 800 MHz**	**3 V/m 80 MHz 800 MHz**	**$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz**

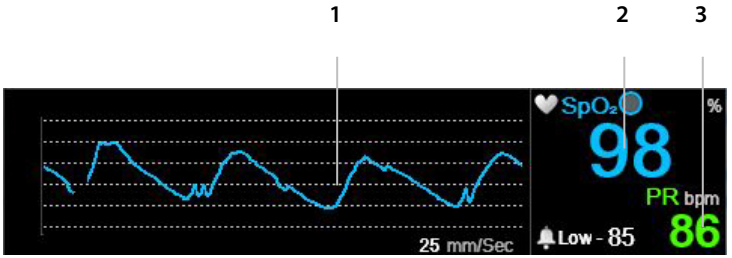
	3 V/m 800 MHz 2.5 GHz	3 V/m 800 MHz 2.5 GHz	$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz

4.11.9. SpO_2 Data Displayed by the Monitor

The monitor Home screen displays real time SpO_2 data. The displayed data includes:

- **SpO_2 numeric value**
- **Pulse Rate**
- **SpO_2 waveform or bar Indicator indicating arterial pulse beat. This is also referred to as the plethysmograph.**

Figure 26. SpO_2 Data on Waveform Screen



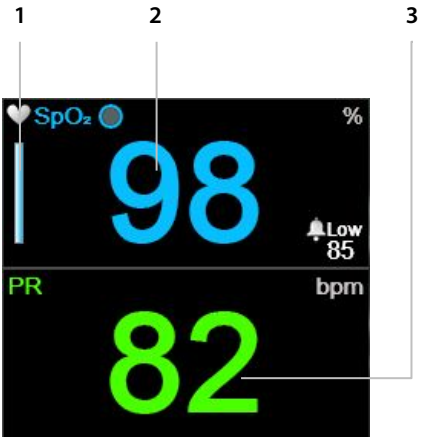
Label	Function	Description
1	SpO_2 waveform	SpO_2 waveform, which indicates the patient's arterial pulse beat

2	SpO_2 value	Current patient SpO_2 value
3	PR value	Current patient pulse rate (PR) value

On home screens with SpO_2 waveforms, the patient's arterial pulse beat is indicated by the plethysmograph waveform on the SpO_2 section of the screen. The plethsysmographic waveform is non-normalized, using real-time sensor signal to reflect relative pulsatile strength.

When home screens with bar Indicator are chosen, the patient's arterial pulse beat is indicated by the rhythm of the blue vertical bar on the SpO_2 section of the screen. The peak of this bar will coincide with the peak of the patient's arterial pulsation. Reference *Figure 27. SpO2 Data in Numeric Screen*, below.

Figure 27. SpO_2 Data in Numeric Screen



Label	Function	Description

1	SpO_2 bar indicator	Blue vertical bar, the rhythm of which indicates the patient's arterial pulse beat
2	SpO_2 value	Current patient SpO_2 value
3	PR value	Current patient pulse rate (PR) value

Additionally, the monitor can display SpO_2 data in trend form, showing time, date, SpO_2, pulse rate (PR), alarms, events.

When the SpO_2 high or low alarm limits are exceeded, the affected reading will flash to alert the attending health care professional to the specific reading that is affected.

4.11.10. Adjustable SpO_2 Parameters

The monitor provides the option of adjusting some parameter settings used for SpO_2 measurement to suit your patients, your institution's requirements, or other needs. To change these settings on a temporary basis, until the monitor is turned off, follow the procedure below. To set changes as institutional defaults so that the settings will remain in effect even after the monitor is turned off, reference *11.1.1 Changing Institutional Defaults* on page 214.

SpO_2 Parameter Settings may be changed as follows:

1. Click the **Menu** button on the front panel.

2. Navigate to and select **Setup** on the **Menu** Screen and **SpO_2 Setup** on the **Setup Menu** screen. Click **Enter**. The **SpO_2 Setup** screen will open.

3. Navigate to the desired parameter and click **Enter**. Select the desired value and click **Enter** to return to the **SpO_2 Setup** screen. Select **Home** to return to the Home screen.

4. To make changes to the SpO2 waveform (Sweep Speed), navigate to and select **SpO_2 Waveform Setup** on the Setup Menu Screen. Click **Enter**. The SpO_2 Setup screen will open.

5. Navigate to the Sweep Speed and click **Enter**. Select the desired value and click **Enter** to return to the SpO_2 Setup screen. Select **Home** to return to the Home screen.

6. For permanent changes to these parameters, change the parameters in Institutional Defaults. For more information reference *11.1.1 Changing Institutional Defaults* on page 214.

7. SatSeconds may be turned on using Institutional defaults; reference *11.1.1 Changing Institutional Defaults* on page 214.

Figure 28. SpO_2 Setup Screen

Table 10. Adjustable SpO_2 Parameters

Parameter	Choices	Factory Default

Pulse Tone	**On/Off**	**On**
SpO_2 Scale for Trend Display (%)	**0-100, 50-100**	**50-100**
PR Scale for Trend Display (bpm)	**150, 300**	**150**
ODI Visual Alert Level	**1-99**	**10**
Sweep Speed Adult/Pediatric	**3, 6.3, 12.5, 25**	**25**
Sweep Speed Infant/Neonatal	**3, 6.3, 12.5, 25**	**25**

Sweep speed is the speed at which the waveform completes one cycle of the graph to cover the entire display screen once.

4.11.11. SpO_2 Alarm Limit Message

When the SpO_2 alarm limit is set below 85%, a message reading SpO_2 Low Alarm Limit: XX will appear in the header area, indicating the level of the SpO_2 LOW alarm limit.

4.12. Integrated Pulmonary Index™

4.12.1. IPI: Introduction

The Integrated Pulmonary Index™ (henceforth referred to as IPI) is a numerical value which integrates four major parameters measured by the monitor in order to provide a simple indication of the patient's overall ventilatory status. The integrated parameters are $etCO_2$, RR, SpO_2, and PR. Only these four parameters are used to calculate IPI; other parameters are not taken into account.

IPI is calculated using the current values of these four parameters and their interactions, based on known clinical data. IPI can thus provide an early indication of a change in ventilatory status which may not be shown by the current value of any of these four parameters individually. The IPI is designed to provide additional information regarding patient status, possibly before etCO_2, RR, SpO_2, or PR values reach levels of clinical concern.

The IPI is an adjunct to, and is not intended to replace, vital sign monitoring.

A technical note containing details regarding the IPI algorithm is available from Covidien.

Since the index uses data from the monitoring of both CO_2 and SpO_2, it will only be available when both parameters are available.

The range of the index is 1-10; index values should be understood as seen in the table below.

Table 11. IPI Values

Index Range	Patient Status
10	Normal
8-9	Within normal range
7	Close to normal range; requires attention
5-6	Requires attention and may require intervention
3-4	Requires intervention
1-2	Requires immediate intervention

The interpretation of the patient's IPI score may change in different clinical environments. For example, patients with specific respiratory

difficulties (in contrast to normally healthy patients who are being monitored during sedation or pain management) may require a lower IPI Low Alarm threshold to reflect their impaired respiratory capacity.

IPI is available for all three groups of pediatric patients (1-3 years, 3-6 years, and 6-12 years), and for adult patients. It is not available for Neonatal/Infant patients (patients up to the age of one year), and thus will not appear on screens for Neonatal/Infant patients.

4.12.2. IPI Warnings

WARNING:
Ensure that the patient type is correctly selected before beginning monitoring of a patient. Choosing an incorrect patient type could produce incorrect patient IPI data.

WARNING:
When an IPI Low Alarm is triggered for a patient, medical staff should review the patient's status to determine if a change in medical care is required.

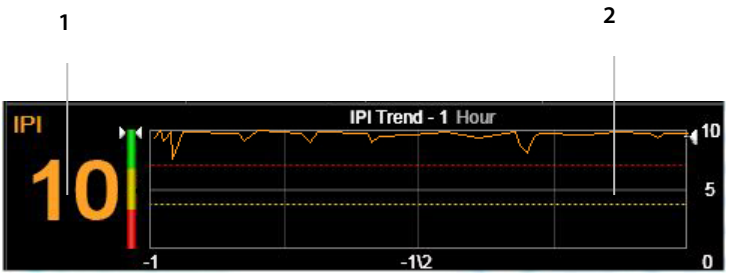
4.12.3. IPI Display

IPI appears on Home screen #3 and Home screen #9 both as a numeric value and in a trend graph. In some of the other home screens it appears only as a numeric value.

The IPI option may be disabled from the Institutional Defaults screen; see below for more information. In the Neonatal measurement mode, the IPI option is automatically disabled.

For, the IPI trend graph (seen on the monitor home screen), reference *Figure 29. IPI Trend Graph*, below.

Figure 29. IPI Trend Graph



Label	Function
1	IPI value
2	IPI trend waveform

4.12.4. IPI Options

The IPI zoom level may be changed as follows:

1. Click the **Menu** button on the front panel.
2. Navigate to and select **Setup** on the Menu Screen and **Trend Waveform Setup** on the Setup Menu Screen. Click **Enter**.
3. Navigate to and select **IPI Trend Zoom (Hour)**. Click **Enter**. Navigate to the desired Zoom level.
4. Click **Enter** and then select **Home** to return to the home screen.

Table 12. Adjustable IPI Options

Parameter	Choices	Factory Default
IPI Trend Zoom (Hour)	1 hour, 2 hour, 4 hour	1 hour

Use the Institutional Defaults option to Enable/Disable the IPI Alert, or to change IPI Display options on a more permanent basis; reference *11.1 Institutional Defaults* on page 214.

4.13. Apneas per Hour (A/hr) and the Oxygen Desaturation Index (ODI)

4.13.1. A/hr and ODI: Introduction

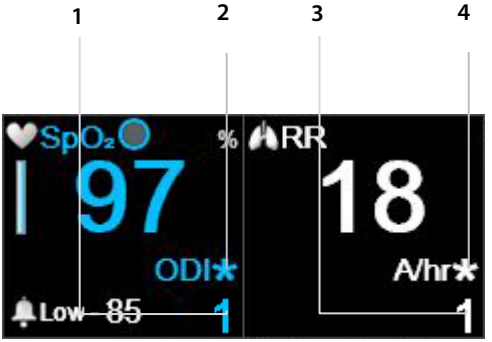
The Apneas per Hour (A/hr) (also known as ASA, Apnea Saturation Alert) and Oxygen Desaturation Index (ODI) algorithm is part of the Smart Capnography™ family of innovative algorithms. Smart Capnography™ simplifies the use of CO_2 monitoring on Microstream™ enabled products, to improve patient safety and clinical workflow.

A/hr and ODI provide an easy way to help with the identification and quantification of apnea and oxygen desaturation events during a patient's hospital stay.

A/hr and ODI report apnea and oxygen desaturation events and calculates the associated Apnea per Hour (A/hr) and Oxygen Desaturation Index (ODI). By using A/hr and ODI, clinicians are able to recognize ventilation and oxygenation abnormalities while patients are being monitored during their hospital stay with the monitor. A/hr and ODI are for adult patients only (age 22 and older).

A/hr and ODI are displayed in real time on one of the home screens (*Figure 13. Home Screen Display #9* on page 36) and on easy-to-read Vent and O_2 Desat Report screens. In the home screen display, an asterisk next to the ODI or A/hr text indicates that the patient has reached the A/hr visual alert level or the ODI visual alert level. The level for both of these indicators can be set in the Institutional Defaults>Parameters screen; see *11.1 Institutional Defaults* on page 214.

Figure 30. ODI and A/hr on the Home Screen



Label	Function
1	ODI value
2	ODI visual alert
3	A/hr value
4	A/hr visual alert

4.13.2. Apneas per Hour

An apnea is a period of time during which breathing stops or is greatly reduced. The Apnea per Hour (A/hr) calculated by the monitor provides a count of the number of pauses of at least 10 seconds in breathing the patient experienced over the past hour.

On the Vent. and Desat Reports A and B, A/hr is the average Apneas per Hour over the selected time period of 2, 4, 8 and 12 hours. On that screen, the number of apnea events of ≥10 seconds; 10-19 seconds; 20-30 seconds; and >30 seconds over the selected time period are also shown.

This A/hr value is used to help indicate to the caregiver the regularity of the patient's breathing.

In the monitor, apnea per hour is a count of the number of times in an hour that breathing ceased for ten seconds or more. Since this is a per-hour count, dashed lines will appear on the screen until one hour has commenced since the beginning of monitoring.

The A/hr visual alert indicates to the caregiver that the A/hr count in any one hour period during the last 12 hours exceeded a set number. The asterisk will appear next to the A/hr only when an A/hr Visual Alert is triggered, and it is updated once every 10 minutes. The visual alert on the screen indicates to the caregiver that the Vent. and O2 Desat Report B (reference *5.2 Reports* on page 148) should be viewed to learn more about the patient's status.

A/hr is currently available for adult patients only and is intended for patients age 22 and older. It is not available for infants (age 0-1) or for patients under age 22.

4.13.3. Oxygen Desaturation Index (ODI)

The Oxygen Desaturation Index (ODI) indicates the "dips" in SpO_2 – that is, the number of times that the SpO_2 value dropped 4% or more from baseline and returned to baseline in 240 seconds or less. (This refers to percent of oxygen saturation, not percent of the patient's current SpO_2 rate). The baseline is created when a consistent and stable (in the range of ± 1 SpO2 point [%]) SpO_2 value is detected over a 20-second period. This baseline, updated once a second, will be the rounded maximum SpO_2 over these 20 seconds. If a valid baseline cannot be established based upon the definition above, then the previous baseline is kept.

A lower ODI (that is, fewer such instances) indicates more stability of the patient's oxygen saturation. Since this index is a per-hour count, dashed lines will appear on the screen until one hour has commenced since the beginning of monitoring.

On the Vent. and Desat Report B, ODI is average per hour "dips" in SpO_2 over the selected time period of 2, 4, 8 and 12 hours.

The ODI visual alert indicates to the caregiver that the ODI count in any one hour period during the last 12 hours exceeded a set number. The asterisk will appear next to the ODI only when an ODI Visual Alert is triggered, and it is updated once every 10 minutes. The visual alert on the screen indicates to the caregiver that the Vent. and O2 Desat Report B (reference *5.2 Reports* on page 148) should be viewed to learn more about the patient's status.

ODI is currently available for adult patients only and is intended for patients age 22 and older. It is not available for infants (age 0-1) or for patients under age 22.

4.13.4. Monitoring with A/hr and ODI

When monitoring patients with A/hr (also known as ASA, Apnea Saturation Alert) and ODI, take the following issues into consideration:

Caution:
Please note that A/hr and ODI do not report hypopnea events.

Caution:
Apnea per Hour (A/hr) and Oxygen Desaturation Index (ODI) do not represent and should not be interpreted as an apnea hypopnea index (AHI) as reported by formal polysomnography studies.

Caution:
Apnea per Hour (A/hr) and Oxygen Desaturation Index (ODI) do not represent and should not be used to diagnose sleep disordered breathing.

Caution:
Alarms and a noisy environment may affect A/hr and ODI values. See the Note regarding recommendations on changing monitor settings for a sleeping patient below.

Caution:
A/hr and ODI are reported by the monitor throughout the monitoring period; however, the monitor cannot discern if the patient is actually sleeping.

Caution:
If a patient removes a sensor, the monitor may indicate apneas when no such apneas took place.

Caution:
The administration of opioid analgesia and sedatives may cause respiratory depression, which will result in transient apnea and O_2 desaturation events that will be reflected in A/hr and ODI values.

Caution:
Please read all user information to ensure complete understanding of A/hr.

Please note that the patient type is used to calculate the A/hr and ODI. For this reason, it is important to select the patient type correctly. For the same reason, changing the patient type (from adult to pediatric, for example) will clear the A/hr and ODI data stored for the current patient. A/hr and ODI headings will not appear for infant/neonatal or pediatric patients.

When using the monitor for A/hr and ODI with a sleeping patient, it is recommended that the monitor be attached to a central monitoring station where alarms will be heard. Once this is done, the alarm sound on the monitor at the patient's bedside can be disabled, so as not to disturb the patient's sleep. The audible alarms are silenced through

System>Service>input Service password (reference *13 Appendix B: Monitor Service* Password on page 247)>**Inst Defaults>Monitor**. In the list of options on this screen, change the **Alarm Volume** to **Audio Off**. This should only be done if the monitor is under constant surveillance via connection to a central station (or another means of surveillance), so that patient alarms are noted by caregivers while the alarm sound is turned off on the bedside monitor.

4.14. Alarms and Messages

4.14.1. Alarms Introduction

The monitor triggers alarms related to patient condition as well as equipment errors. Alarms alert the health care provider that the patient's condition is beyond predefined limits, or indicate a malfunction or operating condition of the monitor hardware.

The monitor contains three levels of alarms and advisories, each defined by a set of audible and/or visual indications. Each alarm has a default alarm priority level, but can be set to another level at the discretion of the institution using Institutional Defaults. The levels of alarms and advisories are as follows:

- High Priority Alarms
- Medium Priority Alarms
- Advisories

The following table describes how the alarms are indicated.

Table 13. Alarm Indications

Alarm Type	Indicators			
	Audible	Numerics	Messages	Indicator Light

Alarm Type	Indicators			
	Audible	Numerics	Messages	Indicator Light
High Priority (Patient) Alarms	High priority beep pattern repeated every 5 seconds	Alternating red background and red frame for numeric value	Appear in message area; certain messages appear also in waveform area	Flashing red indicator
Medium Priority Alarms	Triple beep repeated every 10 seconds	Alternating yellow background and yellow frame for numeric value	Appear in message area; certain messages appear also in waveform area	Flashing yellow indicator
Advisories	No audible alarm	NA	Appear in message area; certain messages appear also in waveform area	No indicator light

Some messages are displayed in the waveform area as well as in the message area; these messages are listed in *Table 16. Non-message Area Messages* on page 131.

4.14.2. Alarm Display

In order to view the visual alarm indicators, the intended position of the operator is in front of the monitor display screen. The intended

position of the operator in order to hear audible signals is any position near the monitor (in a 360° range).

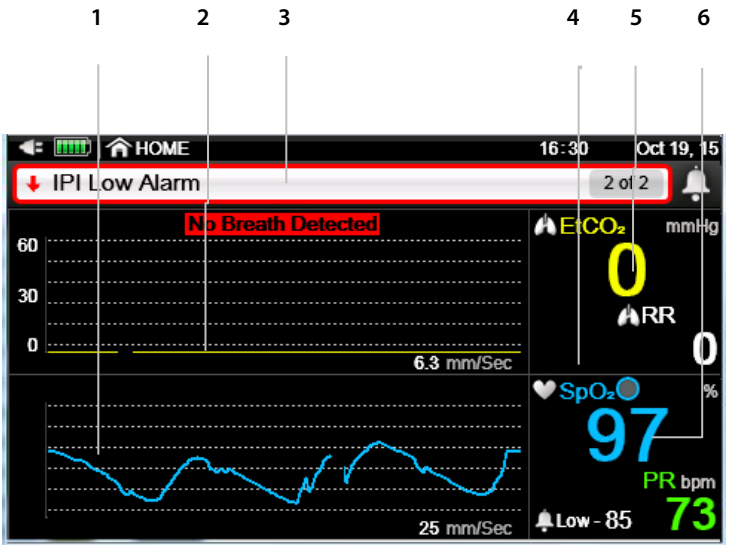
Alarms are indicated, when they occur, on the relevant section of the home screen in the following ways:

- **Indicated in text format in message area (with a directional arrow indicating whether the parameters has crossed a high or low alarm limit and the alarm priority, with red for high priority alarms and yellow for medium priority alarms). Additionally, the dark grey box at the right side of the alarm message area will indicate, for example, 1 of 3, indicating that the alarm displayed is the first of the three currently active alarms. This is useful if there is more than one active alarm at one time.**

- **Indicated in numeric area, with a directional arrow indicating high or low alarm and the alarm priority, with red for high priority alarms and yellow for medium priority alarms, and a red alternating background/frame indicating a high priority alarm or a yellow alternating background/frame indicating a medium priority alarm.**

An example of a screen with an alarm appears below.

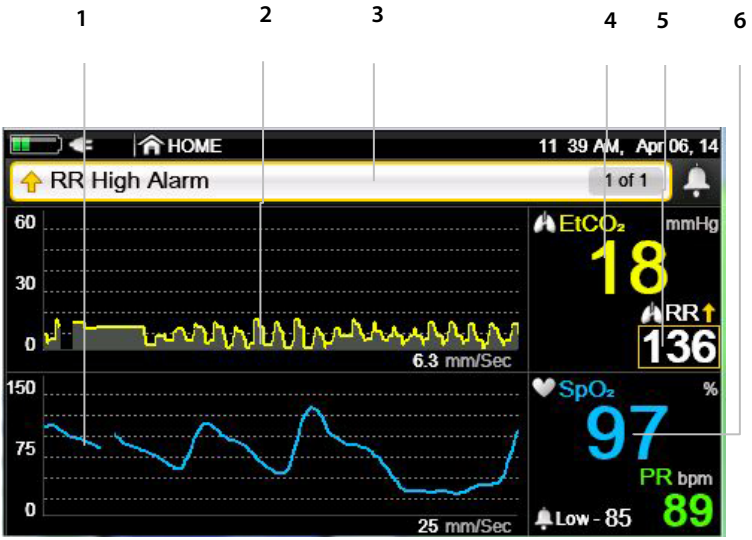
Figure 31. High Priority Alarm Example (No Breath)



Label	Function	Description
1	SpO_2 waveform	Current patient SpO_2 waveform
2	CO_2 waveform	Current patient CO_2 waveform
3	Alarm indicated in message area	Alarm indicated in text format in message area, with red frame indicating a high priority alarm (other high priority alarms will also show a red directional arrow in the message area)
4	Numeric area	For high priority alarms other than No Breath, the alarm is indicated in numeric area, with red arrow and red background for patient value indicating a high priority alarm
5	CO_2 numeric data	Current patient CO_2 numeric data

6	SpO_2 numeric data	Current patient SpO_2 numeric data

Figure 32. Medium Priority Alarm Example



Label	Function	Description
1	SpO_2 waveform	Current patient SpO_2 waveform
2	CO_2 waveform	Current patient CO_2 waveform
3	Alarm indicated in message area	Alarm indicated in text format in message area, with yellow frame and yellow arrow indicating a medium priority alarm
4	CO_2 numeric data	Current patient CO_2 numeric data

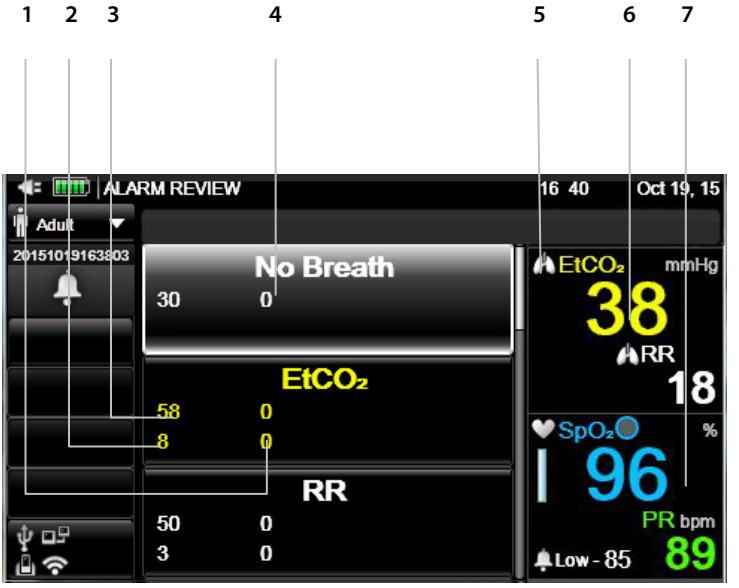
5	Alarm indicated in numeric area	Alarm indicated in numeric area, with yellow arrow and yellow frame for patient value indicating a medium priority alarm
6	SpO_2 numeric data	Current patient SpO_2 numeric data

4.14.3. Alarm Review Screen

The monitor also provides the opportunity to view an Alarm Review screen, so the user can see at a glance the number of alarms the patient has incurred over the previous hour. The Alarm Review screen lists patient alarms (except for SatSeconds; reference list in *Table 14. High/Medium Priority Alarms* on page 122) and indicates both the current upper and lower limits for each alarm and the number of each alarm which has occurred over the last hour. The screen only shows three alarms at a time; scroll down using the scroll bar at right to view additional alarms. An example of the alarm review screen appears below.

The Alarm Review screen can be viewed whether or not you have opened a patient case.

Figure 33. Alarm Review Screen



Label	Description
1	Number of $EtCO_2$ Low alarms in the previous hour indicated here
2	Current lower alarm limit for $EtCO_2$
3	Current upper alarm limit for $EtCO_2$
4	Number of No Breath alarms in the previous hour indicated here
5	Scroll here to view data on additional alarms
6	Real-time $EtCO_2$ patient data
7	Real-time SpO_2 patient data

The Alarm Review screen may be opened as follows:

1. Click the **Menu** button on the front panel.

2. Navigate to and select **Report** on the Menu Screen and **View Report>Alarm Review** on the Setup Menu Screen. Select the **Alarm Review** screen. Click **Enter**.

3. The **Alarm Review** screen will appear. If the alarm that you want to view is not visible, scroll down using the scroll bar at right of the main window to view the rest of the alarms.

4.14.4. Alarm Silence

Alarms may be silenced in one of two ways:

- Temporary Alarm Silence
- Permanent Alarm Silence

Alarms may be silenced permanently only through Institutional Defaults.

In both cases, alarm silence affects only the audible alarms. Visual alarms are not affected.

Temporary alarm silence may be set for the device, as follows:

1. Press the **Alarm Silence** button at the front of the monitor.

2. This will silence the alarms for a 2-minute period only. The alarm indicator will show a broken red X () through the indicator, indicating that the alarm is temporarily silenced.

Permanent alarm silence may be set for the device, as follows:

1. Click the **Menu** button on the front panel.

2. Navigate to and select **Setup** on the **Menu** screen and navigate to and select **Service** on the **Setup Menu** screen.

3. Input Service password and click **Done**.

4. Navigate to and select **Institutional Defaults>Monitor>Factory Defaults**.

5. Navigate to and select **Alarm Volume** and select **Audio Off**.

6. Select **Home** to return to the Home screen. Restart the monitor.

7. The alarm indicator on the Home screen will now show an unbroken red X through it (), indicating that the monitor is currently in a state of permanent alarm silence.

8. To turn off Permanent Alarm Silence, repeat the process, setting the **Alarm Volume** to **Maximum** or **Last Setting**. Select **Home**; at this point the Permanent Alarm Silence status will no longer be in force, with no need to restart the monitor.

When the monitor is set to permanent alarm silence in this manner, the Alarm Silence button will serve as a toggle key for alarm silence; pressing it will turn the audible alarms on or off.

WARNING:
Do not silence the audible alarms until you verify that the patient is being monitored by other means, such as an audible alarm at a central station.

4.14.5. Reminder Signal

When alarms are silenced permanently through Institutional Defaults, a Reminder Signal will provide a single beep every two minutes, to meet regulatory requirements.

The Reminder Signal may be disabled in Institutional Defaults, by clicking **Menu Button**>**Setup**>**Service**. Input Service password and click **Done** and then select **Institutional Defaults**>**Monitor**>Set Reminder Signal to **Disabled**.

4.14.6. Message Priorities

When more than one alarm message appears in the message area, they will appear sequentially, with the following priority: First High Priority messages will be shown, then Medium Priority messages, and then Advisories. A grey box indicating the number of active messages and their order appears on the right side of the message area, so that each message will be accompanied by the indication 1 of 3, or 2 of 4, etc.

4.14.7. Alarm Delay

An alarm delay may be set for the all patient alarms except for No Breath.

If an alarm delay is set, the alarm will not sound or display until the set delay period has passed. If the condition no longer exists by the time the delay period has passed, the alarm will not sound or display at all. Likewise, although the trend display will display the correct data, it will not show an alarm until the delay period has passed.

For all of these alarms, the delay period may be 0, 10, 15, 20, or 30 seconds. By default, no delay periods are set for any alarms.

To set alarm delay, reference *11.1.5.4 Alarm Delay settings* on page 222.

4.14.8. Types of Alarms

4.14.8.1. High/medium priority alarms

Table 14. High/Medium Priority Alarms

Message	Description	Corrective Action	Default Priority	Priority Options
Patient Alarms				

Message	Description	Corrective Action	Default Priority	Priority Options
No Breath Detected xxx Seconds	No valid breath has been detected for xxx seconds	Patient requires immediate medical attention.	High	High
$EtCO_2$ High Alarm	The $etCO_2$ is above the upper alarm limit	Patient requires immediate medical attention.	High	Medium, High
$EtCO_2$ Low Alarm	The $etCO_2$ is below the lower alarm limit	Patient requires immediate medical attention.	High	Medium, High
RR High Alarm	The RR is above the upper alarm limit	Patient requires immediate medical attention.	High	Medium, High
RR Low Alarm	The RR is below the lower alarm limit	Patient requires immediate medical attention.	High	Medium, High
SpO_2 High Alarm	The SpO_2 is above the upper alarm limit	Patient requires immediate medical attention.	High	Medium, High
SpO_2 Low Alarm	The SpO_2 is below the lower alarm limit	Patient requires immediate medical attention.	High	Medium, High

Message	Description	Corrective Action	Default Priority	Priority Options
Pulse Rate High Alarm	The pulse rate is above the upper alarm limit	Patient requires immediate medical attention.	High	Medium, High
Pulse Rate Low Alarm	The pulse rate is below the lower alarm limit	Patient requires immediate medical attention.	High	Medium, High
IPI Low Alarm*	The IPI is below the lower alarm limit.	Patient requires immediate medical attention.	High	Medium, High
SatSec	The set SatSeconds limit has been exceeded	Check patient status	Medium	Medium
Technical (Equipment) Alarms				
CO_2 Error	Failure has occurred which prohibits the operation of the CO_2 function.	Contact Covidien authorized personnel.	Medium	Medium, High
SpO_2 Error	Failure has occurred which prohibits the operation of the SpO_2 function.	Contact Covidien authorized personnel.	Medium	Medium, High

Message	Description	Corrective Action	Default Priority	Priority Options
Pulse Not Found	No detectable pulse.	Patient requires immediate medical attention. Reposition sensor on patient.	Medium	Medium, High
FilterLine Blockage	FilterLine is kinked or clogged.	Disconnect and reconnect the sampling line (FilterLine). Check the airway adapter and if necessary, replace the sampling line.	Medium	Medium, High
Battery Low	Battery charge level is low and monitor will shut down soon.	Connect monitor to AC power.	Medium	Medium, High
SpO_2 Sensor Not On Patient	Sensor is off patient.	Place sensor properly on patient.	Medium	Medium, High

Message	Description	Corrective Action	Default Priority	Priority Options
Replace SpO_2 Cable	SpO_2 cable should be replaced	Replace SpO_2 disposable sensor. If message continues to appear, replace reusable sensor or extension cable	Medium	Medium, High
Check SpO_2 Sensor Connection	SpO2 sensor connection should be checked	Check SpO_2 Sensor Connection	Medium	Medium, High
Communications Stopped	Relevant communication has stopped		Medium	Medium, High
System Reset, Check Settings	The system has reset and will revert to institutional default settings.	Reset your alarm limits and other settings to match the requirements of the patient being monitored.	Medium	Medium, High

***The IPI LOW ALARM is an alert which is intended to indicate a change in patient status to the physician. When this alert appears, levels of other patient parameters should be evaluated.**

4.14.8.2. Advisories

Table 15. Advisory Messages

Message	Description
Clearing FilterLine	Sampling line (FilterLine) kinked or clogged with water. Appears during clearing time until sampling line is unclogged, or a blockage state is determined.
CO_2 FilterLine Disconnected	No sampling line is connected to the monitor. To correct, insert sampling line into CO_2 port on monitor.
SpO_2 Sensor Disconnected	No SpO_2 sensor is connected to the monitor. To correct, insert SpO_2 sensor into SpO_2 port on monitor.
Interference Detected	Patient motion has been detected
Temperature High	Monitor temperature is too high
No USB Device Found	A valid flash memory device is not connected to the USB port.
USB Drive Full	No room on the USB flash memory device.
No SD Card Found	No SD card is inserted in the monitor
SD Card Full	The current SD card is full

Message	Description
SpO_2 Weak. Reposition Sensor. SpO_2 Weak. Too Much Light. SpO_2 Weak. Try Ear Sensor. SpO_2 Weak. Try Nasal Sensor. SpO_2 Weak. Try Adhesive Sensor SpO_2 Weak. Secure Sensor Cable SpO_2 Weak. Try Using Headband SpO_2 Weak. Sensor Too Cold. SpO_2 Weak. Check Bandage. SpO_2 Weak. Nail Polish. SpO_2 Weak. Sensor Too Tight. SpO_2 Weak. Reposition Sensor SpO_2 Weak. Due To Interference. SpO_2 Weak. Clean Sensor Site. Interference Detected	SpO_2 module detects a weak pulse and suggests possible causes.
CO_2 Warm Up	CO_2 module is preparing for operation.
CO_2 Ready	Before the first measurement of CO_2, after the FilterLine is connected and before patient breath is detected, CO2 Ready replaces the CO2 Warm-up message.
Calibration Required	CO_2 calibration is overdue.

Message	Description
Maintenance Required	CO_2 maintenance is overdue.
SpO_2 Extended Averaging	SpO_2 extended averaging is now taking place
Report Transfer Complete	Data communication is complete.
SpO_2 Low Alarm Limit: xx	Displayed if the SpO_2 Low alarm limit is set below 85%.
Performing Autozero	The monitor automatically performs a zeropoint calibration.
RS232 Report Transfer Completed	The transfer of the RS232 report has been completed
Demo Mode - Prerecorded Data	Displayed during Demo Mode when no other message is displayed.
CO_2 Monitoring Has Been Off For Hh:Mm	Displays the hours and minutes the pump has been turned off during PUMP OFF mode.
Remote System Connected*	The monitor is connected to a remote system. This message will only be present if enabled by the host computer, and may have different wording if so programmed by the host computer.
Remote System Disconnected*	The monitor is no longer connected to a remote system. This message will only be present if enabled by the host computer, and may have different wording if so programmed by the host computer.
Incompatible Software Version	Displayed during transfer of institutional defaults

Message	Description
No File Found	The user tried to download data (i.e., defaults, or demo data) but the file with the required data was not found.
Mode Change Invalid During USB Output	The user tried to change the mode (patient type) during USB output; this cannot be done. Perform change after USB output is complete.
Pump Off Mode	Appears during Pump Off status
Ext Battery Low	The capacity of the external battery is low.
CO_2 standby	CO_2 standby has been activated.
SpO_2 standby	SpO_2 standby has been activated.
Internal Memory Full	The monitor internal memory is full.
Incompatible Demo Hardware	Recorded demo file is not appropriate for monitor and cannot play
Keypad Locked	Keypad is locked
Keypad unlocked	Keypad is unlocked
Report Transfer In Progress	Relevant communication is in progress
Data Transfer Aborted	Relevant communication has stopped
Service Mode	Service mode had been entered. No patient monitoring is taking place.

*** When used with a remote system, this message may be displayed with a different wording if so programmed by the host computer. The host computer may also initiate a message which would appear upon the stopping of communications.**

4.14.8.3. Non-message area messages

The following messages will appear in the relevant waveform area in addition to appearing in the message area.

Table 16. Non-message Area Messages

Message	Description
FilterLine Disconnected	No FilterLine is connected to the monitor
Clearing FilterLine	FilterLine kinked or clogged with water. Appears during clearing time until the FilterLine is unclogged, or a blockage state is determined.
FilterLine Blockage	FilterLine is kinked or clogged
Performing AutoZero	Autozero is currently being performed; CO_2 is not available during Autozero
CO_2 Error	Failure has occurred which prohibits the operation of the CO2 function.
CO_2 Standby	CO_2 standby has been activated
SpO_2 Sensor Not On Patient	SpO_2 sensor is off patient.
Pulse Not Found	No detectable pulse
Defective SpO_2 Sensor	SpO_2 sensor is defective; SpO_2 is not available
SpO_2 Sensor Calibrating	SpO_2 sensor is calibrating; SpO_2 is not available
SpO_2 Sensor Disconnected	SpO_2 sensor is disconnected; SpO_2 is not available
SpO_2 Standby	SpO_2 standby has been activated

Message	Description
SpO_2 Error	Failure has occurred which prohibits the operation of the SpO_2 function.
No Breath xxx Seconds	No breath has been detected for xxx seconds

4.14.9. Changing Alarm Limits

In high-altitude environments, $etCO_2$ values may be lower than values observed at sea level, as described by Dalton's law of partial pressures. When using the monitor in high-altitude environments, it is advisable to consider adjusting $etCO_2$ alarm settings accordingly.

Alarm limits may be changed as follows:

To change alarm limits on a temporary basis (until the monitor is turned off):

1. Click the **Menu** button on the front panel.

2. **Setup**>**Alarm Setup** will be the first choice on the **Menu** screen. Click **Enter**.

3. Navigate to the relevant alarm and click **Enter**. The up-and-down indicator arrows on the screen will become active. Using the directional arrows, select the desired alarm limit and click **Enter** for No Breath or **Apply** for other limits.

4. Change additional limits if desired.

5. Select **Home** to return to the Home screen.

To change alarm limits on a permanent basis (that is, also after the monitor is turned off and on):

1. Click the **Menu** button on the front panel.

2. Navigate to and select **Setup** on the **Menu** screen and navigate to and select **Service** on the **Setup Menu** screen.

3. Input Service password and click **Done**.

4. Navigate to and select **Institutional Defaults>Alarms>Factory Defaults**.

5. Select the relevant type of alarm limits and click **Enter**.

6. Select the relevant alarm limit and click **Enter**. A window for these changes will appear on the right side of the screen. Using the directional arrows, move to the desired screen section, select the desired alarm limit, and click **Enter**. Alarms may also be disabled from this screen.

7. Change additional limits if desired.

8. Select **Home** to return to the Home screen.

When the SpO_2 alarm limit is set below 85%, a message reading **SpO_2 Low Alarm Limit: xx** will appear in the header area, indicating the level of the SpO_2 Low alarm limit.

4.14.10. Testing Alarm Settings

In order to test the **No Breath** alarm, establish a display of normal breathing on the monitor. Once normal breathing is displayed, remove the sampling line from the test subject to create a no breath situation. The monitor should then display a **No Breath** alarm.

In order to test the pulse oximetry **Sensor Not on Patient** alarm, establish a display of SpO_2 values on the monitor. Once SpO_2 values are displayed, remove the sensor from the test subject to create a **Sensor Not on Patient** situation. The monitor should then display a **Sensor Not on Patient** alarm.

4.14.11. Alarm Limits - Factory Defaults

For the factory defaults for the Adult and Neonatal alarm limits, reference *Table 29. Factory Default Alarm Limits* on page 217.

4.15. Trends

4.15.1. Introduction

The monitor stores patient data that provides detailed information on the history of the patient during monitoring in a trend screens. The trend displays allow you to look at the patient history as part of the medical analysis to aid in patient assessment.

4.15.2. Trend Storage

Trends are automatically stored. The monitor shall store the previous 48 hours of monitored (turned-on) data regardless of whether there is a period of time during which the monitor is turned off. Data is saved once a second, except for the CO_2 waveform data, which is saved 20 times a second.

Data will be displayed according to the selected trend increment.

The trend data stores the following parameters:

- **Current Date**
- **Current Time**
- **$EtCO_2$**
- **RR**
- **SpO_2**
- **PR**
- **IPI**

- **CO_2 waveform***
- **High/medium priority patient alarms (one per second, one per parameter)**
- **Equipment-caused events such as Low Battery or other monitor-related messages.**
- **Event markers input by the user, along with any event label (one per second)**
- **Case Start marker to indicate start of case**

***Waveform is shown in Graphical Trend.**

During Pump Off mode no CO_2 data shall be recorded.

4.15.3. The Trend Display Screens

Trend data is displayed in two different formats; graphical and tabular.

The Graphical Trend screen allows you to view the patient data over a longer time scale (1, 2, 4, 8, or 12 hours at a time) and scroll through the data looking for patterns, specific events or alarms. The Tabular Trend screen offers views of 1 sec, 5 sec, 15 sec, 30 sec, 1 min, 5 min, 15 min, 30 min, and 1 hour, enabling the user to see more details about patient status.

4.15.3.1. Graphical Trend display screen

The graphical trend display screen may be viewed as follows:

1. **Click the Menu button on the front panel.**
2. **Navigate to and select Trend on the Setup Menu screen.**
3. **Navigate to and select Graphical Trend on the Trend Menu screen. The screen will display the graphical trend currently being recorded in a 4-Hour display. A white indicator line**

with a blue time marker will indicate the selected time seen on the left side of the screen. A red line on the trend waveform will indicate an alarm at that point of time.

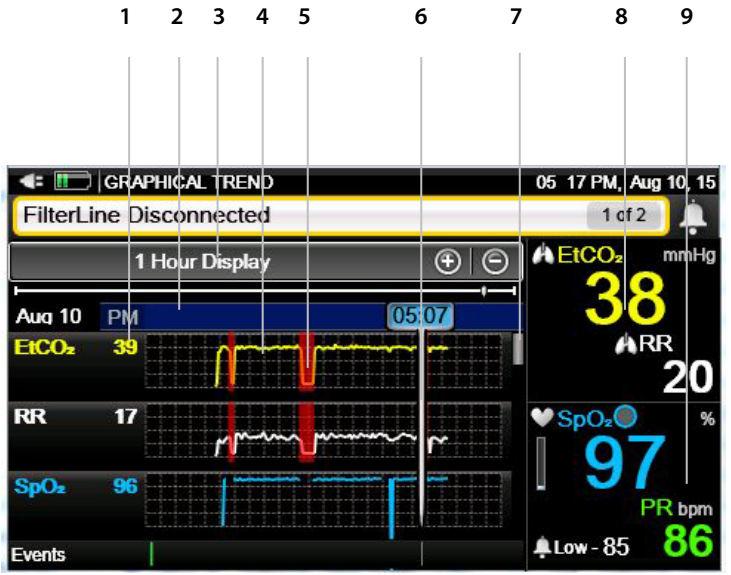
4. **To change the time period being displayed, click the Enter button, and navigate to and select the desired Zoom options from the options that will appear on the screen. Click Enter again. The display will now show the desired display time period.**

5. **To view a different time period, use the directional arrows to adjust the time seen on the screen to the time that you would like to view. The white indicator line with blue time marker will indicate the location of the time indicator and the data at the left will show the data at that period in time.**

6. **To view additional parameters, click the down directional arrow and then the Enter button to scroll down to see those parameters not seen on the screen.**

The data seen on the right side of the screen will continue to display current data.

Figure 34. Graphical Trend Screen - 1 Hour Display



Label	Function	Description
1	$EtCO_2$, RR, and SpO_2 patient data at cursor point	$EtCO_2$, RR and SpO_2 patient values at cursor point in numeric format
2	Cursor data	Date and time of cursor location
3	Time range	Range of selected display time period
4	$EtCO_2$, RR, and SpO_2 patient trend data	$EtCO_2$, RR and SpO_2 patient values during the selected display time period shown in a waveform format
5	Alarm marker	The red section on the trend waveform indicates a red high priority alarm occurring at that point in time; yellow markers would show a yellow medium priority alarm.

6	Cursor bar	Indicates time of cursor location; patient data for this time point is shown at left
7	Scroll bar	Bar used to scroll down to view other parameters (PR and IPI)
8	CO_2 current patient data	Current patient CO_2 values, displayed regardless of what trend data is being displayed on the screen
9	SpO_2 current patient data	Current patient SpO_2 values, displayed regardless of what trend data is being displayed on the screen

4.15.3.2. Graphical Trend screen search

Follow the steps below to search on the graphical trend display screen:

1. **Click the Menu button on front panel of the monitor.**

2. **Navigate to and select Trend on the Setup Menu screen.**

3. **Navigate to and select Search Graphical on the Trend Menu screen. The screen will display the Trend Menu Search Date and Time screen for the graphical view.**

4. **On the Trend Menu: Calendar Search Date and Time screen, navigate to and select the exact date and time that you want to view on the screen.**

5. **When you have selected the desired time, navigate to the search button on the screen and select. If there is recorded data for the selected time point, the monitor will display the Graphical Trend screen view, at the selected time point.**

6. If there is no recorded data for the selected time point, the monitor will inform you of this fact and the screen will indicate that there are no records found for the selected time and request that you select another time value.

Table 17. Trend Increments and Zoom Levels

Trend Increment	Time Frame of Report
15 sec	1 hour
30 sec	2 hours
1 min	4 hours
2.5 min	8 hours

4.15.3.3. Tabular Trend display screen

The tabular trend display screen may be viewed as follows:

1. Click the **Menu** button on front panel of the monitor.

2. Navigate to and select **Trend** on the Setup Menu screen.

3. Navigate to and select **Tabular Trend** on the Trend Menu screen. The screen will display the tabular trend currently being recorded in a 30-second display.

4. To change the time period being displayed, click the **Enter** button, and navigate to and select the desired zoom option from the **Zoom Options** that will appear on the screen. Click **Enter** again. The display will now show the desired display time period.

5. To view a different time period, use the directional arrows to adjust the time seen on the screen to the time that you

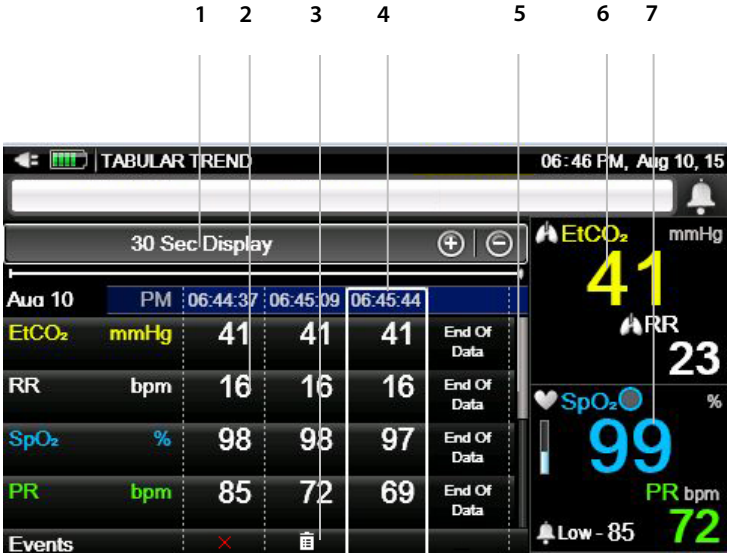
would like to view. The frame will indicate the chosen time period and the data at that period in time.

6. When the latest period of time recorded is reached at the right, the screen will indicate: **End of data**. When the time previous to the recorded data is reached at the left, the screen will indicate: **No data**.

7. To view additional parameters, click the down directional arrow and then the **Enter** button to scroll down to see those parameters not seen on the screen.

8. The data seen on the right side of the screen will continue to display current data.

Figure 35. Tabular Trend Screen – 30 Second Display



Label	Function	Description
1	Time range	Range of selected display time period

2	$EtCO_2$, RR, SpO_2 and PR patient data	$EtCO_2$, RR, SpO_2 and PR patient values during the selected display time period shown for each time period
3	Event marker	A red or yellow X on the events listing indicates a high priority or medium priority alarm (respectively) occurring at that point in time. An event marker will indicate an event.
4	Cursor data	Date and time of cursor location
5	Scroll bar	Bar used to scroll down to view other parameters
6	$EtCO_2$ current patient data	Current patient $etCO_2$ values, displayed regardless of what trend data is being displayed on the screen
7	SpO_2 current patient data	Current patient SpO_2 values, displayed regardless of what trend data is being displayed on the screen

4.15.3.4. Tabular Trend screen search

Follow the steps below to search on the tabular trend screen:

1. Click the **Menu** button on front panel of the monitor.

2. Navigate to and select **Trend** on the Setup Menu screen.

3. Navigate to and select **Search Tabular** on the Trend Menu screen. The screen will display the Trend Menu Search Date and Time screen for the tabular view.

4. On the **Trend Menu: Calendar Search Date and Time** screen, navigate to and select the exact date and time that you want to view on the screen.

5. When you have selected the desired time, navigate to the search button on the screen and select. If there is recorded data for the selected time point, the monitor will display the Tabular Trend screen view, at the selected time point.

6. If there is no recorded data for the selected time point, the monitor will inform you of this fact and the screen will indicate that there are no records found for the selected time and request that you select another time value.

4.15.3.5. Events List screen

The events list display screen may be viewed as follows:

1. Click the **Menu** button on front panel of the monitor.

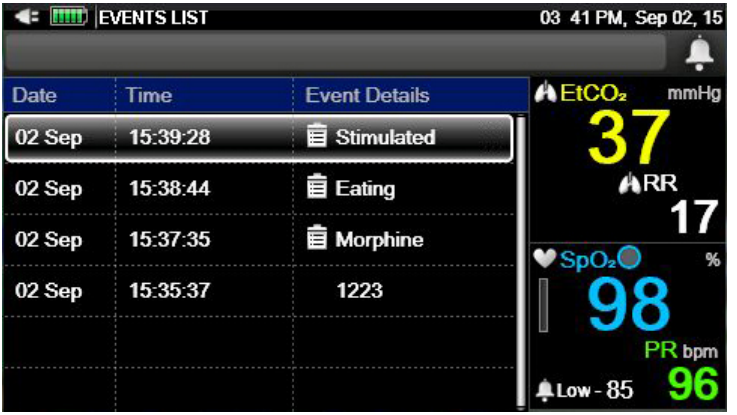
2. Navigate to and select **Trend** on the Setup Menu screen.

3. Navigate to and select **Events List** on the Trend Menu screen. The screen will display a list of events for the current patient case or a list of all events if there is no open patient case. Please note that this list includes events added by the user but not alarms. If there are no events, the list will contain no items.

4. To view additional events, if there are any, click the down directional arrow to scroll down to see those events not seen on the screen.

5. The data seen on the right side of the screen will continue to display current data.

Figure 36. Events List



4.15.3.6. Events List screen search

Follow the steps below to search on the events list search screen:

1. **Click the Menu button on front panel of the monitor.**

2. **Navigate to and select Trend on the Setup Menu screen.**

3. **Navigate to and select Search Events on the Trend Menu screen. The screen will display the Trend Menu Search Date and Time screen for events.**

4. **On the Trend Menu: Calendar Search Date and Time screen, navigate to and select the exact date and time that you want to view on the screen.**

5. **When you have selected the desired time, navigate to the search button on the screen and select. If there is recorded data for the selected time point, the monitor will display the Events list at the selected time point.**

6. **If there is no recorded data for the selected time point, the monitor will indicate that there are no events found for that time point and display the events that occurred closest to the requested time point.**

4.15.4. Choosing Trend Parameters

Reference *11.1.6.3 Trend Display Config settings* on page 226 to change the trend parameters seen on the screen or change the order of the parameters.

4.15.5. Clearing Trend Memory

It is recommended to erase trend memory when the monitor is switched to a new patient, in order to avoid mistaking the earlier data for the present patient's data. Therefore, when the monitor is in single patient mode (the default mode) trend memory will be erased when the case is exited.

4.15.6. Trend Display Mode

The monitor offers two types of trend display modes, Recorded and Calendar. The default is Recorded. In the Recorded mode, if the monitor is turned off and then on, the trend memory will record the time that these actions occur and display those time periods as periods without data on the trend memory recording. In the Calendar Mode, if the monitor is turned off and then on, the trend will include the time during which the monitor is turned off in its trend recording period, and will mark those time periods as periods without data.

In both modes, no data will be shown for those time periods during which the monitor was turned off, since not data is available. However, since the monitor can only record up to 48 hours of data, use of the Calendar Mode might limit the amount of useful data stored in the trend memory.

To change the Trend Mode, reference *11.1.6.1 Main Trend settings* on page 224.

4.15.7. Trends Configuration

4.15.7.1. Event marking mode

There are two types of event marking modes available.

- Detailed Event Marking: When the **Event** button is pushed, you can enter a specific description of the event from a table of 30 user definable values (reference *4.4 Patient Events* on page 59).
- Quick Event Marking: Marks that an event occurred when the **Event** button is pushed, but does not give any details.

The default event marking mode for the monitor is **Detailed**.

To change the Event Marking Mode on a permanent basis (that is, also after the monitor is turned off and on), click the **Menu** button on the front panel of the monitor.

1. Navigate to and select **Setup** on the Menu Screen.
2. Navigate to and select **Service** on the Setup Menu Screen.
3. Input Service password and click **Done**.
4. Navigate to and select **Institutional Defaults>Trend**.
5. Navigate to and select **Event Marking Mode** and click **Enter**.
6. Select the desired mode and select **Enter**.
7. Select **Home** to return to the Home screen.

4.15.7.2. Trend Increment Display

The increments seen on the tabular trend screen can be changed in **Institutional Defaults>Trend**. The options are 1, 5, 15, or 30 seconds, or 5, 15, or 30 minutes, or 1 hour.

The default value is 30 seconds.

4.15.7.3. A/Hr and ODI trends

A/Hr and ODI Trends are accessed using the Reports soft key and are covered in *5.2 Reports* on page 148.

5. Product Data Output

5.1. Report Options

The monitor provides the opportunity to view or store various reports. These reports include Ventilation and Desaturation reports, Alarm Review reports, and case and trend reports.

The various types of report options can be accessed in various ways; reference *Table 18. Report Options Access*, below, for more details.

Table 18. Report Options Access

Report Access	Report Option	Notes
View Report	Vent. And Desat reports A and B CO_2 Statistics report Alarm Review report	
Store Report	Tabular Case Graphical Case Tabular Trend Graphical Trend Realtime Continuous Tabular Realtime Continuous Waveform Real Time Full Continuous Transfer Current Alarm Limits	All stored reports can be printed on an external device; reports saved in Html format may be printed by this method.

For the Report Selection screen, reference *Figure 37. Report Selection*, below.

Figure 37. Report Selection

5.2. Reports

The monitor provides the option to view four types of reports:

- Vent and Desat Report A
- Vent. and Desat Report B
- Parameter Statistics
- Alarm Review

The Vent. and Desat report can only be viewed if a patient case has been opened. If no patient case is open, a message indicating **Open a New Patient Case.** will appear and these reports will not be available.

To open a patient case, reference *4.3 Patient Cases and Patient ID Numbers* on page 58.

To scroll down on these reports, navigate to the main window of the report, click **Enter** and then use the up and down arrows to scroll.

On all of these report screens, real-time data of the current patient is seen on the right side of the screen.

A report may be viewed as follows:

1. Click the **Menu** button on the front panel of the monitor.

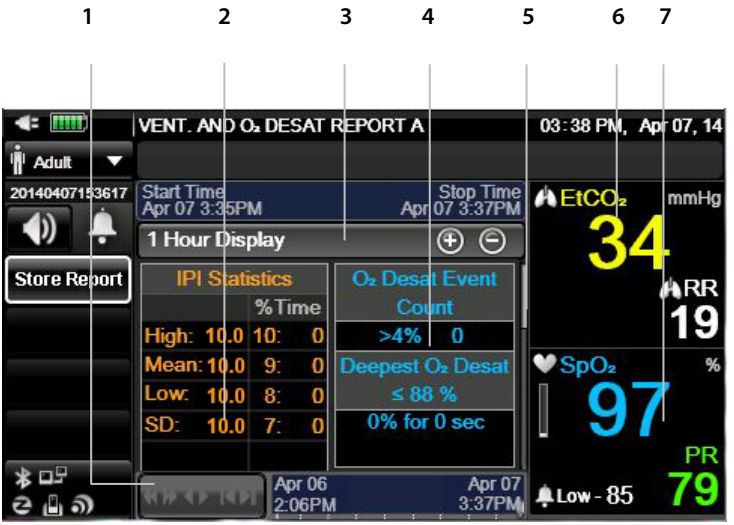
2. Navigate to and select **Report>View Report** on the Setup Menu Screen.

3. Select the desired report and click to view.

A Vent. and Desat report can only be viewed if a patient case has been opened. If the open patient does not have IPI or Apnea and Desaturations data (for example, a neonatal patient), the Vent. and Desat Reports will not be available. An Alarm Review report may be viewed even if a patient case has not been opened.

On the Alarm Review screen, real-time data of the current patient is seen on the right side of the screen.

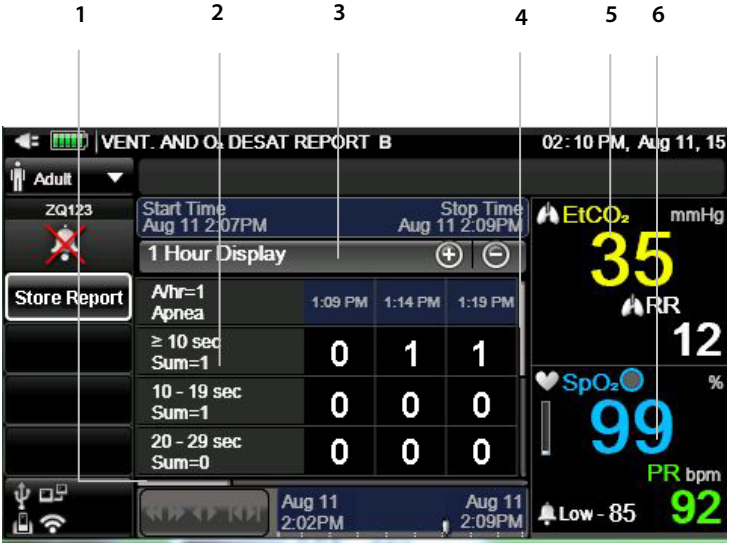
Figure 38. Vent and Desat Report A



Label	Function	Description

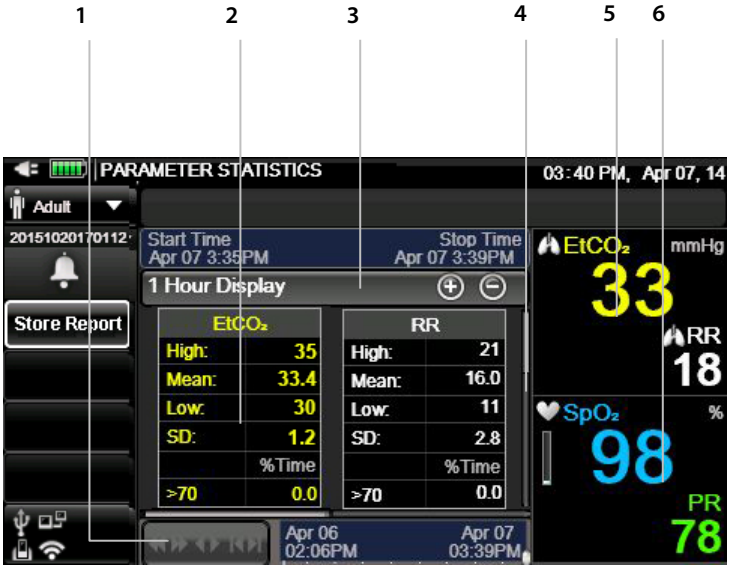
1	Scroll bar (horizontal)	Bar used to scroll right to view additional time periods
2	IPI Statistics data	Patient IPI Statistics data
3	Time range	Range of selected display time period
4	O_2 Desat and Apnea Event Counts data	Patient O_2 Desat and Apnea Event Counts data
5	Scroll bar (vertical)	Bar used to scroll down to view other parameters
6	Real-time etCO_2 data	Current patient real-time data
7	Real-time SpO_2 data	Current patient real-time data

Figure 39. Vent and Desat Report B



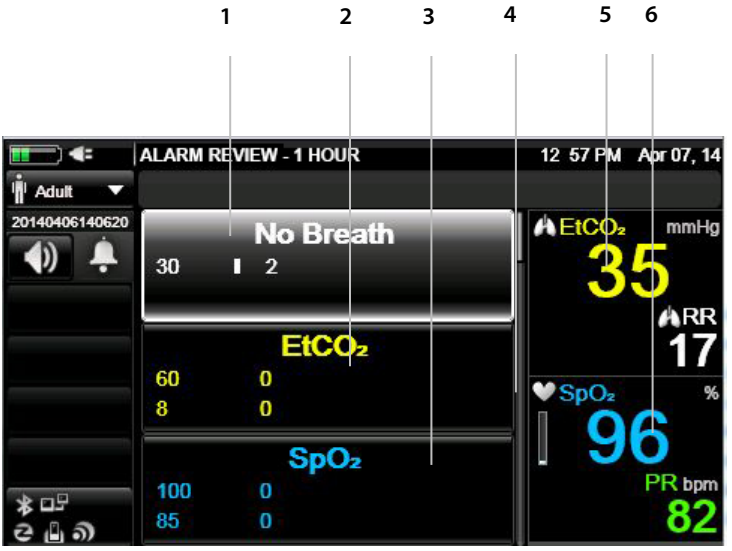
Label	Function	Description
1	Scroll bar (horizontal)	Bar used to scroll right to view additional time periods
2	Apnea and Desat data	Patient Apnea and Desat data
3	Time range	Range of selected display time period
4	Scroll bar (vertical)	Bar used to scroll down to view other parameters
5	Real-time $etCO_2$ data	Current patient real-time data
6	Real-time SpO_2 data	Current patient real-time data

Figure 40. Parameter Statistics Report



Label	Function	Description
1	Scroll bar (horizontal)	Bar used to scroll right to view additional time periods
2	Parameter data	Patient parameter data
3	Time range	Range of selected display time period
4	Scroll bar (vertical)	Bar used to scroll down to view other parameters
5	Real-time $etCO_2$ data	Current patient real-time data
6	Real-time SpO_2 data	Current patient real-time data

Figure 41. Alarm Review Report



Label	Function	Description
1	No Breath data	Patient No Breath data
2	$EtCO_2$ data	Patient $EtCO_2$ data
3	SpO_2 data	Patient SpO_2 data
4	Scroll bar (vertical)	Bar used to scroll down to view other parameters
5	Real-time $etCO_2$ data	Current patient real-time data
6	Real-time SpO_2 data	Current patient real-time data

Table 19. Ventilation and Desaturation and Parameter Statistics Report Types

Report Name	Fields Included	Time Frame of Report
Vent. and Desat Report A	IPI statistics, Apnea Event Count and Desaturation Event Count	1, 2, 4, 8, or 12 hours, as selected
Vent. and Desat Report B	Apnea Event Count and Desaturation Event Count	
Parameter Statistics	$EtCO_2$ and RR data, including High, Mean, Low, SD, and %Time for various values	
Alarm Review	Current alarm limits and number of each type of alarm in the last hour for the current patient.	1 hour

5.3. Data Output

The monitor can export stored and current data to external devices by the following methods:

Data may be transferred to a USB flash memory device or micro SD card for later transfer to a computer and printing using an external printer. Reference *Figure 3. Monitor Right View* on page 21 and *Figure 4. Monitor Left View* on page 23 for the location of the USB and micro SD card ports.

Caution:
Ensure that there are no viruses on the USB flash memory device or micro SD card prior to interfacing with the monitor.

A case or trend report can be stored (downloaded) as follows:

1. **Place the USB flash memory device in the USB flash memory device port.**

2. **Click the Menu button on the front panel of the monitor.**

3. **Navigate to and select Report on the Menu screen.**

4. **Navigate to and select Store Report on the Report Menu Screen.**

5. **Navigate to and select the report you want to store. If a case is not currently active, you will not be able to store a case report.**

6. **If the type of report permits more than one type of report (HTML or Text) navigate to and select the desired report. Some reports are available only in one format; for example, Graphical Trend and Graphical Case Reports are available in BMP format only.**

7. **Navigate to and select Choose Device. Navigate to and select the device on which you want to store the report.**

8. **Navigate to and select Save Report.**

9. **To store another report, repeat the process.**

10. **To stop storing a report (this is generally used for real-time reports, which will continue downloading onto the storage device unless they are stopped), click the Active Reports button.**

11. Navigate to and select the report that you want to stop. Select the report and then navigate to and select the **Stop** button to stop downloading the report.

Selecting **Active Reports** during the download process will display a list of reports that are currently downloading. The list can contain more than one report if more than one download type occurs at the same time, or (even though only one report can be downloaded at one time to a USB device) more than one USB device is used (using a multiplier).

The following data transfer report types are available:

Table 20. Data Transfer Report Types

Report Name	Description	File type	Fields Included
Tabular Case	Stores the tabular trend report of selected patient ID, data shall be from current case start to case stop.	Txt, HTML	Name of report Case ID Patient Type Patient Gender, Age, Weight Case Start Date and Time Report Generation Date and time
			DATE, TIME
			Patient Readings: $etCO_2$, RR, IPI, SpO_2, PR
			Patient Alarm Occurrences
			Equipment Advisory Message Occurrences: CO_2 NOT AVAILABLE,

Report Name	Description	File type	Fields Included
			SpO_2 NOT AVAILABLE, PRIMARY BATTERY LOW, SECONDARY BATTERY LOW
			Events (one per second, one per parameter)
Tabular Trend	Stores the tabular report of the entire trend available in the memory for the current Patient ID from previous stop case to current patient stop case. This report shall include all the parameters available in trend storage based on enable/disable of the parameters. Parameters active for real time monitoring is not related to this report.	Txt, HTML	Name of report Patient ID Patient Type Report Generation Date and time Zoom Selected
			DATE, TIME
			Patient Readings: $etCO_2$, RR, SpO_2, PR, IPI.
			Patient Alarm Occurrences
			Equipment Advisory Message Occurrences: CO_2 NOT AVAILABLE, SpO_2 NOT AVAILABLE, PRIMARY BATTERY LOW, SECONDARY BATTERY LOW

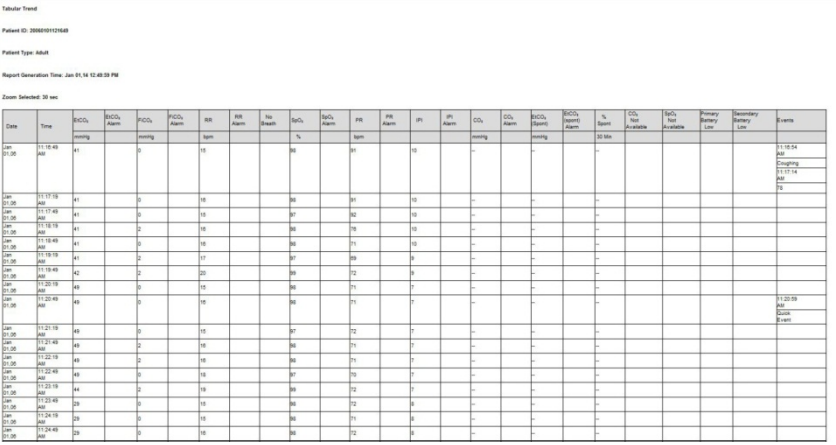
Report Name	Description	File type	Fields Included
			Events (one per second, one per parameter)
Graphical Case	Stores the graphical trend report of the entire trend available in the memory selected Patient ID (data shall be from current case start to case stop). Graph shall be plotted on the BMP page in zoom selected for graphical trend.	BMP	Name of report Case ID Patient Type Patient Gender, Age, and Weight Case Start Time Zoom Selected Report Generation Date and time Start Time Stop Time Graphs for selected parameters
Graphical Trend	Stores the graphical report of all the trend or present displayed page in GRAPHICAL TREND SCREEN with selected zoom	BMP	Name of report Patient ID Patient Type Zoom Selected Report Generation Date and Time Start Time Stop Time Graphs for selected parameters
Real-time Continuous	Stores the tabular report of real time values of the	Txt	Name of report Case ID

Report Name	Description	File type	Fields Included
Tabular	current active parameters with 1 second resolution. Anytime there is a change in the available parameters due to patient type or CO_2 mode change, the current file will be closed and a new file created.		Patient Type Report Generation Date and Time
			DATE, TIME
			Patient Readings: etCO_2, RR, SpO_2, PR, IPI.
			Patient Alarm Occurrences
			Equipment Advisory Message Occurrences: CO_2 NOT AVAILABLE, SpO_2 NOT AVAILABLE, PRIMARY BATTERY LOW, SECONDARY BATTERY LOW
			Events (one per second, one per parameter)
Realtime Continuous waveform	Stores in txt format the graphical report of CO_2 waveform (with one data point every 50 ms)	Txt	Name of report Case ID Patient Type Report Generation Date and time Data to build graph for CO_2 and SpO_2 waveforms
Real-time Full Continuous	Stores the report containing real-time CO_2	Txt	Name of report (Realtime Full Continuous

Report Name	Description	File type	Fields Included
Transfer	**waveform plus real time values of current active parameters with 1 second resolution by repeating numerical values for every 50ms along with waveform.**		**Transfer)** **Case ID** **Patient Type** **Report Generation Date and time**
			DATE, TIME
			Patient Readings (at trend storage resolution): etCO_2, RR, IPI, SpO_2, PR, A/hr, ODI
			Patient Urgent Alarm Occurrences
			Equipment Advisory Message Occurrences: CO_2 NOT AVAILABLE, SpO_2 NOT AVAILABLE, PRIMARY BATTERY LOW, SECONDARY BATTERY LOW
			Events (one per second, one per parameter)
			Patient reading every 50 milliseconds – 20 times a second – (for creating CO_2 waveform): CO_2

Report Name	Description	File type	Fields Included
			wave
Current Alarm Limits	Stores the current selected alarm limits of the available/active parameters	Text, Html	Name of report Case ID Patient Type Report Generation Date and time
			Unit, high limit and low limit for current relevant parameters For patients measured with standard etCO_2 measurement: EtCO_2, RR, No Breath, SpO_2, PR, SatSec, IPI For HiFi patients: CO_2, etCO_2 (spont), SpO_2, PR, SatSec

Figure 42. Sample Html Report: Tabular Trend



Tabular Trend

Patient ID: 20060101121648

Patient Type: Adult

Report Generation Time: Jan 01, 14 12:49:59 PM

Zoom Selected: 30 sec

Date	Time	$EtCO_2$	$EtCO_2$ Alarm	$FiCO_2$	$FiCO_2$ Alarm	RR	RR Alarm	No Breath	SpO_2	SpO_2 Alarm	PR	PR Alarm	PI	PI Alarm	CO_2	CO_2 Alarm	$EtCO_2$ (Spont)	$EtCO_2$ (spont) Alarm	% Spont	CO_2 Not Available	SpO_2 Not Available	Primary Battery Low	Secondary Battery Low	Events
		mmHg		mmHg		bpm			%		bpm				mmHg		mmHg		30 Min					
Jan 01,06	11:16:49 AM	41		0		15			98		91		10		--		--		--					11:18:54 AM Coughing 11:17:14 AM 75
Jan 01,06	11:17:19 AM	41		0		16			98		91		10		--		--		--					
Jan 01,06	11:17:49 AM	41		0		16			97		92		10		--		--		--					
Jan 01,06	11:18:19 AM	41		2		16			98		76		10		--		--		--					
Jan 01,06	11:18:49 AM	41		0		16			98		71		10		--		--		--					
Jan 01,06	11:19:19 AM	41		2		17			97		69		8		--		--		--					
Jan 01,06	11:19:49 AM	42		2		20			99		72		8		--		--		--					
Jan 01,06	11:20:19 AM	43		0		15			98		71		7		--		--		--					
Jan 01,06	11:20:49 AM	43		0		15			98		71		7		--		--		--					11:20:59 AM Quick Event
Jan 01,06	11:21:19 AM	43		0		15			97		72		7		--		--		--					
Jan 01,06	11:21:49 AM	43		2		16			98		73		7		--		--		--					
Jan 01,06	11:22:19 AM	43		2		16			98		73		7		--		--		--					
Jan 01,06	11:22:49 AM	43		0		16			97		73		7		--		--		--					
Jan 01,06	11:23:19 AM	44		2		19			99		72		7		--		--		--					
Jan 01,06	11:23:49 AM	29		0		11			98		72		8		--		--		--					
Jan 01,06	11:24:19 AM	29		0		15			98		71		8		--		--		--					
Jan 01,06	11:24:49 AM	29		0		16			98		72		8		--		--		--					

5.3.1. Printing reports

Report printing is done via an external printer after storing a report using a USB device or micro SD card as described in *5.4 Data Transfer*, below.

5.4. Data Transfer

5.4.1. USB

The monitor provides both a standard USB port and mini USB port on the monitor. The standard USB port on the monitor is for use with a flash memory device only. The mini USB port on the monitor is for use of qualified service personnel only. Do not attempt to power the monitor via either USB port. To use the standard USB port, place the USB flash memory device into the port before beginning the download process.

The monitor recognizes flash memory drive devices manufactured by all major brands. It will recognize flash memory drives with the file systems FAT, FAT32, exFAT; it may not recognize other file systems, including NTFS. Some flash drives may not be able to attach to the

port on the monitor as a result of mechanical incompatibility; check each flash drive to ensure that it fits into the port. A typical flash memory device is shown below.

Figure 43. Typical Flash Memory Device

The standard USB port on the monitor is for use with a flash memory device only. It is not a full service USB port. Do not attempt to connect the monitor to a computer via the USB port.

If the monitor does not detect the flash memory drive, remove and re-insert the flash memory drive. If the flash memory drive is still not detected, check that the drive being used is from a supported manufacturer.

If free disk space on the flash memory drive is less than 100 kb, writing to the USB disk drive is not allowed. Under this condition, if data transfer is already in progress, it will be aborted. Any new data transfer CANNOT be initiated under the low disk space condition.

Note: The USB Flash Memory drive must be inserted with care in the USB port, without using excessive force. If the Flash Memory drive cannot be inserted easily into the port, do not use the drive.

Note: Only one memory device (one flash memory drive or micro SD card) may be used at one time.

Table 21. USB File Naming Convention

Report Name	File Naming Conventions
Tabular Case	TCR_ PATIENT TYPE_DATE_TIME_PATIENT ID_ORIDION
Tabular Trend	TTR_PATIENT TYPE_DATE_TIME_PATIENT ID_ORIDION
Graphical Case	GCR_ PATIENT TYPE_DATE_TIME_PATIENT ID
Graphical Trend	GTR_ PATIENT TYPE_DATE_TIME_PATIENT ID
Real-time Continuous Tabular	RCT_ PATIENT TYPE_DATE_TIME_PATIENT ID_ORIDION
Real-time waveforms	RCW_ PATIENT TYPE_DATE_TIME_PATIENT ID_ORIDION
Real-time Full Continuous Transfer	FCTR_ PATIENT TYPE_DATE_TIME_PATIENT ID_ORIDION
Current Alarm Limits	ALIM_ PATIENT TYPE_DATE_TIME_PATIENT ID

Table 22. USB Files Examples

Report Name	File Naming Conventions
Tabular Case	TCR_ ADULT_060714_141453_20140607121546_ORIDION
Tabular Trend	TTR_ ADULT_060714_141453_20140607121546_ORIDION
Graphical Case	GCR_ ADULT_060714_141453_20140607121546

Graphical Trend	**GTR_ ADULT_060714_141453_20140607121546**
Real-time Continuous Tabular	**RCT_ ADULT_060714_141453_20140607121546_ORIDION**
Real-time waveforms	**RCW_ ADULT_060714_141453_20140607121546_ORIDION**
Real-time Full Continuous Transfer	**FCTR_ ADULT_060714_141453_20140607121546_ORIDION**
Current Alarm Limits	**ALIM_ ADULT_060714_141453_20140607121546**

To read patient data from an html report, simply download the file to a local folder and open the file in html. Txt files may be opened in Excel to facilitate viewing and analyzing the data. Contact your local sales representative for more information.

5.4.2. MMC/SD

The monitor recognizes MMC/SD cards which comply with the Multimedia Card System Specification v4.2 from the MMCA Technical Committee and the SD I/O Card Specification v 2.0 from the SD Association. High-capacity (size >2GB) cards may be used. Its use is similar to the use of a USB flash drive.

5.4.3. Wireless Communication

The monitor can work with three different types of WiFi networks, as follows:

- **Open networks**
- **Secure networks (which require a password and/or a security key)**

- **Enterprise networks (which require a certificate in addition to security requirements)**

Follow the instructions below to set up and turn on WiFi connectivity on the device for the different types of networks.

Caution:
Ensure that there are no viruses on the network to which you are connecting prior to interfacing with the monitor.

5.4.3.1. Turning on WiFi Connectivity

WiFi connectivity must be configured first; reference *5.4.3.2 Configuring WiFi*, below.

Once WiFi is configured to work with a network, clicking On as described below will turn on WiFi for the configured network.

To turn on WiFi connectivity, navigate to and select the connectivity icon on the main Menu screen (reference Connectivity Icon, below) to open the Connectivity screen.

Figure 44. Connectivity Icon

Navigate to Wi-Fi Connection, select, and click On. WiFi will be turned on, the text WiFi connected to: *Network Name* and a green check mark will appear on the screen, the WiFi icon will be in color, and the button will now show Off. Reference *Figure 45*, below. If no networks are available, an on-screen message will inform you of this fact.

Figure 45. Menu Screen showing WiFi connected

By default, WiFi is off. To turn it off when it is on, select and click the Off button.

Once connected, the name of the connected network will appear under the text WiFi in the middle of the Connectivity screen, and the WiFi signal strength indicator ( ) will appear in the upper left-hand corner of all screens.

5.4.3.2. Configuring WiFi

The WiFi configuration step should be performed by technical support personnel, using the Service password in the Service screen.

Take the following steps to set up configuration of your WiFi connection:

1. **Navigate to and select Setup on the Menu Screen.**
2. **Navigate to and select Service on the Setup Menu Screen.**
3. **Input Service password and click Done.**
4. **Navigate to and select the connectivity icon on the service screen to open the Service Mode Connectivity screen. Reference *Figure 46*, below.**

Figure 46. Service Mode Connectivity Screen, with Connected Network

5. Navigate to the Wifi Connection section of the screen and click the **On** button.

6. Navigate to and click the **Configure** button in the WiFi Connection section of the screen.

7. The Service WiFi Configuration screen will open. Each available network will appear as a separate line on this screen. A lock icon indicates that the network requires a security key or a password, and a yellow star indicates that the network is a favorite network; a network will become a favorite network when it is added to the Network list by the user. The network strength will also be indicated on each line.

8. Navigate to the desired network on the list of available networks, using the directional arrows, and select. If the network does not require any security information, click **Connect** to connect to the network.

9. If the network requires a password, a pop-up screen will request that you input the required data. Fill in the **User Name** and **Password** fields and click **Connect** to add the network. If the connection succeeds, the system will add the network; if not, an on-screen message will inform you of this

fact. If connection is not successful, check the password or try another network.

10. If the network requires a security key, a pop-up screen will request that you input the required data. Fill in the security key information and click **Connect** to add the network. If the connection succeeds, the system will add the network; if not, an on-screen message will inform you of this fact. If connection is not successful, check the details or try another network.

11. If you select a network from the list of available networks which requires a certificate, a pop-up window will request that you add the certificate. Follow the instructions below (reference *5.4.3.2.4 Adding a network certificate* on page 171) to upload the certificate.

12. Then, add the certificate following the instructions on the screen in the pop-up window mentioned above, using the relevant certificate which you have already uploaded to the device.

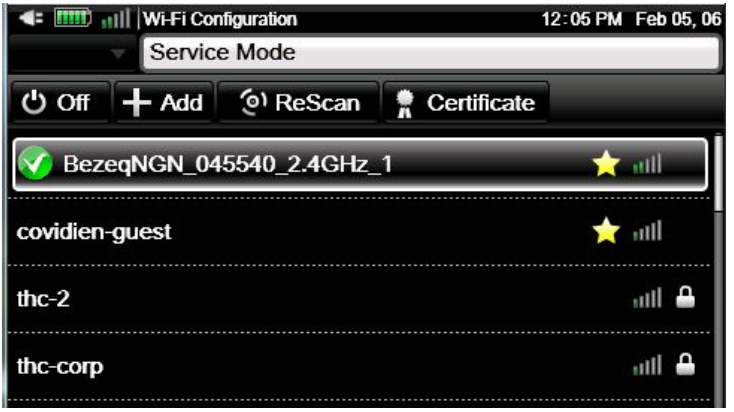
13. If you select a network from the list of available networks which requires a security key, a pop-up window will request that you add the security key. Do so, following the instructions on the screen to add the required information. Click **Connect** to add the inputted information.

When a network is successfully added and all required data is uploaded, the relevant network will show as connected in the WiFi Configuration screen, reference *Figure 47. WiFi Network Configuration*, below.

Figure 47. WiFi Network Configuration, below, shows a list of available networks. The currently connected network is marked by a green check mark icon. Favorite networks are marked with a yellow star.

If 20 networks already appear on the network list and have been marked as preferred, no additional networks can be marked as preferred until one item is removed from the list of networks.

Figure 47. WiFi Network Configuration



Other available options on this screen include the following:

5.4.3.2.1. Adding a network

If the desired network does not appear on the list, navigate to and click Add as seen in Figure 47. WiFi Network Configuration, above, and follow the instructions on the screen.

5.4.3.2.2. Removing a network

To remove a network from the list of available networks, navigate to the relevant network on the list of available networks on the WiFi Network Configuration screen (reference *Figure 47. WiFi Network Configuration*, above), using the directional arrows, and select. On the pop-up window that will open, click Remove. Once the user removes a network from the table, the focus button goes to the first network on the list.

5.4.3.2.3. Rescanning networks

To rescan for available networks to update the list of available networks, navigate to and click Rescan on the WiFi Network Configuration screen (reference *Figure 47. WiFi Network Configuration*, above) to rescan for available networks.

5.4.3.2.4. Adding a network certificate

If you have a network that requires a certificate, begin by loading the required certificate onto a USB flash drive or micro SD card and connecting that USB flash drive or micro SD card to the device. Then, on the WiFi Network Configuration screen (reference *Figure 47. WiFi Network Configuration*, above), navigate to and select **Certificate** to browse for a certificate. Search for and upload the certificate to the device, inputting the password as required, following the instructions on the screen. Navigate to and select **Apply** and **Done** to complete the process.

5.4.3.3. Configuring IP Settings

Navigate to and select **Menu>Setup >Service** >Input the Service password>**Institutional Defaults>Monitor>Interfaces>IP Settings** to view MAC ID and other information regarding the connected network. Correct if required.

Once you are connected, select **Server Settings** for the desired network using **Menu>Setup>Service** >Input the Service password>**Institutional Defaults>Monitor>Interfaces.** Input the Server IP address and Server Port of the network with which you want to interface.

Please note that configuring a network to work with the device can only be performed by a qualified service technician. Consult Capnographytechnicalsupport@medtronic.com for more information.

Table 23. Wireless Specifications

Issue	Value
Wireless certification	FCC certified: TFB-TIWI1-01 and IC 5969A-TIWI101

Frequency for wireless connection	2.4GHz (2.412GHz - 2.484GHz)
Wireless bandwidth	Bandwidth divided into 14 channels, where each channel has a 20MHz bandwidth
Wireless protocol specification	IEEE 802.11b/g/n
Max Tx power	< 10dBm
Rx sensitivity	-89 dBm, 11 Mbps, CCK (b) -76 dBm, 54 Mbps, OFDM (g) -73 dBm, 65 Mbps, OFDM (n)
Available modulation types	CCK and OFDM

The device can connect using three different types of Communication Protocols; the user can choose the desired protocol via: **Menu>Setup >Service** >Input the Service password>**Institutional Defaults>Monitor>Interfaces.** Select the desired Comm Protocol Mode. Reference *11.1.7.2 Interface settings* on page 229; the list of protocols appears in that table.

WARNING
Only use Covidien-approved hardware or remote monitoring software for data port connectivity.

WARNING
Use the appropriate configuration information to ensure proper connectivity.

WARNING
If there are changes to the network with which you are

connecting the device, verify that changes are reflected in the device to ensure connectivity.

5.4.4. Vital Sync™

The Vital Sync™ Virtual Patient Monitoring Platform is Covidien's EMR connectivity and remote continuous patient monitoring software solution that allows clinicians to remotely view patient information from multiple device categories on web enabled devices and send this information to electronic medical records and Clinical Information Systems.

The monitor may be used for data transfer to a Covidien Vital Sync™ system. This option permits regular, real-time transfer of data from the monitor to a Vital Sync™ system.

Before beginning the connection process, ensure that the following equipment is available:

- Server with Vital Sync™ system installed and WiFi capability
- Capnostream™35 monitor

Data is transferred from Capnostream™35 to the Vital Sync™ system via WiFi; therefore connecting the monitor to the system is done using the WiFi configuration procedure described in *5.4.3.2 Configuring WiFi* on page 167.

Take the following steps to configure the WiFi connection for Vital Sync™:

1. Navigate to and select **Setup** on the Menu Screen.

2. Navigate to and select **Service** on the Setup Menu Screen.

3. Input Service password and click **Done**.

4. Input the following settings: In **Institutional Defaults>Monitor>Interfaces**, the Comm Protocol Mode should be **Capnostream**. In **Institutional Defaults>Monitor>Interfaces>Server Settings**, input the **Server Port number** and the **Server IP Address**.

5. Click the **Back** button until you return to the main Service screen (reference *Figure 48. Service Mode Screen* on page 177). Navigate to and select the connectivity icon on the service screen to open the Service Connectivity screen.

6. Navigate to the Wifi Connection section of the screen and click the **On** button.

7. Navigate to and click the **Configure** button in the WiFi Connection section of the screen.

8. The Service WiFi Configuration screen will open. Navigate to and select the Vital Sync™ network on the list of available networks. If the network does not require any security information, click **Connect** to connect to the network.

9. If the network requires security information, follow the instructions in *5.4.3.2 Configuring WiFi* on page 167, and then click **Connect** to connect to the network.

When the Vital Sync™ network is successfully added, data will be transferred automatically from the Capnostream™35 monitor to the Vital Sync™ system.

The following measurement data is transferred:

- $EtCO_2$
- SpO_2
- Resp rate
- Pulse rate
- CO_2 waveform

For more information regarding the Covidien Vital Sync™ system, consult the user guide supplied with the Vital Sync™ system or your local representative.

Please note that the most recent configuration of the device will supersede previous configurations of the device, whether the configuration is done on the device itself or via Vital Sync™.

5.4.5. Printed Reports

Report printing is done via an external printer after storing a report using a USB device or micro SD card as described in *5.4 Data Transfer*, above.

6. Preventive Maintenance

6.1. Introduction

Contact your local Service Center or refer to the Service Manual for service instructions and performance tests and checks. Maintenance should be performed by qualified service technicians only. Contact Capnographytechnicalsupport@medtronic.com for additional information.

When the monitor is in Service Mode, no alarms, whether patient or equipment, will sound.

6.2. Monitor Service Hours

The number of hours the monitor may continue working before service is required and before calibration is required appears in the main Service Mode screen; an example is seen in *Figure 48. Service Mode Screen* on page 177.

In addition to required service as described above, regular maintenance and safety checks should be scheduled with a qualified service technician every 24 months. Contact Capnographytechnicalsupport@medtronic.com for additional information.

Battery back-up time of the Li-ion battery may degrade over a period of time. To avoid degradation of battery capacity, it is recommended that the battery pack be replaced every two years. This should be part of the regular maintenance and safety checks scheduled every 24 months.

This information can be viewed on the service screen by clicking the Menu button on the front panel of the monitor and then Setup>Service. Enter the service password (reference *13.1 Monitor Service Password* on page 247) and click Done to open the Service Mode screen. Use the right arrow to move to the center of the screen and use the down arrow to scroll down to the relevant section, in which the following information is provided:

- **CO_2 Hours Remaining Before Service**
- **CO_2 Hours Remaining Before Calibration**
- **CO_2 Last Calibration**

Figure 48. Service Mode Screen

6.3. CO_2 Calibration

The unit is calibrated when it leaves the factory.

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

CO_2 monitoring on the monitor will enter standby mode automatically in cases when the monitor is left on for 30 minutes or longer without a FilterLine attached. This automatic standby mode reduces the need for frequent calibration in use cases in which the monitor is left on for long periods of time without a FilterLine attached. In these cases, time periods in which a monitor is turned on but a FilterLine is not attached will not count towards time to calibration, thus preventing the need for unnecessary calibrations.

Caution:
The calibration must be performed with a manufacturer authorized Calibration Kit containing a gas mixture of 5% CO_2 21% O_2 and Bal N_2 and the authorized connecting means ("T" piece).

A manufacturer-approved Calibration Kit can be purchased from Scott Medical (part numberT4653ORF-2BD). It includes:

- **Calibration Gas containing 5% CO_2, 21% O_2 Bal N_2**
- **Tubing Adapter ("T" Piece)**
- **Calibration Line (Calibration FilterLine)**

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

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

Calibration shall be performed as follows:

1. **Click the Menu button on the front panel of the monitor.**
2. **Navigate to and select Setup on the Menu screen.**
3. **Navigate to and select Service on the Setup Menu screen.**
4. **Input Service password and click Done.**

5. Select **CO_2 Cal.**

6. Select **Start** and follow the instructions on the screen.

7. The instructions on the screen will guide you regarding the rest of the process, including results, until you reach the screen which will provide you with calibration results.

6.4. CO_2 Calibration Check

Caution:
The calibration check must be performed with a manufacturer authorized Calibration Kit containing a gas mixture of 5% CO_2 21% O_2 and Bal N_2 and the authorized connecting means ("T" piece).

A manufacturer-approved Calibration Kit can be purchased from Scott Medical (part numberT4653ORF-2BD). It includes:

- **Calibration Gas containing 5% CO_2, 21% O_2 Bal N_2**
- **Tubing Adapter ("T" Piece)**
- **Calibration Line (Calibration FilterLine)**

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

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

6.4.1. Calibration Check Procedure

Note:
At any stage in the Calibration Check procedure, you

can go back to the first screen by clicking the **Back** button on the front panel.

The Calibration Check process includes the following steps:

1. **Click the Menu button on the front panel of the monitor.**
2. **Navigate to and select Setup on the Menu screen.**
3. **Navigate to and select Service on the Setup Menu screen.**
4. **Input Service password and click Done.**
5. **Select CO_2 Cal.**
6. **Select Cal Check and follow the instructions on the screen.**
7. **Connect a FilterLine to the monitor and click Start.**
8. **Follow the instructions on the screen and click Continue, or click Abort to stop the Calibration Check.**

The instructions on the screen will guide you regarding the rest of the process, including results.

6.5. Operations Log

The monitor provides the option of accessing a monitor operations log for troubleshooting, maintenance and other purposes.

The Operations log can be accessed as follows:

1. **Click the Menu button on the front panel of the monitor.**
2. **Navigate to and select Setup on the Menu screen.**
3. **Navigate to and select Service on the Setup Menu screen.**
4. **Input Service password and click Done.**

5. Navigate to and select **Software Support** and then **Operations Log**.

6. Navigate to and select drive on which data shall be stored.

7. Select **Start** to begin downloading the data in txt format.

The following information is stored in the Operations Log (with date and time):

- **Institutional defaults settings at turn-on**
- **Any change of settings**
- **Patient Admit/Discharge**
- **Patient IDs**
- **Alarms occurrences**
- **Times in pump-off mode**
- **Error code/messages**
- **User button presses**
- **Times in Temporary/Permanent alarm silence**

The operations log includes a maximum of 4000 entries per category or 30 days of information.

6.6. Service Statistics Report

The monitor provides the option of accessing a Service Statistics Report for troubleshooting, maintenance and other purposes. The report can be stored on USB flash drive or micro SD card as a txt file. This is intended for use by service technicians, who may contact Capnographytechnicalsupport@medtronic.com for more information.

The Service Statistics Report can be stored as follows:

1. **Click the Menu button on the front panel of the monitor.**
2. **Navigate to and select Setup on the Menu screen.**
3. **Navigate to and select Service on the Setup Menu screen.**
4. **Input Service password and click Done.**
5. **Select Software Support>Advanced Support>Service Data.**
6. **Enter Service Mode password and click Done.**
7. **Navigate to and select Output to USB and select the USB device.**

6.7. Maintenance

Contact your local representative to order spare parts, calibration kits, or to get answers to any questions regarding service and periodic maintenance.

6.8. Cleaning

Germicidal disposable cloth wipes, or wipes moistened with Isopropyl alcohol or 96% Ethanol may be used to clean the monitor. Cleaning with a wipes moistened with these solutions should be followed by wiping the monitor with distilled water. Caustic or abrasive cleaners should not be used to clean the monitor.

Read the Instructions for Use enclosed with each reusable SpO_2 sensor before attempting to clean the sensor. Follow the sensor cleaning and disinfecting procedures in the particular sensor's Instructions for Use. SpO_2 sensors which are not reusable should not be cleaned. All Microstream CO_2 sampling lines are not reusable and should not be cleaned.

WARNING:

The device is not sterile. Do not autoclave or sterilize this device.

Caution:

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

Caution:

Do not use caustic or abrasive cleaners, or harsh solvents, including petroleum-based or acetone solutions, to clean the device.

Caution:

Microstream™ etCO_2 consumables are designed for single patient use and are not to be reprocessed. Do not attempt to clean, disinfect or blow out the FilterLine as the monitor can be damaged.

Caution:

Do not expose SpO_2 sensor connector pins to cleaning solution as this may damage sensor.

7. Troubleshooting

7.1. Electrical Issues

Problem	Possible Cause	Action
Monitor does not turn on.	Internal battery is totally discharged and power cable is improperly attached or disconnected, or cable has faulty electrical connection.	Check power cable connection. Ensure that batteries are charging (the indicator on the home screen will indicate if the batteries are charging). If the power cable connection is working, a technician should be called to replace the battery. If there is a battery problem, the battery LED on the front panel of the monitor will be red. Reference *3.2.5 Battery and AC Connections Indicators* on page 50.
	AC wall outlet has no power and internal battery is not charged.	Check connections and correct problem.
AC mains power and monitor on indicator lights are on, but unit will not	Battery pack not correctly placed into monitor.	Open the battery housing and check that the battery pack cable is firmly connected to the battery socket. Reference *3.2.2*

Problem	Possible Cause	Action
operate on battery power when the AC mains power cable is disconnected.		*Removable Battery Pack Installation* on page 47.
Battery is not fully charged after being plugged in for 24 hours.	Battery pack has not recharged completely.	Unplug the monitor from AC power for 3-4 hours, and then plug in again. The battery pack will now recharge completely when connected to AC power. If the battery pack still does not recharge completely, replace the battery pack.

7.2. CO_2 Problems

Problem	Possible Cause	Action
NO BREATH message appears constantly and red alarm indicator flashes.	Physiological cause.	Check patient.
	Clogged or blocked FilterLine.	Check sampling line and replace if blocked.
	FilterLine caught in something or tube is kinked.	Check the sampling line from the monitor all the way to the patient to see if line is kinked, twisted closed or caught in bed or equipment.

Problem	Possible Cause	Action
FilterLine connected but pump is not working and no CO_2, $etCO_2$ or RR readings are shown.	FilterLine not plugged in properly.	Check that the sampling line plug is fully screwed into the monitor.
	Gold ring worn or dirty.	Check that the gold ring on the end of the sampling line connector is present and not damaged or covered with dirt. Wipe off any dirt or replace sampling line as necessary.
$EtCO_2$ 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.
$EtCO_2$ values are consistently higher or lower than expected.	Improper calibration.	Check calibration. Reference CO2 Calibration Check on page 179.
	BTPS setting turned off.	Check BTPS setting in the institutional settings. Reference *11.1.9 CO2 Parameters* on page 231 for details.

7.3. SpO_2 Sensor

Problem	Possible Cause	Action
No SpO_2 signal: Zero display appears for oxygen saturation and pulse rate.	Sensor not properly connected to monitor or extension cable.	Check that the sensor and extension cable (if used) are properly connected to the monitor.
Replace SpO_2 sensor message appears on screen	SpO_2 board is not receiving information from the cable.	Detach and reattach the SpO_2 sensor and try again. If the message still appears, replace the cable or sensor.
Loss of pulse or SpO_2 signal: Zero display appears 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
	Sensor or sensor extension cable may be a non-Covidien-approved part.	Replace sensor or sensor extension cable with a part approved by Covidien

	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.**
Inaccurate SpO_2 measurements appear.	**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.**

7.4. CO_2 Calibration

Problem	Possible Cause	Action
CALIBRATION REQUIRED message appears on the monitor, but salutation screen shows there are still hours remaining before next calibration.	It has been more than one year since the last CO_2 calibration.	Perform a CO_2 calibration.

7.5. Returning the Monitor

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

To repack the monitor, disconnect the accessories from the monitor. Pack the monitor 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 an unused consumable from the same box or lot as the consumable used at the time of malfunction and return it with the monitor for inspection.

7.6. Technical Assistance

For technical information, contact your local Service Center or write to Capnographytechnicalsupport@medtronic.com.

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

See also the Sales and Support Center>Technical Support area at http://www.covidien.com/rms/brands/microstream.

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

8. Accessories

8.1. Microstream $EtCO_2$ Consumables

H Products (for use in humidified environments) are marked with an asterisk (*) in the table below.

Table 24. Microstream Consumables

Microstream Consumables	
Intubated Consumables	
FilterLine Set Adult/Pediatric	**XS04620**
FilterLine Set Adult/Pediatric 100 unit	**010579**
FilterLine H Set Adult/Pediatric*	**XS04624**
FilterLine H Set Adult/Pediatric 100 unit*	**010580**
FilterLine H Set Infant/Neonatal*	**006324**
FilterLine Set Adult/Pediatric Long	**007768**
FilterLine H Set Adult/Pediatric Long*	**007737**
FilterLine H Set Infant/Neonatal Long*	**007738**
VitaLine H Set Adult/Pediatric*	**010787**
VitaLine H Set Infant/Neonatal*	**010807**
Non-intubated Consumables	

Microstream Consumables	
Smart CapnoLine Plus (O_2 connector)	009818
Smart CapnoLine Plus (O_2 connector) 100 unit	010209
Smart CapnoLine Plus Long (O_2 connector)	010340
Smart CapnoLine Plus Long (O_2 conn) 100 unit	010339
Smart CapnoLine Plus O_2 (O_2 tubing)	009822
Smart CapnoLine Plus O_2 (O_2 tubing) 100 unit	010210
Smart CapnoLine Plus O_2 Long (O_2 tubing)	009826
Smart CapnoLine Plus O_2 Long (O_2 tubing) 100 unit	010341
Smart CapnoLine Pediatric	007266
Smart CapnoLine O_2 Pediatric (O_2 tubing)	007269
Smart CapnoLine O_2 Ped Long (O_2 tubing)	007743
Smart CapnoLine H Plus O_2 (O_2 tubing)*	010433
Smart CapnoLine H Plus O_2 (O_2 tubing) 100 unit*	010625
Smart CapnoLine H Plus O_2 Long (O_2 tubing)*	012463
Smart CapnoLine H O_2 Pediatric (O_2 tubing)*	010582
Smart CapnoLine H O_2 Pediatric Long (O_2 tubing)*	012464
Smart CapnoLine Guardian (O_2 connector)	012528
Smart CapnoLine Guardian (O_2 connector) 100 unit	012537
Smart CapnoLine Guardian O_2 (O_2 tubing)	012529
Smart CapnoLine Guardian O_2 (O_2 tubing) 100 unit	012538

Microstream Consumables	
Smart CapnoLine Guardian O_2 long (O_2 tubing)	012530
Smart CapnoLine Guardian O_2 long (O_2 tubing) 100 unit	012539
Hook and Loop Strap	012542
O_2/CO_2 Nasal FilterLine Adult (O_2 tubing)	006912
O_2/CO_2 Nasal FilterLine Adult (O_2 tubing) 100 unit	010304
O_2/CO_2 Nasal FilterLine Adult Long (O_2 tubing)	007739
O_2/CO_2 Nasal FilterLine Adult Long (O_2 tubing) 100 unit	010344

8.2. Available Accessories

See the list of available accessories for the monitor below.

Table 25. Monitor Accessories

Accessory	Covidien Part Number	Use
Extra battery	PM35BTY	Battery for monitor available for purchase separately
Charger	PM35CHG	External charger for monitor battery
AC adapter	PM35PSP1	AC adapter for monitor with power cord for use in the EU

		available for purchase separately
AC adapter	**PM35PSP2**	**AC adapter for monitor with power cord for use in the US available for purchase separately**
Pole Clamp	**PM03898**	**Connecting monitor with the Pole Clamp (VESA mounting kit is also required for connection)**
VESA kit (including mounting plate, adapter and screws)	**PM35VAA**	**Connecting monitor with a VESA mount**

9. Theory of Operations

9.1. Introduction

The Capnostream™35 Portable Respiratory monitor provides accurate, continuous capnography and pulse oximetry monitoring for intubated and non-intubated patients from neonate to adult. Using Microstream™ technology, patented FilterLine™ $etCO_2$ consumables, and Covidien Nellcor pulse oximetry technology, the monitor allows for simultaneous "hassle free" $etCO_2$ and SpO_2 monitoring.

9.2. Features

The monitor's features include:

- **Dual parameter monitor that supports the current standard of care providing CO_2 and SpO_2 measurements**
- **Integrated Pulmonary Index™ (IPI), which provides a simple, clear, and comprehensive indication of a patient's ventilatory status and trends**
- **Apneas per Hour and Oxygen Desaturation Index, indices used to help in the identification and quantification of apnea and oxygen desaturation events (if available)**
- **Simple user interface with color screen**
- **Routine functions are accessed with 2 clicks**
- **48 hour trends to review patient history**
- **Alarm review**

- **SARA™ (Smart Alarm for Respiratory Analysis), an embedded Smart Capnography alarm management technology, which reduces clinically insignificant alarms**

- **SatSeconds™ alarm management parameter, which monitors both degree and duration of desaturation as an index of desaturation severity, in order to help distinguish clinically significant events from minor and brief desaturations that may result in nuisance alarms.**

- **Event marking to compare events and medication administration to changes in patient status**

- **Case recording to help organize patient files**

- **Output to transfer patient data to USB flash memory devices or micro SD cards**

- **Wireless transfer of data via a WiFi network**

9.3. Technology Overview

This section provides a basic overview of Capnography and Pulse Oximetry.

9.3.1. What is Capnography?

Capnography is a non-invasive method for monitoring the level of carbon dioxide in exhaled breath ($etCO_2$) to assess a patient's ventilatory status.

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 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 microprocessor in the monitor calculates the CO_2 concentration by comparing the signals from both detectors.

9.3.2. What is Pulse Oximetry?

Pulse oximetry is based on: the difference in the absorption of red and infrared light (spectrophotometry) by oxyhemoglobin and deoxyhemoglobin; and 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 Spot Oxygen Saturation (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 low power light emitting diodes (LEDs) in the oximetry sensor serve as light sources; a photodiode serves as the photo detector.

Because oxyhemoglobin and deoxyhemoglobin differ in light absorption, the amount of red and infrared light absorbed by blood is related to hemoglobin oxygen saturation. To identify the oxygen saturation of arterial hemoglobin, the monitor uses the pulsatile nature of arterial flow. During systole, a new pulse of arterial blood enters the vascular bed and blood volume and light absorption increase. During diastole, blood volume and light absorption reach their lowest point. The monitor bases its 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.

Pulse oximetry provides arterial oxygen saturation (SpO_2) and pulse rate of adult, pediatric, and neonatal patients, at all perfusion levels. The pulse oximeter is intended for use during both no motion and motion conditions and for patients who are well or poorly perfused.

10. Product Specifications

10.1. Power Supply

Item	Value
Input Voltage	100-240 VAC
Input Power	100-240VAC, ±10% 50-60 Hz

10.2. Battery

Item	Value
Battery Type	Lithium ion
Battery pack nominal voltage and energy	7.2V; 18.72Wh
Battery Operation	3 hours for removable battery pack; 20 minutes for internal battery pack
Battery Charging Time	Up to 5 hours when the monitor is off and up to 8 hours when the monitor is on, for both batteries
Battery Storage	There are differing requirements depending on how long you store the battery without use: 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.

	If the battery is not fully charged, charge before use. **Long–term storage (3-12 months): The battery pack must be stored in a cold, dry area, not inside the monitor. Its charge decreases over time. To restore the battery pack to full power, recharge the battery before use.** **Reference *3.2.7 Storing the Battery* on page 52 for more details.**

10.3. Controls

Item	Value
Front Panel	**1 Switch for monitor On/Off control** **4 specific function keys** **1 Enter key with directional arrows**

10.4. Display

Item	Value
Screen	**109mm (4.3inch) Color TFT Display** **Pixel Pitch: 0.198 (horizontal) x 0.198(vertical) mm** **Active Display Area: 95.04 (horizontal) x 53.856 (vertical) mm** **Resolution 480 x 272 pixels** **Viewing angle (vertical) 125°** **Viewing angle (horizontal) 140°**

Trace Speed	3.0, 6.3, 12.5 and 25 mm/sec
Waveform sampling rate	77.82 samples/sec for SpO_2 (fixed) 20 samples/sec for Capnography (fixed)
Trend Storage	48 hours with 1 second resolution
Trend Display	Graphical Display: 1h, 2h, 4h, 8h, 12h views Tabular Display intervals: 1 sec, 5 sec, 15 sec, 30 sec, 1 min, 5 min, 15 min, 30 min, 1 hour

10.5. Sound Pressure Data

When measured at a distance of 1 m alarm volume is 45 – 55 dB(A) at minimum audio level and 65 – 80 dB(A) at maximum audio level. To adjust the audio volume level of device, reference *4.5.1 Alarm Volume* on page 61. To make a permanent change to alarm volume, reference *11.1.7.1 Main Monitor settings* on page 228.

10.6. Microstream™ Capnography

Item	Value
CO_2 Units	mmHg or kPa or Vol%
CO_2, $etCO_2$ Range	0-150 mmHg
CO_2 Waveform Resolution	0.1 mmHg
$EtCO_2$ Resolution	1 mmHg

CO_2 Accuracy	**0-38 mmHg: ± 2 mmHg** **39-150 mmHg: ± (5% of reading + 8% for every 1 mmHg above 38 mmHg)** **Accuracy applies for breath rates of up to 80 bpm. For breath rates above 80 bpm, accuracy is 4 mmHg or ±12 % of reading whichever is greater, for $EtCO_2$ values exceeding 18 mmHg.**
Respiration Rate Range	**0-150 bpm**
Respiration Rate Accuracy	**0-70 bpm: ±1 bpm** **71-120 bpm: ±2 bpm** **121-150 bpm: ±3 bpm**
CO_2 Alarms	**No breath, $EtCO_2$ high, $EtCO_2$ low, RR high, RR low, IPI low (IPI also requires pulse oximetry information)**
Flow Rate	**50 (42.5 ≤ flow ≤ 65) ml/min, flow measured by volume**
Waveform Sampling	**20 samples/s**
Rise Time	**<190ms when used with sampling lines up to 4m length**
Response Time	**3.4s (typical); with use with 4m sampling lines, ~5.0 s**
Initialization Time	**40 s (typical)**
Calibration Interval	**Initially calibrate after 1,200 operating hours, then once a year or after 4,000 operating hours, whichever comes first**

10.7. Nellcor Oximax™ Pulse Oximetry

Item	Value
SpO_2 Measurement Range	1-100%
SpO_2 Accuracy[1]	
Adult and Pediatric Modes	
SpO_2 range 70% - 100%[2,,3,6,7]	±2 digits over the range of 70 to 100% (when using the accessories defined in this document), including under low perfusion; with motion, ±3 digits; with low saturation (60-80%) ±3 digits
Infant/Neonatal Mode	
SpO_2 range 70% - 100%[4,5]	±2 digits over the range of 70 to 100% (when using the accessories defined in this document), with motion ±3; with low saturation (60-80%) ±3
Pulse Rate Range	20 to 250 beats per minute Pulse Rate values of < 20 beats per minute shall be displayed as 0 beats per minute Pulse Rate values of > 250 beats per minute shall be displayed as 250 beats per minute.
Pulse Rate Accuracy[2,3,4,6,7]	±3 digits over the range of 20 to 250 beats per minute inclusive, including under low perfusion; with motion, 48 to 127 bpm ±5 digits

Alarms	**SpO_2 High, SpO_2 Low, PR High, PR Low**
Sat Sec Range	**10-100**

1. Saturation accuracy varies by sensor type. Refer to the Sensor Accuracy Grid at www.covidien.com/rms.

2. Accuracy specifications were validated using measurements of healthy non-smoking adult volunteers during controlled hypoxia studies spanning the specified saturation ranges. Subjects were recruited from the local population and comprised both men and women ranging in age from 18-50 years old, and spanned a range of skin pigmentations. Pulse oximeter SpO_2 readings were compared to SaO_2 values of drawn blood samples measured by hemoximetry. All accuracies are expressed as ±1 SD. Because pulse oximeter equipment measurements are statistically distributed, about two-thirds of the measurements can be expected to fall in this accuracy (ARMS) range (refer to the Sensor Accuracy Grid for more details).

3. Adult specifications are shown for OXIMAX MAXA and MAXN sensors with the Nellcor™ Bedside Respiratory Patient Monitoring System.

4. Neonate specifications are shown for OXIMAX MAXN sensors with the Nellcor™ Bedside Respiratory Patient Monitoring System.

5. Clinical functionality of the MAXN sensor has been demonstrated on a population of hospitalized neonate patients. The observed SpO_2 accuracy was 2.5% in a study of 42 patients with ages of 1 to 23 days, weight from 750 to 4,100 grams, and 63 observations made spanning a range of 85% to 99% SaO_2.

6. Specification applies to Nellcor™ Bedside Respiratory Patient Monitoring System oximeter performance. Reading accuracy in the presence of low perfusion (detected IR pulse modulation amplitude 0.03% - 1.5%) was validated using signals supplied by a patient simulator. SpO_2 and pulse rate values were varied across the monitoring range over a range of weak signal conditions and compared to the known true saturation and pulse rate of the input signals.

7. Motion performance was validated during a controlled hypoxia blood study. Subjects performed rubbing and tapping movements 1-2 cm in amplitude with aperiodic intervals (randomly changing) with a random variation in frequency between 1-4 Hz. Applicability: OXIMAX MAXA, MAXAL, MAXP, MAXI, and MAXN sensors.

Contact Covidien or a local Service Center for a Nellcor™ Oxygen Saturation Accuracy Specification Grid listing all of the Nellcor™ sensors used with the monitoring system. A soft copy is available at www.covidien.com.

10.8. Alarms

Item	Audible Alarm	Visual Alarm
High Priority Alarm	Beep pattern repeated every 5 seconds.	Flashing Red LED
Medium Priority Alarm	Triple beep repeated every 10 seconds	Flashing Yellow LED
Advisories Alarm	No audible alarm	No LED

10.9. General Characteristics

Item	Value
Unit Dimensions	213 mm (w) x 137 mm (h) x 55 mm (d) [8.4 in (w) x 5.4 in (h) x 2.2 in (d)]
Unit Weight	1.0 kg (2.2 lb.)
Packaged Dimensions	370mm (w) x 200mm (h) x 125mm (d) (14.6in (w) x 7.9in (h) x 4.9in (d)
Packaged Weight	2.10 kg (4.6 lb.)
Operating Temperature	0° C to 40° C (32° F to 104° F) The monitor shall function for at least 20 minutes when placed in an environment with an ambient temperature of -20° C (-4° F) to 50° C (122° F).
Operating Pressure and Altitude	1250 feet (381m) below sea level to 15000 feet (4572m) above sea level (430 mmHg to 795 mmHg) without power supply 1250 feet (381m) below sea level to 9843 feet (3000m) above sea level (430 mmHg

Item	Value
	to 795 mmHg) with power supply
Operating Humidity	Ambient, non-condensing, relative humidity in the range of 10% to 95%
Storage and Transport Temperature	-20° C to +70° C (-4° to 158°F)
Storage and Transport Pressure and Altitude	Stored at altitudes in the range of 1250 feet (381m) below sea level to 50000 feet (15,240m) above sea level (430 mmHg to 795 mmHg).
Storage and Transport Humidity	Ambient, non-condensing, relative humidity in the range of 10% to 90%.
Boot-up Time	Up to 60 seconds
Stabilization Time (from storage to operational conditions)	Up to 2 hours

10.10. Equipment Classification

Item	Value
Types of Protection against Electric Shock	Class 2
Degree of Protection against Electric Shock	Defibrillator-Protected Type BF
Mode of Operation	Continuous
Degree of protection against matter and water ingress	The monitor enclosure is IP54 protected (protected against dust and splashing water) when all port doors are closed.

	The level of protection against dust is reduced from level 5 to level 3 (protected against foreign solid objects above 2.5mm in diameter) when used with the SpO2 sensors noted in Table 7. Nellcor SpO_2 Sensor Models and Patient Sizes on page 86 for EMS environment.

10.11. Compliance

This product is designed to conform to the following standards:

- **IEC 60601-1**
- **IEC 60601-1-2**
- **IEC 60601-2-49**
- **IEC 60601-1-12**
- **IEC 60601-1-6**
- **IEC 60601-1-8**
- **ISO 80601-2-61**
- **ISO 80601-2-55**
- **ISO 15223-1**
- **Waste Electrical and Electronic Equipment (WEEE) Directive 2002/96/EC**
- **Directive on the restriction of the use of certain hazardous substances (ROHS) in electrical and electronic equipment - 2011/65/EU**
- **IEC 62133**
- **UN 38.3**

- **EN 301 489-1 V1.9.2**
- **RTCA/DO-160F**
- **IATA Lithium Battery Guidance Document - Transport of lithium Metal and Lithium Ion Batteries**

10.12. Electromagnetic Immunity

The monitor complies with IEC 60601-1-2.

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.

Table 26. Guidance and Manufacturer's Declaration - Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions 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 other than domestic 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	Complies	

Voltage fluctuations/ flicker emissions IEC 61000-3-3	**Complies**	

Table 27. Guidance and Manufacturer's Declaration – Electromagnetic Immunity

Immunity Test	IEC 60601 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**	**Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.**
Electrical fast transient/burst IEC 61000-4-4	**± 2 kV 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 or hospital environment.**
Surge IEC 61000-4-5	**± 1 kV line(s) to line(s)** **± 2 kV line(s) to earth**	**± 1 kV line(s) to line(s)** **± 2 kV line(s) to earth**	**Mains power quality should be that of a typical commercial or hospital environment.**

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	**<5 % UT[1]** **(>95 % dip in UT) for 0,5 cycle** **40 % UT (60 % dip in UT) for 5 cycles** **70 % UT (30 % dip in UT) for 25 cycles** **<5 % UT (>95 % dip in UT) for 5 s**	**<5 % UT** **(>95 % dip in UT) for 0,5 cycle** **40 % UT (60 % dip in UT) for 5 cycles** **70 % UT (30 % dip in UT) for 25 cycles** **<5 % UT (>95 % dip in UT) for 5 s**	**Mains power quality should be that of a typical commercial or hospital environment. If the user of the monitor requires continued operation during power mains interruptions, it is recommended that the monitor be powered from an uninterruptible power supply or a battery.**
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.**
Conducted RF IEC 61000-4-6	**3 Vrms 150 kHz to 80 MHz**	**3 V**	**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**
61000-4-3	**20 V/m, 1 kHz modulation 80 MHz to 2.5 GHz (per ISO 80601-2-55, 1st ed.)**	**20 V/m**	

			distances: **150 kHz to 80 MHz: $d = 1.2\sqrt{P}$** **80 MHz to 800 MHz: $d = 1.2\sqrt{P}$** **800 MHz to 2.5 GHz: $d = 2.3\sqrt{P}$** **where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).[2]** **Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.[ab]** **Interference may occur in the vicinity of equipment marked with the following symbol:** 

[1] UT is the a.c. mains voltage prior to application of the test level.

[2] At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE: These guidelines may not apply in all situations.

Electromagnetic propagation is affected by absorption and reflection from structures, objects and people
[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 [V1] V/m.

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

Table 28.Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the Monitor

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter in m1		
	150 kHz to 80 MHz d= $1.2\sqrt{P}$	80 MHz to 800 MHz d= $1.2\sqrt{P}$	800 MHz to 2,5 GHz 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	7.27

100	**12**	**12**	**23**

For transmitters rated at a maximum output power not listed above, the recommended 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.

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

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

11. Institutional Settings

11.1. Institutional Defaults

Institutional Defaults provide a way for users at a particular institution to maintain settings as determined by their own institution even when the monitor is turned off. For example, if a monitor is in use in a department that requires specific alarm limits, specific event names, or any other setting, on a regular basis, this can be set up in institutional settings. This avoids the need to constantly change settings.

11.1.1. Changing Institutional Defaults

WARNING:
Changing the settings might adversely affect the monitoring of patients. Changes to the Institutional settings must only be made by authorized personnel.

Patients will not be monitored while in service mode, even if the monitor is connected to a patient. (The monitor is in service mode once the service password is entered.) Therefore, you may want to remove the sampling line from the patient or disconnect the sampling line from the monitor while putting the monitor into service mode. No data will be recorded while the monitor is in service mode, and thus trying to monitor while in service mode will lead to missing data issues.

Institutional Defaults may be changed using the following steps:

1. **Click the Menu button on the front panel of the monitor.**

2. **Navigate to and select Setup on the Setup Menu screen.**

3. Navigate to and select **Service** on the Setup Menu screen.

4. Enter the Service password and select **Done**.

5. Navigate to and select **Institutional Defaults**.

6. Navigate to and select the desired section to update defaults in that section. The sections are: Alarms, Trend, Monitor, Parameters.

7. After any change to the device settings done in service mode, the device will shut down and require a restart.

For specific data regarding these types of Institutional Defaults, reference below.

11.1.2. Institutional Defaults in EMS Mode

Any institutional defaults set while the monitor is in EMS mode will remain relevant only as long as the monitor is in EMS mode. When EMS is disabled, defaults will remain factory defaults (if no changes to Institutional Defaults were ever made when EMS was disabled) or defaults set while EMS was disabled. Likewise, if changes are made to defaults while EMS is disabled, these changes will not be relevant while the monitor is in EMS mode. Thus, if desired, an institution can maintain two sets of Institutional Defaults: one for EMS mode and one for when EMS is disabled.

11.1.3. Reset to Factory Defaults

Reset the monitor to use factory defaults as follows:

1. Click the **Menu** button on the front panel of the monitor.

2. Navigate to and select **Setup** on the Setup Menu screen.

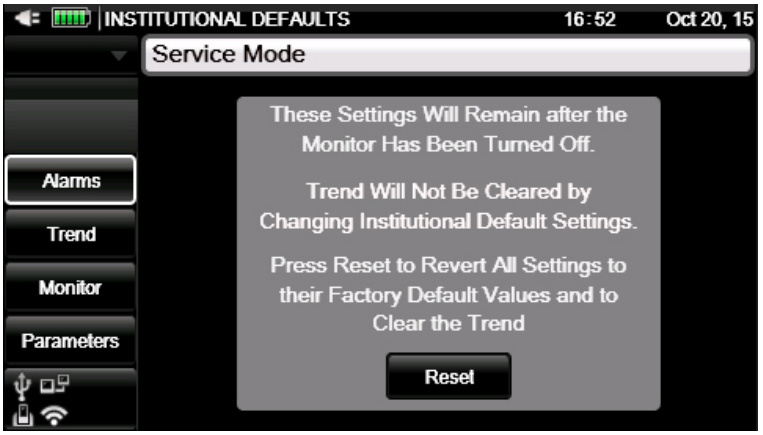
3. Navigate to and select **Service** on the Setup Menu screen.

4. Enter the Service password and select **Done**.

5. Navigate to and select the desired section to update defaults in that section. The sections are: Alarms, Trend, Monitor, Parameters.

The following screen will appear:

Figure 49. Revert To Factory Defaults Screen



6. Select **Reset** to reset all institutional settings to factory defaults.

If you want to reset only one or more sections of the defaults to factory defaults, Navigate to and select the desired section and reset that section only to factory defaults by clicking the **Factory Defaults** button in the relevant section.

In all Institutional Default screens, clicking **Reset** will also clear the trend memory, including the entire patient information database.

11.1.4. Institutional Defaults Export/Import

Institutional Defaults may be exported or imported as follows:

1. Click the **Menu** button on the front panel of the monitor.

2. Navigate to and select **Setup** on the Setup Menu screen.

3. Navigate to and select **Service** on the Setup Menu screen.

4. Enter the Service password and select **Done**.

5. Navigate to and select **Software Support.**

6. Navigate to and select **Software Download>Default Transfer**.

7. Select **Export Defaults** to export current defaults to a USB flash memory drive or SD card, or **Import Defaults** to import defaults from a USB flash memory drive or micro SD card.

8. Select a drive and click **Start**.

9. When the export/import is complete, the monitor will inform you, with the following message: Export Completed, or Import Completed, Shutdown and Restart the Monitor to Resume Normal Operation.

10. Select **Home** to return to the Home screen.

11.1.5. Monitor Alarms Settings

Select **Factory Defaults** in the Inst. Def.: Alarms screen to restore all Alarms Factory Defaults.

11.1.5.1. Alarm Limits

The factory default settings for Adult/Pediatric and Infant/Neonatal alarm limits are given below. Units appear in range column.

Table 29. Factory Default Alarm Limits

Parameter	Adult	All Pediatric Groups	Infant/Neonatal	Alarm Range
$EtCO_2$ High	60	60	60	5-150 mmHg

$EtCO_2$ Low	8	8	20	0-145 mmHg
RR High	50	40	80	5-150 bpm
RR Low	3	10	12	0-145 bpm
No Breath Detected	30	20	15	10-60 sec
SpO_2 High	100	100	98	25-100% saturation
SpO_2 Low	85	85	85	20-95% saturation
Pulse Rate High	140	140	200	25-250 bpm
Pulse Rate Low	50	50	100	20-245 bpm
IPI Low	3	3	N/A	1-9 or OFF
SatSeconds	100	100	OFF	10, 25, 50, 100 or Off

Under Alarm Limits, any alarms can be enabled or disabled as follows:

1. **Click the Menu button on the front panel of the monitor.**
2. **Navigate to and select Setup on the Menu screen.**
3. **Navigate to and select Service on the Setup Menu screen.**
4. **Input the Service password and select Done.**
5. **Navigate to and select Institutional Defaults>Alarms.**
6. **Navigate to and select an Alarm Limits set which includes the relevant alarm.**

7. Navigate to and select the relevant alarm.

8. Navigate to and select the **Enable** button to enable the alarm if it is currently disabled. If the relevant alarm is currently enabled, the button will show **Disable**. Select the Disable button to disable the alarm. If the relevant alarm is currently disabled, the button will show **Enable**. Select the **Enable** button to enable the alarm.

This change will be implemented only for the particular set in which it was made, but not in other sets. For example, if you disable the RR High alarm for pediatric patients, Age 1-3 years, it will still be available for other pediatric patients and for adult patients.

If the alarm limit to be changed is IPI, note that only the following Alarm Limits sets include IPI: either Pediatric 1-3 Years Alarm Limits, Pediatric 3-6 Years Alarm Limits, Pediatric 6-12 Years Alarm Limits, or Adult Alarm Limits. IPI is not available for Infant/Neonatal Patients.

11.1.5.2. Alarm Priority settings

Parameter	Choices	Factory Default
$EtCO_2$ High	Medium, High	High
$EtCO_2$ Low	Medium, High	High
RR High	Medium, High	High
RR Low	Medium, High	High
No Breath Detected	Medium, High	High
SpO_2 High	Medium, High	High
SpO_2 Low	Medium, High	High
Pulse Rate High	Medium, High	High
Pulse Rate Low	Medium, High	High

IPI Low	**Medium, High**	**High**
CO_2 Error	**Medium, High**	**Medium**
Pulse Not Found	**Medium, High**	**Medium**
FilterLine Blockage	**Medium, High**	**Medium**
Battery Low	**Medium, High**	**Medium**
Communications Stopped	**Medium, High**	**Medium**
System Reset – Check Settings	**Medium, High**	**Medium**
SpO_2 Error	**Medium, High**	**Medium**
SpO_2 Sensor Not On Patient	**Medium, High**	**Medium**
Replace SpO_2 Cable	**Medium, High**	**Medium**
Check SpO_2 Sensor Connection	**Medium, High**	**Medium**

Alarm Priority settings may be changed as follows:

1. **Click the Menu button on the front panel of the monitor.**
2. **Navigate to and select Setup on the Menu screen.**
3. **Navigate to and select Service on the Setup Menu screen.**
4. **Input the Service password and select Done.**
5. **Navigate to and select Institutional Defaults>Alarms>Alarm Priority.**
6. **Navigate to the alarm for which you want to change Alarm Priority and select the desired Alarm Priority level.**

7. Repeat for other alarms as required.

8. Return to the Home Screen by clicking the **Home** button.

11.1.5.3. Display Config settings

The order of the parameters below as they appear on the Alarm Review screen may be changed if desired in Institutional Defaults, to any desired order. The Alarm Review screen displays nine parameters.

Table 30. Parameters Available on the Alarm Review Screen

Parameter
No Breath
CO_2
$EtCO_2$
$EtCO_2$ (spont)
RR
SpO_2
PR
IPI
SatSec

Display Config settings (the order of the parameters as they appear on the Alarm Review screen) may be changed as follows:

1. Click the **Menu** button on the front panel of the monitor.

2. Navigate to and select **Setup** on the Menu screen.

3. Navigate to and select **Service** on the Setup Menu screen.

4. Input the Service password and select **Done**.

5. Navigate to and select **Institutional Defaults>Alarms>Display Config**.

6. The list of parameters that appear on the Alarm Review screen with the factory default order is given in the center of the screen. To change the order, select the parameter you want to show in the first place on the screen for the first line of the list, the parameter you want to show in the second place on the screen for the second line of the list, and so on.

7. This is done by navigating to and clicking on the first line, and then navigating to the desired parameter for the first line, and clicking **Enter**. This will replace only the selected parameter with the parameter you have chosen as your first line; it will not move any parameters down the list.

8. To change the order of additional parameters, repeat as many times as required.

Blank (a dash) may be chosen for any line to view less than nine parameters.

Return to the Home Screen by selecting the Home button.

11.1.5.4. Alarm Delay settings

Alarm delay options for the following alarms are listed below. For all alarms, the alarm delay default is 0 sec; that is, no alarm delay.

Table 31. Alarm Delay Settings

Parameter	Choices	Factory Default
$EtCO_2$ High	0, 10, 15, 20, 30	0 sec

$EtCO_2$ Low	0, 10, 15, 20, 30	0 sec
RR High	0, 10, 15, 20, 30	0 sec
RR Low	0, 10, 15, 20, 30	0 sec
SpO_2 High	0, 10, 15, 20, 30	0 sec
SpO_2 Low	0, 10, 15, 20, 30	0 sec
Pulse Rate High	0, 10, 15, 20, 30	0 sec
Pulse Rate Low	0, 10, 15, 20, 30	0 sec
IPI Low	0, 10, 15, 20, 30	0 sec

Alarm Delay settings may be changed as follows:

1. **Click the Menu button on the front panel of the monitor.**
2. **Navigate to and select Setup on the Menu screen.**
3. **Navigate to and select Service on the Setup Menu screen.**
4. **Input the Service password and select Done.**
5. **Navigate to and select Institutional Defaults>Alarms>Alarm Delay.**
6. **Navigate to the alarm for which you want to change Alarm Delay and select the desired Alarm Delay level.**
7. **Repeat for other alarms as required.**
8. **Return to the Home Screen by clicking the Home button.**

11.1.6. Monitor Trend Settings

Selecting Factory Defaults in the Inst. Def.: Trend screen will restore all Trends Factory Defaults.

Trend Defaults settings may be changed as follows:

1. Click the **Menu** button on the front panel of the monitor.
2. Navigate to and select **Setup** on the Menu screen.
3. Navigate to and select **Service** on the Setup Menu screen.
4. Input the Service password and select **Done**.
5. Navigate to and select **Institutional Defaults>Trend**.
6. Navigate to the trend issue which you want to change and select the desired level.
7. Repeat for other issues as required.
8. Return to the Home Screen by selecting the **Home** button.

Changing the Trend resolution will clear the Trend memory, erasing any patient data that was in the monitor.

11.1.6.1. Main Trend settings

Parameter	Choices	Factory Default
Default Tabular Increment Trend View	1 Sec, 5 Sec, 15 Sec, 30 Sec, 1 Min, 5 Min, 15 Min, 30 Min, 1 Hour	30 Sec
Default Graphical Trend View	1, 2, 4, 8, 12 Hours	4 Hours
Home Screen Trend Display View	1, 2, 4 Hours	1 Hour
Default Event Marking Mode	Quick, Detailed	Detailed
Calendar/Recorded Display Mode	Calendar, Recorded	Calendar

11.1.6.2. Events

11.1.6.2.1. Medication events

The following medication events are currently available in the monitor: Fentanyl, Versed, Midazolam, Morphine, Demerol, Propofol, Surfactant, Other.

If your institution requires different or additional events, events may be added or changed, as seen below.

11.1.6.2.2. Patient events

The following patient events are currently available in the monitor: Eating, Drinking, Coughing, Ambulating, Chest Pt, Turned, Snoring, Other.

If your institution requires different or additional events, events may be added or changed, as seen below.

11.1.6.2.3. Intervention events

The following intervention events are currently available in the monitor: Oxygen, Suction, Adj Airway, Narcan, Romazicon, Neb Tx, Stimulated, CO_2 Insuffl (CO_2 Insufflation), ABG, Other.

If your institution requires different or additional events, events may be added or changed, as seen below.

Event defaults may be changed as follows:

1. **Click the Menu button on the front panel of the monitor.**
2. **Navigate to and select Setup on the Menu screen.**
3. **Navigate to and select Service on the Setup Menu screen.**
4. **Input the Service password and select Done.**
5. **Navigate to and select Institutional Defaults>Trend>Edit Event.**
6. **Select the event type in which you want to make changes.**

7. A list of current event names in this event type category will appear.

8. Navigate to and select the event name you want to change.

9. Input the new name and select **Done**.

10. Select **Back** to retain the change. Select **Home** to return to the Home screen.

11.1.6.3. Trend Display Config settings

The parameters shown or the order of the parameters shown may be changed in Institutional Defaults.

In both the Graphical Trend screen and the Tabular Trend screen, six parameters may be chosen to view; only three parameters can be seen at one time. Blank (a dash) may be chosen for any line to view less than six parameters.

In order to view trend parameters on the screen on a larger proportion of the screen, the following can be done:

When choosing parameters to view, if you select the same parameter for multiple lines in a row, that parameter will appear in a larger portion of the Graphical Trend screen. That parameter will simply be repeated in multiple rows in the Tabular Trend screen.

This process may be done for up to six parameters, so that all six parameters may be viewed in this larger format.

The Tabular Trend stored report shows all parameters, with dashes indicating unavailable parameters. The Graphical Trend stored reports will show only three parameters at a time.

Table 32. Parameters Available on the Trend Screens

Parameter
$EtCO_2$

RR
SpO_2
PR
IPI

Display Config settings (the order of the parameters on trend screens) may be changed as follows:

1. Click the **Menu** button on the front panel of the monitor.
2. Navigate to and select **Setup** on the Menu screen.
3. Navigate to and select **Service** on the Setup Menu screen.
4. Input the Service password and select **Done**.
5. Navigate to and select **Institutional Defaults>Trend>Display Config**.
6. The list of parameters with the factory default order as they appear in trend screens is given in the center of the screen. To change the order, select the parameter you want to show in the first place on the screen for the first line of the list, the parameter you want to show in the second place on the screen for the second line of the list, and so on. This is done by navigating to and clicking on the first line, and then navigating to the desired parameter for the first line, and clicking **Enter**.
7. To change the order of additional parameters, repeat as many times as required.
8. Return to the Home Screen by selecting the **Home** button.

11.1.7. Monitor Settings

Selecting Factory Defaults in the Inst. Def.: Monitor screen will restore all monitor Factory Defaults.

The following monitor settings may be changed in the Institutional Defaults: Monitor screen.

11.1.7.1. Main Monitor settings

Parameter	Choices	Factory Default
Date Format	Dd mmm yy, mmm dd, yy	Mmm dd, yy
Time Format	12 Hour, 24 Hour	12 Hour
Language	English, French, German, Spanish, Italian, Dutch, Portuguese, Russian, Swedish, Norwegian, Japanese	English
Alarm Volume	Maximum, Last Setting, Audio Off	Last Setting
Reminder Signal	Enabled, Disabled	Disabled
Patient Type	Adult, Pediatric 1-3 yrs. Pediatric 3-6 yrs, Pediatric 6-12 yrs, Infant/Neonatal	Adult
Patient Weight Unit	Kg, lbs	lbs
RS232 Function	Standard, VueLink: CO_2 Only, VueLink: IPI; VueLink: IPI, A/hr, ODI	Standard
Brightness Index	5,6,7,8,9,10, Auto	Auto
Parameter Standby Mode	Enabled, Disabled	Disabled

EMS Mode	Enabled, Disabled	Enabled

Main monitor settings may be changed as follows:

1. Click the **Menu** button on the front panel of the monitor.
2. Navigate to and select **Setup** on the Menu screen.
3. Navigate to and select **Service** on the Setup Menu screen.
4. Input the Service password and select **Done**. Navigate to and select **Institutional Defaults>Monitor**.
5. Navigate to the monitor issue which you want to change and select the desired level.
6. Click the **Enter** button to return to the list of issues. For IP Settings, use the **Back** button to return to the list of issues.
7. Repeat for other issues as required.
8. Return to the Home Screen by selecting the **Home** button.

11.1.7.2. Interface settings

Parameter	Choices	Factory Default
RS232 Baud rate	Automatic, 9.6K, 19.2K, 38.4K, 57.6K, 115.2K	Automatic
Comm Protocol Mode	Microcap, Capnostream	Capnostream
English Text Report Format	Unicode	ASCII, Unicode
IP Settings	DHCP Disable, Enable IP address, Subnet Mask, Gateway, DNS	DHCP Enabled

	Server	

Monitor Interface settings may be changed as follows:

1. **Click the Menu button on the front panel of the monitor.**
2. **Navigate to and select Setup on the Menu screen.**
3. **Navigate to and select Service on the Setup Menu screen.**
4. **Input the Service password and click Done. Navigate to and select Institutional Defaults>Monitor>Interfaces.**
5. **Navigate to the monitor interface issue which you want to change and select the desired level.**
6. **Click the Enter button to return to the list of issues. For A/hr Visual Alert Level, use the Back button to return to the list of issues.**
7. **Repeat for other issues as required.**
8. **Return to the Home Screen by selecting the Home button.**

11.1.8. Home Screen Configuration

The device provides the option of choosing a Home Screen configuration that best fits your needs as your default Home Screen configuration. Reference *2.3.5 Monitoring Display Screen Options* on page 24 for a list of configurations.

The default Home screen may be changed as follows:

1. **Click the Menu button on the front panel of the monitor.**
2. **Navigate to and select Setup on the Menu screen.**
3. **Navigate to and select Service on the Setup Menu screen.**

4. Input the Service password and click **Done**. Navigate to and select **Institutional Defaults>Monitor>Home Screen Config**.

5. The first Home Screen option will appear. Using the right directional arrow, scroll between the Home Screen options until you reach the one that you want to use as your default Home Screen.

6. When the chosen Home Screen appears on the screen, click **Enter** to select the chosen screen. If you want to choose more than one default home screen, navigate to another screen and click **Enter** to select that screen as well. When you have chosen the final default home screen, click the down directional button and then the **Enter** button to select **Apply**. The **Institutional Defaults: Monitor** screen will appear.

7. Click **Home** to return to the Home Screen. You will be asked to Shut down the device. When the monitor is turned on again after being turned off, this chosen Home Screen will be the default home screen that appears on the screen. If you choose more than one default screen, you may toggle between the chosen home screens using the directional buttons.

11.1.9. CO_2 Parameters

Institutional Defaults can be set for all CO_2 parameters that are settable in the monitor. To change the parameters, select CO_2 in the Institutional Defaults: Parameters screen.

Note:
Selecting Factory Defaults in the Inst. Def.: Parameters screen will restore all Parameters Factory Defaults.

Parameter	Choices	Factory Default
CO_2 Unit	mmHg	mmHg, kPa, Vol%

BTPS	**On**	**On, Off**
PumpOff Timeout (min)	**15**	**5, 10, 15, 30**
CO_2 Waveform Scale (mmHg)	**60**	**20, 60, 120, 150, Auto**
$EtCO_2$ Trend Display Scale (mmHg)	**50**	**50, 100, 150**
RR Trend Display Scale (bpm)	**50**	**50, 100, 150**
A/hr Visual Alert Level	**10**	**1-99**

*** BTPS denotes the standard correction used during measurement for body temperature, pressure, and saturation. BTPS should be set to ON during all measurement procedures. The monitor automatically turns off the BTPS correction during calibration procedures and turns it on again following these procedures. There is no need for the user to make any changes to the BTPS setting.**

CO_2 Parameters settings may be changed as follows:

1. **Click the Menu button on the front panel of the monitor.**
2. **Navigate to and select Setup on the Menu screen.**
3. **Navigate to and select Service on the Setup Menu screen.**
4. **Input the Service password and select Done. Navigate to and select Institutional Defaults>Parameters>CO_2.**
5. **Navigate to the CO_2 parameter for which you want to make changes and select the desired value.**
6. **Click the Enter button to return to the list of issues. Repeat for other parameters as required.**
7. **Return to the Home Screen by selecting the Home button.**

11.1.10. SpO_2 Parameters

Institutional Defaults can be set for all SpO_2 parameters that are settable in the monitor. To change the parameters, select SpO_2 in the Institutional Defaults screen.

Note:
Selecting Factory Defaults in the Inst. Def.: Parameters screen will restore all Parameters Factory Defaults.

Parameter	Choices	Factory Default
Pulse Tone	On, Off	Off
SpO_2 Scale for Trend Display (%)	0-100, 50-100	50-100
PR Scale for Trend Display (bpm)	150, 300	150
ODI Visual Alert Level	1-99	10

SpO_2 Parameters settings may be changed as follows:

1. **Click the Menu button on the front panel of the monitor.**
2. **Navigate to and select Setup on the Menu screen.**
3. **Navigate to and select Service on the Setup Menu screen.**
4. **Input the Service password and select Done. Navigate to and select Institutional Defaults>Parameters>SpO_2.**
5. **Navigate to SpO_2 parameter for which you want to make changes and select the desired value.**
6. **Click the Enter button to return to the list of issues. Repeat for other parameters as required.**
7. **Return to the Home Screen by selecting the Home button.**

11.1.11. Parameters Settings – Set Colors

The device provides the option to set colors for the parameters seen on the visual display.

1. **Click the Menu button on the front panel of the monitor.**
2. **Navigate to and select Setup on the Menu screen.**
3. **Navigate to and select Service on the Setup Menu screen.**
4. **Input the Service password and click Done. Navigate to and select Institutional Defaults>Parameters>Set Colors.**
5. **Navigate to the parameter for which you want to change color and click the right directional button to select another color. Navigate to the color, click Enter and then navigate to and click Apply.**
6. **Click the Back button to return to the parameters list. Repeat for other parameters as required.**
7. **Return to the Home Screen by selecting the Home button.**

12. Appendix A: Pulse Oximetry Clinical Studies

12.1. Clinical Studies Introduction

This section presents data from clinical studies conducted with the Nellcor™ Bedside Respiratory Patient Monitoring System equipped with the pulse oximetry module used in Capnostream™35.

Prospective clinical studies were conducted in accordance to EN ISO80601-2-61:2011 to demonstrate accuracy of pulse oximetry for Nellcor™ OxiMax sensors used with this pulse oximetry module during both motion and non-motion conditions.

12.2. Clinical Studies Methodology

12.2.1. Hypoxia Methodology (Accuracy, Low Saturation, and Motion Studies)

The general purpose of invasive controlled desaturation study is to validate the SpO_2 and pulse rate accuracy in comparison to reference-standard measurements of blood SaO_2 by a CO-oximeter and ECG heart rate. This is achieved through paired observations of SpO_2 and SaO_2 values over the SaO_2 accuracy range of 70% to 100% on a group of healthy adult volunteers. The fraction of inspired oxygen (FiO_2) delivered to test subjects is varied to achieve a series of targeted steady-state

saturation periods. Arterial blood samples are periodically taken from an indwelling arterial catheter for use in the comparison.

In accordance to EN ISO80601-2-61:2011, desaturation to 70% is conducted in a gradual continuous process targeting multiple saturation plateaus (e.g. 98, 90, 80 and 72%). In these studies, six arterial samples were taken, 20 seconds apart at each plateau, resulting in a total of approximately 24 samples per subject. Each sample was drawn while SpO_2 data were simultaneously collected and marked for direct comparison to CO-oximetry.

End tidal CO_2, respiratory rate, respiratory pattern and electrocardiogram were continuously monitored throughout the study.

12.2.2. Low Saturation Methodology (Low Saturation Study Only)

The methodology and purpose of the Low Saturation study is the same as the hypoxia methodology, 12.2.1 Hypoxia Methodology (Accuracy, Low Saturation, and Motion Studies) on page 235. However, the desaturation is to 60% instead of 70%. This lower saturation is obtained by the addition of a new plateau at 60% SaO_2, increasing the range from 70 to 100% to 60 to 100%. This results in approximately 30 arterial samples instead of 24 for this study.

12.2.2.1. Motion Methodology (Motion Study Only)

Standard motions include tapping and/or rubbing at aperiodic intervals with amplitudes of 1-2 cm and 1-4 Hz with a random variation in frequency to simulate physiological motion. In this study, the subject was instructed to tap with finger tips to maintain consistency of area of effect on the pressure pad and to prevent resting hand on pressure pad between motions so that only qualified taps are recorded by the pressure pad system.

Each plateau (70 to 100%) has both an interval of tapping and rubbing. In this study, the order of tapping and rubbing was alternated between subjects.

Two video cameras were used to capture motion of the subjects. These videos were then reviewed to determine if any data points should be removed if the appropriate amplitudes were not being reached during the blood samples.

12.3. Clinical Studies Results

12.3.1. Accuracy Results (No Motion)

The following summary describes the demographic information of the subjects enrolled into the MAXA, MAXN, and MAXFAST Accuracy and Low Saturation study: A total of 11 subjects were analyzed, 5 (45%) males and 6 (55%) females. The mean age of the subjects was 31.8 ± 5.2 years, with a range of 25 to 42 years of age. Two subjects had dark pigmentation (dark olive to extremely dark). Weight ranged from 49 kg to 103.6 kg, and height ranged from 143.5 cm to 192 cm.

The following summary describes the demographic information of the subjects enrolled into the SC-A Sensor study: A total of 16 subjects were analyzed. There were 6 (37.5%) males and 10 (62.5%) female subjects enrolled into the study. The mean age of study participants was 31.44 ± 6.7 years, with a range of 24 to 42 years of age. Three subjects had dark pigmentation (dark olive to extremely dark). Weight ranged from 48.7 kg to 96.9 kg, and height ranged from 143.5 cm to 188 cm.

The following summary describes the demographic information of the subjects enrolled into the study for all other sensors (listed in Table 33. SpO_2 Accuracy Results (No Motion)): A total of 11 subjects were analyzed. There were 4 (36.4%) males and 7 (63.6%) female subjects enrolled into the study. The mean age of study participants was 30.36 ± 7.85 years, with a range of 22 to 46 years of age. Three subjects had dark pigmentation (dark olive to extremely dark). Weight ranged from 58.4 kg to 114.4 kg, and height ranged from 159 cm to 187 cm.

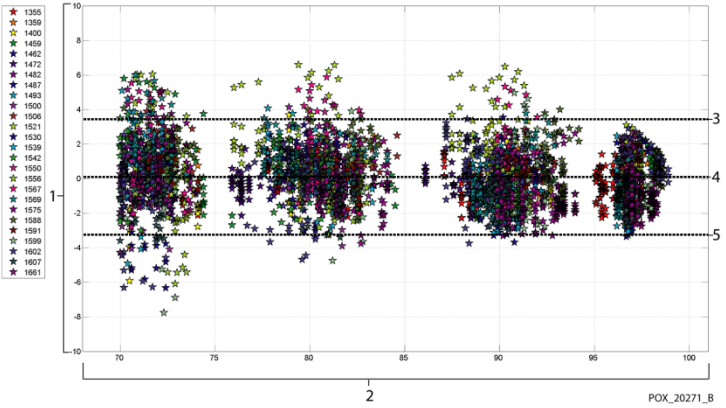
Accuracy results for SpO_2 can be found in *Table 33. SpO2 Accuracy Results (No Motion)*. ARMS (Accuracy root mean square) is used to describe the accuracy of pulse oximetry, which is affected by both bias and precision. As shown in the table, SpO_2 meets the acceptance criteria for all of the listed sensors during non-motion conditions.

Table 33. SpO_2 Accuracy Results (No Motion)

Sensor	Motion	# of Data Points	ARMS (%)	SpO_2 Acceptance Criteria 70%-100% (%)	Pass/Fail
MAXA	No	976	1.54	≤2.0	Pass
MAXN	No	723	1.41	≤2.0	Pass
MAXFAST	No	235	1.42	≤2.0	Pass
SC-A	No	659	1.86	≤2.0	Pass
DS100A	No	411	2.16	≤3.0	Pass
OxiCliq-A	No	480	1.58	≤2.5	Pass
D-YSE	No	458	1.96	≤3.5	Pass

Note:
Each individual subject is represented by a unique color on the plots. Subject identification numbers are indicated in the legend to the left of each plot.

Figure 50. Modified Bland-Altman for SpO_2 (All Data - No Motion): SaO_2 vs. (SpO_2 - SaO_2)



Label	Description
1	SpO_2 - SaO_2 (%)
2	SaO_2 (%)
3	Upper 95% LoA
4	Mean Bias
5	Lower 95% LoA

Pulse oximeters have been known to perform better at the higher saturation levels compared to the lower end. Though, when presenting the ARMS, the common methodology is to provide the data across the whole range (70% to 100%). The data below is presented to show each decade, which includes the RMSD (root mean square difference) and N values. RMSD and ARMS are the same. ARMS is used for pooled data across the whole study to represent accuracy of the system, whereas RMSD is used as the general term. There is no acceptance criteria associated with decade levels of hypoxia, thus represented as RMSD. In *Table 34. RMSD of SpO2 per Decade (No Motion)*, SpO_2 RMSD is presented per decade.

Table 34. RMSD of SpO_2 per Decade (No Motion)

SpO_2 Range	100%-90%	89%-80%	79%-70%
N	1693	1037	1212
RMSD (%)	1.46	1.66	2.01

The plateaus that were used during the study were 70 - 76, 76.01 - 85, 85.01 - 94 and >94%, as presented in *Table 35. RMSD of SpO2 per Plateau (No Motion)*, below.

Table 35. RMSD of SpO_2 per Plateau (No Motion)

SpO_2 Range	Room Air Plateau	90% Plateau	80% Plateau	70% Plateau
N	978	1102	1034	828
RMSD (%)	1.27	1.65	1.69	2.15

12.3.2. Clinical Studies Accuracy Results (Low Saturation)

The accuracy results for SpO_2 can be found in *Table 36* across a SaO2 range of 60 to 80%. As shown in the table, SpO_2 meets the acceptance criteria for the MAXA, MAXN, and MAXFAST sensors during low saturation conditions.

Table 36. SpO_2 Accuracy Results (60 to 80% SaO_2, low saturation)

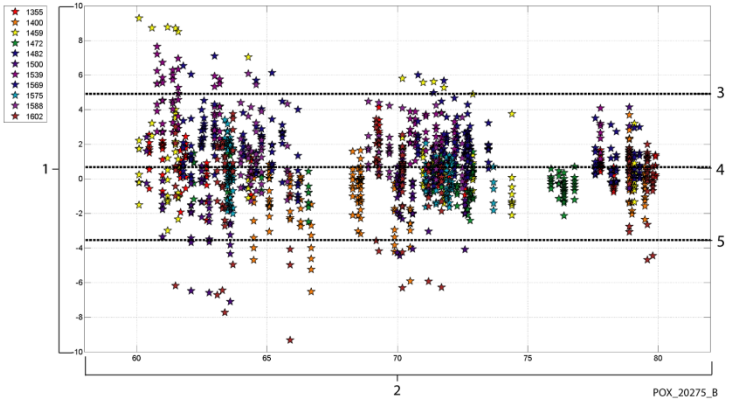
Sensor	Motion	# of Data Points	ARMS (%)	SpO_2 Acceptance Criteria 60%-80%	Pass/Fail

				(%)	
MAXA	No	610	2.40	≤3.0	Pass
MAXN	No	453	1.92	≤3.0	Pass
MAXFAST	No	143	2.41	≤3.0	Pass
ALL	No	1206	2.24	≤3.0	Pass

Modified Bland-Altman plots for all the data are presented in *Figure 51. Modified Bland-Altman for SpO2 (All Data - Low Saturation): SaO2 vs. (SpO2 - SaO2)*.

Note:
Each individual subject is represented by a unique color on the plots. Subject identification numbers are indicated in the legend to the left of each plot.

Figure 51. Modified Bland-Altman for SpO_2 (All Data - Low Saturation): SaO_2 vs. (SpO_2 - SaO_2)



Label	Description

1	SpO_2 - SaO_2 (%)
2	SaO_2 (%)
3	Upper 95% LoA
4	Mean Bias
5	Lower 95% LoA

In *Table 37,* SpO_2 RMSD is presented per decade. In the following table, *Table 38*, RMSD is presented per plateau.

Table 37. RMSD of SpO2 per Decade (Low Saturation)

SpO_2 Range	80%-70%	69%-60%
N	637	569
RMSD (%)	1.73	2.69

Table 38. RMSD of SpO_2 per Plateau (Low Saturation)

SpO_2 Range	70% Plateau	60% Plateau
N	506	483
RMSD (%)	1.93	2.79

12.3.3. Clinical Studies Accuracy Results (Motion)

The following describes the demographic information of the subjects enrolled into the study: A total of 14 subjects were analyzed, 5 (35.7%) males and 9 (64.3%) female subjects. The mean age was 31.57 ± 6.8 years, with a range of 24 to 42 years of age. Three subjects had dark pigmentation (dark olive to extremely dark). Weight ranged from 48.7 kg to 88.6 kg, and height ranged from 143.5 cm to 185 cm.

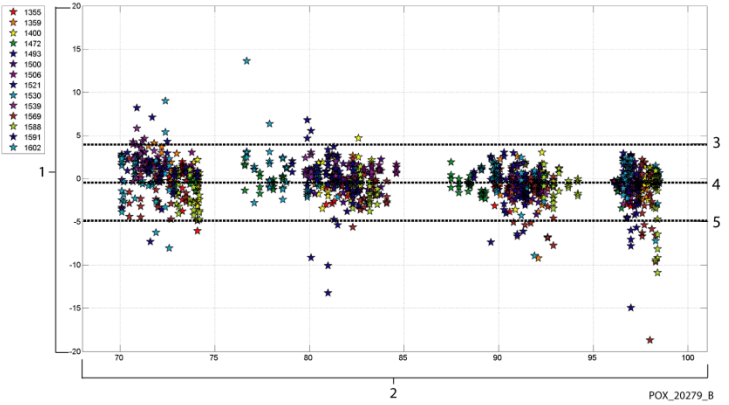
The accuracy results for both SpO_2 and pulse rate during motion are presented in *Table 39*. As shown in the table, SpO_2 meets the acceptance criteria for both the MAXA and MAXN sensor during motion.

Table 39. SpO_2 Accuracy Results during Motion

Sensor	Motion	# of Data Points	ARMS (%)	SpO_2 Acceptance Criteria 70%-100% (%)	Pass/Fail
MAXA	Yes	637	1.70	≤3.0	Pass
MAXN	Yes	618	2.76	≤3.0	Pass
ALL	Yes	1255	2.28	≤3.0	Pass

A modified Bland-Altman plot for the data is presented in *Figure 52. Modified Bland-Altman for SpO2 (All Data - Motion): SaO2 vs. (SpO2 - SaO2)*.

Figure 52. Modified Bland-Altman for SpO_2 (All Data - Motion): SaO_2 vs. (SpO_2 - SaO_2)



Label	Description
1	SpO_2 - SaO_2 (%)
2	SaO_2 (%)
3	Upper 95% LoA
4	Mean Bias
5	Lower 95% LoA

Pulse oximeters have been known to perform better at the higher saturation levels compared to the lower end. Though, when presenting the ARMS, the common methodology is to provide the data across the whole range (70% to 100%). The data below is presented to show each decade, which includes the RMSD and N values. There is no acceptance criteria associated with decade levels of hypoxia. In *Table 40*, SpO_2 RMSD is presented per decade.

Table 40. RMSD of SpO_2 per Decade (Motion)

SpO_2 Range	100%-90%	89%-80%	79%-70%

N	589	322	344
RMSD (%)	2.36	1.97	2.41

RMSD for each decade are well within the acceptance criteria of 3%. The plateaus that were used during the study were 70 - 76, 76.01 - 85, 85.01 - 94 and >94%, as presented in Table 41.

Table 41. RMSD of SpO_2 per Plateau (Motion)

SpO_2 Range	Room Air Plateau	90% Plateau	80% Plateau	70% Plateau
N	318	330	318	289
RMSD (%)	2.61	1.96	2.19	2.33

12.4. Clinical Studies Conclusion

12.4.1. No Motion

The pooled results indicate that the observed SpO_2 ARMS values met the listed specification (dependent on the sensor used) with pulse oximetry module used in this device for SpO_2 during non-motion conditions across the SaO_2 saturation range of 70 to 100%.

The pooled results indicate that for a saturation range of 60-80% for SpO_2, the acceptance criterion was met for the pulse oximetry module used in this device when tested with MAXA, MAXN, and MAXFAST sensors.

12.4.2. Motion

The pooled results indicate that the observed SpO_2 ARMS values met the listed specification of 3% when tested with MAXA, MAXN sensors, with

the pulse oximetry module used in this device, for SpO_2 during motion conditions across the SaO_2 saturation range of 70 to 100%.

13. Appendix B: Monitor Service Password

13.1. Monitor Service Password

The service password is: SERV.

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