# *Capnostream™20*

## *Portable Bedside Capnograph/Pulse Oximeter*

## *Operator's Manual*

**PN: 010461E**

CE 0482

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# *Safety Information*



To use the Capnostream™20 monitor (henceforth referred to as Capnostream) correctly and safely, carefully read this operator's manual and the *Directions for Use* that accompany the $SpO_2$ sensors and Microstream® $EtCO_2$ consumables (FilterLines®, henceforth referred to as FilterLines). Use of the monitor requires full understanding and strict observance of these instructions, the precautionary information in boldface type, and the specifications.

## Warnings

### General

| | |
|---|---|
| **WARNING:** | If uncertain about the accuracy of any measurement, first check the patient's vital signs by alternate means, and then make sure the monitor is functioning correctly. |
| **WARNING:** | The device should not be used as an apnea monitor. |
| **WARNING:** | The device 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. |
| **WARNING:** | Carefully route patient cabling ($SpO_2$ sensor and FilterLine) to reduce the possibility of patient entanglement or strangulation. |
| **WARNING:** | Do not lift the monitor by the $SpO_2$ sensor cable or FilterLine, as they could disconnect from the monitor, causing the monitor to fall on the patient. |
| **WARNING:** | To ensure accurate performance and prevent device failure, do not expose the monitor to extreme moisture, such as rain. |
| **WARNING:** | The use of accessories, transducers, sensors and cables other than those specified may result in increased emission and/or decreased immunity of the equipment and/or system. |
| **WARNING:** | $CO_2$ readings, respiratory rate, pulse oximetry readings, and pulse 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. |

### 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. |
| **CAUTION:** | During MRI scanning, the monitor must be placed outside the MRI suite. When the monitor is used outside the MRI suite, $EtCO_2$ monitoring can be implemented using the FilterLine XL. (Refer to Monitoring CO2 during MRI Scanning on page 53.) |

### Alarms

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

### Fire Hazard

| | |
|---|---|
| **WARNING:** | When using the monitor with anesthetics, nitrous oxide or high concentrations of oxygen, connect the gas outlets to a scavenger system. |
| **WARNING:** | The monitor is not suitable for use in the presence of flammable anesthetic mixture with air, oxygen or nitrous oxide. |
| **WARNING:** | The FilterLine may ignite in the presence of $O_2$ when directly exposed to laser, ESU devices, or high heat. When performing head and neck procedures involving laser, electrosurgical devices or high heat, use with caution to prevent flammability of the FilterLine or surrounding surgical drapes. |

### Electrical

| | |
|---|---|
| **WARNING:** | To protect against electric shock hazard, the monitor's cover is to be removed only by qualified service personnel. There are no user-serviceable parts inside. |
| **WARNING:** | To ensure patient electrical isolation, connect only to other equipment with circuits that are electrically isolated. |
| **WARNING:** | Connect the device only to a three-wire, grounded, hospital grade receptacle. The three-conductor plug must be inserted into a properly wired three-wire receptacle; if a three-wire receptacle is not available, a qualified electrician must install one in accordance with the governing electrical code. Do not under any circumstances remove the grounding connector from the power plug. Do not use extension cords or adapters of any type. The power cord and plug must be intact and undamaged. |
| **WARNING:** | If there is any doubt about the integrity of the protective earth conductor arrangement, operate the device on internal battery power until the AC power supply protective conductor is fully functional. |
| **WARNING:** | Do not connect to an electrical outlet controlled by a wall switch or a dimmer. |
| **WARNING:** | Measure the device's leakage current whenever an external device is connected to the serial port. Leakage current must not exceed 100 microamperes. |
| **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. |

### Electro-magnetic Interference

This device has been tested and found to comply with the requirements for medical devices according to the standard EN60601-1-2/2001. 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. |

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

## 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.

Chapter 1

# About this Manual



## Overview

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

Capnostream 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).
- Fractional inspired carbon dioxide ($FiCO_2$) - level of carbon dioxide present during inhalation.
- Oxygen saturation ($SpO_2$).
- Pulse rate (PR).

The device also provides an Integrated Pulmonary Index™ (henceforth referred to as IPI) value, which is a numerical value that integrates four major parameters measured by Capnostream in order to provide a simple indication of the patient's ventilatory status. The integrated parameters are $EtCO_2$, RR, $SpO_2$, and PR.

## Intended Use

The Capnostream20 combined capnograph/pulse oximeter monitor is intended to provide professionally trained health care providers with continuous, non-invasive measurement and monitoring of carbon dioxide concentration of the expired and inspired breath and respiration rate, and with continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate. It is intended for use with neonatal, pediatric, and adult patients in hospitals, hospital-type facilities, intra-hospital transport and home environments.

The Capnostream20 monitor provides the clinician with an integrated pulmonary index (IPI). The IPI is based on four parameters provided by the monitor: end tidal carbon dioxide, respiration rate, oxygen saturation and pulse rate. The IPI is a single index of an adult or pediatric patient's ventilatory status displayed on a scale of 1 - 10, where 10 indicates optimal pulmonary status. IPI monitoring displays a single value that represents the patient's pulmonary parameters and alerts clinicians to changes in the patient's pulmonary status.

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

## Who Should Read This Manual

This manual should be read by:

- Health Care Professionals who will be using Capnostream.
- 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 Capnostream to a computer via the RS-232 interface.

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

## Contacting Technical Support

For any technical issue involving Capnostream monitor, please contact Oridion Technical Support:

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: technicalsupport@oridion.com

## 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 |
|  | AC power ON indicator |
|  | UNIT ON indicator |
|  | Event selection |
|  | Patient Admit/Discharge |
|  | Pump Off |
|  | Temporarily silence alarms |
|  | Type BF Defibrillator Proof Protection |
|  | Gas inlet |
|  | Gas outlet |
|  | Equipotential ground |
|  | USB flash memory connection port |

Chapter 2

# Technology Overview



## Introduction

The Capnostream bedside 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 pulse oximetry technology, the Capnostream allows for simultaneous "hassle free" $EtCO_2$ and $SpO_2$ monitoring.

## Features

- 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
- Simple user interface with color screen
- Routine functions are accessed with 2 clicks
- 72 hour trends to review patient history
- One-click alarm review
- SARA™ (Smart Alarm for Respiratory Analysis), an embedded Smart Capnography alarm management technology, which reduces clinically insignificant alarms
- Event marking to compare events and medication administration to changes in patient status
- Case recording to help organize patient files
- Nurse call
- Optional internal printer
- USB output to transfer patient data to USB flash memory devices
- Analog output for use in sleep labs and other laboratory environments
- RS-232 port for data transfer

## Technology Overview

This section provides a basic overview of Capnography and Pulse Oximetry.

### 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.

Capnostream 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 ($EtCO_2$), the amount of $CO_2$ present during inhalation ($FiCO_2$), and the Respiratory Rate.

Infrared spectroscopy is used to measure the concentration of molecules that absorb infrared light. Because the

absorption is proportional to the concentration of the absorbing molecule, the concentration can be determined by comparing its absorption to that of a known standard.

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

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

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

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

The microprocessor in the monitor calculates the $CO_2$ concentration by comparing the signals from both detectors.

### What is Pulse Oximetry?

Pulse oximetry is based on the following:

- The difference in the absorption of red and infrared light (spectrophotometry) by oxyhemoglobin and deoxyhemoglobin
- 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.

# Chapter 3

# *The Capnostream Monitor*



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

The Capnostream$^{TM}$20 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.

## Unpacking and Inspection

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

➢ TO UNPACK AND INSPECT THE MONITOR:

1. Carefully remove the Capnostream monitor and the accessories from the box.
2. Check that the items on the enclosed packing list are included:
   - Capnostream Monitor
   - Operating Manual
   - Two 3.15 Amp Type F fuses
   - FilterLine Starter Kit
   - Mains Electrical Power Cord
   - $SpO_2$ Sensor Pack
   - $SpO_2$ Extension Cable
   - Printer Paper Roll (one installed and one extra roll)
   - Battery Pack
   - CD with additional documentation (RS-232 Capnostream Data Transfer Protocols, the Patient Data Transfer Application Note, and this manual in additional languages)
3. Inspect each component.

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

## Installing the Battery Pack

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

The monitor operates on AC power or on a battery. It is equipped with a rechargeable Lithium–Ion battery pack. To install the battery pack, open the battery cover on the side of the monitor as shown below.

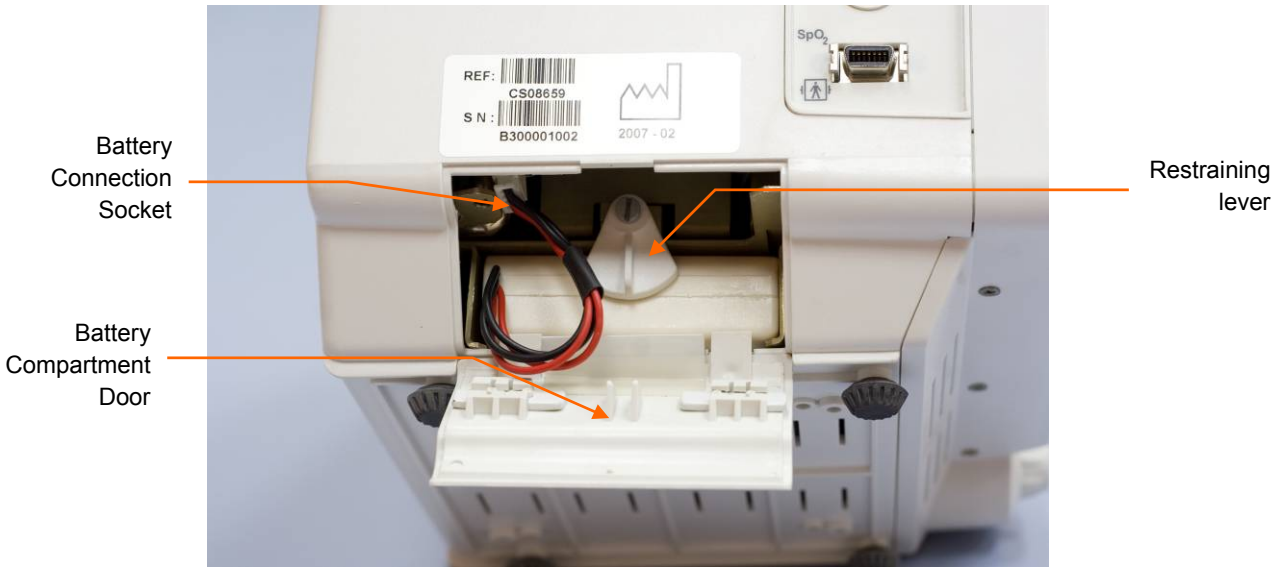



Figure 1 - Installing the Battery Pack

➢ TO INSTALL THE BATTERY PACK:

1. Slide the two release latches on the battery compartment door inward and open the door.
2. While holding the battery pack with the wires on the right, rotate the restraining lever up to the horizontal position and place the battery pack in the monitor.
3. Push the battery pack all the way in.
4. Hold the battery pressed in and lock it in position by returning the restraining lever to the vertical position.
5. Plug the battery cable into the battery connection socket. Push the wires back into the monitor.

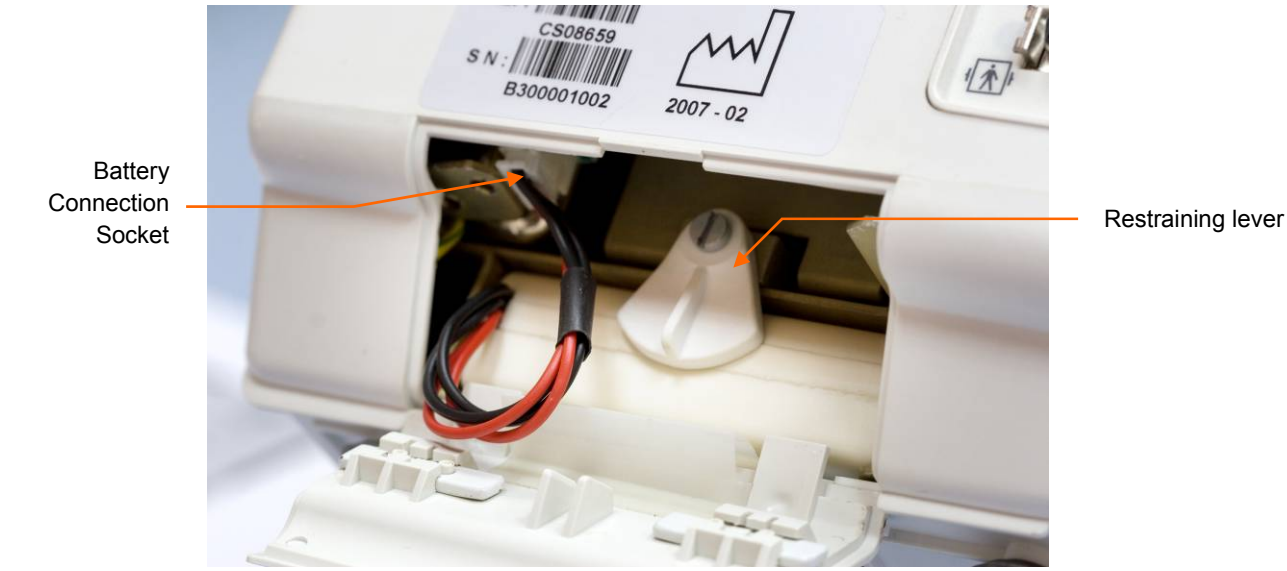



Figure 2 - Battery Pack Close-up

6. Align the flaps on the battery compartment door with the slots in the monitor casing, close the door, and slide the two release latches outward.

Ensure that the battery pack is fully charged before using the monitor without AC power. A fully charged battery pack provides 2.5 hours of operation (without printer usage). When the monitor is connected to the AC mains with the main power switch at the back of the monitor *ON* (even if the monitor is turned off), the battery pack charges automatically. It takes approximately 12 hours to fully charge an empty battery pack.

When you start using the monitor, verify that the battery icon at the bottom left of the monitor screen indicates that the battery is full. Refer to Testing the Battery and AC Connections below for details.

| | |
|---|---|
| **WARNING:** | It is recommended to always have a battery installed. If the battery is not installed, the unit will operate properly on AC power, but if AC power is lost for any reason the monitor will not work.<br><br>Note that with no battery pack, the battery charge level indicator will mistakenly indicate the presence of a fully charged battery. |

**Note:** If the battery is not fully charged, the battery icon will indicate the charge level of the battery.

### Testing the Battery and AC Connections

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

➢ TO TEST THE BATTERY:

1. Press the ON/OFF ⏻ button to turn on the monitor.
2. Observe the battery icon level in the bottom left hand corner of the screen.


Figure 3 - Menu Bar with Battery Charge Level

3. If you have previously fully charged the battery, the battery icon should indicate that the battery is full.

**Note:** As part of the monitor power-up, the battery charge level indicator will show full for about 15 seconds after the monitor is turned on. The monitor will then update the battery charge level indicator to show the true battery level.

Recharge the 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 and the power switch on the rear of the monitor is turned to the *ON* position. The orange AC power indicator on the front panel of the monitor ~ will light up.

For normal operation, always check that the orange AC power indicator light is on during monitor use. This will ensure the battery is charged during use and the monitor is prepared in case of a power outage or a patient transfer. If a patient has to be transferred to another location, 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.

### Handling the Battery Pack

| | |
|---|---|
| **CAUTION:** | Do not immerse the battery pack in water; it may malfunction. |
| **CAUTION:** | Recharge the battery pack only in the monitor, to avoid possible heating, burning or rupture of the battery pack. |

### Storing the Battery

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.

- **Long–term storage (6 months or more)**
  The battery pack must be stored in a cold, dry area. Its charge decreases over time. To restore the battery pack to full power, recharge the battery before 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.

### 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.

### Battery and Power Usage

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

The orange AC power indicator light is on when the monitor operates from an external power source, with no relation to the status of the battery pack. If the orange light is not on, check that the AC power switch on the back panel is set to *ON*.

The green power-on indicator is on when the monitor is switched on.

If the orange AC power indicator light is off and the green power-on indicator is on, the monitor is operating from the battery pack.

The battery icon will show the battery pack's approximate charge level. An advisory message, *BATTERY LOW*, appears when approximately 15 minutes of battery charge remains.

## Mounting the Monitor

The bottom of the Capnostream device is designed to fit a 100mm VESA standard mounting plate. (An example is the GCX model FLP-002-17C mounting plate which fits onto the GCX model RS-0006-64C Roll Stand Assembly). The VESA mounting plate can be ordered from Oridion; part number is 010713. Please refer to the appropriate *Directions for Use* for these products.

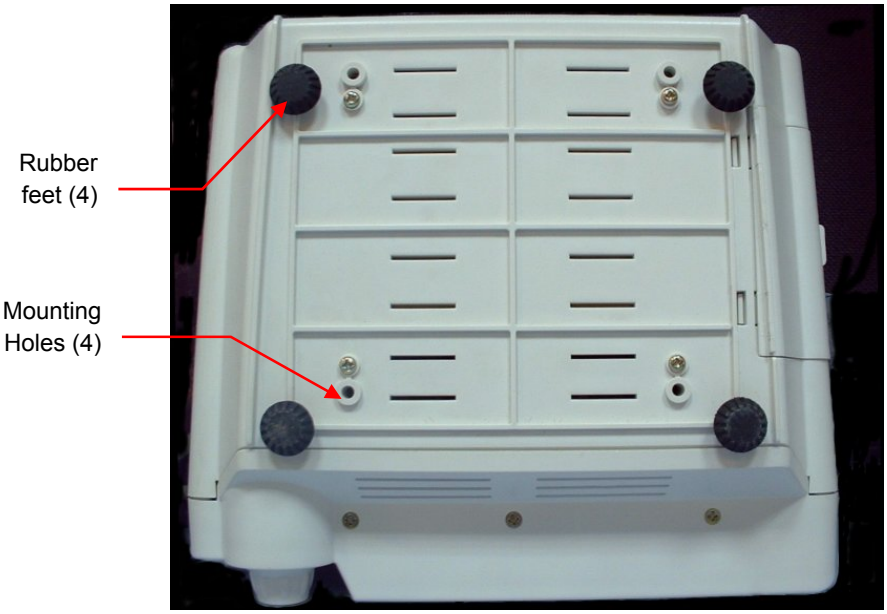



Figure 4 - Monitor Bottom View

**CAUTION:** Do not remove the rubber feet from the bottom of the monitor. These rubber feet are required for operation of the monitor on a table, to prevent unwanted movement of the monitor while in use. Even if the rubber feet are not currently in use, it is suggested that you keep them in place for future need.

# Accessories

## Available Accessories

See the list of available accessories for Capnostream below.

Table 2 - Capnostream Accessories

| Accessory | Oridion Part Number | Use |
|---|---|---|
| Paper (6 rolls) | 010516 | Paper fits Capnostream's integrated printer. Monitor is shipped with one paper roll and one spare paper roll. Refer to Replacing the Printer Paper Roll on page 111 for paper installation. |
| Mounting Adaptor Plate (Vesa) | 010713 | Used for mounting Capnostream to roll stands and other mounting assemblies. Refer to Mounting the Monitor on page 24 for mounting instructions. |
| Quick Release Pole Clamp | 011782 | Clamp fits pole mount (pole diameter 0.75in [19mm] to 1.5in [38mm]) or rail mount (rail size 10mm [0.39in] x 25mm [0.98in]).<br>With quick release mechanism.<br>*Mounting adapter plate is included.* |
| Roll Stand with Basket | Not stocked by Oridion | GCX model RS-0006-64C<br>Roll Stand Kit 38" post with 5" Slide-in type mounting plate – including: 21" base, 4" casters, 10lb Counterweight, handle, and 6" basket.<br>*Mounting plate is required to use Roll Stand.* |
| Mounting Adapter for Bernoulli Transmitter | 011892 | Used with a Bernoulli/Oxinet hospital system. Refer to Operation with Hospital Patient Data Systems on page 105. |
| Battery Pack | 010520 | Refer to Installing the Battery Pack on page 22 for battery installation. |
| Nurse Call Cable | 011149 | Cable length 3.5 meters: Cable is supplied un-terminated so it can be built to fit system. Refer to Nurse Call Operation on page 102 for set up instructions. |
| Digital/Analog (D/A) Cable | 010492 | Used for transfer of data from Capnostream to an analog device such as a polysomnograph. Refer to Analog Data Output on page 98 for set up instructions. |
| Fuse (2 each 3.15 amp 250 Volts | 010543 | Refer to Replacing the Fuses on page 110 for |

| | | |
|---|---|---|
| | | instructions on how to replace fuses. |
| Y Power Cable | CS08707 | Max. 125V cable for use in US and Japan only. For use with Capnostream and a Bernoulli/Oxinet wireless bridge. Refer to Operation with Hospital Patient Data Systems on page 105 for details. |
| US Power Cord | PE03833 | |
| European Power Cord | PE00208 | |

### Monitor Mounting Plate

The mounting kit contains a VESA Mounting Adapter, 100 x 100mm to 75 x 75mm, which can be affixed to the bottom of the monitor as described above. This allows the monitor to be mounted on a wide range of GCX stands and mounts including the GCX model RS-0006-64C Roll Stand Assembly. Please contact GCX (www.gcx.com) for more information on their available solutions for mounting the monitor.

### Digital to Analog Data Transfer Cable

The Digital-to-Analog interface requires the Oridion D/A Data Cable (Oridion part number 010492).

### Printer Paper

The monitor uses thermal printer paper with the following specifications:

Table 3 - Printer specifications

| Item | Value |
|---|---|
| Paper Width | 58mm (2 ¼ in) |
| Paper Roll Diameter (maximum) | 40mm (1 1/2 in) |
| Paper Length (maximum) | 15.2 meters (50 ft) |

**Note:** Some manufacturers use a different thickness of paper, so that a 15.2 meter roll from a different manufacturer may exceed the maximum diameter limit and will not fit in the monitor.

Replacement paper rolls that meet the specifications can be obtained from Oridion (part number 010516 for a package of 6 rolls), or in North America from www.thermalpaperdirect.com (Model number 22550).

## Buttons, Indicators and Connections

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

### Monitor Front View

The front panel of the monitor contains the display screen, action buttons and the control knob.

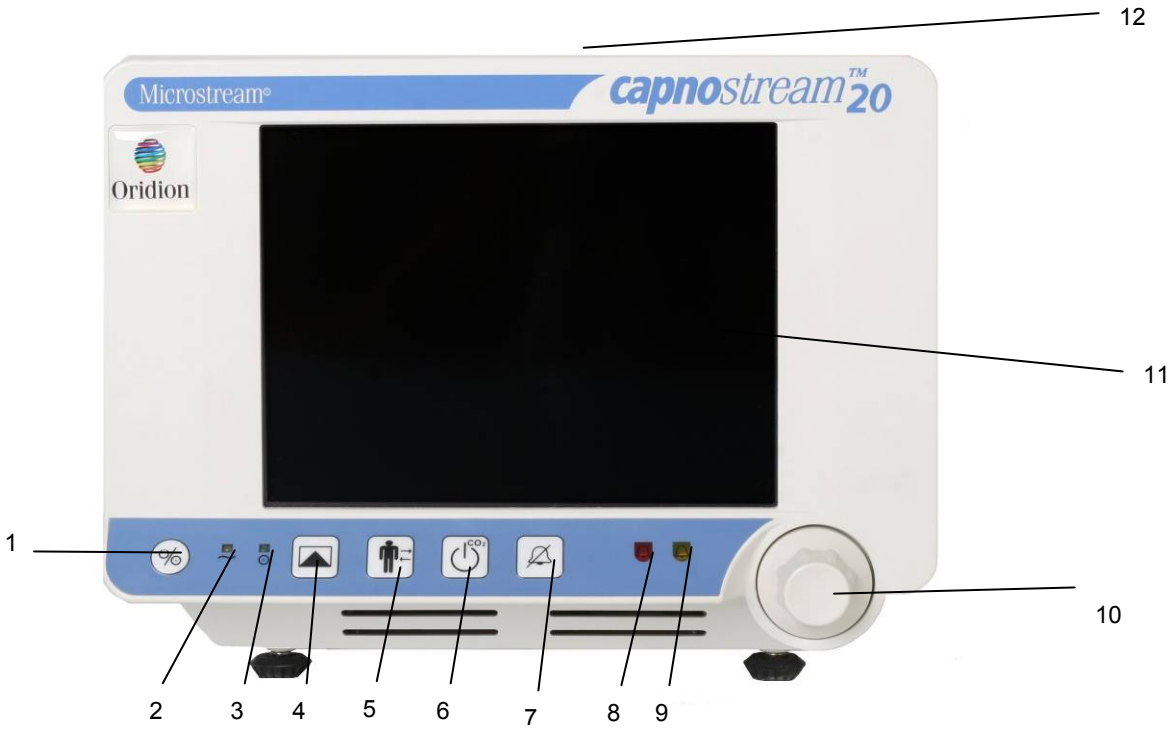



Figure 5 - Capnostream Front View

Table 4 - Capnostream Front View lists the numbered labels.

Table 4 - Capnostream Front View

| Label | Name | Description | Label | Name | Description |
|---|---|---|---|---|---|
| 1 | Monitor power ON/OFF | Button switch | 7 | Temporary alarm silence button | Temporarily disables the Audio Alarm for two minutes. |
| 2 | AC power indicator | Orange light | 8 | Red alarm indicator | Indicator that flashes during High Priority alarms (see Alarms and Messages on page 63). |
| 3 | Monitor power on indicator | Green light | 9 | Yellow alarm indicator | Indicator that lights or flashes according to the alarm status (see Alarms and Messages on page 63). |
| 4 | Event button | Starts the process of placing either a Quick or Detailed Event marker in the trend data. | 10 | Control knob | Rotary knob used to navigate the screen and select a function when pressed. |
| 5 | Patient Admit/Discharge button | Allows Starting and Stopping a case and entering patient ID. | 11 | Display screen | Screen displaying the patient data, menu bar, patient mode, date-time, and any information or |

| | | | | | |
|---|---|---|---|---|---|
| | | | | | error messages. |
| 6 | Pump Off button | Shuts off the Capnography pump for a preset time in order to protect the monitor during suctioning procedures. | 12 | Carrying handle | Allows the monitor to be carried. |

## Front Panel Control Buttons

The figure below is a close-up of the controls shown in Figure 5 - Capnostream Front View on page 27 and described in Table 4 - Capnostream Front View above.

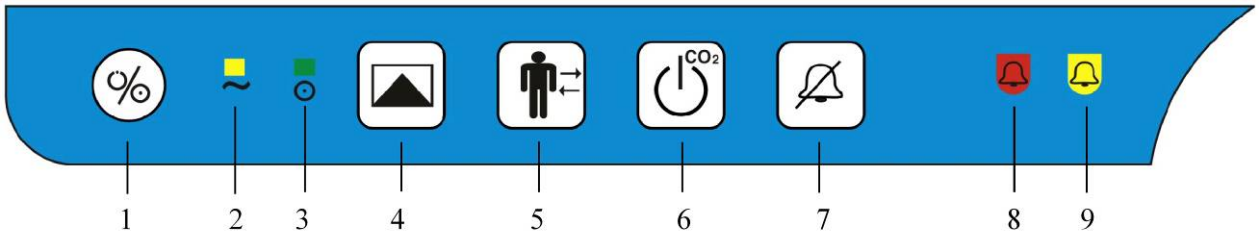



Figure 6 - Front Panel Control Buttons

### Monitor Rear Panel

The rear panel of the monitor contains power and communications connections.

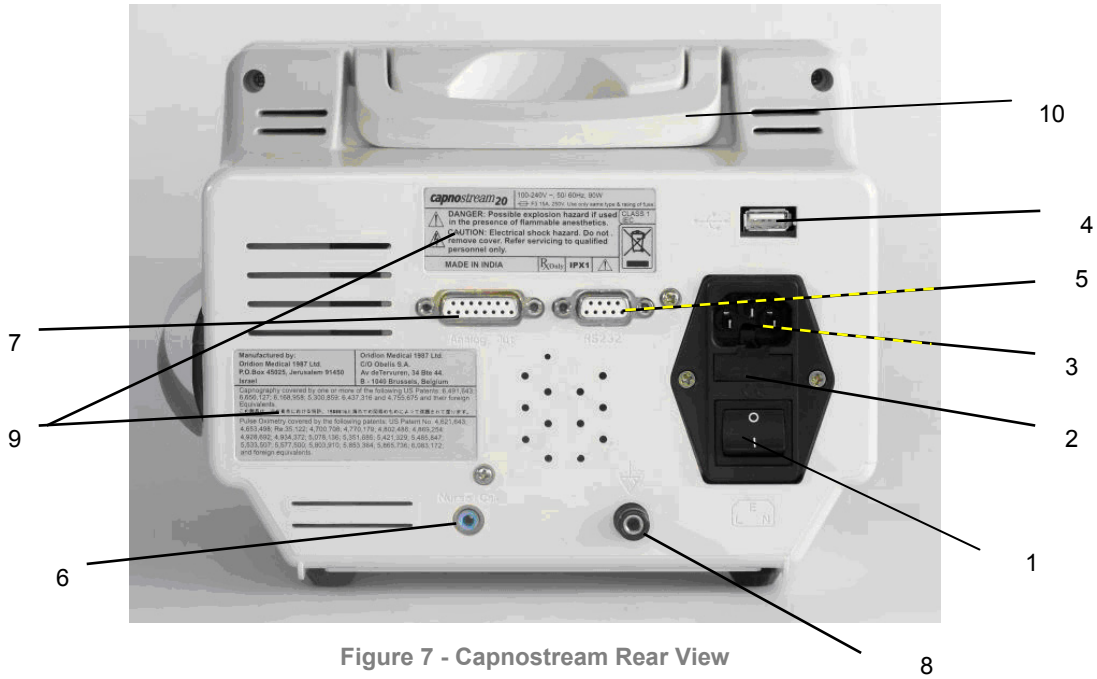



Figure 7 - Capnostream Rear View

Table 5 - Capnostream Rear View describes the functions of the rear-monitor connections.

Table 5 - Capnostream Rear View

| Label | Function | Description | Label | Function | Description |
|---|---|---|---|---|---|
| 1 | Mains power switch | To switch ON or OFF | 6 | Nurse Call | Port used for |

| | | | | | |
|---|---|---|---|---|---|
| | | the Mains power supply to the monitor. | | | attaching to Nurse Call system. |
| 2 | Mains fuse holder | Two 3.15A fast blow fuses. | 7 | Analog output | 15 pin female D type connector for 7 channel analog output. |
| 3 | Mains plug | Connection for AC power. | 8 | Equipotential ground | For external grounding. |
| 4 | USB port | For flash memory stick. | 9 | Manufacturer labels | |
| 5 | RS-232 | 9 pin female D type connector for RS-232 communication. | 10 | Carrying handle | |

### Monitor Left and Right Views

The left side of the monitor contains the battery housing and the connection points to the patient interface.

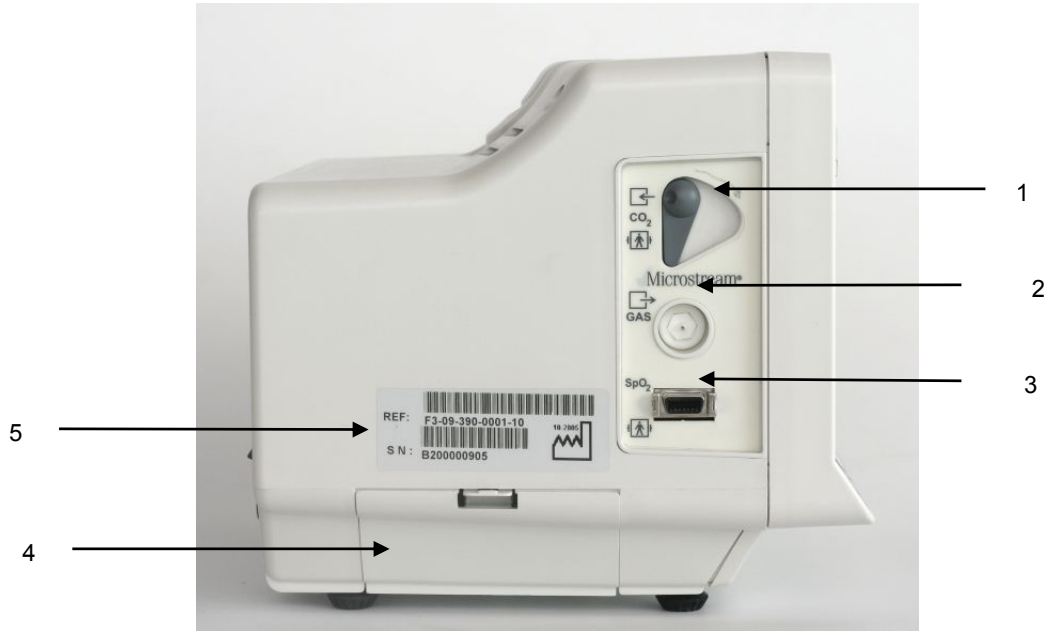



Figure 8 - Capnostream Left View

Table 6 - Capnostream Left View describes the functions of the features on the left side of the monitor.

Table 6 - Capnostream Left View

| Label | Function | Description |
|---|---|---|
| 1 | FilterLine Input connector | To connect the FilterLine to the monitor. Provided with an automatic door close. |
| 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 | $SpO_2$ | To connect $SpO_2$ sensor to the monitor with an extension cable. |
| 4 | Battery housing | Where the battery pack is installed. |
| 5 | Barcode label | Barcode of the Serial Number and Model Number of monitor. |

The right side of the monitor includes only the paper roll used for printing patient reports and buttons used to control that printer. This printer roll holder is seen in Figure 44 - Insert Paper Roll into printer on page 111, and instructions for replacing the printer roll appear in Replacing the Printer Paper Roll on page 111.

## 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® $EtCO_2$ consumables and Nellcor $SpO_2$ sensors, to ensure that the monitor functions properly.

**CAUTION:** Do not connect anything other than an $SpO_2$ sensor to the sensor port (for example, do not attempt to connect a PC to the monitor at the sensor port).

➢ TO TURN ON THE MONITOR:

1. Plug the electrical cord into the mains plug in the rear of the monitor (see Figure 7 on page 28).
2. Plug the electrical cord into the mains AC supply.
3. Turn on the power switch on the back of the unit.
   The orange power indicator on the front panel will light up.

**CAUTION:** If the orange light is not on, the monitor is running on battery power only and will stop operating when the battery is discharged.

4. Press the Power ON/OFF button ⏻ on the front panel to turn on the monitor. The following happens:

- The green power-on indicator lights up, showing that the monitor is turned on.
- An hourglass figure appears on the screen for a few seconds followed by the blue monitor salutation screen for about 5 seconds as the monitor performs a self-test.
- The red alarm and yellow alarm lights will briefly light up and the speaker will beep.

**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.

- You will hear the pump briefly turn on for a few seconds, and then turn itself off. However, if a FilterLine is connected to the monitor, the pump will remain on.

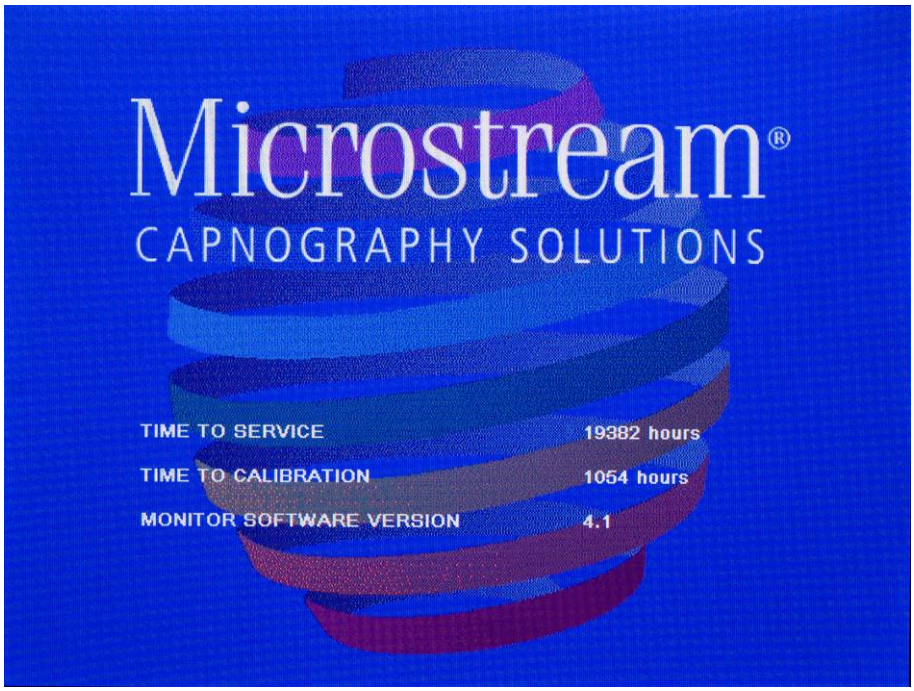



Figure 9 - Salutation Screen

## Standard Sections of the Display Screen

After the blue Salutation screen, a screen requesting that you clear the trend memory will appear. For an explanation of that screen, see Using Patient Cases and Patient ID on page 42. Following that screen, the Home screen will appear.

The Home screen displays $CO_2$ and $SpO_2$ information along with an IPI value and other information that is standard on most other screens. This section explains the main parts of the screen.

The Home screen can display in one of two basic formats: graphical and numeric. The default display is the standard display, described below. The numeric format provides a larger and easier-to-read numeric display without the distraction of the graphical waveform display. To learn about the numeric display, read Home Screen Numeric Display on page 35.

### Home Screen Standard Display

The typical standard home screen shown in Figure 10 - Typical Standard Home Screen on page 32 shows data and waveforms for a patient being monitored with a FilterLine and $SpO_2$ sensor.

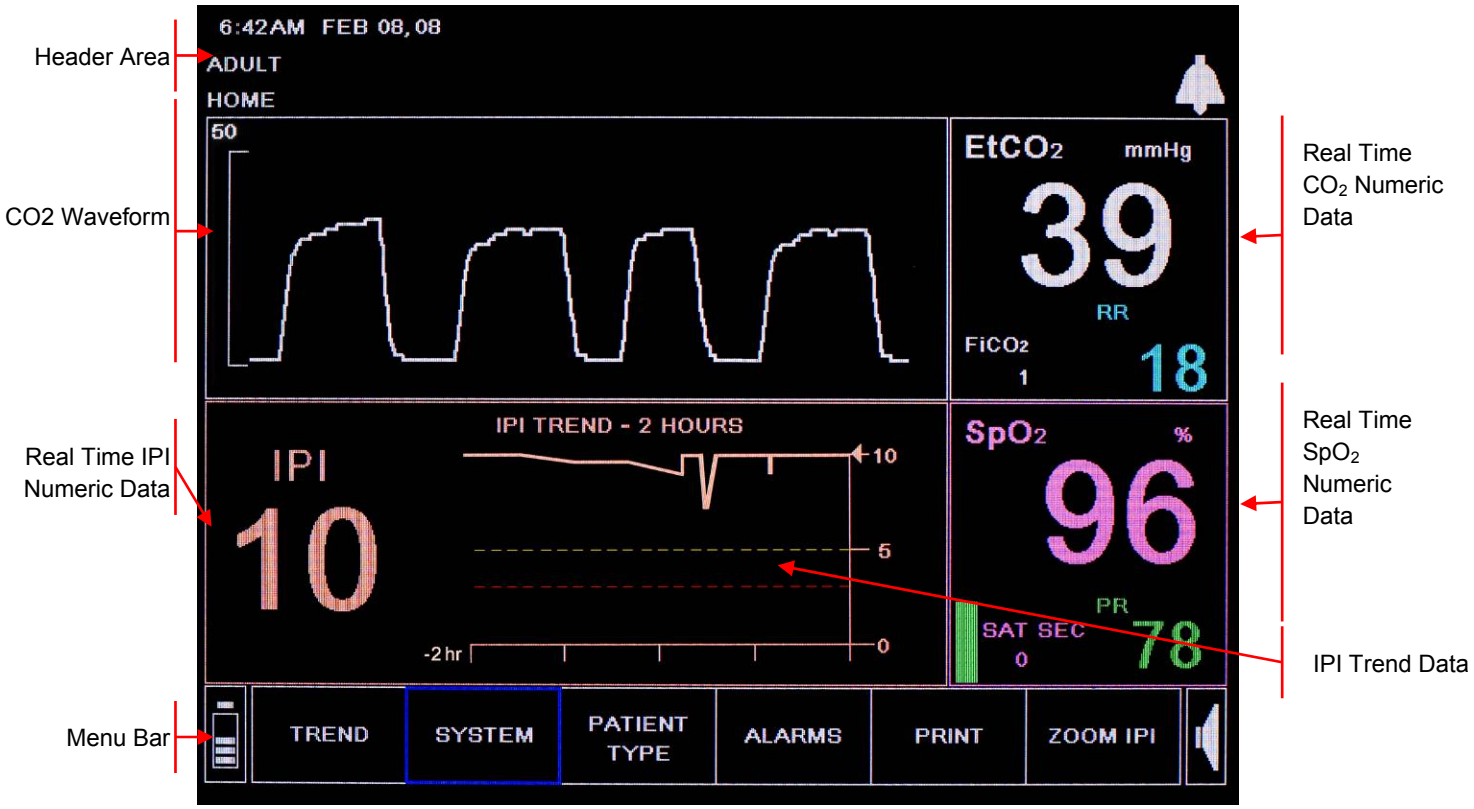



Figure 10 - Typical Standard Home Screen

The Home Screen contains the following sections:

- Header Area described on page 32
- Menu Bar described on page 34
- Real Time IPI Data with Trend Graphical Display described on page 36
- Real Time CO2 Data and $CO_2$ waveform, described on page 34
- Real Time SpO2 Data described on page 34

Most of the other screens contain the Header Area, the Menu Bar, the Real Time $CO_2$ Data, and the Real Time $SpO_2$ Data.

In most cases, as you move from screen to screen, the monitor will always display the Header, Menu Bar, real time $CO_2$ Numeric Data and real time $SpO_2$ Numeric Data sections. The continuous display of the real time $CO_2$ and $SpO_2$ Numeric Data on the right allows continuous patient monitoring even when changing system settings, or observing patient history on the trend screens.

The IPI option on the screen may be disabled as part of the institutional defaults. (If the Patient Type is Infant/Neonatal, the IPI is automatically disabled, and the only available option for the standard Home screen display shows the $SpO_2$ waveforms instead of the IPI trend waveform.) See Integrated Pulmonary Index on page 61 for more information. If the IPI option is disabled, a home screen without the IPI option will be seen. An example of this Home screen is seen in Figure 11 - Standard Home Screen without IPI Option on page 33.

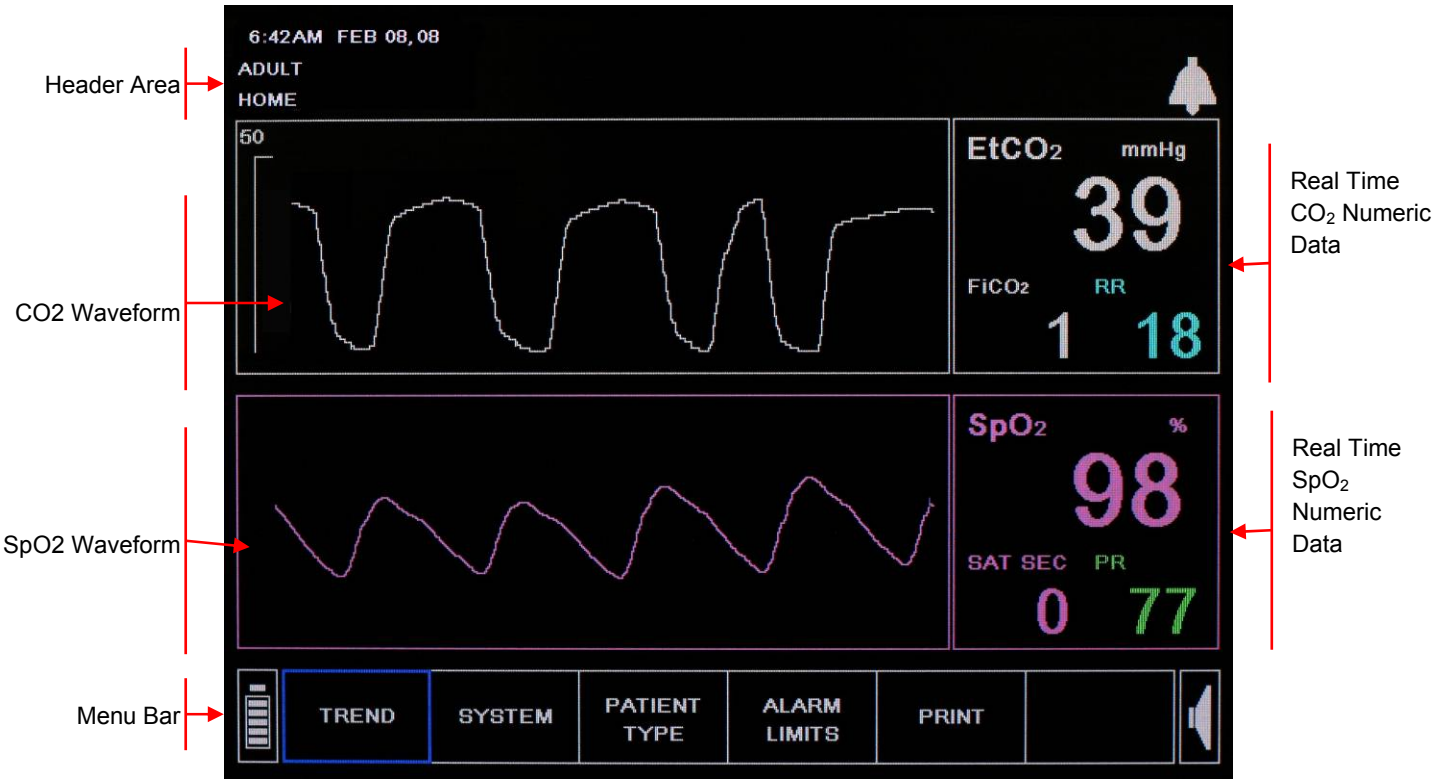



Figure 11 - Standard Home Screen without IPI Option

### Header Area

The Header section is always displayed along the top of the screen and contains the information listed in the table below.

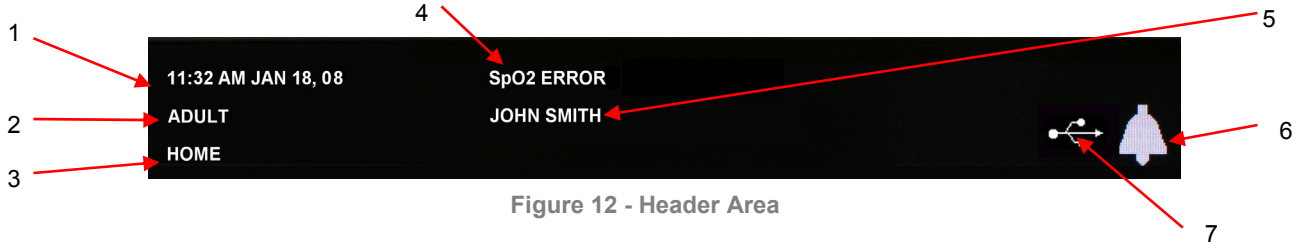



Figure 12 - Header Area

Table 7 describes the elements of the header area.

Table 7 - Header Section

| Item | Function | Description |
|---|---|---|
| 1 | Time/Date | Displays the Time and Date in selected formats. |
| 2 | Patient Type | Indicates patient mode. Options are ADULT, PEDIATRIC 1-3 YRS, PEDIATRIC 3-6 YRS, PEDIATRIC 6-12 YRS, and INFANT/NEONATAL (for infants under 1 year) |
| 3 | Screen name | Displays the current screen name. |
| 4 | Message area | Messages explaining alarms and |

| | | |
|---|---|---|
| | | equipment status appear in this area. |
| 5 | Patient ID | If a patient ID has been entered for the current case, the patient ID will appear. |
| 6 | Alarm status indicator | Indicates whether the audio alarms are enabled, temporarily disabled or permanently disabled. |
| 7 | USB Indicator | Indicates whether a USB Flash Memory device is currently attached to the monitor |

**Menu Bar**

The menu bar of available options and functions is located along the bottom of the monitor display screen. At the left hand side is the battery charge level indicator. At the right hand side is the speaker volume control.

The menu bar will change depending on which options and functions are available for a specific screen. In some screens there are additional selectable options in the screen-specific area.

**Real Time $CO_2$ Data**

This area of the screen displays the real time $EtCO_2$ and $FiCO_2$ values along with selected units, and the respiration rate (RR) in breaths per minute. Numeric display appears at right and a waveform display at left. For more details regarding the displayed information, see Chapter 5 Capnography with the Capnostream Monitor on page 49.

When the $CO_2$ alarm limit threshold is crossed, the device will alarm: the affected numeric will flash, the numeric will appear with a red or yellow background (depending on whether it is an urgent or caution alarm), and a message will appear in the header area of the screen.

This area of the screen can be selected as if it were a menu option. Selecting this area gives access to the setup screen for changing the $CO_2$ parameter values.

**Real Time $SpO_2$ Data**

This area of the screen displays real time numeric $SpO_2$ data, with the $SpO_2$ Waveform (plethysmograph) represented by the green bar at the left of this box.

For more details about the displayed $SpO_2$ data, see Chapter 6 Pulse Oximetry with the Capnostream Monitor on page 55.

When the $SpO_2$ alarm limit threshold is crossed, the device will alarm: the affected numeric will flash, the numeric will appear with a red or yellow background (depending on whether it is an urgent or caution alarm), and a message will appear in the header area of the screen.

This area of the screen can be selected as if it were a menu option. Selecting this area gives access to the setup screen for changing the $SpO_2$ parameter values, including the option to turn the pulse beat tone on or off.

**Real Time IPI Data with Trend Graphical Display**

This area of the screen displays the real-time value of the IPI, a numerical value which summarizes four parameters ($EtCO_2$, RR, $SpO_2$, PR) in order to provide a quick indication of the patient's respiratory status. The IPI trend graph indicates the trend of this value over the chosen period of time (the default period is one hour).

On the IPI trend graph, the red and yellow horizontal lines indicate the currently set urgent and caution alarm limits respectively.

For more information about this parameter, see Chapter 7 Integrated Pulmonary Index on page 61.

When the IPI alarm limit is exceeded, the device will alarm: the affected numeric will flash, the numeric will appear with a red or yellow background (depending on whether it is an urgent or caution alarm), and a message will appear in the header area of the screen.

### Home Screen Numeric Display

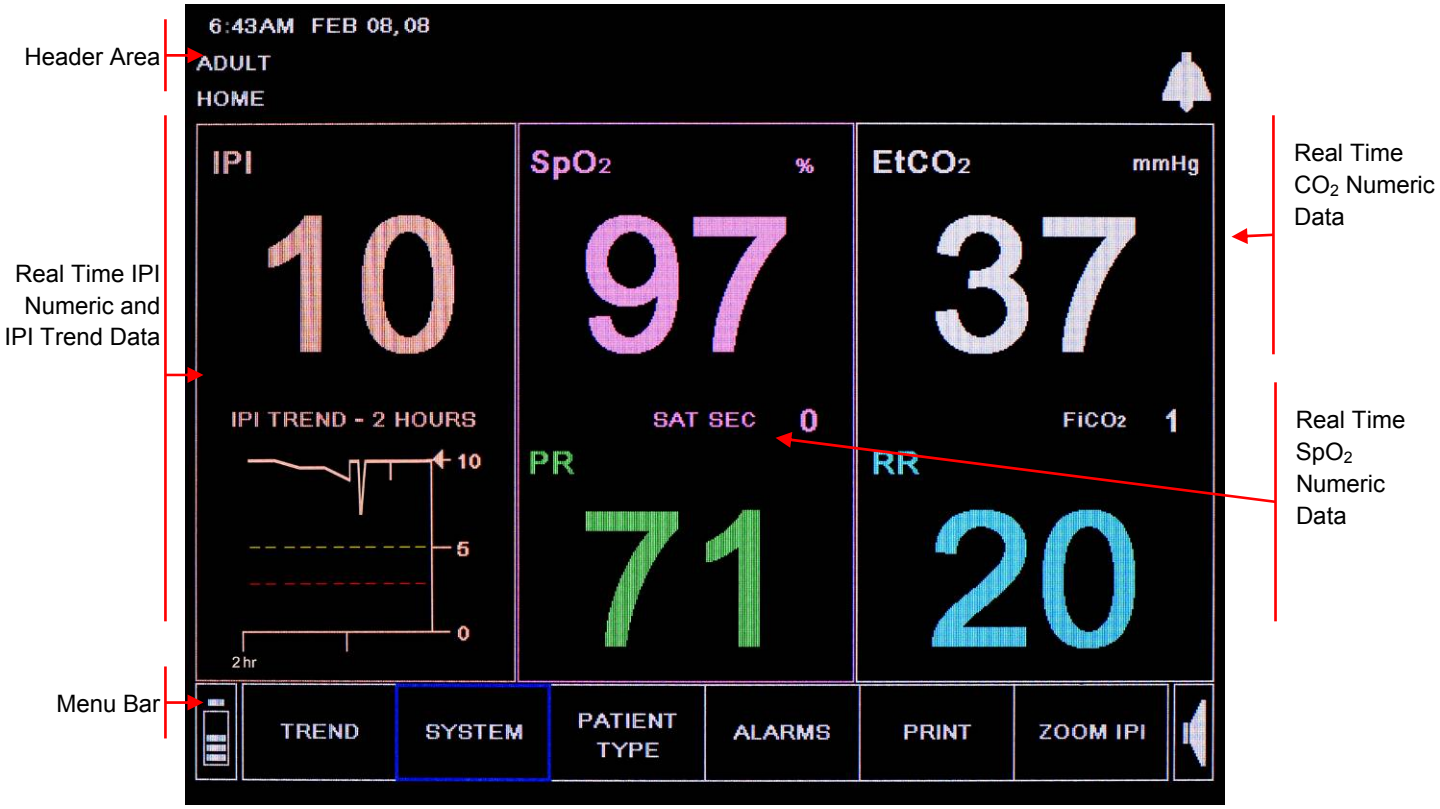



Figure 13 - Typical Numeric Home Screen

The numeric screen contains the following sections:

- Header Area on page 35
- Menu Bar on page 34
- Real Time IPI Data with Trend Graphical Display on page 36
- Real Time CO2 Data on page 34
- Real Time SpO2 Data on page 34

#### Header Area

The Header section is identical to the Header area seen with the standard Home screen.

#### Menu Bar

The menu bar is identical to the menu bar seen with the standard Home screen.

#### Real Time $CO_2$ Data

This area of the screen displays the real time $EtCO_2$ and $FiCO_2$ values along with selected units, and the respiration rate (RR) in breaths per minute. Numeric display only is provided, sized so that it can easily be read even at a distance. For more details regarding the displayed information, see Chapter 5 Capnography with the Capnostream Monitor on page 49.

When the $CO_2$ alarm limit threshold is crossed, the device will alarm: the affected numeric will flash, the numeric will appear with a red or yellow background (depending on whether it is an urgent or caution alarm), and a message will appear in the header area of the screen.

This area of the screen can be selected as if it were a menu option. Selecting this area gives access to the setup screen for changing the $CO_2$ parameter values.

**Real Time $SpO_2$ Data**

This area of the screen displays real time $SpO_2$ data. Numeric display is provided, sized so that it can easily be read even at a distance. For more details about the displayed $SpO_2$ data, see Chapter 6 Pulse Oximetry with the Capnostream Monitor on page 55.

When the $SpO_2$ alarm limit threshold is crossed, the device will alarm: the affected numeric will flash, the numeric will appear with a red or yellow background (depending on whether it is an urgent or caution alarm), and a message will appear in the header area of the screen.

**Real Time IPI Data with Trend Graphical Display**

This area of the screen displays the real-time value of the IPI, a numerical value which summarizes four parameters ($EtCO_2$, RR, $SpO_2$, PR) in order to provide a quick indication of the patient's respiratory status. The IPI trend graph below the numeric value indicates the trend of this value over the chosen period of time.

On the IPI trend graph, the red and yellow horizontal lines indicate the currently set urgent and caution alarm limits respectively.

For more information about this parameter, see Chapter 7 Integrated Pulmonary Index on page 61.

When the IPI alarm limit is exceeded, the device will alarm: the affected numeric will flash, the numeric will appear with a red or yellow background (depending on whether it is an urgent or caution alarm), and a message will appear in the header area of the screen.

## Screen Navigation

Select options and set values using the control knob. The control knob works in a manner similar to that of a regular computer mouse. It is also used as a keyboard for entering letters and numbers.

➢ TO MOVE AROUND THE SCREEN:

1. Turn the control knob to the right or left to move to the next area on the screen, which is highlighted by the frame changing to blue.
2. To make a selection, push the control knob in until it clicks.

➢ TO ENTER LETTERS AND NUMBERS:

1. When required to enter alphanumeric data, turn the control knob for navigation and then click on the input data block on the screen.
   The content of the data block is cleared and a small block with a yellow background will appear in place of the first character. In the block will be an Enter symbol (↵).
2. As you turn the control knob to the right or left, you will see the complete alphabet and numbers 0-9, the ← backspace symbol, a blank space and the ↵ Enter symbol.
3. When the desired character is displayed, press on the control knob until it clicks. The inputted character will return to its regular color (white) and the yellow block will move to the next character space.
4. Turn the control knob again to begin a new character selection.
5. To end alphanumeric entry, press the control knob twice after entering the final letter or symbol.

➢ TO CHANGE SETTINGS:

1. When you are on a screen with settings that can be changed, turn the control knob until the desired setting is highlighted by the frame changing to blue.
2. To select the setting, push the control knob in until it clicks.
3. Turn the control knob until the new setting is reached.
4. To set the setting, push the control knob in until it clicks.
5. Continue to select settings, or turn the control knob to select *BACK* or *HOME*.

### Configuration Changes

On most selection screens, when you make a change to one or more system parameters the new settings will only become effective when you exit the screen by selecting *HOME* or *BACK*. If the selection screen is exited by pressing one of the front panel control buttons located below the screen, or if you wait more than one minute and the screen times out and resets, the changed settings will not be saved.

## Setting the Home Screen Options, Date, Time and Language

After you first turn on the monitor, check the top left hand corner of the header to ensure that the date and time are correct.

➢ TO CHANGE THE HOME SCREEN OPTIONS, DATE, TIME OR LANGUAGE:

1. From the Home screen, use the control knob to select *SYSTEM* in the Menu Bar.
2. To change the Home Screen Option, choose the *STANDARD* or *NUMERIC* option as required. The default is the *STANDARD* option.
3. To adjust the date and time, use the control knob to select and change each setting. The updated date and time are saved in the monitor memory when you exit the screen, and will not need to be re-adjusted after the monitor is turned off.
4. To change the language of the display, use the control knob to change the language.
5. The new home screen option and language will remain in effect until the monitor is turned off. To permanently change the display language and other settings, see the information in Changing Institutional Defaults on page 117.

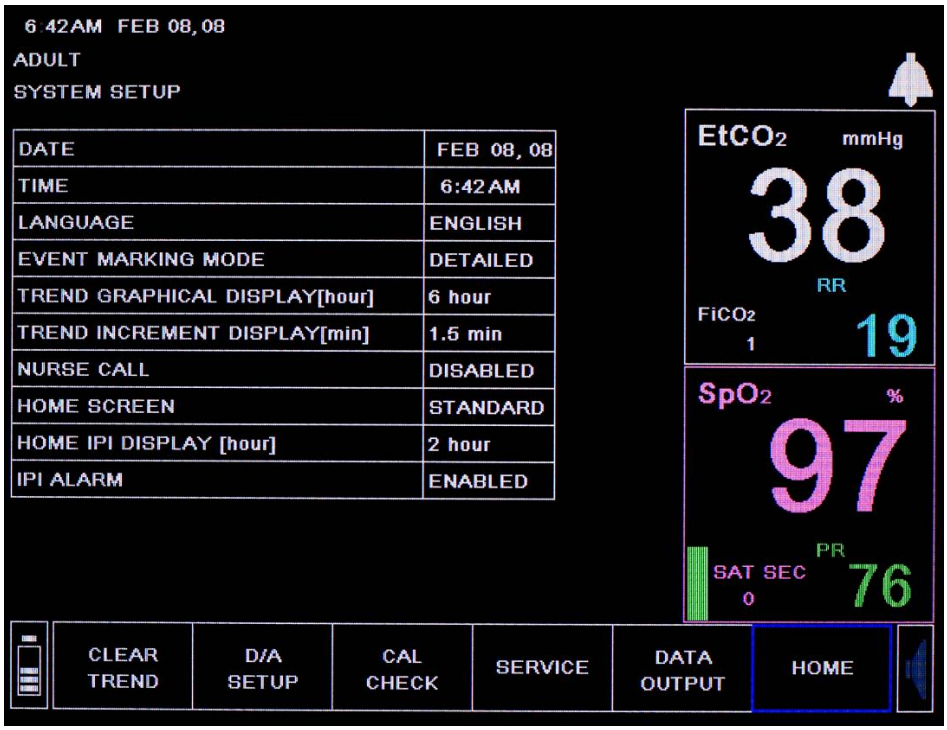



Figure 14 - System Setup Screen

## Screen Timeouts

### Screen Timeouts

All setup and system screens will time out after 60 seconds of no activity with the control knob, and revert back

to the previous screen you came from. This will continue every 60 seconds until you reach the Home or Trend screen (depending on the screen from which the Setup process was started).

## Capnostream™20: Operational Check Sheet

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

❒ **1. Unpack the monitor**

- Remove the Capnostream monitor and the accessories from the box.
- Check that the items on the enclosed packing list are included.
- Check that paper is in printer.

❒ **2. Install the battery pack**

- Refer to Installing the Battery Pack on page 22 for installation instructions.

❒ **3. Turn on the monitor**

- Plug the power cord into the mains plug in the rear of the monitor.
- Plug the power cord into the mains AC supply.
- Turn on the power switch on the back of the unit. The battery power indicator orange light 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 power-on indicator green light will light up, showing that the monitor is turned on.
- Note that both the battery power indicator orange light and the power-on indicator green light should both be on during operation of the monitor.

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

- Use the control knob to select *SYSTEM* in the Menu Bar
- Change each setting on that screen, if desired.

❒ **5. Set the Patient Type**

- Use the control knob to select the *PATIENT TYPE* function on the menu bar of the Home screen
- Select *ADULT*, *PEDIATRIC* (by age), or *INFANT/NEONATAL* as appropriate.

❒ **6. Connect a FilterLine**

- Slide open the FilterLine input connector shutter and connect the appropriate FilterLine.
- Connect the FilterLine to the patient as described in the Directions for Use supplied with the FilterLine. 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.

❒ **7. Connect an $SpO_2$ Sensor**

- Connect the $SpO_2$ extension cord firmly to the monitor $SpO_2$ sensor port, 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.

❒ **8. Once either or both sensors are connected to the monitor, it is ready for operation.**

❒ **9. Check Alarm Limits**

- Check the alarm limits default and make any permanent changes in the institutional defaults.

- Refer to Alarms and Messages on page 63 for more details about alarms.

❒ **10. Open a Patient Case**

- To record patient data so that it is easy to track and retrieve, opening a patient case is recommended. Opening a patient case is required when recording a Tabular Case Report.
- Refer to Using Patient Cases and Patient ID Numbers on page 42 for instructions.

❒ **11. Print Patient Data**

- Choose the desired type of patient report and press the *PRINT* button on the screen.
- Refer to Printing Reports on page 85 for detailed information.

❒ **12. Set Up Nurse Call Operation (if applicable; Nurse Call connectivity accessories must be purchased separately)**

- Plug the Nurse Call cable into the Nurse Call socket on the back of the monitor and connect the other end of the cable to the institution's system as determined by the institution's requirements. Check that all cables are connected and tightened.
- Enable Nurse Call on the monitor as described in Nurse Call Operation on page 102.
- Verify communication between the monitor and the Nurse Call system.

❒ **13. Set Up Analog Data Output Operation (if applicable; analog system connectivity accessories must be purchased separately)**

- Connect the Oridion D/A (Digital/Analog) Data Cable (Part Number 010492) to the back of the monitor and connect the other end of the cable to an analog system such as a polysomnograph as required. Check that all cables are connected and tightened.
- Set up analog data output on the monitor as described in Analog Data Output with Capnostream on page 198.
- Verify that data transfer between the monitor and the system is taking place.

❒ **14. Set Up Bernoulli System Interface (if applicable; central monitoring system and accessories must be purchased separately)**

- Connect the Client Bridge to the RS-232 port at the back of the monitor. Make sure that all connections are in place and sufficiently tightened.
- Verify that the Client Bridge is mounted safely.
- Verify communication between the Capnostream monitor, the client bridge and the Bernoulli central station.
- See Operation with Hospital Patient Data Systems on page 105 for more details.

❒ **15. Set Up Data Transfer via USB (USB flash drive must be purchased separately)**

- Connect the USB Flash drive to the back of the monitor.
- Choose the desired type of patient report and press the *START USB* button on the screen.
- Refer to Data Transfer via the USB Data Port on page 93 for detailed information.

# Chapter 4

# *Using the Capnostream Monitor*



## Preparing the Monitor for a Patient

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

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

➢ TO PREPARE THE MONITOR FOR A PATIENT:

1. Turn on the monitor by pushing the on/off switch ⏻ on the front panel.
2. The complete power on sequence is described in Turning on the Monitor on page 30.
3. Confirm that the green power-on indicator and the orange AC power indicator light are both on.

| | |
|---|---|
| **CAUTION:** | If the orange light is not on, the monitor is running on battery power only and will stop operating when the battery is discharged. See Turning on the Monitor on page 30. |

4. The red alarm and yellow alarm lights will briefly light up and the speaker will beep.

| | |
|---|---|
| **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. |

5. Connect one or both sensors to the monitor, following the instructions in this manual. To connect the sensors, please see Chapter 5 Capnography with the Capnostream Monitor on page 49 and Chapter 6 Pulse Oximetry with the Capnostream Monitor on page 55.

Once either or both sensors are connected to the monitor, it is ready for operation.

If a FilterLine is not connected, there is no $CO_2$ waveform and the message *FILTERLINE DISCONNECTED* will appear.

If an $SpO_2$ sensor is not connected, there is no $SpO_2$ waveform and the message *$SpO_2$ SENSOR DISCONNECTED* will appear.

It is possible to use either the Capnography function ($EtCO_2$) or the Pulse Oximetry function ($SpO_2$) without using the other function. If you only want to operate one function, connect ONLY the sensor for that function, and the monitor will operate normally.

### Setting the Patient Type

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. Setting the patient type is compulsory.

The default patient type on the monitor is ADULT.

**CAUTION:** 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 rate and affect the patient's IPI value.

➢ TO CHANGE THE PATIENT TYPE:

1. If the patient type that appears on the screen is correct for the current patient, there is no need to make any change to the patient type. If you want to make a change, use the control knob to select the *PATIENT TYPE* function on the menu bar of the Home screen.
2. Rotate the control knob to change the patient type, and press the control knob to register the change. This change will remain in effect until the patient type is changed.

The monitor has independent alarm limit settings for Adult/Pediatric and Infant/Neonatal Patients which can be configured according to the physiology observed in the particular age groups. See the relevant information in Changing Alarm Limits on page 70.

## Using Patient Cases and Patient ID Numbers

It is strongly recommended that you associate all data stored in the monitor with a patient ID that will identify its origin with a particular patient. This allows stored trend data to be associated with a patient ID, and avoids the possibility of confusing data from several patients in one trend printout or download.

➢ TO BEGIN A NEW CASE:

1. Once the patient is already connected to the monitor, press the **Patient Admit/Discharge** button  on the front panel of the monitor. The *PATIENT ID* field appears on the screen, and an automatically generated 14-digit ID number will appear in the ID field:

   PATIENT ID 20061209072645

2. This automatically generated ID indicates the start date and time of the case session (format YYYYMMDDhhmmss, indicating year, month, day, hour, minute and second of the session start). To use the automatically generated ID number, use the control knob to select *START CASE* and click the *START CASE* button to begin the case.

3. To change the ID number, if desired, turn the control knob to highlight *PATIENT ID* in blue on the screen and click the control knob. Use the control knob to enter a new alphanumeric Patient ID by rotating and pressing the control knob to select letters and numbers. If you wish to enter a space, turn the knob until you see an empty square instead of a letter or numeral, and click to enter a space. You will note that the space you are currently filling is highlighted in yellow. The maximum permitted length for the Patient ID is 20 characters. Select the ↵ Enter symbol to finish. See the section Screen Navigation on page 36 for instructions on how to enter letters and numbers.

4. If you want to change the patient type for this patient, you may do so from this screen, using the control knob to select and change the patient type.

5. Use the control knob to select *START CASE*.

**Note:** Once the *START CASE* button is pressed, the case has begun, and that button now becomes *STOP CASE*.

A new case cannot begin until the previous case has been stopped with the STOP CASE button.

If you are not sure whether the monitor is currently monitoring a case, click the Patient Admit/Discharge  key to display the screen in which the *START CASE* button appears. The status of the *START CASE* button can provide an indication of current status: when there is no case started, it will show *START CASE*, and, in the middle of a case, it will show *STOP CASE*.

6. To end a case when monitoring the patient is finished, press the Patient Admit/Discharge key, and then select *STOP CASE*. This marks the end of the data for that patient. Stopping a case will erase the Trend Memory, and a warning that indicates *STOPPING THE CASE WILL ERASE TREND MEMORY; PRESS "STOP CASE" AGAIN TO CONFIRM* will appear on the screen when *STOP CASE* is pressed. If you want to transfer or print case or trend data, this ***must*** be done before the case is stopped. If you do not want to stop the case, simply turn the knob to remove the question from the screen and continue the case. If you do want to stop the case, click the control knob again.
7. If *STOP CASE* is not pressed when the user finishes monitoring and powers off the monitor, the case will continue when the monitor is turned off and then on again. However, when the monitor is powered up again in such a case, a warning will suggest that the user clear trend data and close the case (to clear patient ID) before beginning a new monitoring session. This screen is seen in Figure 32 - Trend Memory Message on page 83. Oridion strongly suggests that you do so in order to avoid mis-identification of patient data. However, if you intend to continue monitoring the same patient as previously, you may want to retain the trend and case data.

Clicking *YES* and *CONFIRM?* in the screen seen in Figure 32 - Trend Memory Message on page 83, will clear the trend memory and close the current case, thus erasing all data in the monitor regarding that case.

| | |
|---|---|
| **WARNING** | The monitor can store only one case at a time. The trend memory includes only data for the current case, and, when the case is stopped, the trend memory is erased. |

The monitor automatically stores patient data and records the date and time for all events, whether or not the patient case option is used. As long as the trend memory is not erased, this data remains stored in the monitor, until the trend memory is full and the beginning of the trend data is overwritten by new data. (See Chapter 9 Using Trends on page 75 for more information on trend capacity.) However, case printouts will only include data recorded after the current case was started (even if the trend memory also includes data previous to the current case). On the other hand, displayed trend data and trend printouts will include all data stored in the trend memory.

## Entering 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. The monitor has the ability to record a wide variety of patient events. There are two options: Quick Events and Detailed Events.

If the monitor is set to record Quick events, pressing the event button (⏶) places a mark in the trend memory showing that an event took place at the date and time the button was pushed. See Table 20 - Tabular Display Example for an example of a quick event mark.

Detailed events allow the clinician to record more detail. There are three categories of events: administering medication, physical activity by the patient, and interventions. These events can be marked in the monitor's memory to assist in tracking patient care and appear in the trend displays and data output.

➢ TO USE DETAILED EVENTS:

1. Press the ⏶ event button on the front display panel of the monitor.
2. The table below will appear on the display. Use the control knob to click on an event.
3. Click the control knob again to store the event and then click on *HOME*.

The table below shows the factory default settings. The event names can be changed using the institutional defaults as described in Appendix 1: Institutional Settings on page 117.

Table 8 - Event Markings

| MEDICATION | PATIENT | INTERVENED |
|---|---|---|
| FENTANYL | EATING | OXYGEN |
| VERSED | DRINKING | SUCTION |
| MIDAZOLAM | COUGHING | ADJ AIRWAY |
| MORPHINE | AMBULATING | NARCAN |
| DEMEROL | CHEST PT | ROMAZICON |
| PROPOFOL | TURNED | NEB TX |
| OTHER | SNORING | STIMULATED |
| | OTHER | OTHER |
| | | |
| | | |

If the monitor is set to record detailed events, but you do not wish to designate a specific event name, pressing the ⏶ event button twice will record an unlabeled event similar to a quick event mark. This is useful when there is no time to designate details.

## Changing the Alarm and Pulse Volumes

The alarm volume can be made louder or softer for patient alarms and pulse tone.

### Alarm Volume

➢ TO MAKE THE ALARM VOLUME LOUDER OR SOFTER:

1. Use the control knob to select the speaker icon at the right hand side of the menu.


Figure 15 - Menu Bar

2. Click the control knob once to select the alarm volume control.

3. Turn the control knob to raise or lower the volume. The selected alarm volume level will be audible as you turn the knob. Click the knob twice to set the new volume level.

Figure 16 - Alarm Volume Selection

**Note:** The alarm volume cannot be set to zero using the alarm volume control. The audible alarm can only be disabled in the Institutional Default settings.

### Pulse Tone Volume

The monitor can be set to sound an audible beep for each pulse beat. The monitor is shipped from the factory with the pulse tone turned off.

The pulse tone can also be turned off using the $SpO_2$ menu. By default, the pulse tone is turned off.

**Setting the Pulse Tone Volume**

To make the pulse tone louder or softer, use the control knob to select the speaker icon and click twice to select the Pulse Tone volume setting.

Figure 17 - Pulse Tone Volume Selection

The pulse tone volume can be set to zero.

**Turning the Pulse Tone On/Off**

➢ TO TURN THE PULSE TONE VOLUME ON:

1. Use the control knob to select the $SpO_2$ display area. Click the control knob to go to the $SpO_2$ Setup screen.
2. Turn the control knob to highlight the *PULSE TONE* setting, click the knob to select the option, turn the knob once to change the setting to ON, and push the knob again to set the option.
3. A beep now sounds once for each pulse beat. To turn the pulse tone off, repeat the procedure and select *PULSE TONE* off.

### Alarm Volume Default Options

The institutional default alarm volume can be set to one of the three choices described below, in the Institutional Defaults>Monitor screen. These choices determine the audio alarm volume when the device is turned on. See Institutional Defaults on page 117 to learn more about Institutional Defaults.

Table 9 - Audio Alarm Volume

| Audio Alarm Volume Option | Description |
|---|---|
| Maximum | The audio alarm volume will revert to the maximum volume when the device is turned on, regardless of previous settings. |
| Last Setting | The audio alarm volume will remain at the level last set on the device, even after it is turned off and then turned on again. |
| Audio Off | The audio alarm volume is off. |

## Use of Scavenging System

When the patient is being sedated with a gaseous anesthetic, a scavenging system can be attached to the monitor. The gas output connection is a barbed style connector intended for 3/32 inch ID tubing. Using any

appropriate tubing, connect the scavenging system to the gas outlet, located between the FilterLine and $SpO_2$ connections, as shown in Figure 18, below.

Disposal of sampled gases should be carried out according to according to standard operating procedures or local regulations for the disposal of gases.


Figure 18 - Scavenger System Connection Point

## Turning the Pump Off for Suction or Lavage

Use the Pump Off mode whenever performing suction or lavage. During Pump Off mode, pump activity is suspended to facilitate suctioning and equipment changes.

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 device displays the *FILTERLINE BLOCKAGE* message, replace the FilterLine.

➢ TO CHANGE THE PUMP MODE:

1. Before performing lavage or suction, press the Pump Off button $CO_2$ located on the front of the monitor. The $CO_2$ module pump turns off, the countdown timer begins and the Pump Off screen is displayed. The countdown timer is shown in the $CO_2$ waveform area.

**Note:** While the pump is off, $CO_2$ is not monitored and no breath waveform, $EtCO_2$, $FiCO_2$ or respiration rate number values are displayed. $SpO_2$ and pulse rate monitoring continues.

2. Pump Off mode can be ended by pressing the Pump Off button again.
3. Pump Off mode can be extended by using the control knob to select the *EXTEND TIMER* menu option.

When the monitor is in Pump Off mode, a timer appears in the message area at the top of the screen and shows the total hours and minutes that the $CO_2$ monitoring has been turned off.

When the timer finishes or you manually exit Pump Off by pressing the Pump Off button again, the pump will turn on and $CO_2$ monitoring will resume. The monitor automatically returns to the Home screen.

**Note:** The Pump Off button does not function while scrolling in Graphical and Tabular Trend screens.

## Demo Mode

The Capnostream monitor provides the possibility of viewing pre-recorded standard data to display an example of the monitor's appearance under standard measurement conditions. The Demo Mode permits clinicians and technicians to understand what the screen will show when monitoring patients, and is useful to them as a guide before attaching the monitor to real patients.

➢ TO USE THE DEMO MODE:

1. To enter the Demo Mode, click *SYSTEM* and then *SERVICE* on the menu bar at the bottom of the screen. Enter the Service password (see Changing Institutional Defaults on page 117) to enter the Service screen.
2. On the Service screen, click the *DEMO MODE* button on the menu bar. The monitor will now enter Demo Mode and will display pre-recorded $CO_2$ and $SpO_2$ data. As an indicator of operation under Demo mode, the header will indicate *DEMO MODE – PRERECORDED DATA*. Service options and the Calibration Check feature are not available to the user while the device is in Demo mode.
3. To exit the Demo Mode, you must turn off the monitor using the ON/OFF button at the front of the monitor. When the monitor is turned on again, it will have returned to its standard operating status.

## Monitor Screen Menu Reference Chart

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

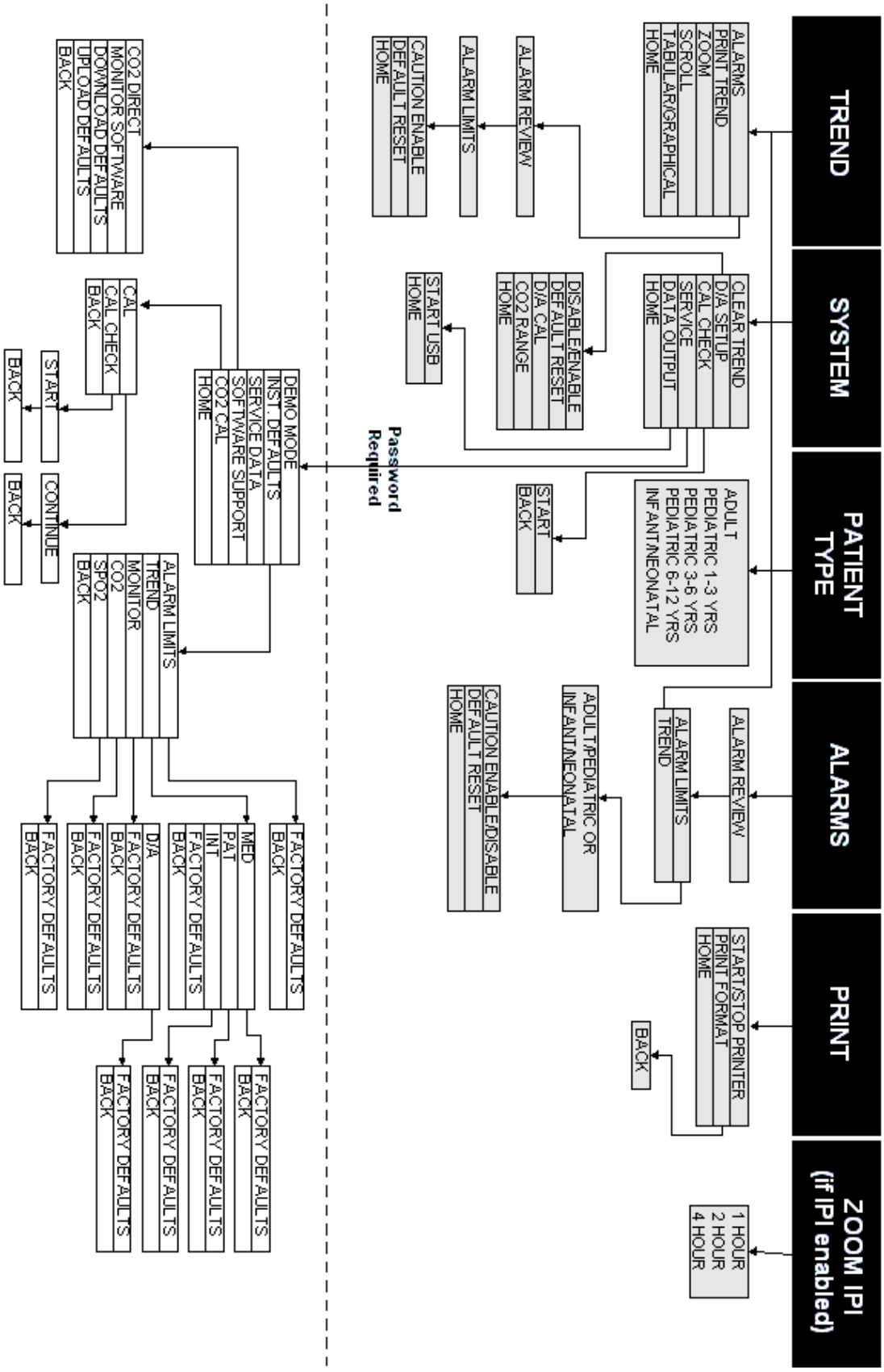



Figure 19 - Screen Menu Reference Chart

# Chapter 5

# *Capnography with the Capnostream Monitor*



## Microstream® $EtCO_2$ Consumables

| | |
|---|---|
| **CAUTION:** | Before use, carefully read the Microstream® $EtCO_2$ consumables *Directions for Use*. |
| **CAUTION:** | Only use Microstream® $EtCO_2$ consumables to ensure the monitor functions properly. |
| **CAUTION:** | Microstream® $EtCO_2$ consumables are designed for single patient use, and are not to be reprocessed. Do not attempt to clean, disinfect or blow out the FilterLine 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 FilterLine (i.e., from ambient humidity or breathing of unusually humid air), the message *Clearing FilterLine* will appear in the Capnostream message area. If the FilterLine cannot be cleared, the message *FilterLine Blockage* will appear in the $CO_2$ waveform display section on the Home screen and in the Capnostream message area. (If there is no waveform display, the message will appear only in the message area.) Replace the FilterLine once the *FilterLine Blockage* message appears. |
| **WARNING:** | The FilterLine may ignite in the presence of $O_2$ when directly exposed to laser, ESU devices, or high heat. When performing head and neck procedures involving laser, electrosurgical devices or high heat, use with caution to prevent combustion of the FilterLine 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. |

### Basic Principles

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

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

For further information, please contact your local representative.

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

### Microstream® $EtCO_2$ Consumables

The following products comprise the Microstream® $EtCO_2$ consumables:

| Product | Description and Suggested Application | Part Number (for box of 25) |
|---|---|---|
| FilterLine® Set Adult/Pediatric | FilterLine set for intubated patients (for non-humid environments). | XS04620 |
| FilterLine® H Set Adult/Pediatric | FilterLine set for intubated patients (for humid environments). | XS04624 |
| Smart CapnoLine™ $O_2$ Adult | Oral/Nasal FilterLine for non-intubated patients requiring oxygen during procedural sedation. | 007267 |
| Smart CapnoLine™ Plus Adult/Intermediate | Oral/Nasal FilterLine for non-intubated patients during procedural sedation. | 009818 |
| Smart CapnoLine™ Plus $O_2$ Adult/Intermediate | Oral/Nasal FilterLine for non-intubated patients requiring oxygen during procedural sedation. | 009822 |
| Smart CapnoLine™ H $O_2$ Adult | Oral/Nasal FilterLine for non-intubated patients requiring oxygen for post-op pain management (for long-term use). | 010478 |
| Smart CapnoLine™ H Plus $O_2$ Adult/Intermediate | Oral/Nasal FilterLine for non-intubated patients requiring oxygen for post-op pain management (for long-term use). | 010433 |
| CapnoLine™ H Adult | Nasal FilterLine for non-intubated patients receiving hi-flow oxygen by mask, on long term CPAP or Bi-PAP, or post-op pain management (for long-term use). | 008177 |
| NIV Line™ Adult | Nasal FilterLine for non-intubated patients under oxygen, CPAP, Bi-PAP, or NPPV mask. | 008174 |
| Smart CapnoBloc™ Adult/Intermediate | Non-intubated patients for use during upper endoscopy procedures. | 010037 |
| Smart CapnoBloc™ $O_2$ Adult/Intermediate | Non-intubated patients requiring oxygen for use during upper endoscopy procedures. | 010131 |
| FilterLine® XL (all sizes) | FilterLine for use during MRI scanning (see Monitoring CO2 during MRI Scanning on page 53). | 006325 |

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

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

**Note:** The listed products are also available in versions designed for other patient sizes.

This listing describes the main products available. For more information about Oridion FilterLines or additional sizing and packaging options for these products, see http://www.oridion.com/.

## Connecting a FilterLine

Before monitoring a patient with capnography, the appropriate FilterLine must be connected to the monitor and

to the patient.

➢ TO MAKE THE CONNECTIONS:

1. Slide open the FilterLine input connector shutter and connect the appropriate FilterLine. Screw the FilterLine connector into the monitor clockwise until it can no longer be turned.
2. Connect the FilterLine to the patient as described in the *Directions for Use* supplied with the FilterLine.

When the FilterLine 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.

## $CO_2$ Data Displayed by the Capnostream Monitor

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

- Real time $EtCO_2$ and $FiCO_2$ values along with selected unit (see Institutional Defaults on page 117 for details regarding the available units)
- Respiration rate (RR) in breaths per minute
- $CO_2$ Waveform

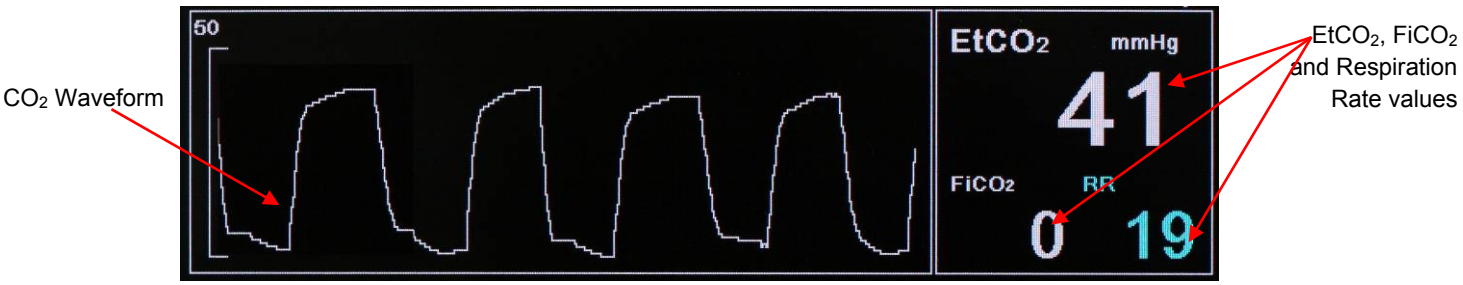



Figure 20 - $CO_2$ Data on the Capnostream Monitor

Additionally, the monitor can display $CO_2$ data in trend form, showing time, date, $EtCO_2$, RR, alarms and events, and a CASE START marker. For more information about trend display, see Using Trends on page 75.

When the $EtCO_2$ High or Low alarm limits are exceeded, the affected numeric will flash to alert the attending health care professional to the specific parameter that is affected.

A 10-second delay may be set on the EtCO2 and RR alarms, if desired, so that these alarms will sound only if the parameter exceeded alarm limits for at least 10 consecutive seconds. This option can be set using Institutional Defaults. See Institutional Defaults on page 117 for more information on how to set Institutional Defaults.

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. The $CO_2$ section of the numeric home screen is seen in Figure 21 - CO2 Section of Numeric Home Screen, below.

**Note:** For both neonatal and adult patients, the EtCO2 numeric displayed on the screen is the maximum value of CO2 over the last 20 seconds, updated once a second. An EtCO2 Alarm will occur based on the EtCO2 value displayed on the screen.

**Note:** 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.

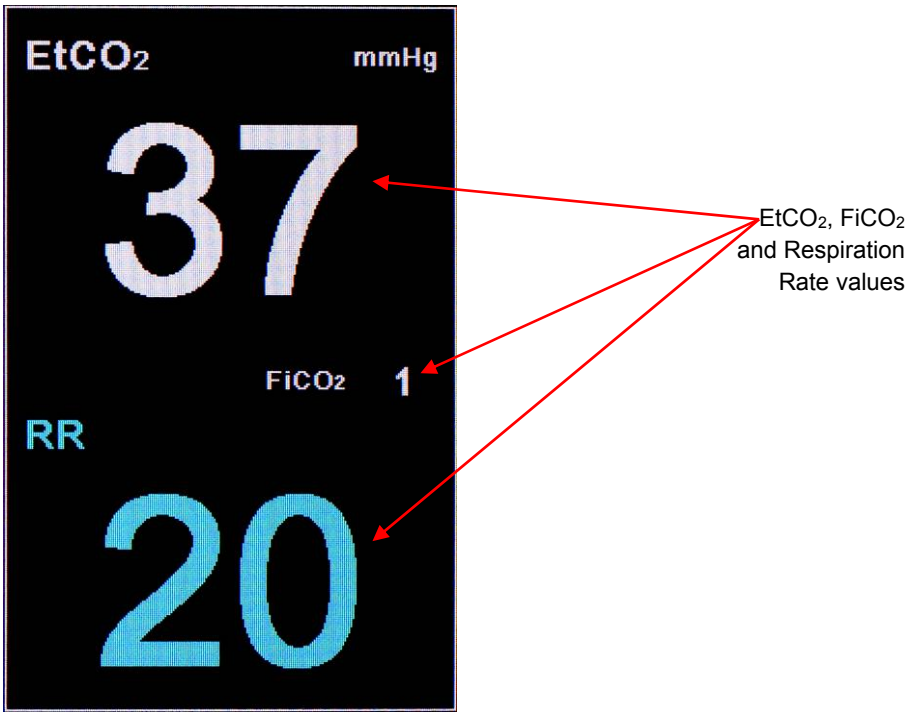



Figure 21 - CO2 Section of Numeric Home Screen

## Adjustable $CO_2$ Parameters

The Capnostream 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 device 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, see CO2 Parameters on page 123.

➢ TO CHANGE $CO_2$ PARAMETER SETTINGS:

1. On the Home screen, move the control knob to the $CO_2$ section of the screen, so that it is outlined in blue. Click the control knob.
2. The $CO_2$ Setup screen will appear. Move the control knob to the parameter that you wish to change and click to select that parameter. Move the control knob to select the desired setting and click to select the setting. A list of the settings that can be changed appears in Table 10 - Adjustable CO2 Parameters, below.
3. Move the control knob to the *HOME* button and click to select. The screen will also revert to the Home screen after a few seconds if no additional actions are taken on that screen, but if the screen timed out and reverted back to the *HOME* screen in this manner, changes will not be saved.
4. The changes in the parameters will remain in effect until the device is turned off.

Table 10 - Adjustable $CO_2$ Parameters

| Parameter | Choices | Factory Default |
|---|---|---|
| BTPS* | On/Off | On |
| $FiCO_2$ Display | On/Off | On |
| Pump-Off Timeout (minutes) | 5, 10, 15 or 30 | 15 |
| $CO_2$ Waveform Scale (mmHg) | 50, 100, 150, Auto | Auto |
| $EtCO_2$ Scale for Trend Display | 50, 100, 150 | 50 |
| RR Scale for Trend Display | 50, 100, 150 | 50 |

| | | |
|---|---|---|
| Sweep Speed (mm/sec)<br>[for current patient type] | 3, 6.3, 12.5, 25 | 6.3 |

* 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 device 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.

## Monitoring $CO_2$ during MRI Scanning

| | |
|---|---|
| **WARNING:** | Do not use the FilterLine® H Set Infant/Neonatal during magnetic resonance imaging (MRI) scanning. Using the FilterLine® H Set Infant/Neonatal during MRI scanning could harm the patient. |
| **CAUTION:** | During MRI scanning, the monitor must be placed outside the MRI suite. When the monitor is used outside the MRI suite, $EtCO_2$ monitoring can be implemented by attaching the FilterLine® XL, to provide extended length. |

Non-invasive $EtCO_2$ monitoring during magnetic resonance imaging (MRI) can be accomplished with the monitor and a FilterLine® XL. The maximum magnetic field (gauss) line in which $EtCO_2$ monitoring can take place is 3 A/m = 0.0375 Gauss.

➢ TO USE THE MONITOR DURING MRI SCANNING:

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.

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

# Chapter 6

# *Pulse Oximetry with the Capnostream Monitor*



## Nellcor $SpO_2$ Sensors

| | |
|---|---|
| **WARNING:** | Before use, carefully read the sensor *Directions for Use*, including all warnings, cautions, and instructions. |
| **WARNING:** | Do not use a damaged sensor. Do not use a sensor with exposed optical components. Do not immerse the sensor in water, solvents, or cleaning solutions (the sensor and connectors are not waterproof). Do not sterilize by irradiation, steam, or ethylene oxide. See the cleaning instructions in the directions for use for reusable pulse oximetry sensors. |
| **WARNING:** | Use only Nellcor sensors for $SpO_2$ measurements. Other sensors may cause improper monitor performance. |
| **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:** | Tissue damage can be caused by incorrect application or use of a pulse oximetry sensor, for example by wrapping the sensor too tightly. Inspect the sensor site as directed in the sensor Directions for Use to ensure skin integrity and correct positioning and adhesion of the sensor. |
| **WARNING:** | Do not use damaged patient cables. Do not immerse the patient cables in water, solvents, or cleaning solutions (the patient cable connectors are not waterproof). Do not sterilize by irradiation, steam, or ethylene oxide. See the cleaning instructions in the Directions for Use for reusable patient cables. |
| **Note:** | The oxygen transducers (sensors) used in this device 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. |

### Selecting Nellcor $SpO_2$ Sensors

When selecting a sensor, consider the patient's weight and activity, the adequacy of perfusion, the available sensor sites, and the anticipated duration of monitoring. The sensor models are summarized in Table 11 - Nellcor SpO2 Sensors, below. For further information, please contact your local representative.

Table 11 - Nellcor $SpO_2$ Sensors

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

### Performance Considerations

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

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

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

Inaccurate measurements can be caused by:

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

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

- the sensor is applied too tightly

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

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.

Select an appropriate sensor, apply it as directed, and observe all warnings and cautions presented in the directions for use accompanying the sensor.

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

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

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

- Verify that the sensor is properly and securely applied.
- Move the sensor to a less active site.
- Use an adhesive sensor that tolerates some patient motion.
- Use a new sensor with fresh adhesive backing.

If poor perfusion affects performance, consider using the MAX-R sensor; it obtains measurements from the nasal septal anterior ethmoid artery, an artery supplied by the internal carotid. This sensor may obtain measurements when peripheral perfusion is relatively poor.

## 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.

➢ TO CONNECT THE $SpO_2$ SENSOR:

1. Connect the $SpO_2$ extension cord firmly to the monitor $SpO_2$ sensor port, 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 *NO PULSE FOUND* and *$SpO_2$ SENSOR NOT ON PATIENT* until the time that the sensor is placed on the patient. This is classified as a Low Priority Alarm, and will generate a triple beep once a minute. 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.

## $SpO_2$ Data Displayed by the Capnostream Monitor

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

- $SpO_2$ Numeric
- Pulse Rate
- Sat Seconds figure (see SpO2 Alarms and SatSeconds on page 72 for an explanation of this issue)
- Plethysmograph ($SpO_2$ waveform)

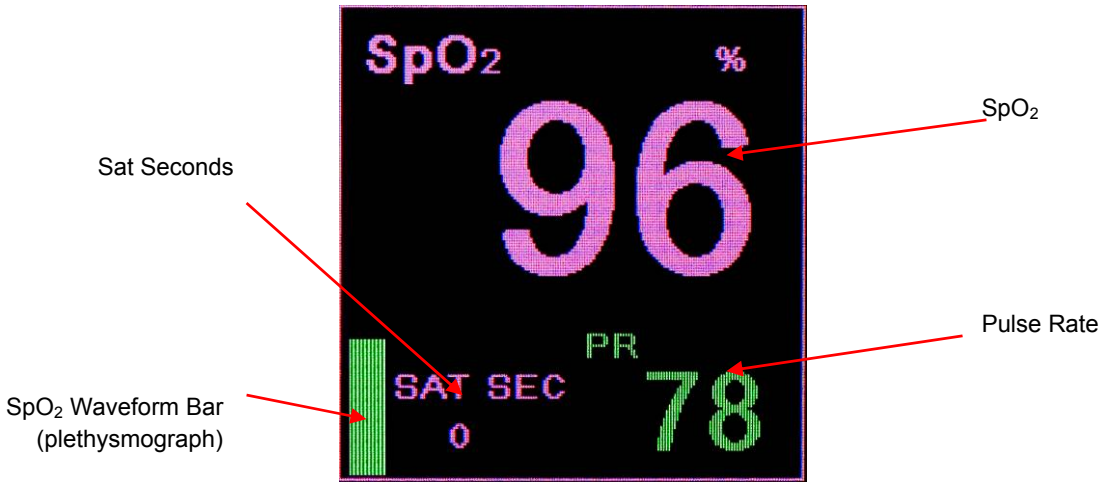



Figure 22 - $SpO_2$ Data on the Capnostream Monitor - Standard Screen

On the standard home screen with IPI enabled (default standard home screen), the plethysmograph (the $SpO_2$ waveform) is seen as a green vertical bar on the $SpO_2$ section of the screen (just to the left of the Sat Seconds value). The bar indicates pulse beat by rising and falling with the patient's pulse beat.

When the IPI display on the home screen is disabled (see IPI Options on page 62 and Institutional Defaults on page 117), the $SpO_2$ section of the home screen will appear as seen in Figure 23 - SpO2 Data on the Capnostream Monitor – Standard Screen with IPI Disabled, below.

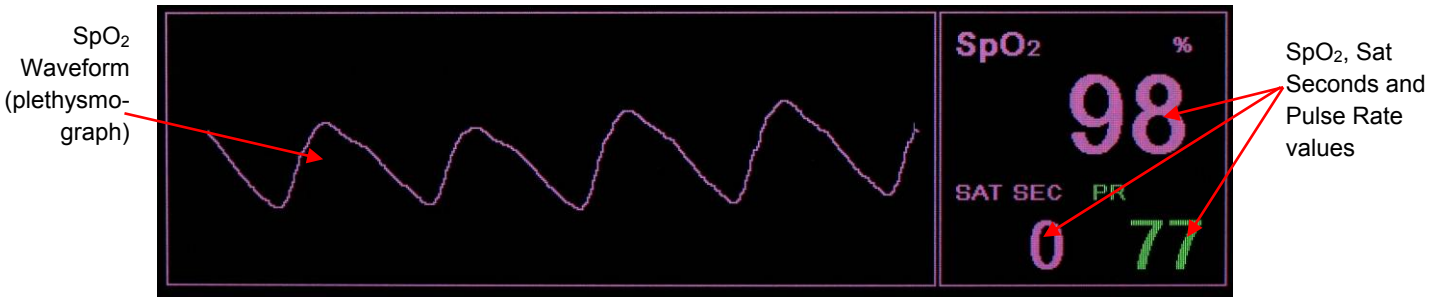



Figure 23 - $SpO_2$ Data on the Capnostream Monitor – Standard Screen with IPI Disabled

Additionally, the monitor can display $SpO_2$ data in trend form, showing time, date, $SpO_2$, pulse rate (PR), alarms, events and case markers to differentiate between patients. For more information about trend display, see Chapter 9 Using Trends on page 75.

When the SpO2 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.

If the numeric home screen is chosen, the $SpO_2$ waveform will not appear. Instead, $SpO_2$ data will appear in a large font, to enable easy viewing, even at a distance. The $SpO_2$ section of the numeric home screen is seen in Figure 24 - SpO2 Section of Numeric Home Screen, below.

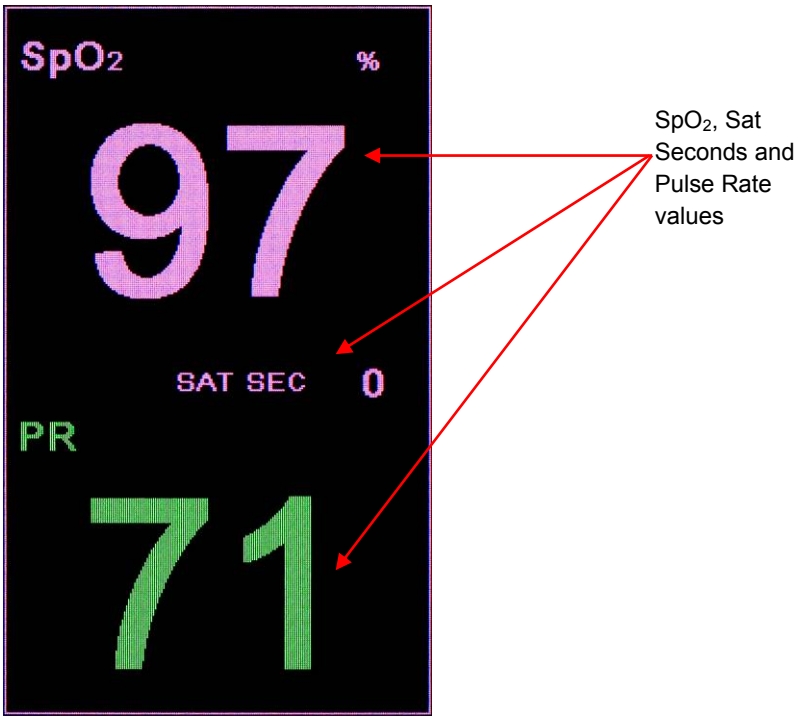



Figure 24 - SpO2 Section of Numeric Home Screen

## Adjustable $SpO_2$ Parameters

The Capnostream 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 device 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, see SpO2 Parameters on page 124.

➢ TO CHANGE $SPO_2$ PARAMETER SETTINGS:

1. On the Home screen, move the control knob to the $SpO_2$ section of the screen, so that it is outlined in blue. Click the control knob.
2. The $SpO_2$ Setup screen will appear. Move the control knob to the parameter that you wish to change and click to select that parameter. Move the control knob to select the desired setting and click to select the setting. A list of the settings that can be changed appears in Table 12 - Adjustable SpO2 Parameters, below.
3. Move the control knob to the *HOME* button and click to select. The screen will also revert to the Home screen after a few seconds if no additional actions are taken on that screen.
4. The changes in the parameters will remain in effect until the device is turned off.

Table 12 - Adjustable $SpO_2$ Parameters

| Parameter | Choices | Factory Default |
|---|---|---|
| Pulse Tone | On/Off | On |
| Sat Sec (Sat Seconds) | On/Off | On |
| $SpO_2$ Scale for Trend Display | 0-100, 50-100 | 50-100 |
| PR Scale for Trend Display | 150, 300 | 150 |
| Sweep Speed (mm/sec) [for current patient type] | 3, 6.3, 12.5, 25 | 25 |

## $SPO_2$ 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.

# Chapter 7

# *Integrated Pulmonary Index™*



## Introduction

The Integrated Pulmonary Index™ (henceforth referred to as IPI) is a numerical value which integrates four major parameters measured by Capnostream 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.

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 trend graph (seen on the Capnostream home screen) is particularly valuable, as it displays the patient ventilatory status trend in one easy-to-use graph, and thus can alert caregivers to changes in patient status. The importance of the IPI, thus, lies not only in its absolute numeric number, but also in its relationship to previous values, so that a graph can display an upward or downward trend in patient status and indicate to the caregiver that attention or intervention may be required.

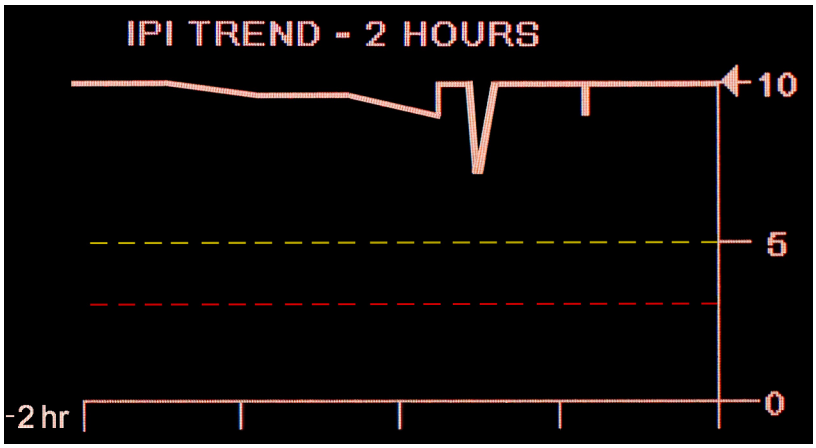



Figure 25. IPI Trend Graph

The IPI is modeled on normal healthy patients (ASA Physical Status value of 1 according to the ASA Physical Status Classification System, as published in *Relative Value Guide® - 2008* of the American Society of Anesthesiologists). Patients with ASA Physical Status values of 3 or higher are expected to have low IPI values by definition. Therefore, for patients with an ASA Physical Status value of 3 or higher, the IPI may have no added value.

Since the IPI 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 IPI is 1-10; values should be understood as seen in the table below.

| 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 |

**Note:** 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 Alert threshold to reflect their impaired respiratory capacity.

The 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.

## 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 Alert is triggered for a patient, medical staff should review the patient's status to determine if a change in medical care is required.

## IPI Display

IPI appears on the Home screen and is available in all Capnostream functions as a default option, along with other patient parameters such as $EtCO_2$ or $SpO_2$. On the Home screen, both numerics and a trend graph are provided for IPI.

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

## IPI Options

➢ TO CHANGE IPI OPTION SETTINGS:

1. On the Home screen, click the SERVICE button in the menu bar at the bottom of the screen.
2. The System Setup screen will appear. Move the control knob to the parameter that you wish to change and click to select that parameter. Move the control knob to select the desired setting and click to select the setting. A list of the IPI settings that can be changed appears in Table 13 - Adjustable IPI Options, below.
3. Move the control knob to the *HOME* button and click to select. The screen will also revert to the Home screen after a few seconds if no additional actions are taken on that screen.
4. If the IPI Low Alert is disabled, it will not appear in the Home screen or in any other screen.
5. The changes in the parameters will remain in effect until the device is turned off.

**Table 13 - Adjustable IPI Options**

| Parameter | Choices | Factory Default |
|---|---|---|
| Home IPI Display | 1 hour, 2 hour, 4 hour | 1 hour |
| IPI Low Alert | Enabled/Disabled | Disabled |

To change IPI Display and IPI Low Alert options on a more permanent basis, use the Institutional Defaults option, described in Institutional Defaults on page 117.

Some IPI options can also be changed from the Institutional Defaults section. See Appendix 1 Institutional Settings on page 117 for details.

# Chapter 8

# *Alarms and Messages*



## Introduction

Capnostream 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 four levels of alarms and advisories, each defined by a set of audible and/or visual indications:

- High Priority Alarms
- Low Priority Alarms
- Advisories
- Silent Advisories

High Priority Alarms are provided with the option of setting two levels of alarms, red urgent and yellow caution, for each alarm issue, if desired, in order to permit the clinician to follow developing alarm situations.

A delay may be set on the EtCO2 and RR alarms (both high-priority alarms), if desired, so that these alarms will sound only if the parameter exceeded alarm limits for at least 10 consecutive seconds. This option can be set using Institutional Defaults. See Institutional Defaults on page 117 for more information on how to set Institutional Defaults.

The following table describes how the alarms are indicated.

Table 14 - Alarm Indications

| Alarm Type | Indicators | | | |
|---|---|---|---|---|
| | Audible | Numerics | Messages | Indicator Light |
| High Priority (Patient) Alarms (red Urgent alarms and yellow Caution alarms) | Repeated Beep Pattern | Flashing Red for Urgent alarms (except NO BREATH) and Flashing Yellow for Caution alarms | Message area | Flashing Red or Flashing Yellow as required |
| High Priority (Patient) NO | Repeated Beep Pattern | Numeric reverts to zero (0) | Message area (with indication of time | Flashing Red |

| Alarm Type | Indicators | | | |
|---|---|---|---|---|
| | Audible | Numerics | Messages | Indicator Light |
| BREATH Alarm | | | elapsed since NO BREATH) and in waveform area | |
| Low Priority | Repeated triple beep | N/A | Message area (some messages also in waveform area – see below) | Solid Yellow |
| Advisories | Single Beep | N/A | Message area | N/A |
| Silent Advisories | None | N/A | Message area | N/A |

Some low priority alarm messages are displayed in the waveform area as well as in the message area; these messages are:

CO2 Waveform Area Messages:

- FILTERLINE BLOCKAGE
- PERFORMING AUTO ZERO
- CLEARING FILTER LINE
- CO2 ERROR

SpO2 Waveform Area Messages:

- SpO2 SENSOR NOT ON PATIENT
- SPO2 ERROR
- PULSE NOT FOUND

## Alarm Display

Alarm occurrences are prominently displayed in the real-time numeric section of all screens by the flashing of the numeric and a change of color of the numeric background: the background of the numeric will flash red if the value crosses the Urgent alarm limit threshold and flash yellow if the value if the value crosses the Caution alarm limit threshold. (The latter is relevant only if Caution alarm limits, which are optional, have been enabled.)

Alarm occurrences are also displayed on all screens in the header area, in order to provide immediate input on alarms to the health care provider. The preference of alarm display in the header area is described in Message Priorities on page 66.

In addition, the message "NO BREATH" and "FILTERLINE BLOCKED" appear in the $CO_2$ waveform area as well as in the header if this alarm condition exists. If the numeric home screen option is displayed (so that there is no waveform area), this message will appear only in the header area.

Likewise, the message "$SpO_2$ SENSOR NOT ON PATIENT" appears in the $SpO_2$ waveform area as well as in the header if this alarm condition exists. If the IPI option is enabled or if the numeric home screen is displayed, (so that there is no $SpO_2$ waveform area), this message will appear only in the header area.

The alarm occurrences for a specific patient over a specific period of time can be reviewed in the trend screen (see Chapter 9 Using Trends on page 75 for more details). Capnostream also provides an Alarm Review screen which displays the absolute number of each type of alarm generated over the last hour for the patient currently being monitored. The Alarm Review screen is seen in Figure 26 - Capnostream Alarm Review Screen, below.

This screen enables the health care provider to see at a glance how many alarms have been generated over the

last hour by the patient, in order to assess patient status. It is reached by clicking the *ALARMS* soft button on the menu bar, from the Home screen or the Trend screens.

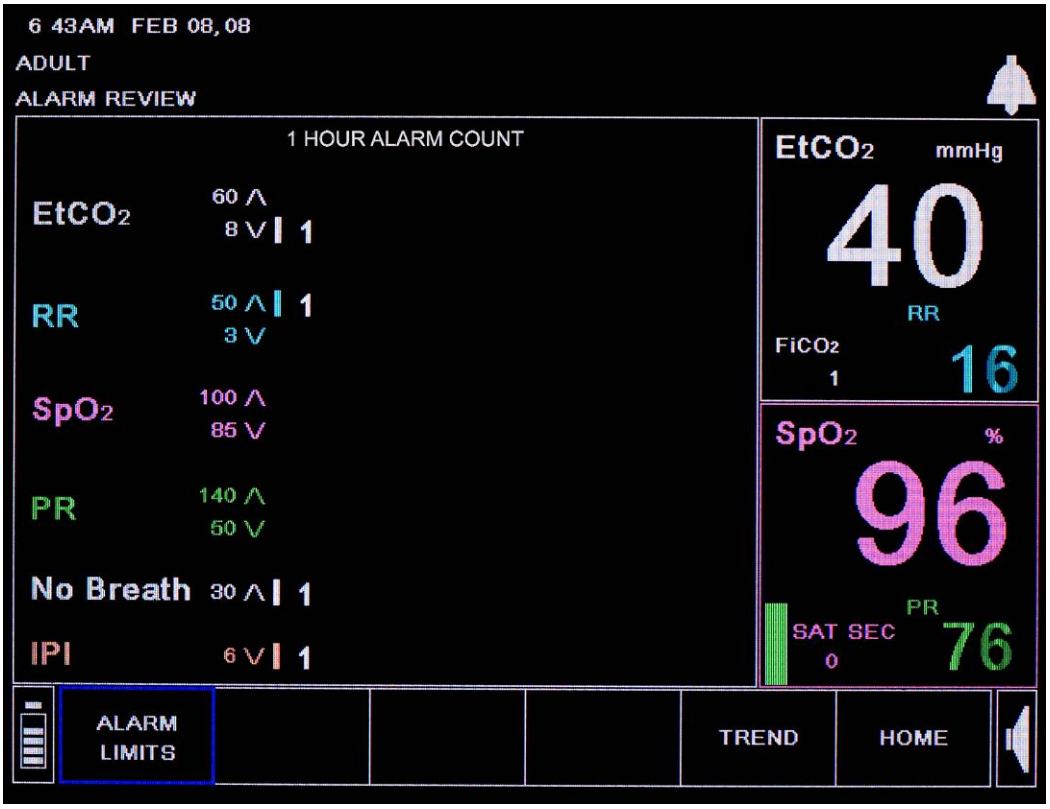



Figure 26 - Capnostream Alarm Review Screen

The Alarm Review screen covers the following alarms:

- $EtCO_2$ High and Low Alarms
- Respiration Rate High and Low Alarms
- $SpO_2$ High and Low Alarms
- Pulse Rate High and Low Alarms
- No Breath Alarm
- IPI Low Alert

The Alarm Review screen displays the absolute number of alarms that occurred in the last hour. Each type of alarm is indicated by a horizontal bar of a different color, sized to represent the quantity of alarms. The number of alarms appears to the left of the bar. The thin red vertical lines seen on the bar indicates the point at which a change in alarm limits occurred.

All alarms displayed are based on the urgent alarm limit set on the device. For example, if the $EtCO_2$ High alarm limit is set at 60, a level of 60 will be shown on the Alarm Review screen for $EtCO_2$ High, to the left of the upper white bar. If the alarm limit has been changed, the current limit will appear, but the number of alarms will reflect the limit in place when that alarm occurred, thereby accurately representing the number of alarms that occurred under each different alarm limit.

The Alarm Review screen will be cleared if the monitor is turned off or if the trend memory is cleared.

The Alarm Review screen will display alarms for the past hour, if the monitor has been running for an hour or more. If the monitor has been running for less than an hour, the screen will display data from the time the monitor was turned on. If the trend memory was cleared, data from the time the trend memory was cleared will be shown.

## Message Priorities

Alarms and advisory messages are displayed in the header area of the monitor in order of priority. When there is an alarm, only the alarm messages will appear in the message area, and advisory messages will not appear until the alarm condition is cleared. For example, if there is a *RR HIGH ALARM*, this alarm message will appear in the message area, and the advisory message *$SPO_2$ WEAK. REPOSITION SENSOR* will not appear even though the condition exists to generate this message.

If more than one alarm condition exists, the monitor will display each alarm message for about 4 seconds and continue to repeat the messages in turn until the alarm conditions are cleared. For example, the *RR HIGH ALARM* and *$SpO_2$ LOW ALARM* messages will alternate in the message area.

If no alarm condition exists but more than one advisory message condition exists, the advisory messages will each appear for four seconds as described above. The advisory messages will continue to appear until the condition clears or an alarm condition occurs and the alarm message is displayed instead of the advisory message.

## Types of Alarms

There are two levels of high priority patient alarms: Red Urgent Alarms and Yellow Caution Alarms.

Urgent Alarms indicate that the particular parameter has exceeded the Urgent limit. A default urgent limit is provided for each alarm situation. Urgent alarm limits can be changed to fit the particular institution, if desired.

Caution Alarms allow the clinician to address a developing situation before it is critical. By default, Caution Alarms are disabled. If the Caution Alarms are enabled, a limit which is between the red urgent alarm limit and the normal level is provided for each alarm situation. To enable Caution Alarms, see Changing Alarm Limits on page 70.

The associated numeric on the display will blink yellow if the numeric has reached the Caution Alarm limit or red if it has reached the Urgent Alarm limit. Also, the red alarm and yellow caution indicators will light appropriately. If a user does not wish to use this early caution system on any particular alarm, he can set both the Urgent and Caution Alarms for that alarm to the same limits (see Changing Alarm Limits on page 70). Then only the red Urgent Alarm will occur. You can also revert to a single level system for all alarms by pressing the button for Caution Disable.

All recording and digital reporting of patient alarms involves only the red Urgent Alarms.

In addition to the two levels of high priority alarms, low priority alarms, which alert the clinician to device issues (as opposed to patient issues, which are covered by high priority alarms), are also provided.

The following is an example for illustration purposes only, showing how the red Urgent and yellow Caution alarms appear on the monitor.

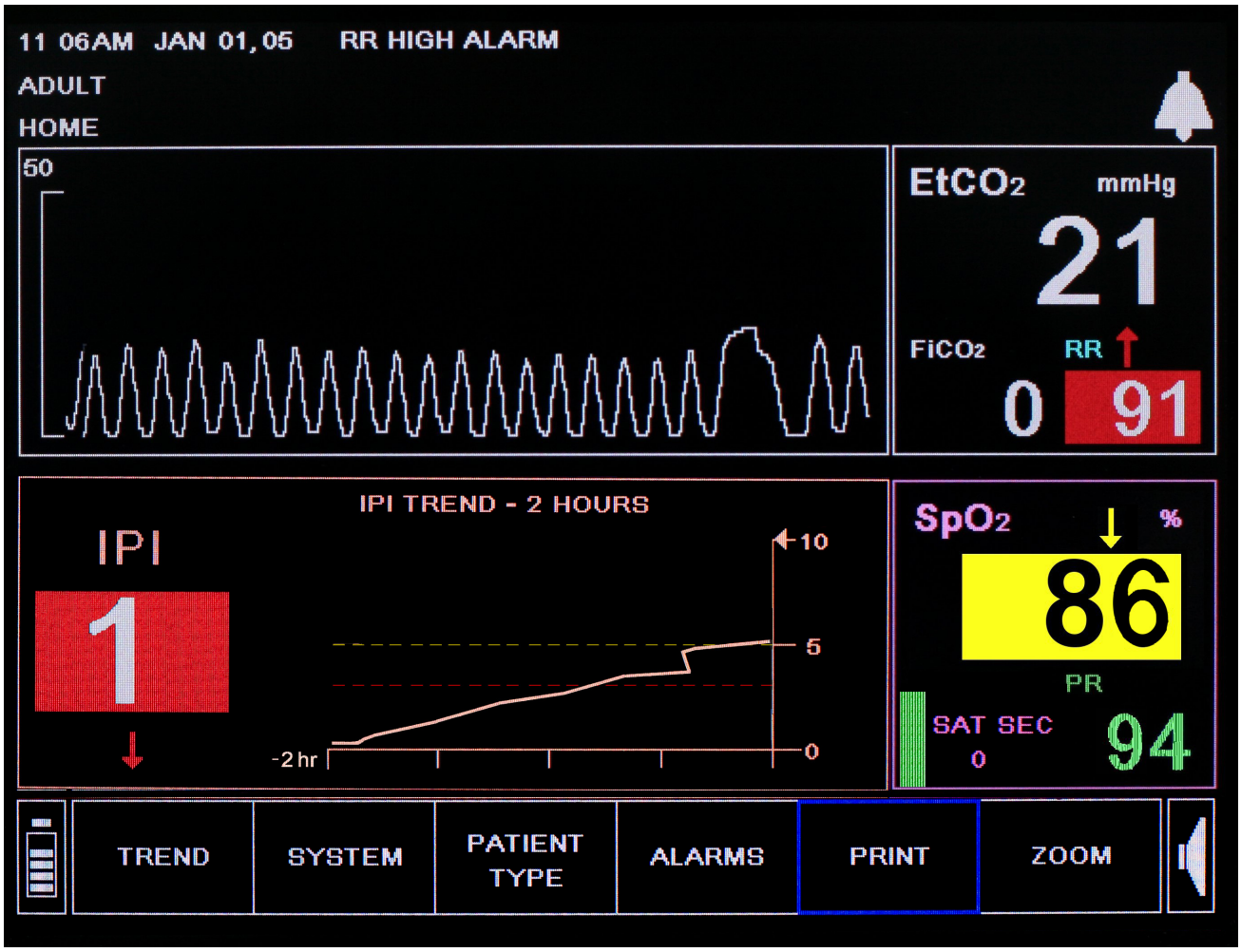



Figure 27 - Example Showing Alarms

In the above example, RR has exceeded the RR HIGH alarm limit. The RR reading will flash red, the red arrow pointing up indicates that the upper limit has been exceeded, and the message *RR HIGH* appears in the message area at the top of the screen. In addition, the IPI value is below the IPI Low Alert limit, indicated by the IPI value flashing red, and the red arrow pointing down. The message *IPI LOW* will also appear on the screen header (alternately with *RR HIGH*).

The yellow alarm on the $SpO_2$ value together with the yellow arrow pointing down indicates that the $SpO_2$ LOW caution alarm level has been exceeded.

### High Priority Alarms

Table 15 - High Priority Alarms

| Message | Description | Corrective Action |
|---|---|---|
| No breath xxx seconds | No valid breath has been detected for xxx seconds | Patient requires immediate medical attention. |
| $EtCO_2$ HIGH ALARM | The $EtCO_2$ is above the upper alarm limit | Patient requires immediate medical attention. |
| $EtCO_2$ LOW ALARM | The $EtCO_2$ is below the lower alarm limit | Patient requires immediate medical attention. |
| RR HIGH ALARM | The RR is above the upper | Patient requires immediate |

| Message | Description | Corrective Action |
|---|---|---|
| | alarm limit | medical attention. |
| RR LOW ALARM | The RR is below the lower alarm limit | Patient requires immediate medical attention. |
| $SpO_2$ HIGH ALARM | The $SpO_2$ is above the upper alarm limit | Patient requires immediate medical attention. |
| $SpO_2$ LOW ALARM | The $SpO_2$ is below the lower alarm limit | Patient requires immediate medical attention. |
| PULSE RATE HIGH ALARM | The pulse rate is above the upper alarm limit | Patient requires immediate medical attention. |
| PULSE RATE LOW ALARM | The pulse rate is below the lower alarm limit | Patient requires immediate medical attention. |
| $FiCO_2$ RATE HIGH ALARM | The $FiCO_2$ rate is above the upper alarm limit | Patient requires immediate medical attention. |
| IPI LOW ALARM* | The IPI is below the lower alarm limit. | Patient requires immediate medical attention. |

* 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.

### Low Priority Alarms

Table 16 - Low Priority Alarms

| Message | Description | Corrective Action |
|---|---|---|
| $CO_2$ ERROR | Failure has occurred which prohibits the operation of the $CO_2$ function. | Contact Oridion authorized personnel. |
| $SpO_2$ ERROR | Failure has occurred which prohibits the operation of the $SpO_2$ function. | Contact Oridion authorized personnel. |
| PULSE NOT FOUND | No detectable pulse. | Patient requires immediate medical attention. Reposition sensor on patient. |
| $SpO_2$ SENSOR NOT ON PATIENT | Sensor is off patient. | Place sensor properly on patient. |
| FILTERLINE BLOCKAGE | FilterLine is kinked or clogged. | Disconnect and reconnect the FilterLine. Check the airway adapter and if necessary, replace the FilterLine. |
| BATTERY LOW | Battery charge level is low and monitor will shutdown soon. | Connect monitor to AC power. |

## Advisories

Table 17 - Advisory Alarms

| Message | Description |
|---|---|
| CLEARING FILTERLINE | FilterLine kinked or clogged with water. Appears during clearing time until FilterLine is unclogged, or a blockage state is determined. |
| PERFORMING AUTOZERO | The monitor automatically performs a zeropoint calibration. |
| NO USB DEVICE FOUND | A valid flash memory device is not connected to the USB port. |
| USB FLASH FULL | No room on the USB flash memory device. |
| USB TIME OUT | USB communication stopped due to lack of response from the USB device. |
| $SPO_2$ WEAK. REPOSITION SENSOR.<br>$SPO_2$ WEAK. TOO MUCH LIGHT.<br>$SPO_2$ WEAK. TRY EAR SENSOR.<br>$SPO_2$ WEAK. TRY NASAL SENSOR.<br>$SPO_2$ WEAK. TRY ADHESIVE SENSOR<br>$SPO_2$ WEAK. TRY USING HEADBAND<br>$SPO_2$ WEAK. SENSOR TOO COLD.<br>$SPO_2$ WEAK. CHECK BANDAGE.<br>$SPO_2$ WEAK. NAIL POLISH?<br>$SPO_2$ WEAK. SENSOR TOO TIGHT?<br>$SPO_2$ WEAK DUE TO INTERFERENCE.<br>$SPO_2$ WEAK. CLEAN SENSOR SITE. | $SpO_2$ module detects a weak pulse and suggests possible causes. |

## Silent Advisories

Table 18 - Silent Advisory Alarms

| Message | Description |
|---|---|
| $CO_2$ 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, *$CO_2$ READY* replaces the *$CO_2$ WARM-UP* message. |
| CALIBRATION REQUIRED | $CO_2$ calibration is overdue. |
| MAINTENANCE REQUIRED | $CO_2$ maintenance is overdue. |
| $SPO_2$ EXTENDED AVERAGING | $SpO_2$ Averaging period has been extended to increase accuracy (under conditions of signal interference). |
| DATA TRANSFER IN PROCESS | Data communication in progress. |
| REPORT TRANSFER COMPLETE | Data communication is complete. |

| Message | Description |
|---|---|
| $CO_2$ MONITORING HAS BEEN OFF FOR HH:MM | Displays the hours and minutes the pump has been turned off during PUMP OFF mode. |
| DEMO MODE - PRERECORDED DATA | Displayed during demo mode when no other message is displayed. |
| INCOMPATIBLE SOFTWARE VERSION | Displayed during transfer of institutional defaults |
| NO FILE FOUND | Displayed during transfer of institutional defaults |

### Non-Message Area Advisories

The following messages appear in the waveform area of the display.

Table 19 - Non-Message Area Advisories

| Message/Description | Corrective Action |
|---|---|
| FILTERLINE DISCONNECTED | Connect a FilterLine to the monitor |
| $SPO_2$ SENSOR DISCONNECTED | Connect an $SpO_2$ sensor to the monitor |

## Alarm Silence

To temporarily silence/disable an alarm, press the alarm silence button.

When the alarm silence button is pressed, all audible alarms are silenced for 2 minutes. This includes both alarms that were already sounding and also alarms that may occur during the 2 minute period. The 2-minute alarm silence can be cancelled by a second press of the alarm silence button.

Visual alarms are still present. While the alarm silence period is active, a bell with crossed dashed lines through it ( ) is displayed on the screen. A crossed bell with solid lines symbol ( ) is shown if audio alarms are permanently disabled in the institutional settings.

## Changing Alarm Limits

Alarm limits differ for Adult/Pediatric (for adults and all pediatric patients) and Infant/Neonatal patients. Each set of alarms is set separately.

Alarm limits can be changed for Urgent and Caution alarms on the Alarm Limits screen. The Alarm Limits screen is accessed from the Alarm Review screen. On the Alarm Limits screen, the Caution alarms can be enabled or disabled. (If Caution Alarms are disabled, the values in the Caution Alarm column will be grayed out.) The limits can also be reset to Institutional Default settings, using the *DEFAULT RESET* button on the screen.

**Note:** 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.


Figure 28 - Alarm Limits Screen

➢ TO CHANGE ALARM LIMITS:

1. Open the Alarm Limits screen by selecting the *ALARM LIMITS* button on the Menu bar at the bottom of the Alarm Review screen.
2. To modify a setting, scroll to the individual limit setting using the control knob. Click the control knob to select that setting, and then turn the control knob to select a new value. Click the control knob again to set the new value.
3. To enable Caution Alarms, click the *CAUTION ENABLE* button on the screen, using the control knob. The Caution Alarm limit values will now become active, and can be changed on this screen in the same manner as Urgent Alarm limits can be changed. The *CAUTION ENABLE* button will show *CAUTION DISABLE* when the Caution Alarms are enabled, and clicking the *CAUTION DISABLE* button will disable the Caution Alarms.
4. Use the control knob to select *HOME* and click the control knob again to return to the Home screen.

Changing the high alarm limit towards the low alarm limit will force the low alarm limit down if necessary, in order to maintain a difference of at least 5 units between high and low alarm limits. This type of adjustment causes the low alarm limit to also change in color to make it obvious that it is active. Similarly, if you change the low alarm limit towards the high alarm limit, the high alarm limit is forced up if necessary, in order to maintain a difference of at least 5 units between high and low alarm limits. This type of adjustment causes the high alarm limit to also change in color to make it obvious that it is active.

The alarm will go off if it exceeds the High Limit value or goes below the Low Limit, not if it only reaches the value.

The SatSeconds value can also be changed in the Alarm Limits screen. For an explanation of SatSeconds, see the following section, SpO2 Alarms and SatSeconds.

Alarm limits will reset to their factory default when the power is turned off. To make the changes permanent, use the Service Mode to change the Institutional Settings for the alarm limits (see Appendix 1: Institutional Settings on page 117).

**Note:** 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.

## Testing Capnography Alarm Settings

In order to test the No Breath alarm, establish a display of normal breathing on the device. Once normal breathing is displayed, remove the sampling line from the patient's mouth to create a no breath situation. The device should then display a No Breath alarm.

## $SpO_2$ Alarms and SatSeconds

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

When monitoring upper and lower alarm limits of oxygen saturation, an audible alarm is triggered when one of these limits is violated by as little as one percentage point. In traditional alarm management, whenever the $\%SpO_2$ level crosses the alarm limit, the alarm sounds every time the limit is exceeded.

If such frequent alarms are not desired, they can be prevented by using the SatSeconds technique developed by Nellcor. Using this technique, upper and lower alarm limits are set in the same way they are set in traditional alarm management. A SatSeconds limit can also be set, in order to sound an alarm while taking into account not only the crossing of the $\%SpO_2$ alarm limit, but also the time for which the patient's $\%SpO_2$ reading is above or below the limit.

The method of calculation is as follows:

SatSeconds is calculated by multiplying the number of percentage points that the $\%SpO_2$ falls outside of alarm limit by the number of seconds that the $\%SpO_2$ level remains outside that limit. This can be stated as an equation:

Points x Seconds = SatSeconds

Where:

Points = $\%SpO_2$ percentage points outside of the limit

Seconds = number of seconds the $\%SpO_2$ remains at that point outside of the limit.

The alarm response time, assuming a SatSeconds limit set at 50 and the $SpO_2$ LOW alarm limit set at 90, is described and illustrated below.

In this example, the $\%SpO_2$ level drops to 88 (2 points) and remains there for a period of 2 seconds (2 points x 2 seconds = 4 SatSeconds).

The $\%SpO_2$ then drops to 86 for 3 seconds and then to 84 for 6 seconds.

The resulting SatSeconds are:

$\%SpO_2$ Seconds SatSeconds

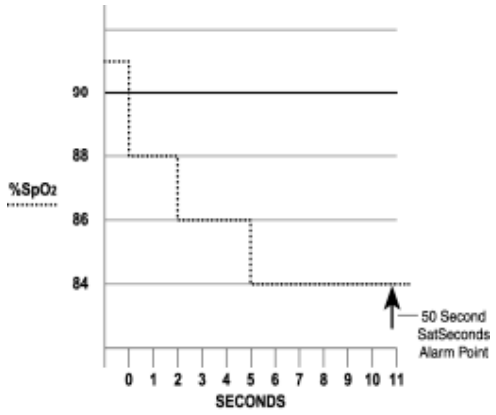
2 x 2 = 4

4 x 3 = 12

6 x 6 = 36

Total SatSeconds = 52

After approximately 10.9 seconds the $SpO_2$ alarm would sound, because 50 SatSeconds had been exceeded (note the arrow in the figure below).




Saturation levels may fluctuate rather than remain steady for a period of several seconds. Often, the $\%SpO_2$ levels may fluctuate above and below the alarm limit, re-entering the non-alarm range several times.

During such fluctuations, the Capnostream integrates the number of $\%SpO_2$ points, both positive and negative, until either the SatSeconds limit (SatSeconds time setting) is reached, or the $\%SpO_2$ level returns to within a normal range and remains there.

### SatSeconds Alarm Display

SatSeconds are displayed in the $SpO_2$ display area on the monitor screen. When SatSeconds is enabled and the $SpO_2$ reading is below the minimum, the SatSeconds counter will begin. If the SatSeconds limit is been reached, an audible alarm sounds and the displayed $\%SpO_2$ numeric rate flashes. As with standard alarm management, the audible alarm may be silenced by pressing the ALARM SILENCE button ( ).

## Alarm Limits - Factory Defaults

The factory defaults for the Adult/Pediatric and Infant/Neonatal alarm limits are given in Table 32 - Factory Default Alarm Limits on page 120.

Caution Alarms are disabled by default.

# Chapter 9

# *Using Trends*



## Introduction

The Capnostream stores patient data that provides detailed information on the history of the patient during monitoring.

The trend displays allow you to look at the patient history as part of the medical analysis to aid in patient assessment.

The institution can define the trend storage to be: 12 hours of data at 5 seconds resolution, 24 hours of data at 10 seconds resolution, or 72 hours of data at a resolution of 30 seconds.

The trend data stores the following parameters:

- Time, Date, $EtCO_2$, RR, $SpO_2$, PR, IPI
- High priority patient alarms (only red urgent alarms) (excluding $FiCO_2$ High alarm, which is not stored in trend memory)
- Equipment-caused events such as LOW BATTERY or other monitor-related messages.
- Event markers input by the user, along with any event label.
- CASE START marker to indicate start of case
- Count of alarm occurrences (for all High Priority alarms)

Changing the resolution of how often data is stored can be done in the Institutional Defaults screen only (See Appendix 1: Institutional Settings on page 117).

**Note:** Changing the resolution setting will clear the trend data previously stored in memory.

The trend data can be viewed on the monitor, printed, and downloaded via an RS-232 connection or a USB flash memory device for transfer to a computer for further analysis.

If the patient will be monitored for a longer period than can be stored in the monitor memory, it is recommended to regularly download patient data using the USB interface as described in Chapter 11 Downloading Patient Data on page 93.

## 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 (2, 4 or 12 hours at a time) and scroll through the data looking for patterns, specific events or alarms.

Once you have located the data of interest, you can zoom in to the specific event, or examine the messages and

data using the Tabular Trend screen. Tabular Trend presents the data in an easy to read table format.

## Graphical Trend Display Screen

➢ TO VIEW THE GRAPHICAL TREND DISPLAY SCREEN:

1. From the Home screen, use the control knob to select *TREND* from the soft buttons in the menu bar at the bottom of the screen. The Graphical Trend screen, seen in Figure 29 - Graphical Trend Display, below, is shown.

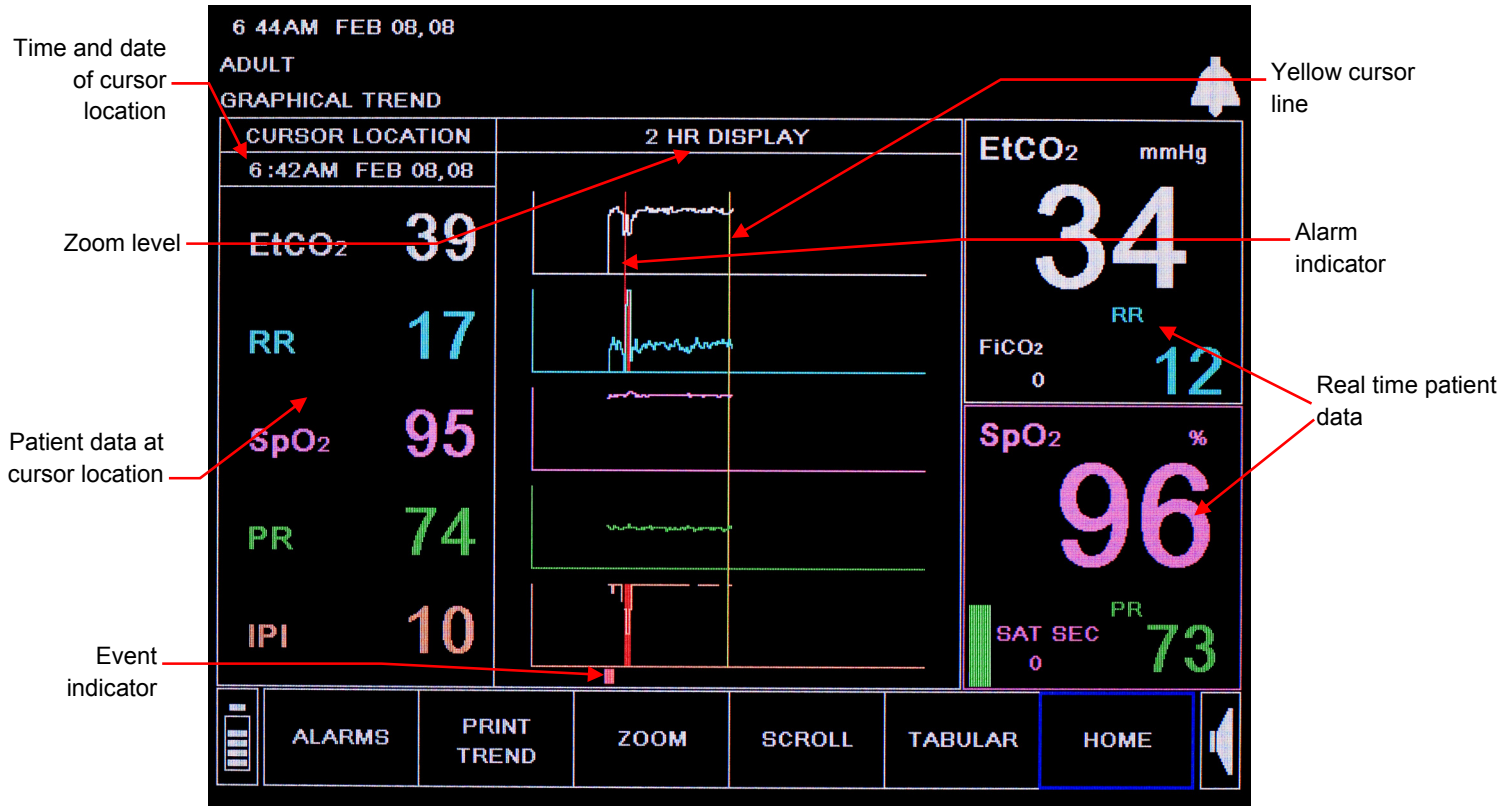



Figure 29 - Graphical Trend Display

2. Please note that the Trend screens display both Trend information (described below) and real time patient numerics, which are displayed on the right hand side of the screen. The Trend data displayed is historic data from the trend memory. When the screen is first opened, it shows the cursor line in the middle of the graphical display, which is the middle point of the displayed data. Data regarding the patient at the point in time indicated by the cursor is displayed at left. Details regarding the graphical trend display appear in the next section.

### Graphical Trend Display

In the center of the screen are the graphic trend displays. The upper two graphs show historic trend capnography data: $EtCO_2$ in white and respiration rate values in blue. Similarly, the two middle graphs show the patient's historic trend pulse oximetry data: $SpO_2$ data in pink and pulse rate values in green. The bottom graph shows IPI values in a orange-colored graph.

On the left hand side of the screen is the historic patient data at the date and time where the cursor is located. The exact recorded date and time of the cursor location are displayed.

- Zoom level: Can be set to 2, 4 or 12 hours using the *ZOOM* key
- Yellow cursor line: The vertical yellow line extends through all four graphs and is movable with the control knob when the *SCROLL* option is selected. The cursor line shows the current location in the trend data, with the exact date and time listed under the *CURSOR LOCATION*

heading near the top left of the screen as shown in Figure 29 - Graphical Trend Display on page 76.

- Alarm indicator: wide vertical red lines that may appear in the four graphs showing where in time an alarm occurred. For $EtCO_2$, $SpO_2$, RR, PR and IPI alarms, the red line is drawn through the respective graph of the waveform for that parameter. In the case of *NO BREATH* alarms, the red line extends though both the $EtCO_2$ and RR graphs. The actual alarm details can be viewed in the Tabular trend display screen, described in Tabular Trend Display Screen on page 79.
- Event indicator: the small vertical pink line along the bottom of the graph shows when an event was registered. The actual event can be viewed in the Tabular trend display screen, described in Tabular Trend Display Screen on page 79.

The following controls for viewing graphical trend are selected from the Menu Bar.

- *TABULAR* – switches the display from Graphical to Tabular display (in the Tabular trend display, this control changes the display to Graphical). See Tabular Trend Display Screen on page 79 for an explanation of the tabular trend display.
- *SCROLL* – allows you to scroll through the patient data. The date and time of the cursor location are indicated under CURSOR LOCATION.
- *ZOOM* - allows you to increase or decrease the time segment being looked at.
- *PRINT TREND* – provides a printout of the trend display currently seen on the screen.
- *ALARM LIMITS* – displays the Alarm Limits screen allowing you to see what the settings are, and modify them if necessary.

### Using SCROLL and ZOOM

There are many ways in which the Trend screens can be used to examine patient data. The following is a brief overview of a general method of searching for and displaying specific events in the graphical Trend screen.

➢ TO VIEW TREND DATA IN SCROLL MODE:

1. In the graphical trend mode, use the control knob to select *SCROLL* from the Menu Bar. The box around the word *SCROLL* in the Menu Bar and the time/date heading both turn yellow, indicating that you are in scrolling mode.

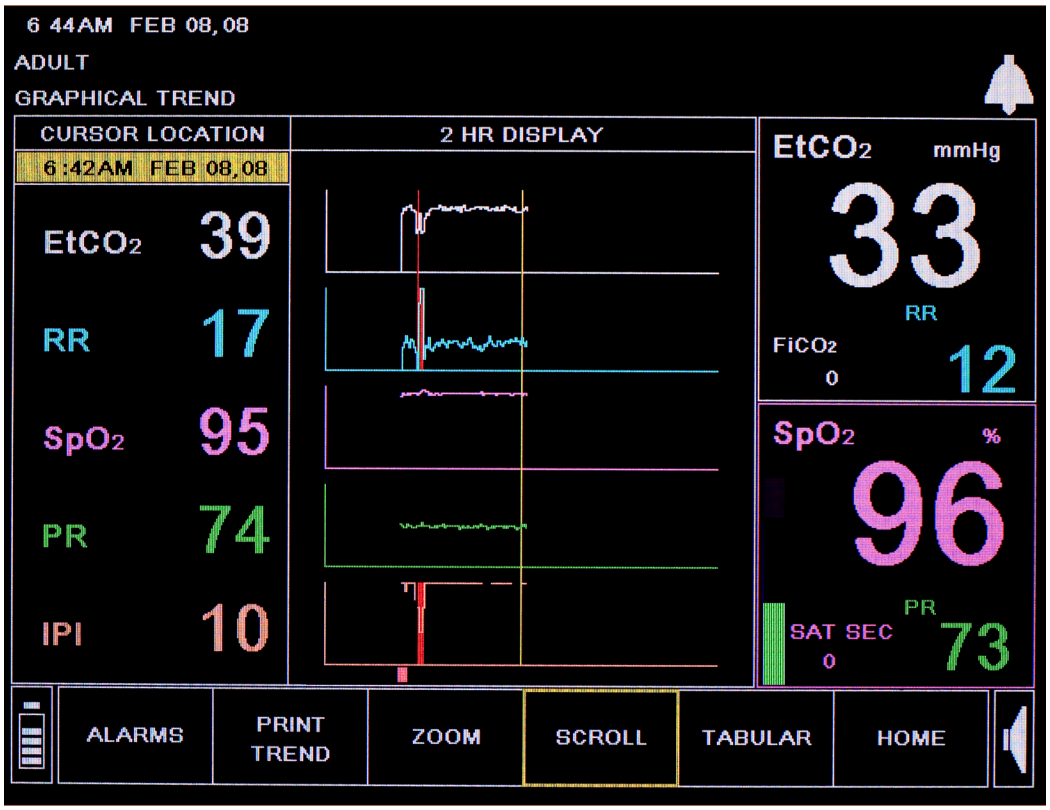



Figure 30 - Scroll mode in the Graphical Trend

2. When you scroll to the end of the screen and continue to scroll, the screen will change to add the next or previous 1/2 time period to the display (for example, if you are viewing a 2 hour display, from 4 PM to 6 PM, and you scroll backward to reach 4 PM, the yellow line will return to the middle of the screen and you will see 3 PM to 5 PM instead on the screen). Scrolling all the way to the right and getting a beep means you are at the current time. Scrolling all the way to the left and getting a beep means that you are at the beginning of the recorded data.
3. To see a longer or shorter time period on the display, select *ZOOM* on the Menu Bar and turn the control knob to change the resolution to 2, 4 or 12 hours. The box on the Menu Bar around *ZOOM* turns yellow to indicate that you are changing the zoom level. Click the control knob again to exit the Zoom function. You can then return to Scroll mode to continue inspecting the patient's recorded data.

   To see the greatest amounts of patient data, change the resolution to 12 hours. To do this, use the control knob to select and click on *ZOOM* on the Menu Bar. The box around *ZOOM* will turn from blue to yellow and the title area showing the display resolution will also turn yellow. Turn the control knob to select *12 HR DISPLAY*, and then click the control knob.

   Now use the control knob to select and click on *SCROLL* on the Menu Bar. The box around *SCROLL* will turn from blue to yellow, and the time and date heading under *CURSOR LOCATION* will also turn yellow. Turn the control knob to move the cursor to the left or right. As you turn the control knob, the time changes, and the patient data on the left hand side of the screen also changes to show the readings at that point in time.

   To find an event or alarm occurrence, scroll the graphic display to look for event and alarm markers as shown above in Figure 29 - Graphical Trend Display on page 76. Place the yellow cursor line on the red alarm marker, then exit the scroll mode by clicking the control knob. When you zoom to a different time display, the cursor will appear in the middle of the graphical screen at the appropriate time that it marked on the previous screen.

   Use the *ZOOM* button to select a Zoom option (i.e., to go to lower zoom level, 4, 2 or 1 hours) and scroll again until you have found your specific area of interest.

   To exit from Zoom change mode, click the control knob.

4. To exit from Scroll mode, click the control knob.

To view more information about the displayed patient, use the control knob to select the *TABULAR* trend display on the Menu Bar, and see the instructions below in the section Tabular Trend Display Screen on page 79.

## Tabular Trend Display Screen

➢ TO VIEW THE TABULAR TREND DISPLAY SCREEN:

1. In the graphical trend mode, use the control knob to select *TABULAR* from the Menu Bar. The Tabular Trend display screen will appear. To enter the Tabular Trend mode from the Home screen, click *TREND* on the Menu bar and then *TABULAR* on the Menu bar.


Figure 31 - Tabular Trend Display

2. Note that the real time patient data is displayed on the right hand side of the screen, while the left side of the screen displays the Tabular Trend with detailed historic patient data.
3. Click *ZOOM* on the Menu bar to change the time resolution from the current display to 60, 15, 3 or 1.5 minutes or the MINIMUM setting. The MINIMUM setting is defined as the trend recording resolution and can be 5, 10 or 30 seconds (see Appendix 1: Institutional Settings on page 117 for instructions on how to change the recording resolution).

The controls for viewing tabular data are:

- *GRAPHICAL* – switches the display from to Graphical from Tabular display (in the Graphical trend display, this changes to Tabular)
- *SCROLL* – allows you to scroll through the table of patient data.
- *ZOOM* – allows you to increase or decrease how much time is averaged into each data point shown in the table. At the lowest setting, the zoom allows you to examine detailed alarms and events.
- *PRINT TREND* – provides a printout of the trend display currently seen on the screen.

- *ALARM LIMITS* – displays the Alarm Limits screen to allow you to see what the settings are, and change them if necessary.

The table below gives a sample of the tabular display at a resolution of 1.5 minutes.

**Table 20 - Tabular Display Example**

| TIME | EtCO2 mmHg | RR bpm | SpO2 % | PR bpm | IPI | EVENTS |
|---|---|---|---|---|---|---|
| 3:45 PM | May 23 08 | | | | | |
| 00 | 34 | 34 | 97 | 62 | 8 | 16* |
| 3:46 PM | May 23 08 | | | | | |
| 30 | 30 | 30 | 98 | 61 | 6 | 1 ▲ 24* |
| 3:48 PM | May 23 08 | | | | | |
| 00 | 30 | 32 | 99 | 63 | 6 | |
| 3:49 PM | May 23 08 | | | | | |
| 30 | 32 | 34 | 98 | 63 | 7 | |
| 3:51 PM | May 23 08 | | | | | |
| 00 | 32 | 32 | 98 | 62 | 7 | 1▲ |
| 3:52 PM | May 23 08 | | | | | |
| 30 | 33 | 33 | 97 | 61 | 7 | |

Events are indicated by a triangle (similar to the event button located on the front panel of the monitor) and alarms are indicated by an asterisk. The number beside each indicates how many alarms or events occurred during that time period.

4. To see the specific events and alarms, change the *ZOOM* setting to the MINIMUM value, which changes the zoom level to the lowest time interval. Specific events and alarms will now appear in the table and you can use the Scroll option to scroll up and down the table. The table below gives a sample of the tabular display at the MINIMUM resolution (in this case the minimum resolution is set at 5 seconds).

**Table 21 - Detailed Tabular Display Example**

| TIME sec | EtCO2 mmHg | RR bpm | SpO2 % | PR bpm | IPI | EVENTS |
|---|---|---|---|---|---|---|
| 3:45 PM | May 23 08 | | | | | |
| 20 | 34 | 88 | 97 | 72 | 7 | OXYGEN |
| 25 | 30 | 90↑ | 98 | 71 | 5 | |
| 30 | 30 | 90↑ | 99 | 73 | 5 | |
| 35 | 32 | 90↑ | 98 | 73 | 6 | |
| 40 | 32 | 91↑ | 98 | 72 | 6 | |
| 45 | 33 | 90↑ | 97 | 71 | 6 | |
| 50 | 34 | 89 | 97 | 73 | 7 | |
| 55 | 34 | 88 | 97 | 72 | 7 | |

| 3:46 PM | May 23 08 | | | | | |
|---|---|---|---|---|---|---|
| 00 | 34 | 88 | 98 | 71 | 7 | |
| 05 | 29 | 89 | 97 | 72 | 5 | |

In the above example, oxygen was given to the patient during the period between 3:45:20 and 3:45:25 PM followed by a rise in respiration rate to a level that triggered the high value alarm. This is indicated by the red up arrow. Similarly, a low respiration rate alarm would have a red down arrow.

If the Event Marking Mode is set to QUICK, no text information is available at the lowest zoom level, but a triangle will still appear to indicate that an event was marked.

5. The monitor will hold up to 72 hours of patient data. If there is more data than you can see on the screen, then scrolling up will change to display earlier data (if you scroll up) or later data (if you scroll down).

## Important Notes Regarding Trend Reports

Please note the following issues regarding trend reports, both on-screen tabular trend reports, printed trend reports, and downloaded trend reports:

- Each number displayed in the trend memory is an average of the results for each second over the sampling period. For example, for a 30-second sampling period, the displayed result each 30 seconds is an average of the data points for each of the 30 seconds within the sampling period.
- If an alarm took place anywhere in the sampling period (i.e., at some point during the 30 seconds of a 30-second time period, when data is being recorded every 30 seconds) it will be noted, even if the averaged number recorded does not indicate a cause for an alarm.
- "$EtCO_2$ not available" is generated every hour for an Autozero and takes 15 seconds. When this occurs, $EtCO_2$ and other physiological values are held at their values prior to the Autozero.

## Specific Events as seen in Trend Data

➢ TO SEARCH FOR SPECIFIC EVENTS IN TREND DATA:

1. Use the cursor in the graphical trend screen to locate an area of interest.
2. Use *ZOOM* to get as close as possible to the specific area.
3. Switch to the Tabular trend display.
4. Use *SCROLL* to find the area of interest.
5. Zoom to minimum resolution to see detailed alarm and event information.

## Using the Graphical Trend Screen for Monitoring Patients

It is possible to use the Graphical Trend screen as the main monitoring screen, rather than the Home screen. Instead of seeing the real time waveforms, the Graphical Trend gives you the ability to easily track changes in the patient's condition. The real time numeric data is shown on the right hand side of the screen for both the Trend and Home screens.

When using the Graphical Trend screen as the main monitoring screen, it is important to ensure that the graphs are updated with the latest data. This will happen automatically as long as the Scroll function has not been used since you entered the Graphical Trend screen. While in automatic update mode, the screen will automatically update new data to the right of the yellow cursor line. When the area to the right of the cursor is filled, the graphs will shift, allowing more data points to be plotted.

If you use the Scroll feature and then want to return to using the Graphical Trend to monitor the patient, simply go to the Home screen and then select *TREND* again.

## Printing the Trend Data

If the optional printer is installed, you can obtain a printout of the trend data that is displayed on the screen by selecting *PRINT TREND* in the Menu Bar.

## 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. If you are working with cases, and the current case is ended, the trend memory is automatically cleared.

➢ TO ERASE TREND MEMORY:

1. To erase the trend data from the monitor memory, use the control knob to go to the Home screen and select *SYSTEM* on the menu.
2. On the System screen, select *CLEAR TREND*. The word *CONFIRM?* will appear just above the Menu Bar.
3. If you are certain that you want to erase the trend memory, click the control knob. If you do not want to erase the trend memory, turn the knob to the left or right to cancel.
4. When the machine is turned on, a message appears, suggesting that you erase the trend memory in order to start a new patient without information from previous patients in the trend memory. This screen appears in Figure 32 - Trend Memory Message, below. Click *YES* to erase the trend memory. If you intend to continue measurement of the same patient as previously, you may want to retain the trend memory. In that case, click *NO*. If you record patient data as part of a case, trend memory will always be erased when you close the case.

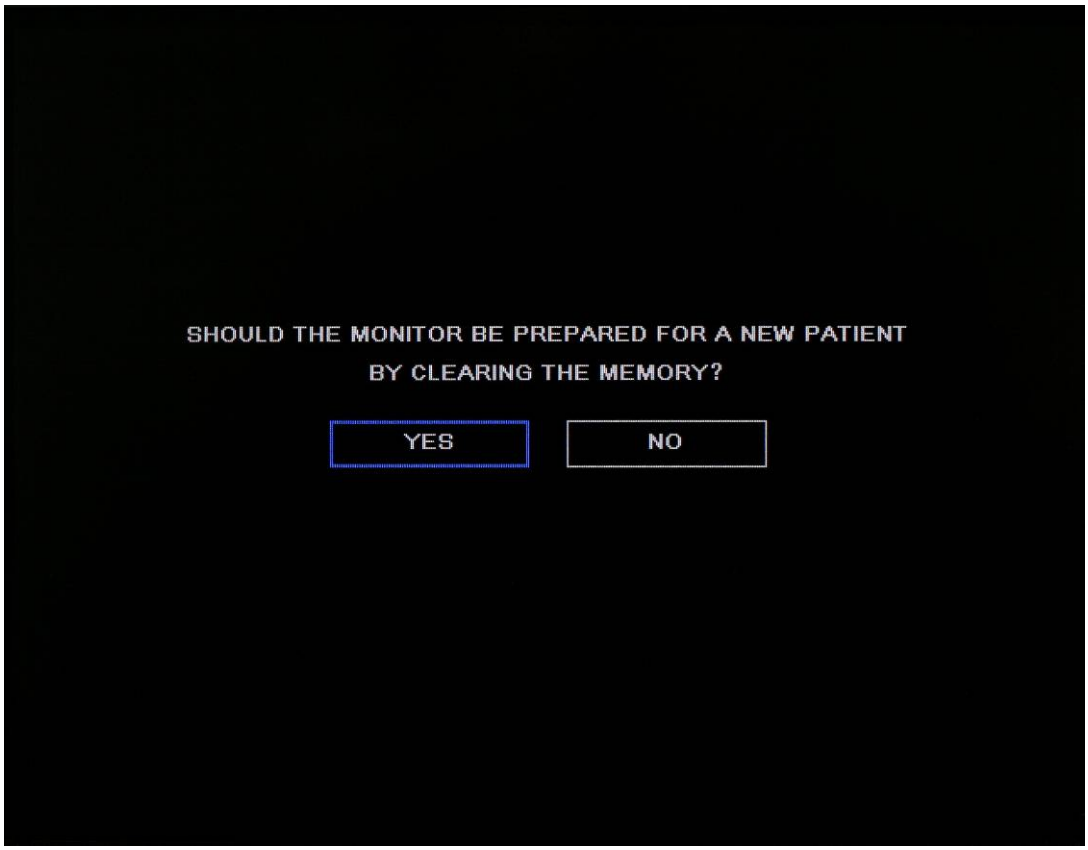



Figure 32 - Trend Memory Message

## Configuring Trends

To change the parameters for trend displays, go to the Home screen and select *SYSTEM* to see the System Setup screen. The table below shows the options as they appear on the System Setup screen.

Table 22 - Monitor Parameters

| | |
|---|---|
| DATE | MAY 25, 2006 |
| TIME | 11:27:32 AM |
| LANGUAGE | ENGLISH |
| EVENT MARKING MODE | DETAILED |
| TREND GRAPHICAL DISPLAY [hour] | 4 hour |
| TREND INCREMENT DISPLAY [min] | 1.5 min |
| NURSE CALL | DISABLED |
| HOME SCREEN | STANDARD |
| HOME IPI DISPLAY [hour] | 1 hour |
| IPI ALARM | DISABLED |

The Trend Data parameters are Event Marking Mode, Trend Graphical Display and Trend Increment Display.

The Trend Display settings refer to how the screen will be initially be displayed when you enter the Trend mode. Once you are on the Trend screen, these views can be easily changed using the Zoom feature. These settings will remain until the monitor is powered off.

Changing the resolution of how often data is stored can be done in the Institutional Defaults screen only (See Appendix 1: Institutional Settings on page 117).

### Event Marking Mode

- 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 (see the section Entering Patient Events on page 43).
- Quick Event Marking: Marks that an event occurred when the Event button is pushed, but does not give any details.

If the monitor is set to Detailed event marking mode, but you don't have time to enter the detailed event, a quick event mark can be entered by pushing the Event button twice.

### Trend Graphical Display

Trend Graphical Display options are 2, 4 and 12 hours. The factory default is 4 hours.

### Trend Increment Display

Trend Increment Display options for the Tabular Trend Display are MINIMUM, 1.5, 3, 15 or 60 minutes. The factory default is 1.5 minutes. The MINIMUM setting is defined as the trend recording resolution and can be 5, 10 or 30 seconds (see Appendix 1: Institutional Settings on page 117 for instructions on how to change the recording resolution).

Changing the resolution of how often data is stored can be done in the Institutional Defaults screen only (See Appendix 1: Institutional Settings on page 117).

# Chapter 10

# *Printing Reports*



## Introduction

The Capnostream can be purchased with a built-in thermal strip printer. The report printing menu in the Capnostream is for use with the optional printer.

To print a report on an external printer, the recommended procedure is to transfer the data to a computer using a USB flash memory device (see Data Transfer via the USB Data Port on page 93). The report can then be formatted and printed using the computer.

The following printed reports are available:

- Tabular Case Report
- Graphical Case Report
- Tabular Trend Report
- Graphical Trend Report
- Real Time Continuous Waveforms
- Real Time Continuous $CO_2$ Waveform
- Real Time Continuous Tabular

The data printed for the trend reports is the data that was last displayed on the Trend screen at the time *PRINT TREND* was selected. The resolution of the case report is always the minimum resolution (maximum detail).

Real Time Continuous Tabular data is printed at the same interval that the numerics on the screen are updated.

The Real Time Continuous Waveform graph/s are printed as displayed on the screen.

Please note that all Trend and Case reports must be printed ***before*** the case is ended. Once a case is ended, the case and trend data is deleted from the memory, and printing is no longer possible.

## Printing Reports

The Print screen is accessed from the Home screen.

The Print screen allows you to choose what report to print, and also to start and stop the printing of a report.

➢ TO PRINT A REPORT:

1. From the Home screen, select *PRINT* to display the Print screen seen in Figure 33 - Print Screen, below.
2. Use the control knob to select the type of report to print. Only one type of report can be selected at a time. An asterisk (*) will indicate the report that has been selected. If you choose a case report and no case is currently active, the field to the right of the report name will read *NO CASES*.


Figure 33 - Print Screen

3. Choose data to be printed:

   Select the *PRINT FORMAT* option from the Print screen. On the Print Format screen, select the parameters that you want to print on the report.

   Three columns of data appear in one printed report in the tabular formats and two graphs appear in one printed report in the graphical formats. The print format selected applies to all reports to be printed.

   **Note:** For tabular trend or graphical trend report, if $FiCO_2$ is selected, the column is left blank, because $FiCO_2$ data is not stored in trend memory.

   For tabular reports, $EtCO_2$, $FiCO_2$, RR, $SpO_2$, PR, IPI, and blank are available for selection. For graphical reports, $EtCO_2$, RR, $SpO_2$, PR, IPI, and blank are available for selection. Selecting blank means that nothing will be printed in that column.

4. Click *BACK* on the Menu bar at the bottom of the screen to return to the Print screen.
5. Click *START PRINTER* on the Print screen to begin printing. To stop printing, in order to stop continuous printing or abort other reports that have not completed, click the *STOP PRINTER* button on the screen.

Table 23 - Printed Reports – Parameters

| Report Name | Description | Fields Included | Time Frame of Report |
|---|---|---|---|
| All reports | | Name of Report (TREND REPORT, CASE REPORT or REAL TIME REPORT)<br>Patient Type (ADULT, PEDIATRIC [3 age ranges] or INFANT/NEONATAL)<br>Case ID<br>DATE, TIME | |
| Tabular Case Report | Patient readings of recorded case in tabular format. The time between data entries is the lowest resolution available for trend increment display (30 seconds). | Patient Readings at start and end of recording period: $EtCO_2$, $FiCO_2$, RR, $SpO_2$, PR, IPI | From start of case until current time; once case is stopped, data is not available |
| | | Patient Readings: Three of the following parameters (according to parameters chosen in the PRINT FORMAT screen, see To print a report on page 85): $EtCO_2$, $FiCO_2$, RR, $SpO_2$, PR, IPI | |
| | | Patient Urgent Alarm Occurrences: $EtCO_2$ HIGH, $EtCO_2$ LOW, RR HIGH, RR LOW, NO BREATH, $SpO_2$ HIGH, $SpO_2$ LOW, PR HIGH, PR LOW, IPI LOW | |
| | | Equipment Advisory Message Occurrences: $CO_2$ NOT AVAILABLE, $SpO_2$ NOT AVAILABLE, BATTERY LOW | |
| | | Events: EVENT 1, EVENT 2, EVENT 3 | |
| Graphical Case Report | Patient readings of recorded case in graphical format. The time between data entries is the lowest resolution available for trend increment display (30 seconds). | Patient Readings at start and end of recording period: $EtCO_2$, RR, $SpO_2$, PR, IPI | From start of case until current time; once case is stopped, data is not available |
| | | Graphs of levels of two of the following parameters (according to the parameters chosen in the PRINT FORMAT screen, see To print a report on page 85) at 30-second intervals: $EtCO_2$ (mmHg), RR (bpm), $SpO_2$ (%), PR (bpm), and IPI | |

| | | | |
|---|---|---|---|
| Tabular Trend Report | Patient readings of trend memory in tabular format. The time between data entries is the resolution set for trend increment display (MINIMUM [30 seconds], 1.5 minutes, 3 minutes, 15 minutes, 60 minutes). | DATE, TIME | From the time sensor is first connected to the device (following the erasure of trend memory) until current time; once trend is erased, data is not available |
| | | Patient Readings at start of recording period: $EtCO_2$, $FiCO_2$ , RR, $SpO_2$ , PR, IPI | |
| | | Patient readings at intervals set for trend increment display: Three of the following parameters (according to parameters chosen in the PRINT FORMAT screen, see To print a report on page 85): $EtCO_2$, $FiCO_2$, RR, $SpO_2$, PR, IPI | |
| | | Patient Urgent Alarm Occurrences: $EtCO_2$ HIGH, $EtCO_2$ LOW, RR HIGH, RR LOW, NO BREATH, $SpO_2$ HIGH, $SpO_2$ LOW, PR HIGH, PR LOW, IPI LOW | |
| | | Equipment Advisory Message Occurrences: $CO_2$ NOT AVAILABLE, $SpO_2$ NOT AVAILABLE, BATTERY LOW | |
| | | Events: EVENT 1, EVENT 2, EVENT 3 | |
| Graphical Trend Report | Patient readings of trend memory in graphical format. The time between data entries is the resolution set for trend increment display (MINIMUM [30 seconds], 1.5 minutes, 3 minutes, 15 minutes, 60 minutes). | Patient Readings at start of recording period: $EtCO_2$, RR, $SpO_2$, PR, IPI<br>Graphs of levels of two of the following parameters (according to the parameters chosen in the PRINT FORMAT screen, see To print a report on page 85) at interval set for trend increment display: $EtCO_2$, RR, $SpO_2$, PR, and IPI | From the time sensor is first connected to the device (following the erasure of trend memory) until current time; once trend is erased, data is not available |
| Real Time Continuous Waveforms | Graphical presentation of levels of $EtCO_2$ and $SpO_2$, with a data point every 50 milliseconds | Patient Readings at start of recording period: $EtCO_2$, $FiCO_2$ , RR, $SpO_2$ , PR, IPI<br>Graphs of levels of $EtCO_2$ and $SpO_2$ | Real-time data from time *START PRINTER* is pressed to time *STOP PRINTER* is pressed |
| Real Time Continuous CO2 Waveform | Graphical presentation of levels of $EtCO_2$, with a data point every 50 milliseconds | Patient Readings at start of recording period: $EtCO_2$, $FiCO_2$ , RR, $SpO_2$ , PR, IPI<br>Graph of $EtCO_2$ level | Real-time data from time *START PRINTER* is pressed to time *STOP PRINTER* is pressed |

| | | | |
|---|---|---|---|
| Real Time Continuous Tabular | Tabular presentation of three chosen parameters with a data line every 2 seconds | Patient Readings at start of recording period: $EtCO_2$, FiCO2 , RR, $SpO_2$ , PR, IPI<br>Patient readings at 2-second intervals: Three of the following aparameters (according to parameters chosen in the PRINT FORMAT screen, see To print a report on page 85): $EtCO_2$, $FiCO_2$, RR, $SpO_2$, PR, IPI | Real-time data from time *START PRINTER* is pressed to time *STOP PRINTER* is pressed |
| * Please note that, in all cases, $EtCO_2$ and $FiCO_2$ are displayed in selected units, $SpO_2$ in percentages, and RR and PR in bpm (beats per minute) | | | |

# Sample Reports

## Sample Case Reports

The following are examples of tabular and graphical case reports as described above.

CASE REPORT

CASE ID: ANN SMITH
ADULT

START: 9:29:55 AM JAN 04, 07

| EtCO2 (mmHg) | RR (bpm) |
|---|---|
| 39 | 15 |

| SpO2 (%) | PR (bpm) |
|---|---|
| 98 | 73 |

| DATE/ TIME | EtCO2 (mmHg) | RR (bpm) | PR (bpm) |
|---|---|---|---|
| 9:30:00AM | 39 | 15 | 71 |
| 9:32:00AM | 39 | 16 | 71 |
| 9:33:30AM | 39 | 15 | 71 |
| 9:35:00AM | 39 | 15 | 71 |
| | TURNED | | |
| 9:36:30AM | 41 | 14 | 68 |
| 9:38:00AM | 41 | 16 | 68 |
| 9:39:30AM | 41 | 15 | 68 |
| 9:41:00AM | 41 | 15 | 68 |
| 9:42:30AM | 41 | 15 | 71 |
| 9:44:00AM | 39 | 16 | 71 |
| 9:45:30AM | 39 | 16 | 71 |
| 9:47:00AM | 39 | 15 | 71 |
| 9:48:30AM | 39 | 15 | 73 |
| | SNORING | | |
| 9:50:00AM | 40 | 15 | 73 |
| 9:51:30AM | 40 | 15 | 72 |
| 9:53:00AM | 39 | 15 | 72 |
| 9:54:30AM | 39 | 15 | 73 |
| 9:56:00AM | 39 | 15 | 73 |

END: 9:56:01 AM JAN 04, 07

| EtCO2 (mmHg) | RR (bpm) |
|---|---|
| 39 | 15 |

| SpO2 (%) | PR (bpm) |
|---|---|
| 98 | 73 |

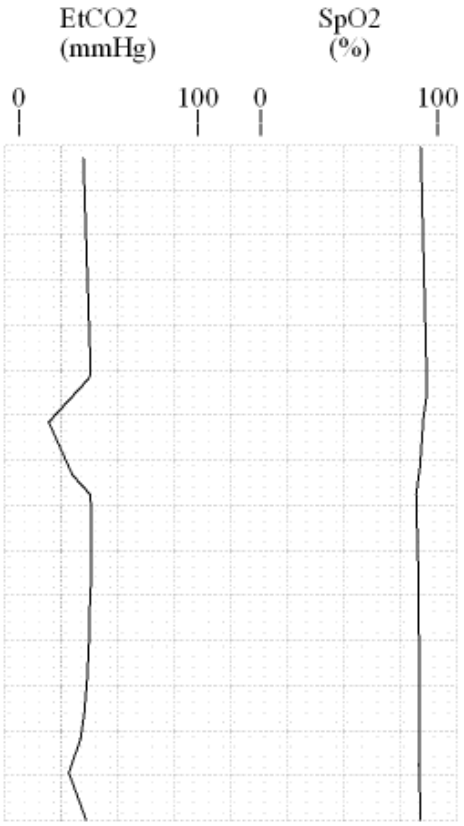
CASE REPORT

CASE ID: ANN SMITH
ADULT

START: 9:29:55 AM JAN 04, 07

| EtCO2 (mmHg) | RR (bpm) |
|---|---|
| 39 | 15 |

| SpO2 (%) | PR (bpm) |
|---|---|
| 98 | 73 |




END: 9:56:01 AM JAN 04, 07

| EtCO2 (mmHg) | RR (bpm) |
|---|---|
| 39 | 15 |

| SpO2 (%) | PR (bpm) |
|---|---|
| 98 | 73 |

Figure 34 - Sample Case Reports Printout

### Sample Trend Reports

The following are examples of tabular and graphical Trend reports as described above.

TREND REPORT

CASE ID: ANN SMITH
ADULT

START: 9:19:55 AM JAN 04, 07

| EtCO2 (mmHg) | RR (bpm) |
|---|---|
| 39 | 15 |

| SpO2 (%) | PR (bpm) |
|---|---|
| 98 | 73 |

| DATE/ TIME | EtCO2 (mmHg) | RR (bpm) | PR (bpm) |
|---|---|---|---|
| 9:20:00AM | 39 | 15 | 71 |
| 9:22:00AM | 39 | 16 | 71 |
| 9:23:30AM | 39 | 15 | 71 |
| 9:25:00AM | 39 | 15 | 71 |
| | TURNED | | |
| 9:26:30AM | 41 | 14 | 68 |
| 9:28:00AM | 41 | 16 | 68 |
| 9:29:30AM | 41 | 15 | 68 |
| 9:31:00AM | 41 | 15 | 68 |
| 9:32:30AM | 41 | 15 | 71 |
| 9:34:00AM | 39 | 16 | 71 |
| 9:35:30AM | 39 | 16 | 71 |
| 9:37:00AM | 39 | 15 | 71 |
| 9:38:30AM | 39 | 15 | 73 |
| | SNORING | | |
| 9:40:00AM | 40 | 15 | 73 |
| 9:41:30AM | 40 | 15 | 72 |
| 9:43:00AM | 39 | 15 | 72 |
| 9:44:30AM | 39 | 15 | 73 |
| 9:46:00AM | 39 | 15 | 73 |
| 9:47:30AM | 40 | 15 | 72 |
| 9:49:00AM | 39 | 15 | 72 |
| 9:50:30AM | 39 | 17 | 73 |
| 9:52:00AM | 39 | 16 | 73 |
| 9:53:30AM | 40 | 16 | 72 |
| 9:55:00AM | 39 | 15 | 72 |

TREND REPORT

CASE ID: ANN SMITH
ADULT

START: 9:29:55 AM JAN 04, 07

| EtCO2 (mmHg) | RR (bpm) |
|---|---|
| 39 | 15 |

| SpO2 (%) | PR (bpm) |
|---|---|
| 98 | 73 |

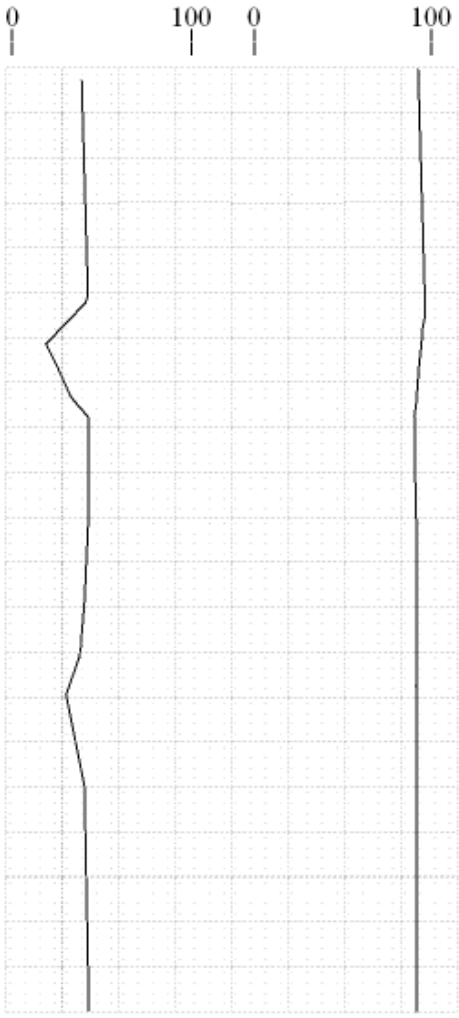



Figure 35 - Printed Trend Reports

# Chapter 11

# *Downloading Patient Data*



## Introduction

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

- Data transfer to a USB flash memory device for later transfer to a computer
- Direct connection to a computer via the RS-232 port
- 7-channel analog output

The occurrence of an alarm condition can also be indicated to an external system via the Nurse Call feature.

## Data Transfer via the USB Data Port

There are seven types of reports that can be transferred to a USB flash memory device, as described in the table below. Five report types are in text format and are suitable for use in applications such as Microsoft Excel. The two binary data report types are for advanced programming applications.

**Table 24 - Data Transfer Types**

| Report Name | Description | Fields Included |
|---|---|---|
| Tabular Case Report | Tab delimited file with the suffix .txt. (Tab delimited files can be exported into Excel using “tab” as the delimiter.) Reports the data stored in trend memory that is assigned to the selected case. The time between data entries is the resolution set for trend storage (5, 10 or 30 seconds). | DATE, TIME |
| | | Patient Readings: $EtCO_2$, RR, $SpO_2$, PR, IPI |
| | | Patient Urgent Alarm Occurrences: $EtCO_2$ HIGH, $EtCO_2$ LOW, RR HIGH, RR LOW, NO BREATH, $SpO_2$ HIGH, $SpO_2$ LOW, PR HIGH, PR LOW, IPI LOW |
| | | Equipment Advisory Message Occurrences: $CO_2$ NOT AVAILABLE, $SpO_2$ NOT AVAILABLE, BATTERY LOW |
| | | Events: EVENT 1, EVENT 2, EVENT 3 |

| | | |
|---|---|---|
| Tabular Trend Report | Tab delimited (.txt) file. Reports all the data stored in trend memory. The time between data entries is the resolution set for trend storage (5, 10 or 30 seconds). | DATE, TIME |
| | | Patient Readings: $EtCO_2$, RR, $SpO_2$, PR, IPI |
| | | Patient Urgent Alarm Occurrences: $EtCO_2$ HIGH, $EtCO_2$ LOW, RR HIGH, RR LOW, NO BREATH, $SpO_2$ HIGH, $SpO_2$ LOW, PR HIGH, PR LOW, IPI LOW |
| | | Equipment Advisory Message Occurrences: $CO_2$ NOT AVAILABLE, $SpO_2$ NOT AVAILABLE, BATTERY LOW |
| | | Events: EVENT 1, EVENT 2, EVENT 3 |
| Real Time Continuous $CO_2$ Waveform | Tab delimited (.txt) file, with data entries every 50 milliseconds. | DATE, TIME |
| | | Patient Readings: $EtCO_2$* |
| Real Time Continuous Tabular | Tab delimited (.txt) file, similar to the Tabular Trend report, but transmitted line by line in real time. | DATE, TIME |
| | | Patient Readings: $EtCO_2$, $FiCO_2$, RR, $SpO_2$, PR, IPI |
| | | Patient Urgent Alarm Occurrences: $EtCO_2$ HIGH, $EtCO_2$ LOW, RR HIGH, RR LOW, NO BREATH, $SpO_2$ HIGH, $SpO_2$ LOW, PR HIGH, PR LOW, IPI LOW |
| | | Equipment Advisory Message Occurrences: $CO_2$ NOT AVAILABLE, $SpO_2$ NOT AVAILABLE, BATTERY LOW |
| | | Events: EVENT 1, EVENT 2, EVENT 3 |
| Real Time Continuous Tabular with real-time continuous waveform (shortened name is FULL CONTINUOUS TRANSFER) | Tab delimited (.txt) file, similar to the real time continuous tabular report, transmitted line by line in real time, but with data entries every 50 milliseconds (20 times a second). CO2 data which can be used to create a real-time continuous waveform is shown, with data entries every 50 milliseconds. Tabular data is recorded at data points based on the resolution set for trend storage (5, 10 or 30 seconds), so data between these points is repeated on additional rows. | DATE, TIME |
| | | Patient Readings (at trend storage resolution): $EtCO_2$, $FiCO_2$, RR, $SpO_2$, PR, IPI |
| | | Patient Urgent Alarm Occurrences: $EtCO_2$ HIGH, $EtCO_2$ LOW, RR HIGH, RR LOW, NO BREATH, $SpO_2$ HIGH, $SpO_2$ LOW, PR HIGH, PR LOW, IPI LOW |
| | | Equipment Advisory Message Occurrences: $CO_2$ NOT AVAILABLE, $SpO_2$ NOT AVAILABLE, BATTERY LOW |
| | | Events: EVENT 1, EVENT 2, EVENT 3 |
| | | Patient reading every 50 milliseconds (for creating CO2 waveform): CO2 |
| Full Binary Continuous Transfer | See the document *Capnostream Data Transfer Protocols* | |
| Full Binary Trend Transfer | See the document *Capnostream Data Transfer Protocols* | |

* $CO_2$ in mm/Hg (millimeters of mercury)

Note that in the .txt files, the first six lines of data are as follows:

Line 1 – The name of the report type.

Line 2 – Blank, or Patient ID if the report is a case report

Line 3 – Patient type (see Setting the Patient Type on page 41 for information on patient types)

Line 4 – Blank

Line 5 – Column headings

Line 6 – Column headings second line

Capnostream recognizes flash memory drive devices manufactured by SanDisk, Lexar, and PNY Technologies. A typical flash memory device is shown below.

Figure 36 - Typical Flash Memory Device

➢ TO RECORD CAPNOSTREAM DATA ON A USB DEVICE:

1. Insert a USB Flash Memory drive into the USB port on the back side of the Capnostream.
2. When the Flash Memory drive is detected the USB icon will appear in the top right-hand corner of the display beside the alarm symbol. Depending on the type of drive, this may take a few seconds.


Figure 37 - USB Icon

**Note:** The USB port on the Capnostream 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.

3. After the USB icon appears, the monitor is ready to begin outputting data to the USB flash memory device.
4. From the Home screen select the *SYSTEM* button on the menu bar to open the System screen, and then select *DATA OUTPUT*.
5. Use the control knob to select the desired report from the *DATA OUTPUT* table as shown below. Please note that the Tabular Case and Tabular Trend options are only available while a case is active. If the current case is closed, the case and trend memory are deleted, and this information will no longer be available.

Table 25 - Select Data Output Type

| |
|---|
| TABULAR CASE |
| TABULAR TREND |
| REALTIME CONTINUOUS $CO_2$ WAVEFORM |
| REALTIME CONTINUOUS TABULAR |
| FULL CONTINUOUS TRANSFER |
| FULL BINARY CONTINUOUS TRANSFER |
| FULL BINARY TREND TRANSFER |

6. An asterisk will appear to the left of the selected report name. If no case is active, the text NO CASES will appear to the right of the Tabular Case option when that option is selected.
7. Turn the control knob to select *START USB* on the Menu Bar and click to begin data transfer. Data output can be aborted by clicking again to select *STOP USB*.

**CAUTION:** If the Flash Memory disk drive is removed from the Capnostream when data transfer is in progress, the data may not be readable. Before removing the Flash Memory drive, data transfer should be completed or stopped by selecting *STOP USB* on the Menu Bar.

**Note:** If the Capnostream 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 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:** Please note additional details regarding trend reports in Important Notes Regarding Trend Reports on page 81.

The maximum amount of data that can be transferred in a single file is 65,536 rows (this corresponds to the maximum sheet size for an Excel file for Excel 2003 and lower). If the data exceeds 65,536 rows, a new file is automatically opened and the data continues to transfer into the new file. In this situation, the new file name is indexed as described below in Table 26 - File Naming Conventions.

The following are estimates of the approximate sizes of the files that can be expected to be generated. For patient cases where events and alarms are recorded extensively, the file sizes will be larger.

Tabular Case: 1 hour @30s resolution: 21kB

Tabular Trend: 1 hour @30s resolution: 24kB

Real time Continuous $CO_2$ Waveform: 1 hour @50ms resolution: 4.2 MB

Real time Continuous Tabular: 1 hour @2s resolution: 264kB

Full Continuous Transfer: 1 hour @50ms resolution: 12 MB

Full Binary Continuous Transfer: 1 hour @50ms resolution: 732kB

Full Binary Trend Transfer: 1 hour @30s resolution: 5kB

### USB File Naming Convention

For the different report types, the following file naming convention is used.

<REPORT TYPE>_<REPORT DATE >_<REPORT TIME>_<SER NO>.ext

Where:

- REPORT TYPE - three-letter report type identifier (see Table 26 - File Naming Conventions).
- REPORT DATE - Start date on which the report was made in yymmdd format.
- REPORT TIME - Start time at which the report was made in hhmmss format.
- SER NO - a running serial number that indicates if the data was split into multiple files.
- File extension .ext is .txt (tab delimited file type) or .bin (binary file type).

The Patient ID field in the monitor contains the '/' character, which is not a valid character for file names. It is replaced with a hyphen '-' for file names. The '/' character is used by the monitor to indicate multiple files with the same Patient ID (e.g.- Smith/1, Smith/2, Smith/3).

**File Name Examples:**

For different reports taken on 2nd March 2006 at 20:30:57 for the patient with Patient ID "PATIENT02/1", the file names would be:

Table 26 - File Naming Conventions

| Report type | File name |
|---|---|
| Tabular Case Report | TCR_PATIENT02-1_060302_203057_1.txt |

| | |
|---|---|
| Tabular Trend Report | TTR_060302_203057_1.txt |
| Real-time Continuous $CO_2$ Waveform | RCW_060302_203057_1.txt |
| Real-time Continuous Tabular | RCT_060302_203057_1.txt |
| Full Continuous Transfer | FCTR_060302_203057_1.txt |
| Full Binary Continuous Transfer | FCT_060302_203057_1.bin |
| Full Binary Trend Transfer | FTT_060302_203057_1.bin |

Examples

Taking the same example described above, multiple files for the same Real-time Continuous Tabular report would look like this:

Report type File name

Real-time Continuous Tabular RCT_060302_203057_1.txt RCT_060302_203057_2.txt RCT_060302_203057_3.txt RCT_060302_203057_4.txt ... RCT_060302_203057_10.txt ... RCT_060302_203057_100.txt ... RCT_060302_203057_1000.txt

**Note:** Binary files are never split into multiple files because they do not have the length limitation imposed by MS Excel.

### USB Error Messages

The following messages may appear in the message area of the monitor:

*NO USB DEVICE FOUND*: Advisory displayed if a USB operation is tried in the absence of a USB device.

*USB DEVICE FAILED*: Displayed when the USB device has been detected, but the data transfer operation cannot be successfully completed.

*USB FLASH FULL*: Advisory displayed when data can no longer be downloaded into a USB memory stick due to the memory being full.

*USB TIME OUT*: Advisory displayed when monitor is unable to establish communication with USB device.

### Reading Patient Data from Saved Capnostream Files

The five USB report types that have a .txt (tab delimited) file type are text files. This makes them easy to read in most spreadsheet and database software applications. In this case, the .txt format type means that there is a tab in between each piece of data in every line of the file. The *Patient Data Transfer Application Note*, explaining the utilization of the transferred data, can be found on the Operator's Manual CD.

The two USB report types that have a .bin file type are binary files. These files are intended for use by programmers who are creating application programs for use with the Capnostream. The binary file formats are described in the document *Capnostream Data Transfer Protocols* that can be found on the Operator's Manual CD.

## Data Transfer via the RS-232 Port

Capnostream is equipped with a 9-pin RS-232 connection on the back of the monitor. For detailed information on the use of this feature, please refer to the document *Capnostream Data Transfer Protocols*, available on the Operator's Manual CD.

The data transfer rate for the RS-232 interface is set in the Institutional Defaults: Monitor screen. The factory default is automatic detection of the data transfer speed. See Appendix 1: Institutional Settings on page 117 for information on how to change the data transfer rate.

Data transfer via RS-232 can take place at the same time as data transfer with a USB Flash Memory drive.

**Note:** The RS-232 port has electrical isolation according to IEC 60101-1. Non-medical devices such as PCs and printers may be connected to this port without additional electrical isolation. These devices must be placed at least 1.5 meters from the patient environment.

The RS-232 port can be used for data transfer to a PC using Profox. For more details, contact Profox Associates, Inc. at http://www.profox.net/.

## Analog Data Output with Capnostream

### Required Equipment

A list of the items required in order to set up data transfer between a Capnostream monitor and an analog system appears below.

| Item | Details/Oridion PN |
|---|---|
| Capnostream monitor | Any Capnostream monitor |
| Digital/Analog Cable | 010492 (must be purchased separately) |
| Analog system (sleep lab or other analog system) | N/A |
| Standard communication cables with 3.5 mm (1/8 in) mono audio plug for transfer of data from the Digital/Analog Converter Cable to the analog system (number of cables required will depend on the number of channels on which data will be transferred). | These cables should be purchased separately and can be obtained from any electronic supply store. |

In order to set up data transfer between the monitor and analog device, the following connections must be set up:

- Connecting the D/A Cable to the Monitor
- Connecting the D/A Cable to the Analog Recording Device

These connections are described below. Once these connections are made, data will flow from the monitor to the analog device as long as the two devices are connected.

The data cable connecting the two devices includes seven data channels. Each data channel gives an output of 0-1 volt (1 volt full scale) with a sink current of at least 12 mA. Each channel is also protected against shorting of outputs.

A list of the available analog signal values appears in the table below.

Table 27 - D/A Signal Values

| Parameter | Scale | 1.0 V Value |
|---|---|---|
| $EtCO_2$ + End of breath indication ($EtCO_2$ value when the end of breath is signaled, 0V otherwise) | 100 mmHg = 0.9 V | 111 mmHg = 1.0 V |
| $EtCO_2$ | 100 mmHg = 0.9 V | 111 mmHg = 1.0 V |
| $FiCO_2$ | 100 mmHg = 0.9 V | 111 mmHg = 1.0 V |
| RR | 150 BPM (Breaths per Minute) = 0.9 V | 167 BPM = 1.0 V |
| $CO_2$ Wave | 100 mmHg = 0.9 V | 111 mmHg = 1.0 V |
| $CO_2$ Measurement Valid | 0 V=yes; 1 V = no | N/A |
| $SpO_2$ Saturation | 100 % Sat = 0.9 V | 111 % = 1.0 V |
| Pulse Rate | 250 BPM (Beats per Minute) = 0.9 V | 278 BPM = 1.0 V |
| $SpO_2$ Wave (pleth waveform) | 255 Pleth = 0.9 V | 283 Pleth = 1.0 V |
| Square wave at 1 Hz, 50% duty cycle | 0 V –1 V p-p | N/A |

| | | |
|---|---|---|
| No signal (always high) | 1 V | N/A |
| No signal (always low) | 0 V | N/A |

### Connecting Capnostream and an Analog Device using the D/A Cable

➢ TO CONNECT THE D/A CABLE TO THE MONITOR

1. Insert the analog output connector of the communication cable into the monitor's 15-pin Analog port. This port, at the back of the Capnostream monitor, is marked with the text *Analog Out*.

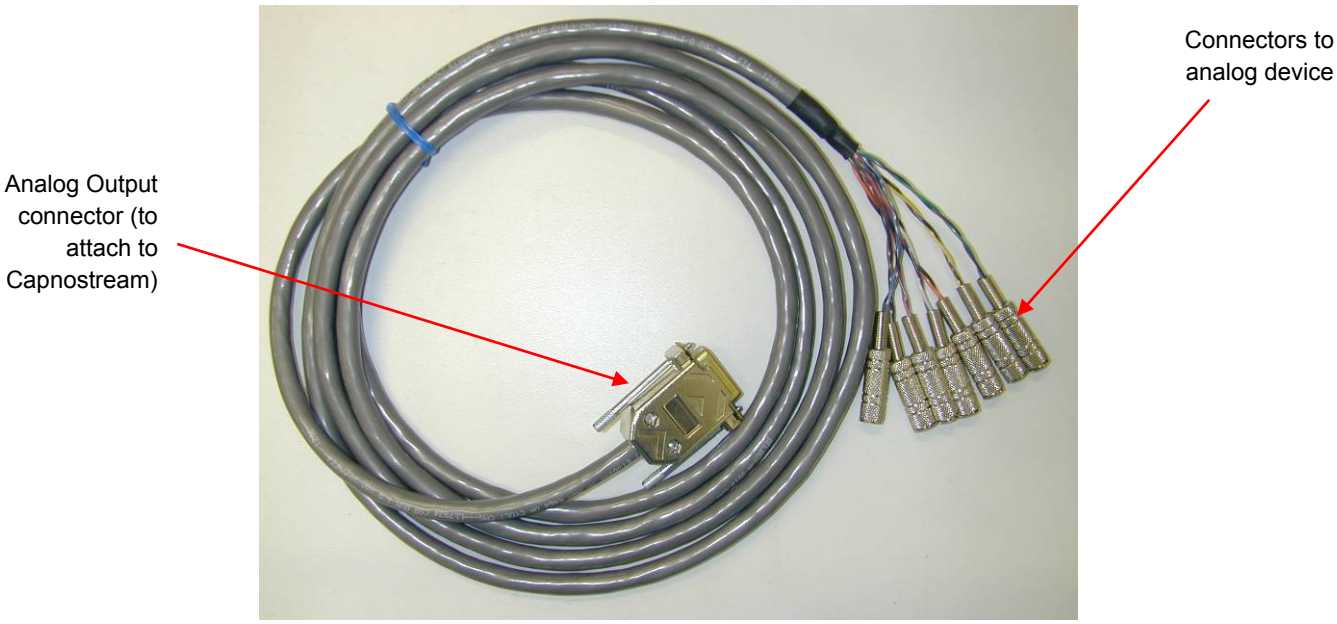



Figure 38 - The Capnostream D/A Cable (PN 010492)

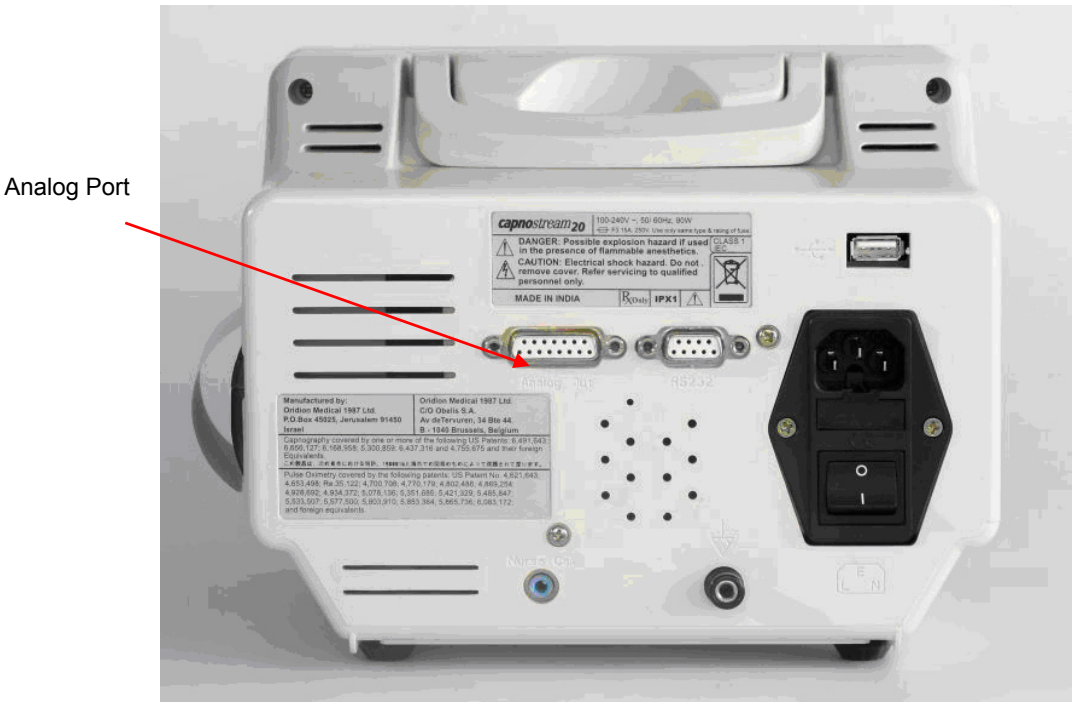



Figure 39 - The Analog Port on Capnostream

2. The Capnostream device is configured to output seven analog signals, each of which will transfer data regarding a different parameter measured by the device.

3. If you want to make changes to the default parameters that are outputted on the different channels, see Changing Default Digital/Analog Channel Values on Capnostream on page 100.
4. If you do not want to make changes to the default signal values for each channel, connect the D/A Cable to the analog device as described below.

➢ TO CONNECT THE D/A CABLE TO THE ANALOG DEVICE

1. On the end of the D/A cable, there are seven wire pairs with connectors, with the seven available channels color coded to match the insulation covering of corresponding wire pair of the D/A cable. See Table 28 - D/A Cable color codes, below, for color coding. You have already specified signal values for each of these connectors.
2. Select each of the desired output connectors (color coded wires), and, using a standard communication cable with 3.5 mm (1/8 in) mono audio plug, attach each connector to the relevant output channel on the analog device. (One end of the cable should have a 3.5 mm (1/8 in) mono audio plug for attaching to the D/A cable; the other end should have the appropriate connector for your analog device.)
3. Repeat this procedure for each connection that you want to make.

The following table lists the cable colors and channels for the D/A cable.

Table 28 - D/A Cable color codes

| Data Channel | Color | |
|---|---|---|
| CH1 | RED | |
| CH2 | WHITE | |
| CH3 | GREEN | |
| CH4 | BLUE | |
| CH5 | YELLOW | |
| CH6 | BROWN | |
| CH7 | ORANGE | |

### Changing Default Digital/Analog Channel Values on Capnostream

The Capnostream can output seven analog signals corresponding to various parameters that it monitors. There are 12 different settings available for these seven data channel outputs. While Capnostream is provided with default signal values for each channel, these may be changed using the following procedure.

The current settings and the available options are shown when you enter the Capnostream Digital to Analog setup screen as shown in Figure 40 - Capnostream Digital / Analog Setup Screen on page 101.

➢ TO CHANGE DEFAULT D/A CHANNEL VALUES ON CAPNOSTREAM:

1. From the Capnostream Home screen, select SYSTEM from the menu bar and then select D/A SETUP from the menu bar. The seven data channels provided are listed on the left hand side of the screen. The signals available to assign to the channels are listed on the right hand side.
2. Use the control knob to select the channel to which you want to assign a signal by turning the control knob until you reach the desired channel. Click when that channel is highlighted. Then turn the control knob to select the signal to be assigned to that channel. Click the control knob again to select the signal. Repeat the process for each channel to which you want to assign or re-assign signals.
3. Any signal can be assigned to any channel. Also, the same signal can be assigned to multiple channels.
4. If you want these settings to be permanently stored in the Capnostream monitor, you must make these changes in the Institutional Defaults screen. On the Capnostream Home screen menu bar, click *SYSTEM>SERVICE*. Enter the Service password (it is *SERV* or *SERVICE*) and click *INST DEFAULTS>MONITOR>D/A*. The procedure for making changes is the same as that described in Step 2 of this section.

5. Once changes have been made as desired, complete the connection process by connecting the D/A cable to the analog device, as described in Connecting Capnostream and an Analog Device using the D/A Cable on page 99.


Figure 40 - Capnostream Digital / Analog Setup Screen

### Calibrating the Analog Device for Capnostream

The analog device must be calibrated with the D/A cable to work with the Capnostream monitor, using the procedure described below. Since the signal sent from the monitor to the analog device is in volts, the analog device must be calibrated so that it can interpret the voltage figure which it receives as the correct patient value.

The calibration procedure includes two parts: Gain Calibration and Zero Calibration.

- Gain Calibration is used to indicate the maximum value for a parameter, which corresponds to the maximum voltage (1.0 V) on the analog device.
- Zero Calibration is used to indicate the minimum patient value (zero) for a parameter, which corresponds to the zero voltage (0.0 V) on the analog device.

#### The Calibration Procedure

➢ TO CALIBRATE AN ANALOG DEVICE (SUCH AS A POLYSOMNOGRAPH) FOR USE WITH CAPNOSTREAM

1. Ensure that the Capnostream monitor and the analog device are connected using the D/A cable as described above, and that each channel has been assigned the signal value required, as described in Changing Default Digital/Analog Channel Values on Capnostream on page 100, if desired.
2. For zero calibration, use the control knob to select the D/A CAL menu button and select the *CAL LOW* setting. All channels will be set to *ALWAYS LOW*. Confirm that the output on the analog device is zero on all channels.
3. For gain calibration, use the control knob to select the D/A CAL menu button and select the *CAL HIGH* setting. All channels will be set to *ALWAYS HIGH*. Confirm the output on the analog device is 1 volt on all channels, corresponding to the highest output of the channel.

4. Turn the control knob on the menu bar and click CAL RESET. All channels will be reset to their original settings.
5. Once these processes are completed, the analog device will be able to interpret the signal it receives from the monitor and record patient values correctly. For example, since it now knows that 0 V = 0 mmHg (for exhaled $CO_2$) and 1.0 V = 111 mmHg (for exhaled $CO_2$), a signal received from the monitor of 0.37 V will be interpreted on the analog device as 41 mmHg.

### Working with the Digital/Analog System

Once the devices are connected and calibrated as described above, you can begin working with the system. Please take note of the following information.

#### Monitor Function

The monitor functions normally during communication.

**Note:** Please note that there is no need to use the DISABLE button on the Capnostream D/A menu bar. By default, the Capnostream D/A option is enabled. (When D/A communication is enabled, this button reads DISABLE.) This button could be used to disable the D/A option on Capnostream, if required.

#### Troubleshooting

Some of the problems you might encounter in setting up the digital/analog conversion system are described below, along with suggestions to solve these problems.

Table 29 - Troubleshooting

| Issue | Relevant Component | Problem | Solution |
|---|---|---|---|
| $CO_2$ data is not transferred. | Analog device | Calibration was not done or done incorrectly. | Calibrate the analog device as described in this document. |
| $CO_2$ data is not transferred. | D/A Cable | Unused connector in D/A cable has been shorted. | Do not short wires/connectors not in use. |
| $CO_2$ data is not transferred. | Monitor | D/A communication has been disabled. | Enter the Capnostream D/A Setup screen and click the ENABLE button on the menu bar. |

## Nurse Call Operation

The Capnostream monitor allows connection to an external Nurse Call system. When connected, the monitor sends information to the institutional nurse call system that an alarm condition has occurred, alerting medical personnel that the patient requires medical care. The only data transferred to a Nurse Call system is alarm data, as described in Table 31 - Nurse Call Indicators on page 105.

The nurse call alarm output becomes active simultaneously with the occurrence of an alarm on the monitor, and remains active while the alarm condition is present. When the alarm condition is no longer present (that is, when the alarm on the monitor ceases) the Nurse Call alarm output also becomes inactive.

A Nurse Call cable (3.5 m) can be purchased from Oridion (part number 011149). One end of the Nurse Call Cable attaches to the Capnostream monitor. The cable is supplied un-terminated so it can be built to fit your nurse call system.

## Types of Nurse Call Systems

From an alarm activation / deactivation perspective, Nurse Call Systems can usually be configured in two ways, latching and non-latching.

**Latching systems:** the nurse call light/alarm will remain active until the connected device ceases to alarm ***and*** until the nurse cancels the alarm by pressing the nurse call system's CANCEL ALARM button.

**Non-latching systems:** the nurse call light/alarm remains active until the connected device ceases to alarm. User intervention is ***NOT*** required if the alarm condition clears. This means that if the alarm condition corrects itself, the nurse call light and tone will automatically cease.

When interfacing between Capnostream and a Nurse Call system, a **non-latching** configuration should be used.

Please note that both types of Nurse Call Systems will not permit a Nurse Call alarm to be silenced while there is an active alarm from a connected device such as the Capnostream monitor.

### The Nurse Call Cable

The monitor has a built-in relay that can be connected to a hospital nurse call system using the nurse call cable. Details about the Nurse Call cable appear below.

Table 30 - Nurse Call Specs

| Parameter | Value |
|---|---|
| Rated Carrying Current | 2A |
| Max Allowable Current | 2A |
| Max Allowable Voltage | 24V DC |
| Stereo Phono-Jack | 1/8" (3.5 mm) |


Figure 41 - Stereo Phono Plug for Nurse Call

A diagram of pin-out of mating stereo phono plug appears in Figure 41 - Stereo Phono Plug for Nurse Call, above. Please note the following:

- N1 (COMMON) - N2 (NORMALLY CLOSED): Normally Closed relay configuration
- N1 (COMMON) - N3 (NORMALLY OPEN): Normally Open relay configuration

➢ TO SET UP NURSE CALL DATA TRANSFER:

1. To use the Nurse Call function, plug the prepared Nurse Call cable into the Nurse Call socket on the back of the monitor as shown below.
2. Connect the other end of the cable to the institution's system as determined by the institution's requirements.
3. Enable the Nurse Call connection as described in Activating Nurse Call, below.


Figure 42 - Connection Point for Nurse Call

### Activating Nurse Call

The factory default setting for Nurse Call is disabled, and to operate the feature it must be enabled. This can be done using the System Setup screen, however, it will reset to disabled again when the monitor is turned off. To permanently enable the Nurse Call feature, enable it using the monitor screen in the Institutional Defaults section of the Service mode as follows:

➢ TO ACTIVATE NURSE CALL:

1. Turn on the monitor and wait for the Home screen to appear. Use the control knob to select the *SYSTEM* button to open the System screen, then select *SERVICE* and enter the service password (see Changing Institutional Defaults on page 117 for instructions on doing so).
2. From the SERVICE screen, select *INST DEFAULTS* (Institutional Defaults) and then select *MONITOR*.
3. Use the control knob to select *NURSE CALL*, and change the option to *ENABLED*.
4. Select *BACK*, *BACK* and *HOME* to exit the Service mode. The new setting is now stored.
5. Test the Nurse Call system as described in Testing Nurse Call, below.
6. Please note that Nurse Call data will not be transferred if alarms have been silenced temporarily (by the Alarm Silence button at the front of the monitor). See Alarm Silence on page 70 for details regarding this feature. Nurse Call data will still be transferred if alarms are silenced through Institutional Defaults (see Institutional Defaults on page 117).

### Testing Nurse Call

Verify that the system is functioning by forcing a test alarm occurrence (such as breathing into the FilterLine for a few seconds, then stop breathing into it to create a NO BREATH alarm). Confirm that the expected result was received according to the standard for the institution's nurse call system. This may be a warning light turned on or an audio signal generated when the alarm event occurs.

The following table describes which alarms are indicated by the Nurse Call output.

Table 31 - Nurse Call Indicators

| Alarm Type | Activates Nurse Call |
|---|---|
| High Priority (Patient) Alarms | YES |
| Secondary (Caution) Patient Alarms | NO |
| Low Priority Alarms | YES |
| Advisories | NO |
| Silent Advisories | NO |

## Operation with Hospital Patient Data Systems

The Capnostream monitor provides connectivity with hospital patient data systems (Bernoulli® and Oxinet® III) produced and/or marketed by Cardiopulmonary Corporation (CPC). This option permits regular, real-time transfer of data from the monitor to hospital patient data systems. Eight-bed or 12-bed configurations are available.

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

- Bernoulli® or Oxinet® III system installed in the hospital
- Bernoulli-MSM or Oxinet Client Bridge terminated with a 9 pin D connector cable
- Capnostream monitor

Connect the system as described in the DFU supplied with the Bernoulli-MSM or Oxinet Client Bridge.

Once the connection between the devices is made as described above, data in binary format will be transferred automatically from the Capnostream monitor to the Bernoulli®/Oxinet® III system. No additional setting of the monitor is required.

The following measurement data is transferred:

- Instantaneous $CO_2$
- $EtCO_2$
- $FiCO_2$
- Resp rate
- $SpO_2$
- Pulse

In addition, information regarding patient type, alarm data, and device settings (alarm limits, etc.) are transferred.

For more information regarding the Bernoulli®/Oxinet® III system, or for troubleshooting the setup procedure, contact your local distributor.

Chapter 12

# Maintenance and Troubleshooting



## Introduction

Capnostream requires no routine service other than any performance testing mandated by the operator's institution. The monitor requires servicing by qualified service personnel only once every 20,000 operating hours.

The monitor's $CO_2$ detection mechanism should be periodically calibrated as detailed below in CO2 Calibration on page 108. $CO_2$ calibration can be checked at any time to ensure the calibration is within proper operating limits.

Troubleshooting on page 111 discusses potential difficulties, possible causes and suggestions for resolving them.

**Note:** Contact your local distributor or refer to the Service Manual for service instructions and performance tests and checks.

## Determining Monitor Service Hours

The information on the Service screen gives the number of hours remaining until servicing or calibration is required. To access the Service screen, select *SYSTEM* from the Menu bar at the bottom of the Home screen, and then select *SERVICE*. No password is required to see the number of hours before servicing is required. The main service screen is shown below.

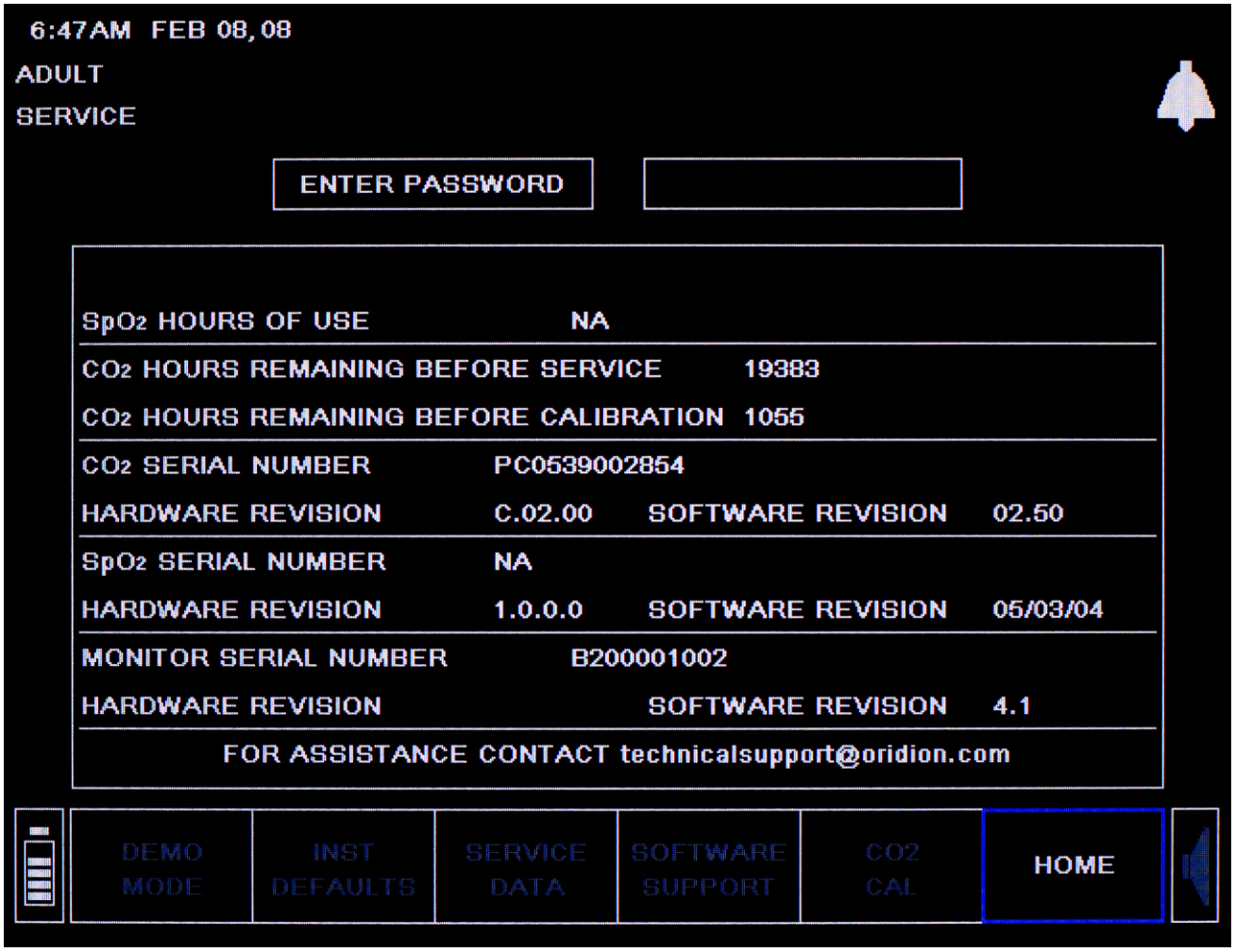



Figure 43 - Service Screen

When the monitor reaches 20,000 hours of use, send it to an authorized service center. Contact your local representative for shipping instructions.

## $CO_2$ Calibration

**Note:** The unit is calibrated when it leaves the factory.

The monitor should be calibrated by qualified service personnel after the first 1,200 operating hours of use or 12 months, whichever comes first. After that, calibration should be performed every 12 months or after 4,000 operating hours, whichever comes first.

To help you plan in advance for the upcoming calibration process, the monitor stores both the number of operating hours before calibration is due and the date of the last calibration.

When calibration is due the monitor will display the advisory message *CALIBRATION REQUIRED* in the message area.

The number of operating hours remaining before calibration appears on the salutation screen every time the monitor is turned on (see Figure 9 - Salutation Screen on page 31). After the operating hour limit has been exceeded, the message will change to *CALIBRATION OVERDUE*. The number of operating hours before calibration can also be viewed on the service screen, and this will also change to *CALIBRATION OVERDUE* in the same manner as the salutation screen if the limit has been reached. The data on the service screen is updated when the monitor is turned on, and also each time the password is entered to enter Service Mode.

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

To display the date of the last calibration, enter the service mode and go to the Calibration Screen. From the Home screen select the *SYSTEM* button to open the System screen and then select the *SERVICE* button to open the Service screen. Enter the service password, and then select *CO2 CAL*. This screen shows the number of hours left before service is due, the date of the last calibration performed, and the date on which the next calibration should take place (one year after the most recent calibration). Use of the password required to enter Service Mode is needed to view this screen.

## $CO_2$ Calibration Check

Depending on institutional policy and procedure, the monitor can be checked at any time to determine if $CO_2$ detection is within the accepted limits. The Calibration Check Procedure below gives the step-by-step instructions to perform a 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 number 0304653ORFBD). It includes:

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

**Note:** 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 Check Procedure

**Note:** At any stage in the Calibration Check procedure, you can go back to the first screen by clicking the *BACK* button.

➢ TO PERFORM CALIBRATION CHECK:

1. Use the control knob to navigate to the $CO_2$ CALIBRATION CHECK screen. From the Home screen select the *SYSTEM* button on the menu and then select *CAL CHECK*. Or, from the Service screen select *CO2 CAL* and then select *CAL CHECK*.

   The $CO_2$ CALIBRATION CHECK screen is displayed. On–screen instructions will guide you through a number of Calibration Check steps.

2. The screen displays the message: *CONNECT FILTERLINE TO MONITOR*. Connect the Calibration Line to the monitor and select *START* to start the calibration check.
3. The screen displays the message: *CONNECT CALIBRATION GAS [5% $CO_2$ 21% $O_2$ BALANCE $N_2$]*. Connect the other end of the Calibration Line to the gas canister, and then select *CONTINUE*.
4. The screen displays the message: *OPEN GAS SUPPLY FROM CYLINDER*. Open the gas canister and select *CONTINUE*.

   At this time, the module performs a calibration check. While doing so, it displays a message *CALIBRATION CHECK IN PROGRESS*. If the $CO_2$ Module is still warming up, the monitor displays the message *NOT READY TO CALIBRATE*. Wait until module is ready and then select *CONTINUE*.
5. When the module has completed the calibration check measurements and is processing data, it displays the message:

   *CALCULATING RESULTS, GAS SUPPLY MAY BE CLOSED.*
6. Close the calibration check gas supply. If you have to stop the calibration check before it is complete, use the control knob to select *STOP*.

7. The screen displays the message: *DISCONNECT CALIBRATION GAS AND FILTERLINE* and *CONTINUE*.

   The module then displays:

   *CALIBRATION CHECK COMPLETE*

   *MEASURED $CO_2$ X.X%*

   *ACCURACY SPECIFICATION FOR A 5% GAS IS 4.7–5.3%.*

   Select *BACK* to return to the Home screen, or *START* to perform the calibration check again.
8. If the calibration check result indicates that the monitor is out of calibration, the message *MEASURED CO2 NOT WITHIN SPECIFICATIONS. CALIBRATION RECOMMENDED* is displayed. In this case, the Calibration Procedure must be performed. Refer to the Service Manual or to authorized Oridion Service personnel.
9. If the monitor is unable to complete the calibration check, a *CALIBRATION FAILED* message appears with one of the following error messages:

   *FILTERLINE NOT CONNECTED*

   *CALIBRATION FAILED: NO GAS, WRONG GAS CONCENTRATION, OR UNSTABLE GAS*

   *MEASUREMENT ERROR; CHECK ALL CONNECTIONS AND TRY AGAIN*

   *CALIBRATION ABORTED BY USER*

   *CO2 MODULE INTERNAL SELF–TEST FAILED*

## Maintenance

The monitor requires no routine service other than any performance testing mandated by the operator's institution. The Troubleshooting section on page 111 below discusses potential difficulties, their possible causes, and suggestions for resolving them.

Periodic maintenance is recommended according to operating hours:

- The $CO_2$ Pump should be replaced every 20,000 operating hours.
- A calibration should be performed after the initial 1,200 hours of use, and following that calibration once a year or every 4,000 operating hours, whichever comes first (see CO2 Calibration on page 108).
- The monitor's number of hours remaining until the 20,000 hour operating limit before service is required is displayed each time when the unit is powered on. This can also be viewed in the Service Screen.
- 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.

**Note:** Contact your local representative to order spare parts, calibration kits, or to get answers to any questions regarding service and periodic maintenance.

## Replacing the Fuses

The monitor is protected from electrical surges by two fuses. If the fuses blow, the monitor will not turn on and the battery pack will not charge.

To replace the fuses, turn the monitor off, disconnect the power cord from the monitor and turn off the main power switch on the back of the monitor.

The fuses are located in the back of the monitor between the ON/OFF power switch and the electrical cord connection. Use a flat screwdriver to pry out the fuse housing cover, and replace the fuses with fuses of the same rating only (F3.15A 250 Volt). Push the fuse housing cover closed, then reconnect the power cord and turn the monitor on.

**Note:** Blown fuses indicate that an abnormal electrical condition occurred. If the cause is not known, contact your representative to determine if servicing is required.

## Replacing the Printer Paper Roll

If the printer runs out of paper, replace it with a roll of thermal printer paper (Oridion part # 010516) or similar paper which meets the specifications outlined in the specifications in Internal Thermal Printer (optional) on page 129.

➢ TO REPLACE THE PRINTER PAPER:

1. Open the plastic cover on the printer.
2. Remove the empty spindle inside the paper compartment.
3. Insert a new roll of paper in the direction shown in the figure below, so that the loose end of the paper comes out at the top of the plastic cover as shown.


**Figure 44 - Insert Paper Roll into printer**

4. Close the door so that it clicks shut. Briefly press the Feed button to verify that the paper is aligned properly and is not caught on the edge of the cover.

## Cleaning

To clean the monitor's surfaces, lightly dampen a cloth with a 70% alcohol solution and wipe all surfaces. Alcohol wipes may also be used. Frequency of the cleaning procedure should be in keeping with hospital policy.

To clean the screen, use a damp, lint-free cloth.

| | |
|---|---|
| **WARNING:** | 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. |

## Troubleshooting

This section lists potential problems you may experience while using the monitor and suggestions for resolving them. If you are unable to correct the problem, contact qualified service personnel or your local representative.

### Electrical

| Problem | Cause | Action |
|---|---|---|
| Monitor does not turn on. | Internal battery is totally discharged and power cable improperly attached or disconnected, or cable has faulty electrical connection. | Check power cable connection and check that on/off switch is on. |
| | Internal battery is totally discharged and main power switch not turned on. | Turn on the main power switch located on the back of the monitor just below the electrical supply cord. |
| | AC wall outlet has no power and internal battery is not charged. | Check connections and correct problem. When AC power is restored ensure that the main power switch on the back of the monitor stays on so that the internal battery pack will charge. |
| | Blown fuses. | Replace the fuses. Contact your representative to determine the reason for the electrical problem. |
| AC mains power and monitor on indicator lights are on, but unit will not operate on battery power when the AC mains power cable is disconnected. | Battery pack not plugged in to monitor. | Open the battery housing and check that the battery pack cable is firmly connected to the battery socket. (See Installing the Battery Pack on page 22) |
| Monitor is plugged in, but does not appear to charge the battery. | AC power not getting to the monitor. | Check if the yellow power indicator light is on. If not, check that the AC power cord is properly plugged in to a live AC mains socket, and that the power switch on the back of the monitor is switched to the on position. |

### $CO_2$ Problems

| Problem | Cause | Action |
|---|---|---|
| NO BREATH message appears constantly and red alarm indicator flashes. | Physiological cause. | Check patient. |
| | Clogged or blocked FilterLine. | Check FilterLine and replace if blocked. |
| | FilterLine caught in something or tube is | Check the FilterLine from the |

| Problem | Cause | Action |
|---|---|---|
| | kinked. | monitor all the way to the patient to see if line is kinked, twisted closed or caught in bed or equipment. |
| 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 FilterLine plug is screwed into the monitor. |
| | Gold ring worn or dirty. | Check that the gold ring on the end of the FilterLine connector is present and not damaged or covered with dirt. Wipe off any dirt or replace FilterLine 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. See CO2 Calibration Check on page 109. |
| | BTPS setting turned off. | Check BTPS setting in the institutional settings. See CO2 Parameters on page 123 for details. |

### $SpO_2$ Sensor

| Problem | 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. |
| 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 |

| | | |
|---|---|---|
| | 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. |

### Printer

| Problem | Cause | Action |
|---|---|---|
| Printer does not print. Red Alarm light on the printer is flashing. | Printer cover is open. | Open the plastic printer cover fully, ensure that a short length of printer paper is outside the monitor, and then close the cover so that it clicks into place. |
| | Printer paper is either not threaded properly over plastic cover or caught in the plastic cover. | Open the plastic printer cover and pull the paper so that a short length is outside the monitor. Hold the paper so that the short length of printer paper remains outside the monitor, and then close the cover so that it clicks into place. |
| | Printer is out of paper. | Open the plastic cover and insert a new roll of paper. |

| Problem | Cause | Action |
|---|---|---|
| Printer does not print. Red Alarm light on the printer is flashing. | Printer cover is open. | Open the plastic printer cover fully, ensure that a short length of printer paper is outside the monitor, and then close the cover so that it clicks into place. |
| | Printer paper is either not threaded properly over plastic cover or caught in the plastic cover. | Open the plastic printer cover and pull the paper so that a short length is outside the monitor. Hold the paper so that the short length of printer paper remains outside the monitor, and then close the cover so that it clicks into place. |
| | Printer is out of paper. | Open the plastic cover and insert a new roll of paper. |
| Printer works, but output paper is blank. | Paper roll is placed backwards in the printer compartment of the monitor. | Open the plastic cover, turn the roll of paper the other way, and replace the plastic cover, taking care to leave a short length of paper outside the monitor. |

### Nurse Call

| Problem | Cause | Action |
|---|---|---|
| Nurse Call output does not work. | Nurse Call not enabled. | Enable the Nurse Call function from the system setup screen, or from the Institutional Defaults screen in Service Mode. |
| | Wiring problem on phono plug. | Check the wiring of the cable and phono plug connected to the Nurse Call socket on the back of the monitor. |

### D/A Connection

| Problem | Cause | Action |
|---|---|---|
| D/A output does not work. | D/A output not enabled. | Go to the D/A setup screen and enable D/A output. |

### $CO_2$ Calibration

| Problem | Cause | Action |
|---|---|---|
| *CALIBRATION REQUIRED* message appears on the monitor, but salutation screen shows there is still time before next calibration. | It has been more than one year since the last $CO_2$ calibration. | Perform a $CO_2$ calibration. |

## 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 pack the consumable used at the time of malfunction with the monitor and return it with the monitor for inspection.

## Technical Assistance

For technical information, contact your local representative or write to technicalsupport@oridion.com.

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

See also the Technical Service area in the Capnography section of our website http://www.oridion.com/.

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

# Appendix 1

# *Institutional Settings*



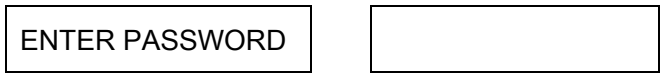
## Institutional Defaults

Capnostream is shipped from the factory with all changeable settings configured according to the tables in the section Changing Monitor Settings on page 119. These are called the Factory Default Settings. If the specific environment of use indicates that other settings are preferable or required, or Institutional policy requires different values than the Factory Defaults, then the default settings can be changed so that they are in effect every time the monitor is turned on. This is more reliable than expecting staff members to change the settings before each use.

Default settings can be changed manually by an authorized technician / biomedical engineer to produce institutional defaults. Default settings are set from the Institutional Defaults screen, which is reached from the Service screen. The Service Screen is password protected. The procedure is described in Changing Institutional Defaults, below.

## Changing Institutional Defaults

From the Home screen use the control knob to select the *SYSTEM* button, and then select the *SERVICE* button on the menu to open the Service screen. The Enter Password box appears near the top of the screen.




As described in Screen Navigation on page 36, use the control knob to select *ENTER PASSWORD*. Using the control knob, enter the password *SERVICE* and click the control knob again after the last letter.

Use the control knob to select *INST DEFAULTS*. You have the option of changing the default settings for *ALARM LIMITS, TRENDS, MONITOR, $CO_2$ and $SpO_2$*.

**WARNING:** Changing the settings might adversely affect the monitoring of patients. Changes to the Institutional settings must only be made by authorized personnel.

## Resetting to Factory Defaults

Each section of settings described below allows you to reset to the factory settings for that specific section. You can also do a global reset of all settings in all sections to their factory defaults. To do this, select *RESET* when you first select the Institutional Defaults screen.

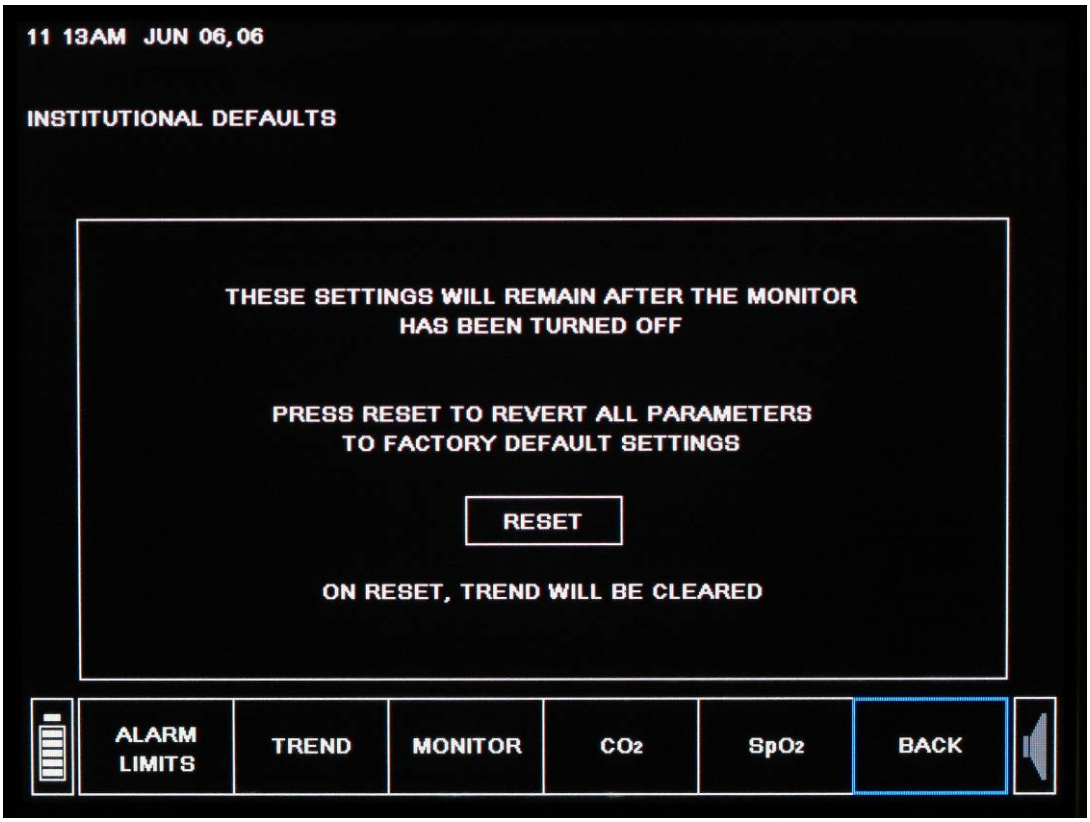



Figure 45 - Institutional Defaults Screen

## Uploading or Downloading Institutional Defaults

Capnostream provides the option of uploading institutional defaults from the monitor to a USB Flash Memory drive or downloading institutional defaults from a USB Flash Memory drive to the monitor.

This utility is used, for example, to simplify the process when an institution wants all devices in a particular group or section to use the same institutional defaults. In such a case, changes can be made to institutional defaults on one device, and those defaults can be uploaded to a USB Flash Memory device as described below. Then, those defaults can be downloaded to the other Capnostream devices in the section/institution using this procedure.

➢ TO UPLOAD OR DOWNLOAD DEFAULTS:

1. For upload, insert a USB Flash Memory drive with at least 2 KB in free memory into the USB port on Capnostream. For download, insert a USB Flash Memory drive with Institutional Defaults previously loaded on it into the USB port on Capnostream.
2. Click the *SYSTEM* menu button to enter the main System screen.
3. Click the *SERVICE* menu button to enter the Service screen and input the Service password (the password is SERV or SERVICE).
4. Click the *SOFTWARE SUPPORT* menu button to enter the Software Support screen. The Software Support screen can be seen in Figure 46 - Software Support Screen on page 119.
5. Click the *DOWNLOAD DEFAULTS* button to download defaults from a USB Flash Memory drive onto Capnostream, or click the *UPLOAD DEFAULTS* button to upload defaults to a USB Flash Memory drive from Capnostream. Downloading defaults will create a folder called *settings* on the USB Flash Memory drive, which will contain files that can be used to upload defaults to another Capnostream. After uploading defaults, the monitor will shut itself off; restart the monitor to resume operation.

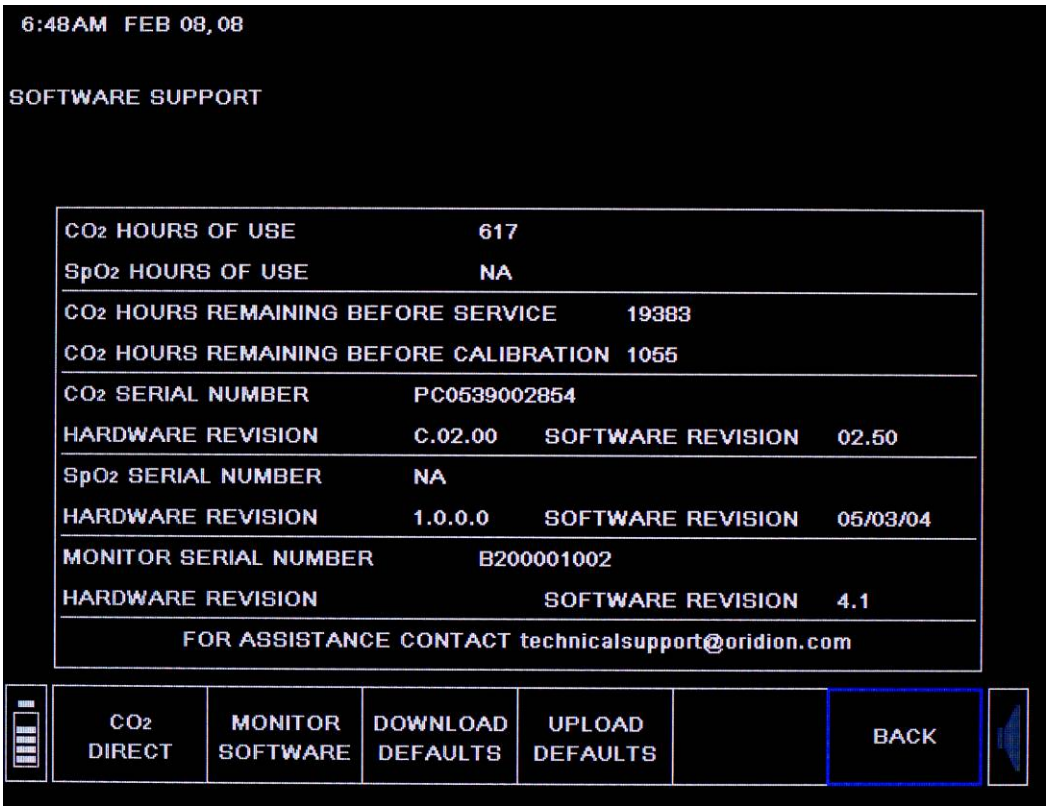



Figure 46 - Software Support Screen

# Changing Monitor Settings

## Alarm Limits

There are two sets of alarm limits that are stored in the monitor, for Adult/Pediatric and for Infant/Neonatal patient types. (The Adult/Pediatric limits are relevant for adult patients and for all three pediatric patient types.) The factory default settings for Adult/Pediatric and Infant/Neonatal alarm limits are given above in Table 32 - Factory Default Alarm Limits on page 120.

To change the alarm limits for each type of patient, open the Institutional Defaults screen. Select *ALARM LIMITS* and then use the control knob to set either *ADULT/PEDIATRIC* or *INFANT/NEONATAL* as the default patient type. You will then be presented with the Institutional Defaults: Alarm Limits: Adult/Pediatric or Infant/Neonatal screen.

Change the settings as described in the section Changing Alarm Limits on page 70.

By default, the Caution alarms are disabled, and in the Alarm Limits screen the numbers for the Caution alarm settings appear in grey. Select *CAUTION ENABLE* if you want to enable the Caution alarms. When the Caution alarms are enabled, the numbers for the Caution alarm settings change to white from grey.

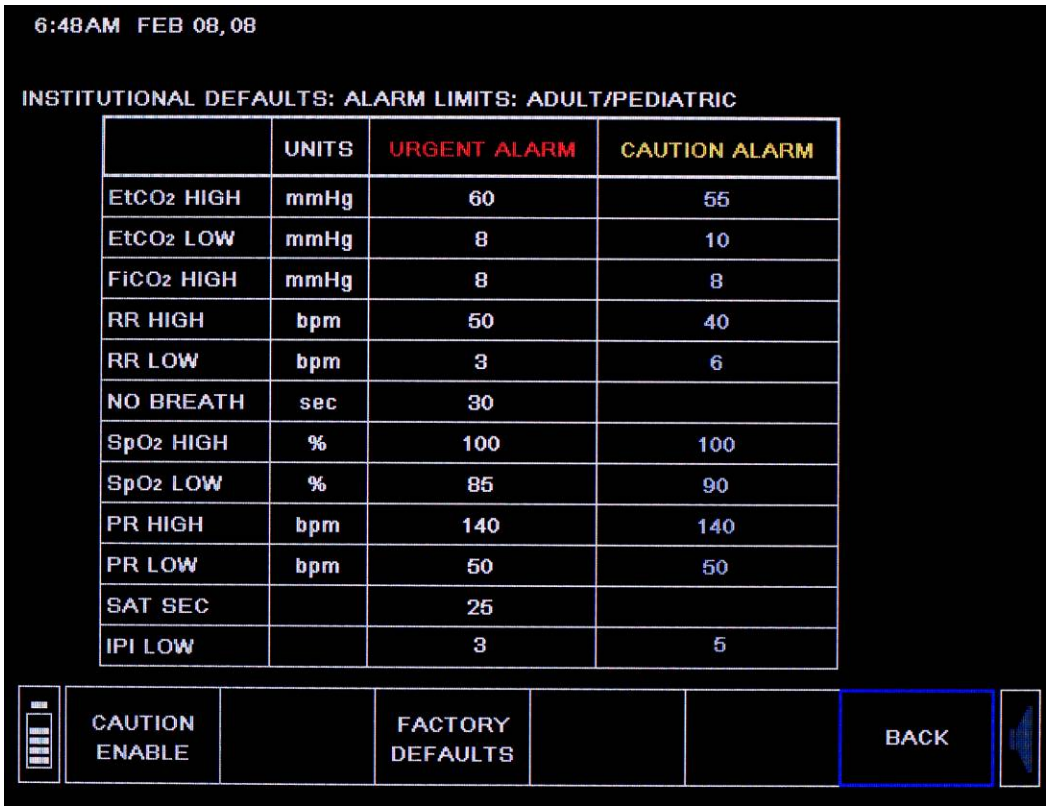



Figure 47 - Institutional Defaults Alarm Limits Screen

The factory default settings for Adult/Pediatric and Infant/Neonatal alarm limits are given below.

Table 32 - Factory Default Alarm Limits

| Parameter | Adult/Pediatric Red Urgent | Adult/Pediatric Yellow Caution | Infant/Neonatal Red Urgent | Infant/Neonatal Yellow Caution | Alarm Range |
|---|---|---|---|---|---|
| $EtCO_2$ High | 60 | 55 | 60 | 55 | 5-150 mmHg |
| $EtCO_2$ Low | 8 | 10 | 8 | 10 | 0-145 mmHg |
| $FiCO_2$ High | 8 | 8 | 8 | 8 | 2-98 mmHg |
| RR High | 50 | 40 | 80 | 70 | 5-150 bpm |
| RR Low | 3 | 6 | 12 | 15 | 0-145 bpm |
| No Breath Detected | 30 | 30 | 20 | 20 | 10-60 sec |
| $SpO_2$ High | 100 | 100 | 98 | 98 | 25-100% saturation |
| $SpO_2$ Low | 85 | 90 | 85 | 90 | 20-95% saturation |
| Pulse Rate High | 140 | 140 | 200 | 200 | 25-250 bpm |
| Pulse Rate Low | 50 | 50 | 100 | 100 | 20-245 bpm |
| SatSeconds | 25 | 25 | 25 | 25 | 10, 25, 50, 100 or Off |
| IPI Low Alert | 3 | 5 | N/A | N/A | 1-9 or OFF |

## Trend Settings

### Trend Settings

Institutional Defaults can be set to change the Trend stored in the monitor, and how it is displayed on the screen. For the specific trend settings for $SpO_2$ and $CO_2$, see the individual settings described below for the $SpO_2$ and $CO_2$ parameters.

Table 33 - Factory Default and Optional Trend Settings

| Parameter | Choices | Factory Default |
|---|---|---|
| Trend Recording Resolution | 5 seconds at 12 hours<br>10 seconds at 24 hours<br>30 seconds at 72 hours | 30 seconds at 72 hours |
| Tabular Increment Display Default | MINIMUM, 1.5, 3, 15 or 60 minutes | 1.5 Minutes |
| Graphical View Default | 2, 4 or 12 hours | 4 hours |

The Home IPI Display Default (see IPI Display on page 62) also appears in the Trend Settings defaults screen.

The default Trend Recording Resolution determines how many hours of patient information can be recorded.

The Tabular Increment Display enables the default to be set to the values in the table.

The Graphical View Default can be changed so that the Trend window will show a different time period of data.

**Note:** Changing the Trend resolution will clear the Trend memory, erasing any patient data that was in the monitor.

To make changes to the Trend Defaults, click *SERVICE>INST DEFAULTS>TREND* on the menu bar. Use the control knob to navigate to the parameters described above and click to view options. Choose an option using the control knob and click again to record that option as the default.

Event labels used in Trend recording can also be changed from the Institutional Defaults: Trend screen, using the menu bar. A detailed explanation appears in Events, below.

### Events

Up to 10 event names in each of three categories can be stored in Capnostream. This allows the attending health care professional to describe the event that is inputted to the monitor's memory. The three categories are medication, patient actions and clinician intervention actions.

Most event names are provided as factory defaults with several left blank in each of the three categories. However, all 30 event names can be edited to provide the most appropriate descriptions for the environment that the monitor will be used in.

Each event name can be up to 11 alphanumeric characters. If an event name is left blank, a selection of that event will be stored in trend memory as a Quick event (see Entering Patient Events on page 43 for information on using Events).

#### Medication Events

Allows the institution to enter a set of 10 event labels which the operator can use to mark the administration of medicine at the time of monitoring. The default medicines are: FENTANYL, VERSED, MIDAZOLAM, MORPHINE, DEMEROL, PROPOFOL and OTHER. The last three settings are blank. All settings are changeable. To reset the Medication Events to the factory settings, use the control knob and select *FACTORY DEFAULTS*.

**Patient Events**

Allows the institution to enter a set of 10 event labels which the operator can use to mark events that happen to the patient at the time of monitoring. The default Patient Events are: EATING, DRINKING, COUGHING, AMBULATING, CHEST PT, TURNED, SNORING and OTHER. The last two settings are blank. All settings are changeable. To reset the Patient Events to the factory defaults, use the control knob and select *FACTORY DEFAULTS*.

**Intervention Events**

Allows the institution to enter a set of 10 event labels which the operator can use to mark events where a physical or other intervention occurred during the time of monitoring. The default Intervention Events are: OXYGEN, SUCTION, ADJ AIRWAY, NARCAN, ROMAZICON, NEB TX, STIMULATED and OTHER. The last two settings are blank. All settings are changeable. To reset the Intervention Events to the factory defaults, use the control knob and select *FACTORY DEFAULTS*.

### How to Change Event Defaults

From the Service screen, select the INST DEFAULTS screen, and then the TREND screen. In the Menu Bar of the Institutional Settings: Trend screen are the options to select *MED* to change medication events settings, *PAT* to change patient events settings, and *INT* to change intervention events settings. To change an event, scroll to a particular event label and click it so as to clear the field and enter another event name.

### Monitor Settings

From the Institutional Defaults screen, select *MONITOR*.

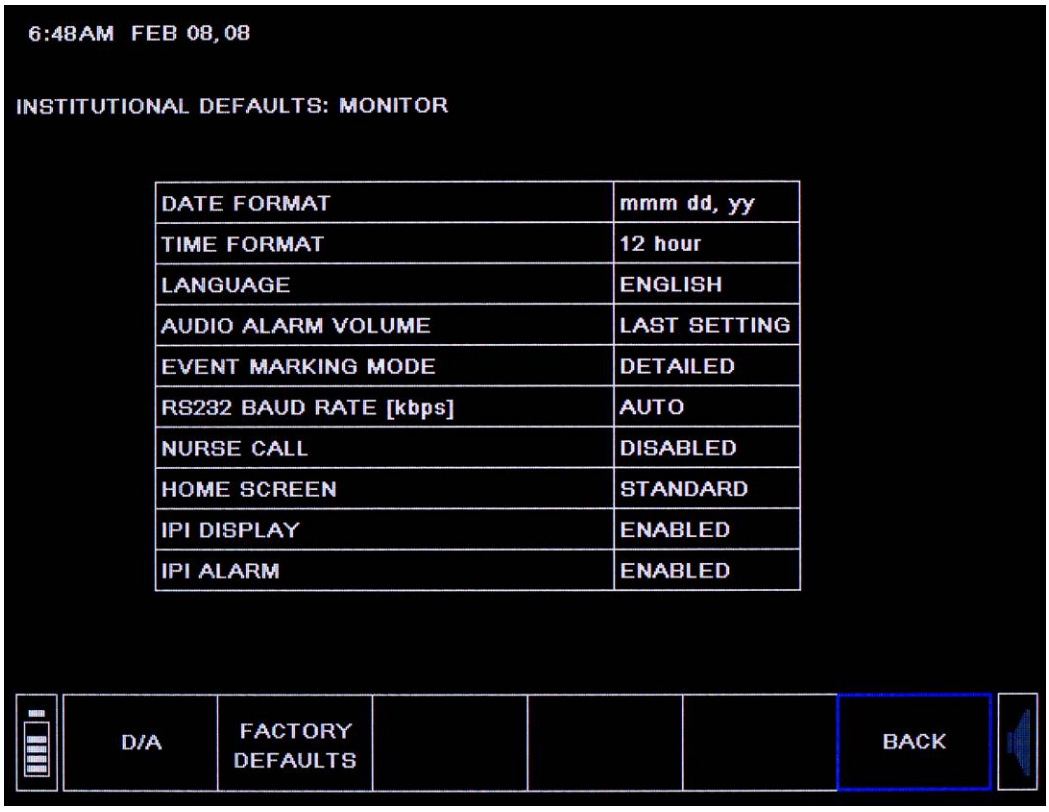



Figure 48 - Institutional Defaults: Monitor

The Institutional Defaults that can be set for the monitor are as follows:

| Parameter | Choices | Factory Default |
|---|---|---|
| Date Format | dd mmm yy *or*<br>mmm dd, yy | mmm dd, yy |
| Time Format | 12 or 24 hour | 12 hour |
| Language | English, Spanish, French, German, Italian, Dutch, Portuguese, Russian, Swedish, Norwegian | English |
| Audio Alarm Silence | Maximum, Last Setting, Audio Off | MAXIMUM |
| Event Marking Mode | Quick/Detailed | DETAILED |
| RS-232 Baud Rate | AUTO; 9600 ; 19.2K; 57.6K; 115.2K | AUTO |
| Nurse Call | Enabled, Disabled | DISABLED |
| Home Screen | Standard, Numeric | STANDARD |
| HOME IPI Display | Enabled, Disabled | ENABLED* |
| IPI Alarm | Enabled, Disabled | DISABLED |

* Please note that IPI is not available for Infant/Neonatal patients, and thus is automatically disabled for Infant/Neonatal patients.

### $CO_2$ 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 screen.

| Parameter | Choices | Factory Default |
|---|---|---|
| $CO_2$ Units | mmHg, kPa, Vol% | mmHg |
| BTPS* | On/Off | On |
| $FiCO_2$ Display | On/Off | On |
| Pump-Off Timeout (minutes) | 5, 10, 15 or 30 | 15 |
| $CO_2$ Waveform Scale (mmHg) | 50, 100, 150, Auto | Auto |
| $EtCO_2$ Scale for Trend Display | 50, 100, 150 | 50 |
| RR Scale for Trend Display | 50, 100, 150 | 50 |
| Sweep Speed Adult/Pediatric (mm/sec) | 3, 6.3, 12.5, 25 | 6.3 |
| Sweep Speed Infant/Neonatal (mm/sec) | 3, 6.3, 12.5, 25 | 6.3 |
| 10 sec EtCO2 High alarm delay | Enabled/disabled | Disabled |
| 10 sec RR High alarm delay | Enabled/disabled | Disabled |

* 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 device 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.

### $SpO_2$ 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.

| Parameter | Choices | Factory Default |
|---|---|---|
| Pulse Tone | On/Off | Off |
| Sat-Seconds | On/Off | On |
| $SpO_2$ Scale for Trend Display | 0-100, 50-100 | 50-100 |
| PR Scale for Trend Display | 150, 300 | 150 |
| Sweep Speed Adult/Pediatric (mm/sec) | 3, 6.3, 12.5, 25 | 25 |
| Sweep Speed Infant/Neonatal (mm/sec) | 3, 6.3, 12.5, 25 | 25 |

### Digital to Analog Channel Settings

To change the default channel assignments for the analog output, from the Institutional Defaults screen select *MONITOR*, and then select *D/A*. Follow the instructions as described in Analog Data Output with Capnostream on page 98.

# Appendix 2

# *Specifications*



## Power Supply

| Item | Value |
|---|---|
| Input Voltage | 100-240VAC, 50/60Hz |
| Fuses | Two F3.15A 250 Volt |
| Input Power | 90 VA |

## Battery

| Item | Value |
|---|---|
| Battery Type | 14.8V, 4Ah Lithium-Ion |
| Battery Operation | 2.5h (without thermal recorder) |
| Battery Charging Time | 100% in 12h |

## Controls

| Item | Value |
|---|---|
| Front Panel | 1 Switch for monitor On/Off control<br>4 specific function keys<br>1 optical encoder with switch |
| Back Panel | 1 Mains ON/OFF Switch |

## Display

| Item | Value |
|---|---|
| Screen | 162mm (6.4in) Color TFT Display<br>Pixel Pitch: 0.204 (H) x 0.204(V) mm (0.008in)<br>Active Display Area: 130.56 (H) x 97.92 (V) mm (5.14in x 3.86in)<br>Resolution 640 x 480 pixels<br>Viewing angle (vertical) 110°<br>Viewing angle (horizontal) 140° |
| Trace Speed | 3.0, 6.3, 12.5 & 25 mm/sec |
| Waveform sampling rate | 75.7 samples/sec for $SpO_2$ (fixed)<br>20 samples/sec for Capnography (fixed) |
| Trend Storage | 8640 point storage<br>- 12h at 5s resolution<br>- 24h at 10s resolution<br>- 72h at 30s resolution |
| Trend Display | Graphical Display:<br>- 2h, 6h, 12h views |
| | Tabular Display<br>- 60 min, 15 min, 3 min, 1.5 min, and minimum resolution (minimum resolution settable to 5, 10, or 30 seconds) |

## Microstream® Capnography

| Item | Value |
|---|---|
| $CO_2$ Units | mmHg or kPa or Vol% |
| $CO_2$, $EtCO_2$, $FiCO_2$ Range | 0-150 mmHg |
| $CO_2$ Waveform Resolution | 0.1 mmHg |
| $EtCO_2$, $FiCO_2$ Resolution | 1 mmHg |
| $CO_2$ Accuracy | 0-38 mmHg: ± 2 mmHg<br>39-150 mmHg: ± (5% of reading + 0.08% for every 1 mmHg above 38 mmHg) |
| Respiration Rate Range | 0-150 bpm |
| Respiration Rate Accuracy | 0-70 bpm: ±1 bpm<br>71-120 bpm: ±2 bpm<br>121-150 bpm: ±3 bpm |
| Flow Rate | 50 (42.5 ≤ flow ≤ 65) ml/min, flow measured by volume |
| Waveform Sampling | 20 samples/s |
| Response Time | 2.95 s (typical) |
| 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 |

## Nellcor Oximax® Pulse Oximetry

| Item | Value |
|---|---|
| $SpO_2$ Measurement Range | 0-100% |
| $SpO_2$ Accuracy | |
| Adult and Pediatric Modes | |
| $SpO_2$ range 70% - 100% | ± 2 digits |
| $SpO_2$ range 0 - 69% | Unspecified |
| Infant/Neonatal Mode | |
| $SpO_2$ range 70% - 100% | ± 3 digits |
| $SpO_2$ range 0 - 69% | Unspecified |
| Pulse Rate Range | 20-250 bpm |
| Pulse Rate Accuracy | ± 3bpm |
| Alarms | Adjustable Alarm Limits<br>$SpO_2$ high, $SpO_2$ low, Pulse Rate high, Pulse Rate low |
| Sat Sec Range | 10, 25, 50, 100 |

## Alarms

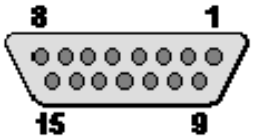
| Item | Value |
|---|---|
| High Priority Patient Warning Alarms | Flashing Red LED<br>Flashing Red Numeric<br>High Priority Alarm beep pattern<br>Alarm Indication on Screen<br>Nurse Call |
| Patient Caution Alarms | Flashing Yellow LED<br>Flashing Yellow Numeric |
| Low Priority Alarm | Lit Yellow LED<br>Triple beep once every minute<br>Alarm Indication on Screen<br>Nurse Call |
| Advisories | Beep once<br>Advisory Indication on Screen |
| Silent Advisories | Advisory Indication on Screen |
| Alarm Volume Control | 5 steps |
| Temporary Alarm Silence | All audible alarms silenced for 2 minutes |

## Outputs

### Analog Output

15-pin female D-type connector

Pinout:




| Pin | Assignment | Pin | Assignment |
|---|---|---|---|
| 1 | Ground | 9 | Ground |
| 2 | Ch 1 Signal | 10 | Ground |
| 3 | Ground | 11 | Ch 5 Signal |
| 4 | Ch 2 Signal | 12 | Ground |
| 5 | Ground | 13 | Ch 6 Signal |
| 6 | Ch 3 Signal | 14 | Ground |
| 7 | Ground | 15 | Ch 7 Signal |
| 8 | Ch 4 Signal | | |

### Nurse Call

Normally Open/ Normally Closed Relay

Rated Carrying current : 2A

Max Allowable Current : 2A

Max Allowable Voltage : 24V DC

Contact Capacity: 2A @ 24V DC.

1/8” stereo phono-jack

Pin out of mating stereo phono plug

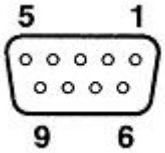

N1 - N2: Normally Closed relay

N1 - N3: Normally Open relay

### RS-232

9-pin female D-type connector

Pinout




| Pin | Assignment |
|---|---|
| 1 | -- |
| 2 | PC_RX |
| 3 | PC_TX |

| | |
|---|---|
| 4 | -- |
| 5 | Isolated Ground |
| 6 | -- |
| 7 | -- |
| 8 | -- |
| 9 | -- |

### USB

USB Type A Host connector (female)

For use only with flash memory drives.

Pinout


| Pin | Assignment |
|---|---|
| 1 | VBUS |
| 2 | Data - |
| 3 | Data + |
| 4 | Ground |

## Internal Thermal Printer (optional)

| Item | Value |
|---|---|
| Type | Two Channel |
| Printing Method | Thermal Recording |
| Dot Density | 203 dpi |
| Paper Width | 58mm (2 ¼ in) |
| Paper Roll Diameter (maximum) | 40mm (1 1/2 in) |
| Paper Length (maximum) | 15.2 meters (50 ft) |
| Speed | 25mm/s |

## General Characteristics

| Item | Value |
|---|---|
| Unit Dimensions | 167mm(h) x 220mm(w) x 192mm(d)<br>(6.6in (h) x 8.7in (w) x 7.6in (d)) |
| Unit Weight | 3.5kg (7.72lb) |
| Operating Temperature | 0°C to 40°C (32°F to 104°F) |
| Operating Pressure and Altitude | Pressure: 430 mmHg to 795 mmHg<br>Altitude: -381m to 4572m (-1,250 feet to 15,000 feet) |
| Operating Humidity | 10% to 95% non-condensing |
| Storage & Transport Temperature | Until lower limit of -35°C (-31°F) |

| Item | Value |
|---|---|
| | Up to upper limit of 70°C (158°F) |
| Storage & Transport Pressure and Altitude | Pressure: 430 mmHg to 795 mmHg<br>Altitude: -381m to 4572m (-1,250 feet to 15,000 feet) |
| Storage & Transport Humidity | 10% -95% non-condensing |
| Packaged Dimensions | 315mm(h) x 340mm(w) x 285mm(d)<br>(12.4in (h) x 13.4in (w) x 11.2in (d)) |
| Packaged Weight | 5.5kg |

## Equipment Classification

| Item | Value |
|---|---|
| Types of Protection against Electric Shock | Class 1 |
| Degree of Protection against Electric Shock | Defibrillator-Protected Type BF |
| Mode of Operation | Continuous |
| Degree of Protection against Ingress of liquids | IEC 60601-1, sub-clause 44.6 for class IPX1 Drip-proof equipment |

## Compliance

This product is designed to conform to the following standards:

IEC/EN60601-1

UL 60601-1

CSA C22.2 No 601.1-M90

IEC/EN60601-1-2/2001 Class A Radiated and Conducted Emission

IEC 60601-1-8 (Audible and Visual Alarms)

ISO 21647 (Capnography)

ISO 9919 (Pulse Oximetry)

IEC 60601-2-49 Particular requirements for the safety of multifunction patient monitoring equipment