Capnostream™20

Portable Bedside

Capnograph/Pulse Oximeter

Operator's Manual

PN: 011414A

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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 Microstream® $EtCO_2$ consumables (FilterLines®, henceforth referred to as FilterLines) and the SpO_2 sensors. 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 46.

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.

The 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 Capnostream combined capnograph/pulse oximeter monitor is intended to provide professionally trained health care providers the continuous, non invasive measurement and monitoring of carbon dioxide concentration of the expired and inspired breath and respiration rate, and for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2 and pulse rate). It is intended for use with neonatal, pediatric and adult patients in hospitals, hospital type facilities, intra hospital moves and home environments.

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.

CAUTION: 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 the 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
- Simple user interface with color screen
- Routine functions are accessed with 2 clicks
- 72 hour trends to review patient history
- 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™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.

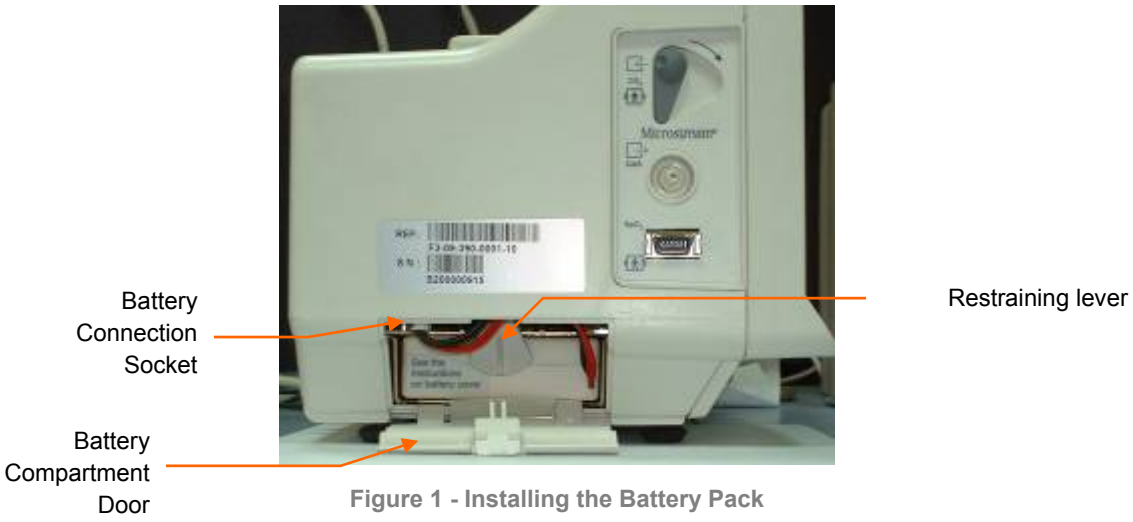


Figure 1 - Installing the Battery Pack

➢ TO INSTALL THE BATTERY PACK:

1. Slide the two release latches outward and open the battery compartment 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.

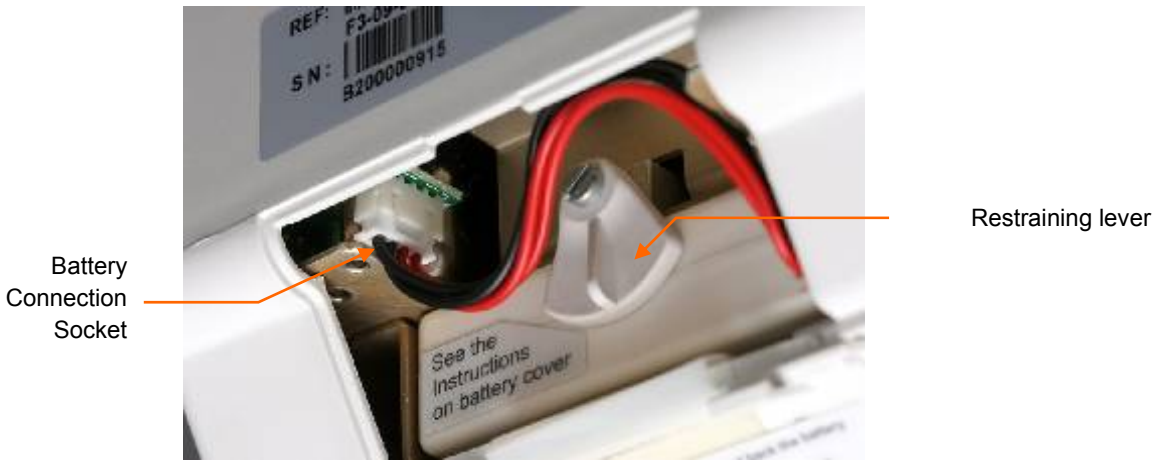


Figure 2 - Battery Pack Close-up

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

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 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.

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: Only recharge the battery pack 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 GCX model FLP-0002-17C Mounting Adaptor with (100mm) VESA Standard Mounting (can be ordered from Oridion; part number is 010713). The adaptor fits the GCX model RS-0006-64C Roll Stand Assembly. Please refer to the appropriate *Directions for Use* for these products.

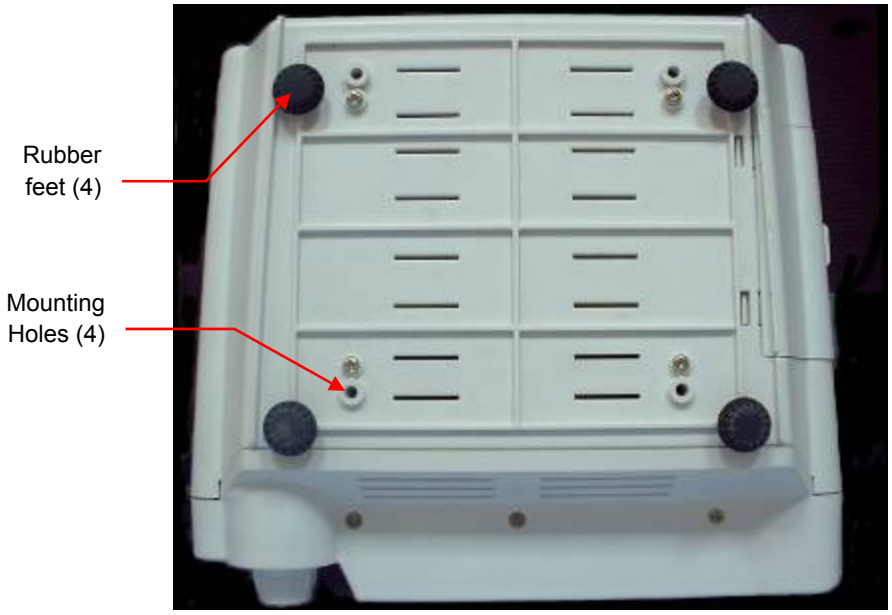


Figure 4 - Monitor Bottom View

CAUTION: Do not remove the rubber feet from the bottom of the monitor. The mounting adaptor includes spacers that allow the monitor to be mounted with the feet in place, ensuring that the air vents on the bottom of the monitor are not covered, so that the monitor does not overheat.

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 90 for paper installation.
Mounting Adaptor Plate (Vesa)	010713	Used for mounting Capnostream to GCX roll stands and other mounting assemblies. (GCX equivalent part number FLP-0002-17C). Refer to Mounting the Monitor on page 22 for mounting instructions.

Pole Clamp	010962	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]). Mounting adapter plate is included.
Roll Stand with Basket	Not stocked by Oridion	GCX Part Number RS-0006-64C Roll Stand Kit 38" post with 5" Slide-in type mounting plate – including: 21" base, 4" casters, 10lb Counterweight, handle, and 6" basket. Mounting plate is required to use Roll Stand.
Battery Pack	010520	Refer to Installing the Battery Pack on page 19 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 82 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 Using Analog Data Output on page 80 for set up instructions.
Y Power Cable	CS08707	Used with a Bernoulli/Oxinet hospital system. Refer to Operation with Hospital Patient Data Systems on page 85 for details.
Fuse (2 each 3.15 amp 250 Volts	010543	Refer to Replacing the Fuses on page 89 for instructions on how to replace fuses.
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 Paper 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.

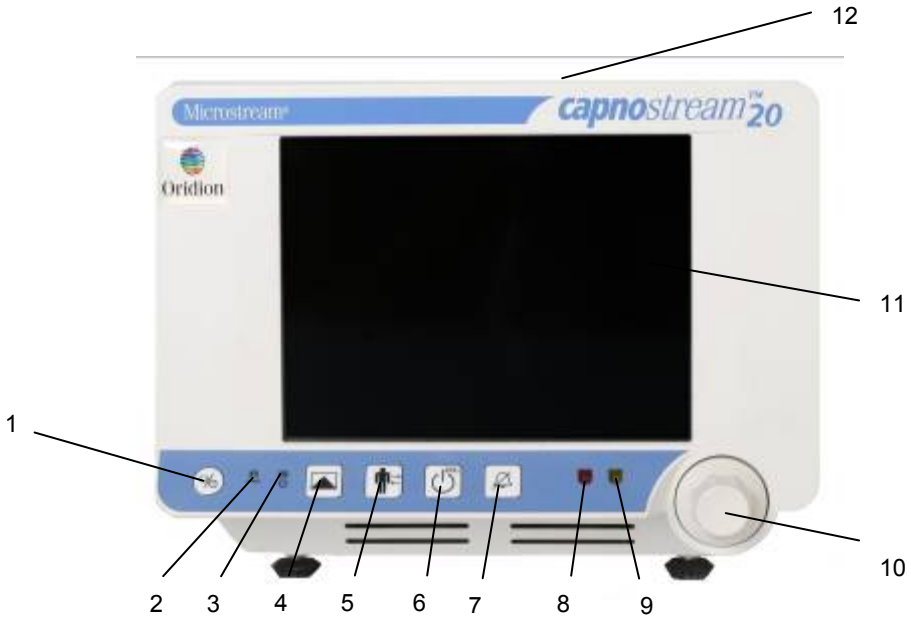


Figure 5 - Capnostream Front View

Table 4 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 Chapter 7 Alarms and Messages on page 52).
3	Monitor power on indicator	Green light	9	Yellow alarm indicator	Indicator that lights or flashes according to the alarm status (see Chapter 7 Alarms and Messages on page 52).
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 24 and described in Table 4 - Capnostream Front View above.

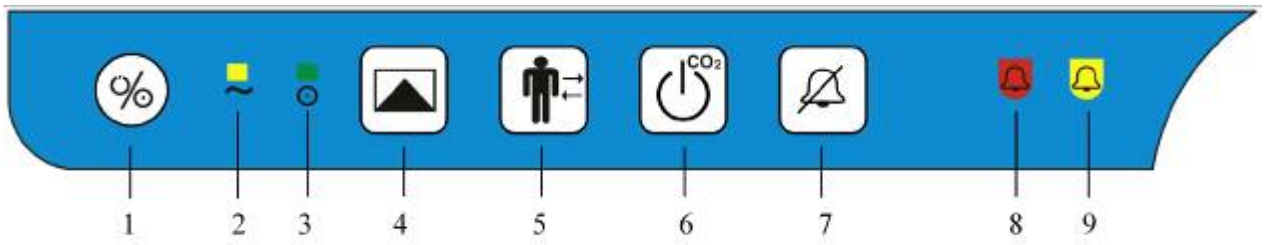


Figure 6 - Front Panel Control Buttons

Monitor Rear Panel

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

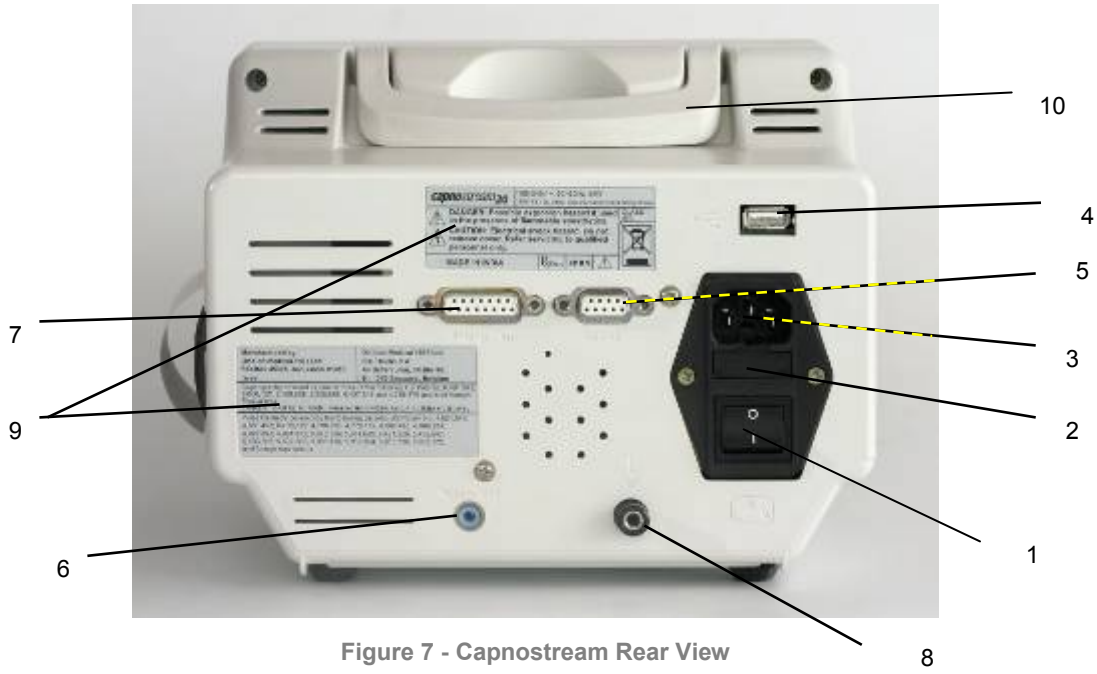


Figure 7 - Capnostream Rear View

Table 5 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 the Mains power supply to the monitor.	6	Nurse Call	Port used for 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 View

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

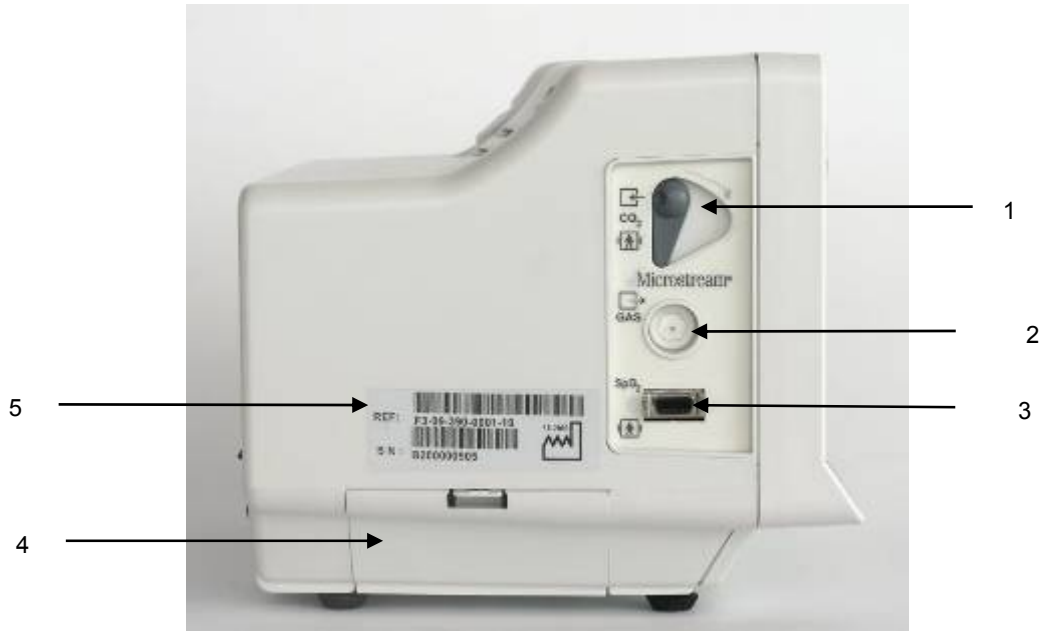


Figure 8 - Capnostream Left View

Table 6 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.

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 Masimo 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 26).
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 36. Following that screen, the Home screen will appear. The Home screen displays the CO_2 and SpO_2 waveforms along with other information that is standard on most other screens. This section explains the main parts of the screen.

Figure 10 - Typical Home Screen

Most of the screens contain the following sections:

- Header Area on page 29
- Menu Bar on page 30
- Real Time CO2 Data on page 30
- Real Time SpO2 Data on page 30

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 allows continuous patient monitoring even when changing system settings, or observing patient history on the trend screens.

Header Area

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

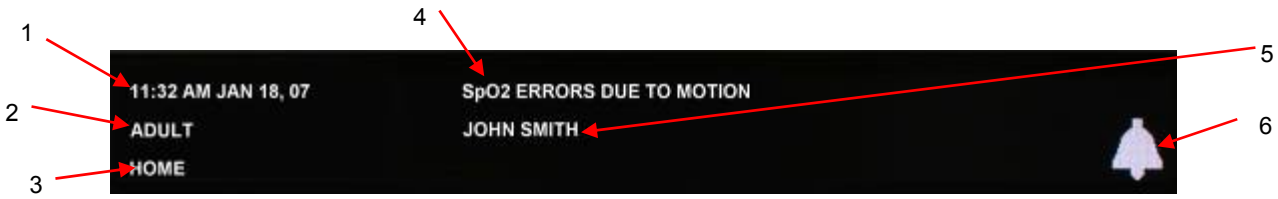


Figure 11 - Header Area

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. ADULT for adults and pediatrics, and NEONATAL for neonatal patients.
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.

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. For more details regarding the displayed information, see Chapter 5 Capnography with the Capnostream Monitor on page 43.

When the monitored parameter limits are exceeded, the affected numeric will flash to alert the attending health care professional to the specific parameter that is affected.

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. For more details about the displayed SpO_2 data, see Chapter 6 Pulse Oximetry with the Capnostream Monitor on page 47.

When the monitored parameter limits are exceeded, the affected reading will flash to alert the attending health care professional to the specific reading that is affected.

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.

Home Screen

The typical home screen shown in Figure 10 - Typical Home Screen on page 29 shows data and waveforms for a patient connected with a FilterLine and SpO_2 sensor.

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 the ↵ Enter symbol appears in the place of the first character in the empty block.
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. Pressing the control knob when the blank space is displayed will insert a blank space (if you want to use a patient name for the Case ID number, for example). The cursor then highlights the next character to be entered and shows the Enter symbol.
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 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 DATE, TIME OR LANGUAGE:

From the Home screen, use the control knob to select *SYSTEM* in the Menu Bar.

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.

To change the language of the display, use the control knob to change the language. The new 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 96.

Figure 12 - System Setup Screen

Screen Timeouts

Screen Timeouts

All setup and system screens will timeout 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 19 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 for an adult or pediatric patient or Neonatal for a neonatal patient.

❒ **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.

❒ **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 52 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 36 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 69 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 82.
- 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 Using Analog Data Output on page 80.
- 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 85 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 75 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 27.
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 27.

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 43 and Chapter 6 Pulse Oximetry with the Capnostream Monitor on page 47.

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 two patient types recognized by the monitor: Adult and Neonatal. The adult setting is used for both adult and pediatric patients. The patient type is displayed at the top left hand corner of the screen. Setting the patient type is compulsory.

CAUTION: The characteristics of a breath are calculated differently for adult and neonates. Setting the correct patient type is therefore very important. Incorrect setting will result in inaccurate monitoring of the patient's respiration rate.

➢ 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 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 and Neonatal Patients which can be configured according to the physiology observed in the particular age groups. See the relevant information in the Message Priorities on page 53.

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. The maximum permitted length for the Patient ID is 20 characters. Select the ↵ Enter symbol to finish. See the section Screen Navigation on page 31 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 25 - Trend Memory Message on page 67. 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 25 - Trend Memory Message on page 67, 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 Using Trends on page 59 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 17 - 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 return to the *HOME* screen.

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 96.

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

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 13 - 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 14 - 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.

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 15 - 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.

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 below in Figure 16, 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 16 - 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 protect the monitor from drawing in liquids which could cause a malfunction.

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

WARNING: If at any time the 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 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 96) 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.

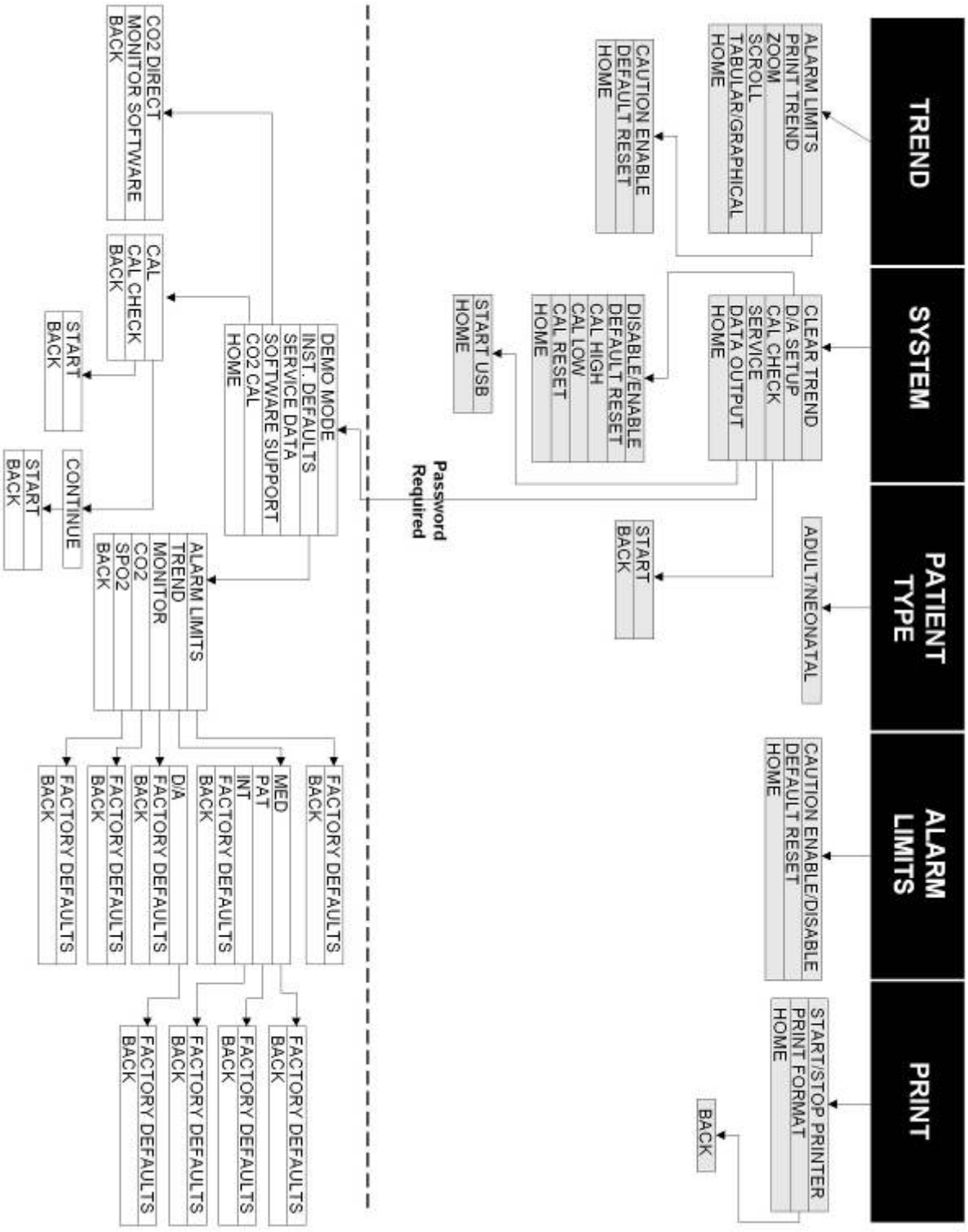


Figure 17 - Screen Menu Reference Chart

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 (ie., 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 Capnostream 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.

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® EtCO2 Consumables

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

Product	Description and Suggested Application	Part Number (for box of 25)
FilterLine® Set	FilterLine set for intubated patients (for non-humid environments).	XS04620
FilterLine® H Set	FilterLine set for intubated patients (for humid environments).	XS04624
Smart CapnoLine™ O2	Oral/Nasal FilterLine for non-intubated patients requiring oxygen during procedural sedation.	007267
Smart CapnoLine™ Plus	Oral/Nasal FilterLine for non-intubated patients during procedural sedation.	009818
Smart CapnoLine™ Plus O2	Oral/Nasal FilterLine for non-intubated patients requiring oxygen during procedural sedation.	009822
Smart CapnoLine™ H O2	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	Oral/Nasal FilterLine for non-intubated patients requiring oxygen for post-op pain management (for long-term use).	010433
CapnoLine™ H	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™	Nasal FilterLine for non -intubated patients under oxygen, CPAP, Bi-PAP, or NPPV mask.	008174
Smart BiteBloc™	Non-intubated patients for use during upper endoscopy procedures.	010037
Smart BiteBloc™ O_2	Non-intubated patients requiring oxygen for use during upper endoscopy procedures.	010131
FilterLine® XL	FilterLine for use during MRI scanning (see Monitoring CO2 during MRI Scanning on page 46).	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.

This listing describes the main products available. For more information about Oridion FilterLines or additional sizing and packaging options for these products, see 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.
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 96 for details regarding the available units)
- Real-time $FiCO_2$ values along with selected unit (see Institutional Defaults on page 96 for details regarding the available units)
- Respiration rate (RR) in breaths per minute
- CO_2 Waveform

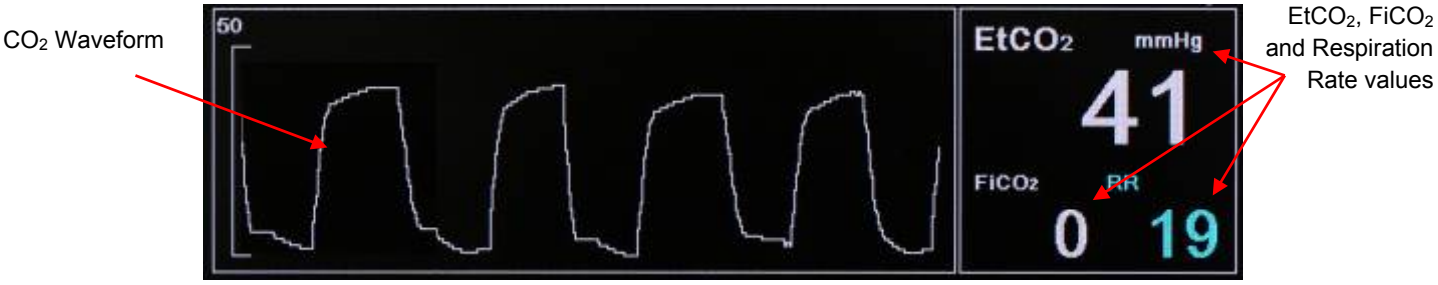


Figure 18 - CO_2 Data on the Capnostream Monitor

Additionally, the monitor can display CO_2 data in trend form, showing time, date, $EtCO_2$, RR, alarms, events, and a CASE START marker. For more information about trend display, see Chapter 8 Using Trends on page 59.

When the monitored parameter limits are exceeded, the affected numeric will flash to alert the attending health care professional to the specific parameter that is affected.

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 101.

➢ 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 9 - 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 9 - 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, Auto	Auto
$EtCO_2$ Scale for Trend Display	50, 100	50
RR Scale for Trend Display	50, 100, 150	50
Sweep Speed (mm/sec) [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 a slower response and a decreased frequency response time.

To purchase the FilterLine XL, contact your local representative.

Chapter 6

Pulse Oximetry with the Capnostream Monitor

Masimo 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 Masimo oximetry 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 Masimo 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 listed below. For further information, please contact your local representative.

Masimo sensor models include:

- LNOP® Reusable Sensors
- LNOP® Adhesive Sensors
- LNCS® Reusable Sensors
- LNCS® Adhesive Sensors
- LNOPv™ Adhesive Sensors

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 Masimo-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
- Significant levels of dysfunctional hemoglobins (HbCO or MetHb)
- venous pulsations

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.

The device may be used during defibrillation, but the readings may be inaccurate for a short time.

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 Masimo SpO_2 sensor to the extension cord.
2. Connect the Masimo SpO_2 sensor to the patient as described in its Directions for Use.
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 *SpO2 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 beep once a minute. To avoid the alarm message and beeping, connect the extension cable to the monitor, but do not 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
- Perfusion Index (see Perfusion Index on page 50)
- Plethysmograph (SpO_2 waveform)
- Signal IQ Waveform (see Signal IQ Waveform on page 50)

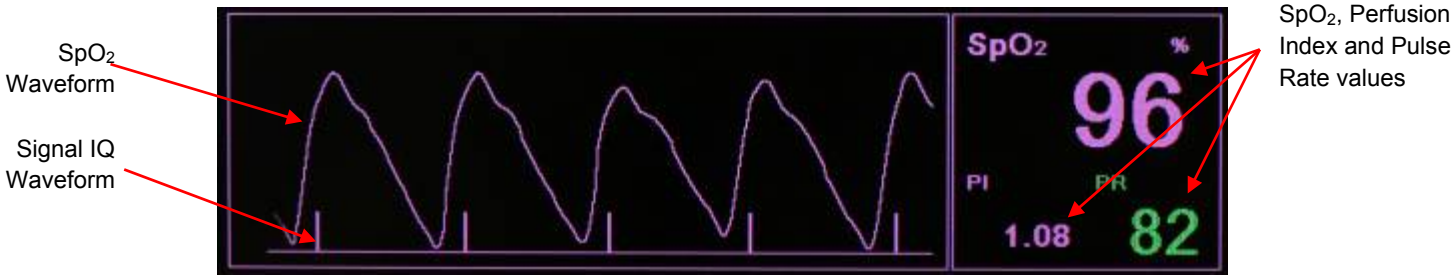


Figure 19 - SpO_2 Data on the Capnostream Monitor

Additionally, the monitor can display SpO_2 data in trend form, showing time, date, SpO_2, pulse rate (PR), alarms, events. For more information about trend display, see Chapter 8 Using Trends on page 59.

When the monitored parameter limits are exceeded, the affected reading will flash to alert the attending health care professional to the specific reading that is affected.

Perfusion Index

The Perfusion Index is a relative assessment of the pulse strength at the monitoring site, expressed as a numerical value that ranges from 0.02% to 20%, where the lower values indicate weak pulse strength and the higher values indicate strong pulse strength. This index represents the ratio of pulsatile to non-pulsatile components of the blood at a particular site, with a higher number indicating a higher proportion of pulsatile blood. The PI is used to assess the relative effectiveness of different application sites, and to alert the clinician to changes in the physiological condition of the patient. Clinically, it is often used to help choose the best body site for pulse oximetry assessment, with clinicians choosing the site in which the Perfusion Index (and thus pulse strength) is highest.

Signal IQ Waveform

The Signal IQ wave is a visual indicator of the confidence associated with the saturation measurement and the timing of the pulse relative to the plethysmosgraph. In the Signal IQ waveform, a tall vertical line indicates a high quality signal, while a small vertical line indicates a low quality signal. The Signal IQ waveform is plotted synchronously with the plethysmograph, and the lines on the waveform will correspond to the patient's arterial pulse.

Thus, a normal Signal IQ waveform will indicate regular, high peaks, while an abnormal Signal IQ waveform will indicated low peaks, peaks of differing heights, or irregularly appearing peaks. When a normal Signal IQ waveform is displayed on the Capnostream monitor, this information serves to increase the clinician's confidence that the plethysmograph is displaying reliable information. When the Signal IQ waveform indicates an abnormal pattern, that information can be taken as a warning of potentially erroneous data. In such a case, a reassessment of sensor placement and patient condition is recommended.

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 101.

➢ 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 10 - Adjustable SpO2 Parameters on page 51.
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 10 - Adjustable SpO_2 Parameters

Parameter	Choices	Factory Default
Pulse Tone	On/Off	Off
SpO_2 Sensitivity	Normal, Maximum, APOD	Normal
Averaging Time [sec]	2 – 4, 4 – 6, 8, 10, 12, 14, 16	8
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

The SpO_2 parameters include the following:

Sensitivity: Sensitivity is the level of response the SpO_2 results will show under conditions of fluctuations in SpO_2 signals. The monitor will display signals based on the information from the patient and the chosen level of sensitivity.

- Normal sensitivity provides the best combination of sensitivity and probe-off detection, recommended for the majority of patients.
- Maximum sensitivity interprets and displays data even for weak signals, recommended for patients with low perfusion, for whom obtaining a pulse oximetry reading is most difficult. Also recommended for situations in which contact between patient and clinician is continuous.
- APOD sensitivity provides information about whether the pulse oximetry probe is on or off the patient, useful in situations where the sensor may become detached, including step-down or ward care, nursing homes, remote monitoring, or patients for whom the sensor is likely to become detached (generally due to excessive movement, often with pediatric or combative patients).

Averaging time: The pulse oximetry function of Capnostream provides averaging algorithms which smooth out the SpO_2 numeric result during rapid desaturations and resaturations to show the average saturation level over each short period, making it easier to track trends of desaturation or resaturation. Averaging helps clinicians avoid a situation in which irrelevant or minor changes might obscure the big picture of the patient's oxygen saturation level. The averaging algorithms in the Capnostream device use the FastSat technology in the lowest averaging time ranges; this technology takes the signal quality of each saturation result into account in calculating the average, minimizing the averaging where required based on signal strength. This procedure results in a numeric that is more representative of the patient's actual oxygenation level than numerics produced with other averaging algorithms. Averaging with FastSat is used clinically to enable rapid tracking of arterial oxygen saturation changes. Clinical indications include the following:

- Lower averaging levels using FastSat (2-4, 4-6) are recommended during procedures in which detecting rapid changes in oxygen saturation is crucial, including induction therapy, intubation, and sleep studies.
- Higher averaging levels (8 and higher) are recommended for patients for whom a general picture of oxygen saturation is required – the same patients for whom the SpO_2 Sensitivity level should be Normal, as described above.

Chapter 7

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.

The following table describes how the alarms are indicated.

Table 11 - Alarm Indications

Alarm Type	Indicators			
	Audible	Numerics	Messages	Indicator Light
High Priority Patient Alarms – Red Urgent	Repeated Beep Pattern	Flashing Red (except NO BREATH)	Message area (NO BREATH in waveform area)	Flashing Red
High Priority Patient Alarms – Yellow Caution	None	Flashing Yellow	None	Flashing Yellow
Low Priority	Repeated triple beep	N/A	Message area	Solid Yellow
Advisories	Single Beep	N/A	Message area	N/A
Silent Advisories	None	N/A	Message area	N/A

Message Priorities

Messages are displayed on 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*, the advisory message *SPO_2 WEAK. REPOSITION SENSOR.* does 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.

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. 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. By default, Caution Alarms are disabled. To enable them, see Changing Alarm Limits on page 57.

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 to the same limits (see Changing Alarm Limits on page 57). Then only the red Urgent Alarm will occur. You can also revert to a single level system 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.

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.

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

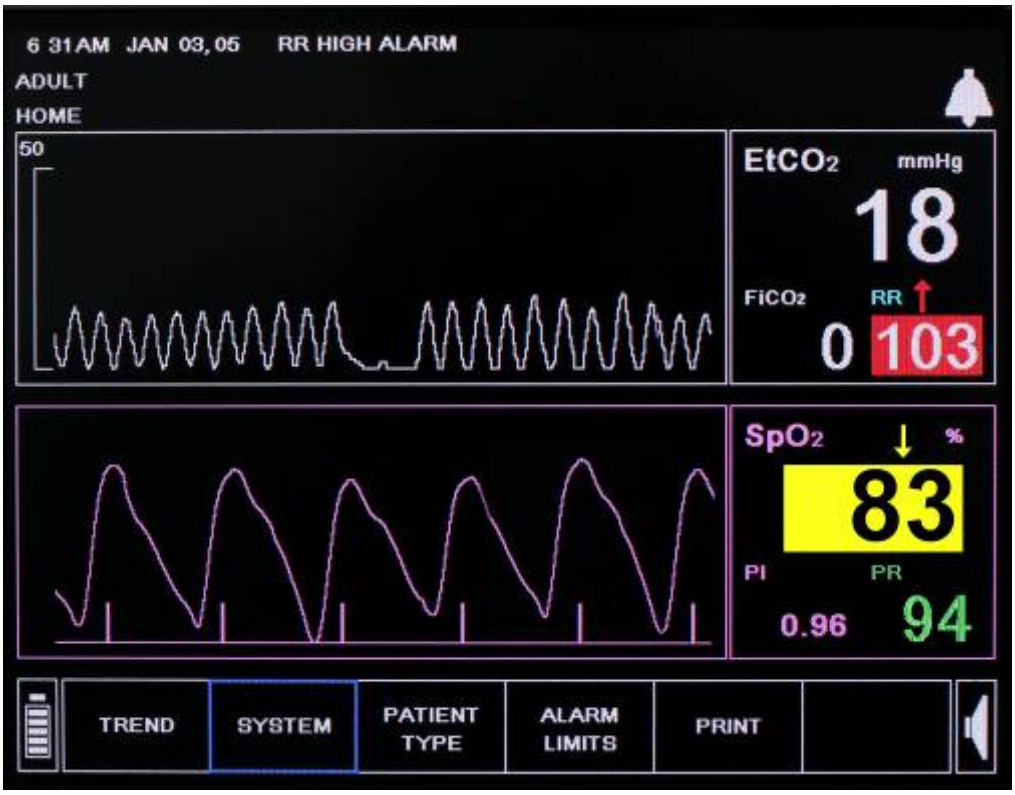


Figure 20 - Example Showing Alarms

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.

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 12 - 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 alarm limit	Patient requires immediate 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.

Message	Description	Corrective Action
SPO_2 LOW ALARM	The SpO_2 is below the upper lower 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.

Low Priority Alarms

Table 13 - 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 14 - 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.

Message	Description
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.
LOW SPO_2 SIGNAL STRENGTH SPO_2 INTERFERENCE SPO_2 INTERFERENCE FROM LIGHT SPO_2 LOW SIGNAL IQ	SpO_2 module detects signal strength or interference problems with the SpO_2 sensor
DEFECTIVE SPO_2 SENSOR UNRECOGNIZED SPO_2 SENSOR	SpO_2 module detects an unrecognized or defective sensor

Silent Advisories

Table 15 - 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.
DATA TRANSFER IN PROCESS	Data communication in progress.
REPORT TRANSFER COMPLETE	Data communication is complete.
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.

Non-Message Area Advisories

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

Table 16 - 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 can be changed for Urgent and Caution alarms on the Alarm Limits screen. The Alarm Limits screen is accessed from the Home Screen, Graphical Trend screen or Tabular Trend 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.

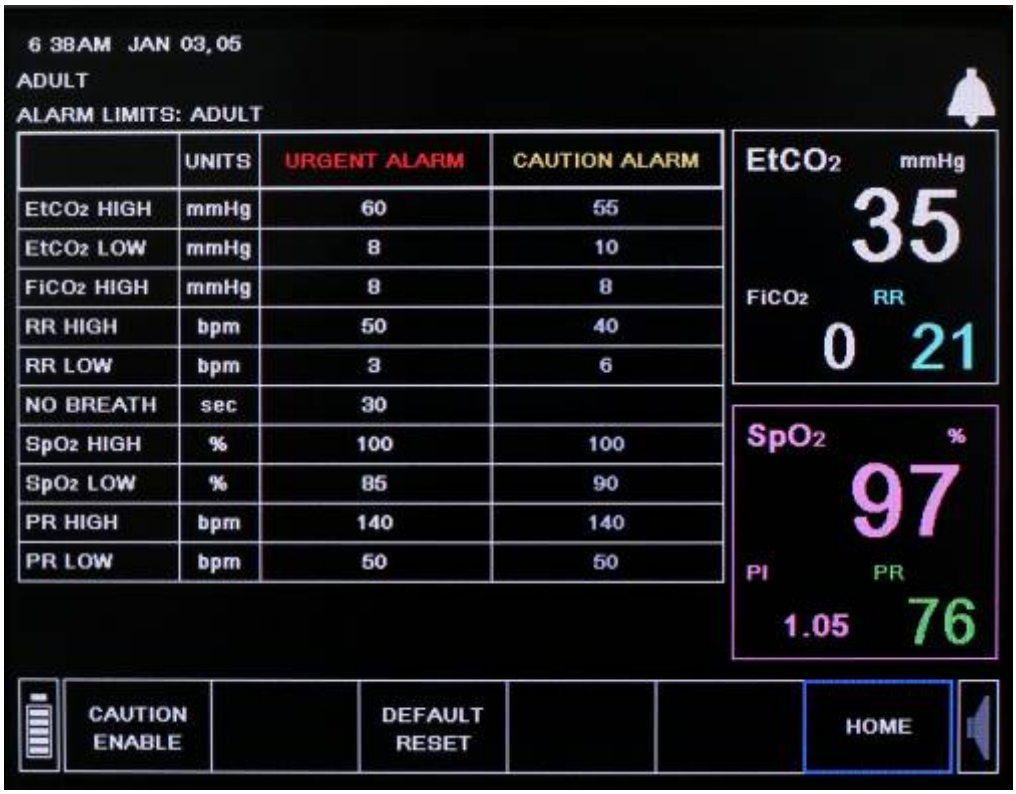


Figure 21 - Alarm Limits Screen

➢ 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 screen, from the Home screen, Graphical Trend screen or Tabular Trend 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.

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 96).

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.

Alarm Limits - Factory Defaults

The factory defaults for the Adult and Neonatal alarm limits are given in Table 28 - Factory Default Alarm Limits on page 98.

Caution Alarms are disabled by default.

Chapter 8

Using Trends

Introduction

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
- High priority patient alarms (only red urgent alarms)
- 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

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 96).

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 10 Downloading Patient Data on page 75.

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, 6 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 22 - Graphical Trend Display, below, is shown.

Figure 22 - 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 lower graphs show the patient's historic trend pulse oximetry data: SpO_2 data in pink and pulse rate values in green.

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, 6 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 22 - Graphical Trend Display on page 60.

- 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 and PR 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 seen on page 63.
- 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 63.

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 63 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 23 - 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, 6 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 22 - Graphical Trend Display on page 60. 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, 6 or 2 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 63.

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 24 - 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 96 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 17 - Tabular Display Example

TIME	EtCO2 mmHg	RR bpm	SpO2 %	PR bpm	EVENTS
May 23, 06	38	38	97	66	
3:45:00 PM	34	34	97	62	16*
3:46:30 PM	30	30	98	61	1 ▲ 24*
3:48:00 PM	30	32	99	63	
3:49:30 PM	32	34	98	63	
3:51:00 PM	32	32	98	62	1▲
3:52:30 PM	33	33	97	61	
3:54:00 PM	34	34	97	63	
3:55:30 PM	34	32	97	62	
3:57:00 PM	34	31	98	61	
3:58:30 PM	29	33	97	62	

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 18 - Detailed Tabular Display Example

TIME	EtCO2 mmHg	RR bpm	SpO2 %	PR bpm	EVENTS
May 23, 06	38	85	97	76	
3:45:20 PM	34	88	97	72	OXYGEN
3:45:25 PM	30	90↑	98	71	
3:45:30 PM	30	90↑	99	73	
3:45:35 PM	32	90↑	98	73	
3:45:40 PM	32	91↑	98	72	
3:45:45 PM	33	90↑	97	71	
3:45:50 PM	34	89	97	73	
3:45:55 PM	34	88	97	72	
3:46:00 PM	34	88	98	71	
3:46:05 PM	29	89	97	72	

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).

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 25 - 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 25 - 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 19 - Monitor Parameters

DATE	MAY 25, 2006
TIME	11:27:32 AM
LANGUAGE	ENGLISH
EVENT MARKING MODE	DETAILED
TREND GRAPHICAL DISPLAY [hour]	6 hour
TREND INCREMENT DISPLAY [min]	1.5 min
NURSE CALL	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 96).

Event Marking Mode

- Detailed = 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 38).
- Quick = 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, 6 and 12 hours. The factory default is 6 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 96 for instructions on how to change the recording resolution).

Chapter 9

Printing Reports

Introduction

Capnostream can be purchased with a built-in thermal strip printer. The report printing menu in 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 75). 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 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 is printed as it is 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 26 - 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 26 - 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, and blank are available for selection. For graphical reports, $EtCO_2$, RR, SpO_2, PR, 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 20 - 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) Patient Type (ADULT or NEONATAL) Case ID	

Report Name	Description	Fields Included	Time Frame of Report
		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	From start of case until current time; once case is stopped, data is not available
		Patient Readings: Three of the following five parameters (according to parameters chosen in the PRINT FORMAT screen, see To print a report on page 69): $EtCO_2$, $FiCO_2$, RR, SpO_2, PR	
		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	
		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	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 69) at 30-second intervals: $EtCO_2$ (mmHg), RR (bpm), SpO_2 (%), and PR (bpm)	
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	
		Patient readings at intervals set for trend increment display: Three of the following five parameters (according to parameters chosen in the PRINT FORMAT screen, see To print a report on page 69): $EtCO_2$, $FiCO_2$, RR, SpO_2, PR	
		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	

Report Name	Description	Fields Included	Time Frame of Report
		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 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 69) at interval set for trend increment display: $EtCO_2$, RR, SpO_2, and PR	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 Waveform	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 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 Tabular	Tabular presentation of $EtCO_2$, RR, and PR, with a data line every 2 seconds	Patient Readings at start of recording period: $EtCO_2$, $FiCO_2$, RR, SpO_2 , PR Patient readings at 2-second intervals: $EtCO_2$, RR, and PR	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

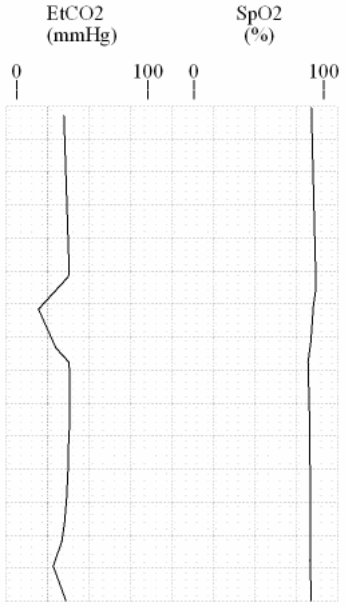
CASE REPORT

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 27 - 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) 39 | RR (bpm) 15

SpO2 (%) 98 | PR (bpm) 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

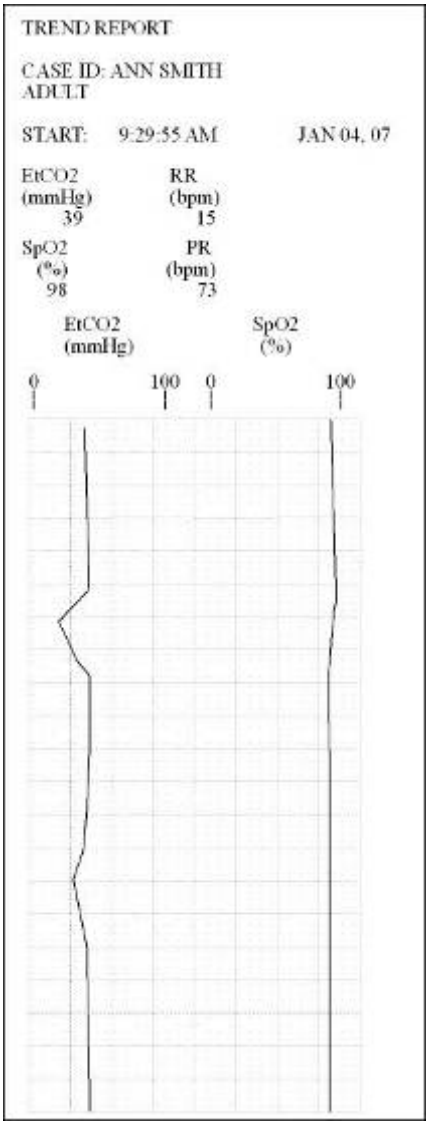


Figure 28 - Printed Trend Reports

Chapter 10

Downloading Patient Data

Introduction

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 six types of reports that can be transferred to a USB flash memory device, as described in the table below. Four 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 21 - Data Transfer Types

Report Name	Description	Fields Included
Tabular Case Report	Comma separated value (.csv) file. 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
		Patient Urgent Alarm Occurrences: EtCO2 HIGH, EtCO2 LOW, RR HIGH, RR LOW, NO BREATH, SpO2 HIGH, SpO2 LOW, PR HIGH, PR LOW
		Equipment Advisory Message Occurrences: CO2 NOT AVAILABLE, SpO2 NOT AVAILABLE, BATTERY LOW
		Events: EVENT 1, EVENT 2, EVENT 3
Tabular Trend Report	Comma separated value (.csv) 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	DATE, TIME
		Patient Readings: $EtCO_2$, RR, SpO_2, PR
		Patient Urgent Alarm Occurrences: EtCO2 HIGH, EtCO2 LOW, RR HIGH, RR LOW, NO BREATH, SpO2 HIGH, SpO2 LOW, PR HIGH, PR LOW

Report Name	Description	Fields Included
	seconds).	Equipment Advisory Message Occurrences: CO2 NOT AVAILABLE, SpO2 NOT AVAILABLE, BATTERY LOW
		Events: EVENT 1, EVENT 2, EVENT 3
Real Time Continuous Waveform	.csv file with data entries every 50 milliseconds.	DATE, TIME
		Patient Readings: $EtCO_2$*, SpO_2**
Real Time Continuous Tabular	.csv 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
		Patient Urgent Alarm Occurrences: EtCO2 HIGH, EtCO2 LOW, RR HIGH, RR LOW, NO BREATH, SpO2 HIGH, SpO2 LOW, PR HIGH, PR LOW
		Equipment Advisory Message Occurrences: CO2 NOT AVAILABLE, SpO2 NOT AVAILABLE, BATTERY LOW
		Events: EVENT 1, EVENT 2, EVENT 3
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)

** The SpO2 waveform (plethysmograph) values provided in the Real Time Continuous Waveform download do not indicate the percentage of oxygen saturation in the patient's blood. These values, which range from 0 – 255, are provided for purposes of building the SpO2 waveform only. Health care practitioners used the shape of the waveform to help analyze patient health. To see SpO2 percentage values for a patient, download data using the Tabular Case, Tabular Trend, or Real Time Continuous Tabular report formats.

Note that in the .csv 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, either ADULT or NEONATAL

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 29 - 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 30 - 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 22 - Select Data Output Type

TABULAR CASE	
TABULAR TREND	
REALTIME CONTINUOUS WAVEFORM	
REALTIME CONTINUOUS TABULAR	
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.

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). 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 23 - 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: 10kB

Tabular Trend: 1 hour @30s resolution: 10kB

Real time Continuous Waveform: 1 hour @50ms resolution: 2.4MB

Real time Continuous Tabular: 1 hour @2s resolution: 150kB

Full Binary Continuous Transfer: 1 hour @50ms resolution: 720kB

Full Binary Trend Transfer: 1 hours @30s resolution: 2.5kB (entire trend memory dump is 175kB)

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 23 - 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 .csv (Comma Separated Value 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 23 - File Naming Conventions

Report type	File name
Tabular Case Report	TCR_PATIENT02-1_060302_203057_1.csv
Tabular Trend Report	TTR_060302_203057_1.csv
Real-time Continuous Waveform	RCW_060302_203057_1.csv
Real-time Continuous Tabular	RCT_060302_203057_1.csv
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.csv RCT_060302_203057_2.csv RCT_060302_203057_3.csv RCT_060302_203057_4.csv ... RCT_060302_203057_10.csv ... RCT_060302_203057_100.csv ... RCT_060302_203057_1000.csv

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 four USB report types that have a .csv (comma separated value) file type are text files. This makes them easy to read in most spreadsheet and database software applications. The .csv format type means that there is a comma 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 96 for information on how to change the data transfer rate.

Note: The RS-232 port has electrical isolation according to IEC 601-1-1. 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.

Using Analog Data Output

Capnostream can output seven analog signals corresponding to various parameters that it monitors. This makes the monitor an ideal tool to provide input to a Polysomnograph in a sleep laboratory.

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.

The analog data output requires the Oridion D/A (Digital/Analog) Data Cable (Part Number 010492). Each data channel shown on the D/A Setup screen on the monitor corresponds to the wire colors of the D/A cable

The channels are color coded to match the insulation covering of corresponding wire pair of the D/A cable.

There are 12 different settings available for the data channel outputs. The current settings and the available options are shown when you enter the Digital to Analog setup screen as shown below in Figure 31 - Digital to Analog Setup Screen on page 81.

➢ TO SET UP D/A DATA OUTPUT:

1. From the 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 (seen in Figure 31 - Digital to Analog Setup Screen on page 81). 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 pressing the control knob when that channel is highlighted. Then turn the control knob to select the signal to be assigned to that channel. Press the control knob 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. If you want these settings to be permanently stored in the monitor, you must make these changes in the Institutional Defaults screen while in Service mode. See Appendix 1: Institutional Settings on page 96.

Using Capnostream with a Polysomnograph

➢ TO RECORD DATA FROM CAPNOSTREAM TO A POLYSOMNOGRAPH:

1. Calibrate the signal output with your data collection equipment before using the analog output of the monitor for data collection.
2. Turn on the Capnostream monitor.
3. Insert the Digital-to-Analog cable in the 15-pin output socket on the back of the monitor.
4. From the Home screen, select *SYSTEM* from the menu bar and then select *D/A SETUP* from the menu bar.

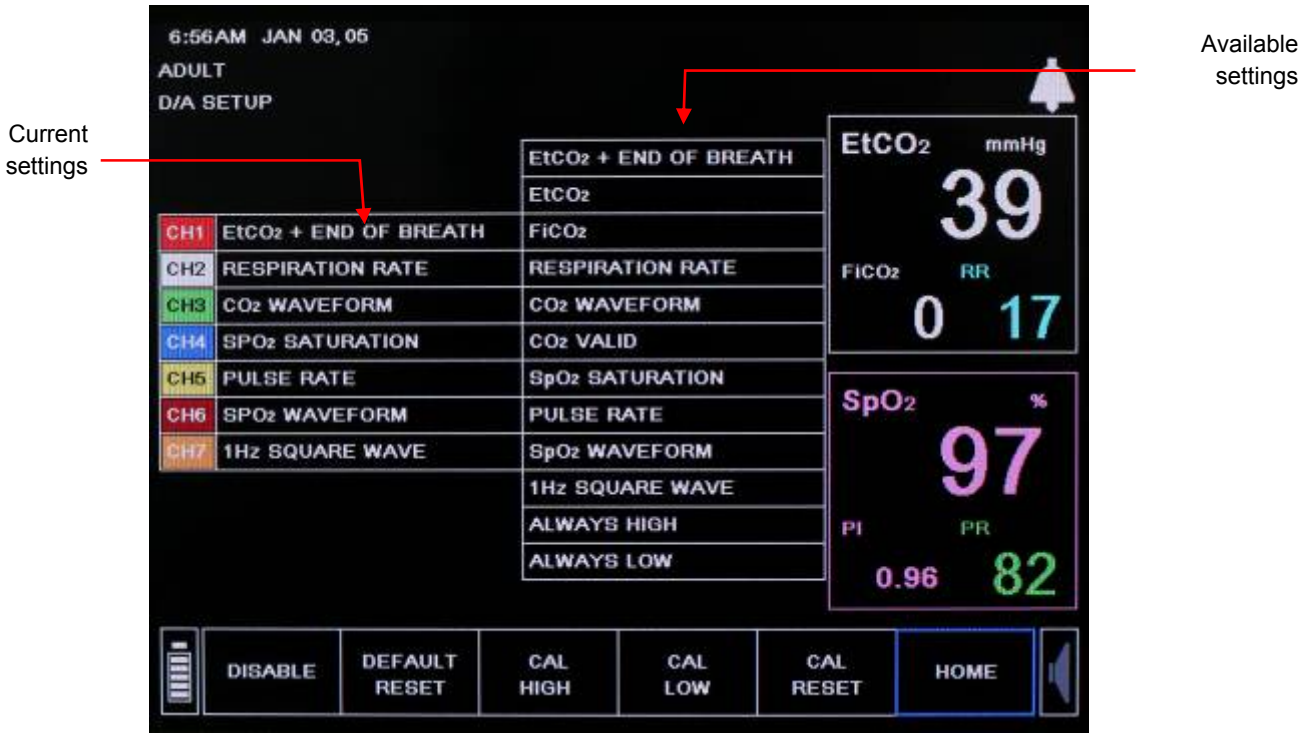


Figure 31 - Digital to Analog Setup Screen

5. For zero calibration, use the control knob to select the *CAL LOW* setting. All channels will be set to *ALWAYS LOW*. Connect each channel cable to your lab equipment to confirm the output is zero.

   For gain calibration, use the control knob to select the *CAL HIGH* setting. All channels will be set to *ALWAYS HIGH*. Connect each channel cable to your lab equipment to confirm the output is 1 volt, corresponding to the highest output of the channel.

6. Use the control knob to select *CAL RESET*. All channels will be reset to their original settings.

Digital/Analog Signal Values

The following table gives the equivalent value that corresponds to the maximum voltage reading for each analog output data channel.

Table 24 - D/A Signal Values

Parameter	Scale
$EtCO_2$ + End of breath indication ($EtCO_2$ value when the end of breath is signaled, 0V otherwise)	100 mmHg = 0.9 V
$EtCO_2$	100 mmHg = 0.9 V
$FiCO_2$	100 mmHg = 0.9 V
RR	150 BPM = 0.9 V
CO_2 Wave	100 mmHg = 0.9 V
CO_2 Measurement Valid	0 V=yes; 1 V = no
SpO_2 Saturation	100 % Sat = 0.9 V
Pulse Rate	250 BPM = 0.9 V

SpO_2 Wave (pleth waveform)	255Pleth = 0.9 V
Square wave at 1 Hz, 50% duty cycle	0 V – 1 V p-p
No signal (always high)	1 V
No signal (always low)	0 V

D/A Cable Color Coding

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

Table 25 - D/A Cable color codes

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

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 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 26 - 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 32 - Stereo Phono Plug for Nurse Call

A diagram of pin-out of mating stereo phono plug appears in Figure 32 - 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 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 33 - 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 96 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.

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 27 - Nurse Call Indicators

Alarm Type	Activates Nurse Call
High Priority (Red) Urgent Patient Alarms	YES
High Priority (Yellow) 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 11

Maintenance and Troubleshooting

Introduction

The monitor 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 87. CO_2 calibration can be checked at any time to ensure the calibration is within proper operating limits.

Troubleshooting on page 91 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.

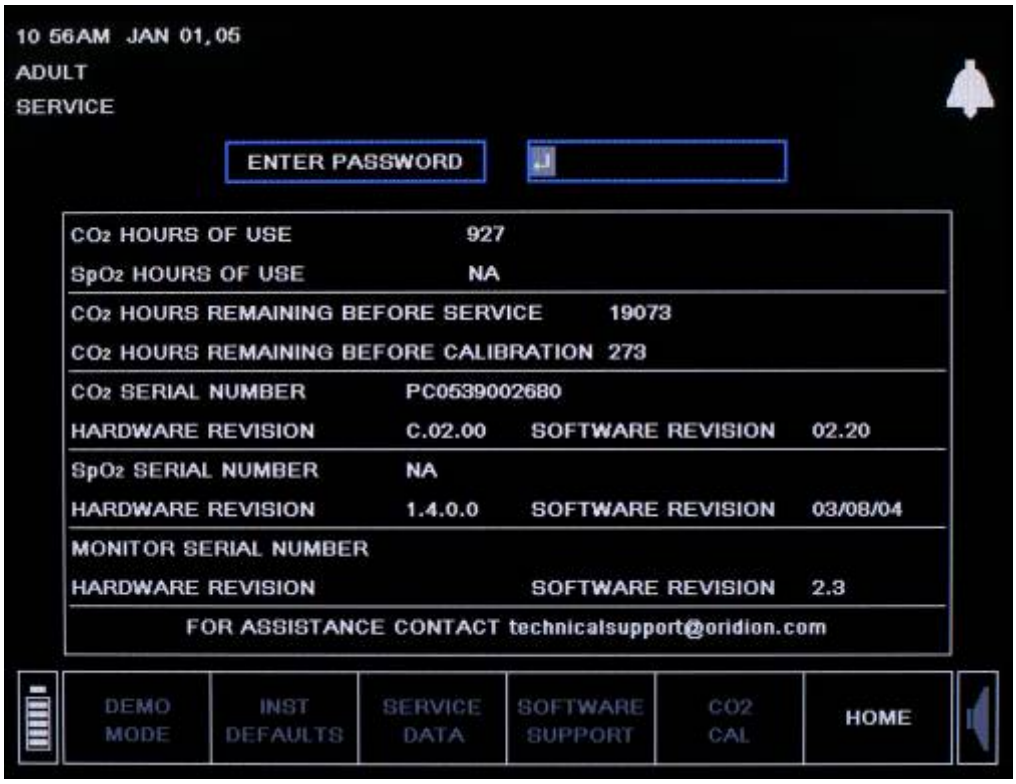


Figure 34 - Service Screen

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 28). 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 91 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 87).
- 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 107.

➢ 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 35 - 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 19)
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

Problem	Cause	Action
		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 kinked.	Check the FilterLine from the 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 88.
	BTPS setting turned off.	Check BTPS setting in the institutional settings. See CO2 Parameters on page 101 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.
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® EtCO2 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 www.oridion.com.

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

Appendix 1

Institutional Settings

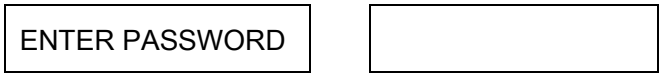
Institutional Defaults

Capnostream is shipped from the factory with all changeable settings configured according to the tables in the section Changing Monitor Settings on page 97. 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 31, 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.

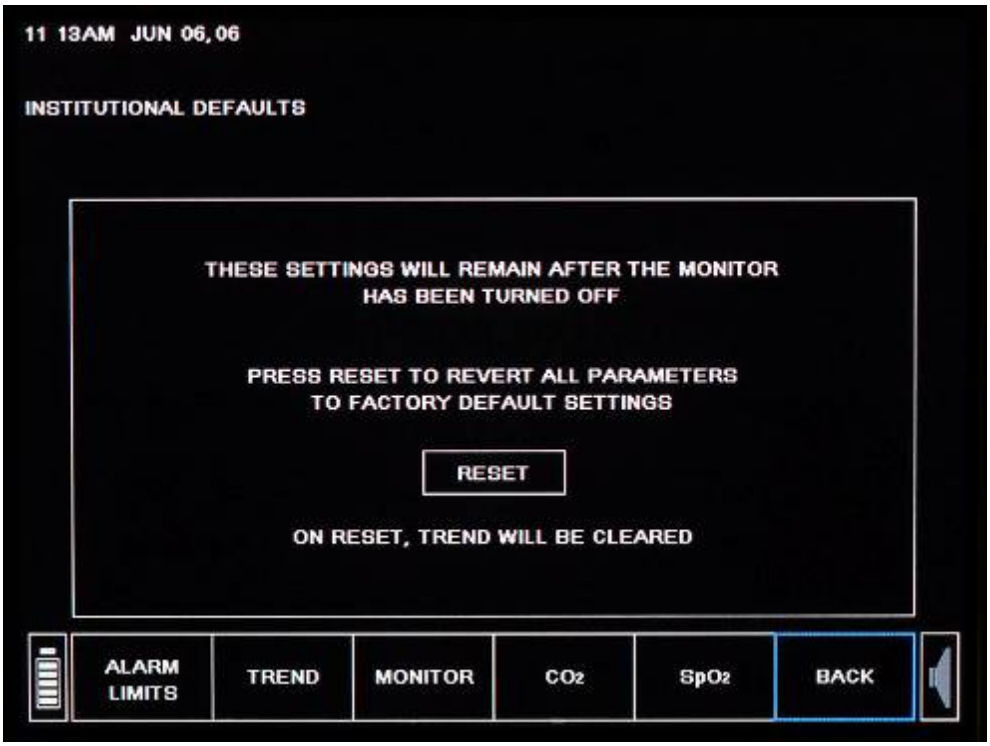


Figure 36 - Institutional Defaults Screen

Changing Monitor Settings

Alarm Limits

There are two sets of alarm limits that are stored in the monitor, for Adult and for Neonatal patient types. The factory default settings for Adult and Neonatal alarm limits are given above in Table 28 - Factory Default Alarm Limits on page 98.

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 *NEONATAL* or *ADULT* as the default patient type. You will then be presented with the Institutional Defaults: Alarm Limits: Adult or Neonatal screen.

Change the settings as described in the section Changing Alarm Limits on page 57.

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.

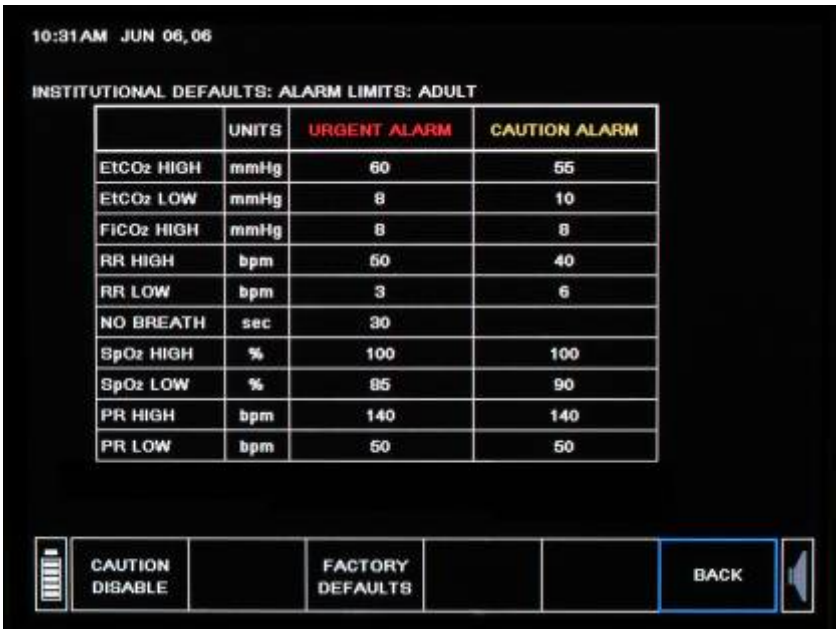


Figure 37 - Institutional Defaults Alarm Limits Screen

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

Table 28 - Factory Default Alarm Limits

Parameter	Adult Red Urgent	Adult Yellow Caution	Neonatal Red Urgent	Neonatal Yellow Caution	Alarm Range
$EtCO_2$ High	60	55	60	55	5-99 mmHg
$EtCO_2$ Low	8	10	8	10	0-94 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	90-100% saturation
SpO_2 Low	85	90	85	90	85-95% saturation
Pulse Rate High	140	140	200	200	30-240 bpm
Pulse Rate Low	50	50	100	100	25-235 bpm

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 29 - Factory Default and Optional Trend Settings

Parameter	Choices	Factory Default
Trend Recording Resolution	5 seconds at 12 hours 10 seconds at 24 hours 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, 6 or 12 hours	6 hours

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. Chose 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 38 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 38 - 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 mmm dd, yy	mmm dd, yy
Time Format	12 or 24 hour	12 hour
Language	English, Spanish, French, German. Additional languages may be available in later software versions.	English
Audio Alarm Silence	ENABLED/DISABLED	DISABLED
Event Marking Mode	Quick/Detailed	DETAILED
RS-232 Baud Rate	AUTO 9600 19.2K 57.6K 115.2K	AUTO
Nurse Call	ENABLED/DISABLED	DISABLED

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, Auto	Auto
$EtCO_2$ Scale for Trend Display	50, 100	50
RR Scale for Trend Display	50, 100, 150	50
Sweep Speed Adult (mm/sec)	3, 6.3, 12.5, 25	6.3
Sweep Speed Neonatal (mm/sec)	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.

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
SpO_2 Sensitivity	Normal, Maximum, APOD	Maximum
Averaging Time (sec)	2-4, 4-6, 8, 10, 12, 14, 16	8
SpO_2 Scale for Trend Display	0-100, 50-100	50-100
PR Scale for Trend Display	150, 300	150
Sweep Speed Adult (mm/sec)	3, 6.3, 12.5, 25	25
Sweep Speed 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 Digital/Analog Signal Values on page 81.

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
	4 specific function keys
	1 optical encoder with switch
Back Panel	1 Mains ON/OFF Switch

Display

Item	Value
Screen	162mm (6.4in) Color TFT Display
	Pixel Pitch: 0.204 (H) x 0.204(V) mm (0.008in)
	Active Display Area: 130.56 (H) x 97.92 (V) mm (5.14in x 3.86in)
	Resolution 640 x 480 pixels
	Viewing angle (vertical) 110°
	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)
	20 samples/sec for Capnography (fixed)
Trend Storage	8640 point storage
	- 12h at 5s resolution
	- 24h at 10s resolution
	- 72h at 30s resolution
Trend Display	Graphical Display:
	- 2h, 6h, 12h views
	Tabular Display
	- 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	0-99 mmHg
CO_2 Waveform Resolution	0.1 mmHg
$EtCO_2$, $FiCO_2$ Resolution	1 mmHg
CO_2 Accuracy	0-38 mmHg: ± 2 mmHg
	39-99 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
	71-120 bpm: ±2 bpm
	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

Masimo Pulse Oximetry

Item	Value
SpO_2 Measurement Range	1-100%
SpO_2 Accuracy	
Adult Mode	
SpO_2 range 70% - 100%	± 2 digits
SpO_2 range 0 - 69%	Unspecified
Neonate Mode	
SpO_2 range 70% - 100%	± 3 digits
SpO_2 range 0 - 69%	Unspecified
Pulse Rate Range	25-240 bpm
Pulse Rate Accuracy During No Motion Conditions	± 3 digits
Pulse Rate Accuracy During Motion Conditions	± 5 digits
Perfusion Index range	0.02% - 20%
Alarms	Adjustable Alarm Limits
	SpO_2 high, SpO_2 low, Pulse Rate high, Pulse Rate low

Alarms

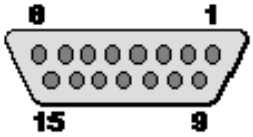
Item	Value
High Priority Patient Warning Alarms	Flashing Red LED Flashing Red Numeric High Priority Alarm beep pattern Alarm Indication on Screen Nurse Call
Patient Caution Alarms	Flashing Yellow LED Flashing Yellow Numeric
Low Priority Alarm	Lit Yellow LED Beep once every minute Alarm Indication on Screen Nurse Call
Advisories	Beep once 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

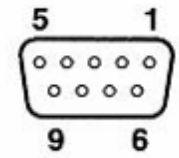
N1 - N2: Normally Closed relay

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) (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)

Item	Value
Operating Pressure and Altitude	Pressure: 430 mmHg to 795 mmHg
	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) Up to upper limit of 70°C (158°F)
Storage & Transport Pressure and Altitude	Pressure: 430 mmHg to 795 mmHg
	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)
	(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