Capnostream®20_p Portable Bedside Monitor Capnograph/Pulse Oximeter

Operator's Manual

PN: 012194C



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Safety Information

Warnings Definitions

To use the Capnostream $^{\$}20_{P}$ monitor (henceforth referred to as Capnostream) correctly and safely, carefully read this operator's manual and the *Directions for Use* that accompany Microstream $^{\$}$ etCO₂ consumables (FilterLines $^{\$}$, henceforth referred to as FilterLines) and the SpO₂ 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:	The monitor should not be used adjacent to or stacked with other equipment; if adjacent or stacked use is necessary, the monitor shall be observed to verify normal operation in the configuration in which it will be used.
WARNING:	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:	Re-use of single-use accessories could pose a cross-contamination risk to the patient or damage the functioning of the monitor.
WARNING:	CO ₂ readings, respiratory rate, pulse oximetry readings, and pulse signals can be affected by sensor application errors, certain ambient environmental conditions, and certain patient conditions.
WARNING:	The monitor is a prescription device and is to be operated by qualified healthcare personnel

WARNING:

only.

No modification of this equipment is allowed.

WARNING: If calibration does not take place as instructed in the relevant service manual, the monitor

may be out of calibration. A monitor that is out of calibration may provide inaccurate

results.

Note: Devices connected to the monitor must be medical grade only.

Note: The accurate display of the following parameters is required in order to fill the essential performance of

the device: Carbon dioxide levels in expired breath (CO₂) and respiration rate when monitoring with capnography, and arterial oxygen saturation of blood (SpO₂) and Pulse rate when monitoring with pulse oximetry. If the patient is being monitored with both functions, all of these parameters will be displayed.

MRI Scanning

WARNING: Do not use oximetry sensors during magnetic resonance imaging (MRI) scanning.

Conducted current could cause burns. The sensors may affect the MRI image, and the MRI

unit may affect the accuracy of oximetry measurements.

WARNING: Do not use the FilterLine H Set Infant/Neonatal 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, etCO₂ monitoring can be implemented using the FilterLine

XL. (Refer to Monitoring CO2 during MRI Scanning on page 56.

CAUTION: Use of a CO₂ sampling line with H in its name (indicating that it is for use in humidified

environments) during MRI scanning may cause interference. The use of non-H sampling lines is advised. For a list of H sampling lines, see Microstream EtCO2 Consumables on

page 137.

Monitor Use with Defibrillators

WARNING: All cables and tubing, including SpO₂ sensors and CO₂ sampling lines, should be kept clear

of the defibrillator and its electrodes, and should not run between, adjacent to, or

overlapping the electrodes and the electrode wires, in order to reduce potential interference

between the monitor and defibrillation equipment.

WARNING: All SpO₂ sensors must be completely intact and undamaged, in order to enable use of a

defibrillator with the monitor.

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.

WARNING: Auditory alarm signal sound pressure levels which are less than ambient sound levels can

impede operator recognition of alarm conditions.

CAUTION: Setting alarm limits to extreme values may impair the alarm system's effectiveness.

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. To avoid the risk of electric shock, this equipment

must only be connected to a supply mains with protective earth.

WARNING: Ensure that the monitor is positioned so that its mains plug is accessible for immediate

disconnection from supply mains, when needed.

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.

WARNING: To avoid risk of electric shock, this equipment must only be connected to a supply mains

with protective grounding.

WARNING: Whenever the equipotential ground at the back of the device (reference Figure 7 -

Capnostream Rear View on page 29) is to be used, the user must connect to the pin in a way

which will ensure that accidental disconnection is avoided.

WARNING: In a facility which provides detachable potential equalization conductors, the Equipotential

ground at the back of the device (reference Figure 7 - Capnostream Rear View on page 29)

may be used for optional connection between the Capnostream and the potential

equalization busbar of the electrical installation. The Equipotential ground at the back of the

device should not be used for a protective earth connection.

WARNING: Always connect power cord to the device first, and then plug the power cord into the wall

outlet.

CAUTION: Electrical installation of the room or the building in which the monitor is to be used must

comply with regulations specified by the country in which the equipment is to be used.

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

required.

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. 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
Intended Use
Specific Indications for Use
Who Should Read This Manual
Contacting Technical Support
Symbols

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 (etCO₂) level of carbon dioxide in exhaled breath.
- Respiratory rate (RR).
- Fractional inspired carbon dioxide (FiCO₂) level of carbon dioxide present during inhalation.
- Oxygen saturation (SpO₂).
- Pulse rate (PR).

The device also provides an Integrated Pulmonary IndexTM (henceforth referred to as IPI) value, which is a numerical value that integrates four major parameters measured by Capnostream in order to provide a simple indication of the patient's ventilatory status. The integrated parameters are etCO₂, RR, SpO₂, and PR. Only these four parameters are used to calculate IPI; other parameters are not taken into account.

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

- A/hr: a count of the number of pauses in breathing (of at least 10 seconds) which the patient experienced, either over the past hour (on the Home screen) or average pauses per hour over a period of time (on the Apnea and O₂ Desaturation screen).
- ODI: the number of times that the SpO₂ value dropped 4% or more from baseline and returned to baseline in 240 seconds or less, either in the last hour (on the Home screen) or average pauses per hour over a period of time (on the Apnea and O₂ Desaturation screen).

The A/hr and ODI indices are not available in all locations. In order to equip your device with the A/hr and ODI feature, contact Capnographyinfo@covidien.com.

Intended Use

The Capnostream $^{\oplus}20_p$ combined capnograph/pulse oximeter monitor and its accessories are intended to provide professionally trained health care providers with continuous, non-invasive measurement and monitoring of carbon dioxide concentration of the expired and inspired breath and respiration rate, and with continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate. It is intended for use with neonatal, pediatric, and adult patients in hospitals, hospital-type facilities, and intra-hospital transport environments.

Capnostream[®] 20p is to be operated by qualified healthcare personnel only.

The Capnostream [®]20_p monitor provides the clinician with an integrated pulmonary index (IPI). The IPI is based on four parameters provided by the monitor: end tidal carbon dioxide, respiration rate, oxygen saturation and pulse rate. The IPI is a single index of an adult or pediatric patient's ventilatory status displayed on a scale of 1 - 10, where 10 indicates optimal pulmonary status. IPI monitoring displays a single value that represents the patient's pulmonary parameters and alerts clinicians to changes in the patient's pulmonary status.

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

Specific Indications for Use

An additional indication of the monitor is to provide information to help in the identification of apnea and oxygen desaturation events in adult patients (age 22 and up) in hospital ICU and general floor environments, through the reporting of these events and calculation of the associated apnea per hour (A/hr) and oxygen desaturation index (ODI).

Who Should Read This Manual

This manual should be read by:

- Health Care Professionals who will be using Capnostream.
- Equipment managers responsible for ensuring that equipment conforms to institutional policies.
- Researchers or laboratory personnel who will be downloading patient data.
- Technical experts who will be connecting Capnostream to a computer via the RS-232 interface.

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

Contacting Technical Support

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

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

Symbols

The following symbols appear on the body of the monitor.

Symbol	Description
%	Monitor ON/OFF button
~	AC power ON indicator
·	UNIT ON indicator
	Event selection
₩₽	Patient Admit/Discharge

Table 1 - Symbols that Appear on the Monitor

Symbol	Description
\bigcup_{co_z}	Pump Off
Ø	Temporarily silence alarms
⊣★⊦	Type BF Defibrillator Proof Protection
<u> </u>	General warning sign
4	Gas inlet
	Gas outlet
\$	Equipotential ground
•<	USB flash memory connection port
C 0482	CE Mark
$R_{\!$	For prescription use only
X	Directive on waste electrical and electronic equipment
Follow instructions for use	Follow instructions for use



Technology Overview

Introduction
Features
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 etCO₂ consumables, and pulse oximetry technology, Capnostream allows for simultaneous "hassle free" etCO₂ and SpO₂ monitoring.

Features

- Dual parameter monitor that supports the current standard of care providing CO₂ and SpO₂ measurements
- Integrated Pulmonary IndexTM (IPI), which provides a simple, clear, and comprehensive indication of a
 patient's ventilatory status and trends
- Apneas per Hour and Oxygen Desaturation Index, indices used to help in the identification and quantification of apnea and oxygen desaturation events (if available)
- Simple user interface with color screen
- Routine functions are accessed with 2 clicks
- 72 hour trends to review patient history
- One-click alarm review
- SARATM (Smart Alarm for Respiratory Analysis), an embedded Smart Capnography alarm management technology, which reduces clinically insignificant alarms
- Event marking to compare events and medication administration to changes in patient status
- Case recording to help organize patient files
- Nurse call
- Optional internal printer
- USB output to transfer patient data to USB flash memory devices
- Analog output for use in sleep labs and other laboratory environments
- RS-232 port for data transfer

Technology Overview

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

What is Capnography?

Capnography is a non-invasive method for monitoring the level of carbon dioxide in exhaled breath (etCO₂) 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 (et CO_2), the amount of CO_2 present during inhalation (Fi CO_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 $^{\otimes}$ etCO₂ 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 CO₂ measurement. Moisture and patient secretions are extracted from the sample, while maintaining the shape of the CO₂ 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 CO₂ 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 (SpO₂) 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 SpO₂ 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.

The Capnostream Monitor

Unpacking and Inspection

Installing the Battery Pack

Mounting the Monitor

Setting up Periodic Maintenance

Accessories

Buttons, Indicators and Connections

Front Panel Control Buttons

Turning on the Monitor

Standard Sections of the Display Screen

Home Screen Numeric Display

Terminating Operation of the Monitor

Screen Navigation

Setting Date, Time, Language, and Other Options

Screen Timeouts

Capnostream[®]20p: Operational Check Sheet

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

The Capnostream $^{8}20_{p}$ 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
 - SpO₂ Sensor Pack
 - SpO₂ 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.

Note:

When unpacking the monitor, packaging waste shall be disposed of as according to local regulations for the disposal of packaging waste.

Installing the Battery Pack

WARNING:

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

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

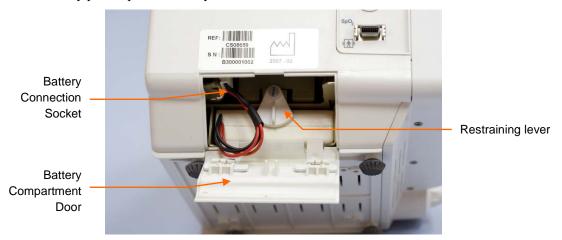


Figure 1 - Installing the Battery Pack

➤ TO INSTALL THE BATTERY PACK:

- 1. Slide the two release latches on the battery compartment door inward and open the 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. Attach the battery connector into the battery connection socket, ensuring that the side with the protruding grooves is on the right, so that the connector fits into the socket. Push the wires back into the monitor.



Figure 2 - Battery Pack Close-up

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

Ensure that the battery pack is fully charged before using the monitor without AC power. A fully charged battery pack provides 2.5 hours of operation (without printer usage). When the monitor is connected to the AC mains, the battery pack charges automatically. It takes approximately 12 hours to fully charge an empty battery pack.

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

If no battery pack is installed during monitor setup, the No Battery icon will appear on the screen and the advisory message *NO BATTERY INSTALLED* will appear.

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.

WARNING: To replace the battery, first turn off the monitor and then unplug the unit from AC power.

Do not attempt to disconnect or connect a battery while the unit is turned on or connected to

AC power.

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.

Battery Charge Level Indicator



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. The orange AC power indicator

on the front panel of the monitor \sim will light up.

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

Handling the Battery Pack

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

CAUTION: Recharge the battery pack only in the monitor to avoid possible heating, burning or rupture

of the battery pack.

Storing the Battery

The battery pack must be stored in a cold, dry area, not inside the monitor. Its charge decreases over time. To restore the battery pack to full power, recharge the battery before use. The battery should be fully recharged every 3 months at minimum. Store at -20 to 25°C.

CAUTION:

Storage or transport of the monitor under environmental conditions beyond those mentioned in the specification will affect monitor performance and damage the battery and/or 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 duration of this backup power usage, based onbattery capacity, is up to 2.5 hours. The monitor maintains its settings, including alarm settings, while on battery operation. If settings have been set in Institutional Defaults, these settings will remain in the monitor memory even if the monitor is not receiving power at all, and will be available once the monitor is turned on again. Likewise, trend data in the device will remain in the monitor memory even if the monitor is not receiving power at all, and will be available once the monitor is turned on again.

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.

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 (equivalent to 14.0 V) remains.

Mounting the Monitor

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

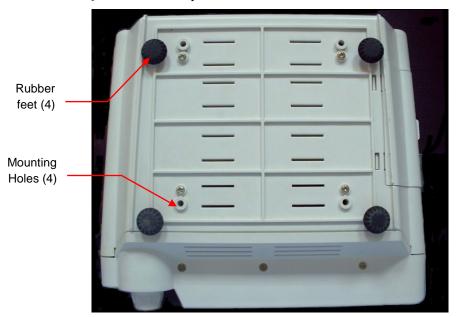


Figure 4 - Monitor Bottom View

CAUTION:

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

Setting up Periodic Maintenance

If your institution has a periodic maintenance database, log the monitor in this database for its periodic calibration procedure. Calibration is required after the first 1,200 hours of use (or 12 months, whichever comes first) and thereafter every 4,000 hours of use (or 12 months, whichever comes first). The number of operating hours will appear just after the monitor turns on and on the monitor's Service Screen. For more details about calibration and other maintenance procedures, see Maintenance and Troubleshooting on page 111.

Accessories

Available Accessories

See the list of available accessories for Capnostream below.

Oridion Part Number Accessory 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 115 for paper installation. Mounting Adaptor Plate 010713 Used for mounting Capnostream to GCX roll stands and other mounting assemblies. Refer (Vesa) to Mounting the Monitor on page 25 for

Table 2 - Capnostream Accessories

Accessory	Oridion Part Number	Use
		mounting instructions.
Quick Release Pole Clamp	011782	Clamp fits pole mount (pole diameter 0.75in [19mm] to 1.5in [38mm]) or rail mount (rail size 10mm [0.39in] x 25mm [0.98in]).
		With quick release mechanism.
		Mounting adapter plate is included.
Roll Stand with Basket	Not stocked by Oridion	GCX model RS-0006-64D 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.
Mounting Adapter for Bernoulli Transmitter	011892	Used with a Bernoulli/Oxinet hospital system. Refer to Operation with Hospital Patient Data Systems on page 110.
Battery Pack	016400	Refer to Installing the Battery Pack on page 22 for battery installation.
Nurse Call Cable	011149	Cable length 3.5 meters: Cable is supplied unterminated so it can be built to fit system. Refer to Nurse Call Operation on page 107 for set up instructions.
US Power Cord	014256	
European Power Cord	014255	

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-0006-64D Roll Stand Assembly. Please contact GCX (www.gcx.com) for more information on their available solutions for mounting the monitor.

Please note that when mounting the monitor on a roll stand or other pole mount, it is important to use a stand that has a minimum 21 inch (53.5 cm) wheel base diameter, to ensure stability.

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.

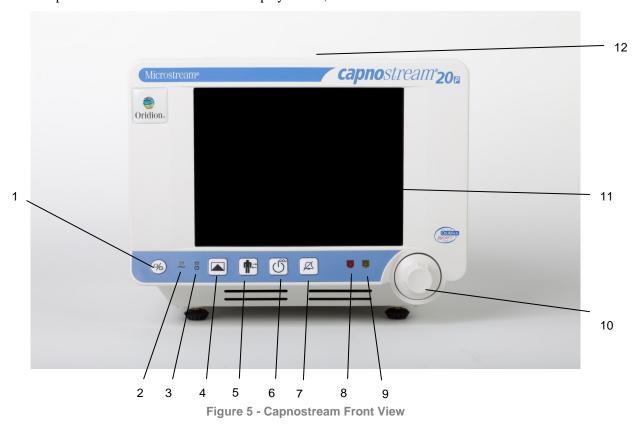


Table 4 - Capnostream Front View lists the numbered labels.

Table 4 - Capnostream Front View

Label	Name	Description	Label	Name	Description
1	Monitor power ON/OFF	Button switch	7	Temporary alarm silence button	Temporarily disables the Audio Alarm for two minutes.
2	AC power indicator	Orange light	8	Red alarm indicator	Indicator that flashes during High Priority alarms (see High Priority Alarms on page 73).
3	Monitor power on indicator	Green light	9	Yellow alarm indicator	Indicator that lights or flashes according to the alarm status (see Alarm Display on page 70).
4	Event button	Starts the process of placing either a Quick or Detailed Event marker in the trend data.	10	Control knob	Rotary knob used to navigate the screen and select a function when pressed.
5	Patient Admit/Discharge button	Allows Starting and Stopping a case and entering patient ID.	11	Display screen	Screen displaying the patient data, menu bar, patient mode, date-time, and any information or error messages.
6	Pump Off button	Shuts off the Capnography pump for a preset time in order to protect the monitor during suctioning procedures.	12	Carrying handle	Allows the monitor to be carried.

Front Panel Control Buttons

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

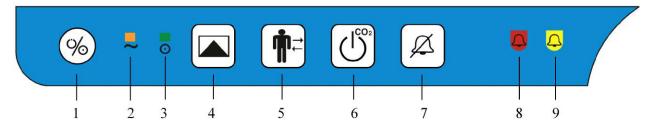


Figure 6 - Front Panel Control Buttons

Monitor Rear Panel

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

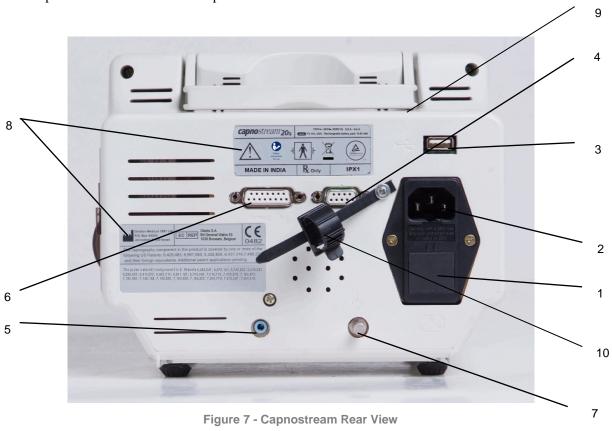


Table 5 - Capnostream Rear View describes the functions of the rear-monitor connections.

Table 5 - Capnostream Rear View

Label	Function	Description	Label	Function	Description
1	Mains fuse holder	Two 3.15A fast blow fuses.	6	Analog output	15 pin female D type connector for 7 channel analog output.
2	Mains plug	Connection for AC power.	7	Potential equalization terminal	For connecting potential equialization conductor.
3	USB port	For flash memory stick.	8	Manufacturer labels	
4	RS-232	9 pin female D type connector for RS-232 communication.	9	Carrying handle	
5	Nurse Call	Port used for attaching to Nurse Call system.	10	Power Cord Strain Relief	

Monitor Left and Right Views

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



Figure 8 - Capnostream Left View

Table 6 describes the functions of the features on the left side of the monitor.

Function Label 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 SpO₂ To connect SpO₂ sensor to the monitor with an extension cable. 4 Battery housing Where the battery pack is installed. 5 Barcode of the Serial Number and Model Number Barcode label of monitor.

Table 6 - Capnostream Left View

The right side of the monitor includes only the paper roll used for printing patient reports and buttons used to control that printer. This printer roll holder is seen in Figure 45 - Insert Paper Roll into printer on page 115, and instructions for replacing the printer roll appear in Replacing the Printer Paper Roll on page 115.

Turning on the Monitor

This section explains how to turn on the monitor.

CAUTION: The monitor is intended only as an adjunct in patient assessment. It must be used in

conjunction with clinical signs and symptoms.

CAUTION: Use only Microstream[®] etCO₂ consumables and Nellcor sensors, to ensure that the monitor

functions properly.

> TO TURN ON THE MONITOR:

- 1. Plug the electrical cord into the mains plug in the rear of the monitor (see Figure 7 Capnostream Rear View on page 29). Clip the power cord strain relief around the cable and tighten to ensure that the power cord does not accidentally disconnect from the monitor.
- 2. Plug the electrical cord into the mains AC supply.
- 3. 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 60 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.

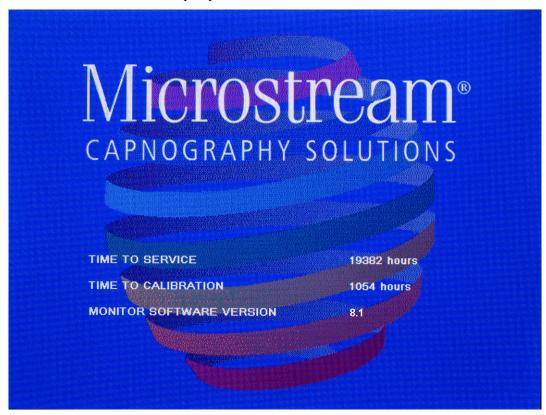


Figure 9 - Salutation Screen

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 <u>Using Patient Cases and Patient ID</u> on page 44. Following that screen, the Home screen will appear.

The Home screen displays the CO₂ and SpO₂ information along with the IPI value and other information that is standard on most other screens. This section explains the main parts of the screen.

The Home screen can display in one of two basic formats: graphical and numeric. The default display is the standard display, described below. The numeric format provides a larger and easier-to-read numeric display without the distraction of the graphical waveform display. To learn about the numeric display, read Home Screen Numeric Display on page 36.

Home Screen Standard Display

The typical standard home screen shown in the two figures below shows data and waveforms for a patient being monitored with a FilterLine and SpO₂ sensor.

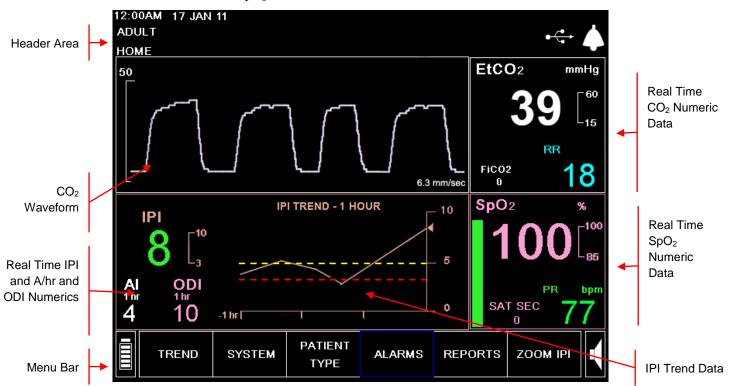


Figure 10 - Typical Home Screen

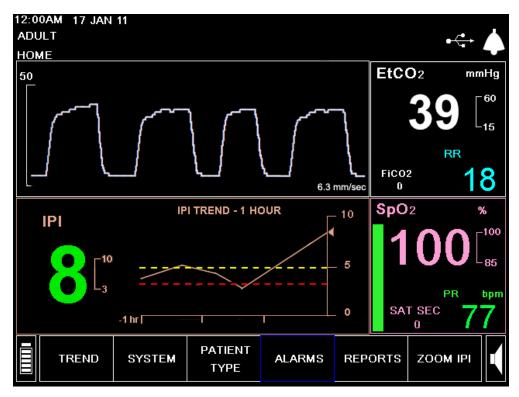


Figure 11 - Typical Home Screen when A/hr and ODI are not Available

The Home Screens contains the following sections:

- Header Area described on page 34
- Menu Bar described on page 35
- Real Time IPI Data with Trend Graphical Display described on page 37
- A/hr and ODI Data described on page 35 (if available)
- Real Time CO2 Data and CO₂ waveform, described on page 35
- Real Time SpO2 Data described on page 35

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

In most cases, as you move from screen to screen, the monitor will always display the Header, Menu Bar, real time CO₂ Numeric Data and real time SpO₂ Numeric Data sections. The continuous display of the real time CO₂ and SpO₂ Numeric Data on the right allows continuous patient monitoring even when changing system settings, or observing patient history on the trend screens.

The IPI option on the screen may be disabled as part of the institutional defaults. (If the Patient Type is Infant/Neonatal, the IPI is automatically disabled, and the only available option for the standard Home screen display shows the SpO₂ waveform instead of the IPI trend waveform.) See Chapter 7 Integrated Pulmonary IndexTM on page 63 for more information. If the IPI option is disabled, a home screen without the IPI option will be seen. An example of this Home screen is seen in Figure 12 - Standard Home Screen without IPI Option on page 34.

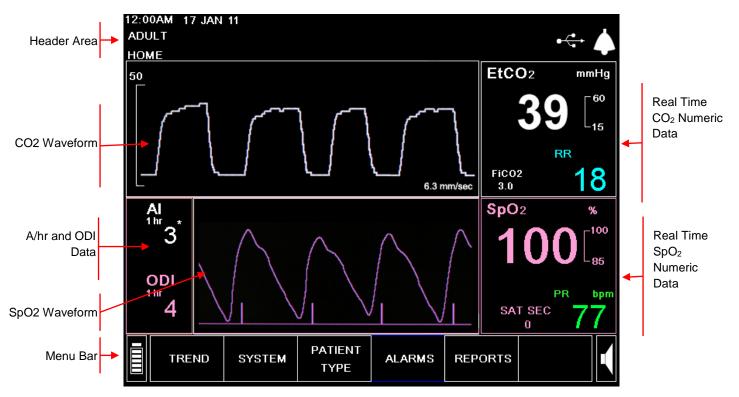


Figure 12 - Standard Home Screen without IPI Option

Header Area

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



Table 7 describes the elements of the header area.

Table 7 - Header Section

ltem	Function	Description
1	Time/Date	Displays the Time and Date in selected formats.
2	Patient Type	Indicates patient mode. Options are ADULT, PEDIATRIC 1-3 YRS, PEDIATRIC 3-6 YRS, PEDIATRIC 6-12 YRS, and INFANT/NEONATAL (for infants under 1 year)
3	Screen name	Displays the current screen name.
4	Message area	Messages explaining alarms and equipment status appear in this area.
5	Patient ID	If a patient ID has been entered for the current case, the patient ID will appear.
6	Alarm status indicator	Indicates whether the audio alarms are enabled, temporarily disabled or permanently disabled.
7	USB Indicator	Indicates whether a USB Flash Memory device is currently attached to the monitor

Menu Bar

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

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

Real Time CO₂ Data

This area of the screen displays the real time etCO₂ and FiCO₂ values along with selected units, and the respiration rate (RR) in breaths per minute. Numeric display appears at right and a waveform display at left. For more details regarding the displayed information, see CO₂ Data Displayed by the Capnostream Monitor on page 54.

When the CO₂ alarm limit threshold is crossed, the device will alarm: the affected numeric will flash, the numeric will appear with a red or yellow background (depending on whether it is a high priority patient [urgent] alarm or a caution alarm), and a message will appear in the header area of the screen.

This area of the screen can be selected as if it were a menu option. Selecting this area gives access to the setup screen for changing the CO₂ parameter values.

Real Time SpO₂ Data

This area of the screen displays real time numeric SpO₂ data: SpO₂, PR, and the pleth waveform or pulse beat bar - is always shown. (If IPI is enabled and thus no SpO₂ waveform is displayed, the SpO₂ pulse beat is represented by the green bar at the left of this box.)

For more details about the displayed SpO₂ data, see Chapter 6 Pulse Oximetry with the Capnostream Monitor on page 57.

When the SpO₂ alarm limit threshold is crossed, the device will alarm: the affected numeric will flash, the numeric will appear with a red or yellow background (depending on whether it is a high priority patient [urgent] alarm or a caution alarm), and a message will appear in the header area of the screen.

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

Real Time IPI Data with Trend Graphical Display

This area of the screen displays the real-time value of the IPI, a numerical value which summarizes four parameters (et CO_2 , RR, SpO_2 , PR) in order to provide a quick indication of the patient's respiratory status. The IPI trend graph indicates the trend of this value over the chosen period of time (the default period is one hour).

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

For more information about this parameter, see Chapter 7 Integrated Pulmonary IndexTM on page 63.

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

IPI data is not available for some patients; for more information, see Chapter 7 Integrated Pulmonary IndexTM on page 63.

A/hr and ODI Data

This area of the screen displays the A/hr and ODI values (if available).

For more information about A/hr and ODI, see Apneas per Hour and the Oxygen Desaturation Index on page 65.

When the apnea count in any one hour period during the last 12 hours exceeds a set number, a Visual Alert, in the form of an asterisk which appears next to the A/hr value, will appear on the screen, indicating to the user

that the A/hr and O₂ Desat screen should be viewed. The A/hr and O₂ Desat screen is reached with the REPORTS menu button. For more information about the A/hr Visual Alert, see A/hr Visual Alert on page 66.

Home Screen Numeric Display

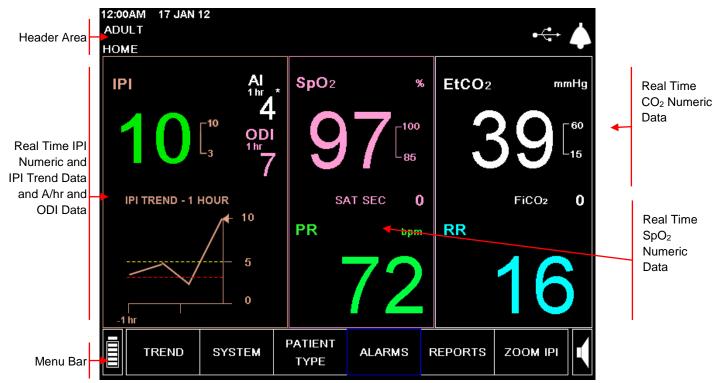


Figure 14 - Typical Numeric Home Screen

The numeric screen contains the following sections:

- Header Area on page 36
- Menu Bar on page 35
- Real Time IPI Data with Trend Graphical Display on page 37
- Real Time CO2 Data on page 35
- Real Time SpO2 Data on page 35
- A/hr and ODI Data on page 35 (if available)

Header Area

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

Menu Bar

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

Real Time CO₂ Data

This area of the screen displays the real time $etCO_2$ and $FiCO_2$ values along with selected units, and the respiration rate (RR) in breaths per minute. Numeric display only is provided, sized so that it can easily be read even at a distance. For more details regarding the displayed information, see CO2 Data Displayed by the Capnostream Monitor on page 54.

When the etCO₂, FiCO₂, or RR alarm limit threshold is crossed, the device will alarm: the affected numeric will flash, the numeric will appear with a red or yellow background (depending on whether it is a high priority patient urgent alarm or a caution alarm), and a message will appear in the header area of the screen.

This area of the screen can be selected as if it were a menu option. Selecting this area gives access to the setup screen for changing the CO₂ parameter values.

Real Time SpO₂ Data

This area of the screen displays real time SpO₂ data. Numeric display is provided, sized so that it can easily be read even at a distance. As in the standard screen, only the parameters which are measured by the probe which is currently connected to the device will appear on the screen. For more details about the displayed SpO₂ data, see Chapter 6 Pulse Oximetry with the Capnostream Monitor on page 57.

When the SpO₂ alarm limit threshold is crossed, the device will alarm: the affected numeric will flash, the numeric will appear with a red or yellow background (depending on whether it is an urgent alarm or a caution alarm), and a message will appear in the header area of the screen.

A/hr and ODI Data

This area of the screen displays the A/hr and ODI values (if available).

For more information about A/hr and ODI, see Apneas per Hour and the Oxygen Desaturation Index on page 65.

When the apnea count in any one hour period during the last 12 hours exceeds a set number, a Visual Alert, in the form of an asterisk which appears next to the A/hr value, will appear on the screen, indicating to the user that the A/hr and O₂ Desat screen should be viewed. The A/hr and O₂ Desat screen is reached with the REPORTS menu button. For more information about the A/hr Visual Alert, see A/hr Visual Alert on page 66.

Real Time IPI Data with Trend Graphical Display

This area of the screen displays the real-time value of the IPI, a numerical value which summarizes four parameters (etCO₂, RR, SpO₂, PR) in order to provide a quick indication of the patient's respiratory status. The IPI trend graph below the numeric value indicates the trend of this value over the chosen period of time.

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

For more information about this parameter, see Chapter 7 Integrated Pulmonary IndexTM on page 63.

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

Terminating Operation of the Monitor

Following patient monitoring, operation of the monitor shall be terminated as follows:

- 1. Remove the FilterLine and SpO₂ sensor from the patient.
- 2. Switch the monitor to OFF by pressing the ON/OFF switch at the front of the monitor.
- 3. If the monitor is connected to AC power using the AC adapter, it may now be disconnected from AC power. To continue charging the monitor when not in use for measurement, the monitor shall remain connected to AC power. The monitor will continue charging its internal battery even when it is switched off.

Screen Navigation

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

> TO MOVE AROUND THE SCREEN:

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

➤ TO ENTER LETTERS AND NUMBERS:

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

> TO CHANGE SETTINGS:

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

Configuration Changes

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

Setting Date, Time, Language, and Other Options

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 DATE, TIME, LANGUAGE, OR OTHER OPTIONS:

- 1. From the Home screen, use the control knob to select SYSTEM in the Menu Bar.
- 2. 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.
- 3. To change the language of the display, use the control knob to change the language.
- 4. The newly set options (including 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 119.
- 5. To change any of the other listed parameters, choose the required option, and then select the *HOME* menu button to return to the Home screen.
- 6. If A/hr and ODI are not available, the display option will not appear on this screen.

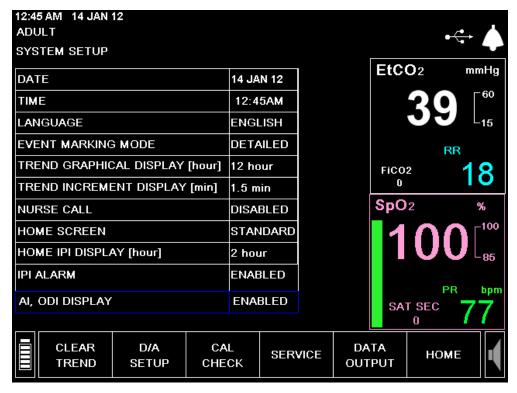


Figure 15 - System Setup Screen

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 home screen.

Capnostream®20p: Operational Check Sheet

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

□ 1. Unpack the monitor

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

☐ 2. Install the battery pack

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

□ 3. Turn on the monitor

- Plug the power cord into the mains plug in the rear of the monitor. Clip the power cord strain relief around the cable and tighten to ensure that the power cord does not accidentally disconnect from the monitor.
- Plug the power cord into the mains AC supply.
- The power indicator orange light at the front of the monitor will turn on.
- Press the Power ON/OFF button 6 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 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 and Mode

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

□ 6. Connect a FilterLine

- Slide open the FilterLine input connector shutter and connect the appropriate FilterLine.
- Connect the FilterLine to the patient as described in the Directions for Use supplied with the
 FilterLine. The sampling line connecter should be screwed clockwise into the monitor CO₂ port
 until it can no longer be turned, to ensure that it is connected securely to the monitor. This will
 assure that there is no leak of gases during measurement at the connection point and that
 measurement accuracy is not compromised.

☐ 7. Connect a SpO₂ Sensor

- Connect the SpO₂ extension cord firmly to the monitor SpO₂ sensor port, and then connect the appropriate SpO₂ sensor to the extension cord.
- Connect the SpO₂ sensor to the patient as described in its Directions for Use.
- \square 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 69 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 44 for instructions.

■ 11. Print Patient Data

- Choose the desired type of patient report and press the *PRINT* button on the screen.
- Refer to Chapter 11 Reports on page 93 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 107.
- Verify communication between the monitor and the Nurse Call system.

☐ 13. 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 110 for more details.

☐ 14. 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 103 for detailed information.

Using the Capnostream Monitor

Preparing the Monitor for a Patient

Using Patient Cases and Patient ID Numbers

Entering Patient Events

Changing the Alarm and Pulse Volumes

Alarm Delay

Use of Scavenging System

Turning the Pump Off for Suction or Lavage

Demo Mode

Monitor Screen Menu Reference Chart

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 60 on the front panel.
- 2. The complete power on sequence is described in Turning on the Monitor on page 30.
- 3. Confirm that the green power-on indicator and the orange AC power indicator light are both on.

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

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

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

5. Connect one or both sensors to the monitor, following the instructions in this manual. To connect the sensors, please see Connecting a FilterLine on page 54 and Connecting an SpO2 Sensor to the Monitor on page 60.

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

If a FilterLine is not connected, there is no CO₂ 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 (etCO₂) or the Pulse Oximetry function (SpO₂) 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.

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

Setting the Patient Type

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

- Infant/Neonatal: for patients from birth to the age of one year
- Pediatric 1-3 yrs: for patients aged one to three years

- Pediatric 3-6 yrs: for patients aged three to six years
- Pediatric 6-12 yrs: for patients aged six to twelve years.
- Adult: for patients aged 12 years and up

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

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

CAUTION:

The characteristics of a breath are calculated differently for the different patient types. Setting the correct patient type is therefore very important. Incorrect setting will result in inaccurate monitoring of the patient's respiration and affect the patient's IPI value.

➤ TO CHANGE THE PATIENT TYPE:

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

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

Using Patient Cases and Patient ID Numbers

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

➤ TO BEGIN A NEW CASE:

1. Once the patient is already connected to the monitor, press the **Patient Admit/Discharge** button

T 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

20101209072645

- 2. This automatically generated ID indicates the start date and time of the case session (format YYYYMMDDhhmmss, indicating year, month, day, hour, minute and second of the session start). To use the automatically generated ID number, use the control knob to select START CASE and click the START CASE button to begin the case.
- 3. To change the ID number, if desired, turn the control knob to highlight *PATIENT ID* in blue on the screen and click the control knob. Use the control knob to enter a new alphanumeric Patient ID by rotating and pressing the control knob to select letters and numbers. If you wish to enter a space, turn the knob until you see an empty square instead of a letter or numeral, and click to enter a space. You will note that the space you are currently filling is highlighted in yellow. The maximum permitted length for the Patient ID is 20 characters. Select the ← Enter symbol to finish. See the section Screen Navigation on page 37 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*.

CASE

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

Note:

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 34 Trend Memory Message on page 90. 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 34 - Trend Memory Message on page 90, will clear the trend memory and close the current case, thus erasing all data in the monitor regarding that case.

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

The monitor automatically stores patient data and records the date and time for all events, whether or not the patient case option is used. As long as the trend memory is not erased, this data remains stored in the monitor, until the trend memory is full and the beginning of the trend data is overwritten by new data. (See Chapter 10 Using Trends on page 83 for more information on trend capacity.) However, case printouts will only include data recorded after the current case was started (even if the trend memory also includes data previous to the current case). On the other hand, displayed trend data and trend printouts will include all data stored in the trend memory.

Entering Patient Events

When scanning patient history in the monitor, it is often useful to have a record of patient events that could have influenced the recorded readings. The monitor has the ability to record a wide variety of patient events. There are two options: Quick Events and Detailed Events.

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

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

> TO USE DETAILED EVENTS:

- 1. Press the event button on the front display panel of the monitor.
- 2. The table below will appear on the display. Use the control knob to click on an event.
- 3. Click the control knob again to store the event and 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 Changing Institutional Defaults on page 119.

MEDICATION	PATIENT	INTERVENED
Fentanyl	EATING	OXYGEN
Versed	DRINKING	SUCTION
MIDAZOLAM	COUGHING	ADJ AIRWAY
Morphine	AMBULATING	NARCAN
Demerol	CHEST PT	ROMAZICON
Propofol	TURNED	NEB TX
SURFACTANT	SNORING	STIMULATED
Other	OTHER	CO2 insuffl*
		ABG
		OTHER

Table 8 - Event Markings

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.

^{*} CO₂ Insufflation



Figure 16 - 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 17 - Alarm Volume Selection

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

Pulse Tone Volume

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

The pulse tone can also be turned off using the SpO₂ menu. By default, the pulse tone is turned off.

Setting the Pulse Tone Volume

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



Figure 18 - 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 SpO₂ display area. Click the control knob to go to the SpO₂ Setup screen.
- 2. Turn the control knob to highlight the *PULSE TONE* setting, click the knob to select the option, turn the knob once to change the setting to ON, and push the knob again to set the option.
- 3. A beep now sounds once for each pulse beat. To turn the pulse tone off, repeat the procedure and select *PULSE TONE* off.

Alarm Volume Default Options

The institutional default alarm volume can be set to one of the three choices described below, in the *Institutional Defaults>Monitor* screen. These choices determine the audio alarm volume when the device is turned on. See <u>Institutional Defaults</u> on page 119 to learn more about Institutional Defaults.

Audio Alarm Volume Option

Maximum

The audio alarm volume will revert to the maximum volume when the device is turned on, regardless of previous settings.

Last Setting

The audio alarm volume will remain at the level last set on the device, even after it is turned off and then turned on again.

Audio Off

The audio alarm volume is off.

Table 9 - Audio Alarm Volume

CAUTION:

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

Alarm Delay

An option for Alarm Delay (for a number of alarms) is available. For more information, see Alarm Delay on page 72.

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 19, below.

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

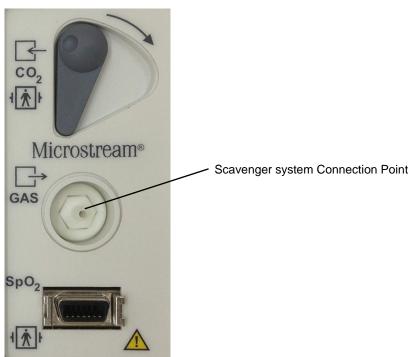


Figure 19 - Scavenger System Connection Point

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 \bigcirc 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, CO₂ is not monitored and no breath waveform, etCO₂, FiCO₂, or respiration rate number values are displayed. SpO₂ 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 CO₂ 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 CO₂ 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 119) 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 CO₂ and SpO₂ data. As an indicator of operation under Demo mode, the header will indicate DEMO MODE on a flashing orange background. An advisory message DEMO MODE PRERECORDED DATA will also appear. 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.

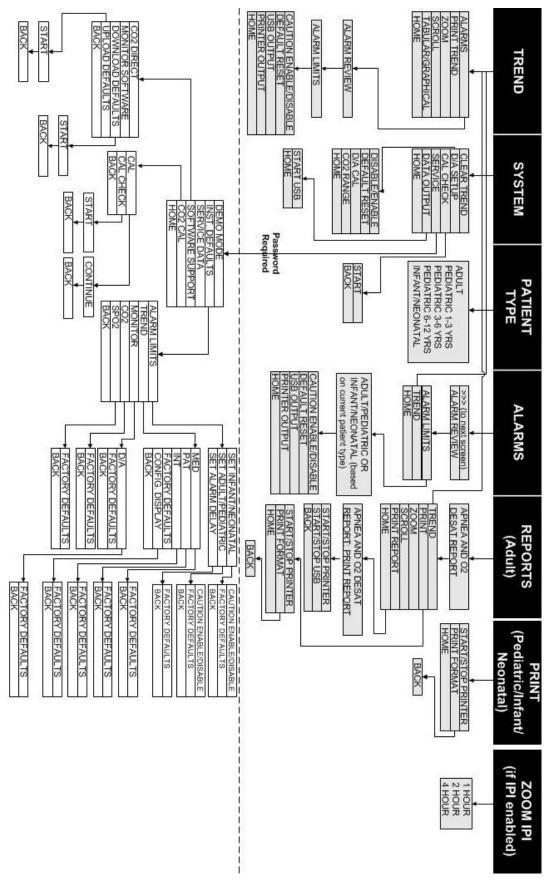


Figure 20 - Screen Menu Reference Chart when A/hr and ODI are available

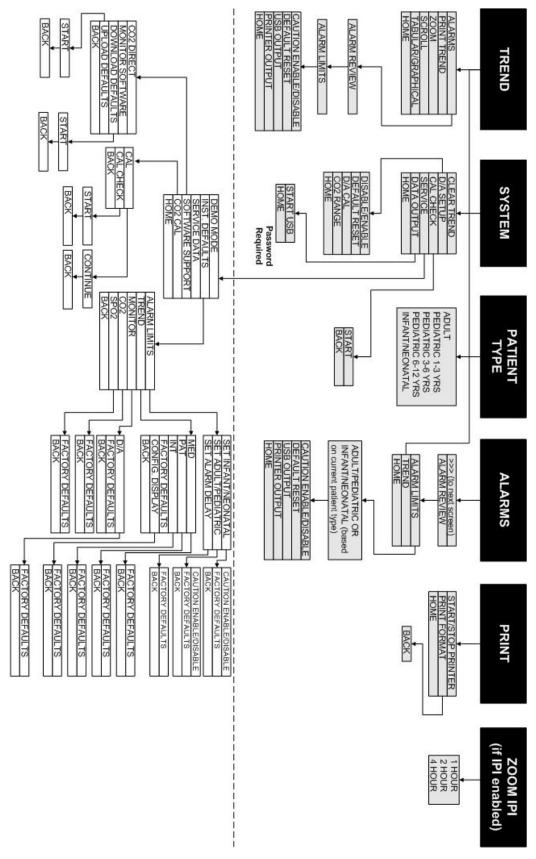


Figure 21 - Screen Menu Reference Chart when A/hr and ODI are not available

Capnography with the Capnostream Monitor

Microstream[®] EtCO2 Consumables Connecting a FilterLine CO2 Data Displayed by the Capnostream Monitor Adjustable CO2 Parameters Monitoring CO2 during MRI Scanning

Microstream[®] EtCO₂ Consumables

CAUTION: Before use, carefully read the Microstream® etCO₂ consumables *Directions for Use*.

CAUTION: Only use Microstream® etCO₂ consumables to ensure the monitor functions properly.

CAUTION: Microstream[®] etCO₂ 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[®] etCO₂ consumables according to standard operating procedures or

local regulations for the disposal of contaminated medical waste.

WARNING: Loose or damaged connections may compromise ventilation or cause an inaccurate

measurement of respiratory gases. Securely connect all components and check connections

for leaks according to standard clinical procedures.

WARNING: If too much moisture enters the FilterLine (i.e., from ambient humidity or breathing of

unusually humid air), the message *Clearing FilterLine* will appear in the Capnostream message area. If the FilterLine cannot be cleared, the message *FilterLine Blockage* will appear in the CO₂ waveform display section on the Home screen and in the Capnostream message area. (If there is no waveform display, the message will appear only in the message

area.) Replace the FilterLine once the *FilterLine Blockage* message appears.

WARNING: The FilterLine may ignite in the presence of O₂ when directly exposed to laser, ESU

devices, or high heat. When performing head and neck procedures involving laser, electrosurgical devices or high heat, use with caution to prevent combustion of the

FilterLine or surrounding surgical drapes.

Note: When connecting a sampling line to the monitor, screw the sampling line connecter clockwise into the

monitor CO₂ port until it can no longer be turned, to ensure that it is connected securely to the monitor. This will assure that there is no leak of gases during measurement at the connection point and that

measurement accuracy is not compromised.

Note: Following connection of the CO₂ sampling line, check that CO₂ values appear on the monitor display.

Basic Principles

When choosing Microstream[®] etCO₂ 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
- Whether the patient is breathing through his nose, his mouth, or alternating between oral and nasal breathing

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® etCO₂ Consumables' *Directions for Use* for proper connection.

Microstream® EtCO₂ Consumables

A list of Microstream[®] etCO₂ consumables appear in Microstream EtCO₂ Consumables on page 137.

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® etCO₂

consumables.

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

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

Connecting a FilterLine

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

TO MAKE THE CONNECTIONS:

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

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

Note:

The Capnostream monitor's CO_2 function will enter standby mode automatically in cases when the Capnostream monitor is left on for 30 minutes or longer without a FilterLine attached. In this case, CO_2 monitoring on the monitor will go into automatic standby mode and then will re-initialize once a FilterLine is attached. This initialization process takes typically 30 seconds; it may take up to 180 seconds.

CO₂ Data Displayed by the Capnostream Monitor

The Capnostream monitor Home screen displays real time CO₂ data. The displayed data includes:

- Real time etCO₂ and FiCO₂ values along with selected unit (see CO₂ Data Displayed by the Capnostream Monitor on page 54 for details regarding the available units)
- Real-time FiCO₂ values along with selected unit (see Adjustable CO2 Parameters on page 55 for details regarding the available units)
- Respiration rate (RR) in breaths per minute
- CO₂ Waveform

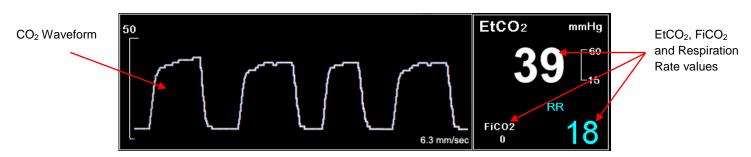


Figure 22 - CO₂ Data on the Capnostream Monitor

Additionally, the monitor can display CO₂ data in trend form, showing time, date, etCO₂, RR, alarms, events, and a CASE START marker. For more information about trend display, see Chapter 11 Using Trends on page 83.

When the EtCO₂ High or Low alarm limits are exceeded, the affected numeric will flash to alert the attending health care professional to the specific parameter that is affected.

A delay may be set on a number of alarms, if desired, so that these alarms will sound only if the parameter exceeded alarm limits for the set number of seconds. This option can be set using Institutional Defaults. See Institutional Defaults on page 119 for more information on how to set Institutional Defaults.

If the numeric home screen is chosen, the CO₂ waveform will not appear. Instead, CO₂ data will appear in a large font, to enable easy viewing, even at a distance. The CO₂ section of the numeric home screen is seen in Figure 23 - CO₂ Section of Numeric Home Screen, below.

Note: For both neonatal and adult patients, the EtCO₂ numeric displayed on the screen is the maximum value

of CO₂ over the last 20 seconds, updated once a second. An etCO₂ alarm will occur based on the EtCO₂

value displayed on the screen.

Note: In high-altitude environments, EtCO₂ 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 EtCO₂ alarm settings accordingly.

Note: Measuring mode corrects the CO₂ value for BTPS setting (Body Temperature, Pressure, Saturation)

which assumes that alveolar gases are saturated with water vapor. BTPS should remain on for patient

measurement. For other purposes, it may be turned off in the CO₂ Setup screen.



Figure 23 - CO₂ Section of Numeric Home Screen

Adjustable CO₂ Parameters

The Capnostream monitor provides the option of adjusting some parameter settings used for CO₂ 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 125.

➤ TO CHANGE CO₂ PARAMETER SETTINGS:

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

4. The changes in the parameters will remain in effect until the device is turned off.

Parameter	Choices	Factory Default	
BTPS*	On/Off	On	
FiCO ₂ Display	On/Off	On	
Pump-Off Timeout (minutes)	5, 10, 15 or 30	15	
CO ₂ Waveform Scale (mmHg)	50, 100, 150, Auto	Auto	
EtCO ₂ Scale for Trend Display	50, 100, 150	50	
RR Scale for Trend Display	50, 100, 150	50	
Sweep Speed (mm/sec) [for current patient type]	1, 2, 3, 6.3, 12.5, 25	6.3	
A/hr Visual Alert Level (Apnea/Hr) (if available)	1-99	10	

Table 10 - Adjustable CO₂ Parameters

Monitoring CO₂ 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.
CAUTION:	Use of a CO ₂ sampling line with H in its name (indicating that it is for use in humidified environments) during MRI scanning may cause interference. The use of non-H sampling lines is advised. For a list of H sampling lines, see Microstream EtCO2 Consumables on page 137.

Non-invasive etCO₂ monitoring during magnetic resonance imaging (MRI) can be accomplished with the monitor, a FilterLine XL, and an appropriate CO₂ sampling line.

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

To purchase the FilterLine XL, contact your local representative.

^{*} 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.

Pulse Oximetry with the Capnostream Monitor

Nellcor SpO2 Sensors Connecting an SpO2 Sensor to the Monitor SpO2 Data Displayed by the Capnostream Monitor Adjustable SpO2 Parameters SPO2 Alarm Limit Message

Nellcor SpO₂ Sensors

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

and instructions.

WARNING: 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: Before each use of SpO_2 sensors, assure that the sensor is intact. Damaged sensors (torn,

worn out [abraded], or exposed optical components, wires or metal) are prohibited for use. Use of damaged sensors may compromise patient safety and may result in patient injury. Protection of the monitor against the effects of the discharge of a cardiac defibrillator is dependent upon the use of appropriate SpO2 cables and sensors listed in Table 11 on

page 58.

WARNING: Use only Nellcor sensors for SpO₂ 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.

Inspect the sensor site as directed in the Instructions for Use. Do not apply the sensor too tightly or by using excessive pressure. Do not wrap the sensor, apply supplemental tape, or leave the sensor too long in one place. If the skin under the sensor becomes irritated, change

the location of the sensor.

CAUTION: Single-patient use sensors and adhesive sensors are intended for single-patient use only. Do

not transfer a single-use sensor or an adhesive sensor from one patient to a second patient.

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.

Note: Because light absorption by hemoglobin is wavelength dependent and because the mean wavelength of

LEDs varies, a monitoring system must know the mean wavelength of the sensor's red LED to accurately measure SpO₂. During monitoring, the monitoring system's software selects coefficients that are appropriate for the wavelength of that individual sensor's red LED; these coefficients are then used to determine SpO₂. Additionally, to compensate for differences in tissue thickness, the light intensity of the sensor's LEDs is adjusted automatically. Together these features provide automatic calibration of the

SpO2 feature.

Data Update Period, Data Averaging, and Signal Processing

The advanced signal processing of the OxiMaxTM algorithm automatically extends the amount of data required for measuring SpO_2 and pulse rate depending on the measurement conditions. The OxiMaxTM algorithm automatically extends the dynamic averaging time required beyond seven (7) seconds during degraded or difficult measurement conditions caused by low perfusion, signal artifact, ambient light, electrocautery, other interference, or a combination of these factors, which results in an increase in the dynamic averaging. If the resulting dynamic averaging time exceeds 20 seconds for SpO_2 , the algorithm sets the pulse search bit while continuing to update SpO_2 and pulse rate values every second.

As such measurement conditions extend, the amount of data required may continue to increase. If the dynamic averaging time reaches 40 seconds, and/or 50 seconds for pulse rate, a technical alarm state results: the algorithm sets the Pulse Timeout bit and the monitoring system reports a zero saturation indicating a loss-of-pulse condition, which should result in an audible alarm.

Functional Testers and Patient Simulators

Some models of commercially available bench top functional testers and patient simulators can be used to verify the proper functionality of Covidien NellcorTM monitoring systems, sensors, and cables. Reference the individual testing device's operator's manual for the procedures specific to the model of tester used. While such devices may be useful for verifying that the sensor, cabling, and monitoring system are functional, they are incapable of providing the data required to properly evaluate the accuracy of a system's SpO_2 measurements.

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

Many functional testers and patient simulators have been designed to inter-face with the monitoring system's expected calibration curves and may be suitable for use with monitoring systems and/or sensors. Not all such devices, however, are adapted for use with the OxiMaxTM digital calibration system. While this will not affect use of the simulator for verifying system functionality, displayed SpO₂ measurement values may differ from the setting of the test device. For a properly functioning monitoring system, this difference will be reproducible over time and from monitoring system to monitoring system within the performance specifications of the test device.

Selecting Nellcor SpO₂ Sensors

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

Nellcor pulse oximetry sensors contain light emitting diodes (LEDs) that emit red light at a wavelength of approximately 660 nm, and infrared light at a wavelength of approximately 900 nm. The total optical output power of the sensor LEDs is less than 15 mW. This information may be useful to clinicians, such as those performing photodynamic therapy.

Oxygen Sensor	Model	Patient Weight
OXIMAX® oxygen transducer	MAX-N	<3 kg or >40 kg
(single patient use)	MAX-I	3 to 20 kg
	MAX-P	10 to 50 kg
	MAX-A	>30 kg
	MAX-AL	>30 kg
	MAX-R	>50 kg

Table 11 - Nellcor SpO₂ Sensors

	MAX-FAST	>40 kg
OxIMAx® OxiCliq® oxygen transducer (single-use only)	P	10 to 50 kg
	A	>30 kg
OxIMax® Dura-Y® multisite oxygen transducer (Nonsterile, reusable)	D-YS	>1 kg
For use with Dura-Y sensor: Ear clip (Reusable, nonsterile)	D-YSE	30 kg
Pedi-Check™ pediatric spot-check clip (Reusable, nonsterile)	D-YSPD	3 to 4 kg
OxIMAx® Oxiband® oxygen transducer (Reusable with disposable nonsterile	OXI-A/N	<3 kg or>40 kg
adhesive)	OXI-P/I	3 to 40 kg
OxIMax® Durasensor® oxygen transducer (Nonsterile, reusable)	DS-100A	>40 kg
Nellcor [™] Preemie SpO ₂ Sensor, non-adhesive (Single-patient use)	SC-PR	<1.5 kg
Nellcor™ Neonatal SpO₂ Sensor, non- adhesive (Single-patient use)	SC-NEO	1.5 to 5 kg
Nellcor [™] Adult SpO ₂ Sensor, non-adhesive (Single-patient use)	SC-A	>40 kg
Nellcor [™] Adult Respiratory Sensor, SpO ₂ , RR	10068119	>30 kg
Sensor cable DOC-10	DOC-10	NA
Sensor cable OC-3	OC-3	NA

Performance Considerations

WARNING: Pulse oximetry readings and pulse signal can be affected by certain ambient environmental

conditions, sensor application errors, and patient conditions.

WARNING: Tissue damage can be caused by incorrect application or inappropriate duration of use of an

 SpO_2 sensor. Inspect the sensor site as directed in the sensor *Directions for Use*.

WARNING: Use only Nellcor-approved sensors and pulse oximetry cables. Other sensors or oximetry

cables may cause improper monitor performance and may also result in increased electromagnetic emission or decreased immunity to electromagnetic interference.

Inaccurate measurements can be caused by:

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

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

- the sensor is applied too tightly
- a blood pressure cuff is inflated on the same extremity as the one with the sensor attached
- there is arterial occlusion proximal to the sensor

• poor peripheral perfusion

Clean and remove any substances such as nail polish from the application site. Periodically check to ensure that the sensor remains properly positioned on the patient.

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

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

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

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

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

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

Reading accuracy in the presence of low perfusion (detected IR pulse modulation amplitude between 0.03% and 1.5%) was validated using signals supplied by a patient simulator. SpO₂ and pulse rate values were varied across the monitoring range over a range of weak signal conditions and compared to the known true saturation and pulse rate of the input signals.

Connecting an SpO₂ 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 SPO₂ SENSOR:

- 1. Connect the SpO₂ extension cord firmly to the monitor SpO₂ sensor port, and then connect the appropriate Nellcor SpO₂ sensor to the extension cord.
- 2. Connect the Nellcor SpO₂ sensor to the patient as described in its Directions for Use, using a Nellcor SpO₂ sensor extension cable.
- 3. When the SpO₂ 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 Medium Priority Alarm, and will generate a triple beep every thirty seconds. To avoid the alarm message and beeping, you can connect the extension cable to the monitor, but wait to connect the SpO₂ sensor to the extension cable until it is time to connect the patient to the monitor.

SpO₂ Data Displayed by the Capnostream Monitor

The Capnostream monitor Home screen displays real time SpO₂ data. The displayed data includes:

- SpO₂ Numeric
- Pulse Rate
- Sat Seconds figure (see SpO2 Alarms and SatSeconds on page 80 for an explanation of this issue)
- Plethysmograph (SpO₂ waveform)
- Interference Indicator

SpO₂

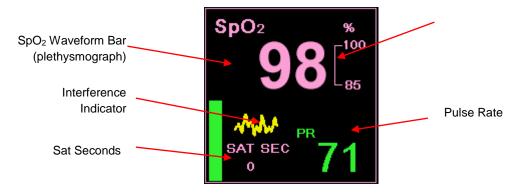


Figure 24 - SpO₂ Data on the Capnostream Monitor - Standard Screen

On the standard home screen with IPI enabled (default standard home screen), the plethysmograph (the SpO_2 waveform) is seen as a green vertical bar on the SpO_2 section of the screen (just to the left of the Sat Seconds value). The bar indicates pulse beat by rising and falling with the patient's pulse beat. An interference indicator (the yellow jagged line seen in the figure above) is shown when the incoming signal is inadequate or degraded. If the signal is adequate, the indicator will not appear.

When the IPI display on the home screen is disabled (see IPI Options on page 64 and Institutional Defaults on page 119), the SpO₂ section of the home screen will appear as seen in Figure 25 - SpO₂ Data on the Capnostream Monitor – Standard Screen with IPI Disabled, below. The plethsysmographic waveform is non-normalized, using real-time sensor signal to reflect relative pulsatile strength.

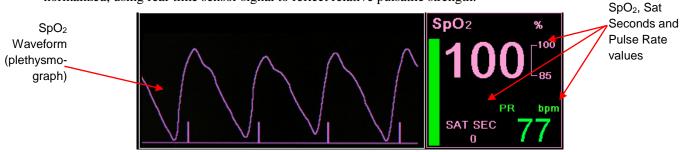


Figure 25 - SpO₂ Data on the Capnostream Monitor - Standard Screen with IPI Disabled

Additionally, the monitor can display SpO₂ data in trend form, showing time, date, SpO₂, pulse rate (PR), alarms, events and case markers to differentiate between patients. For more information about trend display, see Chapter 11 Using Trends on page 83.

When the SpO₂ high or low alarm limits are exceeded, the affected reading will flash to alert the attending health care professional to the specific reading that is affected.

If the numeric home screen is chosen, the SpO₂ waveform will not appear. Instead, SpO₂ data will appear in a large font, to enable easy viewing, even at a distance. The SpO₂ section of the numeric home screen is seen in Home Screen Numeric Display on page 36.

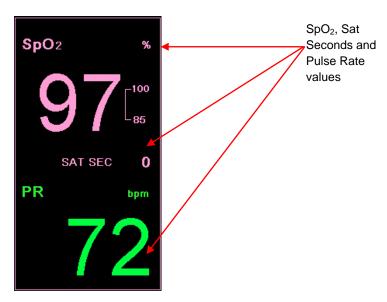


Figure 26 - SpO₂ Section of Numeric Home Screen

Adjustable SpO₂ 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 Institutional Defaults on page 119.

➤ TO CHANGE SPO₂ PARAMETER SETTINGS:

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

Parameter	Choices	Factory Default		
Pulse Tone	On/Off	On		
Sat Sec (Sat Seconds)	On/Off	On		
SpO2 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		

Table 12 - Adjustable SpO₂ Parameters

SPO₂ Alarm Limit Message

When the SpO₂ alarm limit is set below 85%, a message reading SpO₂ LOW ALARM LIMIT: xx will appear in the header area, indicating the level of the SPO₂ LOW alarm limit.



Integrated Pulmonary Index™

Introduction Warnings IPI Display IPI Options

Introduction

The Integrated Pulmonary IndexTM (henceforth referred to as IPI) is a numerical value which integrates four major parameters measured by Capnostream in order to provide a simple indication of the patient's overall ventilatory status. The integrated parameters are EtCO₂, RR, SpO₂, and PR. Only these four parameters are used to calculate IPI; other parameters are not taken into account.

IPI is calculated using the current values of these four parameters and their interactions, based on known clinical data. IPI can thus provide an early indication of a change in ventilatory status which may not be shown by the current value of any of these four parameters individually. The IPI is designed to provide additional information regarding patient status, possibly before EtCO₂, RR, SpO₂, or PR values reach levels of clinical concern.

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



Figure 27 - IPI Trend Graph

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

Since the index uses data from the monitoring of both CO₂ and SpO₂, it will only be available when both parameters are available.

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

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

Note:

The interpretation of the patient's IPI score may change in different clinical environments. For example, patients with specific respiratory difficulties (in contrast to normally healthy patients who are being

monitored during sedation or pain management) may require a lower IPI Low Alert threshold to reflect their impaired respiratory capacity.

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

Warnings

WARNING: Ensure that the patient type is correctly selected before beginning monitoring of a patient.

Choosing an incorrect patient type could produce incorrect patient IPI data.

WARNING: When an IPI Low Alert is triggered for a patient, medical staff should review the patient's

status to determine if a change in medical care is required.

IPI Display

IPI appears on the Home screen and is available in all Capnostream functions as a default option, along with other patient parameters such as etCO₂ or SpO₂. On the Home screen, both numerics and a trend graph are provided for IPI.

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

IPI Options

➤ TO CHANGE IPI OPTION SETTINGS:

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

ParameterChoicesFactory DefaultHome IPI Display1 hour, 2 hour, 4 hour1 hourIPI AlertEnabled/DisabledDisabled

Table 13 - Adjustable IPI Options

To change IPI Display and Alert options on a more permanent basis, use the Institutional Defaults option, described in Institutional Defaults on page 119. The Home IPI Display settings can be changed in the Institutional Defaults: Trend screen and the IPI Low Alert (enabled or disabled) can be changed in the Institutional Defaults: Monitor screen. IPI Low Alert Alarm Limits can be changed in the Institutional Defaults: Alarm Limits:Set Adult/Pediatric screen.

Apneas per Hour and the Oxygen Desaturation Index

Introduction
Apneas per Hour
Oxygen Desaturation Index (ODI)
Apnea and O2 Desaturation Report
Monitoring with A/hr and ODI
Smart A/hr and ODI Home Screen Display
A/hr and ODI Option
A/hr and ODI Demo Mode

Introduction

The Apneas per Hour (A/hr) and Oxygen Desaturation Index (ODI) algorithm is part of the Smart Capnography family of innovative algorithms developed by Oridion. Smart Capnography simplifies the use of CO₂ monitoring on Microstream[®] enabled products, to improve patient safety and clinical workflow.

A/hr and ODI are not available in all locations. In order to equip your device with these algorithms, contact Capnographyinfo@covidien.com.

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

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

A/hr and ODI are displayed in real time on the home screen and on an easy-to-read Apnea and O₂ Desat Report screen, which is available for printed reports and in file format exported to a USB flash drive.

Apneas per Hour

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

On the Apnea and O2 Desat Report screen, A/hr is the average Apneas per Hour over the selected time period of 2, 4, 8 and 12 hours. On that screen, the number of apnea events of \geq 10 seconds; 10-19 seconds; 20-30 seconds; and >30 seconds over the selected time period are also shown.

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

The Capnostream Apneas per Hour

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

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

A/hr Visual Alert

The A/hr Visual Alert, which appears as an asterisk next to the A/hr value, is used to indicate to the caregiver that the apnea count in any one hour period during the last 12 hours exceeded a set number. (The default value which will trigger an A/hr Visual Alert is 10.) The asterisk will appear only when an A/hr Visual Alert is triggered, and it is updated once every 10 minutes. The Visual Alert on the screen indicates to the caregiver that the Apnea and O_2 Desat screen should be viewed to learn more about the patient's breathing patterns. To change the value which will trigger an A/hr Visual Alert, see Adjustable CO2 Parameters on page 55.

Oxygen Desaturation Index (ODI)

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

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

On the Apnea and O₂ Desat Report screen, ODI is average per hour "dips" in SpO₂ over the selected time period of 2, 4, 8 and 12 hours.

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

Apnea and O2 Desaturation Report

The on-screen and printed Apnea and Desat reports show a comprehensive picture of the number of A/hr and ODI events over a set time period of 2, 4, 8, or 12 hours. These reports provide both details regarding the A/hr and ODI status of the patient and a general picture which can help the caregiver spot patient trends in these areas. For more information on this report, see Apnea and O2 Desaturation Report on page 93.

Monitoring with A/hr and ODI

When monitoring patients with A/hr and ODI, please take the following issues into consideration:

CAUTION:	Please note that A/hr and ODI do not report hypopnea events.
CAUTION:	Apnea per Hour (A/hr) and Oxygen Desaturation Index (ODI) do not represent and should not be interpreted as an apnea hypopnea index (AHI) as reported by formal polysomnography studies.
CAUTION:	Apnea per Hour (A/hr) and Oxygen Desaturation Index (ODI) do not represent and should not be used to diagnose sleep disordered breathing.
CAUTION:	Alarms and a noisy environment may affect A/hr and ODI values. See the Note regarding recommendations on changing device settings for a sleeping patient below.
CAUTION:	A/hr and ODI are reported by the monitor throughout the monitoring period; however, the monitor cannot discern if the patient is actually sleeping. Also, if a patient removes a sensor, the monitor may indicate apneas when no such apneas took place.
CAUTION:	The administration of opioid analgesia and sedatives may cause respiratory depression, which will result in transient apnea and O_2 desaturation events that will be reflected in A/hr and ODI values.
CAUTION:	Please read all user information to ensure complete understanding of A/hr.
CAUTION:	ODI values may be affected by the algorithms employed by the pulse oximetry module.

Note: Please note that the patient type is used to calculate the A/hr and ODI. For this reason, it is important to

choose the patient type correctly. For the same reason, changing the patient type (from adult to pediatric, for example) will clear the A/hr and ODI data stored for the current patient. A/hr and ODI

headings will not appear for infant/neonatal or pediatric patients.

Note: No A/hr or ODI data will appear on the Home screen for the first hour of monitoring, since A/hr and ODI

indicate the number of events over the last hour. Once one hour of monitoring has passed, they will

appear on the Home screen.

Note: When using the Capnostream A/hr and ODI with a sleeping patient, it is recommended that the

Capnostream device be attached to a central monitoring station where alarms will be heard. Once this is done, the alarm sound on the Capnostream at the patient's bedside can be disabled, so as not to disturb the patient's sleep. The audible alarms are silenced through SYSTEM>SERVICE>Service password (see Capnostream Service Password on page 139>INST DEFAULTS>MONITOR. In the list of options on this screen, change the AUDIO ALARM VOLUME to AUDIO OFF. This should only be done if the Capnostream is under constant surveillance via connection to a central station (or another means of surveillance), so that patient alarms are noted by caregivers while the alarm sound is turned off on the

bedside Capnostream device.

Smart A/hr and ODI Home Screen Display

A/hr and ODI appear on the Home screen and are available in all Capnostream functions as a default option, along with other patient parameters such as EtCO₂ or SpO₂.

The A/hr and ODI option may be disabled from the SYSTEM screen or from the Institutional Defaults screen; see below for more information. For Infant/Neonatal and Pediatric patients, the Smart A/hr and ODI option is automatically disabled.

A/hr and ODI Option

➤ TO CHANGE A/HR AND ODI OPTION SETTINGS:

- 1. On the Home screen, click the SYSTEM button in the menu bar at the bottom of the screen.
- 2. The System Setup screen will appear. Change A/hr, ODI DISPLAY to ENABLED or DISABLED as desired.
- 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 A/hr and ODI display will remain in effect until the device is turned off.

To change the A/hr and ODI option on a more permanent basis, use the Institutional Defaults option, described in Institutional Defaults on page 119.

A/hr and ODI Demo Mode

To view the A/hr and ODI display without connecting a patient, you may set the monitor to Demo Mode by clicking *System>Service>Enter Service Password>Demo Mode*. (For the Service Password, see Capnostream Service Password on page 139.)

Alarms and Messages

Introduction

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Alarm Delay

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Parameter Standby Mode

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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
- Medium Priority Alarms
- Advisories
- Silent Advisories

High Priority Alarms are provided with the option of setting red urgent alarms for each alarm issue, as well as the possibility of setting yellow caution alarms 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 14 - Alarm Indications

Alarm Type	Indicators			
	Audible	Numerics	Messages	Indicator Light
High Priority (Patient) Alarms (red high priority patient urgent alarms	Repeated Beep Pattern	Flashing Red (except NO BREATH)	Message area	Flashing Red
High Priority (Patient) NO BREATH Alarm	Repeated Beep Pattern	Numeric reverts to zero (0)	Message area (with indication of time elapsed since NO BREATH) and in waveform area	Flashing Red
Yellow caution alarms	Repeated Beep Pattern	Flashing Yellow	Message area	Flashing Yellow

Alarm Type	Indicators			
	Audible	Numerics	Messages	Indicator Light
Medium Priority	Repeated triple beep	N/A	Message area (some messages also in waveform area – see below)	Flashing Yellow
Advisories	Single Beep	N/A	Message area	N/A
Silent Advisories	None	N/A	Message area	N/A

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

CO₂ Waveform Area Messages:

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

SpO₂ Waveform Area Messages:

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

Alarm Display

In order to view the visual alarm indicators, the intended position of the operator is in front of the monitor display screen. The intended position of the operator in order to hear audible signals is any position near the monitor (in a 360° range).

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

Alarm occurrences are also displayed on all screens in the header area, in order to provide immediate input on alarms to the health care provider. The preference of alarm display in the header area is described in Message Priorities on page 72.

In addition, the message "NO BREATH" and "FILTERLINE BLOCKED" appear in the CO₂ waveform area as well as in the header if this alarm condition exists. If the numeric home screen option is displayed (so that there is no waveform area), this message will appear only in the header area.

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

The alarm occurrences for a specific patient over a specific period of time can be reviewed in the trend screen (see Chapter 10 Using Trends on page 83 for more details). Capnostream also provides an Alarm Review screen which displays the absolute number of each type of alarm generated over the last hour for the patient currently being monitored. The Alarm Review screen is seen in Figure 28 - Capnostream Alarm Review Screen, below.

This screen enables the health care provider to see at a glance how many alarms have been generated over the last hour by the patient, in order to assess patient status. It is reached by clicking the *ALARMS* soft button on the menu bar, from the Home screen or the Trend screens.

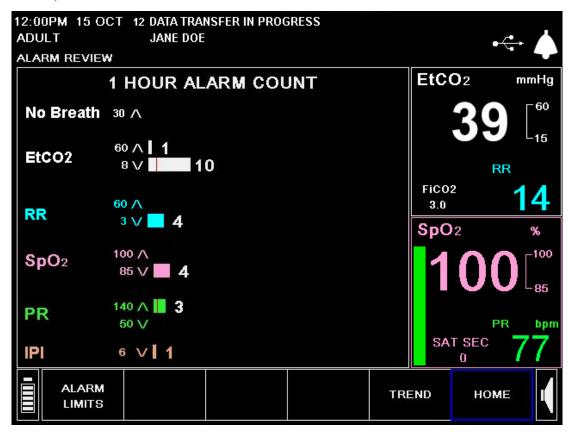


Figure 28 - Capnostream Alarm Review Screen

The Alarm Review screen covers the following alarms:

- No Breath Alarm
- EtCO₂ High and Low Alarms
- Respiration Rate High and Low Alarms
- SpO₂ High and Low Alarms
- Pulse Rate High and Low Alarms
- IPI Low Alert

The order in which the parameters appear in this screen can be changed from the Institutional Defaults screen (once a change is made, it will affect both this screen and the trend screens). See Changing Parameters Order on the Trend Display on page 123 for more information.

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

All alarms displayed are based on the high priority patient (urgent) alarm limit set on the device. For example, if the etCO₂ High alarm limit is set at 60, a level of 60 will be shown on the Alarm Review screen for etCO₂ High, to the left of the upper white bar. If the alarm limit has been changed, the current limit will appear, but the number of alarms will reflect the limit in place when that alarm occurred, thereby accurately representing the number of alarms that occurred under each different alarm limit.

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

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

Message Priorities

Alarms and advisory messages are displayed in the header area of the monitor in order of priority. When there is an alarm, only the alarm messages will appear in the message area, and advisory messages will not appear until the alarm condition is cleared. For example, if there is a *RR HIGH ALARM*, this alarm message will appear in the message area, and the advisory message *SPO*₂ *WEAK*. *REPOSITION SENSOR*. will not appear even though the condition exists to generate this message.

If more than one alarm condition exists, the monitor will display each alarm message for about 4 seconds and continue to repeat the messages in turn until the alarm conditions are cleared. For example, the *RR HIGH ALARM* and *SpO*₂ *LOW ALARM* messages will alternate in the message area.

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

Alarm Delay

Capnostream provides the option to delay alarms (both the audible alarm and the alarm indicator on the screen) by a number of seconds. If this option is used, the alarm signal (audio or visual) will only appear if the alarm condition continues to be present past the delay time which has been set.

EtCO₂, RR and PR High Alarms and SpO₂ and PR Low Alarms can be delayed by 10, 15, 20, or 30 seconds, or not at all (Alarm Delay disabled). The default option is Alarm Delay disabled. This option is available for all patient types.

The Alarm Delay can be set from the Institutional Defaults screen, which can be reached by SYSTEM>SERVICE>Input Service Password>INST DEFAULTS>ALARM LIMITS>SET ALARM DELAY.

Types of Alarms

High priority patient alarms (urgent) indicate that the particular parameter has exceeded the set limit. A default alarm limit is provided for each alarm situation. Alarm limits can be changed to fit the particular institution, if desired.

In addition, Capnostream provides the possibility to set a caution alarm for patient alarms at a lower value level than that set for the standard high priority patient (urgent) alarm, to provide information for caregivers and allow the caregiver to address a developing situation before it is critical. By default these caution alarms are disabled. If they are enabled, a limit which is between the high priority alarm limit and the normal (healthy) level is provided for each alarm situation and may be set to provide a caution alarm. To enable these caution alarms, see Changing Alarm Limits on page 79.

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 high priority patient (urgent) alarm limit. Also, the red alarm LED and yellow caution alarm LED will light appropriately. If a user does not wish to use this caution alarm on any particular alarm, he can set both the high priority patient (urgent) alarm and caution alarm for that alarm to the same limits (see Changing Alarm Limits on page 79). Then only the high priority patient (urgent) alarm will occur. You can also revert to a single level system for all alarms by pressing the button for Caution Disable.

All recording and digital reporting of patient alarms involves both the high priority patient (urgent) alarms and the caution alarms.

In addition, medium priority alarms, which alert the clinician to device issues (as opposed to patient issues, which are covered by high priority alarms and caution alarms), are also provided.

The following is an example for illustration purposes only, showing how the red high priority patient (urgent) alarm and the yellow caution alarm appear on the monitor.

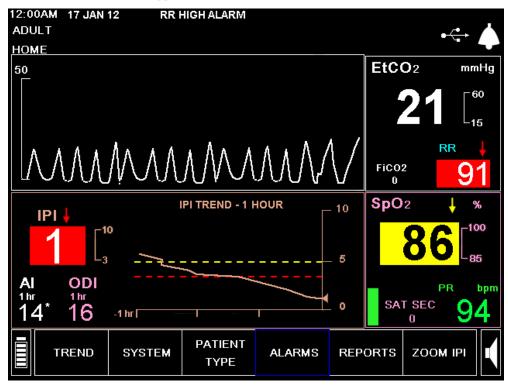


Figure 29 - Example Showing Alarms

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 ALARM* appears in the message area at the top of the screen. In addition, the IPI value is below the IPI Low Alert alarm limit, indicated by the IPI value flashing red, and the red arrow pointing down. The message *IPI LOW ALARM* will also appear on the screen header (alternately with *RR HIGH ALARM*).

The yellow background on the SpO₂ value together with the yellow arrow pointing down indicates that the SpO₂ LOW caution alarm level has been exceeded.

High Priority Alarms

Message **Corrective Action** Description NO BREATH XXX SECONDS No valid breath has been Patient requires immediate detected for xxx seconds medical attention. ETCO₂ HIGH ALARM The etCO₂ is above the upper Patient requires immediate alarm limit medical attention. Patient requires immediate ETCO₂ LOW ALARM The etCO2 is below the lower alarm limit medical attention. RR HIGH ALARM The RR is above the upper Patient requires immediate alarm limit medical attention. RR LOW ALARM The RR is below the lower alarm Patient requires immediate medical attention. SPO₂ HIGH ALARM The SpO₂ is above the upper Patient requires immediate

medical attention.

alarm limit

Table 15 - High Priority Alarms

Message	Description	Corrective Action
SPO₂ LOW ALARM	The SpO ₂ is below the lower alarm limit	Patient requires immediate medical attention.
PULSE RATE HIGH ALARM	The pulse rate is above the upper alarm limit	Patient requires immediate medical attention.
PULSE RATE LOW ALARM	The pulse rate is below the lower alarm limit	Patient requires immediate medical attention.
FiCO₂ HIGH ALARM	The FiCO ₂ is above the upper alarm limit	Patient requires immediate medical attention.
IPI LOW ALARM*	The IPI is below the lower alarm limit.	Patient requires immediate medical attention.
SYSTEM RESET, CHECK SETTINGS	The system has reset and will revert to institutional default settings.	Reset your alarm limits and other settings to match the requirements of the patient being monitored.

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

Medium Priority Alarms

Table 16 - Medium Priority Alarms

Message	Description	Corrective Action
CO₂ ERROR	Failure has occurred which prohibits the operation of the CO ₂ function.	Contact Oridion authorized personnel.
SPO₂ 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.
FILTERLINE DISCONNECTED	No FilterLine is connected to the device.	Will occur only when Parameter Standby is enabled. Insert FilterLine into CO ₂ port on device.
SPO₂ SENSOR DISCONNECTED	No SpO ₂ sensor is connected to the device.	Will occur only when Parameter Standby is enabled. Insert SpO ₂ sensor into SpO ₂ port on device.
SPO ₂ SENSOR NOT ON PATIENT	Sensor is off patient.	Place sensor properly on patient.
REPLACE SpO ₂ CABLE	The SpO ₂ cable is defective.	Replace the SpO ₂ cable.
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 shut down soon.	Connect monitor to AC power.

Message	Description	Corrective Action
REMOTE SYSTEM DISCONNECTED	Capnostream is no longer connected to a remote system. This message will only be present if enabled by the host computer, and may have different wording if so programmed by the host computer.	Check connection with remote system

Advisories

Table 17 - Advisories

Message	Description
CLEARING FILTERLINE	FilterLine kinked or clogged with water. Appears during clearing time until FilterLine is unclogged, or a blockage state is determined.
NO USB DEVICE FOUND	A valid flash memory device is not connected to the USB port.
USB FLASH FULL	No room on the USB flash memory device.
USB TIME OUT	USB communication stopped due to lack of response from the USB device.
SPO ₂ WEAK. REPOSITION SENSOR. SPO ₂ WEAK. TOO MUCH LIGHT. SPO ₂ WEAK. TRY EAR SENSOR. SPO ₂ WEAK. TRY NASAL SENSOR. SPO ₂ WEAK. TRY ADHESIVE SENSOR SPO ₂ WEAK. TRY USING HEADBAND SPO ₂ WEAK. SENSOR TOO COLD. SPO ₂ WEAK. CHECK BANDAGE. SPO ₂ WEAK. NAIL POLISH? SPO ₂ WEAK. SENSOR TOO TIGHT? SPO ₂ WEAK DUE TO INTERFERENCE. SPO ₂ WEAK. CLEAN SENSOR SITE.	SpO ₂ module detects a weak pulse and suggests possible causes.

Silent Advisories

Table 18 - Silent Advisories

Message	Description
CO ₂ WARM UP	CO ₂ module is preparing for operation.
CO₂ 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.
PERFORMING AUTOZERO	The monitor automatically performs a zeropoint calibration.
USB DATA TRANSFER IN PROGRESS	USB data communication in progress.
RS-232 DATA TRANSFER IN PROGRESS*	RS-232 data communication in progress.
USB DATA TRANSFER ABORTED	USB data communication has been stopped.
RS-232 DATA TRANSFER ABORTED	RS-232 data communication has been stopped.

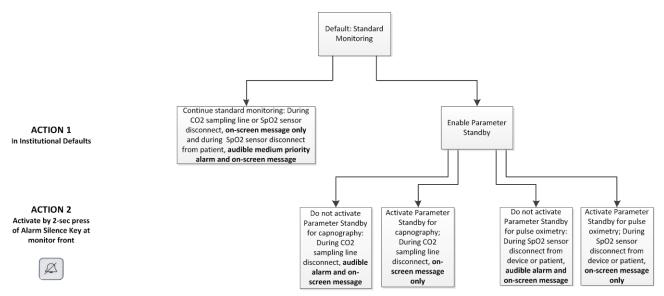
Message	Description
USB DEVICE FAILED	A USB device connected to the monitor has failed.
REPORT TRANSFER COMPLETE	Data communication is complete.
CO ₂ MONITORING HAS BEEN OFF FOR HH:MM	Displays the hours and minutes the pump has been turned off during PUMP OFF mode.
DEMO MODE - PRERECORDED DATA	Displayed during demo mode when no other message is displayed.
SPO2 LOW ALARM LIMIT: XX	Displayed if the SpO ₂ Low alarm limit is set below 85%.
REMOTE SYSTEM CONNECTED*	Capnostream is connected to a remote system. This message will only be present if enabled by the host computer, and may have different wording if so programmed by the host computer.
REMOTE SYSTEM DISCONNECTED*	Capnostream is no longer connected to a remote system. This message will only be present if enabled by the host computer, and may have different wording if so programmed by the host computer.
INCOMPATIBLE SOFTWARE VERSION	Displayed during transfer of institutional defaults
NO FILE FOUND	Displayed during transfer of institutional defaults
A/hr REQUIRES 1 HOUR OF DATA (if available)	A/hr does not appear, since one hour of data is required to compute this value, and one full hour of data is not yet available
ODI REQUIRES 1 HOUR OF DATA (if available)	ODI does not appear, since one hour of data is required to compute this value, and one full hour of data is not yet available
CO ₂ STANDBY	CO ₂ standby has been activated.
SPO ₂ STANDBY	SpO ₂ standby has been activated.
NO BATTERY INSTALLED	No battery is installed in the device

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

Parameter Standby Mode

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

The options are as follows:



In Standard Mode (when Parameter Standby Mode is not enabled), removing a FilterLine or SpO₂ sensor/extension cable from the device will cause a message to appear on the screen (*FILTERLINE DISCONNECTED* or *SpO₂ SENSOR DISCONNECTED*, as relevant) but no alarms will sound. Removing the SpO₂ sensor from patient will set off an audible alarm and an on-screen message. By default, Parameter Standby mode is disabled.

When Parameter Standby Mode is enabled, after a FilterLine has been connected and then removed from the device, a medium priority alarm *FILTERLINE DISCONNECTED* will sound. Likewise, after a pulse oximetry sensor/extension cable has been connected and then disconnected from the device, a medium priority alarm *SPO*₂ *SENSOR DISCONNECTED* will sound. The purpose of this alarm is to prevent unauthorized disconnection of a FilterLine/SpO₂ sensor from the device, perhaps by patients or patients' visitors.

When Parameter Standby Mode is enabled, removing the SpO₂ sensor from patient will set off an audible alarm and an on-screen message, as it does in Standard Mode.

Parameter Standby mode can be enabled by entering SYSTEM>SERVICE>Enter Service password>INST DEFAULTS>MONITOR>Turn PARAMETER STANDBY MODE to ENABLED. Return to the Home screen by clicking BACK>BACK>HOME.

However, there may be situations in which the clinician wants to use the Parameter Standby Mode but does not want these alarms to sound, for either a disconnected FilterLine or an SpO_2 sensor, because they have authorized the disconnection. For these situations, the monitor provides an option to put one or both parameters on standby while these activities take place.

Once Parameter Standby mode is enabled under institutional defaults, it can be made active as follows:

1. Remove the FilterLine and/or SpO₂ sensor from the device or remove the SpO₂ sensor from the patient.

Note: The capnography parameter standby mode can be made active only if the FilterLine Disconnected alarm is currently alarming, or if a FilterLine has not yet been connected to the device, since the time that it was turned on. Likewise, the pulse oximeter parameter standby mode can be accessed only if the SpO₂ Sensor Disconnected alarm or the SpO₂ Sensor Not on Patient alarm is currently alarming, or if an SpO₂ sensor has not yet been connected to the device or sensed a pulse, since the time it was turned on.

Note: The capnography parameter standby mode cannot be activated if the monitor is currently monitoring a patient with capnography. Likewise, the pulse oximeter parameter standby mode cannot be activated if

2. To activate Parameter Standby Mode, press the alarm silence button at the bottom of the front panel () for 2 seconds or longer. A new message CO_2 STANDBY and/or SPO_2 STANDBY (as required) will now appear in the waveform area (if the waveform area is available) and in the message area. (This is in addition

the monitor is currently monitoring a patient with pulse oximetry.

to the FILTERLINE DISCONNECTED or SPO₂ SENSOR DISCONNECTED or SpO₂ SENSOR NOT ON PATIENT alarms, as relevant, which will continue to appear in the waveform and message areas.)

A short press on the Alarm Silence button will still turn off the audible alarms temporarily (for 2 minutes), Note: as previously.

- 3. Once parameter standby is activated, the following will take place: In this mode, CO₂ and/or SpO₂ alarms do not exist, so neither audible alarms, the flashing yellow LED on the Capnostream front panel, storage of these alarms in any data storage method, nor transfer of these alarms to central stations, nurse call indications, etc., will take place.
- 4. To access both parameter standby modes at the same time, enter them one at a time, or press the Alarm Silence button (\swarrow) while the FilterLine is disconnected and the SpO₂ sensor is not connected to a patient or device, to enter both at the same time.

To exit the capnography parameter standby mode, reattach a FilterLine. To exit the pulse oximetry parameter standby mode, reattach the SpO₂ sensor to the patient and device. (Thus, if the user is unaware that the monitor is in the Parameter Standby mode, simply reattaching a FilterLine to the monitor or SpO₂ sensor to the patient will cause the monitor to exit the Parameter Standby mode and monitoring to resume.)

Table 19 - Message and Alarm Status during Different Parameter Standby Situations

Feature	Status when Parameter Standby mode disabled	Status when Parameter Standby mode enabled but not activated	Status when Parameter Standby mode enabled and Parameter Standby activated
FilterLine disconnected (from device) on-screen message / SpO ₂ sensor disconnected (from device) on-screen message	Yes	Yes	Yes
FilterLine disconnected (from device) alarm / SpO ₂ sensor disconnected (from device) alarm	No	Yes	No
SpO ₂ Sensor not on Patient Medium Priority audible alarm	Yes	Yes	No
SpO ₂ Sensor not on Patient on-screen message	Yes	Yes	Yes
CO ₂ Standby message / SpO ₂ Standby message	No	No	Yes
High Priority (patient) alarms	Yes	Yes	No(for the parameter in standby)
Flashing red and yellow LEDs on the Capnostream front panel during high Priority (patient) alarms	Yes	Yes	No, for the parameter in standby (since high priority [patient] alarms related to the parameter in standby do not exist in this case)
Storage or transfer to remote stations of high priority (patient) alarms	Yes	Yes	No, for the parameter in standby (since high priority [patient] alarms related to the parameter in standby do not exist in this case)

Alarm Silence

To temporarily silence/disable an alarm, press the alarm silence button: 4.



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.

If permanent alarm silence has been set in the Institutional Defaults (by clicking SYSTEM>SERVICE>Input Service password>INST DEFAULTS>AUDIO ALARM VOLUME >AUDIO OFF, see Changing

Institutional Defaults on page 119), this alarm silence button () does not set temporary alarm silence. Instead, while permanent alarm silence has been set in the Institutional Defaults, this button does not affect alarm silence; it will emit a wrong-key beep when pressed. When permanent alarm silence is set, the bell icon () will flash periodically.

WARNING:

Do not silence the audible alarms until you verify that the patient is being monitored by other means.

Changing Alarm Limits

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

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

Note:

In high-altitude environments, $EtCO_2$ values may be lower than values observed at sea level, as described by Dalton's law of partial pressures. When using the monitor in high-altitude environments, it is advisable to consider adjusting $EtCO_2$ alarm settings accordingly.

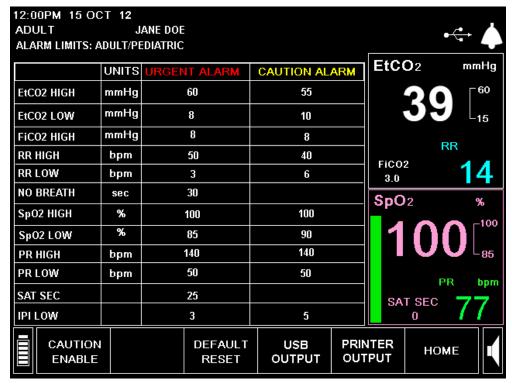


Figure 30 - Alarm Limits Screen

> TO CHANGE ALARM LIMITS:

- 1. Open the Alarm Limits screen by selecting the *ALARM LIMITS* button on the Menu bar at the bottom of the Alarm Review screen.
- 2. To modify a setting, scroll to the individual limit setting using the control knob. Click the control knob to select that setting, and then turn the control knob to select a new value. Click the control knob again to set the new value.
- 3. To enable caution alarms, click the *CAUTION ENABLE* button on the screen, using the control knob. The caution alarm limit values will now become active, and can be changed on this screen in the same manner as high priority patient (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 Institutional Defaults on page 119).

Note:

When the SpO_2 alarm limit is set below 85%, a message reading SpO_2 LOW ALARM LIMIT: xx will appear in the header area, indicating the level of the SPO_2 LOW alarm limit.

Testing 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.

In order to test the pulse oximetry SENSOR NOT ON PATIENT alarm, establish a display of SpO₂ values on the Monitor. Once SpO₂ values are displayed, remove the sensor from the test subject to create a SENSOR NOT ON PATIENT situation. The monitor should then display a SENSOR NOT ON PATIENT alarm.

SpO₂ Alarms and SatSeconds

Capnostream uses Nellcor's SatSeconds technology to help reduce the number and frequency of false SpO₂ alarms.

When monitoring upper and lower alarm limits of oxygen saturation, an audible alarm is triggered when one of these limits is violated by as little as one percentage point. In traditional alarm management, whenever the %SpO₂ level crosses the alarm limit, the alarm sounds every time the limit is exceeded.

If such frequent alarms are not desired, they can be prevented by using the SatSeconds technique developed by Nellcor. Using this technique, upper and lower alarm limits are set in the same way they are set in traditional alarm management. A SatSeconds limit can also be set, in order to sound an alarm while taking into account not only the crossing of the %SpO₂ alarm limit, but also the time for which the patient's %SpO₂ reading is above or below the limit.

The method of calculation is as follows:

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

Points x Seconds = SatSeconds

Where:

Points = %SpO₂ percentage points outside of the limit

Seconds = number of seconds the %SpO₂ remains at that point outside of the limit.

The alarm response time, assuming a SatSeconds limit set at 50 and the SpO₂ LOW alarm limit set at 90, is described and illustrated below.

In this example, the %SpO₂ level drops to 88 (2 points) and remains there for a period of 2 seconds (2 points x 2 seconds = 4 SatSeconds).

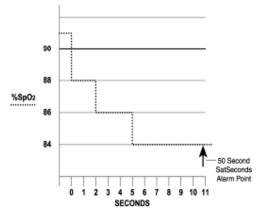
The %SpO₂ then drops to 86 for 3 seconds and then to 84 for 6 seconds.

The resulting SatSeconds are:

$%SpO_{2}$	Seconds		Seconds		SpO ₂ Sec		Sa	atSeconds
2	X	2	=	4				
4	X	3	=	12				
6	X	6	=	36				

Total SatSeconds = 52

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



Saturation levels may fluctuate rather than remain steady for a period of several seconds. Often, the %SpO₂ levels may fluctuate above and below the alarm limit, re-entering the non-alarm range several times.

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

SatSeconds Alarm Display

SatSeconds are displayed in the SpO₂ display area on the monitor screen. When SatSeconds is enabled and the SpO₂ reading is below the minimum, the SatSeconds counter will begin. If the SatSeconds limit is been reached, an audible alarm sounds and the displayed %SpO₂ numeric rate flashes. As with standard alarm management,

the audible alarm may be silenced by pressing the ALARM SILENCE button (\triangle).

Alarm Limits - Factory Defaults

The factory defaults for the Adult and Neonatal alarm limits are given in Table 29 - Factory Default Alarm/Indicator Limits on page 122.

Caution Alarms are disabled by default.

Using Trends

Introduction

The Trend Display Screens
Graphical Trend Display Screen
Tabular Trend Display Screen
Choosing Trend Parameters
Important Notes Regarding Trend Reports
Specific Events as seen in Trend Data
Using the Graphical Trend Screen for Monitoring Patients
Printing the Trend Data
Clearing Trend Memory
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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. Once trend contents reach maximum capacity, new data will overwrite the data recorded at the beginning of the stored trend data.

The trend data stores the following parameters:

- Time, Date, EtCO₂, RR, SpO₂, PR, IPI (where relevant)
- High priority red urgent alarms and yellow caution alarms
- Equipment-caused events such as CLEARING FILTERLINE or other monitor-related messages.
- Event markers input by the user, along with any event label.
- CASE START marker to indicate start of case
- Count of alarm occurrences (for all High Priority red urgent and yellow caution alarms)

Please note that A/hr and ODI (even if available) do not appear on the Trend screens or printouts. A/hr and ODI are recorded, and can be viewed, on the Apnea and O₂ Desaturation Report screen and printout. For more details, see Apnea and O₂ Desaturation Report on page 93.

Changing the resolution of how often data is stored can be done in the Institutional Defaults screen only (See Institutional Defaults on page 119).

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 12 Downloading Patient Data on page 103.

The Trend Display Screens

Trend data is displayed in two different formats; graphical and tabular. The Graphical Trend screen allows you to view the patient data over a longer time scale (2, 4 or 12 hours at a time) and scroll through the data looking for patterns, specific events or alarms.

Once you have located the data of interest, you can zoom in to the specific event, or examine the messages and data using the Tabular Trend screen. Tabular Trend presents the data in an easy to read table format.

In order to change the order of the displayed parameters on the Trend screens, see Changing Parameters Order on the Trend Display on page 123.

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 31 - Graphical Trend Display, below, is shown.

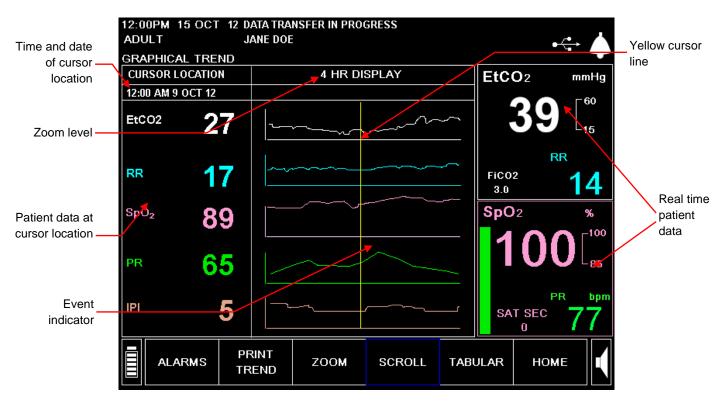


Figure 31 - Graphical Trend Display

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

Graphical Trend Display

In the center of the screen are the graphic trend displays. The upper two graphs show historic trend capnography data: $etCO_2$ in white and respiration rate values in blue. Similarly, the two middle graphs show the patient's

historic trend pulse oximetry data: SpO₂ data in pink and pulse rate values in green. The bottom graph shows IPI values in an orange-colored graph.

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

- Zoom level: Can be set to 2, 4 or 12 hours using the **ZOOM** key
- Yellow cursor line: The vertical yellow line extends through all four graphs and is movable with the control knob when the *SCROLL* option is selected. The cursor line shows the current location in the trend data, with the exact date and time listed under the *CURSOR LOCATION* heading near the top left of the screen as shown in Figure 31 Graphical Trend Display on page 84.
- Alarm indicator: wide vertical red lines (for red urgent alarms) and yellow lines (for yellow caution alarms) that may appear in the four graphs showing where in time an alarm occurred. For EtCO₂, SpO₂, 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 etCO₂ and RR graphs. The actual alarm details can be viewed in the Tabular Trend display screen, described in Tabular Trend Display Screen seen on page 87.
- 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 87.

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 87 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.

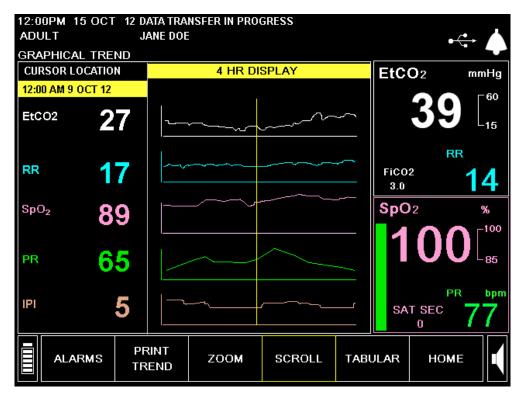


Figure 32 - Scroll mode in the Graphical Trend

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

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

To find an event or alarm occurrence, scroll the graphic display to look for event and alarm markers as shown above in Figure 31 - Graphical Trend Display on page 84. Place the yellow cursor line on the red alarm marker, then exit the scroll mode by clicking the control knob. When you zoom to a different time display, the cursor will appear in the middle of the graphical screen at the appropriate time that it marked on the previous screen.

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

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

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

To view more information about the displayed patient, use the control knob to select the *TABULAR* trend display on the Menu Bar, and see the instructions below in the section Tabular Trend Display Screen on page 87.

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.

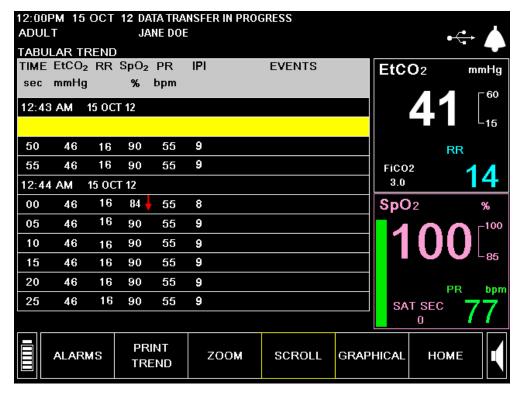


Figure 33 - Tabular Trend Display

- 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 Institutional Defaults on page 119 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.

PR ΙΡΙ TIME EtCO₂ RR SpO_2 **EVENTS** mmHg bpm % bpm 12:23 AM May 23 10 10 41 17 98 71 12:24 AM May 23 10 40 48 16 98 71 7 5* 12:26 AM May 23 10 1▲ 21* 10 49 16 98 70 7 12:27 AM May 23 10 40 17 71 7 22* 35 98 12:29 AM May 23 10 10 1 📥 22* 29 16 98 71 8 12:30 AM May 23 10

Table 20 - Tabular Display Example

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 high priority red urgent and yellow caution 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).

TIME sec	EtCO ₂ mmHg	RR bpm	SpO ₂ %	PR bpm	IPI	EVENTS
3:23 AM	May 23 10					
05	29	22	99	74	8	PROPOFOL
10	29	20	99	73	8	
15	29	20	100	71	8	
20	27	16	92	66	4	
25	26	14	88	64	4	
30	26	14	88	65	4	
35	26	14	88	65	4	
40	26	14	88	65	4	
45	26	14	88	65	4	
50	26	14	88	65	4	

Table 21 - Detailed Tabular Display Example

In the above example, oxygen was given to the patient during the period between 3:23:05 and 3:23:10 AM 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).

Choosing Trend Parameters

The device displays the following trend parameters: EtCO₂, RR, SpO₂, PR, and IPI. The desired order of the parameters can be set by the user using the Trend: Display Configuration screen (see Changing Parameters Order on the Trend Display on page 123 for details). If you do not want to view these parameters in Trend Reports, choose the BLANK option for some slots in the Trend: Display Configuration screen.

Important Notes Regarding Trend Reports

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

- Each number displayed in the trend memory is an average of the results for each second over the sampling period. For example, for a 30-second sampling period, the displayed result each 30 seconds is an average of the data points for each of the 30 seconds within the sampling period.
- If an alarm took place anywhere in the sampling period (i.e., at some point during the 30 seconds of a 30-second time period, when data is being recorded every 30 seconds) it will be noted, even if the averaged number recorded does not indicate a cause for an alarm.
- "EtCO₂ not available" is generated whenever a CO₂ self-maintenance occurs. This occurs one hour after turn-on, every 12 hours after that, and after a significant change in temperature or altitude. The CO₂ self-maintenance lasts approximately 10 seconds. During this process, etCO₂ and other physiological values are held at their values prior to the CO₂ self-maintenance.

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 34 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 34 - Trend Memory Message

Configuring Trends

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

Table 22 - Monitor Parameters

DATE	MAY 25, 2011
TIME	11:27:32 AM
LANGUAGE	ENGLISH

EVENT MARKING MODE	DETAILED
TREND GRAPHICAL DISPLAY [hour]	4 hour
TREND INCREMENT DISPLAY [min]	1.5 min
NURSE CALL	DISABLED
HOME SCREEN	STANDARD
HOME IPI DISPLAY (hour)	1 hour
IPI ALARM	DISABLED

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

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

Changing the resolution of how often data is stored can be done in the Institutional Defaults screen only (See Institutional Defaults on page 119).

Event Marking Mode

- Detailed Event Marking: When the Event button is pushed, you can enter a specific description of the event from a table of 30 user definable values (see the section Entering Patient Events on page 46).
- Quick Event Marking: Marks that an event occurred when the Event button is pushed, but does not give
 any details.

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

Trend Graphical Display

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

Trend Increment Display

Trend Increment Display options for the Tabular Trend Display are MINIMUM, 1.5, 3, 15 or 60 minutes. The factory default is 1.5 minutes. The MINIMUM setting is defined as the trend recording resolution and can be 5, 10 or 30 seconds (see Changing Institutional Defaults on page 119 for instructions on how to change the recording resolution).

Changing the resolution of how often data is stored can be done in the Institutional Defaults screen only (See Institutional Defaults on page 119).

Chapter 11

Reports

Apnea and O2 Desaturation Report Printed Report Options Printed Reports Sample Reports

When the user clicks on the *REPORTS* button on the Home screen, the Apnea and O_2 Desat (Desaturation) Report will appear on the screen. See Apnea and O_2 Desaturation Report, below for more information. To print other patient reports, click on the *PRINT REPORT* button on the Apnea and O_2 Desat Report screen. For more information, see Printed Reports on page 97.

If A/hr and ODI display is not available or disabled (either in Institutional Defaults or in the System Setup screen), or if the Patient Type is set to Infant/Neonatal or one of the Pediatric patient types, the *REPORTS* button will not appear. Instead, clicking the *PRINT* button on the Home screen will open the Print screen. For more information, see Printed Reports on page 97.

Apnea and O₂ Desaturation Report

The on-screen and printed Apnea and Desat reports show a comprehensive picture of the number of apnea and O_2 desaturation events over a set time period of 2, 4, 8, or 12 hours. They show the average A/hr and ODI score for the whole period as well as listing the number of events during each part of the set time period, with the apnea events listed by the number of seconds each event lasted. The sum of events in each row over the entire time period (2, 4, 8, or 12 hours, as chosen by the user) is also shown. These reports provide both details regarding the A/hr and ODI status of the patient and a general picture which can help the caregiver spot patient trends in these areas.

This report is available only for adult patients, since A/hr and ODI are available only for adult patients.

In situations in which part of the information for the set period is missing (for example, SpO₂ was not measured during a particular half hour during the 12 hours seen on the screen, so ODI could not be measured for that half hour) the relevant time section will be shaded in grey, to indicate the presence of missing data. If the first hour of monitoring has not yet been completed, the relevant time section on this screen will also be shaded in grey (since A/hr and ODI are per-hour indicators, they cannot be calculated and thus cannot be displayed if less than one hour of data is available).

Note:

This report is updated every 60 seconds. Since the A/hr and ODI numerics on the Home screen are updated once a second, there may be a slight temporary discrepancy between the numerics on the two screens from time to time.

Note:

The recommended use for this screen is that it be viewed when the caregiver wants to know more about the patient's apnea and O_2 desaturation events, or when an indicator on the Home screen indicates that the report should be viewed. While the report is being displayed on the monitor screen, the display is not updated, so it is best not to continually view this report on the monitor, but to continuously view the Home screen while monitoring a patient. The EtCO₂, FiCO₂, RR, SpO₂, and PR numerics are all updated continuously on all screens, including the A/hr and O2 Desat Report screen.

The Apnea and O_2 Desat Report screen is reached with the *REPORTS* button on the menu on the Home screen. The Print Report seen on the Print Report screen may be printed from the Apnea and O_2 Desat Report screen with the built-in Capnostream printer (using the *START PRINTER* button), or saved to a USB flash memory drive (using the *START USB* button).

Soft buttons on the Apnea and O₂ Desat Report screen are as follows:

- TREND to graphical trend screen
- PRINT brings user to the standard print screen
- ZOOM changes the time period viewed on the screen to another option. Options are 2, 4, and 12 hours.
- SCROLL moves the cursor across the screen so that different time intervals can be viewed
- PRINT REPORT brings user to the Apnea and O₂ Desat Report: Print Report screen.

The information provided in the Apnea and O₂ Desat Report saved to a USB flash memory drive is as follows:

Report Name	Description	Fields Included
Apnea and O ₂ Desat	Tab delimited file with the suffix .txt. Reports A/hr and ODI data and all trend data for the previous 2, 4, 8, or 12 hours (depending on selected ZOOM level).	DATE, TIME, CASE ID, Patient type, ZOOM selected
Report		Apnea Count and Desat Count for each of the time periods on the report, summation of Apnea count and Desat Count for the entire period, and average A/hr and ODI scores
		Patient Readings: EtCO ₂ , RR, SpO ₂ , PR, IPI
		Patient Urgent Alarm Occurrences: EtCO ₂ HIGH, EtCO ₂ LOW, RR HIGH, RR LOW, NO BREATH, SpO ₂ HIGH, SpO ₂ LOW, PR HIGH, PR LOW, IPI LOW
		Equipment Advisory Message Occurrences:
		Events: EVENT 1, EVENT 2, EVENT 3

The printed Apnea and O₂ Desat Report includes the following information:

Report Name	Description	Fields Included
Apnea and O ₂ Desat Report	A/hr and ODI data along with patient readings (as seen in trend report) and graphical trend data. Report with show data for the previous 2, 4, 8, or 12 hours	DATE, TIME, CASE ID, Patient type, ZOOM selected, summation of Apnea count and Desat Count for the entire period, average A/hr and ODI scores for the period, and Apnea Count and Desat Count for each of the time periods on the report.
	(depending on selected ZOOM level).	Patient Readings: EtCO ₂ , RR, SpO ₂ , PR, IPI
		Patient Graphical Trend graphs: EtCO ₂ , RR, SpO ₂ , PR, IPI

An example of the printed Apnea and O₂ Desat Report appears in Figure 36 - Apnea and Desat Printed Report on page 96.

An example of the Apnea and O₂ Desat Report screen is seen in Figure 35 - Apnea and Desat Report Screen on page 95.

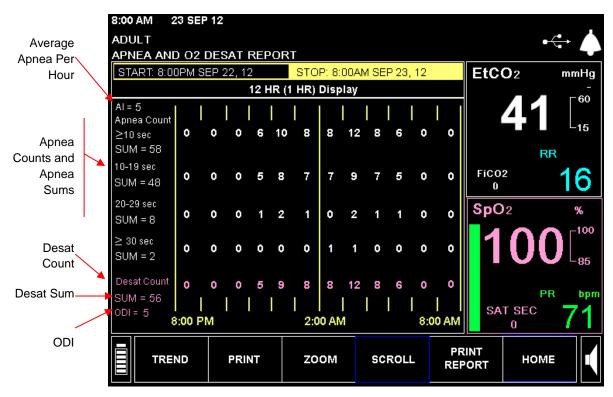


Figure 35 - Apnea and Desat Report Screen

Patient Information Seen on Screen	Explanation
A/hr (Apneas per Hour)	Average A/hr per hour over entire time period which appears on the screen
Apnea Count	Sum of all instances of No breath (apnea) in each time category (≥10 seconds, 10-19 seconds, 20-29 seconds) over the entire time period which appears on the screen
SUM(Apnea sum)	Number of instances of no breath (apnea) in each time category (≥10 seconds, 10-19 seconds, 20-29 seconds) in each of the intervals within the relevant time period (in this case, 12:00 AM to 1:00 AM)
Desat Count	Sum of all instances of Desat over the entire time period which appears on the screen
SUM(Desat sum)	Number of instances of Desaturation in each of the intervals within the relevant time period (in this case, 12:00 AM to 1:00 AM)
ODI	Average ODI per hour over entire time period which appears on the screen

APNEA AND	APNEA AND O2 DESAT REPORT				
PRODUCT IDENTIFICATION CS20P B646113042					
CASE ID: ADULT	CASE ID: ANN SIMON ADULT				
ZOOM SELE	CTED: 12 Hours	5			
START: STOP:	8:00 PM 8:00 AM	SEP 22, 12 SEP 23, 12			
Apnea Count	t (sec)				
≥ 10	-	58			
10 - 1		48			
20 - 2	29 -	8			
≥ 30	-	2			
Desat Count	-	58			
A/hr Over 12		5			
ODI Over 12	Hours -	5			
		Apnea	Desat		
		Count	Count		
		Count			
		≥ 10			
CED 22 42					
SEP 22, 12	0.00 PM	≥ 10 sec			
8:00 PM	9:00 PM	≥ 10 sec	0		
8:00 PM 9:00 PM	10:00 PM	≥ 10 sec 0 0	0 0		
8:00 PM 9:00 PM 10:00 PM		≥ 10 sec	0		
8:00 PM 9:00 PM 10:00 PM SEP 23, 12	10:00 PM 11:00 PM	≥ 10 sec 0 0	0 0 0		
8:00 PM 9:00 PM 10:00 PM SEP 23, 12 11:00 PM	10:00 PM 11:00 PM 12:00 AM	≥ 10 sec 0 0 0	0 0 0		
8:00 PM 9:00 PM 10:00 PM SEP 23, 12 11:00 PM 12:00 AM	10:00 PM 11:00 PM 12:00 AM 1:00 AM	≥ 10 sec 0 0 0 0	0 0 0 5 9		
8:00 PM 9:00 PM 10:00 PM SEP 23, 12 11:00 PM 12:00 AM 1:00 AM	10:00 PM 11:00 PM 12:00 AM 1:00 AM 2:00AM	≥ 10 sec 0 0 0 0	0 0 0 5 9		
8:00 PM 9:00 PM 10:00 PM SEP 23, 12 11:00 PM 12:00 AM 1:00 AM 2:00 AM	10:00 PM 11:00 PM 12:00 AM 1:00 AM 2:00AM 3:00 AM	≥ 10 sec 0 0 0 0 6 10 8 8	0 0 0 5 9 8		
8:00 PM 9:00 PM 10:00 PM SEP 23, 12 11:00 PM 12:00 AM 1:00 AM	10:00 PM 11:00 PM 12:00 AM 1:00 AM 2:00AM	≥ 10 sec 0 0 0 0	0 0 0 5 9		
8:00 PM 9:00 PM 10:00 PM SEP 23, 12 11:00 PM 12:00 AM 1:00 AM 2:00 AM 3:00 AM	10:00 PM 11:00 PM 12:00 AM 1:00 AM 2:00AM 3:00 AM 4:00 AM	≥ 10 sec 0 0 0 0 6 10 8 8	0 0 0 5 9 8 8		
8:00 PM 9:00 PM 10:00 PM SEP 23, 12 11:00 PM 12:00 AM 1:00 AM 2:00 AM 3:00 AM 4:00 AM	10:00 PM 11:00 PM 12:00 AM 1:00 AM 2:00AM 3:00 AM 4:00 AM 5:00 AM	≥ 10 sec 0 0 0 0 6 10 8 8 12 8	0 0 0 5 9 8 8 12 8		
8:00 PM 9:00 PM 10:00 PM SEP 23, 12 11:00 PM 12:00 AM 1:00 AM 2:00 AM 3:00 AM 4:00 AM 5:00 AM	10:00 PM 11:00 PM 12:00 AM 1:00 AM 2:00AM 3:00 AM 4:00 AM 5:00 AM 6:00 AM	≥ 10 sec 0 0 0 6 10 8 8 12 8 6	0 0 0 5 9 8 8 12 8 6		
8:00 PM 9:00 PM 10:00 PM SEP 23, 12 11:00 PM 12:00 AM 1:00 AM 2:00 AM 3:00 AM 4:00 AM 5:00 AM 6:00 AM	10:00 PM 11:00 PM 12:00 AM 1:00 AM 2:00AM 3:00 AM 4:00 AM 5:00 AM 6:00 AM 7:00 AM	≥ 10 sec 0 0 0 6 10 8 8 12 8 6 0	0 0 0 5 9 8 8 12 8 6		

Figure 36 - Apnea and Desat Printed Report

Printed Report Options

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 103). The report can then be formatted and printed using the computer.

The following printed reports are available:

- Tabular Case Report
- Graphical Case Report
- Tabular Trend Report
- Graphical Trend Report
- Real Time Continuous Waveforms
- Real Time Continuous CO₂ Waveform
- Real Time Continuous Tabular

The printed Apnea and O₂ Desat Report (if available) is discussed above.

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

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

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

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

Printed Reports

The Print screen is accessed from the Apnea and O_2 Desat Report screen (if A/hr and ODI are enabled) or the Home screen (if A/hr and ODI is not available or not enabled).

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 *REPORTS*.
- 2. On the Apnea and O₂ Desat screen which will appear, select *PRINT* to display the Print screen seen in Figure 37 Print Screen on page 98.
- 3. For Infant/Neonatal patients, select *PRINT* on the Home screen to view the Print screen.
- 4. 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.

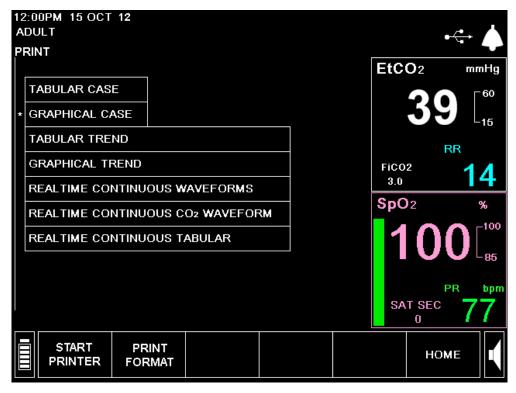


Figure 37 - Print Screen

5. 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.

For tabular reports, EtCO₂, FiCO₂, RR, SpO₂, PR, IPI, and blank are available for selection. For graphical reports, EtCO₂, RR, SpO₂, PR, IPI, and blank are available for selection. Selecting blank means that nothing will be printed in that column.

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

Table 23 - Fillited Reports - Farameters				
Report Name	Description	Fields Included	Time Frame of Report	
All reports		CS20P (this indicates that the report was generated by a Capnostream20P) Serial number of the device on which the		
		report was printed Name of Report (TREND REPORT, CASE REPORT or REAL TIME REPORT)		
		Patient Type (ADULT, PEDIATRIC [3 age ranges] or INFANT/NEONATAL) Case ID		
		DATE, TIME		
Tabular Case Report	Patient readings of recorded case in tabular format. The time	Patient Readings at start and end of recording period: EtCO ₂ , FiCO ₂ , RR, SpO ₂ , PR, IPI.	From start of case until current time; once case is stopped, data is not	

Table 23 - Printed Reports - Parameters

Report Name	Description	Fields Included	Time Frame of Report
	between data entries is the lowest resolution available for trend increment display (30 seconds).	Patient Readings: Three of the following parameters (according to parameters chosen in the PRINT FORMAT screen, see To print a report on page 97): EtCO ₂ , FiCO ₂ , RR, SpO ₂ , PR, IPI. Patient Urgent and Caution Alarm	available
		Occurrences All patient urgent and caution alarms	
		Equipment Advisory Message Occurrences	
0 1: 10	D. (1. 1. 1. 1. 1.	Events: EVENT 1, EVENT 2, EVENT 3	
Graphical Case Report	Patient readings of recorded case in graphical format. The	Patient Readings at start and end of recording period: EtCO ₂ , RR, SpO ₂ , PR, IPI.	From start of case until current time; once case is stopped, data is not available
	time between data entries is the lowest resolution available for trend increment display (30 seconds).	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 97) at 30-second intervals: EtCO ₂ (mmHg), RR (bpm), SpO ₂ (%), PR (bpm), IPI.	avallable
Tabular Trend Report	Patient readings of trend memory in tabular format. The time	DATE, TIME	Trend data as appears on the trend screen which is currently displayed, or, if
	between data entries is the resolution set for trend increment display (MINIMUM [30	Patient Readings at start of recording period: EtCO ₂ , FiCO ₂ , RR, SpO ₂ , PR, IPI.	printing from the PRINT screen, the trend screen which was most recently displayed. Only the data
	seconds], 1.5 minutes, 3 minutes, 15 minutes, 60 minutes).	Patient readings at intervals set for trend increment display: Three of the following parameters (according to parameters chosen in the PRINT FORMAT screen, see To print a report on page 97): EtCO ₂ , FiCO ₂ , RR, SpO ₂ , PR, IPI.	points currently visible on the screen (approximately ten data points) will be printed. Thus, the ZOOM level on the trend screen (choices are 2, 4, and 12
		Patient Urgent and Caution Alarm Occurrences	hours), will determine the number of minutes/hours of data seen in the printout.
		Equipment Advisory Message Occurrences	Once trend is erased, data is not available.
		Events: EVENT 1, EVENT 2, EVENT 3	is not available.
Graphical Trend Report	Patient readings of trend memory in graphical format. The time between data entries is the resolution set for trend increment display (MINIMUM [30 seconds], 1.5 minutes, 3 minutes, 15 minutes, 60 minutes).	Patient Readings at start of recording period: EtCO ₂ , RR, SpO ₂ , PR, IPI. 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 97) at interval set for trend increment display: EtCO ₂ , RR, SpO ₂ , PR, IPI.	Trend data as appears on the trend screen which is currently displayed, or, if printing from the PRINT screen, the trend screen which was most recently displayed. Thus, the ZOOM level on the trend screen (choices are 2, 4, and 12 hours), will determine the number of hours of data seen in the printout. 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

Report Name	Description	Fields Included	Time Frame of Report
Real Time Continuous CO ₂ Waveform	Graphical presentation of levels of etCO ₂ , with a data point every 50 milliseconds	Patient Readings at start of recording period: etCO ₂ , FiCO ₂ , RR, SpO ₂ , PR.	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, IPI. Three of the following parameters (according to parameters chosen in the PRINT FORMAT screen, see To print a report on page 97): EtCO ₂ , FiCO ₂ , RR, SpO ₂ , PR, IPI.	Real-time data from time START PRINTER is pressed to time STOP PRINTER is pressed

^{*} Please note that, in all cases, EtCO₂ and FiCO₂ are displayed in selected units, SpO₂ 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.

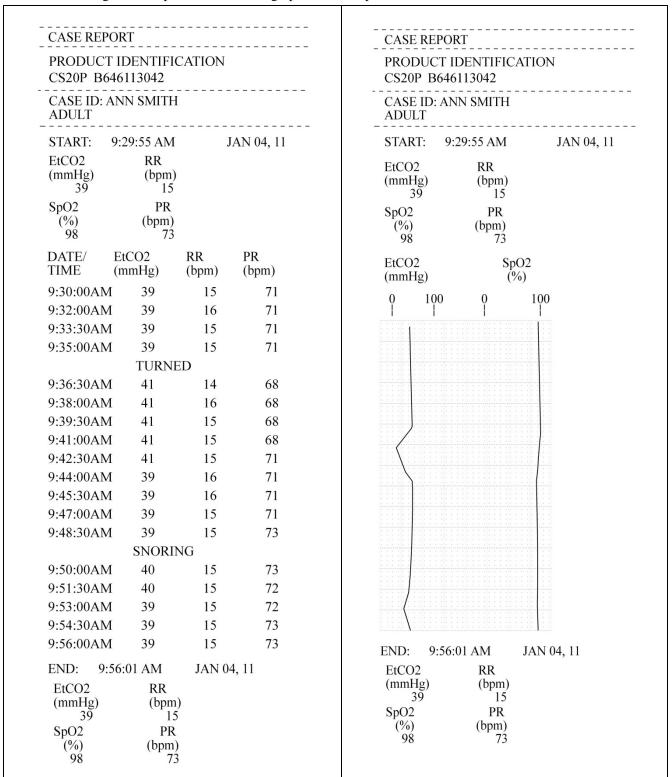


Figure 38 - Sample Case Reports Printout

Sample Trend Reports

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

REND REPOR PRODUCT ID CS20P B6461	ENTIFI	CATION			REPORT CT IDENTIFICAT 3646113042	ION
CS20P B0401 CASE ID: ANN ADULT		I			: ANN SMITH	
				START:	9:29:55 AM	JAN 04, 11
START: 9:19 EtCO2	9:55 AM RR	. J	AN 04, 11			JAN 04, 11
(mmHg) 39	(bpm) 15			EtCO2 (mmHg) 39	RR (bpm) 15	
SpO2 (%) 98	PR (bpm) 73			SpO2 (%) 98	PR (bpm)	
	CO2 nHg)	RR (bpm)	PR (bpm)	EtCO	O2 S	SpO2 (%)
9:20:00AM	39	15	71	0	100 0	100
9:22:00AM	39	16	71	ľ	100 0	100
9:23:30AM	39	15	71	[: : : [] :		
9:25:00AM	39	15	71			
	TURN		, ,			
9:26:30AM	41	14	68			
9:28:00AM	41	16	68			
9:29:30AM	41	15	68			
9:31:00AM	41	15	68			: <u> </u>
):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			
	SNORI	NG				
):40:00AM	40	15	73			
):41:30AM	40	15	72			
9:43:00AM	39	15	72	(::::/:::		
9:44:30AM	39	15	73	1		
9:46:00AM	39	15	73			
9:47:30AM	40	15	72			
):49:00AM	39	15	72			
0:50:30AM	39	17	73			
):52:00AM	39	16	73			
):53:30AM	40	16	72			
):55:00AM	39	15	72			

Figure 39 - Printed Trend Reports

Downloading Patient Data

Introduction

Data Transfer via the USB Data Port
Data Transfer via the RS-232 Port
Analog Data Output with Capnostream
Nurse Call Operation
Types of Nurse Call Systems

Operation with Hospital Patient Data Systems

Operation with Nuvon VEGA Systems

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 (this feature is no longer available)

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

Data Transfer via the USB Data Port

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

In addition, the Apnea and O₂ Desat Report (if A/hr and ODI are available) can be downloaded to a USB flash memory device. See Apnea and O₂ Desaturation Report on page 93 for more information.

All A/ hr and ODI alarms will not be recorded when A/hr and ODI are not available.

Table 24 - Data Transfer Types

Report Name	Description	Fields Included
Tabular Case Report	Tab delimited file with the suffix .txt. (Tab	DATE, TIME
	delimited files can be exported into Excel using "tab" as the delimiter.) Reports the	Patient Readings: EtCO ₂ , RR, SpO ₂ , PR, IPI.
	data stored in trend memory that is	Patient Urgent and Caution Alarm Occurrences
	assigned to the selected case. The time between data entries is the resolution set for trend storage (5, 10 or 30 seconds).	Equipment Advisory Message Occurrences
		Events: EVENT 1, EVENT 2, EVENT 3
Tabular Trend Report	Tab delimited (.txt) file. Reports all the data	DATE, TIME
	stored in trend memory. The time between data entries is the resolution set for trend storage (5, 10 or 30 seconds).	Patient Readings: EtCO ₂ , RR, SpO ₂ , PR, IPI.
		Patient Urgent and Caution Alarm Occurrences
		Equipment Advisory Message Occurrences
		Events: EVENT 1, EVENT 2, EVENT 3

Report Name	Description	Fields Included
Real Time Continuous CO ₂ Waveform	Tab delimited (.txt) file with data entries every 50 milliseconds.	DATE, TIME
		Patient Reading every 50 milliseconds (for creating CO ₂ waveform): CO ₂ *
Real Time Continuous	Tab delimited (.txt) file, similar to the	DATE, TIME
Tabular	Tabular Trend report, but transmitted line by line in real time.	Patient Readings: EtCO ₂ , FiCO ₂ , RR, SpO ₂ , PR, IPI, A/hr, ODI.
		Patient Urgent and Caution Alarm Occurrences
		Equipment Advisory Message Occurrences
		Events: EVENT 1, EVENT 2, EVENT 3
Real Time Continuous	Tab delimited (.txt) file, similar to the real time continuous tabular report, transmitted line by line in real time, but with data entries every 50 milliseconds (20 times a second). CO ₂ data which can be used to create a real-time continuous waveform is shown, with data entries every 50 milliseconds. Tabular data is recorded at data points	DATE, TIME
Tabular with real-time continuous waveform (shortened name is		Patient Readings (at trend storage resolution): EtCO ₂ , FiCO ₂ , RR, SpO ₂ , PR, IPI, A/hr, ODI
FULL CONTINUOUS		Patient Urgent and Caution Alarm Occurrences
TRANSFER)		Equipment Advisory Message Occurrences
		Events: EVENT 1, EVENT 2, EVENT 3
	based on the resolution set for trend storage (5, 10 or 30 seconds), so data between these points is repeated on additional rows.	Patient reading every 50 milliseconds (for creating CO ₂ waveform): CO ₂ wave
Full Binary Continuous Transfer	See the document Capnostream Data Transfer Protocols	
Full Binary Trend Transfer	See the document Capnostream Data Transfer Protocols	

* CO₂ in mm/Hg (millimeters of mercury)

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

- Line 1 The name of the report type.
- Line 2 Blank, or Patient ID if the report is a case report
- Line 3 Patient type (see Setting the Patient Type on page 43 for information on patient types)
- Line 4 Blank
- Line 5 Column headings
- Line 6 Column headings second line

Capnostream recognizes flash memory drive devices manufactured by SanDisk, Lexar, and PNY Technologies. It will not recognize flash memory drives that have advanced capabilities which require the installation of additional drivers, such as the SanDisk U3. The capacity limit for a USB drive that can be used with Capnostream is 8 GB. A typical flash memory device is shown below.



Figure 40 - 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 up to 40 seconds.



Figure 41 - 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.

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

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

Table 25 - Select Data Output Type

TABULAR CASE
TABULAR TREND
REALTIME CONTINUOUS CO2 WAVEFORM
REALTIME CONTINUOUS TABULAR
FULL CONTINUOUS TRANSFER
FULL BINARY CONTINUOUS TRANSFER
FULL BINARY TREND TRANSFER

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

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

Note: If the Capnostream does not detect the Flash Memory drive, remove and re-insert the Flash Memory drive. If the Flash Memory drive is still not detected, check that drive being used is from a supported

manufacturer.

Note: 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.

transfer CANNOT be initiated under the low disk space condition.

Note: Please note additional details regarding trend reports in Important Notes Regarding Trend Reports on

page 89.

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

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

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

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

Real time Continuous CO₂ Waveform: 1 hour @50ms resolution: 4.2MB

Real time Continuous Tabular: 1 hour @2s resolution: 264kB Full Continuous Transfer: 1 hour @50ms resolution: 12MB

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

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

USB File Naming Convention

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

- REPORT TYPE three-letter report type identifier (see Table 26 File Naming Conventions).
- PATIENT TYPE patient type (Adult, Pediatric 6-12 yrs, etc).
- 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.
- PATIENT ID Patient ID as inputted into the device (or automatically supplied by the device).
- FILE NO a running serial number that indicates if the data was split into multiple files.
- File extension .ext is .txt (tab delimited file type) or .bin (binary file type).

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

File Name Examples:

For different reports taken on January 15, 2011 at 5:23:57 for the patient with Patient ID "20090115035705", the file names would be:

Report type	File name
Tabular Case Report	TCR_ADULT_110115_052357_20110115035705_1.txt
Tabular Trend Report	TTR_ ADULT _110115_052357_20110115035705_1.txt
Real-time Continuous CO ₂ Waveform	RCW_ ADULT_110115_052357_20110115035705_1.txt
Real-time Continuous Tabular	RCT_ ADULT _110115_052357_20110115035705_1.txt
Full Continuous Transfer	FCTR_ ADULT _110115_05235720110115035705_1.txt
Full Binary Continuous Transfer	FCT_ ADULT _110115_052357_20110115035705_1.bin
Full Binary Trend Transfer	FTT_ ADULT _110115_052357_20110115035705_1.bin
Apnea and O ₂ Desat Report (if available)	ADR_ ADULT _110115_052357_20110115035705_1.txt

Table 26 - File Naming Conventions

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_110115_052357_1.txt RCT_110115_052357_2.txt

RCT_110115_052357_3.txt RCT_110115_052357_4.txt ...
RCT_110115_052357_10.txt ... RCT_110115_052357_100.txt ...

RCT_110115_052357_1000.txt

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

MS Excel.

USB Error Messages

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

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

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

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

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

Reading Patient Data from Saved Capnostream Files

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

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

Data Transfer via the RS-232 Port

Capnostream is equipped with a 9-pin RS-232 connection on the back of the monitor. For detailed information on the use of this feature, please refer to the document *Capnostream Data Transfer Protocols*, available on the Operator's Manual CD. The data transfer rate for the RS-232 interface is set in the Institutional Defaults: Monitor screen. The factory default is automatic detection of the data transfer speed. See Changing Institutional Defaults on page 119 for information on how to change the data transfer rate.

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

Note:

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

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

Analog Data Output with Capnostream

A digital/analog connection feature is no longer available with Capnostream. Please disregard the digital/analog (D/A) screens in the device software.

Nurse Call Operation

The Capnostream monitor allows connection to an external Nurse Call system. When connected, the monitor sends information to the institutional nurse call system that an alarm condition has occurred, alerting medical personnel that the patient requires medical care. The only data transferred to a Nurse Call system is alarm data, as described in Table 28 - Nurse Call Indicators on page 109.

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 27 - 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 42 - Stereo Phono Plug for Nurse Call

A diagram of pin-out of mating stereo phono plug appears in Figure 42 - 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.

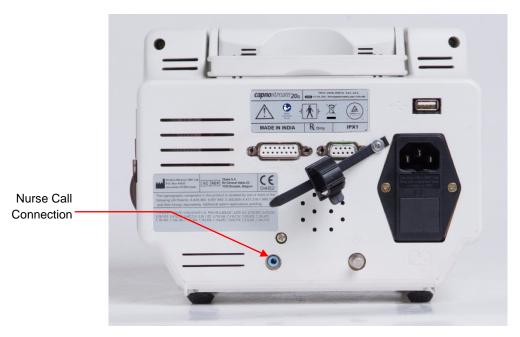


Figure 43 - Connection Point for Nurse Call

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 Capnostream Service Password on page 139).
- 2. From the SERVICE screen, select *INST DEFAULTS* (Institutional Defaults) and then select *MONITOR*.
- 3. Use the control knob to select *NURSE CALL*, and change the option to *ENABLED*.
- 4. Select BACK, BACK and HOME to exit the Service mode. The new setting is now stored.
- 5. Test the Nurse Call system as described in Testing Nurse Call, below.
- 6. Please note that Nurse Call data will not be transferred if alarms have been silenced temporarily (by the Alarm Silence button at the front of the monitor). See Alarm Silence on page 78 for details regarding this feature. Nurse Call data will still be transferred if alarms are silenced through Institutional Defaults (see Institutional Defaults on page 119).

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 28 - Nurse Call Indicators

Alarm Type	Activates Nurse Call
High Priority (Red) Urgent Patient Alarms	YES
(Yellow) Caution Alarms	NO

Medium 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. The system is used with a Y-cable attaching the client bridge, the Capnostream, and wall power. Ensure that all connectors are securely attached so that the Capnostream continues to receive wall power during operation with this system.

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 CO₂
- EtCO₂
- FiCO₂
- Resp rate
- SpO_2
- Pulse

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

An outbound vital signs interface to a clinical information system as well as an ADT (admit, discharge & transfer) inbound interface is also available from the Bernoulli system.

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

CAUTION: If connectivity with the Hospital Patient Data System fails as a result of a fault in the

Hospital Patient Data System or its cabling, Capnostream will not send data to the system.

CAUTION: Only turn off the Capnostream audible alarm indication after assuring that the patient will

be continuously monitored by other acceptable means.

Operation with Nuvon VEGA Systems

The Capnostream can also connect with the VEGA system from Nuvon for the purposes of interfacing to clinical information systems to electronically chart patient vital signs.

Capnostream connection to the VEGA system is completely accomplished by the Nuvon implementation specialist on site with the assistance of an assigned hospital IT department representative. All physiologic patient data developed by the Capnostream is sent to the VEGA system to be used by the clinical information system. For more information regarding the Nuvon VEGA system contact an Oridion sales representative or a Nuvon sales representative directly.

Maintenance and Troubleshooting

Introduction

Determining Monitor Service Hours

CO₂ Calibration

CO₂ Calibration Check

Maintenance

Replacing the Fuses

Replacing the Printer Paper Roll

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Troubleshooting

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Technical Assistance

Introduction

Capnostream requires no routine service other than any performance testing mandated by the operator's institution. The monitor requires servicing by qualified service personnel only once every 30,000 operating hours.

The monitor's CO₂ detection mechanism should be periodically calibrated as detailed below in CO₂ Calibration on page 112. CO₂ calibration can be checked at any time to ensure the calibration is within proper operating limits.

Troubleshooting on page 116 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.

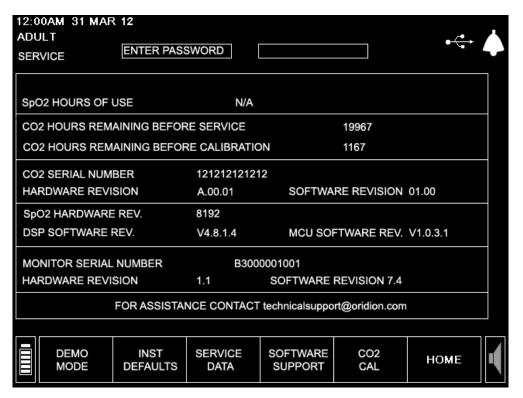


Figure 44 - Service Screen

When the monitor reaches 30,000 hours of use, send it to an authorized service center. Contact your local representative for shipping instructions.

CO₂ Calibration

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

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

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

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

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

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

CO₂ monitoring on the Capnostream monitor will enter standby mode automatically in cases when the Capnostream monitor is left on for 30 minutes or longer without a FilterLine attached. This automatic standby mode reduces the need for frequent calibration in use cases in which the monitor is left on for long periods of time without a FilterLine attached. In these cases, time periods in which a monitor is turned on but a FilterLine is not attached will not count towards time to calibration, thus preventing the need for unnecessary calibrations.

Note:

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 CO_2 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.

CO₂ Calibration Check

Depending on institutional policy and procedure, the monitor can be checked at any time to determine if CO₂ 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% CO₂ 21% O₂ and Bal N₂ and the authorized connecting means ("T" piece).

A manufacturer-approved Calibration Kit can be purchased from Scott Medical (part number T4653 ORF-2BD). It includes:

- Calibration Gas containing 5% CO₂, 21% O₂ Bal N₂
- 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 Note:

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 CO₂ 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 CO₂ 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% CO₂ 21% O₂ BALANCE N₂]. 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 CO₂ 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 CO2 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 CO*₂ *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 116 discusses potential difficulties, their possible causes, and suggestions for resolving them.

Periodic maintenance is recommended according to operating hours:

- The CO₂ Pump should be replaced every 30,000 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 112).
- The monitor's number of hours remaining until the 30,000 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 and disconnect the power cord from the monitor.

The fuses are located in the back of the monitor below 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 131.

➤ 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 45 - 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.

To clean Nellcor reusable sensors, first remove the sensor from the patient and disconnect it from the Capnostream device. The sensor may be surface-cleaned with a solution such as 70% isopropyl alcohol. If low-level disinfection is required, use a 1:10 bleach solution. Do not use undiluted bleach (5%~5.25% sodium hypochlorite) or any cleaning solution other than those recommended here, because permanent damage to the sensor could occur. The ear clip sensor may be cleaned by wiping or soaking it (for 10 minutes) in isopropyl alcohol (70%). If the ear clip is soaked, be sure to rinse it with water and air dry it prior to use on the next patient. Do not sterilize the ear clip by irradiation, steam, or ethylene oxide. Please refer to the DFU for each reusable sensor for specific instructions.

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® etCO₂ consumables are designed for single patient use and are not to be reprocessed. Do not attempt to clean, disinfect or blow out the FilterLine as the monitor can be damaged.
 CAUTION: Do not expose SpO₂ sensor connector pins to cleaning solution as this may damage sensor.

If a 1:10 bleach dilution (0.5% to 1% Sodium Hypochlorite solution) in the form of wipes is used to disinfect external surfaces of the monitor, exposure of the connectors and the display to the bleach solution should be avoided. Repeated cleaning with bleach over time may cause discoloration and residue on the surfaces.

Troubleshooting

CAUTION:

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.
	AC wall outlet has no power and internal battery is not charged.	Check connections and correct problem.
	Blown fuses.	Replace the fuses. Contact your representative to determine the reason for the electrical problem.
AC mains power and monitor on indicator lights are on, but unit will not operate on battery power when the AC mains power cable is disconnected.	Battery pack not plugged in to monitor.	Open the battery housing and check that the battery pack cable is firmly connected to the battery socket. (See Installing the Battery Pack on page 22)
Monitor is plugged in, but does not appear to charge the battery.	AC power not getting to the monitor.	Check if the orange power indicator light is on. If not, check that the AC power cord is properly plugged in to a live AC mains socket.
Battery is not fully charged after being plugged in for 24 hours.	Battery pack has not recharged completely.	Unplug the monitor from AC power for 3-4 hours, and then plug in again. The battery pack will now recharge completely when connected to AC power. If the battery pack still does not recharge completely, replace the battery pack.

CO₂ Problems

Problem	Cause	Action
NO BREATH message	Physiological cause.	Check patient.
appears constantly and red alarm indicator	Clogged or blocked FilterLine.	Check FilterLine and replace if blocked.
flashes.	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	FilterLine not plugged in properly.	Check that the FilterLine plug is screwed into

Problem	Cause	Action
but pump is not working		the monitor.
and no CO ₂ , EtCO ₂ or RR readings are shown.	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	Improper calibration.	Check calibration. See CO2 Calibration Check on page 113.
lower than expected.	BTPS setting turned off.	Check BTPS setting in the institutional settings. See CO2 Parameters on page 126 for details.

SpO₂ 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.
Replace SpO ₂ sensor message appears on Capnostream screen	SpO ₂ board is not receiving information from the cable.	Detach and reattach the SpO ₂ sensor and try again. If the message still appears, replace the cable or sensor.
Loss of pulse or SpO ₂ signal: Zero display	Sensor is improperly applied to patient.	Check sensor application.
appears for oxygen saturation and pulse rate.	Patient's perfusion may be too poor.	Check the condition of the patient.
rate.	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.

CO₂ Calibration

Problem	Cause	Action
CALIBRATION REQUIRED message appears on the monitor, but salutation screen shows there are still hours remaining before next calibration.	It has been more than one year since the last CO ₂ calibration.	Perform a CO ₂ calibration.

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 package the monitor with an unused consumable from the same box or lot as the consumable used at the time of malfunction and return it with the monitor for inspection.

Technical Assistance

For technical information, contact your local Oridion representative or write to Capnographytechnicalsupport@covidien.com.

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

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

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

Appendix 1

Institutional Settings

Institutional Defaults
Changing Institutional Defaults
Resetting to Factory Defaults
Uploading or Downloading Institutional Defaults
Changing Monitor 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 120. 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.

ENTER PASSWORD			
----------------	--	--	--

As described in Screen Navigation on page 37, use the control knob to select *ENTER PASSWORD*. Using the control knob, enter the password and click the control knob again after the last letter. The password appears in Capnostream Service Password on page 139. The service password page may be removed from the manual for safekeeping.

Use the control knob to select *INST DEFAULTS*. You have the option of changing the default settings for *ALARM LIMITS*, *TRENDS*, *MONITOR*, CO₂ and SpO₂.

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

Patients will not be monitored by the device while it is in service mode, even if the monitor is connected to a patient while in service mode. (The monitor is in service mode once the service password is inputted.) Therefore, you may want to remove the FilterLine from the patient or disconnect the FilterLine from the monitor while putting the monitor into service mode. No data will be recorded while the monitor is in service mode, and thus trying to monitor while in service mode will lead to missing data issues.

Note:

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.

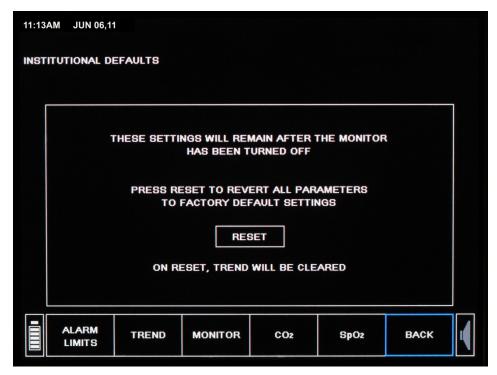


Figure 46 - Institutional Defaults Screen

Uploading or Downloading Institutional Defaults

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

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

> TO UPLOAD OR DOWNLOAD DEFAULTS:

- For upload, insert a USB Flash Memory drive with at least 2 KB in free memory into the USB port on Capnostream. For download, insert a USB Flash Memory drive with Institutional Defaults previously loaded on it into the USB port on Capnostream.
- 2. Click the SYSTEM menu button to enter the main System screen.
- 3. Click the *SERVICE* menu button to enter the Service screen and input the Service password (see Capnostream Service Password on page 139).
- 4. Click the *SOFTWARE SUPPORT* menu button to enter the Software Support screen. The Software Support screen can be seen in Figure 47 Software Support Screen on page 121.
- 5. Click the *UPLOAD DEFAULTS* button to upload defaults to a USB Flash Memory drive from Capnostream, or click the *DOWNLOAD DEFAULTS* button to download defaults from a USB Flash Memory drive to Capnostream. Downloading defaults will create a folder called *settings* on the USB Flash Memory drive, which will contain files that can be used to upload defaults to another Capnostream. After uploading defaults, the monitor will shut itself off; restart the monitor to resume operation.

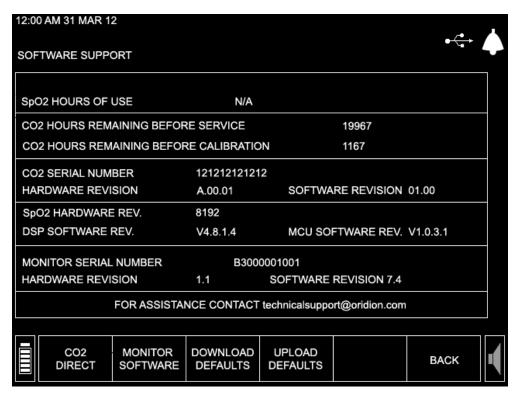


Figure 47 - Software Support Screen

Changing Monitor Settings

Alarm Limits

There are two sets of alarm limits that are stored in the monitor, for Adult/Pediatric and for Infant/Neonatal patient types. (The Adult/Pediatric limits are relevant for adult patients and for all three pediatric patient types.) The factory default settings for Adult and Neonatal alarm limits are given above in Table 29 - Factory Default Alarm/Indicator Limits on page 122.

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 select *SET INFANT/NEONATAL* or *SET ADULT/PEDIATRIC* or *SET ALARM DELAY* as required. You will then be presented with the Institutional Defaults: Alarm Limits: Infant/Neonatal or the Institutional Defaults: Alarm Limits: Adult/Pediatric screen or the Alarm Delay screen. To learn more about Alarm Delay options, see Alarm Delay on page 72.

Change the settings as described in the section Changing Alarm Limits on page 79.

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.

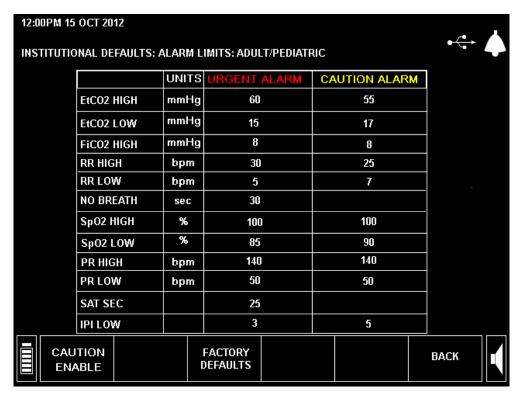


Figure 48 - Institutional Defaults Alarm Limits Screen

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

Table 29 - Factory Default Alarm/Indicator Limits

Parameter	Adult/Pediatric Red Urgent Alarm	Adult/Pediatric Yellow Caution Alarm		Infant/Neonatal Yellow Caution Alarm	
EtCO ₂ High	60	55	50	45	5-150 mmHg
EtCO ₂ Low	15	17	20	22	0-145 mmHg
FiCO ₂ High	8	8	5	5	2-98 mmHg
RR High	30	25	65	60	5-150 bpm
RR Low	5	7	25	28	0-145 bpm
No Breath Detected	30	N/A	15	N/A	10-60 sec
SpO ₂ High	100	100	98	98	25-100% saturation
SpO ₂ Low	85	90	85	90	20-95% saturation
Pulse Rate High	140	140	200	200	30-240 bpm
Pulse Rate Low	50	50	100	100	25-235 bpm
IPI Low Alert	3	5	N/A	N/A	1-9 or OFF
SatSeconds	25	25	25	25	10, 25, 50, 100 or Off

Alarm Delay

A number of alarms can be delayed by a choice of 10, 15, 20, or 30 seconds, or not at all (Alarm Delay disabled). This option is available for all patient types.

The Alarm Delay can be set from the Institutional Defaults screen, which can be reached by SYSTEM>SERVICE>INPUT SERVICE PASSWORD (see Capnostream Service Password on page 139) >INST DEFAULTS>ALARM LIMITS>SET ALARM DELAY.

Parameter	Choices	Factory Default
EtCO ₂ High Alarm Delay	10, 15, 20, or 30 seconds or Disabled	DISABLED
RR High Alarm Delay	10, 15, 20, or 30 seconds or Disabled	DISABLED
SpO ₂ Low Alarm Delay	10, 15, 20, or 30 seconds or Disabled	DISABLED
PR Low Alarm Delay	10, 15, 20, or 30 seconds or Disabled	DISABLED
PR High Alarm Delay	10, 15, 20, or 30 seconds or Disabled	DISABLED

Table 30 - Factory Default and Optional Alarm Delay Settings

Trend Settings

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

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, 4 or 12 hours	4 hours

Table 31 - Factory Default and Optional Trend Settings

The Home IPI Display Default (see IPI Display on page 64) also appears in the Trend Settings defaults screen.

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

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

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

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

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

Changing Parameters Order on the Trend Display

The Graphical and Tabular screens show five different patient parameters. The order of the trend parameters can be changed in the Institutional defaults screen, in order to show the more relevant parameters on the first trend display screen rather than the second screen. The process is as follows: Click SYSTEM>SERVICE>Enter Service password (see Capnostream Service Password on page 139)>INST DEFAULTS>TREND>CONFIG. DISPLAY to open the Institutional Defaults: Trend: Display Configuration screen.

For each position that you wish to change, move the cursor to that line with the control knob, click the control knob, and then choose, from the Parameters Available column, the parameters which you wish to show in that line. For example, in Parameter Position 1, the default is EtCO₂. To change the trend display so that IPI appears as the first parameter on the trend screen, move the cursor to Parameters Selected: EtCO₂, click the control

knob, and then scroll with the control knob until you reach IPI in the Parameters Available column. Click with the control knob to place IPI as the first parameters on the trend displays.

Click BACK>BACK>HOME to retain your choices once you are finished changing the trend display. To return to the default display, click FACTORY DEFAULTS on the Institutional Defaults: Trend: Display Configuration screen.

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 46 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, SURFACTANT, 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, CO₂ INSUFFL (CO₂ Insufflation), ABG, 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.

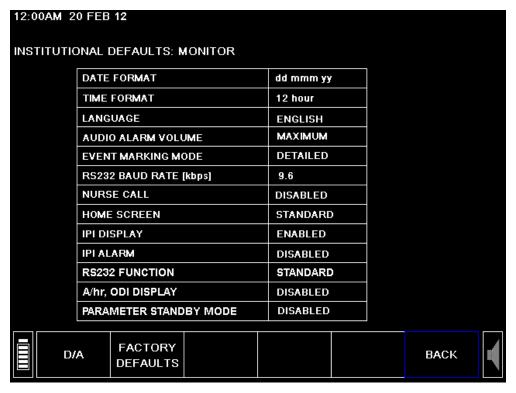


Figure 49 - Institutional Defaults: Monitor

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

Parameter	Choices	Factory Default
Date Format	dd mmm yy <i>or</i> mmm dd, yy	mmm dd, yy
Time Format	12 or 24 hour	12 hour
Language	English, Spanish, French, German, Italian, Dutch, Portuguese, Russian, Swedish, Norwegian, Japanese	English
Audio Alarm Silence	Maximum, Last Setting, Audio Off	MAXIMUM
Event Marking Mode	Quick/Detailed	DETAILED
RS-232 Baud Rate	AUTO; 9600 ; 19.2K; 57.6K; 115.2K	AUTO
Nurse Call	Enabled, Disabled	DISABLED
Home Screen	Standard, Numeric	STANDARD
IPI Display (on HOME, trend and alarm review screens)	Enabled, Disabled	ENABLED*
IPI Alarm	Enabled, Disabled	DISABLED
RS232 FUNCTION	VueLink: IPI, A/hr, ODI VueLink:IPI VueLink: CO₂ ONLY Standard	Standard; VueLink is no longer available with Capnostream
A/hr and ODI Display (if available)	Enabled, Disabled	ENABLED*
Parameter standby mode	Enabled, Disabled	DISABLED

^{*} Please note that IPI is not available for Infant/Neonatal patients, and thus is automatically disabled for Infant/Neonatal patients. Additionally, A/hr and ODI are not available for infant/neonatal or for pediatric patients.

CO₂ Parameters

Institutional Defaults can be set for all CO_2 parameters that are settable in the monitor. To change the parameters, select CO_2 in the Institutional Defaults screen.

Parameter	Choices	Factory Default
CO ₂ Units	mmHg, kPa, Vol%	mmHg
BTPS*	On/Off	On
FiCO ₂ Display	On/Off	On
Pump-Off Timeout (minutes)	5, 10, 15 or 30	15
CO ₂ Waveform Scale (mmHg)	50, 100, 150, Auto	Auto
EtCO ₂ Scale for Trend Display	50, 100, 150	50
RR Scale for Trend Display	50, 100, 150	50
Sweep Speed Adult/Pediatric (mm/sec)	3, 6.3, 12.5, 25	6.3
Sweep Speed Infant/Neonatal (mm/sec)	3, 6.3, 12.5, 25	6.3

^{*} 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.

SpO₂ Parameters

Institutional Defaults can be set for all SpO_2 parameters that are settable in the monitor. To change the parameters, select SpO_2 in the Institutional Defaults screen.

Parameter	Choices	Factory Default
Pulse Tone	On/Off	Off
Sat-Seconds	On/Off	On
SpO ₂ Scale for Trend Display	0-100, 50-100	50-100
PR Scale for Trend Display	150, 300	150
Sweep Speed Adult/Pediatric (mm/sec)	3, 6.3, 12.5, 25	25
Sweep Speed Infant/Neonatal (mm/sec)	3, 6.3, 12.5, 25	25

Specifications

Power Supply

Battery

Controls

Display

Microstream® Capnography

Nellcor Oximax® Pulse Oximetry

Alarms

Outputs

Internal Thermal Printer (optional)

General Characteristics

Equipment Classification

Compliance

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-lon
Battery Operation	2.5h (without thermal recorder)
Battery Charging Time	100% in 12h

Controls

Item	Value
Front Panel	Switch for monitor On/Off control specific function keys optical encoder with 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 and 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	0-150 mmHg
CO ₂ Waveform Resolution	0.1 mmHg
EtCO ₂ , FiCO ₂ Resolution	1 mmHg
CO₂ Accuracy	0-38 mmHg: ± 2 mmHg 39-150 mmHg: ± (5% of reading + 0.08 x (expected reading in mmHg –39mmHg) Accuracy applies for breath rates of up to 80 bpm. For breath rates above 80 bpm, accuracy is 4 mmHg or ±12 % of reading whichever is greater, for etCO ₂ values exceeding 18 mmHg.
Respiration Rate Range	0-150 bpm
Respiration Rate Accuracy	0-70 bpm: ±1 bpm 71-120 bpm: ±2 bpm 121-150 bpm: ±3 bpm
CO ₂ Alarms	No breath, etCO ₂ high, etCO ₂ low, RR high, RR low, IPI low (IPI also requires pulse oximetry information)
Flow Rate	50 (42.5 ≤ flow ≤ 65) ml/min, flow measured by volume
Waveform Sampling	20 samples/s
Response Time	2.95 s (typical); when used with long sampling lines, ~5.0 s
Initialization Time	40 s (typical)
Calibration Interval	Initially calibrate after 1,200 operating hours, then once a year or after 4,000 operating hours, whichever comes first

Nellcor Oximax® Pulse Oximetry

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

^{*} Reading accuracy in the presence of low perfusion (detected IR pulse modulation amplitude between 0.03% and 1.5%) was validated using signals supplied by a patient simulator. SpO₂ and pulse rate values were varied across the monitoring range over a range of weak signal conditions and compared to the known true saturation and pulse rate of the input signals.

Alarms

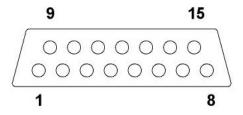
ltem	Value
High Priority Patient Warning	Flashing Red LED
Alarms	Flashing Red Numeric
	Repeated beep pattern
	Alarm Indication on Screen
	Nurse Call
Patient Caution Alarms	Flashing Yellow LED
	Flashing Yellow Numeric
	Repeated beep pattern
Medium Priority Alarm	Flashing Yellow LED
	Triple beep every thirty seconds
	Alarm Indication on Screen
	Nurse Call
Advisories	Beep once
	Advisory Indication on Screen
Silent Advisories	Advisory Indication on Screen
Alarm Volume Control	5 steps
Alarm sound pressure level range	50 to 85 dB(A)
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	5V
5	Isolated Ground
6	
7	5V
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
Туре	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	3.6kg (7.94lb)
Operating Temperature	0°C to 35°C (32°F to 95°F)
Operating Pressure and Altitude	Pressure: 430 mmHg to 795 mmHg
	Altitude: -381m to 3000m (-1,250 feet to 9,843 feet)
Operating Humidity	10% to 95% non-condensing
Storage and Transport	Until lower limit of -20°C (-4°F)
Temperature	Up to upper limit of 60°C (140°F)
Storage and Transport Pressure	Pressure: 430 mmHg to 795 mmHg
and Altitude	Altitude: -381m to 4572m (-1,250 feet to 15,000 feet)
Storage and 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	6.6kg (14.55lb)

Equipment Classification

Item	Value
Types of Protection against Electric Shock	Class 1
Degree of Protection against Electric Shock	Type BF defibrillation proof applied parts
Mode of Operation	Continuous
Degree of Protection against Ingress of liquids	IEC 60601-1, sub-clause 11.6.5 for class IPX1 Drip-proof equipment*

^{*} IPx1 indicates that the device is protected against harmful effects of vertically falling drops of water.

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 Class A Radiated and Conducted Emission

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

ISO 80601-2-55 (Capnography)

ISO 80601-2-61 (Pulse Oximetry)

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

Electromagnetic Immunity

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

Table 32 - Guidance and Manufacturer's Declaration - Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions EN 55011	Group 1	The Capnostream20P uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions	Class A	The monitor is suitable for use in hospitals
EN 55011		
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions EN 61000-3-3	Clause 5	

Table 33 - Guidance and Manufacturer's Declaration - Electromagnetic Immunity

Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD) EN 61000-4-2	± (2, 4, 6) kV contact ± (2, 4, 8) kV air	± (2, 4, 6) kV contact ± (2, 4, 8) kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst EN 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11	<5 % U _T ¹ (>95 % dip in U _T) for 0,5 cycle 40 % U _T (60 % dip in U _T) for 5 cycles 70 % U _T (30 % dip in U _T) for 25 cycles <5 % U _T (>95 % dip in U _T) for 5 ses	<5 % <i>U</i> _T (>95 % dip in <i>U</i> _T) for 0,5 cycle 40 % <i>U</i> _T (60 % dip in <i>U</i> _T) for 5 cycles 70 % <i>U</i> _T (30 % dip in <i>U</i> _T) for 25 cycles <5 % <i>U</i> _T (>95 % dip in <i>U</i> _T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Capnostream20P requires continued operation during power mains interruptions, it is recommended that the monitor be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field EN 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic Environment – Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the Capnostream20P, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distances: $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80 MHz to 800 MHz: $d=2.3\sqrt{P}$ 800 MHz to 2.5 GHz: where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). ² Field strengths from fixed RF transmitters, as determined by an
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	electromagnetic site survey, should be less than the compliance level in each frequency range. ab Interference may occur in the vicinity of equipment marked with the following symbol:

 $^{^{1}}$ U_{T} is the a.c. mains voltage prior to application of the test level.

NOTE: These guidelines may not apply in all situations. Electronmagnetic propogation is affected by absorption and reflections from structures, objects and people.

The monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the monitor as recommended below, according to the maximum output power of the communications equipment.

² At 80 MHz and 800MHz, the higher frequency range applies

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Capnostream20P is used exceeds the applicable RF compliance level above, the Capnostream20P should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Capnostream20P.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

Table 34 - Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the Monitor

Rated maximum output power of transmitter W	Separation distance according to frequency f transmitter in m ¹			
	150 kHz to 80 MHz d= $1.2\sqrt{P}$	800 MHz to 2,5 GHz d= $2.3\sqrt{P}$		
0.01	0.12	0.12	0.23	
0.1	0.38	0.38	0.73	
1	1.2	1.2	2.3	
10	3.8	3.8	7.27	
100	12	12	23	

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

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

 $^{^{1}}$ At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Microstream EtCO₂ Consumables

Microstream EtCO2 Consumables

Microstream EtCO₂ Consumables

H Products (for use in humidified environments) are marked with an asterisk (*) in the table below.

Microstream Consumables		
Intubated Consumables		
FilterLine Set Adult/Pediatric	XS04620	
FilterLine Set Adult/Pediatric 100 unit	010579	
FilterLine H Set Adult/Pediatric*	XS04624	
FilterLine H Set Adult/Pediatric 100 unit*	010580	
FilterLine H Set Infant/Neonatal*	006324	
FilterLine Set Adult/Pediatric Long	007768	
FilterLine H Set Adult/Pediatric Long*	007737	
FilterLine H Set Infant/Neonatal Long*	007738	
VitaLine H Set Adult/Pediatric*	010787	
VitaLine H Set Infant/Neonatal*	010807	
Non-intubated Consumables		
Smart CapnoLine Plus (O ₂ connector)	009818	
Smart CapnoLine Plus (O ₂ connector) 100 unit	010209	
Smart CapnoLine Plus Long (O ₂ connector)	010340	
Smart CapnoLine Plus Long (O ₂ conn) 100 unit	010339	
Smart CapnoLine Plus O ₂ (O ₂ tubing)	009822	
Smart CapnoLine Plus O ₂ (O ₂ tubing) 100 unit	010210	
Smart CapnoLine Plus O ₂ Long (O ₂ tubing)	009826	
Smart CapnoLine Plus O ₂ Long (O ₂ tubing) 100 unit	010341	
Smart CapnoLine Pediatric	007266	
Smart CapnoLine O ₂ Pediatric (O ₂ tubing)	007269	
Smart CapnoLine O ₂ Ped Long (O ₂ tubing)	007743	
Smart CapnoLine H Plus O ₂ (O ₂ tubing)*	010433	
Smart CapnoLine H Plus O ₂ (O ₂ tubing) 100 unit*	010625	
Smart CapnoLine H Plus O ₂ Long (O ₂ tubing)*	012463	
Smart CapnoLine H O ₂ Pediatric (O ₂ tubing)*	010582	
Smart CapnoLine H O ₂ Pediatric Long (O ₂ tubing)*	012464	
Smart CapnoLine Guardian (O ₂ connector)	012528	
Smart CapnoLine Guardian (O ₂ connector) 100 unit	012537	
Smart CapnoLine Guardian O ₂ (O ₂ tubing)	012529	
Smart CapnoLine Guardian O ₂ (O ₂ tubing) 100 unit	012538	

Microstream Consumables	
Smart CapnoLine Guardian O ₂ long (O ₂ tubing)	012530
Smart CapnoLine Guardian O ₂ long (O ₂ tubing) 100 unit	012539
Hook and Loop Strap	012542
O ₂ /CO ₂ Nasal FilterLine Adult (O ₂ tubing)	006912
O ₂ /CO ₂ Nasal FilterLine Adult (O ₂ tubing) 100 unit	010304
O ₂ /CO ₂ Nasal FilterLine Adult Long (O ₂ tubing)	007739
O ₂ /CO ₂ Nasal FilterLine Adult Long (O ₂ tubing) 100 unit	010344

Capnostream Service Password

Capnostream Service Password

Capnostream Service Password

This service password is: SERV