Capnostream™20p
Portable Bedside Monitor
Capnograph/Pulse Oximeter

Operator's Manual

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Exemptions

Liability under this warranty does not include any transportation damage or other charges or liability for direct, indirect or consequential damages or delay resulting from improper use or application of the product or the substitution upon it of parts or accessories not approved.

All information in this manual is believed to be correct and there shall be no liability for errors contained herein with the performance or use of this manual.

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Warranty for Monitors

THIS LIMITED WARRANTY applies to capnography patient monitors purchased under a valid agreement by Customer ("Products"). Subject to the limitations herein, the Products, when delivered by an authorized entity, for two (2) years following the delivery date, but no more than 27 months following the date of production, will be free from defects in material and workmanship and will substantially conform to published specifications for the respective Products and in effect at the time of manufacture. This limited warranty excludes (i) Products purchased through unauthorized third parties; (ii) Products that have been subject to misuse, mishandling, accident, alteration, neglect, unauthorized repair or installation; and (iii) Products that have been used with accessory consumable products other than FilterLine® products. Furthermore, this limited warranty shall not apply to the use of Products in an application or environment that is not within specifications or in the event of any act, error, neglect or default of Customer. Damaged Products may be repaired or replaced at the sole discretion of the selling entity. Customer may not return Products without first obtaining a customer return material authorization (RMA) number from an Authorized Service center and a copy of the Product purchase invoice.

Disclaimer

USER MAY USE THE PARAMETERS (INCLUDING ANY AND ALL REFERENCES TO CO2, SPO2, CURRENT INTEGRATED PULMONARY INDEX™ AND FUTURE AND RELATED INDICES AND CONFIGURATIONS AND SIGNAL ALARM NOTIFICATIONS) WHICH APPEAR ON THE PATIENT MONITORING DEVICES AND/OR THE COMMUNICATION PROTOCOL AND/OR ANY OUTPUT IN REPORTS DOWNLOADED FROM THE PATIENT MONITORING DEVICES TO PRINTERS OR USB MEMORY STICKS OR APPROVED SYSTEMS ("DATA") SOLELY AND EXCLUSIVELY FOR THE PURPOSE OF PATIENT CARE. USER ACKNOWLEDGES THAT DATA TRANSMITTED FROM THE PATIENT MONITORING DEVICES MAY NOT BE TRANSFERRED, INTERFACED, EXCHANGED OR OTHERWISE TRANSMITTED AND THAT THERE IS NO WARRANTY FOR THE ACCURACY OR COMPLETENESS OF DATA THAT HAS BEEN TRANSFERRED, INTERFACED, EXCHANGED OR OTHERWISE TRANSMITTED. USER FURTHER ACKNOWLEDGES THAT IT MAY NOT SELL, LICENSE OR OTHERWISE COMMERCIALIZE THE DATA, IN WHOLE OR IN PART. ANY OTHER USE OF THE DATA OR INTERFACE WITH OTHER SYSTEMS, WHETHER BY USER OR ANY PARTY ON ITS BEHALF, SHALL BE SUBJECT TO A SEPARATE LICENSING ARRANGEMENT INCORPORATING, BUT NOT LIMITED TO, COMMERCIAL TERMS TO BE NEGOTIATED IN GOOD FAITH.
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Safety Information

Warnings
Definitions

To use the Capnostream™20ₚ monitor correctly and safely, carefully read this operator's manual and the *Directions for Use* that accompany Microstream™ etCO$_2$ consumables (FilterLine™) and the SpO$_2$ sensors. Use of the monitor requires full understanding and strict observance of these instructions, the precautionary information in boldface type, and the specifications.

Warnings

General

WARNING:	If uncertain about the accuracy of any measurement, first check the patient's vital signs by alternate means, and then make sure the monitor is functioning correctly.
WARNING:	The device should not be used as an apnea monitor.
WARNING:	The device should be considered an early warning device. As a trend towards patient deoxygenation is indicated, blood samples should be analyzed by a laboratory co-oximeter to completely understand the patient's condition.
WARNING:	To ensure patient safety, do not place the monitor in any position that might cause it to fall on the patient.
WARNING:	Carefully route patient cabling (SpO$_2$ sensor and FilterLine™) to reduce the possibility of patient entanglement or strangulation.
WARNING:	Do not lift the monitor by the SpO$_2$ sensor cable or FilterLine™, as they could disconnect from the monitor, causing the monitor to fall on the patient.
WARNING:	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 only.
WARNING:	No modification of this equipment is allowed.
WARNING:	If calibration does not take place as instructed in the relevant service manual, the monitor may be out of calibration. A monitor that is out of calibration may provide inaccurate results.

WARNING:	If the exhaust connector port appears damaged, do not use the device with anesthetic gases.

Devices connected to the monitor must be medical grade only.

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

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, $etCO_2$ monitoring can be implemented using the FilterLine™ XL. (Refer to Monitoring CO2 during MRI Scanning on page 56.
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 127.

Monitor Use with Defibrillators

WARNING:	All cables and tubing, including SpO_2 sensors and CO_2 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 SpO_2 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™20p 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™20p Rear View on page 29) may be used for optional connection between Capnostream™20P 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.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Capnostream™20p monitor, including its cables. Otherwise, degradation of the performance of this equipment could result.

Note: The emissions characteristics of the Capnostream™20p monitor make it suitable for use in industrial areas and hospitals (EN 55011 class A). If it is used in a residential environment (for which EN 55011 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

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.

About this Manual

Overview

This manual provides directions for setting up and operating the Capnostream™20p monitor.

Capnostream™20p is a portable bedside monitor that continuously monitors a patient's:

- End tidal carbon dioxide ($etCO_2$) - level of carbon dioxide in exhaled breath.

- Respiratory rate (RR).

- Fractional inspired carbon dioxide ($FiCO_2$) - level of carbon dioxide present during inhalation.

- Oxygen saturation (SpO_2).

- Pulse rate (PR).

The device also provides an Integrated Pulmonary Index™ (henceforth referred to as IPI) value, which is a numerical value that integrates four major parameters measured by Capnostream™20p in order to provide a simple indication of the patient's ventilatory status. The integrated parameters are $etCO_2$, RR, SpO_2, and PR. Only these four parameters are used to calculate IPI; other parameters are not taken into account.

In addition, the 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 O_2 Desaturation screen).

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

Intended Use

The Capnostream™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 (SpO_2) 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™20p.
- 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™20p 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.

Symbols

The following symbols appear on the body of the monitor.

Table 1 - Symbols that Appear on the Monitor

Symbol	Description
	Monitor ON/OFF button
	AC power ON indicator
	UNIT ON indicator
	Event selection
	Patient Admit/Discharge
	Pump Off
	Temporarily silence alarms
	Type BF Defibrillator Proof Protection

Symbol	Description
	Gas inlet
	Gas outlet
	Equipotential ground
	USB flash memory connection port
CE 0123	CE Mark
R Only	For prescription use only
	Directive on waste electrical and electronic equipment
Follow instructions for use	Follow instructions for use

<div align="right">

Chapter 2

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Technology Overview

Introduction

The Capnostream™20p bedside monitor provides accurate, continuous capnography and pulse oximetry monitoring for intubated and non-intubated patients from neonate to adult. Using Microstream™ technology, patented FilterLine™ $etCO_2$ consumables, and pulse oximetry technology, Capnostream™20p allows for simultaneous "hassle free" $etCO_2$ and SpO_2 monitoring.

Features

- Dual parameter monitor that supports the current standard of care providing CO_2 and SpO_2 measurements
- Integrated Pulmonary Index™ (IPI), which provides a simple, clear, and comprehensive indication of a patient's ventilatory status and trends
- Apneas per Hour and Oxygen Desaturation Index, indices used to help in the identification and quantification of apnea and oxygen desaturation events
- Simple user interface with color screen
- Routine functions are accessed with 2 clicks
- 72-hour trends to review patient history
- One-click alarm review
- SARA™ (Smart Alarm for Respiratory Analysis), an embedded Smart Capnography alarm management technology, which reduces clinically insignificant alarms
- Event marking to compare events and medication administration to changes in patient status
- Case recording to help organize patient files
- Nurse call
- Optional internal printer
- USB output to transfer patient data to USB flash memory devices
- RS-232 port for data transfer

Technology Overview

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

What is Capnography?

Capnography is a non-invasive method for monitoring the level of carbon dioxide in exhaled breath ($etCO_2$) to assess a patient's ventilatory status.

Capnostream™20p uses Microstream™ non–dispersive infrared (NDIR) spectroscopy to continuously measure the amount of CO_2 during every breath, the amount of CO_2 present at the end of exhalation ($etCO_2$), the amount of CO_2 present during inhalation ($FiCO_2$), and the Respiratory Rate.

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

The Microstream™ etCO$_2$ consumables deliver a sample of the inhaled and exhaled gases from the ventilator consumable or directly from the patient (via an oral/nasal cannula) into the monitor for CO$_2$ measurement. Moisture and patient secretions are extracted from the sample, while maintaining the shape of the CO$_2$ waveform.

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

Once inside the Microstream™ CO$_2$ sensor, the gas sample goes through a micro-sample cell (15 microliters). This extremely small volume is quickly flushed, allowing for fast rise time and accurate CO$_2$ readings, even at high respiration rates.

The Micro Beam IR source illuminates the micro-sample cell and the reference cell. This proprietary IR light source generates only the specific wavelengths characteristic of the CO$_2$ absorption spectrum. Therefore, no compensations are required when different concentrations of N$_2$O, O$_2$, anesthetic agents and water vapor are present in the inhaled and exhaled breath. The IR that passes through the micro-sample cell and the IR that passes through the reference cell are measured by the IR detectors.

The microprocessor in the monitor calculates the CO$_2$ concentration by comparing the signals from both detectors.

What is Pulse Oximetry?

Pulse oximetry is based on the following:

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

- Changes in the volume of arterial blood in tissue during the pulse cycle (plethysmography), and hence, light absorption by that blood.

A pulse oximeter determines Spot Oxygen Saturation (SpO$_2$) by passing red and infrared light into an arteriolar bed and measures changes in light absorption during the pulsatile cycle. Red and infrared low power light emitting diodes (LEDs) in the oximetry sensor serve as light sources; a photodiode serves as the photo detector.

Because oxyhemoglobin and deoxyhemoglobin differ in light absorption, the amount of red and infrared light absorbed by blood is related to hemoglobin oxygen saturation. To identify the oxygen saturation of *arterial* hemoglobin, the monitor uses the pulsatile nature of arterial flow. During systole, a new pulse of arterial blood enters the vascular bed and blood volume and light absorption increase. During diastole, blood volume and light absorption reach their lowest point. The monitor bases its SpO$_2$ measurements on the difference between maximum and minimum absorption (measurements at systole and diastole). The focus of light absorption by pulsatile arterial blood eliminates the effects of nonpulsatile absorbers such as tissue, bone, and venous blood.

The Capnostream™20p Monitor

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

The Capnostream™20$_p$ 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™20p monitor and the accessories from the box.

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

   * Capnostream™20p Monitor

   * Operating Manual

   * Two 3.15 Amp fast blow and low breaking capacity type fuses

   * Mains Electrical Power Cord

   * SpO$_2$ Sensor Pack

   * SpO$_2$ Extension Cable

   * Printer Paper Roll (one installed and one extra roll)

   * Battery Pack

   * CD with additional documentation (this manual in English and French, and the service manual)

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

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.
WARNING:	Battery door should always remain closed during operation or when attached to AC power.

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.
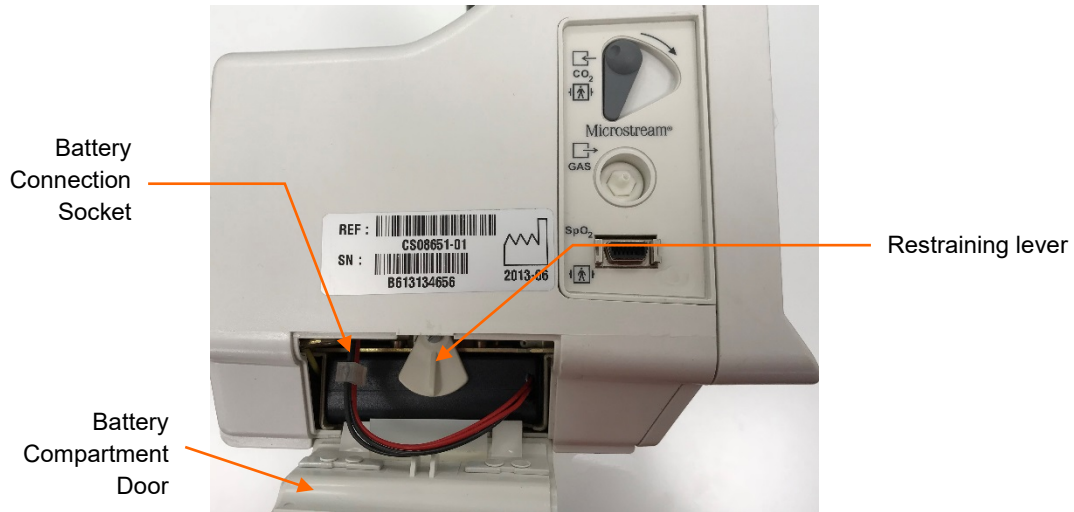
Figure 1 - Installing the Battery Pack

➢ **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.
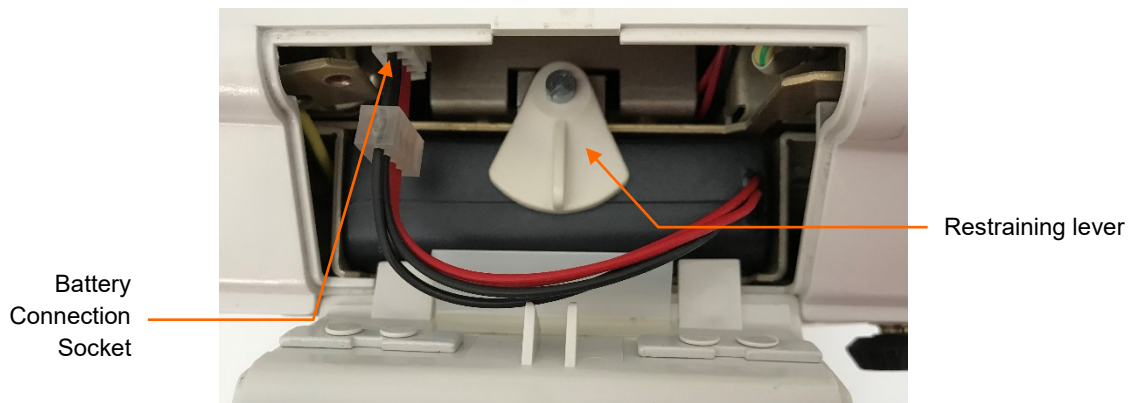
Figure 2 - Battery Pack Close-up

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.

7. Charge the battery pack before first use, by placing the battery pack in the monitor and plugging in the monitor, without turning on the monitor. The battery pack will then charge, within approximately 12 hours. Once the battery pack is charged, you may turn on and start using the monitor. If the monitor is not plugged in, it cannot run on the battery pack provided with the monitor without prior charging.

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, the No Battery icon will appear on the screen and the advisory message *NO BATTERY INSTALLED* will appear. It is best practice to turn off the monitor before installing or switching the battery.

WARNING:	There should always be a removable battery installed in the device. 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.

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
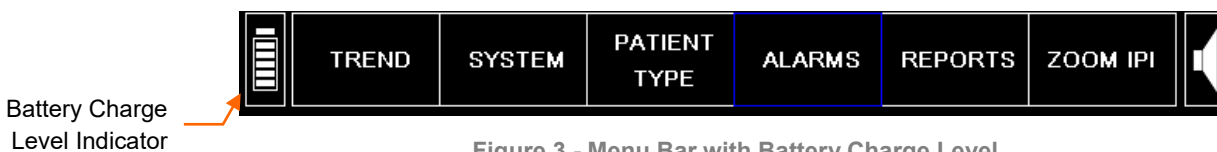
Figure 3 - Menu Bar with Battery Charge Level

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

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 ∼ 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 on battery 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™20p 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 Medtronic; part number is 010713. Please refer to the appropriate *Directions for Use* for these products.

Rubber feet (4)

Mounting Holes (4)
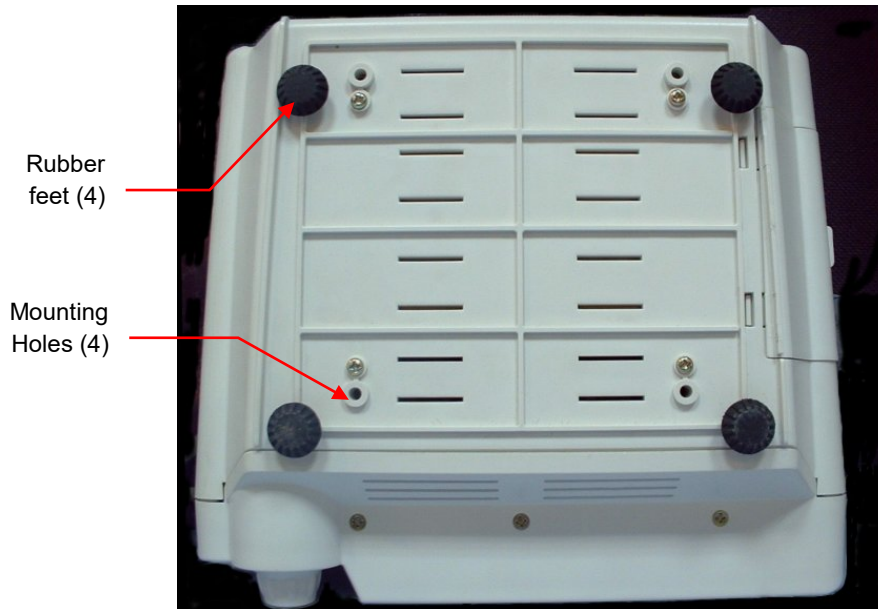
Figure 4 - Monitor Bottom View

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.

Accessories and Spare Parts

Available Accessories and Spare Parts

See the list of available accessories and spare parts for Capnostream™20p below.

Table 2 – Capnostream™20p Accessories/Spare Parts

Accessory	Medtronic Part Number	Use	Type
Paper (6 rolls)	SP010516COV	Paper fits Capnostream™20p integrated printer. Monitor is shipped with one paper roll and one spare paper roll.	Spare part
Mounting Adaptor Plate (VESA™*)	010713	Used for mounting Capnostream™20p to GCX roll stands and other mounting assemblies. Refer to Mounting the Monitor on page 24 for mounting instructions.	Accessory

Accessory	Medtronic Part Number	Use	Type
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.	Accessory
Roll Stand with Basket	Not stocked by Medtronic	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.	Accessory
Battery Pack	SP16400COV	Refer to Installing the Battery Pack on page 22 for battery installation.	Accessory

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)

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 (PN SP010516COV) that meet the specifications can be obtained from your local Medtronic office.

Buttons, Indicators and Connections

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

Monitor Front View

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

Figure 5 – Capnostream™20p Front View

Table 4 – Capnostream™20p Front View lists the numbered labels.

Table 4 – Capnostream™20p 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™20p Front View on page 27 and described in Table 4 – Capnostream™20p Front View above.
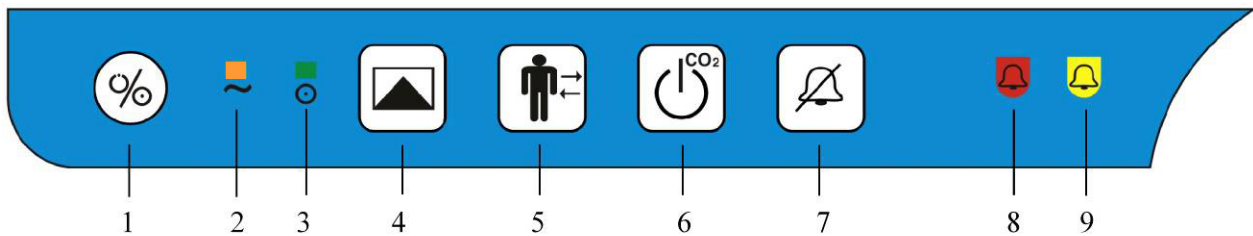
Figure 6 - Front Panel Control Buttons

Monitor Rear Panel

The rear panel of the monitor contains power and communications connections.
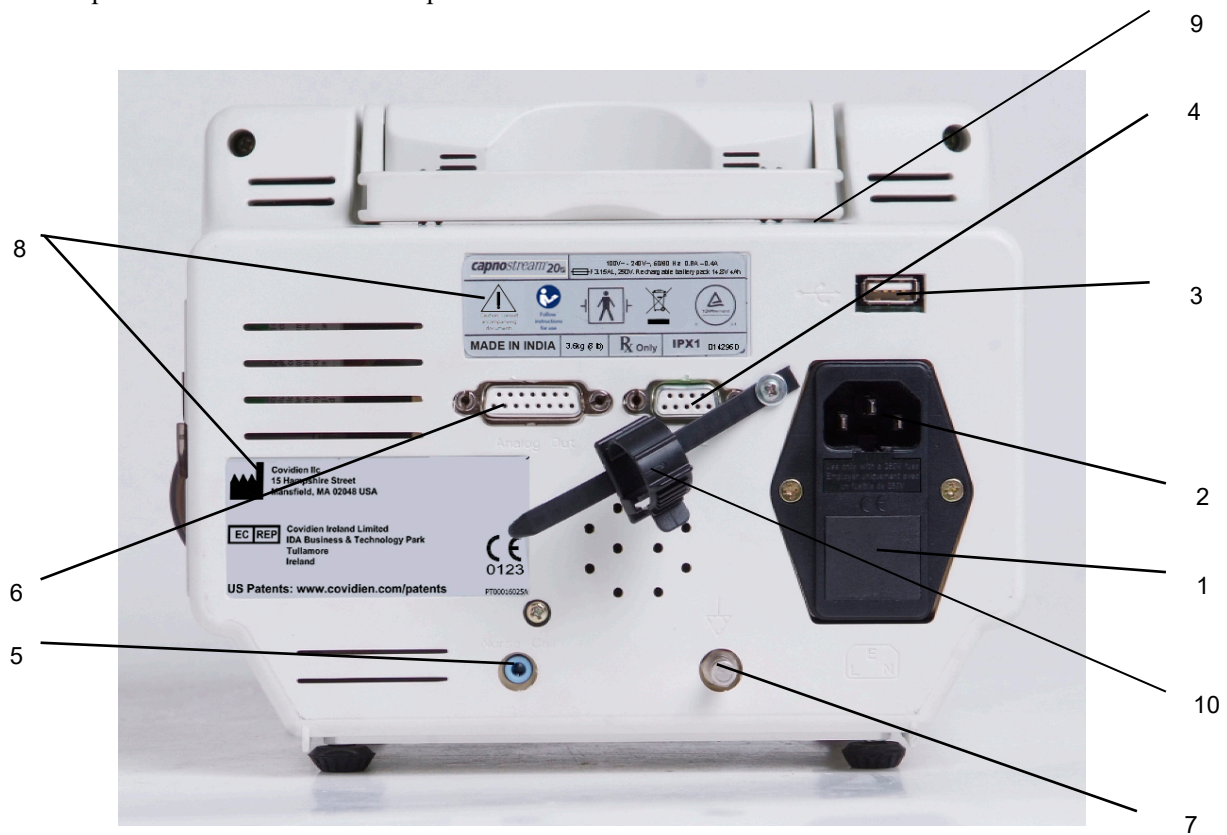
Figure 7 – Capnostream™20p Rear View

Table 5 – Capnostream™20p Rear View describes the functions of the rear-monitor connections.

Table 5 – Capnostream™20p Rear View

Label	Function	Description	Label	Function	Description
1	Mains fuse holder	Two 3.15A fast blow and low breaking capacity type 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 equalization 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™20p Left View

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

Table 6 – Capnostream™20p Left View

Label	Function	Description
1	FilterLine™ Input connector	To connect the FilterLine™ to the monitor. Provided with an automatic door close.
2	Gas outlet	To connect to a scavenger system when the monitor is used in the presence of anesthetic gases. The gas output is a barbed style connector intended for 3/32-inch ID tubing.
3	SpO_2	To connect SpO_2 sensor to the monitor with an extension cable.
4	Battery housing	Where the battery pack is installed.
5	Barcode label	Barcode of the Serial Number and Model Number of monitor.

The right side of the monitor includes only the paper roll used for printing patient reports and buttons used to control that printer.

Turning on the Monitor

This section explains how to turn on the monitor.

CAUTION:	The monitor is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.
CAUTION:	Use only Microstream™ $etCO_2$ consumables and Nellcor™ 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™20p 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 ⑳ on the front panel to turn on the monitor. The following happens:

   • The green power-on indicator lights up, showing that the monitor is turned on.

   • An hourglass figure appears on the screen for a few seconds followed by the blue monitor salutation screen for about 5 seconds as the monitor performs a self-test.

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

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

   • You will hear the pump briefly turn on for a few seconds, and then turn itself off. However, if a FilterLine™ is connected to the monitor, the pump will remain on.
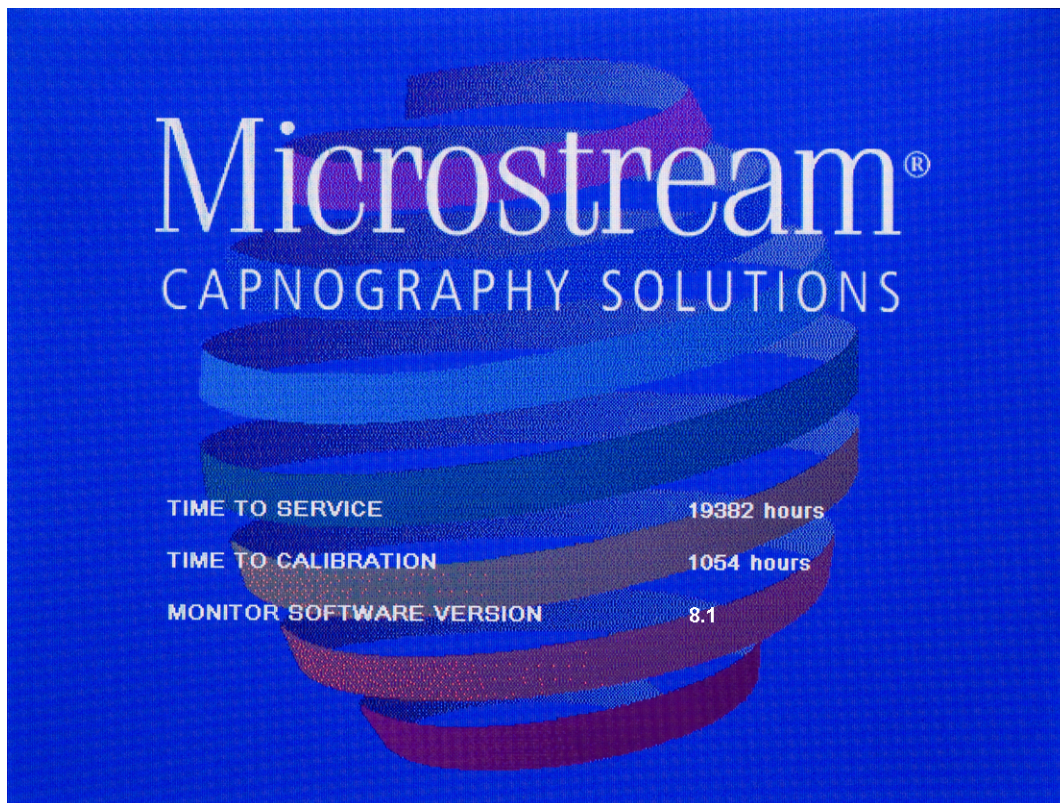
Figure 9 - Salutation Screen

Standard Sections of the Display Screen

After the blue Salutation screen, a screen requesting that you clear the trend memory will appear. For an explanation of that screen, see Using Patient Cases and Patient ID on page 44. Following that screen, the Home screen will appear.

The Home screen displays the CO_2 and SpO_2 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 SpO_2 sensor.
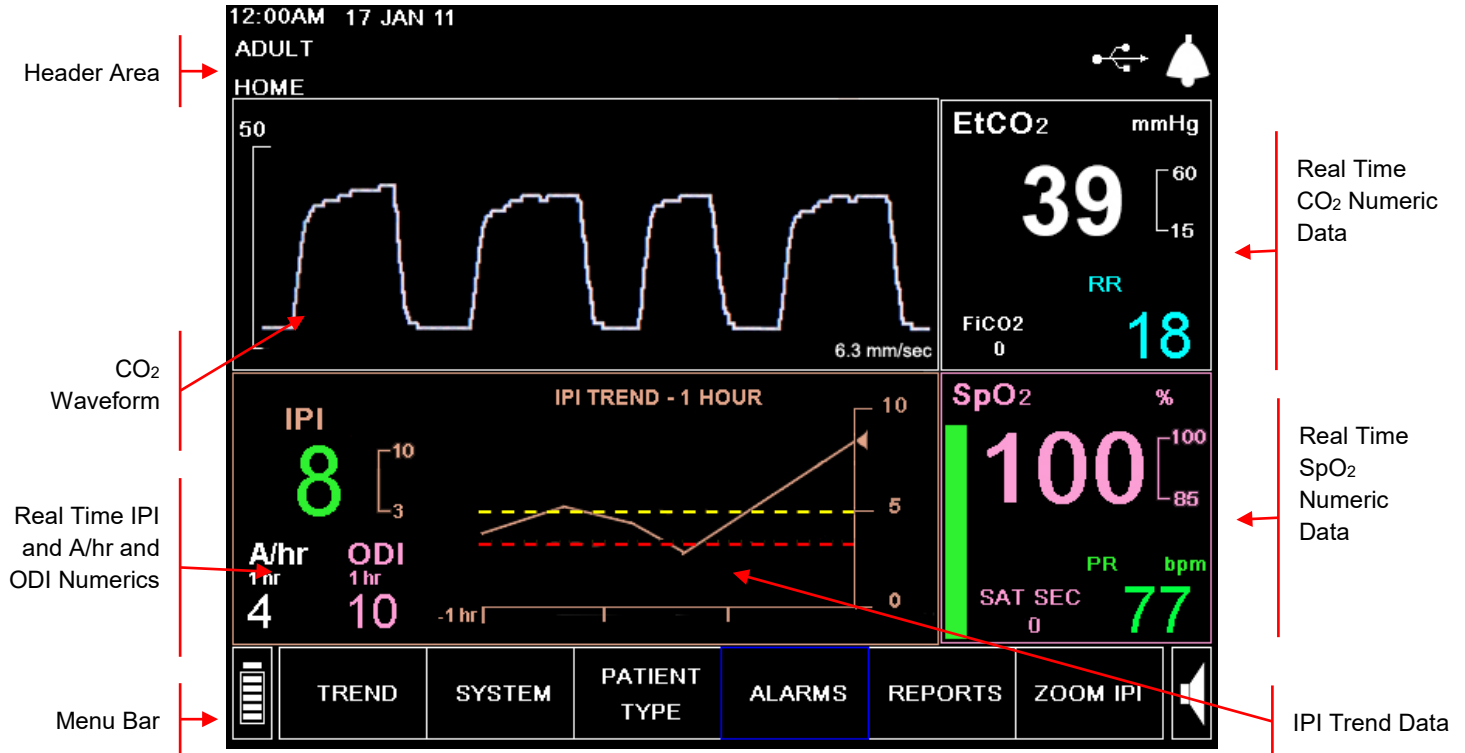
Figure 10 - Typical Home Screen
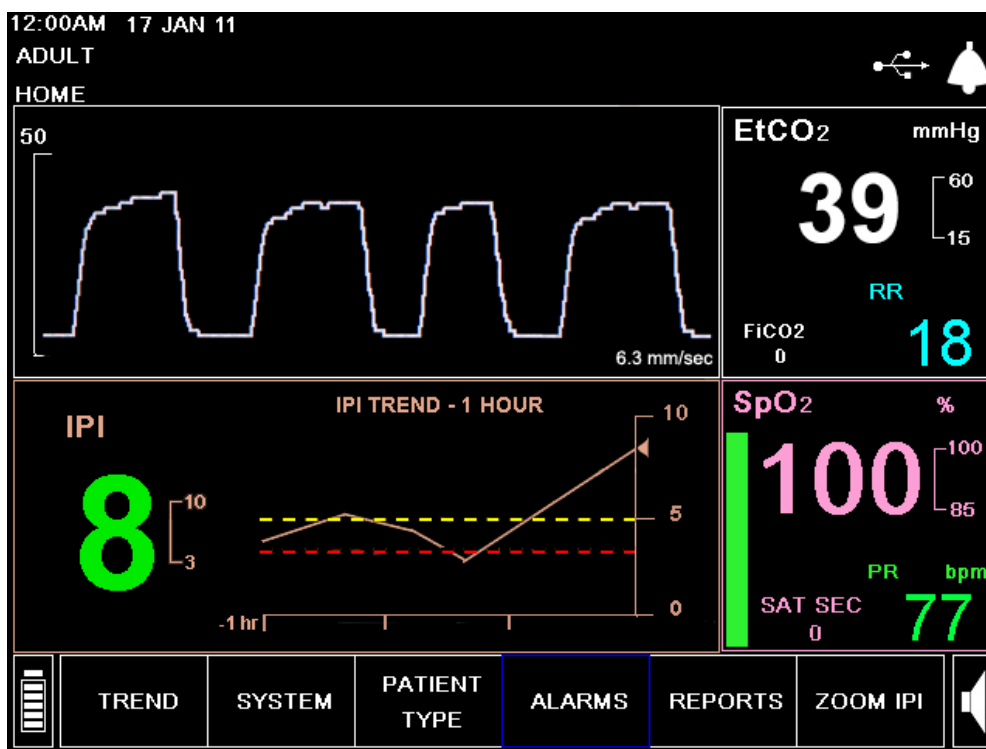
Figure 11 - Typical Home Screen when A/hr and ODI are not Available

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 CO_2 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 CO_2 Numeric Data and real time SpO_2 Numeric Data sections. The continuous display of the real time CO_2 and SpO_2 Numeric Data on the right allows continuous patient monitoring even when changing system settings or observing patient history on the trend screens.

The IPI option on the screen may be disabled as part of the institutional defaults. (If the Patient Type is Infant/Neonatal, the IPI is automatically disabled, and the only available option for the standard Home screen display shows the SpO_2 waveform instead of the IPI trend waveform.) See Chapter 7 Integrated Pulmonary Index™ 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.
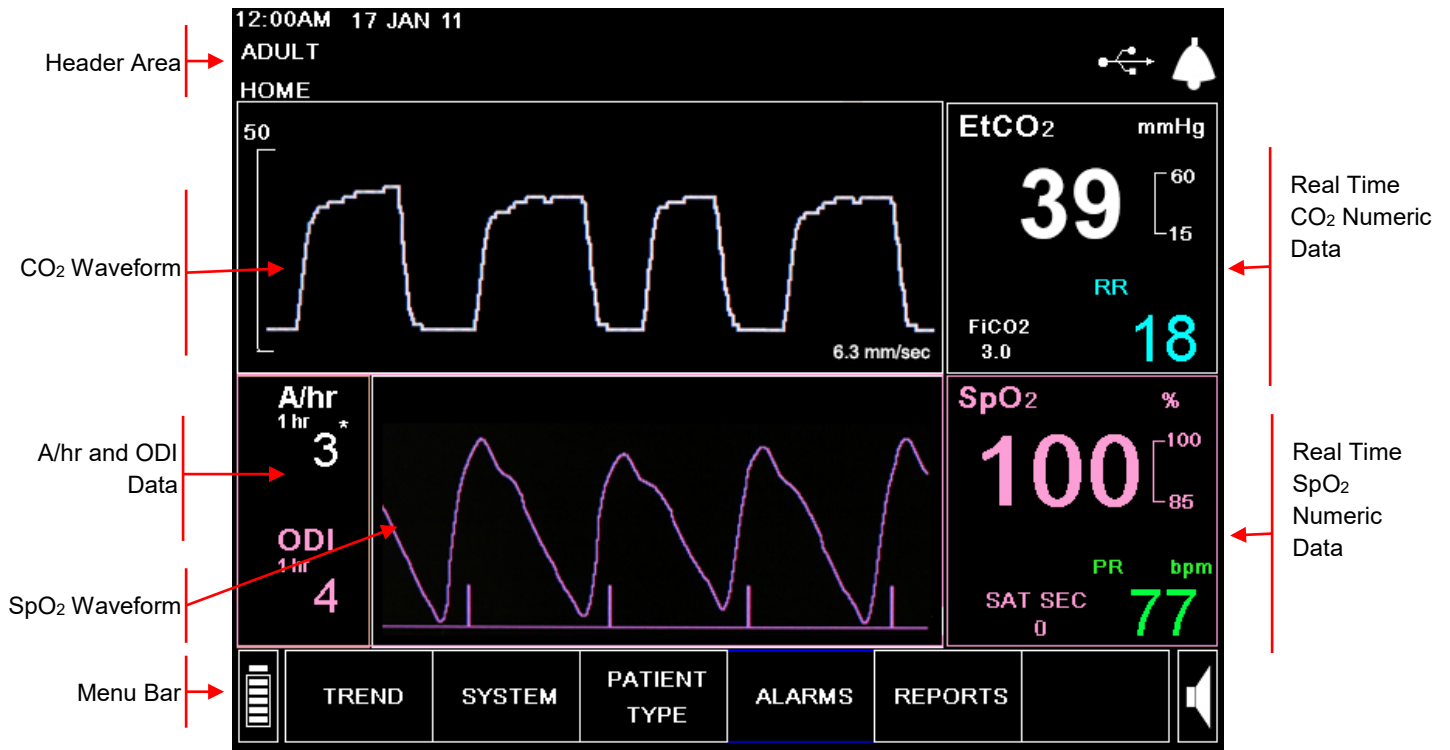
Figure 12 - Standard Home Screen without IPI Option

Header Area

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

Figure 13 - Header Area

Table 7 describes the elements of the header area.

Table 7 - Header Section

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

Menu Bar

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

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

Real Time CO_2 Data

This area of the screen displays the real time $etCO_2$ and $FiCO_2$ values along with selected units, and the respiration rate (RR) in breaths per minute. Numeric display appears at right and a waveform display at left. For more details regarding the displayed information, see CO2 Data Displayed by the Capnostream™20p Monitor on page 54.

When the CO_2 alarm limit threshold is crossed, the device will alarm: the affected numeric will flash, the numeric will appear with a red or yellow background (depending on whether it is 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 CO_2 parameter values.

Real Time SpO_2 Data

This area of the screen displays real time numeric SpO_2 data: SpO_2, PR, and the pleth waveform or pulse beat bar - is always shown. (If IPI is enabled and thus no SpO_2 waveform is displayed, the SpO_2 pulse beat is represented by the green bar at the left of this box.)

For more details about the displayed SpO_2 data, see Chapter 6 Pulse Oximetry with the Capnostream™20p Monitor on page 57.

When the SpO_2 alarm limit threshold is crossed, the device will alarm: the affected numeric will flash, the numeric will appear with a red or yellow background (depending on whether it is 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 ($etCO_2$, RR, SpO_2, PR) in order to provide a quick indication of the patient's respiratory status. The IPI trend graph indicates the trend of this value over the chosen period of time (the default period is one hour).

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

For more information about this parameter, see Chapter 7 Integrated Pulmonary Index™ 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 Index™ 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 O_2 Desat screen should be viewed. The A/hr and O_2 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 65.

Home Screen Numeric Display
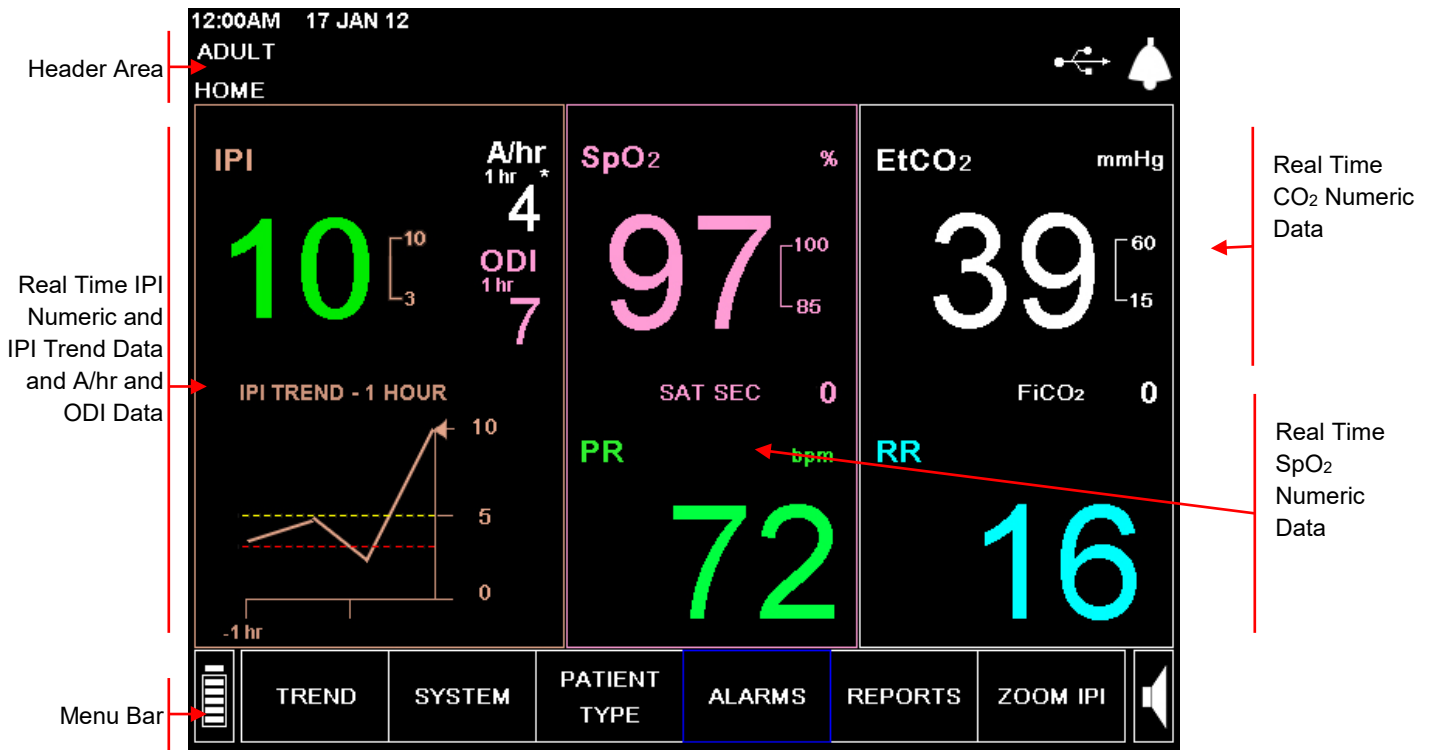
Figure 14 - Typical Numeric Home Screen

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 CO$_2$ Data

This area of the screen displays the real time etCO$_2$ and FiCO$_2$ values along with selected units, and the respiration rate (RR) in breaths per minute. Numeric display only is provided, sized so that it can easily be read even at a distance. For more details regarding the displayed information, see CO2 Data Displayed by the Capnostream™20p Monitor on page 54.

When the etCO$_2$, FiCO$_2$, 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 CO$_2$ parameter values.

Real Time SpO$_2$ Data

This area of the screen displays real time SpO$_2$ data. Numeric display is provided, sized so that it can easily be read even at a distance. 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 SpO$_2$ data, see Chapter 6 Pulse Oximetry with the Capnostream™20p Monitor on page 57.

When the SpO$_2$ alarm limit threshold is crossed, the device will alarm: the affected numeric will flash, the numeric will appear with a red or yellow background (depending on whether it is an urgent 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 O$_2$ Desat screen should be viewed. The A/hr and O$_2$ 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 65.

Real Time IPI Data with Trend Graphical Display

This area of the screen displays the real-time value of the IPI, a numerical value which summarizes four parameters (etCO$_2$, RR, SpO$_2$, PR) in order to provide a quick indication of the patient's respiratory status. The IPI trend graph below the numeric value indicates the trend of this value over the chosen period of time.

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

For more information about this parameter, see Chapter 7 Integrated Pulmonary Index™ 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 SpO$_2$ 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.

Caution:	Always use the on/off switch to turn off the monitor. Do not remove the battery and unplug the monitor to turn it off. If the monitor is turned off by removing the battery and unplugging the monitor, settings data may be lost.

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.

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 111.

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.
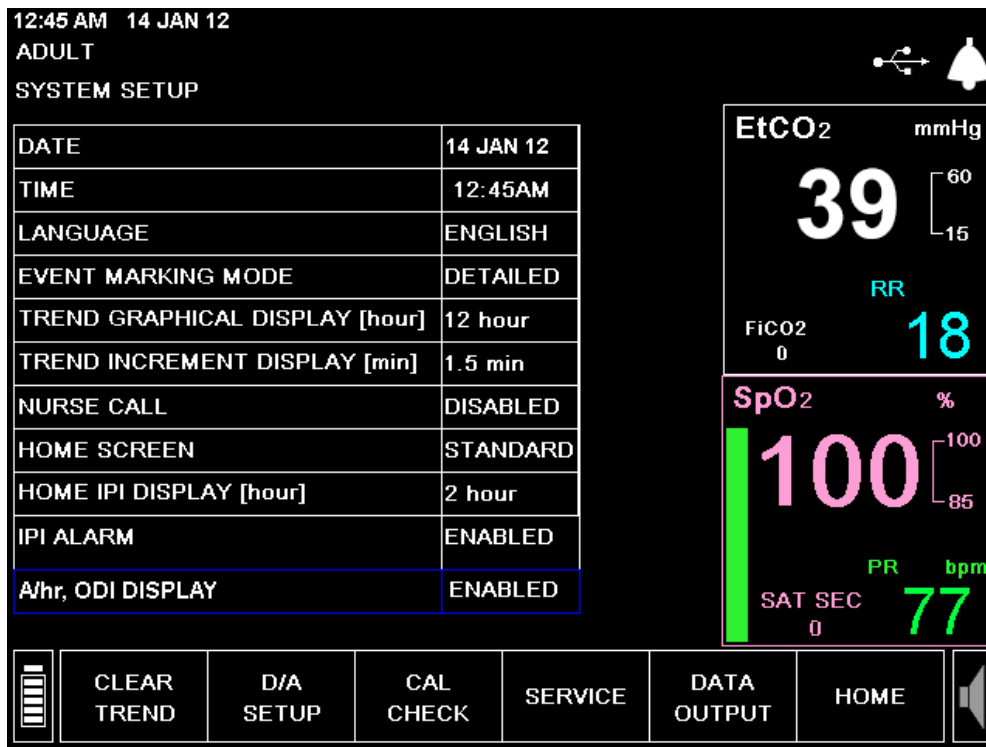
Figure 15 - System Setup Screen

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™20p monitor up and running quickly and smoothly, follow the list of instructions below:

☐ **1.   Unpack the monitor**

- Remove the Capnostream™20p 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 ⊘ 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**

- Check that the date and time that appear are correct.
- Use the control knob to select *SYSTEM* in the Menu Bar
- Change each setting, including date and time, 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 CO_2 port until it can no longer be turned, to ensure that it is connected securely to the monitor. This will assure that there is no leak of gases during measurement at the connection point and that measurement accuracy is not compromised.

☐ **7.   Connect a SpO_2 Sensor**

- Connect the SpO_2 extension cord firmly to the monitor SpO_2 sensor port, and then connect the appropriate SpO_2 sensor to the extension cord.
- Connect the SpO_2 sensor to the patient as described in its Directions for Use.

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

☐ **9.   Check Alarm Limits**

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

- Refer to Alarms and Messages on page 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 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™20p Monitor

Preparing the Monitor for a Patient

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

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

➢ **TO PREPARE THE MONITOR FOR A PATIENT:**

1. Turn on the monitor by pushing the on/off switch ⊗ on the front panel.

2. The complete power on sequence is described in Turning on the Monitor on page 30.

3. Confirm that the green power-on indicator and the orange AC power indicator light are both on.

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

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

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

5. Check date and time to ensure that it matches the current date and time. If it does not, adjust the time using the system screen as described in Setting Date, Time, Language, and Other Options on page 38.

6. 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 CO_2 waveform and the message *FILTERLINE DISCONNECTED* will appear.

If an SpO_2 sensor is not connected, there is no SpO_2 waveform and the message *SpO₂ SENSOR DISCONNECTED* will appear.

It is possible to use either the Capnography function (etCO₂) or the Pulse Oximetry function (SpO_2) without using the other function. If you only want to operate one function, connect ONLY the sensor for that function, and the monitor will operate normally.

The Capnostream™20p 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 🚶 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 38 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*.

Once the *START CASE* button is pressed, the case has begun, and that button now becomes *STOP CASE*. A new case cannot begin until the previous case has been stopped with the *STOP CASE* button.

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

6. To end a case when monitoring the patient is finished, press the Patient Admit/Discharge 👤 key, and then select *STOP CASE*. This marks the end of the data for that patient. Stopping a case will erase the Trend Memory, and a warning that indicates *STOPPING THE CASE WILL ERASE TREND MEMORY; PRESS "STOP CASE" AGAIN TO CONFIRM* will appear on the screen when *STOP CASE* is pressed. If you want to transfer or print case or trend data, this **must** be done before the case is stopped. If you do not want to stop the case, simply turn the knob to remove the question from the screen and continue the case. If you do want to stop the case, click the control knob again.

7. If *STOP CASE* is not pressed when the user finishes monitoring and powers off the monitor, the case will continue when the monitor is turned off and then on again. However, when the monitor is powered up again in such a case, a warning will suggest that the user clear trend data and close the case (to clear patient ID) before beginning a new monitoring session. This screen is seen in Figure 34 - Trend Memory Message on page 90. The company 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 111.

Table 8 - Event Markings

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

* CO_2 Insufflation

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

Changing the Alarm and Pulse Volumes

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

Alarm Volume

➢ **TO MAKE THE ALARM VOLUME LOUDER OR SOFTER:**

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

Figure 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

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

Pulse Tone Volume

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

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

Setting the Pulse Tone Volume

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

Figure 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 SpO$_2$ display area. Click the control knob to go to the SpO$_2$ Setup screen.

2. Turn the control knob to highlight the *PULSE TONE* setting, click the knob to select the option, turn the knob once to change the setting to ON, and push the knob again to set the option.

3. A beep now sounds once for each pulse beat. To turn the pulse tone off, repeat the procedure and select *PULSE TONE* off.

Alarm Volume Default Options

The institutional default alarm volume can be set to one of the three choices described below, in the *Institutional Defaults>Monitor* screen. These choices determine the audio alarm volume when the device is turned on. See Institutional Defaults on page 111 to learn more about Institutional Defaults.

Table 9 - Audio Alarm Volume

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

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.
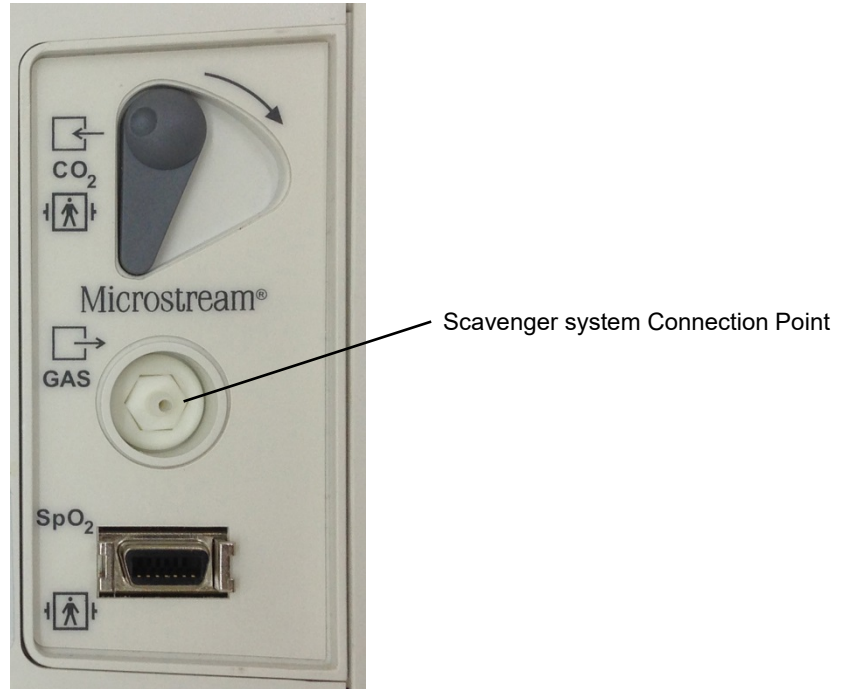
Figure 19 - Scavenger System Connection Point

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 ⏻ 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.

While the pump is off, CO_2 is not monitored and no breath waveform, $etCO_2$, $FiCO_2$, or respiration rate number values are displayed. SpO_2 and pulse rate monitoring continues.

2. Pump Off mode can be ended by pressing the Pump Off button again.

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

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

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

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

Demo Mode

The Capnostream™20p 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 111) to enter the Service screen.

2. On the Service screen, click the *DEMO MODE* button on the menu bar. The monitor will now enter Demo Mode and will display pre-recorded CO_2 and SpO_2 data. As an indicator of operation under Demo mode, the header will indicate *DEMO MODE* 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 Capnostream™20p.
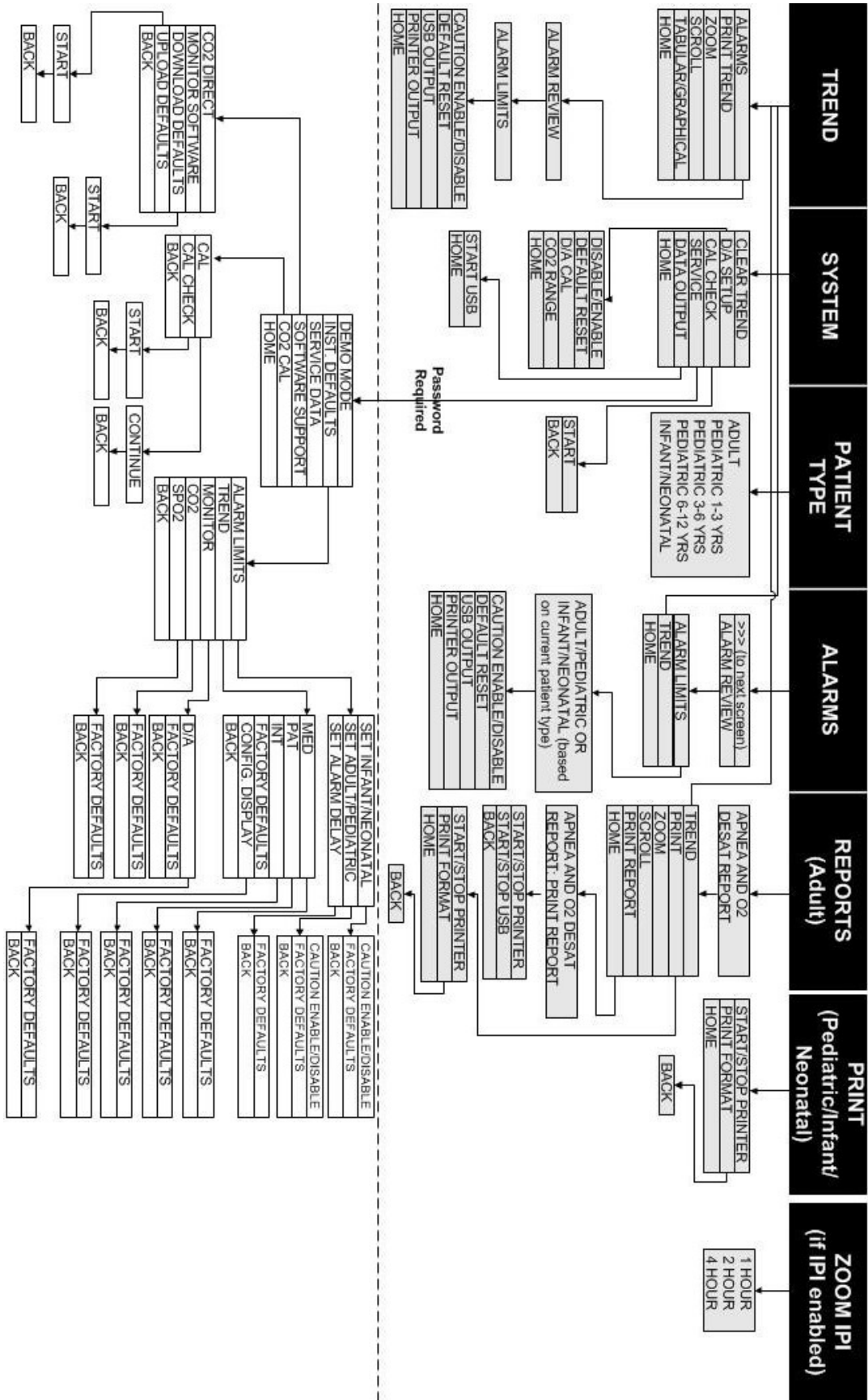
Figure 20 - Screen Menu Reference Chart when A/hr and ODI are available

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

Capnography with the Capnostream™20p Monitor

Microstream™ EtCO$_2$ Consumables

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™20p message area. If the FilterLine™ cannot be cleared, the message *FilterLine Blockage* will appear in the CO$_2$ waveform display section on the Home screen and in the Capnostream™20p message area. (If there is no waveform display, the message will appear only in the message area.) Replace the FilterLine™ once the *FilterLine Blockage* message appears.
WARNING:	The FilterLine™ may ignite in the presence of O$_2$ when directly exposed to laser, ESU devices, or high heat. When performing head and neck procedures involving laser, electrosurgical devices or high heat, use with caution to prevent combustion of the FilterLine™ or surrounding surgical drapes.
CAUTION:	Before use, carefully read the Microstream™ etCO$_2$ consumables *Directions for Use*.
CAUTION:	Only use Microstream™ etCO$_2$ consumables to ensure the monitor functions properly.
CAUTION:	Microstream™ etCO$_2$ consumables are designed for single patient use, and are not to be reprocessed. Do not attempt to clean, disinfect or blow out the FilterLine™ as the monitor can be damaged.
CAUTION:	Dispose of Microstream™ etCO$_2$ consumables according to standard operating procedures or local regulations for the disposal of contaminated medical waste.
CAUTION:	When monitoring with capnography during sedation, please note that sedation may cause hypoventilation and CO$_2$ waveform distortion or disappearance. Waveform attenuation or disappearance is an indicator that the status of the patient's airway should be assessed.
CAUTION:	When monitoring patients during upper endoscopy, partial blockage of the oral airway due to endoscope positioning may cause periods of low readings and rounded waveforms. The occurrence will be more pronounced with high oxygen delivery levels.
CAUTION:	If CO$_2$ insufflation is performed during CO$_2$ monitoring, the etCO$_2$ values will accordingly rise very significantly and this may result in device alarms and abnormally high waveforms until the CO$_2$ is evacuated from the patient.

When connecting a sampling line to the monitor, screw the sampling line connecter clockwise into the monitor CO$_2$ port until it can no longer be turned, to ensure that it is connected securely to the monitor. This will assure that there is no leak of gases during measurement at the connection point and that measurement accuracy is not compromised.

Following connection of the CO$_2$ sampling line, check that CO$_2$ values appear on the monitor display.

CO2 sampling lines used with the monitor are marked as to the upper limit of oxygen that may be provided with the sampling line. At levels of oxygen provision higher than those marked on the sampling line packaging, dilution of CO2 readings may occur, leading to lower CO2 values.

Basic Principles

When choosing Microstream™ etCO$_2$ consumables, the following should be considered:

- Whether the patient is intubated or non-intubated
- Whether the patient is on mechanical ventilation
- Duration of use
- Patient's size and weight
- 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™ etCO$_2$ Consumables' *Directions for Use* for proper connection.

Microstream™ EtCO$_2$ Consumables

A list of Microstream™ etCO$_2$ consumables appear in Microstream™ EtCO2 Consumables on page 127.

Microstream products providing oral and nasal sampling are available.

H products for long term use are also available

The generic term FilterLine™, used in this manual, is interchangeable with any of the Microstream™ etCO$_2$ consumables.

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

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.

The Capnostream™20p monitor's CO$_2$ function will enter standby mode automatically in cases when the Capnostream™20p 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.

CO$_2$ Data Displayed by the Capnostream™20p Monitor

The Capnostream™20p monitor Home screen displays real time CO$_2$ data. The displayed data includes:

- Real time etCO$_2$ and FiCO$_2$ values along with selected unit (see CO2 Data Displayed by the Capnostream™20p Monitor on page 54 for details regarding the available units)
- Real-time FiCO$_2$ values along with selected unit (see Adjustable CO2 Parameters on page 56 for details regarding the available units)
- Respiration rate (RR) in breaths per minute

- CO_2 Waveform

CO₂ Waveform

EtCO₂, FiCO₂ and Respiration Rate values
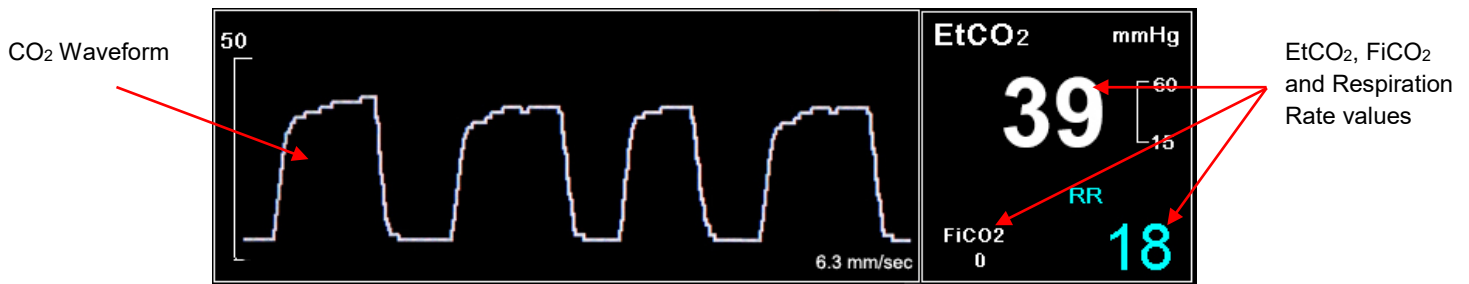
Figure 22 - CO₂ Data on the Capnostream™20p Monitor

Additionally, the monitor can display CO_2 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 111 for more information on how to set Institutional Defaults.

If the numeric home screen is chosen, the CO_2 waveform will not appear. Instead, CO_2 data will appear in a large font, to enable easy viewing, even at a distance. The CO_2 section of the numeric home screen is seen in Figure 23 - CO2 Section of Numeric Home Screen, below.

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.

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.

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

Figure 23 - CO₂ Section of Numeric Home Screen

Adjustable CO$_2$ Parameters

The Capnostream™20p monitor provides the option of adjusting some parameter settings used for CO$_2$ measurement to suit your patients, your institution's requirements, or other needs. To change these settings on a temporary basis, until the device is turned off, follow the procedure below. To set changes as institutional defaults so that the settings will remain in effect even after the monitor is turned off, see CO2 Parameters on page 117.

➢ **To Change CO$_2$ Parameter Settings:**

1. On the Home screen, move the control knob to the CO$_2$ section of the screen, so that it is outlined in blue. Click the control knob.

2. The CO$_2$ Setup screen will appear. Move the control knob to the parameter that you wish to change and click to select that parameter. Move the control knob to select the desired setting and click to select the setting. A list of the settings that can be changed appears in Table 10 - Adjustable CO2 Parameters, below.

3. Move the control knob to the *HOME* button and click to select. The screen will also revert to the Home screen after a few seconds if no additional actions are taken on that screen, but if the screen timed out and reverted back to the *HOME* screen in this manner, changes will not be saved.

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

Table 10 - Adjustable CO$_2$ Parameters

Parameter	Choices	Factory Default
BTPS*	On/Off	On
FiCO$_2$ Display	On/Off	On
Pump-Off Timeout (minutes)	5, 10, 15 or 30	15
CO$_2$ Waveform Scale (mmHg)	50, 100, 150, Auto	Auto
EtCO$_2$ Scale for Trend Display	50, 100, 150	50
RR Scale for Trend Display	50, 100, 150	50
Sweep Speed** (mm/sec) [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

* 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.

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

Please note that if the waveform scale is changed in the CO$_2$ Setup screen or in Institutional Defaults, a CO$_2$ waveform with upper values that exceed the upper level of the scale will appear incompletely, with the higher values cut off. Therefore, the default waveform scale is Auto.

Monitoring CO$_2$ during MRI Scanning

The monitor should not be used for etCO2 monitoring during magnetic resonance imaging (MRI).

Pulse Oximetry with the Capnostream™20p Monitor

Nellcor™ SpO$_2$ 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 SpO$_2$ measurements. Other sensors may cause improper monitor performance.
WARNING:	Do not use oximetry sensors during magnetic resonance imaging (MRI) scanning. Conducted current could cause burns. The sensors may affect the MRI image and the MRI unit may affect the accuracy of oximetry measurements.
WARNING:	Tissue damage can be caused by incorrect application or use of a pulse oximetry sensor. Inspect the sensor site as directed in the Instructions for Use. Do not apply the sensor too tightly or by using excessive pressure. Do not wrap the sensor, apply supplemental tape, or leave the sensor too long in one place. If the skin under the sensor becomes irritated, change the location of the sensor.
CAUTION:	Single-patient use sensors and adhesive sensors are intended for single-patient use only. Do not transfer a single-use sensor or an adhesive sensor from one patient to a second patient.

The 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.

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 SpO$_2$. 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 SpO$_2$. 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 OxiMax™ algorithm automatically extends the amount of data required for measuring SpO_2 and pulse rate depending on the measurement conditions. The OxiMax™ 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 Nellcor™ 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 OxiMax™ digital calibration system. While this will not affect use of the simulator for verifying system functionality, displayed SpO_2 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.

Table 11 – Nellcor™ SpO₂ Sensors

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

Oxygen Sensor	Model	Patient Weight
	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 adhesive)	OXI-A/N	<3 kg or>40 kg
	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 SpO$_2$ Sensor, non-adhesive (Single-patient use)	SC-NEO	1.5 to 5 kg
Nellcor™ Adult SpO$_2$ Sensor, non-adhesive (Single-patient use)	SC-A	>40 kg
Nellcor™ Adult Respiratory Sensor, SpO$_2$, RR	10068119	>30 kg
Nellcor™ Flexible SpO2 Sensor (non-sterile, reusable)	FLEXMAX	≥ 20kg
	FLEXMAX-P	≥ 20kg
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. SpO_2 and pulse rate values were varied across the monitoring range over a range of weak signal conditions and compared to the known true saturation and pulse rate of the input signals.

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 SpO_2 extension cord firmly to the monitor SpO_2 sensor port, and then connect the appropriate Nellcor™ SpO_2 sensor to the extension cord.

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

3. When the SpO_2 sensor is plugged into the extension cable and connected to the monitor, the monitor will immediately begin to search for a pulse. It will indicate *NO PULSE FOUND* and *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 SpO_2 sensor to the extension cable until it is time to connect the patient to the monitor.

SpO₂ Data Displayed by the Capnostream™20p Monitor

The Capnostream™20p monitor Home screen displays real time SpO_2 data. The displayed data includes:

- SpO_2 Numeric
- Pulse Rate

- Sat Seconds figure (see SpO2 Alarms and SatSeconds on page 81 for an explanation of this issue)
- Plethysmograph (SpO$_2$ waveform)
- Interference Indicator
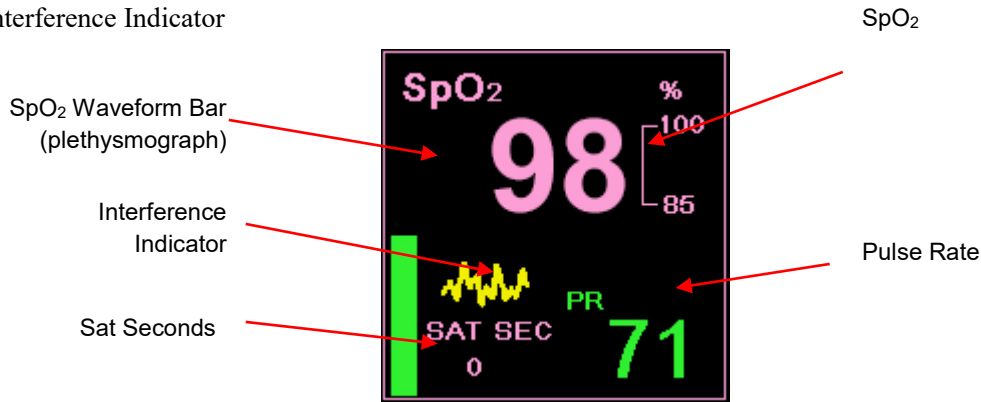
Figure 24 - SpO$_2$ Data on the Capnostream™20p Monitor - Standard Screen

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 111), the SpO$_2$ section of the home screen will appear as seen in Figure 25 - SpO2 Data on the Capnostream™20p Monitor – Standard Screen with IPI Disabled, below. The plethsysmographic waveform is non-normalized, using real-time sensor signal to reflect relative pulsatile strength.
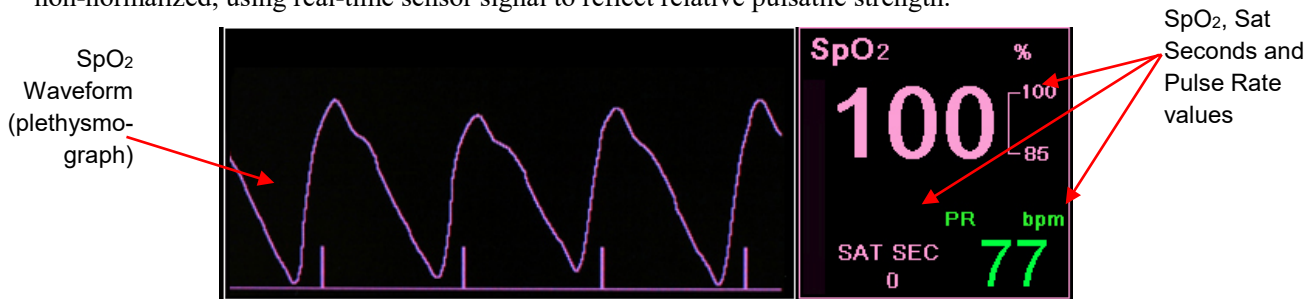
Figure 25 - SpO$_2$ Data on the Capnostream™20p Monitor – Standard Screen with IPI Disabled

Additionally, the monitor can display SpO$_2$ data in trend form, showing time, date, SpO$_2$, pulse rate (PR), alarms, events and case markers to differentiate between patients. For more information about trend display, see Chapter 11 Using Trends on page 83.

When the SpO$_2$ high or low alarm limits are exceeded, the affected reading will flash to alert the attending health care professional to the specific reading that is affected.

If the numeric home screen is chosen, the SpO$_2$ waveform will not appear. Instead, SpO$_2$ data will appear in a large font, to enable easy viewing, even at a distance. The SpO$_2$ section of the numeric home screen is seen in Home Screen Numeric Display on page 36.

SpO$_2$, Sat Seconds and Pulse Rate values
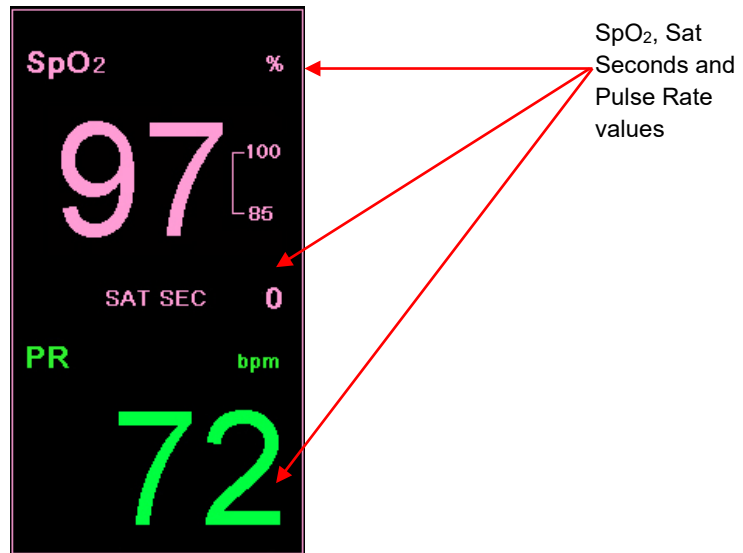
Figure 26 - SpO$_2$ Section of Numeric Home Screen

Adjustable SpO$_2$ Parameters

The Capnostream™20p 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 111.

➢ **TO CHANGE SPO$_2$ PARAMETER SETTINGS:**

1. On the Home screen, move the control knob to the SpO$_2$ section of the screen, so that it is outlined in blue. Click the control knob.

2. The SpO$_2$ Setup screen will appear. Move the control knob to the parameter that you wish to change and click to select that parameter. Move the control knob to select the desired setting and click to select the setting. A list of the settings that can be changed appears in Table 12 - Adjustable SpO2 Parameters, below.

3. Move the control knob to the *HOME* button and click to select. The screen will also revert to the Home screen after a few seconds if no additional actions are taken on that screen.

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

Table 12 - Adjustable SpO$_2$ Parameters

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

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

SpO2 Alarm Limit Message

When the SpO$_2$ alarm limit is set below 85%, a message reading SpO$_2$ LOW ALARM LIMIT: xx will appear in the header area, indicating the level of the SPO$_2$ LOW alarm limit.

Integrated Pulmonary Index™

Introduction

The Integrated Pulmonary Index™ (henceforth referred to as IPI) is a numerical value which integrates four major parameters measured by Capnostream™20p in order to provide a simple indication of the patient's overall ventilatory status. The integrated parameters are $EtCO_2$, RR, SpO_2, and PR. Only these four parameters are used to calculate IPI; other parameters are not taken into account.

IPI is calculated using the current values of these four parameters and their interactions, based on known clinical data. IPI can thus provide an early indication of a change in ventilatory status which may not be shown by the current value of any of these four parameters individually. The IPI is designed to provide additional information regarding patient status, possibly before $EtCO_2$, RR, SpO_2, or PR values reach levels of clinical concern.

The IPI trend graph (seen on the Capnostream™20p 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.
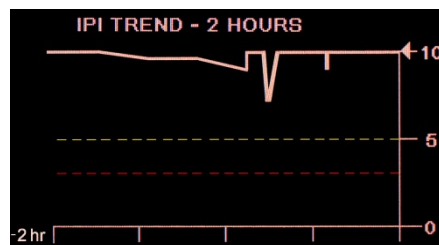
Figure 27 - IPI Trend Graph

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

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

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

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

The interpretation of the patient's IPI score may change in different clinical environments. For example, patients with specific respiratory difficulties (in contrast to normally healthy patients who are being monitored during sedation or pain management) may require a lower IPI Low 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™20p functions as a default option, along with other patient parameters such as etCO$_2$ or SpO$_2$. On the Home screen, both numerics and a trend graph are provided for IPI.

The IPI option may be disabled from 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.

Table 13 - Adjustable IPI Options

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

To change IPI Display and Alert options on a more permanent basis, use the Institutional Defaults option, described in Institutional Defaults on page 111. 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

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

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

A/hr and ODI report apnea and oxygen desaturation events and calculates the associated Apnea per Hour (A/hr) and Oxygen Desaturation Index (ODI). By using A/hr and ODI, clinicians are able to recognize ventilation and oxygenation abnormalities while patients are being monitored during their hospital stay with Capnostream™20p. 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 O_2 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™20p 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 O_2 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 ≥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™20p Apneas per Hour

In the Capnostream™20p 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 56.

Oxygen Desaturation Index (ODI)

The Oxygen Desaturation Index (ODI) indicates the "dips" in SpO_2 – that is, the number of times that the SpO_2 value dropped 4% or more from baseline and returned to baseline in 240 seconds or less. (This refers to percent of oxygen saturation, not percent of the patient's current SpO_2 rate). The baseline is created when a consistent and stable (in the range of ± 1 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 O_2 Desat Report screen, ODI is average per hour "dips" in SpO_2 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.

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.

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.

When using the Capnostream™20p A/hr and ODI with a sleeping patient, it is recommended that the Capnostream™20p device be attached to a central monitoring station where alarms will be heard. Once this is done, the alarm sound on the Capnostream™20p 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 141*>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™20p 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™20p device.

Smart A/hr and ODI Home Screen Display

A/hr and ODI appear on the Home screen and are available in all Capnostream™20p functions as a default option, along with other patient parameters such as EtCO$_2$ or SpO$_2$.

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 111.

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 141.)

Alarms and Messages

Introduction

Capnostream™20p 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	None	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:

CO_2 Waveform Area Messages:

- FILTERLINE BLOCKAGE
- PERFORMING AUTO ZERO
- CLEARING FILTER LINE
- CO_2 ERROR
- CO_2 STANDBY
- FILTERLINE DISCONNECTED

SpO_2 Waveform Area Messages (when there is an SpO2 waveform area instead of IPI information):

- SpO_2 SENSOR NOT ON PATIENT
- SpO_2 STANDBY
- SpO_2 SENSOR DISCONNECTED
- SPO_2 ERROR
- SpO_2 SENSOR 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 CO_2 waveform area as well as in the header if this alarm condition exists. If the numeric home screen option is displayed (so that there is no waveform area), this message will appear only in the header area.

Likewise, the message "SpO_2 SENSOR NOT ON PATIENT" appears in the SpO_2 waveform area as well as in the header if this alarm condition exists. If the IPI option is enabled or 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™20p 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™20p 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.
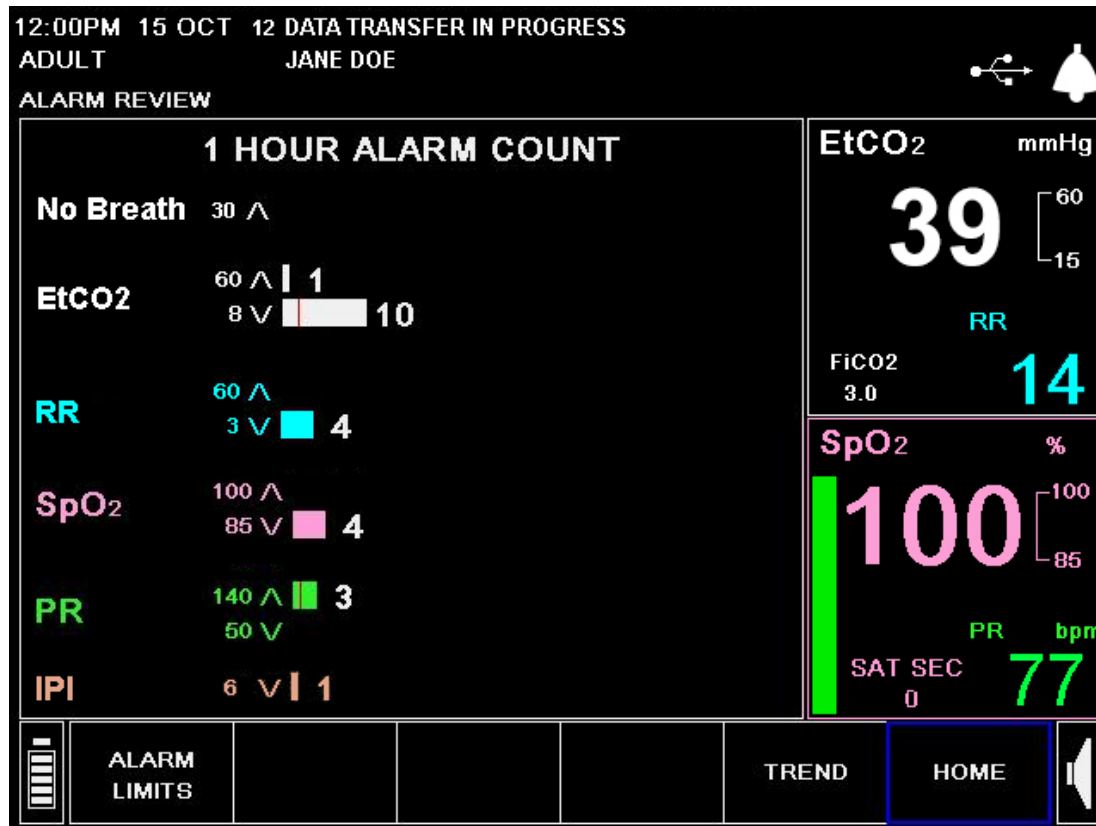
Figure 28 – Capnostream™20p Alarm Review Screen

The Alarm Review screen covers the following alarms:

- No Breath Alarm
- EtCO$_2$ High and Low Alarms
- Respiration Rate High and Low Alarms
- SpO$_2$ 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 115 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 etCO$_2$ High alarm limit is set at 60, a level of 60 will be shown on the Alarm Review screen for etCO$_2$ High, to the left of the upper white bar. If the alarm limit has been changed, the current limit will appear, but the

number of alarms will reflect the limit in place when that alarm occurred, thereby accurately representing the number of alarms that occurred under each different alarm limit.

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

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

Message Priorities

Alarms and advisory messages are displayed in the header area of the monitor in order of priority. When there is an alarm, only the alarm messages will appear in the message area, and advisory messages will not appear until the alarm condition is cleared. For example, if there is a *RR HIGH ALARM*, this alarm message will appear in the message area, and the advisory message *SPO₂ 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 *SpO₂ 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™20p 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.

$EtCO_2$, RR and PR High Alarms and SpO_2 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™20p 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

). 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.
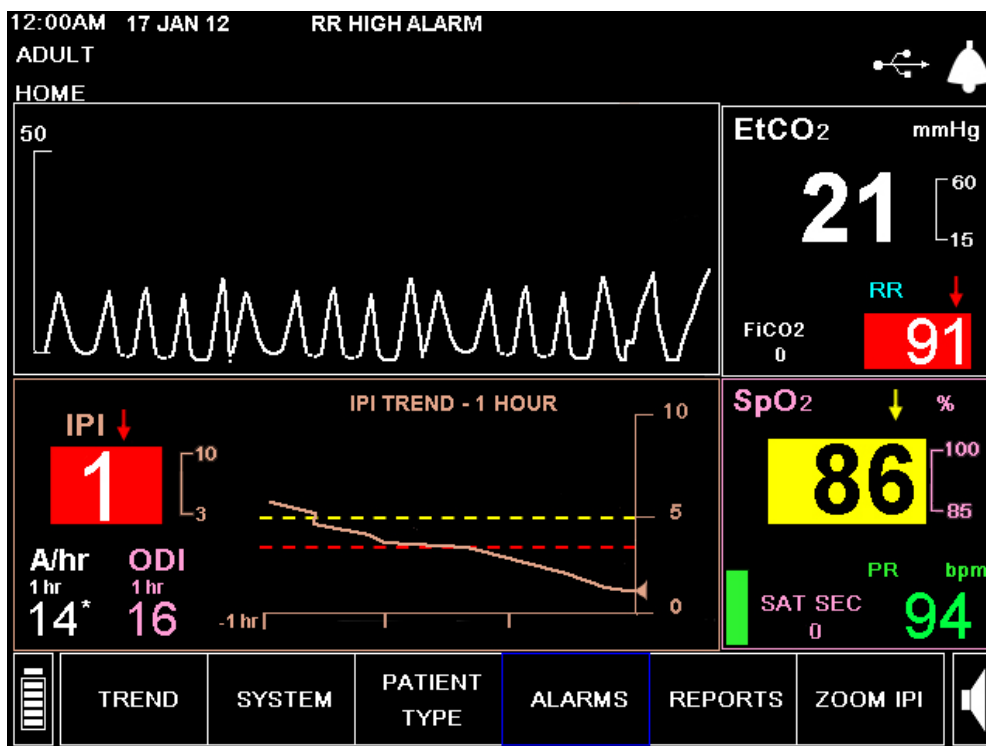
Figure 29 - Example Showing Alarms

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

High Priority Alarms

Table 15 - High Priority Alarms

Message	Description	Corrective Action
NO BREATH XXX SECONDS	No valid breath has been detected for xxx seconds	Patient requires immediate medical attention.
ETCO$_2$ HIGH ALARM	The etCO$_2$ is above the upper alarm limit	Patient requires immediate medical attention.
ETCO$_2$ LOW ALARM	The etCO$_2$ is below the lower alarm limit	Patient requires immediate medical attention.

Message	Description	Corrective Action
RR HIGH ALARM	The RR is above the upper alarm limit	Patient requires immediate medical attention.
RR LOW ALARM	The RR is below the lower alarm limit	Patient requires immediate medical attention.
SPO$_2$ HIGH ALARM	The SpO$_2$ is above the upper alarm limit	Patient requires immediate medical attention.
SPO$_2$ LOW ALARM	The SpO$_2$ is below the lower alarm limit	Patient requires immediate medical attention.
PULSE RATE HIGH ALARM	The pulse rate is above the upper alarm limit	Patient requires immediate medical attention.
PULSE RATE LOW ALARM	The pulse rate is below the lower alarm limit	Patient requires immediate medical attention.
FiCO$_2$ 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
CO$_2$ ERROR	Failure has occurred which prohibits the operation of the CO$_2$ function.	Contact Medtronic authorized personnel.
SPO$_2$ ERROR	Failure has occurred which prohibits the operation of the SpO$_2$ function.	Contact Medtronic authorized personnel.
SpO2 SENSOR ERROR	The SpO$_2$ sensor connected to the device is not functioning.	Contact Medtronic 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.
SPO$_2$ 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™.

Message	Description	Corrective Action
BATTERY LOW	Battery charge level is low and monitor will shut down soon.	Connect monitor to AC power.
REMOTE SYSTEM DISCONNECTED	Capnostream™20p 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.
CO$_2$ READY	Before the first measurement of CO$_2$, after the FilterLine™ is connected and before patient breath is detected, *CO$_2$ READY* replaces the *CO$_2$ WARM-UP* message.
CALIBRATION REQUIRED	CO$_2$ calibration is overdue.
MAINTENANCE REQUIRED	CO$_2$ maintenance is overdue.
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.

Message	Description
RS-232 DATA TRANSFER ABORTED	RS-232 data communication has been stopped.
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.
SPO_2 LOW ALARM LIMIT: XX	Displayed if the SpO_2 Low alarm limit is set below 85%.
REMOTE SYSTEM CONNECTED*	Capnostream™20p 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™20p 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:

ACTION 1
In Institutional Defaults

ACTION 2
Activate by 2-sec press of Alarm Silence Key at monitor front
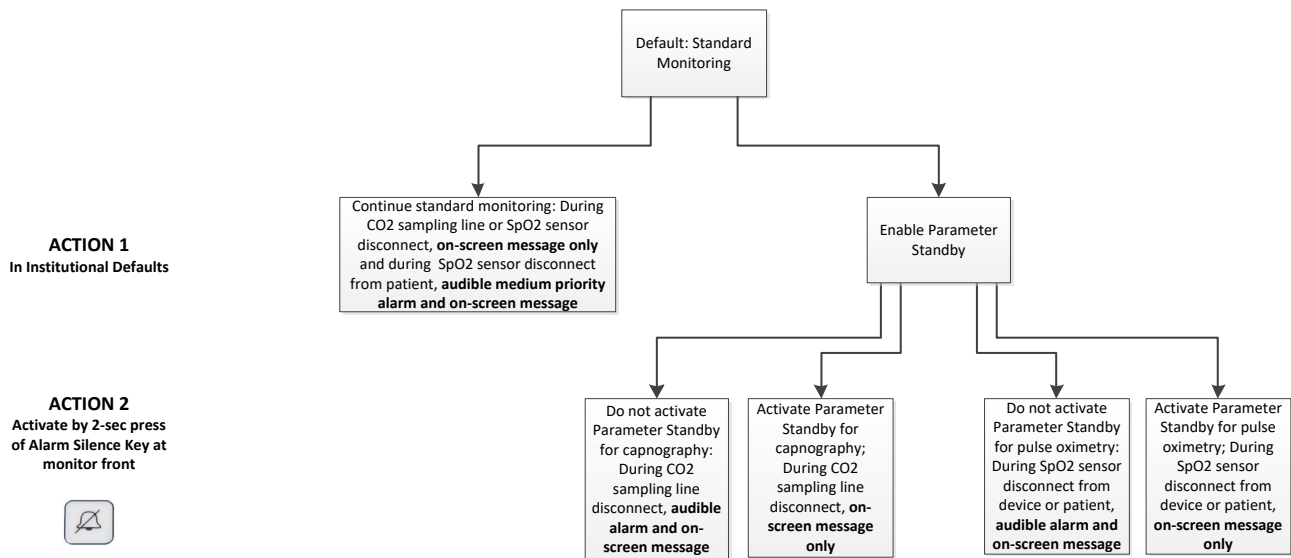
In Standard Mode (when Parameter Standby Mode is not enabled), removing a FilterLine™ or SpO_2 sensor/extension cable from the device will cause a message to appear on the screen (*FILTERLINE DISCONNECTED* or *SpO_2 SENSOR DISCONNECTED*, as relevant) but no alarms will sound. Removing the SpO_2 sensor from 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™/SpO_2 sensor from the device, perhaps by patients or patients' visitors.

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

Parameter Standby mode 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 SpO_2 sensor from the device or remove the SpO_2 sensor from the patient.

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 SpO_2 Sensor Disconnected alarm or the SpO_2 Sensor Not on Patient alarm is currently alarming, or if an SpO_2 sensor has not yet been connected to the device or sensed a pulse, since the time it was turned on.

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 the monitor is currently monitoring a patient with pulse oximetry.

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

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), as previously.

3. Once parameter standby is activated, the following will take place: In this mode, CO_2 and/or SpO_2 alarms do not exist, so neither audible alarms, the flashing yellow LED on the Capnostream™20p 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 ( ) while the FilterLine™ is disconnected and the SpO_2 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 SpO_2 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 SpO_2 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™20p 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: ⚠.

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 111), 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.

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.
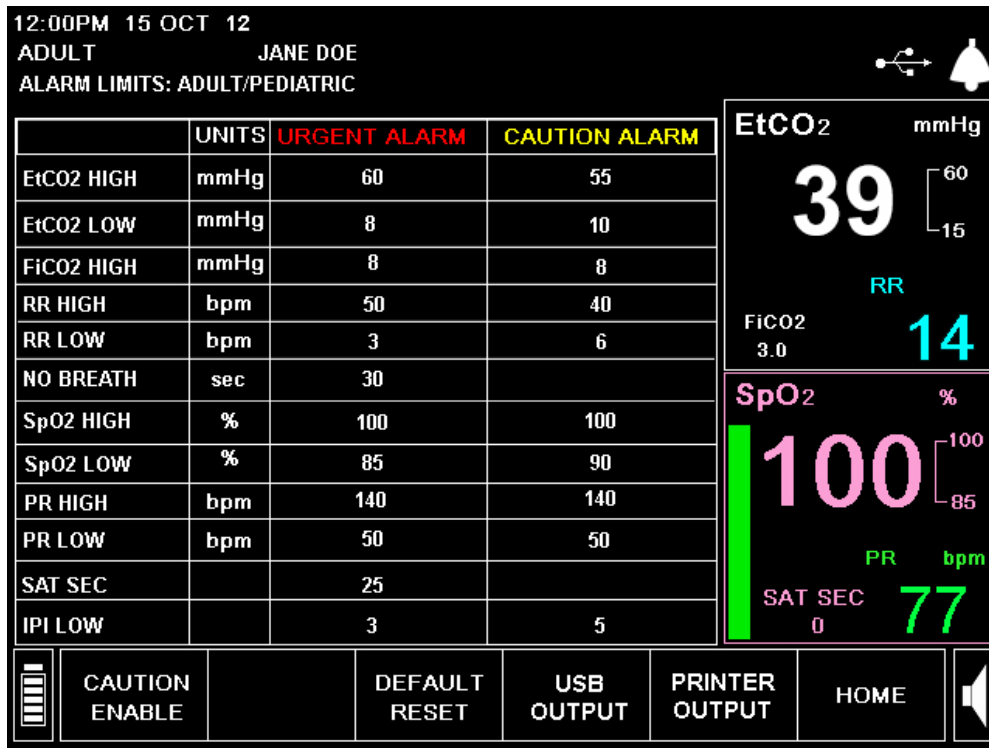
Figure 30 - Alarm Limits Screen

➢ **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 111).

A potential hazard may exist if different alarm pre-sets are used for the same or different equipment in any single area.

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 SpO_2 values on the Monitor. Once SpO_2 values are displayed, remove the sensor from the test subject to create a *SENSOR NOT ON PATIENT* situation. The monitor should then display a *SENSOR NOT ON PATIENT* alarm.

SpO_2 Alarms and SatSeconds

Capnostream™20p uses the Nellcor™ SatSeconds technology to help reduce the number and frequency of false SpO_2 alarms. The technology works with the SpO2 red urgent alarm limits and not with the yellow caution limits.

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

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

The method of calculation is as follows:

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

Points x Seconds = SatSeconds

Where:

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

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

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

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

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

The resulting SatSeconds are:

$\%SpO_2$		Seconds		SatSeconds
2	x	2	=	4
4	x	3	=	12
6	x	6	=	36

Total SatSeconds = 52

After approximately 10.9 seconds the SpO_2 alarm would sound, because 50 SatSeconds had been exceeded (note the arrow in the figure below).
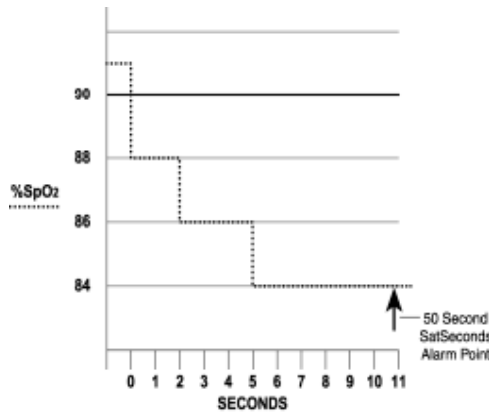
Saturation levels may fluctuate rather than remain steady for a period of several seconds. Often, the $\%SpO_2$ levels may fluctuate above and below the alarm limit, re-entering the non-alarm range several times.

During such fluctuations, the Capnostream™20p integrates the number of $\%SpO_2$ points, both positive and negative, until either the SatSeconds limit (SatSeconds time setting) is reached, or the $\%SpO_2$ level returns to within a normal range and remains there.

SatSeconds Alarm Display

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

Alarm Limits - Factory Defaults

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

Caution Alarms are disabled by default.

Using Trends

Introduction

Capnostream™20p 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, $EtCO_2$, RR, SpO_2, 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 O_2 Desaturation Report screen and printout. For more details, see Apnea and O2 Desaturation Report on page 93.

Download of trend information to a USB device before shutdown or before ending a patient case is strongly recommended to ensure backup of the trend data.

Changing the resolution of how often data is stored can be done in the Institutional Defaults screen only (See Institutional Defaults on page 111).

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 you want to reference this data at a later date, it is recommended to download the trend data before shutdown of the monitor, to ensure backup.

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 115.

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.
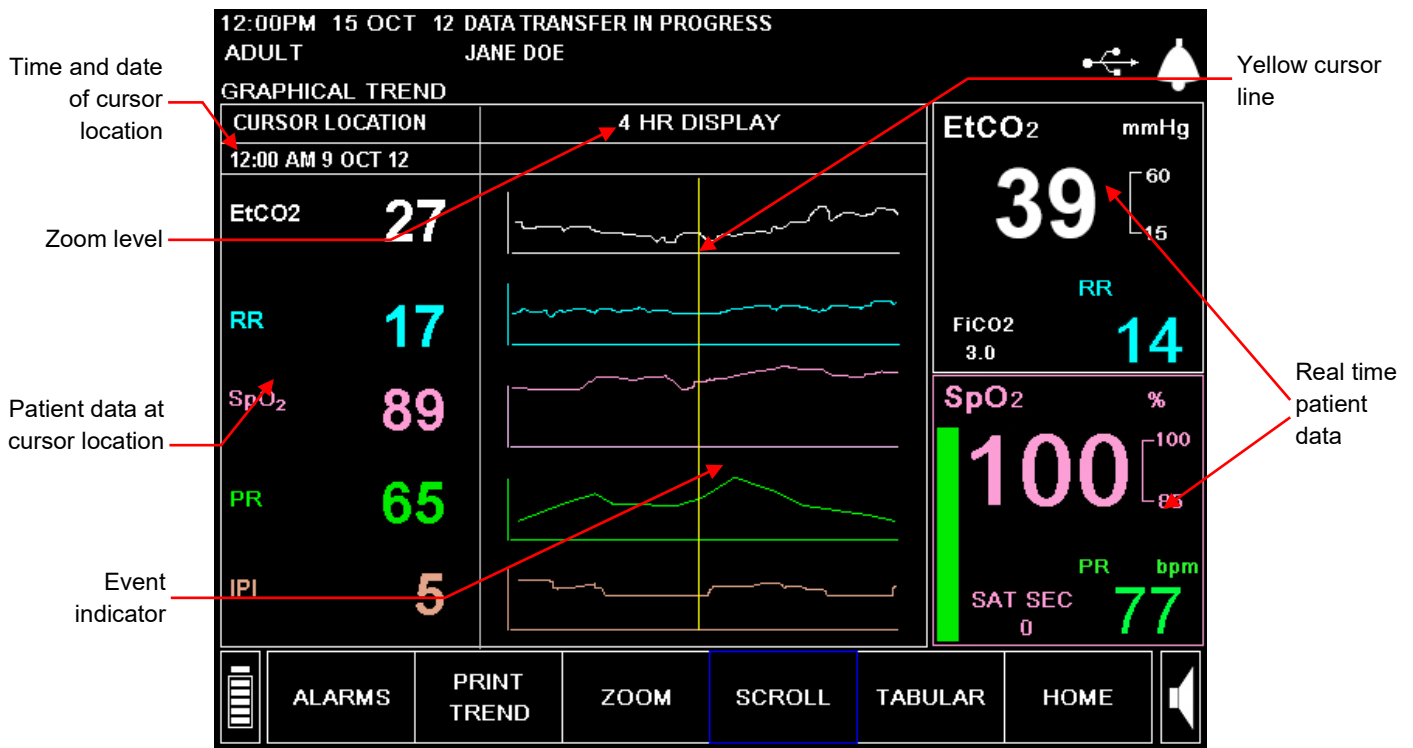
Figure 31 - Graphical Trend Display

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: SpO$_2$ 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 EtCO$_2$, SpO$_2$, RR, and PR alarms, the red line is drawn through the respective graph of the waveform for that parameter. In the case of *NO BREATH* alarms, the red line extends though both the etCO$_2$ and RR graphs. The actual alarm details can be viewed in the Tabular Trend display screen, 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.
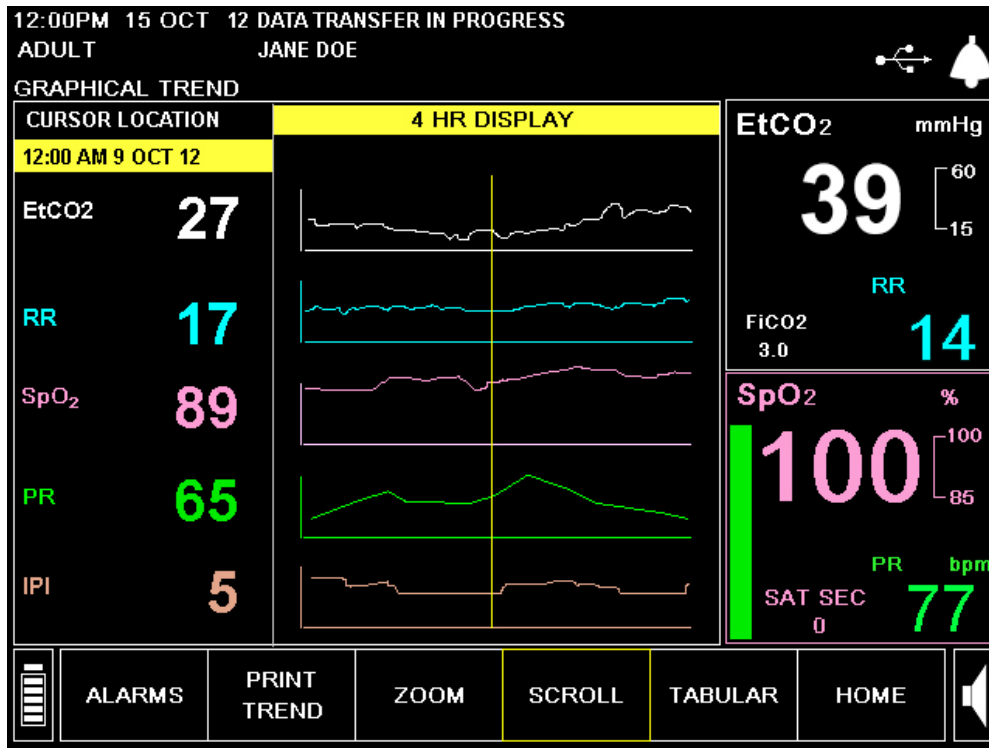
Figure 32 - Scroll mode in the Graphical Trend

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 . 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.
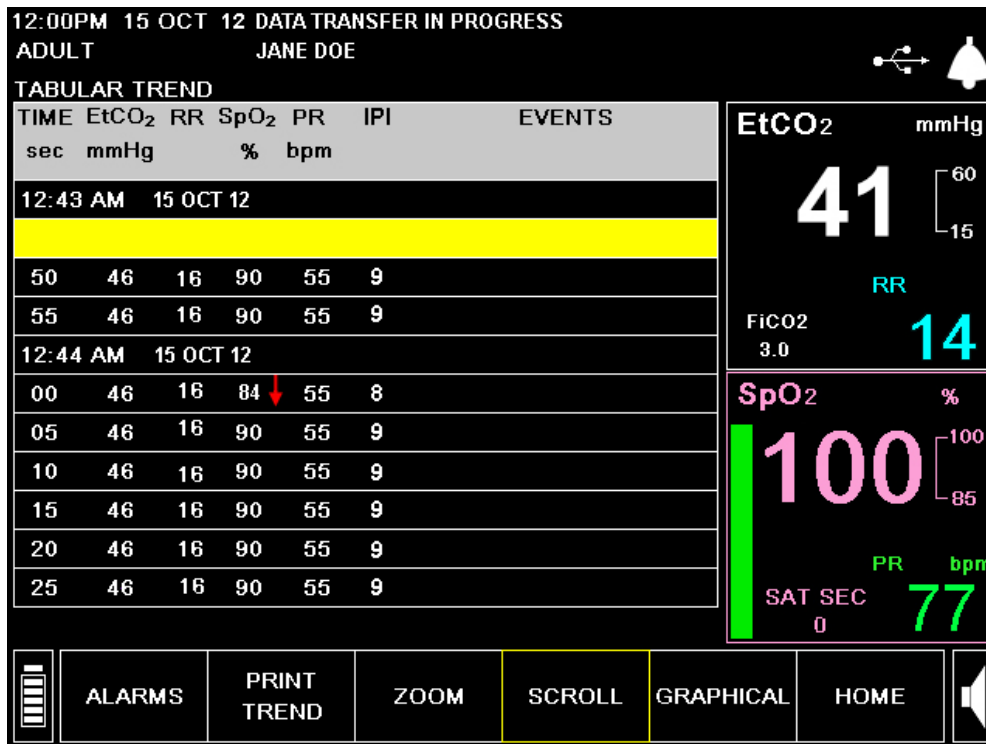
Figure 33 - Tabular Trend Display

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 111 for instructions on how to change the recording resolution).

The controls for viewing tabular data are:

- *GRAPHICAL* – switches the display from to Graphical from Tabular display (in the Graphical trend display, this changes to Tabular)

- *SCROLL* – allows you to scroll through the table of patient data.

- *ZOOM* – allows you to increase or decrease how much time is averaged into each data point shown in the table. At the lowest setting, the zoom allows you to examine detailed alarms and events.

- *PRINT TREND* – provides a printout of the trend display currently seen on the screen.

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

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

Table 20 - Tabular Display Example

TIME	EtCO₂ mmHg	RR bpm	SpO₂ %	PR bpm	IPI	EVENTS
12:23 AM	May 23 10					
10	41	17	98	71	9	2*
12:24 AM	May 23 10					
40	48	16	98	71	7	5*
12:26 AM	May 23 10					
10	49	16	98	70	7	1▲ 21*
12:27 AM	May 23 10					
40	35	17	98	71	7	22*
12:29 AM	May 23 10					
10	29	16	98	71	8	1▲ 22*
12:30 AM	May 23 10					

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).

Table 21 - Detailed Tabular Display Example

TIME sec	EtCO₂ mmHg	RR bpm	SpO₂ %	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	

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: EtCO$_2$, RR, SpO$_2$, 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 115 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 every time the device performs self-maintenance and takes approximately 10 seconds. This occurs after 1 hour of use and thereafter approximately every 12 hours or after an ambient pressure or temperature change. When this occurs, EtCO2 and other physiological values are held at their values prior to the self-maintenance.

    This process allows the module to adjust itself to changes in ambient temperature and pressure.

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.

Download of trend information to a USB device before shutdown or before ending a patient case is strongly recommended to ensure backup of the trend data.

➢ **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.

SHOULD THE MONITOR BE PREPARED FOR A NEW PATIENT
BY CLEARING THE MEMORY?

YES   NO
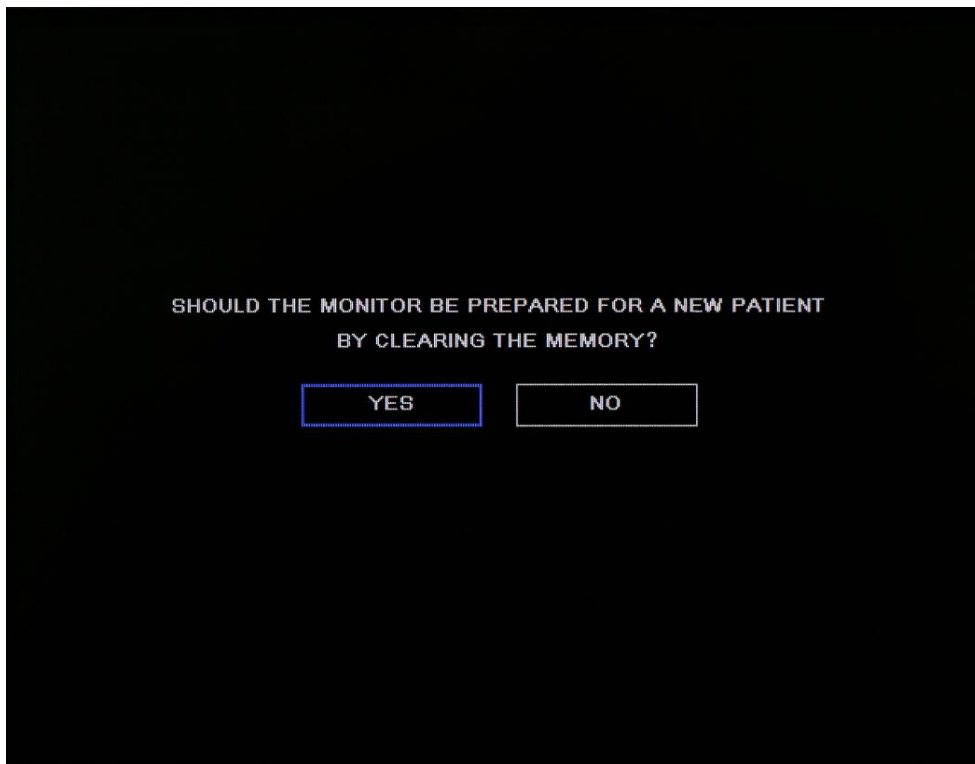
Figure 34 - Trend Memory Message

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 111).

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 45).

- 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 111 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 111).

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 O2 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, SpO_2 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).

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.

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 $EtCO_2$, $FiCO_2$, RR, SpO_2, 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™20p 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 O_2 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 O_2 Desat Report: Print Report screen.

The information provided in the Apnea and O_2 Desat Report saved to a USB flash memory drive is as follows:

Report Name	Description	Fields Included
Apnea and O_2 Desat Report	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
		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 O_2 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 (depending on selected ZOOM level).	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.
		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 O_2 Desat Report appears in .

An example of the Apnea and O_2 Desat Report screen is seen in .

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 O2 DESAT REPORT
- - - - - - - - - - - - - - - - - - - - - - - - - - - - - -
PRODUCT IDENTIFICATION
CS20P B646113042
- - - - - - - - - - - - - - - - - - - - - - - - - - - - - -
CASE ID:    ANN SIMON
ADULT
- - - - - - - - - - - - - - - - - - - - - - - - - - - - - -

ZOOM SELECTED: 12 Hours

START:          8:00 PM        SEP 22, 12
STOP:           8:00 AM        SEP 23, 12

Apnea Count (sec)
          ≥ 10            -       58
          10 - 19         -       48
          20 - 29         -       8
          ≥ 30            -       2
Desat Count               -       58


A/hr Over 12 Hours        -       5
ODI Over 12 Hours         -       5
- - - - - - - - - - - - - - - - - - - - - - - - - - - - - -
                                Apnea          Desat
                                Count          Count
                                ≥ 10
                                sec
SEP 22, 12
 8:00 PM         9:00 PM         0              0
 9:00 PM         10:00 PM        0              0
 10:00 PM        11:00 PM        0              0
SEP 23, 12
 11:00 PM        12:00 AM        6              5
 12:00 AM        1:00 AM         10             9
 1:00 AM         2:00AM          8              8
 2:00 AM         3:00 AM         8              8
 3:00 AM         4:00 AM         12             12
 4:00 AM         5:00 AM         8              8
 5:00 AM         6:00 AM         6              6
 6:00 AM         7:00 AM         0              0
 7:00 AM         8:00 AM         0              0
SEP 23, 12
```

Figure 36 - Apnea and Desat Printed Report

Printed Report Options

Capnostream™20p can be purchased with a built-in thermal strip printer. The report printing menu in Capnostream™20p 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 CO_2 Waveform
- Real Time Continuous Tabular

The printed Apnea and O_2 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 O_2 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.
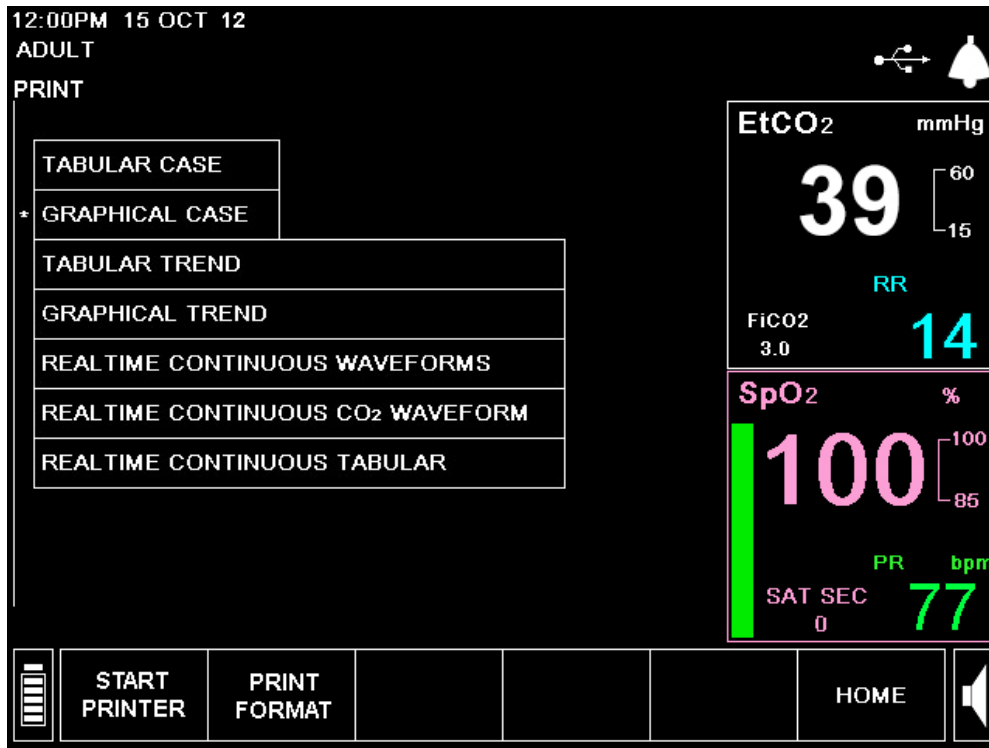
Figure 37 - Print Screen

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

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 - Printed Reports – Parameters

Report Name	Description	Fields Included	Time Frame of Report
All reports		CS20P (this indicates that the report was generated by a Capnostream™20P) 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

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.	stopped, data is not available
		Patient Urgent and Caution Alarm Occurrences All patient urgent and caution alarms	
		Equipment Advisory Message Occurrences	
		Events: EVENT 1, EVENT 2, EVENT 3	
Graphical Case Report	Patient readings of recorded case in graphical format. The time between data entries is the lowest resolution available for trend increment display (30 seconds).	Patient Readings at start and end of recording period: $EtCO_2$, RR, SpO_2, PR, IPI.	From start of case until current time; once case is stopped, data is not available
		Graphs of levels of two of the following parameters (according to the parameters chosen in the PRINT FORMAT screen, see To print a report on page 97) at 30-second intervals: $EtCO_2$ (mmHg), RR (bpm), SpO_2 (%), PR (bpm), IPI.	
Tabular Trend Report	Patient readings of trend memory in tabular format. The time between data entries is the resolution set for trend increment display (MINIMUM [30 seconds], 1.5 minutes, 3 minutes, 15 minutes, 60 minutes).	DATE, TIME	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. Only the data 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 hours), will determine the number of minutes/hours of data seen in the printout. Once trend is erased, data is not available.
		Patient Readings at start of recording period: $EtCO_2$, $FiCO_2$, RR, SpO_2, PR, IPI.	
		Patient readings at intervals set for trend increment display: Three of the following parameters (according to parameters chosen in the PRINT FORMAT screen, see To print a report on page 97): $EtCO_2$, $FiCO_2$, RR, SpO_2, PR, IPI.	
		Patient Urgent and Caution Alarm Occurrences	
		Equipment Advisory Message Occurrences	
		Events: EVENT 1, EVENT 2, EVENT 3	
Graphical Trend Report	Patient readings of trend memory in graphical format. The time between data entries is the resolution set for trend increment display (MINIMUM [30 seconds], 1.5 minutes, 3 minutes, 15 minutes, 60 minutes).	Patient Readings at start of recording period: $EtCO_2$, RR, SpO_2, PR, IPI. 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, $EtCO_2$ and $FiCO_2$ are displayed in selected units, SpO_2 in percentages, and RR and PR in bpm (beats per minute).			

Sample Reports

Sample Case Reports

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

CASE REPORT

PRODUCT IDENTIFICATION
CS20P B646113042

CASE ID: ANN SMITH
ADULT

START:	9:29:55 AM		JAN 04, 11
EtCO2 (mmHg)		RR (bpm)	
39		15	
SpO2 (%)		PR (bpm)	
98		73	

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

END:	9:56:01 AM		JAN 04, 11
EtCO2 (mmHg)		RR (bpm)	
39		15	
SpO2 (%)		PR (bpm)	
98		73	

CASE REPORT

PRODUCT IDENTIFICATION
CS20P B646113042

CASE ID: ANN SMITH
ADULT

START:	9:29:55 AM		JAN 04, 11
EtCO2 (mmHg)		RR (bpm)	
39		15	
SpO2 (%)		PR (bpm)	
98		73	

EtCO2 (mmHg)   SpO2 (%)

0   100   0   100

END:	9:56:01 AM		JAN 04, 11
EtCO2 (mmHg)		RR (bpm)	
39		15	
SpO2 (%)		PR (bpm)	
98		73	

Figure 38 - Sample Case Reports Printout

Sample Trend Reports

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

Left report:

TREND REPORT

PRODUCT IDENTIFICATION
CS20P B646113042

CASE ID: ANN SMITH
ADULT

START: 9:19:55 AM   JAN 04, 11

EtCO2 (mmHg)	RR (bpm)
39	15

SpO2 (%)	PR (bpm)
98	73

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

Right report:

TREND REPORT

PRODUCT IDENTIFICATION
CS20P B646113042

CASE ID: ANN SMITH
ADULT

START: 9:29:55 AM   JAN 04, 11

EtCO2 (mmHg)	RR (bpm)
39	15

SpO2 (%)	PR (bpm)
98	73

EtCO2 (mmHg)   SpO2 (%)
0   100 0   100

Figure 39 - Printed Trend Reports

Downloading Patient Data

Introduction

Capnostream™20p 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

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 Microsoft Excel™*. The two binary data report types are for advanced programming applications.

In addition, the Apnea and O_2 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 delimited files can be exported into Microsoft Excel™* using "tab" as the delimiter.) Reports the data stored in trend memory that is assigned to the selected case. The time between data entries is the resolution set for trend storage (5, 10 or 30 seconds).	DATE, TIME
		Patient Readings: $EtCO_2$, RR, SpO_2, PR, IPI.
		Patient Urgent and Caution Alarm Occurrences
		Equipment Advisory Message Occurrences
		Events: EVENT 1, EVENT 2, EVENT 3
Tabular Trend Report	Tab delimited (.txt) file. Reports all the data stored in trend memory. The time between data entries is the resolution set for trend storage (5, 10 or 30 seconds).	DATE, TIME
		Patient Readings: $EtCO_2$, RR, SpO_2, PR, IPI.
		Patient Urgent and Caution Alarm Occurrences
		Equipment Advisory Message Occurrences
		Events: EVENT 1, EVENT 2, EVENT 3
Real Time Continuous CO_2 Waveform	Tab delimited (.txt) file with data entries every 50 milliseconds.	DATE, TIME
		Patient Reading every 50 milliseconds (for creating CO_2 waveform): CO_2*
Real Time Continuous Tabular	Tab delimited (.txt) file, similar to the Tabular Trend report, but transmitted line by line in real time.	DATE, TIME
		Patient Readings: $EtCO_2$, $FiCO_2$, RR, SpO_2, PR, IPI, A/hr, ODI.

Report Name	Description	Fields Included
		Patient Urgent and Caution Alarm Occurrences
		Equipment Advisory Message Occurrences
		Events: EVENT 1, EVENT 2, EVENT 3
Real Time Continuous Tabular with real-time continuous waveform (shortened name is FULL CONTINUOUS TRANSFER)	Tab delimited (.txt) file, similar to the real time continuous tabular report, transmitted line by line in real time, but with data entries every 50 milliseconds (20 times a second). 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 based on the resolution set for trend storage (5, 10 or 30 seconds), so data between these points is repeated on additional rows.	DATE, TIME
		Patient Readings (at trend storage resolution): $EtCO_2$, $FiCO_2$, RR, SpO_2, PR, IPI, A/hr, ODI
		Patient Urgent and Caution Alarm Occurrences
		Equipment Advisory Message Occurrences
		Events: EVENT 1, EVENT 2, EVENT 3
		Patient reading every 50 milliseconds (for creating CO_2 waveform): CO_2 wave
Full Binary Continuous Transfer	See the document Capnostream™20p Data Transfer Protocols	
Full Binary Trend Transfer	See the document Capnostream™20p Data Transfer Protocols	

* CO_2 in mm/Hg (millimeters of mercury)

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

Line 1 – The name of the report type.

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

Line 3 – Patient type (see Setting the Patient Type on page 43 for information on patient types)

Line 4 – Blank

Line 5 – Column headings

Line 6 – Column headings second line

Capnostream™20p 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™20p is 8 GB. A typical flash memory device is shown below.

Figure 40 - Typical Flash Memory Device

➢ **TO RECORD CAPNOSTREAM™20P DATA ON A USB DEVICE:**

1. Insert a USB Flash Memory drive into the USB port on the back side of Capnostream™20p.

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

The USB port on the Capnostream™20p 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.

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 CO_2 WAVEFORM
REALTIME CONTINUOUS TABULAR
FULL CONTINUOUS TRANSFER
FULL BINARY CONTINUOUS TRANSFER
FULL BINARY TREND TRANSFER

6. An asterisk will appear to the left of the selected report name. If no case is active, the text NO CASES will appear to the right of the Tabular Case option when that option is selected.

7. Turn the control knob to select *START USB* on the Menu Bar and click to begin data transfer. Data output can be aborted by clicking again to select *STOP USB*.

CAUTION:	If the Flash Memory disk drive is removed from the Capnostream™20p 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.
CAUTION:	Ensure that there are no viruses on the USB flash memory drive prior to interfacing with the monitor.

If the Capnostream™20p does not detect the Flash Memory drive, remove and re-insert the Flash Memory drive. If the Flash Memory drive is still not detected, check that drive being used is from a supported manufacturer.

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

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 Microsoft Excel™* file for Microsoft Excel™* 2003 and lower). If the data exceeds 65,536 rows, a new file is automatically opened and the data continues to transfer into the new file. In this situation, the new file name is indexed as described below in Table 26 - File Naming Conventions.

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

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

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

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

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>_<PATIENT TYPE>_<REPORT DATE>_<REPORT TIME>_<PATIENT ID>_<FILE NO>.ext

Where:

- 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:

Table 26 - File Naming Conventions

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

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

Binary files are never split into multiple files because they do not have the length limitation imposed by MS Microsoft 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™20p 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 Capnostream™20p. 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™20p 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 111 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.

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/.

Nurse Call Operation

The Capnostream™20p 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 110.

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.

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™20p 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™20p monitor.

A 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 required to build a 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.
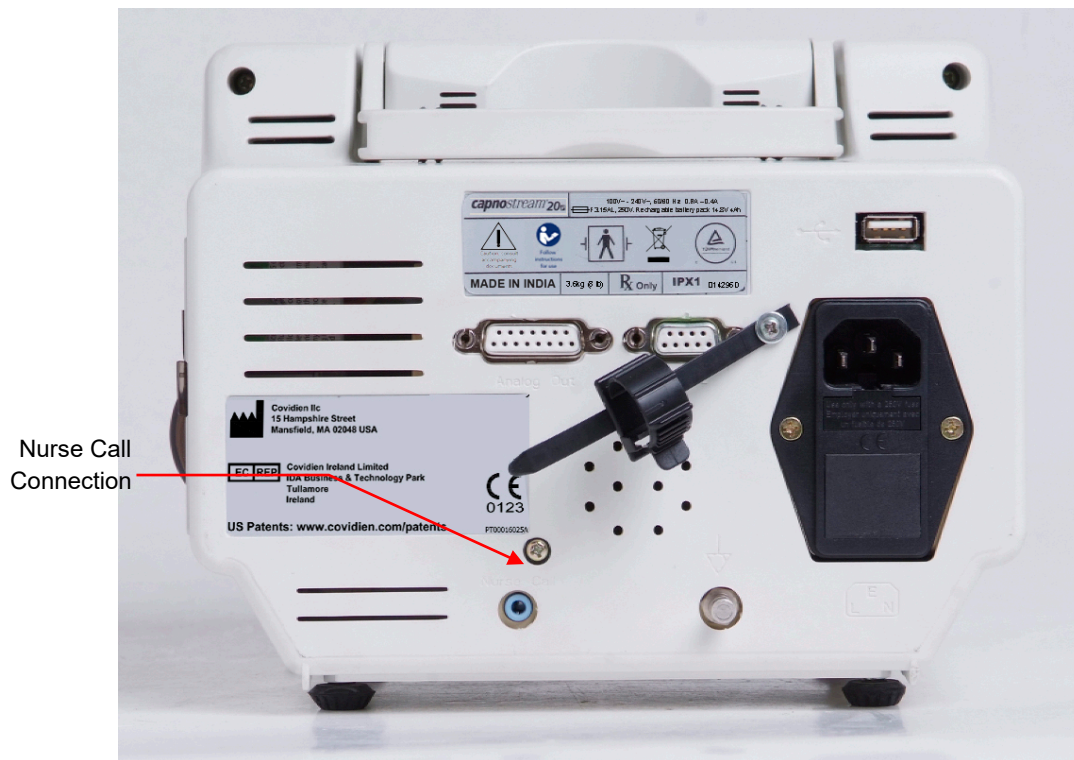
Figure 43 - Connection Point for Nurse Call

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 141).
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 79 for details regarding this feature. Nurse Call data will still be transferred if alarms are silenced through Institutional Defaults (see Institutional Defaults on page 111).

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

Institutional Settings

Institutional Defaults

Capnostream™20p is shipped from the factory with all changeable settings configured according to the tables in the section Changing Monitor Settings on page 112. 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 38, use the control knob to select *ENTER PASSWORD*. Using the control knob, enter the password and click the control knob again twice after the last letter. The password appears in Capnostream™ Service Password on page 141. 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, CO$_2$ and SpO$_2$*.

After changing any factory default setting to an institutional-specific setting, shut down the device using the on/off button and then restart the device, to ensure that the new settings have been saved.

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.

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.
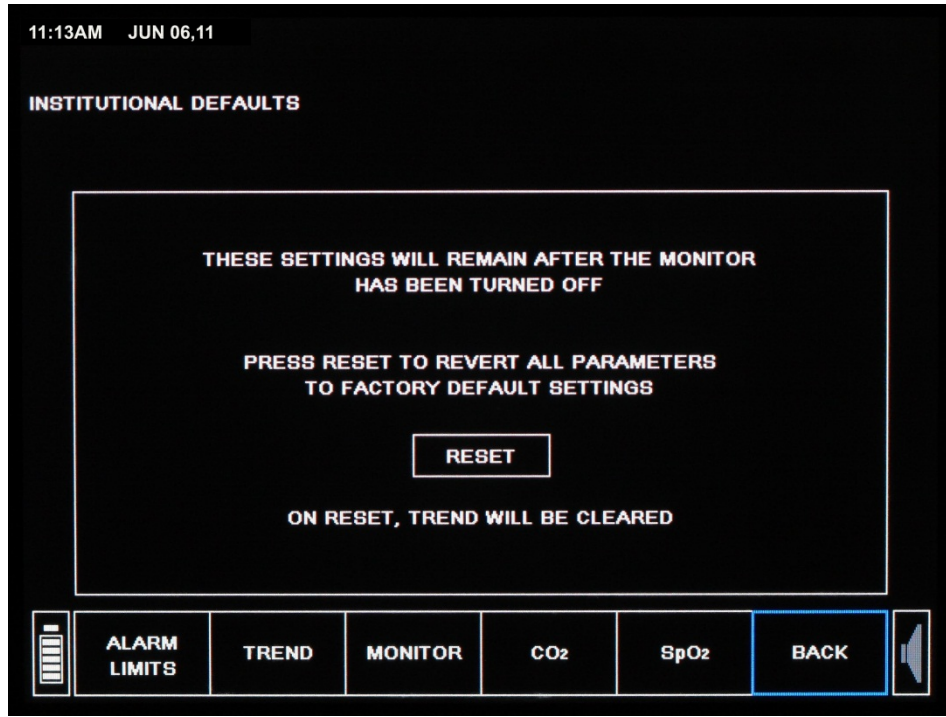
Figure 44 - Institutional Defaults Screen

Uploading or Downloading Institutional Defaults

Capnostream™20p provides the option of downloading institutional defaults from the monitor to a USB Flash Memory drive or uploading 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™20p devices in the section/institution using this procedure.

➢ **TO UPLOAD OR DOWNLOAD DEFAULTS:**

1. For upload, insert a USB Flash Memory drive with at least 2 KB in free memory into the USB port on Capnostream™20p. For download, insert a USB Flash Memory drive with Institutional Defaults previously loaded on it into the USB port on Capnostream™20p.

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 141).

4. Click the *SOFTWARE SUPPORT* menu button to enter the Software Support screen. The Software Support screen can be seen in Figure 45 - Software Support Screen on page 113.

5. Click the *UPLOAD DEFAULTS* button to upload defaults to a USB Flash Memory drive from Capnostream™20p, or click the *DOWNLOAD DEFAULTS* button to download defaults from a USB Flash Memory drive to Capnostream™20p. 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™20p. After uploading defaults, the monitor will shut itself off; restart the monitor to resume operation.

Figure 45 - 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 114.

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.
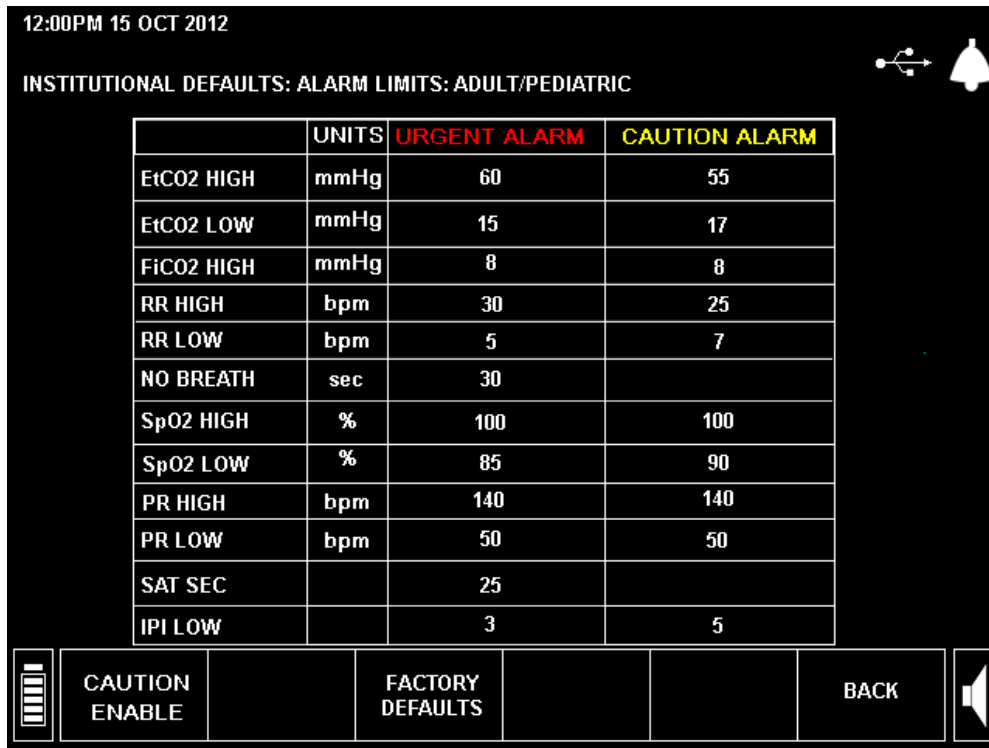
Figure 46 - Institutional Defaults Alarm Limits Screen

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 Red Urgent Alarm	Infant/Neonatal Yellow Caution Alarm	Range
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 141) *>INST DEFAULTS>ALARM LIMITS>SET ALARM DELAY.*

Table 30 - Factory Default and Optional Alarm Delay Settings

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

Trend Settings

Institutional Defaults can be set to change the Trend stored in the monitor, and how it is displayed on the screen. For the specific trend settings for SpO$_2$ and CO$_2$, see the individual settings described below for the SpO$_2$ and CO**$_2$** parameters.

Table 31 - Factory Default and Optional Trend Settings

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

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.

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 141)*>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 EtCO$_2$. 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>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™20p. 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 45 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*.
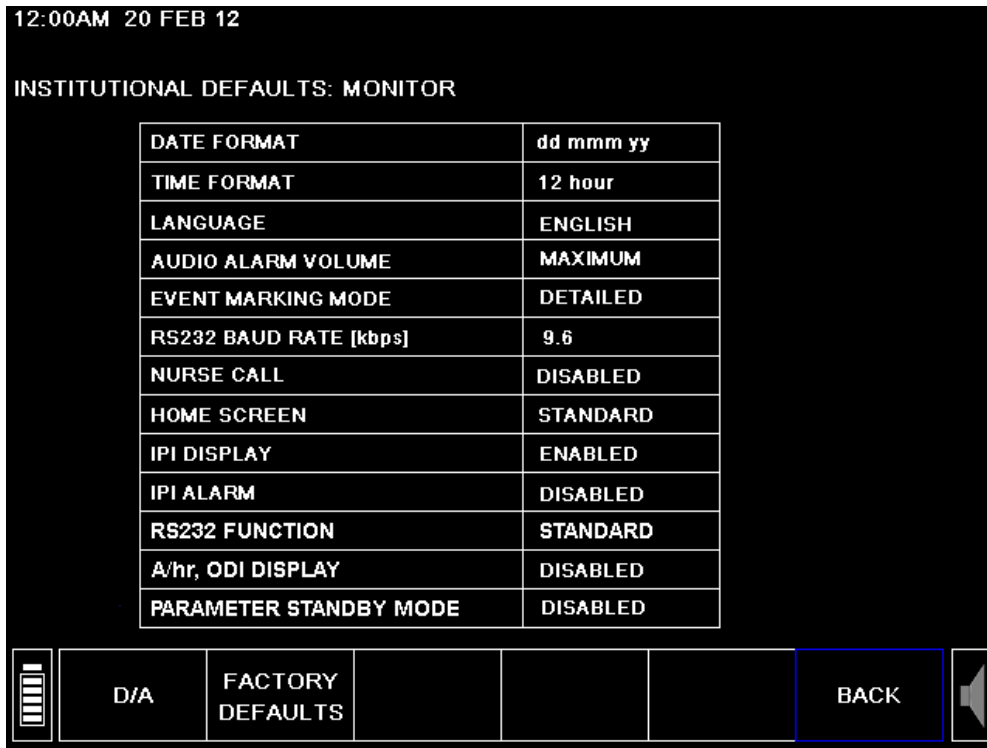
Figure 47 - Institutional Defaults: Monitor

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

Parameter	Choices	Factory Default
Date Format	dd mmm yy *or* 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: CO_2 ONLY Standard	Standard; VueLink is no longer available with Capnostream™20p
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.

CO$_2$ Parameters

Institutional Defaults can be set for all CO$_2$ parameters that are settable in the monitor. To change the parameters, select *CO2* 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.

SpO$_2$ Parameters

Institutional Defaults can be set for all SpO$_2$ parameters that are settable in the monitor. To change the parameters, select SpO$_2$ in the Institutional Defaults screen.

Parameter	Choices	Factory Default
Pulse Tone	On/Off	Off
Sat-Seconds	On/Off	On
SpO$_2$ Scale for Trend Display	0-100, 50-100	50-100
PR Scale for Trend Display	150, 300	150
Sweep Speed Adult/Pediatric (mm/sec)	3, 6.3, 12.5, 25	25
Sweep Speed Infant/Neonatal (mm/sec)	3, 6.3, 12.5, 25	25

Specifications

Power Supply

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

*The manufacturer may choose to provide F3.15A 250 Volt fuses with high breaking capacity instead.

**Use only fuses that are supplied by the manufacturer

Battery

Item	Value
Battery Type	14.4V, 4.5Ah Lithium-Ion
Battery Operation	2.5h (without thermal recorder)
Battery Charging Time	100% in 12h

Controls

Item	Value
Front Panel	1 Switch for monitor On/Off control 4 specific function keys 1 optical encoder with switch

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
CO_2 Accuracy	0-38 mmHg: ± 2 mmHg 39-150 mmHg: ± (5% of reading + 8% for every 1 mmHg over 38 mmHg) Accuracy applies for breath rates of up to 80 bpm. For breath rates above 80 bpm, accuracy is 4 mmHg or ±12 % of reading whichever is greater, for $etCO_2$ values exceeding 18 mmHg.
Respiration Rate Range	0-150 bpm
Respiration Rate Accuracy	0-70 bpm: ±1 bpm 71-120 bpm: ±2 bpm 121-150 bpm: ±3 bpm
CO_2 Alarms	No breath, $etCO_2$ high, $etCO_2$ low, RR high, RR low, IPI low (IPI also requires pulse oximetry information)
Flow Rate	50 (42.5 ≤ flow ≤ 65) ml/min, flow measured by volume
Waveform Sampling	20 samples/s
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%	$\pm$ 2 digits
SpO$_2$ range 0 - 69%	Unspecified
Infant/Neonatal Mode	
SpO$_2$ range 70% - 100%	$\pm$ 3 digits
SpO$_2$ range 0 - 69%	Unspecified
Pulse Rate Range	20-250 bpm
Pulse Rate Accuracy	$\pm$ 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. SpO$_2$ and pulse rate values were varied across the monitoring range over a range of weak signal conditions and compared to the known true saturation and pulse rate of the input signals.

Alarms

Item	Value
High Priority Patient Warning Alarms	Flashing Red LED Flashing Red Numeric Repeated beep pattern Alarm Indication on Screen Nurse Call
Patient Caution Alarms	Flashing Yellow LED Flashing Yellow Numeric No audio alarm
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

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
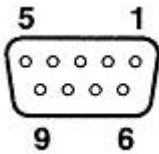
Pin	Assignment
1	--
2	PC_RX
3	PC_TX
4	5V
5	Isolated Ground
6	--
7	5V
8	--
9	--

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

General Characteristics

Item	Value
Unit Dimensions	167mm(h) x 220mm(w) x 192mm(d) (6.6in (h) x 8.7in (w) x 7.6in (d))
Unit Weight	2.2kg (4.85lb)
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 Temperature	Until lower limit of -20°C (-4°F) Up to upper limit of 60°C (140°F)
Storage and Transport Pressure and Altitude	Pressure: 430 mmHg to 795 mmHg 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	5.9kg (13.0lb)

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 Capnostream™20P 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 EN 55011	Class A	The monitor is suitable for use in hospitals
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 60601-1-2 test level	Compliance level	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD) EN 61000-4-2	± 8 kV contact ± (2, 4, 8, 15) kV air	± 8 kV contact ± (2, 4, 8, 15) 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 %. Low relative humidity together with the usage of synthetic materials could result in elevated electrostatic voltage. Electrostatic discharge of elevated voltage may cause a disturbance in the functioning of the device.
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 ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN 61000-4-5	± 2 KV for AC Power ± 500V, ± 1 kV differential mode ± 500V, ± 1 kV, ± 2 kV common mode	± 2 KV for AC Power ± 500V, ± 1 kV differential mode ± 500V, ± 1 kV, ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.

Immunity Test	IEC 60601-1-2 test level	Compliance level	Electromagnetic Environment – Guidance
Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11	0 % U$_T$; 0,5 cycle (0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°) 0 % U$_T$; 1 cycle (0°) 70 % U$_T$; 25/30 cycles (0°)	0 % U$_T$; 0,5 cycle 0 % U$_T$; 1 cycle 70 % U$_T$; 25/30 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Capnostream™20P 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	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms, in ISM band 150 kHz and 80 MHz **Radiated RF EM Fields:** 3 V/m 80 MHz to 2.7 GHz **Radiated RF Proximity Fields:** 27V/m, 385 MHz 28V/m, 450 MHz (28V/m) 9V/m, 710, 745, 780 MHz 28V/m, 810, 870, 930 MHz 28V/m , 1720, 1845, 1970 MHz 28V/m, 2450 MHz 9V/m, 5240, 5500, 5875 MHz	3 Vrms, 6Vrms (unmodulated) 3 V/m (unmodulated, rms) 27V/m 28V/m 9V/m 28V/m 28V/m 28V/m 9V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Capnostream™20P, 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 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: Minimum separation distances for higher IMMUNITY LEVELS shall be calculated using the following equation: $$E= \frac{6}{d}\sqrt{P}$$ Where P is the maximum power in W, d is the minimum separation distance in m, and E is the IMMUNITY TEST LEVEL in V/m. Minimum separation distances is 0.3m for proximity fields.

[1] U$_T$ is the a.c. mains voltage prior to application of the test level.
[2] At 80 MHz and 800MHz, the higher frequency range applies

Immunity Test	IEC 60601-1-2 test level	Compliance level	Electromagnetic Environment – Guidance
NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflections from structures, objects and people.			
a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Capnostream™20P is used exceeds the applicable RF compliance level above, the Capnostream™20P should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Capnostream™20P.			
b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.			

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

Table 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 $d= 1.2\sqrt{P}$	80 MHz to 800 MHz $d= 1.2\sqrt{P}$	800 MHz to 2,5 GHz $d= 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.27
100	12	12	23

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

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

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

Microstream™ EtCO$_2$ Consumables

Microstream™ EtCO2 Consumables

Microstream™ EtCO$_2$ Consumables

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

Microstream™ Consumables	
Intubated Consumables	
Neonatal-Infant Intubated Filter Line with Microstream™ Technology, H, Length 2.0 m	006324COV
Adult-Pediatric Intubated Filter Line with Microstream™ Technology, Length 2.0 m	XS04620COV
Adult-Pediatric Intubated Filter Line with Microstream™ Technology, H, Length 2.0 m	XS04624COV
Non-intubated Consumables	
Adult Oral-Nasal Filter Line with Microstream™ Technology, O2, H, Length 2.0 m	010433COV
Adult Filter Line with Microstream™ Technology, O2, Length 2.0 m	006912COV
Pediatric Oral-Nasal Filter Line with Microstream™ Technology, O2, Length 2.0 m	007269COV
Adult Oral-Nasal Filter Line with Microstream™ Technology, Length 2.0 m	009818COV
Adult Oral-Nasal Filter Line with Microstream™ Technology, O2, Length 2.0 m	009822COV
Adult Oral-Nasal Filter Line with Microstream™ Technology, O2, Length 4.0 m	009826COV
Adult Oral-Nasal Filter Line with Microstream™ Technology, Length 4.0 m	010340COV
Adult-Pediatric Bite Block Filter Line with Microstream™ Technology, O2, Length 2.0 m	012529COV
Adult-Pediatric Bite Block Filter Line with Microstream™ Technology, O2, Length 4.0 m	012530COV

USB Data Transfer

TM* Trademark of its respective owner.

The Capnostream™20p patient monitor (henceforth referred to as the Capnostream™ monitor) is designed to simplify transfer of patient data from the monitor to a PC. The monitor records capnography and pulse oximetry data in a commonly used text file format, which can be opened in Microsoft Microsoft Excel™*, to facilitate clinician access to patient data for patient chart documentation, later review, or research.

TM* Trademark of its respective owner.

Data Transfer via the USB Data Port

There are seven types of reports that can be transferred from Capnostream to a USB flash memory device; these are described in 10

Table 35. Data Transfer TypesData Transfer Types on page 130. Five report types are in text format and are suitable for use in applications like Microsoft Excel™*. The two binary data report types are for advanced programming applications.

These reports enable:

- Storing real-time data on a flash memory device as it occurs

or

- Transferring history data from the Capnostream™ monitor's trend memory. The history data can include a case or the entire current contents of the trend memory.

Waveform data is available only with the real-time data procedure; numeric data is available with both types of procedures.

Important: Please read this entire section so that you can determine which type of report can best fill your needs and what Trend Recording Resolution is required before you begin recording and downloading patient data.

Required Materials

To record data on the Capnostream™ monitor for later download and use on a PC, you will need the following:

- Capnostream™ monitor
- USB flash memory drive. The Capnostream™ monitor recognizes USB flash memory drive devices manufactured by Sandisk, Lexar, and PNY Technologies, with a capacity of up to 8GB.
- PC which includes basic spreadsheet software such as Microsoft Microsoft Excel™* and can recognize a USB flash memory drive.

The Download Process

➢ **TO DOWNLOAD DATA FROM THE CAPNOSTREAM™ MONITOR**

1. Once the Capnostream™ monitor is attached to a patient and patient measurement has begun, click the *Patient Admit/Discharge* button at the front of the monitor ( ) to start the case. Recording data while

patient is admitted as a case (rather than just being monitored without being recorded as a case) is recommended for trend and real-time recording and required when recording a Tabular Case Report.

2. Insert a USB flash memory drive into the USB port on the back side of the Capnostream™ monitor (the port is marked with the ⊷ USB symbol).

3. When the Flash Memory drive is detected the USB icon will appear in the top right-hand corner of the display beside the alarm symbol. Depending on the type of drive, this may take a few seconds. After the USB icon appears, the monitor is ready to begin outputting data to the USB flash memory device.

USB port icon


```
12:00AM 25 MAY 06
NEONATAL
HOME
```

Figure 48. USB Icon on the Capnostream™ Screen

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.

4. From the Home screen on the monitor select the *SYSTEM* screen on the menu bar at the bottom of the screen using the control knob (turn the control knob until it selects the *SYSTEM* box and press the control knob). On the system screen, select *DATA OUTPUT* on the menu bar.

5. Using the control knob, move to the main section of the Data Output screen to select the desired report from the *DATA OUTPUT* table on the screen. To determine which report type best fits your current needs, see 10

6.

7. Table 35. Data Transfer TypesData Transfer Types on page 130. As you move with the control knob, the border around the selected report will turn blue. Click the control knob to select the desired report, and an asterisk will appear to the left of the selected report name.

8. Turn the control knob to select *START USB* on the Menu Bar and click to begin data transfer. The screen will display the *DATA TRANSFER IN PROGRESS* message at the top of the screen.

9. When transfer is complete, a message reading *REPORT TRANSFER COMPLETE* will appear at the top of the screen. The flash memory drive can now be removed from the monitor. Data output can also be aborted during data transfer by clicking again to select *STOP USB*.

10. If you have chosen to transfer a Real Time Continuous Waveform, Real Time Continuous Tabular, or Full Continuous Transfer report, data transfer will continue indefinitely (until the USB flash memory drive becomes full) until you stop the data transfer by clicking to select *STOP USB*.

Table 35. Data Transfer TypesData Transfer Types

Report Name	Description	Uses	Fields Included
Tabular Case Report	Tab delimited file with the suffix .txt. (Tab delimited files can be exported into Microsoft Excel™* using "tab" as the delimiter.) Reports the data stored in trend memory that is assigned to the selected case. The	Provides data in table format about a case as inputted into monitor. Information can be used to track and analyze patient readings over time and determine how readings changes with various events.	DATE, TIME
			Patient Readings: $EtCO_2$, RR, SpO_2, PR, IPI
			Patient Urgent Alarm Occurrences
			Equipment Advisory Message Occurrences
			Events: EVENT 1,

Report Name	Description	Uses	Fields Included
	time between data entries is the resolution set for trend storage (5, 10 or 30 seconds).*	May be downloaded after monitoring is completed.	EVENT 2, EVENT 3
Tabular Trend Report	Tab delimited (.txt) file. Reports all the data stored in trend memory. The time between data entries is the resolution set for trend storage (5, 10 or 30 seconds).*	Provides data in table format as stored in trend memory in the monitor. This is the same as the tabular case report, except that it will include all data stored in the trend memory without case name and number, and may include more than one patient if information on more than one patient is stored in the trend memory. May be downloaded after monitoring is completed.	DATE, TIME
			Patient Readings: $EtCO_2$, RR, SpO_2, PR, IPI
			Patient Urgent Alarm Occurrences
			Equipment Advisory Message Occurrences
			Events
Real Time Continuous CO2 Waveform	Tab delimited (.txt) file with data entries every 50 milliseconds (20 points per second).	Provides data points that can be used to build an $EtCO_2$ waveform. Real-time waveform downloading can take place only during monitoring with the device. The waveform data is not stored following measurement, so this	DATE, TIME
			Patient reading every 50 milliseconds (for creating CO2 waveform): CO2

Report Name	Description	Uses	Fields Included
		information cannot be reconstructed after monitoring.	
Real Time Continuous Tabular	Tab delimited (.txt) file, similar to the Tabular Trend report, but transmitted line by line in real time.	Provides the same data as the tabular trend report, in real time. Real-time downloading takes place during monitoring with the device.	DATE, TIME
			Patient Readings: $EtCO_2$, $FiCO_2$, RR, SpO_2, PR, IPI, A/hr, ODI
			Patient Urgent Alarm Occurrences
			Equipment Advisory Message Occurrences
			Events
Real Time Continuous Tabular with real-time continuous waveform (shortened name is FULL CONTINUOUS TRANSFER)	Tab delimited (.txt) file, similar to the real time continuous tabular report, transmitted line by line in real time, but with data entries every 50 milliseconds (20 times a second). CO2 data which can be used to create a real-time continuous waveform is shown, with data entries every 50 milliseconds. Tabular data is recorded at data points based on the resolution set for trend storage (5, 10 or 30 seconds), so data between these		DATE, TIME
			Patient Readings: $EtCO_2$, $FiCO_2$, RR, SpO_2, PR, IPI, A/hr, ODI
			Patient Urgent Alarm Occurrences
			Equipment Advisory Message Occurrences
			Events
			Patient reading every 50 milliseconds (for creating CO2 waveform): CO2

Report Name	Description	Uses	Fields Included
	points is repeated on additional rows.		
Full Binary Continuous Transfer	See the document Capnostream Data Transfer Protocols		
Full Binary Trend Transfer	See the document Capnostream Data Transfer Protocols		

* The decision regarding the Trend Recording Resolution should be set based on the intended use of the patient data. Health care personnel who wish to collect the most detailed possible data when using the Tabular Trend Report are advised to set the Trend Recording Resolution at 5 seconds / 12 hours (the option with the smallest intervals between recording points). Using this resolution will permit observation of patient levels of EtCO2 and other parameters at a point in time that is close to an alarm, and thus help determine what patient parameters triggered this alarm. If patient data is being recorded at a lower resolution (for example, 30 seconds / 72 hours), this may not be possible. On the other hand, it is easier to observe a broader picture from patient data at lower resolutions. Additionally, a longer period of data can be stored on the device if a lower resolution is used.

CAUTION: Do not remove the flash memory drive from the monitor during the data download process. If it is removed from the monitor when data transfer is in progress, the data may not be readable. Before removing the flash memory drive, data transfer should be completed (as indicated by the REPORT TRANSFER COMPLETE message on the screen) or stopped by selecting *STOP USB* on the Menu Bar.

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

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

For possible error messages during the USB download procedures and recommended actions, see the the Capnostream™ monitor operator's manual.

Interpreting Patient Data Downloaded from the Capnostream™ Monitor

General Information

The downloaded data that you will be using to record and analyze patient data on your PC is provided in the tab delimited format (with the .txt suffix), text files in which a tab separates each field of text. (The Capnostream™ monitor data is also provided in .bin format, if this option is selected; see the Capnostream Data Transfer Protocols document for more information on the .bin files).

The tab delimited text file produced by The Capnostream™ monitor provides one line of data for each time point in the patient file. For example, the file seen in Figure 49. Typical Trend Report Microsoft Excel™* File on page 135, shows one line of patient data every thirty seconds. This data will display the patient values for the displayed patient parameters at that point in time. In this example, the first line of Figure 49 shows that at 8:41:30 AM on September 9, 2006, the patient's EtCO2 value was 44 mmHg, his respiration rate was 33 bpm (beats per minute), his SpO2 was 95%, and his pulse rate was 94 bpm. The zero (0) listed in each alarm column for the patient at this point in time (in EtCO2 HIGH, EtCO2 LOW, and so forth) indicates that there was no

alarm of this type for this patient during this 30-second period. If an alarm has occurred during this period, a one (1) would be seen in the relevant column.

If data was not available for one of the patient parameters at the measured time point, the relevant column would show the value 255, indicating invalid data. For example, if a pulse oximetry sensor was not connected to the patient at this time, the SpO2 column would show a value of 255. A value of 255 should not, of course, be used for any patient calculations.

Opening the Data File

These files can be opened with Microsoft Excel™*, using the *File>Open* menu option in Microsoft Excel™*, indicating *All Files* under *Files of Type*; the file will then open the Text Import Wizard as described below.

You can also open the file in Microsoft Excel™* as follows:

➢ **TO OPEN A .TXT FILE IN MICROSOFT EXCEL™* IN MICROSOFT EXCEL™* 2003**

1. Open Microsoft Excel™* and open a new spreadsheet. Click the *Data>Import External Data>Import Data* menu option. Select the file you want to open in the *Select Data Source* window. In the *Files of type* box, click *Text Files*. In the *Look in* list, locate and double-click the text file you want to import as an external data range.
2. The Text Import Wizard will open. In first step of the Text Import Wizard, choose *Delimited* for the file type in the *Original Data Type* section of the screen.
3. Click *Next*. In the second step of the process, choose *Tab* in the *Delimiters* section of the screen. Click *Next* and in the final screen of the process click *Finish* to import the data. In the *Import Data* window which will open, click *OK* to import data into current cell in the current worksheet and current Microsoft Excel™* file or change the options as desired.
4. The file will display the imported data in correct columns.

➢ **TO OPEN A .TXT FILE IN MICROSOFT EXCEL™* IN MICROSOFT EXCEL™* 2007**

1. Right-click on the .txt file and click *Open With> Microsoft Microsoft Excel™*.* The file will open correctly.
2. In some cases, it may be preferable to do the following: Open Microsoft Excel™* and open a new spreadsheet. Then, click the *Data>From Text* menu option. Select the file you want to open in the *Import Text File* window. Browse to select the desired txt file and click *Import*.
3. The Text Import Wizard will open. Follow the instructions above (in To Open a .txt File in Microsoft Excel™* in Microsoft Excel™* 2003, above) to complete the process.

Case, Trend, and Real-time Tabular Reports

A Microsoft Excel™* file with a tabular report of any type will permit you to carry out typical Microsoft Excel™* calculations and graph building to better understand the patient's health status.

Some examples of uses for the Microsoft Excel™* file would be:

- Tracking CO_2 for a patient under anesthesia/sedation to determine how it affects his breathing and set future recommended levels of anesthesia/sedation
- Following CO_2 for a patient under emergency treatment to determine which interventions improved breathing, both for future treatment of the patient and general knowledge about effects of different interventions
- Tracking levels of SpO_2 (oxygenation) of patient during and following a procedure, including reports of events following the procedure, to learn about changes in oxygenation as the patient's status changes

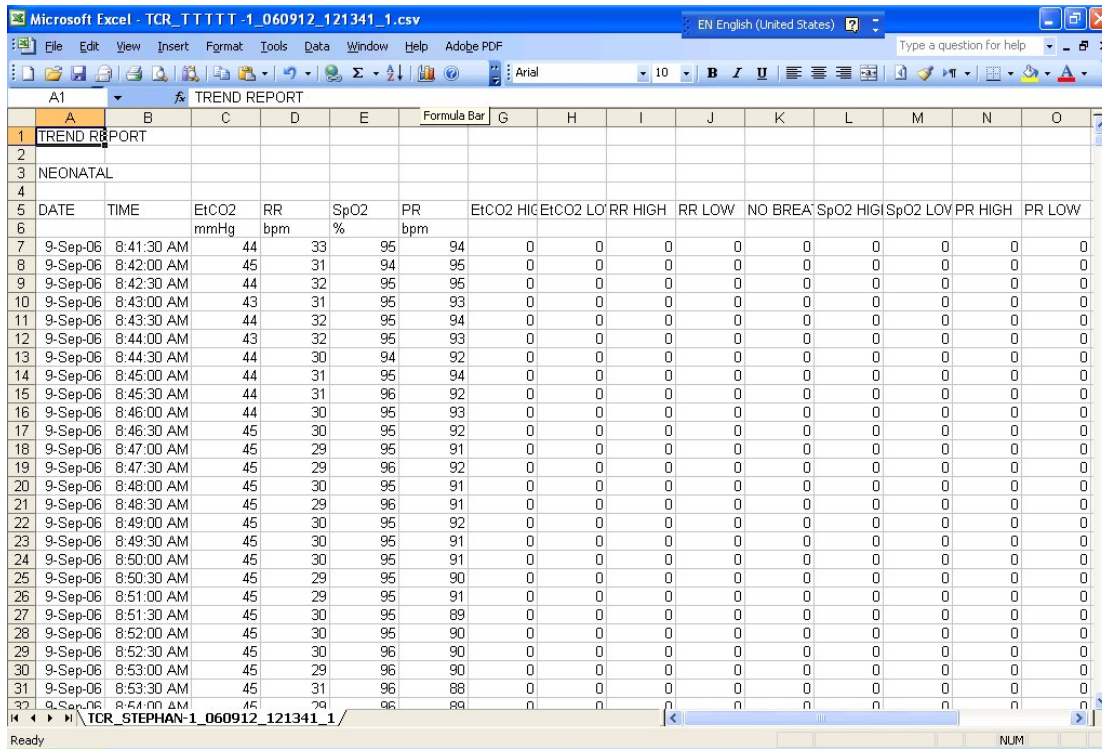Examples of a typical trend report, with and without an added chart, appear below.

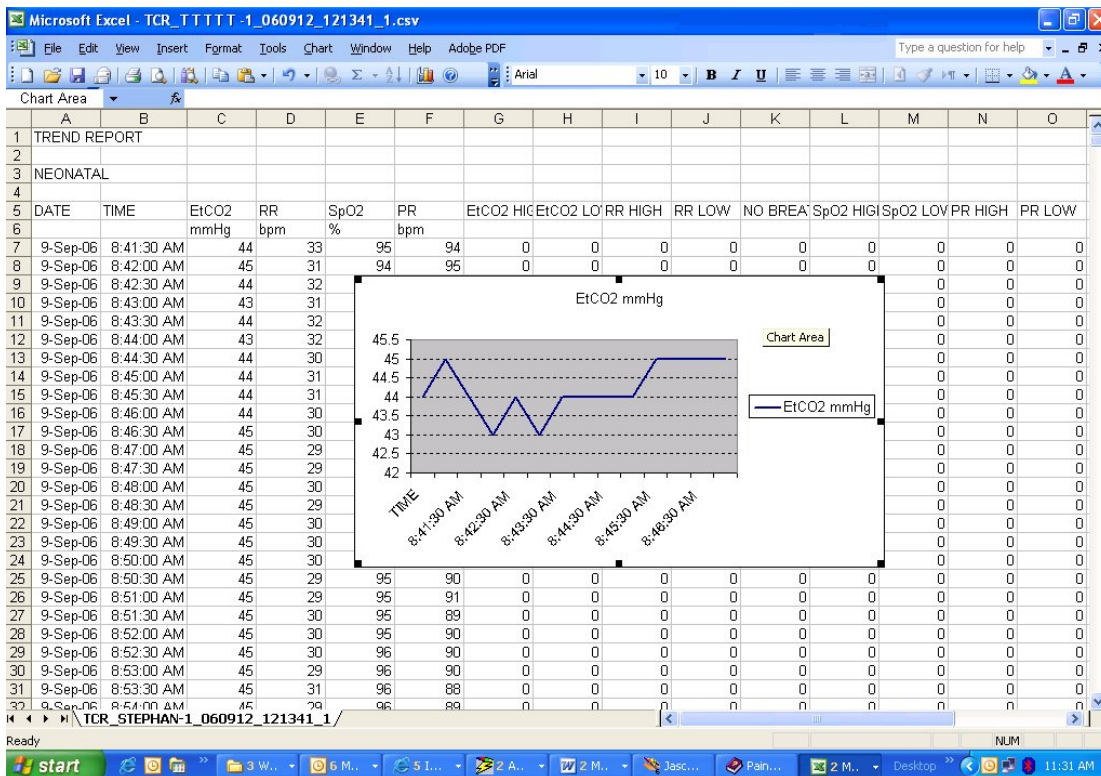**Figure 49. Typical Trend Report Microsoft Excel™* File**

Figure 50. Typical Trend Report Microsoft Excel™* File with Chart

Real-time Continuous Waveform Report

The real-time continuous waveform report is used to construct a waveform using the CO_2 data collected by the device, the same data that is used by the device to construct the waveforms seen on the Capnostream monitor. The Full Continuous Transfer report can also be used to contruct a waveform.

➢ **TO CREATE A WAVEFORM CHART IN MS MICROSOFT EXCEL™***

1. Open a Real Time Continuous Waveform or a Full Continuous Transfer report produced by the Capnostream™ monitor (these files can be identified by the file name; more details about files names are found in 0 Table 37. File Naming Conventions on page 138). The file will include Date, Time, and CO_2 for the patient.
2. Click the *Insert>Chart* menu item. On the first step of the Chart Wizard, choose the *Line* option and a subtype with markers displayed at each data value. Click *Next*.
3. On the second step of the Chart Wizard, in the *Data Range* tab, click on the table icon next to the *Data Range* text and select, with the mouse, the data that you want to appear on the chart. To create a CO_2 waveform, select the cells in the CO_2 column (including the cell with the column heading). (If you are working with a Full Continuous Transfer report, do not use the column with the EtCO2 heading, which represents the EtCO2 numeric parameter.) Click the icon again and a preview of the chart will appear. The radio button next to *Series in:* should be *Columns*. In the *Series* tab in the same window, click the table icon next to the *Category (X) axis labels* text and select the cells in the TIME column on the file that correspond with the data cells you have chosen. (For example, if the data on the chart includes CO_2 data of the selected cells in rows 7 to 200, choose the cells in the TIME column in those rows.)
4. Click *Next*. In the *Titles* tab, label the *Category (X) Axis* (Time) and the *Value (Y) Axis* (CO_2). The title of the chart should already appear (from the heading of the data range); if it does not or if you want to change the title, do so. Click *Next* and choose a location for your chart in the final step of the wizard. Click *Finish* to display the chart.
5. If you would like each tick mark to represent one second on the *Category (X) Axis*, double click on the axis in the chart to open the *Format Axis* window. On the *Scale* tab, change the number of categories between tick-mark labels to 20 (the number of data points per second in the waveform data). Click *OK*.
6. The CO_2 waveform represents CO_2 in mm/Hg (millimeters of mercury), the standard unit for this parameter.

The waveform graph can be stored or printed for patient records and analyzed as required using standard waveform analysis procedures.
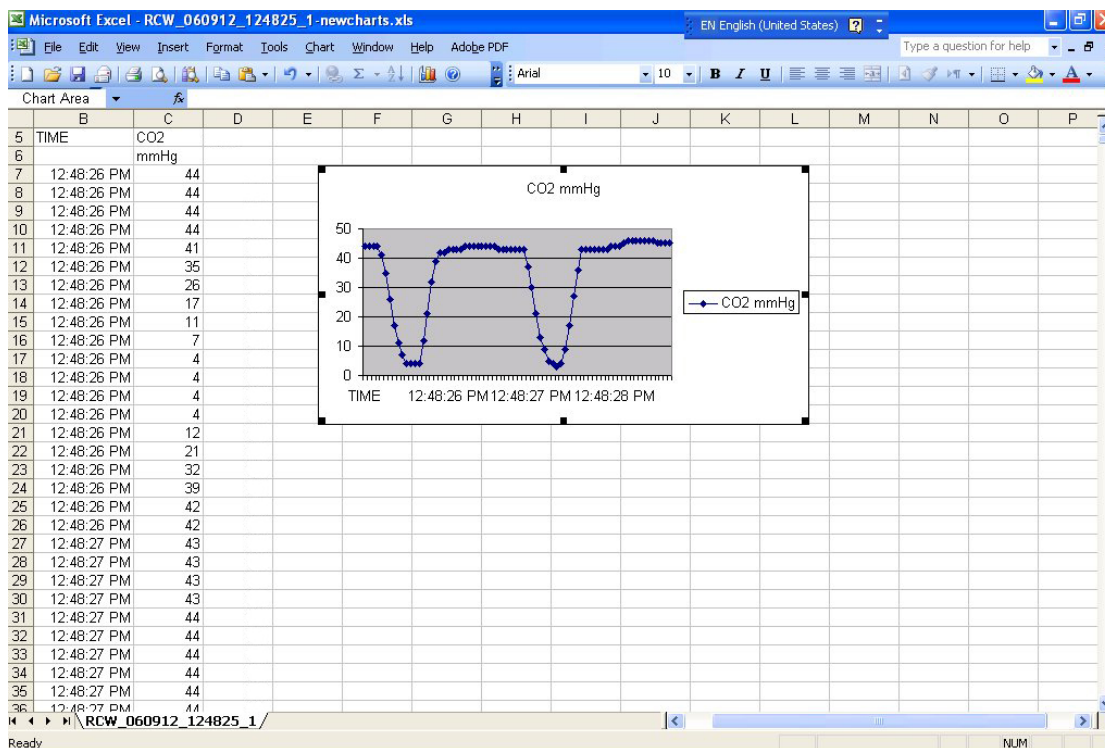
Figure 51. Typical Waveform Report Microsoft Excel™* File

Combined Patient Reports

If you would like to save both waveform and tabular data for a particular patient for a specified time period, use the Real Time Continuous Tabular with real-time continuous waveform report option (the Full Continuous Transfer report).

Please note that there is a maximum time period for which data will be stored in the trend memory of the device (see the table below). Once the maximum time period has passed, the trend memory is full, and any additional data recorded will record over the beginning of the data currently in the trend memory.

Table 36. Time Frame for Memory Storage

Trend recording resolution	Maximum time frame stored in trend memory
5 seconds	12 hours
10 seconds	24 hours
30 seconds	72 hours

Note: The trend memory must be "dumped" from the Capnostream™ monitor into a USB flash memory drive once the trend memory is full (every 12, 24, or 72 hours, depending on trend recording resolution) in order to keep a complete record of patient data. It is recommended that any study protocol include a schedule for regular data download to avoid data loss problems.

File Types, File Naming Conventions and Typical File Sizes

File Types

The USB report types provided by the Capnostream™ monitor include both .txt files and .bin files. The four USB report types that have the .txt file type extension are actually tab delimited text files. This makes them easy to read in most spreadsheet and database software applications. This format type means that there is a tab in between each piece of data in every line of the file. Most users will requires one of the types of .txt files for their data storage and analysis.

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™ monitor. The binary file formats are described in the document Capnostream Data Transfer Protocols (found on the the Capnostream™ monitor Operator's Manual CD accompanying the monitor).

Please note that the first six lines of data in the .txt files include general data, not patient data, as follows:

- Line 1 – The name of the report type.
- Line 2 – Blank, or Patient ID if the report is a case report
- Line 3 – Patient type, either ADULT or NEONATAL
- Line 4 – Blank
- Line 5 – Column headings
- Line 6 – Column headings second line

USB File Naming Conventions

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

<REPORT TYPE>_<PATIENT TYPE>_<REPORT DATE >_<REPORT TIME>_<PATIENT ID>_<FILE NO>.ext

Where:

- REPORT TYPE - three-letter report type identifier (see 0 Table 37. File Naming Conventions on page 138).
- 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 IS 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 is .txt (tab delimited file type) or .bin (binary file type).

The Tabular Case Report will also include the Case ID following the Report 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).

Table 37. File Naming Conventions

Report type	File name
Tabular Case Report	TCR_ADULT_090115_052357_20090115035705_1.txt
Tabular Trend Report	TTR_ ADULT _090115_052357_20090115035705_1.txt
Real-time Continuous CO_2 Waveform	RCW_ ADULT_090115_052357_20090115035705_1.txt
Real-time Continuous Tabular	RCT_ ADULT _090115_052357_20090115035705_1.txt

Full Continuous Transfer	FCTR_ ADULT _090115_05235720090115035705_1.txt
Full Binary Continuous Transfer	FCT_ ADULT _090115_052357_20090115035705_1.bin
Full Binary Trend Transfer	FTT_ ADULT _090115_052357_20090115035705_1.bin

Typical File Sizes

In order to help plan download sessions, you may wish to know the expected size of the data files you will be downloading. 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 Waveform: 1 hour @50ms resolution: 4.2MB
- Real time Continuous Tabular: 1 hour @2s resolution: 264kB
- Full Continuous Transfer: 1 hour @50ms resolution: 12 MB
- Full Binary Continuous Transfer: 1 hour @50ms resolution: 732kB
- Full Binary Trend Transfer: 1 hour @30s resolution:5kB (entire trend memory dump will take less than ten minutes to record on a flash memory device)

The maximum amount of data that can be transferred in a single .txt-type file is 65,536 rows (this corresponds to the maximum sheet size for a Microsoft Excel™* file). If the data exceeds 65,536 rows, a new file is automatically opened and the data continues to transfer into the new file. In this situation, the new file name is indexed as described in USB File Naming Conventions, above. Binary files are not split into multiple files because they do not have the length limitation imposed by Microsoft Excel™*.

FAQs

What's the best type of report for me to use?

Most users will need .txt files, which can be read by any standard data processing program, including Microsoft Excel™*. Use the waveform report type to record waveform data only at 20 times per second. All other types of reports are tabular (that is, they produce a table with numeric results that can be read by Microsoft Excel™*) and include data at the resolution set for trend recording (every 5, 10 or 30 seconds). If you want both waveform and tabular data for the same patient, use the Full Continuous Transfer report.

How much information can I transfer at one time using the .txt files?

All types of Real Time Continuous reports will transfer data in real time until the USB flash memory drive is full. All tabular reports can transfer data up to the maximum amount of data stored in the device (either 12, 24, or 72 hours of data, depending on resolution).

What if I want to add information about the patient to the reports?

The Capnostream™ monitor includes 30 different "event" labels, which are recorded by pressing the event button at the front of the device and then choosing the appropriate event. This information then appears in the transferred data. You may rename these event labels to suit your needs. For example, you can record patient gender or age, beginning or end of case, or other information. For information about how to use the "event" labels, see the the Capnostream™ monitor operator's manual.

What programs can read the data transferred from the the Capnostream™ monitor?

Txt-type files can be read by most data processing programs, including Microsoft Excel™*. Bin files are used for advanced programming procedures.

What does a result of 255 in one of the parameter columns in the report mean?

If data was not available for one of the patient parameters at the measured time point, the relevant column would show the value 255, indicating invalid data. For example, if a pulse oximetry sensor was not connected to the patient at a particular time, the SpO2 column would show a value of 255 at that time. A value of 255 should not, of course, be used for any patient calculations.

In the alarm columns on the report, what do the 0 and 1 mean?

If an alarm has occurred during this period, a one (1) would be seen in the relevant column. If no alarm occurred during the time period, a zero (0) would appear in the relevant column.

Capnostream™ Service Password

Capnostream™ Service Password

This service password is: SERV