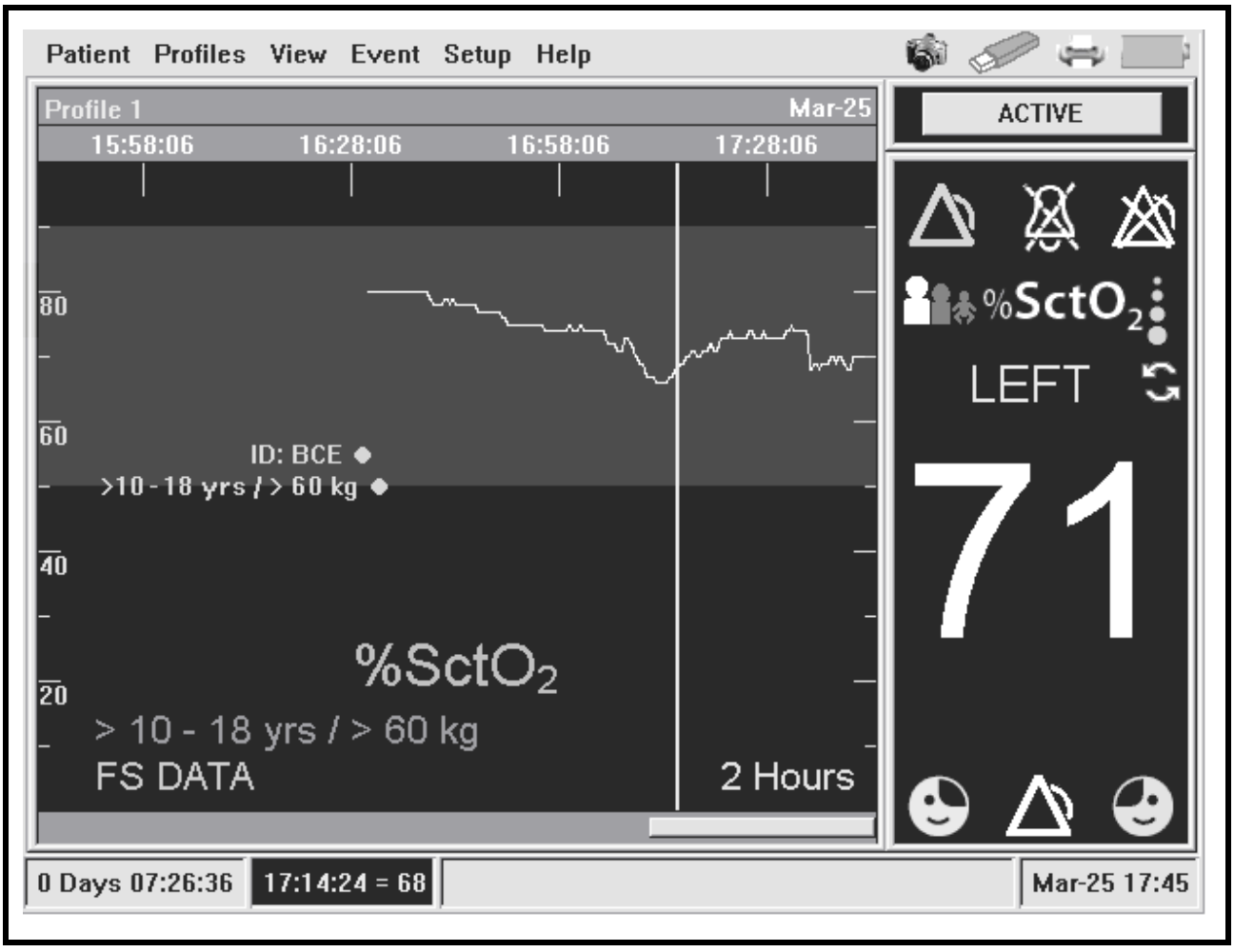
FORE-SIGHT® MC-2000 Series Cerebral Oximeter



User Manual

CE 0086

CASMED®
FOR WHAT'S VITAL

This User Manual describes the features and operations of FORE-SIGHT MC-2000 Series Cerebral Oximeter: Software Version 5.0

Overview

Trademarks

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Please contact the distributor in the country of purchase if product information or service should be required.

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Manufacturer's Declaration of Conformity

Manufacturers Declaration of Conformity
Electronic Emissions and Immunity

The FORE-SIGHT MC-2000 Series Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the FORE-SIGHT MC-2000 Series Monitor should assure it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment
RF emissions – CISPR 11	Group 1	The FORE-SIGHT MC-2000 Series Monitor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions – CISPR 11	Class A	The FORE-SIGHT MC-2000 Series Monitor is suitable for use in all establishments other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions	Complies	

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	Level 3	Level 3	The FORE-SIGHT MC-2000 Series Monitor is designed for use in controlled environments only. Per OSHA guidelines for operating rooms, the area must employ adequate static electricity controls. The relative humidity should be maintained at about 50%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	The FORE-SIGHT MC-2000 Series Monitor is designed for use in controlled environments only. Per OSHA guidelines for operating rooms, the Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) mode ±2 kV line(s) to earth mode	±0.5 kV line(s) to line(s) mode ±2 kV line(s) to earth mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (> 95% dip in U_T) for 0.5 cycle. 40% U_T (60% dip in U_T) for 5 cycles. 70% U_T (30% dip in U_T) for 25 cycles. < 5% U_T (> 95% dip in U_T) for 5 s	< 5% U_T (> 95% dip in U_T) for 0.5 cycle. 40% U_T (60% dip in U_T) for 5 cycles. 70% U_T (30% dip in U_T) for 25 cycles. < 5% U_T (> 95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If user of the FORE-SIGHT MC-2000 Series Monitor requires continued operation during power mains interruptions, it is recommended that the FORE-SIGHT MC-2000 Series Monitor be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U_T is the A.C. mains voltage prior to application of the test level.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The FORE-SIGHT MC-2000 Series Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the FORE-SIGHT MC-2000 Series Monitor should insure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Model MC-2000 Series Monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	***Recommended separation distance:*** $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 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 according to the transmitter manufacturer and d is the recommended separation distance in meters. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is effected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Model MC-2000 Series Monitor is used exceeds the applicable RF compliance level above, the Model MC-2000 Series Monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Model MC-2000 Series Monitor.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Model MC-2000 Series Monitor

The Model MC-2000 Series Monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Model MC-2000 Series Monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Model MC-2000 Series Monitor as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (Watts)	Separation distance according to frequency of transmitter (Meters)		
	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	7.3
100	12	12	23

For transmitters operating at a maximum output power not listed above, the recommended separation distance d in meters 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 according to the transmitter manufacturer.
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

CE Marking Information

Compliance

The FORE-SIGHT MC-2000 Series Monitor bears the CE mark CE-0086 indicating conformity with the provisions of the Council Directive 93/42/EEC concerning medical devices and fulfills the essential requirements of Annex I of this directive.

Exceptions

None

General Information

This manual is an integral part of the product and describes its intended use. Compliance with the manual is a prerequisite for proper product performance and correct operation and ensures patient and operator safety.

The symbol means ATTENTION: Consult accompanying documents.

Indicates protection (BF) of the applied part against the effects of electrical shock.

CLASS 1 LASER PRODUCT

Indicates unit contains a Class 1 Laser Product

The warranty does not cover damages resulting from the use of accessories and consumables from other manufacturers.

CAS Medical Systems, Inc., is responsible for the effects on safety, reliability, and performance of the product only if:

- Assembly, operations, extensions, readjustments, modifications, or repairs are carried out by persons authorized by CAS Medical Systems, Inc.
- The electrical installation of the relevant room complies with the requirements of the appropriate regulations.
- The device is used in accordance with the instructions for use.
- All publications conform to the product specifications and applicable IEC publications on safety and essential performance of electro-medical equipment as well as with applicable UL requirements and AHA recommendations valid at the time of printing.

For complete warranty information, refer to the Warranty Policy located on page 101.

The CAS Medical System, Inc., quality management system complies with the international standards ISO 13485 and the Council Directive on Medical Devices 93/42/EEC.

Note: Due to continuing product innovation, specifications in this manual are subject to change without notice.

In the U.S. the following caution applies:

Caution: Federal law restricts this device to sale by or on the order of a physician or properly licensed practitioner.

Warning: Before using the monitor for the first time, please read the information given in section Safety, starting on page 17.

About This Manual

This User Manual describes the features and operation of the FORE-SIGHT MC-2000 Series Cerebral Oximeter:

Software Version 5.0

Note: This manual addresses all parameters a FORE-SIGHT MC-2000 Series Monitor can have installed. It remains suitable for use if the monitor has a sub-set of parameters only. Please refer to those sections that are applicable for the model in use.

Manual Purpose

This manual contains the instructions necessary to operate the FORE-SIGHT MC-2000 Series Monitor safely and in accordance with its functions and intended use.

Intended Audience

This manual is written for clinical professionals. Clinical professionals are expected to have working knowledge of medical procedures, practices, and terminology as required for monitoring of critically ill patients.

Caution: For continued safe use of this equipment, it is necessary that the listed instructions be followed. However, instructions listed in this manual in no way supersede established medical practices concerning patient care.

Conventions

Warning: Directions that warn of conditions that put the patient or the caregiver at risk.

Caution: Directions that help to avoid damaging the monitor or losing data.

Note: Directions that make it easier to use the monitor, something not readily apparent.

Figures: All illustrations in this manual are provided as examples only. They may not necessarily reflect your monitoring setup or data displayed on your monitor.

Revision History

This manual has a revision number located at the bottom of each page. It changes whenever the manual is updated.

Rev 00	04/2007
Rev 01	05/2007
Rev 02	05/2007
Rev 03	07/2007
Rev 04	10/2007
Rev 05	12/2007
Rev 06	02/2008
Rev 07	06/2008
Rev 09	03/2009
Rev 09	04/2009
Rev 10	07/2009

Read this manual carefully before patient use of the monitor

CAS Medical Systems, Inc., reserves the right to make changes to this manual and improvements to the product it describes at any time without notice or obligation.

Contents

Figures

Tables

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Safety

The operator must comply with the following Warnings, Cautions, and Notes to guarantee safe operation of the monitor. Additional Warnings, Cautions, and Notes, which apply to specific parameters, are listed in the sections that pertain to each parameter.

Indications for Use

The FORE-SIGHT® Cerebral Oximeter, Model MC-2000 Series is indicated for the continuous noninvasive monitoring of regional hemoglobin oxygen saturation of blood in the brain ($SctO_2$). It is intended for use in any individual at risk for reduced-flow or no-flow ischemic states. The FORE-SIGHT should not be used as the sole basis for decisions as to the diagnosis or therapy. The value of data from the FORE-SIGHT has not been demonstrated in disease states.

Contraindications

- The FORE-SIGHT MC-2000 Series Monitor sensor is contraindicated for use on patients with limited skin access or allergic reaction to electrode adhesive.
- Disposable $SctO_2$ sensors are contraindicated for use for prolonged periods. The sensor site must be checked at least every eight hours; and if the circulatory condition or skin integrity has deteriorated, the sensor should be applied to a different site.
- Do not adhere sensors to underdeveloped, immature, compromised, or healing skin.
- The FORE-SIGHT MC-2000 Series monitor is not for use on low birth weight neonates (e.g. <2.5Kg).
- No other contraindications are known at this time.

Installation and Setup

Warning: The FORE-SIGHT MC-2000 Series Monitor is defibrillator-proof. It may remain attached to the patient during defibrillation, but the readings may be inaccurate during use and less than twenty (20) seconds thereafter.

Warning: The FORE-SIGHT MC-2000 Series Monitor is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.

Warning: Do not rely exclusively on the audible alarm system for patient monitoring. Adjustment of alarm volume to a low level during patient monitoring may result in a hazard to the patient. Remember that the most reliable method of patient monitoring combines close personal surveillance with correct operation of monitoring equipment.

Warning: Do not place the FORE-SIGHT MC-2000 Series Monitor face against a surface. This will cause the alarm to be muffled.

Warning: Do not place the FORE-SIGHT MC-2000 Series Monitor back against a surface. This will block the fan and cause the unit to overheat, shutting it off.

Warning: Do not place the FORE-SIGHT MC-2000 Series Monitor or accessories in any position that might cause it to fall on the patient. Do not lift the FORE-SIGHT MC-2000 Series Monitor by any cable.

Warning: Do not place the FORE-SIGHT MC-2000 Series Monitor where the controls can be changed by the patient.

Warning: Do not use the FORE-SIGHT MC-2000 Series Monitor for any purpose other than specified in this manual. Doing so will invalidate the monitor's warranty.

Warning: Do not connect more than one patient to a monitor.

Warning: *Leakage Current Test* – The interconnection of auxiliary equipment, including a patient monitor or other patient-connected equipment, with this device may increase the total leakage current. When interfacing with other equipment, qualified biomedical engineering personnel must perform a test for leakage current before using it with patients. Serious injury or death could result if the leakage current exceeds applicable standards.

Warning: The FORE-SIGHT MC-2000 Series Monitor is to be operated by qualified personnel only. This manual, accessory directions for use, all precautionary information, and specifications should be read before use.

Warning: Do not expose the FORE-SIGHT MC-2000 Series Monitor to excessive moisture such as direct exposure to rain. Excessive moisture can cause the FORE-SIGHT MC-2000 Series Monitor to perform inaccurately or fail.

Warning: Do not place containers containing liquids on or near the FORE-SIGHT MC-2000 Series Monitor. Liquids spilled on the monitor may cause it to perform inaccurately or fail.

Warning: Patient Safety – If a sensor is damaged in any way, discontinue use immediately.

Warning: The FORE-SIGHT MC-2000 Series Monitor is not "Category AP or APG Equipment."

Warning: *Explosion Hazard* – Do not use the monitor in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

Warning: *Electromagnetic Compatibility (EMC)* – The equipment needs special precautions if it is placed close to a strong transmitter such as X-ray equipment, MRI devices, TV, AM/FM radios, police/fire stations, an amateur ("ham") radio operator, an airport, or a cellular phone. Their signals could interfere with the monitor, which may result in disruption of performance of this device or prevent the clear reception of signals by the monitor. This equipment has been tested and found to comply with the limits for medical devices to the EN 60601-1-2: 2002, Medical Device Directive 93/42/EEC. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the devices.
- Consult the manufacturer for help.

Warning: If the integrity of the protective earth conductor is in doubt, the unit may be operated from the internal batteries by disconnecting the AC line cord completely from the unit.

Caution: The Battery fuse must be installed for the unit to operate with the internal batteries. If the unit is not to be used for periods greater than 1 week, the battery should be disconnected (see Disconnecting the Battery on page 95).

Caution: The USB connector accommodates a CASMED USB memory stick; do not connect any other USB type device or cable.

Caution: Qualified biomedical engineering personnel only must interface monitoring equipment with other types of medical equipment. Be certain to consult manufacturers' specifications to maintain safe operation.

Caution: Measurements may be affected in the presence of strong electromagnetic sources such as electro-surgery equipment.

Note: The FORE-SIGHT MC-2000 Series Monitor is designed for continuous operation.

Note: The FORE-SIGHT MC-2000 Series Monitor is suitable for use in the presence of electro-surgery; however, measurements may be inaccurate during use of such equipment.

Note: The FORE-SIGHT MC-2000 Series Monitor can remain connected to the patient during cardio defibrillation. All applied parts are “Type BF Defibrillation Proof.”

The monitor has been designed to promote patient safety. All equipment parts are protected against the effects of the discharge of a defibrillator. No separate actions are required when using this equipment with a defibrillator.

Device Handling

Warning: To ensure patient safety, do not place the monitor in any position that might cause it to fall on the patient.

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

Warning: To avoid electric shock or device malfunction, liquids must not be allowed to enter the device. If liquids have entered a device, take it out of service and have it checked by a service technician before it is used again.

Warning: The FORE-SIGHT MC-2000 Series Monitor provides “DRIP-PROOF” level of protection from ingress to moisture.

Warning: Do not place liquids on top of the monitor. Do not immerse the monitor or power cord in water or any liquid.

Warning: Do not gas sterilize or autoclave the monitor.

Warning: After removal of covers, connectors, etc., do not touch any part of non-medical electrical equipment and the patient at the same time.

Warning: Where the integrity of the external protective conductor in the installation or its arrangement is in doubt, EQUIPMENT shall be operated from its INTERNAL ELECTRICAL POWER SOURCE.

Warning: Isolation of product from mains can only be achieved by removal of external power cord.

Warning: Route and secure all cables away from patient’s throat to reduce the possibly of strangulation.

Caution: Pressing the front panel keys with a sharp or pointed instrument may permanently damage the switch membrane. Press the keys using only your finger.

Caution: If the monitor is accidentally wetted, take it out of operation. It should be thoroughly dried.

Note: There are no known risks with common disposal of equipment or accessories; however, the disposing of accessories should follow in accordance with local hospital policies. The user should ensure these policies do not conflict with any local, state, or federal guidelines.

Safety Checks

Warning: Do not, under any circumstances, perform any testing or maintenance on the monitor or power cord while the unit is being used to monitor a patient. Unplug the power cord before cleaning or servicing the monitor. The operator should not perform any servicing except as specifically stated in this manual.

Warning: The functions of the alarm system for monitoring of the patient must be verified at regular intervals.

Warning: Periodically, and whenever the integrity of the product is in doubt, test all functions.

Warning: Do not use a frayed or damaged power supply cord or any accessory if you notice any sign of damage. Contact CAS Medical Systems, Inc., for assistance.

Warning: The use of accessory equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include:

- Use of the accessory in the patient environment.
- Evidence that the safety certification of the accessory has been performed in accordance to the appropriate IEC 60601-1 and/or IEC 60601-1-1 harmonized national standard.

Caution: Inspect the monitor, cables, and sensors for damage prior to operation. If any damage is noted, the monitor should not be used until it has been serviced. Only personnel authorized to do so by CAS Medical Systems, Inc., should repair the monitor.

Caution: If the monitor fails to respond, do not use it until the situation has been corrected by qualified CAS Medical Systems, Inc., personnel.

Monitoring

Warning: *Conductive Connections* – Extreme care must be exercised when applying medical electrical equipment. Many parts of the human–machine circuit are conductive, such as the patient, connectors, electrodes, and transducers. It is very important that these conductive parts do not come into contact with other grounded, conductive parts when connected to the isolated patient input of the device. Such contact would bridge the patient's isolation and cancel the protection provided by the isolated input. In particular, there must be no contact of the neutral electrode and ground.

Warning: Do not come into contact with patients during defibrillation. Otherwise serious injury or death could result.

Warning: If the accuracy of any value displayed on the monitor is questionable, determine the patient's vital signs by alternative means. Verify that all equipment is working correctly.

Warning: Only use CASMED-supplied patient cables with this monitor. The use of unprotected patient cables creates the potential for making an electrical connection to ground or to a high voltage power source which can cause serious injury or death to the patient.

Warning: As with all medical equipment, carefully route and secure all patient cables to reduce the possibility of patient entanglement or strangulation.

Warning: Always remove sensors from the patient and completely disconnect the patient from the FORE-SIGHT MC-2000 Series Monitor before bathing the patient.

Warning: The $SctO_2$ sensor site must be inspected at least every eight hours; to ensure adequate adhesion, circulation, skin integrity, and correct optical alignment. If the circulatory condition or skin integrity has deteriorated, the sensor should be applied to a different site.

Warning: Interfering substances: Carboxyhemoglobin may erroneously increase $SctO_2$ readings. The level of increase is approximately equal to the amount of carboxyhemoglobin present. Dyes or any substance containing dyes that change usual blood pigmentation may cause erroneous readings.

Warning: Sensors are not sterile and therefore should not be applied to sites with compromised skin integrity. Exercise caution when applying sensors to a site with compromised skin integrity. Applying tape or pressure to such a site may reduce circulation and/or cause further skin deterioration.

Warning: For patients experiencing complete bilateral ECA occlusion, $SctO_2$ measurements may be lower than expected.

Warning: Misapplied sensors or sensors that become partially dislodged may cause either over- or under-reading of oxygen saturation.

Warning: To prevent damage, do not soak or immerse the sensors in any liquid solution. Do not attempt to sterilize.

Warning: Intravascular dyes or externally applied coloring may lead to inaccurate measurements.

Warning: Elevated levels of carboxyhemoglobin (COHb) may lead to inaccurate measurements.

Warning: Elevated levels of methemoglobin (MetHb) will lead to inaccurate measurements.

Warning: Failure to apply sensors properly may cause incorrect measurements.

Warning: Do not modify or alter the $SctO_2$ sensor in any way. Alterations or modification may affect performance and/or accuracy.

Warning: Do not apply the $SctO_2$ sensor to the patient's forehead that has an internal temperature of greater than 39.2 °C to prevent possible damage to the patient's skin.

Warning: Before using SctO2 sensors for the first time, please read the instructions for use provided with the sensors.

Caution: Use only accessories and sensors approved by CAS Medical Systems, Inc., to ensure patient safety and to preserve the integrity, accuracy, and electromagnetic compatibility of the monitor.

Caution: *Electrocautery* – To prevent unwanted skin burns; apply electrocautery electrodes as far as possible from all other sensors, a distance of at least 15 cm (6 in.) is recommended.

Initial Inspection

Before unpacking the monitor, inspect the packaging for damage. If there are any signs of damage to the package, a claim should be filed immediately with the shipping agent. It is the receiver's responsibility to notify the carrier's local office to arrange for the pickup of the damaged items. Save the damaged shipping carton as evidence.

Contact your distributor, CAS Medical Systems sales representative, or CAS Medical Systems, Inc., to report external damage and to arrange for repair or replacement of damaged equipment.

The shipping carton should contain the items listed below. Unpack the monitor and account for each item. Inspect each item for signs of external damage, dents, cracks, scratches, etc. If an item is missing or damaged, contact your distributor, CAS Medical Systems sales representative, or CAS Medical Systems, Inc.

Record the monitor model, serial number, and date of purchase at the back of this manual.

Monitor Checklist

- 1 FORE-SIGHT MC-2000 Series Monitor
- 2 FORE-SIGHT Monitor Cables
- 1 FORE-SIGHT Abbreviated Biomedical Kit
- 1 FORE-SIGHT Laminated Intervention Card w/Velcro dots
- 1 FORE-SIGHT MC-2000 Series Cerebral Oximeter User Manual
- 1 Hospital Grade AC Power Cord
- 1 Cable Bundler
- 1 Service Card and Insert Sleeve

Caution: Use only the CASMED-approved power cord that was shipped with the monitor, to preserve the electromagnetic compatibility of the monitor.

Caution: Grounding reliability can only be achieved when the equipment is connected to an equivalent receptacle marked "Hospital Grade".

Note: The monitor is shipped with the appropriate line cord for the country and voltage being used.

Patient Environment

The FORE-SIGHT MC-2000 Series Monitor has been tested with specific parts of the system used within the patient environment. These parts are:

- The FORE-SIGHT MC-2000 Series Monitor
- Appropriate accessories as listed under Accessories, on page 107, at the back of this manual.
- AC Power Cord

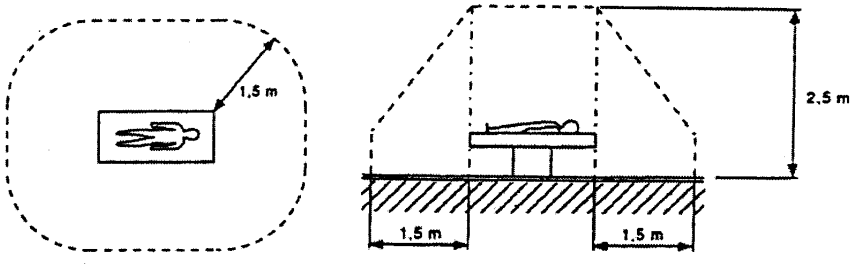

Figure 1: Patient environment

Monitor Classifications of Electrical Insulation

The **FORE-SIGHT MC-2000 Series Monitor** (monitor version with integrated AC power supply) is a Class I device. It is certified in conformance with applicable portions of CFR Title 21 Chapter 1 subchapter J, Radiological Health.

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Basic Operations

Introduction

The FORE-SIGHT MC-2000 Series Monitor is a pre-configured monitor that can include the following measurement functions:

- Absolute cerebral tissue oxygen saturation ($SctO_2$)

The FORE-SIGHT MC-2000 Series Monitor detects oxygenation changes in biological tissue mainly at the microcirculation level (capillary, arteriole, and venula) based on different absorption characteristics of the chromophores oxyhemoglobin (HbO_2) and deoxyhemoglobin (Hb) in the near-infrared spectrum. A biological spectroscopic window exists at the wavelength range 660–940 nm in which Hb and HbO_2 can be differentiated and measured. Brain tissue oxygen saturation ($SctO_2$) is determined from the ratio $((HbO_2)/(HbO_2 + Hb)) \times 100\%$

The FORE-SIGHT MC-2000 Series Monitor uses LASER-LIGHT Technology to project light into tissue to measure oxygen saturation.

The FORE-SIGHT MC-2000 Series Monitor uses COOL-LIGHT Sensor Technology to transmit light from the monitor to the patient contact site via fiber optics, thereby eliminating light-induced heat generation at the patient site.

The Model MC-2010 & 2030 are equipped with a rechargeable backup battery pack that allows the monitor to be used independently from an external power source.

The Model MC-2000 & 2020 are equipped with a rechargeable backup battery pack that allows the monitor to automatically shutdown safely during extended power loss. These units are not designed to run independently from an external power source.

Refer to the Battery Maintenance section on page 95.

Getting Started

Before you operate the monitor, you must thoroughly familiarize yourself with:

All of the warnings and cautions in the Safety section, pages 17 - 23.

The physical configuration of the monitor, page 28

The use of the monitor switches and controls, page 30

The content and use of the monitor display, page 32

The procedures described in this guide, pages 39 and following

To use the monitor:

1 Set up the monitor for the patient (optional). See page 39.
2 Connect the monitor cable(s) to the monitor. See page 40.
3 Connect the patient cable(s) to the monitor cable(s). See page 43.
4 Affix the $SctO_2$ sensor(s) to the patient. See page 48.
5 Begin monitoring. See page 50.
6 Saving Patient Data to USB memory when case is completed. See page 77.
7 Printing Patient Data. See page 82.

Physical Configuration

Front View

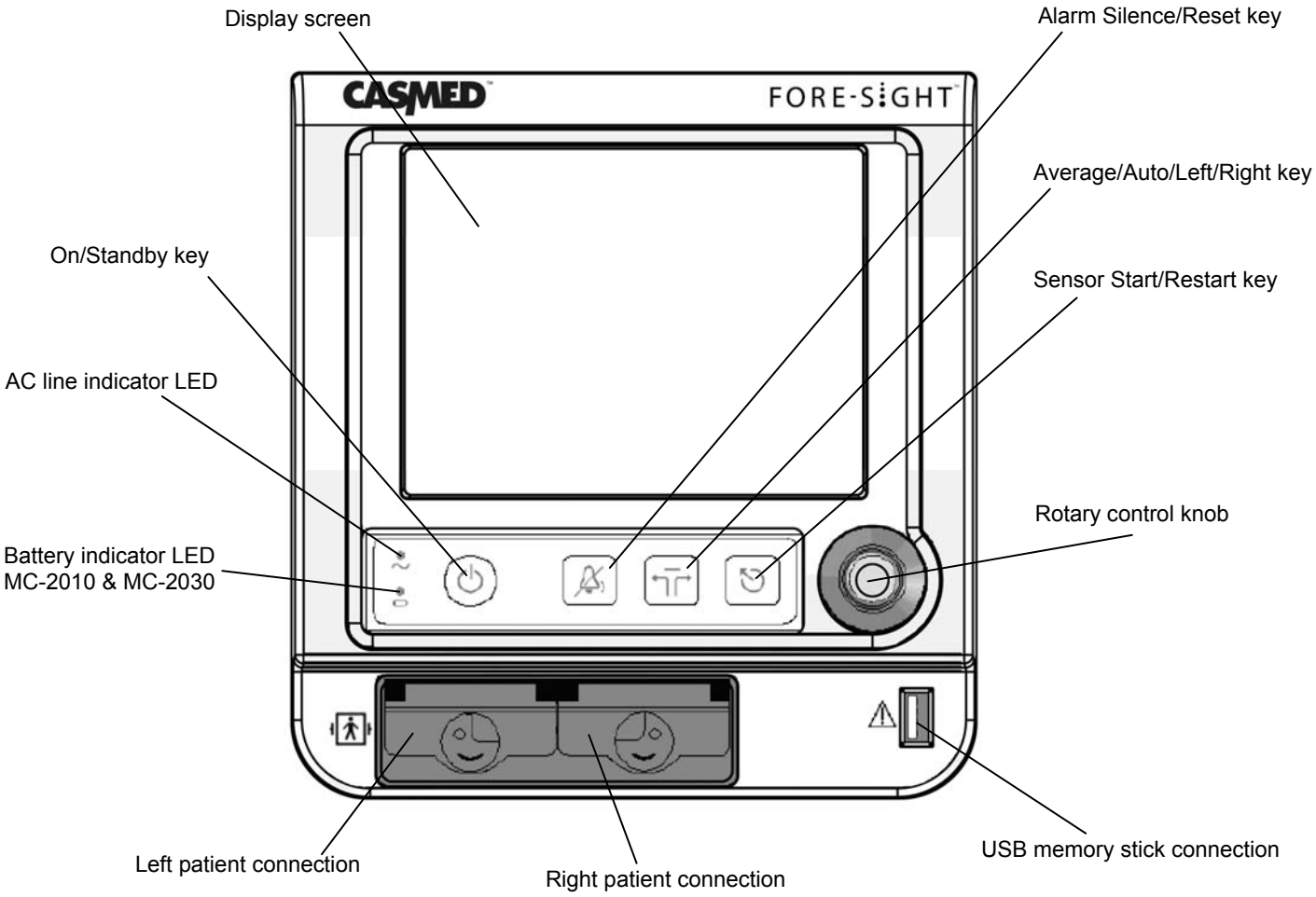


Figure 2: Front view

Rear View

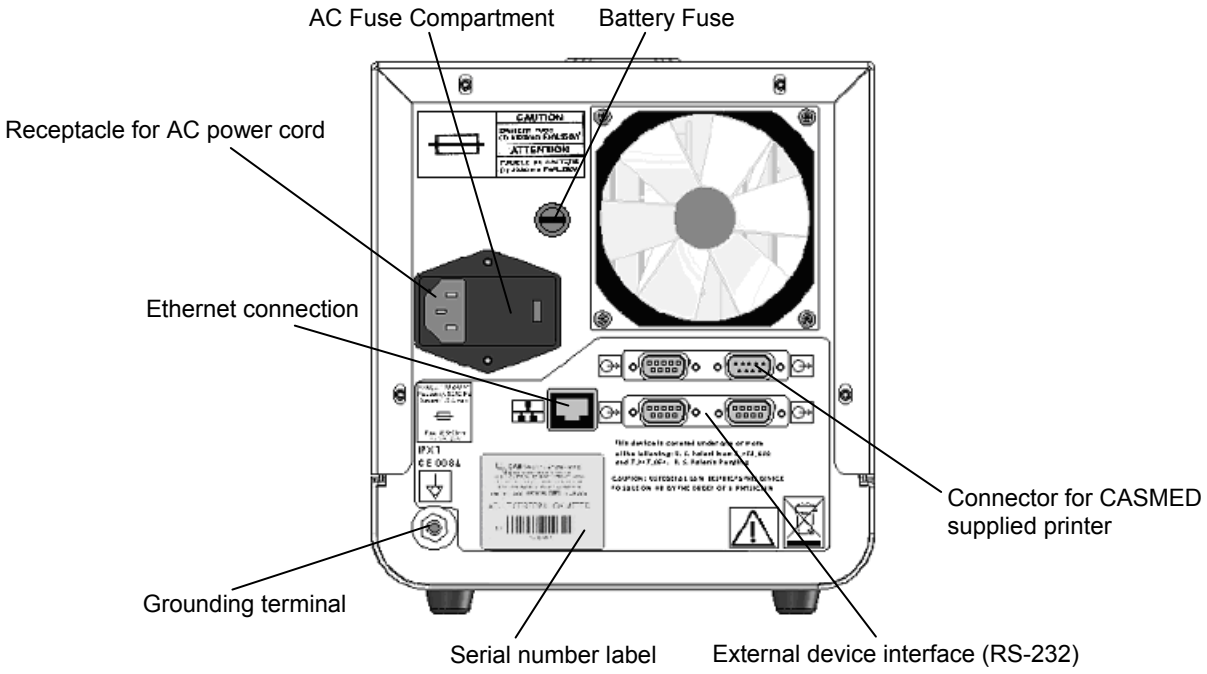


Figure 3: Rear view

Note: The Ethernet connection is for the use of CASMED service personnel only.

Note: The male RS-232 connector (upper right-hand corner) can be used to connect to the CASMED supplied printer. The remaining RS-232 ports are reserved for future applications.

Monitor Switches and Controls

Rotary Control Knob

The rotary control knob gives you access to on-screen monitor functions. You can:

Navigate through all menu selections

Choose optional settings

Enter data

The rotary control knob has two modes of operation:

Turn the rotary control knob to step through choices on the screen

Push the rotary control knob to select a highlighted choice

You can turn the rotary control knob to the right (clockwise) or to the left (counterclockwise).

Right (clockwise) rotation Left (counterclockwise) rotation

Figure 4: Clockwise and counterclockwise directions

Note: Turning the rotary control knob to the right (clockwise) advances the selection on screen to the right when you are navigating the menu. When you are navigating selections on a specific menu, turning the knob clockwise advances the selection down until you reach the bottom of the menu; then it starts over at the top. When you are not on the menu bar, turning the knob clockwise advances the selection to the next section of the display, in a clockwise direction.

Note: Turning the rotary control knob to the left (counterclockwise) advances the selection on screen to the left when you are navigation the menu. When you are navigating selections on a specific menu, turning the knob counterclockwise advances the selection up until you reach the top of the menu; then it starts over at the bottom. When you are not on the menu bar, turning the knob counterclockwise advances the selection to the next section of the display, in a counterclockwise direction.

On / Standby Key

Press to toggle between Standby and On. Press and hold for 2 seconds to toggle between on and standby. Unit will remain in standby mode when connected to AC power.

Warning: Isolation of product from mains can only be achieved by removal of external power cord.

Alarm Silence / Reset Key

Press once to silence the audio for the alarm or acknowledge an alarm condition. When no alarms are present, the alarm silence period will start for two minutes.

Warning: Do not rely exclusively on the audible alarm system for patient monitoring. Adjustment of alarm volume to a low level during patient monitoring may result in a hazard to the patient. Remember that the most reliable method of patient monitoring combines close personal surveillance with correct operation of monitoring equipment.

Warning: Do not place the FORE-SIGHT MC-2000 Series Monitor face against a surface. This will cause the alarm to be muffled.

Average / Auto / Left / Right Key

Press to switch the current display to show patient readings for:

- Simple average of the left and right sensors
- Automatic toggle between the right and left sensors
- Left sensor
- Right sensor

Note: The currently selected sensor is shown on the monitor.

Note: When Auto numeric toggle is selected, the  icon is shown to the right of the currently displayed left or right sensor indicator.

Note: FORE-SIGHT software detects if a single sensor is connected to the monitor and will automatically display the numeric for the side in use

Sensor Start / Restart Key

Press to start or restart sensors. You will be prompted with a message if you need to restart sensors.

Monitor Display

Parts of the Display Screen

The main elements of the monitor display are shown below in Figure 5.

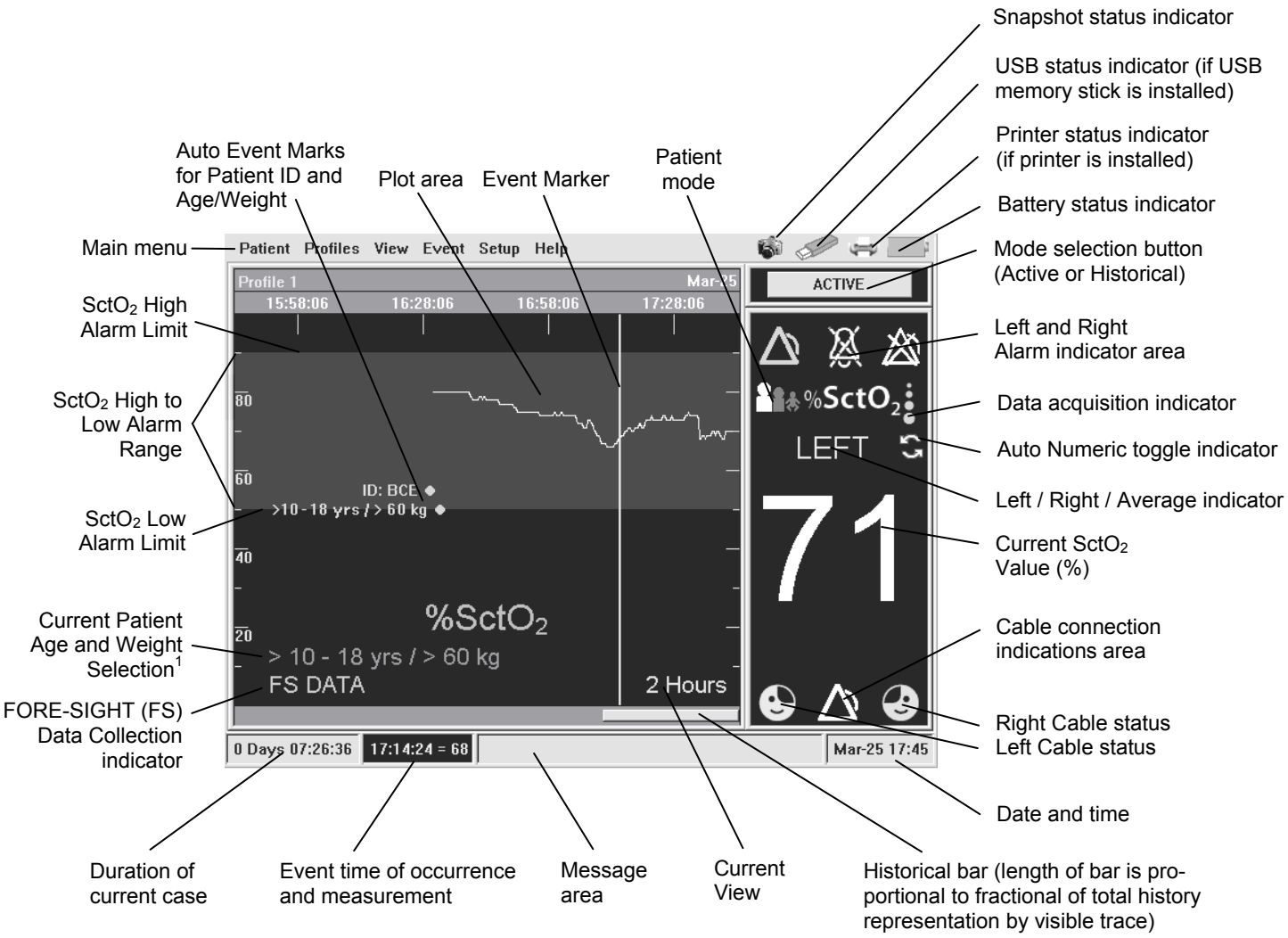


Figure 5: Main areas of monitor display

[1] If the Patient Age or Weight is not selected, "**Unspecified**" will be displayed and the Lasers cannot be turned on.

Menu Navigation

You can control most operations of the FORE-SIGHT MC-2000 Series Monitor through the menu system. The procedures in this manual make frequent reference to the menu system. This section explains how to navigate through it.

Turn the rotary control knob to Main Menu on any drop down list and press the knob to return to the Main Menu

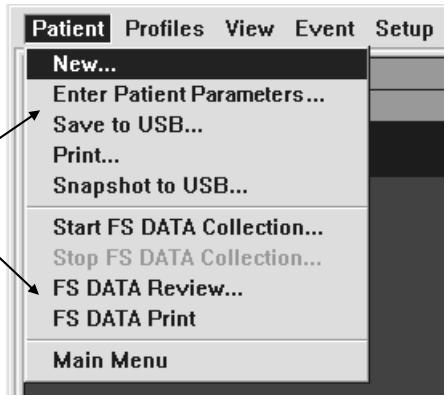


Figure 6: The Patient menu

The following paragraphs briefly describe what you can do from the various menus. This section serves as an orientation to the menu system. Specific procedures making use of the menu system are found in later sections of this user guide.

The Patient Menu

The Patient menu (see Figure 6 above) lets you attach a patient identifier to a recording of measured values over time. It also allows you to print and save data, and to operate and review FS Data collection measurements.

New Patient Popup

Note: When you first power up the system, you will be asked if you are starting a new patient. Answering no will add the new data that you are collecting to the end of the previous data stored on the unit. **Answering yes will delete prior data stored in the unit.**

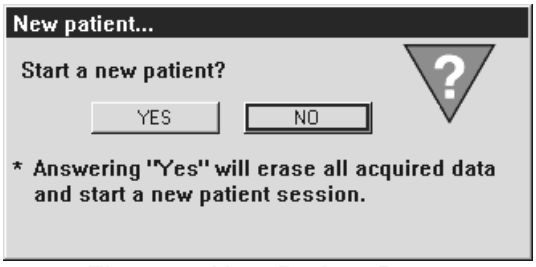


Figure 7: New Patient Popup

Note: When a New Patient is entered an Event Mark shall automatically be added to the Trend Graph. The New Patient Event text shall be “ID:” followed by the new Patient ID (Refer to Adding a new Event Mark to the Patient Record section on 64).

Universal Monitor **Adult Monitor**

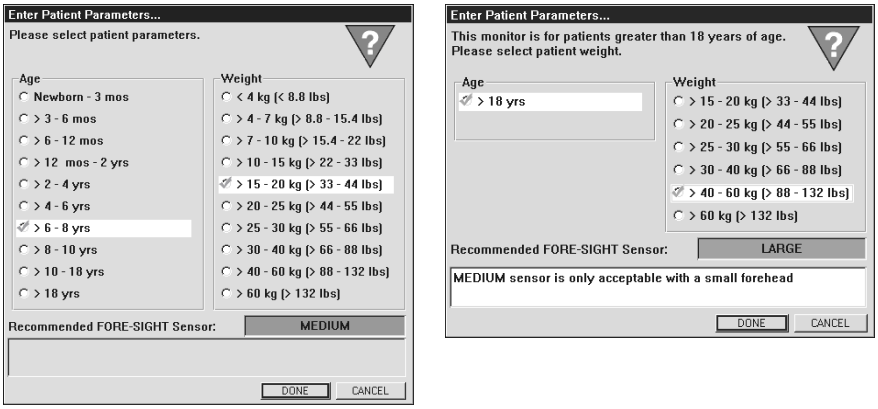


Figure 8: Examples of Enter Patient Parameter… popup dialog

Note: When the Patient's Age and Weight ranges are updated, an Event Mark shall automatically be added to the Patient Record. These Event Marks can not be deleted unless another New Patient is selected and will appear as bright green dots. The Event Text shall be the selected Age & Weight ranges (Refer the Patient Age & Weight section on page 45).

The Profiles Menu

The Profiles menu (see Figure 9 below) lets you set up, name, and manage profiles for different monitor configurations and use situations, to accommodate a user's preferences.

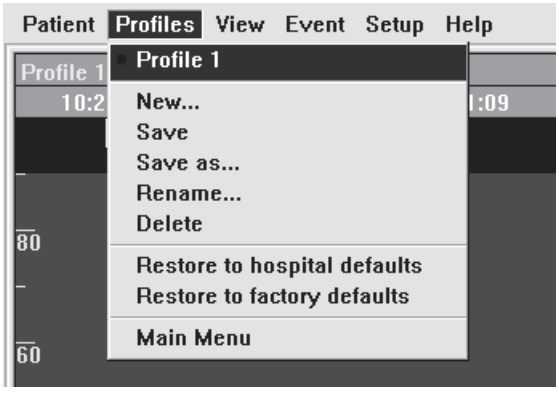


Figure 9: The Profiles menu

The View Menu

The View menu (see Figure 10 below) lets you choose the time interval spanned by the plot area.

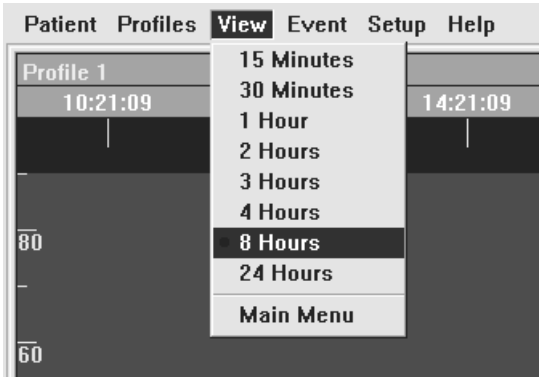


Figure 10: The View menu

The Event Menu

The Event menu (see Figure 11 below) lets you mark events on the plot area and record them with the patient data.

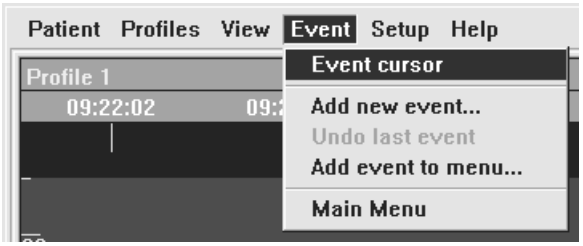


Figure 11: The Event menu

The Setup Menu

The Setup menu (see Figure 12 below) lets you set up alarm limits and alarm volume, graph style, keyboard style, monitor brightness, monitor interface language, and current date and time information. You can save a setup, once configured, using the Profiles menu.

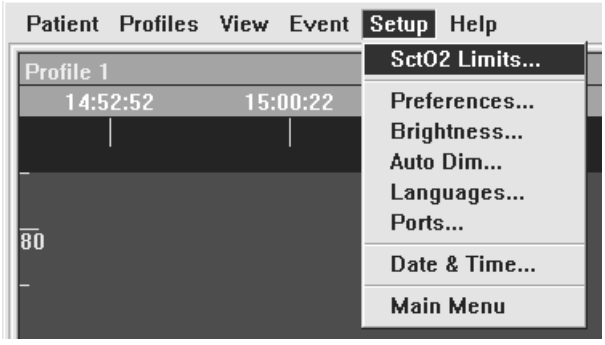


Figure 12: The Setup menu

The Help Menu

The Help menu (see Figure 13 below) provides useful tips regarding icons, buttons, symbols, and settings;

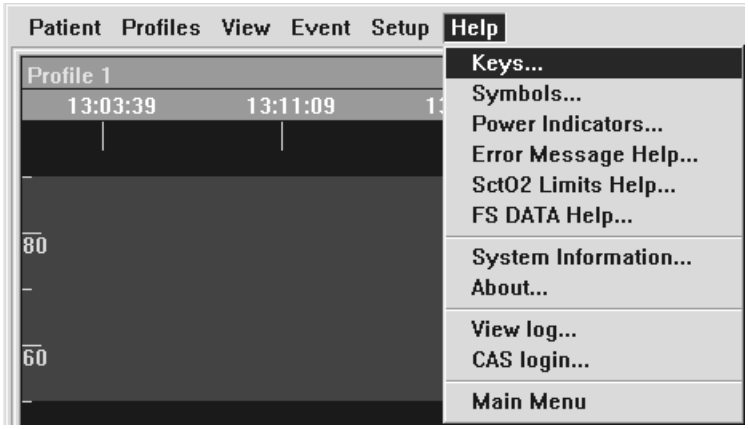


Figure 13: The Help menu

Note: You may see a more selections in the Help menu, with additional functions, when you are being trained to use the monitor, or when a system administrator or service technician is working with the machine. If you see these extended functions in normal use, contact your system administrator or technical service department to correct the condition. Most of the Help screens have a selection that allows that Help screen to be displayed on start up (see Figure 14 below). The default selection is off for all Help screens.

Figure 14: Help Menu - Display at system startup?

To obtain information specific to your FORE-SIGHT unit, including serial number and software version number, select Help > About menu in Figure 13 below.

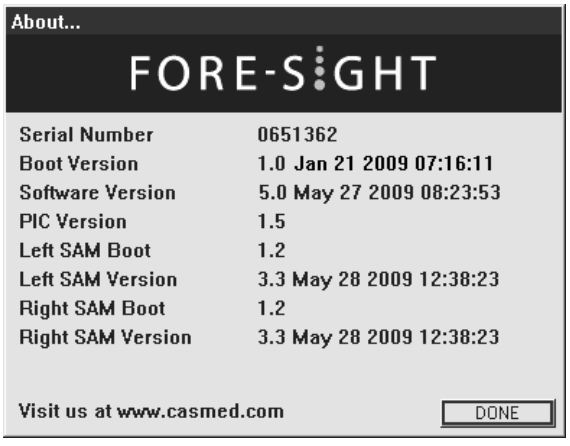


Figure 15: The About menu

Note: The displayed Serial Number and Software versions may be different than your FORE-SIGHT unit.

Entering Text

Several of the menu options give you the opportunity to enter a short text label. For example, you can create and name profiles and you can enter a patient name to identify a data record.

You have the option of using the default keyboard layout (see Figure 16 below) or the extended keyboard layout (see Figure 17 below)

Specifying the Extended Keyboard layout may be done under Setup > Preferences (see Figure 26, page 54).

Note: Selecting a language (on the Setup menu) that uses accented characters automatically enables the extended keyboard.

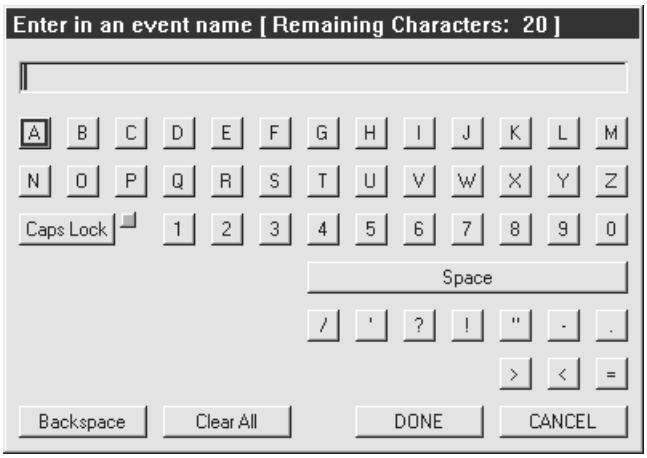


Figure 16: The default keyboard layout

The extended layout provides accented characters that should be sufficient to write names encountered in most European languages.

Use the keyboard as you would a hand-operated label maker (dial, click, dial, click…):

1 Rotate the control knob to the desired key.
2 Press the knob to select the letter or function.

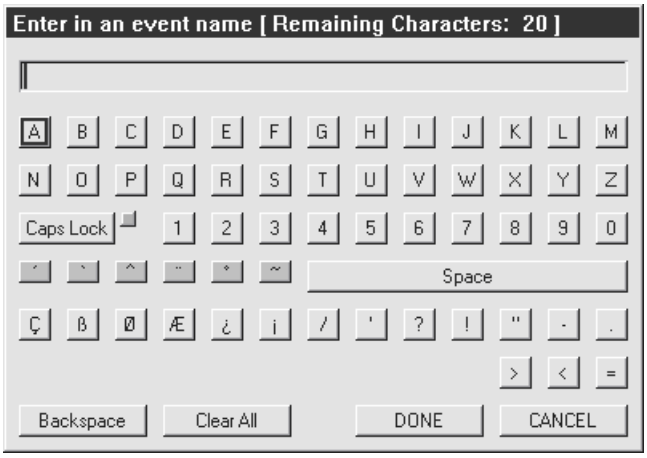


Figure 17: The extended keyboard layout

Note: To type an accented letter, first select the appropriate accent shift key. The letters to which that accent may be applied light up in yellow. Next select one of the highlighted letters. If you selected the accent in error, click it again to return the keyboard to the unselected state.

Note: The keyboard opens initially in all caps mode, as shown in figure 12, with the green Caps Lock indicator on. To access lowercase letters, rotate the control knob to select the Caps Lock key and press the knob. The green indicator toggles off and the letters on the key caps change to lowercase.

Note: The default keyboard layout has the advantage that you can select letters faster, because you have to rotate the knob through fewer selections. If you do not need to use accented characters to identify patients, profiles, or events, there is no reason to select the extended layout.

Note: The number of characters that may be allowed to be entered will be limited based on the type of information being entered.

Note: Not all characters in the default or extended keyboard may be available based on the type of information being entered.

Setting Up the Monitor for the Patient

The procedures in this section are optional. The FORE-SIGHT MC-2000 Series Monitor will operate immediately after being connected to the patient and powered on. If desired, you can bypass the following steps and begin monitoring immediately.

Note: Nothing in this user guide is intended to override procedures and regulations imposed at the institutional level or above. Your hospital's quality system, privacy rules, or other legal or policy requirements may govern whether and how you implement any specific procedure in this section.

Note: When you first power up the system, you will be asked if you are starting a new patient. Answering no will add the new data that you are collecting to the end of the previous data stored on the unit. **Answering yes will delete prior data stored in the unit.**

Note: When printing on-demand Graphic or Tabular information or while saving patient data to a USB Memory stick, the ability to label data with a Patient Identifier is disabled.

Labeling the Data with the Patient Identifier

You can display the patient identifier on the monitor screen and save the patient identifier with the data.

To label data with the patient identifier:

1. On the Patient menu, select New. The system asks if you want to start a new patient and cautions you that answering Yes erases all acquired data and starts a new session.

Note: If a New Patient is selected, all collected FS Data information will be erased (see FORE-SIGHT (FS) Data Collections on page 74).

2. Select Yes. The keyboard opens.
3. Enter the patient identifier; up to 30 characters including spaces (see Entering Text, page 36).
4. Select the DONE button when you are done.
5. Check the Enable FS Data collection box to enable FS Data collection (see FORE-SIGHT (FS) Data Collections on page 74).

Selecting a User Profile

On the Profiles menu, select the profile that you wish to use. If none of the existing profiles is suitable, you can create and save a new profile.

To create and save a new profile:

1. On the Profiles menu, select New.
2. Enter the name of the new profile; up to 15 characters including spaces (see Entering Text, page 36).
3. Select the DONE button when you are done.
4. On the View and Setup menus, make any desired changes to the current settings (see pages 52 and following).

5 On the Profiles menu, select Save.

Alternate method:

1 On the View and Setup menu, make any desired changes to the current settings (see pages 52 and following).
2 On the Profiles menu, select Save As.
3 Enter the name of the new profile; up to 30 characters including spaces (see Entering Text, page 36).
4 Select the DONE button when you are done.

Either procedure automatically selects the new profile.

Connecting the Monitor Cables

Monitor cables (see Figure 18a-d, page 42) connect the monitor to the patient cables. Monitor cables are reusable.

Warning: Do not lift the monitor by any cable or line as they could disconnect from the monitor, causing the monitor to fall on the patient.

Warning: Route and secure all cables away from patient's throat to reduce the possibly of strangulation.

Warning: *Conductive Connections* – Extreme care must be exercised when applying medical electrical equipment. Many parts of the human–machine circuit are conductive, such as the patient, connectors, electrodes, and transducers. It is very important that these conductive parts do not come into contact with other grounded, conductive parts when connected to the isolated patient input of the device. Such contact would bridge the patient's isolation and cancel the protection provided by the isolated input. In particular, there must be no contact of the neutral electrode and ground.

Caution: Inspect the cables and sensors for damage prior to operation. If any damage is noted, the cables or sensor should not be used until it has been serviced or replaced.

Caution: Do not kink or bend cables - Maintain a minimum bend radius of 1 inch.

Note: Monitor cables should remain connected to the monitor between uses.

Note: Monitor cables contain fiber optic elements. Care should be taken to prevent damage to the monitor cables.

Note: Monitor cables should be replaced annually or when no longer properly functioning Keep track of cable installation date and usage. See Accessories on page 107 for reorder information.

Note: The monitor cable includes both an electrical cable and a fiber optic cable. You must take care to ensure that the entire fiber optic pathway is kept clean. Keep the door on the end of the monitor cable (preamplifier) snapped shut whenever the monitor cable is disconnected from the patient cable. If monitor cables are disconnected between uses, clean the fiber optic connections on both the monitor and monitor cable before re-insertion, using CASMED-

supplied fiber optic cleaning tips found in the FORE-SIGHT Biomedical Kit.

Connecting the Monitor Cables for the First Time

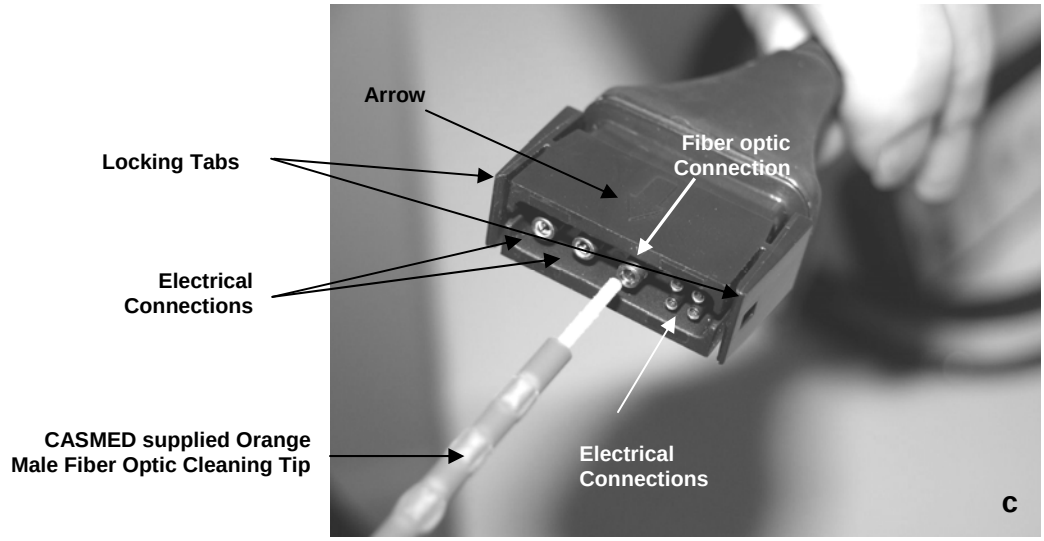
To connect the monitor cables to the monitor:

1. Remove the left monitor cable from the packaging (see Figure 18a, page 41).
2. Remove the black protective cover from the monitor connector cable (see Figure 18b, page 41).
3. Using an Orange Male Fiber Optic Cleaning Tip supplied with the FORE-SIGHT Biomedical Kit, clean the fiber optic connector on the monitor end of the monitor cable (see Figure 18c below).
4. Open the left patient monitor connection door on the monitor and clean the fiber optic connection on the monitor using the Clear Male Fiber Optic Cleaning Tip supplied with the FORE-SIGHT Biomedical Kit (see Figure 18d, page 42).
5. Orient the monitor cable connector with the arrow up.
6. Firmly push the monitor cable connector into the left monitor connection (see Figure 18e, page 42).
7. Repeat the above steps for the right monitor cable.

Removing the Monitor Cables

To remove a monitor cable from the monitor:

1. Squeeze the locking tabs on the sides of the connector.
2. Pull straight out.



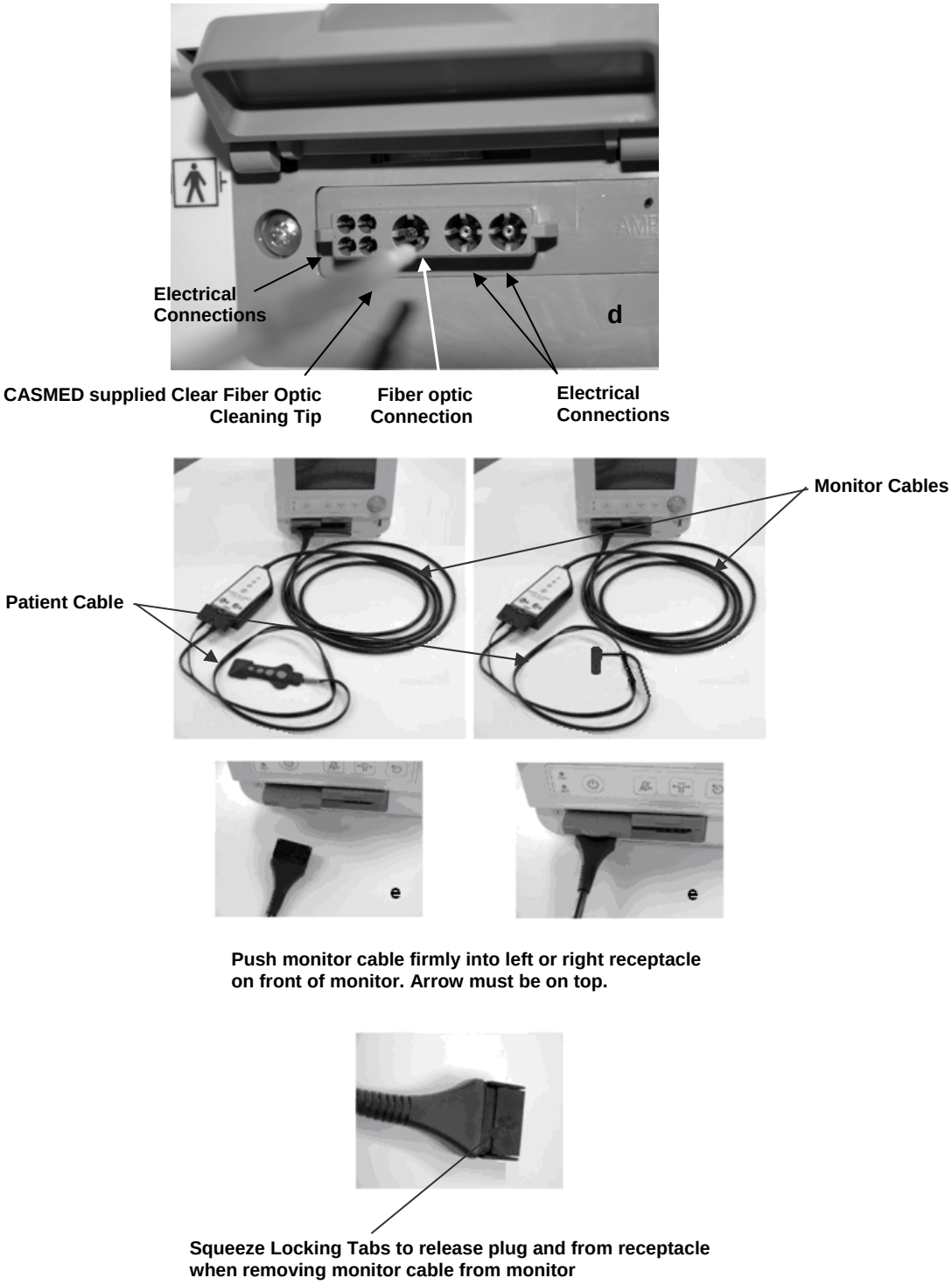


Figure 18: Connecting and disconnecting the monitor cable

Connecting the Patient Cables to the Monitor Cables

Patient cables (see Figure 19a-g) connect the monitor cables to the patient. Patient cables are single-use items. Use new patient cables for every patient and discard after use.

Warning: Do not lift the monitor by any cable or line as they could disconnect from the monitor, causing the monitor to fall on the patient.

Warning: Route and secure all cables away from patient's throat to reduce the possibly of strangulation.

Warning: *Conductive Connections* – Extreme care must be exercised when applying medical electrical equipment. Many parts of the human–machine circuit are conductive, such as the patient, connectors, electrodes, and transducers. It is very important that these conductive parts do not come into contact with other grounded, conductive parts when connected to the isolated patient input of the device. Such contact would bridge the patient's isolation and cancel the protection provided by the isolated input. In particular, there must be no contact of the neutral electrode and ground.

Caution: Inspect the cables and sensors for damage prior to operation. If any damage is noted, the cables or sensor should not be used until it has been serviced or replaced.

Note: The patient cable includes both an electrical cable and a fiber optic cable. You must take care to ensure that the entire fiber optic pathway is kept clean. Keep the patient cable in its original package until you are ready to connect it to the monitor cable. Do not kink or bend cables.

The connector end of the patient cable has two parts. The fiber optic connector has a (non-black) colored plastic overmold and a protective rubber cap.

Note: Remove the rubber cap from the fiber optic connector and discard before attempting to connect the patient cable to the monitor cable. If you do not remove this tip, you will not be able to connect into the receptacle on the monitor cable.

Connecting the Patient Cables

To connect the patient cables to the monitor cables:

1. Remove the left patient cable from the packaging (see Figure 19a, page 44).
2. Remove and discard the protective cap that covers the fiber optic connector, being careful not to touch the fiber optic tip with your fingers (see Figure 19b, page 44).
3. Open the door on the monitor cable connector (preamplifier) (see Figure 19c, page 44).
4. Using the Clear Male Fiber Optic Cleaning Tip found in the sensor packaging, clean the fiber optic connector on the monitor (preamplifier) cable end by inserting gently into the fiber optic receptacle and rotating clockwise 360 degrees (see Figure 19d, page 44).

5 Using the Clear Female Fiber Optic Cleaning Tip found in the sensor packaging, clean the fiber optic connector on the patient cable by gently making contact with the connector and rotating clockwise 360 degrees (see Figure 19e below).

6 Push the fiber optic connector into the receptacle with the matching colored label as far as possible. It is keyed to fit only one way. The key is also identified on the colored label. You should hear or feel a slight click when connector is seated (see Figure 19f below).

7 Hold the electrical connector with the arrow (rounded side) up and push it into the receptacle as far as possible. You should hear or feel a slight click when the connector is seated (see Figure 19g below.

8 Repeat the above steps for the right patient cable.

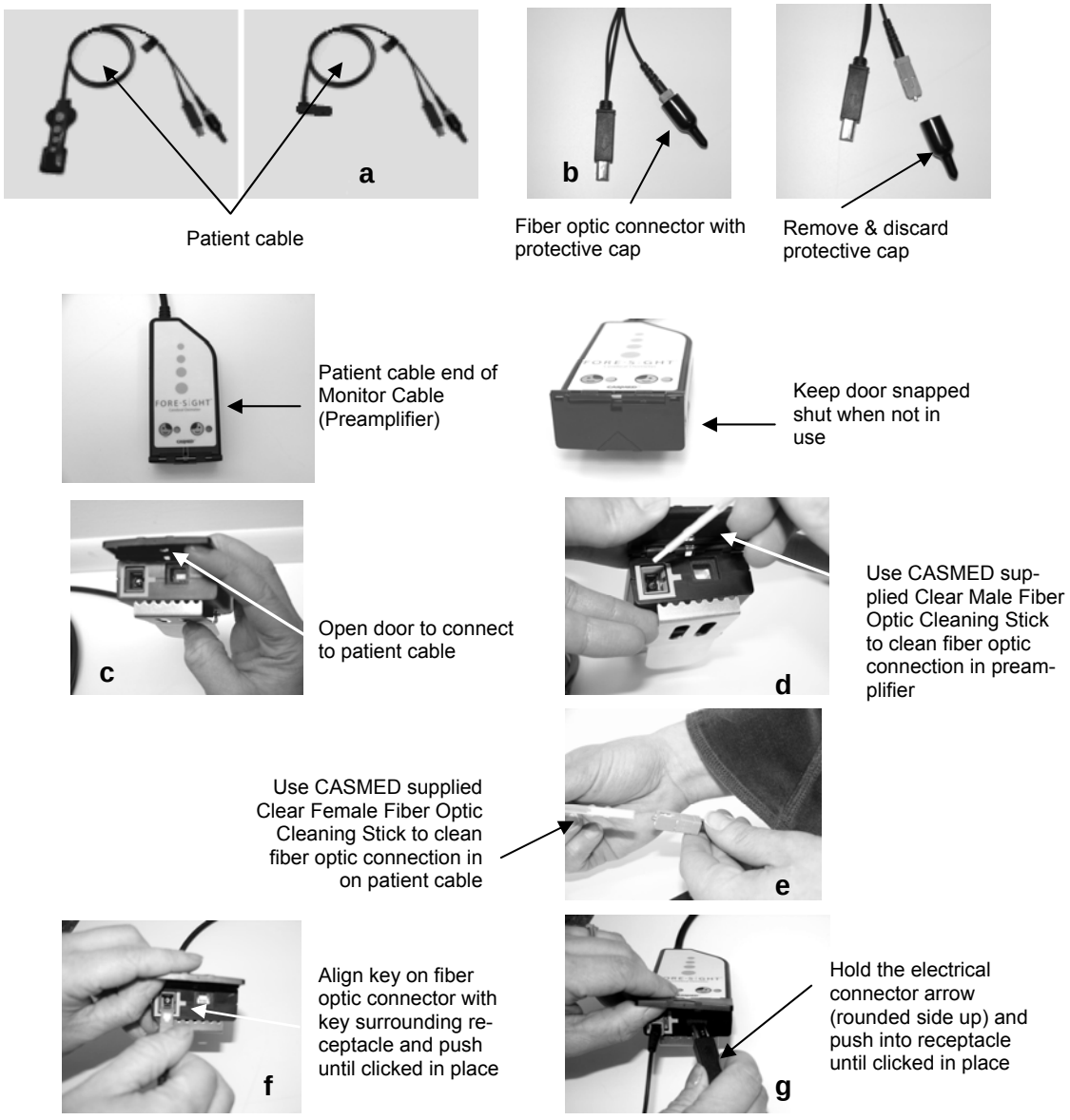


Figure 19: Connecting the Patient cable

Clean fiber optic tip and receptacle before connecting.
Connect fiber optic connector and then electrical connector

Patient Age & Weight

Warning: Before using sensors for the first time, please read the instructions for use provided with the sensors.

Universal Monitor (All Ages)

Note: After selecting and entering a New Patient or selecting Enter Patient Parameters under the Patient Menu (refer to The Patient Menu, page 33), the Universal Monitor Enter Patient Parameters… popup dialog will appear on the screen (refer to Figure 20 below).

Note: Patient Weight and Age selections must be entered otherwise the Lasers will not be allowed to be turned on.

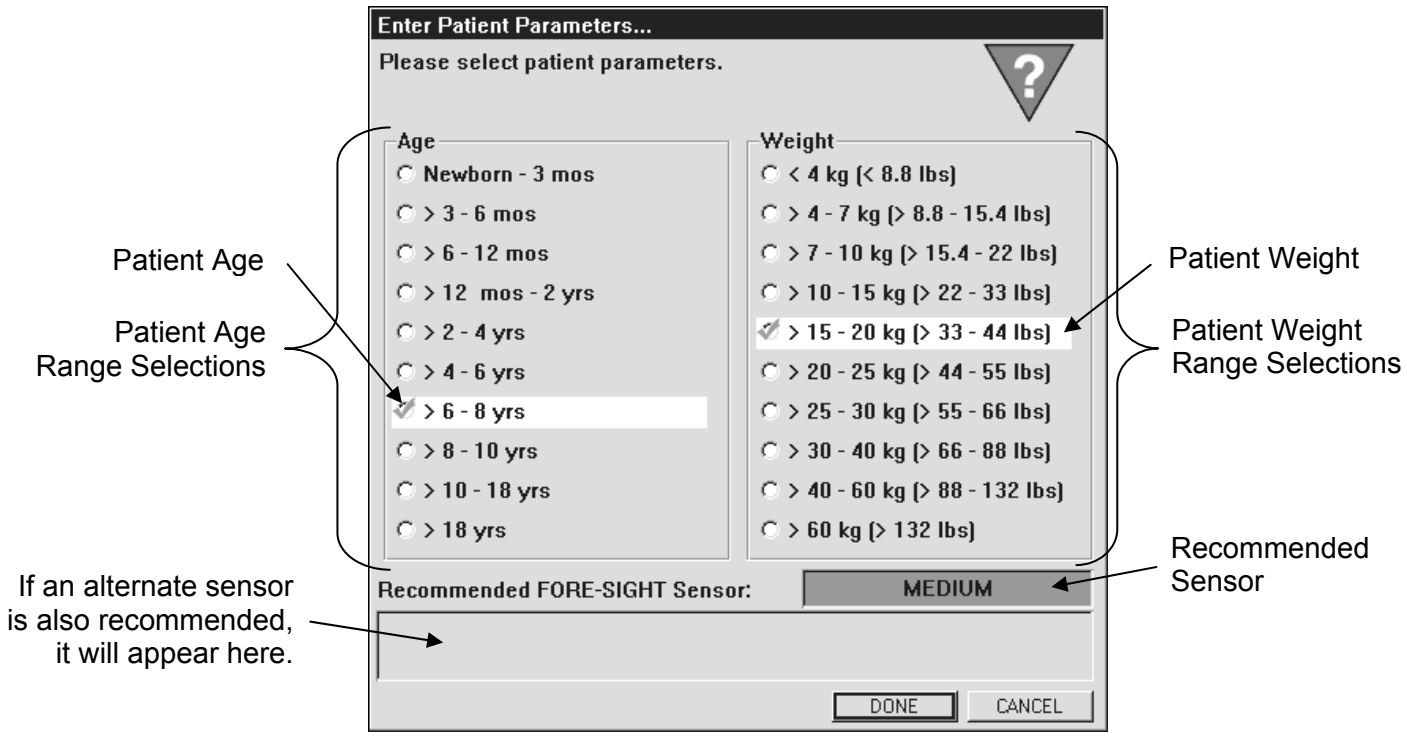


Figure 20: Universal Monitor Enter Patient Parameters… popup dialog

Adult Monitors (> 18 yrs)

Note: After selecting and entering a New Patient or selecting Enter Patient Parameters under the Patient Menu (refer to The Patient Menu, page 33), the Figure 21: Adult Monitor Enter Patient Parameters… popup dialog will appear on the screen (refer to Figure 21 below).

Note: Patient Weight and Age selections must be entered otherwise the Lasers will not be allowed to be turned on.

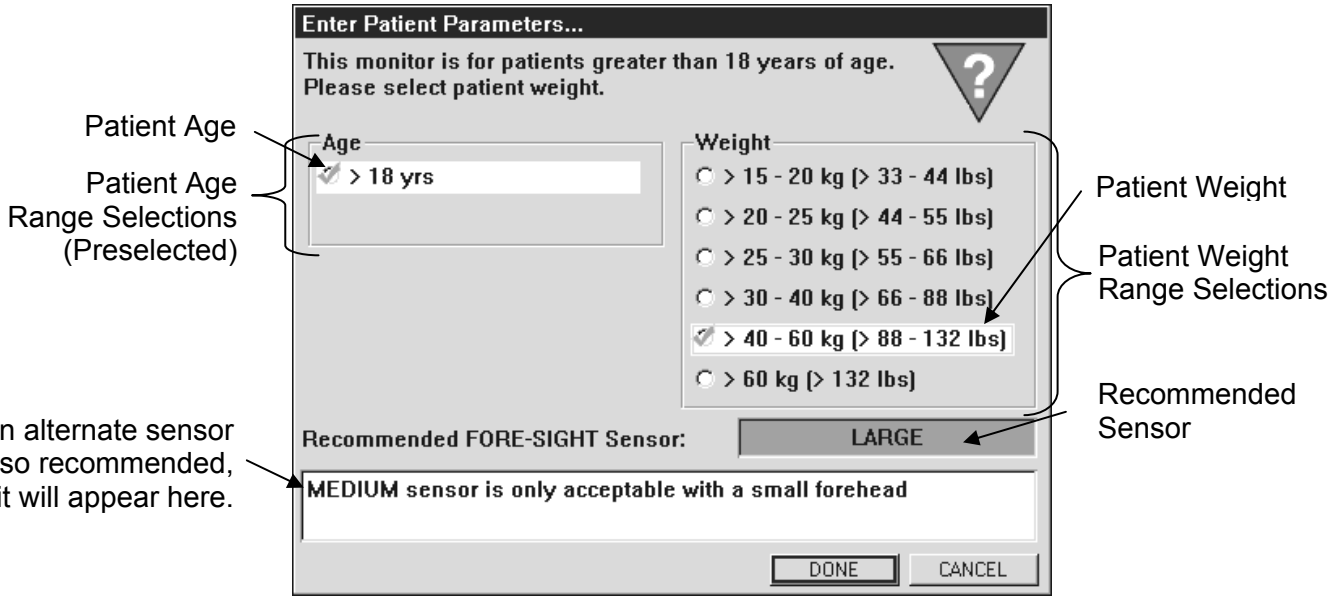


Figure 21: Adult Monitor Enter Patient Parameters… popup dialog

Selecting Patient's Age and Weight

To Enter Patient Age Range:

1. Turn the rotary control knob until the desired Patient Age range is highlighted.
2. Push the rotary control knob to select Age range.

To Enter Patient Weight Range:

1. Turn the rotary control knob until the desire Patient Weight range is highlighted.
2. Push the rotary control knob to select Weight range.

To Accept or Cancel the entry of Patient Parameters:

1. Turn the rotary control knob until DONE is highlighted and push the rotary control knob to Accept the changes.
2. Turn the rotary control knob until CANCEL is highlighted and push the rotary control knob to Cancel the changes.

Note: When the Patient's Age and Weight ranges are updated, an Event Mark shall automatically be added to the Patient Record. The Event Text shall be the selected Age & Weight ranges (Refer to Adding a new Event Mark to the Patient Record section on 64).

Note: If Patient Age range is **NOT** selected, the Patient's Age will indicate "**Unspecified**" and the Lasers cannot be turned on.

Note: If Patient Weight range is **NOT** selected, the Patient's Weight will indicate "**Unspecified**" and the Lasers cannot be turned on.

Note: Lasers will not be allowed to turn on if the installed sensors do not match the recommended Sensors.

Note: Attempting to turn the Lasers on, without entering a Patient Age and Weight, will cause the Universal Monitor Enter Patient Parameters… popup dialog or Adult Monitor Enter Patient Parameters… popup dialog to appear.

Removing the Patient Cables

To remove a patient cable from the monitor cable:

1. Pull the electrical connector straight out.
2. Grasp the fiber optic connector by the colored (non-black) overmold and pull straight out.
3. Snap the door closed over the end of the preamplifier.
4. Discard the patient cable

Affixing the $SctO_2$ Sensor to the Patient

Warning: Before using $SctO_2$ sensors for the first time, please read the instructions for use provided with the sensors.

Warning: As with all medical equipment, carefully route and secure all patient cables to reduce the possibility of patient entanglement or strangulation.

Warning: Always remove the sensor from the patient and completely disconnect the patient from the FORE-SIGHT MC-2000 Series Monitor before bathing the patient.

Warning: The sensor site must be inspected at least every eight hours; and if the circulatory condition or skin integrity has deteriorated, the sensor should be applied to a different site.

Warning: The site must be checked at least every eight hours to ensure adequate adhesion, circulation, skin integrity, and correct optical alignment.

Warning: Patient Safety – If a sensor is damaged in any way, discontinue use immediately.

Warning: Do not lift the monitor by any cable or line as they could disconnect from the monitor, causing the monitor to fall on the patient.

Warning: Route and secure all cables away from patient's throat to reduce the possibly of strangulation.

Warning: *Conductive Connections* – Extreme care must be exercised when applying medical electrical equipment. Many parts of the human–machine circuit are conductive, such as the patient, connectors, electrodes, and transducers. It is very important that these conductive parts do not come into contact with other grounded, conductive parts when connected to the isolated patient input of the device. Such contact would bridge the patient's isolation and cancel the protection provided by the isolated input. In particular, there must be no contact of the neutral electrode and ground.

Caution: Inspect the cables and sensors for damage prior to operation. If any damage is noted, the cables or sensor should not be used until it has been serviced or replaced.

Note: Skin pigmentation does not affect the validity of collected data. The FORE-SIGHT MC-2000 Series Monitor compensates automatically for skin pigmentation.

Note: The sensor must be flush with clean, dry skin. Any oil, perspiration, or hair that prevents good contact between the sensor and the skin will affect the validity of the data collected and may result in an error message.

Note: If possible, locate the sensor away from the midline of the forehead or over a sinus cavity.

Patient cables (see Figure 19a, page 44) connect the monitor cables to the patient. Patient cables are single-use items. Use new patient cables for every patient and discard after use.

Preparing the Patient

Warning: Before using $SctO_2$ sensors for the first time, please read the instructions for use provided with the sensors.

To prepare the patient's forehead for placement of the sensor:

1. Make sure the skin area where the sensor is to be placed is clean, dry, intact and free of powder, oil or lotion.
2. If necessary, shave hair from skin at chosen site.
3. Use an appropriate cleanser to gently clean the intended sensor site. Allow the skin to dry completely before applying the sensors

Applying the Sensors

Warning: Before using $SctO_2$ sensors for the first time, please read the instructions for use provided with the sensors.

Apply sensor using the instructions provided in the sensor kit package.

1. Be sure that all cables are fully connected and sensors are placed on the correct side of the patient's head. (See Starting to Monitor a Patient, page 50)
2. Use the clip/hook on the back of the preamplifier box (located at the patient end of the monitor cable) to secure the cable to a fixture, such as a rail, to prevent the cable from being pulled away from the patient.

Note: Apply the light block over the sensors before monitoring. If the light block is not in place, an alarm will alert you that there is too much ambient light.

Note: The monitor can be used on one or both cerebral hemispheres. In most situations it is advisable to monitor both sides, as some conditions can give rise to desaturation of one hemisphere.

Note: As a reminder, if one or both lasers are not firing (after proper connection of both the monitor and patient cable to the monitor) a low priority audio alert will be sounded (two quick beeps). The audio alert is generated after 90 seconds has lapsed with the cables and sensors set correctly but one or both lasers are not firing. The alert repeats every 10 seconds and cannot be muted.

Removing the Sensors

Warning: Before using $SctO_2$ sensors for the first time, please read the instructions for use provided with the sensors.

If sensor is applied to the skin with an adhesive, carefully peel the sensor from the patient to avoid damaging the skin. Discard adhesive sensors and used light block.

If sensor is applied to the skin without an adhesive, carefully remove the attachment mechanism from the patient to avoid damaging the skin. Discard attachment mechanism and used light block.

Starting the Monitor

Turning the Monitor On

Note: You may turn the monitor on before or after connecting cables and sensors.

To turn the monitor on:

1 Plug the AC power cord into a power outlet.

2 Press the On / Standby key on the front of the monitor. The unit will power up within a few seconds.

Figure 22: On / Standby key

Note: Models MC-2010 & 2030 are equipped with an optional internal battery that allows you to turn the unit on without plugging it into an outlet. The battery status indicator shows the amount of charge remaining in the form of a colored bar filling the battery icon at the upper right of the monitor screen, with the amount of fill corresponding to the amount of charge. If the battery is at more than 30% of capacity, the amount of charge remaining is shown in green. If it is at less than 30%, it is shown in red. If the battery is completely discharged, the battery icon is empty, with neither red nor green showing. A fully charged battery will operate the Model MC-2010 or 2030 unit for approximately 1½ hours.

Refer to the Battery Maintenance section on page 95.

Note: While the monitor software initializes, the monitor displays a brief diagnostic text screen, then an animated FORE-SIGHT splash screen and then switches to the regular display, ready to begin normal operation. You can dismiss the splash screen before the animation finishes by pressing the rotary control knob once.

Note: A help dialog may open at system start. You can dismiss this dialog by pressing the rotary control knob once. You may uncheck the “Display at system start?” to disable displaying this dialog on system startup.

Starting to Monitor a Patient

To start monitoring a patient:

1 Ensure that all cables and sensors are in place

Note: Verify that right and left cables are properly connected by noting the illuminated LED on each preamplifier box. The LED that is illuminated indicates the cable connection at the monitor. If the LED close to the blue face icon is illuminated, it indicates that the monitor cable is connected for the patient’s left side. If the LED close to the green face icon is illuminated, it indicates that the monitor cable is connected for the patient’s right side.

Note: The cable connection indicators (face icons) located on the monitor screen under the $SctO_2$ measurement indicate the connection status of the cables. The black cutout indicates which cable the icon pertains to. A colored face (blue for left, green for right) with a smiling mouth indicates that the cables are fully connected.

Left monitor cable connected; left patient cable not connected. A **white** face with a flat line for the mouth indicates that the monitor cable is connected but the patient cable is not connected.

Left cables fully connected. The **blue** face icon with the black cutout on the right side of the icon pertains to the left patient connection.

Right monitor cable connected; right patient cable not connected. A **white** face with a flat line for the mouth indicates that the monitor cable is connected but the patient cable is not connected.

Right cables fully connected. The **green** face icon with the black cutout at the left side of the icon pertains to the right patient connection.

Note: Be sure that the sensors are placed on the correct side of the patient's head. The patient sensor connected to the preamplifier with the LED close to the blue face illuminated should be attached to the patient's left side. The patient sensor connected to the preamplifier with the LED close to the green face illuminated should be attached to the patient's right side.

Note: Sensors are labeled with green and blue face icon stickers identifying patient right and patient left. Be sure to match the left and right sensors to the appropriate illuminated face icons on the preamplifier. This will help to identify the appropriate side on which to place the sensors.

1 Verify the correct patient ID is displayed on the monitor screen (page 39) and that the desired profile is selected (page 39).

2 Press the Sensor Start / Restart key.

Figure 23: Sensor Start / Restart key

Note: Fire laser reminder - low priority audio alert. If one or both lasers are not firing, a low priority audio alert is generated 90 seconds after "Press sensor start/start 1X" or "… 2X" is displayed.

- The low priority alarm is audio only (no flashing triangle) and repeats every 10 minutes.
- This alarm is meant to be a gentle reminder that sensors are set correctly on the patient, but on or both lasers are not firing.
- Any other alarm in the system overrides this audio alarm.

3 Press the Avg / Auto / Left / Right key to select the initial view.

Figure 24: Average / Auto / Left / Right key

4 Verify that there are no user messages in the message area (see Figure 5, page32). If there is a message in the message area, see Responding to System Messages on page 68.

Configuring Options on the View and Setup Menus

This section explains how to configure the options you can select on the View and Setup menus. You can save these options as a profile (see page 39) or you can make temporary changes during a monitoring session, as needed.

Selecting a View

The View menu (see page 35) lets you choose the time interval spanned by the plot area.

To choose a time interval:

1 Turn the rotary control knob to select the View menu.
2 Press the rotary control knob to open the View menu.
3 Turn the rotary control knob to highlight the desired interval.
4 Press the rotary control knob to select the interval.

Setting Up $SctO_2$ Alarm Limits and Speaker Volume

You can set the lower and upper limits of acceptable $SctO_2$ percentages on the left and right sensors independently or in unison. You can turn off the lower and upper limits of the SctO2 percentages on the left and right sensors independently. When the limits are turned off, no visual or audible alarms are generated. When the monitor detects a level below the Low limit or above the High limit, it sounds an alarm at the speaker volume you set, and flashes a visible alarm on the screen. You can set a delay so that transient conditions do not trigger alarms. You can also adjust the left-to-right differential alarm setting to detect an increasing difference in saturation between the right and left sensors. The default differential alarm setting is 10, but this setting can be changed using the slider bar from a minimum of 1 to a maximum of 50.

To set up $SctO_2$ alarm limits and speaker volume:

1 Turn the rotary control knob to select the Setup menu.
2 Press the rotary control knob to open the Setup menu.
3 Press the rotary control knob a second time to open the $SctO_2$ Limits dialog (see Figure 25, page 53).
4 Make any desired changes.
5 Select the DONE button and press the rotary control knob to save your changes. Select the CANCEL button to cancel your changes.

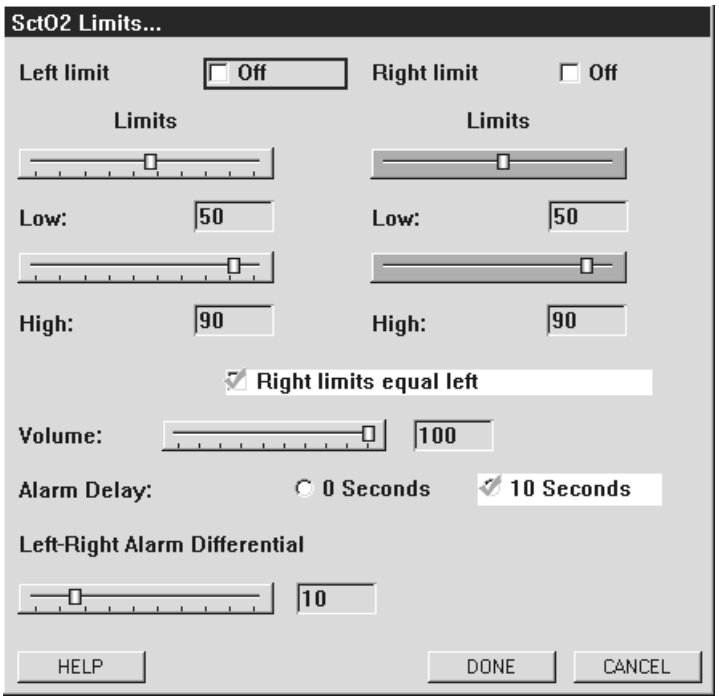


Figure 25: $SctO_2$ Limits dialog

Use the rotary control knob to move the cursor (highlight) around the dialog box. Press the rotary control knob to check or clear an item.

Clear the 'Right limits equal left' checkbox to adjust the left and right limits independently. Check the box to adjust the left and right limits in unison.

Caution: Setting the High $SctO_2$ Alarm limit to the extreme high value (98) can render the High Limit detection ineffective.

Caution: Setting the Low $SctO_2$ Alarm limit to the extreme low value (2) can render the Low Limit detection ineffective.

Note: For proper identification of the Alarm signals generated by the unit, the operator should be positioned directly in the front of the unit, facing the unit's front panel.

Note: To test the Alarm operation, connect a $SctO_2$ simulator (available through CAS) to the patient connection of the monitor. Set the High $SctO_2$ Alarm limits to at least 1% less than the current displayed value and verify the activation of the High limit detection. Reset the High $SctO_2$ Alarm limits to the desired level. Set the Low $SctO_2$ Alarm limits to at least 1% more than the current displayed value and verify the activation of the Low limit detection. Reset the Low $SctO_2$ Alarm limits to the desired level. Testing of the Alarm operation should be done at least once every 6 months.

Note: The High $SctO_2$ (Left or Right channel) Limit can not be set less than the Low $SctO_2$ Limit (for the same channel). The Low $SctO_2$ (Left or Right channel) Limit can not be set greater than the High $SctO_2$ Limit (for the same channel). There is always 5% difference between the Low and High limits (same channel).

Note: The alarm delay remains constant during any alarm condition. The alarm delay may be altered by the User at any time and only affects alarms yet to happen.

Setting the Alarm Delay to **0 Seconds** will cause an alarm to immediately annunciate when a limit violation occurs, (e.g. If the Low Limit is set to 50 and the %$SctO_2$ value falls below 50%, the Low %$SctO_2$ alarm will annunciate immediately).

Setting the Alarm Delay to **10 Seconds** will delay the annunciation of a limit violation for 10 seconds, (e.g. If the Low Limit is set to 50 and the %$SctO_2$ value falls below 50% and remains continuously below 50 for 10 seconds, the Low %$SctO_2$ alarm will annunciate) In this example the %$SctO_2$ value must remain less than the Low limit for 10 continuous seconds.

Note: You can also access the $SctO_2$ Limits dialog by turning the rotary control knob until the %$SctO_2$ display area is highlighted (bright blue background) and pressing the rotary control knob.

Moving a Slider

To move a slider to adjust a limit or to adjust speaker volume:

1. Turn the rotary control knob to select the slider.
2. Press the rotary control knob to activate the slider.
3. Turn the rotary control knob left or right to adjust the level.
4. Press the rotary control knob to set the selected level.
5. Turn the rotary control knob to navigate away from the slider.

Setting Miscellaneous Preferences

You can set preferences for horizontal and vertical grid lines on the plot area or use of the standard or extended keyboard (see page 37)

To set miscellaneous display preferences:

1. Turn the rotary control knob to select the Setup menu.
2. Press the rotary control knob to open the Setup menu.
3. Turn the rotary control knob to the right to select Preferences.
4. Press the rotary control knob a second time to open the Preferences dialog (Figure 26 below).
5. Make any desired changes.
6. Select the DONE button and press the rotary control knob to save your changes. Select the CANCEL button to cancel your changes.

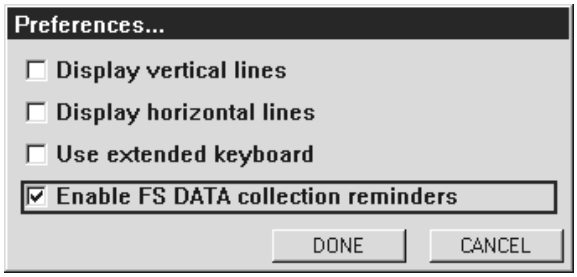


Figure 26: Preferences dialog

Setting Display Brightness

You can adjust the monitor brightness to a comfortable level with respect to ambient light.

To set the display brightness:

1 Turn the rotary control knob to select the Setup menu.
2 Press the rotary control knob to open the Setup menu.
3 Turn the rotary control knob to the right to select Brightness.
4 Press the rotary control knob a second time to open the Brightness dialog (Figure 27 below).
5 Press the rotary control knob a third time to activate the brightness slider.
6 Turn the rotary control knob to the left to reduce brightness or to the right to increase it.
7 Press the rotary control knob again to deactivate the brightness slider.
8 Select the DONE button and press the rotary control knob to save your changes. Select the CANCEL button to cancel your changes.

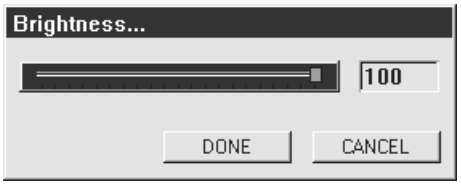


Figure 27: Brightness dialog

Setting Auto Dim

You can set the display to dim automatically after a specified period. This is appropriate, for example, if you are using the monitor in a patient room and the bright display might interfere with the patient's rest.

To set the auto dim feature:

1 Turn the rotary control knob to select the Setup menu.
2 Press the rotary control knob to open the Setup menu.
3 Turn the rotary control knob to the right to select Auto Dim.
4 Press the rotary control knob a second time to open the Auto Dim dialog (Figure 28, page 56).
5 Press the rotary control knob to turn auto dim on or off.
6 Turn the rotary control knob to the right to select the slider.
7 Press the rotary control knob to activate the delay slider.
8 Turn the rotary control knob to the left to reduce the delay or to the right to increase it.
9 Press the rotary control knob again to deactivate the delay slider.
10 Select the DONE button and press the rotary control knob to save your changes. Select the CANCEL button to cancel your changes.

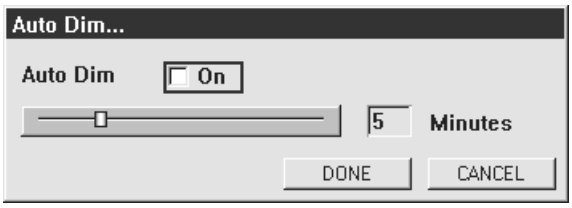


Figure 28: Auto Dim dialog

Deactivating Auto Dim Temporarily

To temporarily deactivate the auto dim function, push any key or turn the rotary control knob. The monitor screen automatically returns to full brightness. Activation of an alarm also temporarily deactivates the auto dim function.

Selecting the Language

(Language selections may be different than the ones indicated in this section)

You can change the language used for menus, dialogs, and screen display.

Note: After you change the language, menus display in the language you selected. You should select a language you can read at least well enough to restore the display to the original language, as the names of languages listed in the Language dialog change, too.

To select a language:

1. Turn the rotary control knob to select the Setup menu.
2. Press the rotary control knob to open the Setup menu.
3. Turn the rotary control knob to the right to select Languages.
4. Press the rotary control knob a second time to open the Languages dialog (Figure 29, page 56).
5. Turn the rotary control knob to select the desired language.
6. Press the rotary control knob to confirm the selection. The focus shifts to the DONE button.
7. Turn the rotary control knob to select the word “DONE” at the bottom of the list of languages.
8. Press the rotary control knob to change the focus to the DONE button.
9. Press the rotary control knob to save your changes. Select the CANCEL button to cancel your changes.

Figure 29: Languages dialog

Selecting the Serial Ports

(Port selections may be different than the ones indicated in this section)

You can change the Port settings for information transmitted and received in and out the 4 serial ports located on the rear of the monitor (see Figure 3, page 29).

To select a serial port:

1 Turn the rotary control knob to select the Setup menu.
2 Press the rotary control knob to open the Setup menu.
3 Turn the rotary control knob to the right to select Ports.
4 Press the rotary control knob a second time to open the Ports dialog (Figure 30a, below).
5 Turn the rotary control knob to select the desired Port to configure.
6 Press the rotary control knob and the focus shifts to the Port Configuration selections.
7 Turn the rotary control knob to display the desired Port Configuration selection.
8 Press the rotary control knob and the focus will change back to the Port selection.
9 Turn the rotary control knob to select the Setup of the Port to configure.
10 Press the rotary control knob and the focus shifts to the Port Setup selections.
11 Turn the rotary control knob to display the desired Port Setup (Baud Rate) selection.
12 Press the rotary control knob to select the desired Port Setup and the focus will change back to the Port selection.
13 Turn the rotary control knob to select another Port to configure.
14 When all the ports have been configured, turn the rotary control knob to DONE button to save your selections or to the CANCEL button to cancel your changes.
15 Press the rotary control knob to save or cancel your changes.

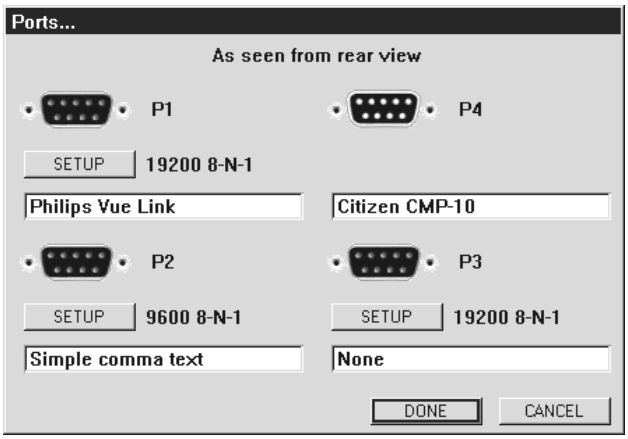


Figure 30 a: Ports dialog

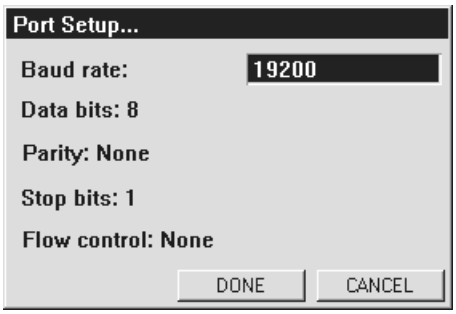


Figure 30 b: Port Setup dialog

You can change the Setup for the Port settings. While in the Ports dialog, to change the Setup for a serial port:

1 Turn the rotary control knob to select the desired SETUP button.

2 Press the rotary control knob to open the Port Setup dialog (Figure 30 b: above).

3 Turn the rotary control knob to highlight the Baud Rate Setup selection.

4 Press the rotary control knob and the focus will change to the Baud Rate selection.

5 Turn the rotary control knob to select the Baud Rate of the Port. Baud Rate selections are:

1200, 2400, 4800, 9600, 19200, 38400, 57600, or 115200.

Note: The default Baud Rate selection to interface to the Philips VueLink is 19200. When interfacing to a Philips VueLink System the valid selections are 4800, 9600 or 19200 baud.

6 Press the rotary control knob and the focus shifts to the Setup selections.

7 Turn the rotary control knob to DONE button to save your selections or to the CANCEL button to cancel your changes.

8 Press the rotary control knob to save or cancel your changes.

Note: Configuring an unused Port to a non-None selection may result in an error message indicating the inability to connect to the Port to the selected device.

Connecting to Philips IntelliVue

The FORE-SIGHT MC-2000 Series monitor may be connected to a Philips IntelliVue Patient Monitor allowing remote display of current $SctO_2$ values and alarm messages.

The FORE-SIGHT MC-2000 Series monitor can interface with the following Philips Patient Monitors using the proper VueLink module and cables:

Philips IntelliVue - MP40/50/60/70/80 and 90

Connecting FORE-SIGHT to the Philips IntelliVue Patient Monitor requires the following:

1 FORE-SIGHT minimum software requirements Version 4.4

2 Philips Hardware Requirements

- Philips IntelliVue Patient Monitor MP40 thru MP 90
- Philips VueLink Module AUXPLUS; PN M1032A #A05
- Philips VueLink Interface Cable: PN M1032A #K6C

Note: Philips contact information:

www.medicalphilips.com

medical@philips.com

3 FORE-SIGHT VueLink Adapter Cable: PN 01-06-2113

Note: Refer to Philips IntelliVue/VueLink Accessories and Options on page 109, for order information.

4 Select an unused communications port, located on the rear of the monitor (see Figure 3, page 29), for connection to the Philips VueLink.

5 Configure the selected communications port to Philips VueLink using the procedure outlined in the Selecting the Serial Ports section, on page 57.

Note: The top right communications port can not be configured for the Philips VueLink protocol.

Note: The Baud Rate selection to interface to the Philips VueLink defaults to 19200. The valid selections, when interfacing to a Philips VueLink System, are 4800, 9600 or 19200.

6 Insert the VueLink Module into an unused slot on the Philips IntelliVue Monitor.

7 Connect the Philips Interface Cable to the VueLink Module.

8 Connect the FORE-SIGHT Extension Cable to the Philips Interface Cable and then to the appropriate RS-232 communication port on the rear of the monitor.

9 Configure the Philips IntelliVue Patient Monitor to display FORE-SIGHT $SctO_2$ numeric. The following options are available:

L$SctO_2$ (Left)

R$SctO_2$ (Right)

A$SctO_2$ (Average)

Note: Touch the area on the Philips Patient Monitor where the FORE-SIGHT numeric is to be displayed. The chosen FORE-SIGHT numeric label & value will appear in the selected area.

Note: If the FORE-SIGHT value is invalid (dashed), a blank value will appear on the Philips screen.

Note: If the FORE-SIGHT value is in alarm, the value will flash and a corresponding red alarm message will be displayed on the Philips IntelliVue Patient Monitor

Note: For additional information, refer to instructions supplied with the Philips IntelliVue Patient Monitor and VueLink Module.

Note: Limit violations have higher priority over equipment alarms when sent from the FORE-SIGHT monitor to the Philips Patient Monitor. Refer to Table 2 for FORE-SIGHT Text messages displayed on the Philips IntelliVue Patient Monitor.

FORE-SIGHT Serial Port Data Output

Simple Comma Text

The monitor allows you to configure the RS-232 serial ports on the back of the monitor to output a live stream of data that us being acquired and displayed on the monitor.

1. Select an unused communications port, located on the rear of the monitor (see Figure 3, page 29).
2. Configure the selected communications port to Simple Comma Text format using the procedure outlined in the Selecting the Serial Ports, on page 57.

Serial Port Data Output

1. Minimum software requirements: Version 4.4
2. Data is output in a simple comma separated value (CSV) text format (i.e. Left, Right, Avg, Alarm values)
3. Left, Right, Avg and Alarm values are outputted once every two (2) seconds.
4. Invalid values (e.g. no sensor) are outputted as -1
5. Set the Serial Port Baud to the desire rate:

   Refer to the Selecting the Serial Ports section, on page 57.
6. Alarm status value transmitted:

   0 = No Violation
   1 = Low Left $SctO_2$
   2 = Low Right $SctO_2$
   4 = High Left $SctO_2$
   8 = High Right $SctO_2$
   16 = $SctO_2$ Differential

Examples:

57, -1, -1, 0
Left = **57**, Right = **no value**, Avg = **no value**, **no limit** violation
57, 49, 53, 4
Left = **57**, Right = **49**, Avg = **53**, **Low Right** violation
57, 49, 52, 20
Left = **57**, Right = **49**, Avg = **52**, **Low Right** & **Differential** violation

Setting the Date and Time

You can change the date and time shown on the screen display and associated with collected data.

Caution: You are not able to change the Time/Date while monitoring a patient. Press the Sensor Start / Restart key once to stop monitoring, select New Patient (see page 39) and then you can change the Time/Date.

Note: Time is kept on a 24-hour clock.

To change the date and time:

1 Turn the rotary control knob to select the Setup menu.
2 Press the rotary control knob to open the Setup menu.
3 Turn rotary control knob to the right to select Date & Time.
4 Press the rotary control knob a second time to open the Date & Time dialog (Figure 31 below).
5 Turn the rotary control knob to select the field to change.
6 Press the rotary control knob to activate the selected field.
7 Turn the rotary control knob left to lower the value in the field or right to increase the value in the field.
8 Press the rotary control knob again to deactivate the selected field.
9 Repeat steps 6 through 8 to change any other fields that you wish to change.
10 Select the DONE button to save your changes. Select the CANCEL button to cancel your changes.

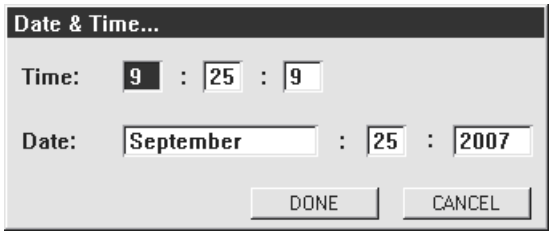


Figure 31: Date & Time dialog

To start monitoring a patient, refer to the Starting to Monitor a Patient section on page 50 for more details.

Monitoring the Patient

This section assumes that you are familiar with the front panel controls (see Figure 2, page 28) and the parts of the display screen (see Figure 5, page 32).

Selecting Average, Auto, Left or Right

You can switch the current display to show readings from the patient's left hemisphere, readings from the patient's right hemisphere, a simple average of the two, or to automatically toggle between the right and left hemisphere readings. Press the Avg / Auto / Left / Right button on the monitor front panel to rotate among these views.

Note: The monitor detects if a single sensor is connected to the monitor and will automatically display the numeric from the side in use.

Right Patient Connection

Left Patient Connection

Note: The cable connection indicators located on the monitor under the $SctO_2$ measurement indicate the connection status of the cables (see Starting to Monitor a Patient, page 50) for more details. The black cutout indicates which cable the icon pertains to. The icon with the black cutout at the left side of the icon pertains to the right patient connection; the icon with the black cutout on the right side of the icon pertains to the left patient connection. A white face with a flat line for the mouth indicates that the monitor cable is connected but the patient cable is not connected. A colored face (blue for left, green for right) with a smiling mouth indicates that the cables are fully connected.

Controlling the Alarm

You can disable or enable audible alarms by pressing the Alarm Silence / Reset key on the monitor front panel. When no alarms are present, pressing the Alarm Silence / Reset key disables the audio associated with high or low limit violations and equipment alarms for two minutes. This does not affect the visual alarms for most conditions. See Responding to System Messages on page 68 for a list of alarm conditions and the actions you can take.

Pressing the Alarm Silence / Reset key, when a Limit Violation alarm condition exists and the alarm is sounding, mutes the audible portion of the alarm condition for up to 30 seconds. If the alarm condition persists at the end of that period, the audible alarm resumes.

Pressing the Alarm Silence / Reset key when an equipment alarm condition exists and the alarm is sounding turns off the audible portion of the alarm condition, and in some cases removes the visible portion.

Note: Limit violation alarm icons are indicated by a flashing red alarm status. Equipment alarm icons are indicated by a flashing yellow alarm status. Refer to Screen Indicators on page 97.

Positioning an Event Cursor over the Patient Data

You can examine data on the patient trace of either Active or Historical mode patient data with an event cursor.

To select the event cursor:

1 Turn the rotary control knob to select the Event menu.
2 Press the rotary control knob to open the Event menu.
3 Turn rotary control knob to the right to select Event cursor.
4 Press the rotary control knob and an Event cursor is placed over the trace.
5 Turn the rotary control knob left or right to position the Event cursor over the trace. A window along the bottom of the trace will indicate the corresponding time and value of where the Event cursor is positioned.
6 Press the rotary control knob once more to exit. The Event cursor and information window will be removed.

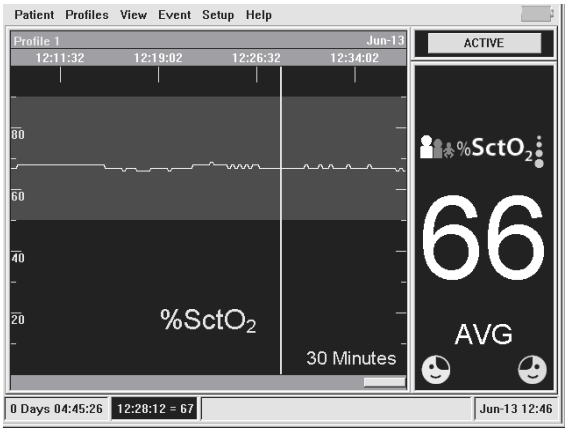


Figure 32: Positioning Event cursor

Adding an Event Mark to Menu

You can create a list of Event Marks to be used at any time. The Event Marks shall be saved to the active Profile and can be used to mark either Active or Historical mode patient data.

To add a new Event Mark:

1 Turn the rotary control knob to select the Event menu.
2 Press the rotary control knob to open the Event menu.
3 Turn the rotary control knob to select Add event to Menu.
4 Press the rotary control knob and enter text to be placed on the trace; up to 20 characters including spaces (see Entering Text, page 36), note the Event name can be left blank.

The new Event Mark text just entered will now appear under the Event Mark Menu (see Figure 33, page 64).

Caution: Placing an Event Mark in the blank area prior to the start of displayed traces will result in the Event not being saved.

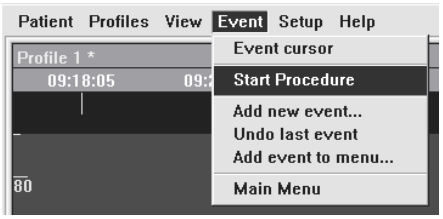


Figure 33: Add Event Mark to Menu

Adding a new Event Mark to the Patient Record

You can label a point on the patient trace with an Event Mark. You can add an Event Mark in either Active or Historical mode. Event Marks will appear as a purple dot with test to the left.

To add a new Event Mark:

1 Turn the rotary control knob to select the Event menu.

2 Press the rotary control knob to open the Event menu.

3 Turn the rotary control knob to select Add new event.

4 Press the rotary control knob and enter text to be placed on the trace; up to 20 characters including spaces (see Entering Text, page 36), Note the Event name can be left blank.

5 Press the rotary control knob and select one of the following:

Yes – Add Event Mark to List and place on trace

No – Place Event Mark on trace

(see

Placing an Event Mark on the Patient Record below)

Note: When a New Patient is entered an Event Mark shall automatically be added to the Patient Record. This Event Mark can not be deleted unless another New Patient is selected and will appear as bright green dots. The New Patient Event text shall be “ID:” followed by the new Patient ID (Refer to New Patient Popup section on page 33).

Note: When the Patient’s Age and Weight ranges are updated, an Event Mark shall automatically be added to the Patient Record. These Event Marks can not be deleted unless another New Patient is selected and will appear as bright green dots. The Event Text shall be the selected Age & Weight ranges (Refer the Patient Age & Weight section on page 45).

Placing an Event Mark on the Patient Record

Note: Adding an Event Mark on the screen, in a View greater than 1 hour (2, 3, 4, 8 or 24), will only place a dot for the Event, the text will not be visible. Changing the View to 15, 30 min or 1 hour will allow the text to be visible.

1 Turn the rotary control knob left or right to position the vertical line correctly on the trace (see Figure 34, below).

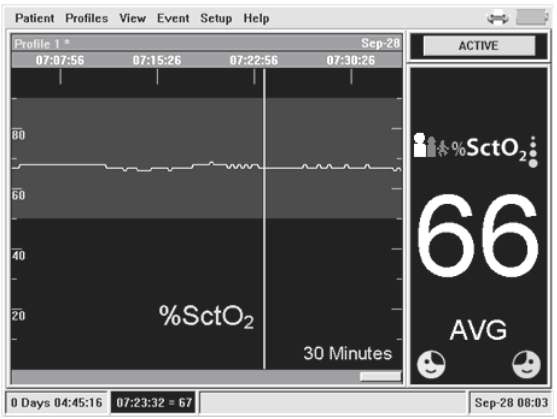


Figure 34: Vertical Position of Event Mark

2 Press the rotary control knob once more to add a horizontal line to the trace (see Figure 35, page 65).

3 Turn the rotary control knob left or right to position the horizontal line correctly on the trace.

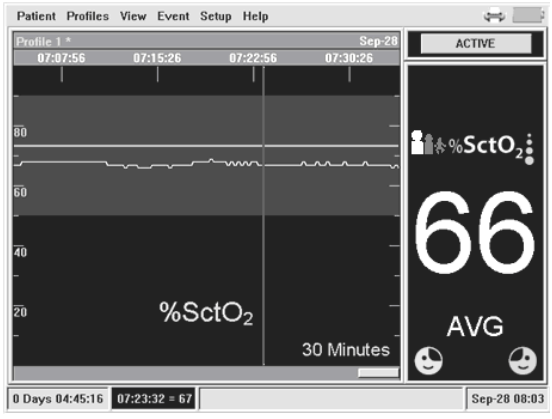


Figure 35: Horizontal Position of Event Mark

4 Press the rotary control knob once more to place the Event Mark on the trace where the two lines intersect (see Figure 36 below).

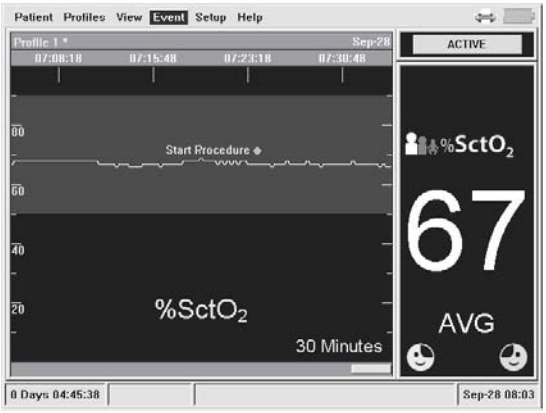


Figure 36: Final Position of Event Mark

Placing or Deleting Existing Event Marks

To place or delete an existing Event Mark:

1 Turn the rotary control knob to select the Event menu.

2 Press the rotary control knob to open the Event menu.

3 Turn rotary control knob to highlight the desired Event Mark.

4 Press the rotary control knob to select the Event Mark and select 1 of the following Event Actions (see Figure 37, page 66):

Place – Place the Event mark on the trace (see Placing an Event Mark on the Patient Record, page 65)

Delete – Delete the Event Mark from the Menu list

CANCEL – Exit Event Mark menu

Figure 37: Event Action

Undo the Last Event Mark

To undo the last Event Mark placed in the Patient Record:

1 Turn the rotary control knob to select the Event menu.

2 Press the rotary control knob to open the Event menu.

3 Turn the rotary control knob to select the Undo last event.

4 Press the rotary control knob and the last event placed shall be removed from the Patient Record

Note: Only the Last Event entered can be undone. The Undo last event selection will be unavailable once the last Event is undone.

Note: New Patient and Patient's Age and Weight Events can not be undone unless another New Patient is selected.

Switching between Active and Historical Mode

You can switch the current display between the active mode (showing data in real time) and the historical mode (showing data previously captured during the current session).

Note: When you are in the historical mode, data continues to be collected and saved to memory. No data is lost and you can switch back to active mode at any time.

To switch between modes, turn the rotary control knob to highlight the active/historical mode selection button at the upper right of the screen (see Figure 5, page 32) and press the rotary control knob.

Note: You can also switch into historical mode by selecting the historical bar at the bottom of the plot area and pressing the rotary control knob. However, you can only return to the active mode by using the active/historical mode selection button.

Reviewing Patient History

The historical bar at the bottom of the plot area changes in length as the session goes on. The length of the bar is proportional to the fraction of the total history represented by the visible trace. For example, if you have selected to view a 30-minute interval and the session has gone on for two hours, then the currently visible trace represents one-fourth of the total data and the historical bar is one-fourth the width of the window. The Active and Historical modes have their own time scales (see The View Menu, page 35)

To review patient history:

1. Turn the rotary control knob to select the historical bar.
2. Press the rotary control knob to activate the historical bar.
3. Turn the rotary control knob left to scroll back through the data or right to scroll forward toward the present.
4. Press the rotary control knob again to release the historical bar and navigate to another part of the screen.

Responding to System Messages

The message area at the bottom of the screen is normally blank. Sometimes a condition arises that causes the system to display a message there. Table 1 lists the User Messages, the conditions they signify, and the recommended action you should take. This information can also be found in the Help Menu by pressing Error Message Help.

Table 1: User Messages

Message	*Condition*	*Recommended Actions*
$SctO_2$ Patient Alarms (Red on White) [1] - High Priority Alarms		
Left $SctO_2$ HIGH	Left $SctO_2$ reading exceeds user-selected High alarm limit	Press alarm silence button to mute alarm for 30 seconds
Left $SctO_2$ LOW	Left $SctO_2$ reading is below user-selected Low alarm limit	Press alarm silence button to mute alarm for 30 seconds
Right $SctO_2$ HIGH	Right $SctO_2$ reading exceeds user-selected High alarm limit	Press alarm silence button to mute alarm for 30 seconds
Right $SctO_2$ LOW	Right $SctO_2$ reading is below user-selected Low alarm limit	Press alarm silence button to mute alarm for 30 seconds
R-L $SctO_2$ differential alarm	Right-Left $SctO_2$ differential exceeds user selected differential alarm limit	Press alarm silence button to mute alarm for 30 seconds
$SctO_2$ Equipment Alarm Messages (Yellow on Black) [2] - Medium Priority Alarms		
L Excessive Ambient Light [3]	Left patient sensor is not in correct contact with patient Light block is not properly positioned to exclude ambient light	Check that sensor is in direct contact with skin and that light block is in place Readjust light block position to more fully cover sensors
R Excessive Ambient light [3]	Right patient sensor is not in correct contact with patient Light block is not properly positioned to exclude ambient light	Check that sensor is in direct contact with skin and that light block is in place Readjust light block position to more fully cover sensors
L $SctO_2$ cable / sensor error	Left patient sensor or monitor cable is defective	Replace left patient cable if necessary Replace left monitor cable if necessary
R $SctO_2$ cable / sensor error	Right patient sensor or monitor cable is defective	Replace right patient cable if necessary Replace right monitor cable if necessary
L $SctO_2$ M cable disconnect	Left monitor cable is disconnected	Check left monitor cable connections Clean fiber optic connections using CASMED-supplied cleaning tips, then reconnect left monitor cable Replace left monitor cable if necessary

1 (Red on White) indicate Red text on White background

2 (Yellow on Black) indicates Yellow text on Black background

3 After pressing the Alarms (Silence/Reset) button, the *** Excessive Ambient light**, or **No Signal - *** message may be replaced with **Press sensor start/reset 1X/2X** message (where * represents L/Left or R/Right)

Message	*Condition*	*Recommended Actions*
$SctO_2$ Equipment Alarm Messages (Yellow on Black) – Medium Priority Alarms Continued		
L $SctO_2$ P cable disconnect	Left patient cable is disconnected	Check left patient cable connections Clean fiber optic connections using CASMED-supplied cleaning tips, then reconnect left patient cable Replace left patient cable if necessary
L Invalid Sensor	An invalid sensor has been plugged into the Left monitor cable	Unplug this sensor and plug in a valid sensor Contact CAS Customer Service if this should be a valid sensor for your unit
L Not calibrated for probe type	An sensor has been plugged into the Left monitor cable that has no Calibration information	Unplug this sensor and plug in a valid sensor Contact CAS Customer Service if this should be a valid sensor for your unit
R $SctO_2$ M cable disconnect	Right monitor cable is disconnected	Check right monitor cable connections Clean fiber optic connections using CASMED-supplied cleaning tips, then reconnect right monitor cable Replace right monitor cable if necessary
R $SctO_2$ P cable disconnect	Right patient cable is disconnected	Check right patient cable connections Clean fiber optic connections using CASMED-supplied cleaning tips, then reconnect right patient cable Replace right patient cable if necessary
R Invalid Sensor	An invalid sensor has been plugged into the Right monitor cable	Unplug this sensor and plug in a valid sensor Contact CAS Customer Service if this should be a valid sensor for your unit
R Not calibrated for probe type	An sensor has been plugged into the Right monitor cable that has no Calibration information	Unplug this sensor and plug in a valid sensor Contact CAS Customer Service if this should be a valid sensor for your unit
$SctO_2$ sensor mismatch	Incorrect patient cable attached	Discard incorrect patient cable and replace with correct patient cable
Incorrect Sensor Detected	Sensor is not compatible with the specified age and weight	Use the sensor recommended for the specified age and weight
Acquiring L $SctO_2$ signal	Informational message	Wait for message to clear
Acquiring R $SctO_2$ signal	Informational message	Wait for message to clear
Press sensor start/restart 2X	A single laser is off	Press Sensor Start / Restart key twice
Press sensor start/restart 1X	Both lasers are off	Press Sensor Start / Restart key once
Note	A reminder tone of 2 quick beeps will be generated when the "Press sensor start/restart 2X" or "… 1X" message is displayed. This tone is repeated every 10 minutes and cannot be muted.	

Message	*Condition*	*Recommended Actions*
$SctO_2$ Equipment Alarm Messages (Yellow on Black) – Medium Priority Alarms Continued		
No Signal – Left [3]	Left sensor Misplacement Excessive patient sensor cable movement Left partial cable disconnections Left patient sensor cable is defective Left monitor cable is defective	Reduce patient movement or patient sensor cable movement Check to be sure that sensor is in direct contact with the skin on the patient's forehead – do not place over hair Disconnect, clean fiber optic connection and reconnect monitor cable and patient sensor cable connections Replace patient sensor cable Replace monitor cable
No Signal – Right [3]	Right sensor misplacement Excessive patient sensor cable movement Right partial cable disconnections Right patient sensor cable is defective Right monitor cable is defective	Reduce patient movement or patient sensor cable movement Check to be sure that sensor is in direct contact with the skin on the patient's forehead – do not place over hair Disconnect, clean fiber optic connection and reconnect monitor cable and patient sensor cable connections Replace patient sensor cable Replace monitor cable
L Ambient Light Warning	Left Ambient light approaching maximum value	Check that sensor is in direct contact with skin and that light block is in place Readjust light block position to more fully cover sensors
R Ambient Light Warning	Right Ambient light approaching maximum value	Check that sensor is in direct contact with skin and that light block is in place Readjust light block position to more fully cover sensors
L Signal out of Range	Left Sensor on inappropriate object	Remove sensor from inappropriate object and place on patient forehead
R Signal out of Range	Right Sensor on inappropriate object	Remove sensor from inappropriate object and place on patient forehead
L Check tissue under sensor	Tissue under sensor may have fluid accumulation/edema	Check patient for scalp edema When tissue condition returns to normal range (i.e. patient is no longer edemic), alarm message will disappear and SctO2 measurement will return
R Check tissue under sensor	Tissue under sensor may have fluid accumulation/edema	Check patient for scalp edema When tissue condition returns to normal range (i.e. patient is no longer edemic), alarm message will disappear and SctO2 measurement will return

Message	*Condition*	*Recommended Actions*
System Alarms (Red on White) – High Priority Alarms		
Dead Battery	Battery needs to be recharged	Plug unit into outlet
Internal Temp Error	Monitor is over operating temperature range	Shut down monitor and contact CASMED customer service
System Alarms (Yellow on Black) – Medium Priority Alarms		
Power Failure	External power interruption or disconnected power cord. Applies only to units w/o batteries	Press the alarm silence button to clear the message or turn monitor off and on again
Set Clock	Clock has not been set	Set date and time (See page 57)
Clock Battery	Clock battery needs to be replaced	Contact CASMED customer service
Low Battery	Battery needs to be recharged	Plug unit into outlet
Loss of AC Power	AC power loss, Unit operating on Battery power	Plug unit into outlet
System Memory Nearly Full	Data storage is near capacity	Save your data and clear the current data by selecting new patient
System Memory Full	Data storage has reached capacity	Data is no longer being stored. Save your data and clear the current data by selecting new patient
Internal Temp Warning	Monitor is beginning to overheat	Check for free flow of temperate air around monitor. Move monitor away from wall or other obstruction. Move it to a cooler area. If condition persists, contact CASMED customer service
Battery Supply Inoperative	Battery Fuse missing or blown, or battery harness disconnected	Install Battery fuse (See page 94) Contact CASMED customer service
Check Serial P1	Serial Communications problem	Inspect the Serial P1 cable connections. Make sure the Serial P1 cable connectors are properly engaged. Verify the FORE-SIGHT Serial P1 settings are correct. Verify target device is turned on and actively displaying information.
Check Serial P2	Serial Communications problem	Inspect the Serial P2 cable connections. Make sure the Serial P2 cable connectors are properly engaged. Verify the FORE-SIGHT Serial P2 settings are correct. Verify target device is turned on and actively displaying information.
Check Serial P3	Serial Communications problem	Inspect the Serial P3 cable connections. Make sure the Serial P3 cable connectors are properly engaged. Verify the FORE-SIGHT Serial P3 settings are correct. Verify target device is turned on and actively displaying information.

Message	*Condition*	*Recommended Actions*
Popup Alarm (Red on White) – High Priority Alarms		
System Error - ## - ###	Internal component failure Left or Right near infrared spectroscopy signal acquisition module (NSAM) error	Contact CASMED customer service For Error 02-018, Install the Battery fuse (See page 94)

Note: Priorities of these Alarm Conditions are Factory configured and cannot be altered by the user.

Note: The alarm delay remains constant during any alarm condition. The alarm delay may be altered by the User at any time and only affect alarms yet to happen.

A High Priority auditory signal is characterized by 10 beeps repeated every 10 seconds at a frequency of 880 Hz.

A Medium Priority auditory signal is characterized by 3 beeps, repeated every 20 seconds at a frequency of 440 Hz.

The following table indicates the conversion of User Messages to text displayed on the Philips IntelliVue:

Note: Alarm messages from the monitor may appear different on the Philips IntelliVue Patient Monitor due to text length limitations.

Table 2: User messages on Philips IntelliVue

User Messages	Philips IntelliVue Text
Left SctO2 HIGH	L SctO_2 HIGH
Left SctO2 LOW	L SctO_2 LOW
Right SctO2 HIGH	R SctO_2 HIGH
Right SctO2 LOW	R SctO_2 LOW
L-R SctO2 differential alarm	L-R SctO_2 Diff
SctO2 sensor mismatch Incorrect Sensor Detected	FS Sens Mismatch
Call Service Internal Temp Error Dead Battery Battery supply inoperative System memory full	FS System Error
Internal Temp Warning Low Battery Loss of AC Power System memory nearly full Set Clock Clock Battery	FS System Warning
L Ambient Light Warning	FS L Chk Sensor
L Excessive Ambient Light	FS L Amb Light
No Signal – Left L Signal out of range	FS L Signal Err
L SctO2 cable/sensor error	FS L Cable Err
L SctO2 M cable disconnect	FS L Cable Disc
L SctO2 P cable disconnect	FS L Sensor Disc
L Excessive Ambient Light	FS L Amb Light
Check L SctO2 sensor contact L Check tissue under sensor	FS L Chk Sensor
L Invalid Sensor L Not calibrated for probe type	FS L Sensor Err
R Ambient Light Warning	FS R Chk Sensor
R Excessive Ambient Light	FS R Amb Light
No Signal – Right R Signal out of range	FS R Signal Err
R SctO2 cable/sensor error	FS R Cable Err
R SctO2 M cable disconnect	FS R Cable Disc
R SctO2 P cable disconnect	FS R Sensor Disc
R Excessive Ambient Light	FS R Amb Light
Check R SctO2 sensor contact R Check tissue under sensor	FS R Chk Sensor
R Invalid Sensor R Not calibrated for probe type	FS R Sensor Err

FORE-SIGHT (FS) Data Collections

FS information may be collected on a case by case basis. The user will be reminded to start and stop data collection based on current equipment state. Under the Miscellaneous Preferences selection (see page 54) the user may choose to display automatic start/stop FS Data collection reminders on the main screen.

Note: Patient data for Left and/or Right channels will be collected based on the connection of the cables/sensors and the laser state at the start of FS Data collection. If one side is not connected or the laser has not been turned on when FS Data collection is started, data from that side will not be included in the FS Data Review.

Note: If FS Data information is being collected, the FS Data text in the bottom left corner of the trace area shall be green. If FS Data information is not being collected, the FS Data text shall be white.

Note: Starting and Stopping of FS DATA collection can be selected at any time. The user does not need to wait for the automatic popup reminders.

Starting FS Data Collection

Note: Starting of the FS Data collection can only be selected if the FS Data collection has been stopped.

Once the sensor(s) have been applied to the patient and the laser(s) have been turned on for a set period of time, an automatic popup reminder to Start FS Data collection may appear on the main screen (see Figure 38, below). Selecting Yes, shall start the collection of FS Data information and remove the popup reminder. Selecting No shall remove the popup reminder and not start the collection of FS Data information. Starting FS Data collection may be accomplished by selecting Start FS Data Collection… under the Patent menu (see page 33).

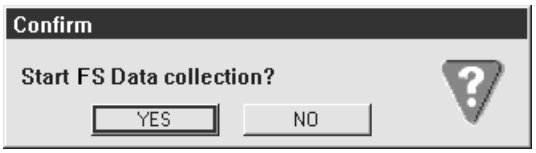


Figure 38: Start FS Data Collection popup dialog

Stopping FS Data Collection

Note: Stopping of the FS Data collection can only be selected if the FS Data collection has been started.

Once the sensor(s) have been removed from the patient or the laser(s) have been turned off for a period of time, an automatic popup reminder to Stop FS Data collection may appear on the main screen (see Figure 39, page 75). Selecting Yes, shall stop the collection of FS Data information and remove the popup reminder. Selecting No shall remove the popup reminder and continue the collection of FS Data information. Stopping FS Data collection may be accomplished by selecting FS Data collection… under the Patent menu (see page 33).

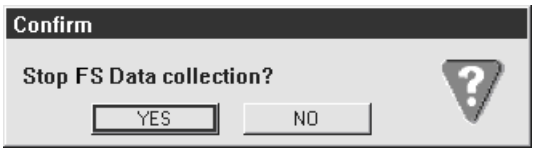


Figure 39: Stop FS Data Collection popup dialog

Reviewing FS Data Information

Note: Starting and Stopping of FS Data collection can be selected at any time. The user does not need to wait for the automatic popup reminders.

Note: Displaying the FS Data Review can be done after the FS Data collection has started or after the FS Data collection has been stopped.

Selecting the FS Data Review… under the Patent menu (see page 33) will display the collected FS Data information. The FS Data information includes the Pre-Induction Baseline Regional Oxygen Saturation, the Cumulative Saturation Below Threshold and the Skin Closure Regional Oxygen Saturation (if FS Data collection has been stopped) see Figure 40 a, below.

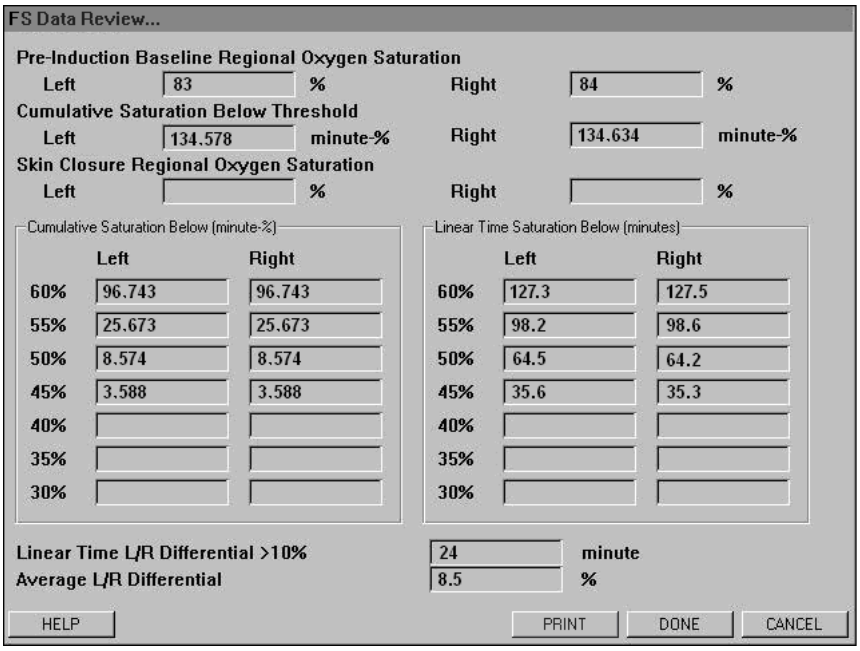


Figure 40 a: FS Data Review… dialog

Additional information including Cumulative Saturation below 60% to 30% (in 5% increments) as well as the Liner Time the Saturation is below 60% to 30% (in 5% increments) is displayed in the FS Data Review dialog. The total number of minutes the left / right differential is >10% and the average left / right differential is also available for analysis in the FS Data review dialog.

In the event measured data is not available for the right or left sensor, the appropriate text box will display dashes, Refer to Figure 40 b below. Possible causes include:

- No sensor attached
- Laser was not fired
- Data capture interrupted

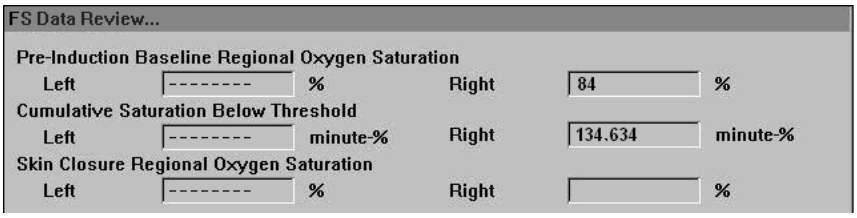


Figure 40 b: FS Data Review… dialog

USB

Memory Sticks

The FORE-SIGHT Series monitor is equipped with a USB port connector on the front of the unit. Refer to Figure 2.

The USB port connection is designed for use to save patient data from a FORE-SIGHT Series monitor to FORE-SIGHT Series USB Memory stick for review on an IBM compatible PC or MAC PC.

Caution: The USB connector accommodates a USB Flash Memory stick; do not connect any other USB device or cable to the USB port.

Caution: For safe and proper usage of USB memory sticks, please observe the following:

- When not in use, remove the USB memory stick from the monitor and place the protective cap on the USB memory stick.
- Avoid places subject to high or low temperature extremes.
- Avoid dusty places and where corrosive gasses are generated.
- Never attempt to dismantle or repair the USB Memory Stick.
- Verify patient data is stored on the USB memory stick prior to erasing the patient data within the FORE-SIGHT monitor.

Saving Patient Data

Insert the USB memory stick into the USB port connection on the front of the FORE-SIGHT monitor. If the USB memory stick will not insert, rotate the USB memory stick ½ turn and re-attempt to insert it into the USB port connection. If the USB memory stick fails to insert, contact the appropriate service personnel.

Caution: If resistance is encountered, do not attempt to force the USB memory stick into the FORE-SIGHT monitor. The USB memory stick is keyed to only be inserted one way. Attempting to force the USB memory stick into the monitor the wrong way, may cause permanent damage to the monitor and/or the USB memory stick.

Refer to page 98 for explanations of the USB Icon displayed in the upper right corner of the Main screen.

To save patient Data to the USB memory stick, select Save to USB… under the Patient menu, refer to Figure 41.

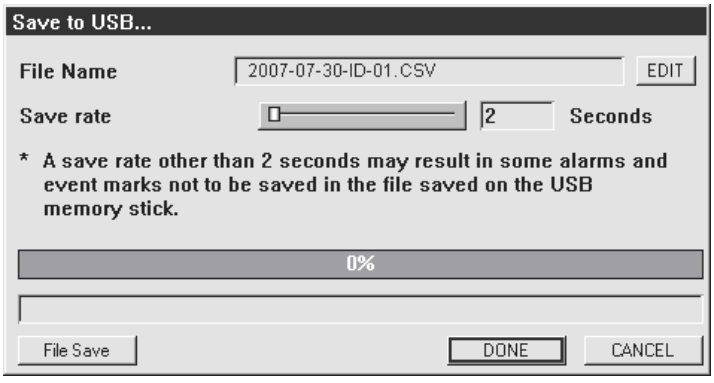


Figure 41: Save to USB… dialog

The FORE-SIGHT Series monitor shall generate a unique default file-name. To change this default file name, select EDIT and then alter the filename (see Entering Text, page 36).

To change the Save rate, navigate to the slider-bar and choose the appropriate rate (2, 4, 6, 8, 10, 12, 14, 16, 18, or 20 sec)

Note: Data is collect at a rate of 2 seconds. A save rate other than 2 seconds will not capture the entire data set and can result in some alarms and event marks being lost

To save the patient data to the USB memory stick, select File Save.

The progress bar will indicate the amount of data saved as a percentage and a solid bar shall fill in from the left, refer to Figure 42.

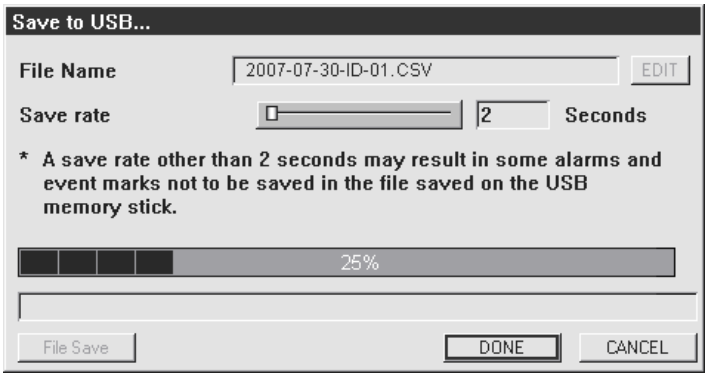


Figure 42: Saving to USB Progress

Note: Data saved to the USB memory stick includes the information reported in the FS DATA review dialog, Refer to Figure 40 a and b.

Data is saved to the USB memory stick at a rate of approximately 1 hour of patient date every 30 sec, e.g. an 8 hour case will take approximately 4 minutes to save (at a Save rate of 2 Sec).

To return to the Main screen select DONE.

Note: Once saving has started, the user may exit the dialog via the DONE selection at any time and the saving will continue.

Note: To stop the saving, select CANCEL or navigate to Save to USB under the Patient menu and then select CANCEL to stop the saving.

Note: If saving is cancelled, the file that was initially saved will be deleted from the USB memory stick.

Caution: Do not remove the USB memory stick while data is being saved to it. Removing the USB memory stick from the monitor, while data is being saved, may cause permanent damage to the USB memory stick.

Once the progress bar has indicated that 100% of the data has been saved, the USB memory stick may be safely removed, refer to Figure 43.

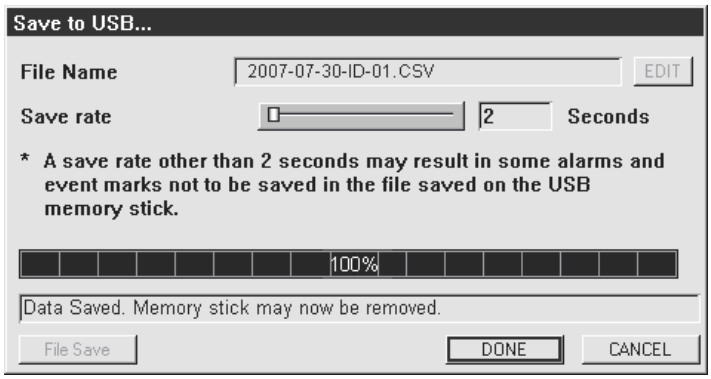


Figure 43: Saving to USB Completed

Patient data is stored in files using comma separated values (CSV) format. Figure 44 illustrates an example of patient data stored in a USB memory stick.

```
…
,23:59:56,67,69,68,0,
,23:59:58,67,69,68,0,
2007-07-16,00:00:00,67,69,68,0,
,00:00:02,67,69,68,0,
,00:00:04,66,69,68,1,PROCEDURE
,00:00:06,65,69,67,5,
...
```

Figure 44: USB Memory File Example

Note: Saving patient data in excess of 1.5 days may exceed the capability of some spread sheet applications.

USB Status

While attempting to save patient data to a USB memory stick, certain conditions may present themselves that will require intervention by the user, refer to Figure 45. Table 3 lists of the possible USB Status Messages and their recommended actions you should take:

Table 3: USB Status Messages

USB Status Message	Recommended Action
File exists – cannot overwrite	Edit name of file to be stored on the USB memory stick. Remove USB memory stick and use PC to remove un-necessary files from USB memory stick.
Memory Stick not plugged in	No USB installed, plug in USB Memory stick.
Not enough room on memory stick	Remove USB memory stick and use PC to remove un-necessary files from USB memory stick.
A non-memory stick detected	Non-USB Memory stick installed, remove device and plug in USB Memory stick.
Memory stick write error	Remove USB memory stick and try another. If condition continues contact the appropriate service personnel.
Memory stick install failure	Remove USB memory stick and try another. If condition continues contact the appropriate service personnel.
Memory stick open file error	Remove USB memory stick and try another. If condition continues contact the appropriate service personnel.
Unknown USB error	Remove USB memory stick and try another. If condition continues contact the appropriate service personnel.

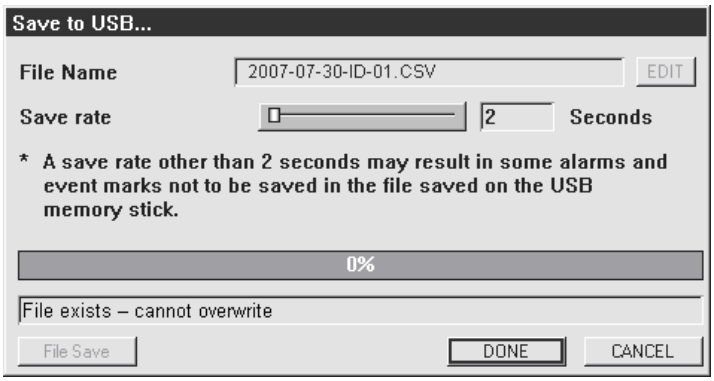


Figure 45: USB Status message display

Screen Snapshots

Insert the USB memory stick into the USB port connection on the front of the FORE-SIGHT monitor. Refer to the previous section, Saving Patient Data for additional details.

To enable saving a Screen Snapshot to the USB memory stick, select Snapshot to USB… under the Patient menu, refer to Figure 6.

The FORE-SIGHT Series monitor shall generate a unique default file-name. The file saved will be 256 color Bitmap type (.bmp). To change this file name, select EDIT and then alter the filename (see Entering Text, page 36).

To enable saving a Screen Snapshot to the USB memory stick, select DONE. Refer to Figure 46.

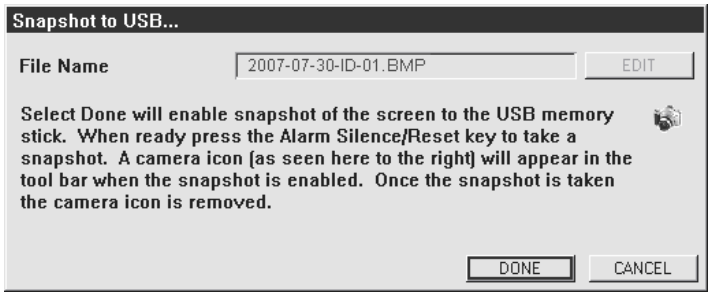


Figure 46: Snapshot to USB… dialog

Note: A camera icon will be displayed in the tool bar whenever the Screen Snapshot feature is “On”.

Note: If “***Done***” is selected and no USB memory stick is installed, the Screen Snapshot feature will not be enabled.

Note: If the Screen Snapshot feature is On and the USB Stick is pulled out before a Screen Snapshot is taken, the Screen Snapshot feature will be turned Off.

Pressing the Alarm Silence / Reset key will take a snapshot of the current screen and save it to the USB Memory Stick.

If the Screen Snapshot feature is enabled, and an Alarm condition occurs, pressing the Alarm Silence / Reset key will take the snapshot, pressing the Alarm Silence / Reset key again will then acknowledge that Alarm condition.

Note: If a Screen Snapshot is not taken within 5 minutes, the Screen Snapshot feature will be turned off.

Printer

Introduction

In the context of this Manual the FORE-SIGHT Series Printer (the Printer) refers to the Citizen Mobile Thermal Printer, Model CMP-10.

For more detailed information on the Citizen Model CMP-10 Mobile Printer, refer to the User's Manual that was supplied with the Printer.

This section contains the instructions necessary to operate the FORE-SIGHT MC-2000 Series Printer safely and in accordance with its functions and intended use.

The Printer interfaces to the Monitor via the direct connect RS232 cable (supplied with Printer).

Caution: For safe and proper usage of the Printer, please observe the following:

- Avoid places where fluid may enter the Printer opening accidentally.
- Avoid places subject to high or low temperature extremes.
- Avoid dusty places and where corrosive gasses are generated.
- Never attempt to dismantle or repair the Printer mechanism.
- Do not drop or bump the Printer.

When handling the thermal paper:

- Store in a dark, cool and dry place.
- Do not place near organic solvents.
- Avoid contact with vinyl chloride films erasers or adhesive tapes for extended periods.
- Avoid exposure to high temperature, humidity, liquid, or sunlight.
- Always use specified thermal paper. Refer to
- Other Accessories and Options on page 108 for order information.

Note: Refer to Selecting the Serial Ports Section on page 57 for additional information on configuring the rear panel Serial Ports.

Printer Controls and Indicators

Figure 47 below shows the printer controls and indicators.

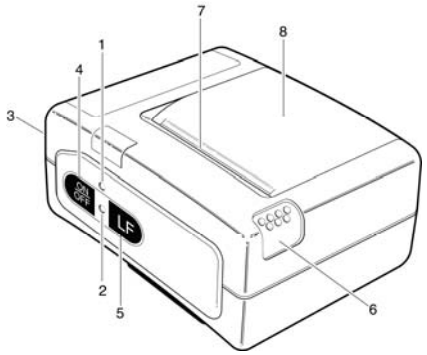


Figure 47: Printer Controls and Indicators

1. Charge LED (red = charging, green = fully charged)
2. Power LED (green = power on, red/green blinking fast = end of paper, red/green blinking slow = print head overheated)
3. RS232 serial interface
4. Power ON/OFF button
5. Line Feed button
6. Paper Cover Release Button (press down to open cover)
7. Paper Cutting Edge
8. Paper Cover

Printer Operation

The Printer cable connects to a DB9 connector, located on the rear panel of the Monitor. Use the cable, supplied with the Printer, to interface to the Monitor on the Printer.

To operate the Printer perform the following steps:

- Configure the monitor for Continuous Tabular Printing under the Patient/Print menu.

  Check the **Continuous Tabular Print** selection to enable transmission of $\%SctO_2$ values every 20 seconds.

  Un-check the **Continuous Tabular Print** selection to enable user initiated printing.

- Connect the Printer to the FORE-SIGHT Monitor with the cable provide with the Printer to the connection (see Figure 3, page 29).

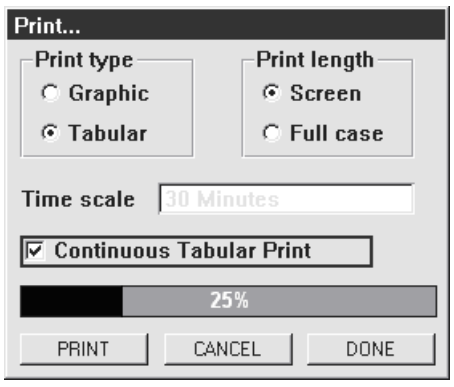


Figure 48: Patient > Print Menu dialog

Note: Connect the Printer to an AC power supply if charging of the Printer battery is required.

- Power on the Printer by pressing power ON/OFF button on the Printer.
- Power on the FORE-SIGHT Monitor by pressing the On/Standby button on the front of the Monitor.

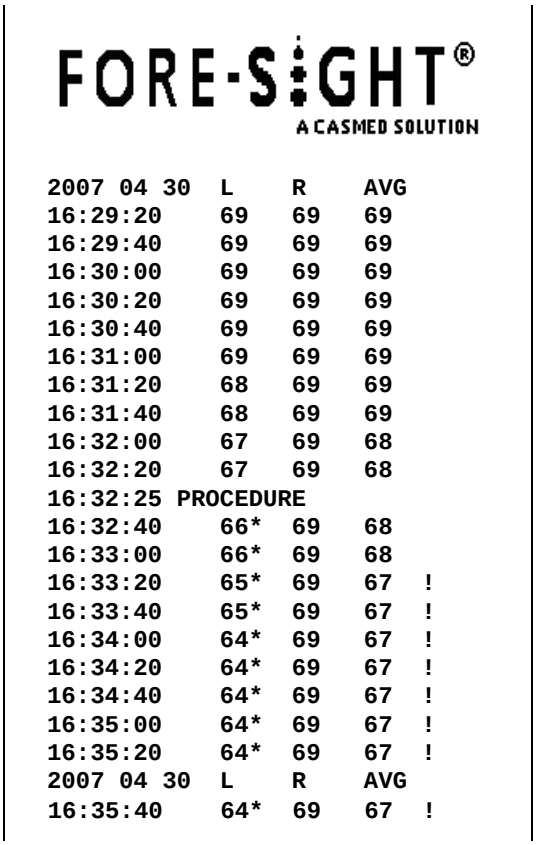
Refer to page 98 for explanations of the Printer Icon displayed in the upper right corner of the Main screen.

Continuous Tabular Print

When the **Continuous Tabular Print** selection is enabled, the monitor will continuously transmit Left, Right and Average %$SctO_2$ values every 20 seconds along with a timestamp (Hour:Minute:Second).

A header, consisting of the date and column identifiers, is printed at the start of data and periodically every 20 lines. A sample printout of real time numerics is shown below (see Figure 49, page 84).

Note: Each time the Monitor is turned on and the Printer is connected and on, the following FORE-SIGHT logo is printed automatically on the paper.


FORE-SIGHT®
A CASMED SOLUTION

2007 04 30	L	R	AVG	
16:29:20	69	69	69	
16:29:40	69	69	69	
16:30:00	69	69	69	
16:30:20	69	69	69	
16:30:40	69	69	69	
16:31:00	69	69	69	
16:31:20	68	69	69	
16:31:40	68	69	69	
16:32:00	67	69	68	
16:32:20	67	69	68	
16:32:25 PROCEDURE				
16:32:40	66*	69	68	
16:33:00	66*	69	68	
16:33:20	65*	69	67	!
16:33:40	65*	69	67	!
16:34:00	64*	69	67	!
16:34:20	64*	69	67	!
16:34:40	64*	69	67	!
16:35:00	64*	69	67	!
16:35:20	64*	69	67	!
2007 04 30	L	R	AVG	
16:35:40	64*	69	67	!

Figure 49: Tabular Print Example

Note: An asterisk (*) after the L(eft) or R(ight) value indicates an alarm condition (High/Low limit violation) has occurred. An exclamation mark (!) after the AVG(Average) value indicates the differential alarm condition has occurred.

Note: Event entries are indicated at the time they are entered.

Tabular Print

When the Continuous Tabular Print selection is disabled, the user must initiate the printing.

To print the tabular data associated with information displayed on the screen, Select Tabular Print type, Screen Print length, and then select PRINT (see Figure 50, page 85).

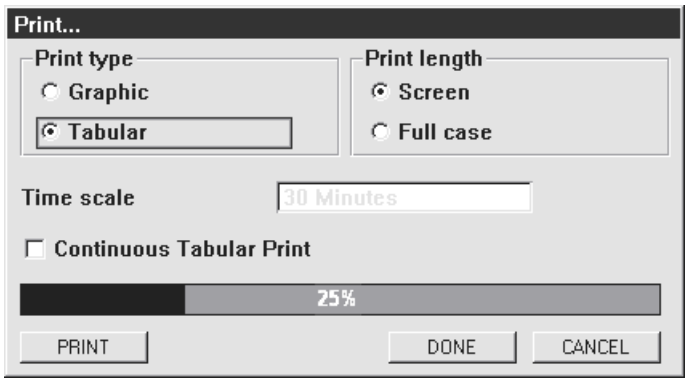


Figure 50: Tabular Screen Print dialog

To print all the tabular data associated with this patient, select Tabular Print type, Full case Print length and then select PRINT as shown in Figure 51 below.

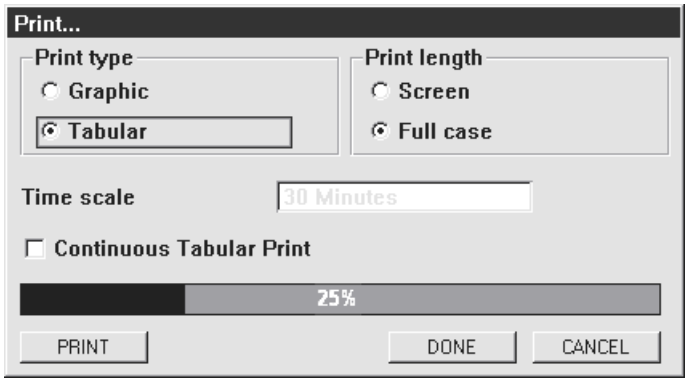


Figure 51: Tabular Full Case Print dialog

Caution: Attempting to print a Full Case longer than 24 hours in tabular mode will require more than 1 roll of 80' thermal paper.

The progress bar will indicate the amount of data printed as a percentage and a solid bar shall fill in from the left.

Note: Once printing has started the user may exit this dialog at any time and the printing will continue.

Note: To cancel the printing, select CANCEL or navigate to the Patient > Print menu and then select CANCEL to stop the printing.

Note: The Time scale selection is not available when Tabular print is selected.

Graphic Print

The user may initiate Graphic printing by navigating to the Patient > Print menu.

To print the graphic data associated with information displayed on the screen, Select Graphic Print type, Screen Print length, and then select PRINT (see Figure 52, page 86).

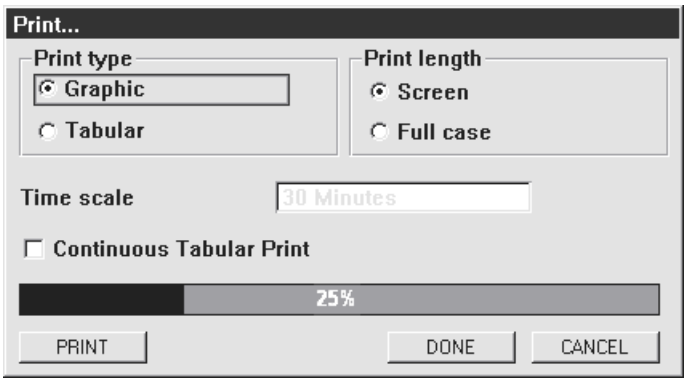


Figure 52: Graphic Screen Print dialog

Note: The Time scale selection is not available when Graph–c - Screen print is selected.

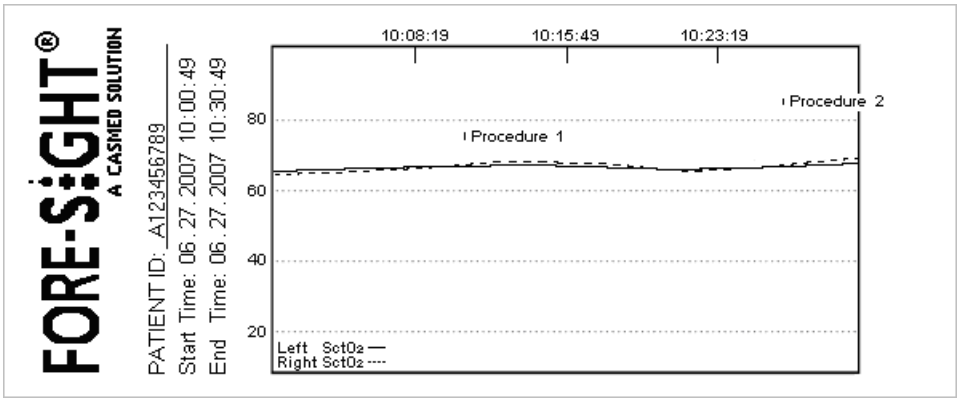


Figure 53: Graphic Screen Print Example

Note: Event text is printed on the paper as it appears on the screen.

Note: If the Event text is too long, the printing of the text continues past the edge of the halted trace printing as shown in Figure 53 above.

To print **all** the graphic data associated with this patient, select Graphic Print type, Full case Print length and then select PRINT as shown in Figure 54 below.

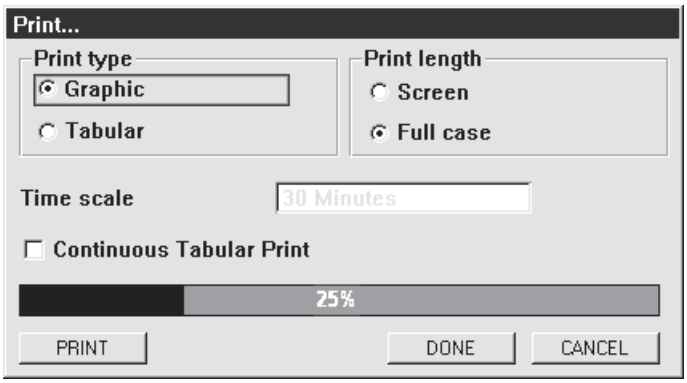


Figure 54: Graphic Full Case Print dialog

Note: If a graphic Full Case print is selected, the Time scale selections are valid and the user is allowed to print the Full Case in a time scale different than the current screen time scale (see Figure 54 above).

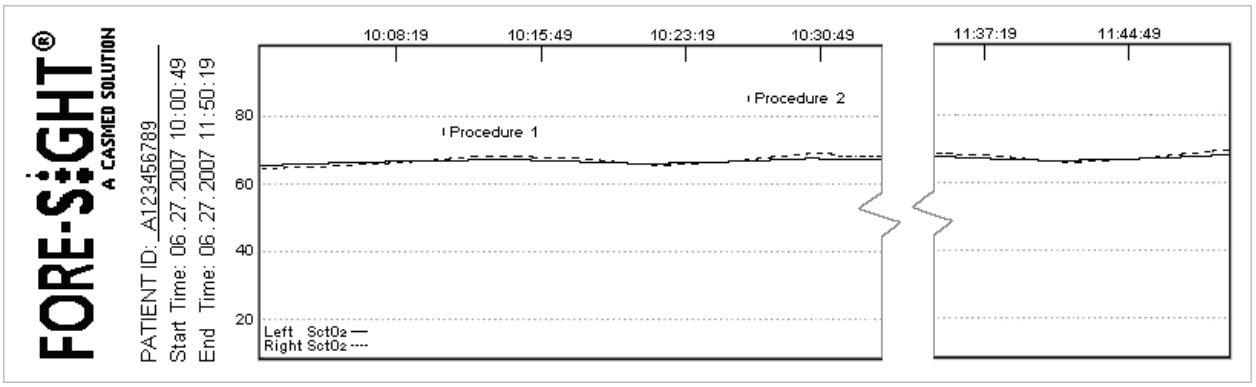


Figure 55: Graphic Full Case Print Example

The progress bar will indicate the amount of data printed as a percentage and a solid bar shall fill in from the left.

Note: Once printing has started the user may exit this dialog at any time and the printing will continue.

Note: To cancel the printing, select CANCEL or navigate to the Patient > Print menu and then select CANCEL to stop the printing.

Charging the Printer Battery

The Printer is equipped with a rechargeable Lithium Ion (LiION) battery pack. When the Printer detects a Low Battery condition, the message “Low Battery” is printed and an audio indicator sounds three times.

Warning: Charge the Printer battery using the AC Adapter, Model TRC-09-1100-M from GROUP WEST, or equivalent, included with the Printer.

- Plug the battery charger’s cord into the Printer battery charger jack, located on the rear panel.
- Plug the charger into an AC wall outlet of the appropriate voltage.
- Verify the Charge LED is lit red.

- Charge the battery a room temperature (5-35°C / 41-95°F)

Battery charge time is approximately 3 hours. Once the battery is fully charged, the Charge LED switches to green.

Caution: After completion of battery charging, Do Not try recharging. Battery performance may be deteriorated

Installing Paper

Note: A red line appears when the remaining supply of thermal paper becomes low.

- Switch the Printer off.
- Press the Cover Open button to access the paper compartment. Remove any remaining paper before installing the new roll.
- Place the new paper roll as shown on the illustration and pull out enough paper to reach out over the control panel of the Printer (see Figure 56, page 88).
- Close the paper door.

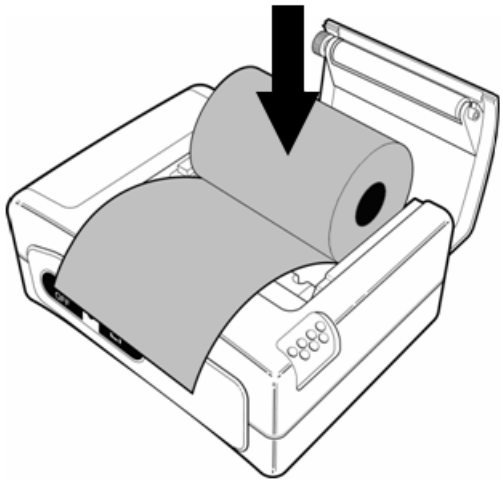


Figure 56: Paper Installation

Note: Make sure that the paper is correctly placed. If it is tilted in one or another direction and does not come out straight from under the cover, open the door and reposition the roll again.

Warning: Do not touch the print head or paper cutter while replacing the Printer paper.

Removing the Battery Pack

Warning: Do not operate the Printer or connect it to the Monitor with the battery pack is removed.

Warning: Never change the battery pack while the battery charger is plugged in and/or the Monitor is being operated.

- Switch the Printer off.

- Disconnect the Printer from the Monitor and unplug the wall charger cord.
- Open the battery door by pressing in on the battery cover and pushing upward as shown in Figure 57 below.

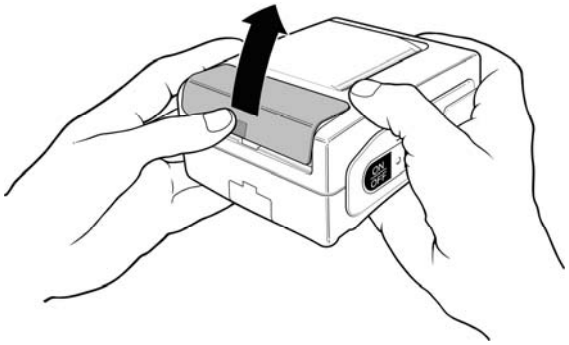


Figure 57: Opening the Battery Door

- Remove the battery cover.
- Remove the battery pack from the compartment and disconnect its connecting cable.

Installing the new Battery Pack:

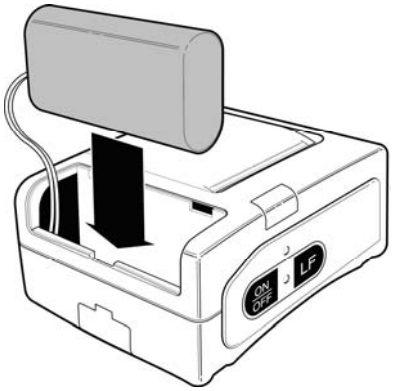


Figure 58: Installing the New Battery

- Connect the battery cable into the battery connector.
- Insert the battery and its connecting cable into the battery compartment as shown in Figure 58 above.
- Replace the battery cover by sliding it in from the back of the Printer and pushing down to lock it in place.

Warning: Do not disassemble the battery pack or batteries. The batteries contain electrolytes, which can cause injury to eyes, skin and clothing.

Caution: Be sure to place the battery cover firmly in its position after installing the new battery pack.

Note: Under various state and local laws, it may be illegal to dispose of this battery into the municipal waste stream. Check with your local authorities for instructions on recycling options in your area.

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Cleaning

Warning: Do not, under any circumstances, perform any cleaning while the monitor is being used to monitor a patient. The monitor must be turned off. Unplug the monitor from the AC power source and disconnect all accessories.

Caution: Do not open the monitor to clean it.

Caution: Do not immerse any part of the electrical connector of the cable or accessories in the cleaning or disinfection solution at any time. This may cause internal damage and reduce the product life.

Caution: Do not use abrasive cleaners, isopropyl alcohol or organic solvent for cleaning. Use of these cleaners can cause damage, stiffness and brittleness to the monitors' surface and to cables and wires.

Cleaning the Monitor

Caution: Disconnect all accessories from the monitor before cleaning.

Examine the monitor's case for damage and check the AC power cord for bent or broken prongs, cracks or fraying. Neither the monitor nor the power cord should be used if damaged. If any damage is noted, contact the appropriate service personnel.

Caution: Do not spray or pour any water or cleaning solution directly onto the monitor.

- **Housing:** The monitor surfaces may be disinfected using a soft cloth dampened with a 10% (1:10) solution of chlorine bleach in tap water. When all of the surfaces have been disinfected, wipe the entire surface of the monitor using a soft cloth dampened with fresh water to remove any trace amounts of residue and/or fumes.
- **Display:** Clean the display window using a soft, lint-free cloth sprayed with an alcohol free glass cleaner. The use of paper towels is not recommended as it may scratch the surface.

Note: Thoroughly wipe off any excess cleaning solutions. Care should be taken to prevent water or cleaning solution to run into connector openings or crevices.

Cleaning Monitor Cables

Note: Cables contain fiber optic elements. Care should be taken to avoid kinking or bending cables during cleaning

Prior to each patient use, inspect the Monitor Cable for damage. Using the male fiber optic cleaning stick (provide in the Biomedical & Abbreviated Biomedical Kits) clean the fiber optic connections in each monitor cable. (The fiber optic connection is surrounded by green plastic)

Clean the Monitor Cable using a soft cloth dampened with a 10% (1:10) solution of chlorine bleach in tap water. Do not use alcohol.

Caution: If the Monitor Cable should become grossly contaminated with blood or other bodily fluids, it should be discarded.

Note: Do not soak or submerse the Monitor Cable in any liquid solution. Liquid should not be permitted to enter the ends of the Monitor Cable because instrument damage may occur. Monitor Cable should be allowed to thoroughly dry before use.

Cleaning Patient Cables

Using the female fiber optic cleaning stick (provide in the Biomedical & Abbreviated Biomedical Kits) clean the fiber optic connections on the patient cables.

Caution: The Patient Cable is designed for single patient use, and is not to be reprocessed.

Caution: Do not soak or immerse the patient cable and sensor in any liquid solution. Do not attempt to sterilize it.

Cleaning the Printer

Refer to the Printer User's Manual for more information.

Caution: Before cleaning the Printer, disconnect the AC adapter.

- Wipe with a soft dry cloth.

To remove extreme dirt buildup:

- Soak a cloth with mild detergent, wring well and wipe. Dry by wiping with a soft dry cloth.

Caution: Do not use volatile chemicals such as thinner, benzene, etc.

Caution: Never wet the inside of the Printer mechanism.

Maintenance

Warning: Do not, under any circumstances, perform any testing or maintenance on the monitor while the monitor is being used to monitor a patient. The monitor must be turned off. Unplug the monitor from the AC power source.

Warning: Do not lift the monitor by any cable or line as they could disconnect from the monitor, causing the monitor to fall on the patient.

Warning: *Conductive Connections* – Extreme care must be exercised when applying medical electrical equipment. Many parts of the human–machine circuit are conductive, such as the patient, connectors, electrodes, and transducers. It is very important that these conductive parts do not come into contact with other grounded, conductive parts when connected to the isolated patient input of the device. Such contact would bridge the patient's isolation and cancel the protection provided by the isolated input. In particular, there must be no contact of the neutral electrode and ground.

Caution: Service performed by unauthorized personnel could be damaging to the monitor and may void the warranty. Internal Batteries are intended to be replaced by authorized personnel only. For service, contact your CAS Representative.

Caution: Inspect the cables and sensors for damage prior to operation. If any damage is noted, the cables or sensor should not be used until it has been serviced or replaced.

Caution: Do not kink or bend cables.

Maintenance Intervals

Preventive maintenance of the monitor is an important function that should be performed routinely to ensure safe and efficient monitor operation. The following maintenance intervals are recommended:

- **Monitor:** No user calibration is required.
- **Batteries:** Should be replaced every 2 years.

Note: To maintain proper battery charge, plug the FORE-SIGHT cerebral oximeter into mains power when not in use. Failure to do so may diminish the service life and function of the battery.

Note: Monitor cables should be replaced annually or when no longer properly functioning. Keep track of cable installation date and usage. See Accessories on page 107 for reorder information.

Fuse Replacement

The FORE-SIGHT MC-2000 Series monitor has a dual fuse AC power input receptacle. Both AC lines are fused.

The FORE-SIGHT MC-2000 Series monitor has a single fuse DC receptacle for the internal batteries.

Caution: The Battery fuse must be installed for the unit to operate with the internal batteries. If the unit is not to be used for periods greater than 1 week, the battery should be disconnected (see Disconnecting the Battery on page 95).

Caution: For continued protection against fire hazard, replace only with identically rated fuses (see Power Section, page 105).

A fuse may need to be replaced if the monitor is plugged into an electrical outlet but the Battery Power Visual Indicator is not illuminated green.

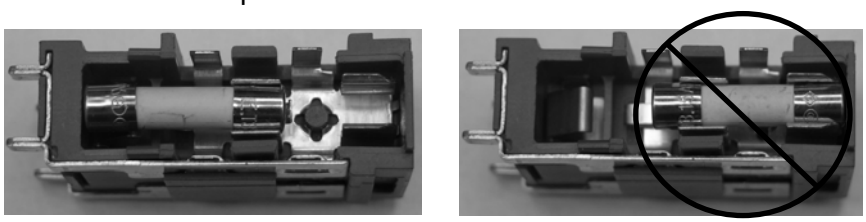
Warning: Before changing any fuse, unplug the power cord.

Note: The FORE-SIGHT MC-2000 Series monitor models have multiple fuses located inside the monitor. These fuses are not user replaceable.

AC Power Fuse

To replace the AC Power fuses, proceed as follows:

- Turn the monitor off and disconnect the power cord.
- Using a small screw driver, open the fuse cover on the AC Fuse Compartment (see Figure 3, page 25)
- Using a small screw driver, pull out the red fuse holder from the AC Fuse compartment.
- Remove the suspect fuse.
- Place the new fuse into the fuse holder as indicated by the orientation in Figure 59 below.
- Repeat this process for the fuse on the other side of holder.
- Insert the fuse holder back into the power input receptacle (the fuse holder can be inserted in either orientation).
- Close the fuse cover on the AC Fuse Compartment.
- There should be an audible click when it is secured.
- Reconnect the power cord back to the monitor.



Correct Placement Incorrect Placement

Figure 59: AC Fuse Placement

Battery Maintenance

The FORE-SIGHT MC-2000 Series monitors are available in two possible back-up battery configurations:

Small battery version (models MC-2000 and MC-2020)

- The small battery version provides sufficient power to allow for a controlled shut down of the monitor while also saving the patient case data, in the event of an interruption of AC power.

Large battery version (models MC-2010 and MC-2030):

- The large battery version provides power to operate the monitor for up to 1½ hours (on a new, fully charged battery). To properly maintain the battery charge level and prolong battery life, the **monitor should be connected to AC power at all times**. As with all batteries, the capacity will diminish over time. It is recommended that properly maintained batteries be replaced by CAS service every 2 years. If the large battery version will not operate for more than 20 minutes on battery power prior to the 2 year replacement interval, then the monitor should be returned to CAS for service and battery replacement.

Disconnecting the Battery

Note: Some units maybe equipped with an automatic Battery Cut-Off circuit that will disconnect the battery when they are not being charged. Please contact our Customer Service department to determine if your unit has this feature.

If this feature is installed and the monitor will not be used for more than 1 week, follow the procedure below to store the unit:

- Charge the unit overnight (16 hr min) prior to storage.
- Using a screwdriver, gently press in and turn the locking tab counterclockwise to release (see Figure 60a on page 96).
- Gently slide the fuse holder tray out of the receptacle as far as it will go - **Do not remove the fuse**.
- Gently slide the fuse holder tray back into the receptacle.
- Using a screwdriver, gently press in and turn the locking tab clockwise to secure (see Figure 60a on page 96).

This action will disconnect the battery and prolong the life of the battery while the unit is being stored.

If this feature is **NOT** installed and the monitor will not be used for more than 1 week, follow the procedure below to store the unit:

- Charge the unit overnight (16 hr min) prior to storage.
- Using a screwdriver, gently press in and turn the locking tab counterclockwise to release (see Figure 60a on page 96).
- Gently slide the fuse holder tray out of the receptacle as far as it will go.
- Remove the fuse completely from the fuse holder tray (see Figure 60b on page 96).

- Gently slide the fuse holder tray back into the receptacle.
- Using a screwdriver, gently press in and turn the locking tab clockwise to secure (see Figure 60a below).
- After storage, repeat the above instructions in reverse, inserting the fuse back into the monitor.

Note: To operate the unit, AC power must be applied.

Battery Power Fuse

To replace the Battery fuse, proceed as follows:

- Turn the monitor off and disconnect the power cord.
- Locate the Battery Fuse on the rear panel (see Figure 3 page 25).
- Using a screwdriver, gently press in and turn the locking tab counterclockwise to release (see Figure 60a below).
- Gently slide the fuse holder tray out of the receptacle as far as it will go.

Note: The fuse holder tray is designed **not** to be removed from the fuse holder. Do not attempt to pull the fuse holder tray out of the fuse holder or permanent damage to the fuse holder may occur.

- Remove the fuse completely from the fuse holder tray (see Figure 60b below.
- Place a new fuse directly into the fuse holder tray (see Figure 60c below).
- Rotate and align the fuse holder tray so that the fuse lies on top of the fuse holder.
- Gently slide the fuse holder tray back into the receptacle.
- Using a screwdriver, gently press in and turn the locking tab clockwise to secure (see Figure 60a below).
- Reconnect the power cord back to the monitor.

Caution: For continued protection against fire hazard, replace only with identically rated fuses (see Power section, page 105).

Note: Do not apply excessive force when removing or installing the fuse holder tray into the receptacle.

Note: When the battery fuse is re-installed, the monitor may automatically turn “ON”.

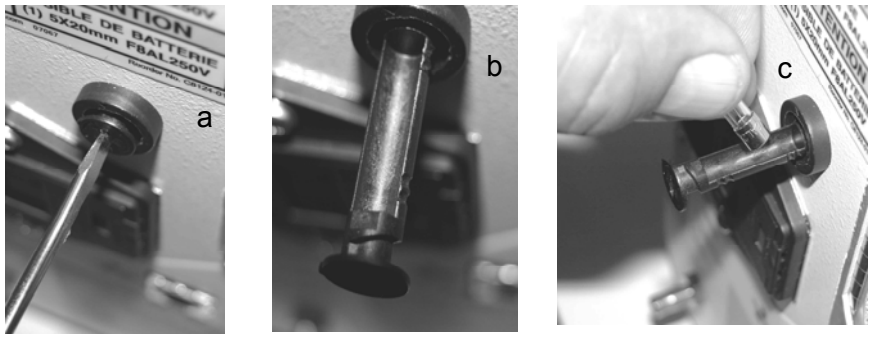


Figure 60: Battery Fuse Placement

Appendix

Symbols

The following is a summary of all symbols used on the monitor and accessories. Symbols may occur on the product or on its packaging.

Front Panel Symbols


Power Indicator


Battery Indicator (Model MC-2010 & 2030 only)


Power (On/Standby)


Alarms (Silence/Reset)


Left/Right/Average


Sensor Start/Restart

Screen Indicators


Alarm turned off (yellow)


Alarm paused (yellow)


High Priority Alarm activated (flashing red)


Medium Priority Alarm activated (flashing yellow)


Laser active indicator (drop from the top down)


Auto numeric toggle selected – left and right numeric values alternate automatically every few seconds.


Large Sensor connected to unit


Medium Sensor connected to unit


Small Sensor connected to unit

FS DATA

White FS DATA – FS Data **not** being collected

Green FS DATA – FS Data being collected

> 10 Yrs – 18 yrs / > 60 kg

Current Patient Age and Weight selection (example) - If Patient's Age or Weight is **NOT** selected, the Age or Weight text will indicate "**Unspecified**" and the Lasers cannot be turned on.

Historical

Monitor's trace display represents Historical information.


Printer w/White paper – Printer is available for printing

Printer w/Green paper – Printer is currently printing

Printer w/Yellow paper – The printer is either out of paper or the cover is open. Add paper or close cover to resolve this problem

Printer w/Red paper – Cannot communicate with printer. Check printer cable and power


White USB memory stick – USB memory connected to monitor

Green USB memory stick – Currently saving data to USB memory

Red USB memory stick – USB memory stick error


Snapshot to USB enabled – Press Alarm Silence / Reset key to save screen image to USB Memory stick


Battery Charge Level Indicator (Model MC-2010 & 2030 only)

Symbols near Accessory Connections


Patient connections are Type BF


Communication port RS-232 Connector

Symbols on Monitor


CAUTION, read instructions before using


Potential equalization post


This symbol appears here instead of on the unit.
The first two digits of the unit's serial number indicate the year of manufacture in the 21st century

IPX1 Protection against ingress of water.

CE 0086 The CE Mark and Notified Body Registration Number signify the device has met all essential requirements of European Medical Device Directive 93/42/EEC.


Indicates this monitor is subject to the Waste Electrical and Electronic Equipment Directive in the European Union.


Alternating current


Recycling suggested

Symbols on Packaging

Lot number


Relative humidity for storage and transport


Do not reuse

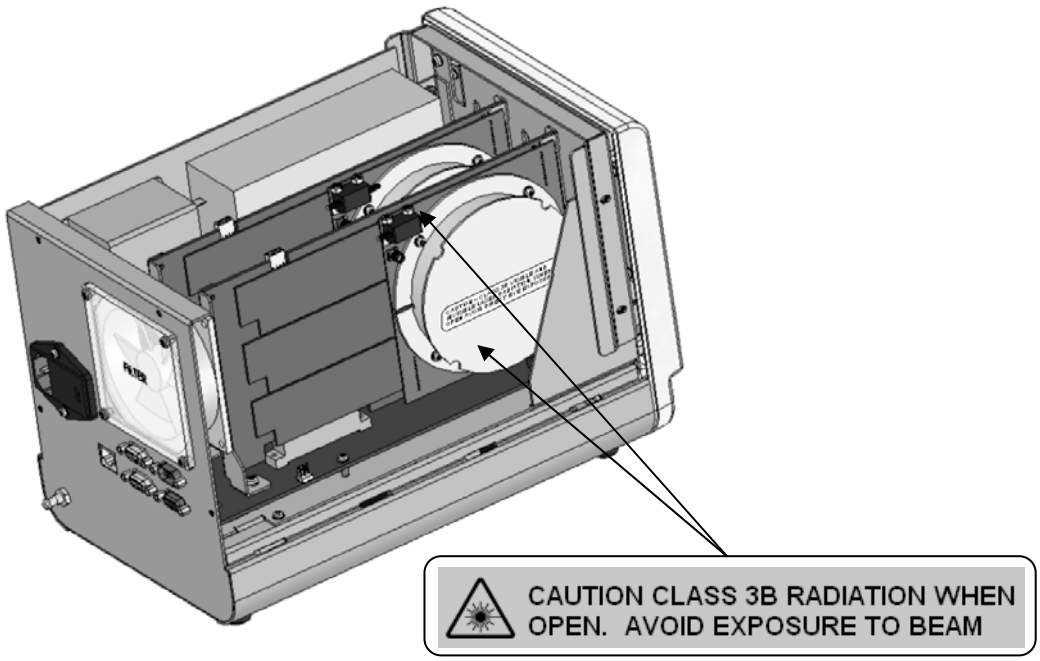

Storage and transport temperatures


Do not Discard – Intended for multiple use

Location of Laser Labels

Figure 61 below shows the location of the laser labels located inside the monitor.

Caution: Service performed by unauthorized personnel could be damaging to the monitor and may void the warranty. Only personnel authorized to do so by CAS Medical Systems, Inc., should repair the monitor



Labels are located on each NSAM Board

Figure 61: Location of Internal Laser Labels

Note: CLASS 1 LASER PRODUCT
This product is designated for use solely as a component of the Model MC 2000 Series Monitor and therefore does not comply with the appropriate requirements of 21 CFR part 1040.10 for complete laser products.

This product complies with IEC 60825-1:2001

Warranty Policy

Monitors (FORE-SIGHT Cerebral Oximeter)

All products are sold by CAS Medical Systems, Inc. (CASMED™), under the warranties set forth in the following paragraphs. Such warranties are extended only with respect to the purchase of this product directly from CAS Medical Systems, Inc., or CASMED's Authorized Distributors as new merchandise and are extended to the first buyer thereof, other than for resale.

The CASMED FORE-SIGHT™ Cerebral Oximeter monitor is warranted for a period of twelve (12) months. All products, if applicable, are warranted to be free from functional defects in materials and workmanship and to conform to the description of the product contained in the User Guide, published specifications, and accompanying labels and/or inserts, provided that the same is properly operated under conditions of normal use in accordance with applicable safety and regulatory requirements, and that replacements and repairs are made in accordance with the instructions provided by CAS Medical Systems, Inc.

The same warranty conditions are made for a period of twelve (12) months with respect to the battery. A ninety (90) days warranty is provided for non-disposable accessories such as reusable monitor cables and other accessories provided by CASMED as part of the original purchase. CASMED warrants disposable or single-patient-use products, including $SctO_2$ sensors for out-of-box failure only. Where the accessory is not a CAS Medical Systems, Inc., manufactured product, the manufacturer's own warranty applies. Warranty of accessories purchased separately from listed suppliers will be the responsibility of such listed suppliers. Damage to any part through misuse, neglect, or accident, or by affixing any accessories or attachments other than CASMED manufactured accessories or attachments, is not covered by this warranty.

The foregoing warranties shall not apply if the product has been configured, modified, adjusted or repaired other than by CAS Medical Systems, Inc., or by persons expressly authorized by CAS Medical Systems, Inc., or not in accordance with written instructions provided by CAS Medical Systems, Inc., or if the product has been subjected to misuse, negligence, or accident.

CASMED reserves the right to perform warranty service operations in its own factory, at an authorized repair facility, or at the customers' site. The sole and exclusive obligation of CAS Medical Systems, Inc., and Buyer's sole and exclusive remedy under the above warranties, is limited to repairing or replacing, free of charge, a product which is reported in writing or via telephone to CAS Medical Systems, Inc., has a Return Material Authorization (RMA) number assigned and which is returned during normal business hours, transporting charges prepaid to:

CAS Medical Systems, Inc.
44 East Industrial Road
Branford, CT 06405 USA

Telephone: +1 203 488 6056
Fax: +1 203 488 9438
E-mail: custsrv@casmed.com

CAS MEDICAL SYSTEMS, INC. SHALL NOT BE OTHERWISE LIABLE FOR ANY DAMAGES INCLUDING, BUT NOT LIMITED TO, INCIDENTAL DAMAGES, CONSEQUENTIAL DAMAGES OR SPECIAL DAMAGES.

THERE ARE NO EXPRESS OR IMPLIED WARRANTIES WHICH EXTEND BEYOND THE WARRANTIES HEREINABOVE SET FORTH. CAS MEDICAL SYSTEMS, INC. MAKES NO WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO THE PRODUCT OR PARTS THEREOF.

Monitor Configurations

FORE-SIGHT MC-2000 Series Monitor Models

Table 4: FORE-SIGHT MC-2000 Series Monitor Models

CAS MC-2000	Dual Channel Cerebral Oximeter
CAS MC-2010	Dual Channel Cerebral Oximeter with internal batteries option
CAS MC-2020	Dual Channel Universal Cerebral Oximeter
CAS MC-2030	Dual Channel Universal Cerebral Oximeter with internal batteries option

Monitor Configuration Record

Monitor Model

CAS MC - 20_____

Serial Number: _____

Installed Options

- ❑ Batteries

Specifications

$SctO_2$ Measurement

Method:	Modified Beer-Lambert Law Near Infrared Spectroscopy (NIRS)
Information output:	Absolute cerebral tissue oxygenation saturation ($SctO_2$)
Measurement range:	0 to 100%
Accuracy:	40–100%: ± 4% to 1 standard deviation 0–39%: unspecified
Display resolution:	1%
Data rates:	Acquisition ≤ 100 Hz, numeric display = .5 Hz

Laser Information

EQUIPMENT MANUFACTURE INFORMATION (DATA SHEET) ABOUT THE COMPONENT CONTAINING LASER	
Type designation	BM4-690-779-808-850-10SM 4-Color Beam Combiner with Power Monitor
Max Output Power	20 mW
Pulse time	3.1 ms

Patient Alarms

Adjustable alarms:	High and low alarms for left, right and differential $SctO_2$
Alarm indicators:	• Left & Right Visual • Audible • Text in alarm message window
Audible sound pressure 100% Volume	High Priority Alarms: 58db (Fast A) @ 1m directly in front of monitor Medium Priority Alarms: <54db (Fast A) @ 1m directly in front of monitor

Patient Parameter	***Low***	***High***
Left $SctO_2$	2 to 93%	7 to98%
Right $SctO_2$	2 to 93%	7 to98%
Differential $SctO_2$	N/A	1 to 50%

Each patient parameter may also be selected “OFF” individually.

Low limits cannot be set above the associated high limit.

High limits cannot be set lower than the associated low limit.

There is a minimum of 5% difference between the Low and High limit values at any time.

Display

Display:	LCD display of measurement results, instructions, troubleshooting messages, waveforms, and signal strength bar.
Numerics:	$SctO_2$ (from left, right or average of left and right channels)
Trace:	1 corresponding to associated $SctO_2$ numeric value
Views:	15 or 30 min, 1, 2, 3, 4, 8 or 24 hr
Events:	May be placed anywhere on trace area.

Physical Dimensions and Weight

H × W × D: (without feet)	8 in. × 8 in. × 13 in. 20.3 cm × 20.3 cm × 33.0 cm
Weight (MC-2000 or 2020):	16.0 lbs (7.3 kg)
Weight (MC-2010 or 2030):	21.9 lbs (9.9 kg)

Operating Environment

Operating temperature:	10–40°C (50–104°F)
Humidity:	30–75% RH, non-condensing
Altitude:	10,000 to –1,000 ft (680 to 1060 hPa)

Monitors may not meet performance specifications if stored or used outside temperature and humidity ranges. When moving the monitor from a storage location, wait at least one hour prior to use to allow the monitor to adjust to room temperature.

Storage/Transport Environment

Storage/transport temperature:	–20 to 60°C (–4°F to 149°F)
Humidity:	15–95% RH, non-condensing
Altitude:	10,000 to –1,000 ft (680 to 1060 hPa)

Power

External power:

AC: 100–240 VAC, 50/60 Hz, 1.5A
Fuse rating: T3.15AH250V (two provided)

Chassis leakage current: 100 µA (maximum)

Model MC-2010 or 2030

Battery: 2 sealed lead-acid batteries
Fuse rating: F8AL250V (one provided)

Charge Time: 16 hours (with unit on)

Operating Time: 1½ hr (minimum)

Serial Interface

Interface type:	Bi-directional serial communication
Speed:	User-programmable
Signal level:	RS-232C
Data length:	8 bits
Start bit:	1 bit
Stop bit:	1 bit
Parity:	None
Flow control:	None

Standards

Units comply with the following requirements:

CE marking according to Directive 93/42/EEC
IEC 60601-1, EN 60601-1-2
IEC 60601-1-1, IEC 60601-1-4, IEC 60601-1-8
UL classified: UL 60601-1, CAN/CSA C22.2 No. 601.1-M90
IEC 60825-1

All units covered by U.S. patents 6,456,862; 7,047,054; 7,072,701. Other patents pending.

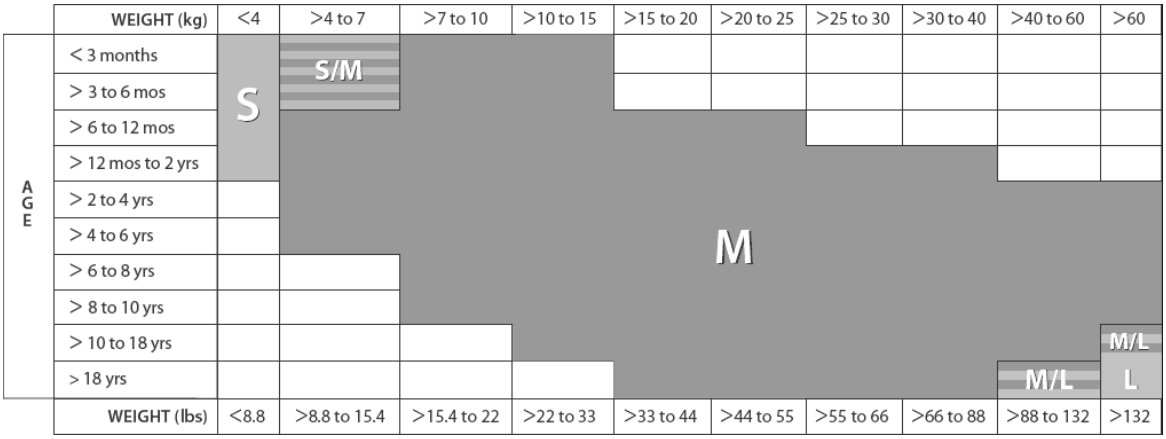
Accessories

Contact our Customer Service department or see our website for the latest product information. Refer to Contact Addresses on page 3 for e-mail and phone number information.

Monitor

Catalog No.	Description
01-06-2000	**FORE-SIGHT** MC-2000 Cerebral Oximeter
Provided With:	(2) **FORE-SIGHT** Universal Monitor Cable with Pre-amp (1) **FORE-SIGHT** Abbreviated Biomedical Kit (1) **FORE-SIGHT** Laminated Intervention Card w/Velcro dots (1) **FORE-SIGHT** CD User Manual (1) **FORE-SIGHT** Quick Start Guide (1) Hospital Grade AC Power Line (1) Cable Bundler (1) Service Card & Sleeve
01-06-2010	**FORE-SIGHT** MC-2010 Cerebral Oximeter with Backup Battery
Provided With:	(2) **FORE-SIGHT** Universal Monitor Cable with Pre-amp (1) **FORE-SIGHT** Abbreviated Biomedical Kit (1) **FORE-SIGHT** Laminated Intervention Card w/Velcro dots (1) **FORE-SIGHT** CD User Manual (1) **FORE-SIGHT** Quick Start Guide (1) Hospital Grade AC Power Line (1) Cable Bundler (1) Service Card & Sleeve
01-06-2020	**FORE-SIGHT** MC-2020 Universal Cerebral Oximeter
Provided With:	(2) **FORE-SIGHT** Universal Monitor Cable with Pre-amp (1) **FORE-SIGHT** Abbreviated Biomedical Kit (1) **FORE-SIGHT** Laminated Intervention Card w/Velcro dots (1) **FORE-SIGHT** CD User Manual (1) **FORE-SIGHT** Quick Start Guide (1) Hospital Grade AC Power Line (1) Cable Bundler (1) Service Card & Sleeve
01-06-2030	**FORE-SIGHT** MC-2030 Universal Cerebral Oximeter with Backup Battery
Provided With:	(2) **FORE-SIGHT** Universal Monitor Cable with Pre-amp (1) **FORE-SIGHT** Abbreviated Biomedical Kit (1) **FORE-SIGHT** Laminated Intervention Card w/Velcro dots (1) **FORE-SIGHT** CD User Manual (1) **FORE-SIGHT** Quick Start Guide (1) Hospital Grade AC Power Line (1) Cable Bundler (1) Service Card & Sleeve

FORE-SIGHT Sensor Selection Guide



Re-order No:

Catalog No.	Description
01-06-0005	**FORE-SIGHT** Universal Monitor Cable with Pre-amp
01-07-2000	**FORE-SIGHT** Single Non-Adhesive Sensor Kit (Small) 10 kits/Carton
01-07-2002	**FORE-SIGHT** Single Sensor Kit (Small) 10 kits/carton
01-07-2003	**FORE-SIGHT** Dual Sensor Kit (Small) 10 kits/carton
01-07-2004	**FORE-SIGHT** Single Sensor Kit (Medium) 10 kits/Carton
01-07-2005	**FORE-SIGHT** Dual Sensor Kit (Medium) 10 kits/Carton
01-07-2006	**FORE-SIGHT** Single Sensor Kit (Large) 10 kits/carton
01-07-2007	**FORE-SIGHT** Dual Sensor Kit (Large) 10 kits/carton
01-07-3001	**FORE-SIGHT** Light-Blocker ambient light block, for use with Non-Adhesive Sensor (Small), 10/Bag
01-07-3002	**FORE-SIGHT** Headband, for use with Sensors, 10/Bag
01-07-3003	**FORE-SIGHT** HOLD-TIGHT™ Hydrogel fixing strip, for use with Non-Adhesive Sensors (Small), 20/Bag
01-06-0035	**FORE-SIGHT** Abbreviated Biomedical Fiber optic Cleaning Kit (10 Male Orange Fiber Optic Cleaning Tips, 10 Male Clear Fiber Optic Cleaning Tips, 10 Female Fiber Optic Cleaning Tips, and 1 can Fiber Connector Cleaner)
01-06-0036	**FORE-SIGHT** User Manual CD, Multi-Language
21-03-0294	**FORE-SIGHT** Quick Start Guide
21-05-0173	**FORE-SIGHT** Laminated Common Intervention Card

- All Sensor Kits include (1) Light-Blocker and one or two sensors, depending on kit.
- Medium and Large Sensor Kits also include (1) Alcohol prep
- Non-Adhesive Sensor Kit also includes (1) Headband and (1) HOLD-TIGHT

Other Accessories and Options

Catalog No.	Description
01-02-0395	Replacement Power Cord, North America
01-02-0384	Replacement Power Cord, U.K.
01-02-0385	Replacement Power Cord, Australian
01-02-0386	Replacement Power Cord, European
01-06-0031	**FORE-SIGHT** $SctO_2$ Simulator
01-06-0032	**FORE-SIGHT** Biomedical Fiber optic Cleaning Kit (40 Male Orange Fiber Optic Cleaning Tips, 40 Male Clear Fiber Optic Cleaning Tips, 40 Female Fiber Optic Cleaning Tips, and 1 can Fiber Connector Cleaner)
01-06-0034	**FORE-SIGHT** USB Memory Drive
01-06-0231	Giraffe Dovetail Attachment
01-06-0232	3 inch Utility Basket for 01-06-0234, 01-06-0235 or 01-06-0236 Arms
01-06-0233	6 inch Utility Basket for 01-06-0234, 01-06-0235 or 01-06-0236 Arms
01-06-0234	**FORE-SIGHT** 16 inch Arm Wall Mount (requires 01-06-0237 Adapter Plate)
01-06-0235	**FORE-SIGHT** 8 inch Arm Giraffe Bed Mount (requires 01-06-0231 Giraffe Dovetail Attachment and 01-06-0237 Adapter Plate)
01-06-0236	**FORE-SIGHT** 16 inch Arm Pole Mount (requires 01-06-0237 Adapter Plate)
01-06-0237	**FORE-SIGHT** Adapter Plate
01-06-0238	**FORE-SIGHT** Roll Stand, with basket & Handle (requires 01-06-0237 Adapter Plate)
01-02-0189	Citizen CMP-10 Mobile Printer
01-02-0188	Printer Battery
01-02-0481	Printer Paper 10/Cs
01-02-0266	Adapter for Printer Europe
01-02-0267	Adapter for Printer UK
01-02-0268	Adapter for Printer Australia
25-01-0124	**FORE-SIGHT** Cable Bundler

Philips IntelliVue/VueLink Accessories and Options

Description - Purchased directly from Philips

Philips VueLink Module AUXPLUS PN: M1032A #A05
Philips Interface Cable PN: M1032A #K6C, M1032-61699

Note: Philips contact information:
www.medicalphilips.com
medical@philips.com

Catalog No.	Description
01-06-2133	FORE-SIGHT VueLink Extension Cable

Notes: