CASMED®
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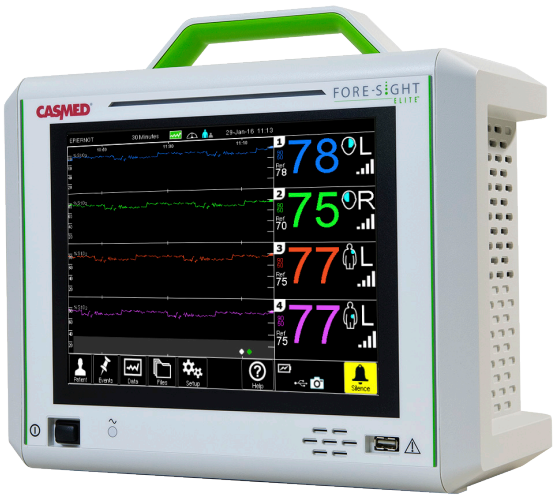


FORE-SIGHT ELITE®
Absolute Tissue Oximetry

*The confidence of knowing™*

# User Manual

This User Manual describes the features and operations of the FORE-SIGHT ELITE Tissue Oximeter: Software Version 3.0 or above.

PN 21-22-3000 Rev 07

## Trademarks

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CASMED devices are patent-protected in the United States; see www.casmed.com/site-info/patents.cfm for more information.

## Revision History

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

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

## Manufacturers Declaration of Conformity — Electronic Emissions and Immunity

| The FORE-SIGHT ELITE Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Oximeter should assure it is used in such an environment. | | |
|---|---|---|
| **Emissions Test** | **Compliance** | **Electromagnetic Environment** |
| RF emissions – CISPR 11 | Group 1 | The Oximeter 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 Oximeter 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)<br>IEC 61000-4-2 | Level 3 | Level 3 | The Oximeter 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<br>IEC 61000-4-4 | ±2 kV for power supply lines<br>±1 kV for input/output lines | ±2 kV for power supply lines<br>±1 kV for input/output lines | The Oximeter 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<br>IEC 61000-4-5 | ±1 kV line(s) to line(s) mode<br>±2 kV line(s) to earth mode | ±0.5 kV line(s) to line(s) mode<br>±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<br>IEC 61000-4-11 | < 5% $U_T$ (> 95% dip in $U_T$) for 0.5 cycle.<br>40% $U_T$ (60% dip in $U_T$) for 5 cycles.<br>70% $U_T$ (30% dip in $U_T$) for 25 cycles.<br>< 5% $U_T$ (> 95% dip in $U_T$) for 5 s | < 5% $U_T$ (> 95% dip in $U_T$) for 0.5 cycle.<br>40% $U_T$ (60% dip in $U_T$) for 5 cycles.<br>70% $U_T$ (30% dip in $U_T$) for 25 cycles.<br>< 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 Oximeter requires continued operation during power mains interruptions, it is recommended that the Oximeter be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60 Hz) magnetic field<br>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 ELITE Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Oximeter should insure that it is used in such an environment.

| Immunity Test | IEC 60601 Test Level | Compliance Level | Electromagnetic Environment – Guidance |
|---|---|---|---|
| Conducted RF<br>IEC 61000-4-6 | 3 Vrms<br>150 kHz to 80 MHz | 3 Vrms | Portable and mobile RF communications equipment should be used no closer to any part of the Oximeter, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br>Recommended separation distance:<br>$d = 1.2\sqrt{P}$<br>$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz<br>$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz<br>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.<br>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]<br>Interference may occur in the vicinity of equipment marked with the following symbol:  |
| Radiated RF<br>IEC 61000-4-3 | 3 V/m<br>80 MHz to 2.5 GHz | 3 V/m | |

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 Oximeter is used exceeds the applicable RF compliance level above, the Oximeter should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Oximeter.

[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 Oximeter**

The Oximeter is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Oximeter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Oximeter 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<br>$d = 1.2\sqrt{P}$ | 80 MHz to 800 MHz<br>$d = 1.2\sqrt{P}$ | 800 MHz to 2.5 GHz<br>$d = 2.3\sqrt{P}$ |
| 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 ELITE Oximeter 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.

CE 0086

**Exceptions** None

## Document Conventions

| | |
|---|---|
| **Warning:** | Directions that warn of conditions that put the patient or caregiver at risk |
| **Caution:** | Directions that help to avoid Oximeter damage or data loss |
| **Note:** | Directions that make it easier to use the Oximeter, which may not be readily apparent |

# Contents

# Figures

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# PREFACE

## Purpose

This *User Manual* describes the features and operation of the FORE-SIGHT ELITE Absolute Tissue Oximeter. It is an integral part of the product and contains the instructions necessary to operate the Oximeter safely and in accordance with its functions and intended use to ensure proper performance, correct operation, and patient and operator safety.

| | |
|---|---|
| **Warning:** | **Read this manual carefully before patient use of the Oximeter.**<br>For continued safe use of this equipment, it is necessary that the listed instructions be followed. Nothing in this user guide is intended to override procedures and regulations imposed at the institutional level or above. A Hospital's quality system, privacy rules, or other legal or policy requirements may govern whether and how to implement any specific procedure in this manual.<br>CASMED reserves the right to make changes to this manual and improvements to the product it describes at any time without notice or obligation. This manual has a revision number in the page footer that indicates the manual version. |

## Intended Audience

This manual is written for clinical professionals with working knowledge of medical procedures, practices, and terminology as required for monitoring critically ill patients.

In the U.S., the following caution applies: $R_x$ only

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

## Training

Training on this oximeter for the safe and effective use of its primary operating functions can be provided through CAS Medical Systems. See *Contact Information* on page ii.

CAS Medical Systems recommends in-service training on the Oximeter after the initial installation. No periodic retraining should be required. Training may also be provided when updates to the system are provided or as deemed appropriate by CAS Medical Systems.

# Safety

| | |
|---|---|
| **Warning:** | The Oximeter is to be operated by qualified personnel only. Failure to read this manual, accessory direction for use, all precautionary information, and specifications could result in injury. Operators must comply with the included Warnings, Cautions, and Notes to guarantee safe operation of the Oximeter.<br>Do not use the Oximeter for any purpose other than specified in this manual. Doing so will invalidate the Oximeter's warranty. |

Also review Chapter 2, *Installing the Oximeter* on page 7 and Appendix D, *Symbol Reference* on page 81. Additional Warnings, Cautions, and Notes that apply to specific parameters are listed in the sections that pertain to each respective parameter.

## Indications for Use

The noninvasive FORE-SIGHT ELITE Absolute Tissue Oximeter is intended for use as an adjunct monitor of absolute regional hemoglobin oxygen saturation of blood under the Sensors in individuals at risk for reduced-flow or no-flow ischemic states and is indicated for use as follows:

- When used with large Sensors, the FORE-SIGHT ELITE Oximeter is indicated for use on adults and transitional adolescents ≥ 40 kg (88.2 lbs).
- When used with Medium Sensors, the FORE-SIGHT ELITE Oximeter is indicated for use on pediatric subjects ≥ 3 kg (6.6 lbs).
- When used with Small Sensors, the FORE-SIGHT ELITE Oximeter is indicated for cerebral use on pediatric subjects < 8 kg (17.6 lbs) and non-cerebral use on pediatric subjects < 5 kg (11 lbs).

## Contraindications

The FORE-SIGHT ELITE Sensor is contraindicated for use on patients:

- with a physical site area too limited for proper Sensor placement.
- with allergic reactions to Sensor adhesive.
- undergoing an MRI scan because of associate risk of injury.

No other contraindications were known at the time this guide was published.

| | |
|---|---|
| **Warning:** | The Oximeter is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.<br>If the accuracy of any value displayed on the Oximeter is questionable, determine the patient's vital signs by alternative means. The functions of the Alarm system for patient monitoring must be verified at regular intervals (every six months) and whenever the integrity of the product is in doubt. Periodically test all functions. Failure to comply may lead to injury. |

## Measurement Accuracy

### Cerebral Accuracy

Accuracy (Bias ± Precision) not determined outside the following ranges:

| | |
|---|---|
| Large Sensors: | 45% to 95%: -0.14 ± 3.05% at 1 SD |
| Medium Sensors: | 48% to 92%: 0.05 ± 5.06% at 1 SD |
| Small Sensors: | 50% to 90%: -0.01 ± 5.38% at 1 SD |

### Non-Cerebral Accuracy

Accuracy (Bias ± Precision) not determined outside the following ranges:

| | |
|---|---|
| Large Sensors: | 45% to 95%: 0.24 ± 5.17% at 1 SD |
| Medium Sensors: | 53% to 88%: -0.03 ± 5.52% at 1 SD |
| Small Sensors: | 66% to 96%: 0.03 ± 5.69% at 1 SD |

## Intended Environment

The Oximeter is intended to be used in the following environments: operating, exam/procedure rooms, surgical recovery, critical care, emergency room, and long-term care.

## Likely Misuse

**Warning:** The Oximeter may be misused if used in the following environments:

- Transport vehicle
- Areas with flammable anesthetic gases
- In or near MRI equipment
- Outside the recommended temperature range
- Outdoors or high humidity environments

**Note:** The Oximeter is intended to be stationary, but may be moved intra-hospital via cart or roll stand. It may also be carried by its handle when in non-operational mode (Off).

## Oximeter Classifications

### Electrical Insulation

The Oximeter (with integrated AC power supply) is a Class I device.

### IEC 60601-1

| | |
|---|---|
| **Warning:** | The Oximeter is not “Category AP or APG Equipment.”<br>There is a risk of an explosion hazard if a damaged Oximeter or accessory is used in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide. |

| | |
|---|---|
| **Note:** | The Oximeter can remain connected to the patient during cardiac defibrillation. All applied parts are “Type BF Defibrillation Proof.” |

## Patient Environment

The Oximeter has been tested with specific parts of the system used within the patient environment (Figure 1). These parts are:

- The Oximeter
- Appropriate accessories as listed in Appendix F, *Parts* on page 93
- AC power cord

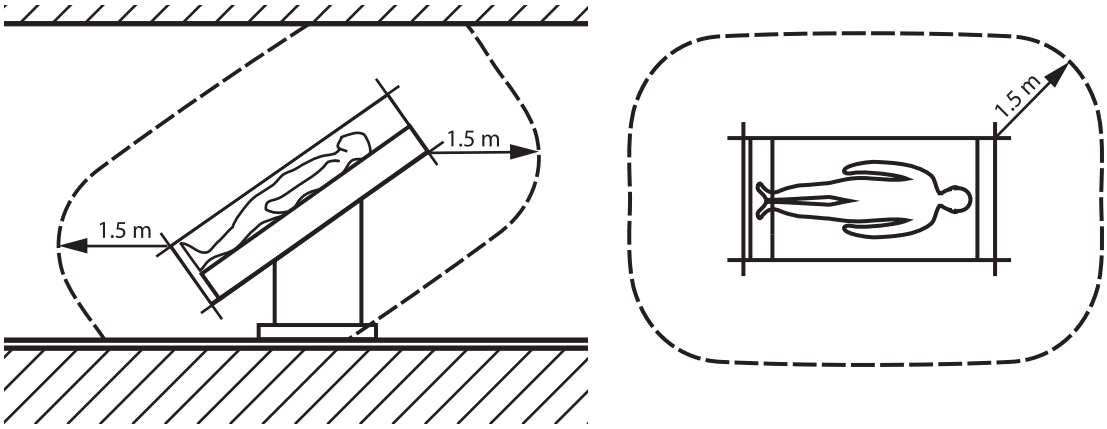



**Figure 1:** Patient Environment

### Safety Checks

| | |
|---|---|
| **Warning:** | Inspect the Oximeter, cables, Sensors, and other accessories for damage prior to operation. There is a risk that damaged parts could reduce the performance of the Oximeter or present a safety hazard. If any damage is noted, or if the Oximeter fails to respond, the Oximeter or accessory should not be used until it has been inspected and serviced or replaced by CASMED-authorized personnel. |

| | |
|---|---|
| **Warning:** | The operator must not perform any servicing on the Oximeter except as specifically stated in Chapter 6, *Cleaning and Maintaining the Oximeter* on page 63.<br>The parts of the Oximeter include the Oximeter, Preamp cable(s), Battery, AC power Cord and Sensor(s). The accessories for the Oximeter include, but are not limited to: USB flash drive, $StO_2$ Simulator and mounting hardware. See Appendix F, Parts on page 93 for a listing of approved parts and accessories. |

| | |
|---|---|
| **Warning:** | Liquids must not be allowed to enter the device. There is a risk of electric shock or device malfunction if liquids enter a device. If the Oximeter or Preamp is accidentally wetted, take it out of operation. It must be thoroughly dried (minimum 1 hour) and checked by a CASMED-authorized service technician before it is used again. |

## Parts and Warranty

CAS Medical Systems, Inc., (CASMED) 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 CASMED.
- 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.

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

| | |
|---|---|
| **Warning:** | Only use CASMED-supplied accessories with this Oximeter. CASMED-supplied accessories ensure patient safety and preserve the integrity, accuracy, and electromagnetic compatibility of the Oximeter. |

The warranty does not cover damages resulting from the use of accessories and consumables from other manufacturers. For complete warranty information, refer to Appendix G, *Warranty Policy*, on page 95.

## Waste Electrical and Electronics Equipment (WEEE)

To facilitate the sound treatment of WEEE, information will be made available for current CASMED products upon request. EU distributors and treatment facility personnel may contact techsrv@casmed.com to obtain relevant information.

# Chapter 1
# Introduction

The FORE-SIGHT ELITE Absolute Tissue Oximeter is a non-invasive device that measures absolute tissue oxygen saturation. It operates on the principle that blood contains hemoglobin in two primary forms — oxygenated hemoglobin ($HbO_2$) and de-oxygenated hemoglobin (Hb) — which absorb near-infrared light in different, measurable ways.

Tissue oxygen saturation ($StO_2$) levels are determined by the ratio of oxygenated hemoglobin to total hemoglobin at the microvascular level (arterioles, venules, and capillaries) in the region to which the Sensor is applied:

$$\%StO_2 = \frac{\text{Oxygenated Hemoglobin}}{\text{Total Hemoglobin}} = \frac{HbO_2}{HbO_2 + Hb} \times 100$$

The FORE-SIGHT ELITE incorporates CAS Medical Systems' exclusive technology to project harmless near-infrared light (in five precise wavelengths) through the scalp and skull and into the brain via a disposable Sensor on the patient's forehead. Reflected light is captured by detectors positioned on the Sensor for optimal signal collection. After analyzing the reflected light, the FORE-SIGHT ELITE displays the cerebral tissue oxygen saturation level on the Oximeter as an absolute number and provides a graphical representation of historical values.

A pulse oximeter only reflects arterial blood oxygen saturation ($SpO_2$) and requires pulsations to operate; whereas, FORE-SIGHT ELITE measures even in pulseless conditions and displays the balance of oxygen supply & demand in a target tissue ($StO_2$), e.g., brain, abdomen, limb muscle. Thus, FORE-SIGHT ELITE $StO_2$ values indicate overall tissue oxygenation state, which provides direct feedback for guiding care interventions.

# About the Oximeter Hardware

The following diagrams provide an overview of the Oximeter's physical features.

## Front View

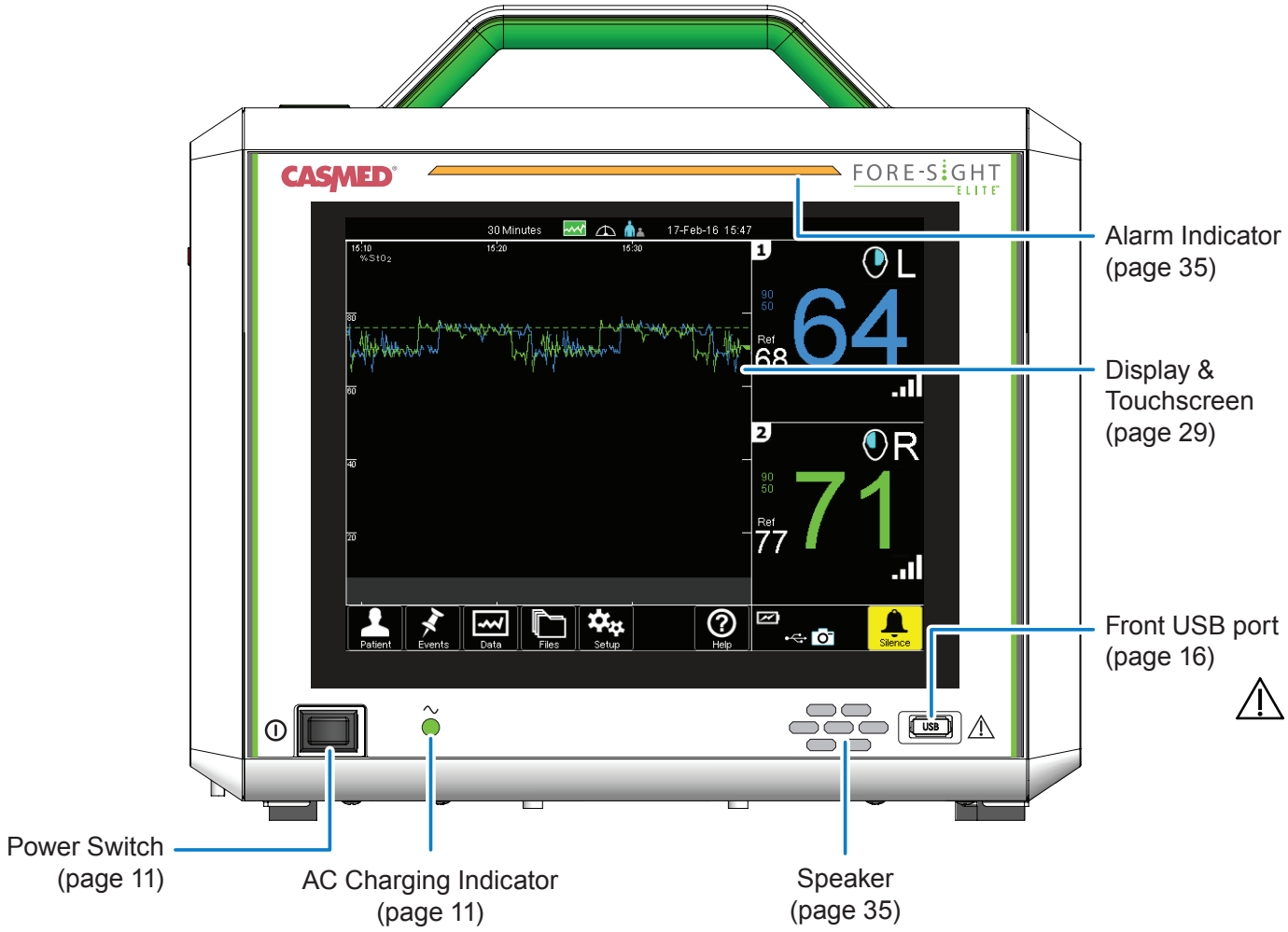



**Figure 2:** Oximeter — Front View

| **Caution:** | The USB ports must only be connected to a USB Flash Drive. Do not connect any other type of device or cable to the USB ports. |
|---|---|

## Rear View

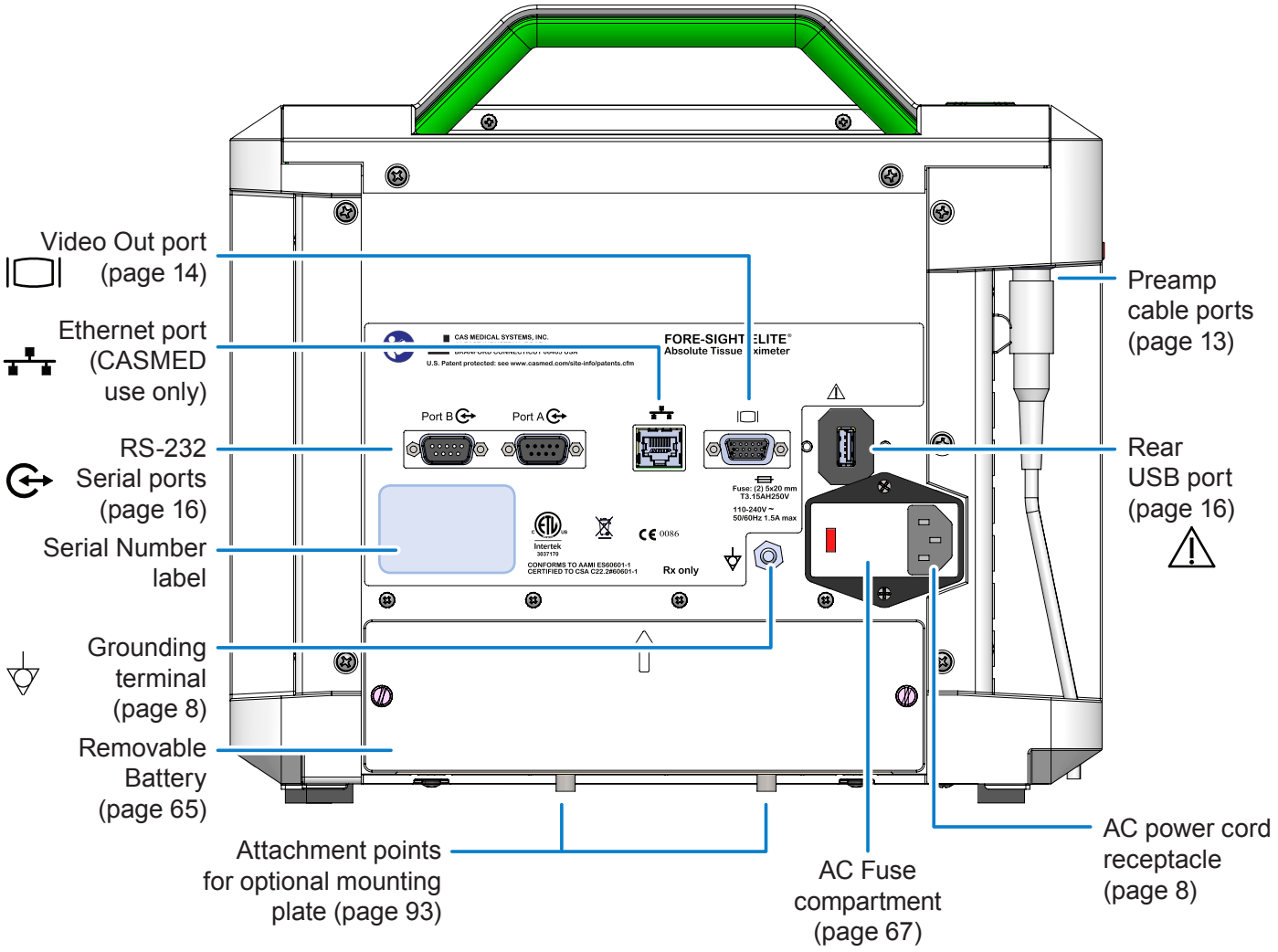



**Figure 3:** Oximeter — Rear View

| | |
|---|---|
| **Caution:** | The USB ports must only be connected to a USB Flash Drive. Do not connect any other type of device or cable to the USB ports. |

| | |
|---|---|
| **Note:** | The Oximeter has one male 9-pin (DTE) DB9 and one female 9-pin (DCE) DB9 Serial Communications Port. Some older units may be shipped with a null modem adapter attached to port A to create a female (DCE) serial port. If the DCE serial port is not required, the null modem adapter may be removed.<br><br>To remove the null modem adapter, unscrew the jackscrews projecting from the DCE adapter. Be careful not to unscrew the jackscrews associated with the male DTE port. The adapter may be reinstalled on a male port by reversing this procedure. |

## Side View

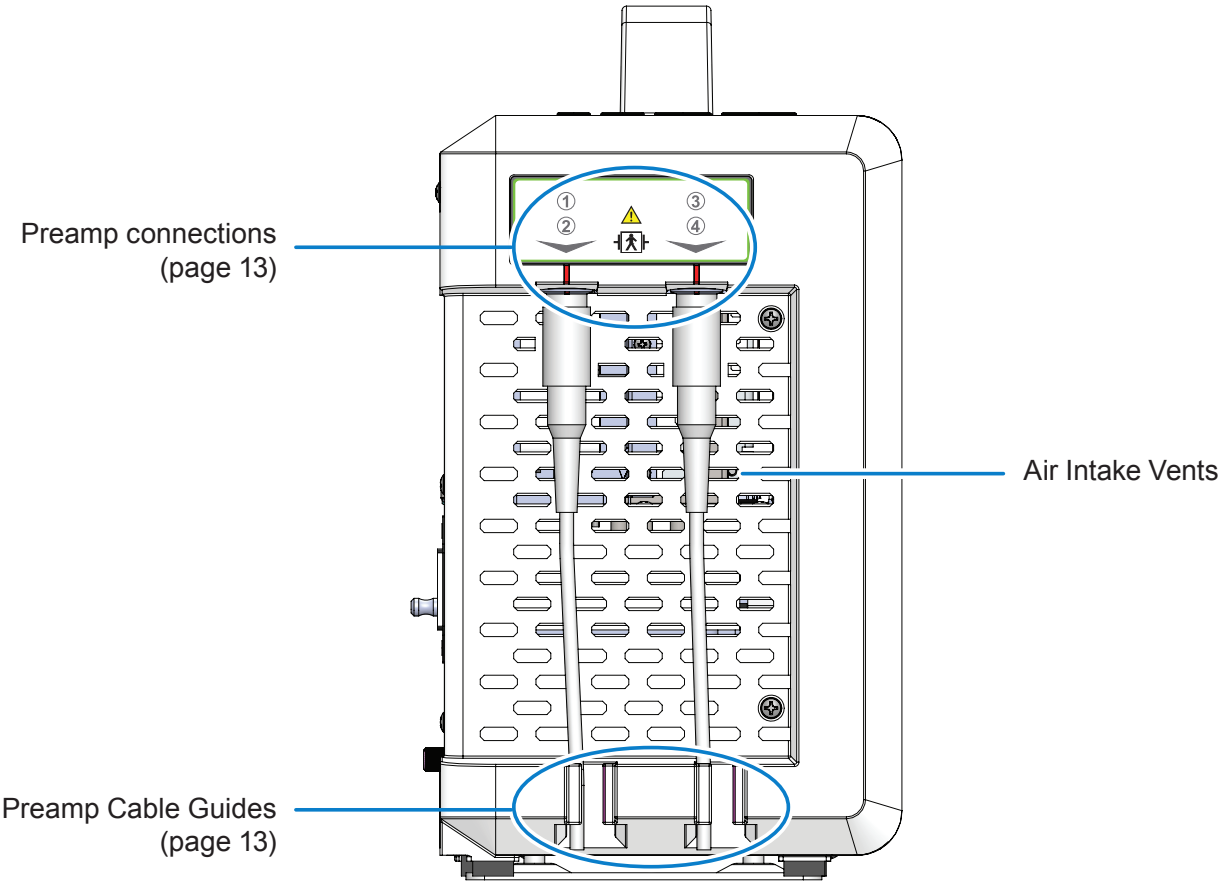



**Figure 4:** Oximeter — Left Side View

| **Caution:** | Keep the air intake vents and exhaust vents (on the right side of the Oximeter) clear of obstructions to allow for proper cooling. |
|---|---|

## About the Touchscreen Display

Figure 5 shows the main sections of the Oximeter display. See *Reading the Oximeter Display* on page 29 for further descriptions of each section.

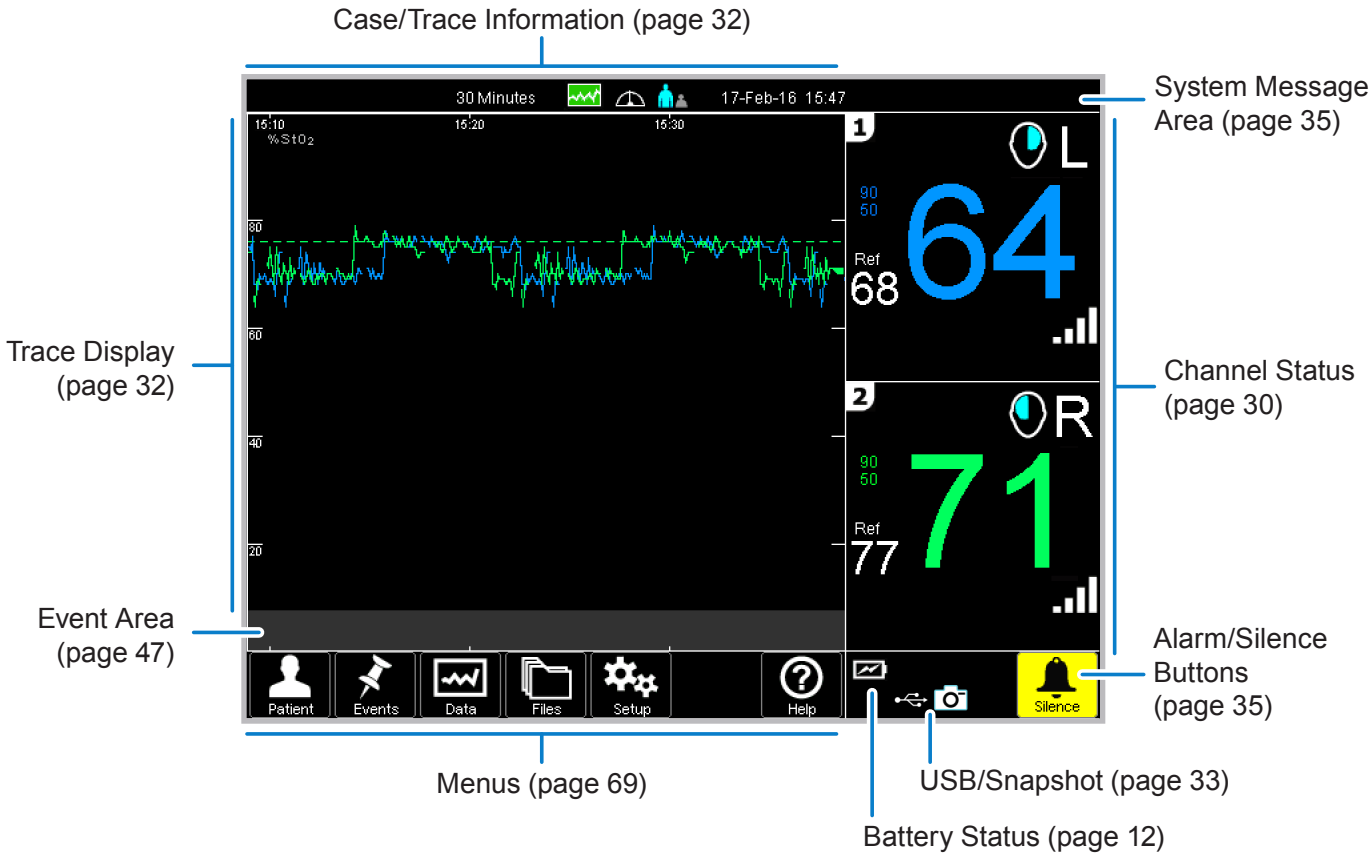



**Figure 5:** Display Overview

| **Caution:** | Pressing on the Oximeter display with a sharp or pointed instrument may permanently damage the touchscreen membrane. Use your finger only. |
|---|---|

## Accessing On-Screen Help

From the Main Menu, touch  to access the Oximeter's on-screen help for the following topics:

**Table 1:** On-Screen Help Options

| Button | | Description |
|---|---|---|
|  | Home | Displays the Main Menu. |
|  | Selection | Displays a matrix of appropriate Sensor size by patient weight. |
|  | Monitoring | Displays a list of tasks to complete before monitoring begins. |
|  | Apply | Displays instructions on selecting a Sensor site and applying a Sensor. |
|  | Numerics | Displays information about the Channel Number portion of the display. |
|  | About | Displays information about the Oximeter and software. |

# Chapter 2
# Installing the Oximeter

## Initial Inspection

Before unpacking the Oximeter, inspect the packaging for damage. If there are any signs of damage to the package, immediately file a claim 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, CASMED sales representative, or CASMED to report external damage and to arrange for repair or replacement of damaged equipment (see *Contact Information* on page ii).

The shipping carton should contain the items listed below; unpack the Oximeter and account for each item:

- FORE-SIGHT ELITE Absolute Tissue Oximeter
- FORE-SIGHT ELITE Battery

  The Battery packaging includes installation instructions (or see *Installing the Battery* on page 66).
- FORE-SIGHT ELITE Dual Preamp cable
- FORE-SIGHT ELITE User Manual
- Hospital-grade AC power cord

  The Oximeter ships with a power cord appropriate for the country and voltage being used.

Inspect each item for signs of external damage, dents, cracks, scratches, etc. If an item is missing or damaged, contact your distributor, CASMED sales representative, or CASMED.

| | |
|---|---|
| **Warning:** | There is a risk that damaged parts could reduce the performance of the Oximeter or present a safety hazard. If any damage is noted, the Oximeter or accessory must not be used until it has been inspected and serviced or replaced by CASMED-authorized personnel. |

# Installation Considerations

Installation can be customized to the institution and department's needs; please contact your local CASMED distributor for assistance.

## Electrical Connections

| | |
|---|---|
| **Warnings:** | Grounding reliability can be achieved only when the Oximeter is connected to an equivalent receptacle marked "Hospital Grade".<br><br>To avoid risk of electric shock, this equipment must only be connected to a supply main with protective earth. If the integrity of the protective earth conductor is in doubt, the Oximeter may be operated from the internal batteries by disconnecting the AC power cord completely from the Oximeter. Do not position the Oximeter in a position that makes it difficult to remove the external AC power cord.<br><br>Isolating the Oximeter from mains can be achieved only by removing the external AC power cord. |

| | |
|---|---|
| **Warning:** | When interfacing with other equipment, qualified biomedical engineering personnel must perform a test for leakage current before using the Oximeter with patients. Serious injury or death could result if the leakage current exceeds applicable standards. |

| | |
|---|---|
| **Note:** | The Grounding Terminal (⏚) on the rear of the Oximeter can provide a connection between the Oximeter and the potential equalization bus-bar of the electrical installation. When using the Grounding Terminal, the power cord must not incorporate a potential equalization conductor. Refer to IEC 60601-1 for additional information. |

## Electromagnetic Interference

| | |
|---|---|
| **Warning:** | The Oximeter needs special precautions if it is placed close to a strong electromagnetic transmitter such as X -ray or Electrosurgical Unit (ESU) devices. There is a risk that these signals could interfere with the Oximeter and disrupt its performance, causing measurements to be inaccurate during use of such equipment.<br><br>For continued protection against this risk, replace the AC power cord only with one provided by CASMED. |

## Physical Placement

| | |
|---|---|
| **Warnings:** | The Oximeter needs special precautions if it is placed close to a strong EMC transmitter such as an X-ray or ESU device. There is a risk that these signals could interfere with the Oximeter and disrupt its performance, causing measurements to be inaccurate during use of such equipment.<br>To reduce the risk of injury, do not move or place the Oximeter or accessory in any position that might cause it to fall on a patient, bystander, or operator.<br>Do not lift or pull the Oximeter by any cable. As with all medical equipment, carefully route and secure all cables to reduce the risk of patient entanglement or strangulation.<br>Avoid placing the Oximeter where a patient could access the controls. |

| | |
|---|---|
| **Caution:** | Avoid placing either side of the Oximeter against objects that could restrict air flow through the air intake vents (left side) and exhaust vents (right side). |

## Mounting Solutions

An optional mounting plate (P/N 01-06-0239) is available for joining the Oximeter with CASMED-approved mounting solutions; the four non-skid feet may also be removed to facilitate installation. Contact your CASMED distributor for more information.

| | |
|---|---|
| **Warning:** | The proper assembly of the various mounting solutions cannot be assured for structural integrity. There is risk that a damaged or improperly assembled Oximeter mounting solution may fall on patient, bystander, or operator. |

# Powering the Oximeter

The Oximeter is designed for continuous operation. It is powered via an AC power cord that also recharges the Oximeter's backup battery, which allows it to operate up to a half hour (on a new, fully charged battery) without an external power source.

## Installing the Battery

The Oximeter ships without the Battery installed; before using the Oximeter you should install the Battery as described below, and charge it as described in the following section.

| | |
|---|---|
| **Warning:** | Use only the CASMED Battery that is listed in *Accessories, Detachable Parts, and Materials* on page 93. |

| | |
|---|---|
| **Caution:** | The Oximeter should not be operated without a battery properly installed. Sudden loss of AC power may cause the Oximeter to lose data. |

1. Ensure that the AC power cord is not connected to the Oximeter.
2. Position the Battery near the Battery Compartment with the arrow on the outside cover pointing up (Figure 6).

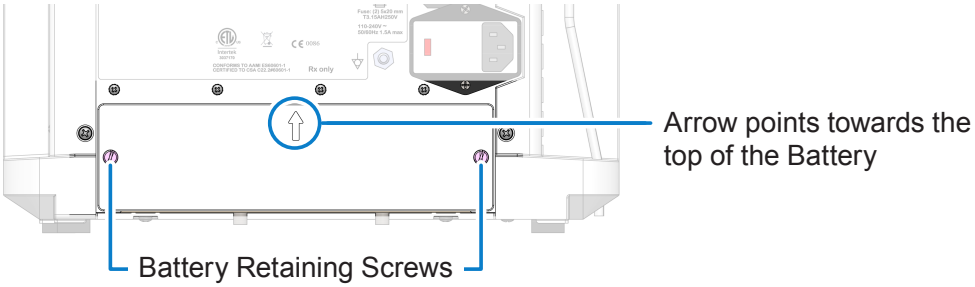



**Figure 6:** Battery Compartment

3. Gently slide the Battery into the Battery Compartment until a slight resistance is encountered.

| | |
|---|---|
| **Caution:** | If significant resistance is encountered, do not force the Battery into the Battery Compartment — it cannot be installed in the incorrect orientation. Ensure that the arrow on the outside cover is facing up and the two side tabs are towards the top of the pack. |

4. Using equal force on both sides of the Battery, push it into the Battery Compartment until the outside of the Battery is flush with the rear of the Oximeter.
5. Hand-tighten the retaining screws on either side of the Battery until snug and then use a screwdriver to tighten an additional 1/4 turn. Do not over-tighten the screws.

## Connecting the Power Cord

The Oximeter ships with a hospital-grade power cord as appropriate for the country and voltage being used.

1. Connect the female end of the cord to the power receptacle on the rear of the Oximeter (Figure 7).
2. Connect the male end of the cord to mains power.

   The AC Charge indicator (⏦) next to the power switch (Figure 8) on the front of the unit turns green when the Oximeter is receiving power and charging the battery.

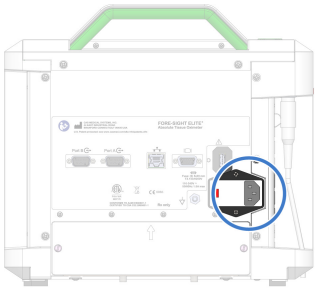


**Figure 7:** AC Connection

| | |
|---|---|
| **Warning:** | Grounding reliability can be achieved only when the Oximeter is connected to an equivalent receptacle marked “Hospital Grade”. See *Electrical Connections* on page 8 for additional warnings. |

3. Allow the battery to charge for six hours.
4. Disconnect the AC power cord.
5. Press the ⏻ power switch on the front of the Oximeter (Figure 8) and verify the Oximeter will power on with the Battery installed.
6. Reconnect the AC power cord to the Oximeter.

| | |
|---|---|
| **Caution:** | To maintain proper battery charge, plug the Oximeter into main power when not in use. Failure to do so may diminish the service life and function of the battery. |

## Turning the Oximeter On and Off

As long as the battery is sufficiently charged, the Oximeter will turn on regardless of whether it is connected to AC power. The Oximeter can be turned on either before or after cables and Sensors are connected.

- Press the ⏻ power switch to turn on the Oximeter (Figure 8).

  The Oximeter powers up within a few seconds, the fan starts, and a splash screen appears while the software initializes and runs diagnostics. The main screen (see *Reading the Oximeter Display* on page 29) appears when the Oximeter is ready for normal operation.
- Press the ⏻ power switch again for one second to turn off the Oximeter.

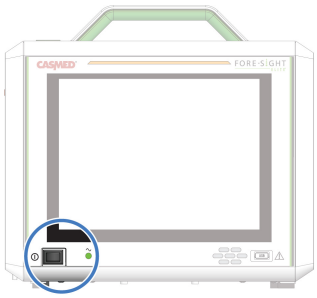


**Figure 8:** Power Switch and AC Charge Indicator

## Monitoring Battery Status

The battery icon in the lower-right corner of the display indicates the battery's charge status (Table 2). The Oximeter displays a system alert when the battery is running low to indicate that AC power should be connected.

**Caution:** When not connected to AC power, the Oximeter may not turn on if the battery charge is less than 60%. Connect AC power to turn on the Oximeter.

**Table 2:** Battery Status Indicators

| Icon | Status | Charge |
|---|---|---|
|  | Charging Battery | — |
|  | Discharging Battery | 80-100% |
|  | Discharging Battery | 60-80% |
|  | Discharging Battery | 40-60% |
|  | Discharging Battery | 20-40% |
|  | Low Battery | 5-20% |
|  | Depleted Battery | < 5% |
|  | Faulty Battery / No Battery | — |

# Testing the Oximeter

When first installed, Preamp cables should be connected to the Oximeter and the Oximeter should then be tested as described in *Testing Alarm Operation* on page 65.

## Connecting the Preamp Cables

Preamp cables connect the Oximeter to the Sensors. Preamp cables are reusable, and can remain connected to the Oximeter between uses. The Preamp packaging includes channel labels to be placed at the end of the Sensor cables.

| | |
|---|---|
| **Warnings:** | Inspect the Preamp cable for damage prior to installation. If any damage is noted, it must not be used until it has been inspected by CASMED-authorized personnel and serviced or replaced. There is a risk that damaged parts could reduce the performance of the Oximeter or present a safety hazard.<br>If a Preamp cable is grossly contaminated with blood or other bodily fluids, it should be discarded to reduce the risk of contamination and cross infection. |

| | |
|---|---|
| **Notes:** | Preamp cables should be regularly cleaned as described in *Cleaning the Oximeter* on page 64.<br>Preamp cables should be replaced when they no longer properly functioning. Keep track of cable installation date and usage. See Appendix F, Table 32 on page 93 for reorder information. |

To connect Preamp cables to the Oximeter:

1. Position the Preamp cable plug under the desired Oximeter Preamp port (Channels ①/② or ③/④) and rest it against the Plug Guide below the connector (see Figure 10 on page 14).
2. Line-up the alignment indicators (red dots) on the Preamp plug and Oximeter Preamp port.
3. Gently push the Preamp cable plug straight up into the Oximeter Preamp port until it snaps into place (Figure 10 on page 14, green arrow).
4. Pull down gently on the Preamp plug to ensure it has fully snapped into place.
5. Inspect the small box in the middle of the Preamp cable; when a Preamp cable is connected to the Oximeter, the white channel Indicators will be lit for the connected channel pair (Figure 9 shows a Preamp connected to Channels 1 & 2).
6. Slide the Preamp cable into the cable guide on the side of the Oximeter to secure it.

Channels 1 & 2
White Indicators lit

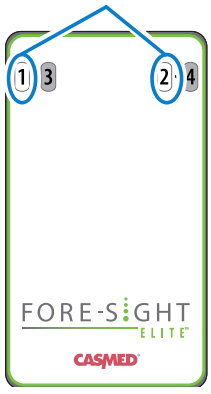



**Figure 9:** Preamp connected to Channels 1 & 2

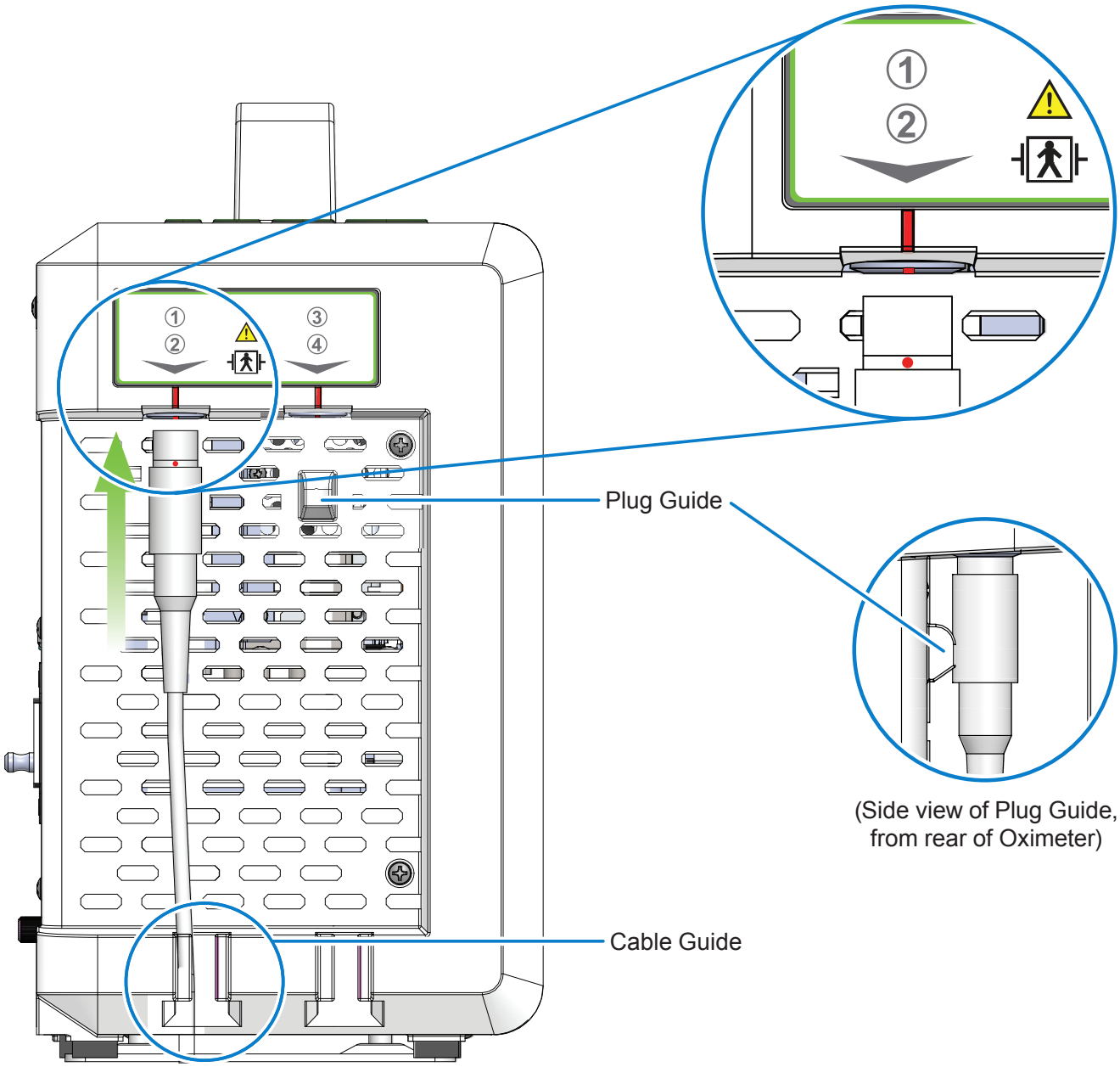



**Figure 10:** Attaching the Preamp Cable

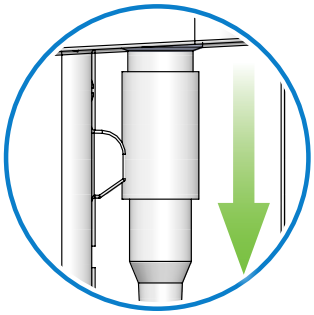


**Figure 11:** Disconnecting the Preamp Cable

## Testing the Oximeter Alarms

CASMED recommends that Alarm operation be tested when the Oximeter is first installed and at least once every 6 months thereafter. To assist with this process, an $StO_2$ Simulator is available through CASMED.

1. Connect the $StO_2$ Simulator to the patient connection of the Oximeter (where a Sensor would normally be attached).

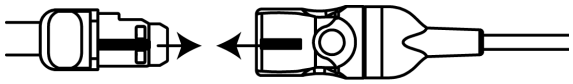


**Figure 12:** Connecting the $StO_2$ Simulator

   The channel will display a *Sensor Simulator Data* message.

2. Set the High Alarm limits to at least 1% less than the current displayed value and verify the activation of the High limit detection.

   See *Configuring $StO_2$ Alarm Limits* on page 45 for instructions on changing alarm limits.

3. Reset the High Alarm limits to the desired level.
4. Set the Low Alarm limits to at least 1% more than the current displayed value and verify the activation of the Low limit detection.
5. Reset the Low Alarm limits to the desired level.

## Disconnecting the Preamp Cables

The Preamp cable(s) may remain attached to the Oximeter from patient to patient. Should they need to be disconnected, do so as follows:

1. Grasp the housing of the connector near Oximeter Preamp port and gently pull straight down on the Preamp cable connector to remove it (Figure 11 on page 14).
2. When the Preamp cable is disconnected from the Oximeter, all Channel ID Indicators on the Preamp housing will be off.

# Interfacing with Other Equipment

The following sections describe the Oximeter interfaces that may be used. Note that the RJ-45 Ethernet port (  ) on the rear of the Oximeter is for CASMED personnel only.

## Connecting a Second Monitor

The Oximeter display can be mirrored onto a second monitor by connecting it to the Oximeter's Video Out port (Figure 13).

Oximeter video output is VGA (RGB 4:3/640px x 480px).

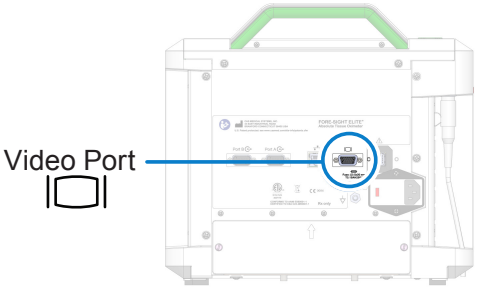



**Figure 13:** Video Out

## Connecting USB Devices

There are USB ports on the front and rear of the Oximeter. Either may be used, but the Oximeter can recognize only one device (whichever was connected first).

| | |
|---|---|
| **Caution** | The USB ports must only be connected to a USB Flash Drive. Do not connect any other type of device or cable to the USB ports. |

## Connecting Serial Devices

The Oximeter has two RS-232C bi-directional serial ports (A and B — note that port B is to the left of port A when looking at the back of the Oximeter, shown in Figure 14) that may be used to interface with other medical equipment (see Table 4 on page 19). Contact your CASMED representative for additional information and technical details.

See Table 33: Philips Accessories on page 94; also see *Philips Patient Monitor Messages* on page 78 for a list of messages that the Oximeter may display on the Philips device.

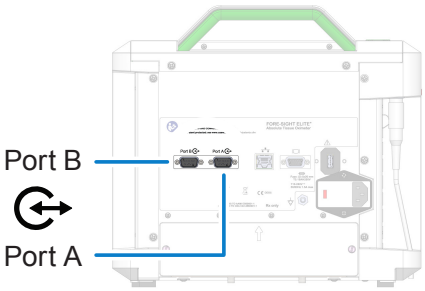



**Figure 14:** Serial Ports

| | |
|---|---|
| **Warning:** | When interfacing with other equipment, qualified biomedical engineering personnel must perform a test for leakage current before using the Oximeter with patients. Serious injury or death could result if the leakage current exceeds applicable standards. |

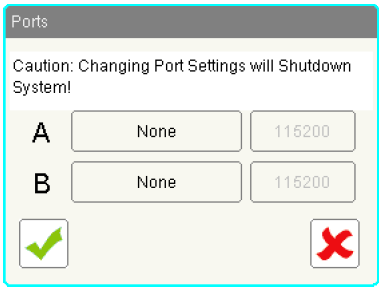
| | |
|---|---|
| **Caution:** | Only qualified biomedical engineering personnel may interface monitoring equipment with other types of medical equipment. Be certain to consult manufacturers' specifications to maintain safe operation. |

| Note: | The Oximeter has one male 9-pin (DTE) DB9 and one female 9-pin (DCE) DB9 Serial Communications Port. Some older units may be shipped with a null modem adapter attached to port A to create a female (DCE) serial port. If the DCE serial port is not required, the null modem adapter may be removed.<br><br>To remove the null modem adapter, unscrew the jackscrews projecting from the DCE adapter. Be careful not to unscrew the jackscrews associated with the male DTE port. The adapter may be reinstalled on a male port by reversing this procedure. |
|---|---|

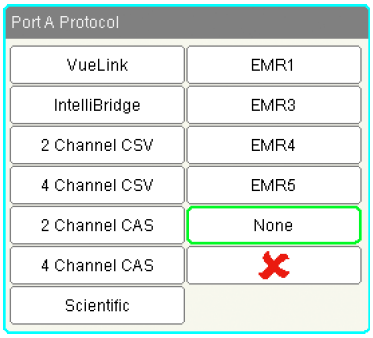
## Configuring Serial Ports

Serial ports A and B may be configured independently, as follows:

1. From the Main Menu, touch **Setup**.
2. Touch **Log In** to display the Password keyboard.
3. Enter the password (2466) and touch ✔ to access the Biomed submenu.
4. Touch **Ports** to display the Ports options.

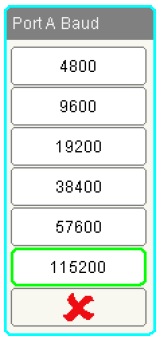



5. To set the port protocol:
   a. Touch the Protocol button immediately to the right of **A** or **B** (it displays **None** by default) to display the protocol selections.




   b. Touch a Protocol (or **None**) to select it or touch ✘ to cancel.

6. To set the baud rate:
   a. Touch the Baud Rate button to the far right of **A** or **B** to display the baud rate options for the selected protocol.




   b. Touch a Baud Rate to select it or touch ✘ to cancel.

   Table 3 on page 18 shows the compatible baud rates for each protocol. For information on the EMR protocols, see the FORE-SIGHT ELITE EMR Protocol User Guide (CAS P/N 21-03-0368).

7. Touch ✔ to save changes and close the Ports screen, or touch ✘ to cancel.

   Saving changes will automatically power off and restart the Oximeter.

**Table 3:** Serial Protocol Baud Rate Compatibility Matrix

| | Serial Protocol | | | | | | |
|---|---|---|---|---|---|---|---|
| **Baud Rate** | **IntelliBridge** | **VueLink** | **2-Channel CAS** | **4-Channel CAS** | **2-Channel CSV** | **4-Channel CSV** | **Scientific** |
| **4800** | | ✔ | ✔ | ✔ | ✔ | ✔ | |
| **9600** | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | |
| **19200** | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | |
| **38400** | | | ✔ | ✔ | ✔ | ✔ | |
| **57600** | | | ✔ | ✔ | ✔ | ✔ | ✔ |
| **115200** | | | ✔ | ✔ | ✔ | ✔ | ✔ |

Table 4 summarizes the third-party solutions that may interface with the Oximeter.

**Table 4:** Third-Party Solutions

| System | Required Hardware / Middleware | Protocol Support |
|---|---|---|
| **Patient Monitoring Systems** | | |
| • Philips Patient Monitors MP40/50/60/70/80/90 (Rev H.0 or higher) | • Philips IntelliBridge EC-10 Module: P/N 865115 #A01 101<br>• Philips IntelliBridge EC5 Module: P/N 865114 #104<br>• Ethernet cable CAT5 (≤ 10 meters) | IntelliBridge |
| | • Philips IntelliVue Module option A05 (Philips P/N M1032A)<br>• Philips Interface Cable option K6C (Philips P/N M1032-61699)<br>• Interface Cable (CAS P/N 01-06-2133) | VueLink |
| **Clinical/Anesthesia Information Management Systems (CIMS/AIMS)** | | |
| • Dräger Innovian Anesthesia PDMS<br>• Excel Medical Electronics-BedMaster<br>• iMDsoft MetaVision<br>• Maquet JOCAP-XL DMS<br>• Nihon Kohden CAP-2500 Philips CompuRecord<br>• Sorin DMS<br>• Spectrum Medical Viper DMS<br>• Terumo TLink DMS | Manufacturer-specific interface cable | 2-channel CSV or 2-channel CAS |
| **Electronic Medical Records (EMR) or Hospital Information Management Systems (HIMS)** | | |
| • AGFA Health Care - ORBIS<br>• AHIS – CcaSol<br>• Axigate<br>• Allscripts –SCM<br>• Cerner Millenium<br>• Chipsoft – HiX<br>• CIS Healthcare<br>• COPRA<br>• CRIIH Grenoble – Cristal Net<br>• CSC-Isoft<br>• Daintel<br>• Datascope (Mindray) – Passport VCS<br>• DocuSys<br>• Dräger Innovian<br>• ELAD - Chameleon<br>• Emergisoft<br>• EPIC<br>(Continued) | • Capsule Tech DataCaptor/Smartlinx MDIS<br>• Moberg CNS<br>• NantHealth (formerly iSirona) | 2-channel or 4-channel CAS |
| | • Nuvon | 2-channel CAS |
| | • Cerner iBus | 2-channel CSV |

**Table 4:** Third-Party Solutions

| System | Required Hardware / Middleware | Protocol Support |
|---|---|---|
| **Electronic Medical Records (EMR) or Hospital Information Management Systems (HIMS) (Continued)** | | |
| • Evolucare – OpeSIM<br>• Evolucare – Réassist<br>• Fukuda Denshi<br>• GE - QS Perinatal – Centricity - Carescape<br>• Home made (La Fé) – O.R.I.O.N<br>• Home-made (HUG) – DPI<br>• InterSystems – TrackCare<br>• iMDSoft – MetaVision<br>• IMS Maxims<br>• KIS<br>• LöSER – Predec View<br>• MainCare – Blocqual – Cora – Crossway<br>• Marand – Ispek<br>• McKesson – Horizon Cardiology – Paragon<br>• Medasys – DxCare<br>• Meditech – Magic – Client/Server<br>• Meierhofer – ISOP-ANA plus<br>• Mindray - Panorama<br>• Nexus / GMT – Medfolio<br>• Nihon Kohden – CGS CS - Gateway<br>• Olympus – Endobase<br>• Philips – ICCA – IIC – CS – CCS – IBS CS<br>• Philips - ICCA – Emmergin - VISICU<br>• Picis<br>• PMDeveloppement – Climco<br>• Quadramed<br>• SAFERsleep<br>• SAP – IshMed<br>• SIB Sillage<br>• Siemens<br>• Siemens – Sonarian Critical Care<br>• Surgical Information Systems<br>• Theronyz<br>• Welch-Allyn – Connex VM<br>• Xperthis – H++ | | |

# Chapter 3
# Monitoring Essentials

This chapter describes the core patient workflow — from connecting the patient to the Oximeter, through the monitoring session, to disconnecting the patient after the session. The following chapter (*Additional Monitoring Tasks* on page 41) describes other tasks that might be performed during a session.

## Core Patient Workflow

1. Verify that the Oximeter is powered on.
2. Verify that the required number of Preamp cables are connected to the Oximeter.

   They are often left attached; if not, see *Connecting the Preamp Cables* on page 13.
3. Verify that the Oximeter is in the appropriate monitoring Mode — Adult or Pediatric (page 22).
4. Attach Sensors to the patient (page 23).
5. Connect Preamp cables to the Sensors (page 28).
6. If necessary, start a new patient case.

   If you changed the Patient Mode or Sensor locations, you will have been prompted to start a new case. See *Starting a New Case* on page 34 for details on what the Oximeter considers a 'new case' vs. a continuing session.
7. Begin monitoring the patient.
8. Remove the Sensors from the patient and disconnect the Sensors from the Preamp cables (see *Disconnecting Sensors After Monitoring* on page 39).

To remove any chance of contamination between patients, the cables and Oximeter should be cleaned after each case as described in *Cleaning the Oximeter* on page 64.

# Selecting the Patient Mode

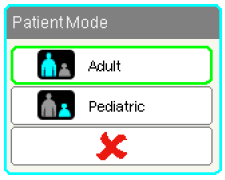
The Oximeter operates in one of two modes, identified by an icon at the top of the screen:

Adult Mode  Pediatric Mode

This mode must be set correctly, as it determines the available Sensor locations (page 44) and, in turn, measurement accuracy. Changing the mode requires starting a new patient.

To change the Patient Mode:

1. Touch the / icon at the top of the screen to display the Patient Mode selection.
   You can also, from the Main Menu, touch **Patient** and then touch **Mode**.




2. Touch or as appropriate, or touch ✘ to cancel.
   After selecting a new mode, the Oximeter prompts you to start a new patient case — touch ✔ to start a new case, or touch ✘ to continue the same case in the current mode.
   Selecting a new mode also resets the $StO_2$ Averaging mode to its default (Normal for Adult or Fast for Pediatric).

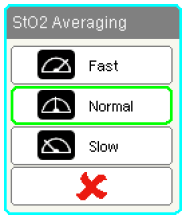
# Selecting the $StO_2$ Averaging Mode

The Oximeter measures $StO_2$ constantly, and updates the display every 2 seconds with the average of multiple consecutive samples. $StO_2$ Averaging modes adjust the number of samples used, which affects the response time, to accommodate the type of intervention or procedure being performed — an icon at the top of the screen indicates the current mode:

- Fast (smaller number of samples for faster response; Pediatric Mode default)
- Normal (Adult Mode default)
- Slow (higher number of samples gives slower response)
- None (fastest response, available if the extended menu is enabled; see page 56)

To change the $StO_2$ averaging mode:

1. Touch the $StO_2$ averaging icon at the top of the screen.
   You can also, from the Main Menu, touch **Patient** and then touch **Averaging**.




2. Touch an averaging mode as appropriate, or touch ✘ to cancel.

# Attaching Sensors to the Patient

The following sections describe how to prepare the patient for monitoring.

## Selecting a Sensor Site

To ensure patient safety and proper data collection, consider the following items when selecting a Sensor site.

| | |
|---|---|
| **Warnings:** | Sensors are not sterile and therefore should not be applied on abraded, cracked, or lacerated skin. Exercise caution when applying Sensors to a site with delicate skin. Applying Sensors, tape or pressure to such a site may reduce circulation and/or cause skin deterioration.<br>Do not place Sensor over poorly perfused tissues. Avoid uneven skin surfaces for best adhesion. Do not place Sensor over sites with ascites, cellulitis, or edema.<br>If electrocautery procedures will be performed, Sensors and electrocautery electrodes should be placed as far apart as possible to prevent unwanted skin burns; a distance of at least 15 cm (6 in) is recommended. |

| | |
|---|---|
| **Cautions:** | Sensors should not to be placed on high density hair areas.<br>The Sensor must be able to rest flush with clean, dry skin. Any debris, lotion, oil, powder, 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 alarm message. |

| | |
|---|---|
| **Notes:** | Skin pigmentation does not affect the validity of collected data. The Oximeter compensates automatically for skin pigmentation.<br>In the event that the location of the selected tissues cannot be palpated or visualized, confirmation by ultrasound or X-ray is recommended. |

## Selecting a Sensor

As described in *Indications for Use* on page xiv:

- When used with large Sensors, the FORE-SIGHT ELITE Oximeter is indicated for use on adults and transitional adolescents ≥ 40 kg (88.2 lbs).
- When used with Medium Sensors, the FORE-SIGHT ELITE Oximeter is indicated for use on pediatric subjects ≥ 3 kg (6.6 lbs).
- When used with Small Sensors, the FORE-SIGHT ELITE Oximeter is indicated for cerebral use on pediatric subjects < 8 kg (17.6 lbs) and non-cerebral use on pediatric subjects < 5 kg (11 lbs).

Table 5 on page 24 provides sensor selection guidelines based on Patient Mode, patient weight, and sensor location.

**Table 5:** Sensor Selection Matrix

| Patient Mode | Sensor | Weight | Body Location | | | | |
|---|---|---|---|---|---|---|---|
| | | | Brain | Flank | Abdomen | Legs | Arms/ Deltoids |
| Adult | Large 01-07-2103 | ≥ 40 kg | ✔ | ✔ | | ✔ | ✔ |
| Pediatric | Medium 01-07-2102 | ≥ 3 kg | ✔ | ✔ | ✔ | ✔ | |
| Pediatric Neonatal | Small 01-07-2101 | < 8 kg | ✔ | | | | |
| | | < 5 kg | ✔ | ✔ | ✔ | | |
| Pediatric Neonatal | Small Non-Adhesive 01-07-2100 | < 8 kg | ✔ | | | | |
| | | < 5 kg | ✔ | ✔ | ✔ | | |

**Notes:**

If you connect a sensor that is sized inappropriately for the current Patient Mode, that channel displays an *Incorrect Sensor Size* alert. If this is the only sensor connected, the Oximeter will prompt you to switch modes; touch ✔ to switch modes and clear the alert, or touch ✘ to dismiss the prompt without switching.

If you connect a sensor that is sized inappropriately for the selected body location, that channel displays an *Incorrect Sensor Size* alert. If this is the only sensor connected, the Oximeter will prompt you to select a different body location or use a different sensor size. Touch ✔ to dismiss the prompt.

**Warnings:**

Use only CASMED-supplied accessories with this Oximeter. CASMED accessories ensure patient safety and preserve the integrity, accuracy, and electromagnetic compatibility of the Oximeter. Connecting a non-CASMED sensor will cause a *Faulty Sensor* alert on that channel and no $StO_2$ values will be recorded.

Sensors are designed for single-patient use, and are not to be reprocessed — re-used Sensors present a risk of cross-contamination or infection.

Use a new Sensor for each patient and discard it after use. Disposal should follow in accordance with local hospital and institution policies.

If a Sensor seems damaged in any way, it must not be used.

Always read the Sensor packaging.

## Preparing the Sensor Site

To prepare the patient's skin for Sensor placement:

1. Verify that 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 the chosen site.
3. Use an appropriate cleanser to gently clean the intended Sensor site.

   The Large and Medium Sensor packages include an alcohol pad. Do not use alcohol pad on newborn or fragile skin.

   You may use Tegaderm or Mepitel under the Sensor in patients with delicate skin or edema.
4. Allow the skin to dry completely before applying the Sensors.

## Applying Sensors

1. Select the appropriate Sensor (see Table 5 on page 24) and remove it from the package.
2. Remove and discard the protective liner from the Sensor (Figure 15).

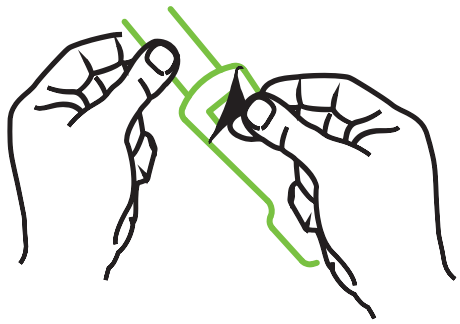


**Figure 15:** Removing Protective Liner from Sensor

| **Notes:** | When using the Non-Adhesive Small Sensor, you must size and cut the Sensor band length to fit the patient.<br>• Shorten the Sensor band away from the patient. Do not cut the Sensor band while on the patient, and do not cut any other part of the Sensor.<br>• Attach the Sensor band to the patient with the print facing out.<br>• Do not over-tighten the Sensor band, as pressure can be transferred to the baby. |
|---|---|

3. Affix the Sensor to the patient in the chosen location.
   - **Cerebral Use** (Figure 16): Select the site on the forehead above the eyebrow and just below the hairline where the Sensors will be linearly aligned.

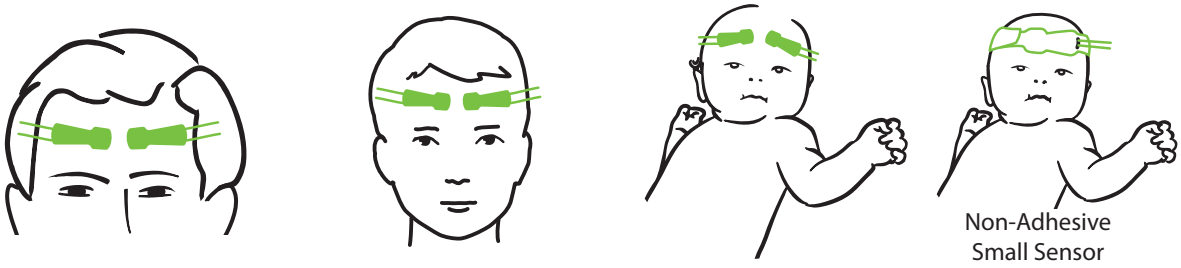



**Figure 16:** Applying Sensors (Cerebral)

   - **Non-Cerebral Use** (Figure 17): Select the site that provides the ideal access to the desired skeletal muscle tissue (if muscle cannot be palpated, too much adipose or edema may be present).
     - Arm: Position Sensor over the deltoid (shoulder), biceps (upper arm), or brachioradialis muscle.
     - Leg: Position Sensor over the quadriceps (upper leg), gastrocnemius (calf), or tibialis (calf) muscle. Apply the Sensor with the connector towards the feet.
     - Flank/Abdomen: Position Sensor over the Latissimus dorsi (flank) or external oblique (abdomen) muscle.

| | |
|---|---|
| **Notes:** | When monitoring muscle tissue, place the Sensor centrally over the selected muscle bed (e.g., middle of upper half of the lower leg as diagrammed).<br>A muscle bed with significant atrophy may not provide enough tissue for monitoring.<br>When monitoring for the effects of vascular obstruction in a limb, place a Sensor on both the limb of concern and in the same location on the opposing limb. |

| | |
|---|---|
| **Warnings:** | Exercise extreme care when applying Sensors. Sensor circuits are conductive and must not come into contact with other grounded, conductive parts other than EEG or entropy monitors. Such contact would bridge the patient's isolation and cancel the protection provided by the Sensor.<br>Failure to apply Sensors properly may cause incorrect measurements. Misapplied Sensors or Sensors that become partially dislodged may cause either over- or under-reading of oxygen saturation.<br>Do not position a Sensor under the weight of the patient. Prolonged periods of pressure (such as taping over the Sensor or the patient lying on a Sensor) transfers weight from the Sensor to the skin, which can injure skin and reduce Sensor performance.<br>The Sensor site must be inspected at least every 12 hours to reduce the risk of inadequate adhesion, circulation, and skin integrity. If the circulatory condition or skin integrity has deteriorated, the Sensor should be applied to a different site. |

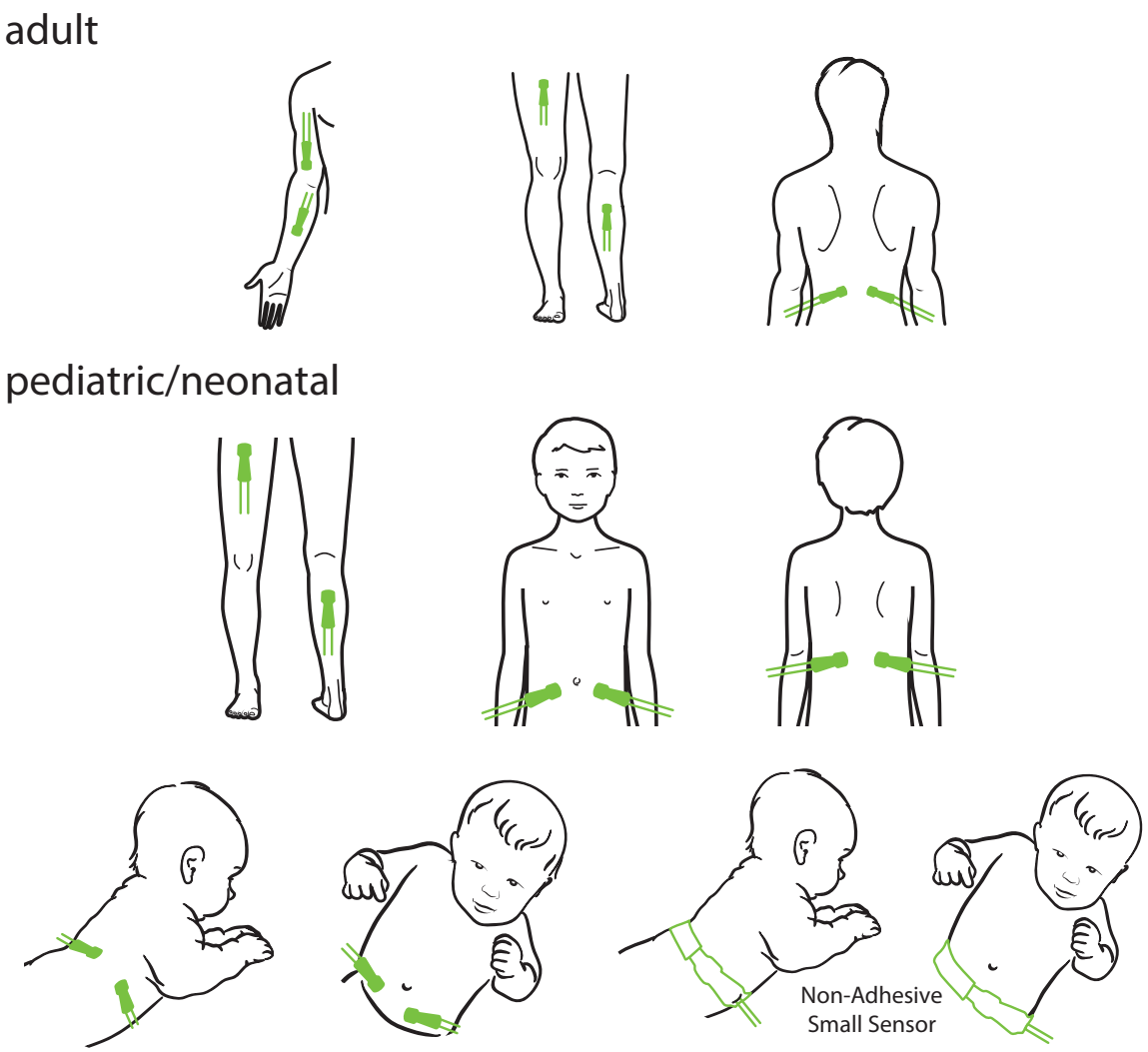



**Figure 17:** Sensor Placement (Non-Cerebral)

## Connecting Sensors to the Preamp Cables

1. Be sure that all necessary Preamp cables are fully connected and that Sensors are placed correctly on the patient's skin.
2. Use the clips on the Preamp cable to secure it to prevent the cable or Preamp from being pulled away from the patient.

| | |
|---|---|
| **Warnings:** | When used in settings with LED lighting, Sensors may need to be covered with a light blocker prior to connection to the Preamp cable, as some high intensity systems can interfere with the Sensor's near infrared light detection.<br>Do not connect more than one patient to the Oximeter.<br>As with all medical equipment, carefully route and secure all cables to reduce the risk of patient entanglement or strangulation.<br>Do not lift or pull the Oximeter by any cable, or place the Oximeter or accessories in any position that might present a risk that the Oximeter may fall on the patient, bystander or operator |

3. Position the Sensor connector in front of the Preamp Sensor connector and align the marks on each (Figure 18).

   By default, Channel 1 is assigned to the patient's left cortex and Channel 2 to the right. See *Configuring the Sensor Location* on page 44 to assign a different location or configure an additional channel.
4. Gently push the Sensor connector straight into the Preamp Sensor connector until it snaps into place.

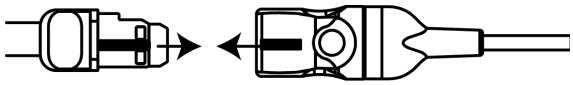


**Figure 18:** Connecting a Sensor to the Preamp Cable

5. Verify that the Channel ID indicator on the Preamp housing changes to green when the Sensor is connected (Figure 19).

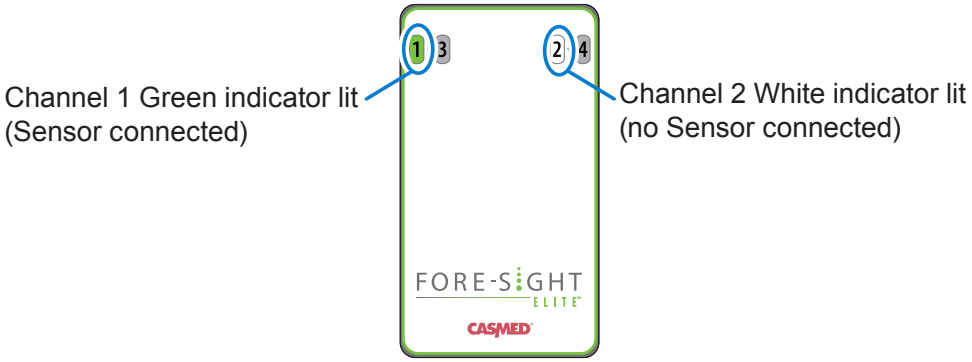



**Figure 19:** Sensor connected to Channel 1

## Reading the Oximeter Display

The Oximeter has a touchscreen display that displays patient monitoring data and provides access to on-screen Oximeter functions. Figure 20 shows the primary areas of the display.

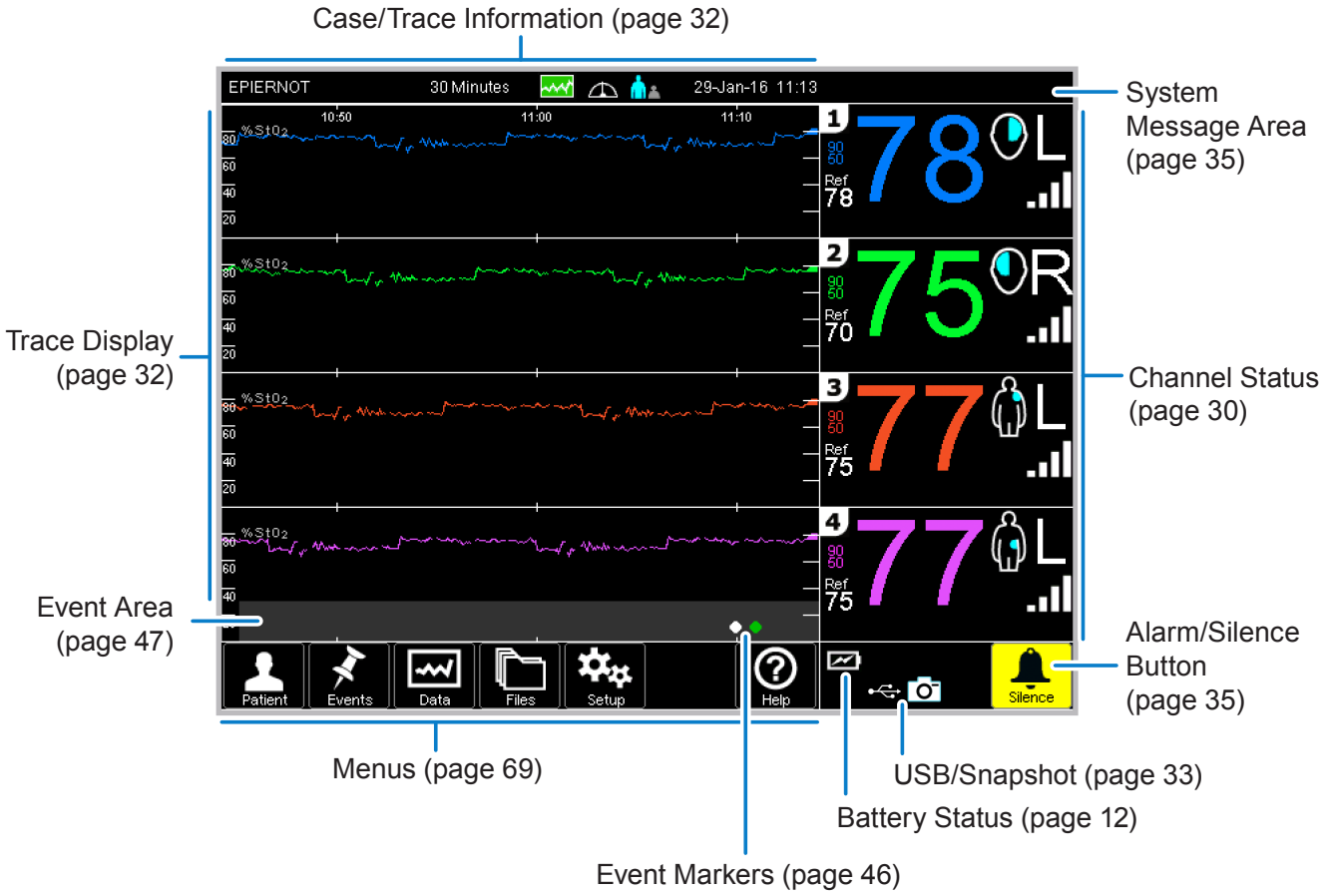



**Figure 20:** Oximeter Display — Main Areas

| **Caution:** | Pressing on the Oximeter display with a sharp or pointed instrument may permanently damage the touchscreen membrane. Use your finger only. |
|---|---|

## Reading the Channel Display

Figure 21 shows a sample Channel 2 Status display as it would appear in a 2-Channel monitoring session; the channel in a 4-Channel session would contain the same components, displayed in half the vertical space.

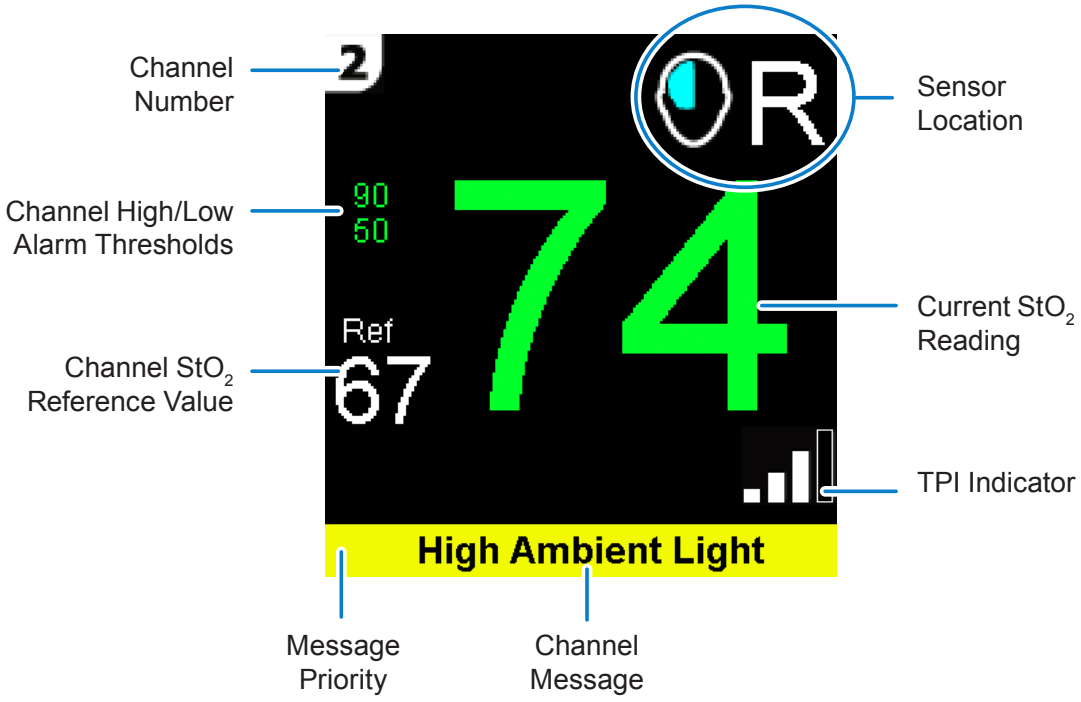



**Figure 21:** Channel Status Indicators

This area displays the following information:

**Table 6:** Channel Status Indicators

| Item | Description |
|---|---|
| Channel Number | Identifies the channel from which Sensor data is being reported. Data elements associated with a channel (Sensor Location, $StO_2$ Reading, High/Low Thresholds, the Trace, and Reference Value line) are all displayed in the same color. |
| Sensor Location | Identifies the Sensor location being monitored. Touch the location icon to change it (see *Configuring Channel Settings* on page 43). |
| $StO_2$ Reading | Displays the current %$StO_2$ (oxygen saturation) level in the location being monitored. Touch the level to set the limits (see *Configuring $StO_2$ Alarm Limits* on page 45) |
| Channel High/ Low Alarm Limits | Displays the upper and lower $StO_2$ limits outside which an alarm will sound. Touch the numbers to change the limits (see *Configuring $StO_2$ Alarm Limits* on page 45). |
| Channel $StO_2$ Reference Value | Displays the most recent $StO_2$ Reference Level saved (see *Resetting the Reference Level* on page 42). Touch the Reference Level to toggle a visual indicator. |
| TPI Indicator | Displays the Tissue Perfusion Indicator, a measure of the data quality being read (see *Monitoring TPI* on page 31). |
| Channel Message & Priority | The bar at the bottom of each Channel Status area displays any system messages specific to that channel, the priority of which is indicated by the colors of the message text and background (see *Responding to Alarms and Messages* on page 35). |

## Monitoring TPI

The Tissue Perfusion Index (TPI) indicator represents the amount of hemoglobin in the tissue under a Sensor and is graphically represented near the $StO_2$ value (see Table 7).

The TPI level is useful for assessing a Sensor site and should be 3 to 4 bars in normal operation.

- If the TPI level changes to 2 bars, verify proper Sensor contact and assess the site for reliability (e.g., presence of edema).
- For subjects that become hemodiluted during monitoring, a decrease in the TPI level is likely (e.g., during initiation of cardiopulmonary bypass, CPB).
- If 1 bar is present, the Sensor must be moved to a location with a higher TPI level. After 10 seconds this condition may trigger a warning message and $StO_2$ values will become dashes.

**Table 7:** Tissue Perfusion Index (TPI) Indications

| Symbol | Description |
|---|---|
|  | NONE (four Gray bars) No Sensor or Preamp connected or Sensor and Preamps connected, but Sensor off patient. |
|  | POOR (one White bar & three Gray bars) Indicates that the Sensor should be moved as monitoring will soon stop. After 10 seconds, this condition triggers the “Check tissue under Sensor” message and $StO_2$ values become two dashes, “--”. |
|  | FAIR (two White bars & two Gray bars) If seen when first placing the Sensor, reposition to achieve a GOOD or EXCELLENT level. If TPI reduces to FAIR during monitoring, verify that the Sensor is well adhered and assess the site for reliability, e.g., edema. |
|  | GOOD (three White bars & one Gray bar) For subjects that become hemodiluted (e.g., initiation of CPB), the TPI may decrease; this change in level is understandable without need to assess the Sensor site. |
|  | EXCELLENT (four White bars) Ideal monitoring state. For subjects that become hemodiluted (e.g., initiation of CPB), the TPI may decrease; this change in level is understandable without need to assess the Sensor site. |

## Reading the Trace Display

Figure 22 shows a sample upper Trace Display for a 4-channel monitoring session.

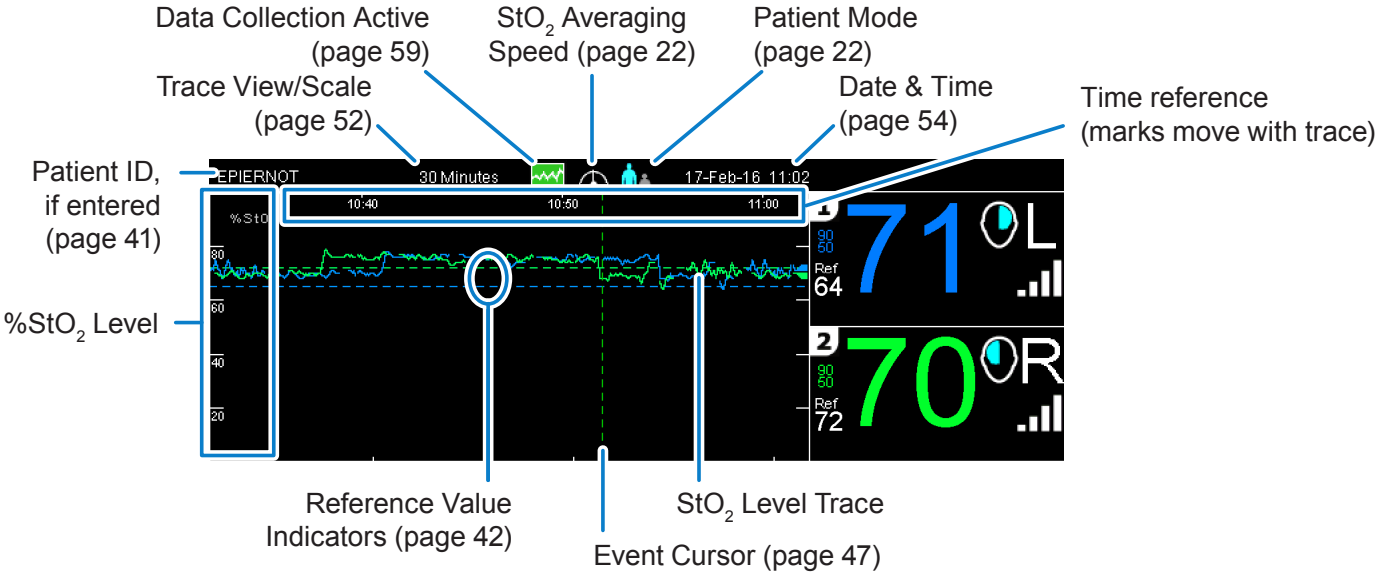



**Figure 22:** Trace Display Elements

The traces show the %$StO_2$ (oxygen saturation) level over time for the channel being monitored, and each trace is color-coded to match that of its associated channel.

When one or two channels are connected (e.g., ①+② or ②+③, the traces are shown in the upper and lower portion of the display. When three or four channels are connected, the upper portion of the display shows ① and/or ②, and the lower portion shows ③ and/or ④.

## Changing the Trace Display Mode

You can toggle the display for each channel pair to show the trace display in separate areas or overlapping each other. For 2-channel monitoring, touch anywhere in the trace area to toggle between individual and overlay modes (Figure 23).

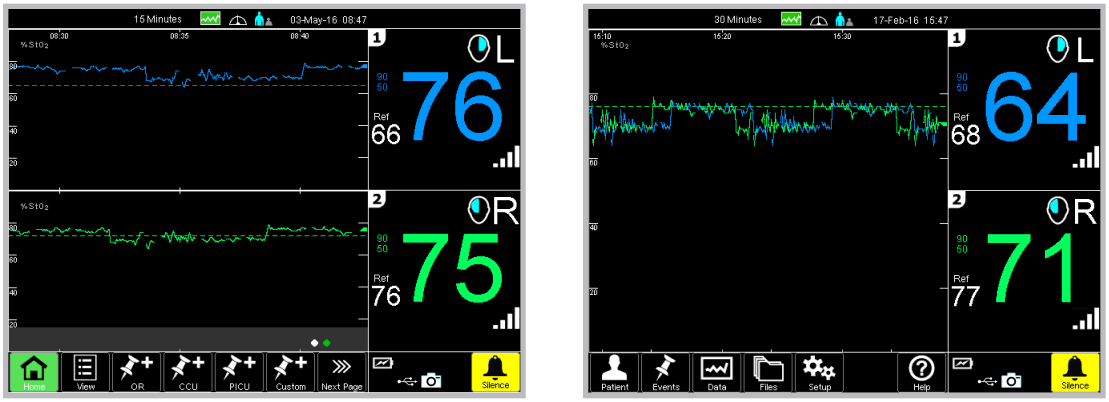



**Figure 23:** 2-Channel Display Modes

For 4-channel monitoring (Channels ①-④, or some combination of [① or ②] + [③ or ④]), touch the upper or lower half of the trace area to toggle that section between separate and overlay views; each pair can be toggled independently (Figure 24).

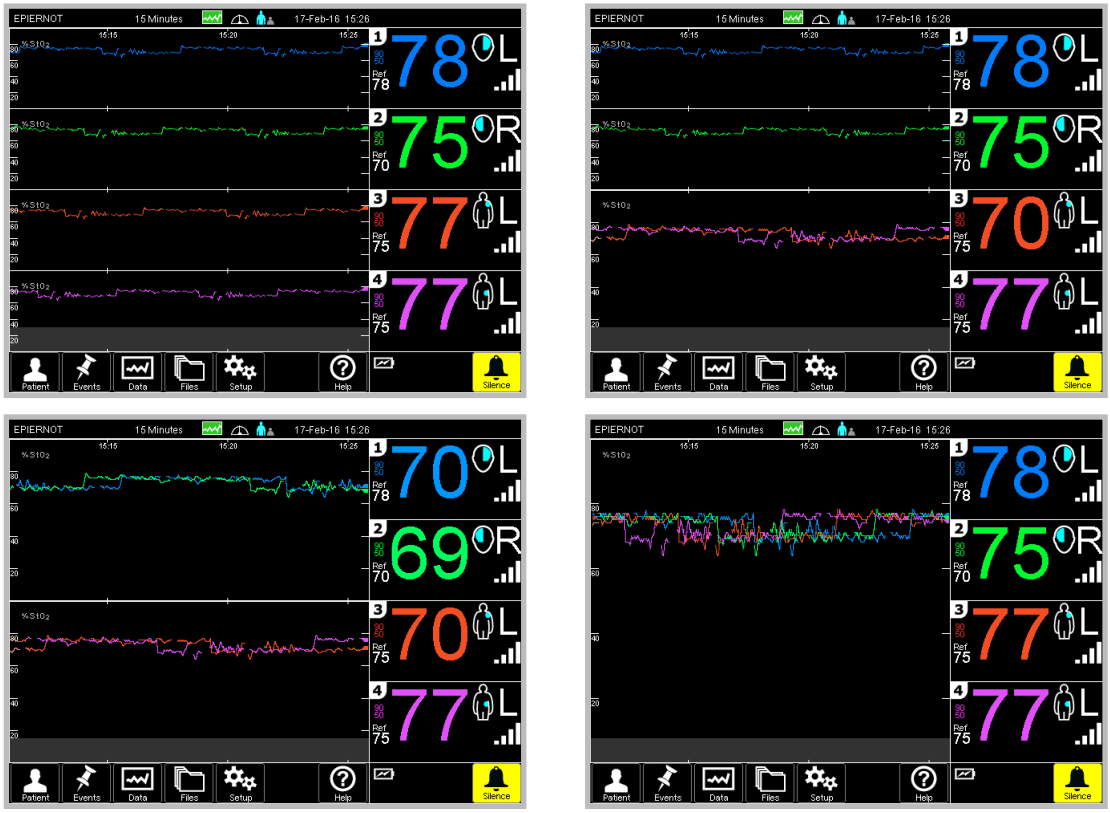



**Figure 24:** 4-Channel Display Modes

## Capturing the Oximeter Display

The Oximeter's snapshot function allows you to save screen captures to a USB flash drive during patient monitoring.

To save a snapshot of the Oximeter display:

1. Insert a CASMED-approved USB flash drive into one of the two USB ports; you may use either the front or rear USB port, though only one may be active at a time.
2. Verify that the USB icon ( ) appears in the lower-right corner of the display (to the left of the / button).
3. Touch the camera icon (which appears next to the USB icon) to save a snapshot.

   The capture takes approximately 5-10 seconds, during which the camera icon is highlighted ( ) and the display is frozen. The camera icon returns to normal after a bitmap (.bmp) image of the display is saved to the USB drive.

# Starting a New Case

The Oximeter collects and saves patient data continuously into individual files that can be downloaded and analyzed (see *Managing Patient Data Files* on page 61).

When a new patient case is started, the following events occur:

- Any data from the previous patient is saved and stored
- STS data storage is stopped and erased
- The Patient ID is reset
- The Skin Check timer is reset
- New patient data will start to be saved (previously configured Sensor locations are used)

To initiate a new case from the Main Menu, touch **Patient** and then touch **New Patient**.

| | |
|---|---|
| **Note:** | If the Oximeter cannot read Sensor data properly after starting a new patient, the message “Verify Sensors are properly applied to the patient” may be displayed.<br>Confirm that Sensors are properly adhered to the patient and then touch ✔ to dismiss the message and begin monitoring. |

The Oximeter automatically starts a new patient case when you start monitoring after it has been more than 30 minutes since data was collected, whether or not the Oximeter was powered on.

| | |
|---|---|
| **Note:** | The Oximeter prompts whether it should create a new patient case when:<br>• The Oximeter is powered on after it has been off for less than 30 minutes<br>• Sensor locations are changed<br>• A new Patient Mode is selected<br>Touch ✔ to start a new case, or touch ✘ to continue with the same case. |

# Responding to Alarms and Messages

When an alarm condition occurs, or when a system message is generated, the Oximeter may signal it with both auditory and visual indicators, depending on the type of alarm/message and its priority (Figure 25).

Table 8 describes the Oximeter alarm and message priorities, and their corresponding auditory and visual signals. Note that an alarm of any level supersedes that of any level below it.

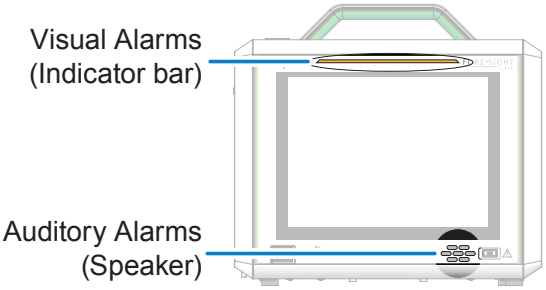



**Figure 25:** Auditory and Visual Alarms

**Table 8:** Auditory and Visual Alarm Indicators by Message Type

| Alarm Message | Auditory Indicator | Visual Indicator |
|---|---|---|
| **High-Priority Alarm (White on Red)** | 10 pulses @ 970 Hz, repeating every 10 seconds | Flashing red indicator |
| **Medium-Priority Alarm (Black on Yellow)** | 3 pulses @ 575 Hz, repeating every 20 seconds | Flashing yellow indicator |
| **Low-Priority Alarm (Yellow on Black)** | 1 pulse @ 575 Hz | Steady yellow indicator |
| **Informational Message (White on Black)** | None | None |

See Appendix B, *Alarms and Messages*, on page 73 for a complete list of alarms and messages, and recommended actions should they occur.

**Warning:** Avoid placing anything in front of the Oximeter that might cause the speaker output to be muffled.

**Note:** For proper identification of the Oximeter Alarm signals, the operator should be positioned directly in the front of the Oximeter, facing the front panel.

## Silencing Alarms

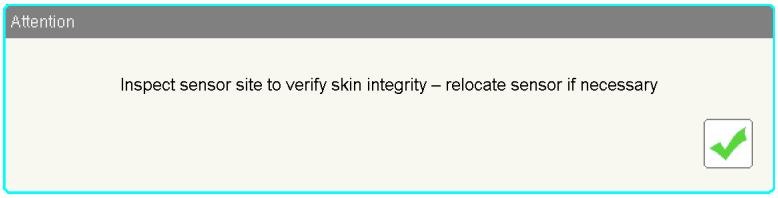
You can temporarily silence the audible alarm by touching **Silence** in the lower-right corner of the display. The Alarm Silenced icon appears and counts down from 2 minutes, during which all audible alarms are silenced (but visual indicators, if any, remain active). When the timer reaches zero, the Alarm Silenced icon disappears and audible alarms are re-enabled. You can also re-enable alarms by touching **Silence** again.

*Configuring Auditory Feedback* on page 57 describes how to adjust the system volume level and alarm delay.

## Checking Sensors

Sensor sites must be inspected at least every 12 hours to reduce the risk of inadequate adhesion, circulation, and skin integrity. If the circulatory condition or skin integrity has deteriorated, the Sensor should then be applied to a different site.

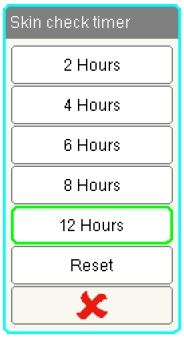
The Oximeter has a Skin Check timer that, by default, displays the following reminder every 12 hours:




Touch ✔ to acknowledge the message and reset the timer.

You may also reset the timer manually or change the timer interval on a per-patient basis:

1. From the Main Menu, touch **Patient** and then touch **Skin Check**.




**Note:** If you do not see Skin Check on the Patient menu, it has been disabled. It can be enabled through the Skin Check configuration option on the Biomed submenu as described in *Setting the Skin Check Timer* on page 55. CASMED recommends that the Skin Check timer should always be enabled.

2. Touch a new Skin Check interval to select it and reset the timer, touch **Reset** to reset the timer without changing the Skin Check interval, or touch ✘ to cancel.

# Monitoring Considerations

## Oximeter Use During Defibrillation

| | |
|---|---|
| **Warnings:** | The Oximeter has been designed to promote patient safety. All Oximeter parts are “Type BF Defibrillation Proof” and are protected against the effects of the defibrillator discharge and may remain attached to the patient. Oximeter readings may be inaccurate during defibrillator use and up to twenty (20) seconds thereafter.<br>No separate actions are required when using this equipment with a defibrillator, but only CASMED-supplied Preamp cables and Sensors must be used for proper protection against the effects of a cardiac defibrillator.<br>Do not come into contact with patients during defibrillation, or serious injury or death could result. |

## Interference

| | |
|---|---|
| **Warnings:** | Measurements may be affected in the presence of strong electromagnetic sources such as electro-surgery equipment, and measurements may be inaccurate during use of such equipment.<br>Elevated levels of carboxyhemoglobin (COHb) or methemoglobin (MetHb) may lead to inaccurate or erroneous measurements, as may intravascular dyes or any substance containing dyes that change usual blood pigmentation. Other factors that may affect measurement accuracy include: myoglobin, hemoglobinopathies, anemia, pooled blood under the skin, interference from foreign objects in the Sensor path, Bilirubinemia, externally applied coloring (tattoos), and birthmarks. |

## Flammable Substances

| | |
|---|---|
| **Warning:** | There is a risk of an explosion hazard if a damaged Oximeter or accessory is used in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide. |

## Interpreting $StO_2$ Readings

| | |
|---|---|
| **Warnings:** | The Oximeter is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.<br>If the accuracy of any value displayed on the Oximeter is questionable, determine the patient's vital signs by alternative means. The functions of the Alarm system for patient monitoring must be verified at regular intervals and whenever the integrity of the product is in doubt. **Testing of the Alarm operation should be done at least once every 6 months, as described in *Testing Alarm Operation* on page 65**. Failure to comply may lead to injury.<br>If the Oximeter fails to respond, it must not be used until it has been inspected and serviced or replaced by CASMED-authorized personnel. |

| | |
|---|---|
| **Note:** | For patients experiencing complete bilateral external carotid artery (ECA) occlusion, measurements may be lower than expected. |

Table 9 summarizes the validation methodology associated with the FORE-SIGHT ELITE Oximeter:

**Table 9:** $StO_2$ Validation Methodology

| Patient Population | FORE-SIGHT Sensor | Cerebral Reference | Non-Cerebral Reference | Type Measurement | Subject Weight Range |
|---|---|---|---|---|---|
| Adult | Large | Co-oximetry of jugular bulb and arterial blood samples | Co-oximetry of central venous and arterial blood samples | Single Point | ≥ 40 kg |
| Pediatric – Adolescents, Children, Infants, & Neonates | Medium | Co-oximetry of internal jugular vein and arterial blood samples | Co-oximetry of central venous and arterial blood samples | Single Point | ≥ 3 kg |
| Pediatric – Adolescents, Children, Infants, & Neonates | Small | Co-oximetry of internal jugular vein and arterial blood samples | Co-oximetry of central venous and arterial blood samples | Single Point | 3 to 8 kg |
| Pediatric – Neonates (Term, Premature, Low Birth Weight, Very Low Birth Weight) | Small | FORE-SIGHT MC3010[1] | Co-oximetry of umbilical venous and pulse oximetry samples | $StO_2$ data averaged in two-minute windows[2] | ≤ 5 kg |

[1] Unlike the other FORE-SIGHT ELITE validation studies, this cerebral validation study did not include invasive measurements because of the challenge for medical centers to obtain consent to insert an internal jugular venous catheter in very small subjects.

[2] $StO_2$ data was averaged in two-minute windows for term, premature low birth weight (LBW), and very low birth weight (VLBW) neonates for the following reasons: 1) to reduce the influence of acute changes in $StO_2$ due to changes in body position or touch as the hemodynamics in premature LBW and VLBW neonates are not as stable compared to normal birth weight neonates, and 2) to enable measurements for both FORE-SIGHT MC3010 and FORE-SIGHT ELITE sensors or across multiple abdominal locations at nominally the same time for the smallest neonates for which only one sensor can be fitted on the head or specific abdominal location at a time.

## Measurement Accuracy

### Cerebral Accuracy

Accuracy (Bias ± Precision) not determined outside the following ranges:

| | |
|---|---|
| Large Sensors: | 45% to 95%: -0.14 ± 3.05% at 1 SD |
| Medium Sensors: | 48% to 92%: 0.05 ± 5.06% at 1 SD |
| Small Sensors: | 50% to 90%: -0.01 ± 5.38% at 1 SD |

### Non-Cerebral Accuracy

Accuracy (Bias ± Precision) not determined outside the following ranges:

| | |
|---|---|
| Large Sensors: | 45% to 95%: 0.24 ± 5.17% at 1 SD |
| Medium Sensors: | 53% to 88%: -0.03 ± 5.52% at 1 SD |
| Small Sensors: | 66% to 96%: 0.03 ± 5.69% at 1 SD |

# Disconnecting Sensors After Monitoring

Once you are done monitoring a patient, you need to remove the Sensors from the patient and disconnect the Sensors from the Preamp cable. Optionally, you can disconnect the Preamp cable from the Oximeter (see *Disconnecting the Preamp Cables* on page 15), but most medical personnel prefer to keep the cable connected to the machine.

Disconnect each Sensor as follows:

1. Slowly and carefully peel the Sensor away from the patient to avoid damaging the skin.
2. Grasp the connector end of the Sensor and gently pull it straight out of the Preamp cable connector (Figure 26).

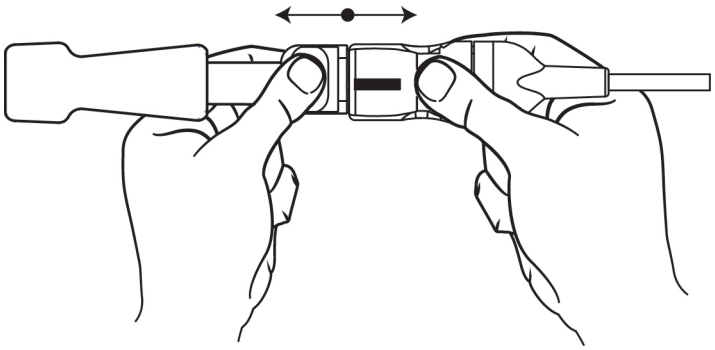


**Figure 26:** Disconnecting a Sensor from the Preamp Cable

3. Discard the Sensor.

| | |
|---|---|
| **Warnings:** | Sensors are designed for single-patient use, and are not to be reprocessed — re-used Sensors present a risk of cross-contamination or infection.<br>Discard Sensors after use. Disposal should follow in accordance with local hospital and institution policies. |

# Chapter 4
# Additional Monitoring Tasks

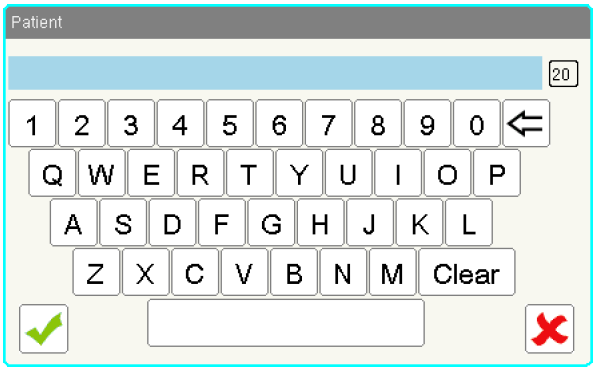
This chapter describes optional tasks (those not part of the core workflow) that you might perform during a monitoring session.

## Entering a Patient ID

Patient IDs are optional. If entered, it appears on the left side of the display, above the Trace area. It is also used to identify patient data files (in addition to the file date; see *Managing Patient Data Files* on page 61).

1. Touch the upper-left corner of the display, above the Trace area, to display the keyboard.

   You can also display it from the Main Menu by touching **Patient** and then touching **Patient ID**.

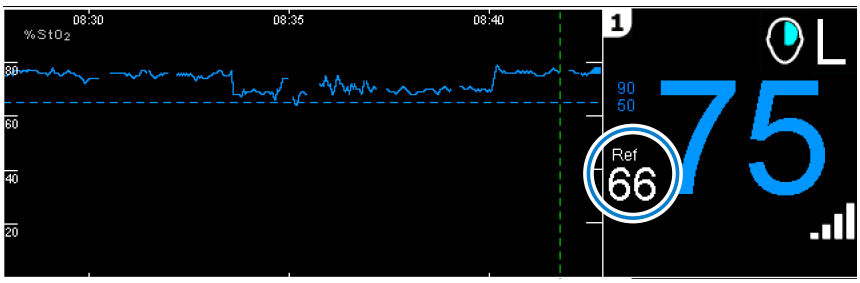



2. Enter up to 20 characters.
3. Touch ✔ to save the Patient ID or touch ✘ to cancel.

# Resetting the Reference Level

When $StO_2$ readings are first detected for a new patient, a reference level for each active channel is automatically set and displayed in the lower left corner of each Channel Status area. Reference values are preserved for the duration of a patient case, until a Sensor location is changed, or until another Reference level is set.

The reference level can also be displayed as a horizontal, color-coded dotted line across each channel's trace; touch a channel's Reference value (circled below) to toggle the display. Toggling the Trace Display between individual and overlay modes (page 32) will not affect the reference level display.




If desired, you can manually reset the Reference level:

1. From the Main Menu, touch **Data**.
2. Touch **Reference**.
3. Touch ✔ to reset the Reference value or touch ✘ to cancel.

   If reference levels (horizontal lines) were visible on the Trace Display, they will be re-drawn at the new reference level.

## Configuring Channel Settings

In many cases you can run a monitoring session without modifying the default channel settings, which are shown in Table 10:

**Table 10:** Default Channel Settings

| Channel | Body Location | High Limit | Low Limit |
|---|---|---|---|
| Channel 1 | Left Forehead | 90 | 50 |
| Channel 2 | Right Forehead | 90 | 50 |
| Channel 3 | <Unassigned> | 90 | 50 |
| Channel 4 | <Unassigned> | 90 | 50 |

If you should need to modify these settings, you can display the Patient Setup options by either of the following methods:

- From the Channel Status area, touch the $StO_2$ reading, body location icon (e.g., or ), or High/Low limit indicator (e.g., 90/50).
- From the Main Menu, touch **Patient** and then touch **Setup**.

Figure 27 describes the Patient Setup options.

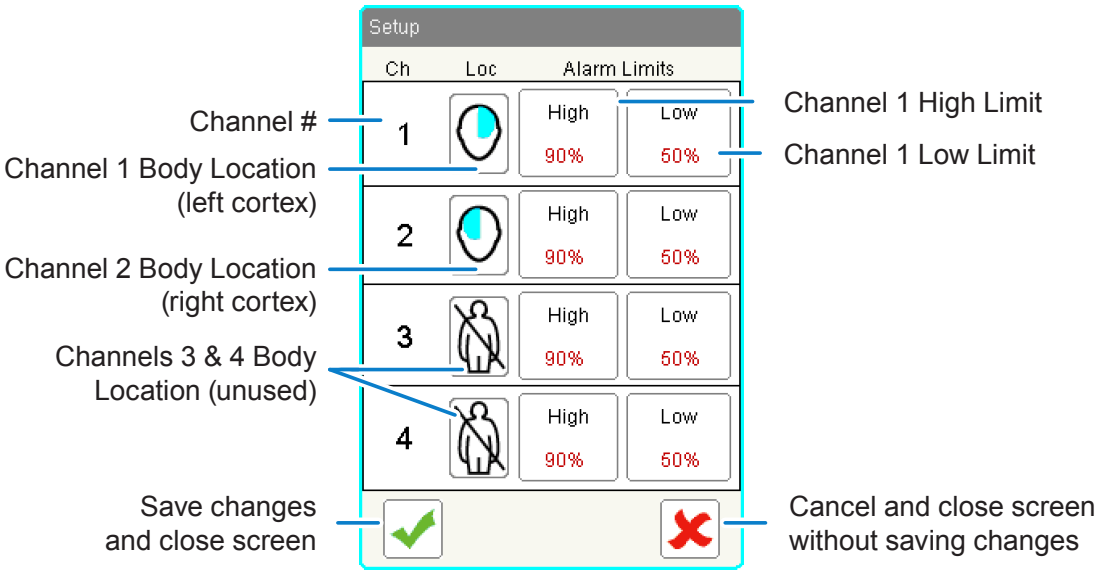



**Figure 27:** Patient Setup Screen

Touching a channel's body location icon or High/Low limit allows you to configure it.

## Configuring the Sensor Location

| **Note:** | The Sensor location setting is used for measurement accuracy, and should be set correctly. To change the Patient Mode, see page 22. |
|---|---|

To change a channel's Sensor location:

1. Access the Patient Setup options by touching a location icon or numeric in the Channel Status area.

   You can also, from the Main Menu, touch **Patient** and then touch **Patient Setup**.
2. Touch the location icon for the channel you wish to assign to view the available locations.
3. Touch the new location (or to unassign it) to select it and return to the previous screen.

   Figure 28 and Figure 29 describe the Sensor location options for each Patient Mode.

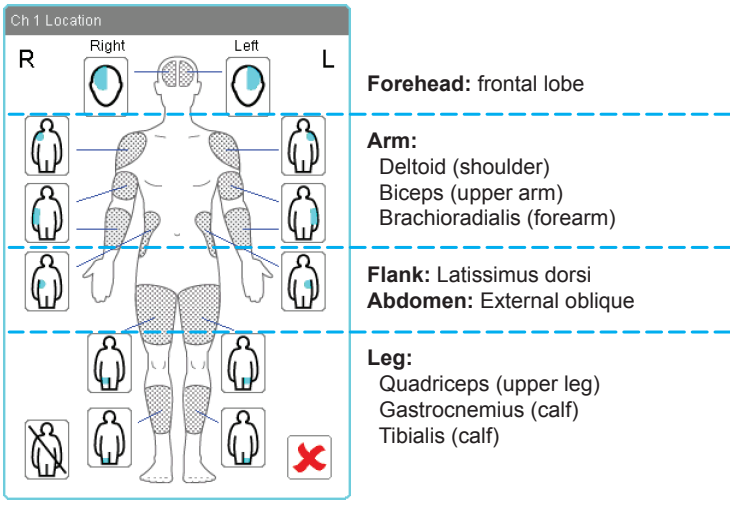



**Figure 28:** Sensor Location Setup Screen (Adult Mode)

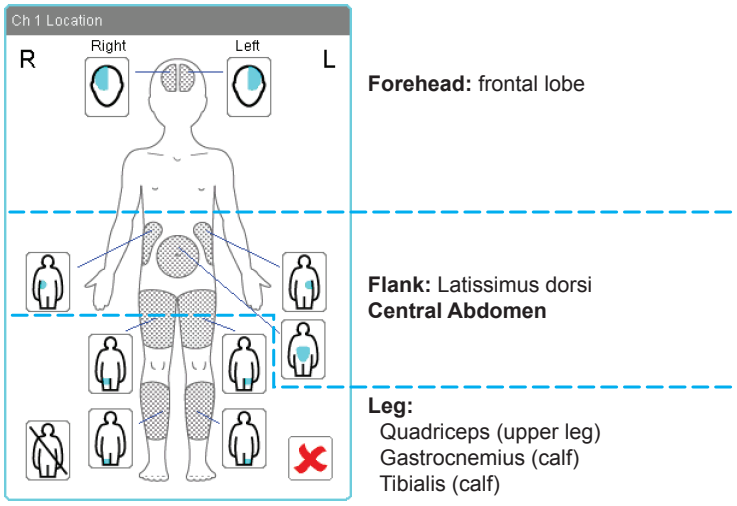



**Figure 29:** Sensor Location Setup Screen (Pediatric Mode)

4. Touch ✔ to save your changes, or touch ✘ to cancel.

Note that, after selecting a new Sensor location, the Oximeter prompts you to start a new patient case — touch ✔ to start a new case, or touch ✘ to continue the current case.

## Configuring $StO_2$ Alarm Limits

$StO_2$ limits (both low and high) can be set independently for each channel. The default values are 50% (low) and 90% (high), and any $StO_2$ reading outside that range will trigger an alarm. The values can be adjusted if necessary.

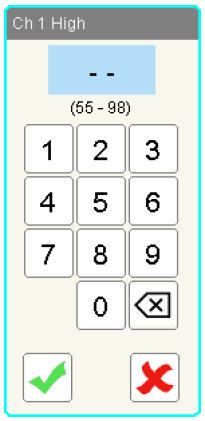
| | |
|---|---|
| **Cautions:** | Setting the Low Alarm limit to an extremely low value can render the Low Limit detection ineffective.<br>Likewise, setting the High Alarm limit to an extremely high value can render the High Limit detection ineffective. |

To change an $StO_2$ alarm limit:

1. Access the Patient Setup screen by touching a numeric or location icon in the Channel Status area.

   You can also, from the Main Menu, touch **Patient** and then touch **Patient Setup**.

2. Touch the button for the channel limit you wish to modify.




3. Use the keypad to enter the new value.

   Allowable ranges are 3-93 for Low and 8-98 for High.

| | |
|---|---|
| **Note:** | For a given channel, the High cannot be set lower than the Low or vice-versa. There must be a minimum 5% difference between the Low and High limits. |

4. Touch ✔ to save your changes and close the Patient Setup screen, or touch ✘ to cancel.

# Marking Events

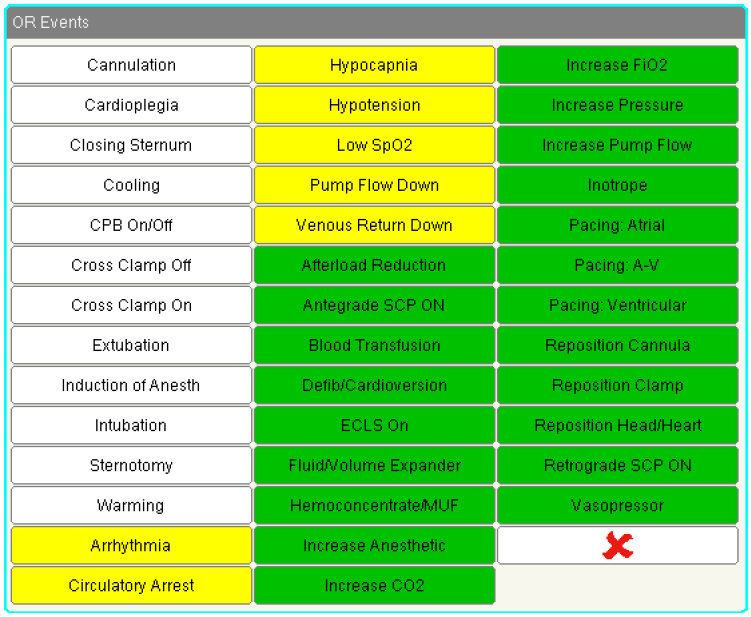
This section how to add events to the Trace view, how to navigate the event area, and how to create and manage custom events.

## Placing Event Markers

During the course of a monitoring session, medical procedures or other events that occur may affect $StO_2$ levels. To help reconcile these changes you can "place" markers (up to 30) on the Trace view to identify events that occur during the monitoring session.

To place a marker:

1. From the Main Menu, touch **Events**.
2. Touch to display a list of **OR**, **CCU**, **PICU**, or **Custom** events; touch **Next Page** to access the **Vascular** list.




Events are listed alphabetically, and are color-coded as shown in Table 11. See Appendix C, *Event Index* on page 79 for a complete list of events in each category, and *Creating Custom Events* on page 49 to create your own events.

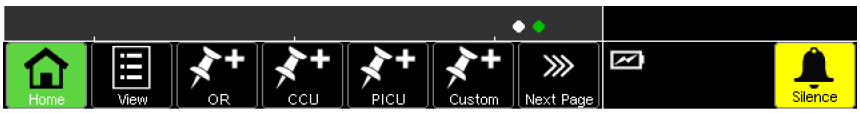
**Note:** Event markers for Pediatric Mode are in the PICU list.

**Table 11:** Event Color Codes

| Event Color | Definition |
|---|---|
| Unshaded | Relatively routine events |
| Yellow | "Cautionary" events that could cause ischemia |
| Dark Green | Interventions taken |
| Light Green | Custom events |

3. Touch an event to place it, or touch ✘ to cancel.

   Once placed, a marker is placed at the lower-right corner of the Trace area (that is, at the current time). Marker colors correspond to the Event colors. If you select the wrong event or add an event by mistake, you can delete it by touching the event marker to display the Event Navigator and then touching 🗑.




## Navigating the Event Area

The Event area (Figure 30) is a gray stripe at the bottom of the Trace display. Color-coded Event markers for events placed in real-time (via the 📌+ buttons) appear in this area, as do others that you may place afterward. Touch anywhere in the Event area to place the cursor (dashed green line) there and display the Event Navigator; touching close to an event marker will position the cursor on that event.

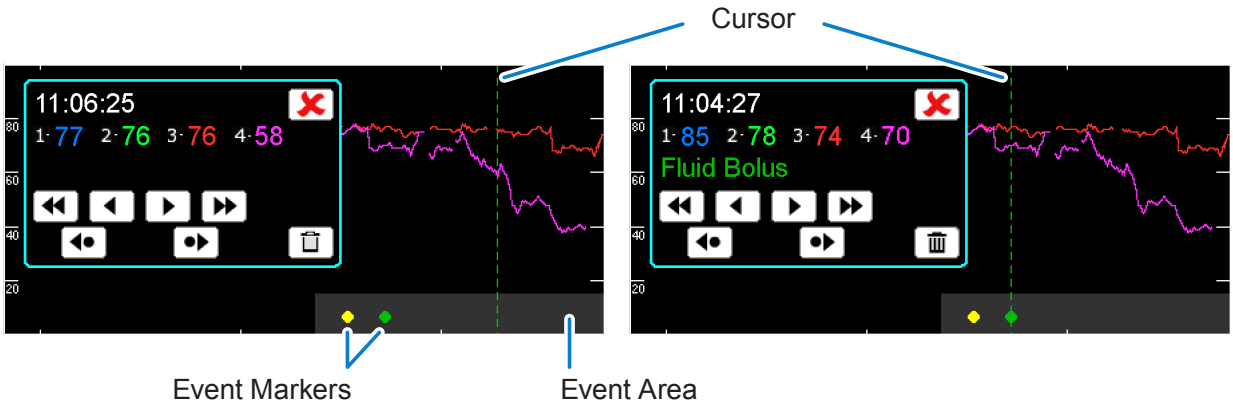



**Figure 30:** Event Area

The Event Navigator (Figure 31) displays the time, channel values, and event (if any) at the cursor location, and provides a number of navigation options (Table 12).

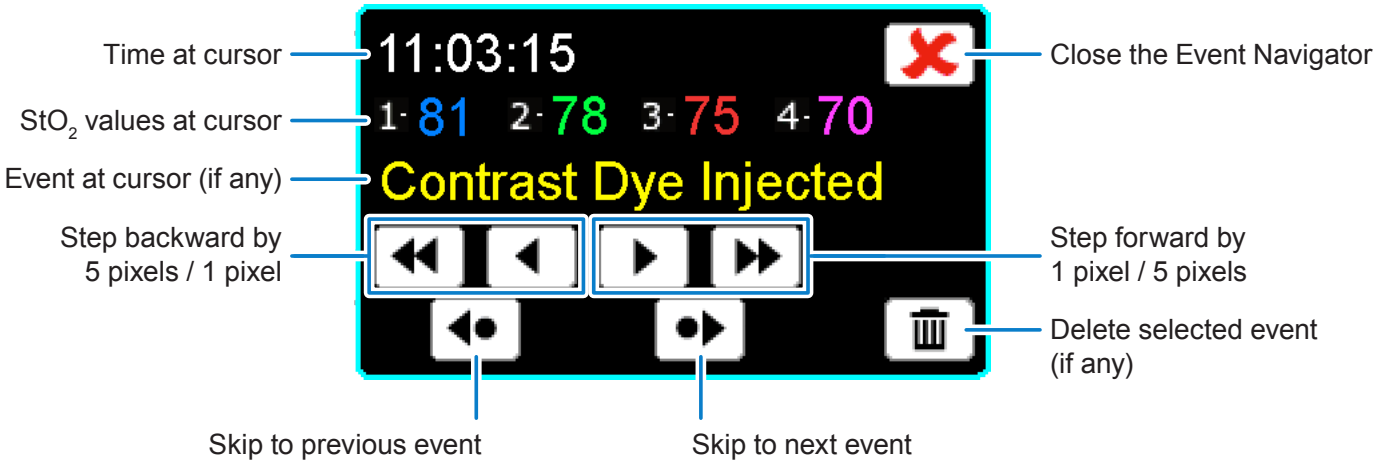



**Figure 31:** Event Navigator

To move the Event Navigator, touch and drag the panel to a new location; touch ✘ to close it.

**Table 12:** Event Navigator Functions

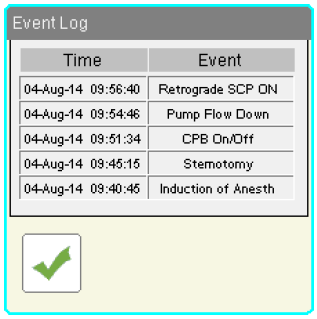
| Button | Description |
|---|---|
| ◀ / ▶ | Moves the cursor in either direction by 1 pixel (approximately 4 seconds, based on the 30-minute Trace View default; the time increment scales accordingly). |
| ◀◀ / ▶▶ | Moves the cursor in either direction by 5 pixels (approximately 20 seconds, based on the 30-minute Trace View default; the time increment scales accordingly). |
| ◀● / ●▶ | Moves the cursor to the next event in either direction.<br>These buttons are disabled if there are no events visible in the current Trace view; change the Trace View scale (page 52) to see older events. |
| 🗑 | Deletes the event at the cursor position. This button is disabled if the cursor is not positioned on an event. |

## Viewing the Event Log

The Event Log displays all events for the current patient, beginning with the most recent.

To display the Event Log:

1. From the Main Menu, touch **Events**.
2. Touch **View**.




Touch ✔ to dismiss the Event Log.

## Creating Custom Events

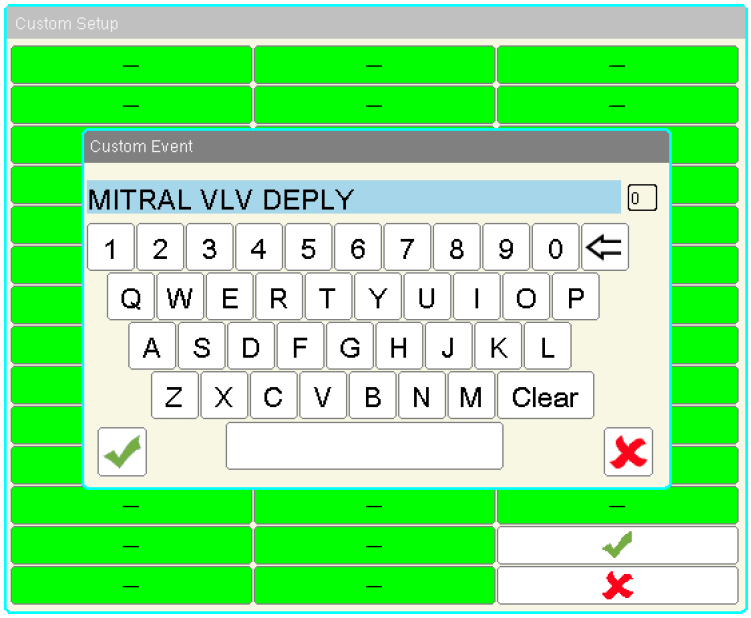
In addition to the main event lists (OR, ICU, PICU, and Vascular), you can create and manage a list of custom events. (To import a new or existing set of events, see *Importing Custom Events* on page 51.)

To create a custom event from the Oximeter:

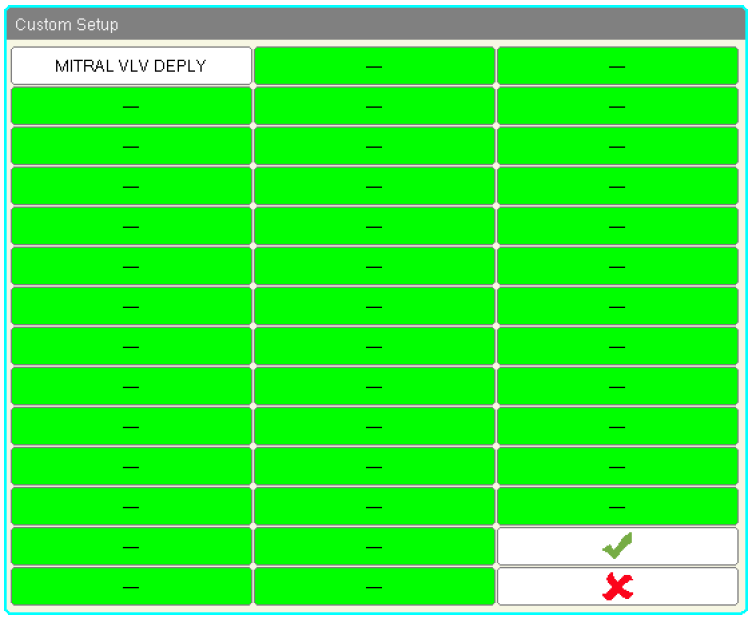
1. From the Main Menu, touch **Events**.
2. Touch **Next Page**.
3. Touch **Custom**.

   The Custom Setup screen appears. If this is the first time you have added custom events, it appears blank:


4. Touch an unused event slot to display the Custom Event keyboard.
5. Enter an event name (up to 16 characters) and touch ✔ to add the event.



6. Add additional events as needed; touch ✔ when you are done adding events.




When you place a custom event (touch **Events** and then touch **Custom**), the Custom Events screen allows you to choose from the configured events:


## Editing Custom Events

To edit a custom event name from the Oximeter:

1. From the Main Menu, touch **Events**.
2. Touch **Next Page**.
3. Touch **Custom**.
4. Touch the event you wish to edit.
5. Touch ✔ to acknowledge that the event name will be changed in the patient file.
6. Edit the event name and touch ✔.
7. Touch ✔ to close the Custom Setup screen.

## Exporting Custom Events

You can export the Oximeter's custom event configuration into a text file (described in *Importing Custom Events* on page 51) that you can edit offline or import into other Oximeters.

To export custom events:

1. Insert a CASMED-approved USB flash drive into the USB port.
2. Verify that the USB icon ( ) is displayed in the lower-right corner of the display.
3. From the Main Menu, touch **Events**.
4. Touch **Next Page**.
5. Touch **Export**.
6. Follow the prompts to export the custom event file.

   A text file named *events.txt* is saved to the USB drive.

## Importing Custom Events

You can create a list of custom events (or modify a previously exported list) using any text editor, and then import that list onto an Oximeter.

Create a plain text file named *events.txt* (in either UNICODE or ASCII format), and type one event per line:

- Only the first 40 events will be imported
- Event names longer than 16 characters will be truncated
- Leading and trailing spaces will be removed; empty lines will be ignored
- Characters not found in the Oximeter font set will be displayed as "-", but the original text file is not altered and will still be present if exported

Note that changing the Oximeter language (page 53) does not affect the Custom Events list.

To import a set of custom events:

1. Insert a CASMED-approved USB flash drive into the USB port.

   The *events.txt* file must be present at the root level.
2. Verify that the USB icon ( ) is displayed in the lower-right corner of the display.
3. From the Main Menu, touch **Events**.
4. Touch **Next Page**.
5. Touch **Import**.
6. Follow the prompts to import the custom event file.

# Adjusting Display Settings

This section describes some of the Oximeter display settings that you may adjust.

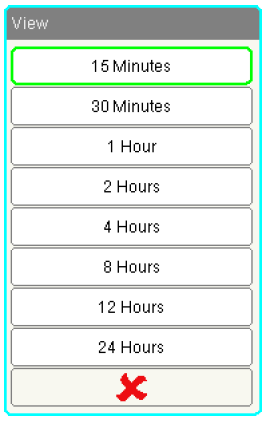
## Changing the Trace View Scale

The time scale for the Trace area is displayed above the Trace area, and is set at 30 minutes by default. You can view more or less historical trace data at once by changing the scale:

1. Touch the Trace time scale at the top of the display to display the View settings.

   You may also, from the Main Menu, touch **Setup** and then touch **View**.

   Options range from 15 minutes to 24 hours.

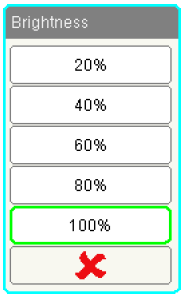



2. Touch the desired time scale to set it, or touch ✘ to cancel.

## Changing the Display Brightness

The Oximeter display brightness defaults to 100%; you can adjust it as necessary per the room's lighting conditions:

1. From the Main Menu, touch **Setup**.
2. Touch **Brightness** to display the Brightness settings.




3. Touch your preferred brightness level to set it, or touch ✘ to cancel.

## Setting the Display Language

The Oximeter's default language is English but can be changed as necessary. Note that, if the Oximeter is reset to factory default settings, that the language setting will *not* be affected.

1. From the Main Menu, touch **Setup**.
2. Touch **Log In** to display the Password keyboard.
3. Enter the password (2466) and touch ✔ to access the Biomed submenu.
4. Touch **Language**.
5. Touch the desired language from the list, or touch ✘ to cancel.

   Language changes take effect immediately.

## Setting the Time and Date

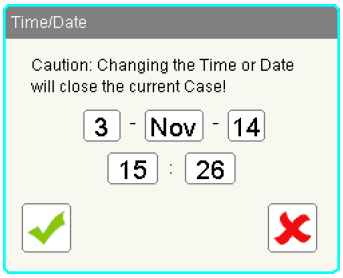
The Oximeter displays the Time and Date at the top of the display at all times, and the Trace View's time markers change to maintain a consistent time reference at the selected scale. The Time and Date settings are also used to name patient data files and in recording patient data and statistics. Note that changing the time or date closes the current patient case and starts another.

An internal clock battery maintains the time even if the Oximeter is without AC or battery power.

1. Touch the current time/date at the top of the display to display the Time/Date settings.

   You may also, from the Main Menu, by touch **Setup** and then touch **Time/Date**.

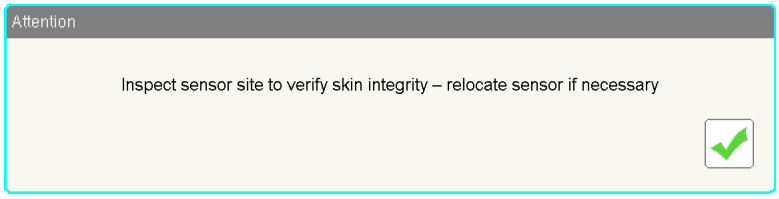
   Each component — month, day, year, hour, and minute — is displayed on its own button.




2. Touch a button to change its respective setting.
   - The Month screen displays a button for each month; touch a month to select it.
   - The other screens each display a number pad that accepts a 2-digit number. Touch the numbers for the current Day (1-31), Year (13-99), Hour (0-23), and Minute (0-59), and then touch ✔.
3. Touch ✔ to close the Time/Date screen and save changes, or touch ✘ to cancel.

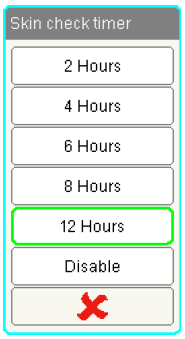
## Setting the Skin Check Timer

Sensor sites must be inspected at least every 12 hours to reduce the risk of inadequate adhesion, circulation, and skin integrity. The Skin Check timer displays the following reminder every 12 hours, by default:




To change or disable the Skin Check timer interval:

1. From the Main Menu, touch **Setup**.
2. Touch **Log In** to display the Password keyboard.
3. Enter the password (2466) and touch ✔ to access the Biomed submenu.
4. Touch **Skin Check**.




5. Touch a new Skin Check interval to select it and reset the timer, touch **Disable** to disable the timer, or touch ✘ to cancel.

   If disabled, the **Skin Check** option will not appear on the Patient menu.

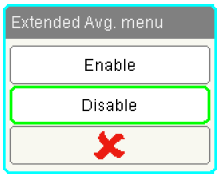
| **Note:** | CASMED recommends that the Skin Check timer should always be enabled.<br>If you enable or disable the Skin Check timer (non-Off selection to Off, or Off to non-Off selection) the Oximeter will automatically power off and restart. |
|---|---|

## Enabling the Extended Averaging Menu

The standard $StO_2$ Averaging modes (see page 22) are Fast, Normal, and Slow. You may enable the extended averaging menu to display a fourth mode, None, which uses the fastest response available.

To enable the extended averaging menu:

1. From the Main Menu, touch **Setup**.
2. Touch **Log In** to display the Password keyboard.
3. Enter the password (2466) and touch ✔ to access the Biomed submenu.
4. Touch **Averaging**.




5. Touch **Enable** to enable the None mode, or touch ✘ to cancel.

   Touching Disable removes the None option; if None is the current mode then it is reset to the default for the current Patient Mode.

# Configuring Auditory Feedback

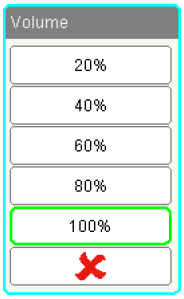
The system volume defaults to 100%, and affects system sounds (such as button clicks) as well as auditory alarms. You can adjust the volume if necessary, and can configure a delay during which auditory alarms will not sound.

You can always silence the audible alarm temporarily by touching **Silence** in the lower-right corner of the display. The Alarm Silenced icon appears and counts down from 2 minutes, during which all audible alarms are silenced (but visual indicators, if any, remain active). When the timer reaches zero, the Alarm Silenced icon disappears and audible alarms are re-enabled. You can also re-enable alarms by touching **Silence** again.

## Setting the System Volume

To adjust the system volume:

1. From the Main Menu, touch **Setup**.
2. Touch **Volume**.




3. Touch the desired volume level, or touch ✘ to cancel.

| | |
|---|---|
| **Warnings:** | Do not rely exclusively on the audible alarm system for patient monitoring.<br>Adjusting the 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.<br>Avoid placing anything in front of the Oximeter that might cause the speaker output to be muffled. |

## Setting the Alarm Delay

By default, when the Oximeter detects an alarm condition or generates a system message that is tied to an auditory alarm, it responds instantly and sounds the appropriate alarm (see Appendix B, *Alarms and Messages* on page 73 for a list of conditions that may trigger an auditory alarm). So, for example, if the Low $StO_2$ limit is set to 50 and the $StO_2$ reading falls below that level, the Low $StO_2$ alarm will sound immediately (0 second delay).

An alarm delay may be set that requires an active alarm condition for some period of time before the alarm sounds. Using the Low $StO_2$ example above, if the alarm delay were set to 10 seconds then the $StO_2$ reading would need to fall below 50 continuously for ten seconds or more before the alarm would sound.

The alarm delay remains constant during any alarm condition; changing the alarm delay affects only future alarms.

To change the alarm delay:

1. From the Main Menu, touch **Setup**.
2. Touch **Alarm Delay**.


3. Touch the desired delay time to set it, or touch ✘ to cancel.

# Chapter 5
# Managing Patient Data

This chapter describes STS Data collection and how to copy patient data files from the Oximeter to a USB flash drive.

## Collecting STS Data

The Oximeter is able to collect data for The Society of Thoracic Surgeons (STS) reporting, which is saved and downloaded with the normal monitoring data for each patient case file (see *Managing Patient Data Files* on page 61).

STS data collection starts automatically with each new patient case, and is indicated by the icon at the top of the display. You can stop and resume STS data collection at any time.

Also, data is collected only for channels that are connected at the time data collection is started; to add (or remove) channels you must stop and then restart data collection.

### Stopping STS Data Collection

To stop data collection:

1. From the Main Menu, touch **Data**.
2. Touch **Stop** and then touch ✔ to confirm.

   The Oximeter displays at the top of the screen (to the right of the view scale) to indicate that data is not being collected.


### Starting STS Data Collection

To resume STS data collection:

1. From the Main Menu, touch **Data**.
2. Touch **Start**.

   The Oximeter displays at the top of the screen (to the right of the view scale) to indicate that data collection has started.

## Viewing STS Data

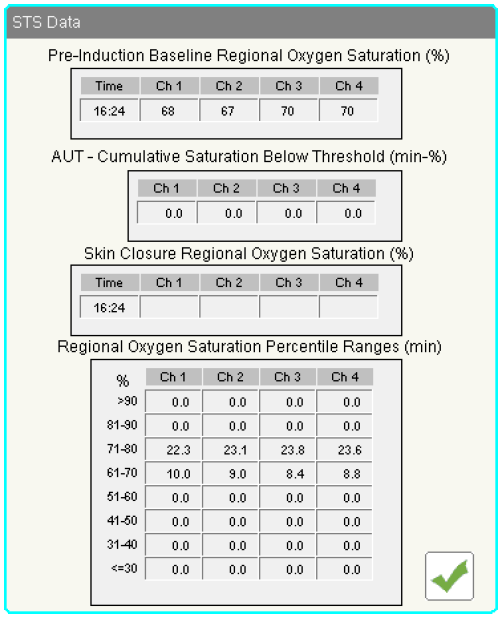
You may view a snapshot of the STS data being collected during a monitoring session either during collection or after collection has stopped.

To view current STS data:

1. Touch the / icon at the top of the screen to display STS Data.

   You can also, from the Main Menu, touch **Data** and then touch **View.**

   This screen summarizes current data. Fields are blank for channels not being monitored.




2. Touch ✔ to dismiss the STS Data screen.

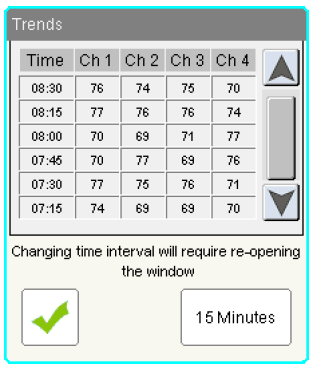
# Viewing Trend Data

You can display $StO_2$ levels for the current patient in tabular form to quantify the trends displayed in each channel's trace view.

To display Trend data:

1. From the Main Menu, touch **Data**.
2. Touch **Tabular**.

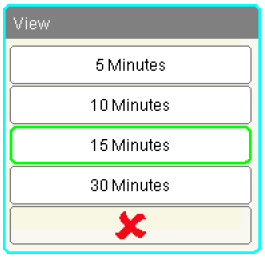
   Data is displayed at the interval shown in the lower-right corner of the Trends screen.




3. Touch ✔ to dismiss the Trends screen.

To change the data interval:

1. From the Trends screen, touch the time interval in the lower-right corner.




2. Touch a new interval.
3. Touch ✔ to dismiss the Trends screen.
4. Touch **Tabular** to display data at the new interval.

## Managing Patient Data Files

You can select a patient file and save it to a connected USB flash drive or delete it from the Oximeter.

### Saving Files to a USB Flash Drive

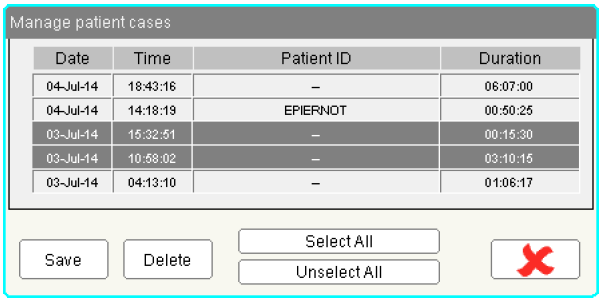
To copy a file from the Oximeter to a USB flash drive:

1. Insert a CASMED-approved USB flash drive into one of the two USB ports; you may use either the front or rear USB port, though only one may be active at a time.

   A maximum of 20 cases over the past 28 days are available in the Files menu for saving. The oldest cases are removed as new cases are added if either threshold is reached.

2. Verify that the USB icon ( ) is displayed in the lower-right corner of the display.
3. From the Main Menu, touch **Files**.

   The Oximeter displays a list of patient data files in memory. The Patient ID column displays the patient name or patient identifier, if entered.




**Note:** The Snapshot function (page 33) is disabled while this window is displayed.

4. Touch one or more files to select them.
5. Touch **Save**.

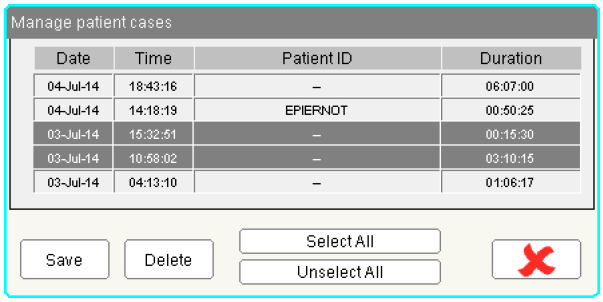
   This screen displays copy progress; wait until copying is complete before removing the USB flash drive, or the data file copy may become corrupted.

## Deleting Data Files from the Oximeter

To delete a patient file from the Oximeter:

1. From the Main Menu, touch **Files**.

   The Oximeter displays a list of patient data files in memory. The Patient ID column displays the patient name or patient identifier, if entered:




2. Touch one or more files to select them.
3. Touch **Delete**.

   The Oximeter prompts you to confirm the deletion.
4. Touch ✔ to delete the files, or ✘ to cancel.
5. Press ✘ to dismiss the Manage Patient Cases screen.

# Chapter 6
# Cleaning and Maintaining the Oximeter

Regular cleaning and preventive maintenance of the Oximeter is an important function that should be performed routinely to ensure safe and efficient Oximeter operation. The Oximeter does not require calibration, but following maintenance intervals are recommended:

- The Oximeter should be tested upon installation and once a year thereafter (see *Testing the Oximeter* on page 13)
- The Battery should be replaced every 2 years
- CAS Medical Systems recommends that the Oximeter be returned to the factory for Preventative Maintenance every 3 years

| | |
|---|---|
| **Warnings:** | Do not, under any circumstances, perform any liquid cleaning or maintenance of the Oximeter or AC power cord while the Oximeter is being used to monitor a patient. The Oximeter must be turned off, Sensors removed from the patient, and the AC power cord disconnected. There is a risk of serious injury or death if this procedure is not followed.<br><br>The operator must not perform any servicing on the Oximeter except as specifically stated in this chapter.<br><br>Before starting cleaning or maintenance of any sort, check the Oximeter, cables, Sensors, and other accessories for damage. Check the AC power cord for bent or broken prongs, cracks, or fraying. If any damage is noted, the Oximeter or accessory must not be used until it has been inspected and serviced or replaced by CASMED-authorized personnel.<br><br>The parts of the Oximeter include the Monitor, Preamp cable(s), Battery, AC power cord and Sensor(s). The accessories for the Oximeter include, but are not limited to: USB flash drive, $StO_2$ Simulator and mounting hardware. See Appendix F, *Parts* on page 93 for approved parts and accessories.<br><br>No modification of this equipment is allowed. |

| | |
|---|---|
| **Caution:** | Service performed by unauthorized personnel could damage the Oximeter and may void the warranty. |

# Cleaning the Oximeter

The Oximeter is designed to be cleaned and disinfected using wipes or towelettes designed for that purpose. Refer to the product's instructions for use and labeling for detailed information on active ingredients and disinfecting claims.

| | |
|---|---|
| **Warnings:** | To remove any chance of contamination between patients, the Oximeter and Preamp cables should be cleaned after each case.<br>Do not, under any circumstances, perform any liquid cleaning of the Oximeter or AC power cord while the Oximeter is being used to monitor a patient. The Oximeter must be turned off, Sensors removed from the patient, and the AC power cord disconnected before servicing or cleaning the Oximeter. There is a risk of serious injury or death if this procedure is not followed.<br>Liquids must not be allowed to enter the device. There is a risk of electric shock or device malfunction if liquids enter a device. Detach any USB drives before cleaning. Caps and plugs for unused ports may be obtained from CASMED. A USB Plug Kit (P/N 01-06-3020) is available from your CASMED distributor.<br>If the Oximeter or Preamp is accidentally wetted, take it out of operation. It must be thoroughly dried (minimum 1 hour) and checked by a CASMED-authorized service technician before it is used again. |

| | |
|---|---|
| **Cautions:** | Do not open the Oximeter to clean it.<br>Do not attempt to sterilize, gas sterilize, or autoclave the Oximeter or accessories.<br>Do not use abrasive cleaners, isopropyl alcohol, or organic solvents for cleaning. Use of these cleaners can cause damage, stiffness, and brittleness to the Oximeter's surface and to cables and wires. |

## Cleaning the Oximeter Case

The Oximeter surfaces may be disinfected wipes or towelettes designed for that purpose. When all surfaces have been disinfected, wipe the entire surface of the Oximeter using a soft cloth dampened with fresh water to remove any trace residue.

## Cleaning the Display

Clean the Oximeter display using a soft, lint-free cloth sprayed with an alcohol-free glass cleaner. The use of paper towels is not recommended as they may scratch the surface.

Thoroughly wipe off any excess cleaning solution.

## Cleaning the Preamp Cables

The Preamp cables may be disinfected wipes or towelettes designed for that purpose. They may be disconnected from the Oximeter or left in place and cleaned by wiping from the Oximeter end down over the Preamp box towards the Sensor connections.

| | |
|---|---|
| **Warning:** | If a Preamp cable should become grossly contaminated with blood or other bodily fluids, it should be discarded to reduce the risk of contamination and cross-infection. |

## Testing Alarm Operation

CASMED recommends that Alarm operation should be tested when the Oximeter is first installed and at least once every 6 months thereafter. An $StO_2$ Simulator is available through CASMED.

1. Connect the $StO_2$ Simulator to the patient connection of the Oximeter (where a Sensor would normally be attached; see *Testing the Oximeter Alarms* on page 15).
2. Set the High Alarm limits to at least 1% less than the current displayed value and verify the activation of the High limit detection (see *Configuring $StO_2$ Alarm Limits* on page 45).
3. Reset the High Alarm limits to the desired level.
4. Set the Low Alarm limits to at least 1% more than the current displayed value and verify the activation of the Low limit detection.
5. Reset the Low Alarm limits to the desired level.

## Replacing the Battery

The Oximeter's backup battery allows it to operate up to a half hour (on a new, fully charged battery) without an external power source. As with all batteries, its capacity will diminish over time. It is recommended that properly maintained batteries be replaced every 2 years; replacement batteries are available from CASMED.

If the Oximeter will not operate for more than 10 minutes on a newly replaced battery, then the Oximeter should be returned to CASMED for service.

| | |
|---|---|
| **Caution:** | The Oximeter should not be operated without a battery properly installed. Sudden loss of AC power may cause the Oximeter to lose data. |

### Removing the Battery

1. Turn the Oximeter off and remove the AC power cord.
2. Locate the Battery on the rear of the Oximeter (Figure 32).

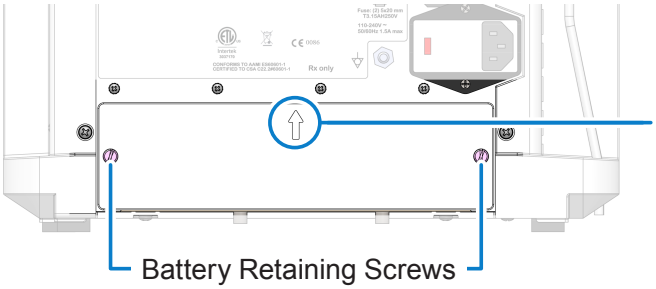



**Figure 32:** Battery Compartment

3. Use a screwdriver to loosen the retaining screws on either side of the Battery.
4. Grasp the retaining screws and pull the Battery out slightly to disconnect the Battery electrically from the Oximeter.
5. Gently slide the Battery out of the remainder of the Battery compartment.

## Installing the Battery

**Warning:** Use only the CASMED Battery that is listed in *Parts* on page 93.

1. Ensure that the AC power cord is not connected to the Oximeter.
2. Position the Battery near the Battery compartment with the arrow on the outside cover pointing up (see Figure 32 on page 65).
3. Gently slide the Battery in to the Battery compartment of the Oximeter until a slight resistance is encountered.

**Caution:** If significant resistance in encountered, do not force the Battery into the Battery compartment — it cannot be installed in the incorrect orientation. Ensure that the arrow on the outside cover is facing up and the two side tabs are towards the top of the pack.

4. Using equal force on both sides of the Battery, push it into the Battery compartment until the outside of the Battery is flush with the rear of the Oximeter.
5. Hand-tighten the retaining screws on either side of the Battery until snug and then use a screwdriver to tighten an additional 1/4 turn. Do not over tighten the screws.
6. Connect the AC power cord and allow the battery to charge for six hours.
7. Disconnect the AC power cord.
8. Press the front panel power button and verify the Oximeter will power on with the Battery installed.
9. Reconnect the AC power cord to the Oximeter.

If the Oximeter will not operate for more than 10 minutes on a newly replaced battery, then the Oximeter should be returned to CASMED for service.

## Replacing the AC Fuses

A fuse may need to be replaced if the Oximeter is plugged into an electrical outlet but the AC Power indicator is not illuminated. The Oximeter has a dual-fuse AC power input receptacle (both AC lines are fused).

| | |
|---|---|
| **Warnings:** | Before changing a fuse, turn the Oximeter off, unplug the AC power cord, and remove the Battery as described in *Removing the Battery on page 65*.<br>For continued protection against fire hazard, replace a fuse only with an identically rated fuse. See *Specifications* on page 89<br>*Other fuses located inside the Oximeter and Battery are not user-replaceable, and must be replaced only by CASMED-authorized Service personnel.* |

To replace the AC power fuses:

1. Turn the Oximeter off, disconnect the AC power cord, and remove the Battery as described on page 65.
2. Insert a small, flat screwdriver under the edge of the AC fuse cover (indicated by the arrow in Figure 33) and pop the cover open.
3. Use the screwdriver to gently pry up the red fuse holder from within the AC Fuse compartment and remove it.
4. Remove the suspect fuse.
5. Place a new fuse into the holder as indicated in Figure 34.
6. Repeat this process for the second fuse.

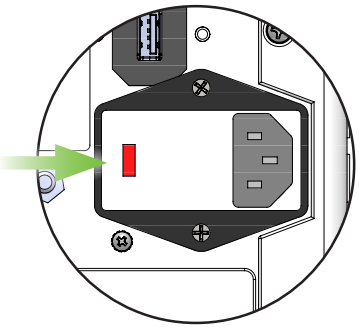
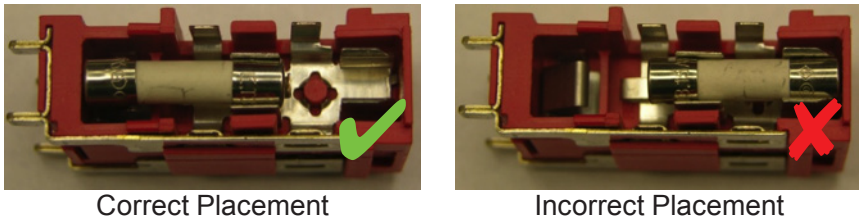


**Figure 33:** AC Fuse Cover



Correct Placement Incorrect Placement

**Figure 34:** AC Fuse Placement

7. Insert the fuse holder back into the AC Fuse compartment (the fuse holder can be inserted in either orientation).
8. Close the AC Fuse compartment and press down until you hear an audible click.
9. Reconnect the AC power cord to the Oximeter.

# Resetting the Oximeter to Factory Settings

If you should need to restore the Oximeter's factory defaults, you can do so from the Setup menu. The following settings are *not* affected by a reset:

- Serial Number
- Asset Number
- Date/Time
- Stored Patient Data

The remaining settings are changed as described in Table 13:

**Table 13:** Factory Default Settings

| Setting | | Default Value |
|---|---|---|
| Channel 1 | Body Location | L-Brain |
| | High Limit | 90% |
| | Low Limit | 50% |
| Channel 2 | Body Location | R-Brain |
| | High Limit | 90% |
| | Low Limit | 50% |
| Channel 3 | Body Location | Unused |
| | High Limit | 90% |
| | Low Limit | 50% |
| Channel 4 | Body Location | Unused |
| | High Limit | 90% |
| | Low Limit | 50% |
| Trace View (scale) | | 30 minutes |
| Language | | English |
| Brightness | | 100% |
| Volume | | 100% |
| Serial Port A<br>Serial Port B | Protocol<br>Baud Rate | None<br>115200 |
| Alarm Limit Delay | | 0 seconds (immediate) |
| Patient ID | | Blank |
| Patient Mode | | Adult Mode |
| Skin Check Timer Duration | | 12 hours |

To reset Oximeter settings:

1. Touch **Setup**.
2. Touch **Log In** to display the Password keyboard.
3. Enter the password (2466) and touch ✔ to access the Biomed submenu.
4. Touch **Defaults**.
5. Touch ✔ to confirm the reset, or touch ✘ to cancel.

   The Oximeter saves the current case and automatically restarts.

# Appendix A
# Menu Reference

This appendix describes each of the Oximeter menus and provides a reference to the relevant section where applicable.

## Main/Home Menu

**Table 14:** Main Menu Options

| Button | | Description | See |
|---|---|---|---|
| | Patient | Lets you start a new case, configure Sensor location and high/low oxygen thresholds for a patient, and enter a patient ID. | Table 15 on page 70 |
| | Events | Lets you select specific events that can occur during a monitoring session and mark that spot on the patient's trace record. | Table 16 on page 70 |
| | Data | Lets you collect patient monitoring data. | Table 17 on page 71 |
| | Files | Lets you manage patient data files, including saving files to a USB flash drive. | *Managing Patient Data Files* on page 61 |
| | Setup | Lets you configure your system, including the volume, brightness, date and time, and your network. | Table 18 on page 71 |
| | Help | Lets you read instructions for common tasks. | Table 19 on page 72 |

## Patient Menu

**Table 15:** Patient Menu Options

| Button | | Description | Page |
|---|---|---|---|
| | Home | Displays the Main Menu. | — |
| | Setup | Lets you specify the body location for each Sensor and the High/Low $StO_2$ limits. | page 43 |
| | Patient ID | Lets you enter a Patient ID, which is shown on the Oximeter display and used to identify patient data files. | page 41 |
| | New Patient | Closes the current case and saves its data, and then creates a new patient file for monitoring. | page 34 |
| | Skin Check | Lets you reset the Skin Check timer or select a new timer interval. This option is not available if the timer has been disabled from the Biomed menu; see *Setting the Skin Check Timer* on page 55 to enable it. | page 36 |
| | Mode | Lets you select Adult or Pediatric mode. | page 22 |
| | Averaging | Lets you adjust the $StO_2$ Averaging mode. | page 22 |

## Events Menu

**Table 16:** Events Menu Options

| Button | | Description | Page |
|---|---|---|---|
| **Events Menu Page 1** | | | |
| | Home | Displays the Main Menu. | — |
| | View | Displays the Event Log for the current case. | page 48 |
| | OR<br>CCU<br>PICU<br>Custom | Displays a list of available events, which you can add to the trace data at the point you select the event.<br>Select events from OR, CCU, PICU, or Custom lists. Events for Pediatric Mode are in the PICU list. | page 46 |
| | Next Page | Displays Page 2 of the Events menu. | — |
| **Events Menu Page 2** | | | |
| | Vascular | Displays a list of available Vascular events, which you can add to the trace data at the point you select the event. | page 46 |
| | Custom | Displays the custom event setup screen, from which you can create new event types. | page 49 |
| | Import | Imports a custom event configuration from a USB flash drive. | page 51 |
| | Export | Saves the custom event configuration to a USB flash drive. | page 51 |
| | Next Page | Displays Page 1 of the Events menu. | — |

## Data Menu

**Table 17:** Data Menu Options

| Button | | Description | Page |
|---|---|---|---|
| | Home | Displays the Main Menu. | — |
| / | Stop / Start | Stops Patient Data collection for comparison to the STS database; touch the button again to restart data collection.<br>Collected data is included in the patient data file. | page 59 |
| | Reference | Lets you save the current $StO_2$ value (displaying on the Oximeter) as a Reference, or baseline, value for each monitored channel. | page 42 |
| | View | Displays the current STS data. | page 60 |
| | Tabular | Displays $StO_2$ values over a given time interval. | page 60 |

## Files Menu

Touching **Files** displays the Manage Patient Cases screen.

See *Managing Patient Data Files* on page 61 for more information.

## Setup Menu

**Table 18:** Setup Menu Options

| Button | | Description | Page |
|---|---|---|---|
| | Home | Displays the Main Menu. | — |
| | View | Sets the time period displayed in the trace area. | page 52 |
| | Volume | Sets the system/alarm volume. | page 57 |
| | Brightness | Sets the Oximeter display brightness. | page 52 |
| | Alarm Delay | Lets you set the amount of delay time before the Oximeter sounds an alarm. | page 58 |
| | Date/Time | Lets you set the system Date and Time. | page 54 |
| | Log In | Accesses the Biomed Submenu (Password: 2466) | — |

**Table 18:** Setup Menu Options

| Button | | Description | Page |
|---|---|---|---|
| **Biomed Submenu Page 1 (via Setup > Log In)** | | | |
| | Home | Displays the Main Menu. | — |
| | Language | Sets the display language. | page 53 |
| | Ports | Lets you configure the serial ports and baud rates for communicating with third-party solutions. | page 16 |
| | Skin Check | Lets you configure or disable the Skin Check timer. | page 55 |
| | LED | Settings for troubleshooting and debugging. | — |
| | Averaging | Lets you enable additional $StO_2$ averaging modes. | page 56 |
| | Next Page | Displays Page 2 of the Biomed Submenu. | — |
| **Biomed Submenu Page 2** | | | |
| | Defaults | Restores most system settings to their default values. | page 68 |
| | Sys Info | Provides system information for troubleshooting and debugging. | — |
| | Next Page | Displays Page 1 of the Biomed Submenu. | — |

## Help Menu

**Table 19:** Help Menu Options

| Button | | Description |
|---|---|---|
| | Home | Displays the Main Menu. |
| | Selection | Displays a matrix of appropriate Sensor sizes by patient age and weight. |
| | Monitoring | Displays a list of tasks to complete before monitoring begins. |
| | Apply | Displays instructions on selecting a Sensor site and applying a Sensor. |
| | Numerics | Displays information about the Channel Number portion of the display. |
| | About | Displays information about the Oximeter and software. |

# Appendix B
# Alarms and Messages

This Appendix describes the Oximeter Alarms and Messages

## System Messages

Table 20 describes the Oximeter system messages in order of descending priority, the conditions they signify, and the recommended action you should take. System messages appear in the System Alarm area as described in *Reading the Oximeter Display* on page 29.

**Note:** Priorities of these Alarm Conditions are preconfigured and cannot be altered.

Signals are as follows for each priority:

- **Medium Priority:** 3 pulses @ 575 Hz every 20 seconds, with a flashing yellow indicator
- **Low Priority:** 1 pulse @ 575 Hz, with a steady yellow indicator
- **Informational:** No auditory or visual signal

An alarm may be silenced for 2 minutes by pressing  , but visual indicators remain active.

**Table 20:** Oximeter System Messages

| Message | Condition | Recommended Actions |
|---|---|---|
| **Medium Priority Alarms (Black on Yellow) – in priority order** | | |
| **System Error E##** | Internal component failure; ## indicates type of Error | If condition persists, contact CASMED technical support |
| **Depleted Battery** | Battery needs to be recharged | Plug Oximeter into AC outlet |
| **Max Internal Temp** | Unit is above maximum operating temperature | Shut down Oximeter or unit will shut down automatically<br>If condition persists, contact CASMED technical support |
| **Low Priority Alarms (Yellow on Black) – in priority order** | | |
| **Low Battery** | Battery needs to be recharged | Plug Oximeter into AC outlet |
| **Check Battery** | Battery is missing or is partially connected | Install battery (see page 10) or remove and re-seat battery (see page 65) |
| **High Internal Temp** | Unit is above upper operating temperature | Attempt to cool Oximeter's operating environment<br>If condition persists, contact CASMED technical support |
| **Informational Messages (White on Black) – in priority order** | | |
| **Connect to AC** | AC power loss — Oximeter operating on Battery power | Plug Oximeter into AC outlet.<br>Make sure outlet is powered |
| **Port X Comm Lost** | Communications problem with bi-directional wired device | Inspect the Serial cable connections<br>Make sure the Serial cable connectors are properly engaged<br>Verify Serial Port settings (see *Connecting Serial Devices* on page 16)<br>Verify target device is turned on and is actively displaying information |

**Table 20:** Oximeter System Messages

| Message | Condition | Recommended Actions |
|---|---|---|
| **Faulty System Fan** | Operation of fan faulty | Check for free flow of temperate air around Oximeter<br>Move Oximeter away from wall or other obstruction<br>Move it to a cooler area<br>If condition persists, contact CASMED technical support |
| **Set Time/Date** | Time & Date not set<br>Clock Battery not capable of retaining Time & Date values | Enter Setup screen and set correct Time & Date (see page 54)<br>If condition persists, contact CASMED technical support to replace Clock Battery |
| **Faulty Clock Battery** | RTC Battery not capable of storing Time & Date values | If condition persists, contact CASMED technical support |

## Channel Messages

Table 21 describes the Channel-specific Oximeter messages in order of descending priority, the conditions they signify, and the recommended action you should take. Channel messages appear in the Channel Alarm area as described in *Reading the Channel Display* on page 30.

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

Signals are as follows for each priority:

- **High Priority:** 10 pulses @ 970 Hz every 10 seconds, with a flashing red indicator
- **Medium Priority:** 3 pulses @ 575 Hz every 20 seconds, with a flashing yellow indicator
- **Low Priority:** 1 pulse @ 575 Hz, with a steady yellow indicator
- **Informational:** No auditory or visual signal

An alarm may be silenced for 2 minutes by pressing , but visual indicators remain active.

**Table 21:** Oximeter Channel Messages

| Message | Condition | Recommended Actions |
|---|---|---|
| **High Priority Alarms (White on Red)** | | |
| **High $StO_2$** | Reading exceeds user-selected High alarm limit | Assess the patient and physiologic Oximeter to verify the condition and then respond accordingly |
| **Low $StO_2$** | Reading is below user-selected Low alarm limit | Assess the patient and physiologic Oximeter to verify the condition and then respond accordingly |
| **Medium Priority Alarms (Black on Yellow) – in priority order** | | |
| **Faulty Preamp** | Preamp cable is defective | If condition persists, contact CASMED to replace the Preamp cable (see page ii) |
| **Preamp Disconnected** | Preamp cable has become disconnected | Connect Preamp cable to Oximeter (see page 13)<br>**Note:** Pressing dismisses the alarm and displays the *Connect Preamp* message. |
| **Faulty Sensor** | Sensor is defective or Non-CASMED Sensor in use | Replace with CASMED Sensor |
| **Sensor Disconnected** | Sensor has become disconnected | Connect Sensor to Preamp (see page 28)<br>**Note:** Pressing dismisses the alarm and displays the *Connect Sensor* message. |
| **Sensor Over Temp** | Temperature under Sensor is > 45 °C | Cooling of patient or environment may be required |
| **High Ambient Light** | Sensor is not in correct contact with patient | Check that Sensor is in direct contact with skin<br>Apply a light blocker or drape over the Sensor to limit exposure to light |
| **Sensor Off** | Computed $StO_2$ not in valid range or sensor placed on an inappropriate object | Sensor may need to be repositioned |

**Table 21:** Oximeter Channel Messages

| Message | Condition | Recommended Actions |
|---|---|---|
| **Signal out of Range** | Sensor on inappropriate object | Remove Sensor from inappropriate object and place on patient |
| **Check under Sensor** | Tissue under Sensor may have fluid accumulation/edema | Check patient for edema under Sensor<br>When tissue condition returns to normal range (e.g., patient is no longer edematous) the Sensor may be reapplied |
| **Stool Interference High** | The Sensor is interrogating primarily stool versus perfused tissue and $StO_2$ cannot be measured | Move the Sensor to a location where the relative amount of intestinal tissue is less, such as the flank |
| **Low Priority Alarms (Yellow on Black) – in priority order** | | |
| **Unrecognized Sensor** | An unknown Sensor is connected; stored information in Sensor is not valid | Replace with CASMED Sensor |
| **Incorrect Sensor Size** | The sensor size is incompatible with either the Patient Mode or body location | Use a different sensor size (see Table 5 on page 24)<br>Change the Patient Mode (see page 22) or body location (see page 44) accordingly |
| **Sensor Simulator Data** | A sensor simulator is connected to the channel | No action required, simulated data generated |
| **Unstable Signal** | Interference from outside source | Move Sensor away from interfering source |
| **Informational Alarms (White on Black) – in priority order** | | |
| **Ambient Light** | Ambient light approaching maximum value | Check that Sensor is in direct contact with skin<br>Apply a light blocker or drape over the Sensor to limit exposure to light |
| **Stool Interference** | Stool Interference is approaching maximum acceptable level<br>The Sensor is interrogating some perfused tissue to make a $StO_2$ measurement, but there is also a high concentration of stool in the Sensor's interrogation path | Consider moving the Sensor to a different abdominal location where the stool interference is less |
| **Sensor Under Temp** | Temperature under Sensor < -10 °C | Warming of patient or environment may be required |
| **Set Body Location** | Sensor connected with no body location assigned | Set body location for channel (see page 44) |
| **Connect Preamp** | Connect Preamp to start monitoring channels | Connect Preamp to Oximeter (see page 13) |
| **Connect Sensor** | Connect Sensor to start monitoring channel | Connect Sensor to Preamp (see page 28) |
| **Acquiring Data** | Channel is acquiring data | Normal operation; wait for message to clear |

## Philips Patient Monitor Messages

| Notes: | • Only High, Medium, and Low Priority System and Channel Alarm Messages are displayed on Philips Patient Monitors.<br>• Oximeter Alarm Messages may appear different on the Philips Patient Monitors due to text length limitations. |
|---|---|

**Table 22:** Oximeter Messages Displayed on Philips Patient Monitors

| Oximeter Message | Philips Message |
|---|---|
| **High $StO_2$** | High $rSO_2$-#[1] |
| **Low $StO_2$** | Low $rSO_2$-#[1] |
| **System Error E##**<br>**Max Internal Temp**<br>**Check Battery**<br>**Depleted Battery**<br>**Low Battery**<br>**High Internal Temp** | FS Sys Warning |
| **Faulty Preamp**[2]<br>**Faulty Sensor** | FS-# Error[1] |
| **Preamp Disconnected**<br>**Sensor Disconnected**<br>**Sensor Over Temp**<br>**High Ambient Light**<br>**Signal out of Range**<br>**Check Under Sensor**<br>**Sensor Off**<br>**Stool Interference High** | FS-# Warning[1] |
| **Incorrect Sensor Size**<br>**Unstable Signal** | FS-# Chk Sensor[1] |

1. # Represents the corresponding Patient Data Channel 1, 2, 3 or 4
2. Preamp messages will present 2 messages, 1 for each Preamp channel: 1 & 2 or 3 & 4

# Appendix C
# Event Index

The tables in this Appendix list the predefined events that can be placed onto a trace during a monitoring session. There are four event lists to choose from:

- OR Events
- CCU Events
- PICU Events
- Vascular Events

| **Note:** | Event markers for Pediatric Mode are in the PICU list. |
|---|---|

Events in each group are listed alphabetically, and are color coded as follows:

| Cell Shading | Definition |
|---|---|
| Unshaded | Relatively routine events |
| Yellow | “Cautionary” events that could cause ischemia |
| Green | Interventions taken |

See *Marking Events* on page 46 for more information.

**Table 23:** Event Menus by Category

| OR Events | CCU Events | PICU Events | Vascular Events |
|---|---|---|---|
| Cannulation | Enteral Feeding | Blood Gas | Cannulation |
| Cardioplegia | Extubation | Cooling Start | Clamp Off Vessel |
| Closing Sternum | Intubation | Diaper Change | Clamp On Vessel |
| Cooling | Apnea | Enteral Feeding | Decannulation |
| CPB On/Off | Arrhythmia | Intubated/Extubated | Extubation |
| Cross Clamp Off | Bradycardia | Nasal CPAP Start/Stop | Heparin Given |
| Cross Clamp On | ICP Changes | Rewarming Start | Incision |
| Extubation | LOC Changes | Repositioning Baby | Intubation |
| Induction of Anesth | Painful Procedure | Stooling | Arrhythmia |
| Intubation | Seizure Activity | Apnea | Blood Loss |
| Sternotomy | Tamponade | Anxious | Contrast Dye Injected |
| Warming | Afterload Reduction | Bradycardia/Arrhythmia | Dissection |
| Arrhythmia | Airway Suctioned | Heel Stick/Lab Draw | EEG Change |
| Circulatory Arrest | Anti-Arrhythmic | Hypocapnia | Hypocapnia |
| Hypocapnia | Anti-Epileptic | Hypotension | Hypotension |
| Hypotension | Blood Transfusion | Low $SpO_2$ | Shunt Clamped |
| Low $SpO_2$ | Chest Closed | Painful Procedure | Thrombus Suspected |
| Pump Flow Down | Defib/Cardioversion | Seizure Activity | Balloon Deflated |
| Venous Return Down | Dialysis/CRRT | Afterload Reduction | Balloon Inflated |
| Afterload Reduction | Diuretic | Airway Suctioned | BiVAD On/Off |
| Antegrade SCP ON | ECLS Off | Anti-Arrhythmic | Blood Transfusion |
| Blood Transfusion | ECLS On | Anti-Epileptic | EPD Deployed |
| Defib/Cardioversion | Fluid Bolus | Blood Transfusion | Fogarty Catheter In |
| ECLS On | High Frequency Vent | Diuretic | IAB Catheter Off |
| Fluid/Volume Expander | Hypothermia | ECMO Start | IAB Catheter On |
| Hemoconcentrate/MUF | Inotrope | ET Ventilation | IAB Pump Off |
| Increase Anesthetic | Nitric Oxide | Fluid/Volume Expander | IAB Pump On |
| Increase $CO_2$ | Paralytic | Hypothermia | Increase Anesthetic |
| Increase $FiO_2$ | PDA Ligated | Increase $CO_2$ | Increase $EtCO_2$ |
| Increase Pressure | Prostaglandin | Increase $FiO_2$ | Increase $FiO_2$ |
| Increase Pump Flow | Reposition Patient | Inotrope/Vasopressor | LVAD On/Off |
| Inotrope | Sedation | Paralytic | RVAD On/Off |
| Pacing: Atrial | Vasopressor | Paw Reduced | Shunt Flushed |
| Pacing: A-V | Ventilator Change | PDA Ligated | Shunt Open |
| Pacing: Ventricular | | Prostaglandin | Shunt Reposition |
| Reposition Cannula | | Nasal CPAP | Stent Deployed |
| Reposition Clamp | | Nasal Ventilation | Thrombus Removed |
| Reposition Head/Heart | | Nitric Oxide | Vasodilator |
| Retrograde SCP ON | | Reposition Heart/Head | Vasopressor |
| Vasopressor | | Sedation | |

# Appendix D
# Symbol Reference

The following tables summarize the symbols used on the Oximeter and its accessories. Symbols may appear on the product or on its packaging. Symbols are black unless otherwise indicated.

## Oximeter Case

**Table 24:** Symbols on the Oximeter Case

| Symbol | Description |
|---|---|
| **Front** | |
| ∿ / ● | AC power indicator / Charge mode enabled (green indicator) |
| ⏻ | On / Off |
| ⚠ | Caution |
| **Left Side** | |
| | Patient connections are Type BF |
| ⚠ | Warning (yellow background) |
| ① ② ③ ④ | Channel numbers |
| **Rear** | |
| ⚠ | Caution |
| ⏚ | Potential Equalization Post (Grounding Terminal) |
| | Manufacturer and Date of Manufacture. |
| 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 Oximeter is subject to the Waste Electrical and Electronic Equipment Directive in the European Union |
| ∿ | Alternating current |
| | Communication port, RS-232 Connector |

**Table 24:** Symbols on the Oximeter Case

| Symbol | Description |
|---|---|
|  | Video port, VGA Connector |
|  | Ethernet port, RJ-45 Connector |
|  | Follow instructions for use (white on blue) |

## Oximeter Display

See Appendix A, *Menu Reference*, on page 69 for Oximeter menu icon descriptions.

**Table 25:** Symbols on the Oximeter Display

| Symbol | | Description |
|---|---|---|
| STS Data Collection |  | STS data is being collected |
| |  | STS data is not being collected |
| Patient Mode |  | The Oximeter is in Adult Mode |
| |  | The Oximeter is in Pediatric Mode |
| Averaging |  | $StO_2$ Averaging is set to Fast |
| |  | $StO_2$ Averaging is set to Normal |
| |  | $StO_2$ Averaging is set to Slow |
| |  | $StO_2$ Averaging is set to None |
| Channel Indicators |  | Channel 1 |
| |  | Channel 2 |
| |  | Channel 3 |
| |  | Channel 4 |

**Table 25:** Symbols on the Oximeter Display

| Symbol | Description | | Adult | Pediatric |
|---|---|---|---|---|
| Sensor Locations | Patient Mode determines the available Sensor locations. | | | |
| |  | Left Brain (frontal lobe) | ✔ | ✔ |
| |  | Right Brain (frontal lobe) | ✔ | ✔ |
| |  | Left Shoulder (deltoid) | ✔ | |
| |  | Left Arm (biceps or brachioradialis) | ✔ | |
| |  | Right Shoulder (deltoid) | ✔ | |
| |  | Right Arm (biceps or brachioradialis) | ✔ | |
| |  | Left Flank/Abdomen (latissimus dorsi or external oblique) | ✔ | ✔ |
| |  | Central Abdomen | | ✔ |
| |  | Right Flank/Abdomen (latissimus dorsi or external oblique) | ✔ | ✔ |
| |  | Left Leg (quadriceps) | ✔ | ✔ |
| |  | Left Calf (gastrocnemius or tibialis) | ✔ | ✔ |
| |  | Right Leg (quadriceps) | ✔ | ✔ |
| |  | Right Calf (gastrocnemius or tibialis) | ✔ | ✔ |
| |  | Unassigned (Sensor is not assigned to a body location) | ✔ | ✔ |

**Table 25:** Symbols on the Oximeter Display

| Symbol | | Description |
|---|---|---|
| TPI Indicators |  | NONE (four Gray bars) No Sensor or Preamp connected or Sensor and Preamps connected, but Sensor off patient |
| |  | POOR (one White bar & three Gray bars) Indicates that the Sensor should be moved as monitoring will soon stop; after 10 seconds, this condition triggers the “Check tissue under Sensor” message and $StO_2$ values become two dashes, “--” |
| |  | FAIR (two White bars & two Gray bars) If seen when first placing the Sensor, reposition to achieve a GOOD or EXCELLENT level; if TPI reduces to FAIR during monitoring, verify that the Sensor is well adhered and assess the site for reliability, e.g., edema |
| |  | GOOD (three White bars & one Gray bar) For subjects that become hemodiluted (e.g., initiation of CPB), the TPI may decrease; this change in level is understandable without need to assess the Sensor site |
| |  | EXCELLENT (four White bars) Ideal monitoring state. For subjects that become hemodiluted (e.g., initiation of CPB), the TPI may decrease; this change in level is understandable without need to assess the Sensor site |
| Battery Status |  | Charging Battery |
| |  | Discharging Battery (80-100% charge) |
| |  | Discharging Battery (60-80% charge) |
| |  | Discharging Battery (40-60% charge) |
| |  | Discharging Battery (20-40% charge) |
| |  | Low Battery (5-20% charge) |
| |  | Depleted Battery (< 5% charge) |
| |  | Faulty Battery / No Battery |
| Active USB Port |  | USB flash drive inserted |
| |  | Snapshot function is available (page 33) |
| |  | The Oximeter is currently saving a Snapshot (this highlighted icon also indicates that the display is temporarily frozen) |
| Alarm Indicator |  | Audio Enabled (black on yellow) - Indicates that the Alarm will sound when appropriate |
| |  | Audio Temporarily Disabled (yellow on black) - Indicates that Alarm Audio is temporarily silenced, and the time remaining before the alarm may sound again |
| Actions | ✔ | Accept (green) - Accepts changes and returns to previous menu |
| | ✘ | Cancel (red) - Discards changes and returns to previous menu |

**Table 25:** Symbols on the Oximeter Display

| Symbol | | Description |
|---|---|---|
| Event Navigator |  | Step forward one pixel |
| |  | Step forward five pixels |
| |  | Step backward one pixel |
| |  | Step backward five pixels |
| |  | Skip to next event |
| |  | Skip to next event, disabled (if there are no visible events) |
| |  | Skip to previous event |
| |  | Skip to next event, disabled (if there are no visible events) |
| |  | Delete current event |
| |  | Delete current event, disabled (if no event is selected) |
| |  | Close the Event Navigator |

## Battery

**Table 26:** Symbols on the Battery

| Symbol | Description |
|---|---|
|  | Caution |
|  | Recycling suggested |
|  | Indicates this Battery contains lead (Pb) and is subject to the Waste Electrical and Electronic Equipment Directive in the European Union |

## Oximeter Packaging

**Table 27:** Symbols on the Oximeter Packaging

| Symbol | Description |
|---|---|
|  | Symbol used to indicate the minimum and maximum storage and transport Temperatures. Refer to *Storage/Transport Environment* on page 90 |
|  | Symbol used to indicate the minimum and maximum relative humidity for storage and transport. Refer to *Storage/Transport Environment* on page 90 |
|  | Symbol used to indicate the minimum and maximum atmospheric pressure for storage and transport. Refer to *Storage/Transport Environment* on page 90 |
| 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 |
|  | Fragile, handle with care |
|  | This end up |

## Preamp

**Table 28:** Symbols on the Preamp

| Symbol | Description |
|---|---|
| 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 Preamp is subject to the Waste Electrical and Electronic Equipment Directive in the European Union |
|  | Do not Discard; Intended for Multiple use; found on the Preamp cable (green background) |
|  | Manufacturer and Date of Manufacture |

## Preamp Packaging

**Table 29:** Symbols on the Preamp Packaging

| Symbol | Description |
|---|---|
| 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 Preamp is subject to the Waste Electrical and Electronic Equipment Directive in the European Union |
|  | Manufacturer and Date of Manufacture |

## Sensor Packaging

**Table 30:** Symbols on the Sensor Packaging

| Symbol | Description |
|---|---|
| Rx only | Federal law restricts this device to sale by or on the order of a physician or licensed practitioner (USA only) |
|  | Caution |
|  | Follow instructions for use |
|  | Storage and transport temperatures |
|  | Assess the Sensor site at least every 12 hours, or more often, as required by the institution's protocol |
|  | Latex free |
|  | PVC free |
|  | Use only once |
|  | Non-Sterile |
|  | Do not apply prolonged pressure to the Sensor |
|  | Manufacturer |
|  | Lot number |
| 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 |
|  | Do not cut or trim Sensor |

# Appendix E
# Specifications

## Physical Dimensions and Weight

| | |
|---|---|
| H × W × D: (without feet) | 11.5 in (29.2 cm) × 12.9 in (32.7 cm) × 6.7 in (17.0 cm) |
| Weight: | 13.3 lbs (6.0 kg) |

## Operating Environment

| | |
|---|---|
| Operating temperature: | 10°C (50°F) to 40°C (104°F) |
| Humidity: | 15 to 75% RH, non-condensing |
| Altitude: | -305 m / -1,000 ft (106 kPa) to 3,000 m / 9,842 ft (70 kPa) |

**Note:** Oximeters may not meet performance specifications if stored or used outside temperature and humidity ranges. When moving an Oximeter from a storage location, wait at least one hour prior to use to allow it to adjust to room temperature.

## Measurement

| | |
|---|---|
| Method: | Modified Beer-Lambert Law Near Infrared Spectroscopy (NIRS) |
| Information output: | Non-invasive measure of percent functional oxygen saturation in hemoglobin of tissue below the Sensor (%$StO_2$) |
| Measurement range: | 1 to 99% |
| Display resolution: | 1% |
| Data rates: | Acquisition ≤ 100 Hz, numeric display = 0.5 Hz |
| Cerebral Accuracy: | Accuracy (Bias ± Precision) not determined outside the following ranges:<br>Large Sensors: 45% to 95%: -0.14 ± 3.05% at 1 SD<br>Medium Sensors: 48% to 92%: 0.05 ± 5.06% at 1 SD<br>Small Sensors: 50% to 90%: -0.01 ± 5.38% at 1 SD |

| | |
|---|---|
| Non-Cerebral Accuracy: | Accuracy (Bias ± Precision) not determined outside the following ranges:<br>Large Sensors: 45% to 95%: 0.24 ± 5.17% at 1 SD<br>Medium Sensors: 53% to 88%: -0.03 ± 5.52% at 1 SD<br>Small Sensors: 66% to 96%: 0.03 ± 5.69% at 1 SD |

## Patient Alarms

| | | |
|---|---|---|
| Adjustable alarms: | High, Low limits for Ch1, Ch2, Ch3, & Ch4 | |
| Alarm indicators: | Visual<br>Audible<br>Text in Channel alarm message window | |
| Audible sound pressure @ 100% Volume: | High Priority Alarms:<br>> 59 dB (Fast A) @ 1 m in front of Oximeter<br>Medium Priority Alarms:<br>< 59 dB (Fast A) @ 1 m in front of Oximeter | |
| Patient Parameter: | Low (Default 50%) | High (Default 90%) |
| Range: Ch1, Ch2, Ch3, Ch 4 | 3 to 93% | 8 to 98% |

| | |
|---|---|
| **Notes:** | A channel's Low limit cannot be set above its High limit.<br>A channel's High limit cannot be set lower than its Low limit.<br>There must be a minimum 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: | 1 corresponding to each channel |

## Storage/Transport Environment

| | |
|---|---|
| Storage Temperature: | -20°C (-4°F) to 60°C (149°F) |
| Transport Temperature: | -20°C (-4°F) to 60°C (149°F) |
| Humidity: | 15 to 90% RH, non-condensing |
| Altitude: | -305 m / -1,000 ft (106 kPa) to 3,000 m / 9,842 ft (70 kPa) |

## Power

| | |
|---|---|
| External AC power: | 100 to 240 VAC, 50/60 Hz, 1.5A Max (1.5A to 0.75A) |
| | Fuse rating: T3.15AH250V (two provided) |
| Chassis leakage current: | 100 µA (maximum) |
| Heat dissipation: | 60 watts (205 BTU/hr) |
| Battery: | Sealed lead-acid battery |
| Charge Time: | 6 hours |
| Operating Time: | 0.5 hour (minimum with new and properly maintained battery) |

| | |
|---|---|
| **Note:** | The life of batteries is influenced by actual use, temperature, charging & discharging cycles, and mechanical abuse. |

## 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 Compliance

The FORE-SIGHT ELITE Oximeter complies with the following requirements:

CE marking according to Directive 93/42/EEC
IEC 60601-1
IEC 60601-1-2
IEC 60601-1-6
IEC 60601-1-8
CAN/CSA C22.2 #60601-1
ANSI/AAMI ES60601:2005

# Appendix F
# Parts

Contact the CASMED Customer Service department (see *Contact Information* on page ii) or visit www.casmed.com for the latest product information.

## Oximeter

**Table 31:** Oximeter Models

| Catalog No. | Description |
|---|---|
| 01-06-3000 | (1) FORE-SIGHT ELITE Oximeter |

All Oximeter models come with:

- (1) FORE-SIGHT ELITE Dual Preamp
- (1) FORE-SIGHT ELITE Battery
- (1) FORE-SIGHT ELITE User Manual
- (1) Hospital Grade AC power cord (country specific)

## Accessories, Detachable Parts, and Materials

**Table 32:** Oximeter Accessories

| 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 |
| 01-06-3100 | FORE-SIGHT ELITE Dual Preamp (4 m) |
| 01-06-3101 | FORE-SIGHT ELITE Dual Preamp (6.5 m) |
| 01-06-3014 | FORE-SIGHT ELITE Battery |
| 01-06-3011 | FORE-SIGHT ELITE USB Flash Drive |
| 01-06-3020 | FORE-SIGHT ELITE USB Plug Kit |
| 21-22-3000 | FORE-SIGHT ELITE User Manual, English |
| 01-07-1110 | FORE-SIGHT ELITE $StO_2$ Simulator |

**Table 32:** Oximeter Accessories

| Catalog No. | Description |
|---|---|
| 01-07-2103 | FORE-SIGHT ELITE Large Sensor Carton (20 Sensors) |
| 01-07-2102 | FORE-SIGHT ELITE Medium Sensor Carton (20 Sensors) |
| 01-07-2101 | FORE-SIGHT ELITE Small Sensor Carton (20 Sensors) |
| 01-07-2100 | FORE-SIGHT ELITE Non-Adhesive Small Sensor Carton (10 Sensors) |
| 01-06-0232 | FORE-SIGHT 3-inch Utility Basket for 01-06-0234, 01-06-0235 or 01-06-0236 Arms |
| 01-06-0233 | FORE-SIGHT 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 |
| 01-06-0236 | FORE-SIGHT 16-inch Arm Pole Mount |
| 01-06-0238 | FORE-SIGHT Roll Stand with Basket & Handle |
| 01-06-0239 | FORE-SIGHT ELITE GCX Mounting Plate Kit |

## Philips Accessories and Options

The following products are available directly from Philips. Contact them via the web at www.medicalphilips.com or by email at medical@philips.com.

**Table 33:** Philips Accessories

| Philips Part Number | Description |
|---|---|
| 865114 #104 | Philips IntelliBridge EC-5 Module |
| 865115 #A01 101 | Philips IntelliBridge EC-10 Module |
| M1032A #A05 | Philips IntelliVue Module AUXPLUS |
| M1032A #K6C, M1032-61699 | Philips Interface Cable |

| | |
|---|---|
| **Warnings:** | Connecting the Oximeter to a Philips Patient Monitor could result in previously unidentified risks to patients or operators, and the integrator must identify, analyze, and control such risks.<br>Changes in the Oximeter connected to a Philips Patient Monitor, including changes to configuration, additional or deletion of items, and updating or upgrading of equipment could introduce new risks that may require new analysis. |

| | |
|---|---|
| **Caution:** | Only qualified biomedical engineering personnel may interface monitoring equipment with other types of medical equipment. Be certain to consult manufacturers' specifications to maintain safe operation. |

# Appendix G
# Warranty Policy

## FORE-SIGHT ELITE Warranty Policy (Purchased Monitors)

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 CASMED or CASMED's authorized Distributors as new merchandise and are extended to the first buyer thereof, other than for resale.

The CASMED FORE-SIGHT ELITE® Absolute Tissue Oximeter monitor is warranted for a period of twenty four (24) 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's 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 those replacements and repairs are made in accordance with the instructions provided by CASMED.

**Accessories:**

- Battery: Twelve (12) months
- Non-Disposable accessories: Ninety (90) days
- Preamp patient cables: One hundred eighty (180) days
- Single patient use products: Out-of-box failure
- $StO_2$ Sensors: Out-of-box failure

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 CASMED, or by persons expressly authorized by CASMED, or not in accordance with written instructions provided by CASMED, 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 CASMED 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 CASMED 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

CASMED may evaluate issues reported by the user and available with the monitor's stored patient data. In accordance with HIPAA requirements, CASMED will not use or disclose any stored patient data to individuals outside of CASMED, unless disclosure is required by law. CASMED will erase all stored patient data prior to the return of the repaired unit.

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.

## FORE-SIGHT ELITE Warranty Policy (Consigned/Leased Monitors)

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 CASMED or CASMED's authorized Distributors as new merchandise and are extended to the first buyer thereof, other than for resale.

The CASMED FORE-SIGHT ELITE® Absolute Tissue Oximeter monitor is warranted for a period of twenty four (24) 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's 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 those replacements and repairs are made in accordance with the instructions provided by CASMED.

**Accessories:**

- Battery: Twelve (12) months
- Non-Disposable accessories: Ninety (90) days
- Preamp patient cables: One hundred eighty (180) days
- Single patient use products: Out-of-box failure
- $StO_2$ Sensors: Out-of-box failure

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 CASMED, or by persons expressly authorized by CASMED, or not in accordance with written instructions provided by CASMED, or if the product has been subjected to misuse, negligence, or accident.

**Monitor Warranty:** CASMED will be responsible for any electronic failures with this product for two (2) years. CASMED reserves the right to repair the equipment at an authorized CASMED service center or by replacing the equipment from our consignment pool of monitors. This is free of charge during the two year warranty period. If a failure occurs after the second year a flat rate service charge for monitor replacement will be incurred.

**Customer Responsibility:** Accessory purchases after warranty, preventative maintenance, and repair after warranty. Contact CASMED Customer Support for current service rates.

**Accessory Cables:** An initial set of Preamp cable 1 set (2) channels or 2 sets (4) channels depending on hospital configuration will be provided at no charge with the placement of each FORE-SIGHT monitor. The cables will be covered under a six month (180 day) warranty and replaced by CASMED should they become defective. It is the customer's responsibility to purchase and replace any accessory cables after this period. Cables can be purchased as new or refurbished. Contact Customer Support for current rates.

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 CASMED 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 CASMED 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

CASMED may evaluate issues reported by the user and available with the monitor's stored patient data. In accordance with HIPAA requirements, CASMED will not use or disclose any stored patient data to individuals outside of CASMED, unless disclosure is required by law. CASMED will erase all stored patient data prior to the return of the repaired unit.

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.

# Index

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