Mini Mitter Company, Inc.

Bend, OR USA

Preliminary
(includes Tinman)

VitalSense®

Integrated Physiological Monitoring System

Instruction Manual

Version 1.1

MINI MITTER COMPANY, INC.

WARRANTY POLICY

1. **WARRANTY:** Mini Mitter warrants that upon delivery the goods sold hereunder will be free of defects in materials and workmanship, and such goods will substantially conform to the specifications furnished by the Seller, and to any drawings or specifications furnished to the Buyer by Mini Mitter if approved by Mini Mitter.

a) **Commencement of Warranty** – The warranty period begins on the date of delivery.

b) **Duration of Warranty** – The goods sold hereunder are warranted for a period of twelve months, except PDT-4000 and PDT-4000HR, which are warranted for two years.

c) **Third Party Product Warranty –** Third party products purchased by Buyer through Mini Mitter are covered by the manufacturer's warranty and ARE NOT COVERED BY THE MINI MITTER WARRANTY.

d) **Place of Repair or Replacement**. Buyer must return the defective or nonconforming goods upon request to Mini Mitter at 20300 Empire Avenue, Building B-3; Bend, OR 97701, not later than 15 days after Mini Mitter's receipt of notice of the alleged defect or nonconformance. Buyer shall prepay transportation charges. Mini Mitter shall pay for the return of the goods to Buyer. No goods are to be returned to Mini Mitter without prior authorization and a valid Corrective Action Request (CAR) number.

e) **Limitation of Warranty** The foregoing warranty shall not apply to defects resulting from (a) improper or inadequate maintenance by Buyer; (b) unauthorized modification of the goods; (c) operation of the goods outside of the environmental specifications for the goods; (d) neglect, misuse or abuse of the goods or (e) modification or integration with other goods not covered by a Mini Mitter warranty when such modification or integration increases the likelihood of damage to the goods.

f) **Technical assistance –** The warranty set forth above shall not be enlarged, diminished or affected by and no obligation or liability shall arise from Mini Mitter's rendering of technical advice, assistance or services in connection with Buyer's order of the goods furnished hereunder. The Buyer is not relying on Mini Mitter's skill or judgment to select or furnish suitable goods.

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Table of Contents

Thank You! .....for purchasing Mini Mitter products. If you need assistance with your VitalSense Physiological Monitoring System, remember Mini Mitter support continues after the purchase. If you have any problems or questions, please call our Technical Support staff of technicians, engineers, and scientists. We are available by telephone, fax, e-mail, or website.

Contacting Mini Mitter Technical Support

Mailing and Shipping Address **Mini Mitter Company, Inc.**
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Bend, OR 97701 USA

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(541) 322-7272

Fax **(541) 322-7277**

E-Mail **mm@minimitter.com**

Website **www.minimitter.com**

Safety Labels and Terminology

⚠ DANGER

DANGER indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.

⚠ WARNING

WARNING indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

⚠ CAUTION

CAUTION (with safety alert symbol) indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury.

CAUTION

CAUTION without safety alert symbol indicates a potentially hazardous situation which, if not avoided, may result in property damage, including equipment and/or data.

If found on a device, this symbol means that there is additional information in the manual that must be read. This symbol is typically used when there is not enough room for text.

NOTE:
A "Note" between two lines is an explanatory statement to aid the practitioner or subject.

Notices to Practitioners and Subjects

Electromagnetic Interference (EMI) Advisories

Introduction

The VitalSense Integrated Physiological Monitoring System uses wireless telemetry to send data over a distance. By nature, wireless devices use an "open" channel which is shared by other wireless devices which may be interfered with, or may interfere with the VitalSense system. Consequently, the customer is advised to carefully consider the environment in which the VitalSense system will be used. The VitalSense system was designed for use in general health care and household environments. It may also be used in research facilities and field research. The VitalSense system can be used in some military environments, but is not intended for use in military aircraft or shipboard.

⚠ WARNING *VitalSense sensors should not be ingested or affixed during Magnetic Resonance Imaging (MRI). Sensors contain ferro-magnetic materials.*

VitalSense Frequency

The channel frequency for the VitalSense system is 40.68 MHz and the frequency band is 40.66 – 40.70 MHz. Although this is a seldom-used band, Mini Mitter recommends that you check the channel frequency of other wireless devices intended for use in the vicinity of the VitalSense system. Other wireless devices operating in the frequency band of 40.66 – 40.70 MHz may interfere with, or may be interfered by the VitalSense system. Generally, the output power of the sensors is extremely low and is unlikely to interfere with any equipment in the area. It is more likely that another device operating in the same band will interfere with the VitalSense system.

EMI Effects on VitalSense System

If the VitalSense system experiences interference, the monitor will no longer receive intelligible transmissions from the sensors. In Standard Mode, whenever transmissions from the sensor are missed, an asterisk is displayed next to the temperature. This asterisk remains until a transmission is received. The data is updated on average every 15 seconds. If the display flashes, but the asterisk remains, the sensors are still experiencing interference. In Medic Mode™, data from a particular sensor experiencing interference will not be displayed at all. Once the interfering signal is eliminated, the asterisk displayed in Standard Mode will disappear, and new data will be displayed in either mode.

EMI Avoidance

The VitalSense system is intended as a short range wireless device. The *maximum* distance at which the capsule sensor can be used is 1 m, and the *maximum* distance at which the patch can be used is 2 m. If transmissions appear to be lost, bring the monitor closer to the sensors. Move the system away from any devices you suspect may be emitting electrical radiation. The VitalSense system is intended to be an ambulatory system worn on the body, with the monitor placed at or near the waist. Because of its low power, it is not recommended for use in electrically noisy environments.

Although protected by filtering, the VitalSense system is susceptible to frequencies other than the channel band. The VitalSense system has been tested for RF immunity between 2 MHz and 1800 MHz. Generally, the system can still be used when the maximum field strength of the interfering signal is 10 V/m. Table 1.1 lists those frequencies which may cause interference at levels below 10 V/m.

Table 1.1 Frequencies where RF Immunity is less than 10 V/m

Frequency	Dermal Patch RF Immunity Level	Capsule RF Immunity Level
17 MHz - 26 MHz	7 V/m	3 V/m
56 MHz - 83 MHz	5 V/m	3 V/m
678 MHz -782 MHz	5 V/m	3 V/m

Radio Frequency Environments

Table 1.2 summarizes the general electromagnetic environments and lists the environments in which the system has been verified to operate. For additional information, contact Mini Mitter Company, Inc.

Operation within environments other than those verified may cause loss of data. Mini Mitter Company, Inc. is not responsible for customer operation of the system within environments other than those verified.

Table 1.2 General Electromagnetic Environments

Environment	Emissions	Susceptibility
General Research	Verified (Note[1])	Verified (Note[2])
Clinical-Hospital	Verified (Note[1])	Verified (Note[2])
Ambulatory	Verified (Note[1])	Verified (Note[2] and Note[5])
Battlefield	Limited (Note[3])	Verified (Note[4])
Helicopter	Not verified	Not verified
Ambulance	Not verified	Not verified
Shipboard	Not verified	Not verified
Aircraft	Not verified	Not verified

Note[1] - Verified in accordance with 47 CFR Part 15.229
Note[2] - Verified in accordance with IEC60601-1-2 and tested in accordance with MIL-STD 461E and MIL-STD 462E, Test CS114, and RS103
Note[3] - Tested in accordance with MIL-STD 461E and MIL-STD 462E, RE102
Note[4] - Tested in accordance with MIL-STD 461E and MIL-STD 462E, CS114 and RS103
Note[5] - Metal detectors may be activated by the VitalSense monitor. Anti-theft security systems (such as found in retail stores and libraries) may be activated by the VitalSense system.

Common Radio and Television Frequencies

Although they may vary somewhat worldwide, the following are commonly used frequencies in North America.

Table 1.3 Commonly Used Frequencies

Transmission Type	Frequency Range
AM Radio	535 kHz to 1605 kHz
FM Radio	88 MHz to 108 MHz
CB Radio	26.965 MHz to 27.405 MHz
VHF Television	55.25 MHz to 83.25 MHz 175.25 MHz to 211.15 MHz
UHF Television	471.25 MHz to 801.25 MHz

Medical Telemetry Systems

VitalSense has been designed in accordance with the FDA advisory, "*FDA Public Health Advisory: Risk of Electromagnetic Interference with Medical Telemetry Systems,*" July 10, 2000; and in accordance with FDA Guidance Document, "*Wireless Medical Telemetry Risks and Recommendations*." In regard to those advisories:

- The VitalSense system does not operate in the TV or PLMRS bands at 174-216 MHz and 450-470 MHz.
- VitalSense does not operate within the frequency bands 26.96-27.28 MHz, utilized by remote control devices.

Electrostatic Discharge Effects on Monitor

The VitalSense Monitor is designed to recover from air discharge Electrostatic Discharge (ESD) effects of 12 kV or less to any surface of the monitor. If an ESD discharge of greater than 12 kV is directly applied to the monitor, it may result in the monitor display momentarily going blank. If this occurs, the VitalSense Monitor will refresh the monitor display either when any button is pressed, or if a sensor transmission is received.

Precautions Prior to Using the VitalSense System

Restrictions

Federal law restricts the VitalSense Physiological Monitoring System products for sale to or on the order of a health care practitioner licensed by the law of the State in which he/she practices to use or order the use of this device.

Emissions

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment has been installed improperly and as a consequence does cause harmful interference to radio or television reception, this can be determined by turning the equipment off and on. The user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Consult the dealer or an experienced radio/TV technician for assistance.

Interference

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

- This device may not cause harmful interference.
- This device must accept any interference received, including interferences that may cause undesired operation.
- Also see “Electromagnetic Interference (EMI) Advisories” on page -vii.

Travel by Commercial Aircraft

Following activation, VitalSense sensors are radio transmitters. The Dermal Patch sensor has a range up to 2 meters, and the Capsule Sensor has a range up to 1 meter. The VitalSense Monitor can be a source of radio interference. They should not be used on commercial aircraft without the expressed permission of the governing aircraft security agency in countries of travel and the airline carrier. In the United States, this is the Transportation Security Administration under the Office of Homeland Security. Mini Mitter suggests the following:

- Do not activate the sensors until your flight has concluded.
- If you do inadvertently find yourself in the position of having to board an aircraft with activated sensors, realize you may have to do the following:

  Remove all Dermal Patch Sensors and leave them behind.

  Turn off the VitalSense Monitor. If it is in Lockout Mode, remove the battery. The monitor will retain the data that has been collected.

  If you have ingested a Capsule Sensor, it is recommended that you tell the security screener that you are wearing an ingested medical device.

It is recommended that you be totally honest with airport security personnel. Although they are familiar with implanted devices, wireless thermometers may be unfamiliar to them. Policies regarding medical devices are typically very accommodating. If there are any questions we can help answer, please call us. See “Contacting Mini Mitter Technical Support” on page -v.

Modification of VitalSense Devices

Any changes to the VitalSense Physiological Monitoring System not expressly approved by Mini Mitter will void the practitioner’s or subject’s authority to operate the devices or the software.

NOTE: VitalSense conforms to all of the requirements established in ASTM-E1112-00, Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature, clauses 4.1 and 4.2.

Sanitizing VitalSense Components

The VitalSense monitor may be sanitized with a soft cloth moistened with a non-alcohol based antibacterial cleaner.

The Capsule Sensor and Dermal Patch Sensor are single-use disposable devices. They are supplied ready-for-use as long as they remain in their original factory packaging.

For VitalSense Monitor maintenance cleaning, see “Cleaning” on page 4-6.

CAUTION

Do not autoclave the VitalSense monitor or the associated sensors. They will be destroyed in the process. Only gas processes may be used.

Precautions Prior to Using the VitalSense Monitor

Safety

This device is classified as having Type CF protection against electrical shocks during the sensor activation procedure.

NOTE: For additional advisories with respect to the VitalSense Monitor, see “Precautions Prior to Using the VitalSense System” on page -xi, and “EMI Effects on VitalSense System” on page -vii.

⚠ CAUTION

Precautions Prior to Using the Dermal Patch Sensor

Read before administering Dermal Patch Sensor!

Description

- Supplied one Dermal Patch Sensor per package
- Patch is biocompatible, colored plastic
- Temperature Sensing Range: -20 °C to 60 °C
- Reception Range: maximum of 2 meters
- Battery life following activation: maximum of 240 hours (10 days)

Indications

An indication is a sign or circumstance that indicates proper treatment.

- The VitalSense Dermal Patch is a wireless, miniaturized, externally activated, dermally affixed, biocompatible thermometer.
- The Dermal Patch Sensor is to be used for monitoring vital signs (external skin temperature) as part of a complete physiological sensor and monitoring system.
- The subject is not restricted to a medical environment. The subject may shower and participate in normal activities while the Dermal Patch is in place.
- The Dermal Patch is a single-use sensor.

Contraindications

A contraindication is any circumstance that indicates a form of treatment may be inappropriate.

This device is contraindicated if the patient presents or has a history of any of the following conditions:

- This product should not be used if the patient has known skin allergies, a break in the skin at the application site, or other abnormal skin conditions. If a skin rash occurs, notify the health care practitioner immediately.

⚠ WARNING

Warnings

A warning indicates a condition that may endanger the subject.

- DO NOT attempt an MRI (magnetic resonance imaging) if a Dermal Patch has been affixed. Remove the device prior to MRI.

  Affix an MRI Warning wrist band (supplied) to the subject with instructions to wear it until the Dermal Patch has been removed.
- DO NOT affix Dermal Patch if any damage is visible to the packaging or the device.
- Keep sensors away from small children. They can be a choking hazard.

Cautions

The following cautions indicate conditions that may result in minor or moderate injury to the subject.

- The Dermal Patch Sensor should be administered only by a health care practitioner.
- Following activation, the Dermal Patch Sensor can be affixed to nearly any flat, hairless area on the body. Placement, however, is limited to the size of the patch. It cannot be trimmed or altered, and should not be bent or crushed. It would, for example, be appropriate for a large muscle of the arm or leg, or axilla, but not on the bottom of the foot or around a bony structure such as the side of the wrist.

The following cautions indicate possible damage to the equipment, or erroneous or incomplete data.

- Data points could be missed if you are close to radio or television transmission sites, or other sources of electrical signals. See “EMI Avoidance” on page -viii of this section.
- DO NOT administer a Dermal Patch Sensor after the expiration date.
- The Dermal Patch Sensor should be administered every 3 to 4 days, when the Patch looses contact with the skin, or as directed by a health care practitioner.
- Avoid the use of lotions and emollients in the area of the Dermal Patch Sensor. Their use may cause the patch adhesive to loosen.
- DO NOT leave the monitor out of range of the Dermal Patch Sensor for more than 30 minutes.

Adverse Reactions

May cause skin rash. Remove hair and clean skin before activation and application of Patch. If discomfort occurs or rash appears, discontinue use and notify health care practitioner.

⚠ CAUTION

Precautions Prior to Using the Capsule Sensor

Read before administering capsule!

Limitations of Capsule Sensor

The VitalSense ingestible capsule thermometer is a Class II Medical Device according to 21 CFR 882.1845 and is classified as a Surface Contacting Device according to ISO 10993-1. The capsule is intended to be used in contact with the mucosal membrane (alimentary tract) only. The VitalSense ingestible capsule thermometer must not be used in any situation where the mucosal membrane is already breached by surgery or trauma. The VitalSense ingestible capsule thermometer is not intended to be used as an implant. For additional information, contact Mini Mitter Company, Inc. See “Contacting Mini Mitter Technical Support” on page -v.

Description

- Supplied as one Capsule Sensor per package
- Sensor is colored biocompatible polycarbonate
- Temperature Sensing Range: 25 °C to 50 °C
- Reception Range: Maximum of 1 meter
- Battery life following activation: maximum of 240 hours (10 days)

Indications

An indication is a sign or circumstance that indicates proper treatment.

- The VitalSense Capsule Sensor is a wireless, miniaturized, externally activated, ingestible, biocompatible thermometer.
- It is to be used for monitoring vital signs (core body temperature) as part of a complete physiological sensor and monitoring system.
- Once ingested, the patient is not restricted to a medical environment.
- The Capsule Sensor may be taken without regard to dietary restrictions.
- It is a single-use sensor.

Contraindications

A contraindication is any circumstance that indicates a form of treatment may be inappropriate.

This device is contraindicated if the patient presents or has a history of any of the following conditions:

- Abnormalities in swallowing
- Esophageal or bowel strictures
- Fistulas
- Gastrointestinal obstructions

If suspected, a contrasted X-ray series should be considered prior to ingestion.

Warnings

A warning indicates a condition that may endanger the subject or patient.

- DO NOT attempt an MRI (magnetic resonance imaging) if a Capsule Sensor has been ingested. Wait until the device is passed from the digestive system.

  Affix an MRI Warning wrist band (supplied) to the subject with instructions to wear it until the Capsule Sensor has been passed.
- DO NOT ingest if any damage is visible to the packaging or the device.
- DO NOT chew prior to swallowing. The electronics within the device will be made inoperable.
- The Capsule Sensor should be swallowed with water or other suitable liquid.
- DO NOT administer a Capsule Sensor after the expiration date.
- If gastrointestinal discomfort occurs following ingestion, report it to the health care practitioner. Nausea, vomiting, or pain should be reported immediately.
- Keep Capsule Sensors away from small children. They can be a choking hazard.
- The Capsule Sensor is not to be implanted.

Cautions

The following cautions indicate possible damage to the equipment, or erroneous or incomplete data.

- DO NOT open the VitalSense Capsule Sensor protective packaging until ready for use.
- The Capsule Sensor should be administered only by a health care practitioner.
-

The following cautions indicate possible damage to the equipment, or provide erroneous or incomplete data.

- Data points could be missed if you are close to radio or television transmission sites, or other sources of electrical signals. See “EMI Avoidance” on page -viii of this section.
- DO NOT administer a Capsule Sensor after the expiration date.
- DO NOT leave the monitor out of range of the Capsule Sensor for more than 30 minutes.
- The VitalSense Monitor battery level should be checked prior to use.

Adverse Reactions

- May cause choking. Should be taken with water.
- In rare instances, may become lodged in the intestines.

Precautions Prior to Using VS-XHR Heart Rate Sensor

⚠ CAUTION

Read before administering VS-XHR Heart Rate Sensor!

Description

VS-XHR is a cardiac monitor sensor, used to detect, measure, and transmit Heart Rate and Respiration Rate values to the VitalSense Integrated Physiological Monitoring System (VS-IPMS). VS-XHR attaches directly to the chest surface using standard disposable ECG (EKG) electrodes. VS-XHR is powered from its own internal rechargeable lithium coin cell; there is no external power source. There are no ECG leads. VS-XHR is not equipped with any alarm function.

Intended Use

VS-XHR Sensor is intended to be used as an HR and/or RR monitor, in conjunction with the VS-IPMS. VS-XHR is not equipped with alarms to signal tachycardia or any other cardiac arrhythmias.

Indications

An indication is a sign or circumstance that indicates proper treatment.

- VS-XHR Sensor is an ambulatory, wireless, chest-worn, dermally affixed, Heart Rate and Respiration Rate Sensor.
- The VS-XHR Sensor is to be used for monitoring vital signs (heart rate and respiration rate) as part of a complete physiological sensor and monitoring system.
- The subject is not restricted to a medical environment. The subject may participate in normal activities while the VS-XHR Sensor is in place.
- The VS-XHR Sensor is a multi-use sensor.
- VS-XHR, in combination with VitalSense Physiological Monitoring System, may be used where quantifiable measurement of human Heart Rate and/or Respiration Rate are needed.

Contraindications

A contraindication is any circumstance that indicates a form of treatment may be inappropriate.

- The VS-XHR Sensor is contraindicated for the detection of Heart Rate due to bigeminal arrhythmias or systoleic arrhythmias.
- The VS-XHR Sensor is contraindicated for use in conjunction with pacemakers, electrosurgical equipment, and defibrillators.
- VS-XHR Sensor is contraindicated for use in measuring ST segment shifts.
- VS-XHR Sensor is contraindicated for use in measuring ventricular ectopic beats, ventricular flutter or fibrillation; or supraventricular ectopic beats, atrial flutter, or fibrillation.
- VS-XHR Sensor is contraindicated for use with neonatal or infant subjects whose body mass is 10 kg or less.
- VS-XHR Sensor is contraindicated for patients with current or known history of dermal allergies, dermal sensitivity to ECG electrodes, or dermal lesions. Consult ECG electrode manufacturer's directions for appropriate ECG electrode type and usage. Discontinue use if dermal irritation or allergic reaction to ECG electrode occurs.

Warnings

A warning indicates a condition that may endanger the subject.

Pacemaker Patients - This device does not reject pacemaker pulses.

Rate meters may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely upon rate meters to measure heart rate for pacemaker patients. Keep pacemaker patients under close surveillance.

Magnetic Resonance Imaging (MRI)

DO NOT attempt an MRI (magnetic resonance imaging) if a VS-XHR Sensor has been affixed. Remove the device prior to MRI.

Affix an MRI Warning wrist band (supplied) to the subject with instructions to wear it until the VS-XHR Sensor has been removed.

Cardiac Arrhythmias

This devices does not provide alarms that signal the onset or presence of cardiac arrhythmias, including tachycardia.

Electrosurgical Equipment

Electrosurgery or electrocautery equipment may interfere with or damage this device. Do not rely on this device to measure heart rate or respiration rate when electrosurgery equipment is being used.

Defibrillation

Defibrillator use may interfere with or damage this device. Do not rely on this device to measure heart rate or respiration rate during defibrillator use. Remove VS-XHR prior to defibrillator use.

⚠ CAUTION

Cautions

The following cautions indicate conditions that may result in minor or moderate injury to the subject.

Infant Use

VitalSense-XHR Heart Rate Sensor is not intended for use on infants weighing less than 10 kg.

ST Segment Shifts

This equipment is not designed to measure ST segment shifts.

CAUTION

The following cautions indicate possible damage to the equipment, or erroneous or incomplete data.

- Data points could be missed if you are close to radio or television transmission sites, or other sources of electrical signals. See “EMI Avoidance” on page -viii of this section.
- Avoid the use of lotions and emollients in the area of the XHR Heart Rate Sensor electrodes. Their use may cause the adhesive to loosen.
- DO NOT leave the monitor out of range of the XHR Heart Rate Sensor for more than 30 minutes.

Electrial Shock Protection

This device provides degree of protection against electric shock as Type B applied part per IEC 60601-1, clause 6.1(l).

Adverse Reactions

Electrodes may cause skin rash. Remove hair and clean skin before activation and application of Patch. If discomfort occurs or rash appears, discontinue use and notify health care practitioner.

Precautions Prior to Using the Multicharger

Read before charging VS-XHR Heart Rate Sensor!

Description

The purpose of the Multicharger is to charge multiple VS-XHR Heart Rate Sensors. An AC to DC converter is provided which powers the device. Up to three VS-XHR Sensors can be mounted on the Multicharger, providing a full charge within 11 hours (typical).

⚠ CAUTION

Cautions

The DC plug on the Multicharger power supply, or the AC power cord on the power supply, both serve as the cutoff switch for power to the Multicharger. Ensure that the socket-outlet providing voltage to the power supply is located nearby and is readily accessible.

Always use the supplied AC power cord with the Multicharger. Do not substitute power cords other than the one supplied with the Multicharger.

SECTION

1

VITALSENSE SYSTEM INTRODUCTION

This is an instruction manual for the operation and maintenance of the VitalSense Integrated Physiological Monitoring System. This wireless system consists of the following components:

VitalSense Components

- VitalSense Monitor
- Dermal Patch Sensor
- Capsule Sensor
- VitalSense Application Software
- Serial monitor-to-PC interface cable

Once a sensor is activated, it measures and reports the temperature data to the monitor an average of four times per minute. The temperature data are time-stamped and recorded in the non-volatile memory.

A Standard Mode VitalSense Monitor can monitor up to ten sensors. In order to do this, each sensor must be activated by the monitor that will be recording that specific sensor. During activation, each sensor and the monitor are synchronized.

In optional Medic Mode™, an unlimited number of sensors may be operationally verified and the temperature recorded with a time stamp.

Getting Started - THIS MUST HAPPEN FIRST

The following must occur before a new data collection session can begin:

- Monitor clock must be set - (from monitor front panel or the host PC)
- Erase data memory - (from monitor front panel or the host PC)
- Logging must be turned on - (from monitor front panel or the host PC)
- Sensor(s) must be activated - (from the monitor only)

See " Monitor Setup for Data Collection " on page 2-4.

Monitor

The VitalSense Monitor is a central element in the VitalSense system. It serves to activate the sensors, track and record data from the sensors, and provide an interface to a computer.

Sensor activation is a key event in the operation of VitalSense. It is used to synchronize the monitor with each sensor. Once activated, the monitor can display the incoming data in real-time and at the same time log the data to the non-volatile memory for future transfer to a computer.

Sensors

VitalSense sensors are activated by the VitalSense Monitor. Once activated, a sensor will begin its monitoring assignment, and will continue to function until the battery expires (approximately 240 hours), the sensor is removed from the sensor schedule, or the sensor is disposed.

Each sensor is given an identity number at the factory, along with temperature calibration data. During activation, these data are automatically retrieved from the sensor and stored in the monitor memory.

All sensors are activated using essentially the same process:

- A specific optical signal from the monitor activates the sensor.
- By radio, the sensor transfers its identification and calibration data to the monitor.

Following activation, the sensor is either swallowed (Capsule Sensor), or affixed to the body (Dermal Patch Sensor). The activation process is identical for each sensor. Sensors are single-use and cannot be de-activated. Additional sensors may be ordered from Mini Mitter Company, Inc. See " Contacting Mini Mitter Technical Support " on page -v.

Tracking

Tracking is a term used in this manual which refers to the synchronization of the VitalSense Monitor and the sensors.

In order to preserve battery power of the VitalSense Monitor and conserve the power of the sensors, the sensors are designed to transmit according to a pre-determined schedule. Both the sensor and the monitor which activated it have this schedule. As a result, the monitor only “listens” for a specific sensor for a short period during the expected transmission time. It is through the activation process and the periodic reception of these transmissions that the monitor remains synchronized with the sensor transmission schedule. The monitor quite literally “tracks” the minor variations between the two clock sources at each transmission.

Firmware

VitalSense firmware is operational information that is programmed into the VitalSense Monitor non-volatile memory. When calling Mini Mitter Technical Support, the version number of this firmware can be very helpful. To find the firmware version using the VitalSense Application Program, see “ Firmware Version ” on page 3-21.

Software

Installed, the VitalSense Application Software converts a PC to “host status” for the VitalSense Application Program, allowing setup of select monitor functions, real-time monitoring of data, and retrieval of data which have been stored on the monitor.

Installation of the VitalSense Application Software can be found under “ Installation of Software ” on page 3-3.

Calibration

VitalSense transmitter/sensors do not require calibration prior to use.

EMI and ESD Susceptibility

It is recommended you read the advisories concerning EMI and ESD. They begin on page -vii.

SECTION

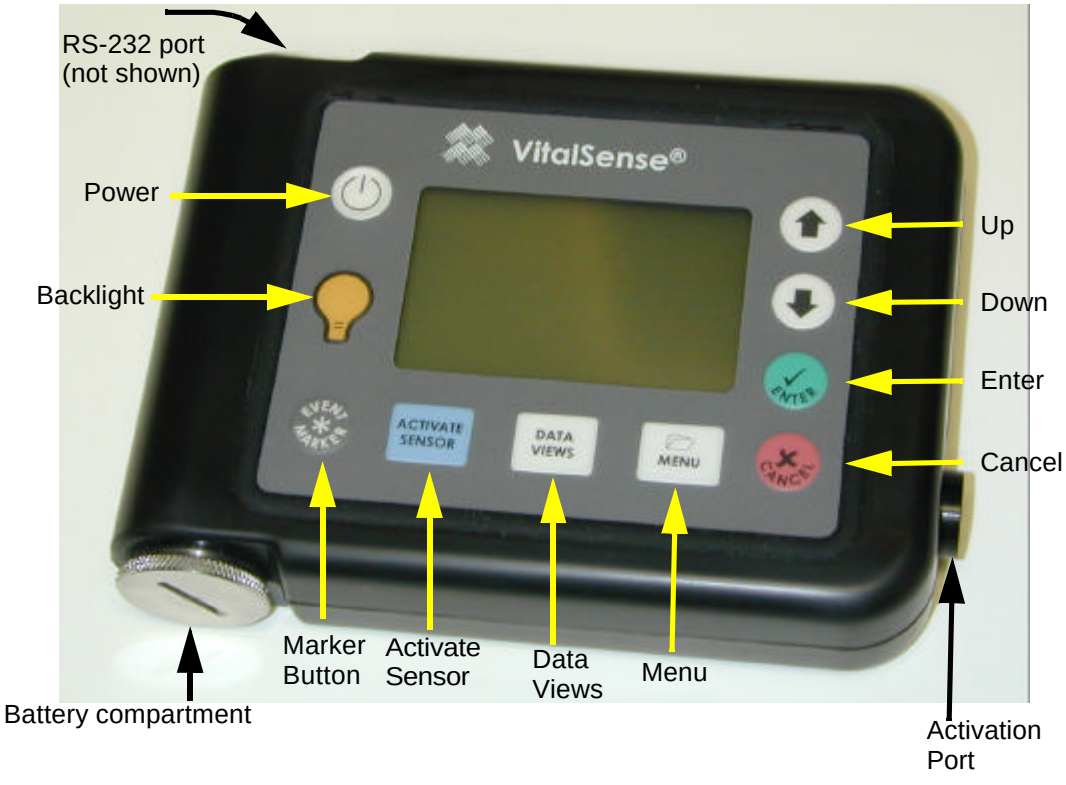
2

VITALSENSE MONITOR OPERATION

VitalSense Monitor - Description

The VitalSense Monitor is a splash-resistant, battery-operated receiver and logger. It activates the sensor via an optical beam, receives data from the sensor by radio, records data in a non-volatile memory, and facilitates transferring the data to a computer via a cable.

Monitor Front Panel



Front Panel Controls

VitalSense controls are sealed, splash-resistant, and provide tactile feedback.

Power On/Off
Turns the monitor on and off. Data and settings are preserved when the power is turned off.

Backlight
Light is activated for approximately 10 seconds when this button is pressed. If subsequent buttons are pressed, the backlight will remain on.

Marker Button
Inserts a time mark into the recorded data.

Data Views
Toggles between the Sensor List and the Data Graph chosen from the Sensor List.

Activate Sensor
Begins process of activation and automatic ID of sensors.

Menu
Front panel access to main menu.

Cancel
Exits various functions, cancels changes, etc.

Enter
Activates functions, inputs changes, etc.

Down Arrow
Selects menu items or decrements parameters.

Up Arrow
Selects menu items or increments parameters.

Other features

- RS-232 Port - Accepts RS-232 serial cable to facilitate transfer of data.
- Battery compartment - Access to lithium power source.
- Activation Port - Activates sensor during activation procedure.

Monitor Setup for Data Collection

Before data collection can begin, the monitor must be set up, or *configured*. All configuring can be done from the monitor front panel, and some configuration functions can be done from the host PC. This section will cover monitor front panel operations.

There are three requirements that may have to be accomplished before the monitor will collect data:

- **“ Erase Data Memory ” on page 2-27**
- **“ Adjusting the Time/Date ” on page 2-20**
- **“ Activating Sensors Using the VitalSense Monitor ” on page 2-7**

Some of these requirements may not be necessary, e.g., if you have configured VitalSense previously, erased the memory, or if you have already set the time.

Time and Date

Time and date must be set carefully. VitalSense data are collected with UTC (Universal Coordinated Time) as a reference. However, the monitor can display Local time as well as UTC.

If the UTC or Local times, and the UTC offset are entered correctly, VitalSense can compensate for Standard and Daylight time changes (US only).

If adjusting the time from the host PC, the monitor may automatically be set to the same time as your PC clock.

CAUTION! You cannot change the UTC time or date with sensors on-line. (UTC offset and Daylight Saving Time compensation are allowed.)

A note on UTC

UTC is based on precise atomic clocks, shortwave time signals, and satellites. This insures that there is a reliable, accurate standard for scientific and navigation purposes.

The difference between local time and UTC is called the UTC offset.

For detailed information on UTC, see “ Universal Coordinated Time ” on page B-1.

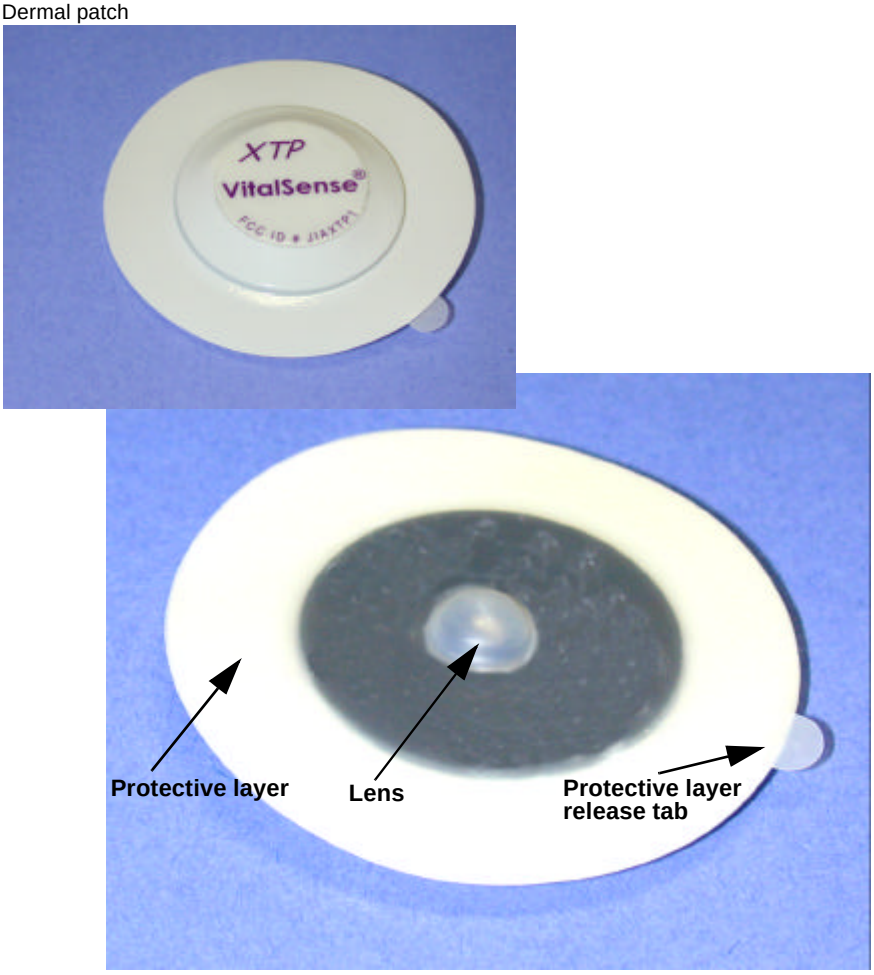
Precautions Prior to Activating the Dermal Patch Sensor

⚠ CAUTION **Read before activating patch sensor!**

Become familiar with the section " Notices to Practitioners and Subjects " on page -vii. It contains important information you need to know prior to activating the sensors.

The VitalSense Dermal Patch Sensor is a wireless, miniaturized, externally activated, temperature monitoring device that is attached to the skin with a pressure sensitive adhesive (PSA) and a protective layer. There are precautions associated with this device.

Dermal patch



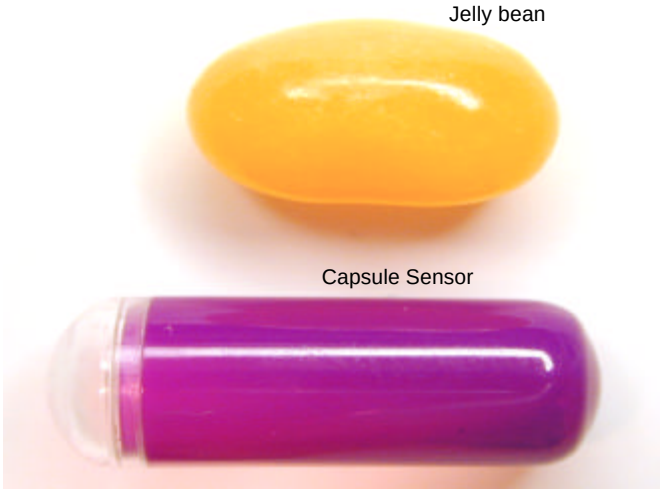
- DO NOT remove the Dermal Patch Sensor from the package until it is to be activated.
- DO NOT remove the protective layer prior to activation.
- Activate the Dermal Patch Sensor prior to application. *It cannot be activated once affixed to the body.*

Precautions Prior to Activating the Capsule Sensor

⚠ CAUTION **Read before activating capsule!**

Become familiar with the section “ Notices to Practitioners and Subjects ” on page -vii. It contains important information you need to know prior to activating the sensors.

Comparative Size



- DO NOT remove the Capsule Sensor from the package until it is to be activated.
- Activate the Capsule Sensor prior to swallowing. *It cannot be activated once swallowed.*

Activating Sensors Using the VitalSense Monitor

1 The process of sensor activation begins by first turning on the monitor. Press the Power button (see 1 below) and hold for approximately ½-second.

2 Next, press Activate Sensor (see 2 below).

Initiating the activation sequence

Activation

3 Follow the directions on the display. Place the sensor lens against the Activation Port. Press Activate Sensor again.

Activation Port alignment

Capsule sensor

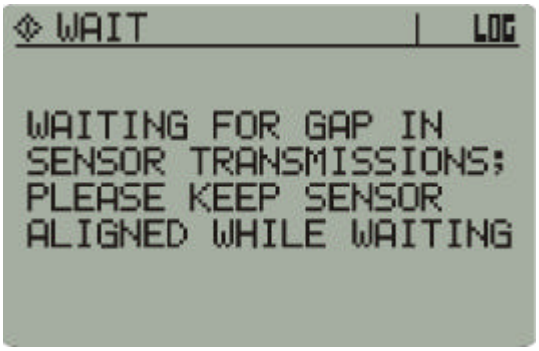
Dermal patch sensor

4 During the activation prompts (below), do not remove the sensor from the Activation Port.

Placement for activation

5 If other sensors are activated, you may receive the following message.

Waiting for transmission gap



6 You will be informed when the sensor has been successfully activated. Remove the sensor from the activation port.

Activation Complete

Successful activation

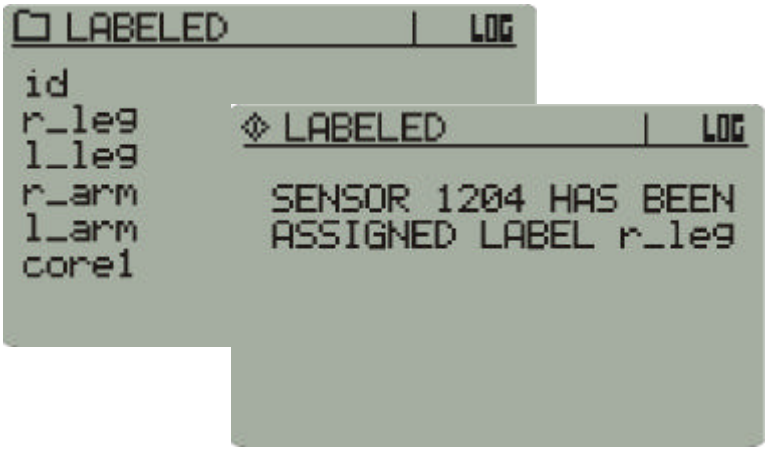
As shown above, you are asked if you want an optional sensor identification, or *label*. If you choose OK, it replaces the identity number of the sensor with placement information. Labeling the sensors *must be done at this time.* You cannot return to the sensor labeling routine.

7 Use the arrow buttons to choose either OK or Cancel, and press Enter.

8 If you choose to label the sensor, use the arrow buttons to choose the appropriate identifier for the sensor, and press Enter. In the illustrations below, the Right Leg (r_leg) is the label assigned to sensor 1204.

Sensor Labeling

Activate Sensor > (activated) > OK > Identifier



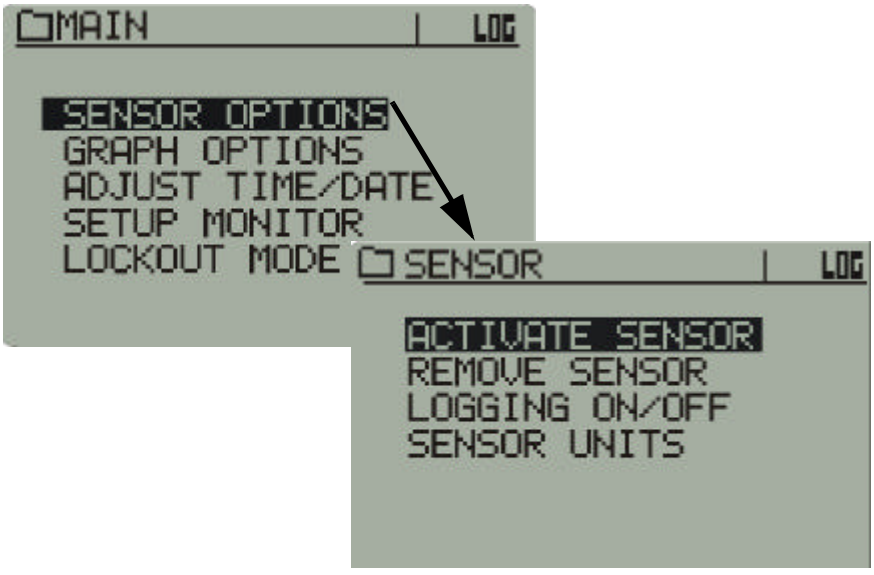
9 Sensor activation is complete. For additional sensors, repeat the procedure. Up to 10 sensors may be placed on-line per monitor.

---

*NOTE: "*id*" uses the numeric sensor identification number instead of a text label.*

Sensor activation can also be initiated from the Main menu as shown below. It is, however, physically easier to hold the sensor and use the Activate Sensor button.

Alternate activation sequence - Main display > Sensor Options > Activate Sensor



Administration

⚠ WARNING *Both the Capsule Sensor and the Dermal Patch contain ferromagnetic materials incompatible with MRI (magnetic resonance imaging) and should not be worn nor ingested if an MRI is planned. Any subject ingesting or affixing the above sensors is to wear an MRI Warning wrist band (supplied with each sensor) as long as the sensors are in place.*

Dermal Patch Sensor

1. Remove excess hair from the area in which the sensor will be mounted.
2. Prepare the skin by cleaning with an alcohol-moistened wipe.
3. Following successful activation, use the tab to peel away the protective layer.
4. Affix the Dermal Patch Sensor to the skin.
5. Affix an MRI Warning wrist band (supplied) to the subject with instructions that it is to be worn as long as the Dermal Patch is in place.

Keep the VitalSense Monitor within 2 meters of your body.

NOTE: Avoid the use of lotions and emollients in the area of the Dermal Patch Sensor. Their uses may cause the adhesive to loosen.

Capsule Sensor

⚠ CAUTION *Do not chew. There are metal components inside the capsule. Swallow whole with liquid.*

1. Following successful activation, swallow the Capsule Sensor with approximately 8-ounces of water, juice, or soft drink.
2. Keep the VitalSense Monitor within 1 meter of your body.
3. Affix an MRI Warning wrist band (supplied) to the subject with instructions that it is to be worn until the Capsule Sensor has been expelled.

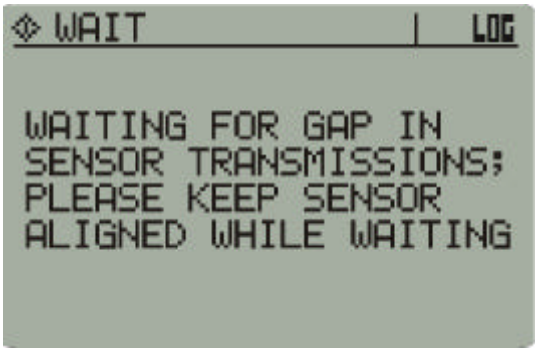
Sensor Does Not Activate

Failure to activate immediately

If the sensor does not activate within a few seconds, it may be waiting for a transmission from a previously activated sensor. Hold the sensor in place. Once the transmission has been received, the monitor will activate the new sensor.

NOTE: As more sensors are brought on-line, the monitor may need to wait for longer periods.

Activation delay notice



Failure to activate

If a sensor fails to activate, you will be prompted. There may be several reasons for non-activation.

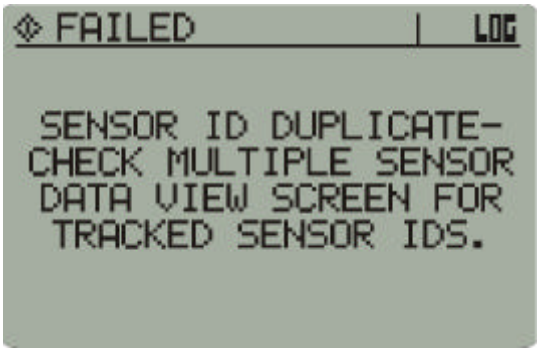
Sensor activation failed

- Wait approximately 5 seconds and try again.
- Check Data Views to verify that there is no sensor activation.
- Check that the sensor lens is aligned properly with the activation port.
- Attempt to re-try at least 3 times. If still not activated, return the sensor to Mini Mitter for analysis.

Duplicate sensor

The sensor will not activate if the identification number of the sensor is identical to one already in the monitor schedule.

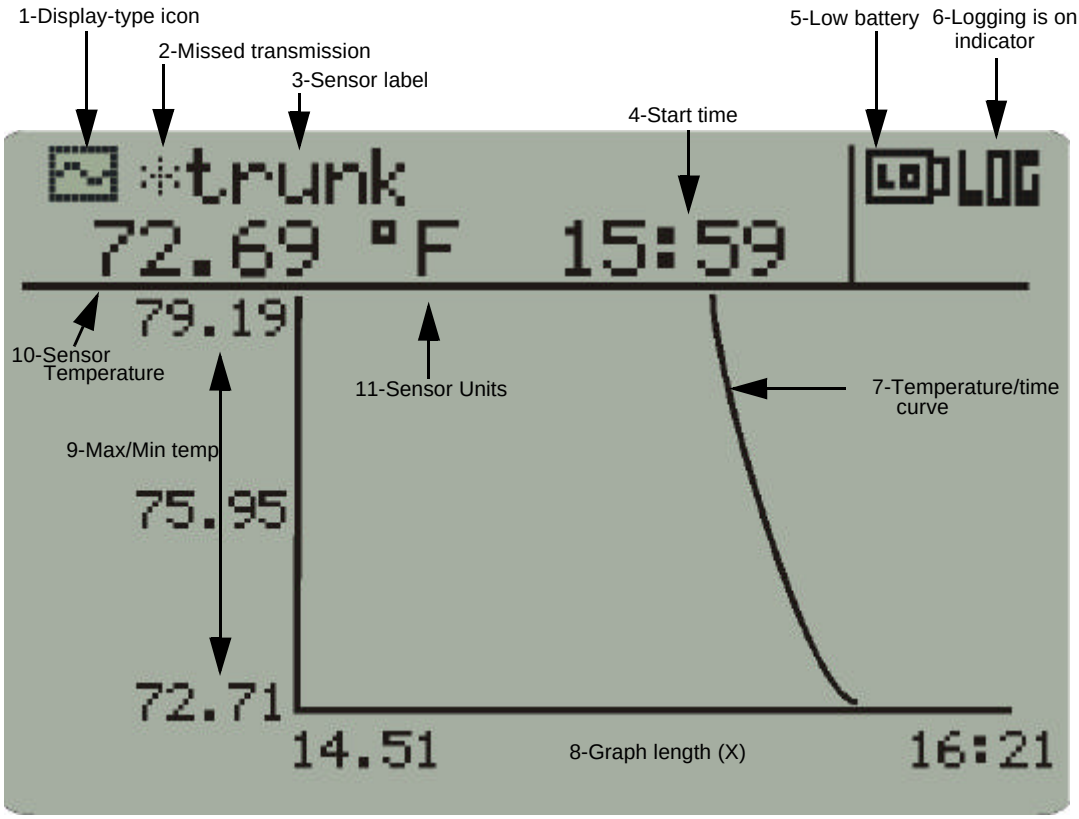
Duplicate sensor notice



NOTE: This error is very unlikely. Very few sensors will ever share the same identification. In the unlikely event this happens, use another sensor.

VitalSense Monitor Details of Operation - Display

The Data Graph displays a variety of operational characteristics.



1 **Display-type** - Activation, Menu, or Data View.

2 **Asterisk** - one or more of the last transmissions was missed. If reacquired, it will disappear.

3 **Sensor label** - option chosen or declined as part of activation sequence.

4 **Start time** - of the logging session.

5 **Low battery indicator** - battery life remaining will depend on the number of sensors and the acquisition mode of the monitor. See " Battery Replacement " on page 4-4 for additional information.

6 **Logging on** - monitor is logging sensor data (change from Menu > Sensor Options > Logging On/Off).

7 **Temperature/time curve** - a "rolling" curve updated as data are collected.

8 **Graph length** - determines the number of hours of data displayed (change from Main > Graph Options).

9 **Y-Scale minimum and maximum** - of the temperatures collected within the displayed time period.

10 **Sensor temperature** - last temperature acquired from any sensor.

11 **Sensor units** - temperature measurement in Celsius or Fahrenheit (change from Main > Sensor Units).

Icon Definitions

-  Activation display
-  Menu display
-  Data View display
-  Low battery indicator
-  Logging enabled

---

NOTE: If the VitalSense Monitor display should inexplicably go blank, momentarily press any button. High discharges of ESD can cause the display to shut down. See “ Electrostatic Discharge Effects on Monitor ” on page -x.

VitalSense Monitor Details of Operation - Menus

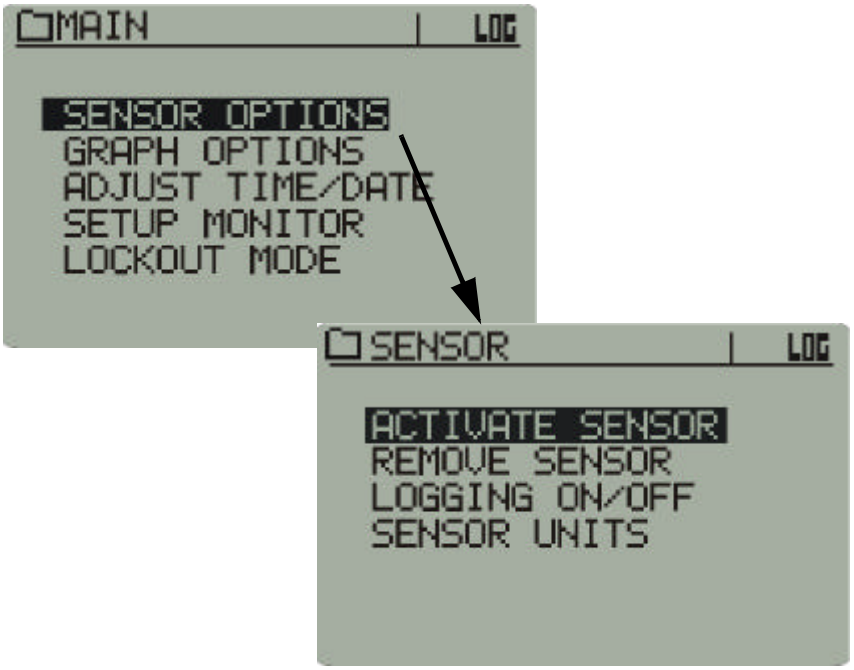
The Main Menu is a gateway to several sub-menus.

Sensor Options

Sensor Options

Activate Sensor

Main > Sensor Options > Activate Sensor



The process described above is identical to the function of the Activate Sensor button on the front panel of the monitor. See “ Activating Sensors Using the VitalSense Monitor ” on page 2-7.

Remove Sensor

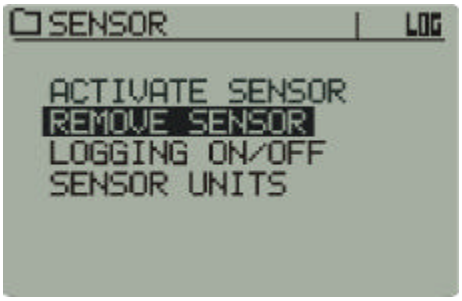
The Remove Sensor function deletes a sensor from the sensor schedule. However, data from that sensor, if logged, will be preserved.

CAUTION *Once a sensor has been removed from tracking, the tracking cannot be reestablished for that sensor.*

---

1 Select Remove Sensor from the Sensor Option list.

Main > Sensor Options > Remove Sensor

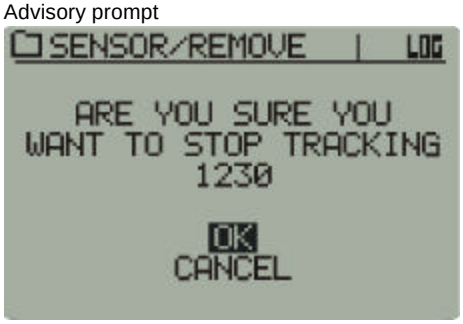


2 From the sensor schedule, use the arrow buttons to select the sensor that is to be removed. Press Enter.

Remove Sensor selection

3 If you want to cease tracking and remove the selected sensor, select OK and press Enter.

Advisory prompt



4 The selected sensor is removed from the sensor schedule.

Sensor removed from schedule

Sensor Options

Logging ON/OFF

This function toggles the VitalSense Monitor logging selection ON or OFF. If turned off, the VitalSense Monitor will continue to communicate with the sensors, but the data memory will not log the data until logging is toggled back to ON.

1 Use the arrow buttons to select between ON and OFF.

2 Press Enter.

Main > Sensor Options > Logging On/Off

Sensor Options

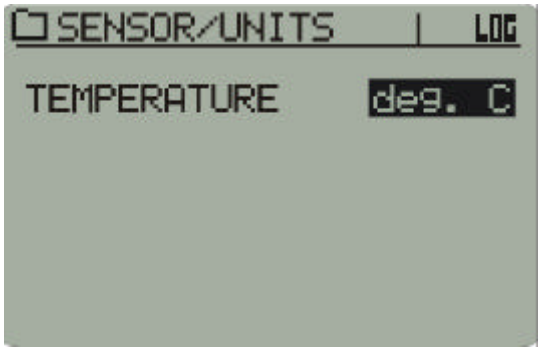
Sensor Units

Temperatures can be displayed in Celsius or Fahrenheit.

1 Use the arrow buttons to select between the two choices.

2 Press Enter.

Main > Sensor Options > Sensor Units



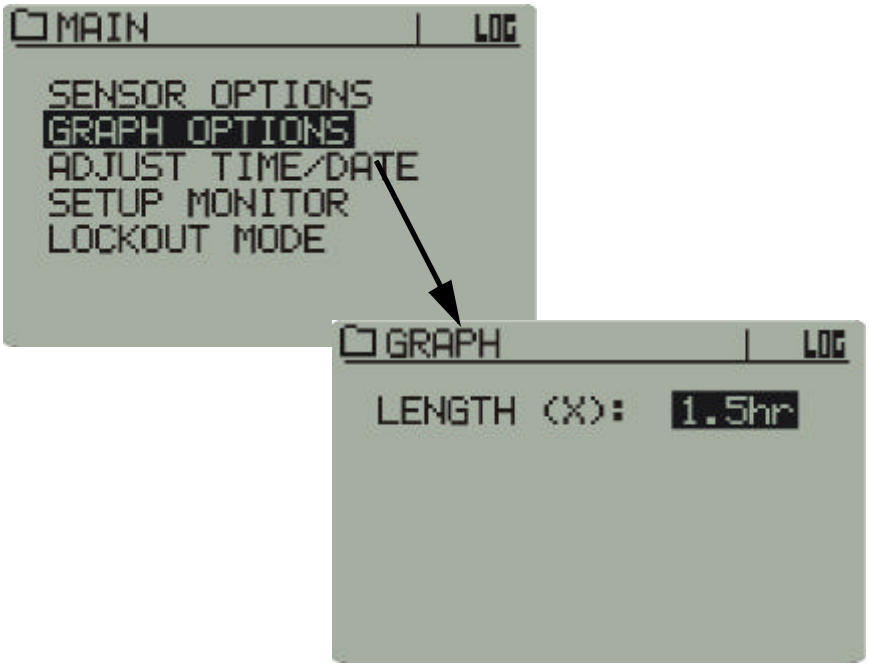
Graph Options

Length (X)

This function sets the length (in hours) of the X-axis displayed in the Data Views graph. Up to 48 hours of data can be displayed. The following choices are available. Use the arrow buttons to make the selection, and press Enter.

- 1.5 hours
- 3 hours
- 6 hours
- 12 hours
- 24 hours
- 48 hours

Main > Graph Options



NOTE: When this parameter is changed while logging is in progress, the graph will be interpolated or extrapolated to the new time scale, which may result in empty areas when increasing the time scale. This has no effect on the integrity of the data being logged, although the data may not be visible until a new graph is drawn.

Adjusting the Time/Date

When setting the clock, use the arrow buttons to navigate through the menus and increment and decrement the highlighted choices. Press Enter to make your selection.

There are two methods by which the clock should be set.

Method A

1. Check (or uncheck) Daylight Saving Time Auto-set.
2. Set the UTC Offset.
3. Set the local time.

If the previous three steps are followed, the UTC clock will be set automatically.

Method B

1. Set the UTC time.
2. Set the UTC offset.
3. Check (or uncheck) Daylight Saving Time Auto-set.

If the previous three steps are followed, the Local Time will be set automatically.

NOTE: Although the clock functions are accessible from the monitor front panel, it is much easier and more efficient to change them from the VitalSense Application Program on the host PC. See " Setting the Monitor Clock " on page 3-9.

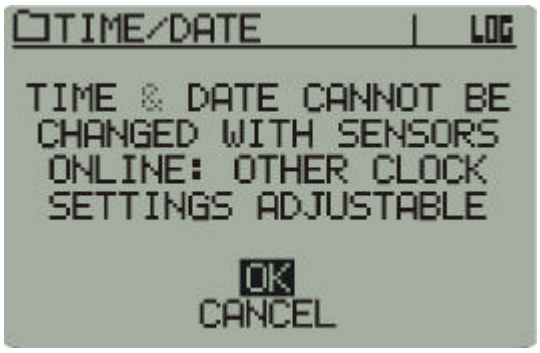
---

1 From the Main menu, use the arrow buttons to select Adjust Time/Date and press Enter.

Adjust Time/Date

2 If you have sensors on-line, you will receive an advisory that the time and date cannot be changed.

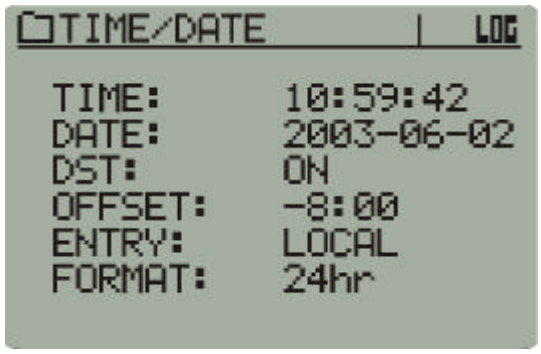
Sensor on-line advisory



3 Use the up and down arrow buttons to select either OK or Cancel, and press Enter.

4 The following menu is the Time/Date entry display. To make changes, use the arrows to navigate to the desired location, and press Enter. Again, use the arrow buttons to make your selection.

Time/Date menu

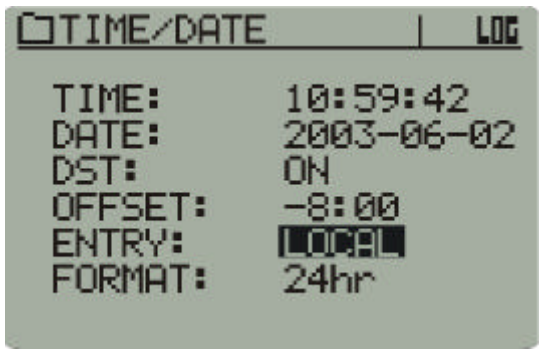


Setting the Time and Date

This procedure will set the monitor to Local or UTC time.

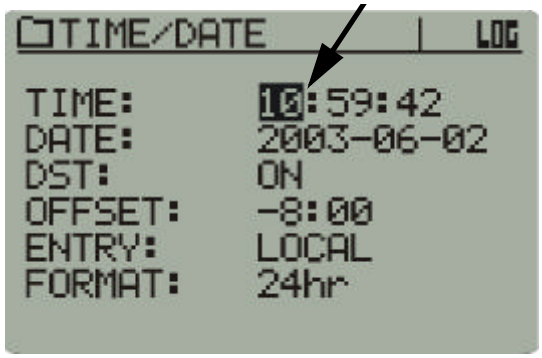
1 The factory default for the Time/Date menu selection is Local. Use the arrow buttons to toggle between Local and UTC time.

Local time



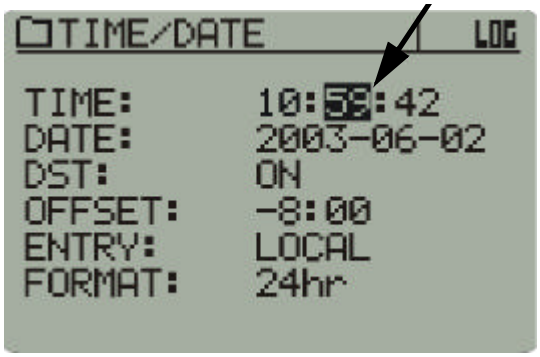
2 Use the arrows to navigate to the *hour* as shown below. (The selection will default to the hour when the Time/Date menu is selected.) Press Enter. Use the arrow buttons to increment and decrement the selection. Press Enter to input the selection.

Hours selected



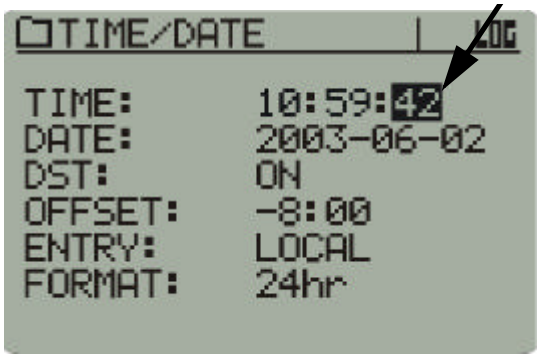
3 Use the arrows to navigate to the *minutes*. Press Enter. Use the arrow buttons to increment and decrement the selection. Press Enter to make your selection.

Minutes selected



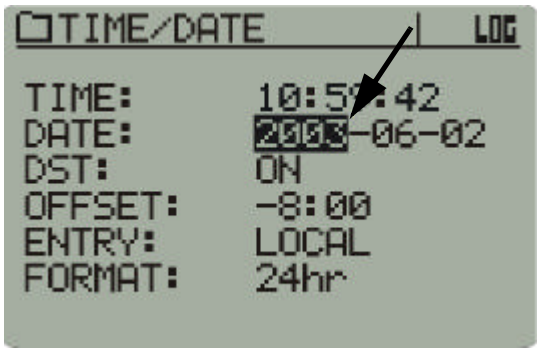
4 Repeat this procedure to change the *seconds*.

Seconds selected



5 This procedure is also used to change the *date*, beginning with the year.

Year selected



Daylight Saving Time Auto-Set

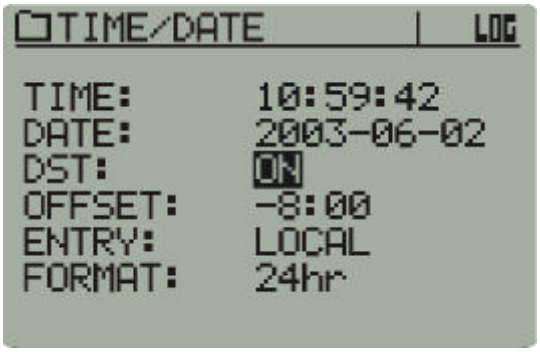
VitalSense will automatically compensate for the change of Daylight Saving Time to Standard Time and back again based on the monitor's time and date settings. However, this feature can be turned off.

NOTE: Automatic Daylight Saving Time should be used only in the United States, and in those regions observing DST.

---

1 Use the arrow buttons to navigate to DST:, and press Enter. Use the arrow buttons to toggle between ON and OFF.

Daylight time selected



2 Press Enter to make your selection.

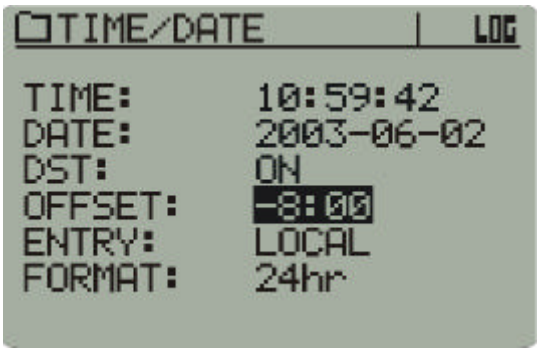
NOTE: Every Leap Year, VitalSense will compensate for Leap Day. No adjustment is necessary.

Setting the UTC Offset

The UTC (Universal Coordinated Time) Offset sets the differential between Local Time and the UTC time, not including Daylight Saving time. The DST setting may contribute an additional 1-hour offset based on the date, if enabled. For more information on UTC, see “ A note on UTC ” on page 2-4, and for detailed information see the appendix entitled “ Universal Coordinated Time ” on page B-1.

NOTE: If the UTC is set correctly, and the correct UTC Offset is entered, local time will be set automatically.

UTC Offset



NOTE: All data are saved in UTC regardless of whether UTC or local time is displayed. When data are transferred to the PC, they can be displayed in UTC or local time.

Setup Monitor

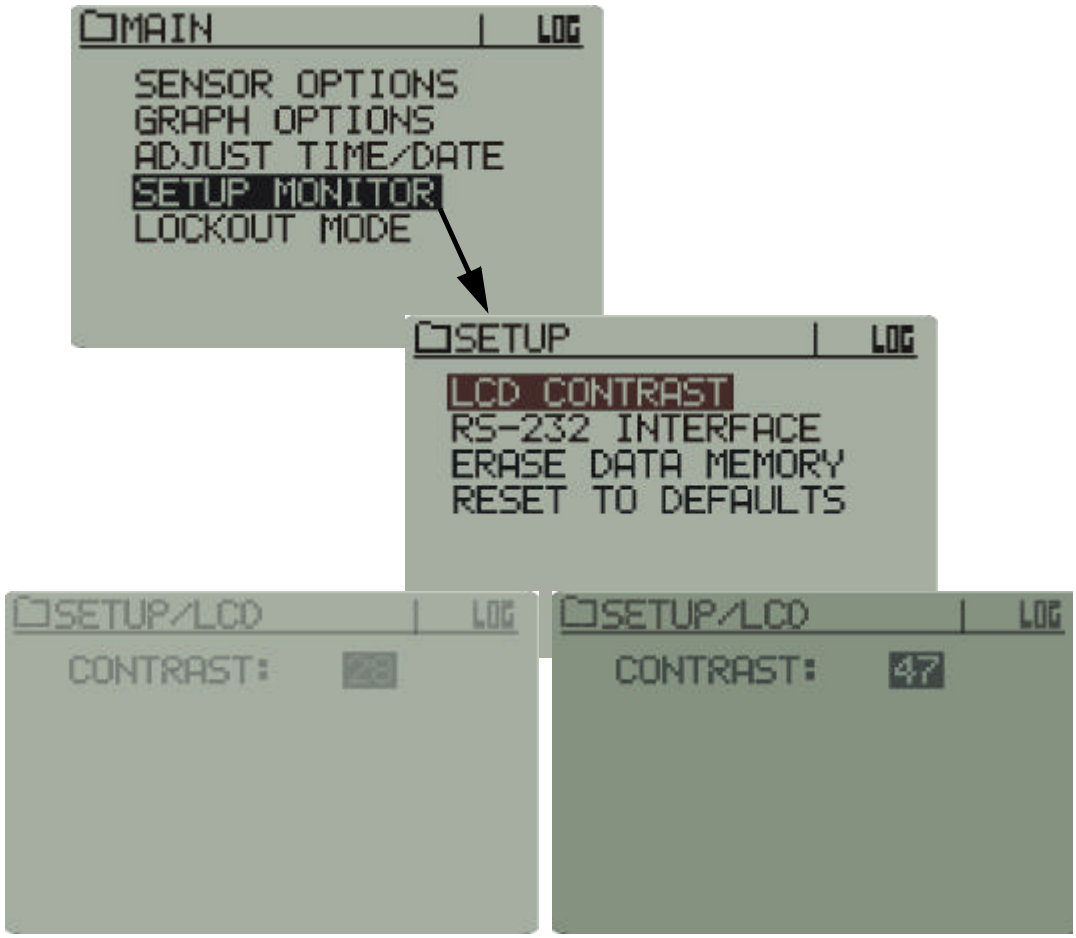
LCD Contrast

If necessary, the contrast of the LCD can be adjusted.

1 Use the arrow buttons to change the contrast.

2 Press Enter.

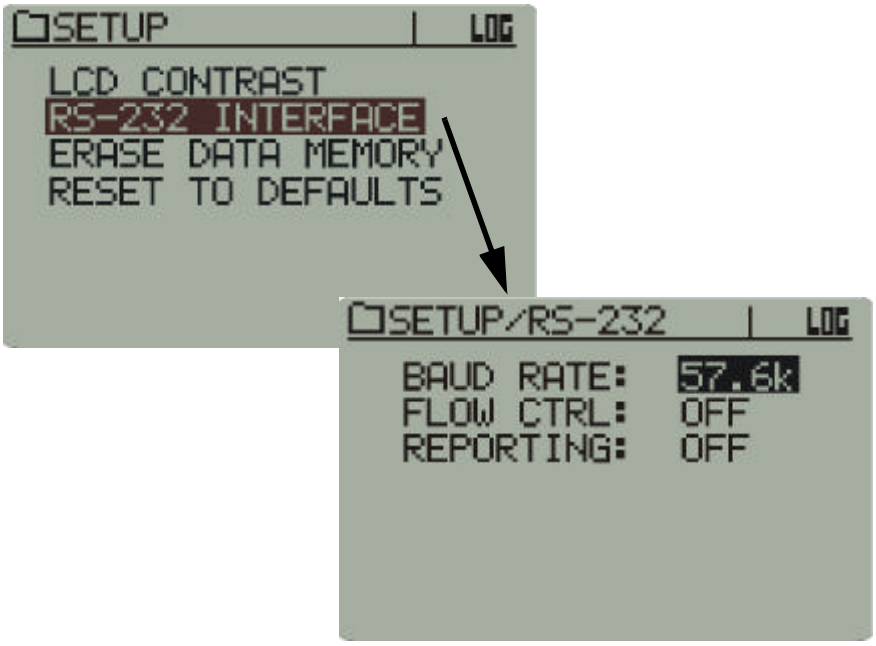
Main > Setup Monitor > LCD Contrast



RS-232 Interface

It may become necessary to change the RS-232 configuration. The default configuration is: 57.6 kilobaud, Flow Control: Off.

Main > Setup Monitor > RS-232 Interface



The combinations available are listed in the table below:

Baud Rate	2400, 4800, 9600, 19.2 k, 38.4 k, 57.6 k, 115.2 k
Flow Control	ON, OFF
Reporting	ON, OFF

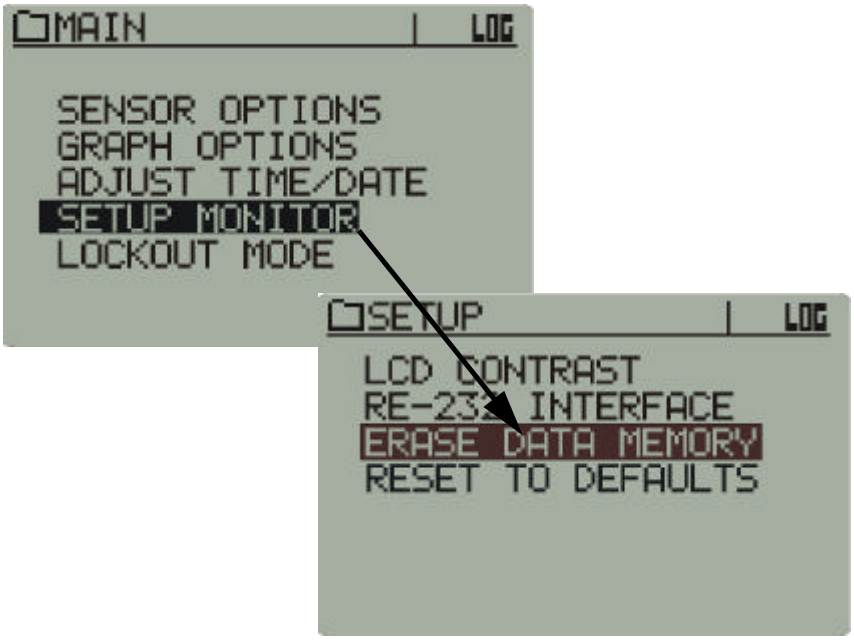
NOTE: It is recommended that if you are unfamiliar with these terms, you leave the settings to the default values.

Erase Data Memory

Prior to initiating a new session, the data memory should be erased to provide maximum storage capacity.

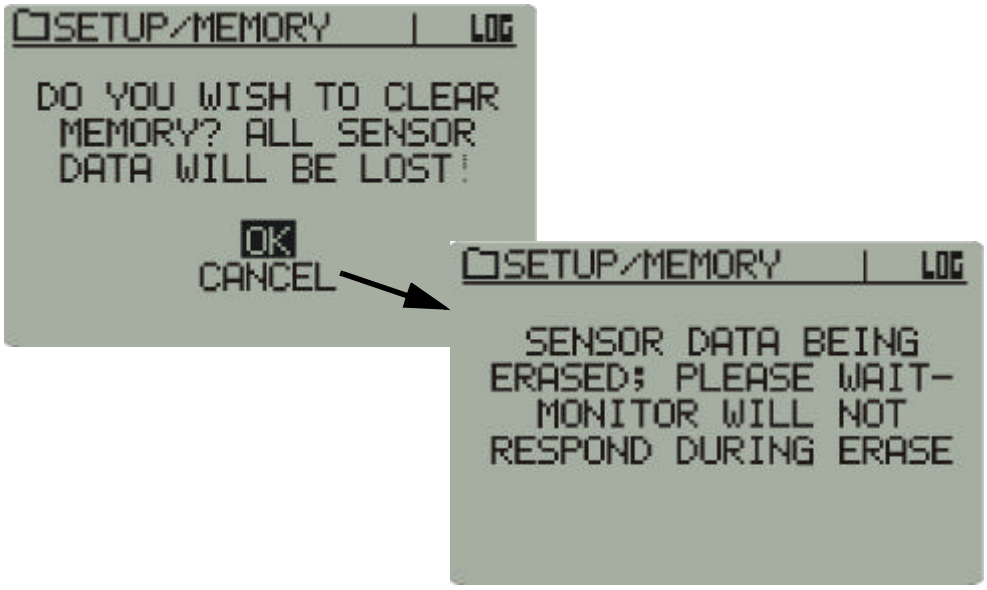
1 Use the arrow buttons to access Erase Data Memory.

Main > Setup Monitor > Erase Data Memory



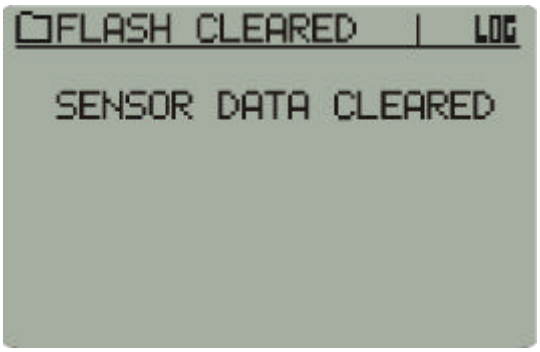
2 Use the arrow buttons to select OK. Memory erasure will take up to 30 seconds. The monitor front panel functions will be locked out until the memory is cleared.

Memory erase safety prompt



3 You will be prompted when the memory is clear.

Memory clear prompt

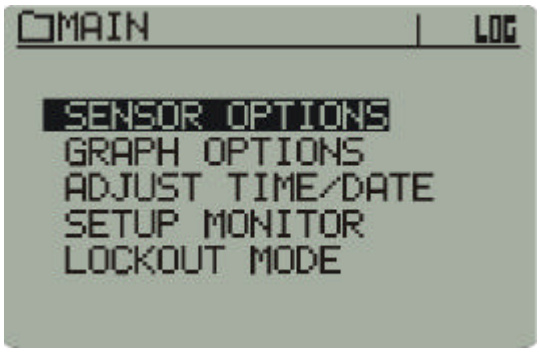


Reset to Defaults

This procedure will return the VitalSense Monitor to the factory configuration.

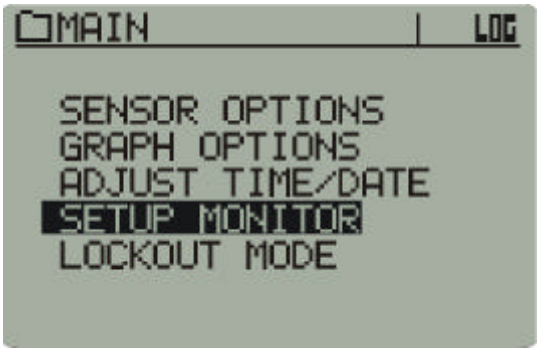
1 Press the Power button on the monitor front panel. The following Main menu will appear.

Main Menu



2 Using the arrow buttons, highlight Setup Monitor, and press Enter.

Main > Setup Monitor



3 Using the arrow buttons, highlight Reset to Defaults, and press Enter.

Main > Setup Monitor > Reset to Defaults

4 A prompt will appear. Use the arrow buttons, select OK, and press Enter.

Advisory prompt

The monitor has now reset to the factory default settings.

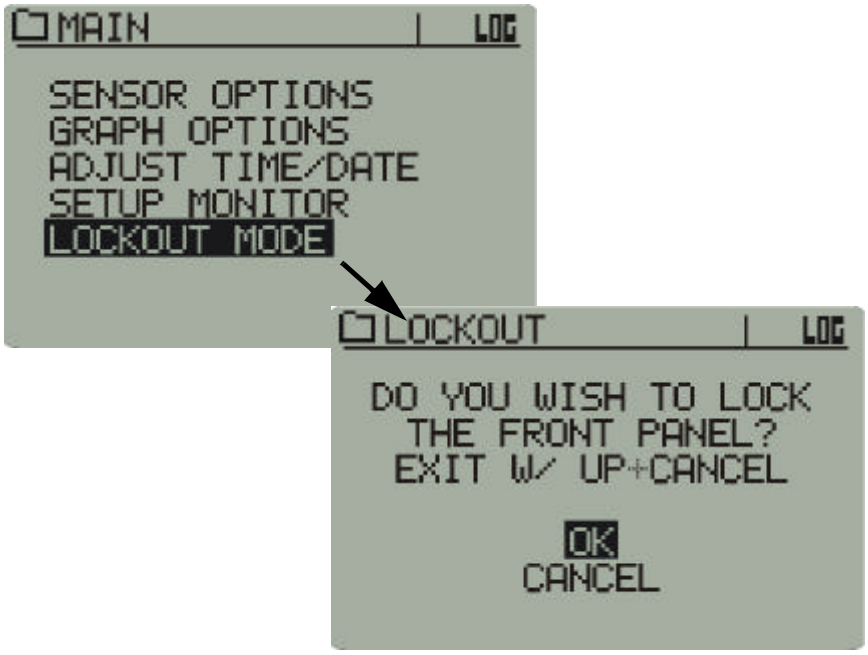
Lockout Mode

Lockout Activate

Lockout Mode enables the practitioner to lock the front panel functions to discourage unauthorized tampering of the settings, or to prevent accidental activation of front panel buttons while the monitor is in the carrying pouch.

1. Use the arrow buttons to select Lockout Mode.
2. Use the arrow buttons to select OK, and press Return to activate.

Main > Lockout Mode



Lockout deactivate

To deactivate Lockout Mode, press and hold the up arrow, and press Cancel. Normal operation of the front panel will resume.

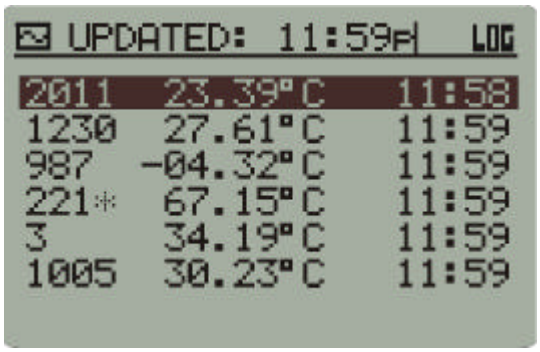
Data Views

Pressing the Data Views button on the VitalSense Monitor front panel will toggle two means by which to view the sensor data: Sensor List and Data Graph.

1 On the monitor front panel, press the Data Views button. A list of sensors will be displayed along with the temperature and time stamp. (Use the up and down arrows to view sensors which may not be visible on the display.)

Sensor List

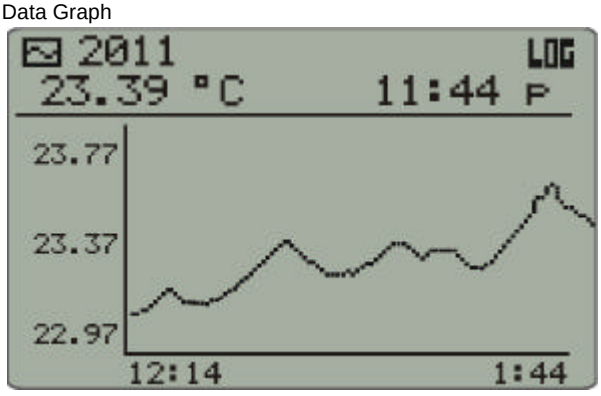
Sensor List



Data Graph

2 To view a sensor in Data Graph mode, highlight the sensor using the arrow buttons, and press Data Views once more. To adjust the amount of time shown on the X-axis of the graph, see “ Graph Options ” on page 2-19.

Data Graph



3 You may toggle between Data Graph and Sensor List with the Data Views button. To view other sensors in Data Graph mode, use the arrow buttons to highlight the sensor of interest and press Data Views once more.

Out-of-Range Conditions

With respect to periodic hygiene, change of clothing, decontamination, and other related tasks, it may be necessary to remove the VitalSense Monitor from the working range of the sensors for short periods of time.

The VitalSense Monitor may be removed from sensor range for up to 30 minutes. Beyond 30 minutes, VitalSense may have difficulty resynchronizing with sensor transmissions, and a significant loss of data may occur. Previously logged data will be preserved in the monitor, but future data collection may not be possible in Standard Mode.

An asterisk will appear beside any sensor for which the last data transmission was missed. The value displayed will be the last valid data for that sensor. The time shown will be when the last reading was recorded.