Mini Mitter Company, Inc.

Bend, OR USA

VitalSense®

Integrated Physiological Monitoring System

Instruction Manual

PRELIMINARY

This document is Mini Mitter Part Number 910-0500-Preliminary C

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.

THE WARRANTY SET FORTH ABOVE IS EXCLUSIVE AND MINI MITTER GIVES NO OTHER WARRANTY WRITTEN OR VERBAL, EXPRESS OR IMPLIED. MINI MITTER SPECIFICALLY DISCLAIMS THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. MINI MITTER'S STANDARD WARRANTY POLICY COVERING ANY MINI MITTER PRODUCTS SHALL BE NULL, VOID, AND OF NO EFFECT IF THE BUYER OR ANY THIRD PARTY USES THAT PRODUCT FOR ANY USE OTHER THAN THE INTENDED USE OF THAT PRODUCT.

2. **LIMITATION OF REMEDIES AND LIABILITY**. The remedies provided herein are Buyer's sole and exclusive remedies. Mini Mitter shall have no responsibility other than, at Mini Mitter's option, to repair or replace defective or nonconforming goods or to refund the purchase price of defective or nonconforming goods in the event of breach of any warranty. IN NO EVENT SHALL MM BE LIABLE FOR ANY DIRECT, INDIRECT SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES (INCLUDING LOSS OF PROFITS) WHETHER BASED ON CONTRACT, TORT OR ANY OTHER LEGAL THEORY. In the event that any limitation of warranty or disclaimer of liability is found to be unlawful or inapplicable, or to have failed of its essential purpose, Mini Mitter's liability shall be limited to the amount paid by the Buyer for the specific goods that caused such liability.

Thank You! .....for purchasing Mini Mitter products. If you need assistance with VitalSense, 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

Telephone **(800) 685-2999**
(541) 322-7272

Fax **(541) 322-7277**

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

Website **www.minimitter.com**

Notice to Practitioners and Subjects

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 limites are designed to provide reasonable protection against harmful interference in a residential intallation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful inteference to radio communications. However, there is no guarantee that interference will not occur in a particular installation,. If this equipment does cause harmful inteference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocated the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio TV technician for help.

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.

Modification of VitalSense Devices

CAUTION! Any changes to the VitalSense monitor or sensors not expressly approved by Mini Mitter will void the practitioner or subject the authority to operate the devices.

Table of Contents

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

- Monitor
- Dermal Patch Sensor
- Capsule Sensor

Once a sensor is activated, it measures temperature data four times per minute, and reports on average of four times per minute to the monitor. The temperature data is timestamped and recorded for the measured time.

Up to ten sensors may be monitored. In order to do this, each sensor must be activated by the monitor that will be recording that particular sensor. During activation, each sensor and the monitor are synchronized.

IMPORTANT!

- **Section Two** of this manual explains the operation of the VitalSense System as controlled from the front panel of the VitalSense monitor. This is a “stand alone” section independent of Section Two, assuming you are operating VitalSense from the monitor front panel.
- **Section Three** of this manual explains the operation of the VitalSense System controlled from the Application Software. This is a “stand alone” section independent of Section one, assuming you are operating VitalSense from the Application Software.

Sensors

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

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

Each sensor is given an identity number at the factory, along with temperature calibration data. During activation, these data are 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.

SECTION

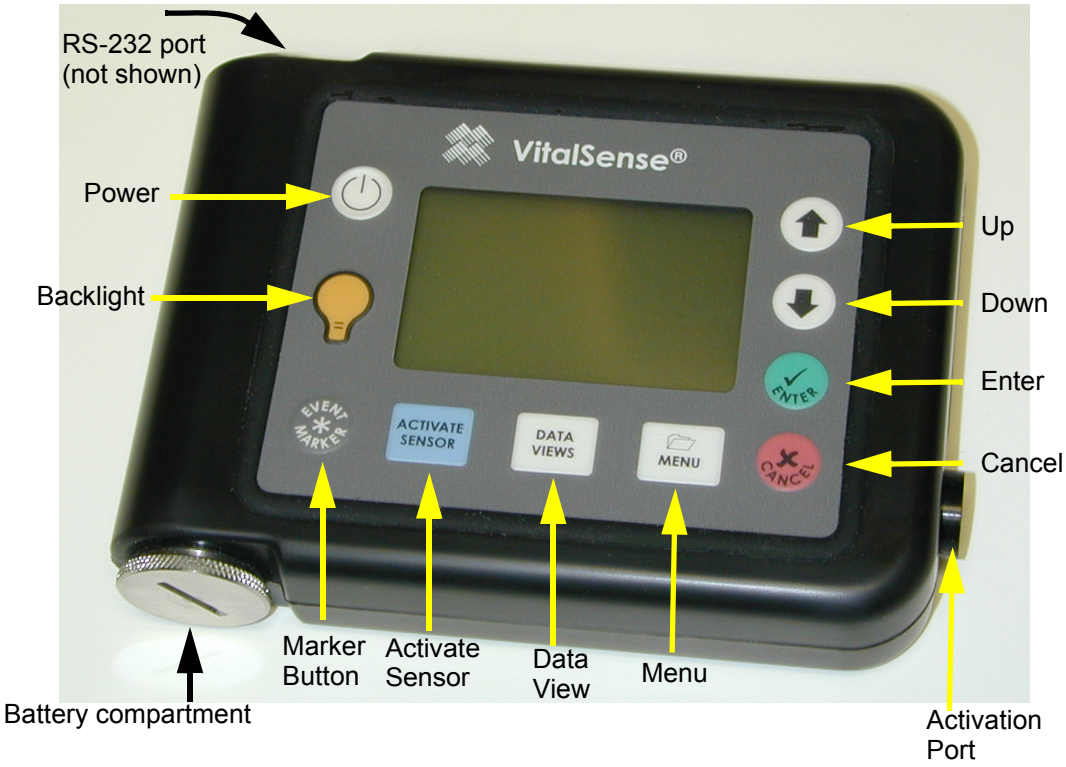
2

VITALSENSE MONITOR - OPERATION FROM FRONT PANEL

VitalSense Monitor - Description

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

Monitor Front Panel



Controls

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

- Power On/Off - Data are preserved when power is turned off
- Backlight - The backlight is activated for approximately 10 seconds when this or subsequent keys are pressed
- Marker Button - Inserts a time mark into the recorded data

  (The Marker button is currently disabled)
- Data Views - Toggles between the Multiple Sensor list and the data graph chosen from the Multiple 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 cable to facilitate transfer of data
- Battery compartment - Access to lithium power source
- Activation Port - Activates sensor during activation procedure

Initial Monitor Setup for Data Collection

Before data collection can begin, the monitor must be set up, or *configured*. This configuration can be done from the PC through the RS-232 port of the monitor, or from the monitor front panel. This section will cover monitor front panel operations.

There are four operations that should be accomplished to assure the monitor will collect data:

- **“ Set to Factory Default ” on page 2-3**
- **“ Adjusting the Time/Date ” on page 2-6**
- **“ Erase Data Memory ” on page 2-11**
- **“ Activating Sensors Using the VitalSense Monitor ” on page 2-15**

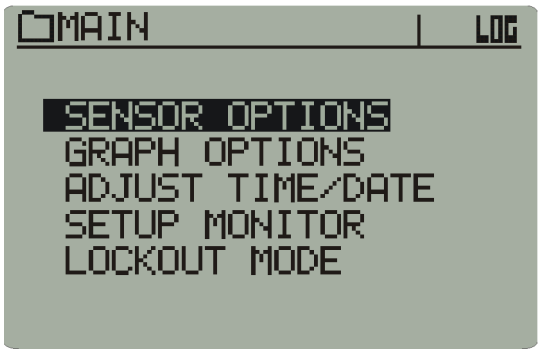
Some or all of the first three items may not be necessary if, for example, you have configured VitalSense previously, erased the memory, or if you have already set the time.

Set to Factory Default

This procedure insures that during initial setup, the default settings are displayed and the subsequent setup procedure can be followed without confusion.

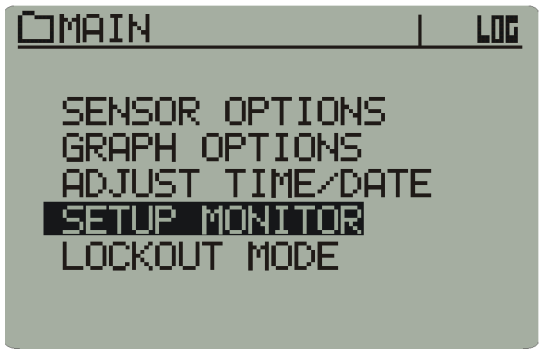
1 Press the power button on the Monitor front panel. The following Main menu will appear.

Main Menu



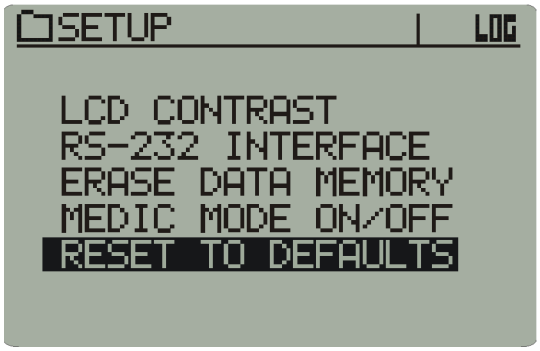
2 Using the arrow buttons, highlight Setup Monitor, and press Enter.

Setup Monitor



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

Set to Defaults



4 A warning will appear. Select OK, and press Enter.

Warning prompt

The Monitor is now set to the factory default settings.

Time and Date

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

If the UTC or Local times, and the UTC offset are entered correctly, VitalSense can compensate between Standard and Daylight time, and take into account your PC's clock.

CAUTION! When collecting data from sensors which are on line, do not change the time setting or the sensor may be lost.

A note on UTC

UTC, or Universal Coordinated Time, 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.

Adjusting the Time/Date

In the following instructions, use the arrow keys to navigate through the menus and increment and decrement the highlighted choices.

NOTE: Although the clock functions are accessible from the monitor front panel, it is easier to change them from the VitalSense software on your PC.

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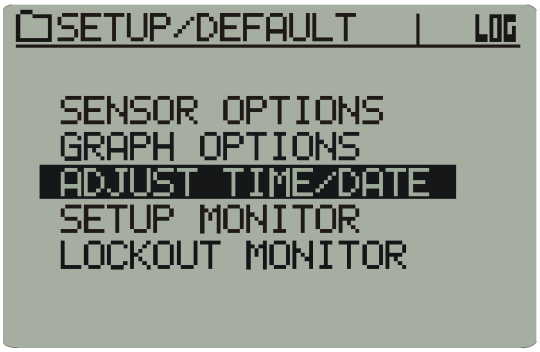
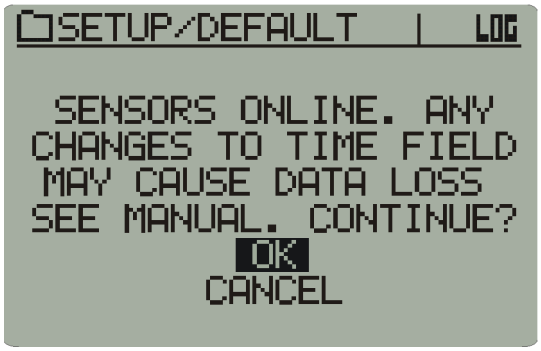
1 From the Main menu, select Adjust Time/Date and press Enter.

Adjust Time/Date



2 If you have sensors on line, you will receive a warning.

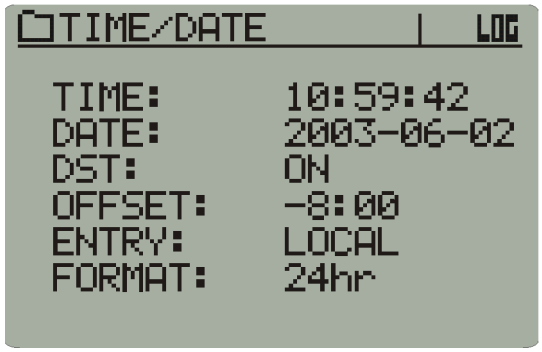
Sensor on-line warning



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

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

Time/Date menu

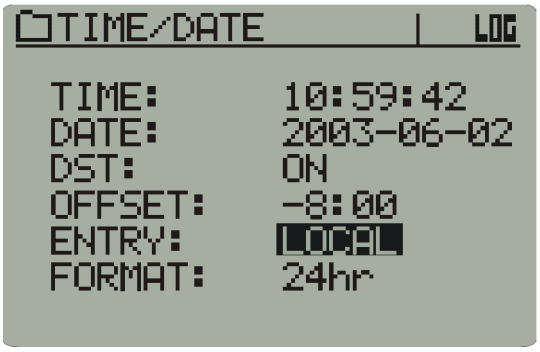


Setting the Local Time and Date

This procedure will set the Monitor to Local time.

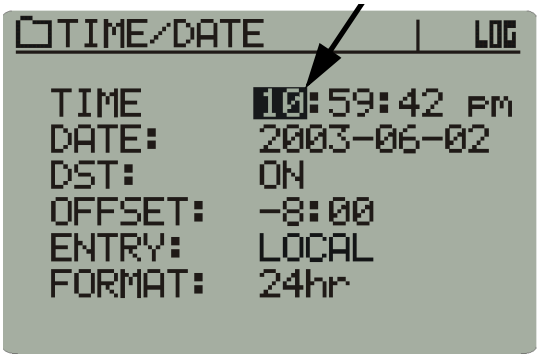
1 The factory default for the Time/Date menu selection is Local.

Local time



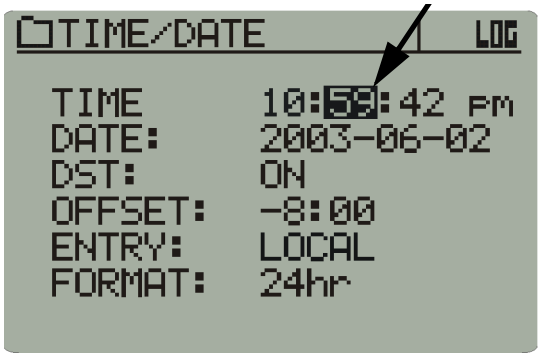
2 Use the arrows to navigate to the hour as shown below. (The selection will default to the hour when the Time/Date menu is selected.) Press Enter. Use the arrows to increment and decrement the selection. Press Enter to input the selection.

Hours selected



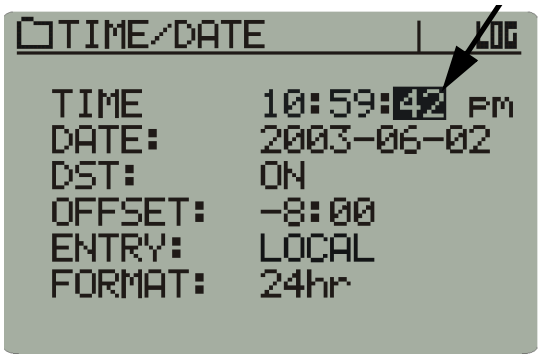
3 Use the arrows to navigate to the minutes. Press Enter. Use the arrows to increment and decrement the selection. Press Enter to input the selection.

Minutes selected



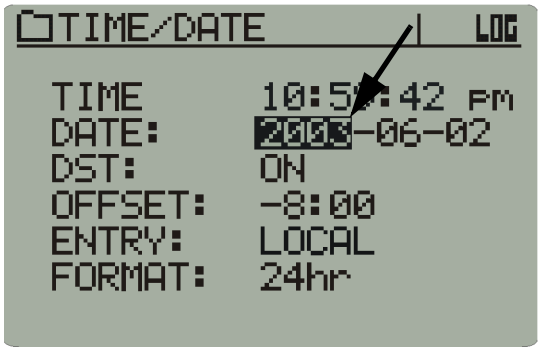
4 Continue this procedure to change the seconds.

Seconds selected



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

Year selected

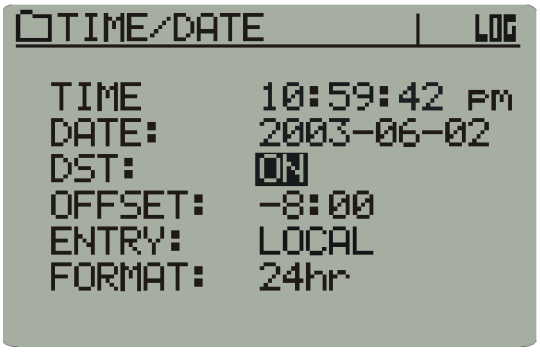


Daylight Savings Time Auto-Set

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

1 Use the arrows to navigate to Daylight Savings Time On, and press Enter. Use the arrows to toggle between On and Off.

Daylight time selected

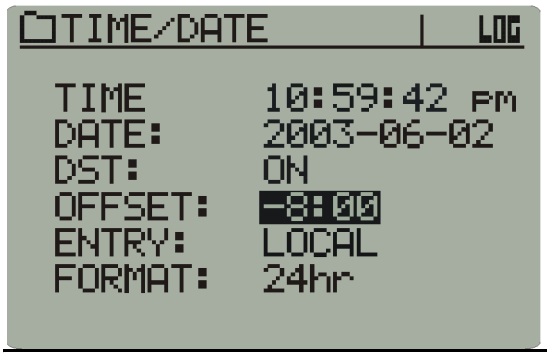


2 Press Enter to input your selection.

Setting the UTC Offset

Setting the UTC Offset sets the differential between Local Time and the UTC time, not including Daylight Savings time. The SDT 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 2-5.

UTC Offset



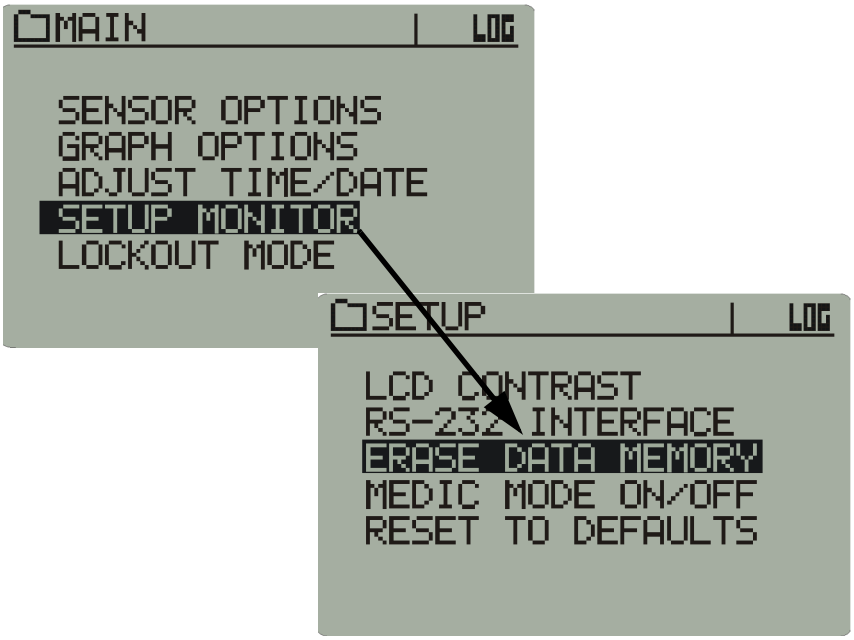
NOTE: All data are saved in UTC regardless of whether UTC or local time is displayed. When data are transferred to the PC, it can be displayed in local or UTC time.

Erase Data Memory

Prior to collecting data, the data memory should be erased to provide maximum storage capacity.

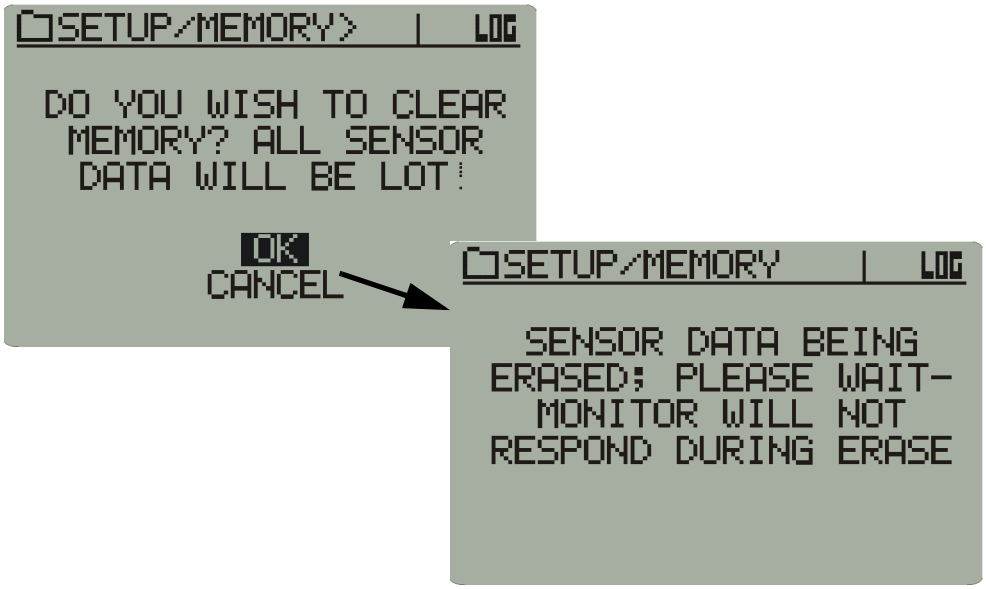
1 Use the Up/Down controls to access Erase Data Memory.

Setup Monitor > Erase Data Memory



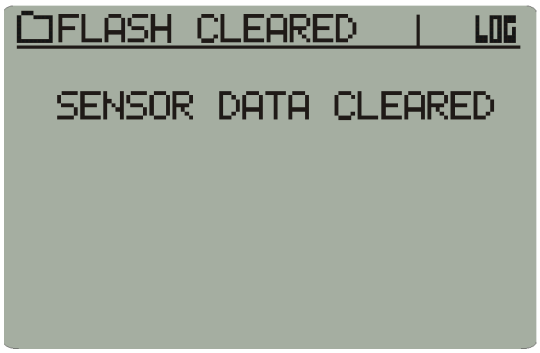
2 Use the Up/Down controls to select OK. Memory erasure will take up to 30 seconds. The monitor front panel will be locked out until the memory is cleared.

Memory erase safety prompt



3 You will be prompted when the memory is clear.

Memory clear prompt

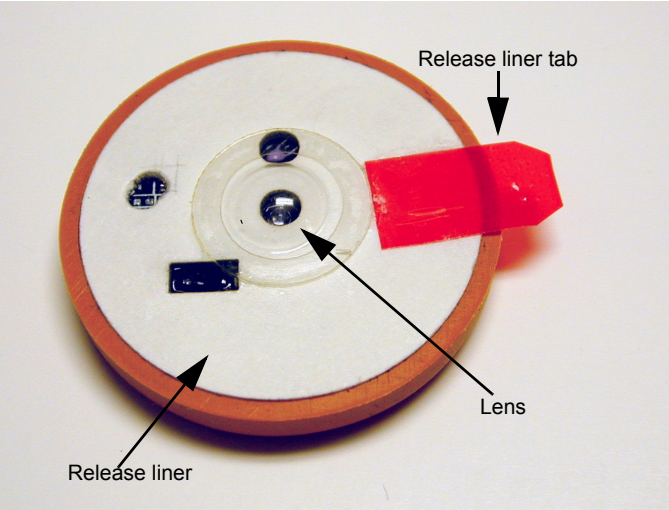


Precautions Prior to Activating the Dermal Patch Sensor

CAUTION! - Read before activating patch sensor!

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) release liner. There are precautions associated with this device.

Dermal patch



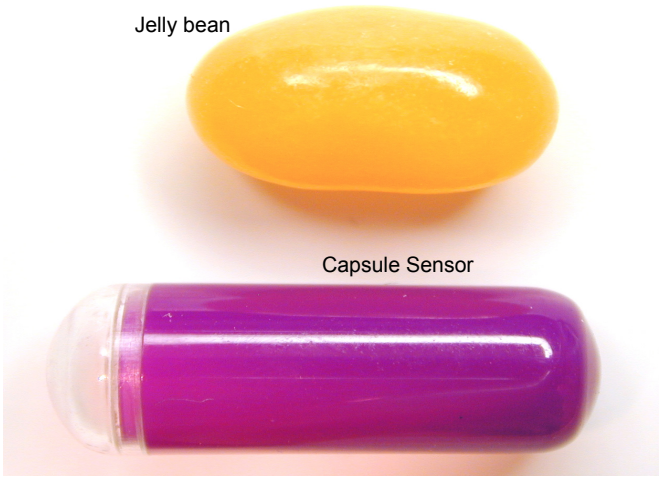
- DO NOT remove the Dermal Patch Sensor from the package until it is to be activated.
- DO NOT remove the release liner prior to activation.
- Activate the Dermal Patch Sensor prior to application. It cannot be activated once affixed to the body.

Precautions Prior to Activating the Capsule Sensor

CAUTION! - Read before activating capsule!

There are precautions associated with the Capsule Sensor prior to activation.

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 pressing Sensor Activation on the front panel.

2 Follow the directions on the display. First, place the sensor lens against the optical port. Press Activate Sensor.

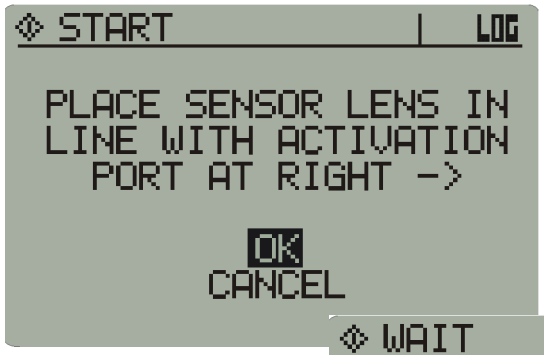
Activation Port alignment

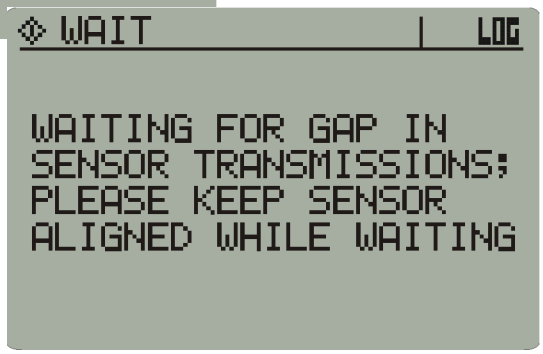
Capsule sensor

Dermal patch sensor

3 During the activation prompt (below), do not remove the sensor from the Activation Port.

Attempting to activate



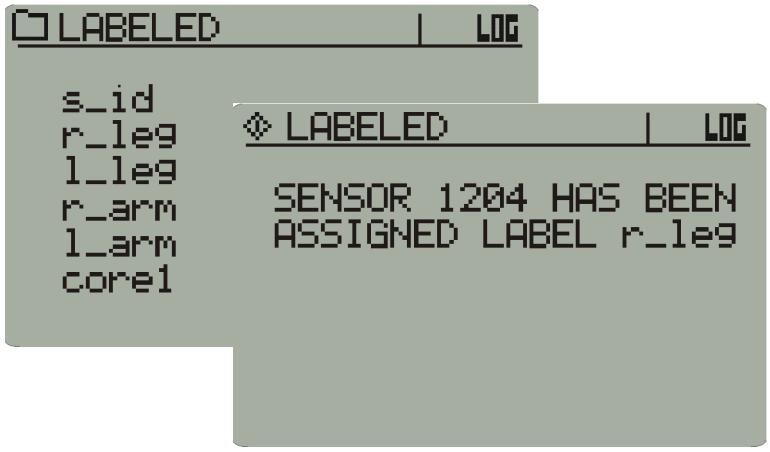


4 You will be informed when the sensor has been successfully activated, and you will be asked if you want a sensor identified, or *labeled*. If you choose OK, you may append the identity number of the sensor with additional information.

Successful activation

5 Choose the appropriate identifier for the sensor, and press Enter. In the illustrations below, the Right Legis the label for sensor 1204.

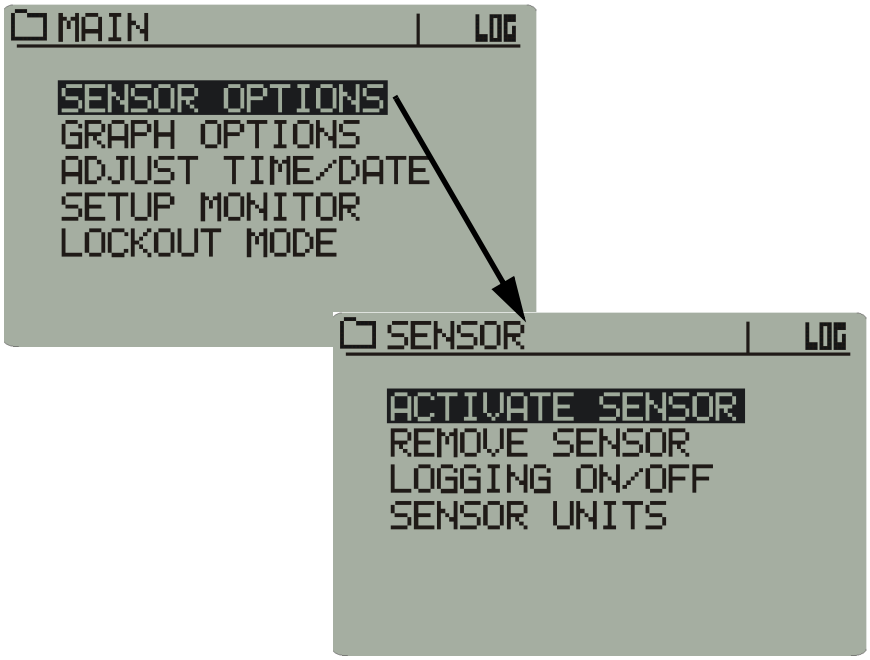
Sensor identifier



6 The sensor activation is complete. For additional sensors, repeat the procedure.

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 key.

Main display



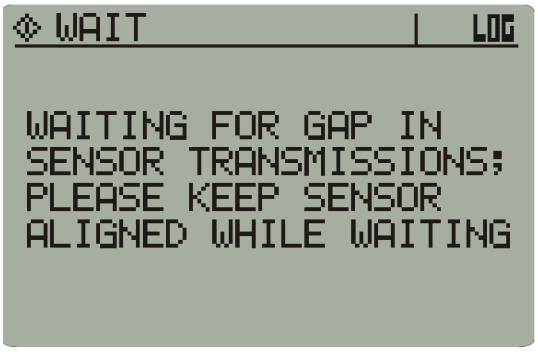
Sensor Does Not Activate

Failure to activate immediately

If the sensor does not activate with 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.

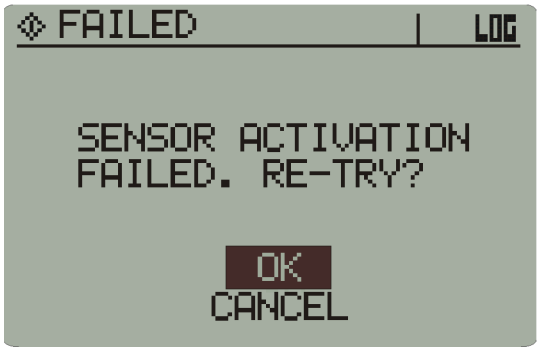
Activation failure notice



Failure to activate

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

Sensor activation failed

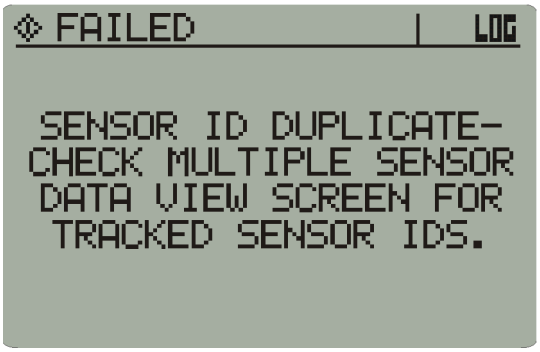


- Wait approximately 5 second and try again.
- Check that the sensor lens is aligned properly with the activation port.
- Attempt to re-try at least 3 times. If still not activated, return the sensor to Mini Mitter for analysis.

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



Capsule Sensor - Indications and Contraindications

CAUTION! - Read before administering capsule!

Description

- Supplied as one Capsule Sensor per package
- Sensor is biocompatible, colored plastic
- Temperature Sensing Range: 25 °C to 50 °C
- Reception Range: approximately 1 meter
- Operating Time: up to 240 hours

Indications

- 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.
- It is a single-use sensor.
- Federal law restricts this device for sale by or on the order of a practitioner licensed by the law of the State in which he/she practices to use or order the use of this device.

Contraindications

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, the should consider a contrasted X-ray series prior to ingestion.

Warnings

A warning indicates a condition that may endanger the patient.

- 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 may be taken without regard to dietary restrictions. It is, however, recommended that the device be swallowed with water.
- DO NOT attempt an MRI (magnetic resonance imaging) if this device has recently been ingested. Wait until the device is passed from the digestive system.
- DO NOT enter areas of extreme EMI (electromagnetic interference) which may cause interference.
- 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.

Precautions

A precaution indicates a condition that may damage the equipment or provide erroneous or incomplete data.

- DO NOT enter areas of extreme EMI (electromagnetic interference)) which may cause interference such as in-band radio transmissions, arc welders and similar devices.
- 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 one hour.
- DO NOT open the VitalSense Capsule Sensor protective packaging until ready for use.
- The Capsule Sensor should only be administered by a health care practitioner.
- 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.

Administration

1. DO NOT CHEW. Swallow whole with water.
2. Place the VitalSense Monitor close to the patient's body, using the accessory belt pouch, or a waist strap or neck strap.
3. During bathing or showering the VitalSense monitor should be removed from the subject. Removal is limited to one hour.

Dermal Patch Sensor Administration

CAUTION! - 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: 2 meters
- Operating Time: 240 hours

Indications

- 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.
- Federal law restricts this device for sale by 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.

Contraindications

- This product is contraindicated 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.

Warnings

A warning indicates a condition that may endanger the patient.

- DO NOT affix Dermal Patch if any damage is visible to the packaging or the device.
- DO NOT attempt an MRI (magnetic resonance imaging) if a Dermal Patch has been affixed. Remove the device prior to MRI.
- DO NOT enter areas of extreme EMI (electromagnetic interference) which may cause interference.
- DO NOT administer a Dermal Patch Sensor after the expiration date.
- Keep sensors away from small children. They can be a choking hazard.

Precautions

- The Dermal Patch Sensor should only be administered 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 Dermal Patch Sensor should be administered every 3 to 4 days or when Patch looses contact with skin, or as directed by a health care practitioner.
- DO NOT leave the monitor out or range of the Dermal Patch Sensor for more than 1 hour.

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.

Administration

1 Select a flat skin surface. Remove excess hair.

2 Prepare skin with skin preparation wipe supplied with patch.

3 Once Patch is activated, remove release paper and affix to skin.

Dermal Patch sensor properly affixed

4 Place the VitalSense Monitor close to the patient's body, using the accessory belt pouch, or a waist or neck strap.

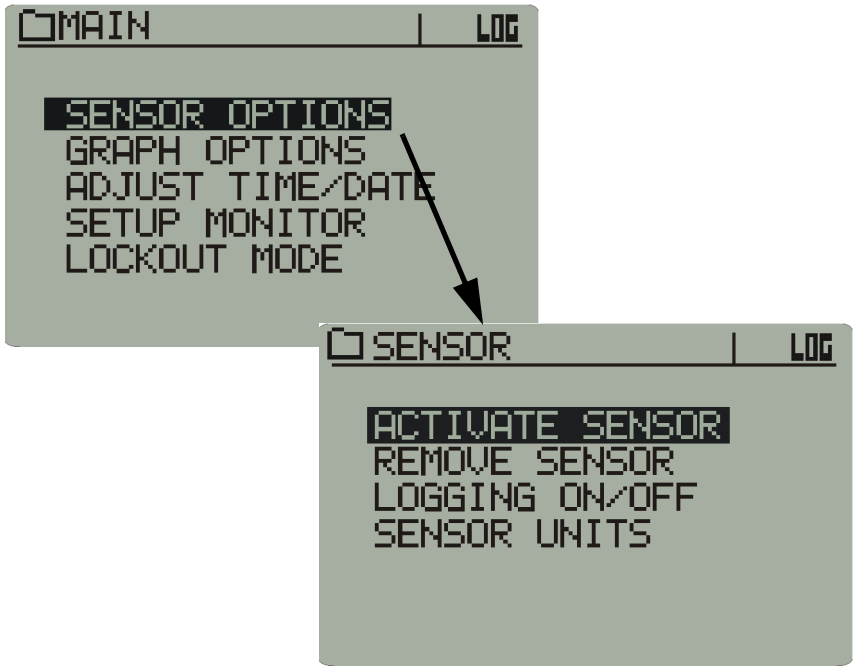
5

The Main Menu is a gateway to several submenus. The first offers several submenus of sensor options. The first is Activate Sensor.

Sensor Options

Activate Sensor

Sensor options



This is identical to the function of the Monitor Activate Sensor button on the front panel. See “ Sensor Activation ” on page 3-1.

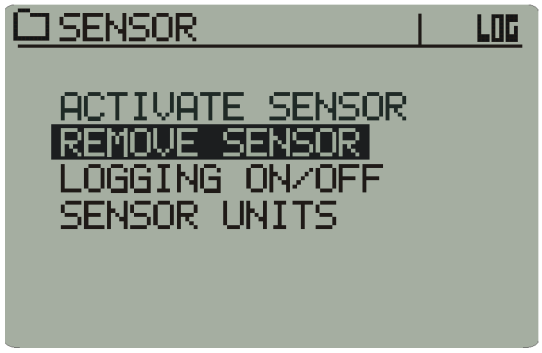
Sensor Options

Remove Sensor

The Remove Sensor function removes a sensor selected from the sensor schedule.

1 Select Remove Sensor from the Sensor Option list.

Remove Sensor sub-menu



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 remove the selected sensor, choose OK.

Warning prompt

4 The selected sensor will be removed from the sensor schedule.

Sensor removed from schedule

Sensor Options

Logging ON/OFF

This function toggles the VitalSense Monitor logging 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 it is toggled back to On.

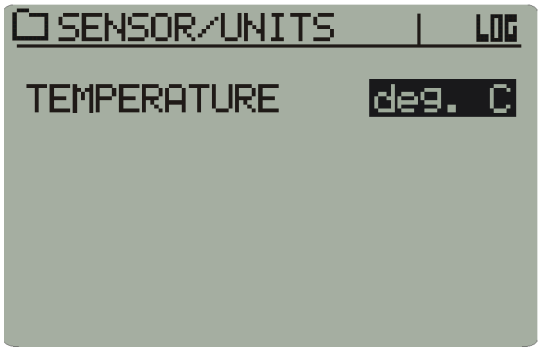
Logging on or off

Sensor Options

Sensor Units

Use the arrow buttons to toggle between the temperatures displayed in °F or °C.

Temperature display selection



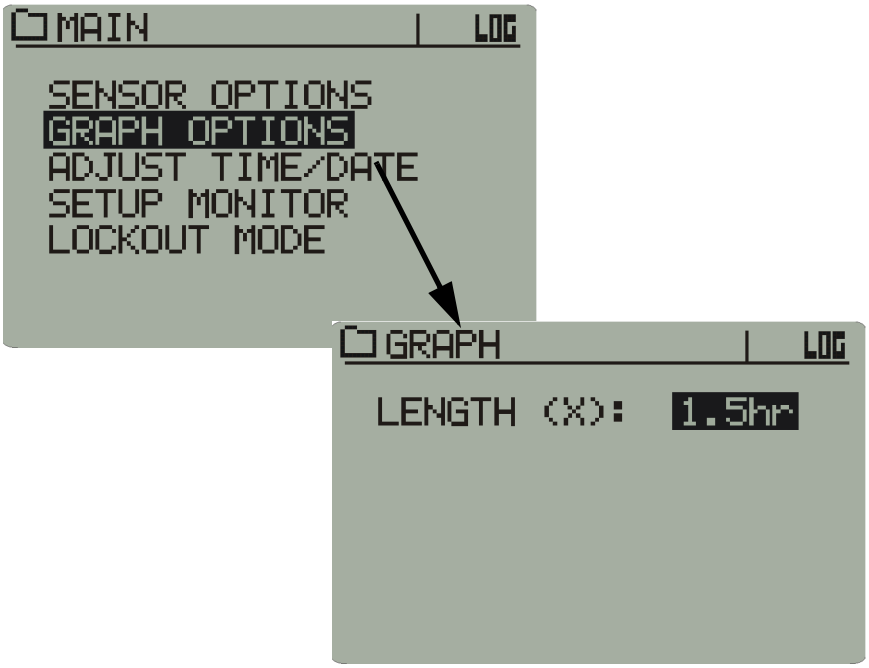
Graph Options

Graph

This function can expand or narrow the amount of temperature sensor data displayed in the Data Views graph. Up to 48 hours of data can be displayed. The following are the choices:

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

Graph



Adjust Time/ Date

This function has been documented previously under Monitor Setup. Refer to “ Adjusting the Time/Date ” on page 2-3.

Setup Monitor

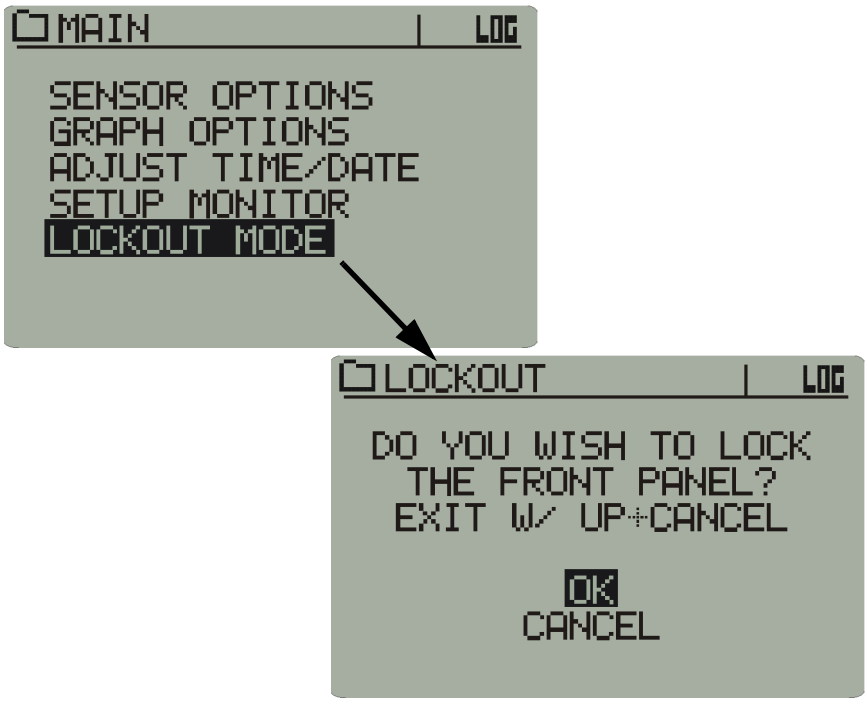
This function has been documented previously in “ Monitor Setup ” on page 2-1.

Lockout Mode

Lockout mode gives the practitioner the abillity to lock the front panel functions to prohibit unauthorized tampering of the settings.

1 Click on OK to activate the lockout.

Lockout Mode



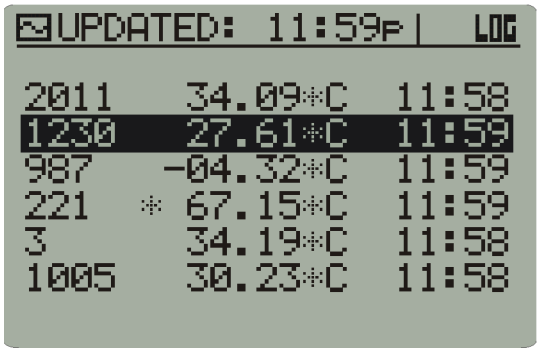
2 To de-activate lockout mode, press and hold the up arrow, and press Cancel. Normal operation of the front panel will commence.

Data Views

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

1 On the Monitor front panel, press the Data Views button. A list of sensors will be displayed along with the temperature and time data. (Use the up and down arrows to view sensor which may be off the display.)

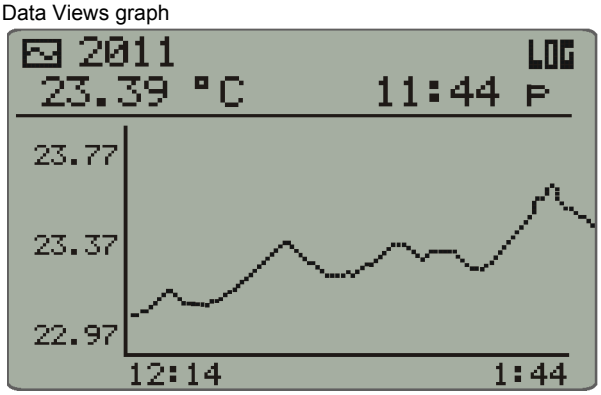
Data View list



2 To view other sensors, use the arrows to scroll through the sensors that are activated.

3 To view a sensor in Graph mode, press Data Views once more. (To change the amount of time shown on the graph, see “ Graph ” on page 2-29).

Data Views graph



4 You may toggle between Graph and List with the Data Views button. To view other sensors in Graph mode, use the arrow buttons.

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 one hour. Beyond one hour, VitalSense may have difficulty resynchronizing with sensor transmissions. Beyond one hour, a significant loss of data may occur. Previously logged data will be preserved in the monitor, but future data collection may not be possible after extended periods of separation.

An asterisk will appear beside any sensor for which the last data transmission was missed. The sensor data displayed will be the last valid sensor data for that sensor.

SECTION

3

VITALSENSE MONITOR OPERATION - FROM APPLICATION SOFTWARE

Introduction

VitalSense Application Software is a software utility program that communicates to the VitalSense monitor via an RS-232 cable. With this link, a variety of functions can be accomplished from a PC.

- Setup of the VitalSense monitor.
- Setup and initialization of the sensors.
- Provides real-time temperature data.
- Retrieves recorded data from the VitalSense monitor.

PC Preparation Prior to Installation

PC Requirements for VitalSense

- IBM® Compatible PC
- Pentium® II Processor with a clock speed of at least 266 MHz
- 64 MB of RAM
- Windows® '98, 2000, XP, Millennium, or Windows NT 4.0
- CD-ROM drive
- 4 MB of free space on the hard disk
- 9-pin or 25-pin RS-232 communications serial port
- Super Video Graphics Array (SVGA - 800 x 600 pixels required to view all data displays)
- Printer (optional)

NOTE: Recommended is a Pentium® III or IV Processor, 866 MHz to 1+ GHz, and 128MB or more of RAM.

Preferred Settings

VitalSense software is best used with the following computer display settings. Directions for changing these settings can be found in the Online Help feature of your specific operating system.

Monitor area or monitor resolution

Set the resolution for 800 x 600 or higher. 1024 x 768 is recommended.

Appearance scheme (or theme)

Avoid "High Contrast" or "Extra large" schemes. Windows Standard is recommended.

Font sizes

For display items related to fonts and font sizes, select "Normal" or "Small font" (font sizes of 12 points or less). Eight points is recommended in the sense it will allow you to see more information than larger point sizes.

Installation of Software

NOTE: Before beginning the installation procedure, make sure that no other applications are currently running on the Host PC. This includes MS Office® and any other utilities. These can interfere with proper installation, resulting in software conflicts.

1. The CD-ROM is set to auto-install. Load the CD into your drive, and wait for the menu to appear.
2. If your CD drive does not accommodate auto installation, click the Start button, then Run, type D:\setup.exe, then click OK. ("D" is the letter commonly used for the CD drive).
3. At the next prompt, enter the destination directory for the installation. The default is C:\Program Files\VitalSense. Click the PC icon to proceed with the installation.
4. If the installation is successful, a prompt will notify you. Click OK to complete installation.

For convenience, you may create a shortcut to your desktop.

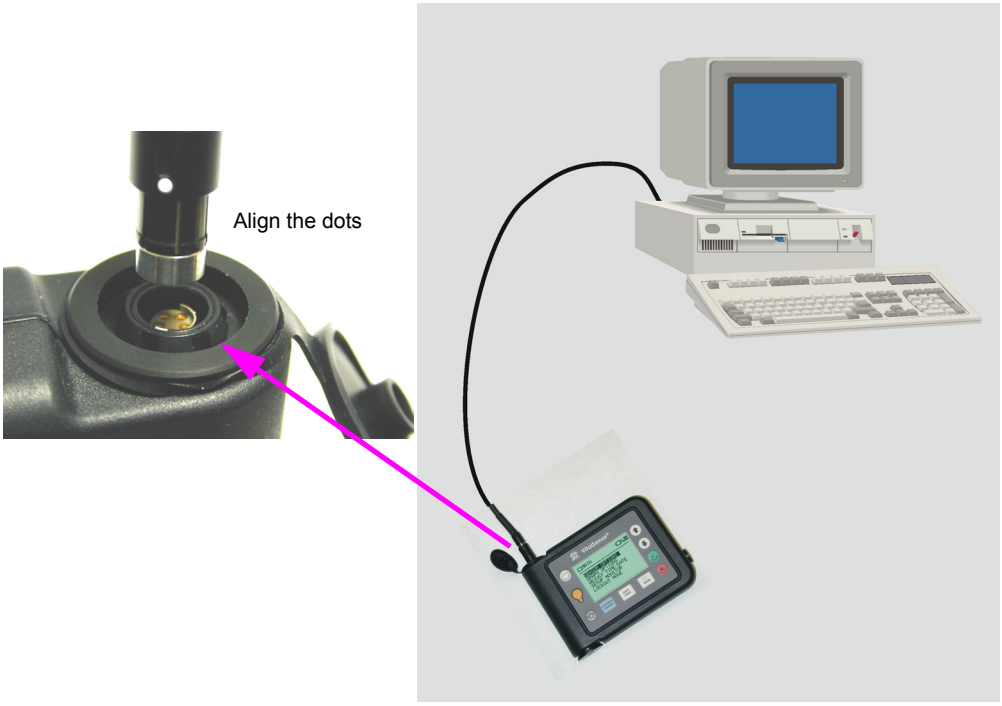
Connecting VitalSense Hardware

To connect the VitalSense monitor to a computer, use the RS-232 cable supplied with the software.

1 Plug the 9-pin DB9 connector into an available COM port on the PC.

2 Plug the miniature 5-pin barrel connector into the VitalSense monitor. Align the dot on the barrel connector with the dot on the monitor connector for proper insertion.

Connecting VitalSense to computer



3 To start the VitalSense Application program, click on the icon established during installation. An introductory splash display should appear, followed by the Main window.

Splash display

4 If there are communication errors, refer to “ Establishing RS-232 Communications ” on page 3-5.

Establishing RS-232 Communications

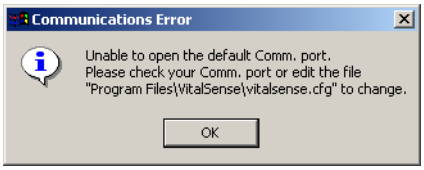
When there is a failure to communicate, typically the cause of one of two major COM port errors:

- COM port is already in use.
- General communication errors

COM Port Already in Use

The VitalSense monitor default COM port is COM1. If the following error appears, the COM1 port must be changed. This is done by editing the configuration file.

COM port warning



1 Open the configuration file using Wordpad, Notepad, etc. This file is located in the VitalSense installation folder:

```
Program Files\VitalSense\vitalsense.cfg
```

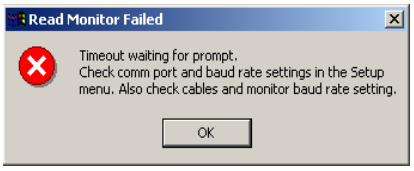
2 Change the second line in the file to match an available COM port, e.g., COM2.

3 Save the file and restart VitalSense.

General Communication Error

In this type of error, the program can open the serial port, but cannot establish communications with the VitalSense monitor.

COM port warning



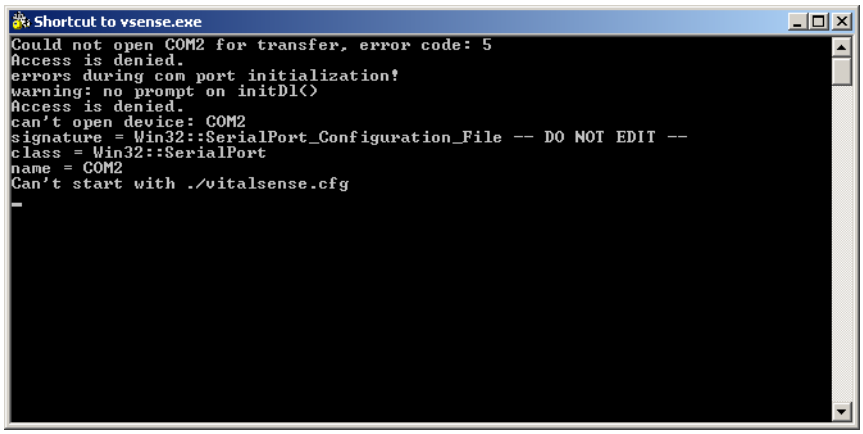
1 Check the serial cable connection at the PC, and at the VitalSense monitor.

2 Verify the default baud rate of the VitalSense monitor is set to 57.6K. This can be found from the monitor front panel:

```
SETUP > RS-232 INTERFACE > BAUD RATE: 57.6K
```

3 Additional information can be obtained by opening the VitalSense console window. This diagnostic information may be of use to you, or in case you need to contact Mini Mitter Technical Support.

VitalSense console



Once communication has been established via the RS-232 cable, setup and data collection can begin.

Initial Monitor Setup for Data Collection

This procedure is very similar to portions of “ VitalSense Monitor - Operation from Front Panel ” on page 2-1. This section, however, contains instructions on additional functions, such as retrieving data and real time obsservation of data collection.

Before data collection can begin, the monitor must be set up, or *configured*. This configuration can be done from the PC through the RS-232 port of the Monitor.

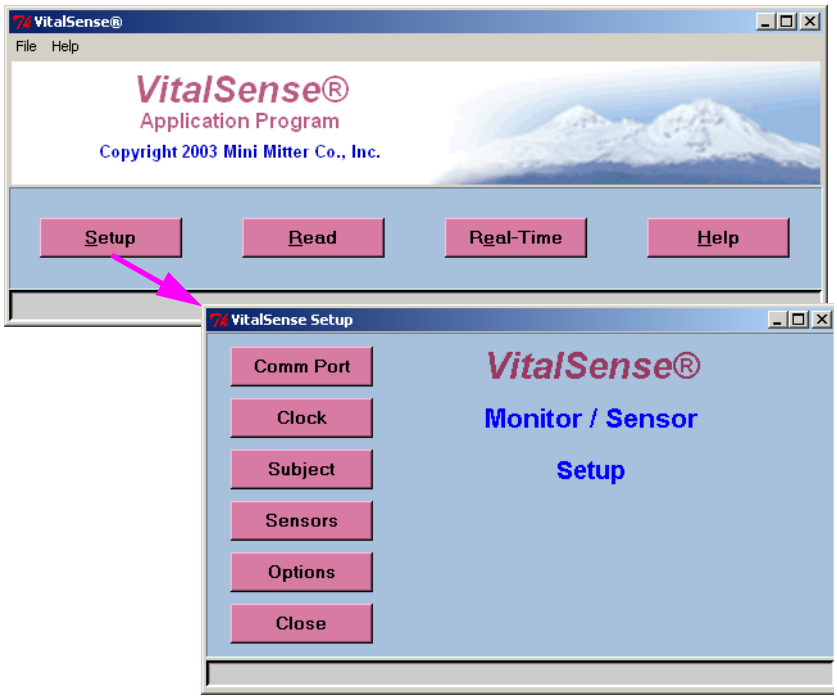
There are three operations that should be accomplished to assure the monitor will collect data:

- **“ Options - Clear memory ” on page 3-9**
- **“ Setting the Clock ” on page 3-10**
- **“ Subject Information ” on page 3-11**

Some or all of the items may not be necessary. If, for example, you have configured VitalSense previously, erased the memory, or if you have already set the time.

Monitor/Sensor Setup

Setup begins with the Main display, and the Setup menu.



COM Port

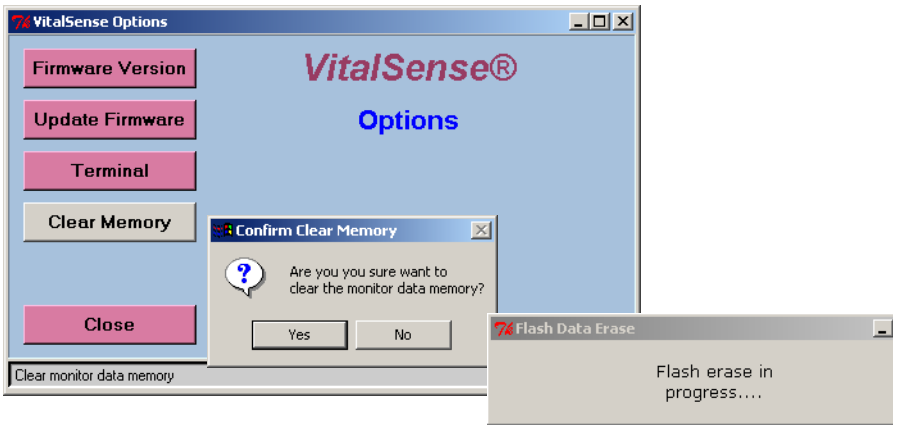
If necessary, you may change the COM port by clicking on Comm Port, and follow the directions.

Options - Clear memory

If you are beginning a new data collection session, it is recommended that you first erase the data memory. The data memory only pertains to data, not the sensor or subject information.

NOTE: If you plan to change or delete subjects, this step may be skipped. You will be given the opportunity to clear the data memory at that time.

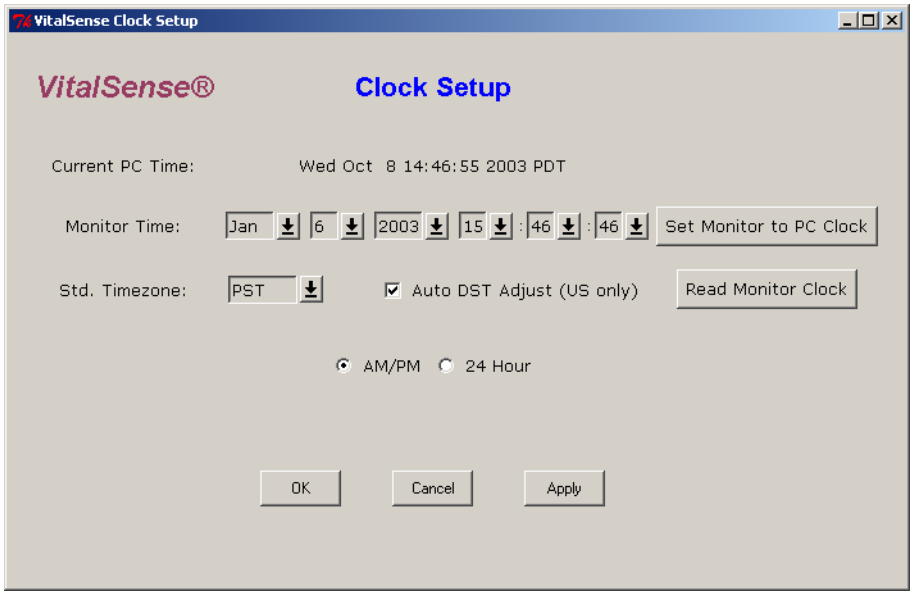
Clearing the data memory



Setting the Clock

The Clock Setup is accessed from the Main window.

Main Window > Setup > Clock



There are two ways to change the time in the VitalSense monitor from the Application Software.

- Selectively set each field individually, then click on Apply or OK.
- Click on Set Monitor Clock to PC Clock. The PC time will be entered into the VitalSense monitor automatically.

Subject Information

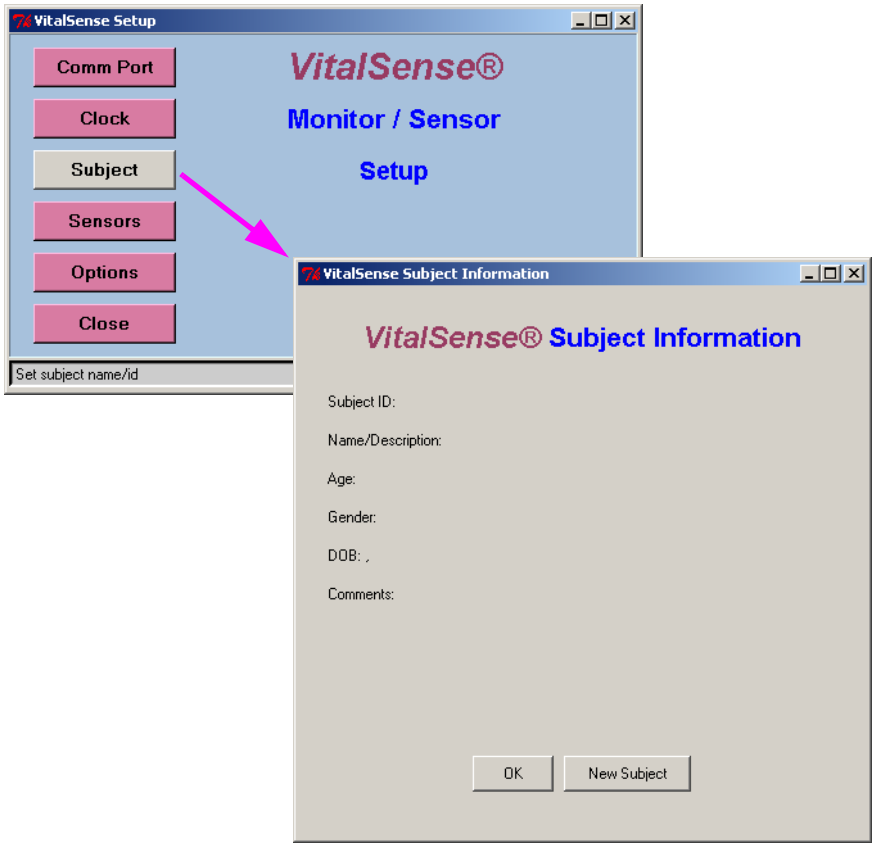
The VitalSense Application Software uses a wizard to enter subject information into the monitor. This wizard is accessed from the Setup window.

CAUTION! This wizard gives you the opportunity to erase the data memory as well as sensor assignments.

---

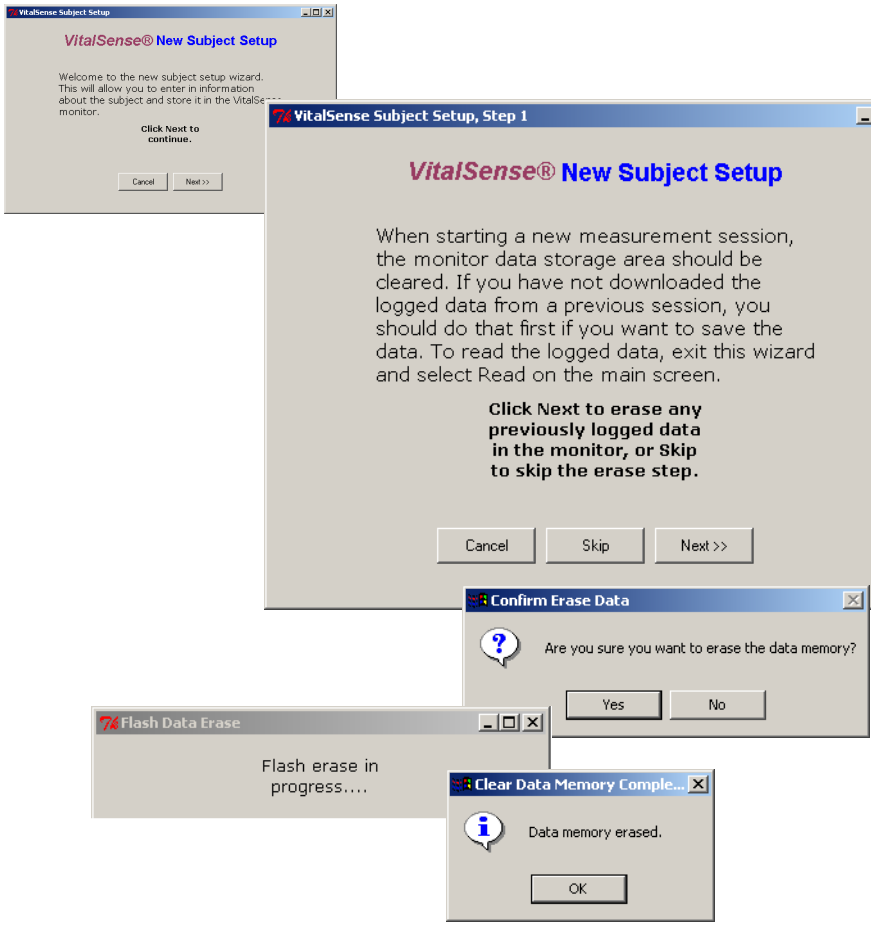
1 From the Setup window, click on Subject. To enter a new subject, click on New Subject.

Main window > Setup > Subject



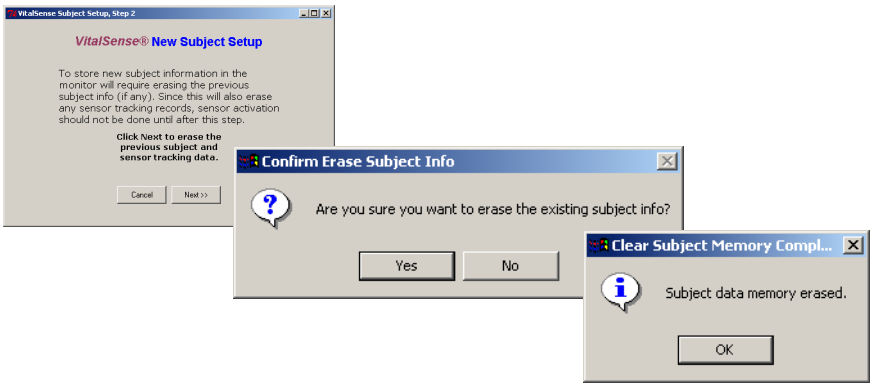
2 The wizard will suggest you download any previous data, and then gives you the opportunity to erase the data memory. By clicking on Next and the confirmation prompt Yes, the data memory will be erased. The subject and sensor data will remain.

Data memory erasure



3 Entering a new subject will result in any previous subject and sensor information being erased.

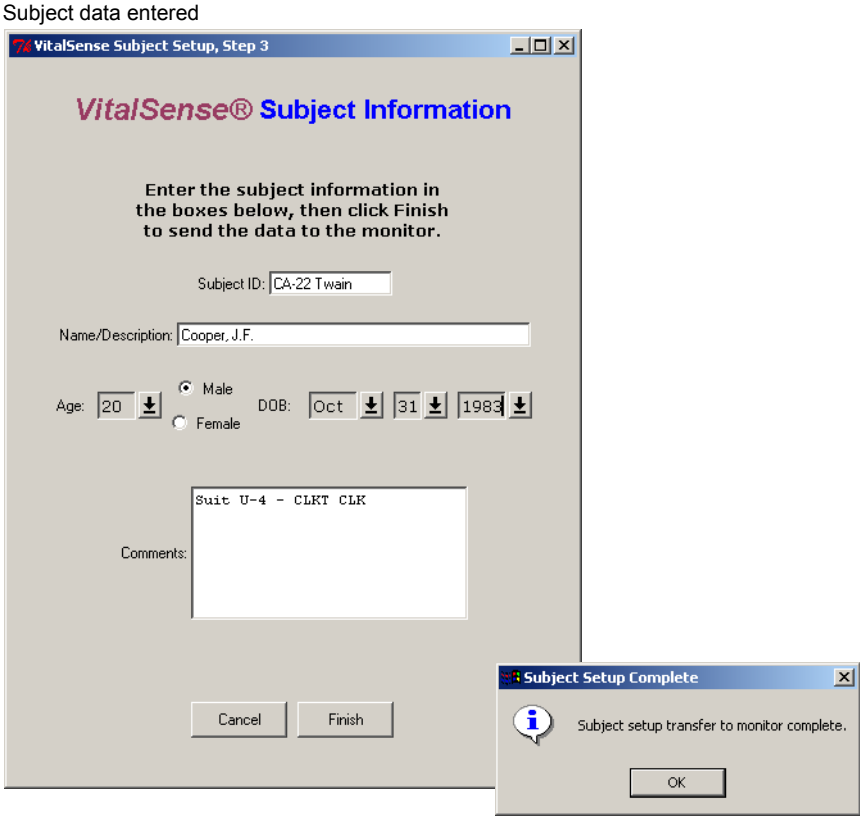
Subject data erasure



4 New subject data can now be entered. Age and date of birth may be entered using the arrows, or double-click-and-enter in each field.

5 Click OK to complete the entry.

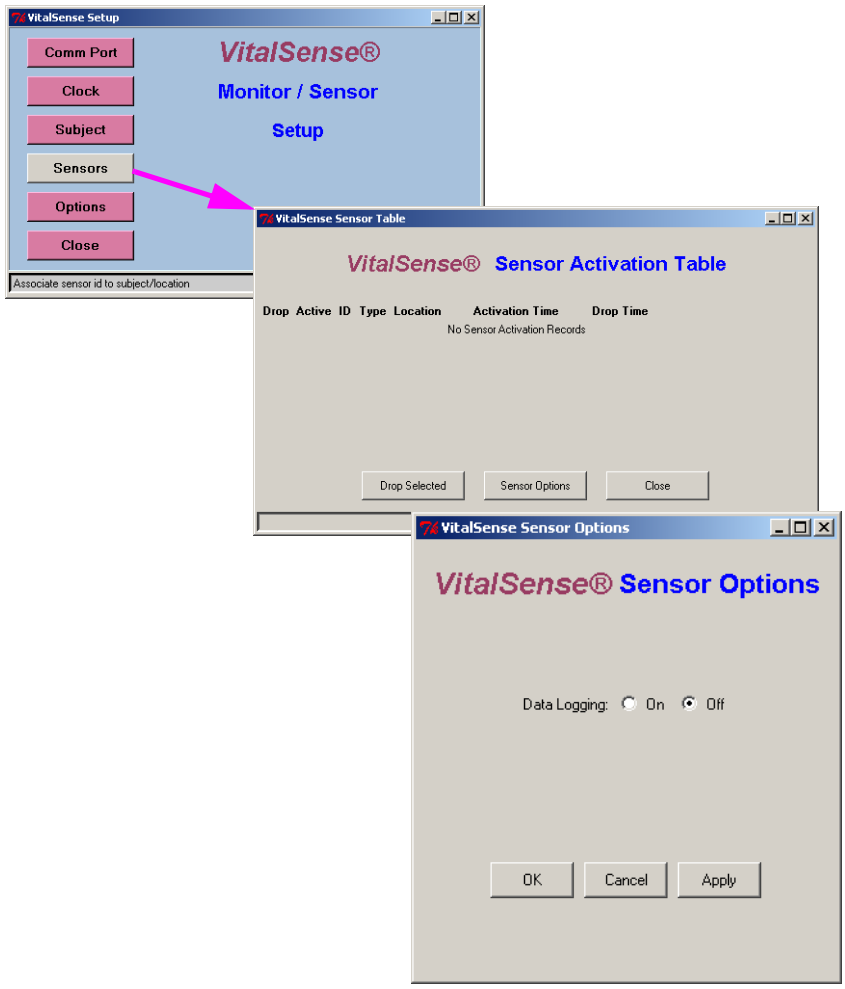
Subject data entered



Sensors

Sensor logging may be toggled on or off from the VitalSense Application Software.

Main window > Sensors

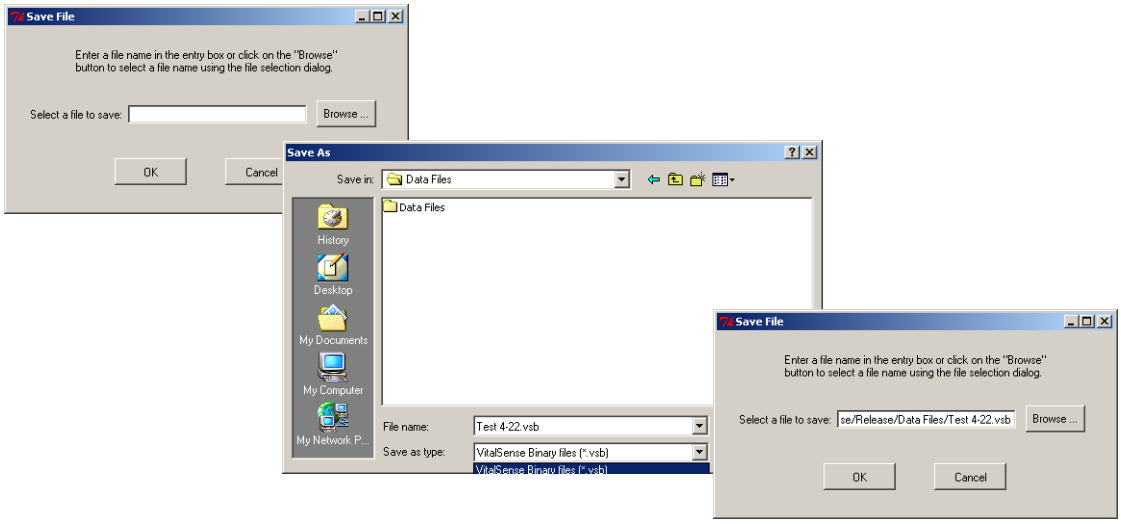


Read Data

This function retrieves the data from the VitalSense monitor.

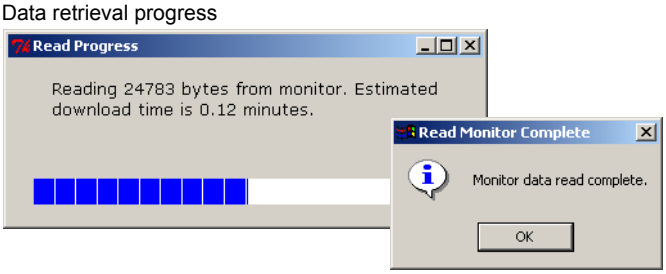
1 Read is accessed from the Main window. Click on Read. You will be prompted to name a file where this data is to be saved.

Read data



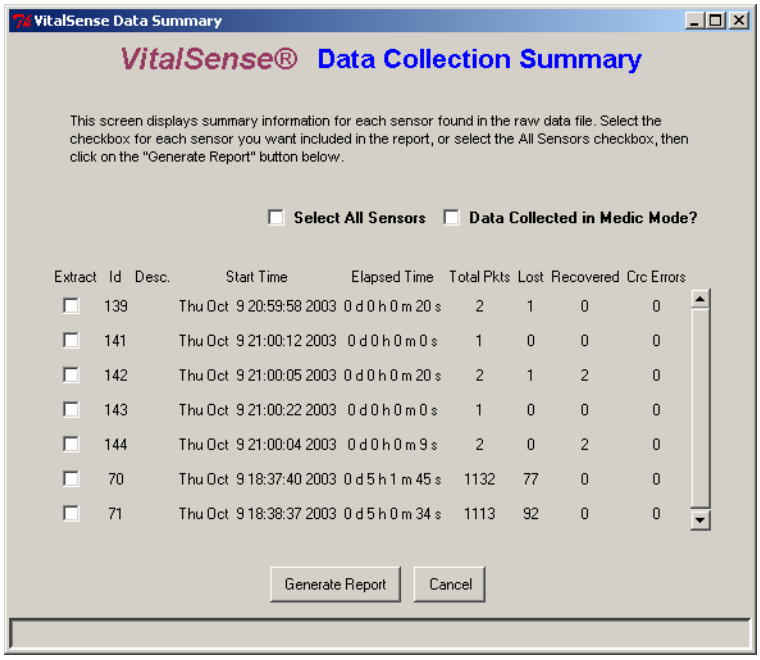
2 The data may be saved as a VitalSense Binary File (.vsb), the default, or a text file (.txt). Name the file, choose its location, and click on Save. You will be prompted as to the progress of the data retrieval.

Data retrieval progress



A Data Collection Summary will appear. This is essentially an “index” of the data collected.

Data Collection Summary



NOTE: If you choose not to generate a report at this time, you may use the Open File command and generate a report at a later time.

VitalSense Data Collection Summary

The table of sensors as shown above contains the following information for each sensor listed:

- Sensor ID.
- Timestamp of first data record for that sensor.
- Elapsed time to the last data record for that sensor.
- Total number of packets, or measurement records.
- Number of lost packet (records with a timestamp outside the allowable window.
- Number of recovered packets (a missing measurement recovered from the “previous value” field on the next data packet.
- The number of CRC errors.

The data summary also includes the following functions:

- Extract check box selects the data you want to see.
- Data Collected in Medic Mode check box. When checked, lost packet detection is disabled, since it is unknown when a packet is expected to arrive.
- Generate Report starts the file extraction and decoding process.
- Cancel disables this function.

Generate Report

Two output files will be generated:

- A Microsoft Excel file with an .xls extension. The filename will remain identical to the original Read Data filename.
- A plain text file with a .txt extension. The filename for the text file will be comprised of the original Read Data filename, along with "_d_nnn." "nnn" is the sensor number.

Both files will be named after the original Read Data filename. To change the filename, rename it using Windows Explorer.

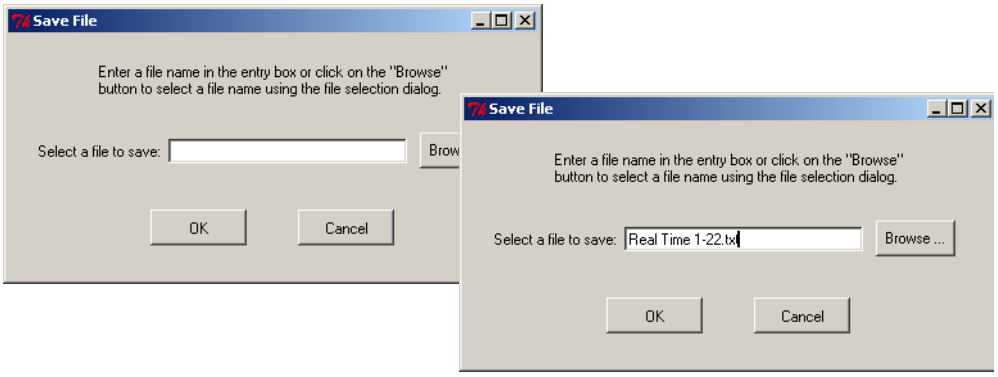
Monitoring Data in Real Time

Monitoring in Real Time allows data collection to be observed as it is being saved.

1 From the Main window, click on Real Time.

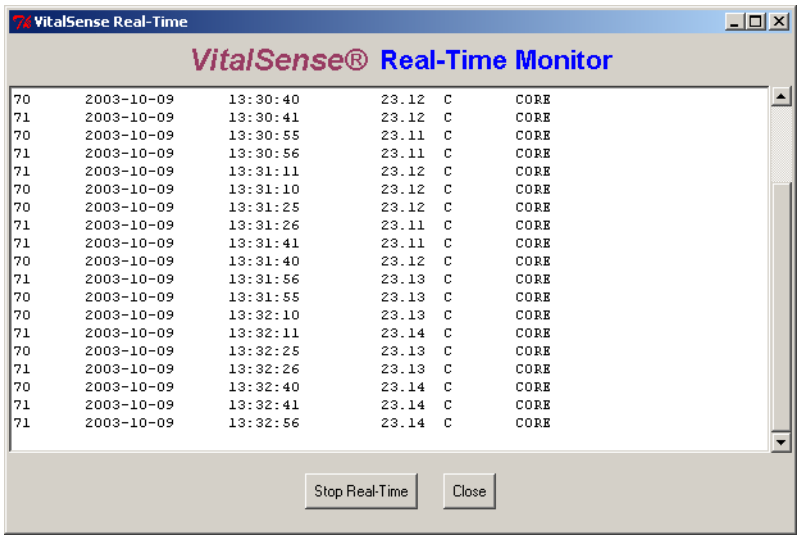
2 You will be asked where the information is to be saved, and to name the file. Once named, click OK.

Saving real-time data



3 The following window will fill as the data begins to be retrieved.

Real-time data



4 Click Close to stop the observation in real time. The data will be saved in the above-named file.

Setup

Options

Firmware Query

Firmware Upgrade

Terminal Mode

Clear Memory

SECTION

4

MAINTENANCE

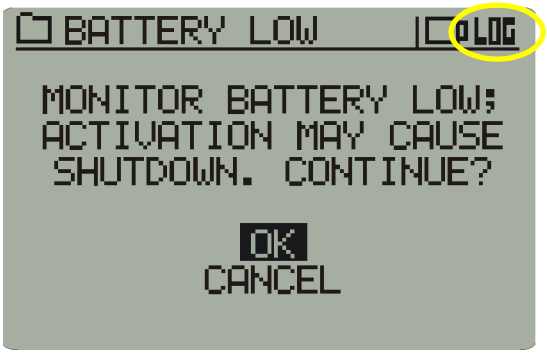
This section applies to the VitalSense monitor, including hardware maintenance such as battery replacement, cleaning, and sterilization.

Battery Replacement

NOTE: The sensor batteries cannot be replaced. These instructions are for the VitalSense Monitor.

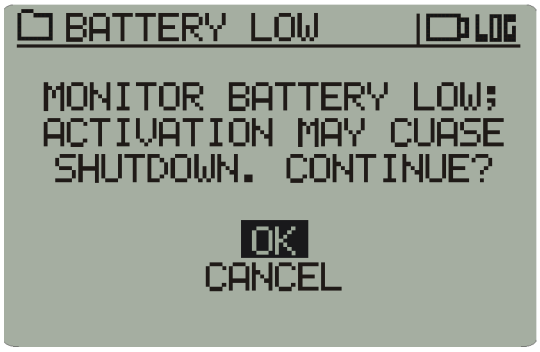
A low battery condition will be indicated on the front panel display by a battery icon. However, a low battery indication may vary according to the display that is currently chosen.

Low battery warning



If attempting to activate sensors during a low battery condition, the following cautionary statement may appear. An attempt to activate sensors during this condition may result in the monitor shutting down.

Monitor shutdown precaution



NOTE: While replacing the battery, the non-volatile memory will retain the acquired data.

---

1 Press the power button to turn the VitalSense Monitor power off.

2 The VitalSense Monitor battery is located in the battery compartment, and is accessible from the bottom of the device as shown below.

Monitor battery compartment

3 Remove the lithium cell by unscrewing the battery compartment cover. If necessary, you may use a coin or screwdriver.

WARNING! Do not dispose of lithium batteries in fire or flame. An explosion may result. Only dispose in accordance with manufacture's recommendation, or local codes.

4 Replace the battery as shown below, with the positive end inserted first.

Replacement battery inserted

5 Replace the battery compartment cover, and finger-tighten. *Do not overtighten.*

6 Press the power button to turn the Monitor power back on.

NOTE: If sensors are active, VitalSense will re-establish communication with them and begin data acquisition. This may take a few minutes.

Cleaning

Cleaning of the VitalSense monitor can be accomplished by wiping the surface with a soft, damp cloth. A mild detergent and water can be used to remove dirt and stains. Do not use abrasives or alcohol. The seals and display may be damaged.

Sterilization

SECTION

5

SPECIFICATION

Parameter	Value	Condition/Note
Physical Attributes (Monitor)		
Size	120 x 90 x 25mm	Outside dimensions
Weight	200 grams	Monitor only
Case material	Polycarbonate/ABS co-polymer	
Interface Panel	Non-permeable membrane switch	
Display	Monochrome LCD with backlight	
Physical Attributes (Capsule Sensor)		
Capsule appearance	Purple, cylindrical, with hemispherical ends	
Size	8.6 mm O.D. x 23mm long	Total
Weight	1.6 grams	
Capsule Material	Plastic	
Physical Attributes (Dermal Patch Sensor)		
Patch appearance	Tan or off-white, circular, flat	
Size	36.5mm O.D. x 5.8mm thick	Total
Weight	7.5 grams	
Encapsulation material	Silicone rubber	
Dermal contacting surface	Biocompatible polyurethane foam	

Parameter	Value	Condition/Note
Functional Attributes		
Temperature sensing range	25 °C to 50 °C	Ingestible capsule
	-20 °C to 60 °C	Dermal patch
Temperature sensing accuracy	±0.1 °C ±0.25 °C ±0.25 °C	32 °C to 42 ° -20 °C to 32 ° 42 °C to 60 °
Temperature display resolution	±0.01 °C	
Display update rate	15 seconds	Average
Monitor battery life	10 days with 10 sensors on line, plus 20 days standby	Battery life increases with fewer sensors on line
Sensor battery life	1 year storage plus 10 days active transmission	Capsule and patch
Calibration	None required	
Number of co-active sensors	One to ten	Per monitor
Sensor identification	Automatic tracking	
Crosstalk	Not allowed	
Environmental Attributes		
Moisture protection	IEC529-IP52 NEMA 250-5	
Storage temperature	-20 to 50 °C	@ 5-95% humidity
Operating temperature	0 to 40 °C	
Radio Frequency Attributes		
Transmission radio carrier frequency	40.68 MHz	ISM band (capsule and patch)
Typical transmission range	1 meter 2 meters	Capsule sensor Dermal Patch
Software/PC Attributes		
Software features	Data transfer, ASCII conversion	
Compatibility	Windows 2000, NT, XP	
Communications interface	RS-232 cable	Custom, water protected

APPENDIX

FREQUENTLY ASKED QUESTIONS

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APPENDIX

B

SYSTEM DIAGNOSTICS