SECTION

3

VITALSENSE OPERATION - APPLICATION PROGRAM

Introduction

The VitalSense Application Program is a software utility that communicates with the VitalSense Monitor via an RS-232 cable. With this link, a variety of functions can be accomplished from the host PC.

Functions of VitalSense Application Program

- Establish communication with VitalSense Monitor
- Load Subject Information into VitalSense Monitor
- Turn off logging function of VitalSense Monitor
- Set the on-board clock VitalSense Monitor
- Drop a Sensor from VitalSense Monitor Sensor List
- Real-time viewing of temperature data from VitalSense Monitor
- Erase the subject/sensor data, and the temperature data from VitalSense Monitor
- Retrieve data from VitalSense Monitor
- Identify firmware of VitalSense Monitor
- Load updated firmware version into VitalSense Monitor

PC Preparation Prior to Installation

PC Requirements for VitalSense

- IBM®-compatible PC
- Pentium® II processor with a clock speed of at least 350 MHz
- 64 MB of RAM
- Windows® '98, 2000, XP, Millennium, or Windows NT 4.0 SP 6
- CD-ROM drive
- 4 MB of free space on the hard disk
- 9-pin or 25-pin RS-232 communications serial port, or USB port with USB-to-serial adapter
- 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 On-line 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

Select "Normal" or "Small font" (font sizes of 12 points or less). Eight-point is recommended because it will allow you to see more information than larger font 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.

The VitalSense Application Program software is distributed as a MicroSoft® Installation package (.msi) file.

If you have Windows® 2000 or XP, simply double-click on the filename and follow the instructions. The default installation path is \Program Files\ VitalSense.

Earlier versions of Windows may require installing the Microsoft Installer program on your computer. This program can be obtained as a free download from the Microsoft Website. A copy of Microsoft Installer version 2.0 for Windows 95/98/ME (InstmsiA.exe), and for Windows NT SP6/Windows 2000 (InstmsiW.exe) is supplied on the VitalSense CD. Windows XP comes with Microsoft Installer 2.0 pre-installed.

Connecting VitalSense Hardware

Serial COM Port

Today's computers typically have either a 9-pin DB9 serial port or a USB (Universal Serial Bus) port. These will look similar to the ones pictured below.

9-pin Serial COM ports

Computer connector

Cable connector

USB ports

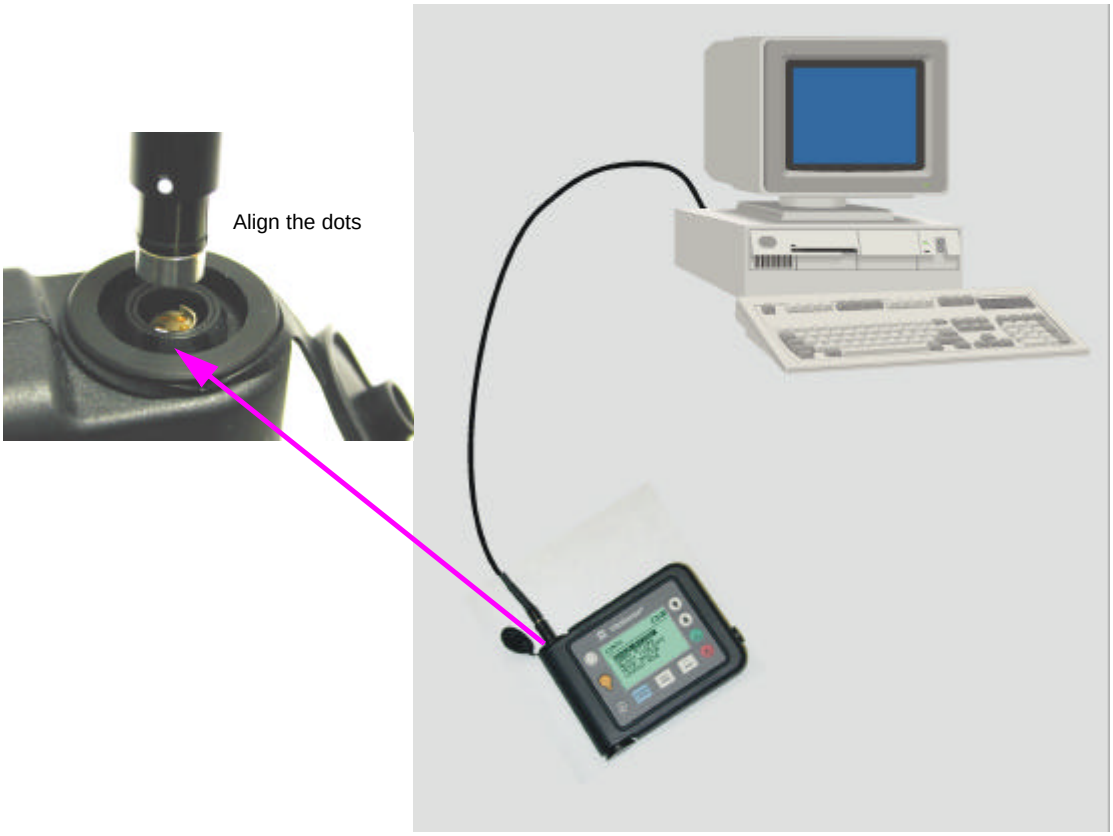
Computer connector

Cable connector

The 9-pin serial cable is the type supplied with your system. If your computer does not have a 9-pin serial port, it is suggested that you obtain a 9-pin to USB adapter. These are available at most computer supply or electronics stores.

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. For proper insertion, align the dot on the barrel connector with the dot on the monitor connector.

Connecting VitalSense to computer



The hardware connections are complete. The next step will be starting the VitalSense Application Program, and then establishing communication between the PC and monitor via the serial COM port cable.

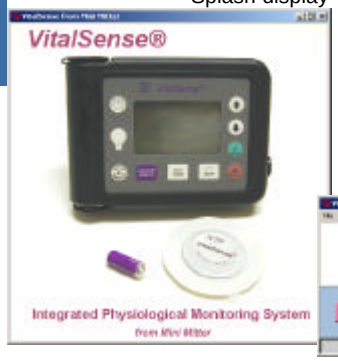
Starting the VitalSense Application Program

1 Turn on the VitalSense Monitor by pressing the Power button.

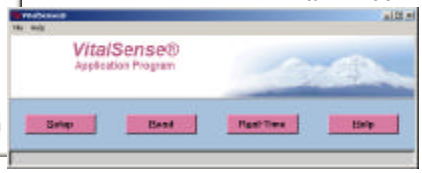
2 Start the VitalSense Application program. Click on the shortcut established on your desktop during installation. An introductory splash display should appear, followed by the Main window.

VitalSense shortcut icon

Splash display



Main window

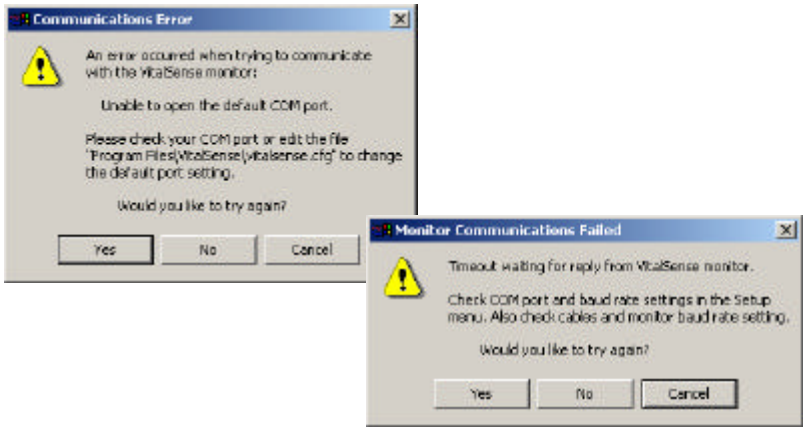


No communication errors?

If there are no communications errors, you have established communications with the VitalSense Monitor. Proceed to “ Monitor Setup for Data Collection ” on page 3-8.

Typical communication errors

You may receive one of two communication errors. This is not unusual.



The most likely reasons for communication errors are:

- COM port 1 is being used by other hardware, e.g., printer, scanner.
- VitalSense defaults to COM port 1. The serial COM port cable is plugged into another port other than COM port 1.

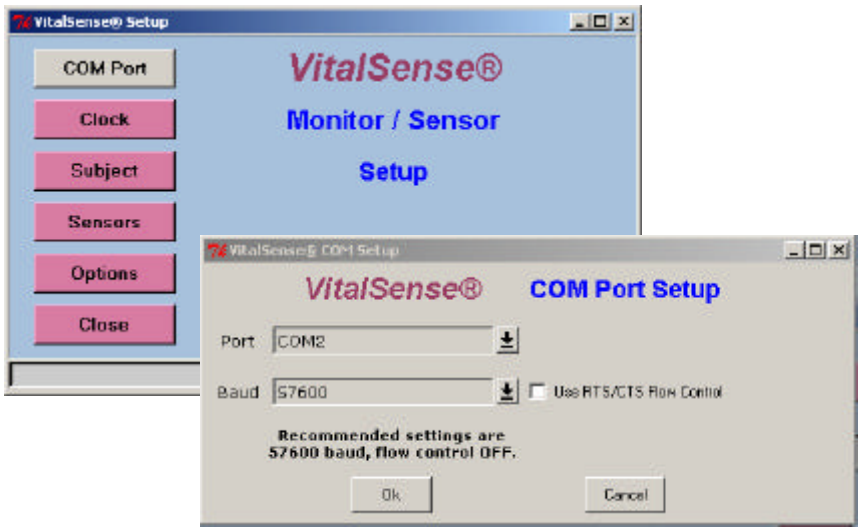
Proceed to “ COM Port Setup ” on page 3-7.

COM Port Setup

If necessary, you may change the COM port with which your computer communicates with VitalSense, as well as baud rate and flow control.

1 Click on Setup, then click on COM Port.

Main > Setup > COM Port



2 Select the COM port using the drop-down menu.

3 Select the baud rate.

4 Check or uncheck the Flow Control box.

5 Click OK.

NOTE: The recommended (and factory defaults) for baud rate and flow control 57,600 and flow control OFF respectively.

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6 Attempt to communicate with the monitor. This may be done by exiting VitalSense and restarting the Application Program.

NOTE: You may also test the communication link by attempting a function such as reading the monitor clock. See “ Read Monitor Clock ” on page 3-10.

If, after repeatedly changing the COM port selection, you cannot establish communication with the monitor, refer to “ Establishing RS-232 Communications - Advanced ” on page 3-24.

Monitor Setup for Data Collection

Setup for Data Collection from the VitalSense Application Program is very similar to portions of “ VitalSense Monitor Operation ” on page 2-1. This section, however, contains instructions on additional functions, such as retrieving data and real-time observation of data collection.

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

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

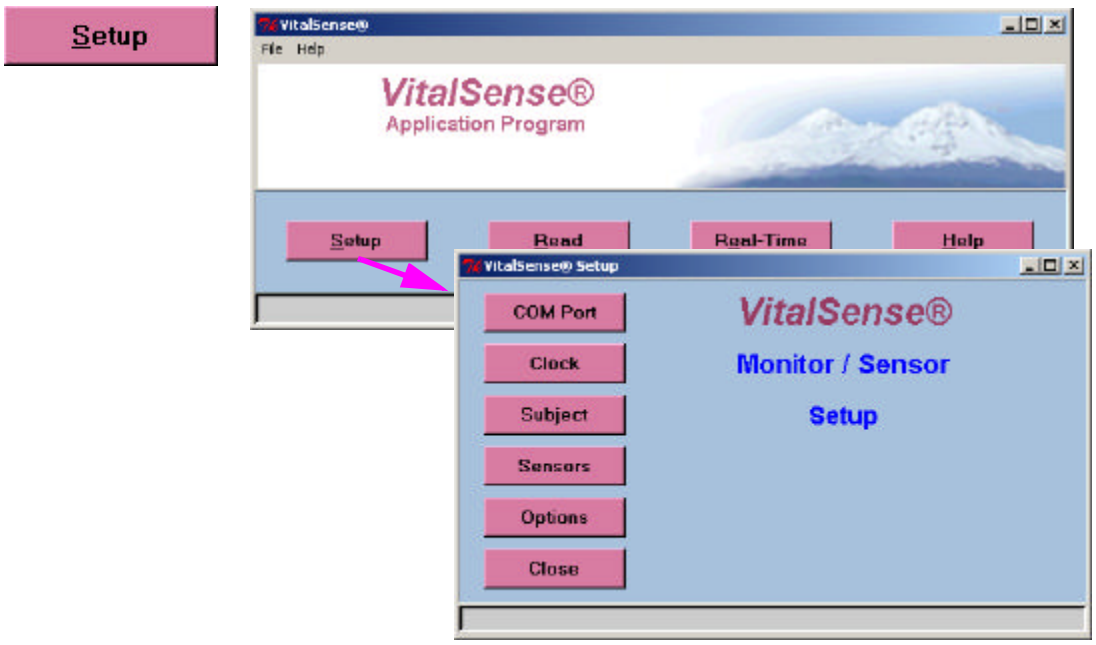
NOTE: The following are somewhat similar to the steps used when configuring the monitor from the front panel (see “ Monitor Setup for Data Collection ” on page 2-4).

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

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

These steps are generally in the same order in which the monitor should be configured. Setup begins with the Main display, and the Setup menu.

Main > Setup



Clock

Setting the Monitor Clock

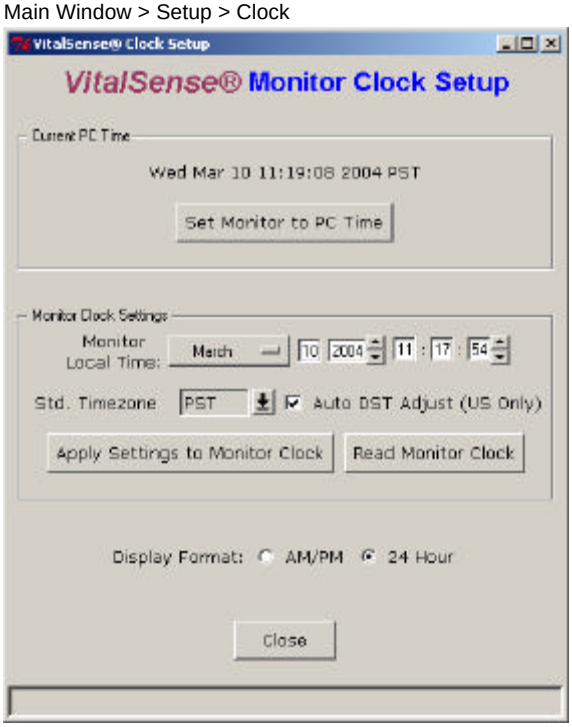
The Clock Setup is accessed from the Main window.

To void confusion, the following steps should be accomplished in order. If done in this manner, the UTC clock will automatically be set as well as local time.

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

NOTE: You cannot change Monitor Clock Settings functions with sensors on-line.

Main Window > Setup > Clock



Read Monitor Clock

This function will enable you to read the on-board monitor clock, and will display it in the Monitor Clock Settings fields.

There are two ways to change the time in the VitalSense Monitor from the Application Program.

Manually Set Monitor Time

- Selectively set each field individually, then click on Apply Settings to Monitor Clock button.

Set Monitor to PC Time

- Click on Set Monitor Clock to PC Clock. The PC time will be entered into the VitalSense Monitor automatically.

Clear Memory

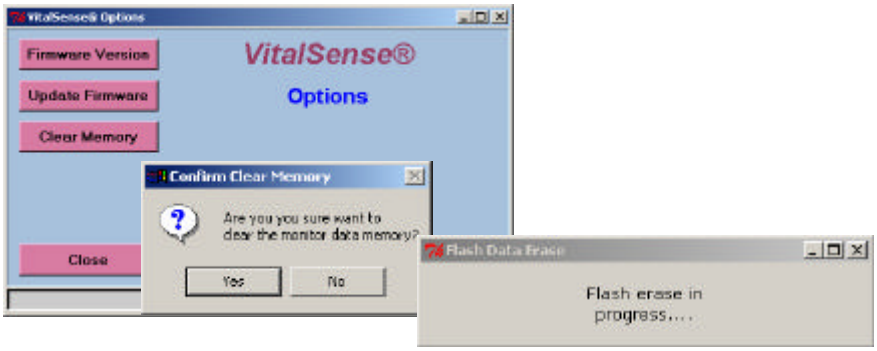
Clear Memory

The VitalSense Monitor uses a portion of its memory for data, and another portion for subject and sensor information. Clear Memory erases the data portion of the memory, i.e., the temperature information sent by the sensors. The data memory pertains only to data, not the sensor or subject information. Making changes within the Subject Information function will erase the subject and sensor portion of the memory.

- If you have downloaded the data from an on-going experiment, you may Clear Memory and begin another data collection session with the same subject/sensors information.
- If you are beginning a new experiment, you should Clear Memory.

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 later.

Main > Setup > Options > Clear Memory



Subject

Subject Information

Subject Information is the identification information that the practitioner can download to the VitalSense Monitor using the Application Program. The VitalSense Application Program uses a wizard to gather subject information. This wizard is accessed from the Setup window.

The Subject Information is provided to identify the monitor and data collection session, therefore only one Subject is possible.

CAUTION

This wizard will assist you in assigning subject information. However, it will also allow you to erase the data memory as well as current sensor assignments. Pay close attention to the prompts.

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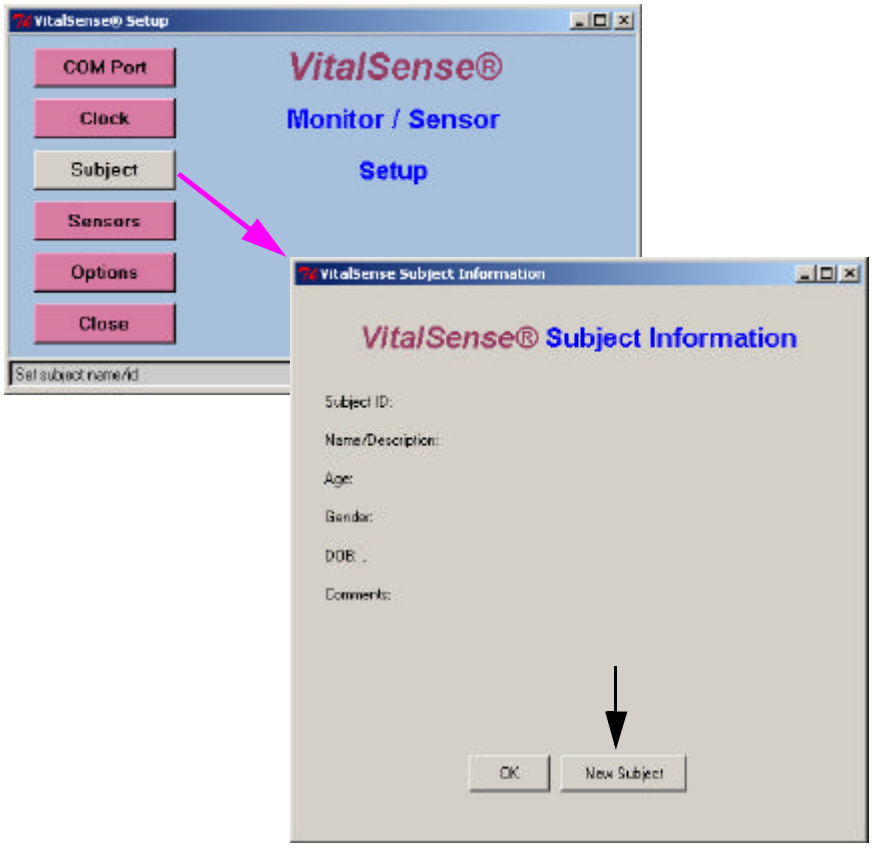
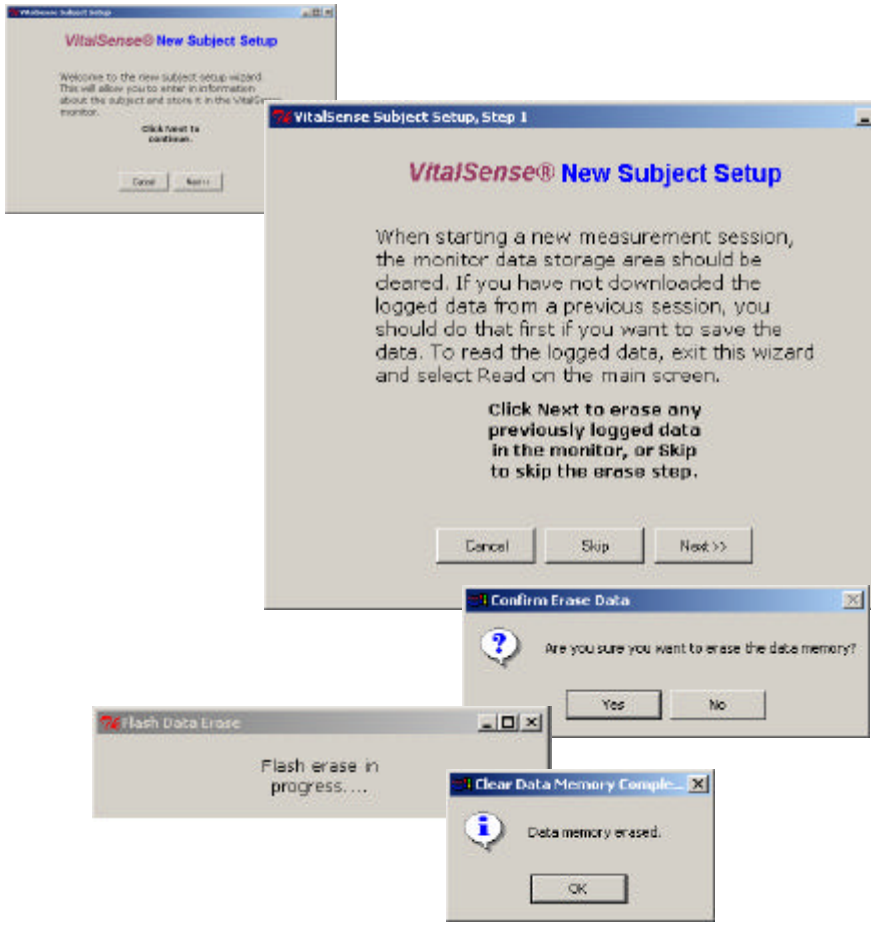
1 From the Setup window, click on Subject. To enter a new subject, click on New Subject (arrow below).

Main window > Setup > Subject



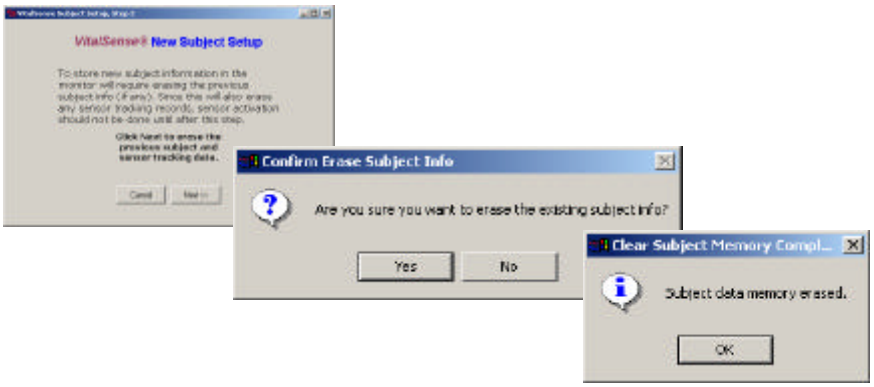
2 The wizard will suggest you download any previously acquired data, and then gives you the opportunity to erase the data memory. By clicking on Next and the confirmation prompt Yes, the data memory will be erased. The subject and sensor data will remain.

Data memory erasure



3 Entering a new subject, however, will result in the erasure of any previous subject and sensor information.

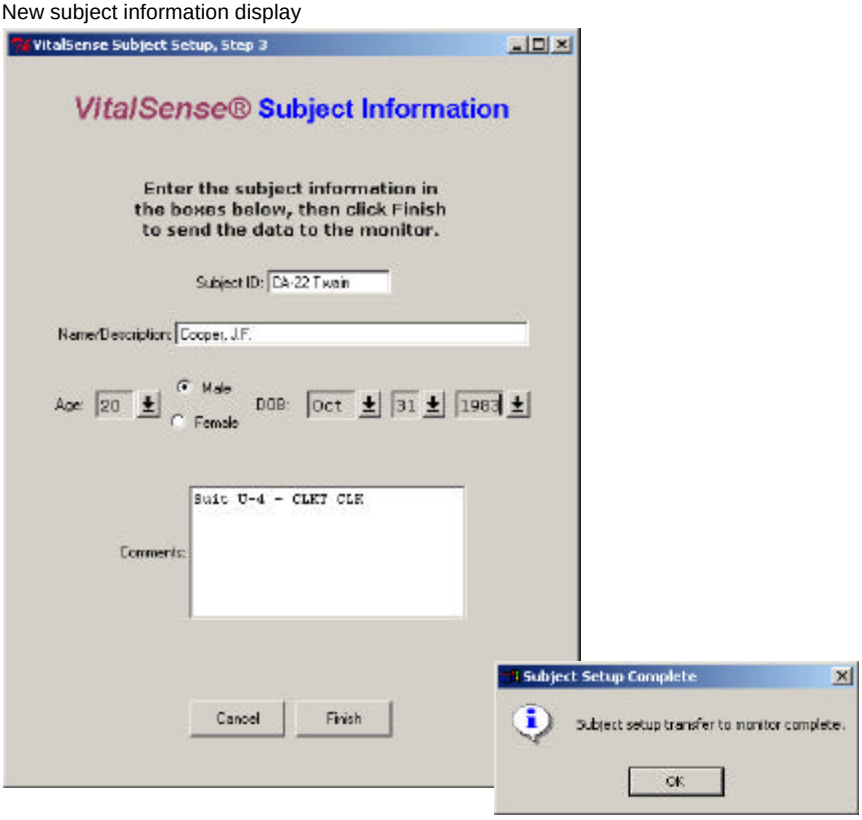
Subject data erasure



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 Finish to complete the entry.

New subject information display



Sensors

Sensors

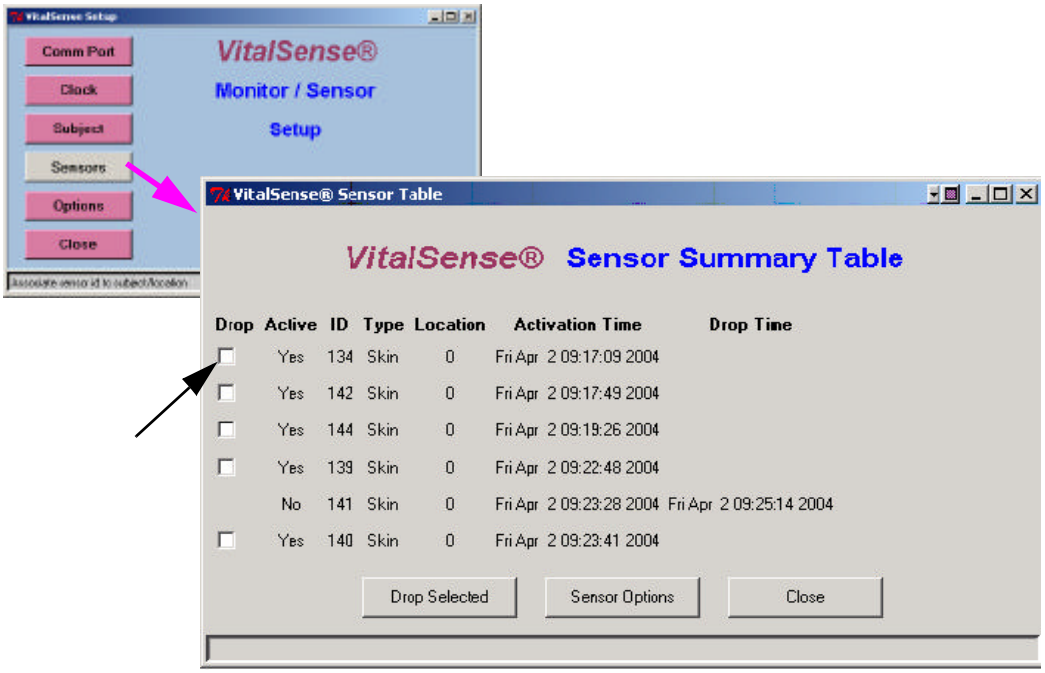
Sensor logging may be toggled on or off, or the sensor dropped from the activated sensor list. Follow the prompts as shown below.

Drop Sensor

Drop Sensor from Sensor Summary Table

1. From the Main menu, click on Sensors.
2. Check the Drop boxes of the sensors you want to drop from the activated list.
3. Click on Drop Selected. The sensor will no longer appear on the Sensor List. To acquire the sensor list on the VitalSense Monitor, press the Data Views button on the front panel. See “ Data Views ” on page 2-32.

Main window > Sensors



Logging On/ Off

Data Logging On or Off

This function turns the logging function of the VitalSense Monitor on or off. This effects data collection on all sensors, without regard to which sensors have been selected in the Activated Sensor Table (see previous function).

1. From the Activated Sensor Table, click on Sensor Options.
2. Click on Data Logging On or Off.
3. Click OK or Apply to enter your selection.

Main > Sensors > Sensor Options

Read Data

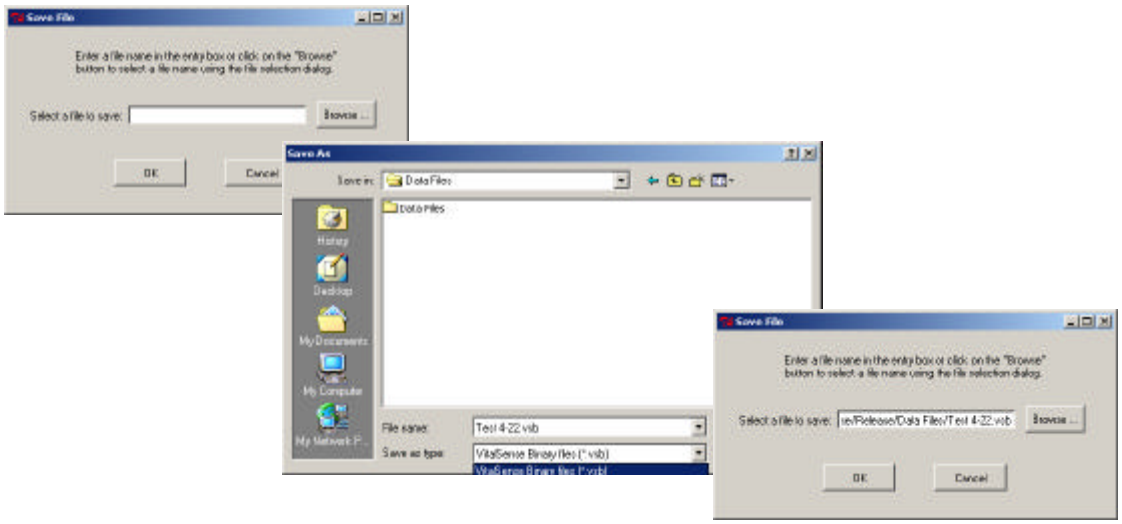
This function retrieves recorded data from the VitalSense Monitor.

1 Read is accessed from the Main window. Click on Read.

Main Display

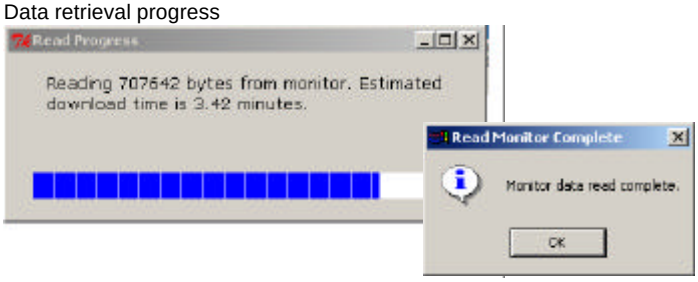
2 You will be prompted to name the file where this data are to be saved, and select a location. You may either type in the path or use the browser to select the location.

Read data



3 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 on 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:

- **Extract -** Check box that selects the data that will appear in the report.
- **Sensor ID** - Number assigned sensor at factory.
- **Sensor type** - Core (Capsule Sensor), Skin (Dermal Patch Sensor).
- **Start Time** - Time stamp of first data record for that sensor.
- **Elapsed time** - The time elapsed to last data record for that sensor.
- **Total pkts** - Number of measurement records.
- **Lost** - Number of lost packets (records with a time stamp outside the allowable window of 18.75 seconds).
- **Recovered** - Number of recovered packets (a missing measurement recovered from the “previous value” field on the next data packet).

- **Data Collected in Medic Mode™** - When checked, lost packet detection is disabled, since it is unknown when a packet is expected to arrive. (Medic Mode is a VitalSense Monitor option.)
- **Generate Report** - Begins the file extraction and decoding process.
- **Cancel** - Disables the extraction and decoding process.

Generate Report

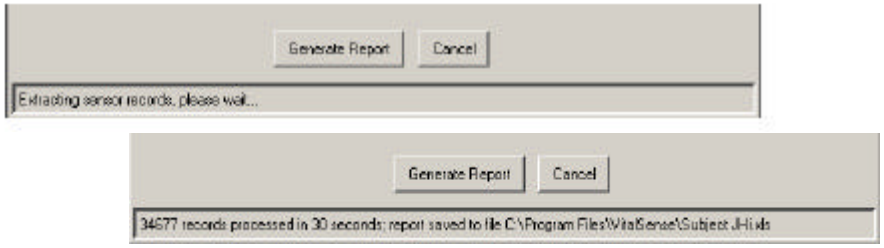
This function will generate two files (explained below).

1 Choose the sensors that will appear in the report.

2 Click on Generate Report.

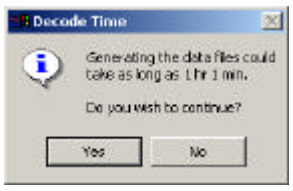
You will be prompted on the generation progress.

Report generation progress



NOTE: If the estimated time to generate the report will exceed two minutes, a prompt will indicate the approximate time required to generate it (see below). The processing time is affected by the number of sensors and data records selected, the PC's CPU speed, and any other tasks that may be running concurrently on the PC.

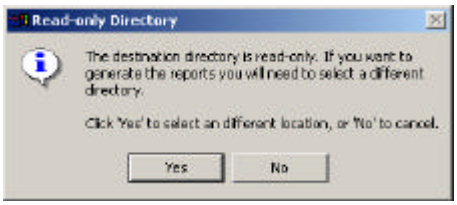
Excessive time prompt

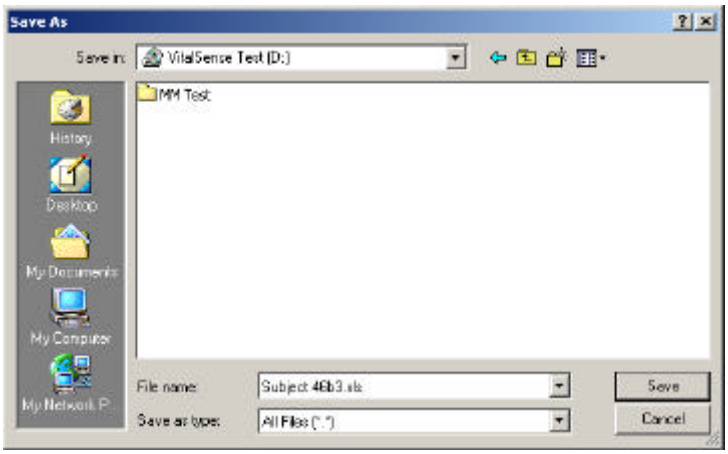


NOTE: The report will generated and then written by default to the same location as the raw data (.vsb) file. You must have Write permission for that directory.

The following is an attempt to read a .vsb file from a CD. The VitalSense Application Program asks for another destination for the report because it cannot write to a CD.

Prompt to change report destination





Output Files

Two output files will be generated. Both files will be named with the original Read Data filename. To rename, use Windows Explorer.

- A Microsoft Excel file with an .xls extension. The filename will remain identical to the original Read Data filename.

  ```
  Final download 23Oct04.xls
  ```

- 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. "d" stands for "devices(s)." For example:

  ```
  Final download 23Oct04_d_141_70_142_71_143_144_139.txt
  ```

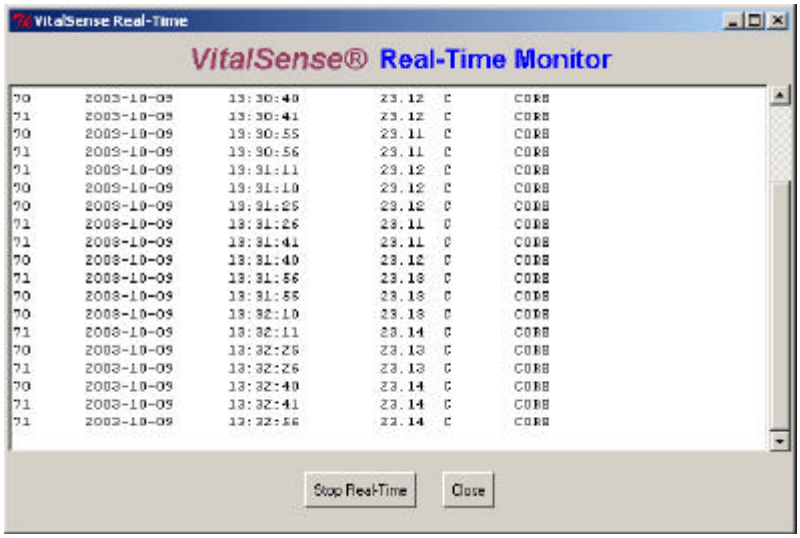
Monitoring Data in Real Time

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

NOTE: There is a delay of one sample interval in the time the data appears on the PC display.

Real-time data



4. Click Close to stop the observation in real time. The data will continue to be saved in the file named in Step 2.

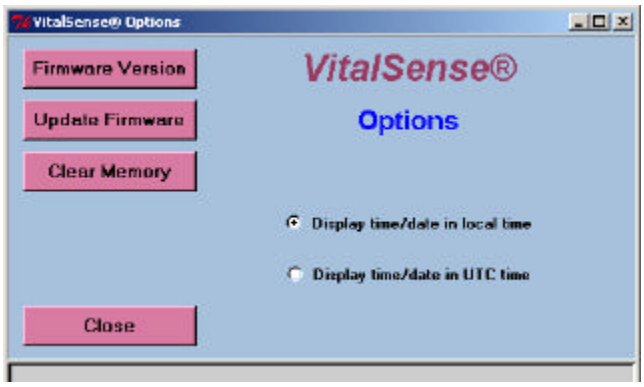
Application Program Options

Firmware Version

Firmware Version

Clicking on this feature will query the monitor for the firmware version currently on board the VitalSense Monitor. This information is particularly useful when calling Mini Mitter for Technical Support.

Main > Setup > Options



Display Time

The two buttons enable either the local time or UTC time to be shown on the display.

Update Firmware

Update Firmware

Periodically new firmware may be released by Mini Mitter Company, Inc. These releases may be made by CD, Website, e-mail, or other means. Without regard to the distribution, the following process is to be used to upgrade the firmware.

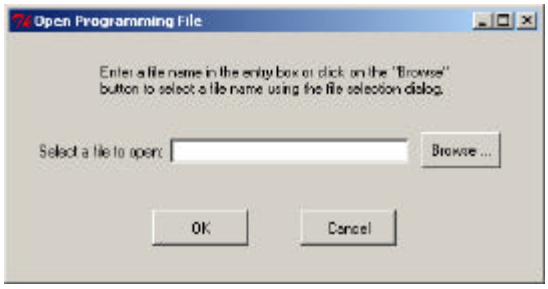
CAUTION

This procedure will erase all portions of the VitalSense monitor memory. All setup and data information will be lost. If data are in the memory, you must download prior to beginning the upgrade procedure.

---

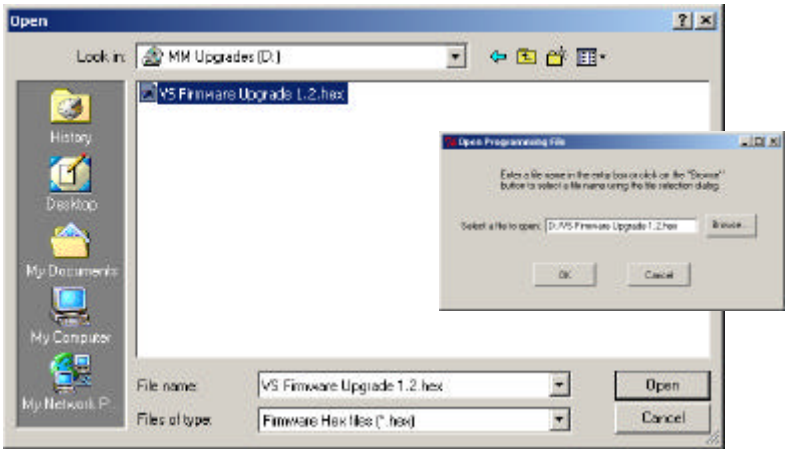
1. The VitalSense Monitor must be connected to the host PC, and communication established (see " Connecting VitalSense Hardware " on page 3-4).
2. Begin from the VitalSense Options window. Click on Upgrade Firmware. The following display will appear.

Main > Setup > Options > Firmware Upgrade



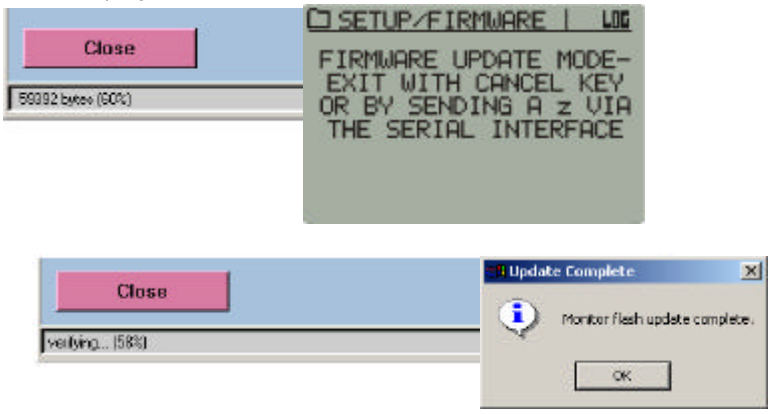
3. Use the browser to navigate to the source of the firmware. In this case, the firmware upgrade is located on a CD. Select the appropriate file. It will have an .hex extension as shown below. Click on Open, and the selected file will appear in the upgrade field.

Firmware file selection



4 Click on OK. Progress can be verified from the PC and the monitor. Once downloaded, the firmware upgrade will be verified. When verified, a prompt will confirm that the upgrade is completed.

Download progress



Clear Memory

See “ Clear Memory ” on page 3-10.

Establishing RS-232 Communications - Advanced

When there is a failure to communicate via the serial RS-232 cable, typically the cause is one of two major COM port errors:

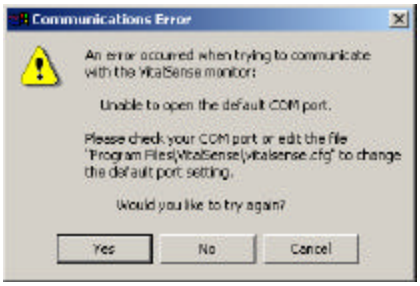
- COM port is already in use.
- General communication errors

NOTE: This following procedure requires modification of the configuration file. If you are inexperienced or uncomfortable with this procedure, contact your System Administrator for assistance.

COM Port Already in Use

The VitalSense Application Program 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 advisory



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

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

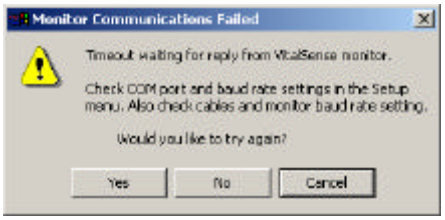
2 Change the second line in the file to match an available COM port, e.g., COM2.

3 Save the file and restart the VitalSense Application Program.

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 advisory



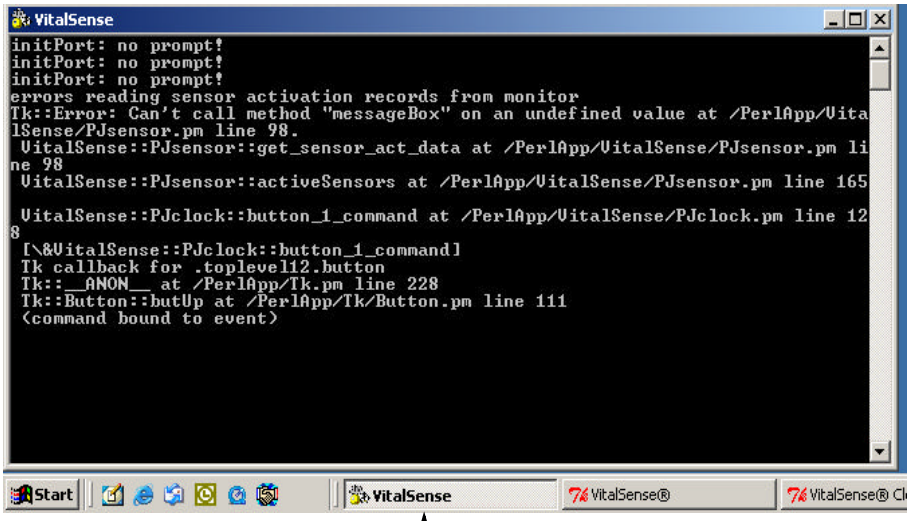
1. Check the serial cable connection at the PC, and at the VitalSense monitor.
2. Verify the default baud rate of the VitalSense Monitor is set to 57.6 kilobaud. This can be found from the monitor front panel. Use the following path:

   `Setup > RS-232 Interface > Baud Rate: 57.6k`

   If it is not, use the arrow buttons to select 57.6k and press Enter.
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. To access, click on VitalSense in the Windows task bar.

   The console lists important errors that may have occurred in the VitalSense Monitor.

VitalSense diagnostic console



Click here for console

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

USB Adapter

Persistent RS-232 Errors

If you still have difficulty establishing communications with the VitalSense Monitor, it may be necessary to use a USB to serial adapter. Some brands of laptops have demonstrated peculiar problems due to hardware and/or driver incompatibility. The use of a USB-to-serial port adapter will require you to install the new driver supplied with the adapter, and this may result in successful communication.

A USB-to-serial port adapter may be purchased from Mini Mitter Company, or your local computer store. The recommended adapter type at this printing is the Aten® UC232A.

Installing the USB Adapter

1. To install the proper drivers, follow the directions included with the adapter.
2. Connect the adapter to the USB port on your computer.
3. Use the Windows Device Manager to find the COM port assigned by the adapter driver. See the Windows help function for instructions.
4. Once the assigned COM port is known, enter the port number in VitalSense Application Program Setup (see “ COM Port Setup ” on page 3-7).

SECTION

4

MAINTENANCE

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

CAUTION *The VitalSense Monitor uses a very specific battery. When replacing the battery, use* ***only a lithium 3.6 volt AA-size battery (SAFT LS 14500)****. Any battery other than the one specified may cause damage to the circuitry of the VitalSense Monitor, or cause reduced performance. Do not attempt to recharge the lithium battery.*

NOTE: The sensor batteries cannot be replaced.

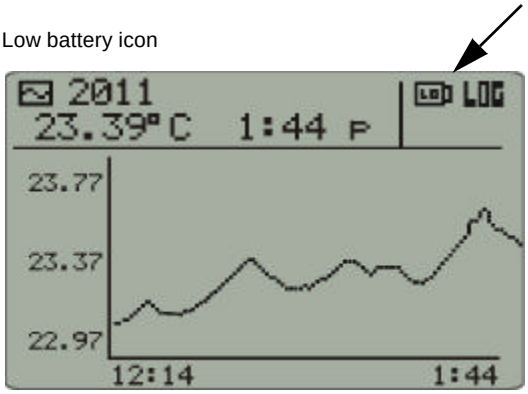
⚠ WARNING *Do not dispose of lithium batteries in fire or flame. An explosion may result. Only dispose in accordance with manufacture's recommendation, or local codes.*

Low Battery Conditions

Low Battery Warning Icon

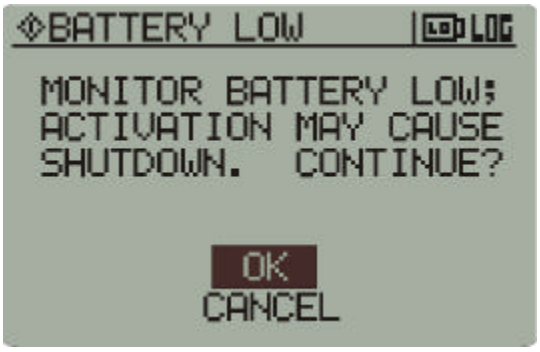
A low battery condition will be indicated on the front panel display by a low-battery icon. This is not a “fuel gauge,” i.e., it means that the battery level has dropped below a set point and should be changed.

Low battery icon



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.

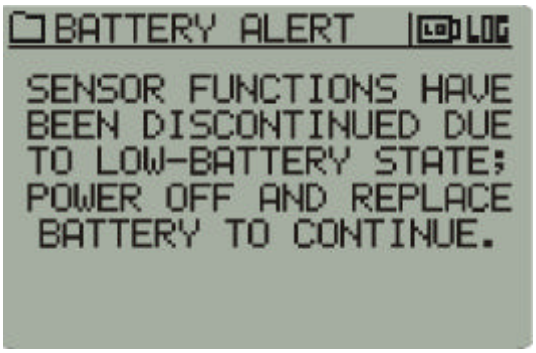
Monitor shutdown precaution



CAUTION *Be aware of the following conditions when in a low-battery or no-battery state. Tracking may be lost as well as the Real Time Clock.*

- The non-volatile memory will retain sensor data indefinitely.
- If the monitor is off (with or without the battery) for more than one hour, the monitor may not be able to resynchronize with the sensors.
- The longer the battery is missing, the greater the risk of the monitor Real Time Clock losing the correct time. If the RTC time is lost, the sensor tracking is lost.

CAUTION *The following display means that the monitor is no longer functioning other than displaying the following LCD warning. Data collection has ceased, but may continue if the battery is replaced quickly (less than one hour).*

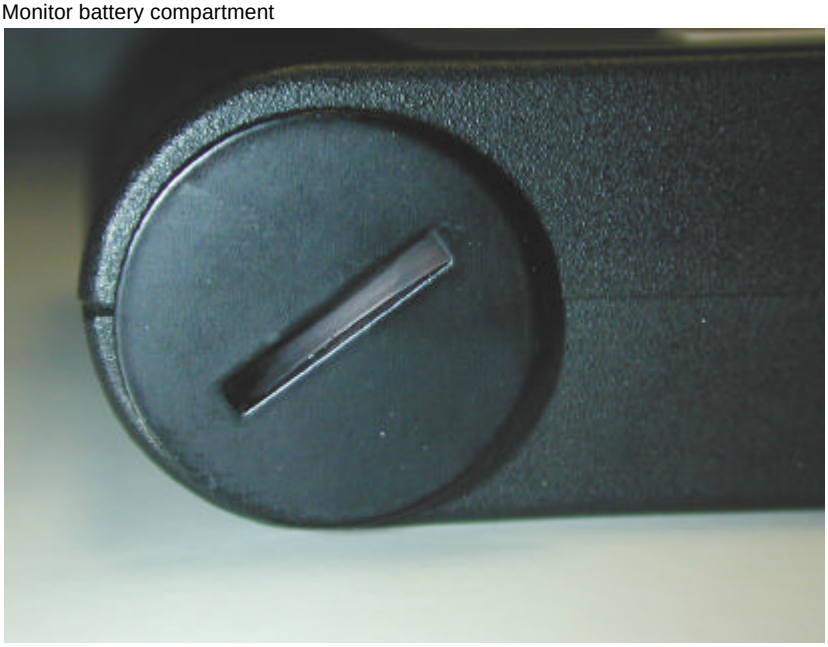


1. Press the Power button to power down the VitalSense Monitor.
2. DO NOT remove the battery until you have a replacement at hand. The residual power in the battery may be enough to retain time-keeping information.
3. When a replacement is available, install a fresh battery.

Battery Replacement

1. Press the Power button to turn the VitalSense Monitor off.
2. The VitalSense Monitor battery is located in the battery compartment, accessible from the bottom of the monitor as shown below.

Monitor battery compartment



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

⚠ 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.*

CAUTION *When replacing the battery, use **only** a lithium 3.6 volt AA-size battery (SAFT LS 14500 or equivalent).*

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 over-tighten.*

6 Press the Power button to turn the monitor power on.

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

Calibration

Sensors

Sensors are factory calibrated and do not require user to enter calibration values.

Monitor

The VitalSense Monitor is calibrated at the factory. An annual factory calibration and refurbishment schedule is recommended.

Storage

Although the shelf-life of the monitor battery is extremely long, it is recommended that the battery be removed if the monitor is to be placed in storage for more than 180 days.

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. Also see “ Sanitizing VitalSense Components ” on page -xiii.

SECTION

5

VS-XHR HEART RATE SENSOR

⚠ CAUTION

Read the material at the end of this section for indications, contraindications, cautions, and warnings with regard to the VS-XHR Heart Rate Sensor and the associated re-charging devices.

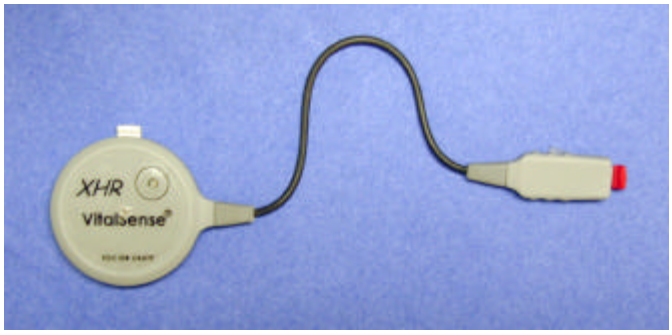
Description

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.

Introduction

There are four key elements in using the VS-XHR Sensor:

- Charge the batteries
- Activate the sensor
- Attach the sensor
- Reset the sensor after use

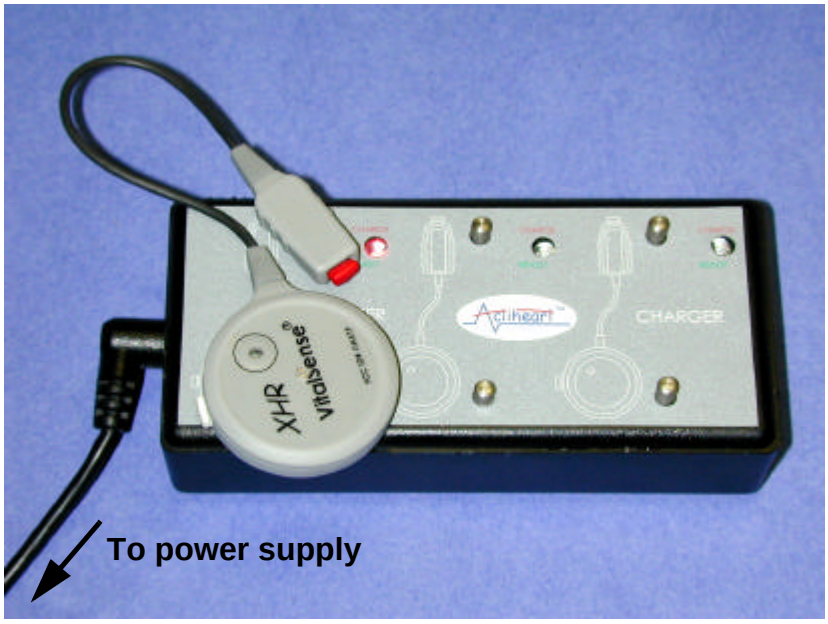


Charging the VS-XHR Sensor

⚠ CAUTION *Read “ Precautions Prior to Using the Multicharger ” on page -xxiii.*

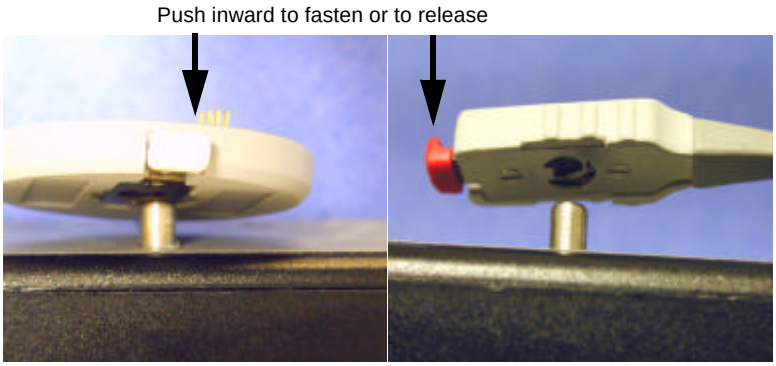
1 Plug the Multicharger power supply into a standard 120 volt outlet.

2 Plug the power supply plug into the Multicharger jack (refer to the illustration below).



3 The VS-XHR Sensor is attached to the metal post on the top of the Multicharger. Attach the sensor body by pushing the clip inward toward the center of the device.

4 Place over the metal post that is marked with the round sensor symbol, and release the clip. The tail clip is attached in a likewise manner to the post marked appropriately with the tail clip symbol. The LED will illuminate red indicating that the sensor is charging.



The VS-XHR Sensor's optimum charge-time is 11 hours. Fully charged, the device will function continuously for four days.

5 When the sensor is fully charged, the LED will turn green. Remove the sensor from the charger and activate.

Precautions Prior to Activating the VS-XHR Sensor

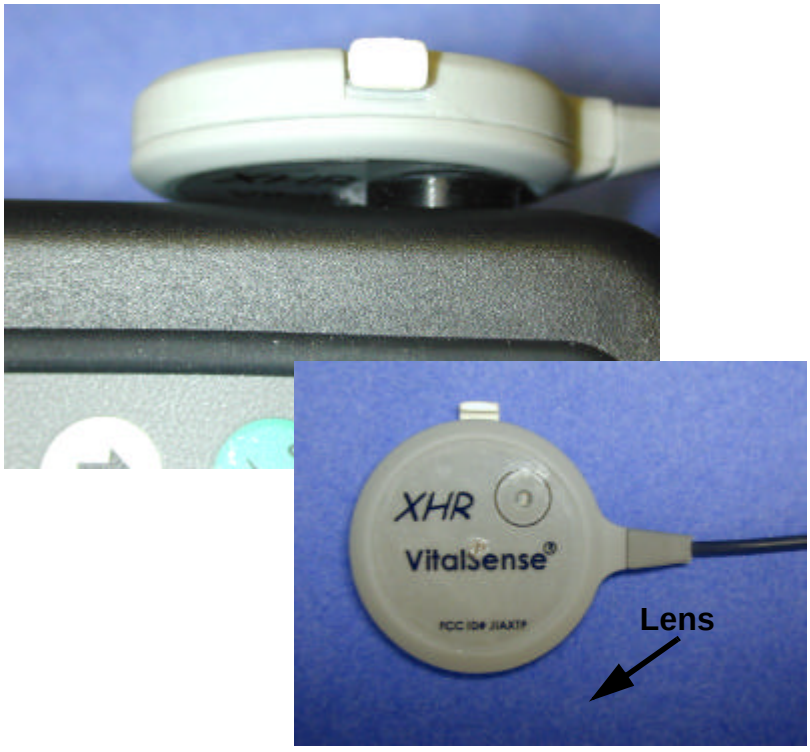
⚠ CAUTION **Read before activating sensor!**

Become familiar with the section “ Notices to Practitioners and Subjects ” on page -vii. It contains important information you need to know prior to activating and using the VS-XHR Heart Rate Sensor.

Activation

Activation is nearly identical to the Capsule and Dermal sensors. The primary difference is the VS-XHR Sensor can be re-activated and re-used.

1. The process of activation begins by turning on the VitalSense Monitor (for an illustration, see “ Activating Sensors Using the VitalSense Monitor ” on page 2-7). Press the Power button for approximately ½-second.
2. Press the Activate Sensor button on the monitor.
3. Follow the directions on the display. Place the VS-XHR Sensor lens against the Activation Port. The lens is marked with a black circle as shown below.



4. Press Activate Sensor again.
5. Follow the directions on the display just as with the VitalSense Capsule and Dermal sensors.

Resetting the VitalSense XHR

Unlike the Capsule Sensor and the Dermal Sensor, the VS- XHR Sensor can be re-used.

The following procedure is very similar to the charging procedure except the VS-XHR Sensor is left on the multi-charger for only a short time.

1. Connect the multi-charger to the power supply as described on page 5-2.
2. Clip the VS-XHR on the multi-charger as indicated by the diagram on the top of the multi-charger.
3. Leave the VS-XHR Sensor on the unit for two (2) minutes to erase the previous data and reset the unit for activation and re-use.

XHR Sensor Placement

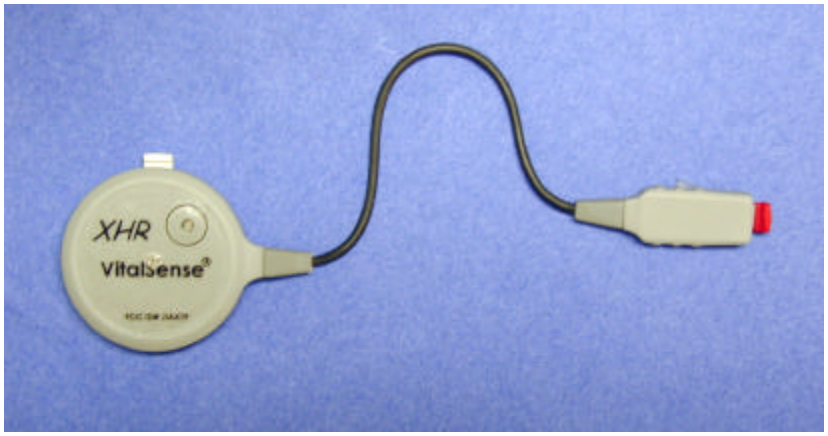
NOTE: Before collecting data, make sure the battery is fully charged.

ECG Electrode Positioning

Accurate lead positioning is important if accurate data are to be acquired. The following is a brief description of where the leads should be placed. For additional information on lead placement and cardiophysiology, see “ The Heart ” on page B-1.

The VS-XHR Sensor consists of the larger, round, main sensor, and a lead to the positive electrode lead that is typically worn on the left side of the chest. Both sensor leads have snap-clips which will affix to the ECG electrode’s male snap. Each electrode must be placed in a specific location.

Main sensor Tail (Left) lead



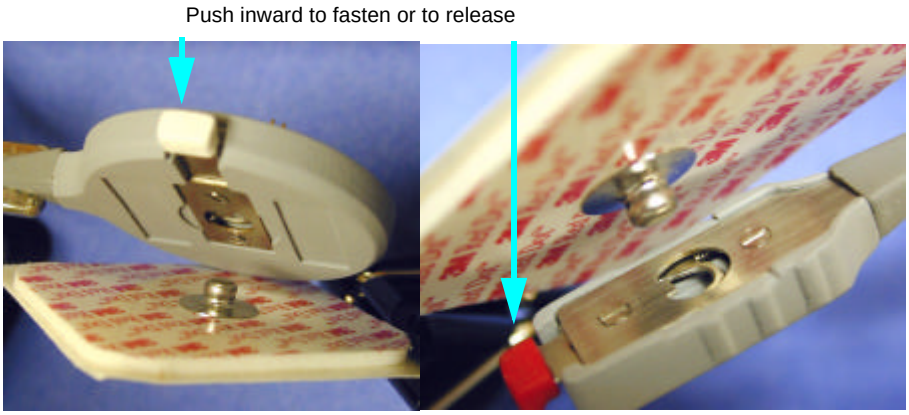
The main sensor and left lead should be placed as shown above, with the snap-clip on top of the main sensor, and the logos on both devices right-side up.

NOTE: A variety of electrodes have been successfully used with the XHR Sensor. See “ ECG (EKG) Electrodes ” on page A-6.

Attachment to ECG Electrodes

XHR Heart Rate Sensor is attached to the ECG electrodes as follows:

1. The Main Sensor body is attached to the mail snap portion of the ECG electrode. Attach the sensor body to the electrode by pushing the clip inward toward the center of the device as shown below.
2. Place the sensor body over the ECG electrode male snap and release the clip as shown below.
3. The tail of the sensor is attached in a likewise manner.



Release

To remove either end of the sensor, press inward on the clip and remove the device.

Site Preparation

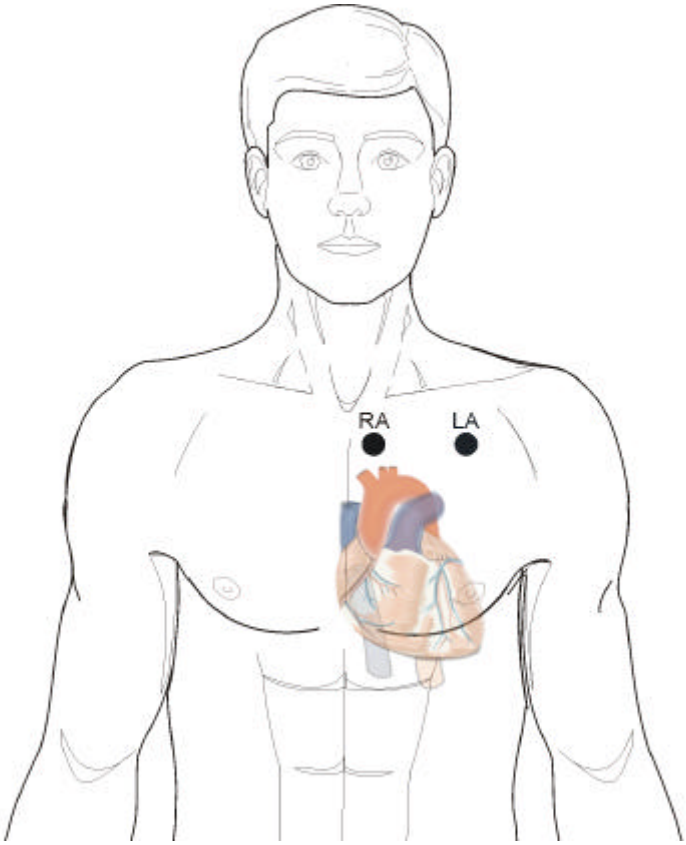
1. Both sites must be free of hair. Shaving the sites not only allows the electrodes to be affixed more securely, but removing the hair will allow better contact and less resistance.
2. Clean both sites with alcohol. This will remove excessive skin oils and allow better contact of the electrodes.
3. Peel away the ECG sensor's protective layer and affix the electrodes per the following instructions.

Lead I Electrode Site

In addition to acquiring a good ECG signal, the Lead I position may also be used if the subject has excessive adipose tissue, injury, or pendulous breasts. It may be necessary to affix the electrodes as shown below.

- The main sensor (RA) electrode must be placed near the center of the sternum centered on the arms.
- The left lead (LA) must be placed the length of the connecting wire, along the mid-clavicular line.

Lead I



Connecting the XHR Sensor to Electrodes

1. Press to open the snap-clips on the XHR Sensor, and clip on to the main sensor electrode pad.
2. Repeat the process with the left lead and the remaining electrode pad stud connector.

NOTE: The electrode pads should be replaced every three days to prevent irritation, inflammation, or infection. The site of the electrodes should be varied slightly.

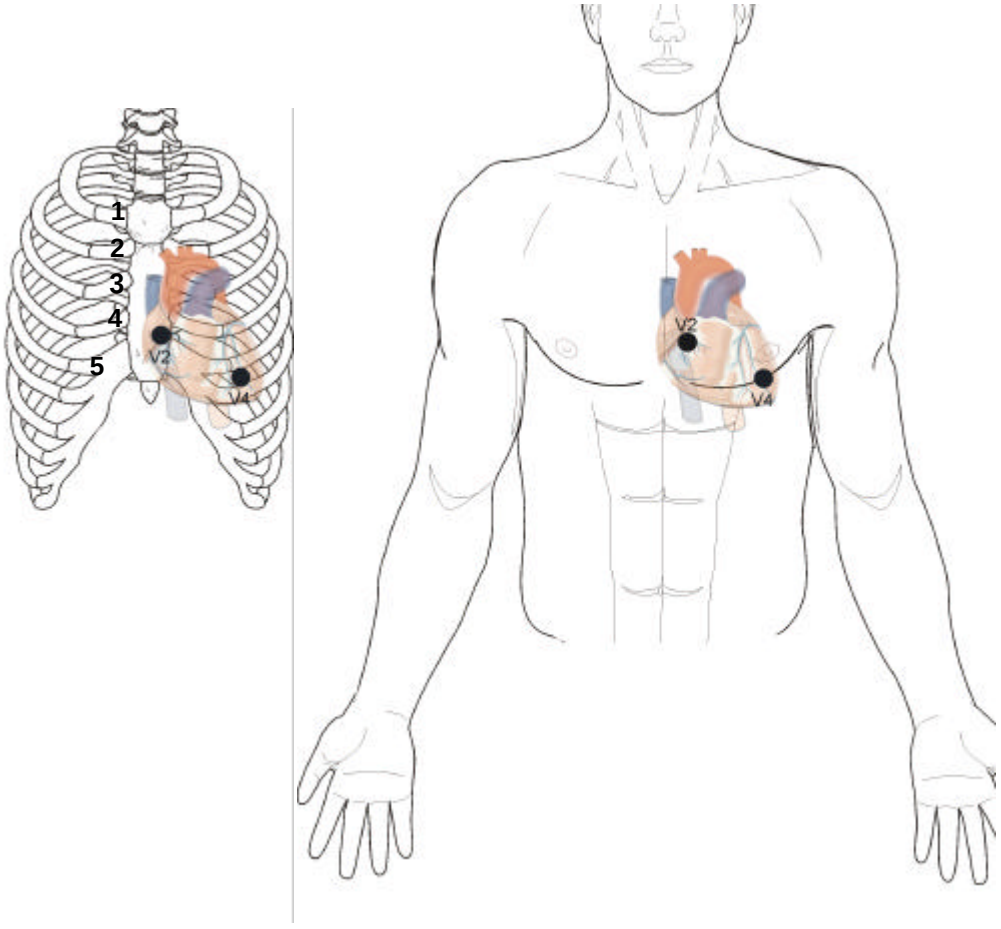
Lead II Electrode Site

The Lead II site may be used if the Lead I site provides a low signal, or perhaps the subject may require an alternate site.

The main sensor electrode pad should be placed as shown below at location V2. V2 is to the immediate left of the sternum at the fourth intercostal space (the space between the ribs). Ribs are counted from top to bottom.

The left lead must be placed as shown below. V4 is located at the 5th intercostal space in the mid-clavicular line.

Lead II



NOTE: Do to variances in the human body, it is recommended that a brief session be recorded and downloaded to ensure the electrode placement is optimum.

VitalSense XHR Sensor Specification

Intended Use

VS-XHR Sensor is intended to be used as a heart rate and/or respiration rate monitor, in conjunction with the VitalSense Integrated Physiological Monitoring System. VS-XHR Sensor is not an ECG monitor. VS-XHR Sensor is not equipped with alarms to signal tachycardia or any other cardiac arrhythmias.

Physical Attributes:Sensor

Parameter	Value	Condition/Note
Size	195 mm length, overall 38 mm diameter, 12.5 mm tail clip	Outer dimensions
Weight	12 grams	With no ECG electrodes attached
Case material	Polycarbonate/ABS	Flammability rating 94V-0
Attachment clip material	Stainless steel	
Attachment type	Adult ECG snap	
Battery type	3.0 volt lithium rechargeable	Not user replaceable
Indicators	Green LED	Coincident with heart beat

ECG Electrode Types

VS-XHR Sensor is considered a two-lead ECG detection sensor. It uses a modified Lead I or Lead II connection. See “ Site Preparation ” on page 5-7 for a description of the preferred lead placement sites.

Lead Type	Sensor Body	Sensor Tail
Lead I	White (RA)	Red (LA)
Lead II	White (RA)	Red (LL)

Physical Attributes: Reader/Charger

Parameter	Value	Condition/Note
Size	TBD	Outer dimension
Weight	TBD	
Case material	ABS	
Indicators	Red LED	Flammability rating 94V-HB

Physical Attributes: Multicharger

Parameter	Value	Condition/Note
Size	TBD	Outer dimension
Weight	TBD	
Case material	ABS	Flammability rating 94V-HB
Charging pin material	Stainless steel	
Number of Charging Ports	3	Simultaneous
Indicators	Green/Red LED	One for each charging port
Overcharge protection	Automatic	Each charging port independent

Environmental Attributes: Sensor

Parameter	Value	Condition/Note
Moisture protection	Splash proof	Meets IP-52 per NEMA 250
Storage temperature	-20 to 50 °C	5-95% humidity
Operating temperature range	0 to 45 °C	
Shock	1 meter to tiled concrete floor, any face	
Transportation temperature	-20 to 50 °C	5-95% humidity

Environmental Attributes: Reader/Charger and Multicharger

Parameter	Value	Condition/Note
Moisture protection	Not water resistant	
Storage temperature	-20 to 50 °C	5-95% humidity
Operating temperature	0 to 40 °C	
Shock	1 meter to tiled concrete floor, any face	
Transportation temperature	-20 to 50°C	5-95% humidity

Functional and performance specifications

NOTE: When AAMI-EC13 is referenced, it refers to 2002 version.

Parameter	Value	Condition/Note
Reception range	1 to 2 meters	From sensor to monitor
Heart Rate sensing range	16 to 255 BPM	Averaged on 15-second interval
Heart Rate resolution	±1 BPM	
Sensing interval	15 seconds	Fixed
Sensor battery life	4 days	Typical
Sensor battery recharge time	11 hours	Typical
Calibration	None required	
Sampling rate	256 samples/second	
Analog bandwidth	3.5 Hz to 100 Hz	
Input protection per AAMI-EC13-4.1.2.1(a)	Not resistant	VS-XHR may be damaged or its accuracy may be affected by use of electrosurgery or electrocautery equipment
Open lead detection current per AAMI-EC13-4.1.2.1(b)	Maximum voltage 900 µV Maximum current 990 nA	20 millisecond pulse
Tall T-wave rejection per AAMI-EC13-4.1.2.1(c)	Meets requirements for 0.5 mV, 0.75 mV, 0.875 mV, 1.0 mV, 1.2 mV, and 1.4 mV	AAMI test waveform definition
HR averaging method per AAMI-EC13-4.1.2.1(d)	Averages ensemble of last 16 IBIs	Rejects any IBI values greater than 37.5% from ensemble average
Irregular rhythm response	See table below	
Response to change in HR per AAMI-EC13-4.1.2.1(f)	80 BPM to 120 BPM: 15 sec 80 BPM to 40 BPM: 15 sec	Logged data
Alarms per AAMI-EC13-4.1.2.1 (g), (i), (j), (q)	Do not apply	VS-XHR does not provide any alarm functions
RF frequency and modulation per AAMI-EC13-4.1.2.1(1)-1)	40.68 MHz ISM band FSK modulation	
Special skin preparation per AAMI-EC-13-4.1.2.1(1)-2)	Preparation per instruction manual	
Detached leads, transmitter battery depletion per AAMI-EC-13-4.1.2.1(1)-3)	Message displayed on monitor	Press any key to eliminate message
Out-of-range per AAMI-EC13-4.1.2.1(1)-3)	Asterisk shown next to sensor ID on Data Views	
Electrode polarization per AAMI-EC13-4.1.2.1(o)	See for recommended electrodes	
Common mode rejection	Does not apply	VS-XHR directly attached to chest surface
Input impedance	5 MΩ	
Input range (ac)	15 mV peak-to-peak	
Input range (dc)	+5 V to -0.9 mV	
Defibrillator use	See warnings	
Leakage current per AAMI-EC13-4.2.3 and 4.2.5	TBD	
QRS detection voltage range per AAMI-EC13-4.2.6.1	0.5 mV	Waveform defined in AAMI-EC13 Fig 6
QRS detection time base range per AAMI-EC13-4.2.6.2	TBD	

Irregular Rhythm Responses

Per AAMI EC13-5.1.2.1(e)

ECG Complex	Waveform	VitalSense-XHR Response (Avg BPM)	Expected (BMP)
3a: Ventricular bigeminy	AAMI 3a	83	80
3b: Slow alternating ventricular bigeminy	AAMI 3b	58	60
3c: Rapid alternating ventricular bigeminy	AAMI 3c	58	120
3d: Bidirectional systoles	AAMI 3d	123	90

Regulatory Standards

VitalSense-XHR Sensor will be tested according to the following standards:

Test Standard	Description	VS-XHR Sensor	Multi-charger	Reader/ Charger
IEC60601-1	Medical Electrical Equipment - Part 1: General Requirements for Safety	✓		
IEC60601-1-2	Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests	✓	✓	✓
IEC60950-1	Information Technology Equipment - Safety - Part 1: General Requirements		✓	✓
47 CFR 15.229	Intentional Radiator Permissive Change	✓		
ASTM/AAMI-ESI:1993	Safe current limits for electromedical apparatus	✓		
AAMI-EC13:2002	Cardiac Monitors, Heart Rate Meters, and Alarms	✓		

ECG (EKG) Electrodes

(See footnotes 1, 2, and 3)

A number of electrodes have been used successfully with the Actiheart Logger.

Electrode type and part number[5]	Subject age	Recommended term of use[4]	Contact type	Pad type	Shape, size	Pkg Qty
3M Red Dot 2560	Adult	1-5 days	Sticky gel	Foam	Rectangular 38mm x 40 mm	50
Lead-Lok Skintact Elite FS-VB01	Adult	1-5 days	Wet gel	Foam	Oval 50mm x 35 mm	30
Quinton Quik-Trace 00310-001	Adult	1-3 days	Solid gel	Clear perforated tape	Round 43 mm	30
Lead-Lok Skintact CT601	Adult	24 hours maximum	Solid gel	Clear tape	Round 50 mm	30
Lead-Lok P-7	Pediatric, infant	1-2 days	Solid gel	Foam	Teardrop 22 mm	3
3M Red Dot 2248	Pediatric	1-2 days	Solid gel	Surgical tape	Round 44 mm	25
3M Red Dot 2258	Infant	1-2 days	Solid gel	Soft cloth	Round 32 mm	3

Notes:

[1] All listed electrodes are Ag/Ag/Cl formulation

[2] All listed electrodes are single-use only. Do not re-use electrodes.

[3] All listed electrodes contain no latex and no PVC.

[4] Discontinue use if irritation develops at any time.

[5] For measurement of HR during rigorous exercise, 3M Red Dot 2560 electrode is recommended.

APPENDIX

A

FREQUENTLY ASKED QUESTIONS

What is Standard Mode?

Standard Mode is the default mode in all VitalSense Monitors. When operated in Standard Mode, a monitor receives data from sensors activated by that monitor and excludes transmissions from other sensors not activated by that monitor.

The model number of the Standard Mode monitors begin with STD. The model number can be found on the back of the device.

The alternative to Standard Mode is Medic Mode™, an option installed in some VitalSense Monitors.

How long will the battery last in Standard Mode?

With 10 sensors on line (maximum), the disposable lithium cell will last approximately 10 days receiving, and 20 days standby.

What is Medic Mode™?

Medic Mode allows the monitor to receive transmissions from all active sensors within range, without regard to which monitor activated them. It also allows more than 10 sensors to be activated with a single monitor. This feature comes at a cost in that sensors activated while in Medic Mode cannot be tracked if the monitor is switched back to Standard Mode.

However, switching from Standard to Medic Mode will not, in most cases, cause the monitor to stop tracking sensors when switching from Medic Mode back to Standard Mode. The monitor will attempt to re-synchronize with the sensors. Re-synchronization is not guaranteed, therefore switching to Medic Mode from Standard Mode is not recommended if data loss cannot be tolerated.

Another key difference is that in Medic Mode, sensor data are time-stamped with the time the data are received. Standard Mode sensor data are time-stamped with the actual time of measurement. The difference between those two times may vary from 3 to 12 seconds.

How long will the battery last in Medic Mode™?

If the monitor is left on continuously in Medic Mode, the disposable lithium cell will last approximately 48 hours.

How do I know if my monitor has the Medic Mode™ option?

Medic Mode will be listed in the Setup Monitor menu. Press the Menu button on the monitor, then select Setup Monitor.

You can also look at the label on the back of the monitor. The model number will begin with MED.

Will a common AA alkaline or Ni-Cad battery work in my monitor?

No! They are the wrong voltage and wrong design. Use only SAFT LS14500 batteries, available from Mini Mitter.

What should I do if the monitor and sensors are separated for more than 30 minutes?

First, try bringing the monitor within range of the sensors and wait for 2 minutes. If the monitor does not lock on to the sensors, try turning the monitor power off, then back on. The monitor will attempt to lock on to the sensors. If this is not successful, it is likely the sensors have been lost from tracking. Unfortunately, once a sensor is lost from tracking, it may not be brought back on line. A lost sensor should be removed from the tracking list by using “Remove Sensor” on page 2-16. This is under the Sensors Option menu.

Can I still receive data from a “lost” sensor?

Yes, but only if you have Medic Mode, an optional feature of VitalSense. Details can be found in “Medic Mode” on page C-1.

Why does the Power button seem to work intermittently?

This is actually by design. The Power button must be held down at least ½-second to power up the monitor. This is to prevent the accidental operation of the button if jostled in the carrying pouch.

What is the purpose of Lockout Mode?

Lockout Mode is a feature that prevents “idle tampering” of the monitor, and also reduces the chance of the inadvertent pressing of front panel buttons during use.

Why may I not have an MRI?

The components within both the Capsule Sensor and Dermal Sensor contain elements which are incompatible with MRI procedures. You would risk injury to yourself.

What if a Capsule Sensor should leak while ingested?

VitalSense ingestible capsule shells are composed of inert plastic and medical grade plastic adhesive. Each capsule is individually inspected to insure a complete seal at the factory. VitalSense capsules have been tested for resistance to moisture, varying pH levels, heat, enzyme reaction, saline, and alcohol exposure. We know of no condition within the alimentary tract that could lead to a breach of the capsule seal. However, as an added precaution, the circuits within the capsule are further coated with a plastic, water-resistant coating. Finally, the components within the capsule would pass through the digestive system without noticeable influence on the subject's system.

What is the temperature range of the sensors?

See "Specification" on page D-1.

How is the accuracy of the thermometer sensors guaranteed?

The accuracy of the sensors is established with a process traceable to the Nation Bureau of Standards and Technology.

Can a glass bulb thermometer be used to check the accuracy of my sensors?

No. Glass bulb thermometers are not accurate enough.

How can I check the accuracy of my Capsule Sensors?

You will need a highly temperature-stabilized water bath (better than 0.05 °C stability and accuracy), and a NIST traceable RTD digital electronic thermometer.

Will the accuracy of the sensors degrade as their batteries become low?

The sensors will remain accurate for up to 10 days of transmission.

How long will the sensors transmit?

Following activation, approximately 10 days (240 hours). This holds true following a shelf life of up to one year.

After ingestion, when will the Capsule Sensor begin to transmit actual core temperature?

Approximately one minute.

What is the best way to administer the Capsule Sensor?

Take it with a glass of water or a soft drink as you would most capsules or pills.

Are there any dietary restrictions while the Capsule Sensor is inside me?

None.

Can my Capsule Sensor be re-used?

Capsule Sensors must not be re-used in human applications.

What if a Dermal Patch Sensor causes a rash or discomfort?

Discomfort may be the result of inadequate hair removal, or placing the patch on an area of skin that is subject to flexing or stretching. A rash may be a sign of dermatitis or allergy. Notify your practitioner immediately.

Can the Dermal Patch Sensor be worn in the shower or bath tub?

Yes. However the VitalSense Monitor must be left outside the shower or tub.

What is UTC and why is it important?

It stands for Universal Coordinated Time. A complete section has been devoted to this subject. Turn to “Universal Coordinated Time” on page B-1.

How does VitalSense software get installed and uninstalled?

The VitalSense Application Program is supplied in two distribution formats: a Microsoft Installer (.msi) package, and as a self-extracting Zip file. Normally just double-clicking on the MSI version will install the package. Older versions of Windows may require you to obtain the installer from the Microsoft website, or use the Zip file. The files will be installed in C:\Program Files\VitalSense. The MSI package will automatically create a shortcut on your desktop.

Uninstallation can be done using the Add/Remove Programs feature found in your control panel. If the installation was done using the Zip package, simply delete the VitalSense directory and the associated shortcut.

What is the “version” of my firmware?

See “Firmware Version” on page 3-21.

The display on the VitalSense Monitor went blank.

Occasionally, to protect itself from electrostatic discharge, the LCD will shut down. The display will reactivate when a transmission is received, or when you momentarily press any button.

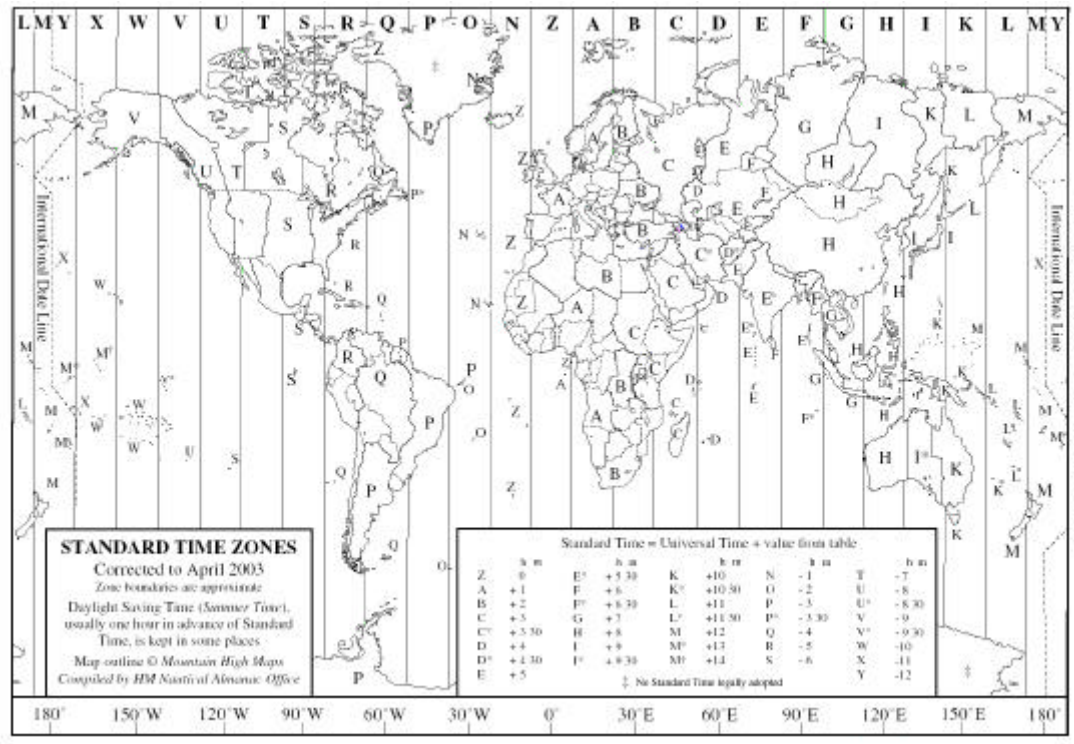
APPENDIX

B

UNIVERSAL COORDINATED TIME

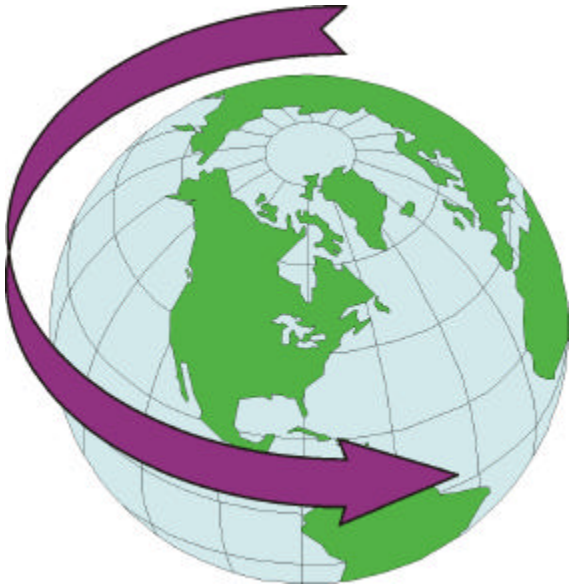
If the world were ideal, we would have one time the world over, and all clocks would read the same. However, because our planet is divided between day and night, our global structure has generally adopted *solar time*. This divides the planet into a series of time zones. Although it makes it easy to keep time based on daylight, it is very difficult for scientists, pilots, military, and others to use.

Another complication is the occurrence of Daylight Saving Time in selected areas. Navigation, exchanging data, astronomy, synchronization of experiments, and other fields require a single means by which to keep time.



WORLD MAP OF TIME ZONES

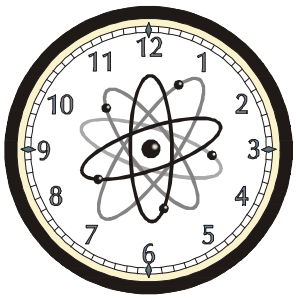
Another way of keeping time is similar to solar time, called Universal Time. Within this category are variations. UT1 is a measure of the rotation angle of the Earth as observed astronomically. Solar time varies slightly. Because of the Earth's tides, the earth slows down, wobbles, and introduces slight variations in measurements. UT1 accounts for these variations, making it useful for astronomy.



Universal Coordinated Time is the basis for worldwide civil time-keeping. Timing laboratories around the world contribute to provide the international standard Universal Coordinated Time (UTC).

NOTE: "UTC" technically does not represent a series of words. During international discussions, the three letters were agreed upon as a "symbol" rather than an abbreviation or acronym.

The UTC second is based on the atomic transition of the element cesium under specific conditions. It is independent of astronomical variations, and because of its stability is accurate to a nanosecond (1,000,000,000th of a second) per day.



UT1 (based on rotation of the Earth) and UTC (based on man-made instruments) may differ, but never more than 0.9 second. By agreement, when the difference begins to reach this point, a “leap-second” is introduced in the UTC. This occurs, on average, every 12 to 18 months.

Universal Coordinated Time may be referred to colloquially (and historically) as Greenwich Mean Time (GMT). This village lies on the Greenwich meridian (0° longitude) in England, and for years was the point of reference for all other time zones. Pacific Standard Time, for example, is 8 hours behind UTC (UTC-8).

UTC and GMT may also be called Zulu time. This is a common military term, and is typically shown in 24-hour format, such as 1800Z (6pm).

Finding the Universal Coordinated Time

There are a variety of ways to obtain the UTC. By computer, radio, and even telephone.

United States Naval Observatory

- **Internet**

  http://tycho.usno.navy.mil

United States Government

- **Internet**

  http://www.time.gov

National Institute of Standards and Technology

- **Internet**

  http://physics.nist.gov/time

- **Telephone** (delayed by approximately 30 ms because of land line)

  (303) 499-7111 in Ft. Collins, Colorado (not toll-free)

  (808) 335-4363 in Kauai, Hawaii (not toll-free)

- **Radio**

  WWV - 2.5 MHz, 5 MHz, 10 MHz, 15 MHz, 20 MHz

  WWVH - 2.5 MHz, 5 MHz, 10 MHz, 15 MHz

UTC and VitalSense

When collecting time-sensitive data, specifically across time zones, it is not advisable to change the clock during data collection. Within the VitalSense Monitor, the real time clock is to be set to UTC. This insures that the data is universally time-stamped, and can be recognized and analyzed by scientists throughout the world without regard to time-conversion or gaps in the data caused by clock changes.

UTC Offset

Since few people operate on UTC on a daily basis, VitalSense needs a means to display local time. This is done with the UTC offset. Typically the UTC is entered into the monitor followed by the offset. For example, the offset for the US Eastern Time Zone is -5 hours. Once the offset is entered, the local time is correctly displayed.

Conversely, if the Local Time is entered, and the offset is entered, the Universal Coordinated Time is calculated and displayed.

Daylight Saving Time

Daylight Saving Time within the United States is automatically compensated for by VitalSense. However, when setting the Time and Date in the VitalSense Monitor, Local Time should be entered. Once Local Time is entered, the Daylight Saving compensation box can be checked, and Vital Sense will, based on the time and date, change the Local Time automatically if appropriate.

For regions within the United States that do not follow DST, DST may be disabled and the UTC offset would be used to set the correct local time. The same is true for local time outside the United States.

Keeping it Simple

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.

For more detailed information on setting the VitalSense Monitor clock, refer to:

- “Adjusting the Time/Date” on page 2-20
- “Setting the Monitor Clock” on page 3-9

APPENDIX

C

MEDIC MODE

Medic Mode Details

Medic Mode puts the VitalSense Monitor in a special configuration to allow continuous monitoring of unlimited sensors.

- An unlimited number of sensors may be monitored in Medic Mode. Ten can be monitored in Standard Mode.
- In Medic Mode, a VitalSense Monitor can monitor sensors activated by another monitor. This is not possible in Standard Mode.
- Although data are logged if enabled, sensors are not tracked.
- Medic Mode can be used to monitor sensors that are still transmitting, but are no longer in synchronization with their respective VitalSense Monitor.
- When the VitalSense Monitor is in Medic Mode, a unique icon will appear on the Data Views display and on the activation sequence display.

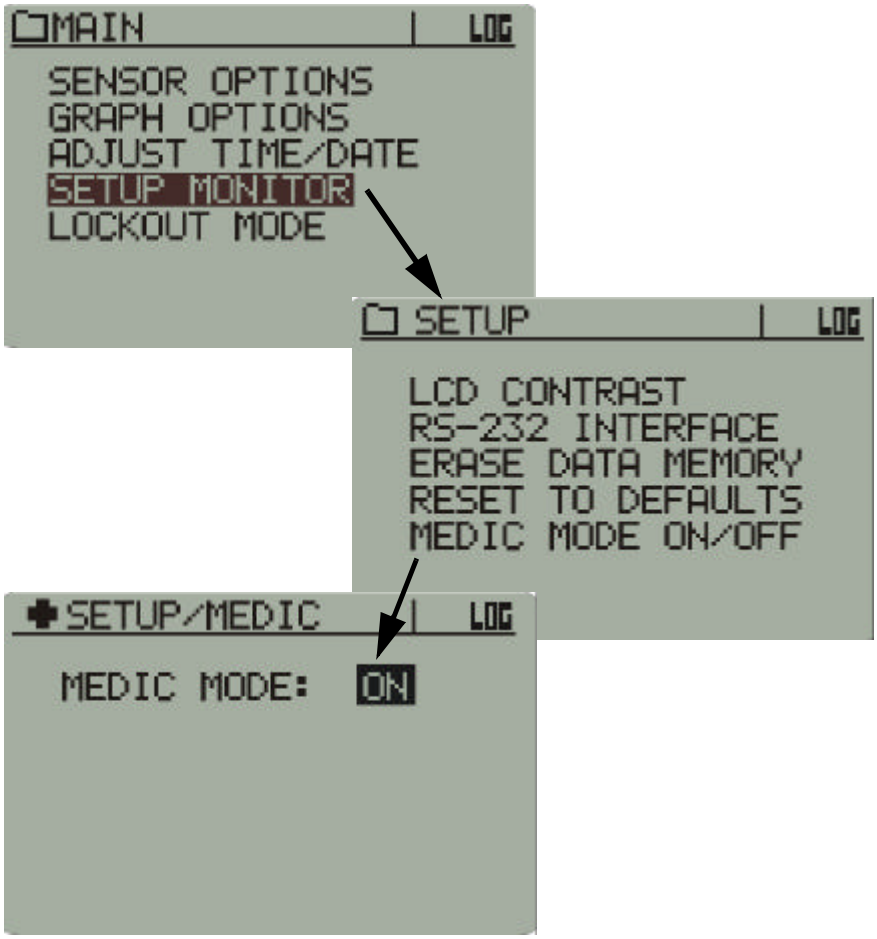
NOTE: Using Medic Mode dramatically reduces the battery life of the VitalSense Monitor. Expected battery life in continuous use is approximately 48 hours.

Battery life may be extended by:

- Placing the monitor back in Standard Mode.
- Turning the monitor power off.
- Activating fewer sensors (activation requires the most power of any VitalSense function).

Accessing Medic Mode

Main > Setup > Medic Mode ON/OFF



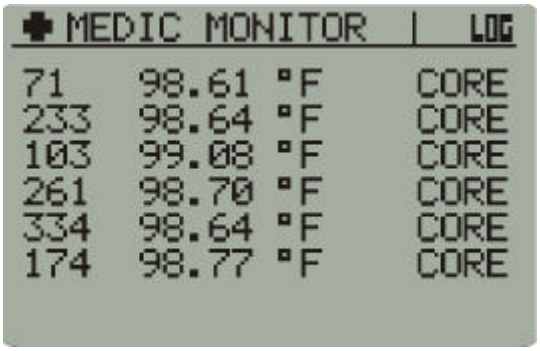
Medic Mode is primarily for checking sensor performance and temperature of individual sensors. Other characteristics of Medic Mode are as follows:

- If sensors have been activated with Medic Mode off and are being tracked, they will stop being tracked when Medic Mode is turned on. However, when Medic Mode is turned back off, tracking will resume. For details on tracking, see “Tracking” on page 1-3.
- If sensors are activated with Medic Mode on, they will not be tracked, but the data will be logged.
- With Medic Mode off, only ten sensors may be tracked and monitored. With Medic Mode on, an unlimited number of sensors may be activated and monitored, but none will be tracked.
- In Data Views, VitalSense will display a Medic Monitor. Each sensor detected will be added to a scrolling list. Only six sensors will be displayed at any one time as the list updates.

Medic Mode Display

The display is a continuous monitoring of all sensors in the order in which they are acquired. The list may be scrolled using the arrow buttons.

Medic Mode display



SECTION

D

SPECIFICATION

NOTE: Also see " VitalSense XHR Sensor Specification " on page 5-10.

Parameter	Value	Condition/Note
Physical Attributes (Monitor)		
Size	120 x 90 x 25mm	Outside dimensions
Weight	200 grams	Monitor only
Case material	Polycarbonate/ABS copolymer	
Interface Panel	Non-permeable membrane switch	
Display	Monochrome LCD with backlight	
Physical Attributes (Capsule Sensor)		
Capsule appearance	Purple, cylindrical, with hemispherical ends	
Size	8.7 mm O.D. x 23mm long	Total
Weight	1.6 grams	
Physical Attributes (Dermal Patch Sensor)		
Patch appearance	Off-white, circular, flat	
Size	57.2 mm O.D. x 6.0 mm thick	Total
Weight	7.5 grams	

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	±0.10 °C	32 °C to 42 °C (Guaranteed[1])
	±0.05 °C	32 °C to 42 °C (Typical)
	±0.25 °C	-20 °C to 32 °C (Guaranteed)
	±0.25 °C	42 °C to 60 °C (Guaranteed)
Temperature display resolution	±0.01 °C	
Display update rate	15 seconds	Average
Monitor battery life	10 days (240 hours) 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	
Maximum logging time	6 days 10 days	10 sensors 5 sensors
Environmental Attributes		
Moisture protection	IEC529-IP52 NEMA 250-5.3	Monitor and sensors
Storage temperature*	-20 to 50 °C	@ 5-95% humidity Monitor and sensors
Operating temperature*	0 to 40 °C	Monitor
Shock**	1 meter drop to tiled concrete floor	Monitor
Transportation Environment Attributes		
Moisture protection	IEC529-IP52 NEMA 250-5.3	Monitor and sensors
Storage temperature	-20 to 50 °C	@ 5-95% humidity Monitor
Shock	1 meter drop to tiled concrete floor	Monitor

[1] This specification has been verified in accordance with ASTM-E1112-00.
*Operation and storage outside the stated temperature and humidity range may degrade performance.
**Subjecting to shock outside the stated range may degrade performance.

Parameter	Value	Condition/Note
Radio Frequency Attributes		
Transmission range	Maximum 1 meter Maximum 2 meters	Capsule sensor Dermal Patch
Software/PC Attributes		
Software features	Data transfer, ASCII conversion	
Compatibility	Windows® '98, 2000, XP, Millennium, or Windows NT 4.0 SP 6	
Communications interface	RS-232 cable	Custom, water protected

Agency Standards Met

Limitations

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.

Medical Device

VitalSense system is cleared by the United States Food and Drug Administration for marketing as a Class II medical device.

Clinical Thermometer

VitalSenses meets ASTM-E1112-00, Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature.

(For those VitalSense System owners needing “Determination of Accuracy” documentation related to this specification, please contact Mini Mitter.)

Radio Emissions

VitalSense meets CFR Title 47, Part 15, Subpart C. FCC listing code is JIAXTP1.

Human Safety

This device is classified as Type CF protection against electrical shock.

The VitalSense Monitor conforms to IEC 60601-1 (UL 2601-1).

Water Resistance

VitalSense monitor meets IEC 529-IP52, and NEMA 250-5.

Safety Labeling and Terminology

Instruction manual conforms to ANSI Z535.4-2002

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