Remote Viewer

User manual

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Information for servicing the ViSi Mobile Monitoring System is contained in the ViSi Mobile Monitoring System Technical Manual, Part Number: 6-000147. For additional information or assistance, please contact Sotera Wireless or an authorized Sotera Wireless representative in your area.

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Contents

1. Preface

1.1 Introduction

The suite of ViSi Mobile Monitoring System™ user manuals are intended to provide information for the proper operation of the Sotera Wireless ViSi Mobile Monitoring System™. The suite of manuals comprises of:

- ViSi Mobile Monitoring System User Manual
- ViSi Mobile Remote Viewer User Manual
- ViSi Mobile myRemote Viewer User Manual[1]

A formal knowledge of patient monitoring and an understanding of the features and functions of the system are prerequisites for its proper use.

These manuals are written for trained clinicians. Although the manuals describes guidelines for optimizing monitoring techniques, clinicians using this system should be trained to take and interpret patient vital signs. Automatic vital signs monitoring is an adjunct to clinical assessment; good clinical judgment should always prevail.

Do not operate the ViSi Mobile Monitoring System before reading these instructions.

1. The ViSi Mobile myRemote Viewer User Manual is a system that comprises the functionalies of the ViSi Mobile Appliance and the ViSi Mobile Remote Viewer. The ViSi Mobile myRemote Viewer User Manual only contains instructions specific to the myRemote Viewer functionality. Refer to the ViSi Mobile Remote Viewer Manual for wireless technology and system specifications, operating characteristing, quality of service, wireless security measures, information regarding wireless coexistence issues and mitigations, EMC standards compliance and warnings about possible effects from RF sources in the vicinity of the device.

1.2 Intended Use

The ViSi Mobile Monitoring System is intended for use by clinicians and medically qualified personnel for single or multi-parameter vital signs monitoring of adult patients (18 years or older). It is indicated for ECG (3 or 5 lead-wirelead-wire), respiration rate, heart rate, non-invasive blood pressure (NIBP), continuous non-invasive blood press (cNIBP), non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate, and skin temperature in hospital-based facilities; including general medical-surgical floors, intermediate care floors, and emergency departments.

Continuous non-invasive blood pressure (cNIBP) testing has not be conducted on ambulatory patients.

The ViSi Mobile Monitoring System may be used as standalone devices or networked to a ViSi Mobile Remote Viewer through wireless 802.11 communication.

1.2.1 Contraindications

- Impedance pneumography for the determination of Respiration Rate (RESP) is not recommended for use in the presence of mechanically induced high frequency ventilation.
- The ViSi Mobile Monitoring System has not been tested for use on neonatal or pediatric patients under the age of 18 years.
- Do not use the same ViSi Mobile Monitor System to measure the NIBP of one patient while it is connected simultaneously to another patient.
- Do not use the ViSi Mobile Monitor on a patient with an Intra-Aortic Balloon Pump (IABP), or a Left Ventricular Assist Device (LVAD). The Monitor requires an unperturbed arterial pulse waveform for non-invasive blood pressure calculations. IABP and LVAD perturb the arterial pulse waveform.
- Do not use the ViSi Mobile Monitor System on a patient on cardio-pulmonary bypass.
- Do not use the ViSi Mobile Cuff Module on a patient’s arm where the use of a blood pressure cuff is contraindicated.
- Do not use the ViSi Mobile Monitoring System in an MRI Suite.
- The effectiveness of the ViSi Mobile Monitoring System’s blood pressure monitoring has not been established in the presence of any dysrhythmias.

2. Warnings and Cautions

2.1 Introduction

Please read and adhere to all warnings, cautions and notes listed here and in the associated sections throughout this manual.

Do not operate the ViSi Mobile Monitoring System before reading these instructions.

Warning statements alert the user to conditions or practices that could result in injury to a person, or serious adverse events associated with the use or misuse of the ViSi Mobile Monitoring System.

Caution statements alert the user to conditions or practices that could result in problems with the ViSi Mobile Monitoring System associated with its use or misuse.

Note: Note statements provide supplemental information to the user.

2.2 Warnings

Intended Use

Do not use the ViSi Mobile Monitoring System outside the intended use described in this manual. Doing so can result in a delay in or inappropriate therapy.

Do not use the ViSi Mobile Monitoring System in neonatal or pediatric patients under the age of 18 years since the System has not been tested for these patient groups.

Do not use the ViSi Mobile Monitor as a primary hypoxia diagnostic tool.

Safety

Do not use the ViSi Mobile Monitor in an MRI suite or a hyperbaric chamber.

Avoid electrosurgery burns at the ECG monitoring sites by ensuring the electrosurgery-return circuit is connected properly.

Monitoring may be temporarily interrupted during the use of electrosurgery in the vicinity of/or on a patient being monitored with a ViSi Mobile Monitoring System. Observe the patient closely while electrosurgery is in use.

To ensure patient safety, use only components and accessories recommended or supplied by Sotera Wireless, Inc. Accessories must always be used in accordance with your facility's policies and the manufacturer's recommendations.

Use only the AC adapter recommended for the ViSi Mobile Charger. Use of other AC adapters may result in damage to the unit.

There may be a possible hazard caused by the summation of leakage currents when several items of equipment are interconnected.

The ViSi Mobile Monitoring System has not been tested in the presence of flammable anesthetics or other flammable agents in combination with air, nitrous oxide, or oxygen-enriched environments.

Route the patient cabling to avoid the possibility of patient entanglement or strangulation.

To ensure patient safety, the conductive parts of the ECG electrodes, including connectors and other patient-applied components, should not contact other conductive parts, or earth ground, at any time.

Never connect the ViSi Mobile Chest Sensor Cable directly to the AC power outlet.

Never connect the ViSi Mobile Cuff Module directly to an AC power outlet. To recharge the battery, disconnect the Cuff Module from the patient, and then place it in the ViSi Mobile Charger.

Warnings 

To prevent possible cross-contamination, properly clean and disinfect all reusable components between patients.

The ViSi Mobile Monitor should never be used to measure the NIBP of one patient while the Monitor is simultaneously connected to another patient.

Do not attempt to take NIBP measurements with the ViSi Mobile Monitor while the patient is undergoing cardio-pulmonary bypass.

Do not attempt to take NIBP measurements with the ViSi Mobile Monitor while the patient is being treated with an intra-aortic balloon pump or left ventricular assist device.

Periodically observe the patient's arm for signs of impaired circulation, which may be a result of measurements made too frequently. Loosen or remove the ViSi Mobile Disposable Cuff if signs and/or symptoms of prolonged impaired circulation are evident.

Never place the ViSi Mobile Monitor or the ViSi Mobile Cuff Module into the ViSi Mobile Charger while connected to a patient.

Never connect the ViSi Mobile Monitor directly to an AC power outlet. To recharge the battery, disconnect the Monitor from the patient, and then place it in the ViSi Mobile Charger.

Do not clean the ViSi Mobile Monitor with detergents while worn by the patient.

Do not place the ViSi Mobile Monitoring System on or over an implanted programmable medical device.

When the "Monitor Too Hot" alarm is in progress, ViSi Mobile Monitoring System should be removed from the patient immediately. Leaving on the patient for an extended period of time may lead to a skin burn.

When the "Cuff Battery Temp" alarm is in progress, ViSi Mobile Cuff Module should be removed from the patient immediately. Leaving on the patient for an extended period of time may lead to a skin burn.

Disposable Components

All disposable components of the ViSi Mobile Monitoring System are for single patient use only. To avoid possible cross contamination, do not reuse any disposable items on a patient other than the original patient. Dispose of the components after use per your facility's policy.

Warnings

Patient Monitoring

Do not connect more than one ViSi Mobile Monitor to a patient.

Do not connect more than one patient to a single ViSi Mobile Monitor.

The ViSi Mobile Monitor, Thumb Sensor, Cuff Module, and the Chest Sensor Cable must all be connected to the same arm for the System to function correctly.

The Wrist Strap should securely hold the ViSi Mobile Wrist Cradle in place without impairing circulation. Immediately loosen the Wrist Strap if the patient complains of pain, tingling, or numbness in the affected hand or wrist.

Only use the ViSi Mobile Chest Sensor Cable provided by Sotera Wireless, Inc. for the ViSi Mobile Monitoring System. The Chest Sensor Cable is designed to provide defibrillation protection as indicated in the Specifications section of this manual. ViSi Mobile is designed to be compatible with the use of external defibrillators.

Only use the ViSi Mobile Thumb Sensor provided by Sotera Wireless, Inc. with the ViSi Mobile Monitoring System. Using non-approved Thumb Sensors may result in inaccurate SpO_2 readings or damaged equipment.

The ViSi Mobile Thumb Sensor is intended for use on the patient's thumb only. Do not apply the Thumb Sensor to the patient's fingers.

Inspect patient's skin at sensor site per your facility's protocol. If skin surface has been compromised, reposition the ViSi Mobile Thumb Sensor or move the Thumb Sensor to the patient's other thumb.

Ensure the ViSi Mobile Thumb Sensor is securely fastened. A Thumb Sensor that is wrapped too tight or too loose can adversely affect SpO_2 measurement.

Inspect patient's skin at sensor site every 8 hours. If skin surface has been compromised, reposition the ViSi Mobile Thumb Sensor or move the Thumb Sensor to the patient's other thumb.

The Thumb Strap should securely hold the ViSi Mobile Thumb Sensor in place without impairing circulation. Immediately loosen the Thumb Strap if the patient complains of pain, tingling, or numbness in the affected thumb.

Before monitoring a new patient, ensure all the sensors have been removed and that monitoring was stopped using the Stop Monitoring procedure.

To prevent settings from being inadvertently changed, lock the ViSi Mobile Monitor screen (if enabled) as soon as tasks are completed.

Warnings 

Keep all pacemaker patients under close or constant observation. Pacemaker signals can differ among pacemakers, ICDs, or CRT devices. The Association for the Advancement of Medical Instrumentation (AAMI) cautions: “In some devices, rate meters may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely upon rate meter alarms”.

Other RF radiating devices (such as high powered RFID readers and Bluetooth devices) that are in close proximity with the ViSi Mobile Monitor may interfere with the Monitor’s wireless communications. During such interference, the Monitor continues to monitor and will alarm locally. If wireless communication is affected when using the Monitor in close proximity with another RF radiating device, move the other device away from the Monitor or discontinue use of the other device.

After monitoring has been stopped on the ViSi Mobile Monitor, removing the patient from the ViSi Mobile Remote Viewer cannot be undone. Once removed, the patient will no longer be available on the Remote Viewer.

All wireless devices are susceptible to radio frequency interference that can disrupt connectivity. If excessive ViSi Mobile Monitoring System disconnections are observed, notify your biomedical engineer. Excessive disconnections can cause interrupted patient monitoring; disconnections must be investigated and corrected.

Locate the ViSi Mobile Remote Viewer so that clinicians can view it without obstruction. Remove any objects that obstruct the display.

A qualified clinician must always be in direct view of the ViSi Mobile Remote Viewer. If the Remote Viewer display is blank, contact your biomedical engineer immediately for service.

If a ViSi Mobile Monitor or the ViSi Mobile Remote Viewer display screen is scratched or damaged, immediately send it for servicing. A scratched or damaged screen can interfere with patient monitoring.

Always consult Sotera Wireless before performing any changes to the ViSi Mobile Appliance. Server changes can result in communication failure between components of the ViSi Mobile Monitoring System. If system communication stops, monitor patients at the ViSi Mobile Monitors.

Perform a risk assessment and verification before implementing a change or modification to the IT infrastructure. Changes to IT network configurations can compromise continuous vital signs monitoring and alarm delivery.

Warnings

Vital Signs

If a vital signs measurement is questionable, retake the measurement. If the result is still questionable, use a different method of measurement.

ViSi Mobile arterial measurements have not been clinically tested in the presence of actual or ventricular arrhythmias. Use alternative BP methods if these arrythmias are present.

Chest Sensor Cable: ECG, Respiration, Temperature (Skin)

Use all of the same type of high quality ECG electrodes on the patient. Mixing ECG electrode types can adversely affect ECG monitoring.

Avoid placing the ViSi Mobile Cable Securements and ECG electrodes over areas of abrasions, irritation, or other sensitive areas. If possible, remove, reposition, and replace ECG electrodes and Cable Securements if the patient complains of pain/itching at the sites.

The ViSi Mobile Monitor does not provide automated arrhythmia analysis. As a result, certain arrhythmias may cause the Monitor to display variable heart rates. If frequent arrhythmias are suspected, their presence should be confirmed by visual observation of the ECG waveform or another method, such as a 12-lead ECG.

The ViSi Mobile Monitor does not have automated ST segment analysis, therefore, if a change in the ST segment of the ECG waveform is suspected, it should be confirmed by visual observation of the ECG waveform or another method, such as a 12-lead ECG.

Pacemaker signals can differ among pacemakers, ICDs, or CRT devices. The Association for the Advancement of Medical Instrumentation (AAMI) cautions: “In some devices, rate meters may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely upon rate meter alarms”. All pacemaker patients should be kept under close or constant observation.

External pacemakers or other external electrical stimulators may cause the ViSi Mobile Monitor to produce erroneous results.

RESP (chest wall motion) can continue in the absence of ventilation (obstructed airway). Do not rely on the RESP alone to determine adequacy of ventilation. Other vital signs, such as HR and SpO_2, should be assessed as well.

TEMP monitoring with the ViSi Mobile Monitoring System is intended for trending purposes only and is not intended to replace core temperature monitoring. Before making clinical decisions based on the skin temperature measurement, verify the measurement using another clinically acceptable method of core temperature measurement.

Warnings 

Impedance pneumography for the determination of respiration (RESP) is not recommended for use in the presence of mechanically induced, high frequency ventilation.

Cuff Module / NIBP

ViSi Mobile Disposable Cuffs are for single patient use only. To avoid possible cross contamination, do not reuse a Cuff on a patient other than the original patient.

The ViSi Mobile Disposable Cuff should be snug enough to support the Cuff Module while not impairing circulation when deflated.

Avoid applying the ViSi Mobile Disposable Cuff over a wound as this can cause further injury.

Avoid applying the ViSi Mobile Disposable Cuff on any limb where intravascular access or therapy, or an arterio-venous (A-V) shunt, is present because of temporary interference to blood flow which could result in injury to the patient.

Take care in the application of the ViSi Mobile Disposable Cuff when applying the Cuff to an arm on the same side of a mastectomy. Recommend using the ViSi Mobile Monitoring System on the opposite arm.

ViSi Mobile NIBP measurements have not been clinically tested in the presence of actual or ventricular arrhythmias. Use alternative BP methods if these arrythmias are present.

Inflate the ViSi Mobile Disposable Cuff only after proper application to the patient's limb.

If you are uncertain of the reliability of an NIBP measurement, repeat the measurement. If the reading is still suspect, use another method to measure the blood pressure.

SpO_2

Oxygen saturation measurements using SpO_2 are dependent on proper sensor placement, exposure to ambient light conditions, and general patient conditions. Before making clinical decisions based on SpO_2 measurements, verify the measurement using another clinically acceptable method, such as arterial blood gas analysis.

High ambient light condition, including direct sunlight, may interfere with the performance of the ViSi Mobile Thumb Sensor.

Low perfusion, electrosurgical devices, dysfunctional haemoglobin, the presence of certain dyes and inappropriate positioning of the ViSi Mobile Thumb Sensor may result in erroneous measurements.

Warnings 

Alarms / Alerts

When alarms are paused, there is no notification of a potentially clinically significant change in the patient's vital signs. Observe the patient by other means when alarms are paused.

When alarms are turned OFF, there is no notification of a potentially clinically significant change in the patient's vital signs. Observe the patient by other means when alarm limits are set to OFF.

Once Auto Set is selected (on the ViSi Mobile Monitor), review the newly calculated alarm limits carefully before deciding to confirm or cancel the new alarm limits. Once new alarm limits are confirmed on the ViSi Mobile Monitor, they cannot be changed back to the original pre-set limits from the ViSi Mobile Monitor. Use the ViSi Mobile Remote Viewing Device to change the alarm limits back to the original pre-set limits.

When the ViSi Mobile Monitor is not connected or loses wireless connection to the ViSi Mobile Appliance, the ViSi Mobile Remote Viewer does not receive patient alarms or alerts from the ViSi Mobile Monitor.

When the last source of monitoring is lost due to equipment (such as thumb sensor off, ECG leads off, all sensors disconnected) the visual annunciation of the alert will not have an audible component.

Line isolation monitor transients may resemble actual cardiac waveforms and inhibit heart rate alarms. Ensure correct electrode placement and cable arrangement to minimize line isolation monitor transients.

To avoid possible hearing damage, do not place your ear too close to the ViSi Mobile Monitor that is alarming audibly.

When the ViSi Mobile Monitor alarms or alerts, check the patient first to confirm that there is no immediate danger to the patient.

When testing the speaker at the ViSi Mobile Remote Viewer, if the tone does not sound or it is not loud enough check the speaker volume is turned up. If the sound is still not sound loud enough, immediately contact a biomedical engineer. The test indicates how alarm and alert tones sound at the Remote Viewer. If the volume is inadequate, clinicians could miss alarms and alerts.

User Maintenance

To avoid contaminating or infecting personnel, the environment or other equipment, make sure to disinfect and decontaminate the ViSi Mobile Monitoring System components appropriately before disposing of them in accordance with your country’s laws for equipment containing electrical and electronic parts.

Warnings 

Wireless Communications

When the ViSi Mobile Monitor is not configured to connect to the facility's network or loses wireless connection to the ViSi Mobile Appliance, the ViSi Mobile Remote Viewer does not receive patient alarms or alerts from the ViSi Mobile Monitor.

If you have any concerns regarding a cyber security breach or vulnerability, contact Sotera Wireless or an authorized Sotera Wireless representative in your area.

Off-The-Shelf (OTS) Software

The use of any software other than those specified in this manual will violate the safety, effectiveness and design controls of this medical device and such use may result in an increased risk to users and patients. Customer installed virus protection software will be permitted on the ViSi Mobile Remote Viewer but not permitted on the ViSi Mobile Appliance.

2.3 Cautions 

Intended Use

Federal (U.S.A.) law restricts the ViSi Mobile Monitoring System to the sale, distribution, or use by, or on the order of a licensed medical practitioner.

The effectiveness of the ViSi Mobile Monitoring System's blood pressure monitoring has not been established in pregnant, including pre-eclamptic, patients.

General

When the application is shutdown, remote monitoring will not be available.

Placing the ViSi Mobile Monitor into the Charger when the "All Sensors Disconnected" alert is displayed will result in the patient's monitoring session being stopped. It is recommended that you follow the correct stop/pause monitoring flows.

When monitoring has been paused, monitoring may only be resumed using the same ViSi Mobile Monitor. If you place the ViSi Mobile Monitor into the Charger with other Monitors, label the Monitor so that is can be identified when monitoring is to be resumed.

Moving the ViSi Mobile Monitor out of the network range will break the radio link, immediately stopping communication of patient vital signs data to the ViSi Mobile Remote Viewer.

When the wireless connector symbol is yellow, the ViSi Mobile Monitor is unable to connect to the ViSi Mobile Remote Viewer (via the ViSi Mobile Appliance).

Safety

The ViSi Mobile Monitoring System has not been tested in the presence of flammable anesthetics or other flammable agents in combination with air, nitrous oxide, or oxygen-enriched environments.

Do not use a ViSi Mobile Monitor, its components, or accessories that appear damaged. Inspect all reusable components for damage before each use.

Do not attempt to connect any patient worn component, ViSi Chest Sensor Cable or ViSi Mobile Cuff Module to an electrical outlet of any kind.

A component that has been dropped or severely abused should be checked by qualified service personnel before use on a patient.

The ViSi Mobile Monitoring System is not intended for home use.

Do not use the ViSi Mobile Monitoring System to monitor a patient in a wet environment, such as a shower.

Cautions 

Explosion Hazard. Do not use in the presence of a flammable anesthetic mixture with air, or with oxygen or nitrous oxide.

Use care when using automatic cuff inflation for prolonged periods on unconscious or semi-conscious patients since the patient may not be able to alert the clinician to any pain he/she may be experiencing. Pressing the “Stop NIBP” button interrupts the NIBP measurement and deflates the cuff.

Consult your Biomed department or vendors for assistance in identifying EMC compliance status of other medical devices when using the ViSi Mobile Monitoring System.

Using accessories other than those specified may result in increased electromagnetic emission or decreased electromagnetic immunity of the monitoring equipment.

Changes in posture can affect ViSi cNIBP accuracy. Recalibrate ViSi cNIBP whenever torso changes by more than 30^{o} above supine position.

The accuracy of the cNIBP measurement cannot be relied upon in patients with a BMI greater than 35.

Due to cNIBP signal averaging, there is a time delay between the instantaneous blood pressure reading and the displayed reading.

You should manually recalibrate cNIBP after any drug administration. The Calibrate cNIBP alert will not be annunciated.

If using the ViSi Mobile Monitor with any other monitor on the same patient, check that each monitor does not interfere with the operation of the other. If interference is detected, remove one or more of the sensors until there is no longer any interference.

Service / Maintenance

If the ViSi Mobile Monitor detects an unrecoverable problem, an error message containing the error number is displayed. Remove the Monitor from use and report the error to Sotera Wireless, Inc.

When the ViSi Mobile Monitor is in the Charger and a charging alert occurs, remove the Monitor from service.

General maintenance of the ViSi Mobile Monitoring System should be conducted at the hospital defined intervals.

The ViSi Mobile Monitoring System components should only be serviced by Sotera Wireless, Inc. technicians or authorized service providers.

Cautions 

Equipment / Components

If the ViSi Mobile Monitor is to be stored for an extended period of time, it is recommended the Monitor be stored with the Shipping Plug inserted to reduce the battery discharge. The ViSi Mobile Monitor must always have the Shipping Plug inserted when shipped by a common carrier to comply with Federal Regulations regarding electromagnetic emissions.

When inserting the ViSi Mobile Monitor into the Wrist Cradle, ensure proper alignment: flat end to flat end and the round end is pointing down towards the wrist.

Selection of the correct ViSi Mobile Disposable Cuff size is necessary to ensure accurate NIBP measurements. A Cuff that is too small can result in a falsely high NIBP measurement. A Cuff that is too large can result in a falsely low NIBP measurement.

Avoid touching the ViSi Mobile Disposable Cuff during cuff inflation as it may disrupt the measurement.

To avoid damage from dropping the ViSi Mobile Monitor, ensure that the Wrist Strap is snugly wrapped around the wrist.

To avoid damage from dropping the ViSi Mobile Monitor, make sure that the Monitor is securely snapped into the ViSi Mobile Wrist Cradle.

The performance of the automated sphygmomanometer may be affected by extremes of temperature, humidity and altitude.

The ViSi Mobile Monitor may not perform to specification if stored or shipped outside the specified temperature range.

The ViSi Mobile Monitor may be temporarily interrupted by UHF RFID Systems (860-960MHz).

Cleaning / Disinfecting

Do not clean the ViSi Mobile Monitor or the Cuff Module while it is plugged into the ViSi Mobile Charger.

Do not apply liquid to the ViSi Mobile Cuff Module. To clean, use a damp cloth.

Ensure the sensor connector contacts are thoroughly dried to prevent possible malfunction.

Thumb sensors which are saturated with liquid should be allowed to air dry thoroughly before re-use.

Do not use abrasive cleaning agents or organic solvents on any of the ViSi Mobile Monitoring System components.

Cautions 

Use only recommended cleaning / disinfecting agents to prevent damage to the device and components.

Do not autoclave the ViSi Mobile Monitor, its components, or accessories.

Do not use excessive amounts of liquid when cleaning the ViSi Mobile Chest Sensor Cable or the ViSi Mobile Thumb Sensor.

After patient use, the disposables from the ViSi Disposable Kit may contain bio-hazard materials.

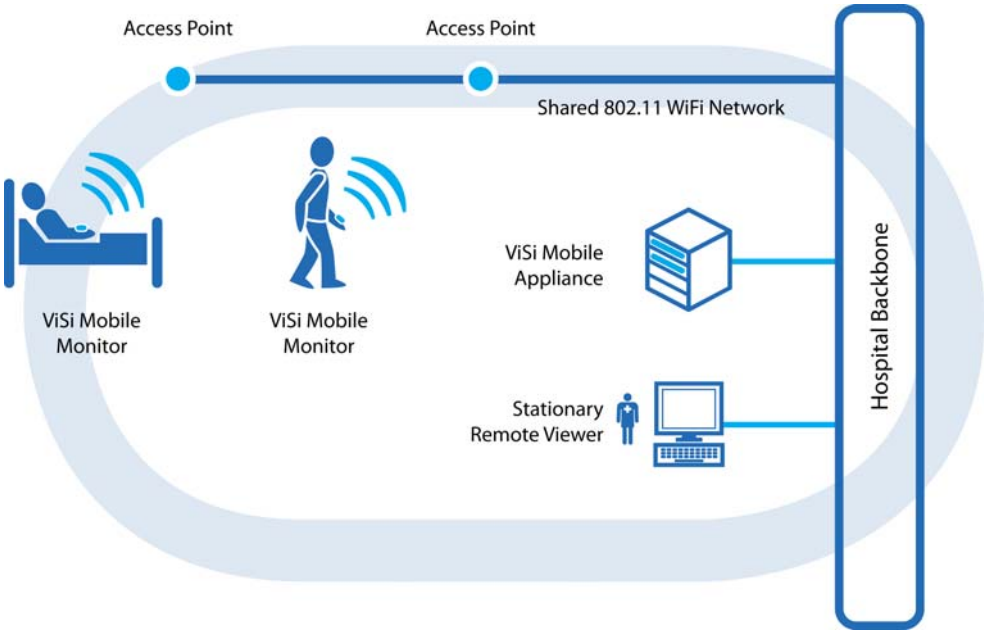
When the ViSi Mobile Cuff Module is connected to the other ViSi Mobile Components, the entire system has an ingress protection rating of IPX0.

2.4 Notes

Note: Figures in this manual are provided for reference purposes only. Screens may differ based on the monitoring device configuration, licenses available, parameters selected and patient configuration of the ViSi Mobile Monitoring System.

Note: All ViSi Mobile Monitoring System alarms and alerts annunciate with icons and colors that comply with IEC 60601-1-8.

3. Overview



ViSi Mobile Monitoring System

The ViSi Mobile Monitoring System enables clinicians to remotely monitor patients who are connected to ViSi Mobile Monitors. A system includes ViSi Mobile Monitors (*see 95-10134*), a ViSi Mobile Appliance and a ViSi Mobile Remote Viewer. Information flows wirelessly and bidirectionally between components.

After connecting a patient to a ViSi Mobile Monitor, the patient's information appears on the ViSi Mobile Remote Viewer. Once monitoring has been started, the following tasks may be accomplished remotely:

- View vital sign measurements, for the care unit and for individual patients
- Assign room and identification to patients
- Adjust vital sign alarm limits
- View ECG and other waveforms for individual patients
- Receive and acknowledge alarm and alert notifications

3.1 Areas on the ViSi Mobile Remote Viewer

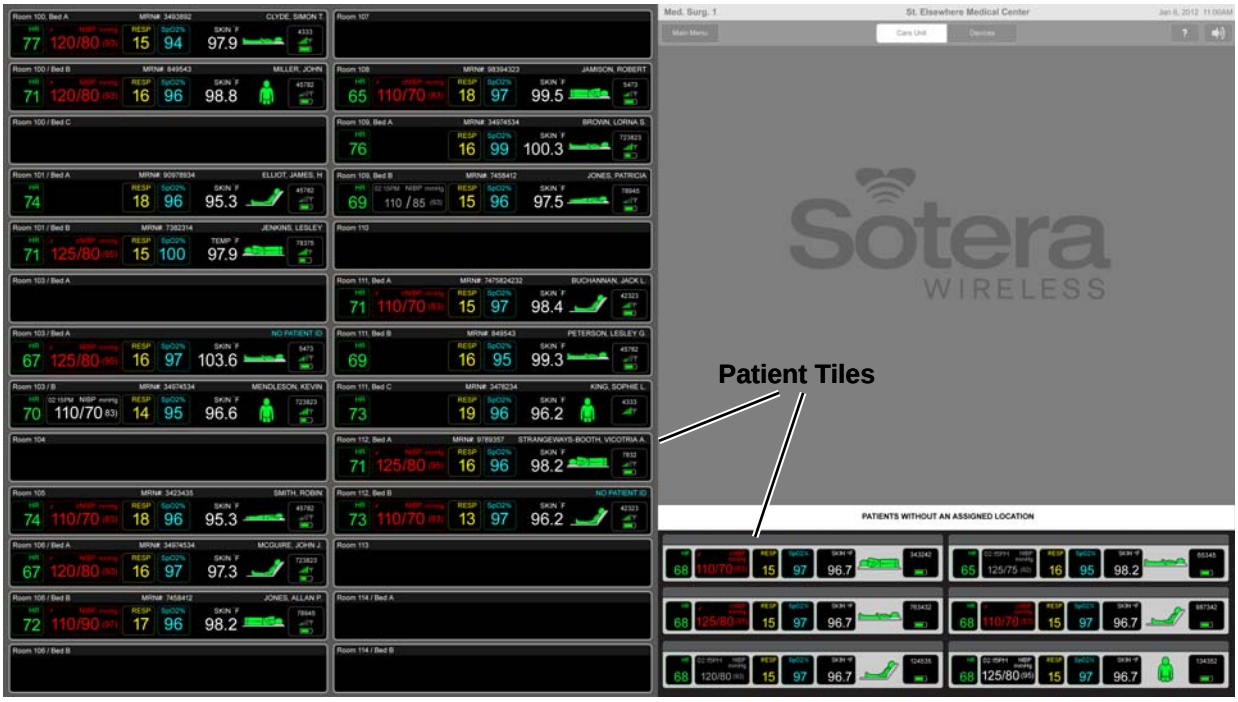
The ViSi Mobile Remote Viewer includes a Care Unit area and a Work Area.

3.1.1 Care Unit Area

The Care Unit Area always appears, displaying Patient Tiles for all actively monitored patients in the unit:

- The Assigned Location Zone shows patients with assigned rooms/beds.
- The Unassigned Location Zone shows patients without assigned rooms/beds.

Depending on your system configuration, the number and appearance of Patient Tiles on your ViSi Mobile Remote Viewer can vary.



Care Unit Area

3.1.2 Work Area

Views that open in the Work Area display further information about one patient.

Touching a Patient Tile selects the patient and their Patient Home View opens in the Work Area (*shown on page 28*). From the Patient Home View, touch or click tabs to navigate to other views for the selected patient.

In patient views, the following tasks may be performed:

- Edit patient information
- View and adjust alarm limits
- View more in-depth vital sign measurements, such as current waveforms
- Remove a patient from the care unit

To open patient views for a different patient, touch or click the patient's Patient Tile. To close all patient views and return to a blank Work Area, touch or click the currently selected Patient Tile.

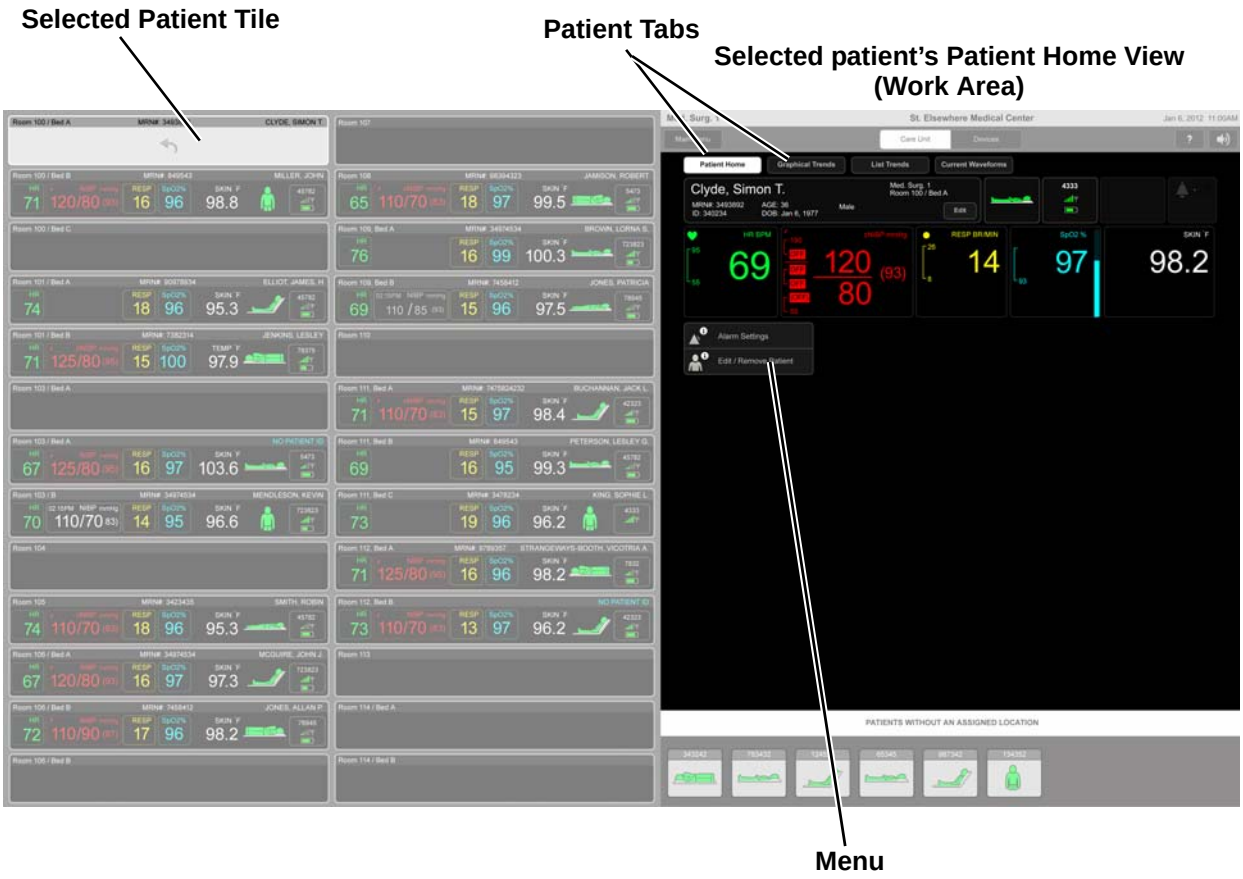
Patient Home View and Other Patient Views

When a Patient Tile in the Assigned Location Zone or Unassigned Location Zone is touched or clicked, the patient is selected and their Patient Home View opens in the Work Area.

When a patient has been selected, a set of Patient Tabs will be displayed at the top of the Work Area. These tabs enable navigation around the different patient views.

When the Patient Home menu is displayed. These menu items enables the following tasks:

- Adjust the patient's alarm limits
- Edit the patient's information
- Remove a patient from the care unit



3.2 Patient Tiles

Patient Tiles appear in the Care Unit Area and in the Work Area.

3.2.1 Care Unit Patient Tiles

Patient Tiles in the Assigned Location Zone

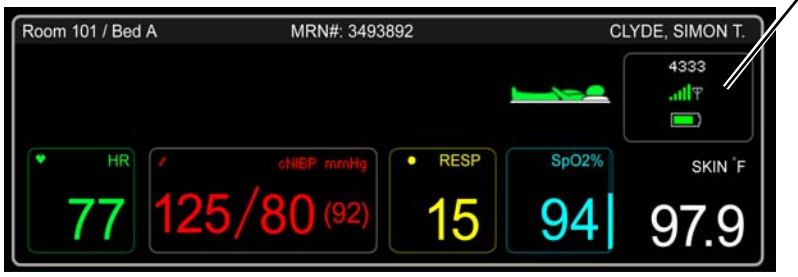
Patient Tiles in the Assigned Location Zone vary in size, depending on your care unit configuration.

Patient's Vital Sign Measurements

Patient Posture/Status (ViSi Man™) / Equipment Status

OR

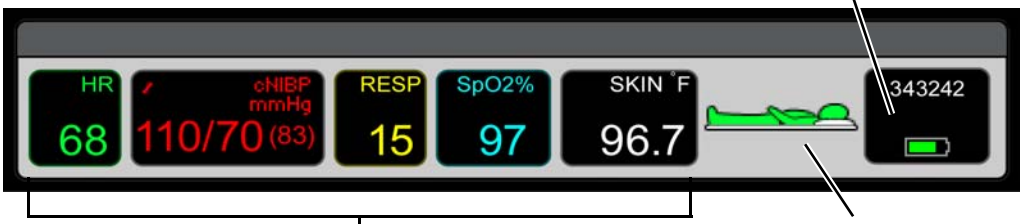
ViSi Mobile Monitor Status
- **Monitor Number**
- **Network Connection Strength**
- **Battery Status**



Patient Tiles in the Unassigned Location Zone

The Unassigned Location Zone of the Care Unit Area holds Patient Tiles for patients that have not been assigned a room/bed.

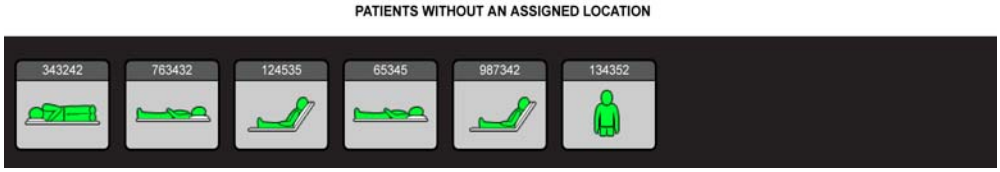
ViSi Mobile Monitor Status
- Monitor Number
- Network Connection Strength
- Battery Status



Patient's Vital Sign Measurements

Patient Posture/Status (ViSi Man™) / Equipment Status

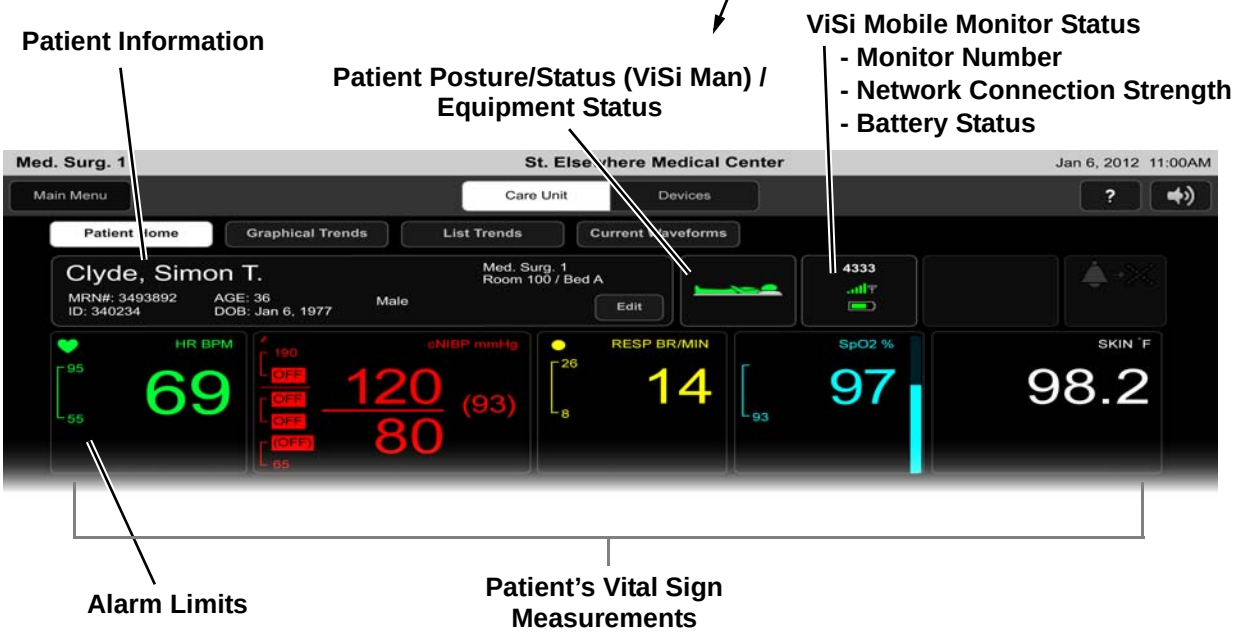
Note: When a patient has been selected from either the Assigned Patients or the Unassigned Patients Zones, the Unassigned Patients Zone will be condensed to provide enough room to display the selected patient's details.



3.2.2 Work Area Patient Tiles

Patient views in the Work Area include a Patient Tile similar to tiles in the Care Unit Area, but patient view tiles also show alarm limits and patient information.

Patient Tile in the Patient Home View



Patient Tiles in Other Patient Views

In other patient views, vital sign measurements appear on the right side of the view.

Vital sign measurements and alarm limits

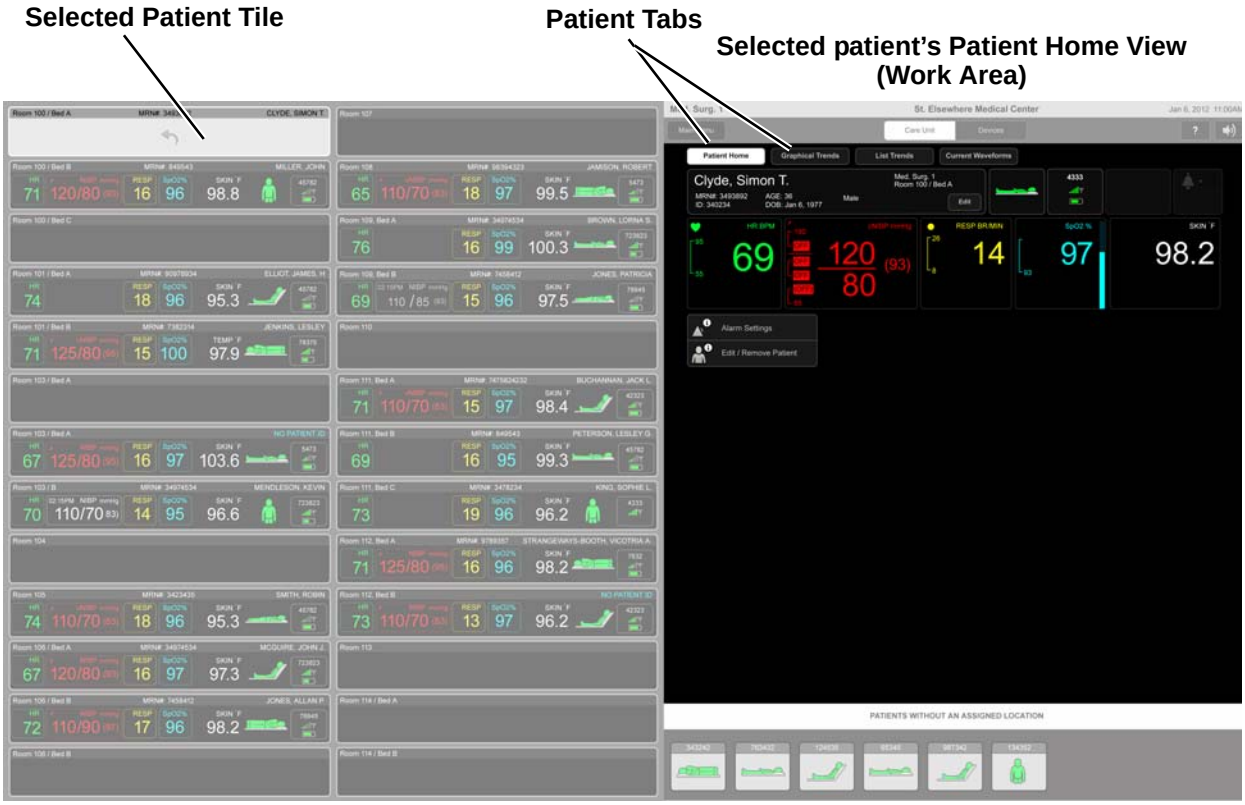
3.3 Navigating to a Patient Home View

Navigation to a patient's Patient Home View is permissible from any location.

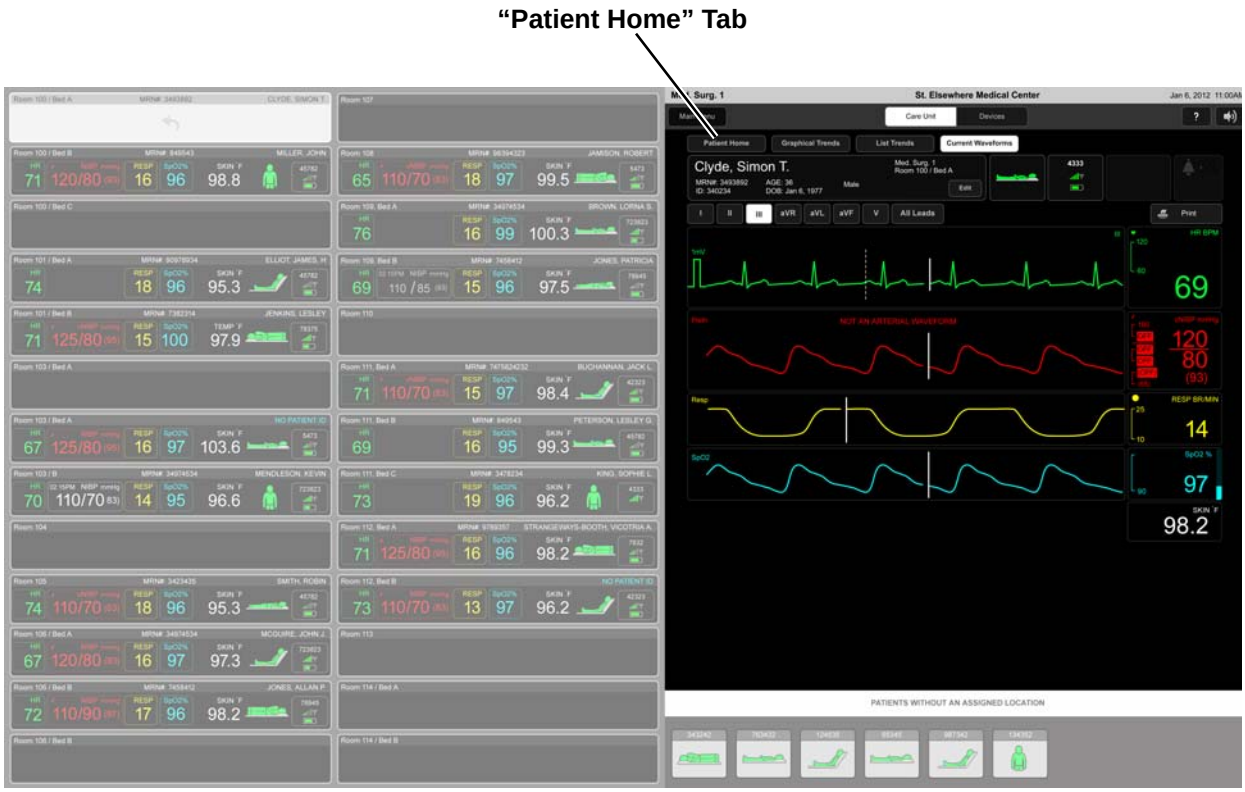
To navigate to a Patient Home View from the Care Unit Area

From anywhere in the Care Unit Area (Assigned Location Zone or Unassigned Location Zone), touch or click a **Patient Tile**.

The Patient Tile will display as "selected" and the patient's Home Page view will be displayed in the Work Area.



To navigate to the Patient Home View from another patient view



When the Work Area is already open for the desired patient, touch or click the **Patient Home Tab**.

The patient's Home Page view will be displayed in the Work Area.

3.4 System Help

The System Help View may be used to identify which software release is currently in use.

To access the system help

In the **System Toolbar**, touch or click the **System Help** button.

The System Help screen will be displayed in the Work Area.

3.5 Shutdown the Application

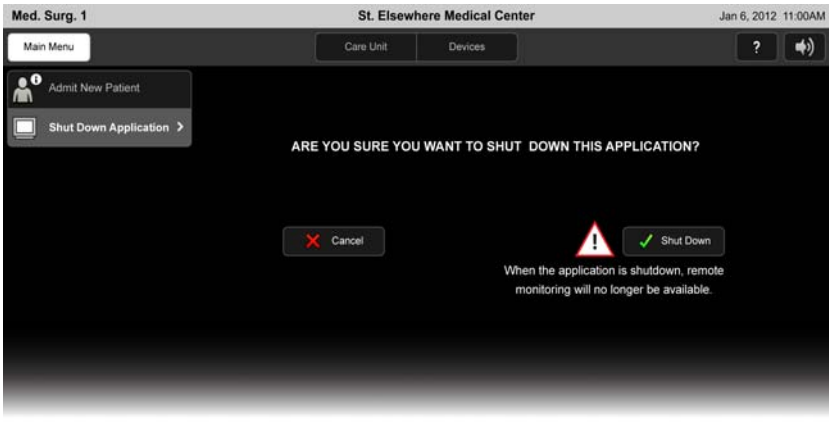
To shutdown the application

When the application is shutdown, remote monitoring will not be available.

1. In the **System Toolbar**, touch or click the **Main Menu** button.

   The main menu will be displayed in the Work Area.
2. Touch or click the **Shut Down Application** menu option.

   The clinician will be prompted to confirm they wish to shut down the application.



3. Touch **Shut Down** to shut down the application.

   The application will shut down.

   -or-

   Touch **Cancel** *to cancel the shut down request.*
   The Shut Down Application menu option will no longer be selected and the shut down request will be cancelled.

4. Wireless Monitoring

4.1 Wireless Monitoring with ViSi Mobile Remote Viewer

ViSi Mobile Monitors can operate either as standalone devices or in communication with the ViSi Mobile Remote Viewer through the ViSi Mobile Appliance. While the ViSi Mobile Monitor is connected to the network, patient data gathered by the monitor is continuously stored by the ViSi Mobile Appliance. This data is accessible from the ViSi Mobile Remote Viewer. Additional tasks may be performed remotely from the Remote Viewer:

- Review patient data (vital signs, alarm limits, etc)
- Edit the patient demographics data (name, date of birth, gender, etc)
- Assign a room/bed location

When the ViSi Mobile Monitor is not connected or loses wireless connection to the ViSi Mobile Appliance, the ViSi Mobile Remote Viewer does not receive patient alarms or alerts from the ViSi Mobile Monitor.

4.2 Communication with ViSi Mobile Remote Viewer

ViSi Mobile Monitor's wireless networking transmission methods are based on the 802.11b standard. This specification has the marketing name of Wi-Fi. Security is provided by the implementation of WPA2-PSK security protocols. For specifications pertaining to the wireless radio, *see section Wireless Communications / Radio on page 118*. The ViSi Mobile Monitor's wireless communications depends on your hospital's IT infrastructure for connectivity to the ViSi Mobile Appliance, where all data from the Monitors are aggregated, stored, and interfaced to external systems. For requirements, *see Section 11.3.7 ViSi Mobile Appliance on page 124*. A risk analysis summary for use by your hospital's IT department is provided in *Section 11.7 Wireless Network Risk Mitigation on page 140* to assist with ISO 80001-1 compliance. For additional information or assistance, please contact Sotera Wireless or an authorized Sotera Wireless representative in your area.

The ViSi Mobile Monitor automatically establishes connection whenever the monitor is within range of the network. Verify that the ViSi Mobile Monitor displays the following symbol (in green) to indicate the connection to the ViSi Mobile Remote Viewer has been established: 

When the wireless connector symbol is yellow, the ViSi Mobile Monitor is unable to connect to the ViSi Mobile Remote Viewer (via the ViSi Mobile Appliance).

For information on monitoring vital signs, refer to the ViSi Mobile Monitor User Manual, reference#: 95-10134 (USB).

4.3 Monitoring a patient outside of network range

While the ViSi Mobile Monitor typically continually communicates with the ViSi Mobile Appliance and ViSi Mobile Remote Viewer, occasionally communication may be lost during ambulation or transport outside the wireless coverage area. When the ViSi Mobile Monitor goes outside of the network range, monitoring continues locally. The ViSi Mobile Monitor provides local Respiration, NIBP, HR/PR and SpO2 alarms and alerts. When this happens an alert occurs at the ViSi Mobile Remote Viewer with the message “CONNECTIVITY LOST”.

When the monitored patient is again within range of the network, the ViSi Mobile Monitor automatically reconnects to the network and wireless monitoring resumes. Be aware that it can take a few minutes to restore communication with the network and resume the communication of patient vital signs data.

Moving the ViSi Mobile Monitor out of the network range will break the radio link, immediately stopping communication of patient vital signs data to the ViSi Mobile Remote Viewer.

- Notes -

5. Setting Up Monitoring

5.1 Admit New Patient

A new patient may be admitted to the ViSi Mobile Monitor / Remote Viewer before monitoring has been started.

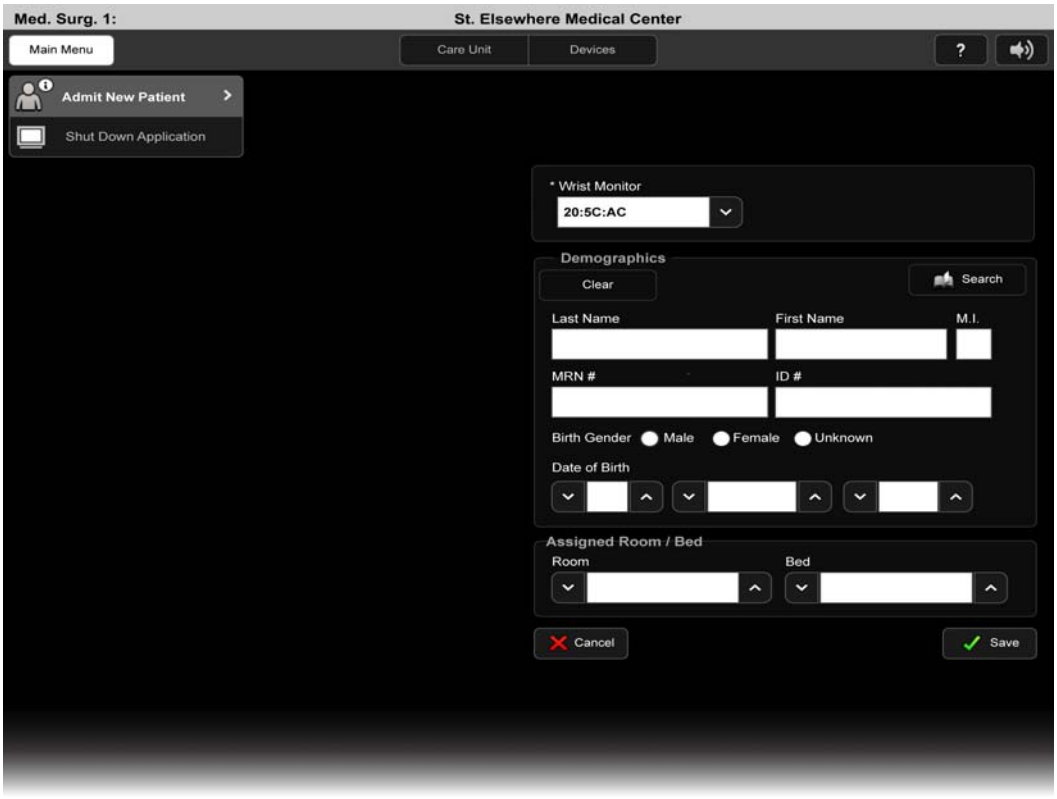
To admit a new patient

1. In the **System Toolbar**, touch or click the **Main Menu** button.

   The main menu will be displayed in the Work Area.

2. Touch or click the **Admit New Patient** menu option.

   The Admit New Patient pane will be displayed in the Work Area. From the Admit New Patient pane, the patient's demographics and room/bed location may be assigned.



3. In the Admit New Patient pane, select the ViSi Mobile Monitor by its ID# and enter the patient's demographics.

   When the ViSi Mobile Monitor has been selected and at least one ID field (patient's name, MRN# or ID#) the Save button will be enabled.

Note: The ID# is located on the **Monitor Status** screen in the top row of the display.

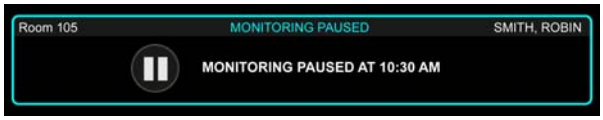
4. Touch or click **Save** to confirm the changes.

   -or-

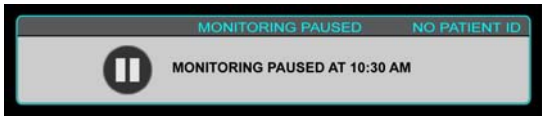
   Touch or click **Cancel**.

   If cancelled, no changes will be saved and the Admit New Patient pane will be closed.

   If saved, the Patient Tile will be displayed with the message "Monitoring Paused". If a room/bed was selected, the Patient Tile will be displayed in the Assigned Location Zone. If no room/bed was selected, the Patient Tile will be displayed in the Unassigned Location Zone. See 8.1 Pause Monitoring on page 85.



Patient Tile in Assigned Location Zone



Patient Tile in Unassigned Location Zone

5. Go to the bedside and place the ViSi Mobile Monitor on the patient, and apply sensors.

   The Patient Tile will automatically display the patient's vital signs.

5.2 Start Monitoring Before Admit

Monitoring of a patient may be started before the patient is admitted through the ViSi Mobile Remote Viewer. When a ViSi Mobile Monitor begins monitoring before the patient is admitted (through the Remote Viewer), the Remote Viewer shows the patient's active data in the Unassigned Location Zone of the Care Unit Area.

Note: Adjusting alarm limits is covered in section *Manage Alarm Limits on page 81*.

To start monitoring before admit

1. Place the ViSi Mobile Monitor on the patient, and apply sensors.

   A Patient Tile will automatically appear in the Unassigned Patients Zone.

Patient will appear in the Unassigned Location Zone

2. At the ViSi Mobile Remote Viewer, touch or click the patient's **Patient Tile** in the Unassigned Location Zone.

   The Patient Tile will display as "selected" and the patient's Home Page view will be displayed in the Work Area.

3. Navigate to the patient's Demographics pane and enter the demographic information (for instructions, *see Editing Patient Demographics on page 45*).

5.3 Editing Patient Demographics

The Demographics pane may be used to edit information for a patient being monitored by the ViSi Mobile Monitoring System.

To edit patient information

1. Navigate to the patient's Patient Home View (for instructions, *see Navigating to a Patient Home View on page 33*).

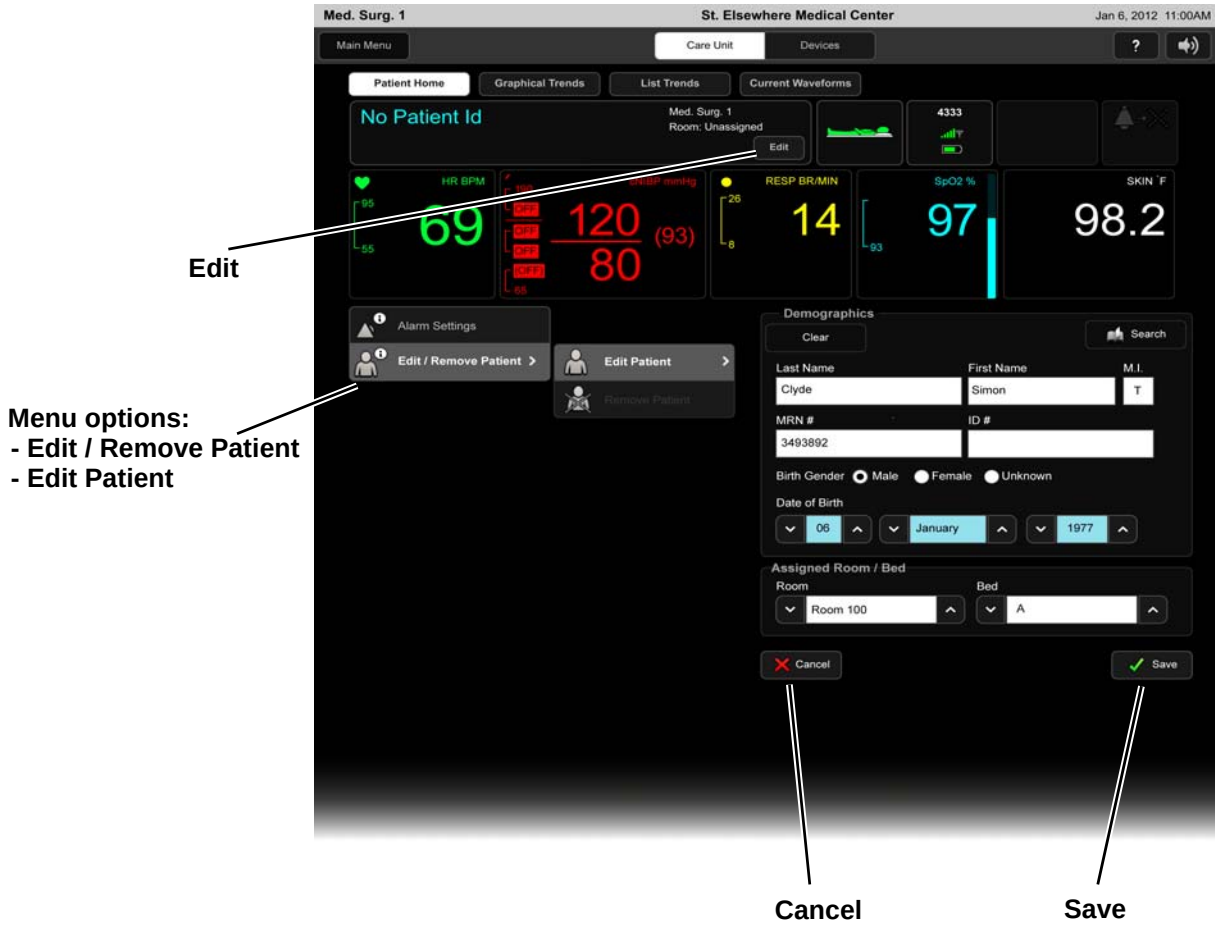
   The Patient Tile will display as selected and the patient's Home Page view will be displayed in the Work Area.

2. In the Patient Demographics Zone in the Patient Home View, touch or click **Edit**.

   -or-

   Touch or click the **Edit/Remove Patient** menu option followed by the **Edit Patient** menu option.

   The patient Demographics pane will be displayed in the Work Area. From the Demographics pane, the patient's demographics and assigned room/bed may be modified.



3. In the **Demographics pane**, add or change patient information.

   When any field within the Demographics pane has been modified, the Save button will be enabled.

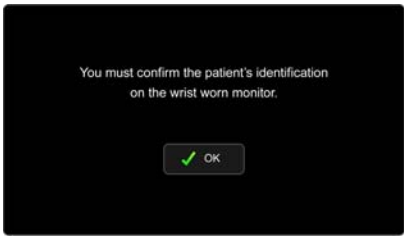
4. Touch or click **Save** to confirm the changes.

   -or -

   Touch or click **Cancel**.

   If cancelled, no changes will be saved and the Demographics pane will be closed.

   If saved and modifications were made to any of the patient's identification fields (Name, MRN# or alternative ID), a popup window will appear on the Remote Viewer with instructions on how to complete the patient confirmation process. Additionally, on the ViSi Mobile Monitor, the Confirm Patient ID screen will be displayed when navigating from the Patient View screen to the Vital Signs screen.



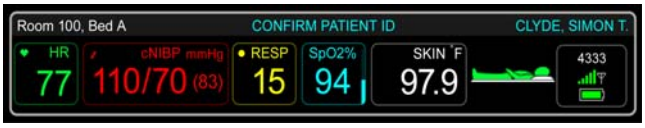
Instructions on the Remote Viewer

Confirmation on the Mobile Monitor

5. On the popup window, touch or click **OK**.

   The Patient Tile will display the patient's primary ID in blue as a reminder that the patient's ID must be confirmed at the patient's bedside (on the ViSi Mobile Monitor).

   If a room and bed were entered, the Patient Tile will move from the Unassigned Location Zone to the Assigned Location Zone.



6. Go to the bedside, wake up the ViSi Mobile Monitor, unlock the Monitor and confirm the patient's ID when prompted to do so.

   The patient's primary ID and secondary ID will be displayed in white text to indicate confirmation is complete.

Note: The patient's ID will continue to display in blue until the patient's ID is confirmed on the ViSi Mobile Monitor. There is no time limit in which you much confirm the patient's ID.

5.4 Designating Patient Locations

A new location for a patient may be designated in any of these ways:

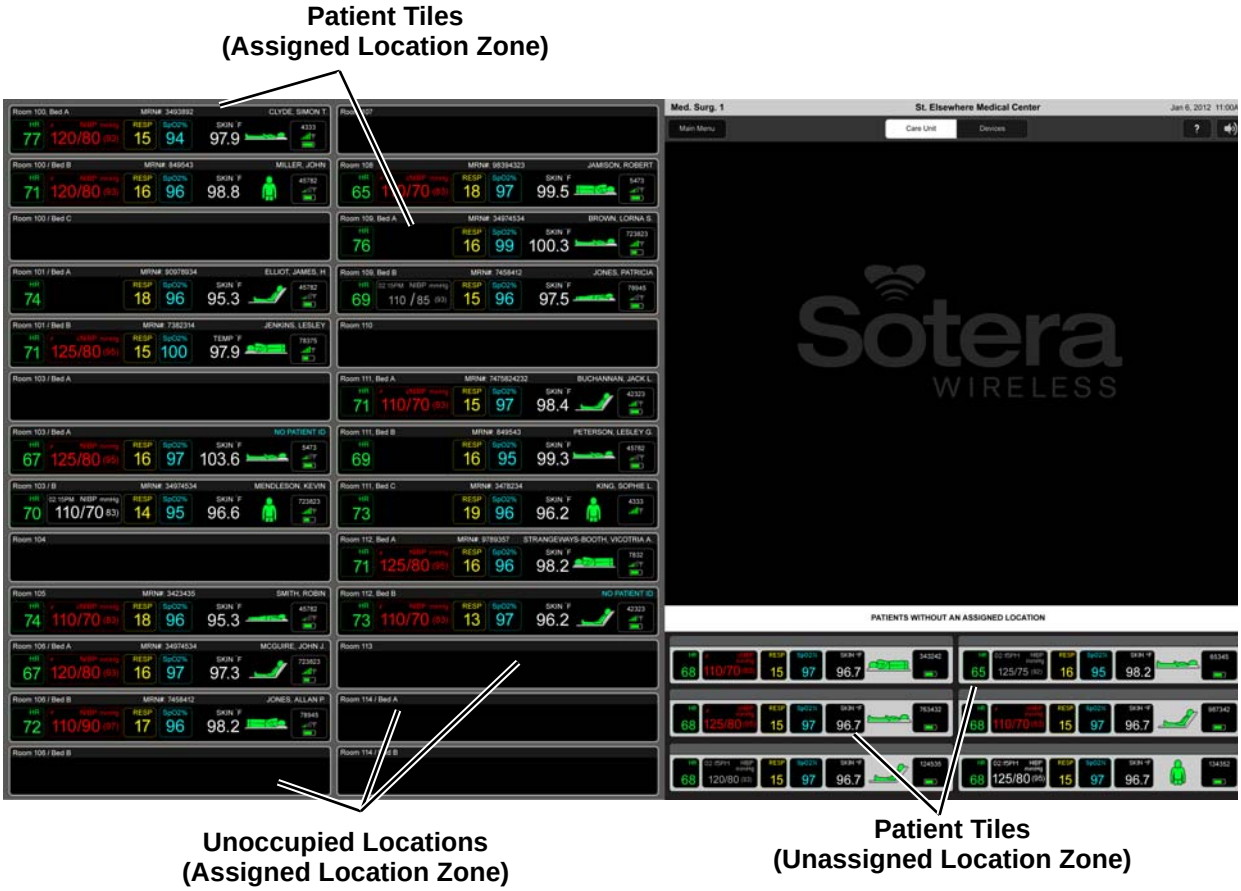
- Drag and drop the patient's Patient Tile to an unoccupied location in the Care Unit Area.
- Enter or change location information in the Demographics pane in the Patient Home View.

5.4.1 Dragging and Dropping to a New Location

Drag and drop a Patient Tile in the Care Unit Area to accomplish these tasks:

- Move a patient without a room/bed assignment to a room/bed
- Move a patient from one location to another location in your care unit
- Un-assign a patient's room/bed

To drag and drop a Patient Tile



While touching or clicking on the patient's Patient Tile, drag and drop the tile to an unoccupied location in the Care Unit Area.

The patient will be moved to the new location.

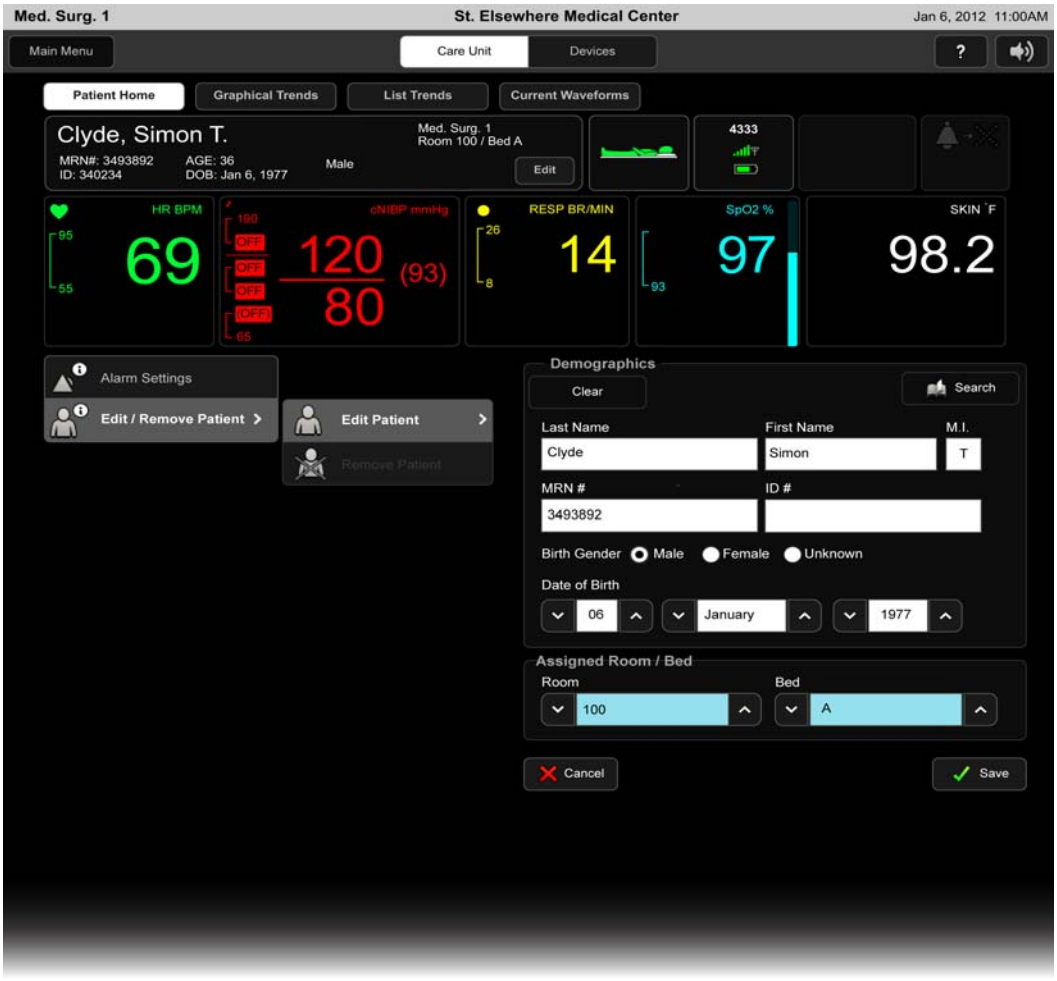
5.4.2 Entering Location Information

Enter a patient's location in the Demographics pane of the Patient Home View.

To enter location information

1. Navigate to the patient's Demographics pane (*for instructions, see section Editing Patient Demographics on page 45*).

   The patient Demographics pane will be displayed in the Work Area.



2. In the Assigned Room/Bed area of the Demographics pane, add or change location information.

   When any field within the Demographics pane has been modified, the Save button will be enabled.

3. Touch or click **Save** to complete the move to a new location.

   -or -

   Touch or click **Cancel**.

   If cancelled, the patient will remain in their original location.

   If saved the patient's Patient Tile will move to the newly selected location.

5.5 ADT Interface

When the ViSi Mobile System interfaces with the facilities ADT system, you will not be able to manually enter the patient's demographic data. You will need to select patients from the ADT system.

To Select Patients from ADT

1. Navigate to the patient's Patient Home View (for instructions, *see Navigating to a Patient Home View on page 33*).

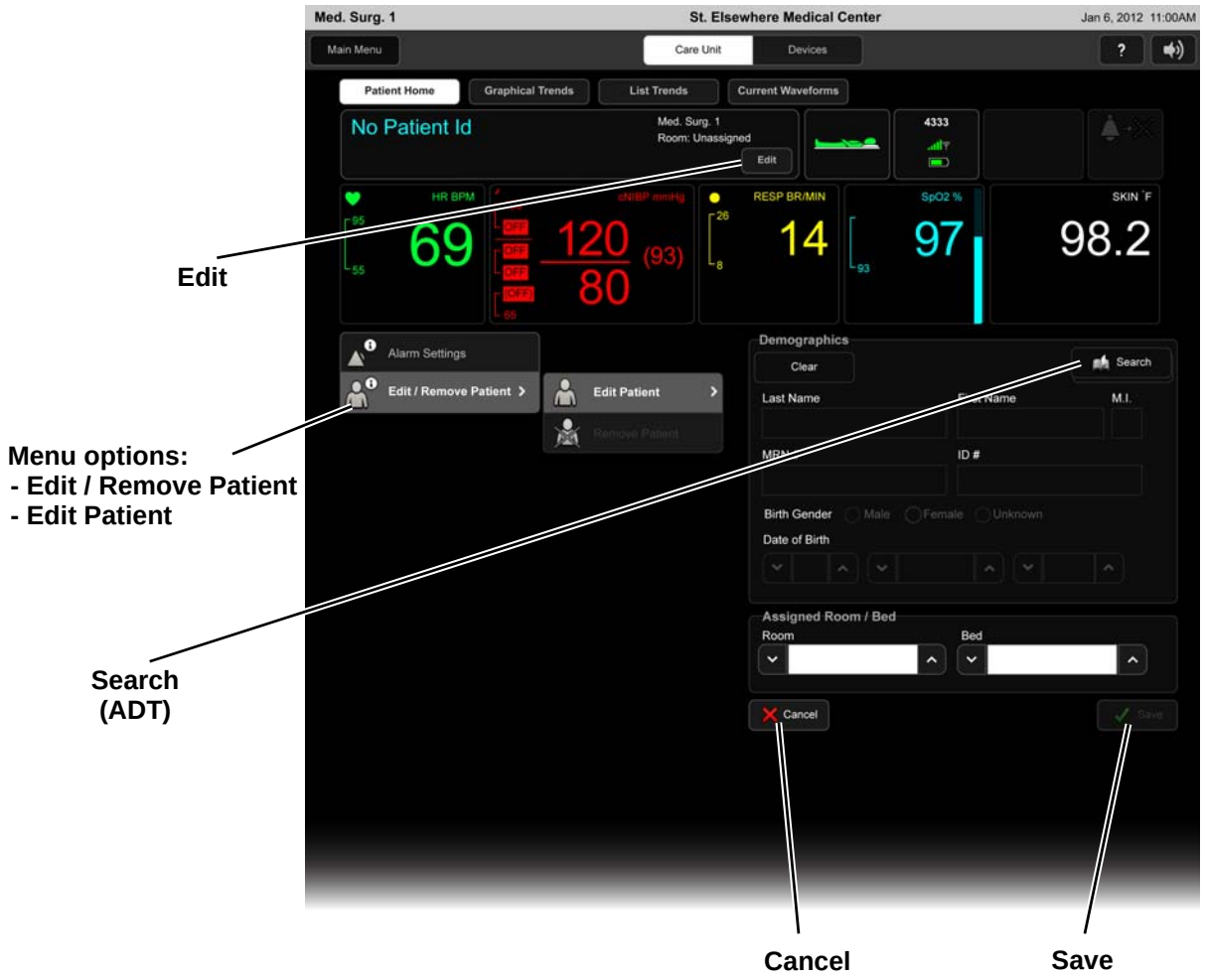
   The Patient Tile will display as selected and the patient's Home Page view will be displayed in the Work Area.

2. In the Patient Demographics Zone in the Patient Home View, touch or click **Edit**.

   -or-

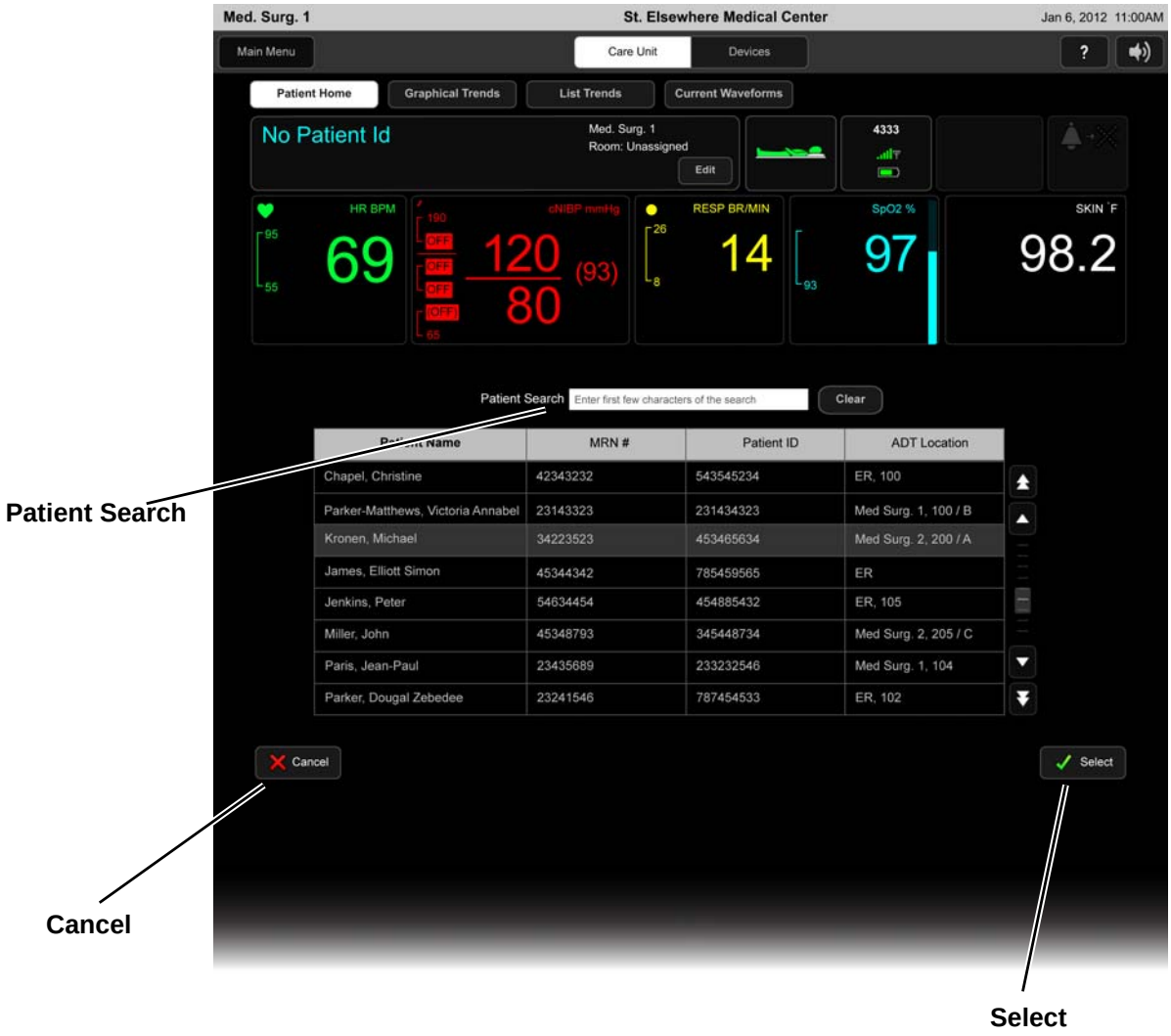
   Touch or click the **Edit/Remove Patient** menu option followed by the **Edit Patient** menu option.

   The patient Demographics pane will be displayed in the Work Area.



3. In the Demographics area of the Demographics pane, touch or click the **Search** button.

   The ADT Patient Search pane will be displayed.



4. In the ADT Search pane, enter the search criteria in the Patient Search field and then touch or click on the desired patient in the "Results" table.

   As data is typed into the "Patient Search" field, the "Results" table will automatically update with patients who match the entered search criteria.

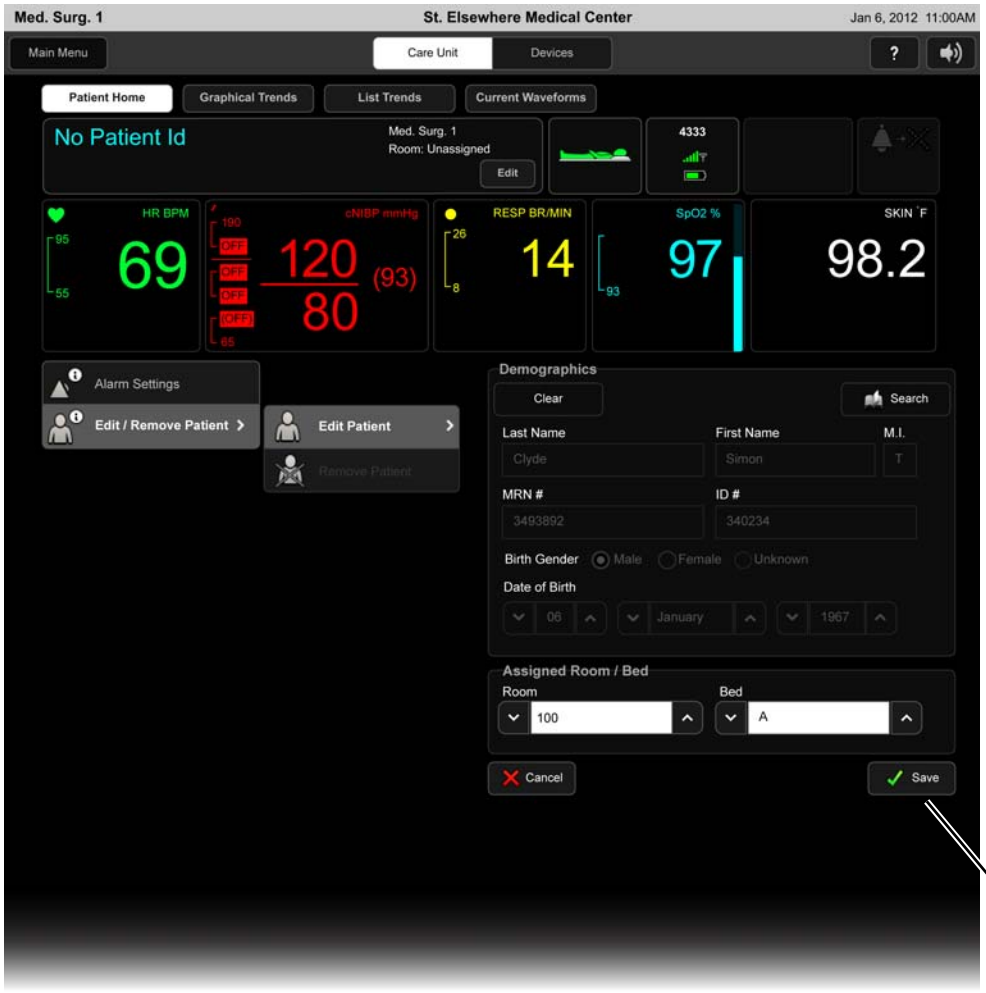
5. Touch or click **Select** to select the highlighted patient.

   -or-

   Touch or click the **Cancel** button.

   If cancelled, the selected patient will not be displayed in the Demographics area in the Demographics pane.

If selected, the patient will be displayed in the Demographics area in the Demographics pane.



Note: The selected patient is not saved until the Save button is clicked or touched on the Demographics pane.

6. Patient Monitoring

6.1 Viewing Vital Sign Measurements

Vital sign measurements may be viewed in Patient Tiles.

Vital Sign Measurements Displayed in the Care Unit Area

The Care Unit Area shows Patient Tiles for all patients being monitored by the care unit. Each Patient Tile shows the patient's vital sign measurements. The Care Unit Area is always visible on the ViSi Mobile Remote Viewer.

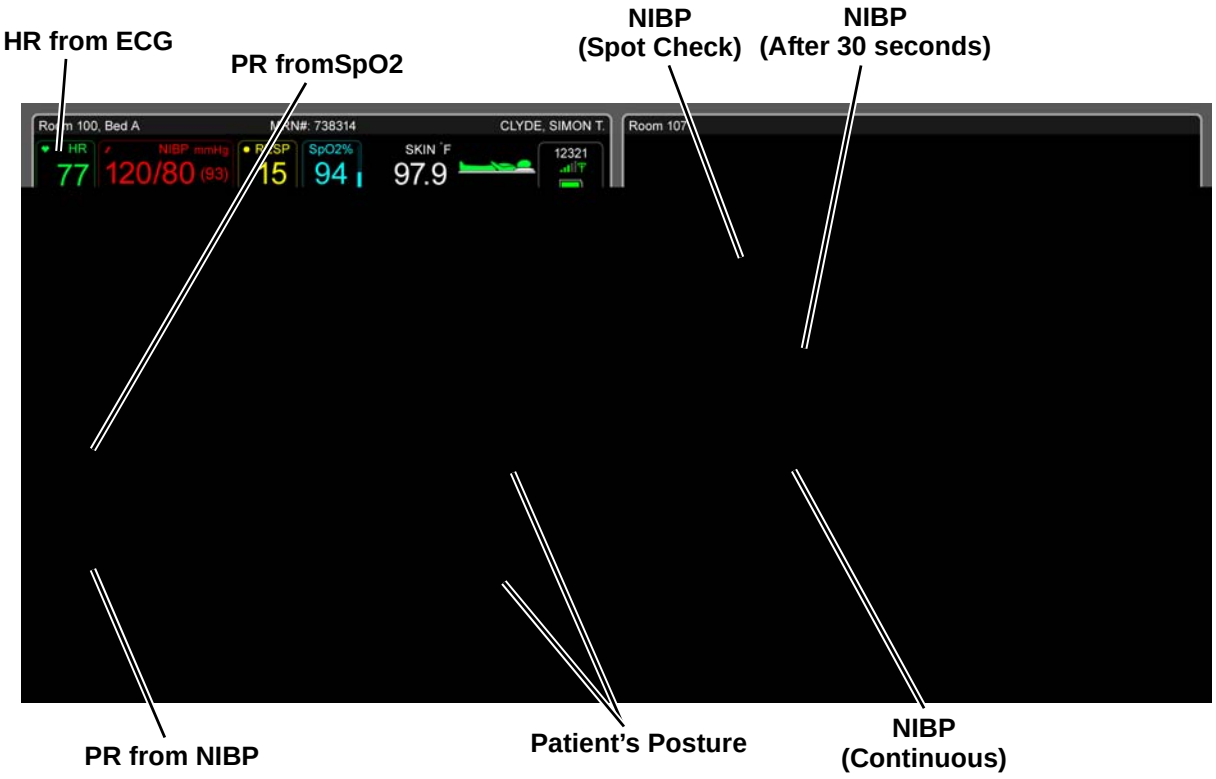
The HR/PR source is as follows:

- The HR source is from ECG (ViSi Mobile Chest Sensor Module)
- In the absence of an HR source from an ECG, the Pulse Rate (PR) can be measured and displayed from the SpO2 channel.
- In the absence of an HR source from an ECG and a PR from the SpO2 channel, PR can be measured and displayed from the NIBP reading.

NIBP measurements will fade to gray after 30 seconds. After 30 minutes, the measurements will no longer be displayed.

The patient's posture will only be displayed after the user has confirmed the patient's posture on the ViSi Mobile Monitor. Until the patient's posture has been confirmed, the unknown posture icon will be displayed.

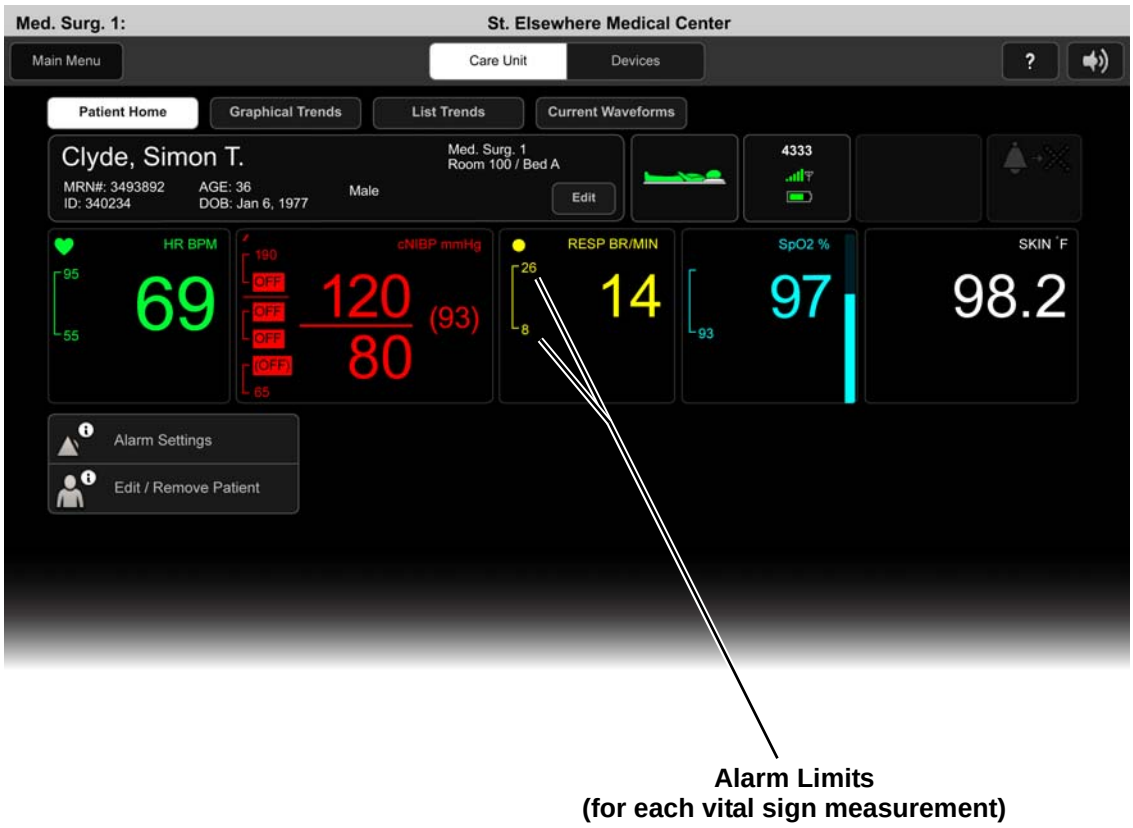
Note: The vital sign measurements (including the patient's posture) are refreshed every 3 seconds.


HR from ECG
PR fromSpO2
NIBP
(Spot Check)
NIBP
(After 30 seconds)
Room 100, Bed A
MRN#: 738314
CLYDE, SIMON T.
Room 107
HR
77
NIBP mmHg
120/80 (93)
RESP
15
SpO2%
94
SKIN °F
97.9
12321
PR from NIBP
Patient's Posture
NIBP
(Continuous)

To view one patient's measurements in a patient view

Navigate to the patient's Patient Home View (*for instructions, see Navigating to a Patient Home View on page 33*).

The patient's Home Page will be displayed in the Work Area.



Note: In the Work Area, only the vital sign measurements for the selected patient will be displayed.

6.2 Viewing Graphical Trends

Graphical Trends is a view of the patient's vital signs over time displayed in graphical format. There are trend lines for the five vital signs monitored by the ViSi Mobile Monitor: heart/pulse rate; NIBP; respiration rate; SpO2 and skin temperature. Additionally, there is a status bar that shows either the alarm status or a list of events (such as cuff inflation, demographic updates, etc).

When navigating to the Graphical Trends view from a non-historical view (such as the Patient Home view or the Current Waveforms view), the Graphical Trends view will display trends for the last hour and the **Time Cursor** will be located at t_{Now} - 30 minutes.

When navigating to the Graphical Trends view from a historical view (such as List Trends), the Graphical Trends view will display the previously selected time scale (if applicable) or the most appropriate time scale (if not previously selected). The **Time Cursor** will be located at the selected time line.

6.2.1 Viewing all Vital Sign Trends

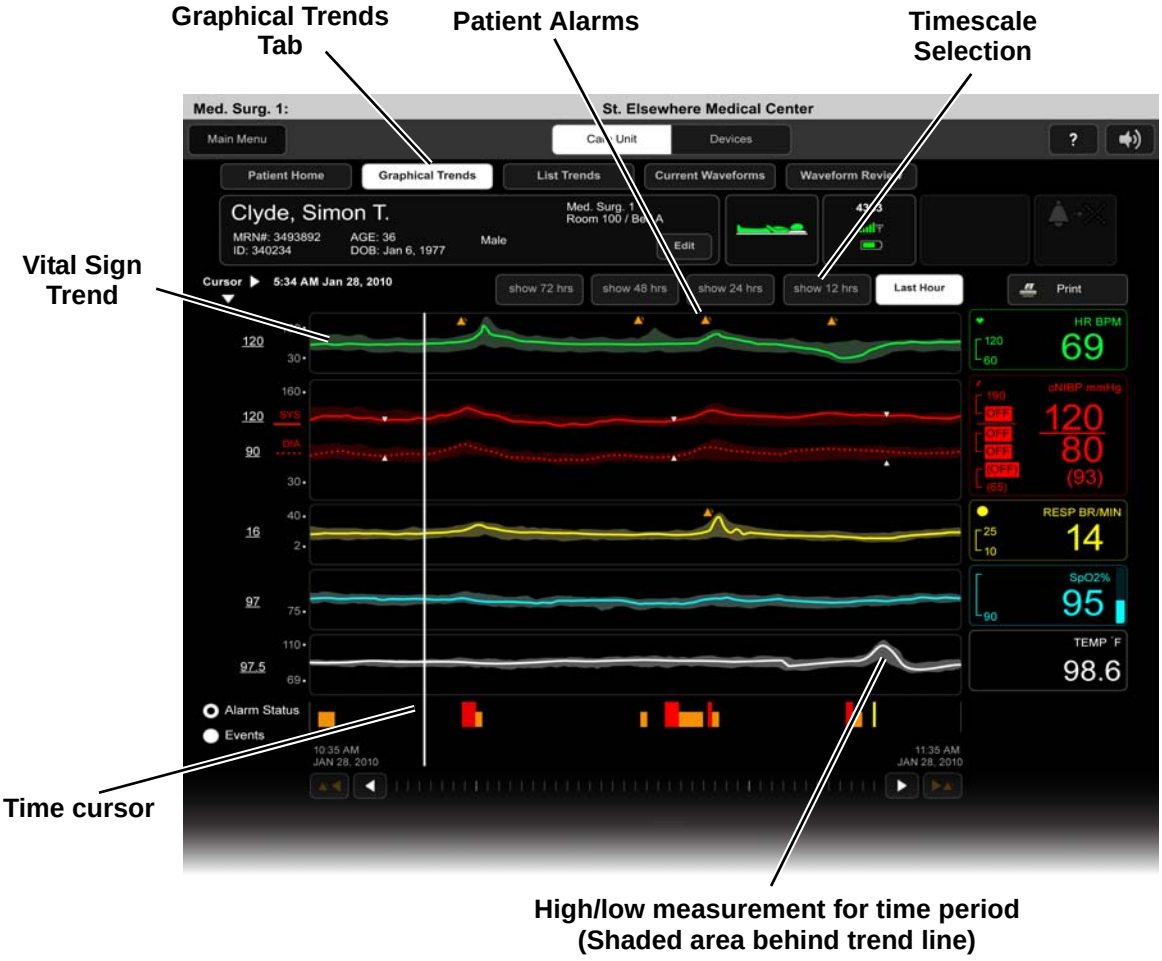
To view vital sign trends in graphical format

1. Navigate to the patient's Patient Home View (for instructions, *see Navigating to a Patient Home View on page 33*).

   The patient's Home Page will be displayed in the Work Area.

2. Touch or click the **Graphical Trends Tab**.

   The Graphical Trends View will be displayed in the Work Area.



Note: When monitoring is resumed after an interruption in monitoring (such monitoring paused, all sensors being disconnected), the graphical trends view will only display the trend data collected since the resumption of monitoring until the patient's identity has been confirmed on the ViSi Mobile Monitor.

6.2.2 Viewing a Single Vital Sign Trend

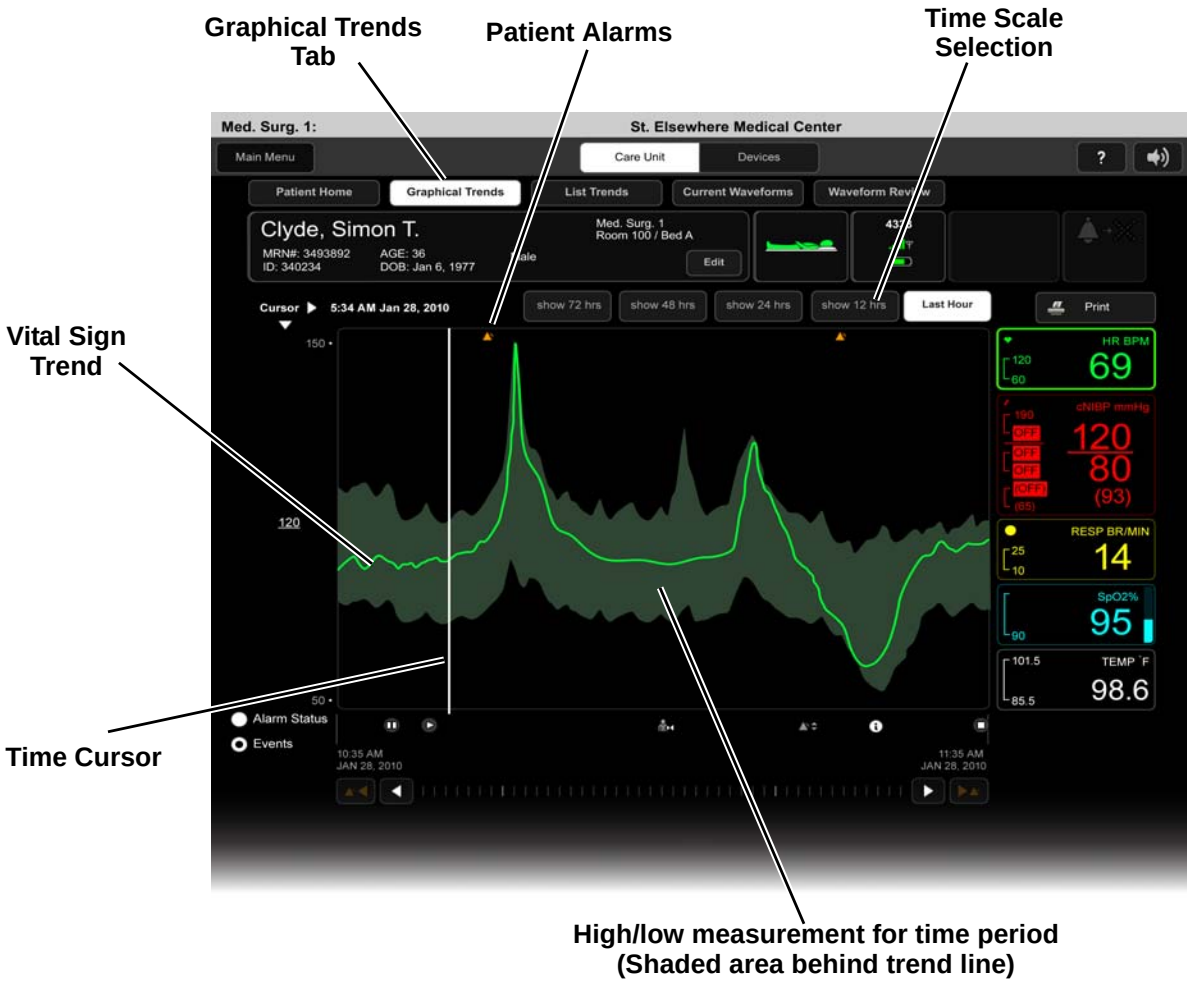
To view a single vital sign trend in graphical format

1. Navigate to the Graphical Trends view (*see above*).

   The Graphical Trends view will be displayed in the Work Area.

2. Touch or click the **Vital Sign box**.

   The Graphical Trends View showing the selected vital sign trend will be displayed in the Work Area.



6.2.3 Graphical Trend Features

Time scale Displays

Clicking on any of the time scale buttons will change the time scale display. There are 5 time scales available: last hour; 12 hours; 24 hours; 48 hours; and 72 hours.

When viewing the last hour time scale, the last hour will always end at t^{Now} (or at the time monitoring was stopped). The trend will automatically update every minute. The trend will not automatically update when viewing any other timescale.

Use the scroll bar to move the trend display either left or right of the current view. The scroll bar is not active when the last hour timescale is displayed.

Clicking on the next/previous alarm buttons will move the trend view to the next/previous alarm and place the **Time Cursor** on the alarm event. The next/previous alarm buttons will be disabled when there is no next/previous alarm.

Trend Line

Each dot (pixel) along the trend line will display the median vital sign measurement over the time period the dot (pixel) represents. The time period represented will change depending on the view currently selected. See table below.

Selected View	Time Period
Last Hour	30 seconds
12 Hours	12 minutes
24 Hours	24 minutes
48 Hours	48 minutes
72 Hours	72 minutes

Each NIBP measurement taken will be represented as follows:

- Systolic: Downward arrowhead
- Diastolic: Upward arrowhead
- MAP: White dot (expanded view only)

Behind each trend line, there is a shaded graph representing the minimum and maximum vital sign measurement during the time period the pixel represents. See *High/low measurement for time period* label in the diagram above.

The alarm limits for each vital sign are displayed as gray shaded blocks behind the trends lines.

Time Cursor

The date/time corresponding to the **Time Cursor** position will be displayed to the right of the "Cursor" label and the vital signs will be displayed to the left of the corresponding trend line.

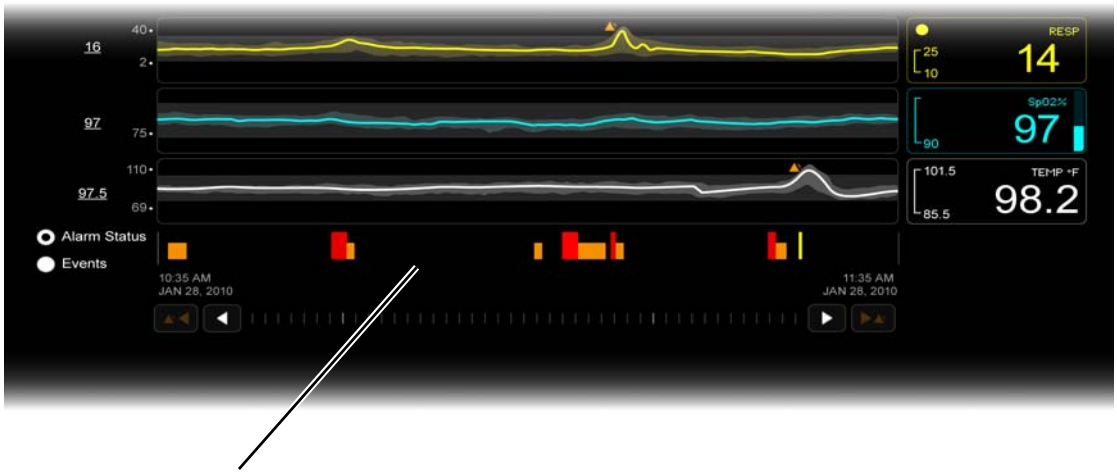
When the **Time Cursor** has been moved, the time selected will become the central point when switching to one of the other historical views, such as List Trends.

Grabbing and moving the **Time Cursor** will move it in the direction of the move; the trend display will remain static.

Patient Alarms

Alarm event markers will be displayed at the top of their corresponding trend box to indicate when the patient went into alarm. Double clicking on the alarm event marker will navigate to the List Trends view. Hovering the mouse over the event marker will display the details of the event: alarm type and date/time of occurrence.

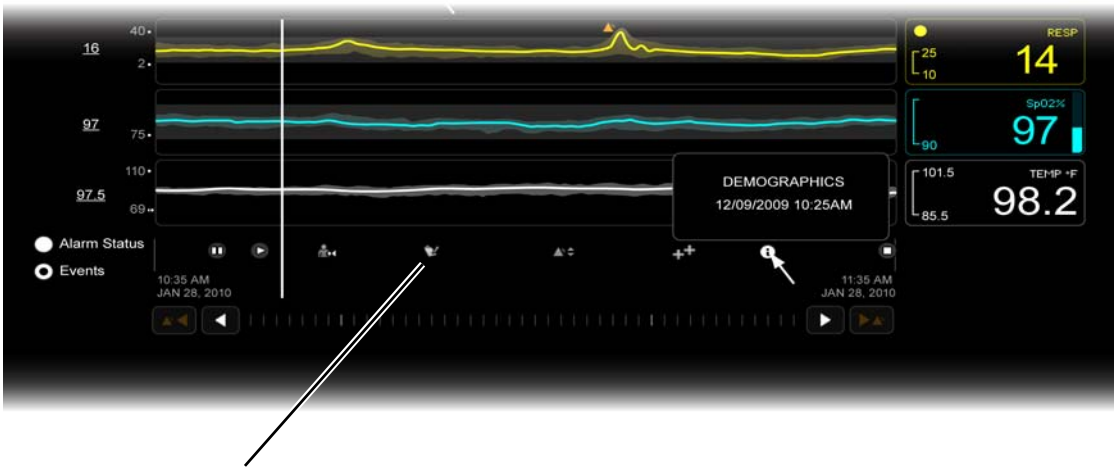
Alarm/Events Status Bar



Alarm/Events Status Bar

When the "Alarms Status" radio button is selected, the **Alarms/Events Status Bar** will display the alarm states:

- When no alarms have occurred and alarms are turned on for the duration of the time period for which the "Alarm Status" pixels represent, the pixels will be black.
- When a life-threatening or high severity alarm occurred during the time period for which the "Alarm Status" pixels represent, the pixels will be red.
- In the absence of any alarms, when the alarms are turned off or paused during the time period for which the "Alarm Status" pixels represent, the pixels will be orange.



Alarm/Events Status Bar

When the "Events" radio button is selected, the **Alarm/Events Status Bar** will display the patient events:

- Start NIBP cuff inflation
- Alarms changed
- Patient demographics changed
- Alarms paused / turned off / resumed
- Monitoring paused
- Monitoring stopped
- All sensors disconnected from the Monitor

Hovering the mouse over the event marker will display the details of the event: event name and date/time of occurrence.

When multiple event icons overlap, they will be replaced by the "multiple events" icon. Hovering over the "multiple events" icon will display a list of all events.

6.3 Viewing List Trends

List Trends is a view of the patient's vital signs over time displayed in tabular format. There are columns within the List Trends table for the five vital signs monitored by the ViSi Mobile Monitor: heart/pulse rate; NIBP; respiration rate; SpO2 and skin temperature. In addition to the vital sign measurements, the List Trends table will include events (such as cuff inflation, demographics updates, etc).

When navigating to the List Trends view from a non-historical view (such as the Patient Home view or the Current Waveforms view), the List Trends view will display trends and events at 30 minute intervals, synchronous to the clock.

When navigating to the List Trends view from a historical view (such as Graphical Trends), the List Trends view will display the previously selected time line in the middle of the trend table. The row associated with the selected time line will be highlighted.

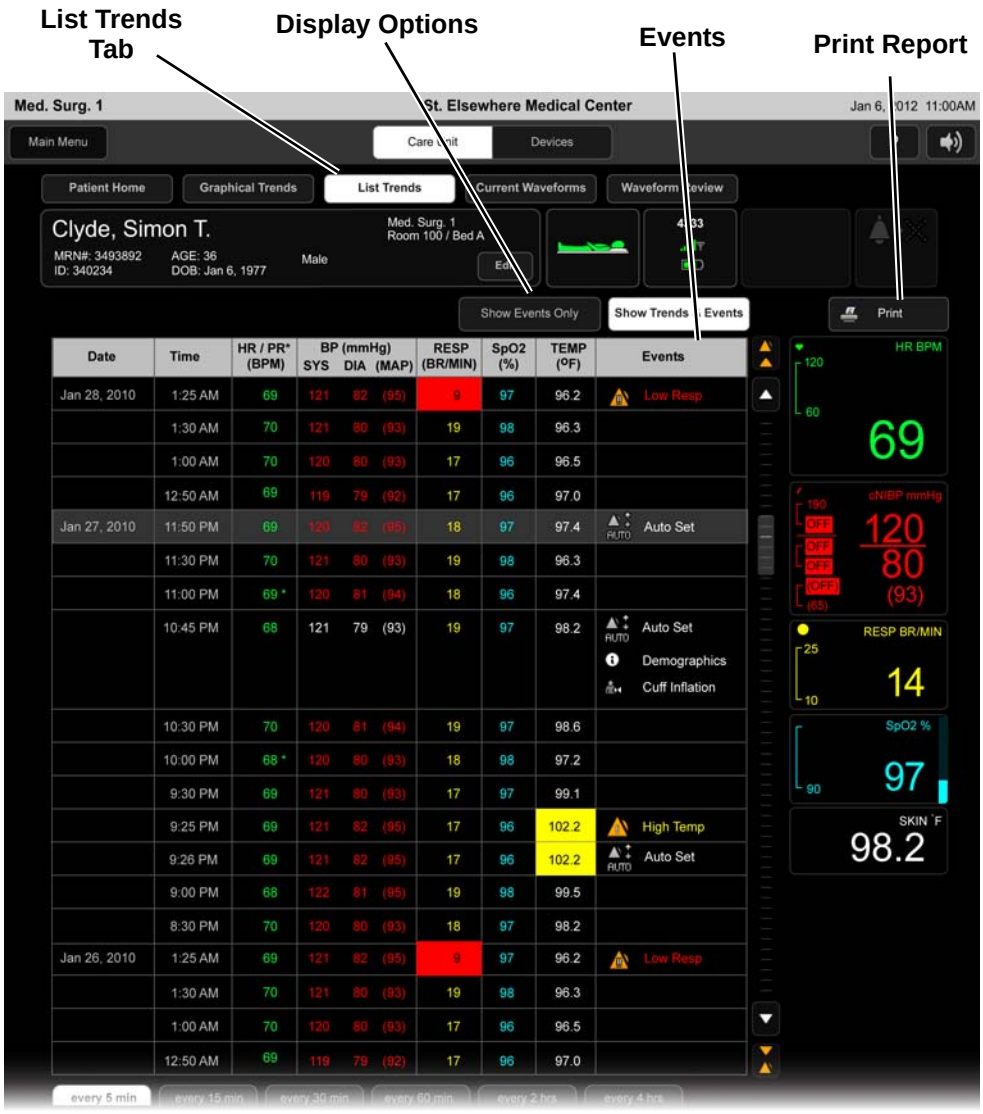
To view vital sign trends in tabular format

1. Navigate to the patient's Patient Home View (for instructions, *see Navigating to a Patient Home View on page 33*).

   The patient's Home Page will be displayed in the Work Area.

2. Touch or click the **List Trends Tab**.

   The List Trends View will be displayed in the Work Area.



Note: When monitoring is resumed after an interruption in monitoring (such monitoring paused, all sensors being disconnected), the list trends view will only display the trend data collected since the resumption of monitoring until the patient's identity has been confirmed on the ViSi Mobile Monitor.

6.3.1 List Trend Features

Trend Displays

There are three different trend displays:

- When “Show Events Only” is selected, the List Trends table will only display a row for each event occurrence.
- When “Show Trends & Events” is selected, the List Trends table will display a row of vital signs for each interval time period selected and a row for each event occurrence.

The following events will be displayed within the List Trends table when events are included:

- Start NIBP cuff inflation
- Alarms changed
- Patient demographics changed
- Alarms paused / turned off / resumed
- Monitoring paused
- Monitoring stopped
- All sensors disconnected from the Monitor

The data within the List Trends table may be displayed ascending or descending by date/time. To toggle between descending/ascending, click the column header for either the date and/or time.

When displaying trends within the List Trends table, the following intervals are available: 5 minutes; 15 minutes; 30 minutes; 60 minutes; 2 hours and 4 hours. Every 30 minutes is the default.

Navigation/Scrolling

Use the scroll bar or arrow keys, to scroll forward or backwards in time to view the trends/events.

Clicking an “alarm” arrow when the next/previous alarm is displayed in the current view, the selection bar will move to the next/previous alarm. When the next/previous alarm is not displayed in the current view, the list view will change such that the alarm event will be displayed in the middle row of the List Trend table.

6.4 Viewing Current Waveforms

Keep all pacemaker patients under close or constant observation. Pacemaker signals can differ among pacemakers, ICDs, or CRT devices. The Association for the Advancement of Medical Instrumentation (AAMI) cautions: “In some devices, rate meters may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely upon rate meter alarms”.

6.4.1 Viewing ECG Waveforms

A patient’s current ECG waveform (generated from one lead) may be viewed.

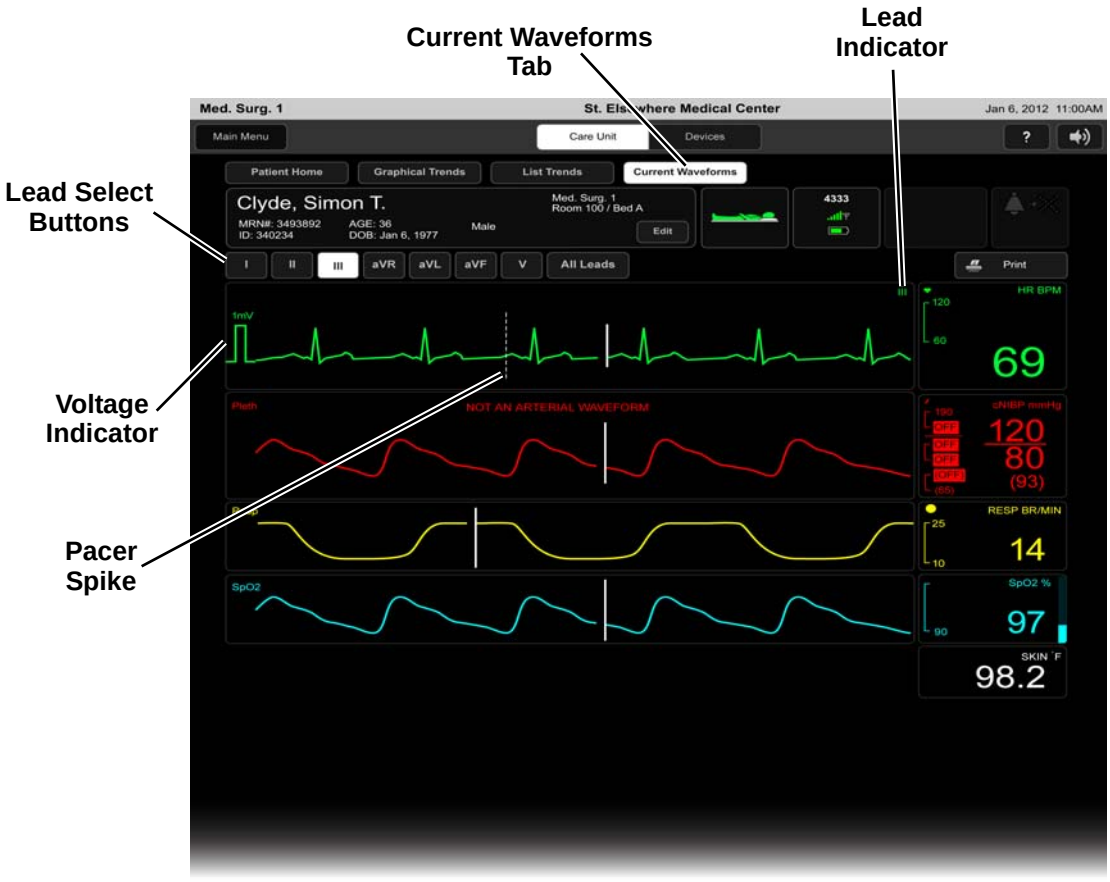
To view a patient’s current ECG waveform

1. Navigate to the patient’s Patient Home View (for instructions, *see Navigating to a Patient Home View on page 33*).

   The patient’s Home Page will be displayed in the Work Area.

2. Touch or click the **Current Waveforms Tab**.

   The Current Waveform View will be displayed in the Work Area.

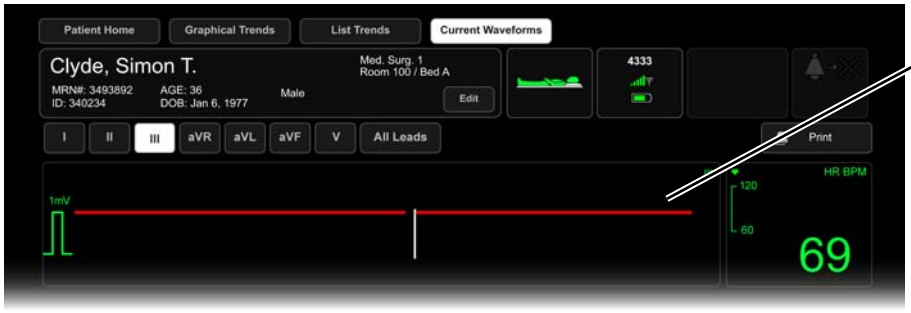


3. (Optional) If the patient is monitored with a 5 lead-wire Chest Sensor Cable:
   - Touch or click an alternative **Lead button** to view a waveform derived from a different ECG lead.

     The waveform corresponding to the selected lead button will be displayed.

Input Overload/Dynamic Range

The ViSi Mobile Monitor display indicates an input overload condition (i.e. the input dynamic range of the amplifier associated with the displayed ECG lead has been exceeded) by displaying the trace in red at the top (or bottom) of the ECG waveform display area.



Amplifier is over-loaded due to an input that exceeds the positive limit of the dynamic range on a continuous basis

Positive limit of the dynamic range is being exceeded only at the peaks of the QRS complex of the ECG waveform

Dynamic range of the ECG amplifier has not been exceeded. The peaks of the QRS complex of the ECG waveform extend beyond the upper edge of the display area.

Note: When an input overload / dynamic range issue occurs, check the lead fail status.

6.5 Patient Reports

Note: The use of a thermal printer is not recommended.

6.5.1 List Trends

To Print the List Trends Report

1. Navigate to the List Trends view (or instructions, *see Viewing List Trends on page 62*).

   The List Trends view will be displayed in the Work Area.

2. Touch or click the **Print** button.

   The list trends report will be printed.

Sotera WIRELESS

Trend Report
List Trends and Events

Page 1 of x

Clyde, Simon T. Male
MRN #: 389437589-ABC AGE: 36
ID: 3493489 DOB: Jan 6, 1977

Trend Period: 8 hours
Trend Interval: Every 5 minutes

Date	Time	HR / PR* (BPM)	BP (mmHg) SYS DIA	RESP (BR/MIN)	SpO2 (%)	SKIN (°F)	Event
Jan 28, 2010	9:35 AM	121	121 82 (95)	19	97	96.2	High Heart Rate (120)
	9:30 AM	123	121 80 (93)	19	98	96.3	High Heart Rate (120)
	9:25 AM	120	120 80 (93)	17	96	96.5	High Heart Rate (120)
	9:20 AM	69	119 79 (92)	17	96	97.0	
	9:15 AM	69	120 82 (95)	18	97	97.4	
	9:10 AM	70	121 80 (93)	19	98	96.3	
	9:05 PM	0	120 81 (94)	18	96	97.4	Critical Low HR
	9:00 PM	0	121 79 (93)	19	97	98.2	Critical Low HR
	8:55 PM						Monitoring Paused
	8:50 PM						Monitoring Paused
	8:45 PM	70	120 81 (94)	19	97	98.6	Patient Demographics
	8:40 PM	68 *	120 80 (93)	18	98	97.2	Cuff Inflation
	8:35 PM	69	121 80 (93)	17	97	99.1	Cuff Inflation
	8:30 PM	69	121 82 (95)	17	96	102.2	
	8:25 PM	69	121 82 (95)	17	96	102.2	
	8:20 PM	+++	122 81 (95)	19	98	99.5	High Heart Rate (120) Cuff Inflation
	8:15 PM	70	120 80 (93)	18	97	98.2	Cuff Inflation

Report generated by ViSi Mobile - Sotera Wireless, Inc

6.5.2 Waveforms

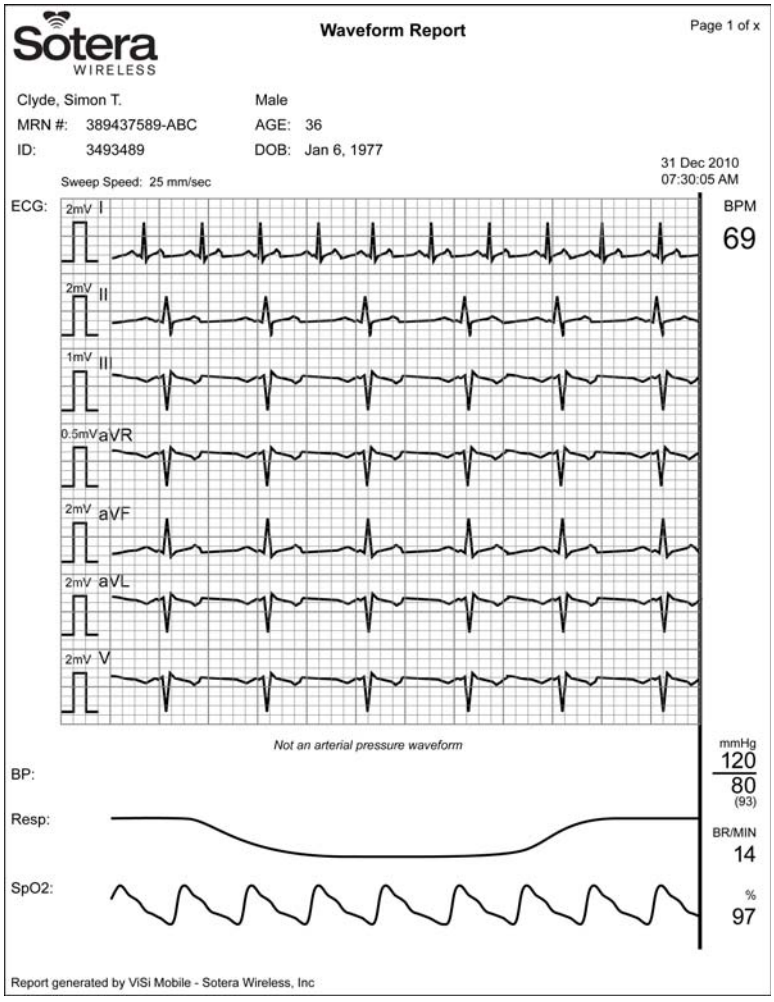
To Print the Waveform Report

1. Navigate to the Current Waveforms view (or instructions, *see Viewing Current Waveforms on page 65*).

   The Current Waveforms view will be displayed in the Work Area.

2. Touch or click the **Print** button.

   The waveforms report will be printed.



7. Alarms

7.1 Introduction

The ViSi Mobile Monitoring System provides a comprehensive alarm system that alarms on changes to the patient's physiologic status (alarms) and technical alarms (alerts).

The system provides default alarm limits for physiological alarms. The clinician can manually change the alarm limits for each patient to provide individualized care.

Note: Changes made to the alarm limits from the ViSi Mobile Remote Viewer do not come into effect until the ViSi Mobile Monitor has received the change request.

Technical alarms (alerts) are provided to notify the clinician of situations that may impede the ability to monitor your patient.

7.1.1 System Alarm Management

During the installation of the ViSi Mobile Monitoring System, alarm configurations may be modified to conform to the alarm policies set by the clinical care unit.

General Alarm Management Rules

The following general alarm management rules pertain to the ViSi Mobile Monitoring System:

- All ViSi Mobile Monitoring System alarms conform to IEC 60601-1-8.
- Alarms and alerts originate from the ViSi Mobile Monitor (worn by the patient).
- Silencing/acknowledging a patient's alarm or alert suspends the audio tones for up to 2 minutes. When a new alarm/alert occurs during the 2 minute silenced/acknowledged period, the new alarm/alert will be immediately annunciated.

Note: When the clinician silences/acknowledges an alarm/alert, all active alarms/alerts in progress will also be silenced/acknowledged for the 2 minutes. The clinician does not need to silence/acknowledge each alarm/alert individually.

- Alarm annunciation may be turned off for an indefinite period of time. This disables the annunciation of alarms and alerts on both the ViSi Mobile Monitor and the Remote Viewer for the "off" duration. *Turning the alarms off must be done directly from the ViSi Mobile Monitor (worn by the patient), however, alarms may be turned back on from either the ViSi Mobile Monitor or the Remote Viewer.*
- Alarm annunciation may be paused for 2 minutes. This disables the annunciation of alarms and alerts on both the ViSi Mobile Monitor (worn by the patient) and the Remote Viewer for the paused duration. *Pausing the alarms must be done directly from the ViSi Mobile Monitor (worn by*

the patient), however, alarms may be resumed from either the ViSi Mobile Monitor or the Remote Viewer.

Note: When the annunciation of alarms/alerts has been turned off or paused, certain important alarms and alerts will continue to annunciate (known as break-through alarms and alerts). These are generally equipment alerts that inhibit the ability to monitor the patient appropriately.

Note: When alarms/alerts are paused, alarms/alerts currently in progress will no longer be annunciated. The annunciation of any new alarms/alerts will be disabled for the 2 minute duration.

Note: When alarms/alerts are silenced/acknowledged, the audio tone will be silenced. Any new alarms/alerts occurring during the 2 minute silenced/acknowledged duration will be immediately annunciated.

In Network Rules

When the ViSi Mobile Monitor is in network and connected to the ViSi Mobile Remote Viewer:

- When the ViSi Mobile Monitor is connected to the Remote Viewer, the audio alarm and alert tones will be deferred from the Monitor to the Remote Viewer, for a pre-configured length of time.

Note: Audio tones for life threatening alarms will not be delayed.

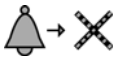
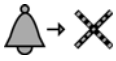
- Alarms/alerts may be silenced/acknowledged from either the ViSi Mobile Monitor or Remote Viewer.

Note: Silencing/acknowledging a life threatening alarm directly from the ViSi Mobile Remote Viewer will only silence/acknowledge the alarm on the Remote Viewer. To silence/ acknowledge the life threatening alarm on the ViSi Mobile Monitor, the clinician must silence/acknowledge the alarm directly from the Mobile Monitor (worn by the patient).

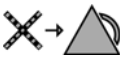
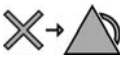
- When alarm annunciation has been turned off, alarm annunciation may be turned back on from either the ViSi Mobile Monitor or Remote Viewer. Turning alarm annunciation off can only be done directly from the ViSi Mobile Monitor (worn by the patient).
- When alarm annunciation has been temporarily paused, alarm annunciation may be resumed from either the ViSi Mobile Monitor or Remote Viewer. Pausing alarm annunciation can only be done directly from the ViSi Mobile Monitor (worn by the patient).

7.2 Physiological Alarms (Alarms) / Technical Alarms (Alerts) Summary

7.2.1 Responding to Alarms/Alerts

Silencing Audible Alarms/Alerts from ViSi Mobile Remote Viewer					
Priority	**Type of Alarm**	**Silence Button**	**Where to Respond to Alarm**		**Audio Tones**
			Remote Viewer *(At Clinician's Station)*	**Mobile Monitor** *(At Patient)*	
1	**Life Threatening** 		Silence at Remote Viewer or Mobile Monitor. (2 minute audible silenced on both Remote Viewer and Mobile Monitor.)		Beep Beep Beep - Pause - Beep Beep
2	**High** 		Silence at Remote Viewer or Mobile Monitor. (2 minute audible silenced on both Remote Viewer and Mobile Monitor.)		Beep Beep Beep - Pause - Beep Beep
3	**Alerts** (High) 		Silence at Remote Viewer or Mobile Monitor. (2 minute audible silenced on both Remote Viewer and Mobile Monitor.)		Beep Beep - Pause -
4	**Alerts** (Low) 		Visual Only - No Sound Acknowledge at the Remote Viewer or Mobile Monitor. (Acknowledged for 2 minutes at both the Remote Viewer and Mobile Monitor.)		No audio tones.

7.2.2 Managing Alarm/Alert Annunciations

Action	Action Button	Duration	Allow Where	Effects
Pause Alarms/ Alerts 	N/A	2 Minutes	May only be paused from the ViSi Mobile Monitor.	Annunciation disabled at both the ViSi Monitor and Remote Viewer.
Resume Alarms/ Alerts		N/A	ViSi Mobile Monitor and Remote Viewer.	Annunciation resumed at both the ViSi Mobile Monitor and Remote Viewer.
Turn Alarms/ Alerts Off 	N/A	Indefinitely	May only be turned off from the ViSi Mobile Monitor.	Annunciation disabled at both the ViSi Monitor and Remote Viewer.
Turn Alarms/ Alerts On		N/A	ViSi Mobile Monitor and Remote Viewer.	Annunciation turned on at both the ViSi Mobile Monitor and Remote Viewer.

Annunciation: Refers to the audible and visual display of alarms/alerts.

Note: When multiple alarms and alerts occur simultaneously, the message text will only display messages associated with the highest alarm severity. The vital measurements will display all existing alarms, regardless of their severity.

7.3 Responding to Physiological Alarms (Alarms)

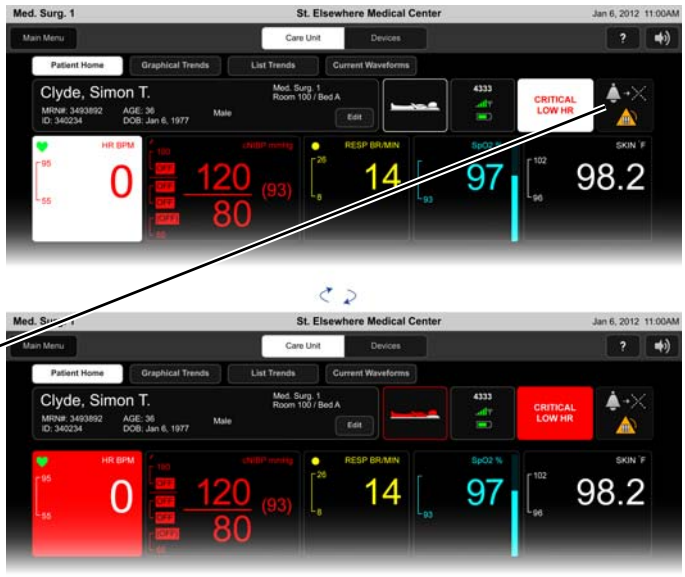
7.3.1 To Silence/Acknowledge Life Threatening Severity Alarms

Life threatening severity alarms require urgent clinician response.

Symbol	Annunciation Color	Audio Tone	Duration (ms)	Spacing (ms)
	White / Red	BBB P BB P BBB P BB... B - Beep / P - Pause	100	50

Summary View

Detail View



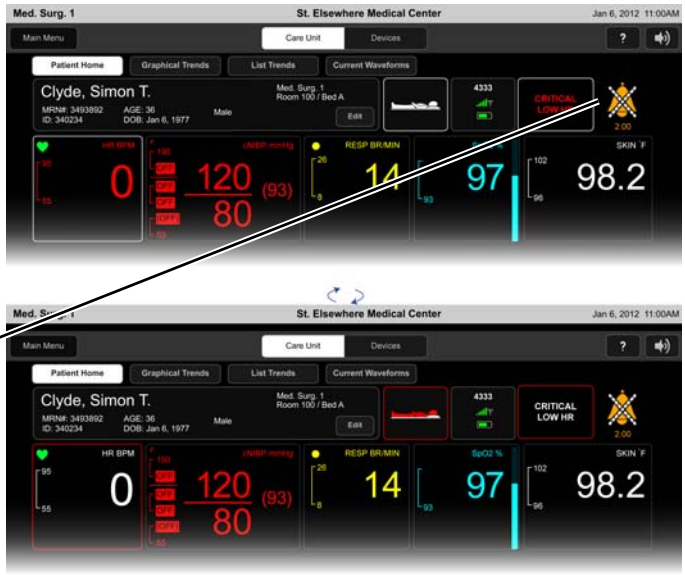
Silence/Acknowledge Alarm

To silence/acknowledge the alarm, touch the **Silence/Acknowledge Alarm** button. 

The alarm is silenced/acknowledged and the "Silenced/Acknowledged" symbol and countdown will be displayed. After the 2 minute countdown has expired, the alarm will be re-annunciated

Summary View

Detail View

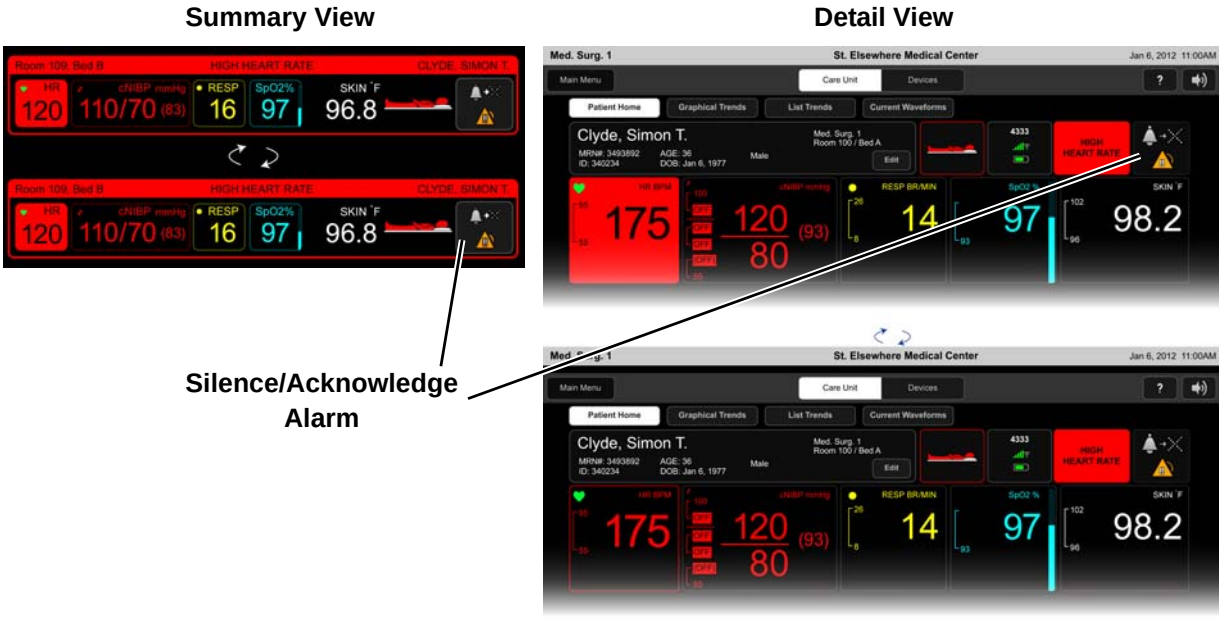


Silenced/Acknowledged symbol and countdown

7.3.2 To Silence High Severity Alarms

High severity alarms require immediate clinician response at the bedside.

Symbol	Annunciation Color	Audio Tone	Duration (ms)	Spacing (ms)
	Red	BBB P BB P BBB P BB... B - Beep / P - Pause	200	100



To silence/acknowledge a high alarm, touch the **Silence/Acknowledge Alarm** button. 

The alarm is silenced/acknowledged and the silenced/acknowledged symbol and countdown will be displayed.

Summary View **Detail View**

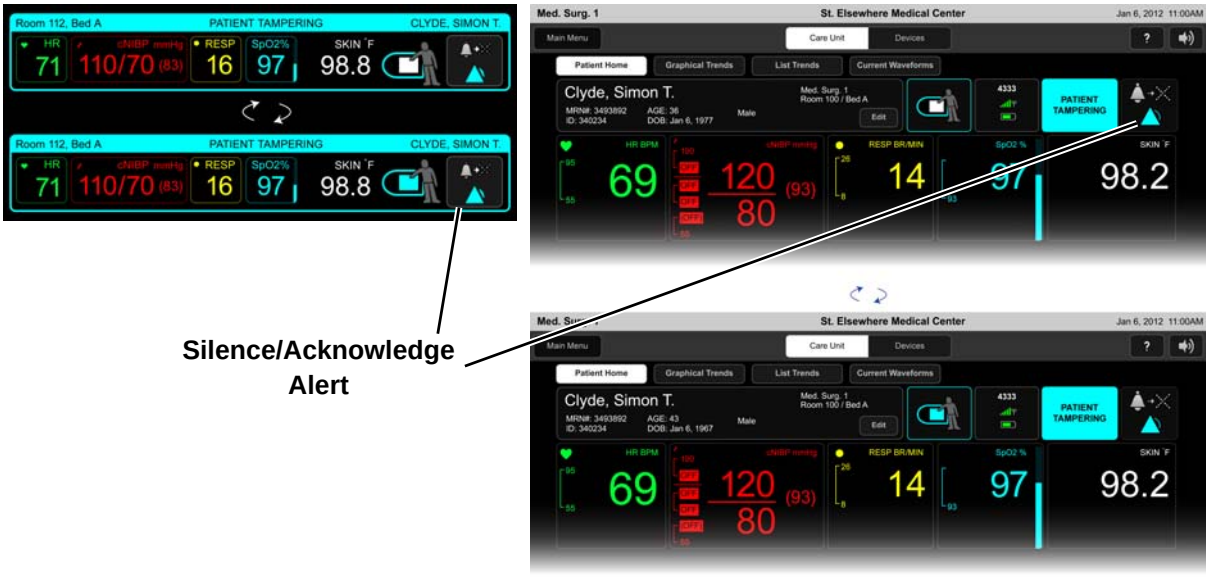
Note: When a high alarm occurs and the alarming condition resolves itself before a clinician is able to respond, the high alarm message will be displayed (in gray) for up to 5 minutes in the message area. This serves as a reminder to the clinician that the high alarm has occurred.

7.4 Responding to Equipment Alarms (Alerts)

7.4.1 To Silence/Acknowledge Alerts (All Severities)

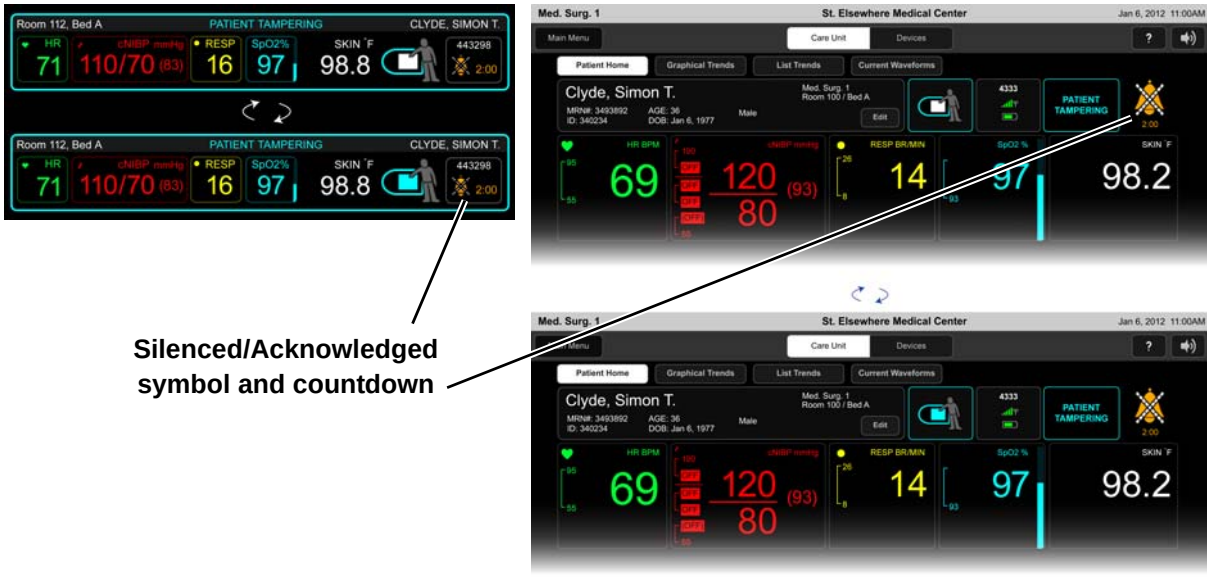
Equipment alerts are used when the ability to monitor the patient and detect a patient's physiological alarms may be affected.

Symbol	Annunciation Color	Severity	Audio Tone	Duration (ms)	Spacing (ms)
	Cyan	High	B B P B - Beep / P - Pause There will be a 15 second pause after each sequence.	250	250
		Low	No audio tones.	N/A	N/A



To silence/acknowledge an alert, touch the **Silence/Acknowledge Alert** button. 

The alert is silenced/acknowledged and the silenced/acknowledged symbol and countdown will be displayed.

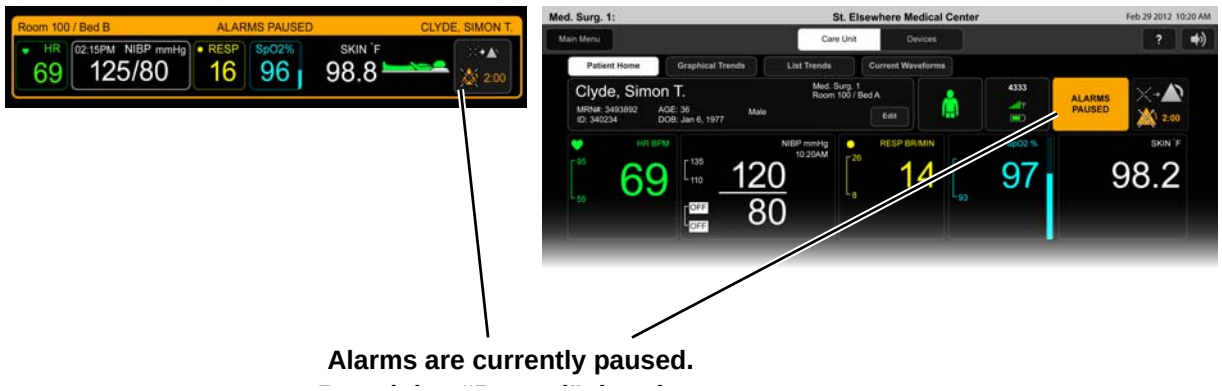


Note: When an alert condition (of any severity) resolves itself before a clinician is able to respond, the alert condition will no longer be annunciated.

7.5 Resume / Turn On Alarm Annunciation

7.5.1 To Resume Alarm Annunciation

When alarms are paused, the annunciation of any existing and new alarm will be disabled at both the ViSi Mobile Monitor and Remote Viewer. Alarms may be resumed from either Mobile Monitor or Remote Viewer.

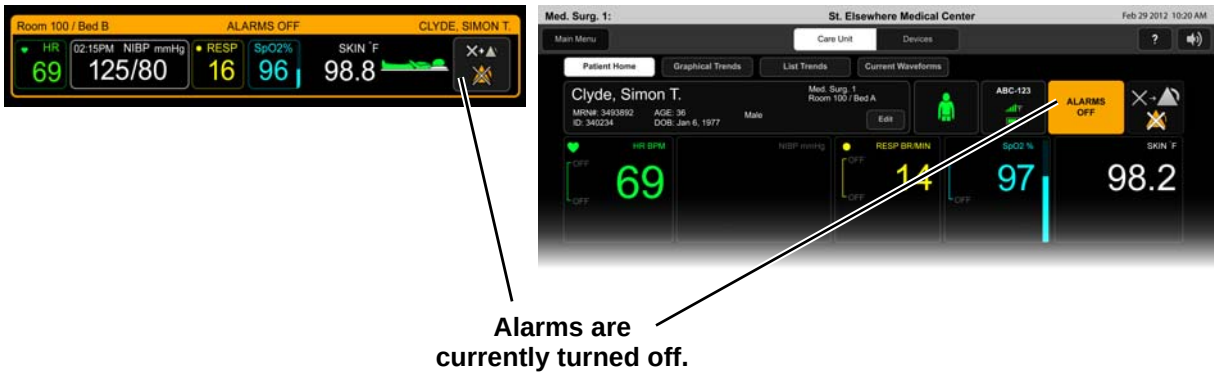


To resume alarm annunciation, touch the **Resume** button. 

Note: Alarm annunciation will resume at both the ViSi Mobile Monitor and Remote Viewer.

7.5.2 To Turn On Alarm Annunciation

When alarms are turned off, the annunciation of any existing and new alarm will be disabled at both the ViSi Mobile Monitor and Remote Viewer. Alarms may be turned back on directly from the Remote Viewer.



To turn the alarm annunciation back on, touch the **Turn Alarms On** button.

Note: Alarm annunciation will be turned on at both the ViSi Mobile Monitor and Remote Viewer.

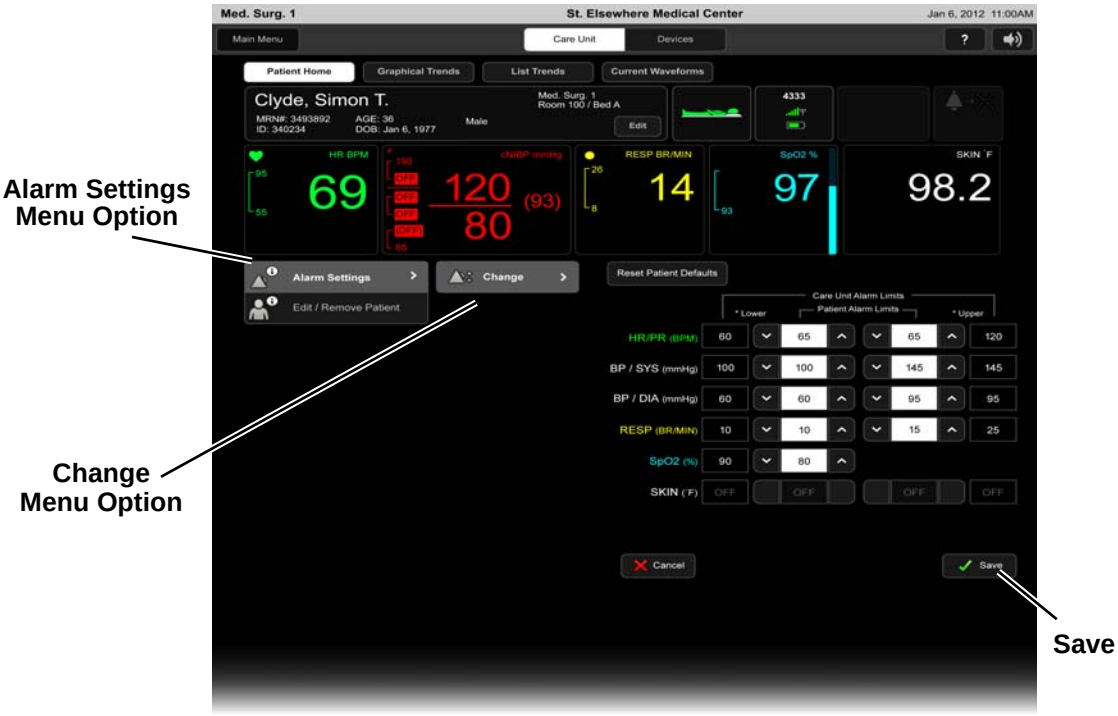
7.6 Manage Alarm Limits

Alarm limits for the selected patient may adjusted individually or reset back to their factory default values.

7.6.1 To change alarm limits individually

1. Navigate to the patient's **Patient Home View**.

   The Patient Home View for the selected patient will be displayed. The patient menu is located directly below the patient's vital signs.



2. Touch/click the **Alarm Settings** option from the menu.

   The Alarm Settings menu will be displayed to the right of the selected Alarm Settings menu option.

3. Touch/click the **Change** option from the **Alarm Settings** menu.

   Alarm limits for all sensors currently connected to the ViSi Mobile Monitor will be displayed.

4. Touch/click the data entry box for the alarm limit to be changed.

   The cursor will now be placed into the selected alarm limit.

5. Directly type in the new alarm limit using the keyboard.
   -or-
   Click/touch the up/down arrows to adjust the alarm limit.
   The new alarm limit will be displayed.

6. Repeat steps 4 through 6 for all alarm limits to be changed.

7. Touch **Save** to save the new alarm limits. 

   The new alarm limits will be communicated to the ViSi Mobile Monitor and will become active immediately. If the alarm limits are not communicated to the Monitor, a message will be displayed on the ViSi Mobile Remote Viewer.

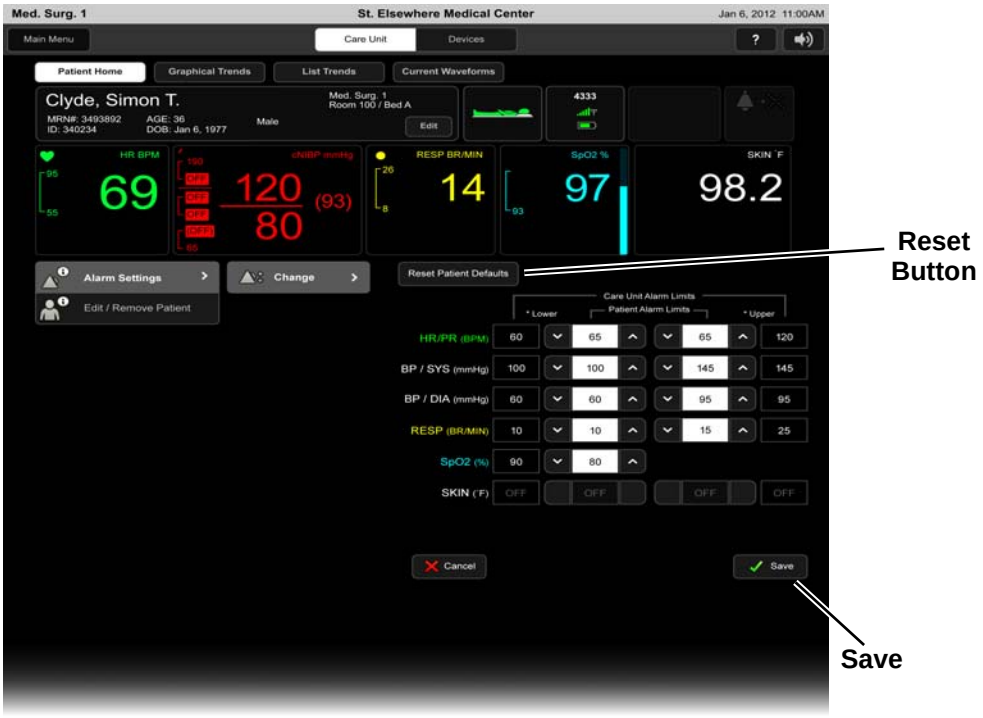
   -or-

   Touch **Cancel** to return to close the current view. 
   Any modifications to the alarm limits will be discarded.

7.6.2 To reset alarm limits to default values

1. Navigate to the patient's **Patient Home View**.

   The Patient Home View for the selected patient will be displayed. The patient menu is located directly below the patient's vital signs.



2. Touch/click the **Alarm Settings** option from the menu. 

   The Alarm Settings menu will be displayed to the right of the selected Alarm Settings menu option.

3. Touch/click the **Change** option from the **Alarm Settings** menu. 

   Alarm limits for all sensors currently connected to the ViSi Mobile Monitor will be displayed.

4. Touch/click the **Reset Patient Defaults** button.

   The new alarm limit will be displayed.

5. Touch **Save** to save the new alarm limits. 

   The new alarm limits will be communicated to the ViSi Mobile Monitor and will become active immediately. If the alarm limits are not communicated to the Monitor, a message will be displayed on the ViSi Mobile Remote Viewer.

   -or-

   Touch **Cancel** *to close the current view.* 
   Any modifications to the alarm limits will be discarded.

7.7 ViSi Mobile Remote Viewer Audio Test

7.7.1 To test the ViSi Mobile Remote Viewer Speaker

Test the ViSi Mobile Remote Viewer speaker to determine if audio tones sound at the Remote Viewer and how loud they are.

Touch/click the **Speaker Test** button.

An audio tone will start to play and the speaker icon on the Speaker Test button will animate.

Click/touch the Speaker Test button to stop the speaker test.

When testing the speaker at the ViSi Mobile Remote Viewer, if the tone does not sound or it is not loud enough check the speaker volume is turned up. If the sound is still not sound loud enough, immediately contact a biomedical engineer. The test indicates how alarm and alert tones sound at the Remote Viewer. If the volume is inadequate, clinicians could miss alarms and alerts.

8. Pause / Stop Monitoring

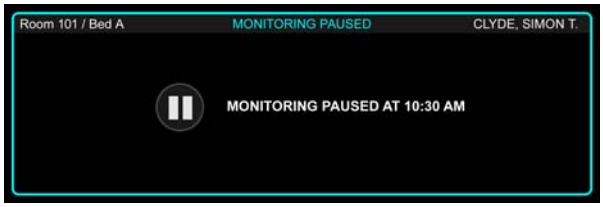
8.1 Pause Monitoring

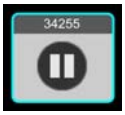
When monitoring is paused on the ViSi Mobile Monitor, the corresponding Patient Tile on the ViSi Mobile Remote Viewer will display an acknowledged MONITORING PAUSED alert the time at which monitoring was paused. If monitoring of the patient is not going to be resumed, monitoring may be stopped by removing the patient from the Remote Viewer using the Remove Patient workflow, outlined below.

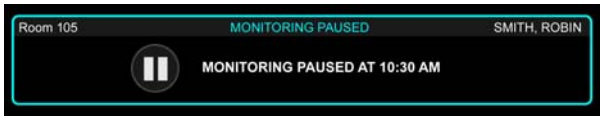
For information on how to Pause Monitoring on the ViSi Mobile Monitor, see the ViSi Mobile Monitor User Manual.

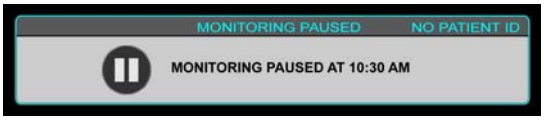
Note: It is not possible to stop monitoring directly from the ViSi Mobile Monitor after monitoring has been paused.

Pause Monitoring









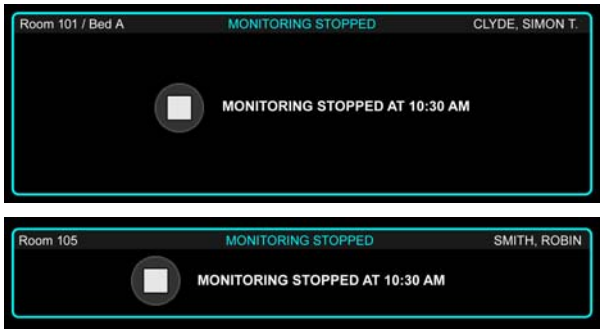
Patients tiles with assigned locations **Patients tiles with no assigned location**

Patient Home View

8.2 Stop Monitoring

When monitoring is stopped on the ViSi Mobile Monitor, the corresponding Patient Tile on the ViSi Mobile Remote Viewer will display an acknowledged MONITORING STOPPED alert and the time at which monitoring was stopped. To remove the patient from the Remote Viewer and complete the "stop" process, follow the Remove Patient workflow, outlined below.

For information on how to Stop Monitoring on the ViSi Mobile Monitor, see the ViSi Mobile Monitor User Manual.



Patients tiles with assigned locations

Patients tiles with no assigned location

Patient Home View

8.3 Removing Patients from the Care Unit

Remove Patient will be enabled for the selected patient when one of the following has occurred:

- Monitoring has been stopped
- Monitoring has been paused
- The patient's monitor is not currently connected to the network.

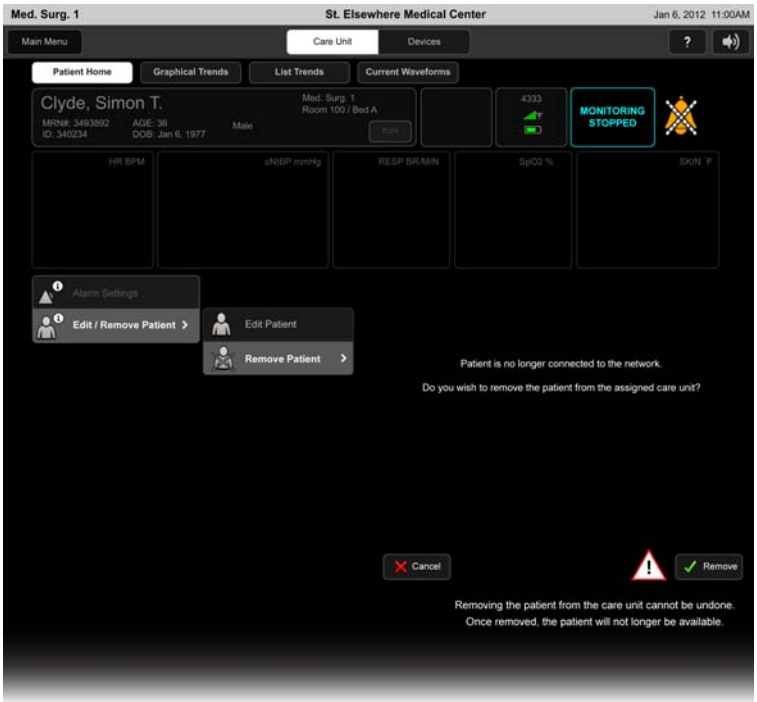
To remove the patient (and their information) from the ViSi Mobile Remote Viewer, use the "Remove" feature.

8.3.1 To remove a patient from the Care Unit View

1. If the patient is not already selected, select the patient from the Care Unit view. *See "Work Area" on page 27.*
2. Touch or click the **Edit / Remove Patient** menu option.

   The second level menu associated with the Edit / Remove Patient menu will be displayed to the right of the Edit / Remove Patient menu.
3. Touch or click the **Remove Patient** menu option.

   The Remove Patient view will be displayed.



4. Touch or click **Remove** to remove the patient from the care unit.

   -or -

   Touch or click **Cancel**.

   If cancelled, the patient will continue to be displayed in the Care Unit Area.

   If the removal is confirmed, the patient will be removed from the Care Unit.

After monitoring has been stopped on the ViSi Mobile Monitor, removing the patient from the ViSi Mobile Remote Viewer cannot be undone. Once removed, the patient will no longer be available on the Remote Viewer.

- Notes -

9. Care Unit Views

9.1 Care Unit Devices

The Care Unit Devices view allows the clinician to see all the ViSi Mobile Monitors currently in use by patients. The screen provides a view of the battery state for each Monitor.

To view the ViSi Mobile Monitors currently in use

Touch or click on the **Devices Tab** in the **System Menu**.

The Care Unit Devices view will be displayed in the Work Area.

Note: Hovering the mouse over any of the Devices boxes will display the patient's primary ID, secondary ID and their assigned location. See image above.

- Notes -

10. Troubleshooting

10.1 Introduction

The ViSi Mobile Monitoring System is designed to alert the clinician to technical issues that may occur while monitoring a patient's vital signs.

The following tables provide troubleshooting solutions to potential problems that may be encountered while monitoring a patient.

10.1.1 Customer Support

Toll-Free: +1-866-232-6126

International: +1-858-427-4620

Fax: +1-858-427-4639

E-mail: support@soterawireless.com

10.2 ViSi Mobile Monitor

Problem	Potential Cause	Solution
The screen is blank	The display is in Quiet Monitoring Mode.	Touch the screen with one finger for two seconds to activate display. Plug in a sensor to initiate monitoring.
	The display is in Hibernation Mode.	Plug in a sensor to initiate monitoring.
	The battery charge is too low.	Disconnect all sensors from the Monitor, clean the Monitor, and place it in the Charger.
Sensors won't plug into the Monitor	Plug is oriented with the connector contacts facing downwards.	Orient the Plug so that the connector contacts are facing upwards.
	Trying to Plug into wrong end of the Monitor.	Only the Thumb Sensor is designed to be Plugged into the rounded end of the Monitor. All other sensors can be Plugged into any port on the flat end of the Monitor.
	Monitor is not seated in the cradle correctly.	Ensure the Monitor is pushed all the way into the cradle and secure with either the Thumb Sensor or Locking Plug.

10.2.1 Screen Access

Problem	Potential Cause	Solution
No response to touching any buttons	Touching the screen with more than one finger.	Touch the button with only a single finger.
	Button is not an active button.	Active buttons are those with borders, and are not dimmed in appearance compared to other buttons.
	Touching the screen with a pen or stylus. **Note: May cause damage to the touch screen.**	Touch the button with only a single finger.
Cannot access the Vital Signs screen	Screen is locked.	Touch the Unlock button and enter the correct PIN.
	Access denied due to entering the wrong PIN code.	Enter the correct PIN code.

Problem	Potential Cause	Solution
Patient has accessed the monitoring functions	Screen was not locked after last clinician interaction.	• Once all interactions are complete, make sure to lock the screen. • Remind the patient that this is a medical device, and that tampering may result in missing important clinical events.
	Patient guessed PIN correctly.	• Define appropriate PIN codes (not 0000 for example). • Remind the patient that this is a medical device, and that tampering may result in missing important clinical events.

10.3 ViSi Mobile Chest Sensor Cable

Problem	Potential Cause	Solution
Chest Sensor Cable is too short to plug into the Monitor	Monitor is oriented in the wrong direction.	Make sure that the flat end of the Monitor is oriented towards the elbow.
	The Chest Sensor Cable is secured to the side of the chest opposite the arm with the Monitor.	Secure the Chest Sensor Cable midway between the sternum and the shoulder of the same arm that the Monitor is on.
	The Chest Sensor Module has been put on upside down.	Rotate the Chest Sensor Module 180^{o} such that the analog cable is facing upwards from the top of the Chest Sensor Module and the digital cables are facing downwards.
No HR numeric	ECG electrodes not connected to lead-wires.	Ensure that the lead-wires are snapped securely onto the ECG electrodes.
	ECG electrodes not firmly attached to the patient’s chest.	Ensure that the ECG electrodes are securely attached to the chest; ECG electrode sites are clean and free of excess hair.
	ECG electrode gel is dry.	Replace ECG electrodes.
	Broken/damaged lead-wires.	Replace damaged Chest Sensor Cable.
	Chest Sensor Cable not securely Plugged into the Monitor.	Make sure that the Chest Sensor Cable is securely Plugged into the Monitor.
HR displays “XX”	A lead-wire or sensor problem is affecting the measurement.	If the problem persists, replace the ECG electrodes and/or Chest Sensor Cable.

Problem	Potential Cause	Solution
HR is erratic	ECG electrodes are not all the same.	Use all the same ECG electrode type, size, materials, and manufacturer.
	ECG electrode gel is dry.	Replace ECG electrodes.
	ECG electrodes not firmly attached to the patient's chest.	Check the ECG electrodes are securely attached to the chest; ECG electrode sites are clean and free of excess hair.
	Skin is not prepared correctly.	See instructions for skin preparation.
No ECG waveform	*See No HR numeric above.*	*See No HR numeric above.*
ECG waveform too small	Using a 3-lead Chest Sensor Cable: Lead II has a low amplitude. Lead II only available with a 3-lead Chest Sensor Cable.	• Select alternate ECG electrode sites; prepare skin sites; connect lead-wires to new ECG electrodes and place on the chest. • Replace 3-lead Chest Sensor Cable with 5-lead Chest Sensor Cable.
	Using a 5-lead Chest Sensor Cable: Selected lead has low amplitude.	5-lead Chest Sensor Cable: select a different lead to view.
ECG waveform is noisy; looks like pacer indicators in the waveform	ECG electrodes not firmly attached to the patient's chest.	Ensure that the ECG electrodes are securely attached to the chest; ECG electrode sites are clean and free of excess hair.
	ECG electrode gel is dry.	Replace ECG electrodes.
	Skin is not prepared correctly.	See instructions for skin preparation.
No RESP numeric	See No HR numeric above.	See No HR numeric above.
	The Monitor is not capable of measuring RESP.	Contact your biomedical engineer.
RESP displays "XX"	A lead-wire or sensor problem is affecting the measurement.	If the problem persists, replace the ECG electrodes and/or Chest Sensor Cable.
RESP is erratic	ECG electrodes not firmly attached to the patient's chest.	Ensure that the ECG electrodes are securely attached to the chest; ECG electrode sites are clean and free of excess hair.
	ECG electrode gel is dry.	Replace ECG electrodes.

Problem	Potential Cause	Solution
No SKIN temperature numeric	The Chest Module sensor is placed on the patient with the Temperature Sensor facing away from the patient.	Place the Chest Module sensor on the patient such that the Temperature Sensor is in direct contact with the patient's chest.
	Sensor is not attached to the patient's chest.	Secure the Chest Sensor Cable to the chest. Make sure that a change in position does not affect the sensor's contact with the skin.
SKIN temperature displays "XX"	The Temperature Sensor may have failed.	If the problem persists, replace the Chest Sensor Cable.
SKIN temperature is erratic	Chest Sensor Cable is not in contact with the skin completely/ securely.	Secure the Chest Sensor Cable to the chest. Make sure that a change in position does not affect the sensor's contact with the skin.
	Skin is not clean and dry.	Clean and dry the skin thoroughly and secure the Chest Sensor Cable to the chest.

10.4 ViSi Mobile Thumb Sensor

Problem	Potential Cause	Solution
Sensor cable too short to Plug into Monitor	Monitor is oriented in the wrong direction.	Make sure that the rounded end of the Monitor is oriented towards the hand.
	Thumb sensor is routed wrong.	Make sure the cable is routed around the outside of the thumb.
No SpO_2 numeric	Broken/damaged Thumb Sensor.	Replace the Thumb Sensor
	Something is blocking the optics or detector in the Thumb Sensor.	Make sure nothing is blocking the optics or detector.
	Thumb Sensor not secured in the Thumb Sensor Cradle.	Place the Thumb Sensor securely in the Thumb Sensor cradle.
	Thumb Sensor not secured to the base of the thumb.	Secure the Thumb Sensor to the base of the thumb.
	Thumb Sensor not securely Plugged into the Monitor.	Make sure that the Thumb Sensor is securely Plugged into the Monitor.
SpO_2 displays “XX”	A sensor problem is affecting the measurement.	If the problem persists, replace the Thumb Sensor.
SpO_2 is erratic	Something is partially blocking the optics or detector in the Thumb Sensor.	Make sure nothing is blocking the optics or detector.
	Thumb Sensor not secured to the base of the thumb.	Secure the Thumb Sensor to the base of the thumb.
	Thumb Sensor is not in the correct location.	Reorient the Thumb Sensor at the base of the thumb and secure with the Thumb Wrap.
	Thumb Strap is too tight.	Loosen the Thumb Strap making sure that it is still secure.

10.5 ViSi Mobile Cuff Module

Problem	Potential Cause	Solution
Cuff Module cable is too short to Plug into Monitor	Monitor is oriented in the wrong direction.	Make sure that the flat end of the Monitor is oriented towards the arm.
	Cuff Module is on the arm opposite the Monitor.	Place the Cuff Module on the same arm that the Monitor is on.
No NIBP measurement	Battery charge is too low.	Replace the Cuff Module.
	Cuff Module not Plugged securely into the Monitor.	Make sure that the Cuff Module is Plugged securely into the Monitor.
	Not set up for automatic measurements.	From the NIBP Settings screen, select an automatic interval.
	The time from the last measurement exceeds the period of time to display a measurement.	Initiate a measurement from the Vital Signs screen.
	Disposable Cuff was touched during inflation.	Avoid touching the ViSi Mobile Disposable Cuff during inflation as this may disrupt the measurement.
	Disposable Cuff not placed correctly.	Ensure Disposable Cuff is placed onto the patient's arm correctly. Line up the arterial line as indicated on the Disposable Cuff.
NIBP measurement doesn't match an auscultatory measurement	Measurements were not taken at the same time.	Measurements are taken at the same time.
	Measurements were taken on different arms.	The BP in both arms is the same, sometimes there is a difference between arms.
	Different size cuffs were used.	Ensure the BP cuff size is the same on both arms, and the correct size for the arm.
	Both arms were not at the same level when the BP was measured.	The arms are positioned at the same level relative to the heart.
	Disposable cuff was touched during inflation.	Avoid touching the ViSi Mobile Disposable Cuff during inflation as this may disrupt the measurement.

Problem	Potential Cause	Solution
Blood pressure mode set to continuous NIBP but only one NIBP measurement taken.	The patient's PATis not stable.	Ensure the patient is still before calibration is started and remains still during the calibration process. **Note: When the patient's PAT is stable, the "c" on the Calibrate cNIBP button will be displayed in red. When PAT is not stable, the "c" will be displayed in gray.**
LED on Cuff Module displays red when in the Charger.	Voltage level has exceeded expectation.	• Remove Cuff Module from the Charger. • Report the problem to Sotera Wireless Inc. Customer Service Department or the Sotera Wireless representative in your area.
	Current level has exceeded expectation.	• Remove Cuff Module from the Charger. • Report the problem to Sotera Wireless Inc. Customer Service Department or the Sotera Wireless representative in your area.
	Over temperature protection current temperature has exceeded expectation.	• Remove Cuff Module from the Charger. • Report the problem to Sotera Wireless Inc. Customer Service Department or the Sotera Wireless representative in your area.

10.6 ViSi Mobile Battery Charger

Problem	Potential Cause	Solution
Batteries in the Monitor and Cuff Module do not charge	The Monitor and Cuff Module are not securely seated in the Charger.	Make sure that the Monitor and Cuff Module are securely seated in the Charger. The monitor and Cuff Module are designed to fit into the Charger in one direction.
	The Charger is not completely Plugged in to the wall socket.	• Make sure that the Plug is securely Plugged into an active wall socket and there is a green light on the Battery Charger. • Make sure that the power cord is not damaged.
	AC Adapter is not Plugged into the Charger.	• Plug the AC Adaptor into the Charger.
	The Monitor and/or Cuff Module were insterted into the Charger without being thoroughly dried (after cleaning/disinfecting).	• Dry equipment thoroughly before placing in the Charger.

10.7 General Troubleshooting

10.7.1 Connectivity Lost

Problem	Potential Cause	Solution
On the ViSi Mobile Remote Viewer, “XX” appears where all vital sign measurements should be displayed.	The patient wearing the ViSi Mobile Monitor has moved outside of the wireless network area.	Move the patient back into the wireless network area.
On the ViSi Mobile Remote Viewer, all patients have disappeared from the Care Unit Area.	The network cable has been disconnected from the ViSi Mobile Remote Viewer.	Reconnect the network cable to the Remote Viewer.

10.7.2 Alarms and Alerts

When testing the speaker at the ViSi Mobile Remote Viewer, if the tone does not sound or it is not loud enough check the speaker volume is turned up. If the sound is still not sound loud enough, immediately contact a biomedical engineer. The test indicates how alarm and alert tones sound at the Remote Viewer. If the volume is inadequate, clinicians could miss alarms and alerts.

Problem	Explanation
I acknowledge an alarm at the ViSi Mobile Remote Viewer, but the audio tone still occurs at the ViSi Mobile Monitor.	• Life-Threatening alarms latch at the ViSi Mobile Monitor until they are acknowledged there, even if the alarm condition resolves. • Certain alerts (such as a sensor being disconnected) continue to annunciate at the ViSi Mobile Monitor until the alert is acknowledged at the Monitor.
An alarm occurs, but the audio tone stops before I acknowledge it.	• If an alarm or alert condition resolves before it is acknowledged, the audio tones stops. • If the alarm condition was a high-level severity, the alarm message will remain visible (in gray) for five minutes.
I stop monitoring a patient at the ViSi Mobile Monitor, according to procedure, but a MONITOR STOPPED alert still appears on the ViSi Mobile Remote Viewer.	The alert informs all clinicians who are remotely monitoring the patient that monitoring has stopped. Acknowledge the alert to remove the patient from the care unit.
My patient had a vital sign alarm. I did not acknowledge the alarm, but I removed the sensor from the patient. The vital sign alarm continued.	The vital sign alarm must be acknowledged, even if the sensor is removed.

Problem	Explanation
An alert with the  icon and PATIENT TAMPERING message occurred. What does it mean?	Someone has unsuccessfully tried to log in to the ViSi Mobile Monitor five or more times. The visual indications go away after the alert is acknowledged and after a clinician successfully logs in at the Monitor.
When an alarm or alert occurs, the audio annunciation is heard on the ViSi Mobile Remote Viewer, but there is no audio on the ViSi Mobile Monitor.	Most alarms and alerts will audibly annunciate at the ViSi Mobile Remote Viewer before they audibly annunciate at the ViSi Mobile Monitor. This is to minimize disturbing the patient.
Sometimes if more than one alarm or alert occurs for a patient at the same time, one or more of the messages don't show.	• If the alarms or alerts are the same severity level, the messages will cycle through. • Messages for alarms or alerts that are at a lower severity level will not be displayed. • If alarms and alerts occur simultaneously, only messages associated with the alarms will be displayed. • Other visual indications usually show for lower level alarms and alerts.
Sometimes I acknowledge an alarm or alert, and all alarm or alert indications go away. The audio tone never returns.	Some alarms and alerts are acknowledged permanently.
At the ViSi Mobile Monitor, I set all alarming to OFF, or I set all alarming to PAUSED. But some alarms and alerts continue to be annunciated.	Some important alarms and alerts (such as sensor being disconnected) will continue to annunciate even when all alarms are turned off, or paused.
When an alarm or alert occurs, the ViSi Mobile Remote Viewer does not sound an audio tone, or the tone is not loud enough.	• Some alerts do not have an audio tone. When an audio tone is associated with an alarm or alert, the Speaker Test button will animate. • When an audio tone is expected, but not present (or not loud enough), immediately contact your biomedical engineer. • The speaker volume for the ViSi Mobile Remote Viewer can be tested at any time.
The ViSi Mobile Remote Viewer displays a CONNECTIVITY LOST alert, what does it mean?	The ViSi Mobile Monitor is no currently connected to the network.

10.8 ViSi Mobile Remote Viewer

10.8.1 Setting Alarm Limits

Problem	Explanation
When I try to adjust individual limits in the Alarm Settings pane, I cannot go past certain limit values.	Patient alarm limits may not be set beyond the care unit alarm limits.
When I adjust an upper limit, the lower limit also changes, or vice versa.	When a vital sign limit is adjusted to equal the opposite limit, the opposite limit adjusts. Upper and lower limits for a vital sign cannot be the same value.
The alarm limits on the ViSi Mobile Monitor and the limits at the ViSi Mobile Remote Viewer do not match.	The alarm limits were set on the ViSi Mobile Monitor while the Monitor was not connected to the network. The new limits will not be communicated back to the ViSi Mobile Remote Viewer until the Monitor reconnects to the network.
	The alarms were changed on the ViSi Mobile Remote Viewer but before the new alarm limits were communicated to the ViSi Mobile Monitor, the Monitor moved out of network. The limits on the Monitor are the operating limits at all times.

11. Specifications

11.1 Introduction

This section provides specifications regarding measurement ranges, accuracy levels and environmental operating conditions for the ViSi Mobile Monitoring System.

Do not use the ViSi Mobile Monitoring System in neonatal or pediatric patients under the age of 18 years since the System has not been tested for these patient groups.

11.2 Vital Sign Measurements

11.2.1 Heart Rate

Heart Rate	
Display Range	0 to 240 BPM
Accuracy Range	30 to 240 BPM
Accuracy	±3 BPM
Resolution	1 BPM
Pacemaker	• The monitor detects and rejects pacemaker impulses in accordance with AAMI EC13:2002 • Performs heart rate calculations on a patient with a pacemaker • Will not recognize a pacemaker impulse as a QRS • Displays pacer markers on ECG waveforms
Pacemaker Pulse Rejection Without Overshoot	Tested per EC13:2002, 4.1.4.1: Pulse Rejection Range: Amplitude from ±2 mV to ±700 mV Pulse Width from 0.1 ms to 2 ms **Note: Amplitude limited to 660mV for pulse widths from 1.5 to 2.0ms** **Note: Pulses with polarization overshoot > 25mS may cause R-Wave detection.** Indicated Heart Rate: Ventricular Pacing: Case (a): 0 BPM Case (b): 60 BPM Case (c): 30 BPM Atrial / Ventricular Pacing: Case (a): 0 BPM Case (b): 60 BPM Case (c): 30 BPM

Heart Rate	
Pacemaker Pulse Rejection With Overshoot	Tested per EC13:2002, 4.1.4.2, Method A: Pulse Rejection Range: Amplitude from ±2 mV to ±700 mV Pulse Width from 0.1 ms to 2 ms **Note: Amplitude limited to 660mV for pulse widths from 1.5 to 2.0ms** **Note: For pulse width > 1.0mS, recovery time limited to 25mS.** Indicated Heart Rate: Ventricular Pacing: Case (a): 0 BPM Case (b): 60 BPM Case (c): 30 BPM Atrial / Ventricular Pacing: Case (a): 0 BPM Case (b): 60 BPM Case (c): 30 BPM
Pacer Pulse Detector Rejection of Fast ECG Signals	Tested per EC13:2002, 4.1.4.3: • Minimum Slew Rate: 25 V/s
Defibrillation Response	• Defibrillator protected • Displays HR measurement < 30 seconds after a defibrillation event • Displays an ECG waveform < 10 seconds after a defibrillation event **Note: Defibrillation events may be implanted or external.** **Note: Defibrillation recovery is dependent upon using proper disposable electrodes. Use only Ag-AgCl disposable electrodes.**
T-Wave Rejection	Tested per EC13:2002, 5.1.2.1: • T-waves up to 1.2 mV in amplitude: • T-waves not detected, no change in indicated heart rate.
Heart Rate Averaging	Tested per EC13:2002, 5.1.2.1 d): • 20 second moving average
Heart Rate Accuracy and Response to Irregular Rhythm	Tested per EC13:2002, 5.1.2.1 e): • Waveform 3a: 80 BPM • Waveform 3b: 48 BPM • Waveform 3c: 90 BPM • Waveform 3d: 90 BPM
Change in Heart Rate	Tested per EC13:2002, 5.1.2.1 f): • 80 BPM to 120 BPM: < 13 seconds • 80 BPM to 40 BPM: < 13 seconds
Time to Alarm for Cardiac Standstill	Tested per EC13:2002, 4.2.8.4: • < 10 seconds

Heart Rate	
Time to Alarm for Tachycardia	Tested per EC13:2002, 5.1.2.1 g): Figure 4a: • Gain = 1.0x: 5 seconds • Gain = 2.0x: 5 seconds • Gain = 0.5x: 9 seconds Figure 4b: • Gain = 1.0x: 6 seconds • Gain = 2.0x: 6 seconds • Gain = 0.5x: 7 seconds
Input Impedance	> 20 Mohms
Frequency Response	0.5 to 125Hz
Lead Off Detection Current	< 24 nA
Common Mode Rejection Ratio	> 85 dB

11.2.2 Respiration

Respiration	
Method	Impedance Pneumography
Display Range	0 to 50 BR/MIN
Accuracy Range	3 to 50 BR/MIN
Accuracy	± 3 BR/MIN or 10% of reading, whichever is greater
Resolution	1 BR/MIN
Respiration Drive	Voltage: 1.00 V P-P ±5% Frequency: 32.0 KHz ±2%

11.2.3 Pulse Oximetry (SpO_2, Functional Oxygen Saturation)

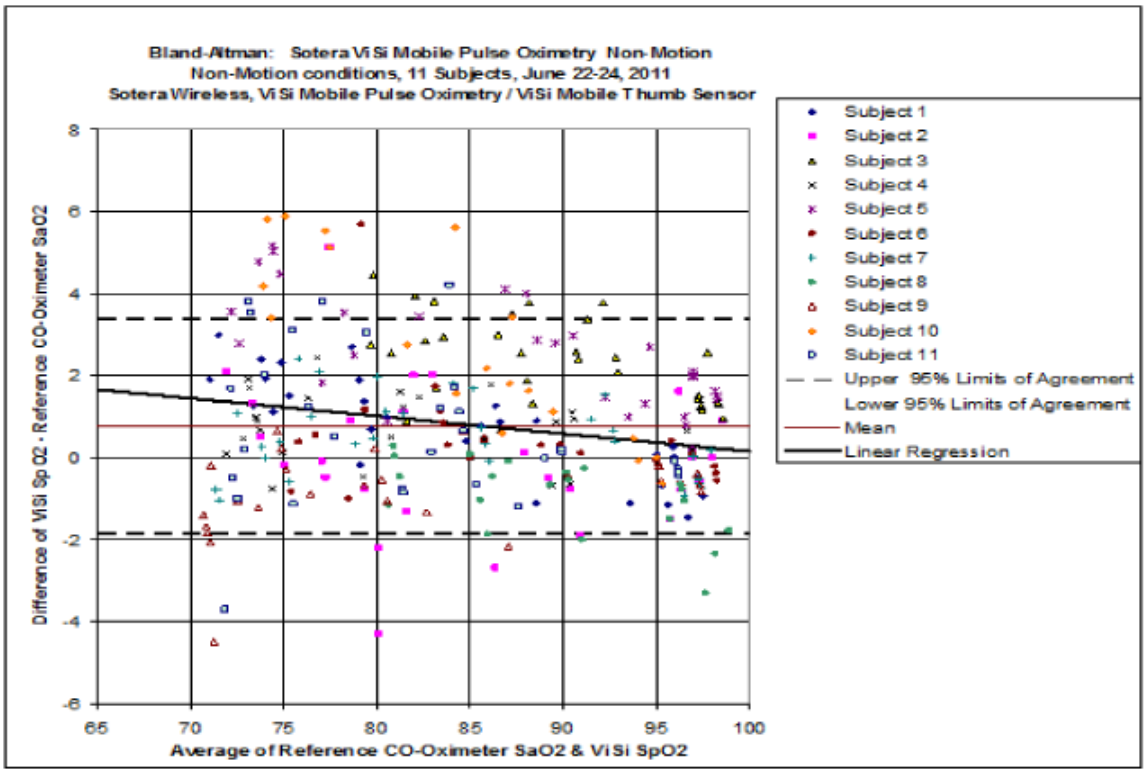
Pulse Oximetry (SpO_2, Functional Oxygen Saturation)		
Normative Reference	ISO 9919: 2005	
SpO_2	Display Range	49 to 100%
	Accuracy Range	70 to 100%
	Accuracy	≤ 2% from 70-100% (no motion)[a] Unspecified from 49-69%
	Resolution	1%
Pulse Rate	Display Range	0 to 240 BPM
	Accuracy Range	30 to 240 BPM
	Accuracy (No Motion)	± 3 BPM; < 50 BPM @ ≥ 0.6% Pulsatile Modulation ± 3 BPM; ≥ 50 BPM @ ≥ 0.4% Pulsatile Modulation
	Accuracy (RMS Error)	≤ 3 BPM
	Rate Resolution	1 BPM
Validation Study	Per ISO 9919. The ViSi SpO_2 is calibrated to display functional oxygen saturation and validated against human subjects arterial blood sample reference measured with CO-Oximeter (see Bland-Altman: ViSi Mobile Pulse Oximetry table). **Note: A functional tester cannot be used to assess the accuracy of a pulse oximeter probe or a pulse oximeter monitor.**	
Calculation Rate	Every pulse	
Display Refresh Rate	Every 3 seconds	
Averaging	12 beat average following initialization	
Alarm Range	Low - Fixed at 85%	
Alarm Delay	30 seconds (fixed)	
Waveform Display	• Amplitude is normalized • Sweep speed is scaled to 25mm/sec to match ECG	
Sensor Application Time	Sensor should be checked every 8 hours	
Optical Wavelengths / power	Red: 660nm / max 6.5mW (±15%) Infra-Red: 905nm / max 5.2mW (±15%)	
Interference	SpO_2 can be adversely effected by the presence of dyshaemoglobins, ambient light (including photosynamic therapy); electromagnetic interference; electrosurgical units; dysfunctional hemoglobin; presence of certain dyes; inappropriate positioning of the pulse oximeter probe.	
Toxicity	Thumb sensor uses white silicone which has no known toxicity effects.	

a. Bench testing indicates accuracy may be compromised at pulse rates below 50BPM at modulations less than 0.6% and extremely low pulse rates of 30BPM at modulations less than 0.8%.

The table below shows A_{rms} values measured using the ViSi Mobile Thumb Sensor (Model 92-10020) with the ViSi Mobile Monitoring System in a clinical study:

Validation Data (per ISO 9919)				
Age of Volunteers	18 - 45			
SpO_2 Accuracy (No Motion)				
SpO_2 Range	70-100%	90-100%	80-90%	70-80%
Accuracy (A_{rms}) - No Motion	1.9	1.2	1.9	2.4

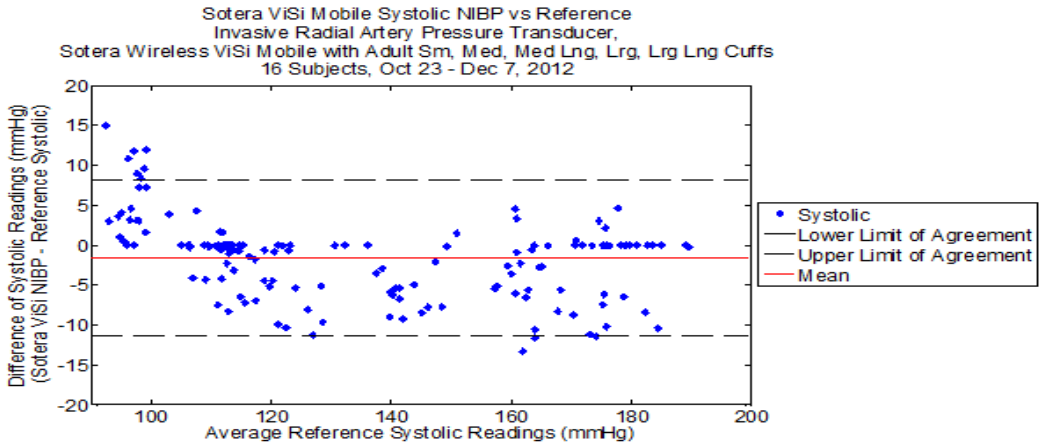
Bland-Altman: ViSi Mobile Pulse Oximetry



11.2.4 Non-Invasive Blood Pressure (NIBP)

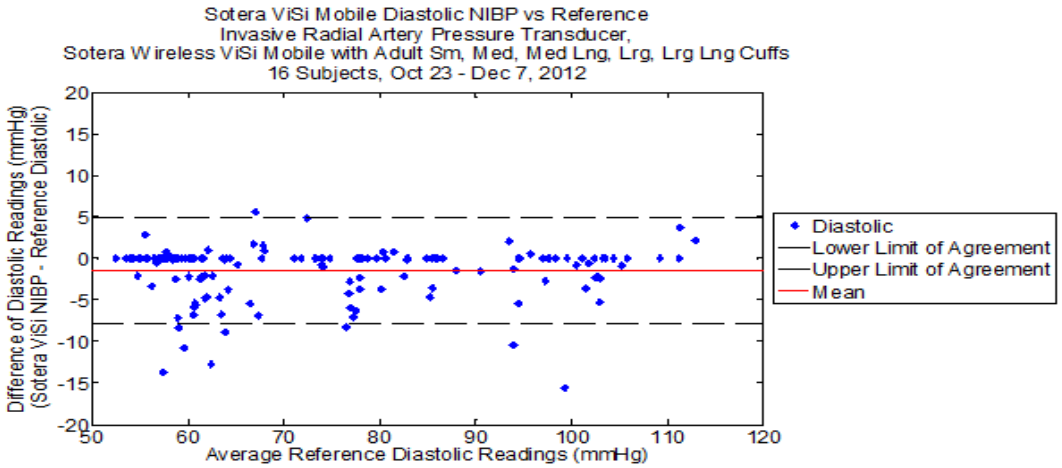
Non-Invasive Blood Pressure (NIBP)		
Normative Reference	ISO 81060-2: Non-invasive Sphygmomanometers - Part 2: Clinical validation of automated measurement type.	
Principle of Operation	Oscillometry	
Systolic	Range:	60 to 240 mmHg
	Accuracy:	Mean error of less than ± 5 mmHg and a std. dev. of ≤ 8 mmHg
	Resolution:	1 mmHg
Diastolic	Range:	40 to 160 mmHg
	Accuracy:	Mean error of less than ± 5 mmHg and a std. dev. of ≤ 8 mmHg
	Resolution:	1 mmHg
Mean Arterial Pressure	Range:	50 to 185 mmHg
	Accuracy:	Mean error of less than ±5 mmHg and a std. dev. of ≤ 8 mmHg
	Resolution:	1 mmHg
Pulse Rate	Accuracy (NIBP) <3 BPM	
Validation Study	Invasive blood pressure (radial artery) reference Number of subjects: 16 Subject Age Range: 19-48	

Systolic Bland Altman Analysis (NIBP)



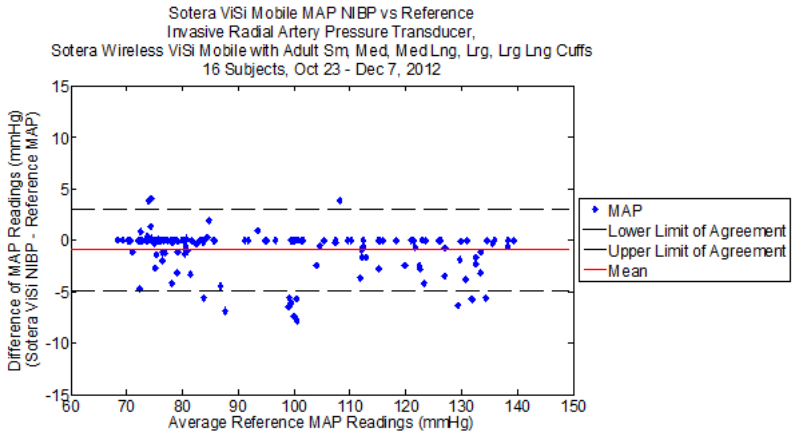
Sample Size:	152 data points
Mean:	-1.65 mmHg
Standard Deviation:	5.01 mmHg
Upper 95% Limits of Agreement (+1.96 SD):	8.2 mmHg
Lower 95% Limits of Agreement (-1.96 SD):	-11.5 mmHg

Diastolic Bland Altman Analysis (NIBP)



Sample Size:	152 data points
Mean:	-1.49 mmHg
Standard Deviation:	3.22 mmHg
Upper 95% Limits of Agreement (+1.96 SD):	4.8 mmHg
Lower 95% Limits of Agreement (-1.96 SD):	-7.8 mmHg

Mean Arterial Pressure Bland Altman Analysis (NIBP)



Sample Size:	152 data points
Mean:	-0.91 mmHg
Standard Deviation:	2.04 mmHg
Upper 95% Limits of Agreement (+1.96 SD):	3.1 mmHg
Lower 95% Limits of Agreement (-1.96 SD):	-4.9 mmHg

11.2.5 Continuous Non-Invasive Blood Pressure (cNIBP)

Continuous Non-Invasive Blood Pressure (cNIBP)	
Normative Reference	ISO 81060-2: Non-invasive Sphygmomanometers - Part 2: Clinical validation of automated measurement type.
Principle of Operation	cNIBP is based on the relationship between blood pressure and the time it takes a pulse that originates from a cardiac contraction to arrive at a peripheral location.
Display Update	Continuous blood pressure is displayed based on averaging PAT calculations from the previous 60 seconds and updating the display every 3 seconds.
Systolic	Range: 60 to 240 mmHg Accuracy[a,b]: Mean error of ≤ ± 5 mmHg and a std.dev. of ≤ 8 mmHg Resolution: 1 mmHg
Diastolic	Range: 40 to 160 mmHg Accuracy[a,b]: Mean error of ≤ ± 5 mmHg and a std.dev. of ≤ 8 mmHg Resolution: 1 mmHg
Mean Arterial Pressure (MAP)	Range: 50 to 185 mmHg Accuracy[a,b]: Mean error of ≤ ± 5 mmHg and a std.dev. of ≤ 8 mmHg Resolution: 1 mmHg
Validation Study	Invasive blood pressure (radial artery) reference Number of subjects: 15 Subject age range: 19-48 years Arm circumference range tested: 21-38 cm

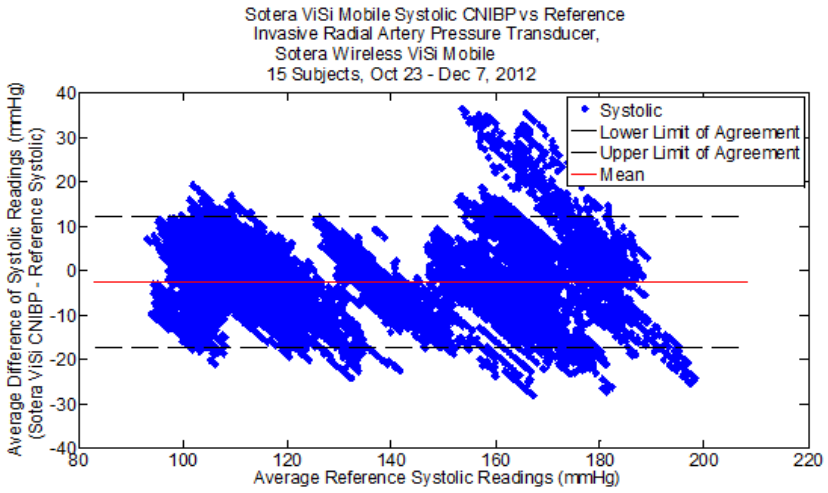
a. *ViSi Mobile Monitoring System accuracy claim is not met when the subject is inclined more than 30 degrees from horizontal.*
b. *The accuracy and precision of the cNIBP measurement met ISO 81060-2 requirements for the first 2.5 hours of testing.*

cNIBP Clinical Study Results
Sotera ViSi cNIBP vs. Reference Invasive Radial Artery Transducer (n=15 subjects)

Subject Position		Supine	30º	60º	Overall
Systolic	Bias	-1.61	-4.77	-7.36	-1.88
	Std. Dev.	5.69	7.87	9.97	6.17
Diastolic	Bias	-1.33	-3.97	-8.31	-1.65
	Std. Dev.	3.16	4.49	6.07	3.62
MAP	Bias	-0.33	-3.01	-7.23	-0.67
	Std. Dev.	3.36	5.37	6.67	3.86
Data Points		47,572	1,774	1,724	54,179

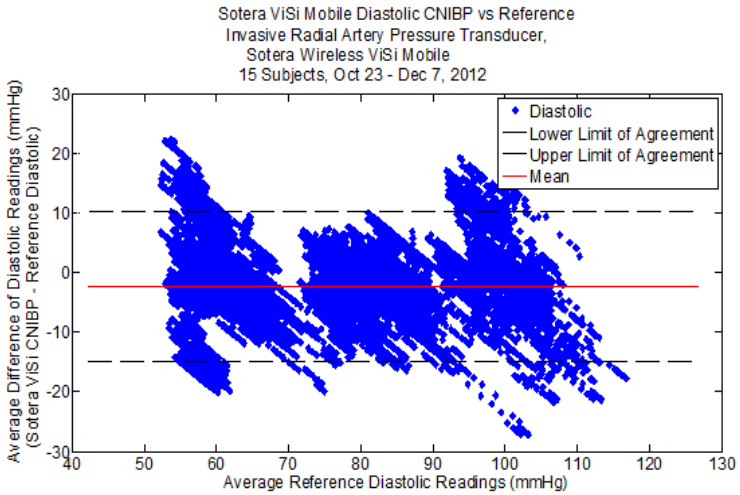
Changes in posture can affect ViSi cNIBP accuracy. Recalibrate ViSi cNIBP whenever torso changes by more than 30^{o} above supine position.

Systolic Bland Altman Analysis (cNIBP)



Sample Size:	54,179 data points
Mean:	-1.88 mmHg
Standard Deviation:	6.17 mmHg
Upper 95% Limits of Agreement (+1.96 SD):	10.2 mmHg
Upper 95% Limits of Agreement (-1.96 SD):	-14.0 mmHg

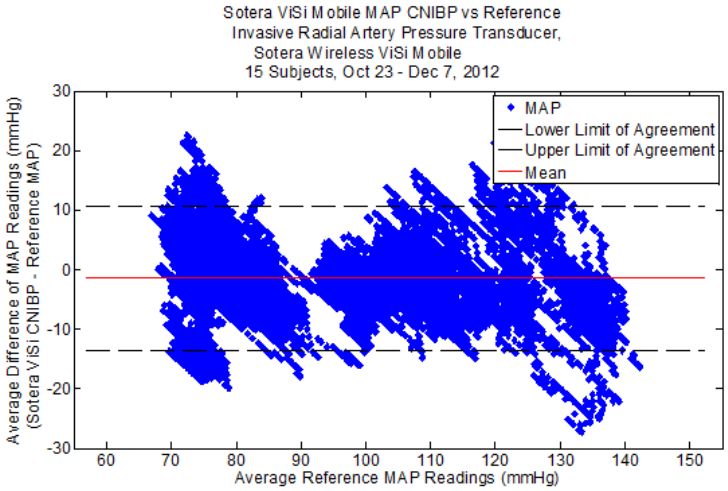
Diastolic Bland Altman Analysis (cNIBP)



Sample Size:	54,179 data points
Mean:	-1.65 mmHg

Standard Deviation:	3.62 mmHg
Upper 95% Limits of Agreement (+1.96 SD):	5.4 mmHg
Upper 95% Limits of Agreement (-1.96 SD):	-8.7 mmHg

MAP Bland Altman Analysis



Sample Size:	54,179 data points
Mean:	-0.67 mmHg
Standard Deviation:	3.86 mmHg
Upper 95% Limits of Agreement (+1.96 SD):	6.9 mmHg
Upper 95% Limits of Agreement (-1.96 SD):	-8.2 mmHg

11.2.6 Skin Temperature

Temperature				
Scale	^{o}C		^{o}F	
Range / Accuracy (measurement at approximately 102 kPa / 768 mmHg)	Range	Accuracy	Range	Accuracy
	0^{o} - 19.9^{o}	$\pm 0.3^{o}$	32^{o} - 67.9^{o}	$\pm 0.5^{o}$
	20^{o} - 24.9^{o}	$\pm 0.3^{o}$	68^{o} - 76.9^{o}	$\pm 0.5^{o}$
	25^{o} - 35.9^{o}	$\pm 0.2^{o}$	77^{o} - 96.7^{o}	$\pm 0.3^{o}$
	36^{o} - 39.9^{o}	$\pm 0.1^{o}$	96.8^{o} - 103.9^{o}	$\pm 0.2^{o}$
	40^{o} - 41.9^{o}	$\pm 0.2^{o}$	104^{o} - 107.5^{o}	$\pm 0.3^{o}$
	42^{o} - 50.0^{o}	$\pm 0.3^{o}$	107.6^{o} - 122^{o}	$\pm 0.5^{o}$
Resolution	$\pm 0.1^{o}$		$\pm 0.1^{o}$	
Transient Response	< 6 min (25^{o} - 37^{o})		< 6 min (77^{o} - 98.6^{o})	

11.3 Physical Components

11.3.1 ViSi Mobile Monitor

ViSi Mobile Monitor		
Physical Characteristics	Dimensions	2.59 cm H x 4.85 cm W x 9.35 cm L 1.02 in. H x 1.91 in. W x 3.68 in. L exclusive of connectors and Wrist Cradle
	Weight	110 g / 3.92 oz
Monitor	Display	OLED, 160 x 128 pixels, full color
	Audio	Alarm annunciation, QRS, self-test
	Waveforms	One waveform, user selectable Aspect Ratio: 0.4 Sec/mV Scaled equivalent to 25 mm/sec sweep speed Respiration waveform scaled equivalent to 6.25 mm/sec sweep speed
Battery	Operating Time	> 12 hours
	Fuel Charge Display	Battery Symbol Charge Level with Full Indication
	Charge Time	Less than 4 hours
	Battery Type	Li-Ion, 3.7 V., 2000 mAh, single cell
	Maximum Temperature	45ºC / 113ºF *Refer to IEC 60601-1:2005 (Section 11)*
Cleaning / Disinfecting	Liquid Ingress Rating	IPX7 During cleaning cycle only, not during monitoring
	Solutions / Compounds	• Isopropyl alcohol (IPA) • Detergent (Alconox)

Wireless Communications / Radio

Wireless Communications	
Frequency	2.402 - 2.480 GHz
Protocol	802.11b
Modulation	Direct Sequencing Spread Spectrum
Security	WPA2 / PSK
Power Output (max)	8 mW (9 dBm)
WiFi Alliance Compliant	Yes; Reference Protocol: ASD 0478
Data Throughput	< 20 KBps

If you have any concerns regarding a cyber security breach or vulnerability, contact Sotera Wireless or an authorized Sotera Wireless representative in your area.

Mode Plugs

Mode Plugs	
Shipping Plug	Turns device off completely
Bio Med Plug[a]	Enables configuration and test functions
Locking Plug	Secures Monitor into Wrist Cradle

a. The Bio Med Plug is not currently available.

11.3.2 ViSi Mobile Chest Sensor Cable

ViSi Mobile Chest Sensor Cable		
Mechanical	Complies with EC53	
Weight (5 lead-wire / 3 lead-wire)	72 g / 62 g (2.54 oz. / 2.19 oz.)	
Maximum Temperature	43ºC / 109.4ºF *Refer to IEC 60601-1:2005 (Section 11)*	
Cleaning / Disinfecting	Liquid Ingress Rating	IPX7 During cleaning cycle only, not during monitoring
	Solutions / Compounds	• Isopropyl alcohol (IPA) • Detergent (Alconox)

11.3.3 ViSi Mobile Cuff Module

ViSi Mobile Cuff Module		
Physical Characteristics	Dimensions	3.10 cm H x 4.85 cm W x 12.19 cm L (1.22 in. H x 1.91 in. W x 4.80 in. L) exclusive of cable
	Weight	157 g (5.54 oz)
Battery	Operating Time	> 30 cuff inflations or 24 hrs, whichever occurs first
	Charge Display Status	Eight LEDs: Six levels of Green, Yellow, Red
	Charge Time	< 4 hours
	Battery Type	Battery Pack, Li-Ion, 2000 mAh
	Maximum Temperature	45ºC / 113ºF *Refer to IEC 60601-1:2005 (Section 11)*
Cuff Sizes Arm Circumference (cm)	Small	20 – 26
	Medium	25 – 34
	Medium+	25 – 34
	Large	32 – 43
	Large+	32 – 43
Cleaning / Disinfecting	Liquid Ingress Rating	IPX0
	Solutions / Compounds	• Isopropyl alcohol (IPA) • Detergent (Alconox)

When the ViSi Mobile Cuff Module is connected to the other ViSi Mobile Components, the entire system has an ingress protection rating of IPX0.

11.3.4 ViSi Mobile Thumb Sensor

ViSi Mobile Thumb Sensor		
Cleaning / Disinfecting	Liquid Ingress Rating	IPX7 During cleaning cycle only, not during monitoring
	Solutions / Compounds	• Isopropyl alcohol (IPA) • Detergent (Alconox)

11.3.5 ViSi Mobile Charger - 8 Bay

ViSi Mobile Charger		
Physical Characteristics	Dimensions	7.7 cm x 46.3 cm x 5.9 cm (3.0 in x 18.2 in x 2.3 in)
	Weight	0.7 kg (1.5 lb)
AC Mains	AC Line Voltage	100-240 V, 50-60 Hz
	Power (all bays charging)	75 W
Cleaning / Disinfecting	Liquid Ingress Rating	IPX0
	Solutions / Compounds	• Isopropyl alcohol (IPA) • Detergent (Alconox)

11.3.6 ViSi Mobile Charger - 2 Bay

ViSi Mobile Charger		
Physical Characteristics	Dimensions	7.7 cm x 12.9 cm x 5.9 cm (3.0 in x 5.1 in x 2.3 in)
	Weight	0.25 kg (0.6 lb)
AC Mains	AC Line Voltage	100-240 V, 50-60 Hz
	Power (all bays charging)	30 W
Cleaning / Disinfecting	Liquid Ingress Rating	IPX0
	Solutions / Compounds	• Isopropyl alcohol (IPA) • Detergent (Alconox)

11.3.7 ViSi Mobile Appliance

ViSi Mobile Appliance	
Server Configuration	Single 1u, redundant hardware and internal RAID 10, dedicated hardware.
Processor	Single Intel Xeon 5620 2.4 GHz (or equivalent CPU) 8 GB memory
Storage	Server contains at a minimum 4 x 500 GB 7200 RPM hard drives in RAID 10 array
Operating System	**Note: SUSE Linux Enterprise Server (Version 11, Patch Level 2)**
Network Requirements	Static IP address or DHCP reservation required Multicast configuration on network backbone devices
Dimensions (Single Appliance, may vary)	H: 43.0 cm x W: 43.4 cm x L: 62.7 cm (w/o ear, w/o bezel) H: 1.7 in x W: 17.1 in x L: 24.7 in
Weight (Single Appliance)	35.02 lb (15.9 kg) (Maximum configuration weight)
Power Requirements (Single Appliance)	100-240 VAC, 50-60 Hz, 7 A - 3.5 A w/ redundant power supply
Backup Power Requirement (Full System)	Customer supplied Uninterruptable Power Supply and Hospital Emergency Power recommended.

11.3.8 ViSi Mobile Remote Viewer

ViSi Mobile Remote Viewer (Desktop PC with Touchscreen Display)	
No. of Patients per Remote Viewer	Maximum 32
Display	23 in display / 1920 x 1080 resolution (screen is touch sensitive to issue commands alternative to mouse/keyboard)
Processor	Intel i5 2400 CPU 4 Core 3.10 GHz 4 GB Memory
Storage	One 500 GB 7200 RPM SATA
Operating Systems	Microsoft® Windows® 7 Professional (version 6.1) x64 Bit SP1
Network Requirements	Ethernet Connection, DHCP
Dimensions	H: 45.0 cm x W: 58.5 cm x D: 10.3 cm H: 17.7 in x W: 23.0 in x D: 4.1 in
Weight	26.7 lb (12.1 kg)
Power Requirements	AC/DC Adapter Input: 100-240 V ~3.5 A, 50-60 Hz Output to Viewer: 19.5 V / 11.8 A
Backup Power Requirement	Customer supplied Uninterruptable Power Supply and Hospital Emergency Power recommended.

Note: Sotera Wireless recommends installation of Trend Micro anti-virus software on Windows platforms. Anti-virus software is not installed on the ViSi Mobile Appliance.

Note: For printing capability, Sotera Wireless recommends connecting a printer directly to the ViSi Mobile Remote Viewer or to an in-network printer via an IP address. Sotera Wireless does not support additional configurations.

11.3.9 Customer Network

Wireless Network	
Wireless Network Standard	IEEE 802.11b
Recommended Channels	1, 6, 11
Network Latency	< 150 ms
Wireless Network Security Support	WPA2-PSK
Minimum Receiver Sensitivity	-65 dBm (edge coverage)
Wireless access point cell overlap	15-20%
Signal-to-Noise Ratio	≥25 dB
Packet loss	≤6%
SSID	Dedicated or shared with other medical devices

Wired Network	
Appliance (Server)	Requires static IP Address
Network availability	>99.9%

11.4 Alarms / Alerts Annunciation

Note: An "Annunciation Delay" is the time that an alarm system deliberately delays the alarm annunciation (audibly and visually) to ensure clinical relevance of the detected alarming condition. Within the tables below, see column "Annunciation Delay" for the pre-defined periods of time.

Note: When the ViSi Mobile Monitor is connected to a network (as indicated by the network symbol in the top left hand corner of the display), the audio annunciation of non-life-threatening alarms/alerts will be deferred to the ViSi Mobile Remote Viewer for a pre-configured period of time. Within the tables below, see column "Deferral Delays" for the pre-defined periods of time.

11.4.1 Physiological Alarms (Alarms)

Visual Display

The following table outlines the visual display when alarms are in progress:

Severity	Indicator Attributes	Toggle / Flash Speed	Duty Cycle
High Priority	Red	1.5 Hz	50% ON
Life-Threatening Priority	Red / White	1.5 Hz	50% ON

Audio Tones

The following table outlines the audio tones when alarms are in progress:

Severity	Melody[a]	Volume [dB]	Frequency (f_o) [Hz]	Duration (t_d) [ms]	Spacing (t_s) [ms]	5th-6th [s]	Inter-Burst (t_b) [s]
Life Threatening	b5.b5.b5..b5.b5	78	987.767	100	50	0.35	2.5
High	b5.b5.b5..b5.b5	78	987.767	200	100	0.35	5

a. Melodies are defined as musical notes.

Alarm Limits and Delays (factory default settings).

Vital Sign	Lower Limit		Upper Limit		Annunciation Delay[a] (seconds)		Deferral Delay (seconds)
	Care Unit	Patient	Patient	Care Unit	Patient	Care Unit[b]	
Critical Low HR (BPM)	18	18	N/A	N/A	5	5	30
Heart Rate (BPM)	30	30	150	200	5	5	60
Pulse Rate (BPM)	30	30	150	200	30	30	60
BP Systolic (mmHg)	70	OFF	190	240	60	30	90
BP Diastolic (mmHg)	40	OFF	OFF	150	60	30	90
BP MAP (mmHg)	60	65	OFF	170	60	30	90

Vital Sign	Lower Limit		Upper Limit		Annunciation Delay[a] (seconds)		Deferral Delay (seconds)
	Care Unit	Patient	Patient	Care Unit	Patient	Care Unit[b]	
Respiration (BR/MIN)	4	4	35	40	120	60	90
SpO_2 (%)	85	85	N/A	N/A	30	30	60
Skin Temperature	N/A	N/A	N/A	N/A	N/A	N/A	N/A

a. When measurement blood pressure as a 1-time measurement or at automatic intervals, there will be no annunciation delay.
b. As the vital sign measurement approaches the care unit limit, the annunciation delay will decrease linearly.

No Pulse Detected Alarms	Limit	Delays	
		Annunciation	Deferral
When Thumb Sensor is primary source	No Pulse	No delay	60
When Cuff Module is primary source	No Pulse	No delay	60

Battery Alarms

	Battery Alarms	Limit	Delays (in seconds)	
			Annunciation	Deferral
Monitor	Monitoring Mode	45ºC (113ºF)	No delay	No deferral
	In the Charger	45ºC (113ºF)	No delay	N/A
	Not monitoring / Not in the Charger	45ºC (113ºF)	No delay	N/A
Cuff Module	Connected to the Monitor	45ºC (113ºF)	No delay	No deferral
	In the Charger	45ºC (113ºF)	No delay	N/A
	Not monitoring / Not in the Charger	45ºC (113ºF)	No delay	N/A

11.4.2 Equipment Alarms (Alerts)

Visual Display

The following table outlines the visual display when alerts are in progress:

Severity	Indicator Attributes	Toggle / Flash Speed	Duty Cycle
All Severities	Cyan (Blue)	Constant (ON)	100% ON

Audio Tones

The following table outlines the audio tones when alerts are in progress:

Severity	Melody[a]	Volume [dB]	Frequency (f_o) [Hz]	Duration (t_d) [ms]	Spacing (t_s) [ms]	Inter-Burst (t_b) [s]
High	e5.c5	68/63	659.255, 523.251	250	250	15

a. Melodies are defined as musical notes.

Note: There are no audio tones associated with low severity alerts.

Alarm Limits and Delays (factory default settings)

Chest Sensor Alerts	Limit (if applicable)	Audible Alert	Delays (in seconds)	
			Annunciation	Deferral
ECG Lead Failure	N/A	No	No delay	N/A
All ECG Lead Failure	N/A	No	No delay	N/A
Chest Sensor Disconnected	N/A	No	No delay	N/A
General Fault Detected	N/A	No	No delay	N/A
Multiple Connections	N/A	No	No delay	N/A
Temperature Sensor Fault	N/A	No	No delay	N/A
Accelerometer Fault - Chest Module	N/A	No	No delay	N/A
Accelerometer Fault - Upper Arm	N/A	No	No delay	N/A

Thumb Sensor Alerts	Limit (if applicable)	Audible Alert	Delays (in seconds)	
			Annunciation	Deferral
Thumb Sensor Off	N/A	No	< 30	N/A
Thumb Sensor Disconnected	N/A	No	No delay	N/A

Cuff Module Alerts	Limit (if applicable)	Audible Alert	Delays (in seconds)	
			Annunciation	Deferral
Low Battery	4% to 10%	No	No delay	N/A
Battery Empty	< 4%	No	No delay	N/A
Check Cuff	N/A	No	No delay	N/A
Cuff Occluded	N/A	No	No delay	N/A
NIBP Unobtainable	N/A	No	No delay	N/A
Invalid Software Loaded	N/A	No	No delay	N/A
Pressure Accuracy Fault	N/A	No	No delay	N/A
General Fault Detected	N/A	No	No delay	N/A
Pressure Exceeded	300mmHg	Yes	No delay	No deferral
Multiple Connections	N/A	No	No delay	N/A

Wrist Monitor Alerts	Limit (if applicable)	Audible Alert	Delays (in seconds)	
			Annunciation	Deferral
Calibrate cNIBP	N/A	N/A	No delay	N/A
Low Battery	3 hours	No	No delay	N/A
Critical Low Battery	1 hour	No	No delay	N/A
Too Low to Monitor	10 minutes	No	No delay	N/A
Invalid Plug Connected	N/A	Yes	No delay	No deferral
Audio System Failure	N/A	No	No delay	N/A
Wireless Radio Failure	N/A	No	No delay	N/A
All Sensors Disconnected	N/A	No	No delay	N/A
Accelerometer Failure	N/A	No	No delay	N/A
Shock Hazard	N/A	Yes	No delay	No deferral
Patient Tampering (number of incorrect pin code entries)	5 invalid pin codes	No	No delay	N/A

11.5 Environmental Conditions

Environmental Conditions for all ViSi Mobile Components (Monitor, Cuff Module, Chest Sensor Cable, Cuff, Thumb Sensor)		
Condition	**Storage (Packaged / Unpacked)**	**Operating (Unpack aged)**
Temperature	-20°C to +55°C (50°C for NIBP) -4°F to +131°F (122°F for NIBP)	0°C to +50°C / 32°F to +122°F Battery Charger: 0°C to +40°C
Humidity	15% to 95% non-condensing (90% for NIBP)	10% to 95% non-condensing (90% for NIBP)

Environmental Conditions for all ViSi Mobile Components (Monitor, Cuff Module, Chest Sensor Cable, Cuff, Thumb Sensor)		
Condition	**Storage (Packaged / Unpacked)**	**Operating (Unpack aged)**
Atmospheric Pressure Range	107 kPa to 50 kPa 803 mmHg to 375 mmHg 1.06 atm to 0.49 atm	107 kPa to 70 kPa 803 mmHg to 525 mmHg 1.06 atm to 0.69 atm

The ViSi Mobile Monitor may not perform to specification if stored or shipped outside the specified temperature range.

11.6 Compliances

Observe any national regulations on the qualification of the testing personnel and suitable measuring and testing facilities. See *User Maintenance on page 127* for a list of required tests.

11.6.1 Federal Communications Commission (FCC)

The equipment device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) This device must accept any interference received including interference that may cause undesired operation.

Changes or modifications not expressly approved by Sotera Wireless could void the user's authority to operate the equipment. Manufacturer is not responsible for any radio or TV interference caused by unauthorized modifications to this equipment.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference 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 relocate 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

This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

Class B digital device notice / "CAN ICES-3 (B)/NMB-3(B)".

This equipment complies with the FCC/IC radiation exposure limits set fourth for portable transmitting devices operation in a controlled environment. End users must follow the specific operating instructions to satisfy RF exposure compliance.

The equipment should only be used where there is normally at least 22.651mm separation between the antenna and all person/user.

This transmitter must not be co-located or operation in conjunction with any other antenna or transmitter.

Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.

11.6.2 Electromagnetic Compatibility (EMC) Specifications

Take special precautions regarding electromagnetic compatibility (EMC) when using medical electrical equipment. Operate your monitoring equipment according to the EMC information provided in this manual. Portable and mobile radio frequency (RF) communications equipment can affect medical electrical equipment.

Consult your Biomed department or vendors for assistance in identifying EMC compliance status of other medical devices when using the ViSi Mobile Monitoring System.

Accessories Compliant with EMC Standards

All accessories (e.g. ViSi Mobile Charger) comply with either IEC 60601-1-2 or IEC 60950-1.

Using accessories other than those specified may result in increased electromagnetic emission or decreased electromagnetic immunity of the monitoring equipment.

11.6.3 Electromagnetic Emissions

The ViSi Mobile Monitor is suitable for use in the electromagnetic environment specified in the table below. Ensure that the Monitor is used in such an environment.

Emissions Test	Compliance	Avoiding Electromagnetic Interference
Radio Frequency (RF) emissions	Group 1	The ViSi Mobile Monitor uses RF energy only for its internal function[a]. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The ViSi Mobile Monitor is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations IEC 61000-3-3	N/A	

a. The battery operated ViSi Mobile Monitor contains a 2.4 GHz DSSS transmitter for the purpose of wireless communication. The radio is excluded for the EMC requirements of IEC 60601-1-2, but should be considered when addressing possible interference issues between this and other devices.

11.6.4 Electromagnetic Immunity

The ViSi Mobile Monitor is suitable for use in specified electromagnetic environment. The user must ensure that it is used in the appropriate environment as described below.

Immunity Test	IEC 60601-1-2		Electromagnetic Environment Guidance
	Test Level	Compliance Level	
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical medical and/or hospital environment.
Surge IEC61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical medical and/or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycles	<5% UT (>95% dip in UT) for 0.5 cycles	
	40% UT (60% dip in UT) for 5 cycles	40% UT (60% dip in UT) for 5 cycles	
	70% UT (30% dip in UT) for 25 cycles	70% UT (30% dip in UT) for 25 cycles	
	<5% UT (>95% dip in UT) for 5 sec	<5% UT (>95% dip in UT) for 5 sec	
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical cial and/ or hospital environment.

In the above table, UT (Unit in Test) is the ViSi Mobile Monitoring System.

11.6.5 Recommended Separation Distance

The ViSi Mobile Monitor may be temporarily interrupted by UHF RFID Systems (860-960MHz).

Portable and mobile RF communications equipment should be used no closer to any part of the ViSi Mobile Monitor, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter.

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.

Interference may occur in the vicinity of equipment marked with this symbol: 

In the following table, P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).

Immunity Test	**IEC 60601-1-2 Test Level**	**ViSi Mobile Monitoring System Compliance Level**	**Electromagnetic Environment Guidance**
Conducted RF IEC 61000-4-6	3 V_{RMS} 150 kHz to 80 MHz	3 V_{RMS}	Recommended separation distance: $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Recommended separation distance: 80 MHz to 800 MHz 80 MHz to 800 MHz $d = 3.5\sqrt{P}$ 800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$ 2.0 to 2.3 GHz for short radio $d = 7.0\sqrt{P}$

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

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

From Portable and Mobile RF Communication Equipment

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

In the following table, P is the maximum power output rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).

Frequency	**150 kHZ to 80 MHz**		**80 MHz to 800 MHz**		**800 MHz to 2.5 GHz**	
Equation	**$d = 1.2\sqrt{P}$**		**$d=1.2\sqrt{P}$**		**$d=2.3\sqrt{P}$**	
Rated max. output power of transmitter	**Separation Distance**		**Separation Distance**		**Separation Distance**	
	(m)	**(ft)**	**(m)**	**(ft)**	**(m)**	**(ft)**
0.01 W	0.1	0.4	0.1	0.4	0.2	0.8
0.1 W	0.4	1.2	0.4	1.2	0.7	2.4
1 W	1.3	3.9	1.3	3.9	2.3	7.5
10 W	3.8	12.4	3.8	12.4	7.3	23.9
100 W	12.0	39.4	12.0	39.4	23.0	75.5

Electrosurgery Interference/Defibrillation/Electrostatic Discharge

The equipment returns to the previous operating mode within 10 seconds without loss of any stored data. Measurement accuracy may be temporarily decreased while performing electrosurgery or defibrillation. This does not affect patient or equipment safety. Do not expose the equipment to x-ray or strong magnetic fields (MRI).

Fast Transients/Bursts

The equipment will return to the previous operating mode within 30 seconds without loss of any stored data.

11.6.6 Standards

Agency Compliances
• ANSI/AAMI EC13, Cardiac monitors, heart rate meters, and alarms • ANSI/AAMI EC53, ECG cables and lead-wires. • CAN/CSA C22.2 No 601.1 M90 Part 1: General requirements for basic safety and essential performance • EN 1060-1:1995 Non-invasive sphygmomanometers - Part 1: General requirements • EN 1060-3:1997 Non-invasive sphygmomanometers - Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems • IEC 60601-1 Medical electrical equipment - Part 1: General requirements for safety • IEC 60601-1-2, Med. Elect. Equipment – Part 1-2: General requirements for safety – Collateral standard: EMC – Req. and tests. • IEC 60601-1-4, Medical electrical equipment - Part 1-4: General requirements for safety – Collateral standard: Programmable electrical medical systems • IEC 60601-1-6, Medical electrical equipment – Part 1-6: General requirements – Collateral standard: Usability. • IEC 60601-1-8, Medical electrical equipment – Part 1-8: Gen. req. – Col. Std. Gen. requirements, tests and guidance for alarm systems • IEC 60601-2-27, Medical electrical equipment, Part 2-27: Particular requirements or the safety, including essential performance, of ECG monitoring equipment • IEC 80601-2-30, Medical electrical equipment – Part 2-30: Particular requirements for the safety, including essential performance, of auto. cycling non-invasive BP monitoring equipment. • IEC 60601-2-49, Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multi-function patient monitoring equipment. • ISO 9919, Medical electrical equipment - Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use. • ISO 81060-2, Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type. • UL 60601-1 Part 1: General requirements for basic safety and essential performance

11.7 Wireless Network Risk Mitigation

Reference: ISO 80001-1

ViSi Mobile System utilizes the Responsible Organization's wireless IT network to communicate between individual ViSi Mobile Monitors connected to patients and the ViSi Appliance. Physiologic data and alarms originating from the ViSi Mobile Monitors are transmitted over the IT network to the ViSi Mobile Remote Viewer where supplemental alarm notification occurs. Reliability of the IT network is essential in ensuring the supplementary alarm notification meets the intended use.

Other RF radiating devices (such as high powered RFID readers and Bluetooth devices) that are in close proximity with the ViSi Mobile Monitor may interfere with the Monitor's wireless communications. During such interference, the Monitor continues to monitor and will alarm locally. If wireless communication is affected when using the Monitor in close proximity with another RF radiating device, move the other device away from the Monitor or discontinue use of the other device.

Perform a risk assessment and verification before implementing a change or modification to the IT infrastructure. Changes to IT network configurations can compromise continuous vital signs monitoring and alarm delivery.

11.7.1 Risk Analysis Summary

- The ViSi Mobile Monitors are the source of all alarms and alerts.
- The ViSi Mobile Remote Viewer provides a supplemental alarm notification. When connectivity is present audio alarms are deferred to the ViSi Mobile Remote Viewer.
- In the event that network connectivity is lost, all audio alarms are annunciated at the ViSi Mobile Monitors. A connectivity lost alert is annunciated at the ViSi Mobile Remote Viewer.

11.7.2 Residual Risks

Loss of network connectivity will result in failure in supplemental alarm notification to the ViSi Appliance and ViSi Mobile Remote Viewer. Management of this risk is the responsibility of the Responsible Organization for the IT Network. This risk is minimized with the following mitigations:

Sotera Responsibilities

- Sotera Inc network assessment prior to installation.
- Sotera Inc verification that the Responsible Organization network meets ViSi Mobile System connectivity requirements at the time of installation.
- Hand over protocol with all settings/configurations as installed and configured (Training)

Responsible Organization Responsibilities

- Conduct a risk assessment of the IT Network prior to installation and mitigate technical risk.
- Maintain backup and emergency power resources for ViSi System network components.
- Maintain network configuration post installation of the ViSi Mobile System.
- Notify Sotera prior to modifications to the network, including any configurations changes that could potentially compromise the IT Network as verified at the initial installation of the ViSi System. For support contact Sotera Wireless or an authorized Sotera Wireless representative in your area.

- Notes -

Appendix A - Alarm Summary

Patient Alarms

Life Threatening Alarms

Display Message	Symbol(s)	Alarm Summary	Cause
CRITICAL LOW HR		Critical Low Heart Rate	Patient's heart rate is less than 18 BPM. **Note: The patient's posture will toggle white/red.**
MONITOR TOO HOT		Monitor - Battery Over-Temperature Failure	• Battery in the Monitor has exceeded a safe temperature. • The Chest Module has exceeded a safe temperature. ***Return the Monitor and the Chest Sensor to Sotera Wireless.***
CUFF BATTERY TEMP		Cuff Module - Battery Over-Temperature Failure	Battery in the Cuff Module has exceeded a safe temperature. ***Return the Cuff Module to Sotera Wireless.***

When the "Monitor Too Hot" alarm is in progress, ViSi Mobile Monitoring System should be removed from the patient immediately. Leaving on the patient for an extended period of time may lead to a skin burn.

When the "Cuff Battery Temp" alarm is in progress, ViSi Mobile Cuff Module should be removed from the patient immediately. Leaving on the patient for an extended period of time may lead to a skin burn.

Note: When the Cuff Module is in the Charger, the LED on the front of the Cuff Module will display red.

High Alarms 

Display Message	Alarm Summary	Cause
THUMB NO PULSE	SpO_2 Module - No Pulse Detected	Unable to detect a pulse from the Thumb Sensor. Thumb Sensor is the primary source of PR.
CUFF NO PULSE	Cuff Module - No Pulse Detected	Chest Sensor Cable and Thumb Sensor are not connected. Cuff Module is the only source of PR. Unable to detect a pulse from the cuff inflation.
HIGH PULSE RATE	High Pulse Rate	Pulse rate exceeds the defined upper alarm limit.
LOW PULSE RATE	Low Pulse Rate	Pulse rate is less than the defined lower alarm limit
HIGH HEART RATE	High Heart Rate	Heart rate exceeds the defined upper alarm limit.
LOW HEART RATE	Low Heart Rate	Heart rate is less than the defined lower alarm limit.
HIGH BP SYSTOLIC	BP - High Systolic	Systolic pressure exceeds the defined upper alarm limit.
LOW BP SYSTOLIC	BP - Low Systolic	Systolic pressure is less than the defined lower alarm limit.
HIGH BP DIASTOLIC	BP - High Diastolic	Diastolic pressure exceeds the defined upper alarm limit.
LOW BP DIASTOLIC	BP - Low Diastolic	Diastolic pressure is less than the defined lower alarm limit.
HIGH BP MAP	BP - High MAP	MAP pressure exceeds the defined upper alarm limit.
LOW BP MAP	BP - Low MAP	MAP pressure exceeds the defined lower alarm limit.
HIGH RESP	High Respiration	Respiration exceeds the defined upper alarm limit.
LOW RESP	Low Respiration	Respiration is less than the defined lower alarm limit.
LOW SpO_2	Low SpO_2	SpO_2 is less than the defined lower alarm limit.

Equipment Alerts

ViSi Mobile Monitor Alerts

Display Message	Symbol(s)	Severity	Cause	Solution
AUDIO FAILURE		Low	Either the microphone or the speaker on the Monitor has failed.	Stop monitoring and replace the Monitor. Return the Monitor to Sotera Wireless, Inc.
WIRELESS RADIO		Low	The wireless radio in the Monitor is not transmitting.	Stop monitoring and replace the Monitor. Return the Monitor to Sotera Wireless, Inc.
MONITOR BATTERY CRITICAL		Low	Monitor battery charge is critically low.	Replace the Monitor.
MONITOR BATTERY LOW		Low	Monitor battery charge is low.	Prepare to replace the Monitor.
UNABLE TO MONITOR		Low	Battery in the Monitor is too low to continue monitoring.	Replace the Monitor.
CONNECT TO PATIENT	N/A	Low	A sensor has been connected to the Monitor but not yet applied to the patient. No vital sign measurement has been detected.	Apply the sensor to the patient.
ACCEL MONITOR		Low	Unexpected error occurred with the accelerometer in the Monitor.	Replace the Monitor and return it to Sotera Wireless, Inc.

ViSi Mobile Chest Sensor Cable and ECG Alerts 

Display Message	Severity	Cause	Solution
CHEST SENSOR	Low	The Chest Sensor Cable is disconnected from the Monitor and not yet acknowledged by the clinician.	Acknowledge the alert and remove the Chest Sensor Cable from the patient, or reconnect the Chest Sensor Cable to the Monitor.
	Low	More than one Chest Sensor Cable is simultaneously connected to the Monitor.	Remove the extra Chest Sensor Cable(s) from the Monitor.
CHEST FAULT	Low	Various failure modes related to the Chest Sensor Cable.	Replace the Chest Sensor Cable and return it to Sotera Wireless, Inc.
	Low	The Chest Sensor Cable does not contain the correct software.	Replace the Chest Sensor Cable and return it to your biomedical engineer.
ECG LEAD (+ lead label)	Low	One or more lead-wires have failed.	Reconnect the ECG electrode, if necessary. Replace the ECG electrode, if necessary.
ECG LEADS	Low	All ECG lead-wires have failed.	Reconnect the lead-wires to the ECG electrodes. Replace the ECG electrodes if necessary.
TEMPERATURE FAULT	Low	Unexpected error occurred with the Temperature Sensor.	Replace the Chest Sensor Cable and return it to Sotera Wireless, Inc.
ACCEL. CHEST	Low	Unexpected error occurred with the accelerometer in the Chest Sensor Cable.	Replace the Chest Sensor Cable and return it to Sotera Wireless, Inc.
ACCEL. UPPER ARM	Low	Unexpected error occurred with the Upper Arm accelerometer.	Replace the Chest Sensor Cable and return it to Sotera Wireless, Inc.

Use all of the same type of high quality ECG electrodes on the patient. Mixing ECG electrode types can adversely affect ECG monitoring.

ViSi Mobile Thumb Sensor and SpO2 Alerts

Display Message	Severity	Cause	Solution
THUMB SENSOR	Low	The Thumb Sensor has been disconnected from the Monitor and has not yet been acknowledged by the clinician.	Acknowledge the alert, or reconnect the Thumb Sensor to the Monitor.
THUMB SENSOR OFF	Low	The optical signal has been lost.	Reposition the Thumb Sensor at the base of the patient's thumb. Replace the Thumb Sensor.

ViSi Mobile Cuff Module and NIBP Alerts

Display Message	Severity	Cause	Solution
CHECK CUFF	Low	An issue has been found with the cuff during inflation	Check the connection between the Cuff and the Cuff Module. Check the Cuff for damage.
CUFF OCCLUDED	Low	Something is blocking the air from being pumped into the Cuff.	Check for a kinked hose. Check to make sure that the connection between the Cuff and the Cuff Module is not blocked.
NIBP UNOBTAINABLE	Low	NIBP measurement is unobtainable.	Make sure that the Cuff is positioned on the arm correctly, and wrapped snugly around the arm.
CUFF MODULE	Low	The Cuff Module is disconnected from the Monitor and the alert is not yet acknowledged by the clinician.	Acknowledge the alert and either reconnect the Cuff Module to the Monitor or remove the Cuff Module from the Cuff and remove the Cuff from the patient.
	Low	More that one Cuff Module is simultaneously connected to the Monitor.	Remove the extra Cuff Module(s) from the Monitor.
CUFF MODULE 300 mmHg	High	A pressure of 300mmHg was reached when inflating the Cuff.	Check the patient. Make sure that the Cuff is positioned on the arm correctly, and wrapped snugly around the arm.

Display Message	Severity	Cause	Solution
CALIBRATION FAILED	Low	An attempt to calibrate cNIBP has failed.	• Make sure the cuff is positioned on the arm correctly and wrapped snugly around the arm. • Ensure the patient remains still during the calibration process.
CALIBRATE cNIBP	Low	A recalibration event has occurred.	Calibrate cNIBP.
NIBP FAULT	Low	Cuff accuracy “zero pressure” test failed.	Return the Cuff Module to your biomedical engineer. Replace with another Cuff Module.
	Low	The Cuff Module does not contain the correct software.	Replace the Cuff Module and return it to your biomedical engineer.
	Low	This can indicate various failure modes related to the Cuff Module.	Replace the Cuff Module and return it to Sotera Wireless, Inc.
NIBP LOW BATTERY	Low	Battery in the Cuff Module is low.	Replace the Cuff Module with one that has a full battery charge.
NIBP EMPTY BATTERY	Low	Battery in the Cuff Module is empty. No measurements are possible.	Replace the Cuff Module with one that has a full battery charge.

Miscellaneous Alerts

Display Message	Symbol(s)	Severity	Cause	Solution
INVALID PLUG		High	During monitoring the Bio Med or Shipping Plug has been connected to the rounded end of the Monitor.	Remove the invalid Plug.
PATIENT TAMPERING		Low	Someone has unsuccessfully attempted to log into the Monitor.	Enter the correct PIN and check settings to confirm nothing has changed.
SENSORS DISCONNECT		Low	All sensor connections to the Monitor have been removed without going through the Stop Monitoring process.	Either reconnect the sensor(s) to the Monitor or stop monitoring using the Stop Monitoring process.
SHOCK HAZARD		High	Cuff Module has been placed in the Charger while still connected to the Monitor.	Remove the Cuff Module from the Charger or disconnect the Cuff Module from the Monitor.

ViSi Mobile Charging Alerts

Display Message	Severity	Cause	Solution
CHARGE CURRENT FAULT	High	Monitor charging over current protection error.	Remove the Monitor from the Charger and contact Sotera Wireless, Inc. Customer Service.
CHARGE TEMP FAULT	High	Monitor charging over temperature protection level.	Remove the Monitor from the Charger and contact Sotera Wireless, Inc. Customer Service.
CHARGE VOLTAGE FAULT	High	Voltage level has exceeded the limit when the Monitor is in the Charger.	Remove the Monitor from the Charger and contact Sotera Wireless, Inc. Customer Service.

ViSi Mobile Monitor Status Icons

Battery Charge

Battery Icon	Status
	The battery status in the ViSi Monitor is good. **Note: The fill level will diminish as the battery level goes down.**
	The battery in the ViSi Monitor is low. There is less than 3 hours of monitoring available.
	The battery in the ViSi Monitor is critically low. There is less than 1 hour of monitoring available.
	The battery in the ViSi Monitor is too low to continue monitoring. There is less than 10 minutes of battery charge left.

Wireless Radio Signal Strength

Signal Strength Icon	Status
	Connectivity between the ViSi Monitor to the Appliance is good. The number of green bars indicate the signal strength.
	The ViSi Mobile Monitor recognizes the network but is unable to connect to the Appliance. The number of yellow bars indicates the signal strength.
	Connectivity between the ViSi Mobile Monitor and the Appliance has been lost. **Note: This connectivity lost icon is only displayed on the ViSi Mobile Remote Viewer.**

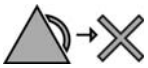
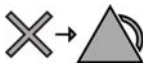
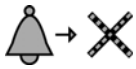
Appendix B - Symbols

Alarms / Alerts

Alarm / Alert States

Symbol	Description
	Unacknowledged life threatening severity alarm in progress.
	Unacknowledged high severity alarm in progress
	Unacknowledged alert in progress (any severity).
	All alarms in progress have been acknowledged by the clinician.
	Alarm annunciation (visual and audio) has been paused for 2 minutes.
	Alarm annunciation (visual and audio) has been turned off.

Alarm Management

Symbol	Description
	Pause alarm annunciation (visual and audible) for 2 minutes.
	Turn off alarm annunciation (visual and audible).
	Resume alarm annunciation from a paused state.
	Turn alarm annunciation back on.
	Acknowledge an alarm/alert that is in progress.

Battery States

Symbol	Description
	Battery good: the Monitor’s battery is fully charged.
	Battery Low: the Monitor’s battery voltage is low.
	Battery Critically Low: the Monitor’s battery voltage is critically low.

General Icons

Out of Range Vital Signs

Symbol	Description
+++	Vital sign measurement is above the upper display range.
---	Vital sign measurement is below the lower display range.

Navigation

	Unlock the ViSi Mobile Monitor to gain access to the clinical features.
	Lock the ViSi Mobile Monitor to prevent unwanted access to the clinical features.
	Confirm activity.
	Cancel activity.
	Return to the previous screen.

Vital Signs Menu

Symbol	Description
	Access to the clinical menu.
	Start a manual cuff inflation. Cuff inflations are set up to be taken on an ad hoc basis.
	Start a manual cuff inflation. Cuff inflations are set up to be taken automatically at a selected time interval.
	Start a manual cuff inflation. Blood pressure measurements are set up to be continuous after the initial calibration.

Symbol	Description
	Calibrate NIBP for continuous measurements.
	Stop a cuff inflation currently in progress.

Clinical Menu

Symbol	Description
	BP management. Setup the cuff inflation intervals or define as ad-hoc only inflations.
	Initiate the pause/stop monitoring sequence.
	Initiate the stop monitoring sequence.
	Initiate the pause monitoring sequence.
	Access information regarding the ViSi Mobile Monitor: Monitor ID, MAC address, Serial #, software version installed and battery status.
	Alarm management. Review the patient's current alarm limits, adjust the alarm limits using "Auto Set" or turn off the alarm annunciation.
	QRS beep is turned on.
	QRS beep is turned off.

Other

Symbol	Description
	Change a patient's alarm limits using "Auto Set".
	Setup cuff inflation to be on an ad hoc basis.
	Setup cuff inflation such that the cuff will inflate at defined intervals.
	Setup cuff inflation such that NIBP measurements will be taken on a continuous basis.

Patient's Postures

Unknown Posture

Symbol	Description
	Patient is currently out of the network.[a]
	Patient's posture has not been selected and confirmed on the ViSi Mobile Monitor. There are no alarm conditions in progress.
	Patient's posture has not been selected and confirmed on the ViSi Mobile Monitor. A life-threatening alarm condition is in progress.[b]
	Patient's posture has not been selected and confirmed on the ViSi Mobile Monitor. When the question mark is static red, a high alarm condition is in progress.

a. The ViSi Mobile Monitor always displays the question mark in gray irrespective of the alarm status.
b. In the event of a life-threatening alarm, the question mark above the patient symbol will toggle white/red.

Postures

Symbol	Description
	Patient's torso is in an upright position.
	Patient's torso is at a reclined position.
	Patient is lying in a supine position.
	Patient is lying on their front.
	Patient is lying on their right side.
	Patient is lying on their left side.

Note: In the event of an alarm, the patient's posture will be displayed in the color associated with the alarm severity.

Labelling

Symbol	Description
	Warning, refer to accompanying documents
	Caution, refer to accompanying documents
	WiFi Alliance certification
	Conforms with EEC directives
	Catalog number
	Serial Number
	Manufactured By
	Defibrillator proof type CF equipment
	This product is designated for separate collection at an appropriate collection point. Do not dispose of as household waste.
Li-ion	Lithium Ion battery
IPX0	No special protection.
IPX7	Protected against water immersion. Immersion for 30 minutes at a depth of 1 meter.
	Latex free
	Do not reuse
	Fragile

Symbol	Description
CONT	Contents
	MRI Unsafe

- Notes -

Appendix C - Warranty

Warranty

Sotera warrants to End User, for a period of one (1) year from the date of delivery, unless otherwise noted in specific documentation, that the products sold by Sotera will operate in accordance with Sotera's published documentation in effect on the date of delivery or Sotera will, at its sole discretion and expense, repair or replace the products. Replacements will be warranted for the remainder of the warranty period in effect on the original product purchased, unless otherwise mandated by applicable law. Products include Sotera equipment only but does not include disposables / consumables. Sotera warrants that its disposables / consumables products will be free from defects in workmanship and materials for a period of one (1) year from the date of purchase or the expiration date whichever occurs first.

Third Party Branded Products

Sotera will not be deemed to provide, nor be responsible for, warranty, related remedy or support with respect to hardware, software or services purchased from a third party unless such party is a Sotera authorized partner services Sotera Products and Services, unless otherwise agreed in writing between the parties.

Typically, in case of a defective 3rd party item under warranty, Sotera will make arrangements with the 3rd party manufacturer to issue a replacement. The replacement will be sent directly to the End User site from the 3rd party manufacturer. No Return Material Authorization (RMA) will be issued by Sotera, instead a Sotera Case Number will be issued for the reported issue. The End User is responsible for complying with the manufacturer's replacement procedures.

Warranty Exclusions

Sotera will not be liable under this warranty if its testing and/or examination discloses that the alleged defect in the Sotera equipment does not exist or was caused by end user's or any unauthorized third person's misuse, neglect, improper installation or testing, attempts to repair, or any other cause beyond the scope of the intended use, or by accident, fire, lightning or other hazard or event of force majeure. The warranty for any hardware will become void if a hardware component is installed as an add-on and or replacement part on the original hardware and such component part has not been approved for such inclusion by Sotera. The warranty for software will voided if the software is modified, except as authorized in writing by Sotera.

In no event shall Sotera be liable to end user or any third parties for any consequential, incidental, indirect, exemplary, punitive, contingent, statutory or any other special damages. Sotera's liability for damages on account of a claimed defect in any product delivered by Sotera shall in no event exceed the purchase price of the product on which the claim is based. Specifically, and without limiting the generality of the foregoing, Sotera shall not be responsible or liable to end user or any third party for any lost profits, or any consequential, incidental, punitive, contingent, statutory or any other special damages for any breach of warranty or other breach of Sotera's obligations under this agreement. Sotera shall not be liable for damages relating to any instrument, equipment, or apparatus with which the product sold under this agreement is used. In addition, Sotera disclaims all liability of any kind of Sotera's suppliers.

The foregoing warranties and remedies are exclusive and are in lieu of all other warranties, express or implied, either in fact or by operation of law, statutory or otherwise including warranties of merchantability and fitness for a particular purpose or non infringement.

Sotera does not assume or authorize any other person to assume for it any other or greater liability in connection with the sale, installation, servicing, maintenance or use of Sotera hardware, and Sotera makes no warranty whatsoever with respect to any third-party branded products supplied by it hereunder.

Sotera Wireless Responsibility

Sotera Wireless Inc. is responsible for the effects on safety, reliability and performance of the equipment only if:

1. Assembly operations, extensions, readjustments, modifications or repairs are carried out by persons authorized by Sotera Wireless Inc. and
2. The equipment is used in accordance with the instructions for use.

Contact Sotera Wireless

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Index

R

S

T

V

W