Monitoring System

User manual

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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, Inc. ViSi Mobile Monitoring System. The suite of manuals consists of:

- ViSi Mobile Monitoring System User Manual
- ViSi Mobile Remote Viewer User Manual
- ViSi Mobile Technical Reference Manual
-

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.

1.2 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-wire), respiration rate (RESP), heart rate (HR), non-invasive blood pressure (NIBP), continuous non-invasive blood pressure (cNIBP), non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate (PR), skin temperature (TEMP) in hospital-based facilities; including general medical-surgical floors, intermediate care floors, and emergency departments.

The ViSi Mobile Monitoring System may be used as standalone devices or networked to ViSi Mobile Remote Viewers 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 evaluated 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 accuracy of the ViSi Mobile Monitoring System’s NIBP and cNIBP monitoring has not been established in the presence of any dysrhythmias.
- Continuous non-invasive blood pressure (cNIBP) measurements have not been evaluated on patients during ambulation.

2. ViSi Mobile 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: Statements provide supplemental information to the user.

2.2 Warnings 

Intended Use

Do not use the ViSi Mobile Monitoring System or Power Pack 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 evaluated for these patient groups.Do not use the ViSi Mobile Monitor as a primary hypoxia diagnostic tool.

Safety

The ViSi Power Pack is not intended to be worn by the patient.

Do not modify the ViSi System in any way.

Do not use the ViSi Mobile Monitor, Cuff Module, Chest Sensor or Power Pack in an MRI suite or a hyperbaric chamber.

The ViSi System is protected against damage from electrosurgery. Avoid electrosurgery burns at the ECG monitoring sites by ensuring the electrosurgery-return circuit is connected properly and monitoring electrodes are located as far as possible from the electrosurgery site.

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.

Do not connect more than one ViSi Power Pack to the ViSi Mobile Monitor simultaneously.

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 all ViSi Mobile Monitoring System cabling to avoid the possibility of patient entanglement or strangulation.

Warnings 

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 directly to an 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.

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.

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

Do not touch the electrical contacts on the ViSi Power Pack or use the ViSi Power Pack without it first being inserted into the ViSi Power Pack Cradle. Doing so may result in electric shock from the battery.

When not in use, disconnect the ViSi Power Pack from the Monitor.

Do not modify the ViSi Power Pack in any way.

If the ViSi Power Pack beeper/buzzer sounds or the Red LED is permanently lit, the ViSi Power Pack should be disconnected from the patient immediately.

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 NIBP 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, the ViSi Mobile Cuff Module, or the ViSi Power Pack into the ViSi Mobile Charger while connected to a patient.

Do not clean the ViSi Mobile Monitor, Cuff Module, Chest Sensor, Thumb Sensor, or ViSi Power Pack with detergents while worn by the patient.

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

When the “Monitor Too Hot” alarm is in progress, the ViSi Mobile Monitor and Chest Sensor should be removed from the patient immediately. Leaving them on the patient for an extended period of time may lead to a skin burn.

When the “Cuff Battery Temp” alarm is in progress, the ViSi Mobile Cuff Module should be removed from the patient immediately. Leaving it 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 and any packaging material after use per your facility’s policy or national requirements.

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 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 provided by Sotera Wireless, Inc. for the ViSi Mobile Monitoring System. The Chest Sensor 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, index and middle finger for SpO_2 measurements; however, cNIBP can only be measured while on the patient's thumb.

Warnings 

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

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

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

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

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".

ViSi cNIBP has not been evaluated in patients with pacemakers that pace the ventricle. ViSi's NIBP may be used instead.

After monitoring has been stopped on the ViSi Mobile Monitor, and the patient has been removed from the Remote Viewer, this action cannot be undone. Once removed, the patient's monitoring session data will no longer be available on the Remote Viewer.

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, Inc. 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.***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 blood pressure measurements (NIBP and cNIBP) have not been clinically evaluated in the presence of atrial or ventricular arrhythmias. Use alternative BP methods if these arrhythmias are present.

Chest Sensor: 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 provide ST segment analysis. Therefore, if a change in the ST segment of the ECG waveform is suspected, it should be confirmed by 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 (1-time measurements or continuous measurements) have not been clinically evaluated in the presence of atrial or ventricular arrhythmias. Use alternative BP methods if these arrhythmias 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 conditions, including direct sunlight, may interfere with the performance of the ViSi Mobile Thumb Sensor.

Warnings 

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

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 (artifacts) 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 when it 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, you are testing how the alarm and alert tones will sound at the Remote Viewer during typical operation. If the volume is inadequate, clinicians could miss alarms and alerts. During testing, if the tone does not sound or it is not loud enough, adjust the speaker volume.If the sound is still not loud enough, immediately contact a biomedical engineer.

The ViSi Power Pack Alarms/Alerts DO NOT audibly annunciate on the ViSi Mobile Monitor or the Remove Viewing Device.

Warnings 

If the ViSi Mobile Monitor displays a “Battery Pack Fault” , “Electric Shock”, or “Monitor Too Hot” message, disconnect the Power Pack immediately.

User Maintenance

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

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.

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.If you have any concerns regarding a cyber security breach or vulnerability, contact Sotera Wireless, Inc. or an authorized Sotera Wireless, Inc. 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.

2.3 Cautions 

Intended Use

Federal (U.S.A.) law restricts the ViSi Mobile Monitoring System and Power Pack 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

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).

Only the ViSi Power Pack should be placed into the accompanying cradle.

To avoid damage, the ViSi Power Pack should only be connected to the ViSi Mobile® Monitor.

Monitoring

The accuracy of cNIBP is dependent on the initial cuff calibration. Use good clinical practice to confirm cNIBP accuracy before initiating or treating a patient.

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 of up to 120 seconds between the instantaneous blood pressure reading and the displayed reading.

The ViSi Mobile Monitoring System accuracy claim (mean error of ≤ ±5 mmHg and a std. dev. of ≤ 8 mmHg) is not met when the subject is in a semi-Fowlers position (inclined more than 30 degrees from horizontal).

2-way radios may cause waveform distortion when placed within 1 foot of the ViSi Mobile Monitor.

Some brands of television may cause temporary waveform distortion and data loss when placed within 6 feet of the ViSi Mobile Monitor.

Safety

The ViSi Mobile Monitoring System or Power Pack have 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, Power Pack or other 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 or ViSi Mobile Cuff Module, or ViSi Power Pack 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 or Power Pack are not intended for home use.

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

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 or Power Pack.

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

Changes in posture and arm height can affect ViSi cNIBP accuracy. If the cNIBP measurement is questionable, retake the measurement. Ideally recalibrate in the same position as the initial calibration.

Cautions 

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 the administration of an IV vasoactive drug or a new oral vasoactive drug. The Calibrate cNIBP alert will not be displayed.

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 Customer Service.

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, including the ViSi Power Pack should only be serviced by Sotera Wireless, Inc. technicians or authorized service providers.

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, with the round end pointing 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.**Cautions** 

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 while it is connected to the patient, secure the ViSi Mobile Monitor by plugging in the thumb sensor or locking key.

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

The ViSi Mobile Monitoring System 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).

When using a ViSi Power Pack equipped with a mount, ensure the clamp is properly secured to the bedside or IV Pole to avoid damage from being dropped.

Avoid from putting the ViSi Power Pack directly below an IV bag.

Avoid putting anything other than the ViSi Power Pack into the cradle.

Route the ViSi Power Pack cable away from other medical equipment in its vicinity.

Cleaning / Disinfecting

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

Do not apply liquid to the ViSi Mobile Cuff Module or the Power Pack. 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 bleach, abrasive cleaning agents or organic solvents on any of the ViSi Mobile Monitoring System components.

Use only recommended cleaning/disinfecting agents to prevent damage to the device and components. See page 107

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 or the ViSi Mobile Thumb Sensor.

Cautions 

After patient use, the disposables from the ViSi Disposable Kit may contain bio-hazard materials. Handle and dispose of these items according to your facility’s policies.

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.

Notes

3. General Description

3.1 Introduction

The ViSi Mobile Monitoring System is a patient worn, portable, battery operated, physiological monitoring device indicated for the monitoring of ECG (3 lead-wire or 5 lead-wire), heart rate (HR), pulse rate (PR), respiration (RESP), non-invasive blood pressure (NIBP), continuous non-invasive blood pressure (cNIBP), pulse oximetry (SpO_2), and skin temperature (TEMP).

The System consists of the ViSi Mobile Monitor, Thumb Sensor, Chest Sensor (either 3 lead-wire or 5 lead-wire), Cuff Module, Charger, Disposable Kit, and optional ViSi Power Pack.

Powered by a rechargeable battery lasting at least 12 hours, the Monitor is a lightweight (weighing approximately 125 grams) portable patient vital signs monitor featuring a high resolution, full color display touchscreen with visual and audible alarms and alerts.

3.2 Unpacking

Remove the Monitor and associated components from the shipping cartons and examine them for signs of shipping damage. Save all packing materials, invoice, and bill of lading. These may be required to process a claim with the carrier. Check all materials against the packing list. Contact the Sotera Wireless, Inc. Customer Service Department or the Sotera Wireless, Inc. representative in your area for prompt assistance in resolving shipping problems.

3.2.1 Removing and Inserting the Shipping Plug

All Monitors are shipped in the Wrist Cradle with a Shipping Plug (airplane symbol) inserted. This Plug is found in the Thumb Sensor connector (on the rounded end) of the Monitor. The Shipping Plug's only function is to completely power off the Monitor. Reinserting the Plug into a Monitor powers down the Monitor in a controlled fashion, and allows internal operations to be completed before completely powering off.

To remove the Shipping Plug

Grasp the tip of the Plug that extends out from the Wrist Cradle and pull firmly outward.

The contact points are disconnected. The Monitor begins a power up phase and the initial information screen appears.

To insert the Shipping Plug

Ensure that the ViSi Mobile Monitor is properly seated in the Wrist Cradle, the Plug is oriented with the connector contacts facing upwards, and push in firmly.

The power down process begins. The power down cycle is complete once the screen goes blank and the green LED indicator has stopped blinking.

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.

3.3 System Components

3.3.1 ViSi Mobile Disposable Kit

The Disposable Kit contains the disposable components of the system. The Disposable Kit components are for single patient use only. The Disposable Kits are available in five adult sizes: small, medium, medium+, large, and large+. Choose the Disposable Kit that contains the Cuff size best suited for the patient. Cuff sizes follow standard range of arm circumference. *See 5.2.5 Selecting the ViSi Mobile Disposable Kit on page 60.*

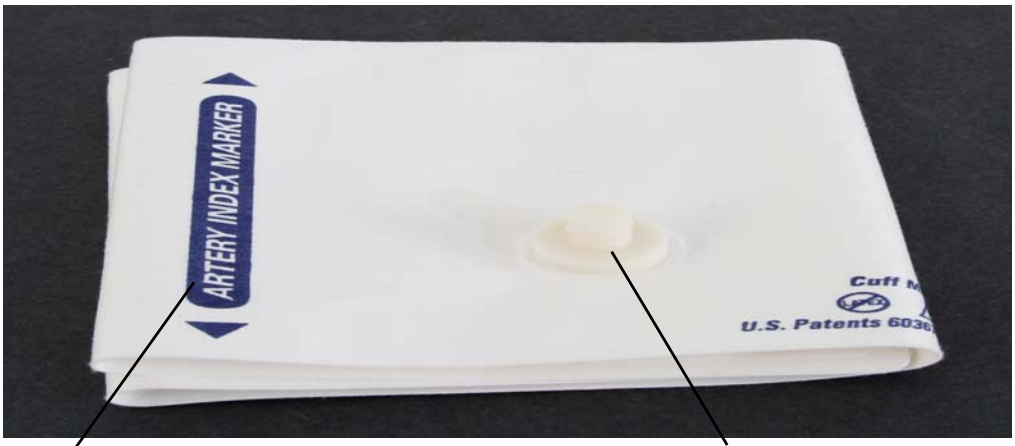
All disposable components of the ViSi Mobile Monitoring System are for single patient use only. To avoid possible cross contamination, do not reuse any disposable items on a patient other than the original patient. Dispose of the components and any packaging material after use per your facility's policy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

ViSi Mobile Disposable Kit Contents	
Equipment	**Quantity**
ViSi Mobile Disposable Cuff (Welch Allyn FlexiPort Soft cuff with adaptor)	1
ECG Electrode	5
ViSi Mobile Wrist Cradle	1
ViSi Mobile Thumb Wrap	1

ViSi Mobile Disposable Kit Contents	
Equipment	**Quantity**
ViSi Mobile Setup Guide	1
ViSi Mobile Cable Securement	2

ViSi Mobile Disposable Cuff

The Cuff is available in five adult sizes: small, medium, medium+, large and large+ (*see 3.3.1 ViSi Mobile Disposable Kit on page 31).* The Cuff is used to take a NIBP measurement once the Cuff Module is attached to the Cuff and plugged into the ViSi Mobile Monitor. *See 3.3.4 ViSi Mobile Cuff Module on page 37*.



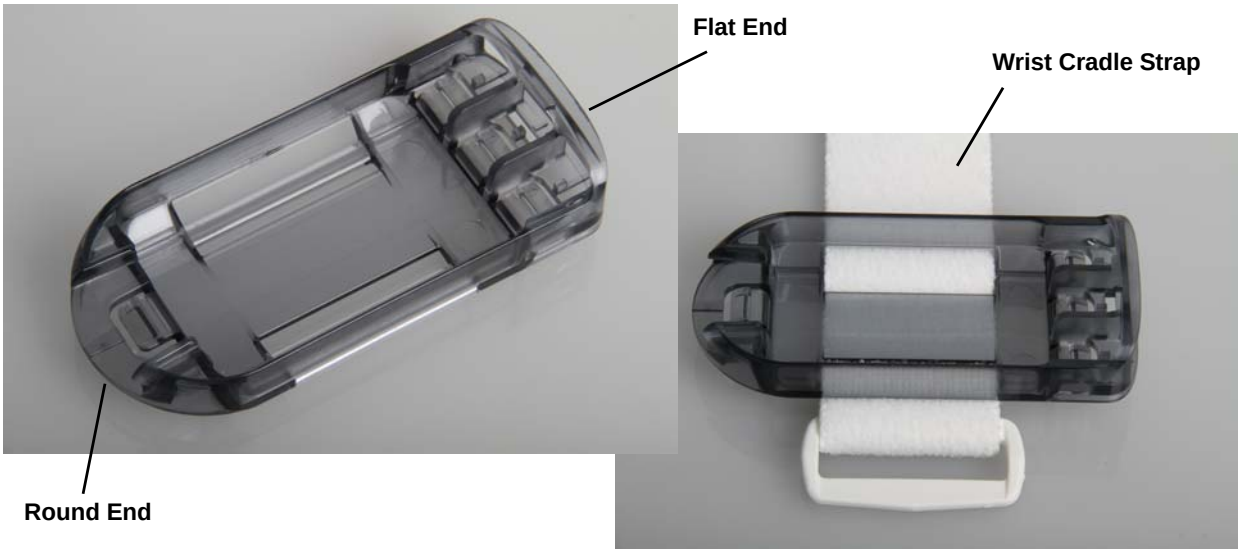
Note: Only cuffs designed for use with the ViSi Mobile Cuff Module may be used.

ECG Electrodes

ECG Electrodes are adhesive pads with conductive gel that are connected to the ECG lead-wires of the Chest Sensor to display the ECG waveforms and detect the HR. Use only snap-on type electrodes.

ViSi Mobile Wrist Cradle

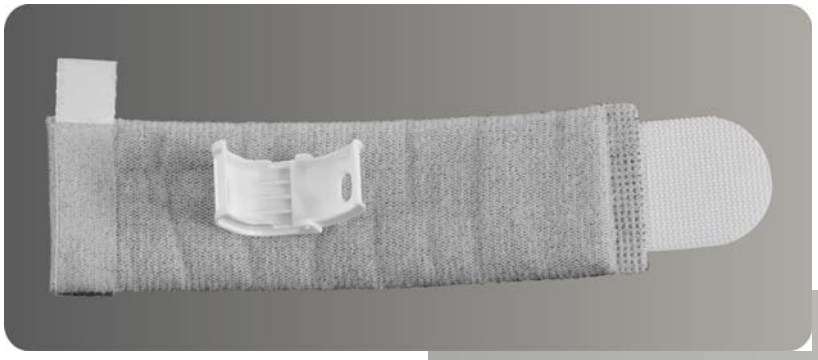
The Wrist Cradle holds the Monitor and provides the connectors for the sensors. The Wrist Cradle is held in place on the patient's wrist with a strap.



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

ViSi Mobile Thumb Wrap

The Thumb Wrap holds the Thumb Sensor and secures it to the base of the thumb.

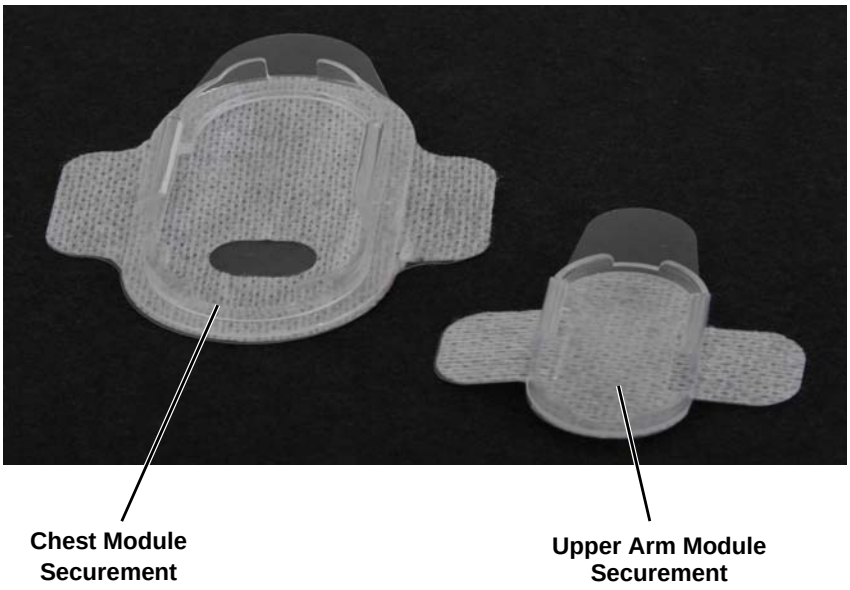


Top View

Bottom View
(with labelling)

ViSi Mobile Chest Sensor Securements

There is one large and one small Chest Sensor Securement in the Disposable Kit. The large Securement secures the Chest Module of the Chest Sensorto the patient's torso. The small Securement secures the Upper Arm Module of the Chest Sensorto the upper arm. *See 3.3.5 ViSi Mobile Chest Sensor CableChest Sensor on page 38.*



3.3.2 ViSi Mobile Monitor

The Monitor is a compact and lightweight device that is worn on the patient's wrist. The Monitor is held in place by the Wrist Cradle, which allows sensors to be connected. The Monitor can be removed from the Wrist Cradle in order to charge, or swap for another Monitor. The Monitor uses a touchscreen user interface to access the displays and monitoring functions.

Note: When the Monitor is not in the Charger, the power indicator shows the approximate monitoring time left:

- **Green: Battery has at least 3 hours of monitoring time left.**
- **Yellow: Battery is low with less than 3 hours of monitoring time left.**
- **Red: Battery is critically low with less than 1 hour of monitoring time**

3.3.3 ViSi Mobile Thumb Sensor (SpO_2/PR)

The Thumb Sensor is applied to the patient's thumb and is plugged into the rounded end of the Wrist Cradle with the connector contacts facing upwards.

Insert with connector contacts facing upwards

Note: The Thumb Sensor locks the ViSi Mobile Monitor into the Wrist Cradle and must be unplugged to remove the Monitor from the Wrist Cradle.

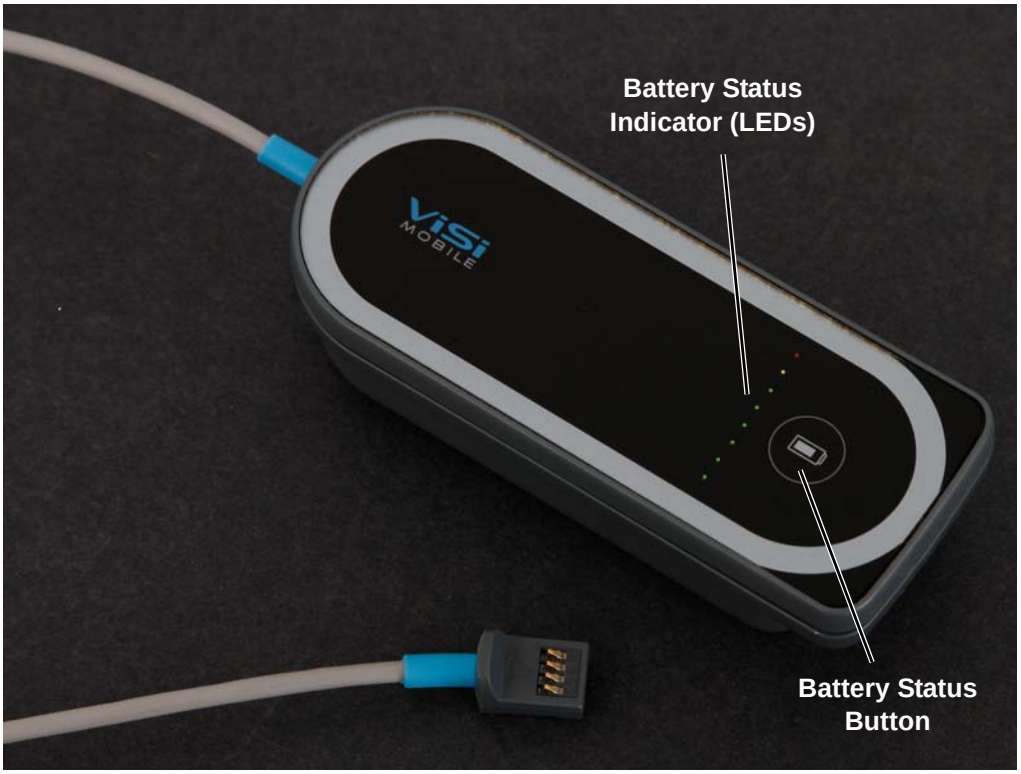
Note: A Locking Plug should be used to lock the Monitor into the Wrist Cradle if the Thumb Sensor is not used. Locking Plugs may be ordered separately from Sotera Wireless, Inc.

3.3.4 ViSi Mobile Cuff Module

The Cuff Module is used to take NIBP measurements and to initiate the cNIBP calibration. The Cuff Module plugs into any one of the connectors on the flat end of the Wrist Cradle.

For ease of use, the Monitor features three interchangeable plug-in sites for the Chest Sensor, Cuff Module, and optional ViSi Power Pack. *See "ViSi Power Pack" on page 207.*

The industry-standard technique of oscillometry is used for non-invasively taking single measurements of the systolic and diastolic blood pressure (NIBP) as well as pulse rate. The method is based on the observation of oscillations in the sphygmomanometer cuff pressure that are caused by the oscillations of blood flow, i.e., the pulse in the patient's upper arm. It uses a sphygmomanometer cuff like the auscultatory method, but with an electronic pressure sensor (transducer) to observe cuff pressure oscillations, electronics to automatically interpret them, and automatic inflation and deflation of the Cuff. The Cuff Module measures during Cuff inflation.



Note: When the battery status button is pressed, the battery status indicator shows the level of the Cuff Module's battery charge. Green lights indicate the battery has a minimum of 11% charge. The more green lights indicate a greater charge level. A yellow light indicates the battery charge is less than 10%. A red light indicates there is less than 4% battery charge.

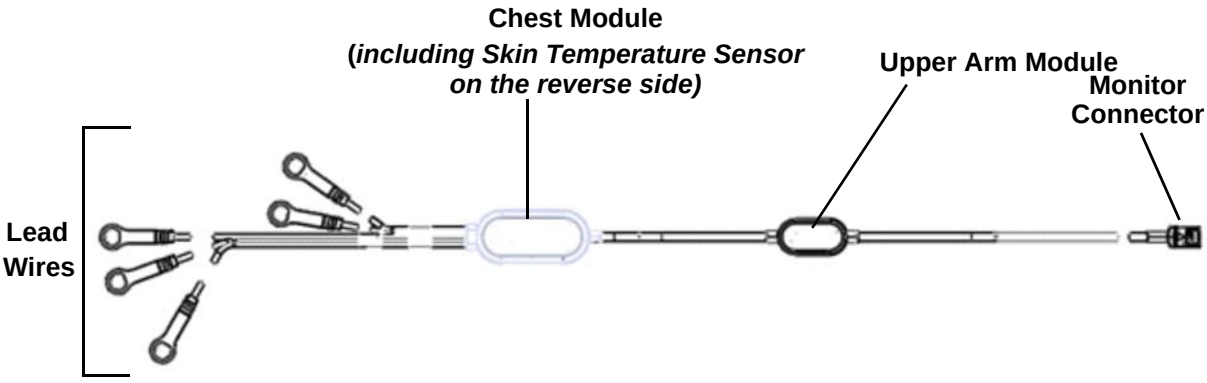
Note: When a calibration check is required, return the Cuff Module to the biomedical engineer. An annual calibration check of the Cuff Module is recommended.

3.3.5 ViSi Mobile Chest Sensor

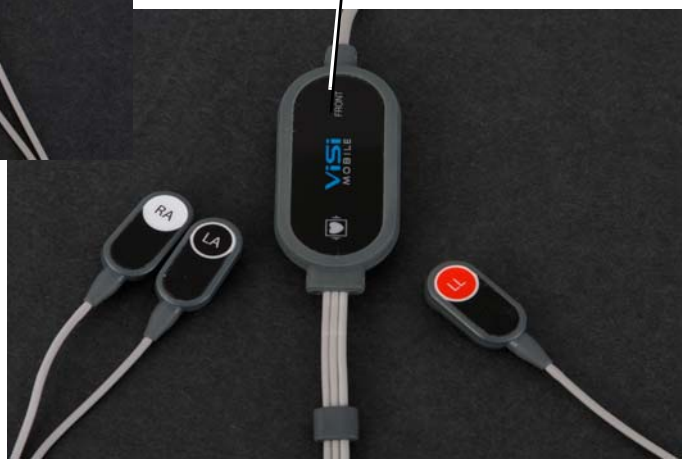
The Chest Sensor is either a 3 lead-wire or 5 lead-wire cable and plugs into any one of the connectors on the flat end of the Wrist Cradle. *See 5.3.4 Applying the ViSi Mobile Chest Sensor CableChest Sensor and ECG Electrodes on page 69 for recommended Chest Sensor placement.*

For ease of use, the Monitor features three interchangeable plug-in sites for the Chest Sensor, , Cuff Module, or optional ViSi Power Pack.

The ViSi Mobile Chest Sensor is designed to be fully compatible with external defibrillators. No additional precautions are required.



Chest Sensor
5 Lead



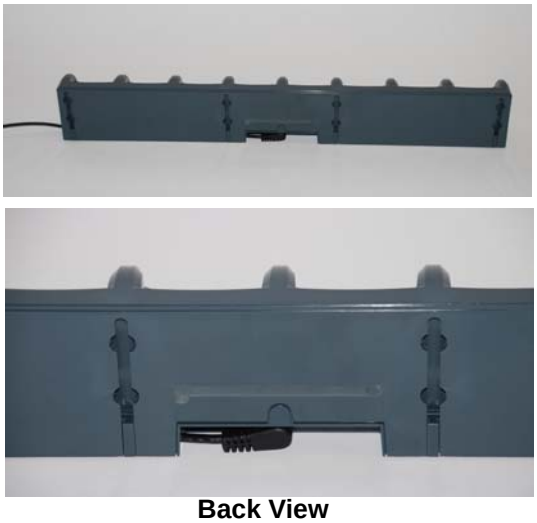
Chest Sensor
3 Lead

3.3.6 ViSi Mobile Charger

The Charger is used to charge ViSi Mobile Monitors, Cuff Modules, and ViSi Power Packs providing two or eight charging docks for simultaneously charging multiple units.

The Charger consists of a desktop/wall mount charger, power supply and power cable.

Front View



Back View

Note: The ViSi Mobile Charger is available as a 2-bay charger or 8-bay charger (shown above).

To set up the Charger

1. Connect the power cable to the back side of the desktop/wall mount charger.
2. Plug into the AC power outlet.

   The light on the front of the Charger will display green when the Charger is connected to the AC power outlet.

   The Charger will beep once when it is connected to the AC power outlet.

Note: When connected to the AC power outlet, if a fault with the ViSi Mobile Charger is detected, the Charger will audibly beep every second.

Note: Do not position the ViSi Mobile Charger so that it is difficult to disconnect the power cable.

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

3.3.7 Charging the ViSi Mobile Monitor and Cuff Module

The ViSi Mobile Charger provided by Sotera Wireless, Inc. is the required Charger for both the Monitor and the Cuff Module as well as for the optional ViSi Power Pack. The Charger is capable of charging up to eight of any combination of Monitors, Cuff Modules and Power Packs. To charge either the Monitor or the Cuff Module place the flat end into one of the slots with the front facing outwards.

Note: The ViSi Mobile Charger is to be used for ViSi Mobile components only.

ViSi Mobile Monitors and Cuff Modules contain sealed batteries that are not replaceable by the user. If a Monitor or Cuff Module has a battery issue, contact the Sotera Wireless, Inc. Customer Service Department. The LED on the Charger is used to indicate the charging status of devices that are currently inserted:

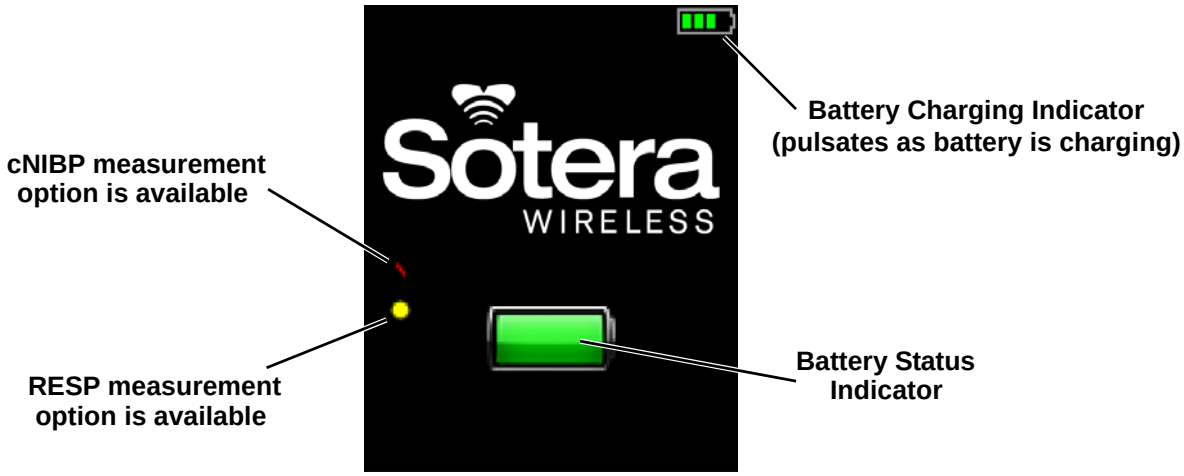
LED Color	Charging Status
Steady Green	Everything is functional: • No devices in the Charger. • All devices are charging normally or are fully charged.
Flashing Green / Yellow	At least one device in the Charger has not properly registered with the Charger, but charging continues on all devices. Devices with fully drained batteries cannot register with the Charger until after a charge cycle starts and will cause this condition until they reach a minimum charge level. Removing and reinserting an unregistered device can give it another chance to register in the Charger. If this condition is repeatedly observed on devices that are not fully drained, contact Sotera Wireless, Inc. or an authorized Sotera Wireless, Inc. representative in your area.
Steady Yellow	At least one device in the Charger is not being charged due to a fault with the device. All other devices are charging. Contact Sotera Wireless, Inc. or an authorized Sotera Wireless, Inc. representative in your area.
Steady Red	Charger fault. No devices are charging, the Charger has shutdown. Contact Sotera Wireless, Inc. or an authorized Sotera Wireless, Inc. representative in your area.

Charging the Monitor

Insert the Monitor that you want to charge into one of the Charger docks.

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

The Charge Status screen will be displayed briefly. The Monitor's battery status indicator (in the top right hand of the screen) stops pulsating when the battery is fully charged



Note: When the red bar is displayed on the screen, it indicates the Monitor will measure continuous blood pressure (cNIBP) when the Chest Sensor and Thumb Sensor are connected to a Monitor.

Note: When the yellow dot is displayed on the screen, it indicates the Monitor will measure RESP when a Chest Sensor is connected to a patient. RESP is not available as part of the default set of vital sign measurements and must be purchased separately.

Note: If the screen is blank, touch the screen for two seconds to activate the display and show the battery charge status.When a Monitor that is not fully charged is removed from the Charger, the Monitor shall beep and display the Charge Status screen. The Monitor does not have to be fully charged in order to start monitoring. Ensure the Monitor has been charged sufficiently before monitoring is started.

Note: When the Monitor is in the Charger, the power indicator shows the charging state:

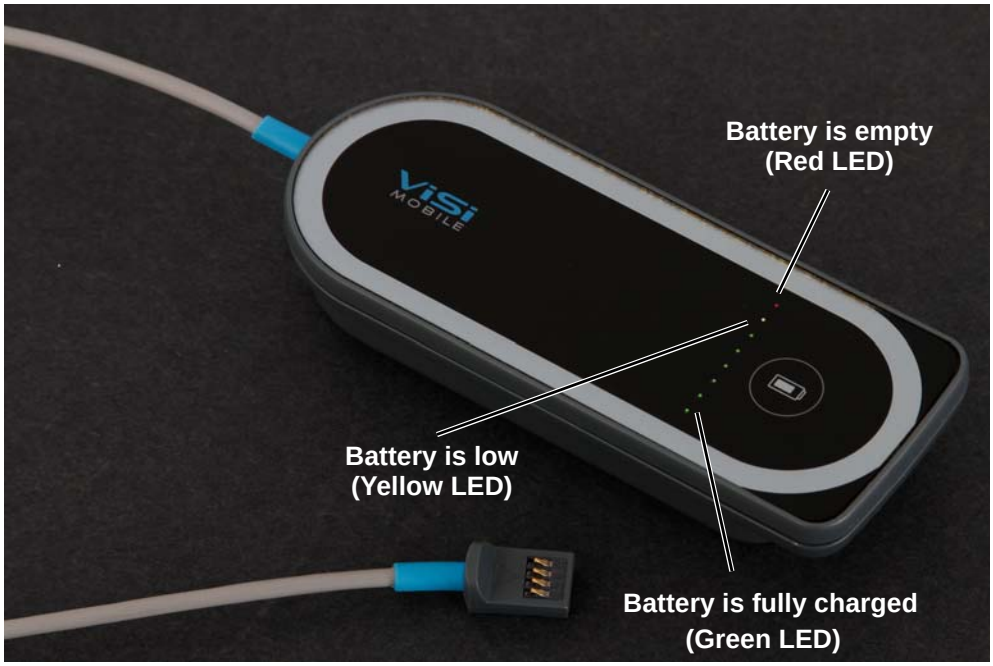
Green: The Monitor is fully charged.
Yellow: The Monitor is still charging

The charge level (when the Monitor is in the Charger) is different from the monitoring time remaining (when the Monitor is out of the Charger).

Charging the Cuff Module

Insert the Cuff Module that you want to charge into one of the Charger docks.

One of the charging indicator lights will blink while the Cuff Module is charging.



When one of the green charging indicators is flashing, the battery in the Cuff Module is charging. The position of the green charging indicator represents the level of charge. When the charge indicator furthest away from the red charging indicator is flashing, the Cuff Module is fully charged.

When the yellow charging indicator is flashing, the battery in the Cuff Module is low. At least one additional measurement may be taken.

When the red charging indicator is flashing, the battery in the Cuff Module has insufficient charge to take a measurement. No cuff inflations are possible.

Charging the Optional ViSi Power Pack

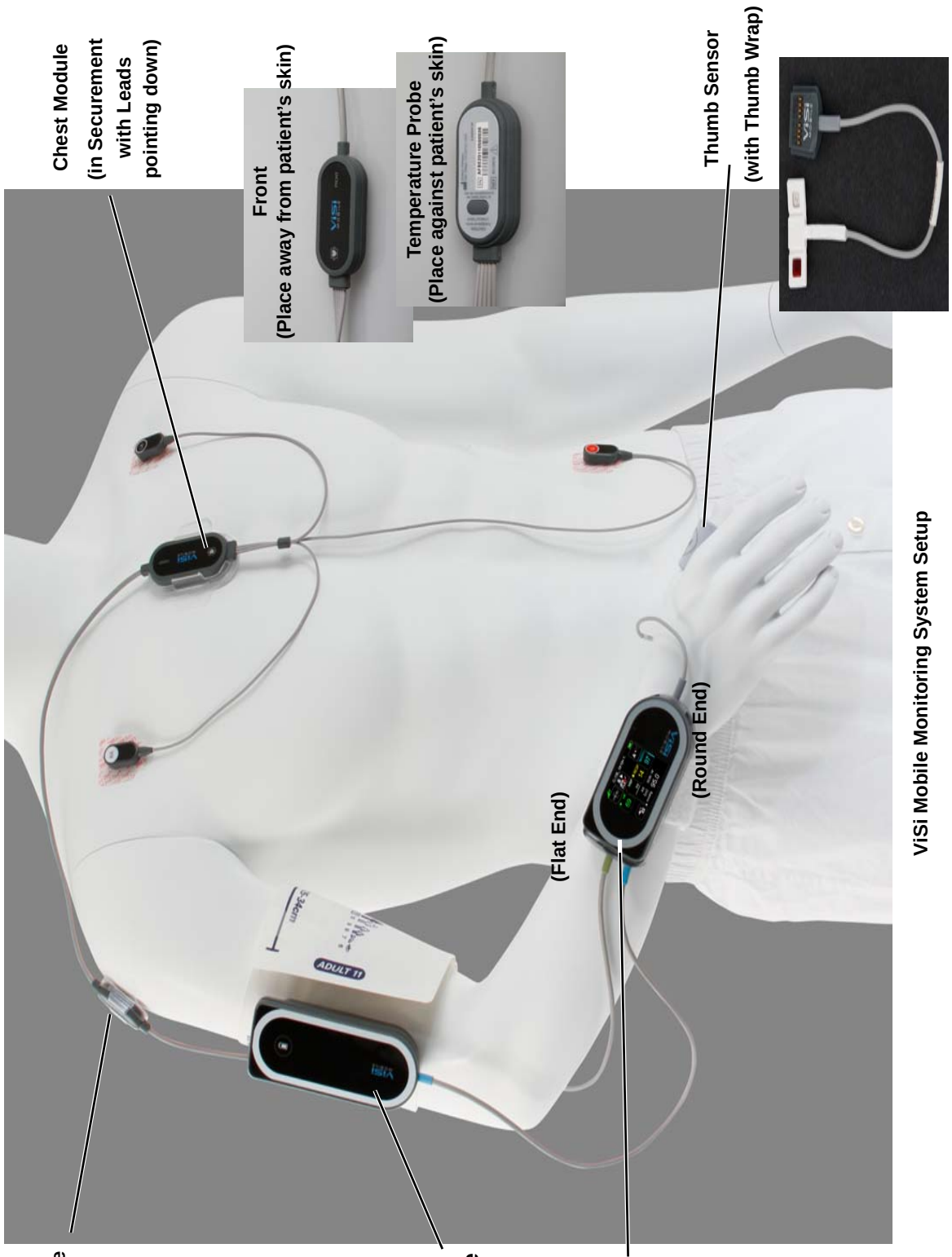
See “ Charging the ViSi Power Pack on page 212”

4. Clinical Features

4.1 Introduction

The ViSi Mobile Monitor is completely body-worn and designed to continuously measure ECG/HR, SpO_2, PR, RESP, and TEMP. The ECG, SpO_2, and RESP waveforms are viewable on demand. NIBP can be measured as a one-time measurement, automatically at predefined intervals or continuously.

The Chest Sensor measures the ECG/HR, RESP, and TEMP. The illustration on the next page shows a 3 lead-wire placement.



ViSi Mobile Monitoring System Setup

4.2 Key Features

- Chest Sensor options: 3 lead-wire and 5 lead-wire (HR and ECG waveforms)
- RESP (measurement and waveform)
- SpO_2% (measurement and waveform)
- TEMP ($^oC/^oF$) (Skin Temperature measurement)
- NIBP (single measurement, automatic measurements at predefined cycles and continuously)
- Touchscreen display
- Alarms and Alerts generated with visual and audible indication on the Monitor
- Self Test

4.3 Overview of Clinical Features

The ViSi Mobile Monitoring System is a lightweight portable patient vital signs monitor featuring a high resolution, full color display with visual and audible alarms and alerts. The ViSi Mobile Monitor is completely body-worn and designed to continuously measure ECG/HR, SpO_2, PR, RESP, NIBP and TEMP. The ECG, SpO_2, and RESP. Waveforms are viewable on demand. NIBP can be measured as a one-time measurement, automatically at programmed intervals or continuously.

The Monitor is powered by a rechargeable battery. For ease of use, the Monitor features interchangeable plug-in sites for the ViSi Mobile Chest Sensor and ViSi Mobile Cuff Module. The Chest Sensor measures the ECG/HR (with a 3 lead-wire or 5 lead-wire), RESP, and TEMP.

4.3.1 ECG Monitoring and Heart Rate (HR) Monitoring

With the 3 lead-wire Chest Sensor, the Monitor continuously monitors Lead II.

With the 5 lead-wire Chest Sensor, the Monitor continuously monitors seven ECG lead views simultaneously, Leads I, II, III, aVR, aVL, aVF, and a V lead. The ECG waveform can be displayed one lead at a time.

The ability to monitor multiple leads simultaneously improves beat detection to determine the HR and minimizes false detections as a result of muscle artifact.

4.3.2 Respiration Rate (RESP) Monitoring

RESP is determined by measuring the AC impedance between the RA and LL ECG electrodes. Chest wall motion, rise and fall, associated with inspiration and expiration is automatically detected when the RA and LL leads are placed in the standard Lead II configuration on the chest, or in the MCL II position.

RESP is determined from the frequency of the respiration (chest wall motion). The respiration channel can detect the absence of RESP.

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 SpO2, should be assessed as well.

Note: Respiration rate monitoring is an optional feature that requires an additional license key.

4.3.3 Skin Temperature (TEMP) Monitoring

TEMP continuously measures skin temperature using the sensor located on the underside of the Chest Module. The sensor must be placed directly in contact with the patient's skin. TEMP can be displayed in °C or °F. *See To apply the Chest Sensor CableChest Sensor on page 72.*

Note: Skin temperature is not synonymous with core body temperature or temperature measured using the oral or tympanic methods.

Note: Skin temperature representative of skin surface temperature will take approximately 6 minutes from the time the Chest Module is applied.

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.

4.3.4 Pulse Oximetry (SpO_2 and Pulse Rate) Monitoring

The Pulse Oximetry channel non-invasively and continuously measures the functional oxygen saturation of the hemoglobin in arterial blood using the transmittance across the base of the thumb. A pulsatile arterial source at the base of the thumb is required to measure the SpO_2.

In the absence of a heart rate source from an ECG, the pulse rate can be measured and displayed from the SpO_2 channel.

When turned on, the tone pitch of the heart beat will change with the level of oxygen saturation. A higher pitch is associated with higher SpO_2 levels.

Oxygen saturation measurements using SpO2 are dependent on proper sensor placement, exposure to ambient light conditions, and general patient conditions. Before making clinical decisions based on SpO2 measurements, verify the measurement using another clinically acceptable method, such as arterial blood gas analysis.

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

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

4.3.5 NIBP Monitoring

The ViSi Mobile Cuff Module is intended for measuring arterial blood pressure (systolic, diastolic and MAP) using a Cuff. Measurements may be initiated manually (one at a time), automatically at selectable predefined intervals of 5, 10, 15, 30, 60, 90 and 120 minutes or continuously.

The accuracy of NIBP measurements is influenced by several factors:

- Correct cuff size
- Correct cuff placement on the arm
- The position of the upper arm in relation to the heart at the time of the measurement
- Motion artifacts

Note: To measure continuous non-invasive blood pressure (cNIBP), the Cuff Module is only required for the initial inflation to determine the Pulse Arrival Time (PAT) and for periodic recalibrations.

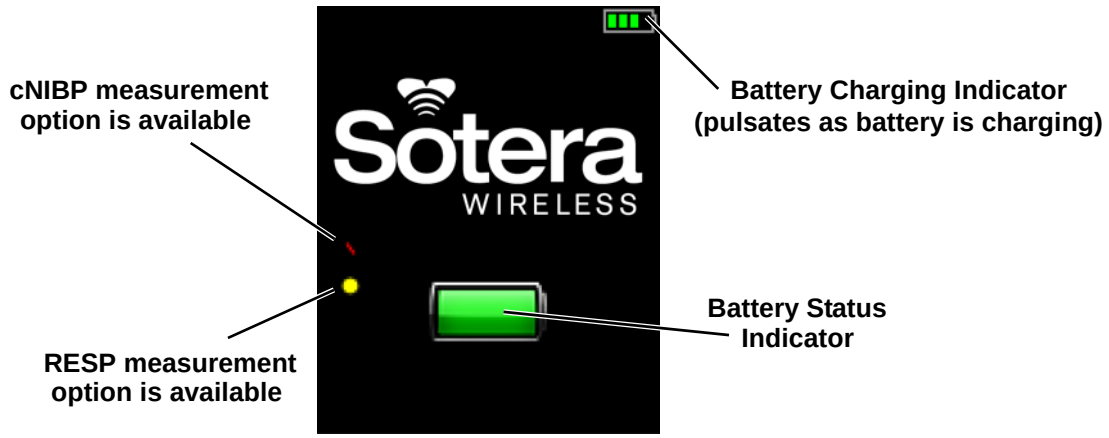
Avoid touching the ViSi Mobile Disposable Cuff during cuff inflation as it may disrupt the measurement.

4.4 Display Screens

This section describes various screens displayed on the ViSi Mobile Monitor. Each screen is accessed by interacting with the touchscreen display.

4.4.1 Battery Charge Screen

The **Battery Charge** screen displays the battery status while the Monitor is charging in the Charger.



Note: When the red bar is displayed on the screen, it indicates the Monitor will measure continuous blood pressure (cNIBP) when the Chest Sensor, Cuff Module and Thumb Sensor are connected to a Monitor.

Note: When the yellow dot is displayed on the screen, it indicates the Monitor will measure RESP when a Chest Sensor is connected to a Monitor.

Note: cNIBP and RESP measurements are not available as part of the default set of vital sign measurements and must be purchased separately.

4.4.2 Hibernation Screen

The **Hibernation** screen (blank screen) is the default when no monitoring is currently in progress.

The **Hibernation** screen conserves battery power under the following conditions:

- The Shipping Plug is not plugged into the Monitor
- The Monitor is not in the Charger
- No sensors are connected to the Monitor

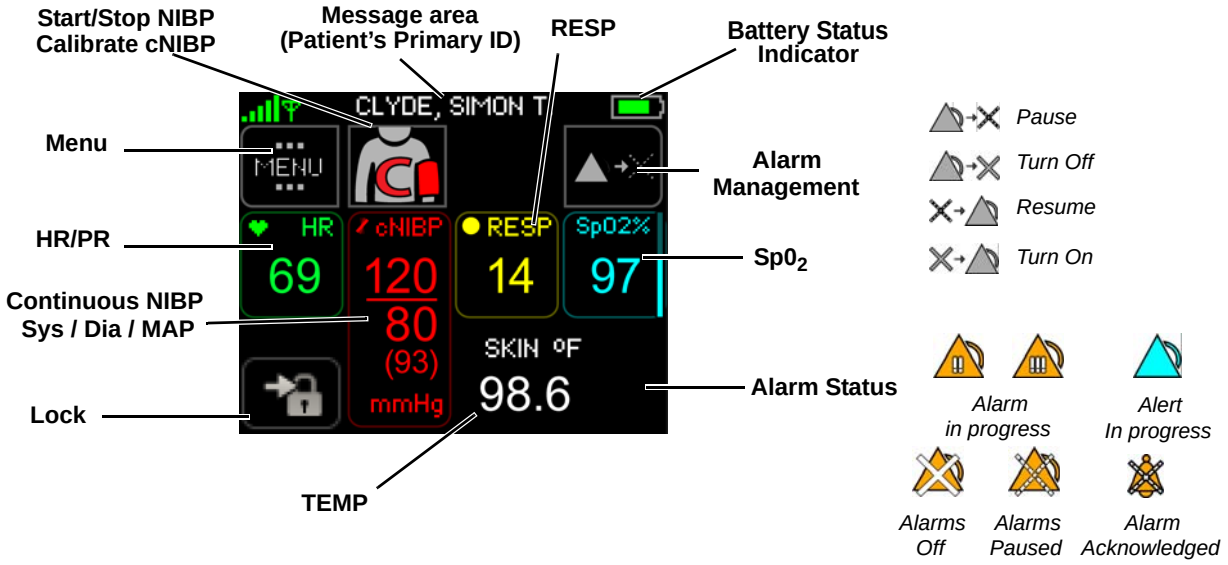
Note: When the Monitor is not in the Charger, the power indicator shows the approximate monitoring time left:

Green: Battery has at least 3 hours of monitoring time left.
Yellow: Battery is low with less than 3 hours of monitoring time left.
Red: Battery is critically low with less than 1 hour of monitoring time.

Note: Connecting a sensor to the Monitor displays the Vital Sign screen. There will be a brief delay before the Vital Sign screen is displayed to allow the Monitor's self test to complete.

4.4.3 Vital Signs Screen

The **Vital Signs** screen is the default screen that displays automatically (on initial setup) when sensors are placed on the patient and connected to the Monitor.



Use the **Vital Signs** screen to:

- View current vital sign measurements
- Vital Signs Measurement: Access the waveforms *(see page 117)*
- Alarm Status: View alarm status
- Battery Status Indicator: View the battery status
- Menu: Access the Menu screen *(see page 53)*
- Start/Stop NIBP: Start and stop manual NIBP measurement *(see page 124)*
- Calibrate NIBP for continuous monitoring of blood pressure *(see page 128)*.
- Alarm Management: Pause alarms/alerts *(see page 91)*
- Alarm Management: Acknowledge (silence) alarms/alerts *(see pages 85 and 89)*
- Lock: Lock the Monitor to prevent unauthorized access

Note: Systolic, diastolic and MAP measurements of cNIBP will be displayed in red when measuring NIBP continuously. Spot-check NIBP measurements are displayed in white.

Note: A respiration measurement will not be displayed until 60 seconds have elapsed since the time the ECG leads were connected to the patient and 6 breaths have been identified.

4.4.4 Menu Screen

Touch **Menu** on the **Vital Sign** screen to view the **Menu** screen. 

Use the **Menu** screen to:

- Change the NIBP measurements between Manual, Auto (including setting the auto inflation interval) and continuous. *(see page 127)*

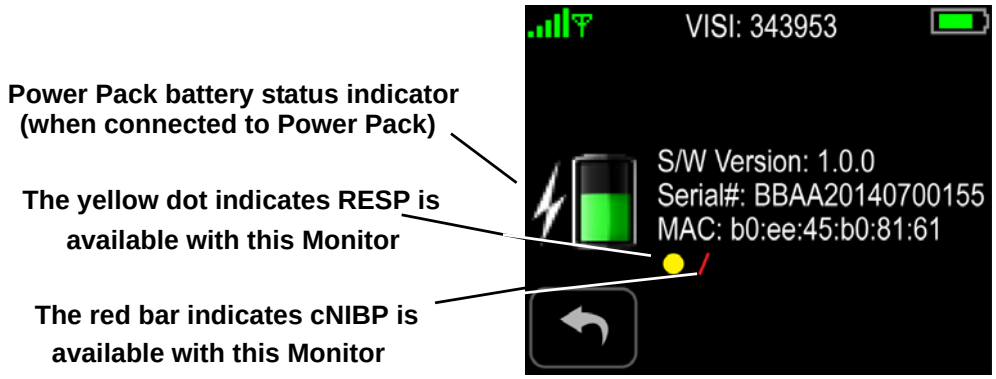
- Pause or stop monitoring *(see pages 139 and 142)*
- View Monitor status
- View and change the alarm limits settings *(see page 96)*
- View patient demographics *(see page 135)*
- Select the patient's current posture *(see page 132)*.

Note: Silence or enable the QRS/PR beep tone**The Select Patient's Posture button will be enabled when the ViSi Mobile Chest Sensor is connected to the Monitor.**

Note: **When turned on, the tone pitch of the heart beat will change with the level of oxygen saturation. A higher pitch is associated with higher SpO_2 levels.**

4.4.5 Monitor Status Screen

Touch **Monitor Status** on the **Menu** screen to access the **Monitor Status** screen. 



Use the **Monitor Status** screen to:

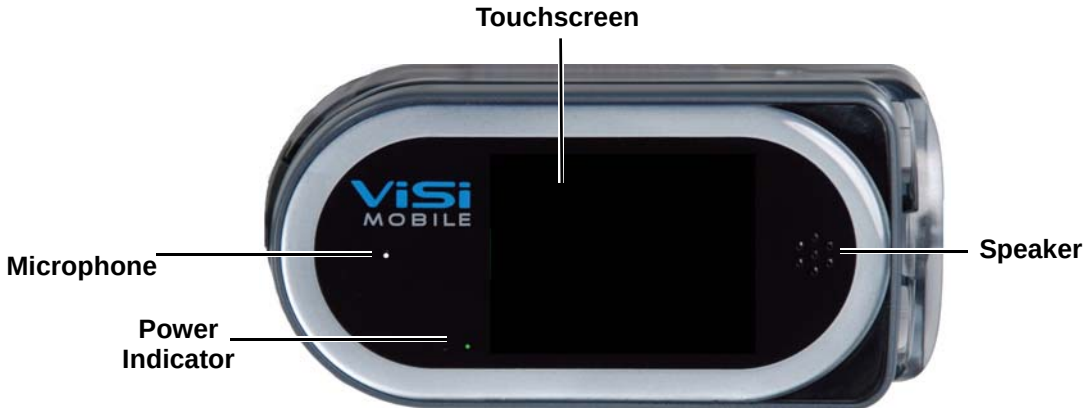
- View the battery status
- View the version of the Monitor's software
- View the Monitor's serial number
- View the Monitor's MAC address
- View the licensed features that are available, such as RESP and continuous NIBP
- View the battery status of the Power Pack, if connected

4.4.6 Quiet Monitoring Screen

The **Quiet Monitoring** screen (blank screen) is the default when sensors are connected both to the Monitor and the patient and no user interaction has occurred for a predefined period of time. Continuous monitoring is in progress during this time.

Note: **After a predefined period of no direct interaction with the Monitor, the Monitor locks automatically and enters Quiet Monitoring.**

The **Quiet Monitoring** Screen conserves battery power and minimizes patient disturbance. Vital signs alarms and alerts remain active. Touching the screen continuously for 2 seconds resumes the Monitor's display with the **Patient View** screen.

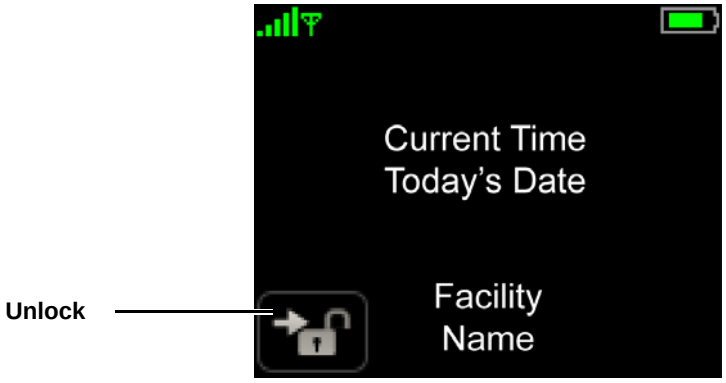


Note: When the Monitor is not in the Charger, the power indicator shows the approximate monitoring time left:

Green: Battery has at least 3 hours of monitoring time left.
Yellow: Battery is low with less than 3 hours of monitoring time left.
Red: Battery is critically low with less than 1 hour of monitoring time.

4.4.7 Patient View Screen

The **Patient View** screen appears whenever the touchscreen is touched continuously for 2 seconds during **Quiet Monitoring**.



Use the **Patient View** screen to:

- View the current time
- View battery charge level
- Unlock the Monitor

- Notes -

5. Operation

5.1 Introduction

The ViSi Mobile Monitoring System is a sophisticated multi-parameter vital signs monitor. In order to optimize the user of ViSi, please adhere to the following instructions related to patient set-up, initiating monitoring and the removal of the System.

5.2 Preparing for a New Patient

In order to set up the complete ViSi Mobile Monitoring System, you will need the following components:

- ViSi Mobile Disposable Kit (select size)
- ViSi Mobile Monitor
- ViSi Mobile Cuff Module
- ViSi Mobile Thumb Sensor
- ViSi Mobile Chest Sensor (3 lead-wire or 5 lead-wire configuration)

Note: Skin preparation equipment (skin preparation pads, scissors and/or razor as needed) is not included.

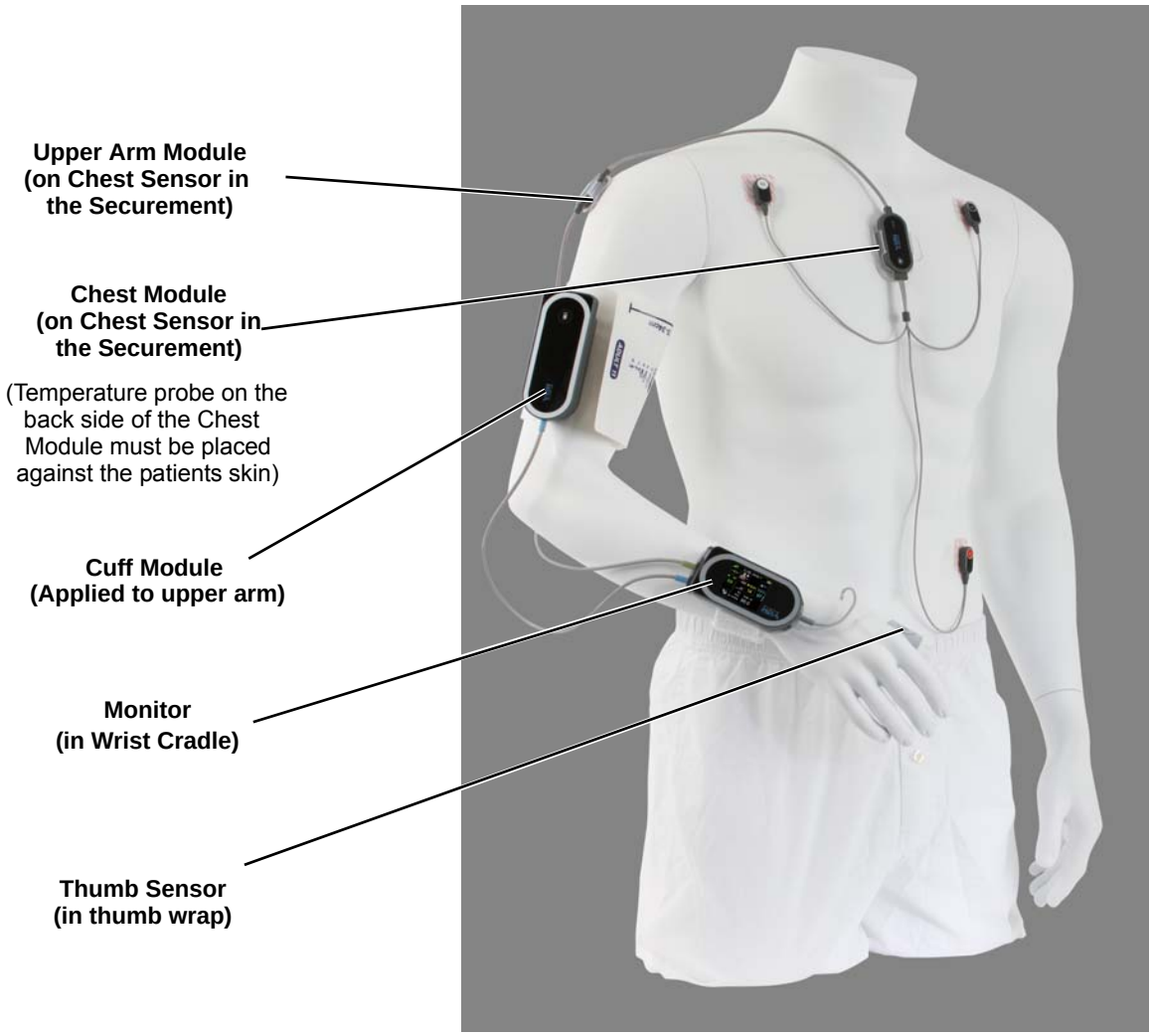
5.2.1 Inspecting the Equipment and Accessories

Before starting patient monitoring, you should visually inspect the ViSi Mobile Monitoring System components:

1. For each component, examine the exteriors for cleanliness and general physical conditions. Ensure the housings are not cracked or broken, that everything is present, there are no spilled liquids and no signs of abuse.
2. Inspect all component cables for damage. Check their strain relief (at flex points) for general condition. Ensure there are no breaks or cracks in the cables . If any cables show signs of damage, do not use.
3. Inspect all disposable accessories (Wrist Cradle, Cuff, Thumb Strap, Securements, etc). If any show signs of damage or pre-use, do not use.

5.2.2 Applying Sensors

Applying the sensors is simple and may be done in any order. At the completion of the setup, the components of the ViSi Mobile Monitoring System will be connected to the patient as shown in the diagram below.



Whenever a sensor is connected to the Monitor, a self-test of that sensor is initiated automatically to verify the sensor is in good working order. If the sensor and Monitor speaker are in good working order, you will hear a double beep. This process takes a few seconds, after which monitoring of the selected vital sign commences as soon as the sensor is connected to the patient.

The double beep is also a validation that the Monitor speaker is in good working order and that audio tones associated with alarms will be annunciated accordingly.

Alarm limits are set automatically according to default settings. *See 6.6 Manage Alarm Limits on page 96.*

Successful vital signs monitoring is dependent on several factors:

- Determining the vital signs to be monitored
- Selecting a Monitor and Cuff Module that are adequately charged for maximum duration of uninterrupted monitoring
- Selecting the 3 lead-wire or 5 lead-wire Chest Sensor
- Selecting the appropriately sized Cuff (from the Disposable Kit)
- Preparing the skin for ECG electrode placement
- Correctly applying all sensors used for monitoring

Note: The battery in the Monitor will deplete at a faster rate when sensors are connected to the Monitor, even when monitoring has not been started.

Note: The Chest Module includes a body surface temperature sensor. To ensure proper function, place the temperature sensor on the body with the Chest Module "Front" label facing forward (away from the patient's skin).

5.2.3 Selecting Vital Signs to Monitor

The following vital signs may be monitored:

- Chest Sensor (one or seven simultaneous leads, using the 3 lead-wire or 5 lead-wire Chest Sensor respectively)
  - ↳ HR (from the ECG)
  - ↳ RESP (optional)
  - ↳ TEMP (Skin Temperature)
- Thumb Sensor
  - ↳ SpO_2
  - ↳ PR (from the Thumb Sensor)
- Cuff Module (single measurement, automatically at set intervals or continuously)
  - ↳ SYS
  - ↳ DIA
  - ↳ MAP
  - ↳ PR (from NIBP)

5.2.4 Selecting the ViSi Mobile Chest Sensor

The Chest Sensor provides the sensors to monitor the ECG, HR, RESP (optional), and TEMP.

Note: The skin surface temperature sensor is on the underside of the Chest Module. It must be placed on the skin surface in order to properly measure skin surface temperature.

Select the Chest Sensor that best suits the monitoring needs of your patient:

- The 3 lead-wire Chest Sensor monitors Lead II, or the MCL configuration.
- The 5 lead-wire Chest Sensor monitors seven leads of ECG simultaneously in lead configurations I, II, III, aVR, aVL, aVF, and a V lead. The specific V lead depends on the placement of the V electrode.

5.2.5 Selecting the ViSi Mobile Disposable Kit

The System's disposable components, including the Cuff are contained in the Disposable Kit. The Disposable Kits are designated as S, M, M+, L and L+ based on the Cuff size.

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.

Cuff / Disposable Kit Size	Arm Circumference (cm)	
Adult S	20 – 26	
Adult M / M+	25 – 34	
Adult L / L+	32 – 43	

5.2.6 Checking the Battery Charge of the ViSi Mobile Monitor and Cuff Module

Before you start to monitor your patient with the System, you will need to select both a Monitor and a Cuff Module that are adequately charged for maximum duration of uninterrupted monitoring.

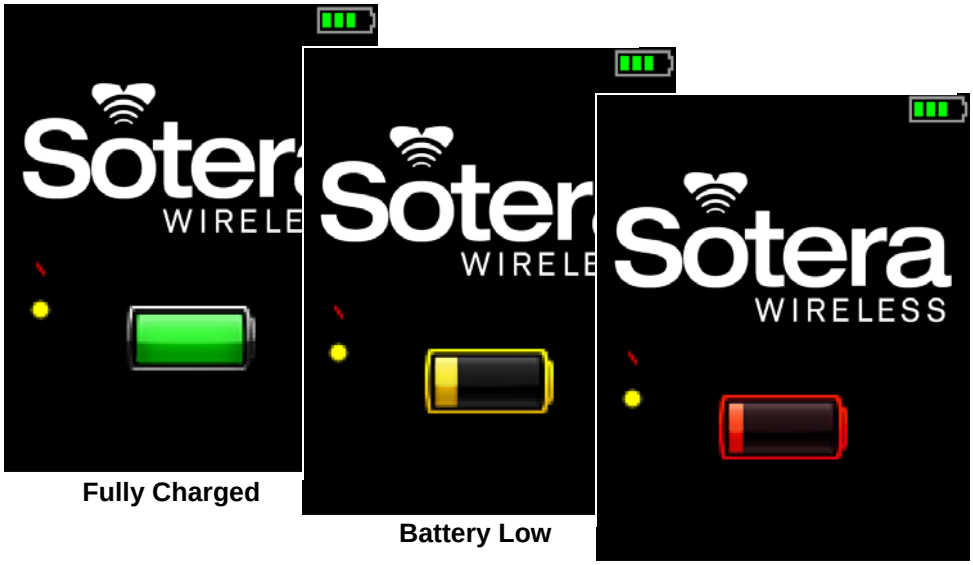
To check the battery charge of the Monitor

1. Turn on the display by touching the screen while the Monitor is in the Charger.
2. Review the large battery icon in the center of the screen.

   The battery color should be interpreted as follows:

   - *When the battery is green, the battery is at least 90% charged.*
   - *When the battery is yellow, the battery is charged between 40% and 90%.*
   - *When the battery is red, the battery charge is less than 40%.*

A red battery symbol indicates the battery is critically low with less than 30 minutes of monitoring time left.



Fully Charged

Battery Low

Battery Critically Low

Note: When the red bar is displayed on the screen, it indicates the Monitor will measure continuous blood pressure (cNIBP) when a Chest Sensor and Thumb Sensor are connected to a Monitor.

Note: When the yellow dot is displayed on the screen, it indicates the Monitor will measure RESP when a Chest Sensor is connected to a Monitor.

Note: cNIBP and RESP measurements are not available as part of the default set of vital sign measurements and must be purchased separately.

To check the battery charge of the Cuff Module

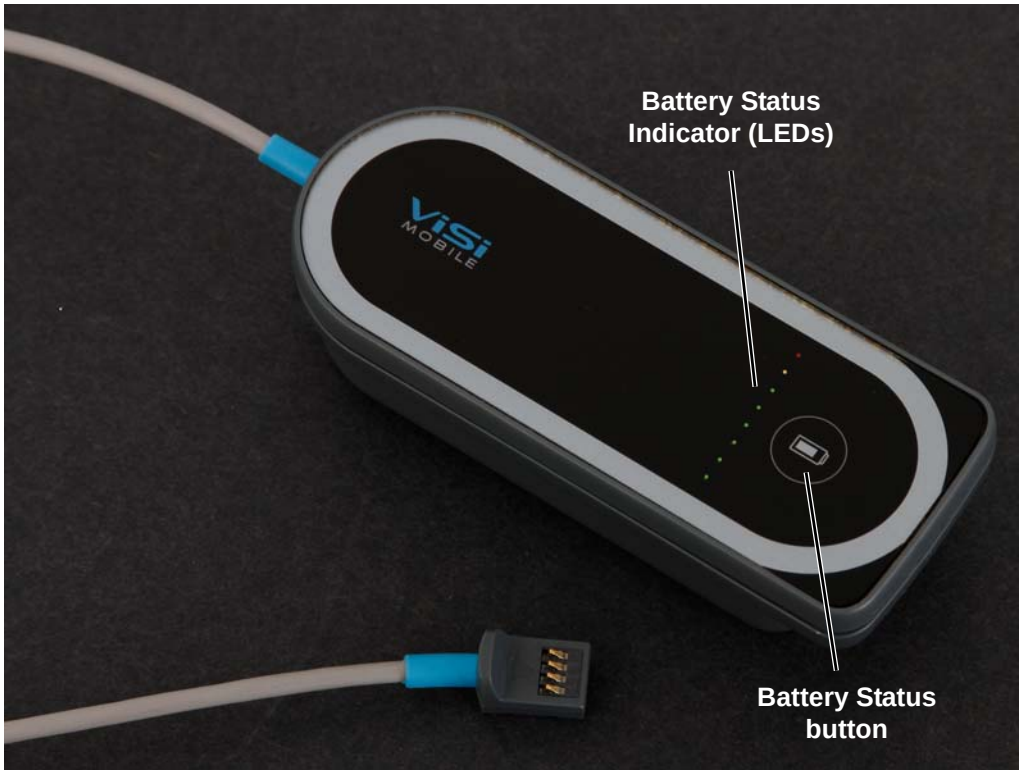
Press the **Battery Status** button on the front of the Cuff Module.

There is a row of eight colored lights on the front surface of the Cuff Module.

Illuminated green lights indicate that the level of the battery charge is adequate for at least several NIBP measurements. When six illuminated green lights are visible on the Cuff Module, the Module is fully charged.

When the yellow light is illuminated, the battery charge is low. At least one NIBP measurement is possible.

When the red light is illuminated, the battery charge is too low for any further NIBP measurements.



5.3 Applying ViSi Mobile Monitoring System / Initiate Monitoring

The ViSi Mobile Monitor may be used to monitor one vital sign, such as SpO_2, or multiple vital signs simultaneously. Apply the appropriate sensor for each vital sign to be monitored, as described below. Start by selecting the appropriately sized Disposable Kit (S, M, M+, L or L+).

The Monitor's ECG channel is capable of monitoring patients with an Implanted Pacemaker (PM), Implantable Cardioverter-Defibrillator (ICD), or Cardiac Resynchronization Therapy (CRT) device. A vertical dashed line before the *P* wave (atrial pace), and before the *QRS* (ventricular pace) indicates paced events. In the case of biventricular pacing (CRT), two vertical dashed lines occur before the QRS.

Note: Vertical dashed lines from pacemaker stimulus pulses may occur. These are not counted as heartbeats, as defined by the pacer pulse rejection specification. *See Chapter 10. Specifications on page 161.*

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.

ViSi cNIBP has not been evaluated in patients with pacemakers that pace the ventricle. ViSi's NIBP may be used instead.

Only use the ViSi Mobile Chest Sensor CableChest Sensor provided by Sotera Wireless, Inc. for the ViSi Mobile Monitoring System. The Chest Sensor CableChest Sensor 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 SpO2 readings or damaged equipment.

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 and any packaging material after use per your facility's policy or national requirements.

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

5.3.1 Applying the ViSi Mobile Wrist Cradle

If there are no contraindications, apply the Wrist Cradle to the patient's wrist (either left or right).

To apply the Wrist Cradle

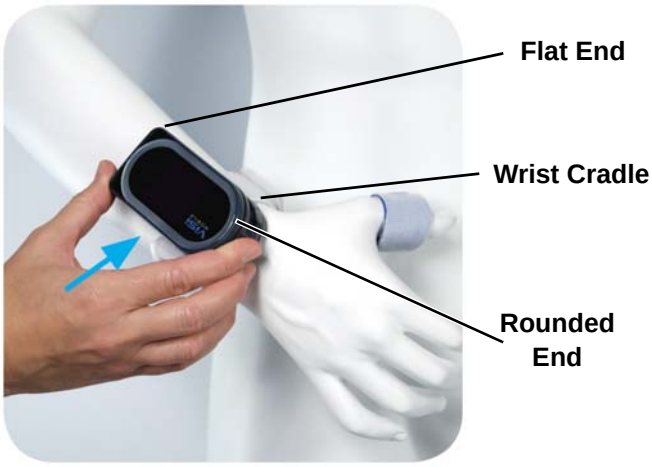
1. Remove the Wrist Cradle from the Disposable Kit.
2. Orient the Wrist Cradle with the flat end pointed towards the elbow, slide the patient's hand through the Wrist Strap and position the cradle on the top side of the wrist.
3. Pull snugly and secure.

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.

4. Placing the flat end in first, insert the Monitor into the Wrist Cradle and push down.

When the Monitor is pushed down all the way, you will hear a "clicking" sound.

Note: The Monitor is not completely secured within the Wrist Cradle until the Thumb Sensor or Locking Plug is inserted into the connector on the rounded end of the Monitor.



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

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 while it is connected to the patient, secure the ViSi Mobile Monitor by plugging in the thumb sensor or locking key.

5. If you are not performing SpO_2 monitoring, secure the Monitor to the cradle by inserting a Locking Plug into the opening on the rounded end of the Monitor.

Locking Plug

5.3.2 Applying Sensors

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

Vital signs monitoring starts automatically as soon as a sensor is connected to the Monitor and attached to the patient. When performing a patient setup, the alarms pause automatically, allowing time to complete the setup before the alarms are turned on.

Sensors are designed to securely plug into the Monitor so that they cannot fall out unintentionally.

You should hear a double-beep sound when a sensor is inserted correctly.

5.3.3 Applying the ViSi Mobile Thumb Sensor

The ViSi Mobile Thumb Sensor is intended for use on the patient's thumb, index and middle finger for SpO2 measurements; however, cNIBP can only be measured while on the patient's thumb. only. Do not apply the Thumb Sensor to the patient's fingers.

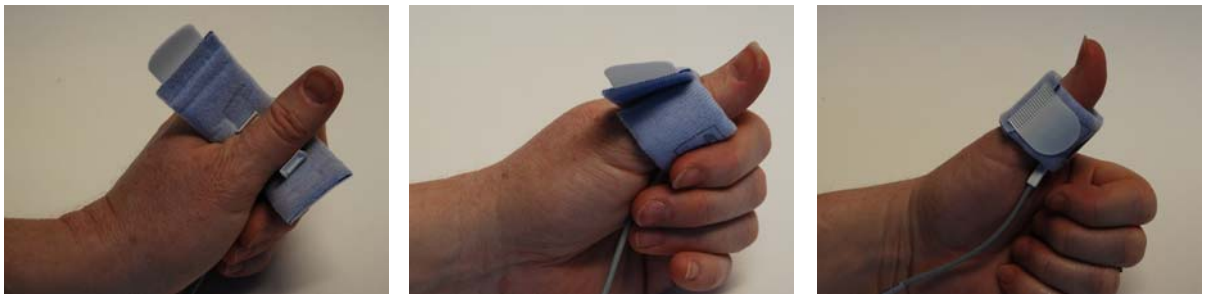
To apply the Thumb Sensor

1. Remove the Thumb Wrap from the Disposable Kit.
2. Insert the Thumb Sensor into the Thumb Wrap such that the sensor optics are pointing away from the Thumb Wrap.

Thumb Sensor

Thumb Wrap

3. Remove the plastic from the adhesive strip to minimize movement and rotation of the Thumb Wrap.
4. Place the Thumb Sensor at the base of the thumb and secure it with the Thumb Wrap.



The Thumb Wrap is designed to hold the Thumb Sensor in place securely without impairing circulation.

Ensure that the ViSi Mobile Thumb Sensor is securely fastened. A Thumb Sensor that is wrapped too tightly or too loosely can adversely affect SpO2 measurement.

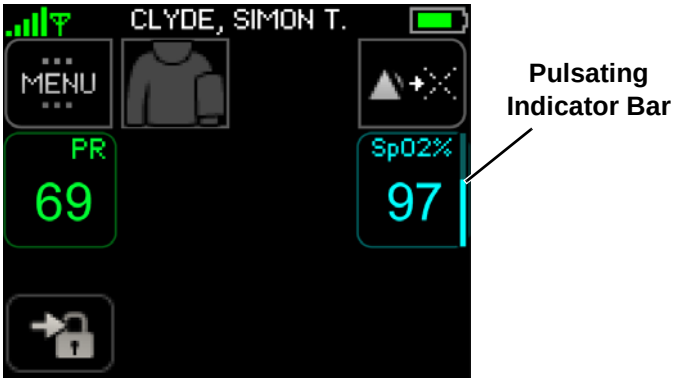
Inspect the patient's skin at the sensor site per your facility's protocol. If the skin surface has been compromised, reposition the ViSi Mobile Thumb Sensor or move the Thumb Sensor to the patient's other thumb. If the thumb sensor is moved to the other thumb, move the other sensors as well.

5. Check the patient's thumb for good color and circulation to ensure that the Thumb Sensor has not restricted circulation.

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

6. Connect the Thumb Sensor into the connector on the rounded end of the Monitor with the connector contacts facing upwards.

The monitoring of SpO_2 and the PR starts after a few seconds. Alarm limits are set automatically according to predefined settings. *See 6.6 Manage Alarm Limits on page 96.*



7. While palpating the pulse in the wrist of the arm opposite the Monitor, watch the pulsating indicator bar to the right of the SpO_2 numeric and ensure that the bar fluctuates with the pulse.

   The pulsating indicator bar confirms signal adequacy by moving up and down in sync with the detection of pulsating blood flow. Use the pulsating indicator bar to confirm the Thumb Sensor is optimally placed. It may take several seconds for the signal to stabilize.

   The indicated PR should match the palpated pulse rate. PR is replaced with HR when measuring ECG and SpO_2 simultaneously.

Note: If sensing of the SpO_2 or the PR is erratic, loosen the Thumb Strap from the thumb and reposition the Thumb Sensor until a stable SpO_2 and PR are obtained. Re-secure the Thumb Sensor with the Thumb Strap.

Note:

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 SpO2 readings or damaged equipment.

5.3.4 Applying the ViSi Mobile Chest Sensor and ECG Electrodes

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

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.

Only use the ViSi Mobile Chest Sensor CableChest Sensor provided by Sotera Wireless, Inc. for the ViSi Mobile Monitoring System. The Chest Sensor CableChest Sensor 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.

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.

Skin Preparation

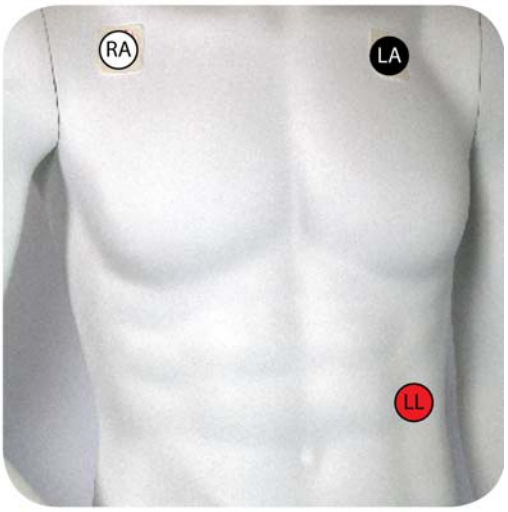
Skin preparation and ECG electrode placement directly impact the quality of the ECG signal and HR determinations. Follow your facility's protocol for skin preparation.

Note: To avoid skin irritation, avoid areas that appear damaged; remove ECG electrodes if the patient complains of pain/itching; replace ECG electrodes per the electrode manufacturer's instructions and place on different sites.

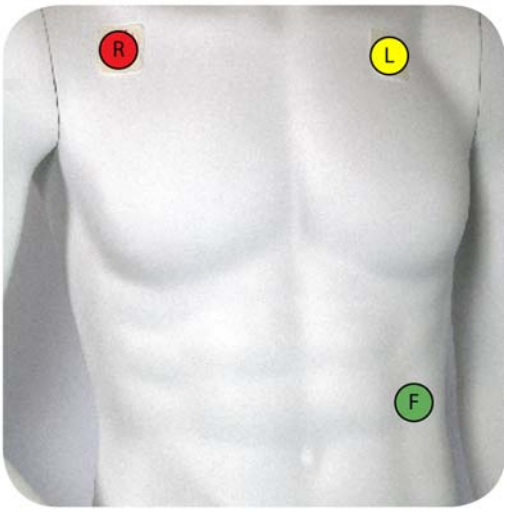
Note: Only use snap-on type electrodes.

3 lead-wire and ECG Electrode Placement

With the 3 lead-wire Chest Sensor, the ECG channel provides Lead II only. The ECG electrode placement shown in the diagram below is recommended for Lead II monitoring



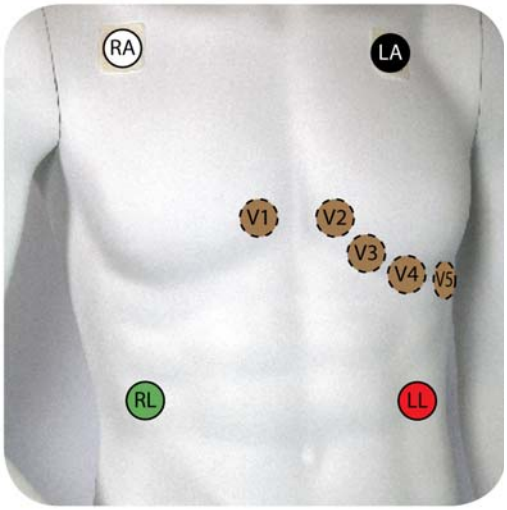
lead-wire Color Code - U.S. (AAMI)
RA - White
LA - Black
LL - Red



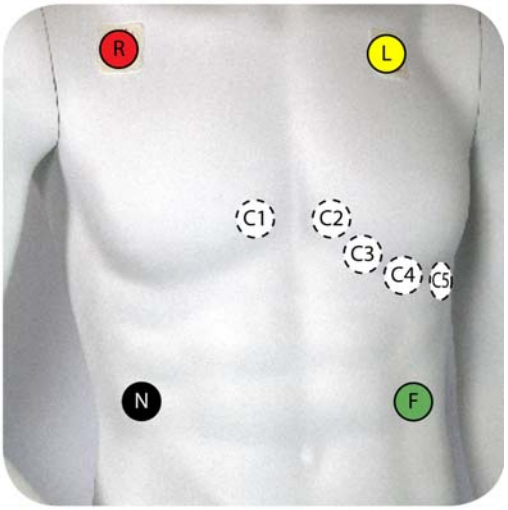
lead-wire Color Code - International (IEC)
R - Red
L - Yellow
F - Green

5 lead-wire and ECG Electrode Placement

With the 5 lead-wire Chest Sensor, the ECG channel is capable of monitoring seven leads simultaneously (Lead I, II, III, aVR, aVL, aVF, and a V lead). The ability to monitor multiple leads simultaneously improves beat detection to determine the HR and minimizes false detections as a result of artifact. The ECG electrode placement shown in the diagram below is recommended.



lead-wire Color Code - U.S. (AAMI)
RA - White
LA - Black
LL - Red
V - Brown
RL - Green



lead-wire Color Code - International (IEC)
R - Red
L - Yellow
F - Green
C - White
N - Black

V1/C1	4th intercostal space (just right of sternum)
V2/C2	4th intercostal space (just left of sternum)
V3/C3	Midway between V2 and V4
V4/C4	Mid clavicular line, 5th intercostal space
V5/C5	Anterior axillary line, in line with V4, or 5th intercostal space
V6/C6	Mid axillary line, in line with V5, or 5th intercostal space

Note: Place the V lead in the position appropriate to your monitoring requirements: V1, V2, V3, V4, V5 or V6.

Note: The ECG waveform can be displayed one lead at a time on the ViSi Mobile Monitor.

To apply the Chest Sensor

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.

1. Remove the securements from the Disposable Kit and snap the Chest and Upper Arm Modules into the securements.
2. Secure the Chest Module of the Chest Sensor between the sternum and the shoulder (same side as the Monitor). The ideal location is the lower half of the sternum. If contraindicated, move the Chest Module of the Chest Sensor higher on the sternum or laterally from the sternum.

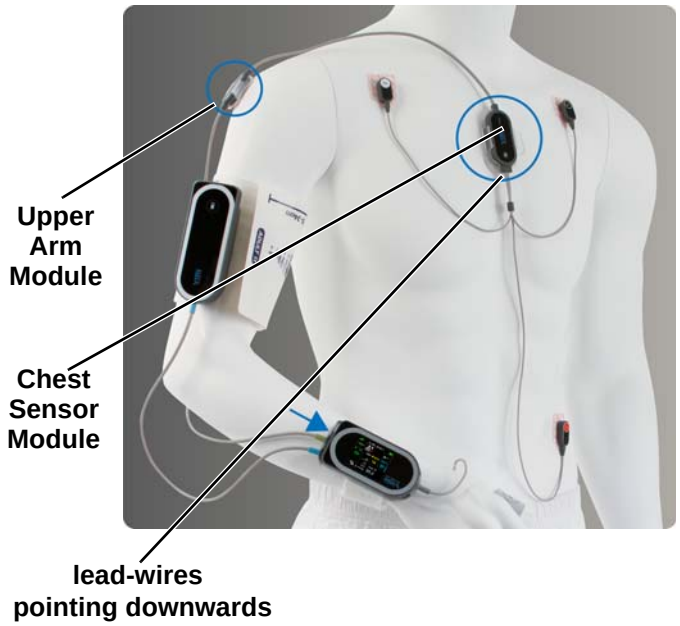
Note: The Chest Sensor should be oriented vertically, with the lead wires hanging downward. Do not orient the sensor more than a few degrees to the left or right.

Note: Ensure the "Front", "ViSi Mobile" and "Defibrillation" labels on the Chest Module of the Chest Sensor are facing outwards away from the patient's skin.

Note: Ensure the "barcode" label and the Temperature sensor on the Chest Module of the Chest Sensor are placed inwards directly against the patient's skin.

Note: For patient comfort, shave or clip the hair in the areas where the Chest Module Securement comes in contact with the chest.

3. Secure the Upper Arm Module of the Chest Sensor vertically on the outside of the upper arm.
4. Remove the ECG electrodes from the Disposable Kit.
5. Connect the Chest Sensor lead-wires to the ECG electrodes.
6. Apply the ECG electrodes to the prepared sites on the chest as shown.



Chest Module (front view)
(Place this side away from the patient's skin)

Chest Sensor Module (rear view)
(Place this side against patient's skin)

Note: The default ECG configuration is Lead II.

7. Plug the Chest Sensor into any of the three ports on the flat end of the Monitor with the connector contacts facing upwards.

Note: Monitoring of ECG, HR, RESP (optional), and TEMP starts automatically. Alarm limits are set automatically according to predefined settings.

Note: Only attach one ViSi Mobile Chest Sensor to the patient and ViSi Mobile Monitor.

Insert with connectors contacts facing upwards

8. While palpating the pulse in the wrist of the arm opposite the Monitor, watch the beating heart symbol at the top left of the HR numeric to ensure that it fluctuates with the patient's heart beat.

   The heart symbol beats with the pulse to confirm that the sensor is optimally placed. It may take several seconds for the signal to stabilize.

   - The indicated HR should match the palpated pulse rate. It may take several seconds for the rate to stabilize on the Monitor.
   - If the indicated HR is erratic or doesn't match the palpated pulse rate, check to make sure that the ECG electrodes and lead-wires are secure.

Note: In rare circumstances, the ECG electrodes may need to be placed in different locations to improve the ECG signal.

9. While observing the patient, count the respiration rate and compare it to the **RESP** rate on the Monitor. It may take several seconds for the signal to stabilize.

   - The indicated RESP should match the observed rate.
   - If the indicated RESP is erratic or doesn't match the observed rate, check to make sure that the ECG electrodes and lead-wires are secure.

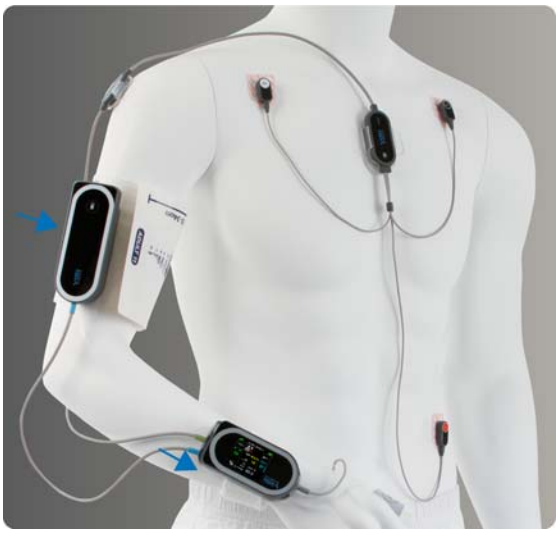
Note: The Temperature sensor may take up to 6 minutes to reach a stable temperature reading.

5.3.5 Applying the ViSi Mobile Cuff Module and Disposable Cuff

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.

To apply the Cuff Module

1. Remove the Cuff from the Disposable Kit.
2. Squeeze as much air out of the Cuff as possible.
3. Ensure that the patient is resting so that the upper arm muscles are relaxed. The level of the middle of the Cuff, while the arm is at rest, should be approximately at heart level.
4. Connect the Cuff Module securely to the Cuff.
5. Wrap the Cuff around the upper part of the same arm to which the Monitor is attached.
    - Align the bottom part of the Cuff approximately 1” above the antecubital fossa.
    - Align the artery marker on the Cuff with the brachial artery.
    - The connector for the Cuff Module should be to the outside of the arm, away from the body.
    - The cable from the Cuff Module should be hanging down in the direction of the Monitor.
    - Have the patient remain still to avoid the introduction of unnecessary motion artifact.



Note: The ViSi Mobile Disposable Cuff is designed to be used on the same arm with the other ViSi Mobile sensors. It may temporarily cause the loss of function of other devices (not ViSi Mobile) simultaneously used on the same limb.

Note: Only attach one ViSi Mobile Cuff Module to the ViSi Mobile Monitor..

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 blood pressure measurements (NIBP and cNIBP) have not been clinically evaluated in the presence of atrial or ventricular arrhythmias. Use alternative BP methods if these arrhythmias are present.

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

6. Plug the Cuff Module into any of the open ports on the flat end of the Monitor with the connector contacts facing upwards.

Insert with connector contacts facing upwards

The NIBP Start button will be enabled, prompting you to start a Cuff inflation. See Taking a NIBP Measurement on page 124 for instructions on how to take a NIBP measurement.

5.4 Removing ViSi Mobile Monitoring System

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 and any packaging material after use per your facility's policy or national requirements.

Note: Before removing ALL the ViSi Mobile Monitoring System components, you should either pause monitoring temporarily *(see Pause Monitoring on page 139)* or stop monitoring, if the patient will no longer be monitored *(see Stop Monitoring on page 142)*.

To remove Cuff and Cuff Module

1. Disconnect the Cuff Module from the Monitor: Grasp the Cuff Module cable near the plug and, while holding the Monitor still, pull out the plug.
2. Unwrap the Cuff from the arm.
3. If the patient will no longer be monitored:
    - Disconnect the Cuff Module from the Cuff.
    - Dispose of the Cuff according to your facility's policy.

To remove the Chest Sensor

1. Disconnect the Chest Sensor from the Monitor: Grasp the Chest Sensor cable near the plug and, while holding the Monitor still, pull out the plug.
2. Remove the Cable Securements from the patient's chest and arm and dispose of them according to your facility's policy.
3. To prevent placing stress on the lead-wires, grasp each lead-wire near the connection to the ECG electrodes. Pull the lead-wires from the ECG electrodes.
4. Carefully remove the ECG electrodes from the patient and dispose of them according to your facility's policy.

To remove the Thumb Sensor

1. Disconnect the Thumb Sensor from the Monitor: Grasp the Thumb Sensor cable near the plug and, while holding the Monitor still, pull out the plug.
2. Remove the Thumb Sensor from the patient.
3. Holding the ends of the Thumb Sensor between your thumb and index finger, gently bend the Thumb Sensor backwards until it releases from the Thumb Wrap.
4. If the patient will no longer be monitored, dispose of the Thumb Wrap according to your facility's policy.

To remove the Wrist Cradle and Monitor

1. For ease of removal of the Wrist Cradle and Monitor, ensure all sensors are disconnected from the Monitor.
2. Remove the Monitor from the Wrist Cradle.
3. Unwrap the Wrist Strap from the patient's wrist and remove the Wrist Cradle from the patient's wrist.

4. If the patient will no longer be monitored, dispose of the Wrist Cradle and Wrist Strap according to your facility's policy.

Clean the reusable components of the System: Monitor, Chest Sensor, Thumb Sensor, and Cuff Module, in accordance with your facility's procedures and the cleaning recommendations in this manual. *See Chapter 7. User/Preventative Maintenance on page 105.*

5.5 Clinical Configurations

5.5.1 .XML File

The configuration options in the table below will configure the Monitor for the Facility's Care Unit through the .XML file that is stored on the server. Once the Monitor has connected to the network, the clinical configurations will automatically be updated to the configurations set in the .XML file.

Note: Once the Monitor has connected to the network, any other configurations that were previoulsy set using, including while in Bio Med Mode, will be over-written.

5.5.2 Units of Measure

Configuration Options	Option Values	Level Updateable
Blood Pressure	mmHg (*default*) kPa	Facility: *yes* Care Unit: *no*
Temperature	Fahrenheit (^{o}F) (*default*) Centigrade (^{o}C)	Facility: *yes* Care Unit: *no*
Date Display Format	Mon DD, YYYY(*default*) DD Mon YYYY MM/DD/YYYY DD/MM/YYYY	Facility: *yes* Care Unit: *no*
Time Display Format	12 hr (*default*) 24 hr	Facility: *yes* Care Unit: *no*
ECG Line Noise Filter	50 Hz 60Hz (*default*)	Facility: *yes* Care Unit: *no*

5.5.3 Monitor Timeout

The Clinical screen on the Wrist Monitor will timeout after a specified period of inactivity.

Configuration Options	Option Values	Level Updateable
Monitor Timeout	15 Seconds 30 Seconds 1 Minute 3 Minutes *(default)* Off	Facility: *yes* Care Unit: *no* Monitor: *no*

a. The Wrist Monitor screen can be set to timeout at different intervals and the user will be required to authenticate before viewing the screen again.
b. When “Off” has been selected, the screen will never timeout; a user will not be required to authenticate to view the screen again.

5.5.4 Clinical Authentication

The Clinical Authentication option determines if a user must authenticate using a 4-digit PIN before accessing the Monitor features.

Configuration Options	Option Values	Level Updateable
Clinical Authentication	On *(default)* Off	Facility: *yes* Care Unit: *yes* Monitor: *yes*

a. When “On” has been selected, the user will be prompted to authenticate using a 4-digit PIN before being able to access the clinical screens.

b. When “Off” has been selected, the user will have full access to the clinical screens without having to authenticate with a 4-digit PIN before accessing.

5.5.5 Skin Temperature Configuration

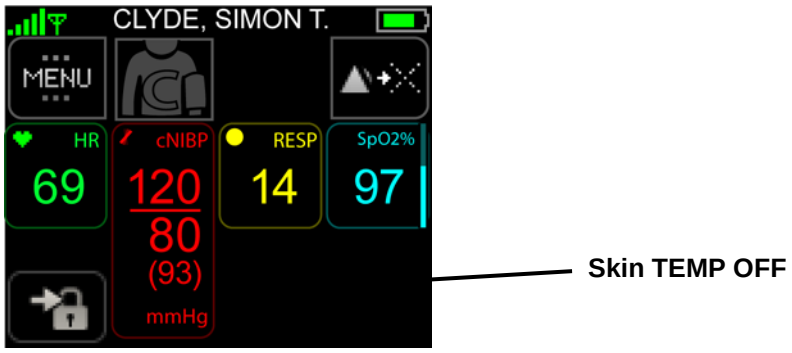
The Skin Temperature Configuration is an available option to turn “On” or “Off” within the Facility’s Care Unit. This option cannot be changed on a per Monitor basis on a netoworked floor.If Skin Temperature is turned “On” for the Facility’s Care Unit through the network, then all networked Monitors’ configurations will be synched to the .XML file once the Monitor connects to the network again.

Note: Only while in Bio Med Mode is it possible to turn the Skin Temperature vital sign “On” or “Off.”

Note: Un-Networked/Standalone Monitors are the only Monitors that are able to have Skin Temperature turned “On” or “Off” while in Bio Med Mode.

Configuration Options	Option Values	Level Updateable
Skin Temperature	On *(default)* Off	Facility: *yes* Care Unit: *yes* Monitor: *yes*

a. When “On” is selected for Skin Temperature and the Chest Sensor is connected to the Wrist Monitor, the Skin Temperature vital sign measurement will be displayed.
b. When ”Off” is selected for Skin Temperature and the Chest Sensor is connected to the Wrist Monitor, the Skin Temperature vital sign will not be displayed.



6. Alarms

6.1 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 manage the alarm limits for each patient to provide individualized care.

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

6.1.1 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).

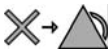
6.2 Physiological Alarms (Alarms) / Technical Alarms (Alerts) Summary

6.2.1 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[a]**
			Remote Viewer *(At Clinician's Station)*	**Mobile Monitor** *(At Patient)*	
1	**Life Threatening** 		Silenced at the Remote Viewer for 2 minutes. Continues on Mobile Monitor	Audible continues on Mobile Monitor until silenced on 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.

a. Audio tones associated with alarms/alerts will only occur on the ViSi Mobile Monitor when the Monitor is not connected to a known network. Audio tones will always occur on the ViSI Mobile Remote Viewer.

6.2.2 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 display messages associated with only the highest alarm severity. The vital signs measurements will display all existing alarms, regardless of their severity.

6.3 Responding to Physiological Alarms (Alarms)

6.3.1 To Silence/Acknowledge Life Threatening Severity Alarms

Life threatening severity alarms require urgent clinician response at the bedside.

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

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

- or -

Touch the **Alarm Status**. 

The alarm is silenced/acknowledged and the "Silenced/Acknowledged" symbol and countdown appear. After the 2 minute countdown expires, the alarm is re-annunciated.

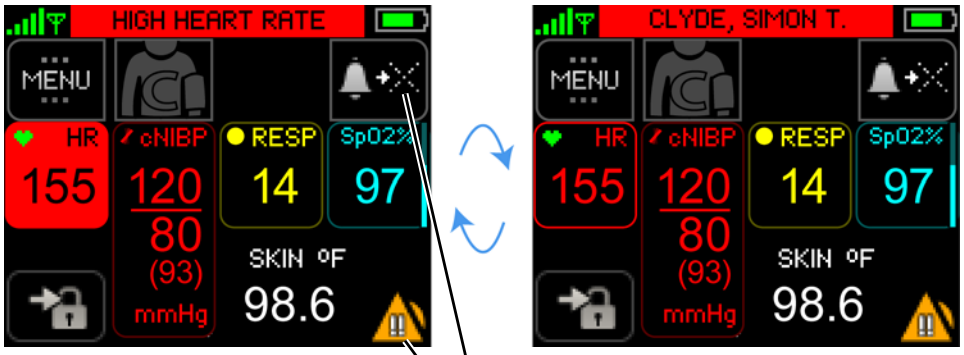
Silenced/Acknowledged symbol and countdown

Note: When a Life Threatening alarm occurs and the alarming condition resolves itself before a clinician is able to respond, visual and audio indications of the life threatening alarm continue to annunciate until the clinician silences the alarm.

6.3.2 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

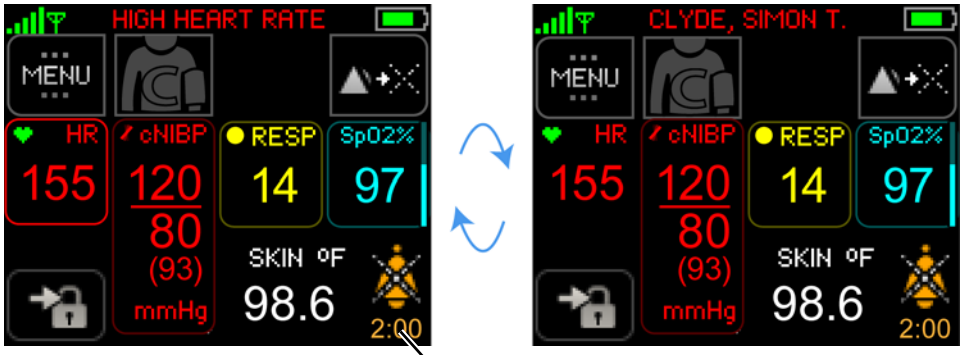


To silence/acknowledge the alarm, touch **Silence/Acknowledge Alarm** button 

- or -

Touch the **Alarm Status**. 

The alarm is silenced/acknowledged and the silenced/acknowledged symbol and countdown appear.



Silenced/Acknowledged symbol and countdown

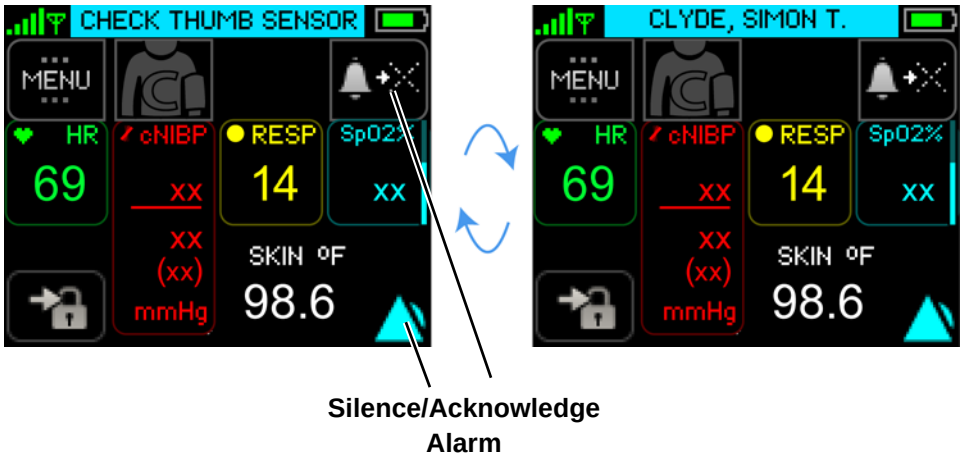
Note: When a high alarm occurs and the alarming condition resolves itself before a clinician is able to respond, the high alarm message appears (in gray) for up to 5 minutes in the message area. This serves as a reminder to the clinician that a high alarm has occurred.

6.4 Responding to Equipment Alarms (Alerts)

6.4.1 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

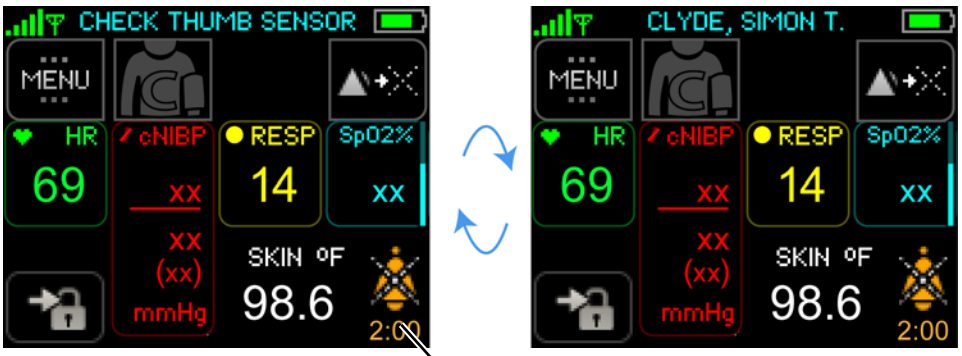


To silence/acknowledge the alert, touch **Silence/Acknowledge Alarm** button 

- or -

Touch the **Alert Status**. 

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



Silenced/Acknowledged symbol and countdown

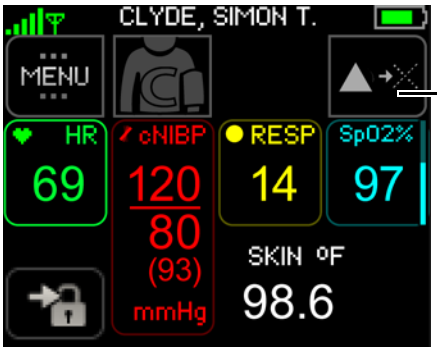
Note: When an alert condition (of any severity) resolves itself before the clinician is able to respond, the alert condition will no longer be annunciated.

6.5 Managing Alarm Annunciations

6.5.1 Pause / Resume Alarms

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.

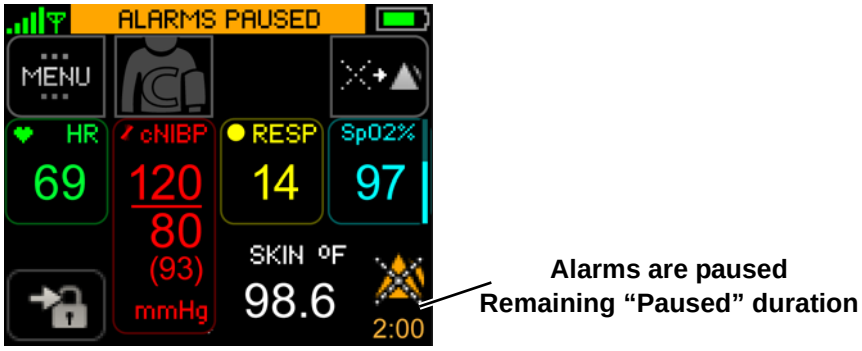
To pause the alarms



From the **Vital Signs** screen, touch **Pause Alarms.**

The alarms will be paused for 2 minutes.

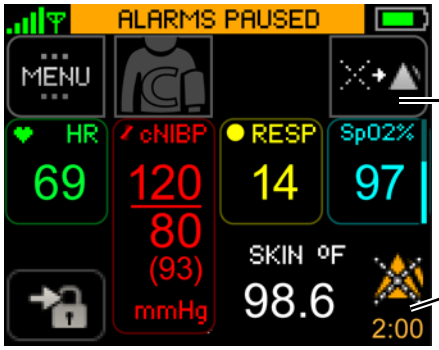
When paused, the words ALARMS PAUSED appear at the top of the screen and an ALARMS PAUSED icon appears in the lower right corner of the screen.



Note: When the clinician logs out of the ViSi Mobile Monitor, the alarms will automatically be resumed.

To Resume Alarms

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 the Mobile Monitor or Remote Viewer.



Resume alarms

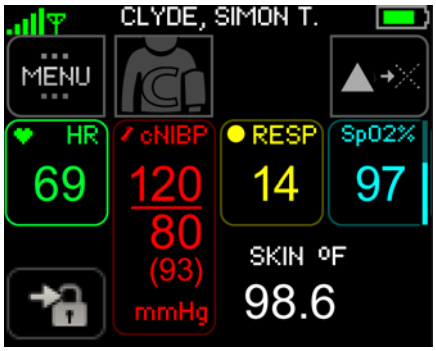
Alarms are currently paused.
Remaining "Paused" duration.

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

- or -

Touch the **AlarmStatus**.

The alarms resume and annunciate at both the ViSi Mobile Monitor and Remote Viewer.



6.5.2 Turn Alarm Annunciation On / Off

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.

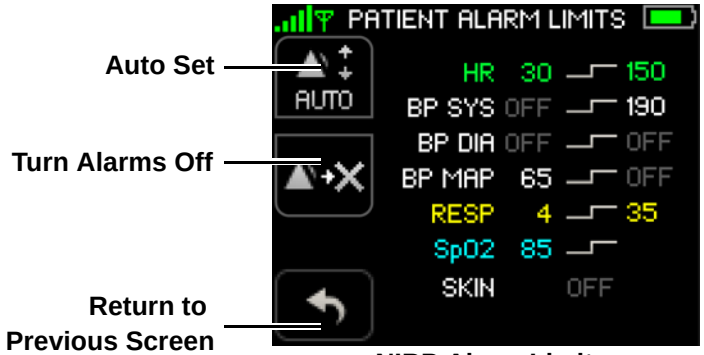
To turn all alarms off

1. Touch **Menu** on the **Vital Signs** screen. MENU

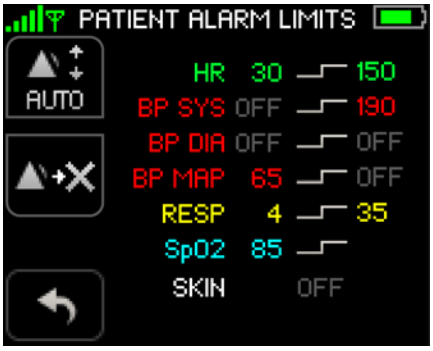
   The Menu screen appears.

2. Touch **Alarms Settings.**

   The Patient Alarm Limits screen appears. Alarm limit settings appear for the connected sensors.



NIBP Alarm Limits (Alarm limits in white)



cNIBP Alarm Limits (Alarm limits in red)

Note: Systolic, diastolic and MAP alarm limits for cNIBP appear in red when measuring NIBP continuously. Normal NIBP alarm limits appear in white.

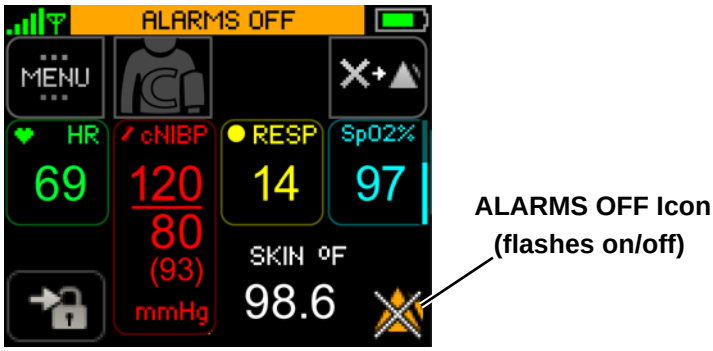
3. To turn all alarms off, touch **Turn Alarms Off**.

   The Turn Alarms Off confirmation screen appears.

4. Touch **Confirm** to confirm that you want to turn all alarms off.
   -or-
   Touch **Cancel** to leave the alarms turned on.

If cancelled, the system returns to the Patient Alarm Limits screen and the alarms remain turned on.

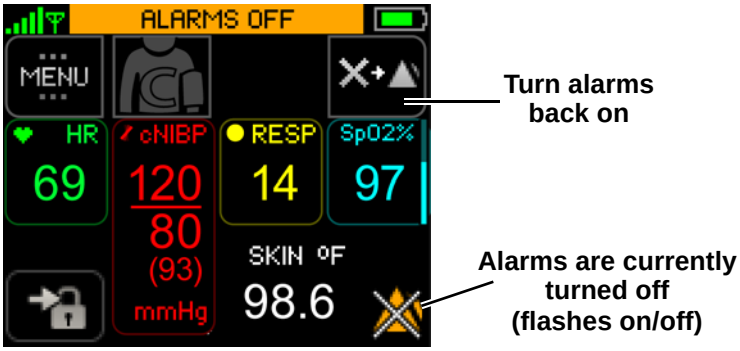
If confirmed, the alarms are turned off and the Vital Signs screen appears. The words ALARMS OFF appear at the top of the screen and an ALARMS OFF icon appears in the lower right corner of the screen.



Note: Alerts that indicate the Monitor is unable to measure a vital sign (such as ECG Lead Fail) can not be turned off.

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 Monitor and Remote Viewer.

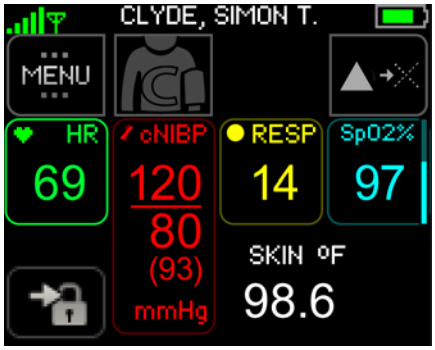


To turn the alarm annunciation back on, touch the **Turn Alarms On** button.

- or -

Touch the **Alarm Status**.

The alarms will be turned back on.



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

6.6 Manage Alarm Limits

Alarm limits for each vital sign parameter are predefined and turned on automatically when sensors are connected to the patient and to the Monitor. Sometimes it is desirable to adjust the alarm limits to meet a patient's monitoring requirements.

The Auto Set function only sets alarm limits for vital sign measurements that are currently in alarm. The new alarm limits are based on the current vital signs measurements.

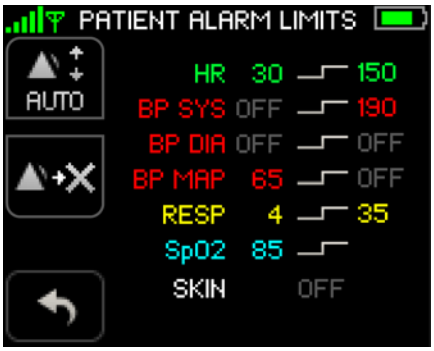
Once Auto Set is selected (on the ViSi Mobile Monitor), review the newly calculated alarm limits carefully before deciding to confirm or cancel the new alarm limits. Once new alarm limits are confirmed on the ViSi Mobile Monitor, they cannot be changed back to the original pre-set limits from the ViSi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

To change alarm limits using Auto Set

1. Touch **Menu** on the **Vital Signs** screen. MENU
2. Touch **Alarms Settings.**

   The Patient Alarms Settings screen appears.

NIBP Alarm Limits
(Alarm limits in white)



cNIBP Alarm Limits
(Alarm limits in red)

Note: Systolic, diastolic and MAP alarm limits for cNIBP appear in red when measuring NIBP continuously. Normal NIBP alarm limits appear in white.

Note: Alarm limit settings appear only for the currently monitored vital signs.

3. Touch **Auto Set**. 

   The Confirm New Alarm Limits screen appears.

   Alarm limits for all vital sign measurements currently in alarm are recalculated based on the current vital signs measurements.

NIBP Alarm Limits
(Alarm limits in white)

cNIBP Alarm Limits
(Alarm limits in red)

Note: Systolic, diastolic and MAP alarm limits for cNIBP appear in red when measuring NIBP continuously. Normal NIBP alarm limits appear in white.

Note: Upper and lower alarm limits cannot be set for TEMP.

4. Touch **Confirm** to confirm that you want to accept the new alarm limits.

   -or-

   Touch **Cancel** to return to the **Patient Alarm Limits** screen.
   The previous alarm limits are retained.

   Once confirmed, the system returns to the Vital Signs screen.

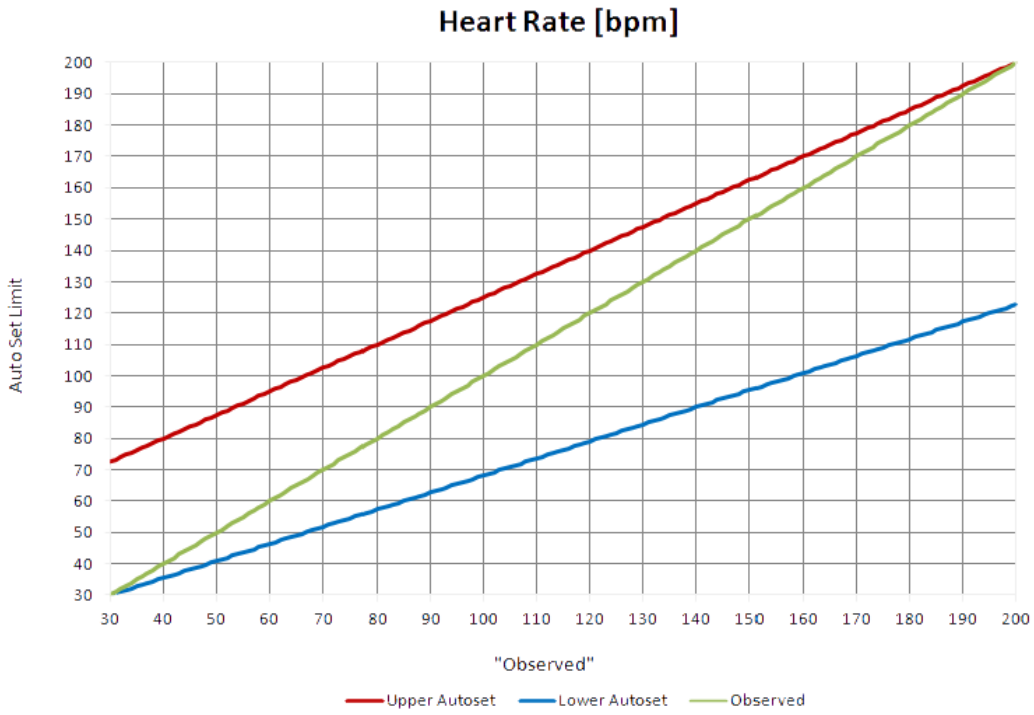
5. Navigate to the **Patient Alarm Limits** screen to review the current alarm limits.

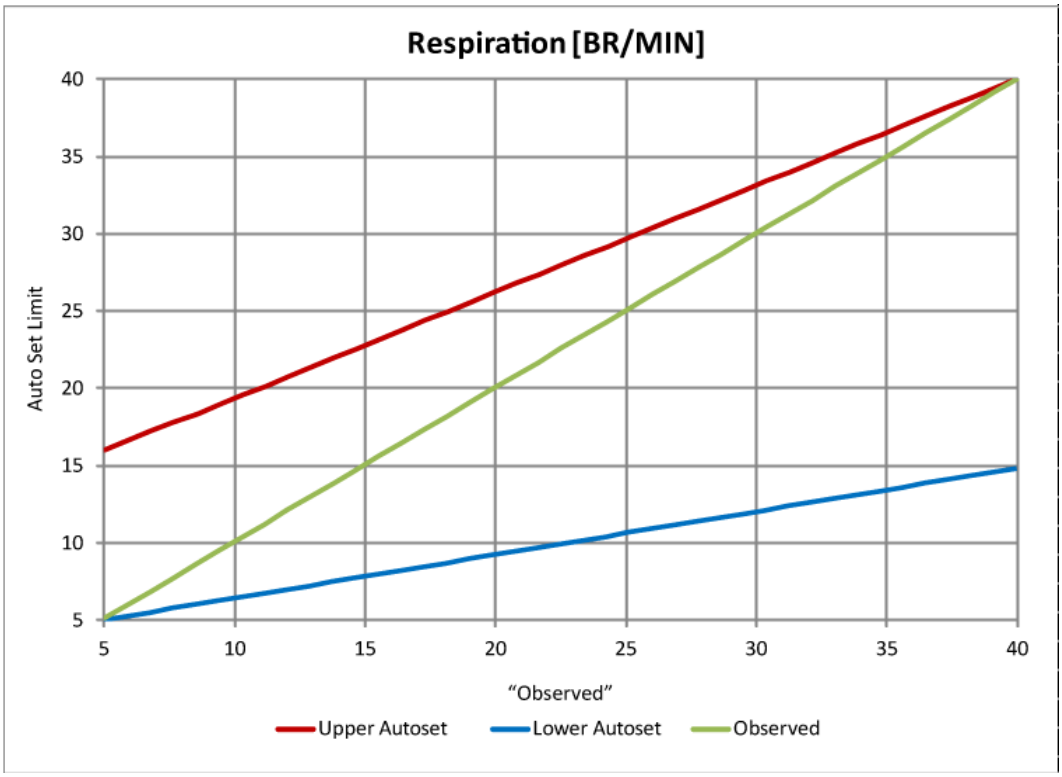
When selecting Auto Set, alarm limits are calculated to clinically relevant values based on the patient's present condition. Auto Set is not available for temperature. The minimum and maximum values to which auto set will adjust the limits are listed in the table below.

Auto Set Alarm Limits				
Alarm	**Limit**	**Default Limits**	**Auto Set Range**	**Auto Set Limit Calculation (based on current reading)**
Heart Rate (BPM)	High	140	90-200	HR x .75 + 50
	Low	40	30-80	HR x .545 + 13.636
Pulse Rate (BPM)	High	140	90-160	PR x 0.66 + 53.3 .75 + 50
	Low	40	30-80	PR x 0.54 + 13.6 .545 + 13.636
BP Systolic (mmHg)	High	190	160-240	BP x 0.75 + 60.0
	Low	OFF	60-120	BP x 0.71 + 17.1
BP Diastolic (mmHg)	High	OFF	95-150	BP x 0.60 + 60.0
	Low	OFF	30-90	BP x 0.72 + 8.3
BP MAP (mmHg)[a]	High	OFF	N/A	.66 + 60.0
	Low	65	N/A	.718 + 11.838
Respiration (BR/M)	High	35	12-40	RR x 0.69 + 12.5
	Low	6	5-8	RR x 0.28 + 3.6
SpO_2 (%)	Low	85	85-90	SpO_2 less than 87, limit set to 85 SpO_2 between 87 and 90, limit set to SpO_2 - 2% SpO_2 between 90 and 95, limit set to SpO_2 - 3% SpO_2 greater than 95, limit set to 90

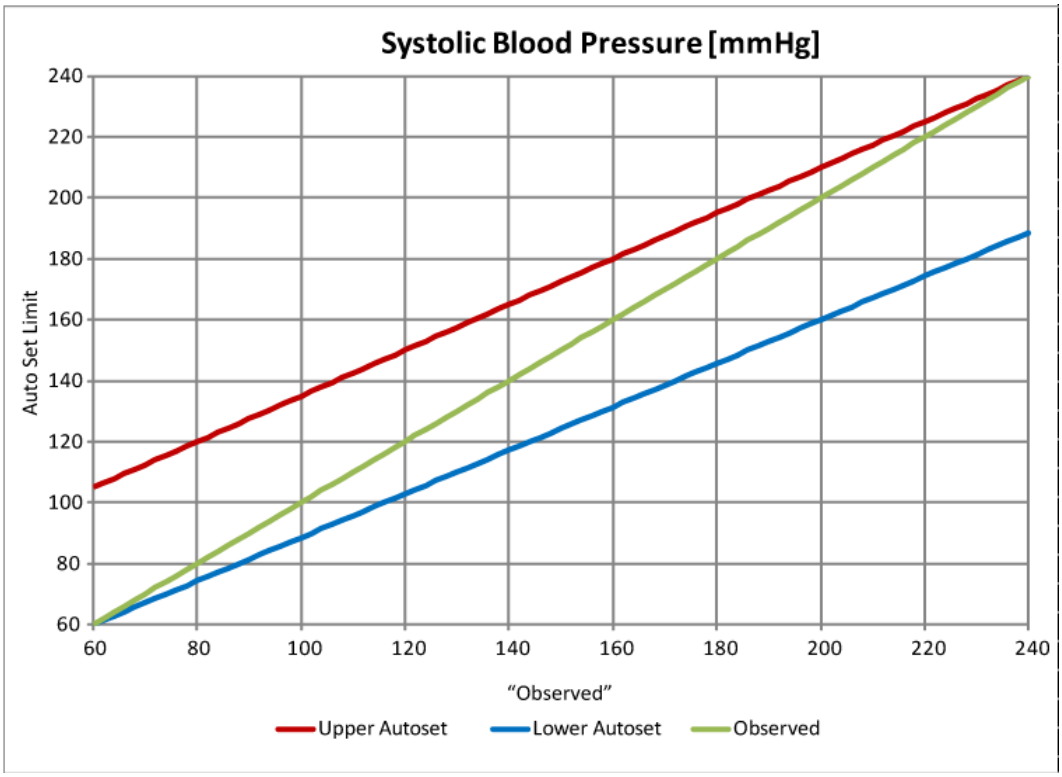
a. There is no autoset associated with BP MAP vital sign measurements.

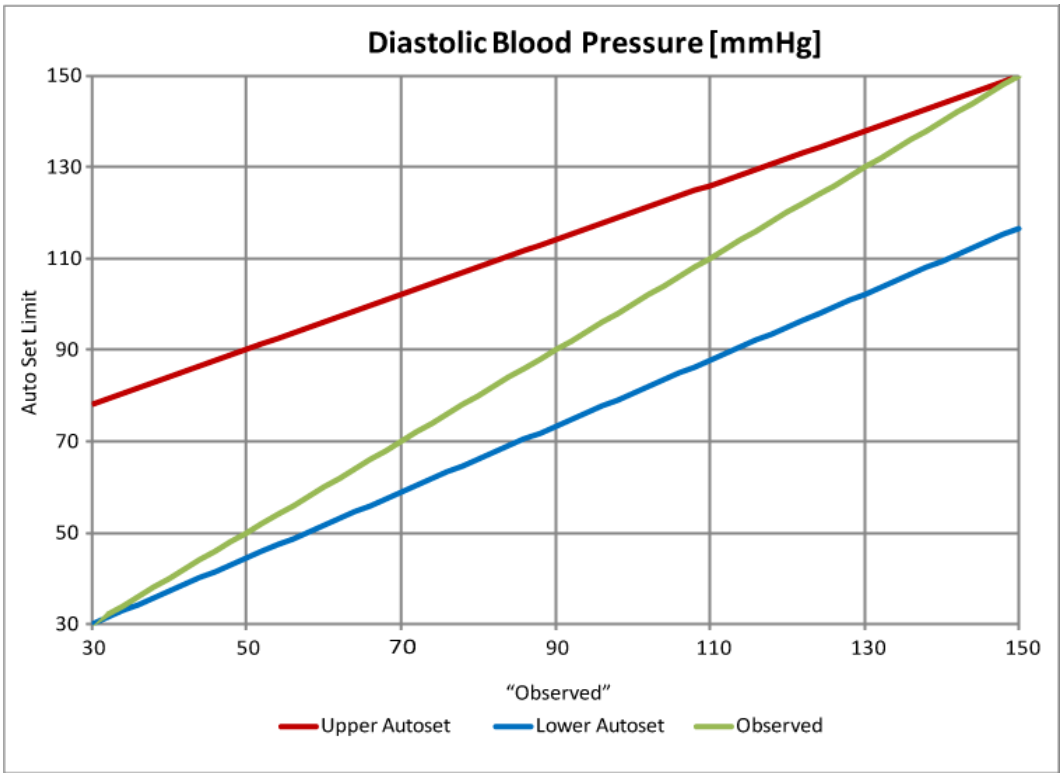
Note: Individual alarm limits may only be manually set from the ViSi Mobile Remote Viewer and not from the ViSi Mobile Monitor. Auto Set recalculates all alarm limits for vital sign measurements currently in alarm.





Auto Set Alarm Limits
(Heart Rate / Respiration)





Auto Set Alarm Limits (Blood Pressure)

6.6.1 Testing Alarms

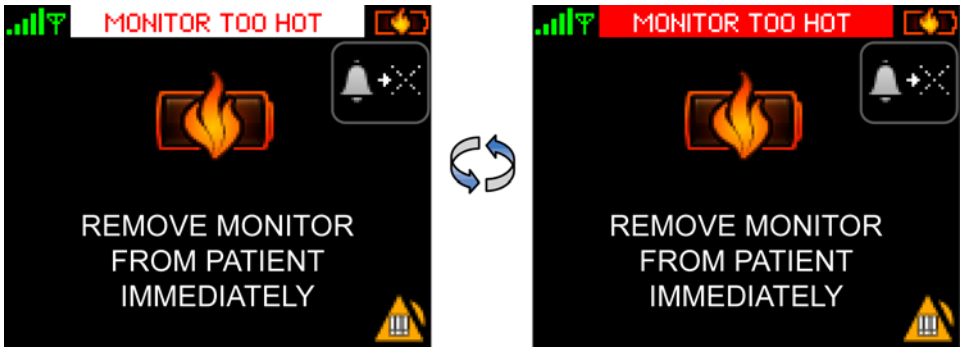
Whenever a sensor is connected to the Monitor, a self-test of that sensor is initiated automatically to verify the sensor is in good working order. If the sensor and Monitor speaker are in good working order, you will hear a double beep.

Do not cover the microphone of the Monitor during the self-test

6.7 Battery Too Hot Alarms

6.7.1 Monitor Too Hot

When the “Monitor Too Hot” alarm is in progress, the ViSi Mobile Monitor and Chest Sensor should be removed from the patient immediately. Leaving them on the patient for an extended period of time may lead to a skin burn.



The **Monitor Too Hot** alarm annunciates when one of the following occurs:

- The battery in the ViSi Mobile Monitor exceeds the defined safety limits.
- The temperature sensor in the ViSi Mobile Chest Sensor exceeds the defined safety limits.
- The current between the ViSi Mobile Monitor and the Chest Sensor exceeds an 80 second average of 250mA.

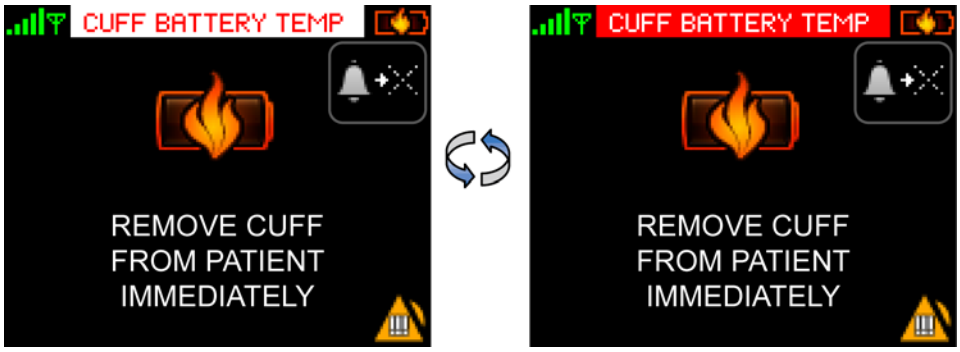
Remove the ViSi Mobile Monitor and Chest Sensor from the patient immediately and allow the components to cool down. Do not put the Monitor into the Battery Charger until it has cooled down.

Return the Monitor and Chest Sensor to Sotera Wireless, Inc.

Note: If the battery in the ViSi Mobile Monitor exceeds the defined safety limits while it is in the Charger, remove the Monitor from the Charger and allow the Monitor to cool down.

6.7.2 Cuff Module Battery Temp (Cuff Too Hot)

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



The **Cuff Battery Temp** alarm annunciates when the battery in the ViSi Mobile Cuff Module exceeds the defined safety limits.

Remove the ViSi Mobile Cuff Module from the patient immediately and allow it to cool down. Do not put the Cuff Module into the Battery Charger until it has cooled down.

Return the Cuff Module to Sotera Wireless, Inc.

Note: If the battery in the ViSi Mobile Cuff Module exceeds the defined safety limits while it is in the Charger, remove the Cuff Module from the Charger and allow the Cuff Module to cool down.

- Notes -

7. User/Preventative Maintenance

7.1 Introduction

This section of the manual outlines routine maintenance that should be performed by the user. The ViSi Mobile Monitoring System is designed for stable operation over long periods of time and, under normal circumstances, should not require technical maintenance beyond that described in this section.

7.2 Preventative Maintenance

All ViSi Mobile components are designed to internally calibrate each time they are used. Therefore, no routine calibration checks are required during routine preventative maintenance cycles. Routine testing of functionality/accuracy can be verified using standard electronic patient simulators and compared against the references in this manual.

Sotera Wireless, Inc. recommends preventative maintenance as follows:

Chest Sensor / Monitor	Visual inspections for mechanical abuse is recommended at a frequency consistent with use. Annual inspection is recommended but not required.
Cuff Module	Visual inspection and routine calibration checks against a known volume is recommended on an annual basis. The air filter should be replaced at this time. Calibration volume and replacement air filters can be purchased from Sotera Wireless, Inc. or the units can be returned to Sotera for a nominal fee.
SpO_2 Sensor	The SpO_2 sensor comes with a standard 3 month warranty. Actual life cycle duration is dependent on use and care. No preventative maintenance is required.
Optional ViSi Power Pack	Regular visual inspection for mechanical abuse is recommended at a frequency consistent with use. The ViSi Power Pack does not require calibration.

Note: Prior to any preventative or corrective service, ViSi Mobile components should be cleaned and disinfected. See below.

In the event any component needs to be returned to Sotera Wireless, Inc; contact the Sotera Wireless, Inc. Customer Service Department or the Sotera Wireless, Inc. representative in your area. Prior to shipping, ensure the returned components have been properly disinfected.

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

7.3 Cleaning and Disinfection

The ViSi Mobile Monitor, Cuff Module, Chest Sensor, Thumb Sensor, and Power Pack require cleaning and disinfection prior to reuse on a different patient. To prevent possible cross-contamination, properly clean and/or disinfect all ViSi Mobile reusable components between patients.

If the ViSi Power Pack beeper/buzzer sounds or the Red LED is permanently lit, the ViSi Power Pack should be disconnected from the patient immediately.

Do not clean the ViSi Mobile Monitor, Cuff Module, Chest Sensor, Thumb Sensor, or ViSi Power Pack with detergents while worn by the patient.

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

Do not apply liquid to the ViSi Mobile Cuff Module or the Power Pack. 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 bleach, abrasive cleaning agents or organic solvents on any of the ViSi Mobile Monitoring System components.

Use only recommended clenaing/disinfecting agents to prevent damage to the device and components. See page 107.

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 or Thumb Sensor.

Prior to cleaning and disinfecting:

1. Pre-clean at the point of use to remove and prevent drying of soil and contaminants.
2. Ensure all components are disconnected, including the ViSi Mobile Monitor from the Wrist Cradle and the Thumb Sensor from the Thumb Wrap.
3. When cleaning the optional ViSi Power Pack, first remove the Power Pack from the Power Pack Cradle. All components of the ViSi Power Pack should be cleaned and disinfected between uses.

Recommended cleaning/disinfection agents. Use either of the following:

1. Clean with soap or detergent followed by disinfection with 70% isoprophyl alcohol.
2. Clean and disinfect with Super Sani-Cloth® Germicidal Disposable Wipes.

To clean the ViSi Mobile Monitoring System components

1. Hand-wash the System components using mild soap or detergent (e.g. Alconox) and water.

   Do not appy liqiud to the Cuff Module or Power Pack, instead use a damp cloth.
2. A soft-bristled brush may be used for heavily soiled areas, as needed.
3. Dry thoroughly using a soft cloth or paper towel.
4. Visually examine the reusable components to ensure all soil contaminants have been removed.
5. Repeat the above cleaning process as required.

Note: Use a new Super Sani-Cloth®; disinfect according to manufacturer's recommended procedure.

To disinfect the ViSi Mobile Monitoring System components

Do not use bleach, abrasive cleaning agents or organic solvents on any of the ViSi Mobile Monitoring System 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 CableChest Sensor or the ViSi Mobile Thumb Sensor.

To disinfect the ViSi Mobile Monitoring System components:

1. Disinfect the reusable components by wiping with a Super Sani-Cloth® (purple top) or use a basic wipe moistened with ≤70% isopropyl alcohol.
2. Dry thoroughly using a soft cloth or paper towel.

Note: Use a new Super Sani-Cloth®; disinfect according to manufacturer's recommended procedure.

7.4 Inspecting Equipment and Accessories

After cleaning and disinfecting, you should visually inspect the ViSi Mobile Monitoring System components and replace any System components that show evidence of anomalies.

1. For each component, examine the exteriors for cleanliness and general physical conditions. Ensure the housings are not cracked or broken, that everything is present, there are no spilled liquids and no signs of abuse.
2. Inspect all component cables for damage. Check their strain relief (at flex points) for general condition. Ensure there are no breaks or cracks in the cables . If any cables show signs of damage, do not use.
3. Inspect all disposable accessories (Wrist Cradle, Cuff, Thumb Strap, Securements, etc). If any show signs of damage or pre-use, do not use.

7.4.1 ViSi Mobile Chest Sensor

The Chest Sensor measures ECG/Respiration Rate (impedance pneumography) and skin surface temperature. A standard patient simulator can be used to verify operation against the specifications found in this Manual. The temperature sensor can be checked by submersing the sensor in a heated water bath until the temperature sensor is submerged and comparing the ViSi displayed temperature against a calibrated thermometer. Allow time for the ViSi temperature sensor to equilibrate with the water bath for the time specified in the Temperature Specifications in this Manual.

7.4.2 ViSi Mobile SpO_2 Sensor

The functionality of the SpO_2 sensor can be verified using standard patient simulators. However, accuracy should NOT be determined from patient simulators since they cannot duplicate human physiology. The only way to determine accuracy is to compare the ViSi reading against a blood gas value. When troubleshooting in a clinical setting, first inspect the sensor for proper placement as shown in this User Manual.

7.4.3 ViSi Mobile Cuff Module

The functionality of the Cuff Module can be verified using a patient simulator capable of simulating oscillometric blood pressure during the cuff inflation cycle. Consult your NIBP patient simulator manual for information.

7.4.4 ViSi Mobile Charger

The charger initiates an internal calibration each time it is powered. In the case of an internal failure, the indicator light will NOT turn green under any condition. If such a condition occurs return the Charger to Sotera for service.

7.4.5 ViSi Mobile Remote Viewer/Appliance

Refer to hardware manuals provided at installation for functional verification. Software checks are provided remotely by Sotera Wireless, Inc. over a secure remote access (similar to a VPN) connection installed at the time of installation.

7.4.6 ViSi Mobile Monitoring System Battery Replacement

Within the ViSi Mobile Monitor, Cuff Module, and Power Pack, the battery is sealed. The battery technology is closely integrated with safety circuits and software to protect from hazardous and harmful conditions. The battery cannot be replaced with normal biomedical service tools. All battery service and replacement is performed by Sotera Wireless. Inc.

7.4.7 ViSi Mobile Optional Power Pack

Please see Appendix B -ViSi Power Pack on page 207

7.5 Product Disposal

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

The ViSi Mobile Monitoring System components are designated for separate collection at an appropriate collection point. Do not dispose of as household waste. Refer to your facility's procedures.

After patient use, the disposables from the ViSi Disposable Kit may contain bio-hazard materials. Handle and dispose of these items according to your facility's policies.

Disposables from the ViSi Disposable Kit should be disposed of per your facility's procedures for bio-hazard materials.

Contact the Sotera Wireless, Inc. Customer Service Department or the Sotera Wireless, Inc. representative in your area to obtain additional information about cleaning and disinfecting the ViSi Mobile Monitoring System components or product disposal.

Product Disposal

8. Patient Monitoring

8.1 Introduction

The ability to monitor patients with a patient-worn ViSi Mobile Monitoring System opens up many opportunities to assess vital signs during all phases and activities involved in a patient's recovery process.

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 SpO2, should be assessed as well.

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

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 provide ST segment analysis. Therefore, if a change in the ST segment of the ECG waveform is suspected, it should be confirmed by another method, such as a 12-lead ECG.

Oxygen saturation measurements using SpO2 are dependent on proper sensor placement, exposure to ambient light conditions, and general patient conditions. Before making clinical decisions based on SpO2 measurements, verify the measurement using another clinically acceptable method, such as arterial blood gas analysis.

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.

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

8.2 Securing the Monitor

8.2.1 Locking the Monitor

When you have finished working with the Monitor, you should lock the Monitor to prevent the patient from accidentally accessing clinical settings.

To lock the Monitor

1. When you are finished interacting with the patient and the Monitor, touch **Lock**.

   The Vital Signs screen is locked to prevent settings from being inadvertently changed. The Patient View screen appears.

8.2.2 Unlocking the Monitor

If your System is configured to require authorization to view the **Vital Signs** screen, you must first unlock the Monitor by entering a PIN code. If you do not have a PIN code, please see your system administrator.

If your System is not configured to require authorization, the **Enter Pin Code** screen does not appear.

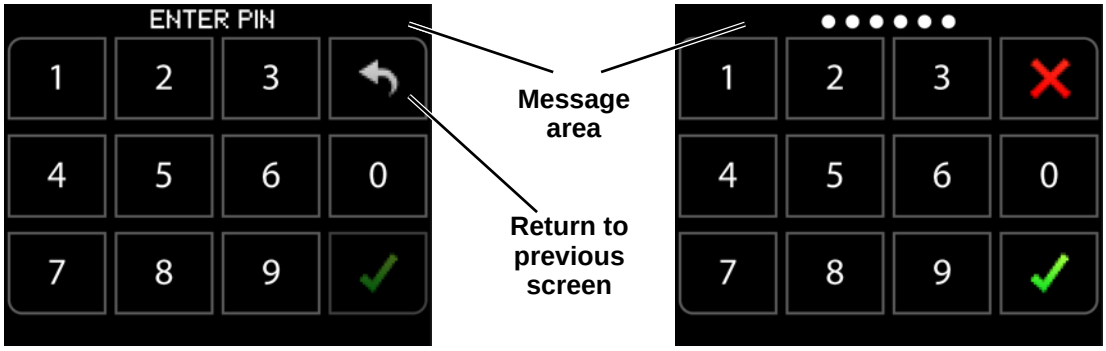
To unlock the Monitor

1. With one finger, touch the Monitor's screen for two seconds to activate the Monitor's display.

   The Patient View screen appears.

2. Touch **Unlock** in the lower left corner of the screen. 

   The Enter PIN Code screen appears.



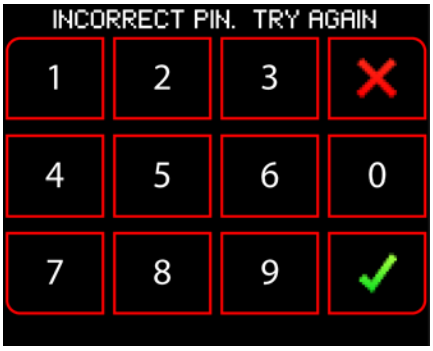
3. Enter PIN code on the PIN code pad.

   As PIN digits are entered, a white dot appears in the message area for each digit entered and the Return to Previous Screen button changes to a Cancel button.

4. Touch **Confirm** to enter the PIN code and confirm authorization.

   If you touch the Confirm button the system navigates to the Vital Signs screen (when a valid PIN code has been entered). If you touch the Cancel button, the entered PIN code is cleared and the Return to Previous Screen button appears, allowing the return to the Patient View screen.

Note: When an invalid PIN code is entered, the outline of the PIN code buttons will flash red and the entered PIN code is cleared.



8.3 Patient Monitoring

8.3.1 Viewing Vital Signs

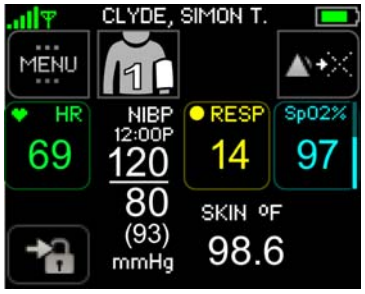
Vital signs monitoring, with alarms, starts as soon as a sensor is connected to the patient and plugged into the Monitor. When there has been no interaction with the Monitor for a period of time, the display goes into **Quiet Monitoring**.

To view vital signs

1. With one finger, touch the Monitor screen for two seconds to activate the display.
2. Enter your PIN code if required. *See To unlock the Monitor on page 114.*

   The Vital Signs screen appears and displays all currently monitored vital signs.

Continuous Measurements
Cuff Module not connected



Single Measurement
Cuff Module connected

Single Measurement
Cuff Module not connected

Note: If the Cuff Module is not connected and NIBP is not being measured continuously (cNIBP), the Start NIBP button is disabled and the NIBP numeric display area is blank.

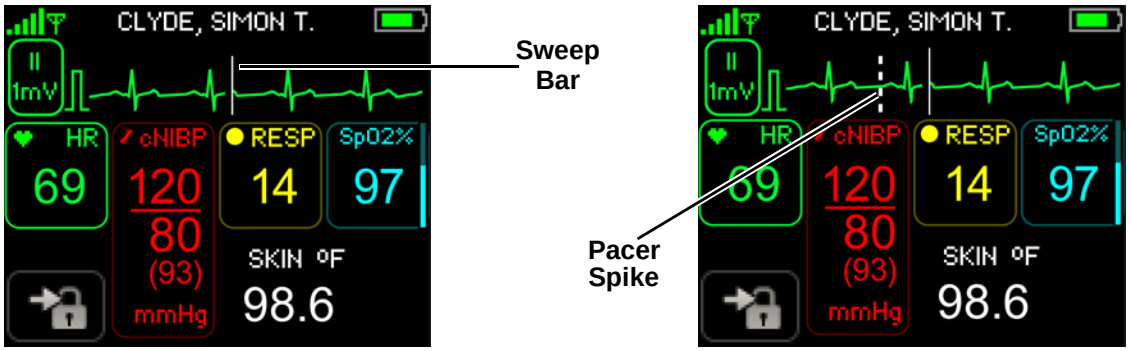
Note: If the Cuff Module is not connected and NIBP is being measured continuously (cNIBP), the Calibrate cNIBP button is disabled. The NIBP measurements will continue to be displayed.

Note: Systolic, diastolic and MAP measurements will be displayed in red when measuring NIBP continuously (cNIBP).

Note: The vital sign measurements are refreshed every 3 seconds.

8.3.2 Viewing Waveforms Associated with Vital Signs

Waveforms move across the display from left to right. A *sweep bar* erases the oldest waveform and replaces it with the newest waveform as it moves from left to right.



The speed of the waveform display (sweep speed) is scaled to 25 mm/sec for ECG, and SpO_2 waveforms.

The sweep speed of the RESP waveform display is scaled to 6.25 mm/sec. The RESP frequency is less than the ECG or SpO_2. The slower sweep speed for the RESP waveform compensates for the lower frequency of activity in order to display several RESP cycles on the display.

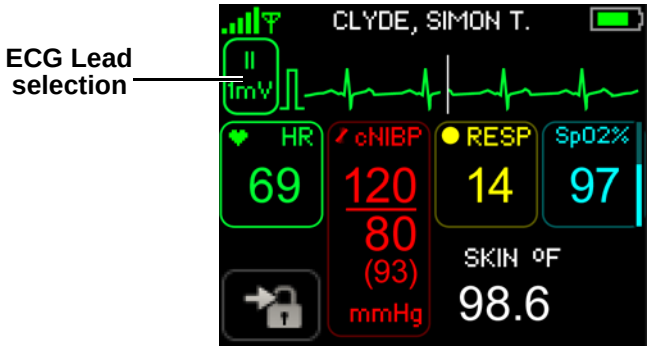
Note: The NIBP (manual or continuous) and skin temperature measurements do not have a waveform.

To view the ECG waveforms

Depending on which Chest Sensor is connected (3 lead-wire or 5 lead-wire), several views (leads) of the ECG waveform may be available for view.

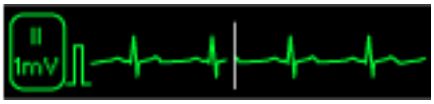
Note: It is recommended that you step through the available ECG waveform leads to confirm the ECG setup is correct.

1. Touch the **HR** numeric. 

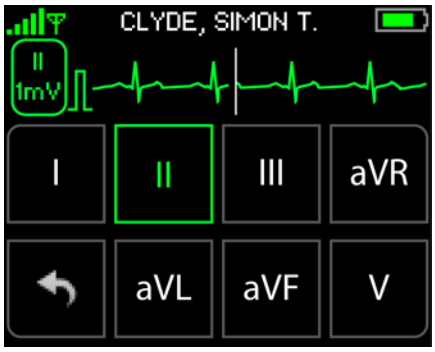


The top third of the display is replaced with the ECG waveform. The displayed lead is indicated to the left of the waveform. The square wave indicates the standard calibration of the ECG waveform.

To view other leads with the Chest Sensor

1. Touch **ECG Lead Selection** or the **waveform**. 

   The lower part of the display is replaced with Lead Selection buttons.



2. Select the lead corresponding to the waveform that you want to view.

   All available leads can be viewed one at time from this view.

Note: Selecting different leads to view has no effect on monitoring. All available leads are monitored simultaneously and continuously. The lead selection affects only the display.

3. Touch **Return to Previous Screen** to exit this view. 

   The display returns to the previous view of the ECG waveform and vital signs.

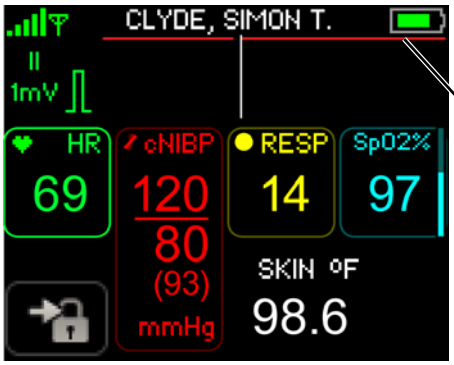
4. To return to the main **Vital Signs** screen, touch the **HR** numeric.

   The ECG waveform is no longer displayed.

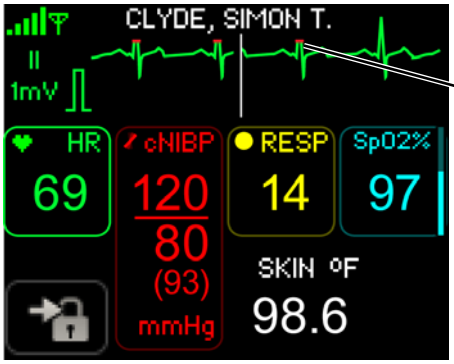
Note: When you touch a vital sign, its corresponding waveform is displayed, even if another waveform is currently displayed.

Input Overload / Dynamic Range

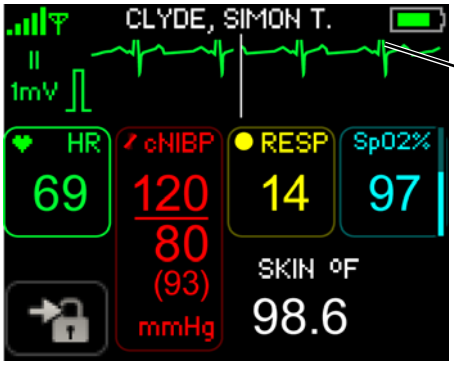
The ViSi Mobile Monitor display indicates an input overload condition (i.e. the input dynamic range of the amplifier associated with the displayed ECG lead has been exceeded) by displaying the trace in red at the top (or bottom) of the ECG waveform display area.



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



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



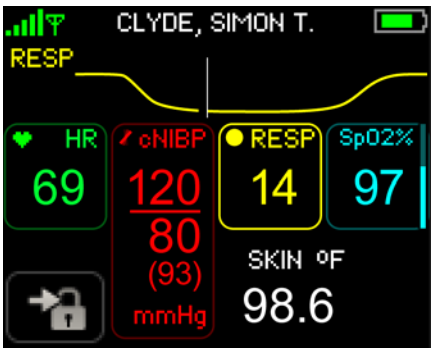
Dynamic range of the ECG amplifier has not been exceeded. The peaks of the QRS complex of the ECG waveform extend beyond the upper edge of the display area

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

To view the RESP waveform

1. Touch the **RESP** numeric. 

   The top third of the display is replaced with the RESP waveform.



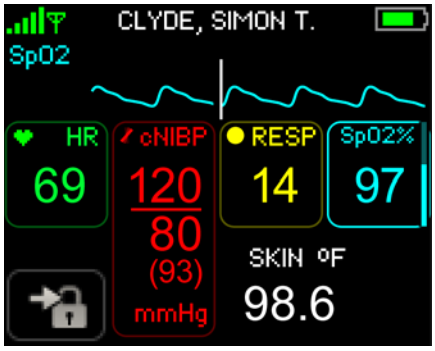
2. To return to the main **Vital Signs** screen, touch the **RESP** numeric.

   The RESP waveform is no longer displayed.

To view the SpO_2 waveform

1. Touch the **SpO_2** numeric. 

   The top third of the display is replaced with the SpO_2 waveform.

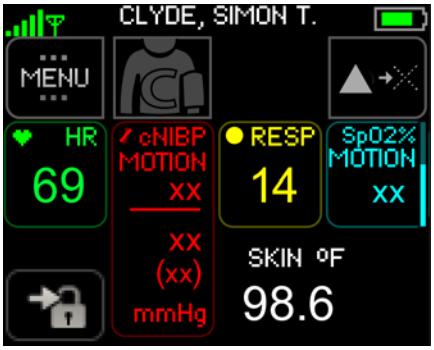


2. To return to the main **Vital Signs** screen, touch the **SpO_2** numeric.

   The SpO_2 waveform is no longer displayed.

8.3.3 Motion Artifact

If a vital sign cannot be measured due to a motion artifact, the word “MOTION” displays below the vital sign name, and “xx” is displayed in place of the numeric(s). See SpO_2 below.



8.4 Setting Up/Taking NIBP Measurements

The industry-standard technique of oscillometry is used for non-invasively measuring systolic blood pressure (SBP) and diastolic blood pressure (DBP). The method is based on the measurement of oscillations through the occluding cuff which is placed on the patient's upper arm during an NIBP measurement. The pulsatile oscillations are measured using a pressure transducer, and then digitized using a microprocessor. The NIBP algorithm uses the digitized oscillations and applied cuff pressure as input to an empirical model to calculate SBP and DBP.

Blood pressure measurements can be affected by the patient's position and/or physiological condition:

- The cuff should be at the same level as the patient's heart.
- NIBP measurements may not be reliable in the presence of atrial fibrillation or ventricular arrhythmias.
- Improper cuff size or application may lead to inaccurate readings.

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 NIBP measurements made too frequently. Loosen or remove the ViSi Mobile Disposable Cuff if signs and/or symptoms of prolonged impaired circulation are evident.

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.

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

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

Note: The ViSi Mobile Cuff Module cannot be used with the auscultatory method of measuring NIBP.

8.4.1 Selecting Blood Pressure Mode

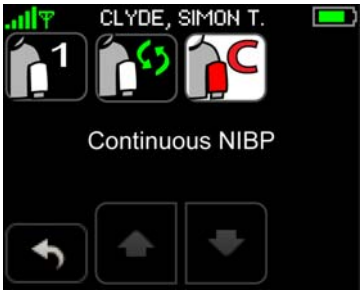
Note: The Monitor will automatically default to a NIBP mode depending on which sensors are connected. You only need to select a NIBP mode if you want to change the default.

To select the blood pressure mode

1. Navigate to the BP Management screen:
   a. Touch **Menu** on the **Vital Signs** screen to display the **Menu** screen.
   The Menu screen appears.
   b. Touch **Blood Pressure Settings** to display the **BP Management** screen.
   The BP Management screen appears.

Manual Cuff Inflation

Automatic Cuff Inflation



cNIBP

Note: On initial entry into the BP Management screen, the default blood pressure mode will automatically be selected. The default mode is dependent on the connected sensors and the cNIBP license.

2. Select the desired NIBP mode.
   a. If Automatic is selected, touch the **Up** or **Down** arrow to increase or decrease the time interval.
   b. Touch **Confirm** to confirm the new settings.
   - or -
   Touch **Cancel** to return to the **Menu** screen.

   Once you have touched Confirm, the cuff inflation method setting is saved and the system returns to the Vital Signs screen. If you touch Cancel, the system discards the changed settings and returns to the Menu screen.

Note: As long as the NIBP Module is plugged in, a manual NIBP measurement can be initiated at any time. When the NIBP mode is set to Automatic, if the timing of the manual measurement overlaps with the automatic measurement interval, then that automatic measurement is skipped; otherwise the automatic measurement occurs as scheduled.

Note: Touching the "Stop NIBP" button on the Vital Signs screen interrupts any NIBP measurement cycle presently in progress. When the NIBP mode is set to Automatic, the next automatic measurement will occur as scheduled.

Note: To calibrate cNIBP, the Chest Sensor, Thumb Sensor and Cuff Module are required. After calibration, the Cuff and Cuff Module may be removed.

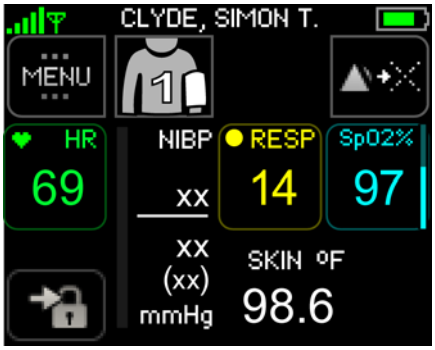
8.4.2 Taking a NIBP Measurement

This section describes how to take a single NIBP measurement and how to initiate automatic NIBP measurements at various intervals. For patient comfort, when the NIBP is set to manual, remove the Cuff and the Cuff Module from the patient's arm. Once removed, disconnect the Cuff Module from the Monitor between measurements. Store the Cuff and Cuff Module in a convenient location.

To take a single NIBP measurement

1. Apply the Cuff and Cuff Module. *See Applying the ViSi Mobile Cuff Module and Disposable Cuff on page 75.*

   After the Cuff Module has been connected to the Monitor, the NIBP vital sign numerics (Systolic, Diastolic and MAP) display as "xx", indicating no measurement has been taken.



Manual / Automatic Cuff Inflation

2. Touch **Start NIBP** to start a measurement. 

   After a few seconds to zero and calibrate the barometric pressure, the Cuff begins inflating.

   An inflation pressure indicator bar, located to the left of the NIBP numerics, increases/decreases in height as the pressure increases/decreases in the Cuff. The actual cuff pressure is displayed under the NIBP label.

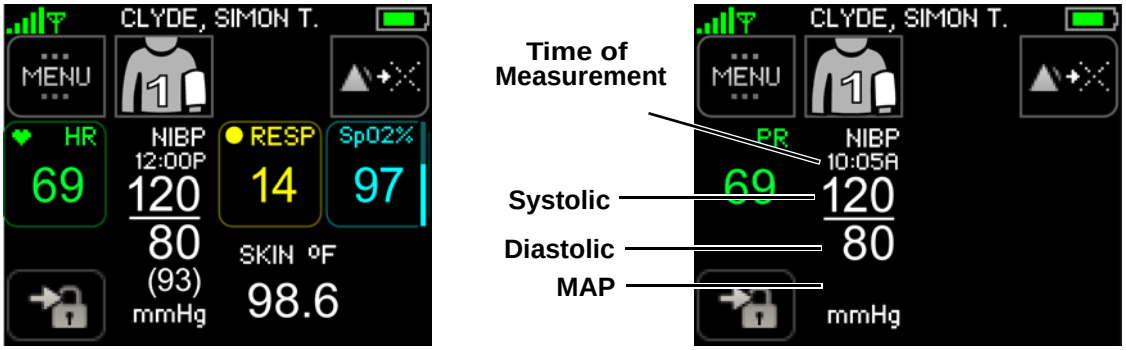
   Once the Cuff begins to inflate, the Start NIBP button changes to Stop NIBP. 

Note: **If unexpected readings occur, confirm the correct application of the ViSi Mobile Disposable Cuff (*see page 75*) and then retake the measurementIf the measurement is still suspect, check NIBP by another method and have maintenance performed as described in the Technical Reference Manual.**

Note: If viewing a waveform, the Start NIBP button will be hidden.

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

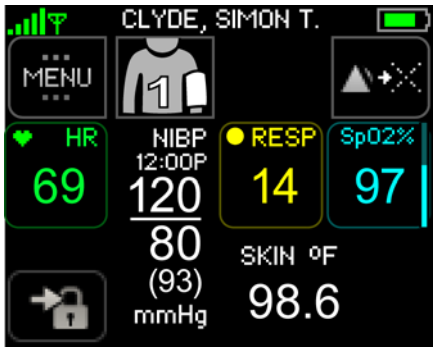
Upon completion of a successful measurement, the Systolic, Diastolic and MAP measurements are displayed in white. The time of the measurement is displayed below the NIBP label. If there is no other heart rate/pulse rate source (i.e. Thumb Sensor or Chest Sensor are not connected to the Monitor), then a one-time PR from the NIBP measurement is displayed for 30 seconds.



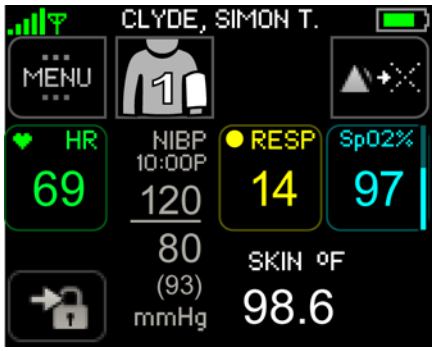
Note: If the NIBP measurement was unsuccessful, the Cuff Module automatically retries to measure the blood pressure. "Retry" messages appear on the screen directly below the NIBP label. A maximum of 3 attempts will be made.

Note: If the failure is due to a cuff leak or cuff occlusion, there is no retry and the LEAK or OCCL message appears on the screen directly below the NIBP label.

NIBP numerics fade and shrink in size after 30 seconds to indicate that the reading is not recent.



Current Reading

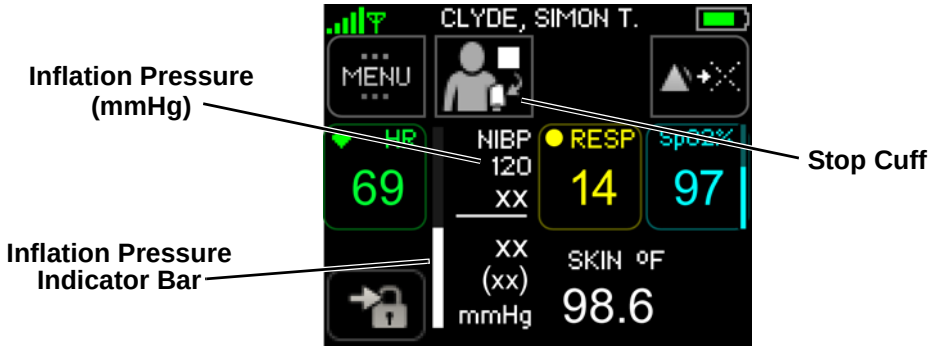


Older Reading
Note that the numerics for the older reading are faded and shrunken in size

NIBP measurements that are older than 30 minutes are no longer displayed.

To stop an NIBP measurement

An NIBP measurement currently in progress may be stopped at any time.



Touch **Stop NIBP** to stop the cuff inflation and NIBP measurement. 

The cuff will deflate.

8.4.3 Initiating Automatic NIBP Measurements

When frequent NIBP measurements are required, the Monitor can be set up to automatically take a blood pressure measurement every 5, 10, 15, 30, 60, 90 or 120 minutes.

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.

To initiate automatic NIBP measurements

1. Apply the Cuff and Cuff Module, if not already on the patient.
   See Applying the ViSi Mobile Cuff Module and Disposable Cuff on page 75.
2. Set the **NIBP mode** to **Automatic**, if the mode is not already Automatic.

   See Selecting Blood Pressure Mode on page 123.
3. On the Vital Signs screen, touch **Automatic Cuff Inflation**. 

   See Taking a NIBP Measurement on page 124

   An automatic NIBP measurement is taken immediately, and again at the set interval.

Note: As long as the NIBP Module is plugged in, a manual NIBP measurement can be initiated at any time. If the timing of the manual measurement overlaps with the automatic measurement interval, then that automatic measurement is skipped; otherwise the automatic measurement occurs as scheduled.

Note: Touching the "Stop NIBP" button on the Vital Signs screen interrupts any NIBP measurement cycle presently in progress. The next automatic measurement will occur as scheduled.

8.4.4 Calibrating Continuous NIBP Monitoring

Sotera's continuous blood pressure monitor (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. Pulse Arrival Time (PAT) is measured from the time an ECG R-Wave is detected to its arrival at the SpO_2 thumb sensor. The shorter the time, the higher the blood pressure. Calibration of PAT for an individual patient requires an initial NIBP cuff measurement. Once this measurement is made, continuous blood pressure is displayed based on averaging PAT calculations from the previous 60 seconds and updating the display every three seconds.

Calibrate whenever any of the following conditions occur:

- A new patient starting cNIBP monitoring for the first time.
- A monitor has been swapped.

Note: Recalibrate whenever an alert message requesting cNIBP calibration appears on the Monitor and Remote Viewer. The message appears when any of the conditions stated in section *To recalibrate cNIBP on page 131* occur. .**Continuous NIBP monitoring is an optional feature that requires an additional license key.**

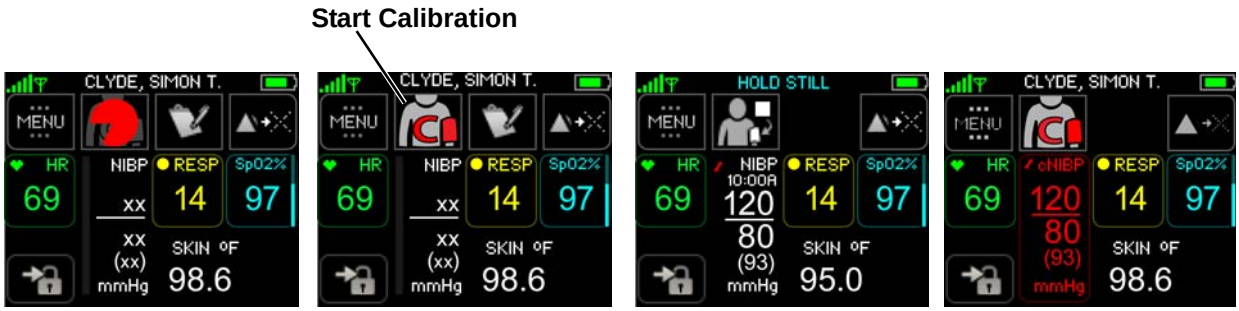
The accuracy of cNIBP is dependent on the initial cuff calibration. Use good clinical practice to confirm cNIBP accuracy before initiating or treating a patient.

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

The ViSi Mobile Monitoring System accuracy claim (mean error of ≤ ±5 mmHg and a std. dev. of ≤ 8 mmHg) is not met when the subject is in a semi-Fowlers position (inclined more than 30 degrees from horizontal).

Due to cNIBP signal averaging, there is a time delay of up to 120 seconds between the instantaneous blood pressure reading and the displayed reading.

To calibrate NIBP for continuous monitoring



Criteria to calibrate cNIBP has not yet been met

Start calibration (Calibrate cNIBP button enabled)

Spot-Check Reading Displayed

cNIBP Calibrated

1. Connect the ViSi Mobile Chest Sensor, Thumb Sensor and Cuff Module and navigate to the **Vitals Signs** screen.

Note: Have the patient positioned in a supine, semi-Fowler's, or side-lying position during cNIBP calibration.

The Start Cuff button  *will change to the Calibrate cNIBP button.* 

When the patient's PAT, posture and arm height are stable for approximately 30 seconds, the Calibrate cNIBP button appears with a red cuff indicating cNIBP is ready to be calibrated.

When the patient's PAT, posture or arm height is not stable for approximately 30 seconds, the Calibrate cNIBP button is disabled. The button will be disabled until the patient's PAT, posture and arm height are stable.

Note: When the criteria to calibrate cNIBP has not been met, a pie symbol  **will be displayed on top of the disabled "cNIBP Calibrate" button. The pie will fill and empty to reflect the readiness of the calibration criteria: patient's PAT, posture and arm height are stable for approximately 30 seconds.**

If the patient's posture has not already been confirmed, you will be prompted to confirm the posture before the cNIBP process starts. See "To Select/Confirm the Patient's Posture" on page 132.

Note: The patient should not move until after the red cNIBP measurements are displayed.

2. Touch **Calibrate cNIBP** on the **Vital Signs** screen.

The Cuff will start to inflate, indicating the calibration process has started. After a single NIBP measurement has been taken, the ViSi Mobile Monitor will calibrate cNIBP. The NIBP measurement will be displayed in white during the calibration process.

After cNIBP has been calibrated, Systolic, Diastolic and MAP measurements will be displayed in red. The displayed measurement will be refreshed every 3 seconds.

Note: The calibration process takes approximately 1 to 2 minutes to complete.

Note: If the calibration is not successful, the monitor will use the previous calibration curve (if it exists). If no previous calibration curve exists, the NIBP measurements will continue to show in white text. The failure will be indicated by a "Calibration Failed" alert.

After the calibration process is completed, it is acceptable for the patient to change position.

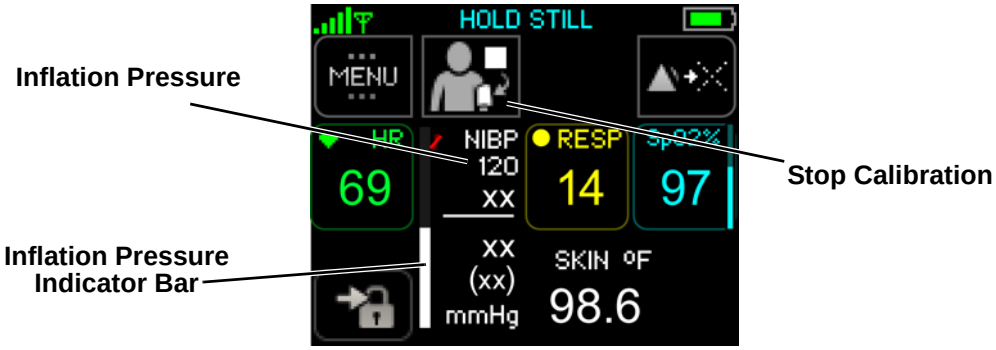
Note: The accuracy of cNIBP measurements have not been confirmed when the posture is greater than a semi-Fowler's position of 30 degrees.

3. Remove the Cuff from the patient and the ViSi Mobile Cuff Module from the Monitor.

   The continuous measurements will continue to display/update even after the cuff has been disconnected.

To stop the cNIBP calibration

A cNIBP calibration currently in progress may be stopped at any time.



Touch **Stop NIBP** to stop the cuff inflation and NIBP measurement. 

The cuff will deflate.

To recalibrate cNIBP

On the Monitor and Remote Viewer, a “Calibrate cNIBP” message appears when any of the following events occur:

- The MAP measurement changed since calibration by ±30% or more for a period longer than 5 minutes.
- A cNIBP calibration has been continuously unavailable for four hours.
- An unexpected interruption of monitoring occurred, such as all sensors being disconnected. If the interruption is less than 30 seconds, no recalibration is required. *See section All Sensors Disconnected on page 145.*
- A vasoactive drug is administered to the patient.
  - IV vasoactive drug administration: Recalibrate within 3-5 minutes of drug administration.
  - Oral administration of vasoactive drugs for the first time: Recalibrate based on the onset of the drug action.
- Change in the ECG pattern.

To manually recalibrate cNIBP, following the steps outlined in section *To calibrate NIBP for continuous monitoring on page 129*.

Note: When a recalibration event is detected, the ViSi Mobile Monitor will display the Calibrate cNIBP alert. Connect the Cuff Module, if not already connected, and recalibrate manually.

You should manually recalibrate cNIBP after the administration of an IV vasoactive drug or a new oral vasoactive drug. The Calibrate cNIBP alert will not be displayed.

8.5 Patient's Posture

Note: When cNIBP is initiated for the first time, the Posture Selection screen will automatically display before calibration starts. The patient's posture must be selected and confirmed before cNIBP can be calibrated. ***See Calibrating Continuous NIBP Monitoring on page 128.***

To View the Patient's Posture

1. Navigate to the **Patient Information** screen.

   See Viewing Patient's Demographics on page 134.

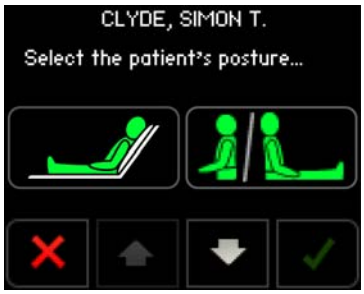
To Select/Confirm the Patient's Posture

1. Touch **Menu** on the **Vital Signs** screen to display the **Menu** screen. 

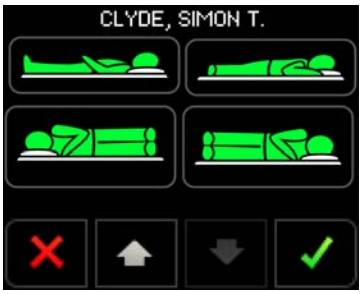
   The Menu screen appears.

2. Touch Patient Posture on the **Menu** screen to display the **Select Patient Posture** screen. 

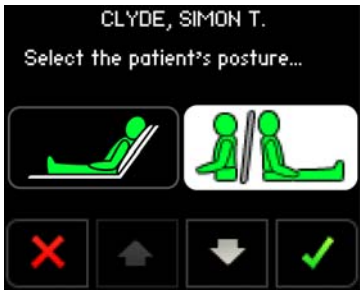
   The Select Patient Posture screen is displayed.



First set of postures



Second set of postures



Posture selected

3. Select the posture button that matches the patient's current posture.

   You may need to touch the up or down arrows to view all the postures. Once selected, the button will display as highlighted.

Posture Icon	Description	Posture Icon	Description
	Patient is in a reclined position (semi-Fowler's position).		Patient is lying on their front/prone position.
	Patient is either standing, walking or sitting upright.		Patient is lying on the right-hand side.
	Patient is lying on their back.		Patient is lying on their left-hand side.

4. Touch **Confirm** to confirm the selected posture is correct.

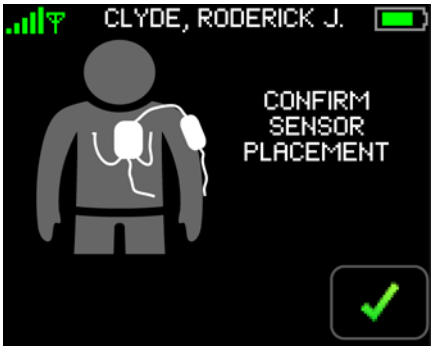
   The Confirm button will be disabled until a posture has been selected.

   - or -

   Touch **Cancel**.
   If cancelled, the selected posture will be discarded and the Select Patient's Posture screen will be closed. You will be returned to the screen from where the select posture was initiated.

   If confirmed and the selected posture matches the calculated posture, the selected posture will be saved. The Select Patient's Posture screen will be closed and you will be returned to the screen from where the select posture was initiated.

   If the selected posture does not match the calculated posture, the Confirm Sensor Placement screen will be displayed.



5. Check the sensor placements and touch **Confirm** to confirm the sensors are positioned correctly.

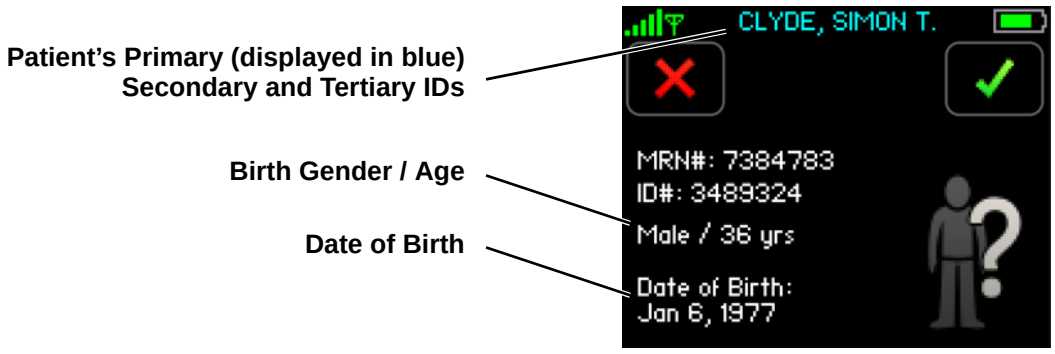
   You may need to reposition the Chest Module Cable as shown in the screen image above.

Note: When the posture is selected as part of the cNIBP calibration process, the calibration process will continue after the selection is made.

8.6 Viewing Patient's Demographics

To Confirm Patient's Demographics

When the patient's demographics have been changed on the ViSi Mobile Remote Viewer or there is an interruption of monitoring of more than 30 seconds, the demographics must be confirmed (or rejected) directly on the ViSi Mobile Monitor.



Note: The patient's primary ID will be displayed in blue to indicate the demographics have been changed and require confirmation.

Note: The primary ID is configured to be the patient's name. The secondary ID is configured to be the patient's MRN#. The tertiary ID is configured to be an alternative ID.

1. Touch **Confirm** to confirm the patient's demographics are correct.

   - or -

   Touch **Cancel**.
   If cancelled, the patient's demographics will be removed from the ViSi Mobile Monitor and an alert will be annunciated on the ViSi Mobile Remote Viewer.

   If confirmed, the patient's demographics will be displayed in white to indicate they have now been confirmed.

To View Patient's Demographics

1. Touch **Menu** on the **Vital Signs** screen to display the **Menu** screen. 

   The Menu screen appears.

2. Touch **Patient Information** on the **Menu** screen to display the **Patient Information** screen. 

   The Patient Information screen is displayed.

Note: The patient's demographics are entered on the ViSi Mobile Remote Viewer.

The patient's posture will be displayed on this screen. *See Patient's Posture on page 132.*

8.7 Exchanging a Monitor With Low Battery

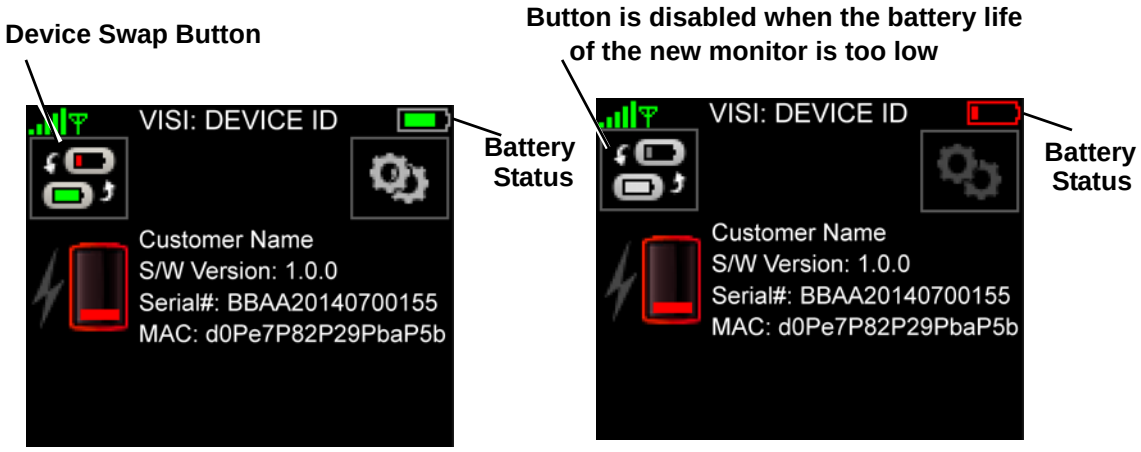
To exchange a monitor with a low battery

When the ViSi Mobile Monitor's battery becomes low during monitoring, it may be exchanged with a new Monitor without stopping the patient's monitoring session.

Note: You will not be able to exchange the monitoring using the method described below if the monitor's battery is too low to monitor.

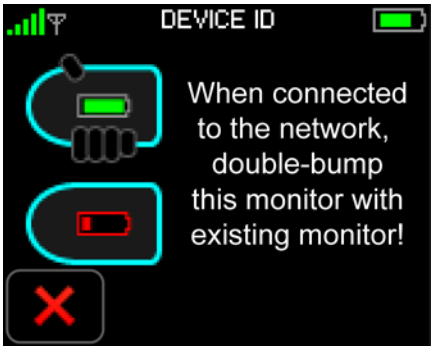
1. Remove the new Monitor from the ViSi Mobile Charger.

   The Device Status screen will be displayed.



2. Touch **Device Swap**. 

   The Exchange Instructions screen will be displayed and the Monitor will connect to the network.



Note: **The Monitor may take a few seconds to connect to the network. Do not attempt to bump the two monitors together until the new Monitor has connected to the network.**

Note: **The two Monitors must be double-bumped together such that the long ends of the Monitors make contact with each other. See the image on the ViSi Mobile Monitor Instructions screen above.**

Note: **You must be logged into the patient's current monitor before bumping the two monitors together.**

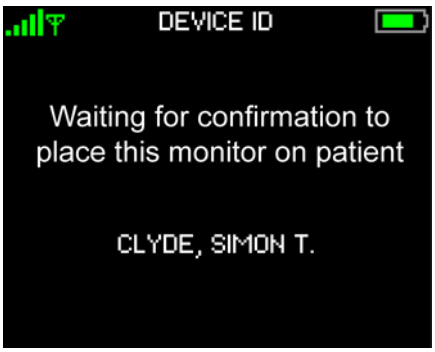
3. Double bump the new Monitor with the Monitor on the patient's wrist.

   - or -

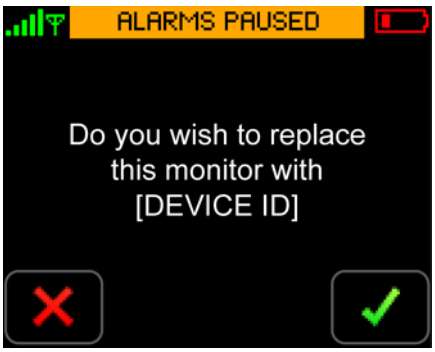
   Touch **Cancel**.
   If cancelled, the Device Swap will automatically be cancelled.

   If the monitors are successfully double bumped, the Exchange process will be initiated. The new Monitor will display the Waiting Patient Transfer screen and the patient's Monitor will display the Confirm Device Swap screen.

Note: Once the Exchange process has been initiated, the alarms will be paused on the patient's current Monitor. Alarms will be paused until the process is successfully completed or cancelled.



Waiting Patient Transfer
(Instructions on the new Monitor)



Confirm Device Swap
(Instructions on the patient's Monitor)

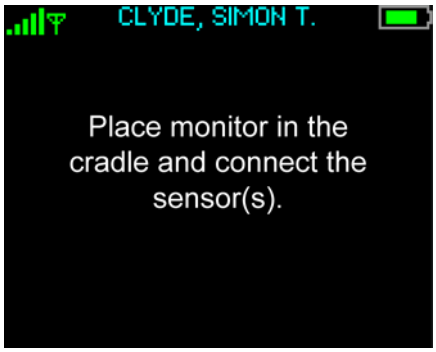
4. Touch **Confirm** to replace the existing patient's Monitor with the new Monitor.

   - or -

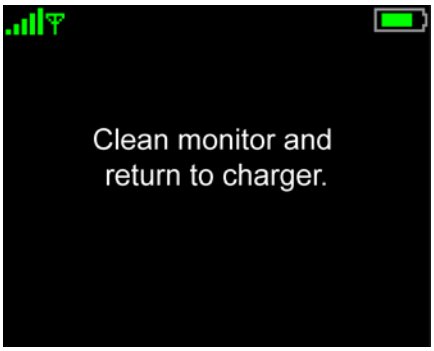
   Touch **Cancel**.
   If cancelled, the Exchange process will automatically be cancelled.

   If confirmed, the patient's monitoring session will be transferred from the patient's current Monitor to the new Monitor.

   The new Monitor will display the Instructions screen and the patient's old Monitor will display the Clean Monitor screen.



Instructions
(Patient's New Monitor)



Clean Monitor
(Patient's Old Monitor)

Note: If the clinician has not already authenticated on the patient's current monitor before the device exchange is initiated, the clinician will be prompted to authenticate before the Clean Monitor screen is displayed.

Note: If the clinician has not confirmed the patient's id on the patient's current monitor, the clinician will be prompted to confirm the patient's id before the Clean Monitor screen is displayed.

5. To restart monitoring, place the new Monitor into the Wrist Cradle (attached to the patient's wrist) and connect the sensors.

Note: When monitoring is restarted, the patient's demographics will need to be reconfirmed on the new Monitor.

Note: Once the device swap has been successfully completed, the cuff inflation method will transfer to the new monitor.

cNIBP will need to be calibrated/initiated on the new Monitor.

8.8 Pause Monitoring

Pause monitoring when vital signs monitoring needs to be stopped temporarily and you intend to restart monitoring the same patient with the same monitor.

Note: Monitoring may not be paused until the patient's demographic data has been confirmed (on the Monitor).

To pause monitoring

1. With one finger, touch the Monitor screen for two seconds to activate the display.

   The Patient View screen appears.

2. Enter your PIN code if required. *(See To unlock the Monitor on page 114.)*

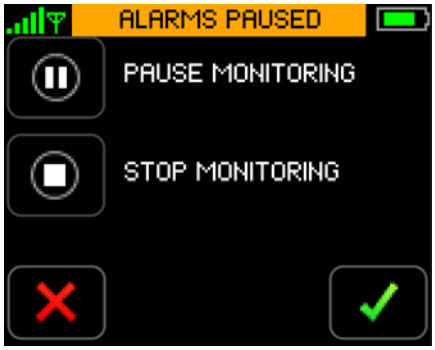
   The Vital Signs screen appears.

3. Touch **MENU**. 

   The Menu screen appears.

4. Touch **PAUSE / STOP**. 

   The Pause/Stop Monitoring screen appears.



Note: Once the Pause/Stop Monitoring process has been initiated, the alarms will be paused until the process is successfully completed or cancelled.

5. Touch **Pause Monitoring**. 

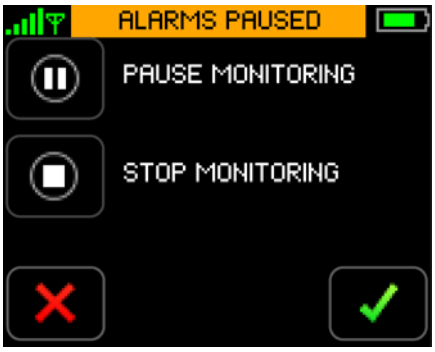
   The Confirm button will be enabled.

6. Touch **Confirm** to confirm that you want to stop monitoring. 

   - or -

Touch **Cancel**.
If cancelled, the program returns to the Menu screen and monitoring continues uninterrupted.

If confirmed, the Monitoring Paused screen is displayed. Monitoring is paused effective immediately.



Note: Remove all the sensors from the Monitor and the patient.

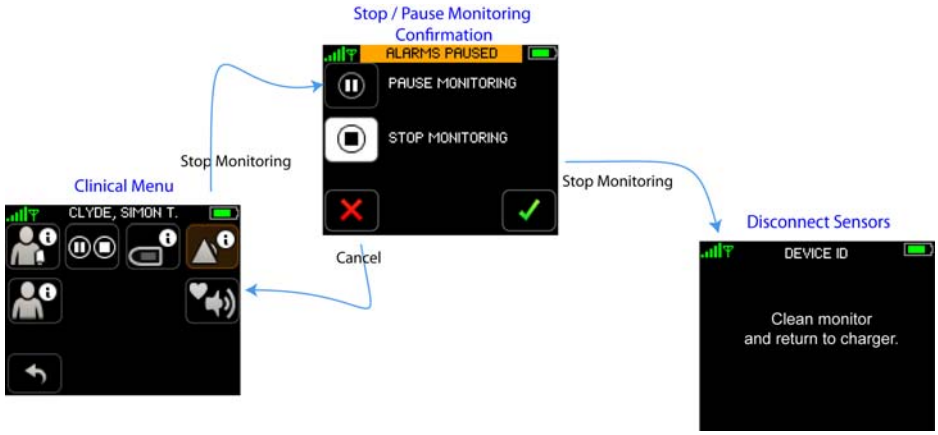
Note: To remove the sensors from the Monitor, grasp the sensors near the plug, and while holding the Monitor firmly, pull out the plug.

If you want to stop monitoring permanently, follow the steps outlined in section *8.9 Stop Monitoring on page 142*.

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.

8.9 Stop Monitoring

Stop monitoring when ALL vital signs monitoring is no longer required.



To stop monitoring

1. With one finger, touch the Monitor screen for two seconds to activate the display.

   The Patient View screen appears.

2. Enter your PIN code if required. *(See To unlock the Monitor on page 114.)*

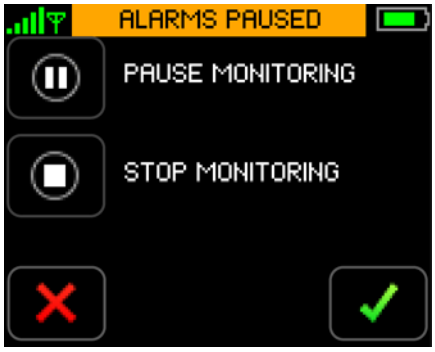
   The Vital Signs screen appears.

3. Touch **MENU**. MENU

   The Menu screen appears.

4. Touch **PAUSE / STOP**.

   The Pause/Stop Monitoring screen appears.



Note: Once the Stop Monitoring process has been initiated, the alarms will be paused until the process is successfully completed or cancelled.

5. Touch **Stop Monitoring**.

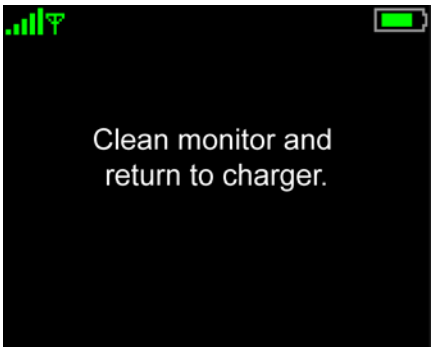
   The Confirm button will be enabled.

6. Touch **Confirm** to confirm that you want to stop monitoring.

   - or -

   Touch **Cancel**.
   If cancelled, the program returns to the Menu screen and monitoring continues uninterrupted.

If confirmed, the Clean Monitor screen is displayed. Monitoring is stopped effective immediately.



Note: Remove all the sensors and the Monitor from the patient.

Note: To remove the sensors from the Monitor, grasp the sensors near the plug, and while holding the Monitor firmly, pull out the plug.

7. Dispose of disposable components per your facility's procedures.

If you want to pause monitoring temporarily, follow the steps outlined in section *8.8 Pause Monitoring on page 139*.

To clean and prepare reusable components

1. Clean and prepare the reusable components of the System (Monitor, Chest Sensor, Thumb Sensor, and Cuff Module) in accordance with your facility's procedures and the cleaning recommendations in this manual. *See section 7. User/Preventative Maintenance on page 105.*
2. Place the cleaned Monitor and Cuff Module into the Charger.

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

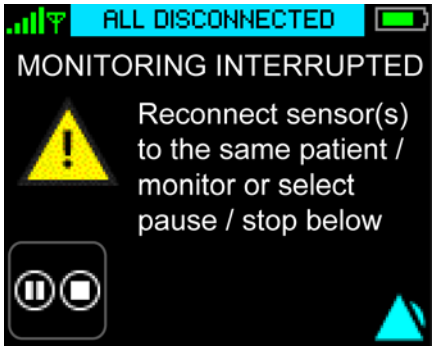
Never connect the ViSi Mobile Monitor directly to an AC power outlet. To recharge the battery, disconnect the Monitor from the patient, and then place it in the ViSi Mobile Charger.

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.

If the ViSi Power Pack beeper/buzzer sounds or the Red LED is permanently lit, the ViSi Power Pack should be disconnected from the patient immediately.

8.10 All Sensors Disconnected

The “All Sensors Disconnected” screen will be displayed when the last sensor is disconnected from the ViSi Mobile Monitor without going through the proper “Stop Monitoring” procedure. (*see 8.6Viewing Patient’s Demographics on 134*). An “All Disconnected” alert will be generated.



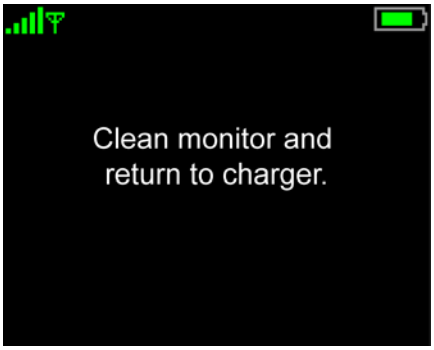
1. To stop monitoring the patient, touch **Stop** to initiate the Stop Monitoring process.

   - or -

   to resume monitoring, connect the sensor(s) to restart monitoring.
   Monitoring will automatically continue.

2. Enter your PIN code if required. *(See To unlock the Monitor on page 114.)*

   The Clean Monitor screen appears.



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 as outlined in sections *8.8 Pause Monitoring on page 139* and *8.9 Stop Monitoring on page 142*.

8.11 Disable Skin Temperature

In the event that a Facility's Care Unit chooses to not monitor the Skin Temperature vital sign, that feature can be turned off through the Facility's Care Unit .XML configuration file that is pushed from the server.

Note: Only while in Bio Med Mode is it possible to turn the Skin Temperature vital sign "On" or "Off." on page 80

Note: Un-Networked/Standalone Monitors are the only Monitors that are able to have Skin Temperature turned "On" or "Off" while in Bio Med Mode. on page 80

More detailed information can be found: Skin Temperature Configuration on page 80

- Notes -

9. Troubleshooting

9.1 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.

9.1.1 Customer Service

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

International: +1-858-427-4620

Fax: +1-858-999-2487

E-mail: support@soterawireless.com

9.2 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.

9.2.1 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.

9.3 ViSi Mobile Chest Sensor

Problem	Potential Cause	Solution
Chest Sensor 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 is secured to the side of the chest opposite the arm with the Monitor.	Secure the Chest Sensor 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 leads 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.
	Chest Sensor not securely Plugged into the Monitor.	Make sure that the Chest Sensor 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.

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 that 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: Lead II has a low amplitude. Lead II only available with a 3-lead Chest Sensor.	• 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 with 5-lead Chest Sensor.
	Using a 5-lead Chest Sensor: Selected lead has low amplitude.	5-lead Chest Sensor: 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.
	Motion is present.	Have the patient remain still until the measurement is displayed.
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 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.
SKIN temperature is erratic	Chest Sensor is not in contact with the skin completely/ securely.	Secure the Chest Sensor 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 to the chest.

9.4 ViSi Mobile Thumb Sensor

Problem	Potential Cause	Solution
Thumb 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.
	Motion is present.	Have the patient remain still until the measurement is displayed.
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.

9.5 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 PAT is not stable.	Ensure that the patient is still before calibration is started and remains still during the calibration process. When the patient's PAT is stable, the "c" on the Calibrate cNIBP button appears in red. When PAT is not stable, the "c" appears in gray.
cNIBP displays "XX"'	Motion is present.	• Check SpO_2 for noisy pleth. • Check sensor placements. • Confirm the selected patient's posture is correct.
cNIBP did not calibrate	Patient's PAT not stable.	• Have the patient remain still. • Manually press the Start Calibration button.
	NIBP reading failed.	• Manually press the Start Calibration button.
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, Inc. 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, Inc. 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, Inc. representative in your area.

9.6 ViSi Mobile Battery Charger

Problem	Potential Cause	Solution
Batteries in the Monitor, Cuff Module, or optional Power Packdo not charge	The Monitor and Cuff Module are not securely seated in the Charger.	Make sure that the Monitor, Cuff Module, and Power Pack are securely seated in the Charger. The Monitor, Cuff Module, and Power Pack 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 inserted into the Charger without being thoroughly dried (after cleaning/disinfecting).	• Dry equipment thoroughly before placing in the Charger.

9.7 ViSi Power Pack (Optional Accessory)

Problem	Potential Cause	Solution
Power Pack Does Not Beep when plugged into Monitor	Power Pack battery is too low	Disconnect from ViSi Monitor, replace Power Pack and place depleted Power Pack into ViSi Mobile Charger
	ViSi Power Pack connector is not properly inserted into the Monitor.	Make sure the connector is in the correct orientation and is firmly inserted into the port on the flat end of the Monitor.
	The Power Pack was inserted into the Cradle without being thoroughly dried (after cleaning/ disinfecting).	Remove from Cradle and dry Power Pack thoroughly before replacing in the Cradle or Battery Charger.
Monitor battery continues to depleat when using a ViSi Power Pack	Power Pack battery is too low	Disconnect from ViSi Monitor, replace Power Pack and place depleted Power Pack into ViSi Mobile Charger
	ViSi Power Pack connector is not properly inserted into the Monitor.	Make sure the connector is in the correct orientation and is firmly inserted into the port on the flat end of the Monitor.
	The Power Pack was inserted into the Cradle without being thoroughly dried (after cleaning/ disinfecting).	Remove from Cradle and dry Power Pack thoroughly before replacing in the Cradle or Battery Charger.
Power Pack Red LED is permanently lit when in the Charger	Votage level has exceeded expectation	• Remove Power Pack from the Charger and quarantine • Report the problem to Sotera Wireless, Inc. Customer Service Department or the Sotera Wireless, Inc. representative in your area.
	Current level has exceeded expectation	
	Internal temperature has exceeded expectation	
Power Pack Red LED is flashing and the beeper/buzzer does not annunciate.	Power Pack battery is too low	Disconnect from ViSi Monitor, replace Power Pack and place depleted Power Pack into ViSi Mobile Charger
Power Pack Red LED is permanently lit and beeper/ buzzer annuciates.	Power Pack has internal fault	• Discontinue use of Power Pack and quarantine. • Report the problem to Sotera Wireless, Inc. Customer Service Department or the Sotera Wireless, Inc. representative in your area.
Power Pack Red LED is permanently lit and beeper/ buzzer does not annuciate.	Power Pack has internal fault	• Discontinue use of Power Pack and quarantine. • Report the problem to Sotera Wireless, Inc. Customer Service Department or the Sotera Wireless, Inc. representative in your area.

9.8 General Troubleshooting

9.8.1 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.

9.8.2 Alarms and Alerts

When testing the speaker at the ViSi Mobile Remote Viewer, you are testing how the alarm and alert tones will sound at the Remote Viewer during typical operation. If the volume is inadequate, clinicians could miss alarms and alerts. During testing, if the tone does not sound or it is not loud enough, adjust the speaker volume.If the sound is still not loud enough, immediately contact a biomedical engineer.

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 display 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 not currently connected to the network.

9.9 ViSi Mobile Remote Viewer

9.9.1 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.

10. Specifications

10.1 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 evaluated for these patient groups.Do not use the ViSi Mobile Monitor as a primary hypoxia diagnostic tool.

10.2 Vital Sign Measurements

10.2.1 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 ANSI/AAMI/IEC 60601-2-27:2011 - • 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 ANSI/AAMI/IEC 60601-2-27:2011 , 201.12.1.101.13: Pulse Rejection Range: Amplitude from ±2 mV to ±700 mV Pulse Width from 0.1 ms to 2 ms 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 **Note: At 30 BPM, asynchronous pacing may trigger occassional R-wave detection**

Heart Rate	
Pacemaker Pulse Rejection With Overshoot	Tested per ANSI/AAMI/IEC 60601-2-27:2011 , 201.12.1.101.13, Method A: Pulse Rejection Range: Amplitude from ±2 mV to ±700 mV Pulse Width from 0.1 ms to 2 ms **Note: Pulses with polarization overshoot > 4 ms may cause R-wave** 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 **Note: At 30 BPM, asynchronous pacing may trigger occassional R-wave detection**
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 ANSI/AAMI/IEC 60601-2-27:2011 , 201.12.1.101.17: • T-waves up to 1.65 mV in amplitude: • T-waves not detected, no change in indicated heart rate.
Heart Rate Averaging	Tested per ANSI/AAMI/IEC 60601-2-27:2011 , 201.7.9.2.9.101, b) 3): • 20 second moving average
Heart Rate Accuracy and Response to Irregular Rhythm	Tested per ANSI/AAMI/IEC 60601-2-27:2011 , 201.7.9.2.9.101, b) 4): • Waveform 3a: 80 BPM • Waveform 3b: 60 BPM • Waveform 3c: 60 BPM • Waveform 3d: 90 BPM
Change in Heart Rate	Tested per ANSI/AAMI/IEC 60601-2-27:2011 , 201.7.9.2.9.101, b) 5): • 80 BPM to 120 BPM: 15 seconds • 80 BPM to 40 BPM: 15 seconds
Time to Alarm for Cardiac Standstill	Tested per ANSI/AAMI/IEC 60601-2-27:2011 , 208.6.6.2.103: • < 15 seconds
Time to Alarm for Low Heart Rate	Tested per ANSI/AAMI/IEC 60601-2-27:2011 , 208.6.6.2.103: • < 15 seconds

Heart Rate	
Time to Alarm for High Heart Rate	Tested per ANSI/AAMI/IEC 60601-2-27:2011 , 208.6.6.2.103: • < 15 seconds
Time to Alarm for Tachycardia	Tested per ANSI/AAMI/IEC 60601-2-27:2011 , 201.7.9.2.9.101, b) 6): Figure 4a: • 12 seconds • Gain = 2.0x: <12 seconds • Gain = 0.5x: < 5 seconds Figure 4b: • Gain = 1.0x: < 10 seconds • Gain = 2.0x: <10 seconds • Gain = 0.5x: < 5.5seconds
Input Impedance	> 20 Mohms
Frequency Response	0.5 to 125Hz
Lead Off Detection Current	< 24 nA
Common Mode Rejection Ratio	> 85 dB

10.2.2 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%

10.2.3 Pulse Oximetry (SpO_2, Functional Oxygen Saturation)

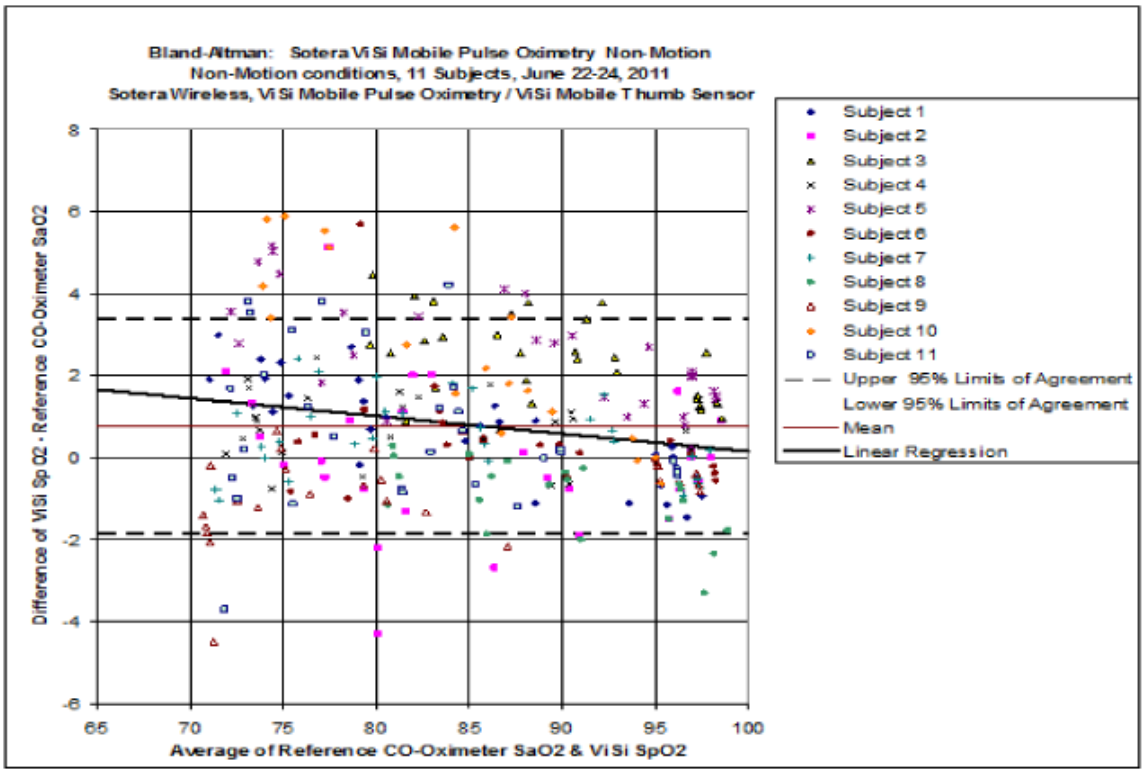
Pulse Oximetry (SpO_2, Functional Oxygen Saturation)		
Normative Reference	ISO 9919: 2005	
SpO_2	Display Range	49 to 100%
	Accuracy Range	70 to 100%
	Accuracy	≤ 2% from 70-100% (no motion)[a] Unspecified from 49-69%
	Resolution	1%
Pulse Rate	Display Range	0 to 240 BPM
	Accuracy Range	30 to 240 BPM
	Accuracy (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 affected by the presence of dyshemoglobin, ambient light (including photodynamic therapy); electromagnetic interference; electrosurgical units; dysfunctional hemoglobin; presence of certain dyes; inappropriate positioning of the pulse oximeter sensor.	
Toxicity	Thumb sensor uses white silicone which has no known toxicity effects.	
Measuring Maximum Temperature	Measuring the maximum temperature of the Thumb Sensor at the skin should be done with a calibrated temperature probe placed under the sensor when attached to the thumb.	

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

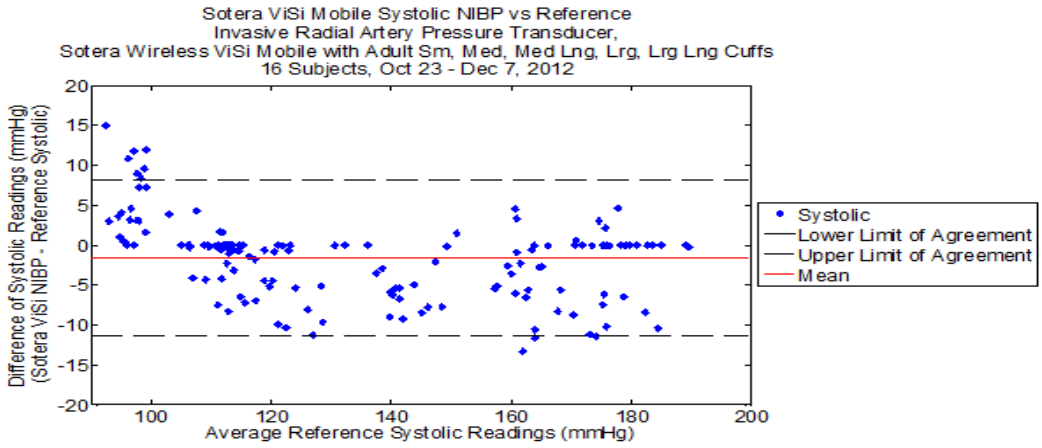


Note: Test subjects were healthy, in an age range from 21 to 45 years (7 males and 4 females), with a wide range of skin pigmentation.

10.2.4 Non-Invasive Blood Pressure (NIBP)

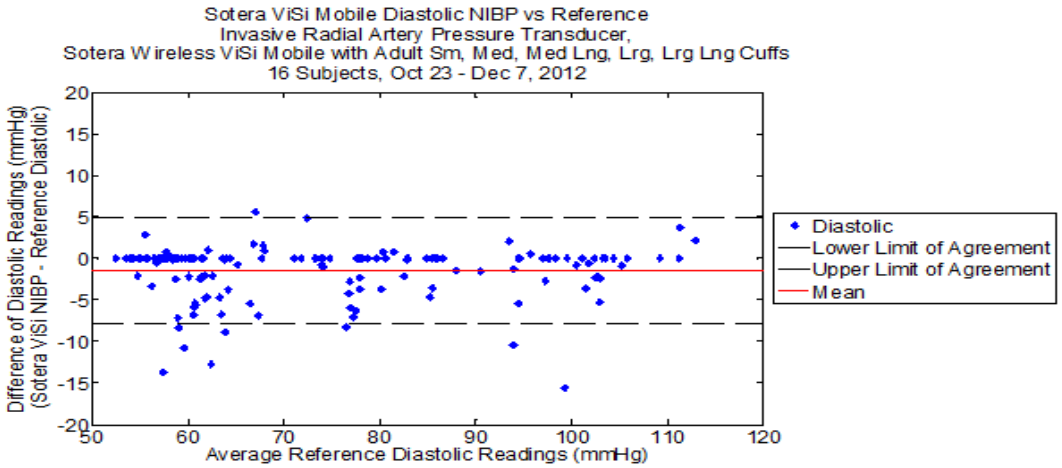
Non-Invasive Blood Pressure (NIBP)		
Normative Reference	ISO 81060-2: Non-invasive Sphygmomanometers - Part 2: Clinical validation of automated measurement type.	
Principle of Operation	Oscillometry	
Systolic	Range:	60 to 240 mmHg
	Accuracy:	Mean error of less than ± 5 mmHg and a std. dev. of ≤ 8 mmHg
	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)



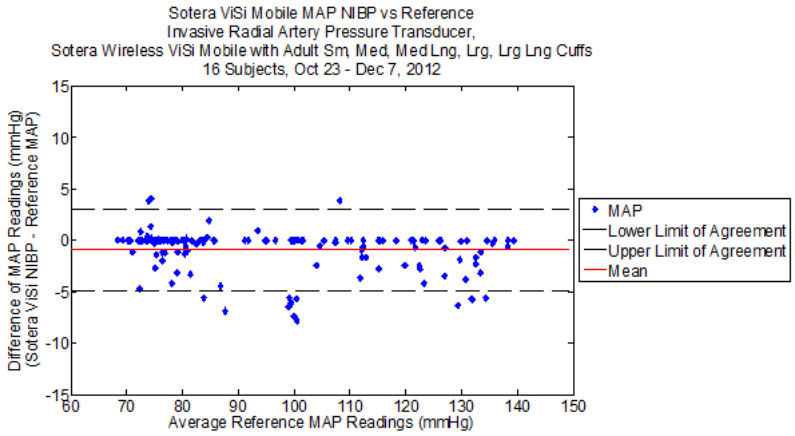
Sample Size:	152 data points
Mean:	-1.65 mmHg
Standard Deviation:	5.01 mmHg
Upper 95% Limits of Agreement (+1.96 SD):	8.2 mmHg
Lower 95% Limits of Agreement (-1.96 SD):	-11.5 mmHg

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

10.2.5 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

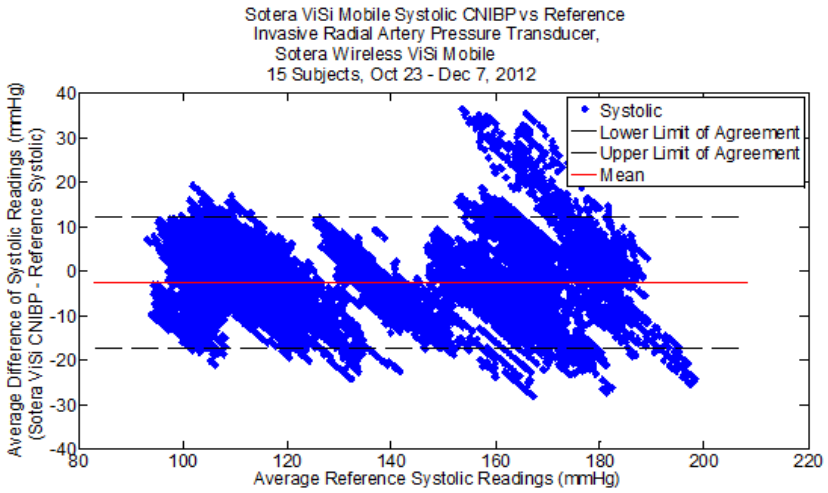
a. *ViSi Mobile Monitoring System accuracy claim is not met when the subject is inclined more than 30 degrees from horizontal.*
b. *The accuracy and precision of the cNIBP measurement met ISO 81060-2 requirements for the first 2.5 hours of testing.*

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

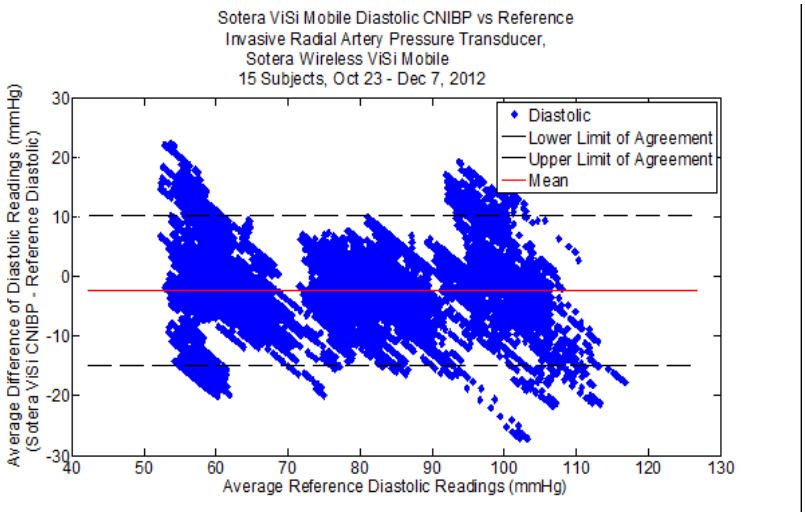
Changes in posture and arm height can affect ViSi cNIBP accuracy. If the cNIBP measurement is questionable, retake the measurement. Ideally recalibrate in the same position as the initial calibration.

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

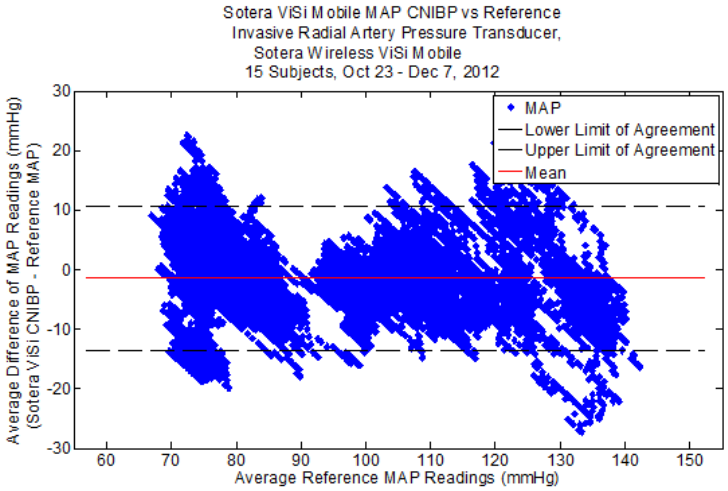
Diastolic Bland Altman Analysis (cNIBP)



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

10.2.6 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}	$\pm 0.3^{o}$
Resolution	$\pm 0.1^{o}$		$\pm 0.1^{o}$	
Transient Response	< 6 min (25^{o} - 37^{o})		< 6 min (77^{o} - 98.6^{o})	

Note: The above skin temperatures have not been evaluated for correlation to core temperatures.

10.3 Physical Components

10.3.1 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	• ≤70% Isopropyl alcohol (IPA) • Detergent (Alconox)

Wireless Communications / Radio

Wireless Communications	
Frequency	2.412 - 2.462 GHz
Protocol	802.11 b/g/n
Modulation	DSSS, OFDM, DBPSK, DQPSK, CCK, 16-QAM and 64-QAM
Security	WPA2 / PSK, AES
Power Output (max)	802.11 b: 15.8 dBm (38.3 mW)
	802.11 g: 12.9 dBm (19.5 mW)
	802.11 n: 11.8 dBm (15.1 mW)
Data Throughput	< 30 KBps

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

Mode Plugs

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

a. The Bio Med Mode is only available to hospital Bio Meds.

10.3.2 ViSi Mobile Chest Sensor

ViSi Mobile Chest Sensor		
Mechanical	Complies with EC53	
Weight (5 lead-wire / 3 lead-wire)	72 g / 62 g (2.54 oz. / 2.19 oz.)	
Operating Temperature	0 - 40ºC / 32ºF - 104ºF *Refer to IEC 60601-1:2005 (Section 11)*	
Cleaning / Disinfecting	Liquid Ingress Rating	IPX7 During cleaning cycle only, not during monitoring
	Solutions / Compounds	• ≤70% Isopropyl alcohol (IPA) • Detergent (Alconox)

10.3.3 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	• ≤70% 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.

10.3.4 ViSi Mobile Thumb Sensor

ViSi Mobile Thumb Sensor		
Cleaning / Disinfecting	Liquid Ingress Rating	IPX7 During cleaning cycle only, not during monitoring
	Solutions / Compounds	• ≤70% Isopropyl alcohol (IPA) • Detergent (Alconox)

10.3.5 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	• ≤70% Isopropyl alcohol (IPA) • Detergent (Alconox)

10.3.6 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	• ≤70% Isopropyl alcohol (IPA) • Detergent (Alconox)

10.3.7 ViSi Mobile Power Pack (Optional Accessory)

ViSi Power Pack		
Physical Characteristics	Dimensions	3.13 cm H x 4.87 cm W x 12.19 cm L (1.23 in. H x 1.91 in. W x 4.80 in. L) Cable Length 3 to 5 ft.
	Weight	172 g (6.07 oz.)
Battery	Operating Time	minimum 24 hrs
	Charge Display Status	Eight LEDs: Six levels of Green, Yellow, Red
	Charge Time	< 6 hours
	Battery Type	Battery Pack, Li-Ion, 2000 mAh
	Maximum Temperature	50ºC / 122ºF *Refer to IEC 60601-1:2005 (Section 11 for equipment not intended to contact patient)*
Cleaning / Disinfecting	Liquid Ingress Rating	IPX0
	Solutions / Compounds	• ≤70% Isopropyl alcohol (IPA) • Detergent (Alconox)

ViSi Power Pack Cradle

ViSi Power Pack Cradle		
Physical Characteristics	Dimensions	4.87 cm H x 9.5 cm W x 10.0 cm L (1.91 in H x 3.74 in W x 3.93 in L)
	Weight	Without clamp: 91.3 g (3.22 oz.)
		With clamp 0.53 kg (1.17 lb.)
Cleaning / Disinfecting	Liquid Ingress Rating	IPX0
	Solutions / Compounds	• ≤70% Isopropyl alcohol (IPA) • Detergent (Alconox)

10.3.8 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.

In the ViSi Mobile Monitoring System, data is captured in the ViSi Mobile Appliance, which acts as an enterprise hub. The Appliance is dedicated hardware installed in the IT datacenter for secure network connectivity and emergency power backup. For more information on the ViSi Mobile Appliance, see the *ViSi Mobile Monitoring System Technical Reference Manual.*

10.3.9 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, Inc. recommends installation of Trend Micro anti-virus software on Windows platforms. Anti-virus software is not installed on the ViSi Mobile Monitor.

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

10.3.10 Customer Network

Wireless Network	
Wireless Network Standard	IEEE 802.11b/g/n
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%

10.4 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.

10.4.1 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]
	Care Unit	Patient	Patient	Care Unit	(seconds)
Critical Low HR (BPM)	18	18	N/A	N/A	5
Heart Rate (BPM)	30	30	150	200	5
Pulse Rate (BPM)	30	30	150	200	30
BP Systolic (mmHg)	70	OFF	190	240	120
BP Diastolic (mmHg)	40	OFF	OFF	150	120
BP MAP (mmHg)	60	65	OFF	170	90
Respiration (BR/MIN)	4	4	35	40	120
SpO_2 (%)	85	85	N/A	N/A	60
Skin Temperature	N/A	N/A	N/A	N/A	N/A

a. When measuring blood pressure as a 1-time measurement or at automatic intervals, there will be no annunciation delay.

Battery Alarms

No Pulse Detected Alarms	Limit	Annunciation Delay
When Thumb Sensor is primary source	No Pulse	No delay
When Cuff Module is primary source	No Pulse	No delay

	Battery Alarms	Limit	Annunciation Delay
Monitor	Monitoring Mode	45ºC (113ºF)	No delay
	In the Charger	45ºC (113ºF)	No delay
	Not monitoring / Not in the Charger	45ºC (113ºF)	No delay
Cuff Module	Connected to the Monitor	45ºC (113ºF)	No delay
	In the Charger	45ºC (113ºF)	No delay
	Not monitoring / Not in the Charger	45ºC (113ºF)	No delay
Power Pack	Connected to the Monitor	50ºC (122ºF)	No delay
	In the Charger	50ºC (122ºF)	No delay
	Not monitoring / Not in the Charger	50ºC (122ºF)	No delay

10.4.2 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	Annunciation Delay
ECG Lead Failure	N/A	No	No delay
All ECG Lead Failure	N/A	No	No delay
Chest Sensor Disconnected	N/A	No	No delay
General Fault Detected	N/A	No	No delay
Multiple Connections	N/A	No	No delay
Temperature Sensor Fault	N/A	No	No delay
Accelerometer Fault - Chest Module	N/A	No	No delay
Accelerometer Fault - Upper Arm	N/A	No	No delay

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

Cuff Module Alerts	Limit (if applicable)	Audible Alert	Annunciation Delay (in seconds)
Low Battery	4% to 10%	No	No delay
Battery Empty	< 4%	No	No delay

Cuff Module Alerts	Limit (if applicable)	Audible Alert	Annunciation Delay (in seconds)
Check Cuff	N/A	No	No delay
Cuff Occluded	N/A	No	No delay
NIBP Unobtainable	N/A	No	No delay
Invalid Software Loaded	N/A	No	No delay
Pressure Accuracy Fault	N/A	No	No delay
General Fault Detected	N/A	No	No delay
Pressure Exceeded	300mmHg	Yes	No delay
Multiple Connections	N/A	No	No delay

cNIBP Alerts	Limit (if applicable)	Audible Alert	Annunciation Delay (in seconds)
Calibration Failed	N/A	N/A	No delay
Calibrate cNIBP	N/A	N/A	No delay
Hold Still	N/A	N/A	No delay

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

ViSi Power Pack Alerts	Description of Annunciation	Audible Alert	Annunciation Delay (in seconds)
Power Pack Connected	1 Beep	Yes	No delay
Power Pack Disconnected	1 Beep	Yes	No delay
Power Pack Low Battery	Red LED Flashes (< 4% charge) Yellow LED Flashes (4%-10% charge)	No	No delay

ViSi Power Pack Alerts	Description of Annunciation	Audible Alert	Annunciation Delay (in seconds)
Battery Temp. Exceeds Limit	Red LED Solid and Continuous Beep Tone	Yes	No delay
Battery Current. Exceeds Limit	Red LED Solid and Continuous Beep Tone	Yes	No delay
Battery Pack Fault	Message on ViSi Monitor	Beep/Buzz on Power Pack ONLY	No delay

10.5 Environmental Conditions

Environmental Conditions for all ViSi Mobile Components (Monitor, Cuff Module, Chest Sensor, Cuff, Thumb Sensor, Power Pack)		
Condition	**Storage (Packaged / Unpacked)**	**Operating (Unpackaged)**
Temperature	-20°C to +55°C (50°C for NIBP) -4°F to +131°F (122°F for NIBP)	0°C to +40°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) (15% to 95% non-condensing for Power Pack)
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 Monitoring System may not perform to specification if stored or shipped outside the specified temperature range.

10.6 Compliances

Observe any national regulations on the qualification of the testing personnel and suitable measuring and testing facilities. *See "User/Preventative Maintenance" on page 105.* for a list of required tests.

10.6.1 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, Inc. 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 operated 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.

10.6.2 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 or Power Pack.

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.

10.6.3 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 from the EMC requirements of IEC 60601-1-2, but should be considered when addressing possible interference issues between this and other devices.

10.6.4 Electromagnetic Immunity

The ViSi Mobile Monitor is suitable for use in specified electromagnetic environments. 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 hospital environment.

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

10.6.5 Recommended Separation Distance

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

2-way radios may cause waveform distortion when placed within 1 foot of the ViSi Mobile Monitor.

Some brands of television may cause temporary waveform distortion and data loss when placed within 6 feet of the ViSi Mobile Monitor.

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.

10.6.6 Standards

Agency Compliances
• CAN/CSA C22.2 No 60601-1, Part 1: General requirements for basic safety and essential performance • IEC 60601-1:2005 Medical electrical equipment - Part 1: General requirements for safety (EN 60601-1:2006) • IEC 60601-1-2:2007, Med. Elect. Equipment – Part 1-2: General requirements for safety – Collateral standard: EMC – Req. and tests. • IEC 60601-1-6:2010, Medical electrical equipment – Part 1-6: General requirements – Collateral standard: Usability. • IEC 60601-1-8:2012, Medical electrical equipment – Part 1-8: Gen. req. – Col. Std. Gen. requirements, tests and guidance for alarm systems • IEC 60601-2-27:2011, Medical electrical equipment, Part 2-27: Particular requirements or the safety, including essential performance, of ECG monitoring equipment (except 208.6.6.2.103). • IEC 80601-2-30:2009, Medical electrical equipment – Part 2-30: Particular requirements for the safety, including essential performance, of auto. cycling non-invasive BP monitoring equipment. • IEC 60601-2-49:2011, Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multi-function patient monitoring equipment. • ISO 80601-2-61:2011, Medical electrical equipment - Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use. • IEC 62304:2006, Medical device software – Software life cycle processes • IEC 62366:2007, Medical devices – Application of usability engineering to medical devices.

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

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. on page 18

10.7.1 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.

10.7.2 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 Wireless, Inc. prior to making modifications to the network, including configuration changes that could potentially compromise the IT Network as verified at the initial installation of the ViSi System.

For support contact Sotera Wireless, Inc. or an authorized Sotera Wireless, Inc. 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	**Note:** Patient's heart rate is less than 18 BPM.
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, Inc.***
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, Inc..***

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

When the "Cuff Battery Temp" alarm is in progress, the ViSi Mobile Cuff Module should be removed from the patient immediately. Leaving it 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 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 and ECG Alerts 

Display Message	Severity	Cause	Solution
CHEST SENSOR	Low	The Chest Sensor is disconnected from the Monitor and not yet acknowledged by the clinician.	Acknowledge the alert and remove the Chest Sensor from the patient, or reconnect the Chest Sensor to the Monitor.
	Low	More than one Chest Sensor is simultaneously connected to the Monitor.	Remove the extra Chest Sensor(s) from the Monitor.
CHEST FAULT	Low	Various failure modes related to the Chest Sensor.	Replace the Chest Sensor and return it to Sotera Wireless, Inc.
	Low	The Chest Sensor does not contain the correct software.	Replace the Chest Sensor and return it to your biomedical engineer.
ECG LEAD (+ lead label)	Low	One or more lead-wires have failed or become disconnected from the electrode(s).	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 and return it to Sotera Wireless, Inc.
ACCEL. CHEST	Low	Unexpected error occurred with the accelerometer in the Chest Sensor.	Replace the Chest Sensor and return it to Sotera Wireless, Inc.
ACCEL. UPPER ARM	Low	Unexpected error occurred with the Upper Arm accelerometer.	Replace the Chest Sensor 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 SpO_2 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 that the cuff is positioned on the arm correctly and wrapped snugly around the arm. • Ensure that 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.

ViSi Power Pack Alerts

Note: In the event of a Power Pack malfunction while it is connected to a ViSi Mobile Monitor, the Monitor will indicate “Battery Pack Fault”.

Display Message	Severity	Cause	Solution
BATTERY PACK FAULT	High	Battery Pack current/voltage/ temperature protection error.	Discconnect Power Pack from Patient or remove from the Charger and contact Sotera Wireless, Inc. Customer Service.

Alert	Audible	Cause	Solution
BATTERY PACK FAULT	High	Battery Pack current/voltage/ temperature protection error.	Discconnect Power Pack from Patient or remove from the Charger and contact Sotera Wireless, Inc. Customer Service.

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	
	Monitoring a Patient / Not in Charger	**In Charger**
	The battery status in the ViSi Monitor is good and has at least three hours of monitoring available. **Note: The fill level will diminish as the battery level goes down.**	The battery is at least 90% charged. **Note: The LED on the front of the Monitor will be flashing green.**
	The battery in the ViSi Monitor is low. There is less than 3 hours of monitoring available.	The battery is charged between 40% and 90%. **Note: The LED on the front of the Monitor will be flashing yellow.**
	The battery in the ViSi Monitor is critically low. There is less than 1 hour of monitoring available.	The battery charge is less than 40%. **Note: The LED on the front of the Monitor will be flashing yellow.**
	The battery in the ViSi Monitor is too low to continue monitoring. There is less than 10 minutes of battery charge left.	The Monitor will not wake up when it is in the Charger.

Wireless Radio Signal Strength

Signal Strength Icon	Status
	Connectivity between the ViSi Monitor and the Appliance is good. The number of green bars indicates 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.**

ViSi Power PackIntroduction

Do not operate the ViSi Mobile Power Pack before reading these instructions.

This user manual describes how to use the Sotera Wireless, Inc. ViSi Power Pack and provides information for its proper operation. This product should only be used in conjunction with the ViSi Mobile Monitoring System. Please review Appendix B -ViSi Power Pack in its entirety prior to use.

A formal knowledge of the features and functions of the ViSi Mobile Monitoring System are prerequisites for its proper use.

Intended Use

The ViSi Power Pack is intended to be used by clinicians and medically qualified personnel only and is used in conjunction with the ViSi Mobile Monitor. The ViSi Power Pack's only purpose is to extend battery life for the ViSi Mobile Monitor so that battery power lasts a minimum of 24 hours.

Proper use of the ViSi Power Pack requires that it be in its cradle while connected to the ViSi Mobile Monitor. This reduces the risk of electric shock from exposure to the contact pins on the bottom rear of the ViSi Power Pack.

Note: The ViSi Power Pack is only designed to sustain the battery life of the internal ViSi Mobile Monitor battery; it will not recharge the battery. When the ViSi Power Pack is disconnected, the ViSi Mobile Monitor battery charge level is not expected to have increased.

Warnings And Cautions

Do not operate the ViSi Mobile Power Pack before reading these instructions.

Never connect the ViSi Power Pack directly to an AC power outlet. To recharge the battery, disconnect the Power Pack from the patient, and then place it in the ViSi Mobile Charger. on page 15

General Description

Do not touch the electrical contacts on the ViSi Power Pack or use the ViSi Power Pack without it first being inserted into the ViSi Power Pack Cradle. Doing so may result in electric shock from the battery. on page 15

If the ViSi Power Pack beeper/buzzer sounds or the Red LED is permanently lit, the ViSi Power Pack should be disconnected from the patient immediately. on page 15

ViSi Power Pack

ViSi Power Pack

ViSi Power Pack Cradle

The ViSi Power Pack is a portable, battery operated power source that is used with the ViSi Mobile Monitor. The ViSi Power Pack is not intended to be worn by the patient. It comes with a ViSi Power Pack Cradle which only acts as a base for the Power Pack when in use and contains no electrical components.

The ViSi Power Pack should always be seated in the Power Pack Cradle when connected to the ViSi Mobile Monitor. The Cradle has an integrated pole mount which can be attached securely at the patient bedside. Alternately, the Cradle can be placed on a flat, fixed surface.

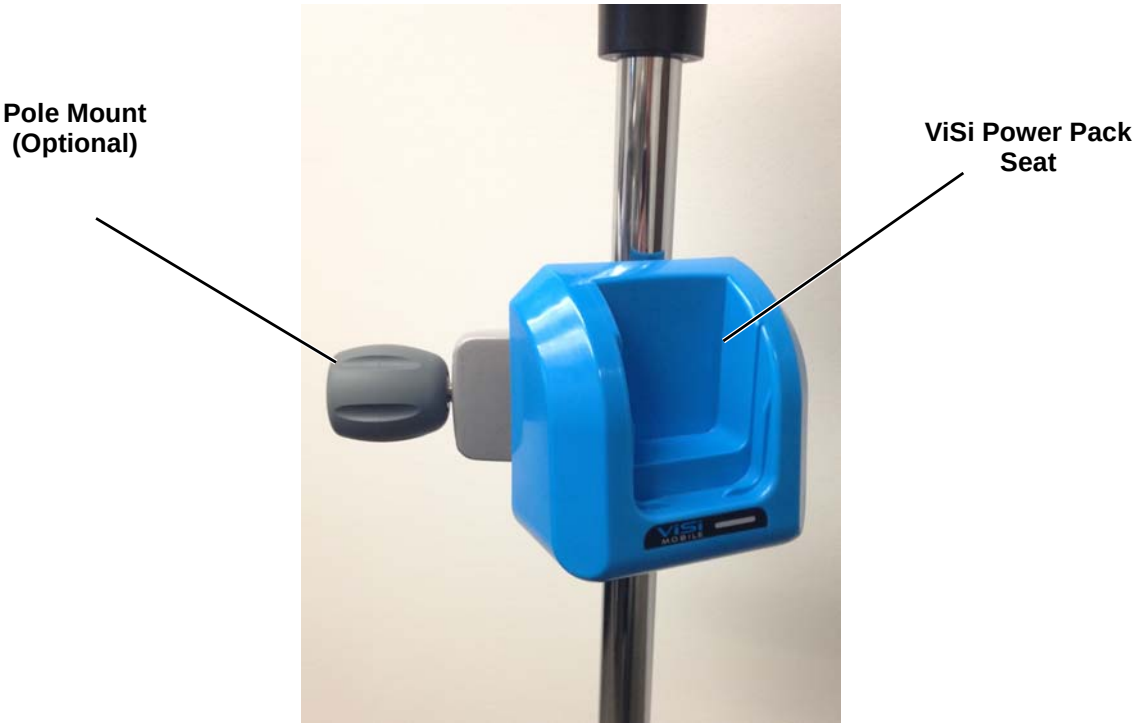
The ViSi Power Pack contains a rechargeable lithium-ion battery and should only be recharged using a ViSi Battery Charger.

The Power Pack and has a cable that connects to the flat side of the ViSi Mobile Monitor when the Monitor is in its Wrist Cradle. In addition to battery power, the cable also provides information on temperature, voltage and current to the Monitor which will show a alert in case of failure.

The ViSi Power Pack can sustain the charge of the ViSi Mobile Monitor battery for at least 24 hours.

The ViSi Power Pack has a series of LED lights that indicate the amount of battery charge left (similar operation to the ViSi NIBP Module) and will also communicate alerts as described on page 212. The ViSi Power Pack will also beep and vibrate in the event of a failure.

ViSi Power Pack Cradle



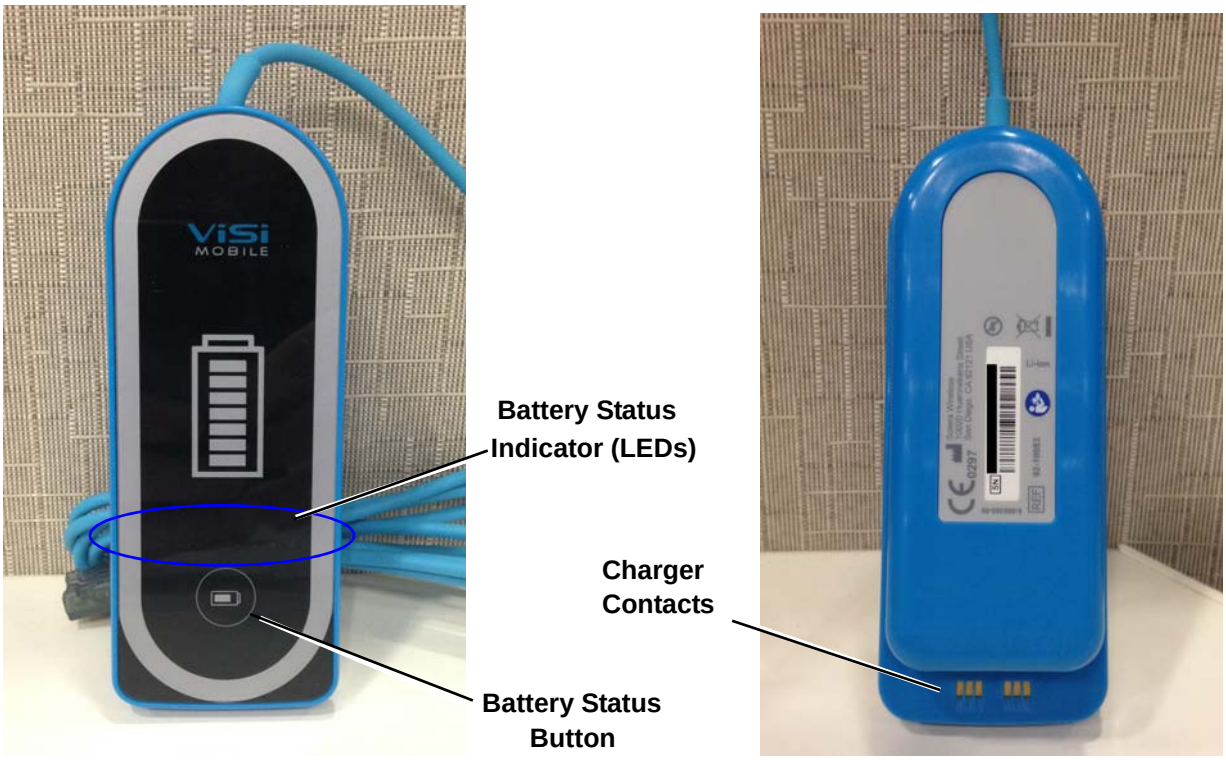
The ViSi Power Pack cradle comes with an optional pole mount that attaches to a bedside or IV pole for greater stability or mobility for the patient.

Operation Inspecting the Equipment

Before using the ViSi Power Pack, visually inspect each component of the ViSi Mobile Monitoring System and Power Pack.

1. For each component, examine the exteriors for cleanliness and general physical conditions. Ensure the housings are not cracked or broken, that everything is present, there are no spilled liquids and no signs of abuse.
2. For each component, examine the exteriors for cleanliness and general physical conditions. Ensure the housings are not cracked or broken, that everything is present, there are no spilled liquids and no signs of abuse.For each component, examine the exteriors for cleanliness and general physical conditions. Ensure the housings are not cracked or broken, that everything is present, there are no spilled liquids and no signs of abuse.
3. Ensure there the ViSi Power Pack has adequate charge.

Checking the Battery Charge of the ViSi Power Pack



ViSi Power Pack Front **ViSi Power Pack Back**

Press the **Battery Status** button on the front of the ViSi Power Pack.

There is a row of eight colored lights (Battery Status Indator LEDs) on the front surface of the ViSi Power Pack.

Illuminated lights indicate the level of the battery charge:

- *Green lights indicate the battery has a minimum of 11% charge. More green lights indicate a greater charge level.*
- *When six illuminated green lights are visible, the ViSi Power Pack is fully charged.*
- *A yellow light indicates the battery charge is less than 10%.*
- *A flashing red light indicates there is less than 4% battery charge.*

Note: A solid illuminated red light may indicate a failure of the ViSi Power. Disconnect ViSi Power Pack from patient, or remove from ViSi Battery Charger and contact Sotera Wireless, Inc. Customer Service.

Charging the ViSi Power Pack

Note: For more information on setting up and using the ViSi Mobile Charger, see ViSi Mobile Charger on page 40

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

The ViSi Mobile Charger provided by Sotera Wireless, Inc. is the required Charger for ViSi Power Pack. The Charger is capable of charging up to eight of any combination of Power Packs, To charge the Power Pack, place the flat end into one of the slots with the front facing outwards.

Insert the Power Pack that you want to charge into one of the Charger docks.

One of the charging indicator lights will blink while the Power Pack is charging.

Like with the Cuff Module, when one of the green charging indicators is flashing, the battery in the Power Pack is charging. The position of the green charging indicator represents the level of charge. When the charge indicator furthest away from the red charging indicator is flashing, the Power Pack is fully charged.

When the yellow charging indicator is flashing, the battery in the Power Pack is low.

When the red charging indicator is flashing, the battery in the Power Pack has insufficient charge to power the Monitor.

Note: The ViSi Mobile Charger is to be used for ViSi Mobile components only.

Note: ViSi Mobile Power Packs contain sealed batteries that are not replaceable by the user. If a Power Pack has a battery issue, contact the Sotera Wireless, Inc. Customer Service Department.

Setting up the ViSi Power Pack Cradle

The ViSi Power Pack Cradle can either be placed on a sturdy horizontal surface or can be attached to a pole or bedframe with the optional pole mount.

To use the pole mount:

1. *Loosen the pole clamp by turning the knob Counter-Clockwise*
2. *Tighten the pole clamp by turning the knob Clockwise*
3. *Place the Visi Power Pack in the Cradle with the front facing the outward with the flat side down.*

Note: When the ViSi Power Pack is inserted in its Cradle, the Charger Contacts should not be accessible.

Note: The ViSi Power Pack grooves will align with those of the Cradle when the Power Pack is correctly seated.

Using the ViSi Power Pack

Note: Only attach one ViSi Power Pack to the ViSi Mobile Monitor.

Do not touch the electrical contacts on the ViSi Power Pack or use the ViSi Power Pack without it first being inserted into the ViSi Power Pack Cradle. Doing so may result in electric shock from the battery.

Route all ViSi Mobile Monitoring System cabling to avoid the possibility of patient entanglement or strangulation.

The ViSi Power Pack Alarms/Alerts DO NOT audibly annunciate on the ViSi Mobile Monitor or the Remove Viewing Device.

If the ViSi Power Pack beeper/buzzer sounds or the Red LED is permanently lit, the ViSi Power Pack should be disconnected from the patient immediately.

Plug the Power Pack connector into any of the open ports on the flat end of the Monitor with the connector contacts facing upwards.

Insert with connectors contacts facing upwards

The ViSi Power Pack and the Monitor will make a beeping noise to indicate that the Power Pack is connected. Once connected, the Power Pack will automatically begin to provide auxilliary power to the Monitor.

To stop using the Power Pack, simply disconnect from the Monitor.

When not in use, disconnect the ViSi Power Pack from the Monitor.

It is recommended to place the ViSi Power Pack in the ViSi Mobile Charger (see section ViSi Mobile Charger on page 40) between uses.

Replacing the ViSi Power Pack

To replace a depleted ViSi Power Pack while still monitoring a patient:

Do not touch the electrical contacts on the ViSi Power Pack or use the ViSi Power Pack without it first being inserted into the ViSi Power Pack Cradle. Doing so may result in electric shock from the battery.

1. Disconnect the ViSi Power Pack from the Monitor
2. Remove the Power Pack from the Power Pack Cradle
3. Insert new Power Pack into the Cradle
4. Connect the new Power Pack to the Monitor

Equipment Alerts

The ViSi Power Pack has technical alerts that are intended to notify the clinician of situations that may be hazardous or impede the ability of the Power Pack to provide power to the Monitor.

Note: For a listing of these Alerts, please see Alarm Summary on page 199

Note: In the event of a Power Pack malfunction while it is connected to a ViSi Mobile Monitor, the Monitor will indicate "Battery Pack Fault".

The ViSi Power Pack Alarms/Alerts DO NOT audibly annunciate on the ViSi Mobile Monitor or the Remove Viewing Device.

If the ViSi Mobile Monitor displays a "Battery Pack Fault" , "Electric Shock", or "Monitor Too Hot" message, disconnect the Power Pack immediately.

User/Preventative Maintenance

See *User/Preventative Maintenance on page 105* for instructions on the maintenance of the ViSi Power Pack.

Troubleshooting

See section Troubleshooting on page 147 for instructions on troubleshooting the ViSi Power Pack.

- Notes -

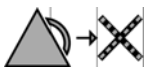
Appendix C - Symbols

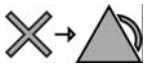
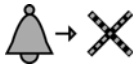
Alarms / Alerts

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).

Symbol	Description
	Resume alarm annunciation from a paused state.
	Turn alarm annunciation back on.
	Acknowledge an alarm/alert that is in progress.

Battery States

ViSi Mobile Monitor

Battery Icon	Status	
	Monitoring a Patient / Not in Charger	**In Charger**
	The battery status in the ViSi Monitor is good and has at least three hours of monitoring available. **Note: The fill level will diminish as the battery level goes down.**	The battery is at least 90% charged. **Note: The LED on the front of the Monitor will be flashing green.**
	The battery in the ViSi Monitor is low. There is less than 3 hours of monitoring available.	The battery is charged between 40% and 90%. **Note: The LED on the front of the Monitor will be flashing yellow.**
	The battery in the ViSi Monitor is critically low. There is less than 1 hour of monitoring available.	The battery charge is less than 40%. **Note: The LED on the front of the Monitor will be flashing yellow.**
	The battery in the ViSi Monitor is too low to continue monitoring. There is less than 10 minutes of battery charge left.	The Monitor will not wake up when it is in the Charger.

ViSi Power Pack

When the ViSi Power Pack is connected to a Monitor, the Monitor screen will show the battery level of the Power Pack.

Battery Icon	Status
	The battery in the Power Pack is charged. Remaining battery level is >10 % .
	The battery in the Power Pack is low. Remaining battery level is between 4% - 10%.

Battery States

Battery Icon	Status
	The battery in the Power Pack is critically low. Remaining battery level is <4% and too low to charge a Monitor.

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 a PRN basis.
	Start automatic cuff inflations. Cuff inflations are set up to be taken automatically at a selected time interval.
	Calibrate NIBP for continuous measurements.

Symbol	Description
	Calibrate cNIBP for continuous measurements. Patient's PAT is not yet stable.
	Stop a cuff inflation currently in progress.

Clinical Menu

Symbol	Description
	BP management. Setup the cuff inflation intervals.
	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 a PRN basis.

Symbol	Description
	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.
	Monitor is ready to perform device swap.

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 or the Patient is walking[a] on the Wrist Monitor.
	Patient is walking. This symbol will be displayed on the ViSi Mobile Remote Viewer only.
	Patient's torso is at a semi-Fowler's position.
	Patient is lying in a supine position.
	Patient is lying in a prone position.
	Patient is lying on their right side.
	Patient is lying on their left side.

a. When the ViSi Mobile Monitor has identified a Patient as walking for two consecutive updates, the cNIBP monitoring will be paused for a mininum of 30 seconds.

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
	Non-ionizing radiation
	Caution, refers to accompanying electronic document

- Notes -

Appendix D - Warranty

Warranty

Sotera Wireless, Inc. 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 Wireless, Inc. will operate in accordance with Sotera Wireless, Inc.'s published documentation in effect on the date of delivery or Sotera Wireless, Inc. 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 Wireless, Inc. equipment only but does not include disposables / consumables. Sotera Wireless, Inc. 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 Wireless, Inc. 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 Wireless, Inc. 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 Wireless, Inc. 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 Wireless, Inc., 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 Wireless, Inc. will not be liable under this warranty if its testing and/or examination discloses that the alleged defect in the Sotera Wireless, Inc. 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 Wireless, Inc. The warranty for software will be voided if the software is modified, except as authorized in writing by Sotera Wireless, Inc.

In no event shall Sotera Wireless, Inc. be liable to end user or any third parties for any consequential, incidental, indirect, exemplary, punitive, contingent, statutory or any other special damages. Sotera Wireless, Inc.'s liability for damages on account of a claimed defect in any product delivered by Sotera Wireless, Inc. 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 Wireless, Inc. 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 Wireless, Inc.'s obligations under this agreement. Sotera Wireless, Inc. 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 Wireless, Inc. disclaims all liability of any kind of Sotera Wireless, Inc.'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 Wireless, Inc. 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 Wireless, Inc. hardware, and Sotera Wireless, Inc. makes no warranty whatsoever with respect to any third-party branded products supplied by it hereunder.

Sotera Wireless, Inc. 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.

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