Monitoring System

User manual

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Information for servicing the ViSi Mobile Monitoring Systems is contained in the ViSi Mobile Monitoring System Technical Manual, Reference#: 95-10061 (hardcopy) / 95-10059 (CD). For additional information or assistance, please contact Sotera Wireless or an authorized Sotera Wireless representative in your area.

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1. Preface

1.1 Introduction

This User Manual is intended to provide information for the proper operation of the Sotera Wireless ViSi Mobile Monitoring System™. A formal knowledge of patient monitoring and an understanding of the features and functions of the system are prerequisites for its proper use.

This manual is written for trained clinicians. Although this manual 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 Warnings, Cautions and Notes

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

1.2.1 Definitions

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

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

Note: Note statements provide supplemental information to the user.

Warnings 

Intended Use

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

Do not use the ViSi Mobile Monitoring System in neonatal or pediatric patients under the age of 12 years since the System has not been tested for these patient groups.

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

Safety

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

The ViSi Mobile Monitoring System has not been tested in the presence of electro-surgical devices.

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

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

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

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

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

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

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

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

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

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

Warnings 

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

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

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

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

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

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

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

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

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

Disposable Patient Kit

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

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.

Patient Monitoring

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

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

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

Warnings 

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

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

Only use the ViSi Mobile Thumb Sensor provided by Sotera Wireless, Inc. with the ViSi Mobile Monitoring System.

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

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

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

Only Sotera Wireless, Inc. supplied ViSi Mobile Thumb Sensors should be used. Using non-approved Thumb Sensors may result in inaccurate SpO2 readings.

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

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

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

Other RF radiating devices (such as high powered RFID readers and Bluetooth devices) that are in close proximity with the ViSi Mobile Monitor may interfer 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.

Warnings

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

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

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

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

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

Perform a risk assessment and verification before you implement 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.

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

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

If ECG electrodes need to be replaced, use all of the same type of ECG electrode on the patient. Mixing ECG electrode types can adversely affect ECG monitoring.

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

Warnings 

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

The ViSi Mobile Monitor does not have automated ST segment analysis, therefore, if a change in the ST segment of the ECG waveform is suspected, it should be confirmed by 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.

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.

Warnings 

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.

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

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

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

SpO_2

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

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

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

Alarms / Alerts

When using the Monitor as a standalone device or the patient is out of network range, a responsible clinician must be within audible range of the assigned patient wearing the ViSi Mobile Monitor at all times.

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 new alarm limits are confirmed, they cannot be changed back to the original pre-set limits. Once Auto Set is selected, review the newly calculated alarm limits carefully before deciding to confirm or cancel the new alarm limits.

Warnings 

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

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

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

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

User Maintenance

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

Wireless Communications

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

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

Off-The-Shelf (OTS) Software

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

Cautions 

Intended Use

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

Safety

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

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

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

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

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

Do not use the ViSi Mobile Monitoring System 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.

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

Service / Maintenance

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

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

Cautions 

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

The ViSi Mobile Monitoring System components 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 and the round end is pointing down towards the wrist.

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

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

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

The ViSi Mobile Monitoring System does not support printing capability.

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

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

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

Cleaning / Disinfecting

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

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

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

Cautions

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

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

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

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

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

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

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

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

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.

1.3 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. It is indicated for ECG (3 or 5 lead-wire), respiration rate (RESP), heart rate (HR), non-invasive blood pressure (NIBP), non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate (PR), and 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 a Remote Viewer through wireless 802.11 communication.

1.3.1 Contraindications

- Impedance pneumography for the determination of Respiration Rate (RESP) is not recommended for use in the presence of mechanically induced high frequency ventilation.
- The ViSi Mobile Monitoring System has not been tested for use on neonatal or pediatric patients under the age of 12 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.

2. General Description

2.1 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), Pulse Oximetry (SpO_2), and Skin Temperature (TEMP).

The System comprises the ViSi Mobile Monitor, Thumb Sensor, Chest Sensor Cable (either 3 lead-wire or 5 lead-wire), Cuff Module, Charger and Patient Kit.

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.

For ease of use, the Monitor features three interchangeable plug-in sites for the Chest Sensor Cable and Cuff Module.

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 on inflation. The measurement is realized by a Cuff, to which the Cuff Module is attached (pneumatic connection). The electric connection to the Monitor is established through a cable that connects to its upper side.

2.2 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 representative in your area for prompt assistance in resolving shipping problems.

2.2.1 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 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 on a common carrier to comply with Federal Regulations regarding electromagnetic emission.

2.3 System Components

2.3.1 ViSi Mobile Patient Kit

The Patient Kit contains the disposable components of the system. The Patient Kit components are for single patient use only. The Patient Kits are available in three Adult sizes: Small, Medium, and Large. Choose the Patient Kit that contains the Cuff size best suited for the patient. Cuff sizes follow standard range of arm circumference. *See 4.2.5Selecting the ViSi Mobile Patient Kit on page 47.*

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

ViSi Mobile Patient Kit Contents	
Equipment	**Quantity**
ViSi Mobile Disposable Cuff (with pneumatic connector)	1
ECG Electrode	6
ViSi Mobile Wrist Cradle	1
ViSi Mobile Thumb Cradle	1
ViSi Mobile Setup Guide	1
ViSi Mobile Cable Securement	2

ViSi Mobile Disposable Cuff

The Cuff is available in small, medium and large adult sizes (*see 4.2.5Selecting the ViSi Mobile Patient Kit on page 47*). The Cuff is used to take a NIBP measurement once the Cuff Module is plugged in. *See ViSi Mobile Cuff Module on page 28*.

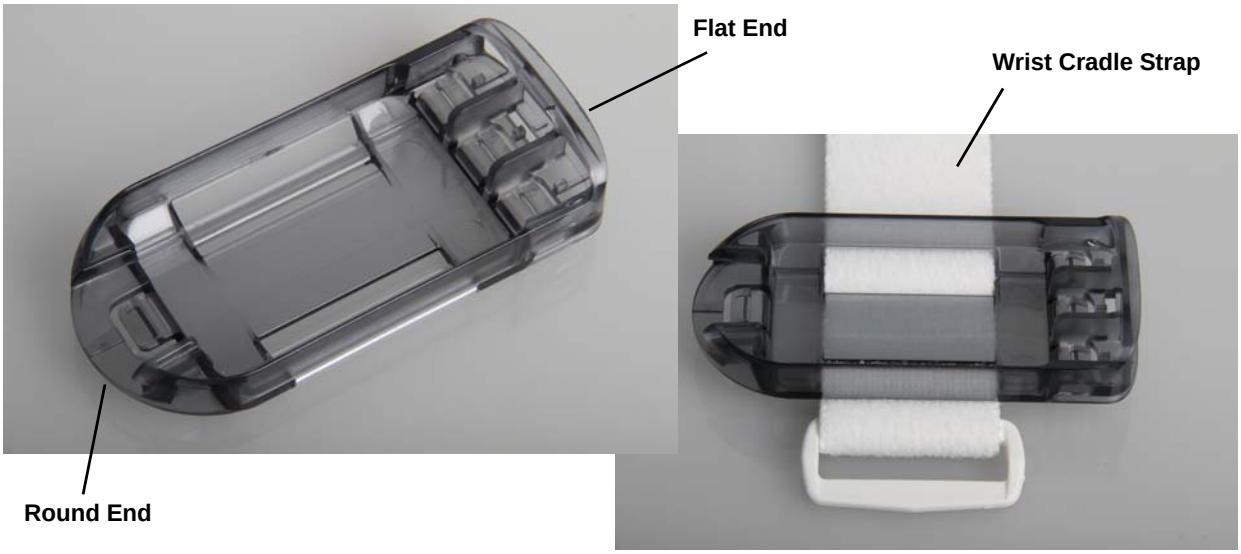
Note: Only cuffs designed for use with the ViSi Mobile Cuff Module may be used.

ECG Electrode

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

ViSi Mobile Wrist Cradle

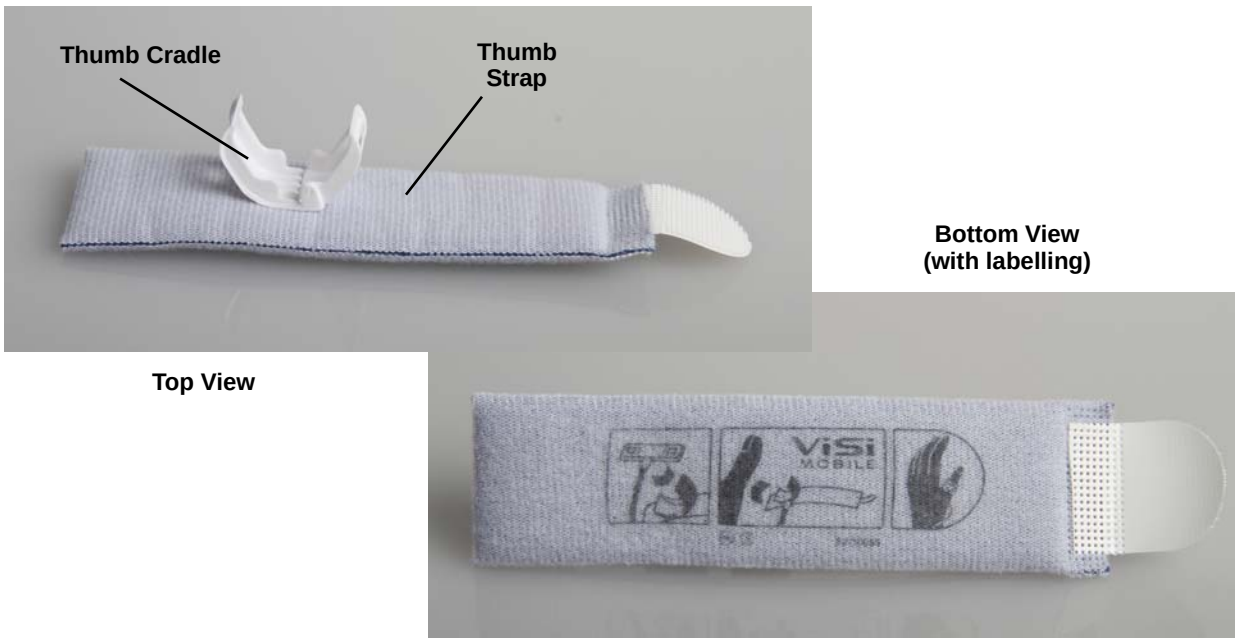
The Wrist Cradle holds the Monitor and provides the electrical connectors for the sensors. The Wrist Cradle is held in place on the patient's wrist with a strap. The Wrist Cradle Strap is available in small, medium and large adult sizes.



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

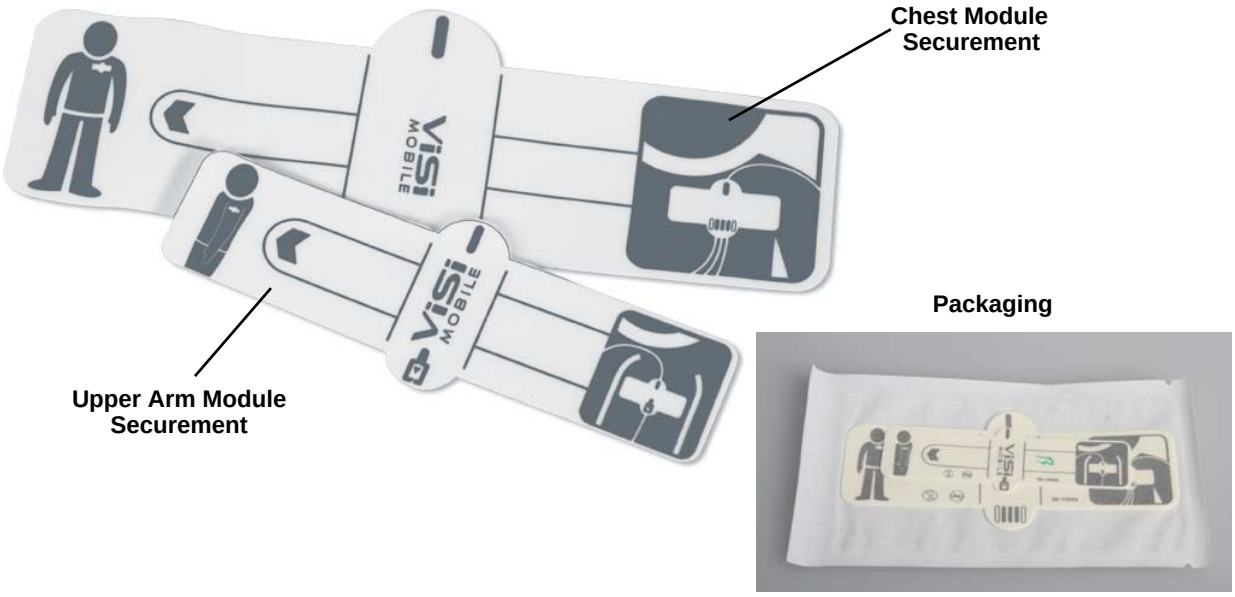
ViSi Mobile Thumb Cradle

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



ViSi Mobile Cable Securement

There is one large and one small Cable Securement in the Patient Kit. The large Cable Securement secures the Chest Module of the Chest Sensor Cable to the patient's torso. The small Cable Securement secures the Upper Arm Module of the Chest Sensor Cable to the upper arm. *See ViSi Mobile Chest Sensor Cable on page 29.*



2.3.2 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: The power indicator shows the level of Monitor's battery charge by flashing green (the battery has at least 2 hours of monitoring time left), yellow (the battery is low with less than 2 hours of monitoring time left), and red (the battery is critically low with less than 30 minutes of monitoring time left).

2.3.3 ViSi Mobile Thumb Sensor (SpO_2)

The Thumb Sensor is applied to the patient's thumb with the sensor and sensor cradle facing the patient's palm. The Thumb Sensor 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. 

2.3.4 ViSi Mobile Cuff Module

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

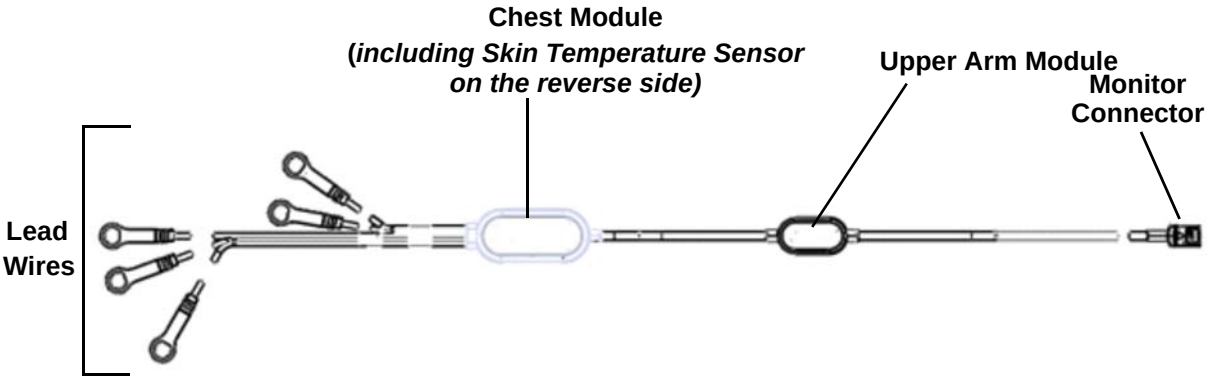
Note: When the battery status button is pressed, the battery status indicator shows the level of the Cuff Module's battery charge. Green lights indicate the battery has a minimum of 11% charge. More green lights indicate a greater charge level. A yellow light indicates the battery charge is less than 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 Bio Med. It is recommended a calibration check is performed ever year.

2.3.5 ViSi Mobile Chest Sensor Cable

The Chest Sensor Cable is either a 3 lead-wire or 5 lead-wire and plugs into any one of the connectors on the flat end of the Wrist Cradle. *See Applying the ViSi Mobile Chest Sensor Cable and ECG Electrodes on page 56 for recommended Chest Sensor Cable placement.*

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



Chest Sensor Cable
5 Lead

Front View
(Place this side away from the patient's skin)

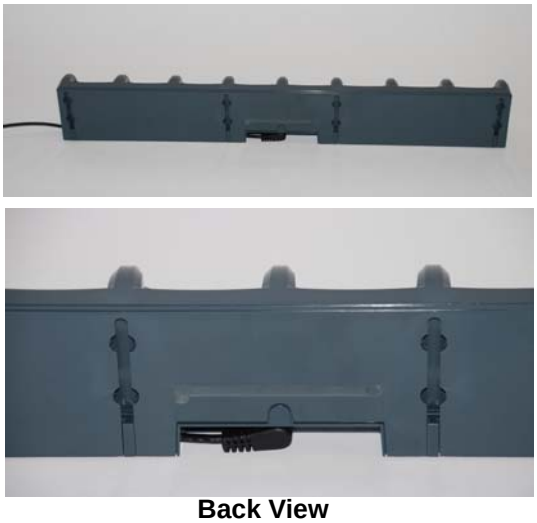
Chest Sensor Cable
3 Lead

2.3.6 ViSi Mobile Charger

The Charger is used to charge both Monitors and Cuff Modules, providing 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

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.

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

2.3.7 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. The Charger is capable of charging up to eight of any combination of Monitors and Cuff Modules. 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.

Note: ViSi Mobile Monitors and Cuff Modules contain sealed batteries that are not replacable by the user. If a Monitor or Cuff Module has a battery issue, contact the Sotera Wireless Inc. Customer Service Department or the Sotera Wireless representative in your area.

The LED on the Charger is used to indicate the charging status of devices that are currently inserted:

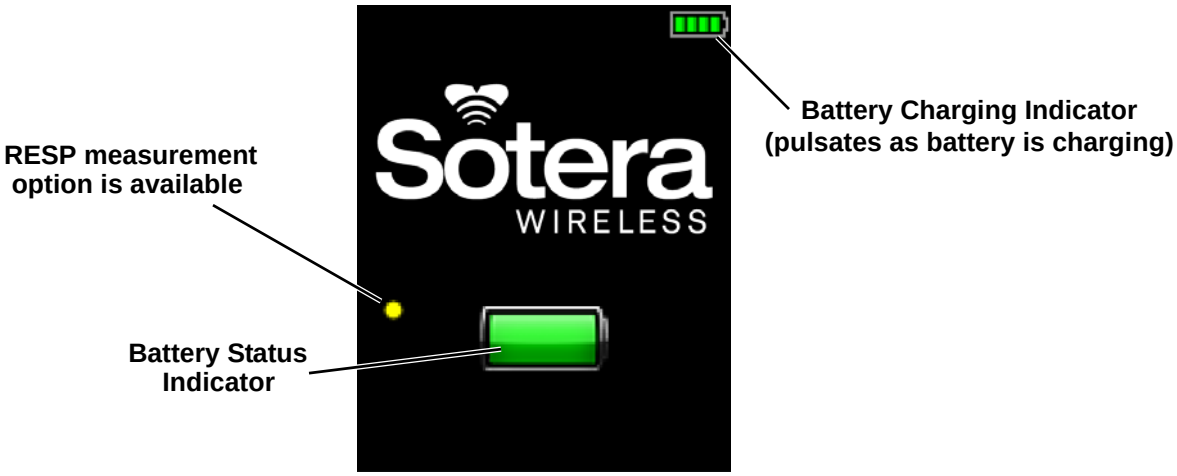
LED Color	Charging Status
Steady Green	Everything is normal: • No devices in the Charger. • All devices are charging normally or are fully charged.
Flashing Green / Yellow	At least one device in the Charger is in battery recovery mode with the device not talking to the Charger.
Steady Yellow	At least one device in the Charger is not being charged due to a fault with the device. The other devices are charging.
Steady Red	Charger fault. No devices are charging, the Charger has shutdown.

To charge a 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 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 to activate the display and show the battery charge status.

The power indicator will blink while the Monitor is charging: green indicates there is enough charge to monitor a patient for at least two hours; yellow indicates the battery charge is low (less than two hours of monitoring); and red indicates the battery charge is critically low (less than 30 minutes of monitoring).

To charge a 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. No more than a couple of cuff inflations are possible.

When the red charging indicator is flashing, the battery in the Cuff Module is empty. No cuff inflations are possible.

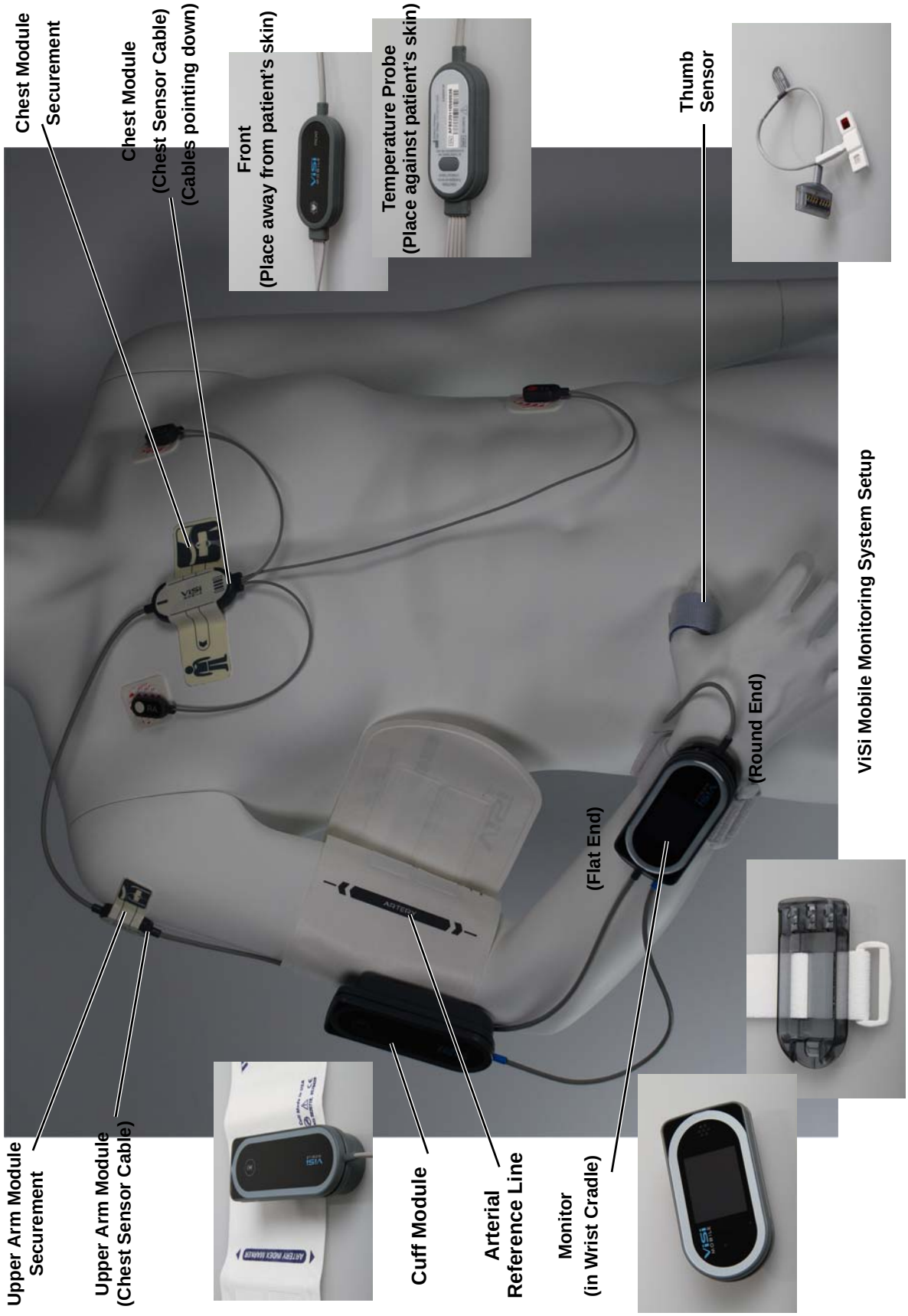
- Notes -

3. Clinical Features

3.1 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, or it can be measured automatically at predefined intervals.

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



ViSi Mobile Monitoring System Setup

3.2 Key Features

- Battery life > 12 hours
- Full charge reached after approximately 2 hours of charging
- Chest Sensor Cable 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 and automatic measurements at predefined cycles)
- Touchscreen display
- Alarms and Alerts generated with visual and audible indication on the Monitor
- Self Test

3.3 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, and TEMP. ECG, SpO_2, and RESP waveforms are viewable on demand. NIBP can be measured as a one-time measurement, or it can be measured automatically at programmed intervals.

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 Cable and ViSi Mobile Cuff Module. The Chest Sensor Cable measures the ECG/HR (with a 3 lead-wire or 5 lead-wire), RESP, and TEMP.

3.3.1 ECG Monitoring and Heart Rate (HR) Monitoring

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

With the 5 lead-wire Chest Sensor Cable, 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.

3.3.2 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 configuration.

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 SpO_2 should be assessed as well.

3.3.3 Skin Temperature (TEMP) Monitoring

TEMP is continuously measured skin surface temperature as measured by the probe located on the underside of the Chest Module. The probe 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 Cable on page 59.*

Note: Skin temperature may not be the same as core body temperature or temperature measured from 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 implementing therapy based on the skin temperature measurement, verify the measurement using another clinically acceptable method of core temperature measurement.

3.3.4 Pulse Oximetry (SpO_2 and Pulse Rate) Monitoring

The Pulse Oximetry channel non-invasively 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 HR source from an ECG, the Pulse Rate (PR) can be measured and displayed from the SpO_2 channel.

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

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

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

3.3.5 NIBP Monitoring

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

The accuracy of NIBP measurements is influenced by several factors:

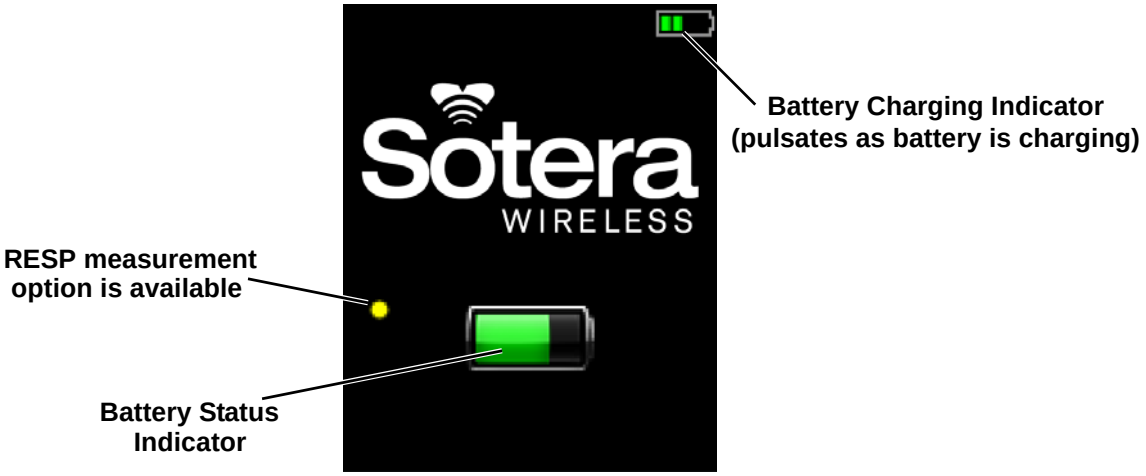
- Correct cuff size
- Correct cuff placement on the arm
- The position of the upper arm in relation to the heart at the time of the measurement
- Motion artifacts

3.4 Display Screens

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

3.4.1 Battery Charge Screen

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



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.

3.4.2 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:

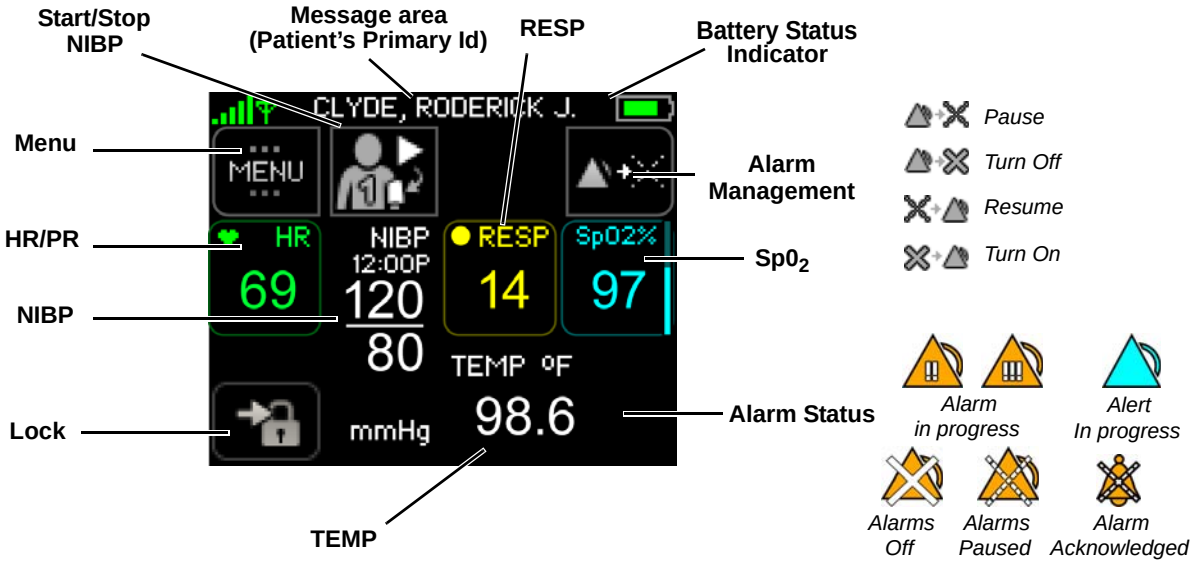
- The Shipping Plug is not plugged into the Monitor
- The Monitor is not in the Charger
- No sensors are connected to the Monitor

Note: When in Hibernation, the power indicator blinks approximately every 9 seconds. The power indicator color is reflective of the battery status: "Green" indicates there is sufficient battery charge for at least two hours of monitoring; "Yellow" indicates the battery charge is depleted and there is less than 2 hours of monitoring available; and "Red" indicates the battery charge is depleted and there is less than 30 minutes of monitoring available. When the power indicator stops blinking, the battery charge is empty.

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.

3.4.3 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.

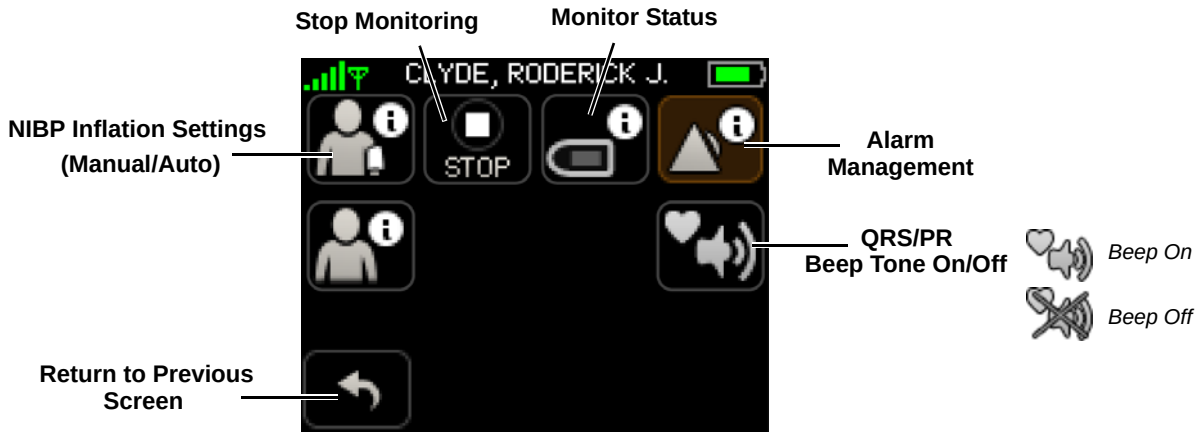


Use the **Vital Signs** screen to:

- View current vital sign measurements
- Vital Signs Measurement: Access the waveforms *(see page 70)*
- Alarm Status: View alarm status
- Battery Status Indicator: View the battery status
- Menu: Access the Menu screen *(see page 42)*
- Start/Stop NIBP: Start and stop manual NIBP measurement *(see page 75)*
- Alarm Management: Pause alarms/alerts *(see page 99)*
- Alarm Management: Acknowledge (silence) alarms/alerts *(see pages 93 and 97)*
- Lock: Lock the Monitor to prevent unauthorized access

3.4.4 Menu Screen

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



Use the **Menu** screen to:

- Change the NIBP measurements from Manual to Auto and set auto inflation interval *(see page 79)*
- Stop monitoring *(see page 81)*
- View Monitor status *(see page 42)*
- View and change the alarm limits settings *(see page 104)*
- Silence or enable the HR / PR beep tone

3.4.5 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 Monitor's software

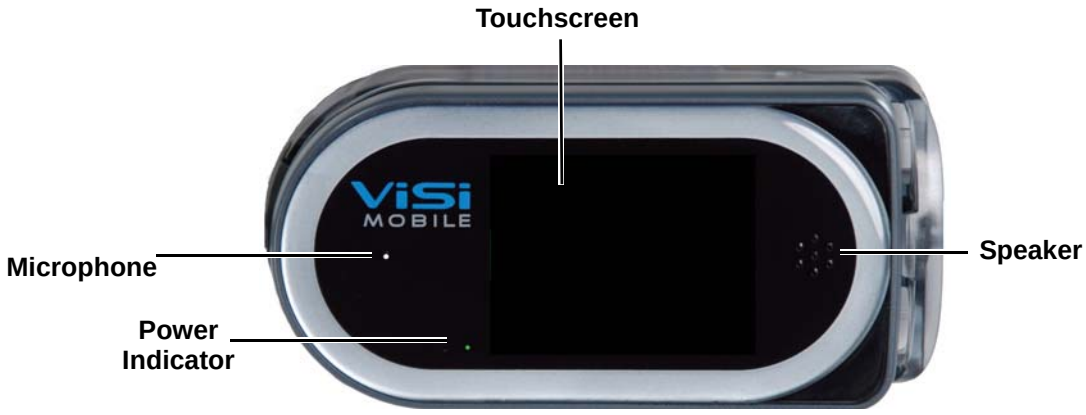
- View the Monitor's serial number
- View the Monitor's MAC address
- View features that are available, such as RESP

3.4.6 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.

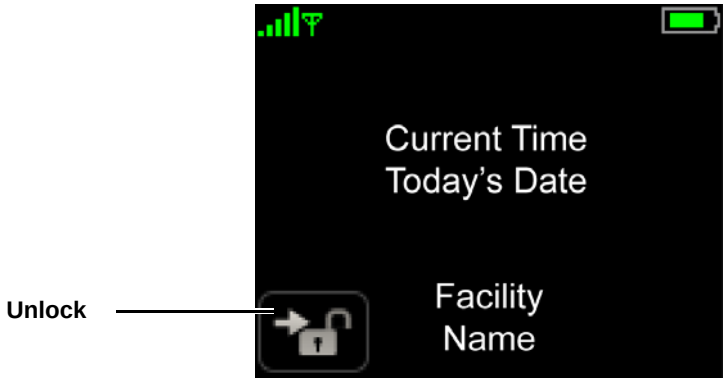
The **Quiet Monitoring** Screen conserves battery power and minimizes patient disturbance. Vital signs alarms and alerts remain active. Touching the screen continuously for 2 seconds resumes the Monitor's display with the **Patient View** screen.



Note: When in Quiet Monitoring, the power indicator blinks approximately every 3 seconds. The power indicator color is reflective of the battery status: "Green" indicates there is sufficient battery charge for at least two hours of monitoring; "Yellow" indicates the battery charge is depleted and there is less than 2 hours of monitoring available; and "Red" indicates the battery charge is depleted and there is less than 30 minutes of monitoring available. When the power indicator stops blinking, the battery charge is empty.

3.4.7 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

4. Operation

4.1 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.

4.2 Preparing for a New Patient

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

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

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

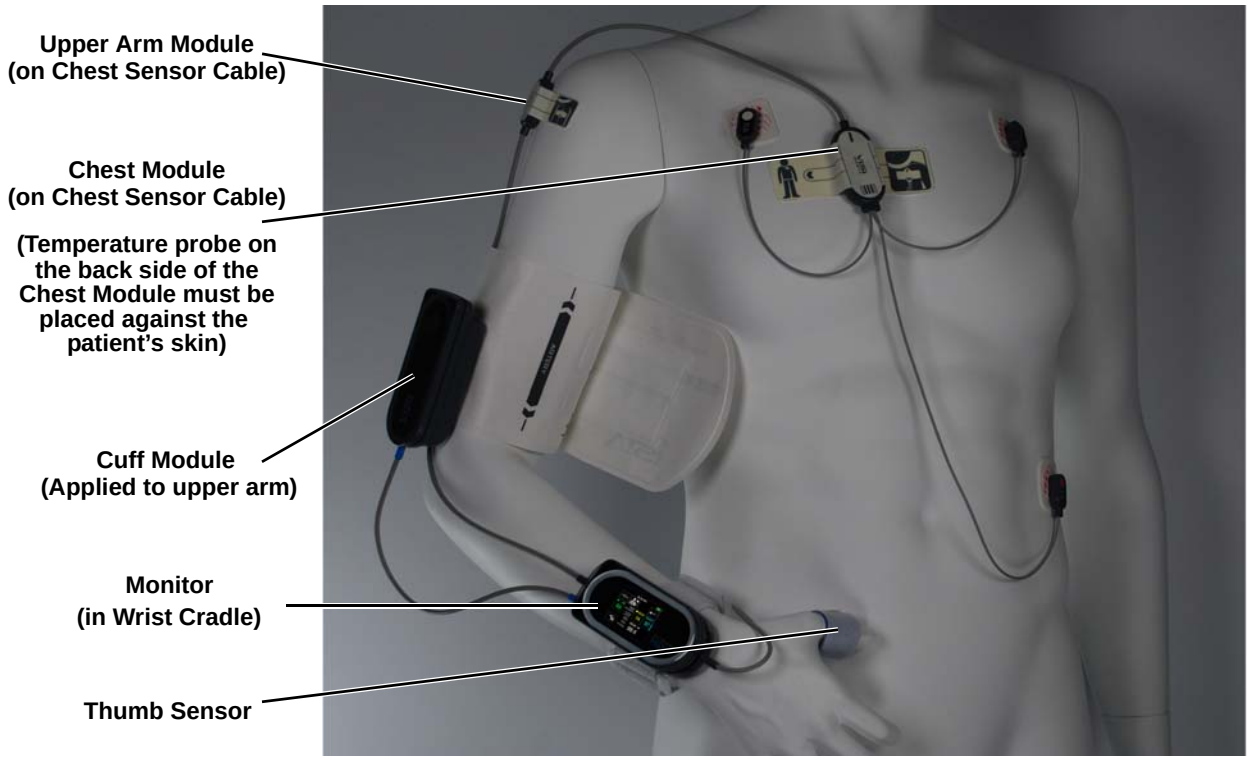
4.2.1 Inspecting the Equipment and Accessories

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 for general condition. Ensure there are no breaks in the insulation. 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.

4.2.2 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 104.*

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 Cable
- Selecting the appropriately sized Cuff (from the Patient 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 probe. 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).

4.2.3 Selecting Vital Signs to Monitor

The following vital signs may be monitored:

- ECG (one or seven simultaneous leads, using the 3 lead-wire or 5 lead-wire Chest Sensor Cable respectively)
  - ↳ HR (from the ECG)
  - ↳ RESP (optional)
  - ↳ TEMP (Skin Temperature)
- SpO_2
  - ↳ PR (from the Thumb Sensor)
- NIBP
  - ↳ SYS
  - ↳ DIA
  - ↳ PR (from NIBP)

4.2.4 Selecting the ViSi Mobile Chest Sensor Cable

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

Note: The skin surface temperature probe 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 Cable that best suits the monitoring needs of your patient:

- The 3 lead-wire Chest Sensor Cable monitors Lead II, or the MCL configuration.
- The 5 lead-wire Chest Sensor Cable 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.

4.2.5 Selecting the ViSi Mobile Patient Kit

The System's disposable components, including the Cuff are contained in the Patient Kit. The Patient Kits are designated as S, M, 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 / Patient Kit Size	Arm Circumference (cm)
Adult S	20 – 26
Adult M	25 – 34
Adult L	32 – 43

4.2.6 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.

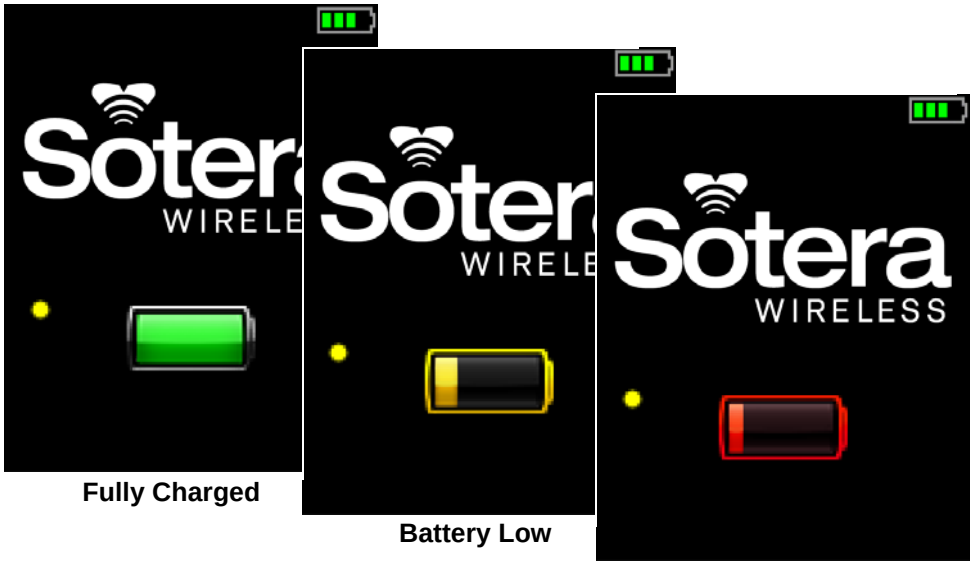
To check the battery charge of the Monitor

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

A full green battery symbol indicates that the battery is fully charged. A partially green battery symbol indicates the degree to which the battery is charged. The full monitoring period will not be achieved unless the battery is fully charged

A yellow battery symbol indicates the battery is low with less than 2 hours of monitoring time left.

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

To check the battery charge of the Cuff Module

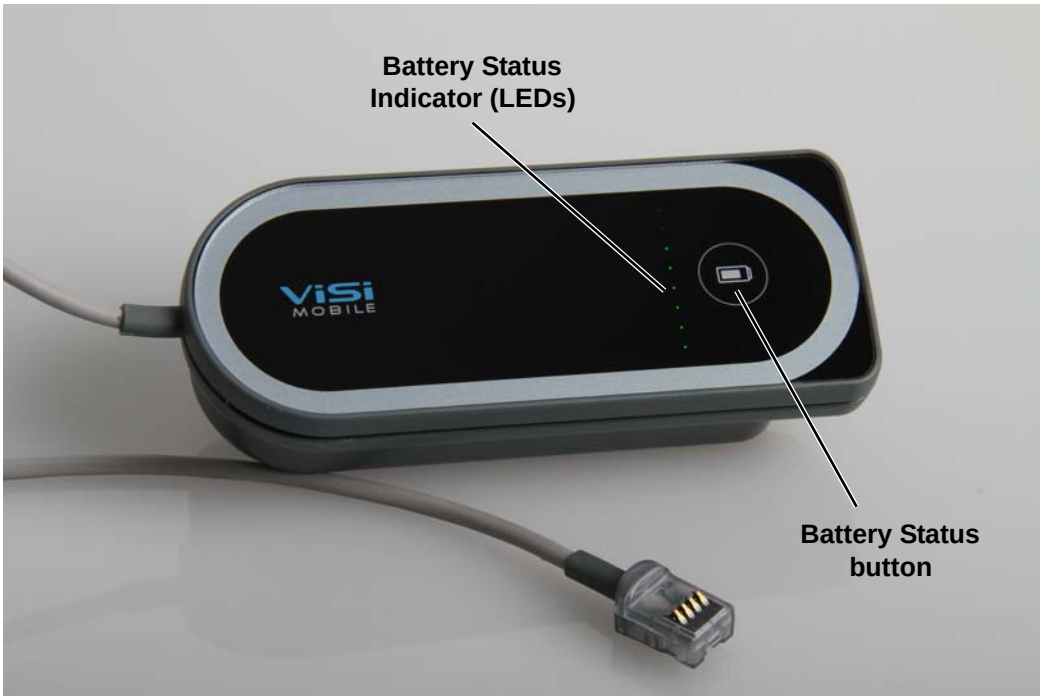
Press **Battery Status** button on the front of the Cuff Module.

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.



4.3 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 Patient Kit (S, M, 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) indicate paced events. In the case of biventricular pacing (CRT), two vertical dashed lines occur before the QRS.

Note: Stimulus pulses from a pacemaker, as indicated by the vertical dashed lines, are not counted as heartbeats, as defined by the pacer pulse rejection specification. *See 9. Specifications on page 125.*

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.

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

Only use the ViSi Mobile Thumb Sensor provided by Sotera Wireless, Inc. with the ViSi Mobile Monitoring System.

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

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

4.3.1 Applying the ViSi Mobile Wrist Cradle

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

To apply the Wrist Cradle

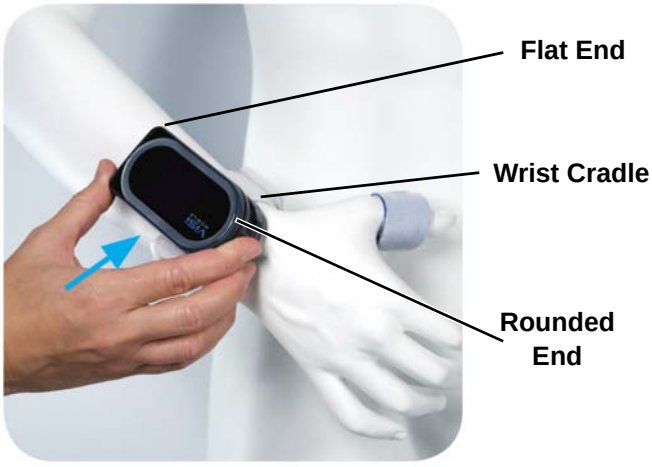
1. Remove the Wrist Cradle from the Patient Kit.
2. Orient the Wrist Cradle with the flat end pointed towards the elbow, slide the patient's hand through the Wrist Strap and position the cradle on the top side of the wrist.
3. Pull snugly and secure.

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 and the round end is pointing down 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, make sure that the Monitor is securely snapped into the ViSi Mobile Wrist Cradle.

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

4.3.2 Applying Sensors

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

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 you 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.

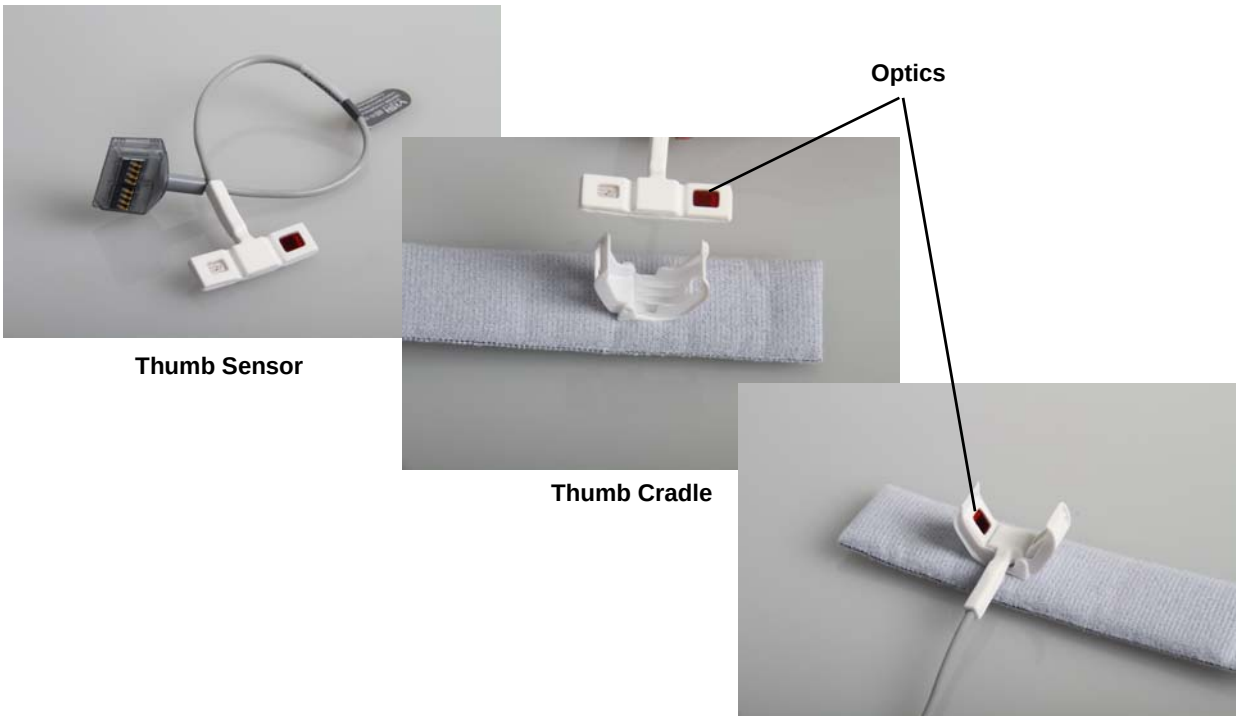
You should hear a double-beep sound when a sensor is inserted correctly.

4.3.3 Applying the ViSi Mobile Thumb Sensor

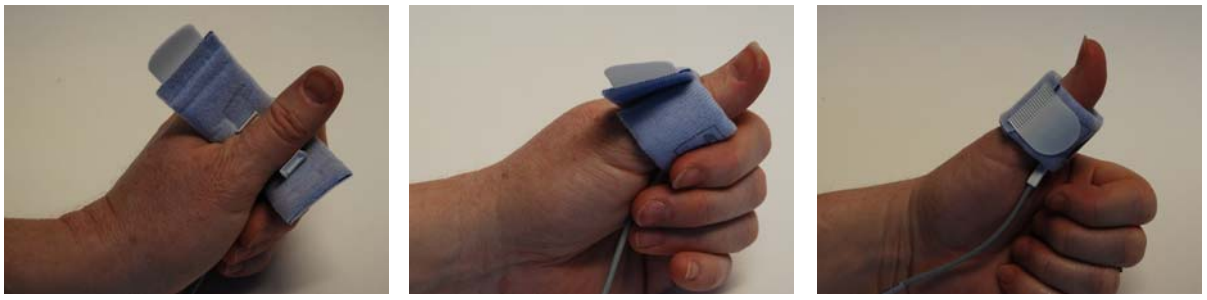
The ViSi Mobile Thumb Sensor is intended for use on the patient's thumb only. Do not apply the Thumb Sensor to the patient's fingers.

To apply the Thumb Sensor

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



3. Place the Thumb Sensor at the base of the thumb and secure it with the Thumb Strap.



The Thumb Cradle 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 tight or too loose can adversely affect SpO_2 measurement.

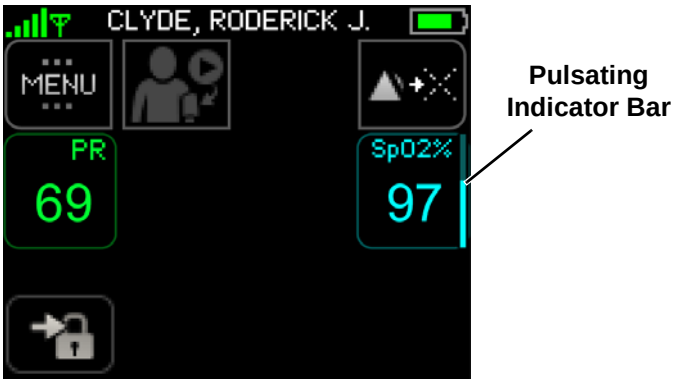
Inspect patient's skin at sensor site every 8 hours. If skin surface has been compromised, reposition the ViSi Mobile Thumb Sensor or move the Thumb Sensor to the patient's other thumb.

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

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

5. 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 104.



6. 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.

Only Sotera Wireless, Inc. supplied ViSi Mobile Thumb Sensors should be used. Using non-approved Thumb Sensors may result in inaccurate SpO2 readings.

4.3.4 Applying the ViSi Mobile Chest Sensor Cable 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, 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.

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

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

Skin Preparation

Skin preparation and ECG electrode placement directly impact the quality of the ECG signal and HR determinations. The following steps are recommended for skin preparation:

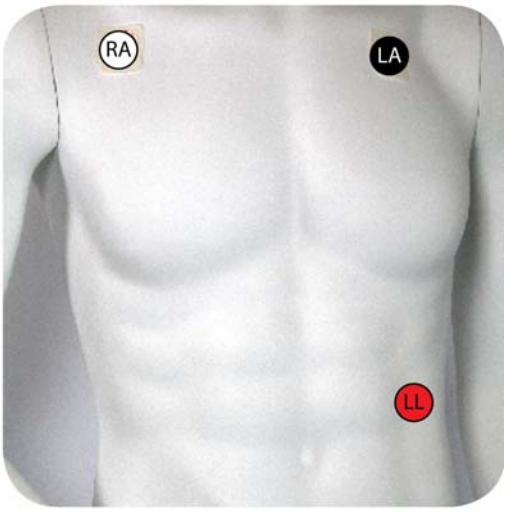
- Select ECG electrode sites on the patient's chest
  - ↳ Choose sites that are flat, avoiding fatty areas and major muscles.
  - ↳ For patient comfort, avoid placing ECG electrodes where lying on the side will put pressure on the ECG electrode.
  - ↳ Sites just below the middle of the clavicles are good locations for the RA and LA ECG electrodes.
- If needed, shave or clip hair in approximately a 1.5 to 2-inch diameter area for each ECG electrode site.
  - ↳ Also, for patient comfort, shave or clip hair from the areas where the Chest Sensor Cable and upper arm sensor are secured.
- Thoroughly clean the sites to remove excess skin oils, skin cells, and residue from the ECG electrode sites.
  - ↳ You may use isopropyl alcohol prep pads or another skin preparation pad, or soap and water.
  - ↳ Gently rub the site dry with a dry gauze pad or other dry pad.

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.

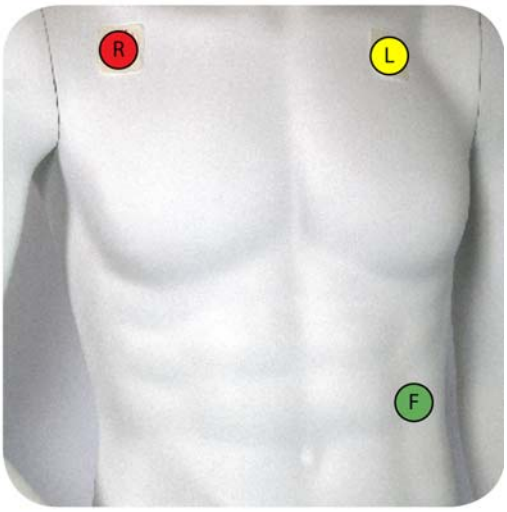
Note: Only use snap-on type electrodes.

3 lead-wire and ECG Electrode Placement

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



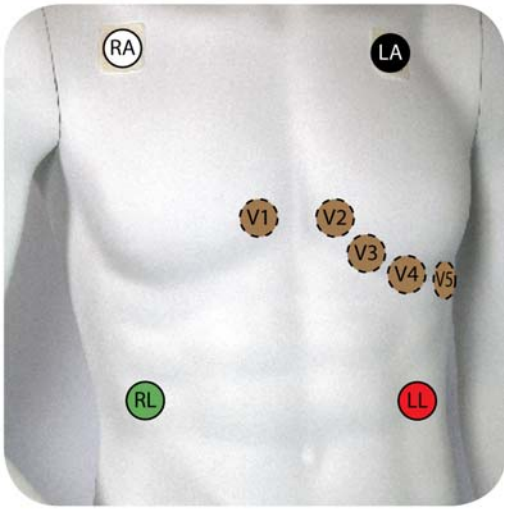
Lead Wire Color Code - U.S. (AAMI)
RA - White
LA - Black
LL - Red



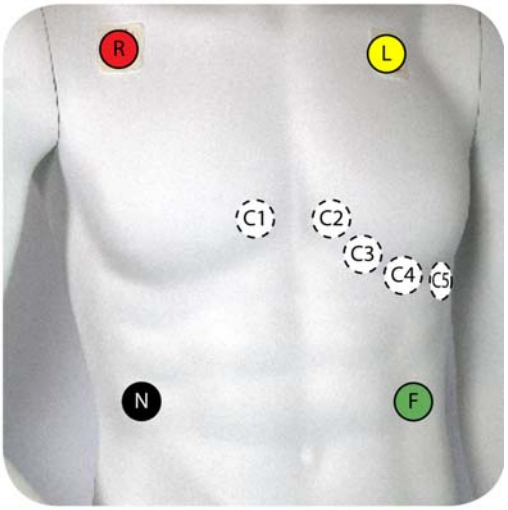
Lead Wire Color Code - International (IEC)
R - Red
L - Yellow
F - Green

5 lead-wire and ECG Electrode Placement

With the 5 lead-wire Chest Sensor Cable, 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	4th intercostal space (just right of sternum)
V2	4th intercostal space (just left of sternum)
V3	Midway between V2 and V4
V4	Mid clavicular line, 5th intercostal space
V5	Anterior axillary line, between V4 and V6
V6	Mid axillary line, horizontal with V4

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 Cable

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

1. Remove the ECG electrodes from the Patient Kit.
2. Apply the ECG electrodes to the prepared sites on the chest as shown.
3. Remove the large Cable Securement from the Patient Kit.
4. Secure the Chest Module of the Chest Sensor Cable between the sternum and the shoulder (same side as the Monitor) using the large Cable Securement.

Note: The Chest Sensor Cable should be oriented vertically. Do not orient the sensor more than 45 degrees to the left or right.

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

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

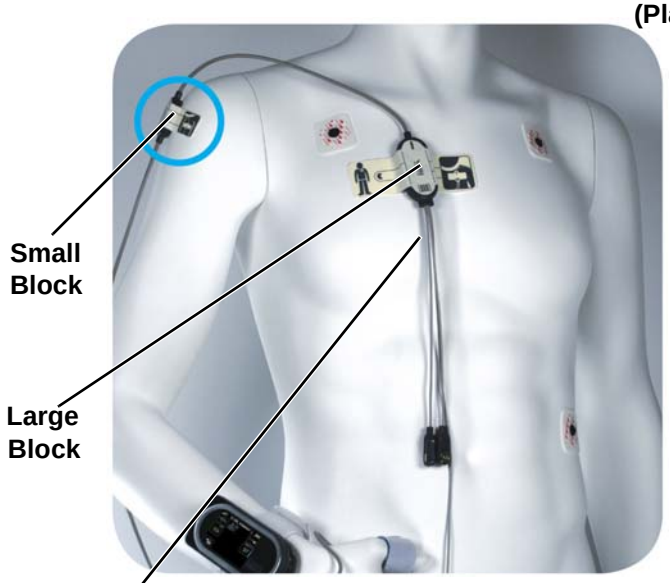
Note: For patient comfort, shave or clip the hair in the areas where the Cable Securement come in contact with the chest.

5. Apply the lead wires from the Chest Sensor Cable to the ECG electrodes.

Note: For patient comfort lead wires may be attached to ECG electrodes prior to applying the electrodes to the patient's chest.

6. Remove the small Cable Securement from the Patient Kit.

7. Secure the Upper Arm Module of the Chest Sensor Cable on the outside of the upper arm using the small Cable Securement.



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

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

Note: The default ECG configuration is Lead II.

8. Plug the Chest Sensor Cable 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 Cable to the patient and ViSi Mobile Monitor.

Insert with connectors contacts facing upwards

9. 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.
- 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.

10. 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 takes several minutes to reach a stable temperature reading.

4.3.5 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 Patient 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. 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.
    - 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.

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

5. Connect the Cuff Module securely to the Cuff with the cable in the direction of the Monitor.

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 Start symbol on the NIBP Start button blinks, prompting you to start a Cuff inflation. See Taking a NIBP Measurement on page 75 for instructions on how to take a NIBP measurement.

4.4 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.

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 Cable

1. Disconnect the Chest Sensor Cable from the Monitor: Grasp the Chest Sensor Cable 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 Cradle.
4. If the patient will no longer be monitored, dispose of the Thumb Cradle and Thumb Strap 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 Cable, Thumb Sensor, and Cuff Module, in accordance with your facility's procedures and the cleaning recommendations in this manual. *See 7. User Maintenance on page 109.*

5. Patient Monitoring

5.1 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.

5.2 Monitoring the Patient

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.

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 inaccurate heart rates. If frequent arrhythmias are suspected, their presence should be confirmed by another method, such as a 12-lead ECG or Holter monitoring.

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

Oxygen saturation measurements using SpO_2 are dependent on proper sensor placement and general patient conditions. Before making clinical decisions based on SpO_2 measurements, verify the measurement using another clinically acceptable method, such as an 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 temperature measurement.

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

The ViSi Mobile Monitoring System does not support printing capability.

5.2.1 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.

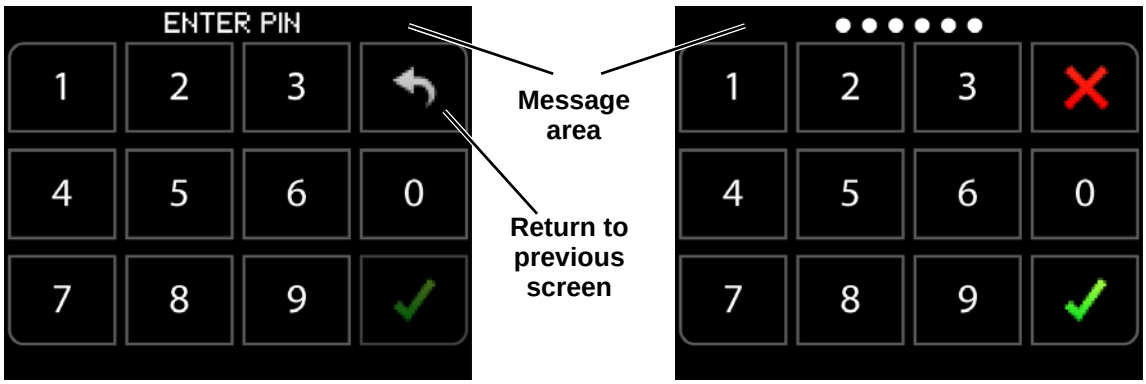
To unlock the Monitor

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.



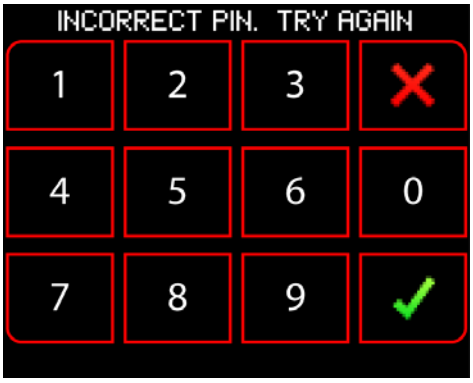
3. Enter PIN code on the PIN code pad.

   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 to 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.



5.2.2 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.

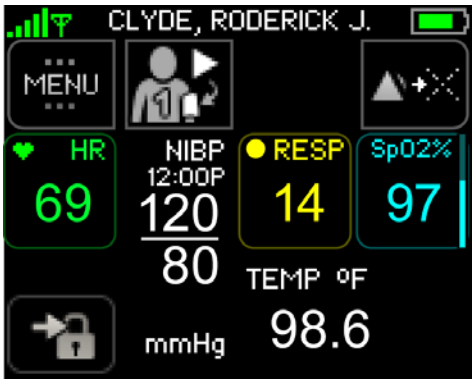
5.2.3 Viewing Vital Signs

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**.

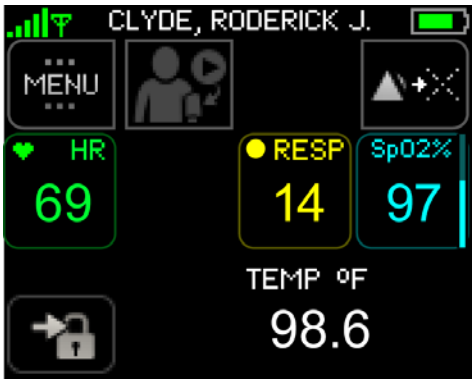
To view vital signs

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 67.*

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



Cuff Module connected



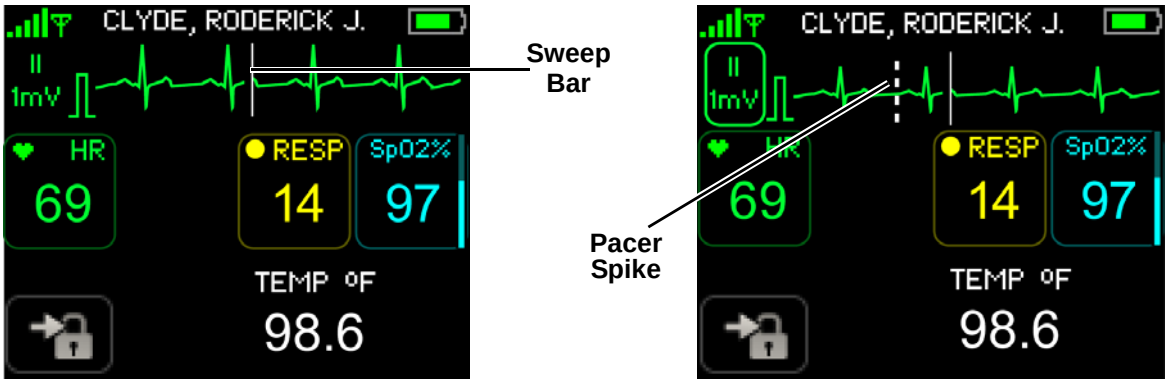
Cuff Module not connected

Note: If the Cuff Module is not connected, the Start NIBP button is disabled and the NIBP numeric display area is blank.

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

5.2.4 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 measurement does not have a waveform.

To view the ECG waveforms

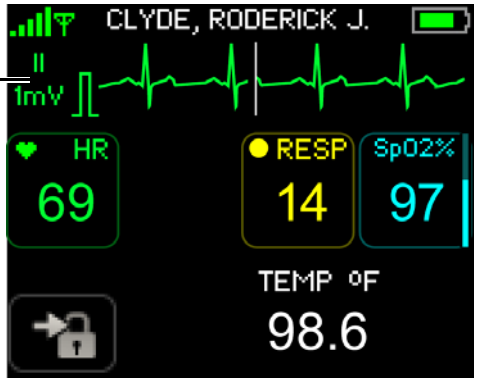
Depending on which Chest Sensor Cable is connected (3 lead-wire or 5 lead-wire), several views (leads) of the ECG waveform may be available for view.

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

Note: When using a 3 lead-wire Chest Sensor Cable, only a Lead II waveform is available.

Note: There is no pacer detection with a 3 lead-wire Chest Sensor Cable.

1. Touch the **HR** numeric. 

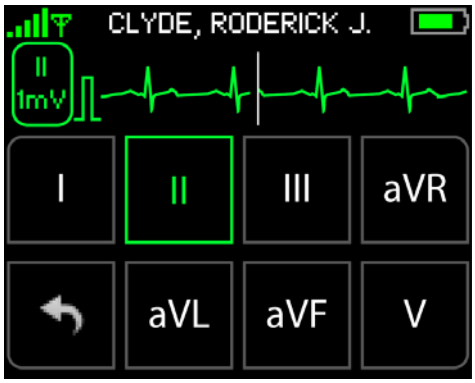


The top third of the display is replaced with the ECG waveform. The displayed lead is indicated to the left of the waveform. The square wave indicates the standard calibration of the ECG waveform.

To view other leads with the 5 lead-wire Chest Sensor Cable

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

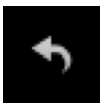
The lower part of the display is replaced with Lead Selection buttons.



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 affect 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.

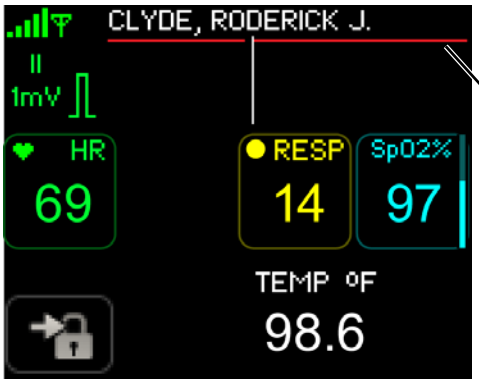
4. To return to the main **Vital Signs** screen, touch the **HR** numeric.

   The ECG waveform is no longer displayed.

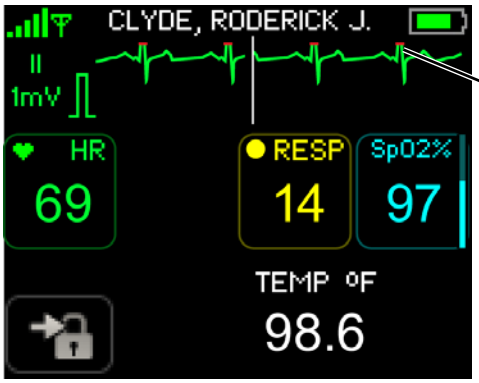
Note: When you touch a vital sign, its corresponding waveform is displayed, even if another waveform is currently displayed.

Input Overload / Dynamic Range

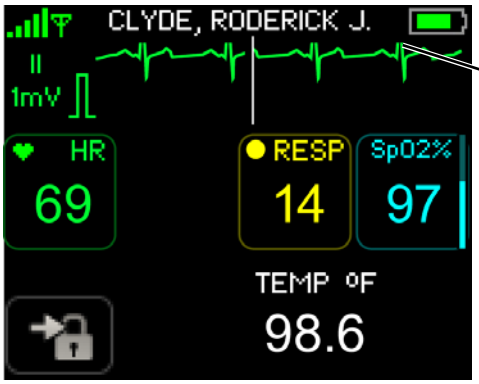
The ViSi Mobile Monitor display indicates an input overload condition (i.e. the input dynamic range of the amplifier associated with the displayed ECG lead has been exceeded) by displaying the trace in red at the top (or bottom) of the ECG waveform display area.



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



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

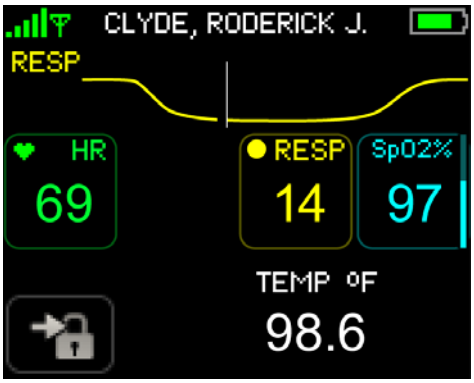


Dynamic range of the ECG amplifier has not been exceeded, but in which the peaks of the QRS complex of the ECG waveform extend beyond the upper edge of the display area

To view the RESP waveform

1. Touch the **RESP** numeric. 

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



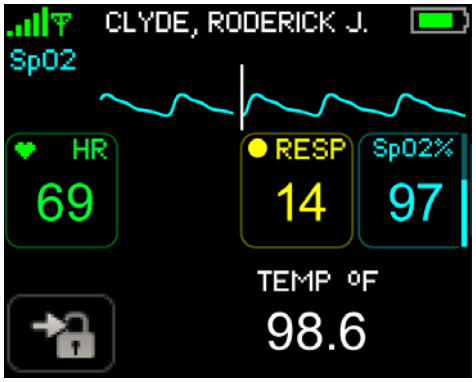
2. To return to the main **Vital Signs** screen, touch the **RESP** numeric.

   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.

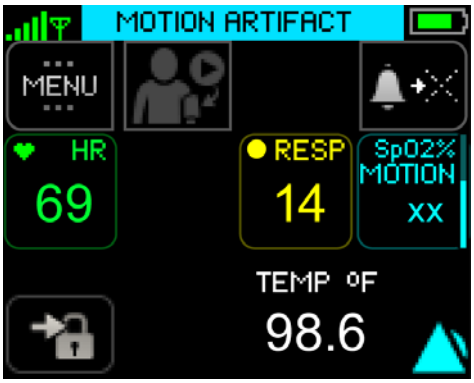


2. To return to the main **Vital Signs** screen, touch the **SpO_2** numeric.

   The SpO_2 waveform is no longer displayed.

5.2.5 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).



5.2.6 Taking a NIBP Measurement

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 are not reliable indicators for patients with arterial or frequent premature ventricular beats.
- Improper cuff size or application may lead to inaccurate readings.

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.

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

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

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

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

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.

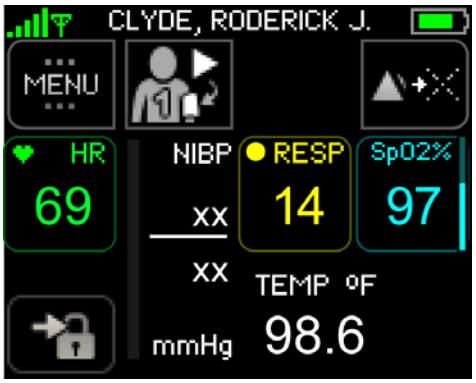
The ViSi Mobile Disposable Cuff should be snug enough to support the Cuff Module while not impairing circulation when deflated.

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

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 61.*

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



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

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

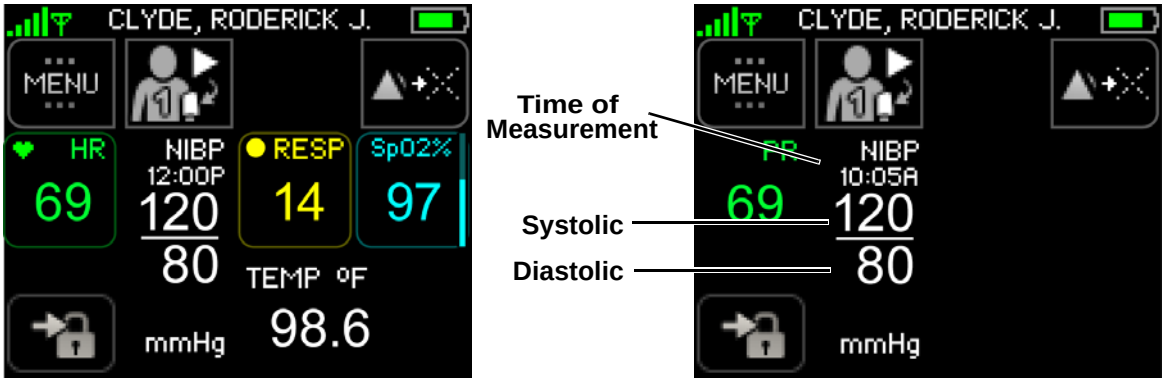
   An inflation pressure indicator bar, located to the left of the NIBP numerics, increases/decreases in height as the pressure increases/decreases in the Cuff. The actual cuff pressure is displayed under the NIBP label.

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

Note: If unexpected readings are encountered, confirm the correct application of the ViSi Mobile Disposable Cuff (*see page 61*). If unexpected readings persist, have maintenance performed as described in the Technical Reference Manual.

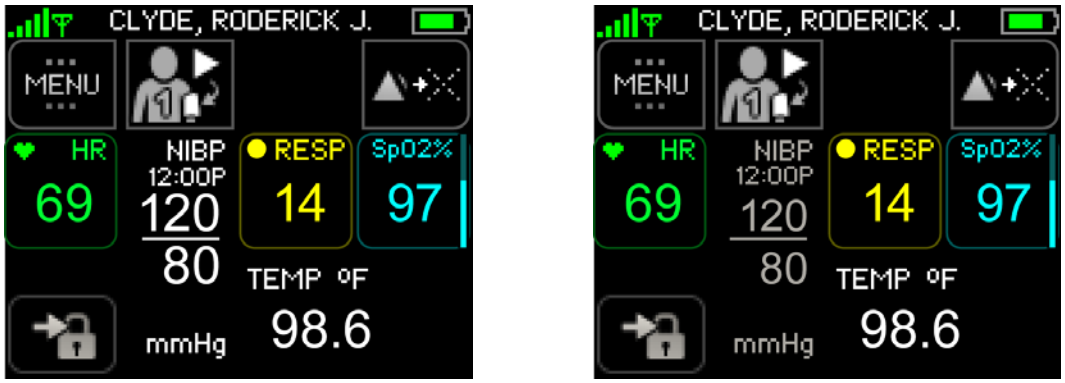
The performance of the automated sphygmomanometer may be affected by extremes of temperature, humidity and altitude. *See "Specifications" on page 125.*

Upon completion of a successful measurement, the Systolic and Diastolic 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 Cable are not connected to the Monitor), then a one-time PR from the NIBP measurement is displayed next to the NIBP measurement for 30 seconds.



Note: If the NIBP measurement was unsuccessful, the Cuff Module automatically retries to measure the blood pressure. A maximum of 3 attempts will be made. 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.



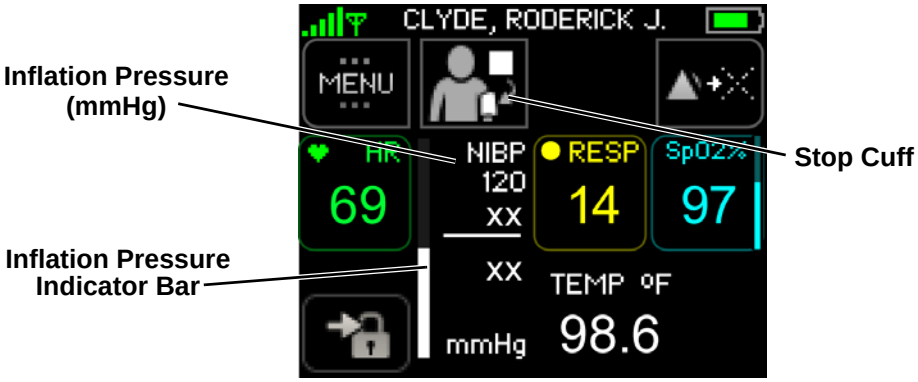
Current Reading

Older Reading
Note that the numerics for the older reading are faded and shrunk 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.

5.2.7 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.

To initiate automatic NIBP measurements

1. Apply the Cuff and Cuff Module.
   See Applying the ViSi Mobile Cuff Module and Disposable Cuff on page 61.

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

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.

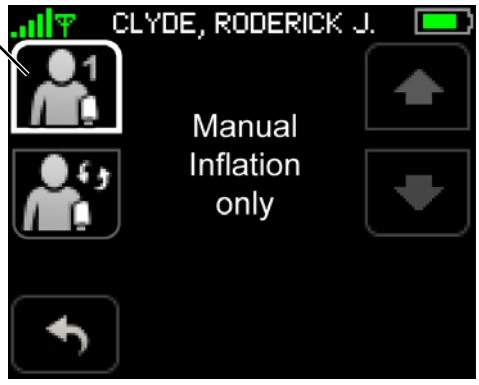
2. Set the **NIBP mode** to **Automatic**.

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

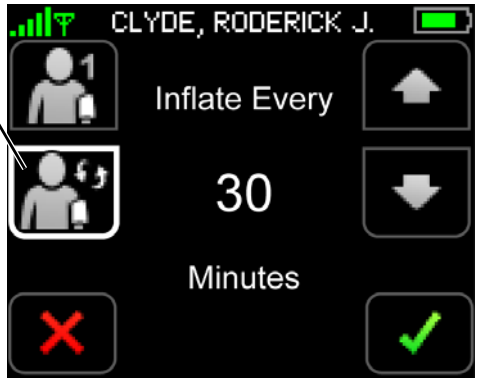
   The Menu screen appears.

   b. Touch **NIBP Settings** to display the **Cuff Management** screen. 
   The Cuff Management screen appears.

Manual Cuff Inflation



Automatic Cuff Inflation



   c. Touch **Automatic Cuff Inflation**. 
   d. Touch the **Up** or **Down** arrow to increase or decrease the time interval.

e. Touch **Confirm** to confirm the new settings. 

- or -

Touch **Cancel** to return to the **Menu** screen. 

Once you have touched Confirm, an automatic NIBP measurement is taken immediately, and again at the set interval. The Automatic 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.

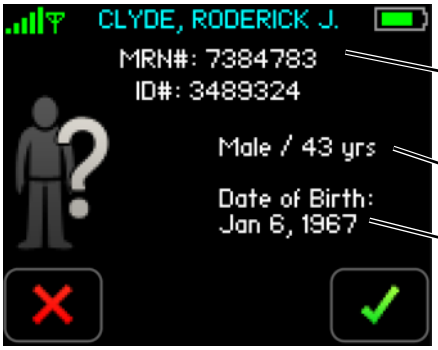
Note: As long as the NIBP Module is plugged in, a manual NIBP measurement can be initiated at any time. If the timing of the manual measurement overlaps with the automatic measurement interval, then that automatic measurement is skipped; otherwise the automatic measurement occurs as scheduled.

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.

5.2.8 Viewing Patient's Demographics

To Confirm Patient's Demographics

When the patient's demographics have been changed on the ViSi 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.



Patient's Primary (displayed in blue)
Secondary and Tertiary Ids

Birth Gender / Age

Date of Birth

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 Remote Viewer.

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

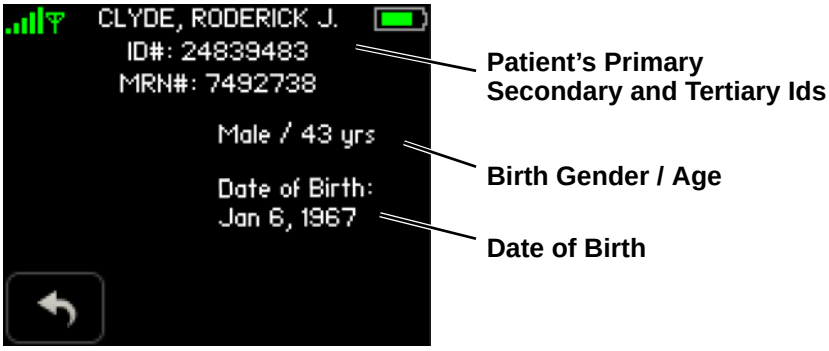
To View Patient's Demographics

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

   The Menu screen appears.

2. Touch Patient Information to display the Patient Information screen. 

   The Patient Information screen is displayed.



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.

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

5.2.9 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.

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

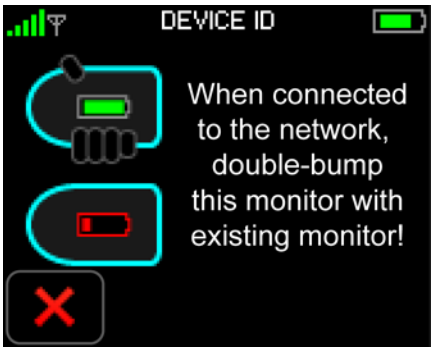
   The Device Status screen will be displayed.

Device Swap button

Button is disabled when the battery life of the new monitor is too low

2. Touch **Device Swap**. 

   The Device Swap 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.

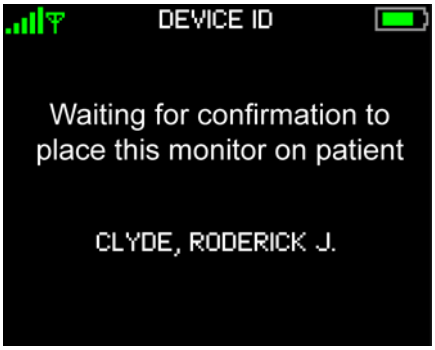
Note: Monitors must be double bumped with long ends in the same direction. See image on the ViSi Mobile Monitor instructions screen.

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 Device Swap 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.



Waiting Patient Transfer
(Instructions on the new Monitor)

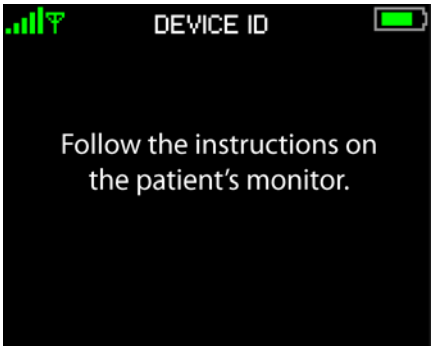
Confirm Device Swap
(Instructions on the patient's Monitor)

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

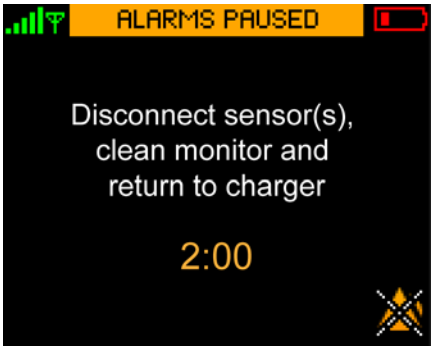
   - or -

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

   If confirmed, the patient's demographics will be transferred from the patient's Monitor to the new Monitor. The new Monitor will display the Operation Instructions screen and the patient's Monitor will display the Disconnect Sensors screen.



Operation Instructions
(Instructions on the new Monitor)



Disconnect Sensors
(Instructions on the patient's Monitor)

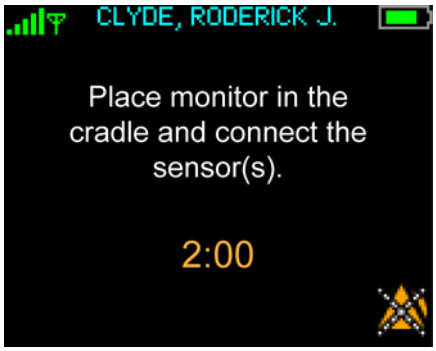
Note: During the exchange, you will need to confirm the patient's identification on the patient's Monitor, if it has not already been confirmed.

Note: During the exchange, you will need to enter your pin code on the patient's Monitor, if it has not already been entered.

5. To stop monitoring on the patient's Monitor and complete the exchange, disconnect the sensors from the Monitor within 2 minutes.

   If the sensors are not disconnected from the patient's Monitor within 2 minutes, monitoring will continue on the patient's Monitor and the Device Swap process will be cancelled.

   Once the sensors have been disconnected, the new Monitor may be placed in the cradle and the sensors connected.



Instructions
(Patient's New Monitor)

Device Status
(Original Patient's Monitor)

6. 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.

5.2.10 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 67.)*

   The Vital Signs screen appears.

3. Touch **MENU**. 

   The Menu screen appears.

4. Touch **STOP**. 

   The Stop Monitoring screen appears.

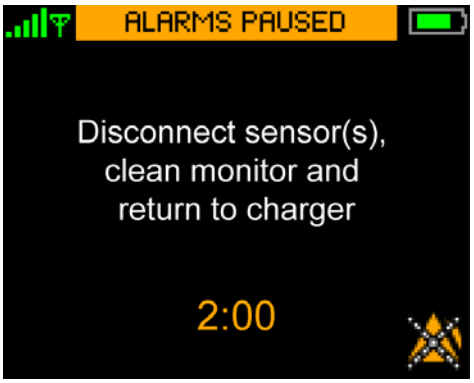
5. Touch **Confirm** to confirm that you want to stop monitoring. 

   - or -

   Touch **Cancel**. 

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

   If confirmed, the Stop-Disconnect Sensors/Clean Monitor screen is displayed showing a 2 minute countdown timer.



6. Remove all the sensors and the Monitor from the patient.

   All sensors must be removed from the patient and/or the Monitor to stop monitoring. When the countdown has elapsed, if vital sign measurements are still being detected (at least one sensor is still connected to the patient and Monitor), monitoring will continue without interruption.

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

   Once all the sensors are disconnected from the Monitor, the Monitor Status screen appears briefly before the System transitions into the Hibernate mode.

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

If you want to stop monitoring temporarily or change the Monitor, you will need to stop monitoring on the current Monitor and start monitoring again using the steps outlined in section *Applying ViSi Mobile Monitoring System / Initiate Monitoring on page 50*.

To clean and prepare reusable components

1. Clean and prepare the reusable components of the System (Monitor, Chest Sensor Cable, Thumb Sensor, and Cuff Module) in accordance with your facility's procedures and the cleaning recommendations in this manual. *See 7.User Maintenance on page 109.*
2. Place the cleaned Monitor and Cuff Module into the Charger.

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

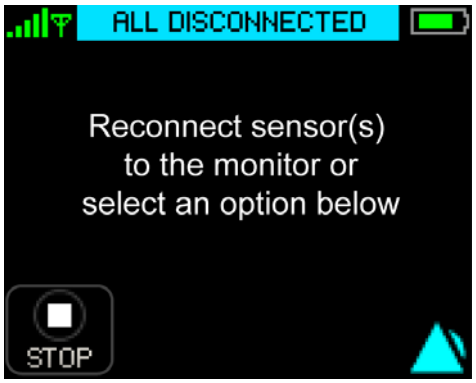
Never connect the ViSi Mobile Monitor directly to an AC power outlet. To recharge the battery, disconnect the Monitor from the patient, and then place it in the ViSi Mobile Charger.

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.

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

5.3 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 5.2.8Viewing Patient’s Demographics on 81*). An “All Disconnected” alert will be generated.



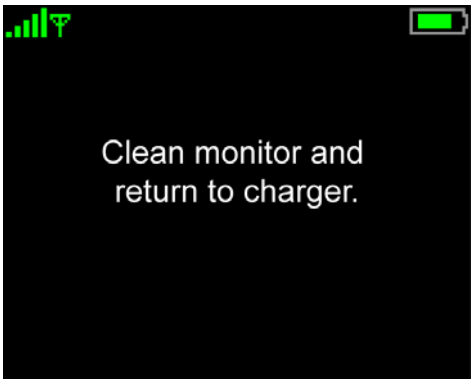
1. To stop monitoring the patient, touch **Stop** to initiate the Stop Monitoring process. 

   - 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 67.)*

   The Clean Monitor screen appears.



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 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 Remote Viewer					
Priority	**Type of Alarm**	**Silence Button**	**Where to Respond to Alarm**		**Audio Tones**
			Remote Viewer *(At Clinician's Station)*	**Mobile Monitor** *(At Patient)*	
1	**Life Threatening**  LATCHED		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**  Non-Latched		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 / Medium)  Non-Latched		Silence at Remote Viewer or Mobile Monitor. (2 minute audible silenced on both Remote Viewer and Mobile Monitor.)		Beep Beep - Pause -
4	**Alerts** (Low)  Non-Latched		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.

Latched: The alarm remains in an active state until the clinician silences/acknowledges the alarm on the ViSi Monitor.

Non-Latched: Alarms/alerts can self-correct themselves without any action by the clinician.

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

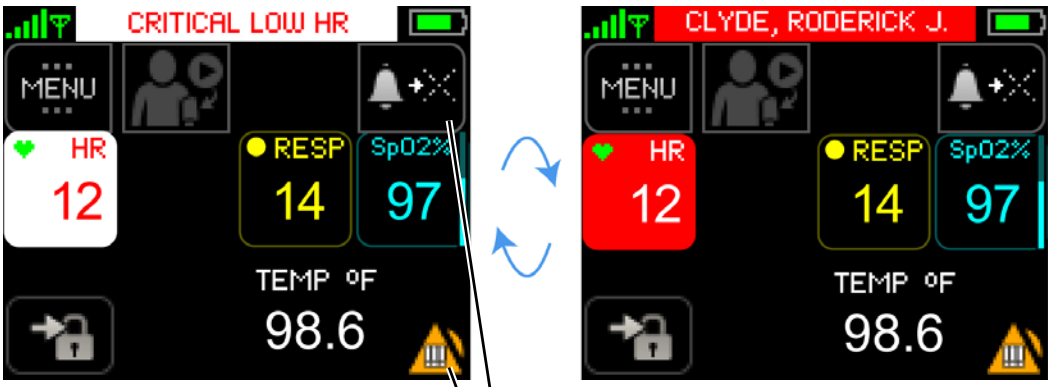
6.3 Responding to Physiological Alarms (Alarms)

A responsible clinician must be within audible range of the ViSi Mobile Monitor at all times.

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



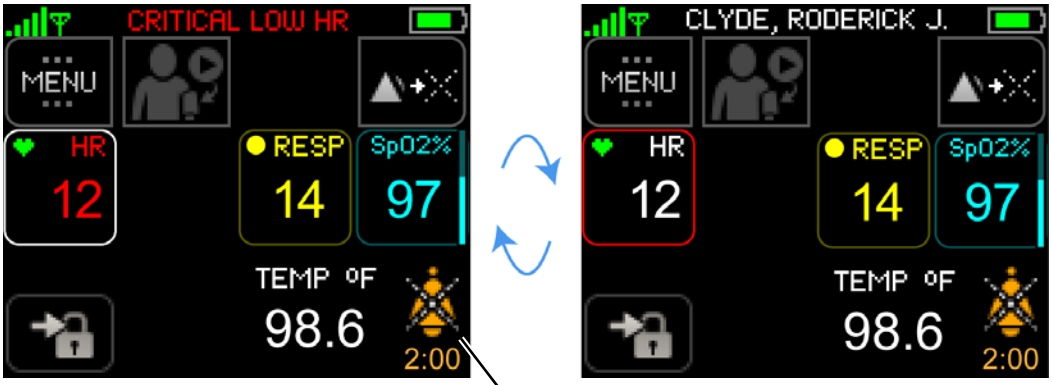
Silence/Acknowledge Alarm

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 will be displayed. After the 2 minute countdown has expired, the alarm will be re-annunciated.



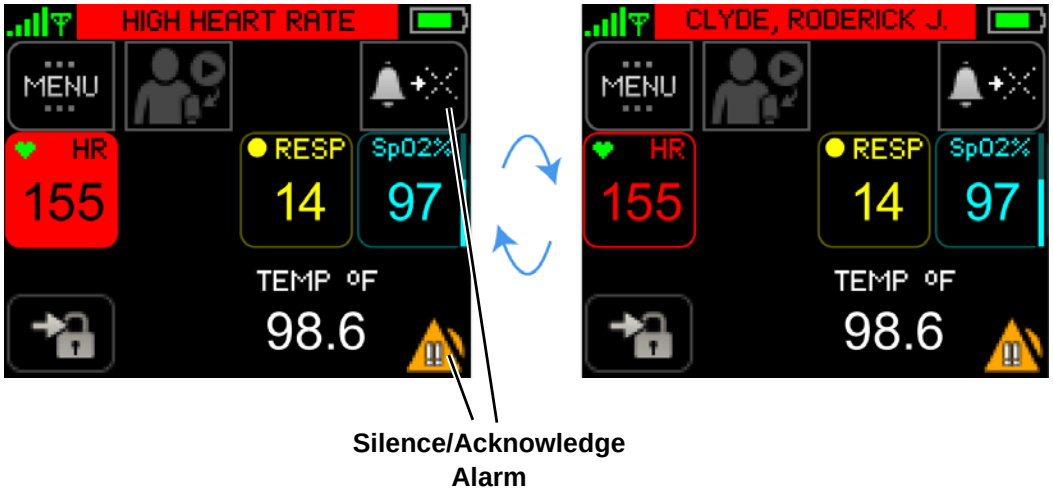
Silenced/Acknowledged symbol and countdown

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

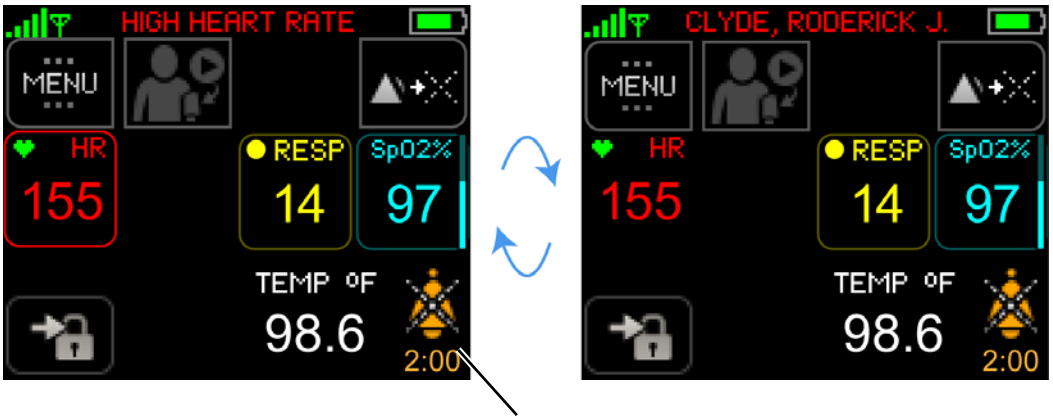


To silence/acknowledge the alarm, touch **Silence/Acknowledge Alarm** button 

- or -

Touch the **Alarm Status**. 

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



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 will be displayed (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.

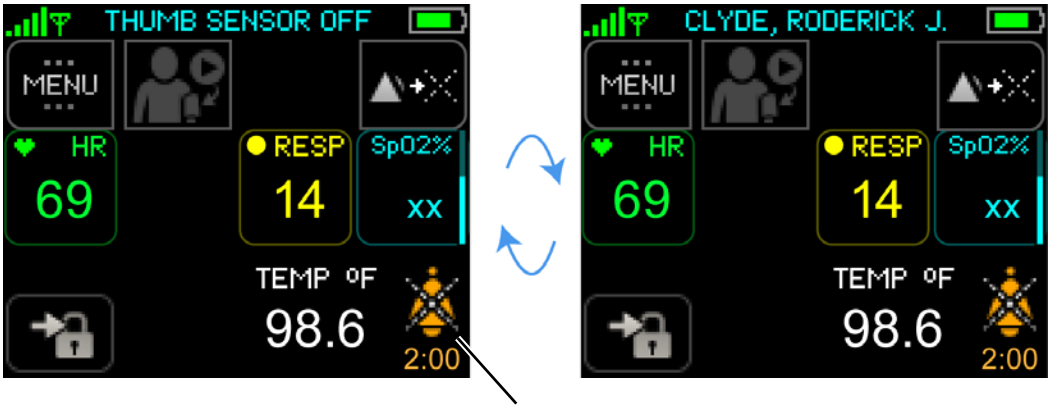
Symbol	Annunciation Color	Severity	Audio Tone	Duration (ms)	Spacing (ms)
	Cyan	High	B B P B - Beep / P - Pause There will be a 15 second pause after each sequence.	250	250
		Medium	B B P B - Beep / P - Pause There will be a 15 second pause after each sequence.	250	250
		Low	No audio tones.	N/A	N/A

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

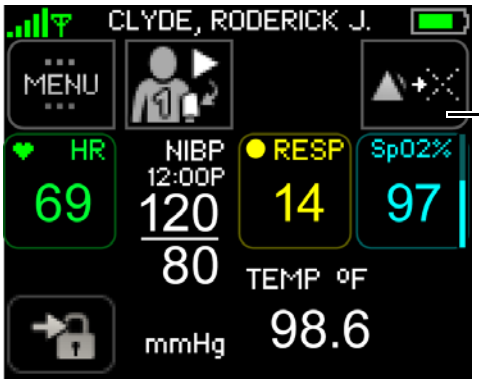
Note: When an alert condition (of any severity) resolves itself before the clinician is able to respond, the alert condition will no longer be annunciated.

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.

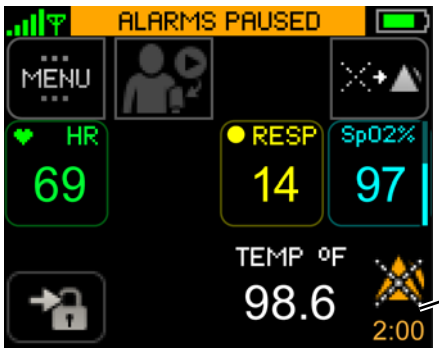
To pause the alarms



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

The alarms will be paused for 2 minutes.

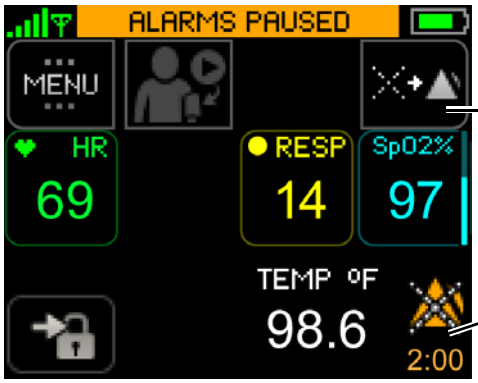
When paused, the words ALARMS PAUSED are displayed at the top of the screen and an ALARMS PAUSED icon is displayed in the lower right corner of the screen.



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 Mobile Monitor or Remote Viewer.



Resume alarms

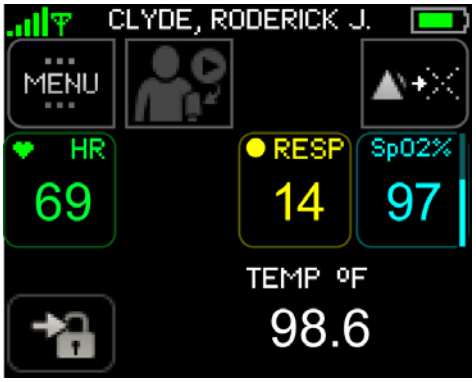
Alarms are currently paused.
Remaining "Paused" duration.

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

- or -

Touch the **AlarmStatus**. 

The alarms are resumed and will annunciate on both the ViSi Mobile Monitor and Remote Viewer.



Note: Alarm annunciation will resume 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 alarms are turned OFF.

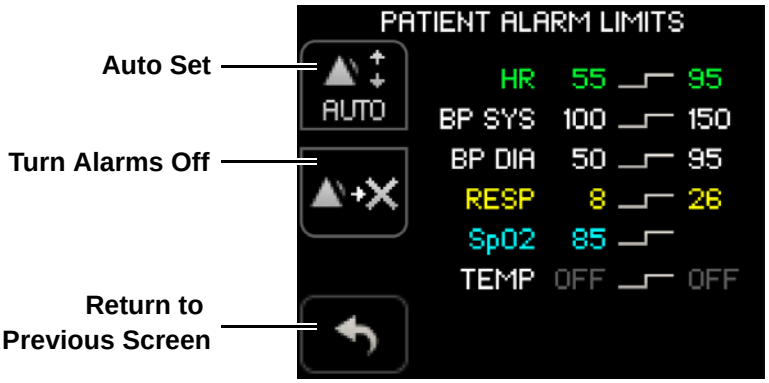
To turn all alarms off

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

   The Menu screen appears.

2. Touch **Alarms Settings.** 

   The Patient Alarm Limits screen appears. Alarm limit settings are only displayed for the connected sensors.



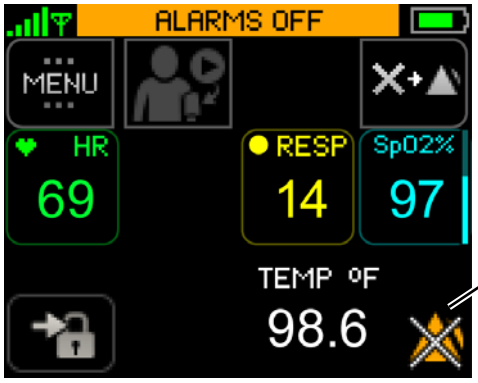
3. To turn all alarms off, touch **Turn Alarms Off**. 

   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.

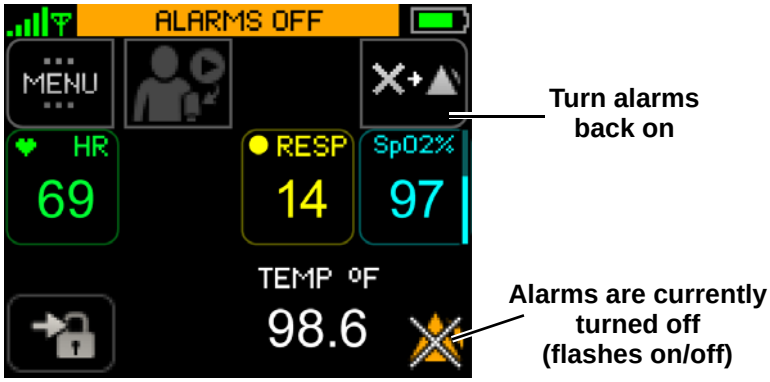
   If confirmed, the alarms are turned off and the Vital Signs screen appears. The words ALARMS OFF are displayed at the top of the screen and an ALARMS OFF icon is displayed in the lower right corner of the screen.



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 Remote Viewer.

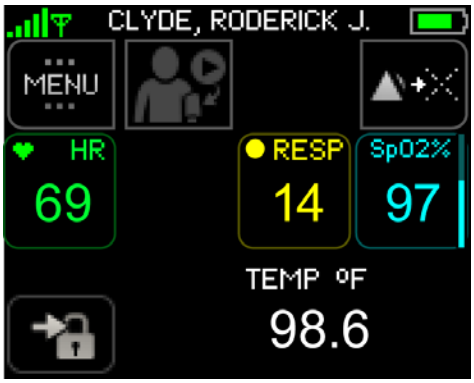


To turn the alarm annunciation back on, touch the **Turn Alarms On** button. 

- 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 whenever a sensor is 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 sets alarm limits based on the current vital signs measurements for all connected sensors. If the alarms are turned off prior to initiating the Auto Set process, the alarms are turned back on when the new alarm limits are confirmed.

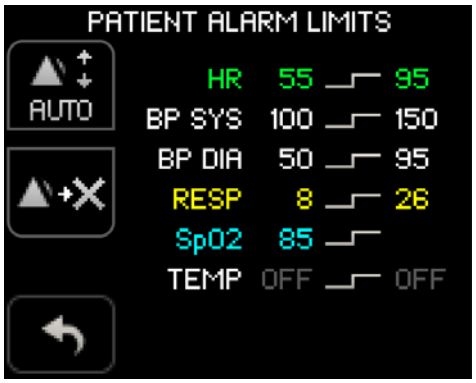
Once new alarm limits are confirmed, they cannot be changed back to the original pre-set limits. Once Auto Set is selected, review the newly calculated alarm limits carefully before deciding to confirm or cancel the new alarm limits.

To change alarm limits using Auto Set

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

2. Touch **Alarms Settings.** 

   The Patient Alarms Settings screen appears.



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

3. Touch **Auto Set**. 

   Alarm limits for all currently monitored vital signs are recalculated based on the current vital signs measurements. The Confirm New Alarm Limits screen appears.

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-

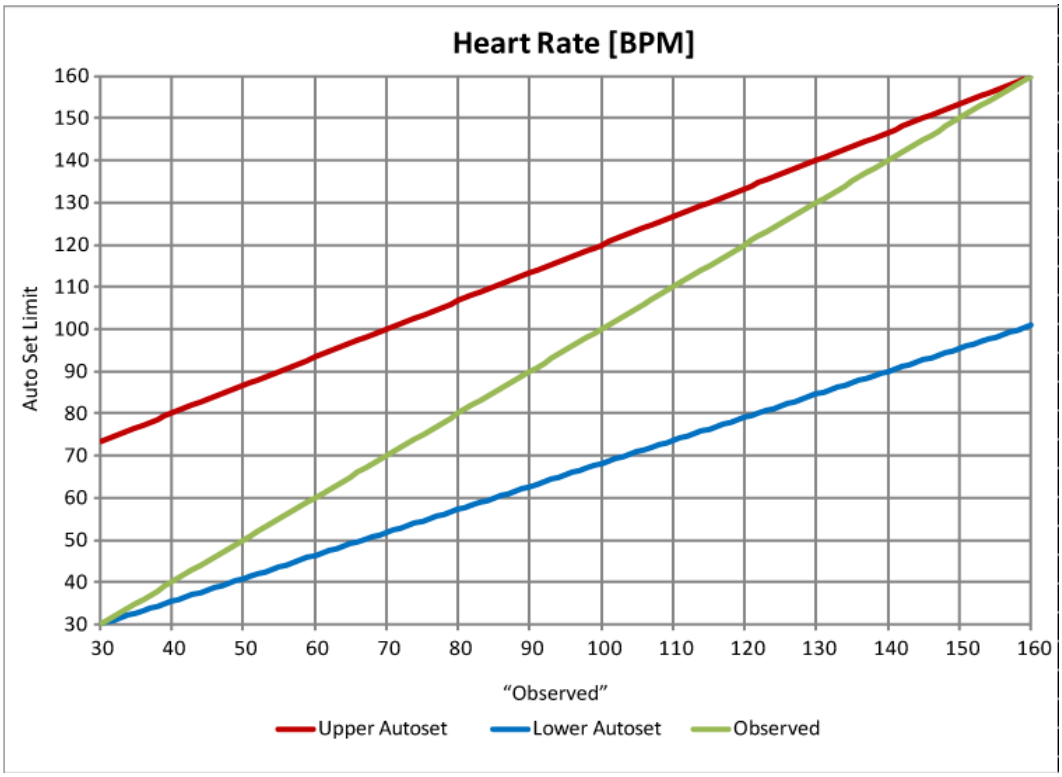
   Touch **Cancel** to return to the **Patient Alarm Limits** screen. 
   The previous alarm limits are retained.

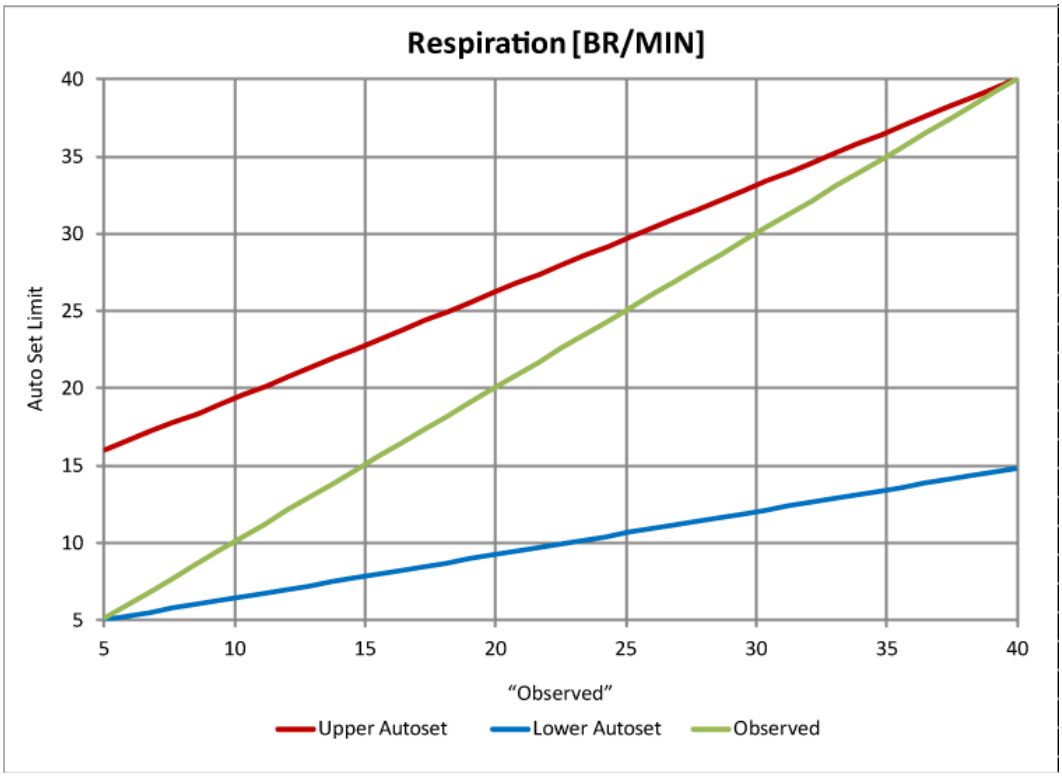
   Once confirmed, the system returns to the Vital Signs screen.
5. Navigate to the **Patient Alarm Limits** screen to review the current alarm limits.

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 SpO2 and temperature. The minimum and maximum values to which auto set will adjust the limits are listed in the table below.

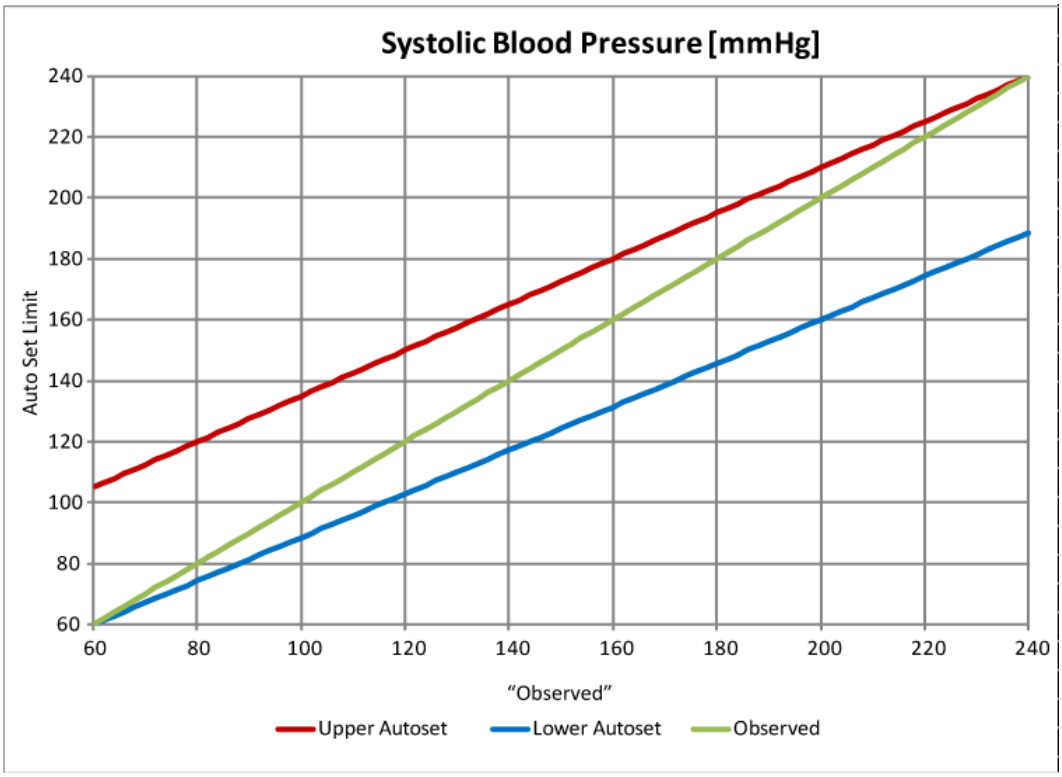
Auto Set Alarm Limits				
Alarm	**Limit**	**Default Limits**	**Auto Set Range**	**Auto Set Limit Calculation (based on current reading)**
Heart Rate (BPM)	High	140	90-160	HR x 0-66 + 53.3
	Low	40	30-80	HR x 0.54 + 13.6
Pulse Rate (BPM)	High	140	90-160	PR x 0-66 + 53.3
	Low	40	30-80	PR x 0.54 + 13.6
BP Systolic (mmHg)	High	190	160-240	BP x 0.75 + 60.0
	Low	90	60-120	BP x 0.71 + 17.1
BP Diastolic (mmHg)	High	120	95-150	BP x 0.60 + 60.0
	Low	40	30-90	BP x 0.72 + 8.3
Respiration (BR/M)	High	35	12-40	RR x 0.69 + 12.5
	Low	6	5-8	RR x 0.28 + 3.6

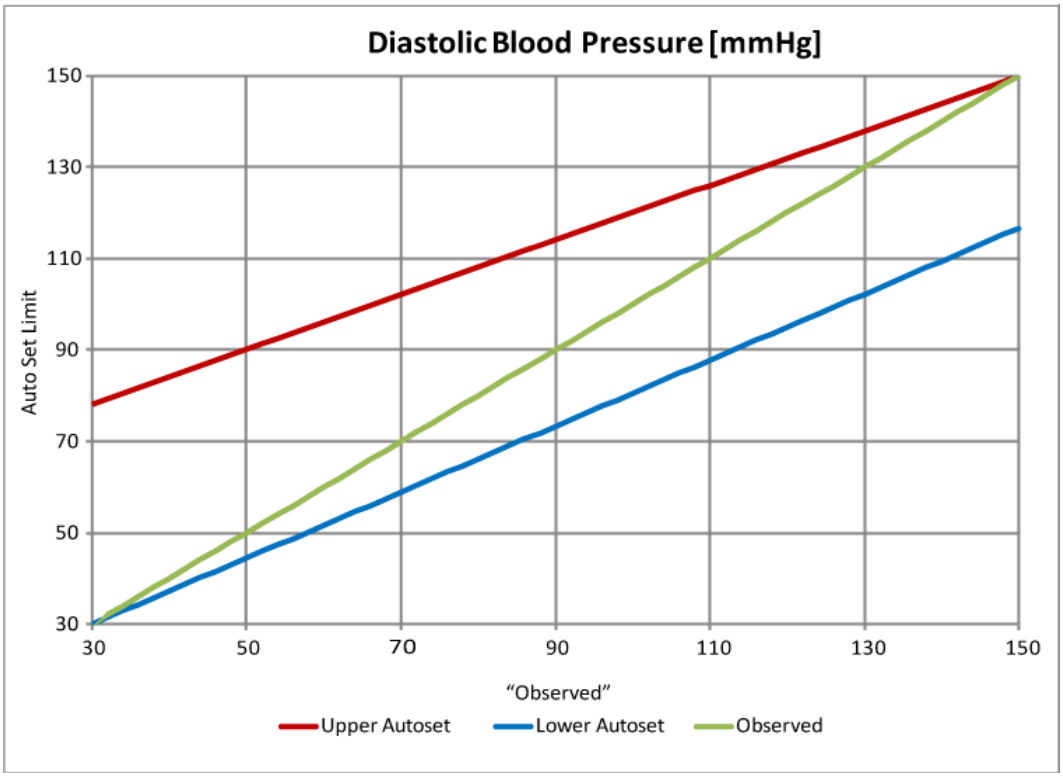
Note: There is no manual way set individual alarm limits. Auto Set recalculates all alarm limits.





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

7. User 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. However, it is recommended that routine maintenance (including checking components for damage), calibration, and safety checks be performed at least once a year as required by your facility administration practice.

Routine testing of functionality, alarms and alerts can be verified using standard electronic patient simulators.

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 representative in your area. Prior to shipping, ensure the returned components have been properly disinfected.

The ViSi Mobile Cuff Module contains an air filter that should be inspected by the Bio Med in accordance to the service schedule as described in the Technical Reference Manual. The ViSi Mobile Disposable Cuff should be used on one and only one patient.

For more technical information, refer to the ViSi Mobile Monitoring System Technical Manual.

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

7.2 Cleaning and Disinfection

The ViSi Mobile Monitor, Cuff Module, Chest Sensor Cable and Thumb Sensor require cleaning and disinfection prior to reuse on a different patient.

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

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

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

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

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

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

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

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 Thumb Sensor from the Thumb Cradle.

After cleaning and disinfection is complete, inspect the System components for wear, damage, discoloration, fraying and cracking. Replace any System components that show evidence any of these anomalies.

To clean the ViSi Mobile Monitoring System components

1. Hand wash the System components using mild soap or detergent and water. Use moistened lint-free cloths to remove residual cleaner.

   A soft-bristled brush may be used for heavily soiled areas, where needed.
2. Dry the System components using a lint-free cloth.
3. Visually examine each System component to ensure all soil contaminants have been removed.
4. Repeat the above cleaning process as required.

To disinfect the ViSi Mobile Monitoring System components

Do not use 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.

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

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

1. Disinfect all System components by wiping components with a lint-free cloth moistened with isopropyl alcohol.
2. Dry thoroughly using a lint-free cloth.

7.3 Inspecting Equipment and Accessories

After cleaning and disinfecting, 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 for general condition. Ensure there are no breaks in the insulation. 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 Product Disposal

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

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 Patient Kit may contain bio-hazard materials.

Disposables from the ViSi Patient 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 representative in your area to obtain additional information about cleaning and disinfecting the ViSi Mobile Monitoring System components or product disposal.

8. Troubleshooting

8.1 Introduction

The ViSi Mobile Monitoring System is designed to alert you 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

8.2 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.

8.2.1 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.	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.	• Make sure to lock the screen each time you complete your interactions. • 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.

8.3 ViSi Mobile Chest Sensor Cable

Problem	Potential Cause	Solution
Chest sensor Cable is too short to Plug into the Monitor	Monitor is oriented in the wrong direction.	Make sure that the flat end of the Monitor is oriented towards the elbow.
	The Chest Sensor Cable is secured to the side of the chest opposite the arm with the Monitor.	Secure the Chest Sensor Cable midway between the sternum and the shoulder of the same arm that the Monitor is on.
No HR numeric	ECG electrodes not connected to lead wires.	Ensure that the lead wires are snapped securely onto the ECG electrodes.
	ECG electrodes not firmly attached to the patient's chest.	Ensure that the ECG electrodes are securely attached to the chest; ECG electrode sites are clean and free of excess hair.
	ECG electrode gel is dry.	Replace ECG electrodes.
	Broken/damaged lead wires.	Replace damaged Chest Sensor Cable.
	Chest Sensor Cable not securely Plugged into the Monitor.	Make sure that the Chest Sensor Cable is securely Plugged into the Monitor.
HR displays "XX"	A lead-wire or sensor problem is affecting the measurement.	If the problem persists, replace the ECG electrodes and/or Chest Sensor Cable.

Problem	Potential Cause	Solution
HR is erratic	ECG electrodes are not all the same.	Use all the same ECG electrode type, size, materials, and manufacturer.
	ECG electrode gel is dry.	Replace ECG electrodes.
	ECG electrodes not firmly attached to the patient's chest.	Check the ECG electrodes are securely attached to the chest; ECG electrode sites are clean and free of excess hair.
No ECG waveform	*See No HR numeric above.*	*See No HR numeric above.*
ECG waveform too small	Using a 3-lead Chest Sensor Cable: Lead II has a low amplitude. Lead II only available with a 3-lead Chest Sensor Cable.	• Select alternate ECG electrode sites; prepare skin sites; connect lead wires to new ECG electrodes and place on the chest. • Replace 3-lead Chest Sensor Cable with 5-lead Chest Sensor Cable.
	Using a 5-lead Chest Sensor Cable: Selected lead has low amplitude.	5-lead Chest Sensor Cable: select a different lead to view.
ECG waveform is noisy; looks like pacer indicators in the waveform	ECG electrodes not firmly attached to the patient's chest.	Ensure that the ECG electrodes are securely attached to the chest; ECG electrode sites are clean and free of excess hair.
	ECG electrode gel is dry.	Replace ECG electrodes.
No RESP numeric	See No HR numeric above.	See No HR numeric above.
	The Monitor is not capable of measuring RESP.	See Bio Med.
RESP displays "XX"	A lead-wire or sensor problem is affecting the measurement.	If the problem persists, replace the ECG electrodes and/or Chest Sensor Cable.
RESP is erratic	ECG electrodes not firmly attached to the patient's chest.	Ensure that the ECG electrodes are securely attached to the chest; ECG electrode sites are clean and free of excess hair.
	ECG electrode gel is dry.	Replace ECG electrodes.
No TEMP numeric	The Chest Module sensor is placed on the patient with the Temperature Sensor facing away from the patient.	Place the Chest Module sensor on the patient such that the Temperature Sensor is in direct contact with the patient's chest.
	Sensor is not attached to the patient's chest.	Secure the Chest Sensor Cable to the chest. Make sure that a change in position does not affect the sensor's contact with the skin.
TEMP displays "XX"	The Temperature Sensor may have failed.	If the problem persists, replace the Chest Sensor Cable.

Problem	Potential Cause	Solution
TEMP is erratic	Chest Sensor Cable is not in contact with the skin completely/ securely.	Secure the Chest Sensor Cable to the chest. Make sure that a change in position does not affect the sensor's contact with the skin.
	Skin is not clean and dry.	Clean and dry the skin thoroughly and secure the Chest Sensor Cable to the chest.

8.4 ViSi Mobile Thumb Sensor

Problem	Potential Cause	Solution
Sensor cable too short to Plug into Monitor	Monitor is oriented in the wrong direction.	Make sure that the rounded end of the Monitor is oriented towards the hand.
	Thumb sensor is routed wrong.	Make sure the cable is routed around the outside of the thumb.
No SpO_2 numeric	Broken/damaged Thumb Sensor.	Replace the Thumb Sensor
	Something is blocking the optics or detector in the Thumb Sensor.	Make sure nothing is blocking the optics or detector.
	Thumb Sensor not secured in the Thumb Sensor Cradle.	Place the Thumb Sensor securely in the Thumb Sensor cradle.
	Thumb Sensor not secured to the base of the thumb.	Secure the Thumb Sensor to the base of the thumb.
	Thumb Sensor not securely Plugged into the Monitor.	Make sure that the Thumb Sensor is securely Plugged into the Monitor.
SpO2 displays “XX”	A sensor problem is affecting the measurement.	If the problem persists, replace the Thumb Sensor.
SpO_2 is erratic	Something is partially blocking the optics or detector in the Thumb Sensor.	Make sure nothing is blocking the optics or detector.
	Thumb Sensor not secured to the base of the thumb.	Secure the Thumb Sensor to the base of the thumb.
	Thumb Sensor is not in the correct location.	Reorient the Thumb Sensor at the base of the thumb and secure with the Thumb Wrap.
	Thumb Strap is too tight.	Loosen the Thumb Strap making sure that it is still secure.

8.5 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.
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.

Problem	Potential Cause	Solution
LED on Cuff Module displays red when in the Charger.	Voltage level has exceeded expectation.	• Remove Cuff Module from the Charger. • Report the problem to Sotera Wireless Inc. Customer Service Department or the Sotera Wireless representative in your area.
	Current level has exceeded expectation.	• Remove Cuff Module from the Charger. • Report the problem to Sotera Wireless Inc. Customer Service Department or the Sotera Wireless representative in your area.
	Over temperature protection current temperature has exceeded expectation.	• Remove Cuff Module from the Charger. • Report the problem to Sotera Wireless Inc. Customer Service Department or the Sotera Wireless representative in your area.

8.6 ViSi Mobile Battery Charger

Problem	Potential Cause	Solution
Batteries in the Monitor and Cuff Module do not charge	The Monitor and Cuff Module are not securely seated in the Charger.	Make sure that the Monitor and Cuff Module are securely seated in the Charger. The monitor and Cuff Module are designed to fit into the Charger in one direction.
	The Charger is not completely Plugged in to the wall socket.	• Make sure that the Plug is securely Plugged into an active wall socket and there is a green light on the Battery Charger. • Make sure that the power cord is not damaged.
	AC Adapter is not Plugged into the Charger.	• Plug the AC Adaptor into the Charger.

8.7 General Troubleshooting

8.7.1 Connectivity Lost

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

8.7.2 Alarms and Alerts

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

Problem	Explanation
I acknowledge an alarm at the ViSi Mobile Remote Viewer, but the audio tone still occurs at the ViSi Mobile Monitor.	• Life-Threatening alarms latch at the ViSi Mobile Monitor until they are acknowledged there, even if the alarm condition resolves. • Certain alerts (such as a sensor being disconnected) continue to sound at the ViSi Mobile Monitor until you acknowledge the alert 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.	You must acknowledge the vital sign alarm, 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 Remote Viewer, but there is no audio on the ViSi Mobile Monitor.	Most alarms and alerts will audible annunciate at the ViSi 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 a Bio Med. • The speaker volume for the ViSi Mobile Remote Viewer can be tested at any time (*see section ViSi Remote Viewer Audio Test on page 67*).
The ViSi Mobile Remote Viewer displays a CONNECTIVITY LOST alert, what does it mean?	The ViSi Mobile Monitor is no currently connected to the network.

8.8 ViSi Mobile Remote Viewer

8.8.1 Setting Alarm Limits

Problem	Explanation
When I try to adjust individual limits in the Alarm Settings pane, I cannot go past certain limit values.	You cannot set limits beyond the care unit alarm limits.
When I adjust an upper limit, the lower limit also changes, or vice versa.	If you adjust a vital sign limit 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 Remote Viewer until the Monitor reconnects to the network.
	The alarms were changed on the ViSi 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.

9. Specifications

9.1 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 12 years since the System has not been tested for these patient groups.

9.2 Vital Sign Measurements

9.2.1 Heart Rate

Heart Rate	
Display Range	0 to 240 BPM
Accuracy Range	30 to 240 BPM
Accuracy	3 BPM or ±3% of reading, whichever is greater
Resolution	1 BPM
Pacemaker	• The monitor detects and rejects pacemaker impulses in accordance with AAMI EC13:2002 • Performs heart rate calculations on a patient with a pacemaker • Will not recognize a pacemaker impulse as a QRS • Displays pacer markers on ECG waveforms
Pacemaker Pulse Rejection Without Overshoot	Tested per EC13:2002, 4.1.4.1: Pulse Rejection Range: Amplitude from ±2 mV to ±700 mV Pulse Width from 0.1 ms to 2 ms **Note: Amplitude limited to 660mV for pulse widths from 1.5 to 2.0ms** 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
Pacemaker Pulse Rejection With Overshoot	Tested per EC13:2002, 4.1.4.2, Method A: Pulse Rejection Range: Amplitude from ±2 mV to ±700 mV Pulse Width from 0.1 ms to 2 ms **Note: Amplitude limited to 660mV for pulse widths from 1.5 to 2.0ms** **Note: For pulse width > 1.0mS, recovery time limited to 25mS.** Indicated Heart Rate: Ventricular Pacing: Case (a): 0 BPM Case (b): 60 BPM Case (c): 30 BPM Atrial / Ventricular Pacing: Case (a): 0 BPM Case (b): 60 BPM Case (c): 30 BPM

Heart Rate	
Pacer Pulse Detector Rejection of Fast ECG Signals	Tested per EC13:2002, 4.1.4.3: • Minimum Slew Rate: 25 V/s
Defibrillation Response	• Defibrillator protected • Displays HR measurement < 30 seconds after a defibrillation event • Displays an ECG waveform < 10 seconds after a defibrillation event **Note: Defibrillation events may be implanted or external.** **Note: Defibrillation recovery is dependent upon using proper disposable electrodes. Use only Ag-AgCl disposable electrodes.**
T-Wave Rejection	Tested per EC13:2002, 5.1.2.1: • T-waves up to 1.2 mV in amplitude: • T-waves not detected, no change in indicated heart rate.
Heart Rate Averaging	Tested per EC13:2002, 5.1.2.1 d): • 10 second moving average
Heart Rate Accuracy and Response to Irregular Rhythm	Tested per EC13:2002, 5.1.2.1 e): • Waveform 3a: 80 BPM • Waveform 3b: 30 BPM • Waveform 3c: 120 BPM • Waveform 3d: 60 BPM
Change in Heart Rate	Tested per EC13:2002, 5.1.2.1 f): • 80 BPM to 120 BPM: < 8 seconds • 80 BPM to 40 BPM: < 8 seconds
Time to Alarm for Cardiac Standstill	Tested per EC13:2002, 4.2.8.4: • < 10 seconds
Time to Alarm for Tachycardia	Tested per EC13:2002, 5.1.2.1 g): Figure 4a: • Gain = 1.0x: 22 secs • Gain = 2.0x: 21 secs • Gain = 0.5x: 10 sec with HR = 0 Figure 4b: • Gain = 1.0x: 16 secs • Gain = 2.0x: 18 secs • Gain = 0.5x: 31 sec with HR = 0
Input Impedance	> 20 Mohms
Frequency Response	0.5 to 125Hz
Lead Off Detection Current	< 6 nA
Common Mode Rejection Ratio	> 85 db

9.2.2 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%

9.2.3 Pulse Oximetry (SpO_2, Functional Oxygen Saturation)

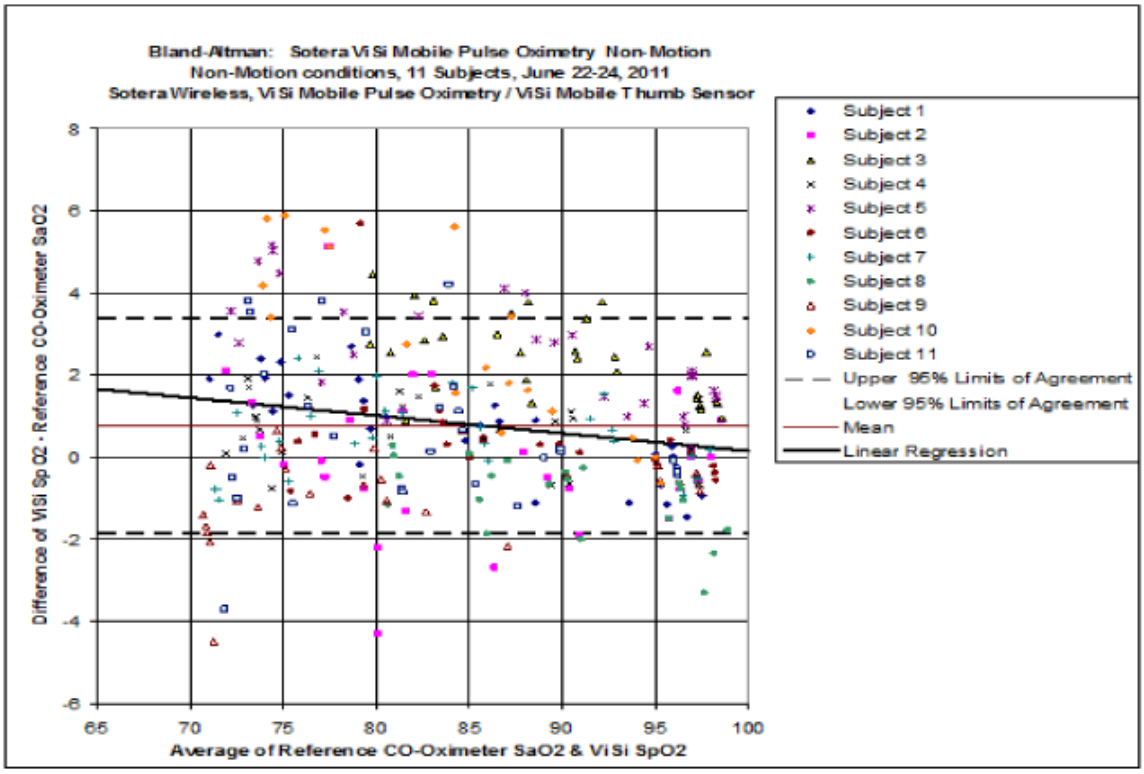
Pulse Oximetry (SpO_2, Functional Oxygen Saturation)		
Normative Reference	ISO 9919: 2005	
SpO2	Display Range	49 to 100%
	Accuracy Range	70 to 100%
	Accuracy	≤ 2% from 70-100% (no motion)[a] Unspecified from 49-69%
	Resolution	1%
Pulse Rate	Display Range	0 to 240 BPM
	Accuracy Range	30 to 240 BPM
	Accuracy (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 SpO2 is calibrated to display functional oxygen saturation and validated against human subjects arterial blood sample reference measured with CO-Oximeter (see table below). **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	SpO2 can be adversely effected by the presence of dyshaemoglobins, ambient light (including photosynamic therapy); electromagnetic interference; electro-surgical units; dysfunctional hemoglobin; presence of certain dyes; inappropriate positioning of the pulse oximeter probe.	
Toxicity	Thumb sensor uses white silicone which has no known toxicity effects.	

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

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

Validation Data (per ISO 9919)				
Age of Volunteers	18 - 45			
SpO2 Accuracy (No Motion)				
Spo2 Range	70-100%	90-100%	80-90%	70-80%
Accuracy (A_{rms}) - No Motion	1.9	1.2	1.9	2.4

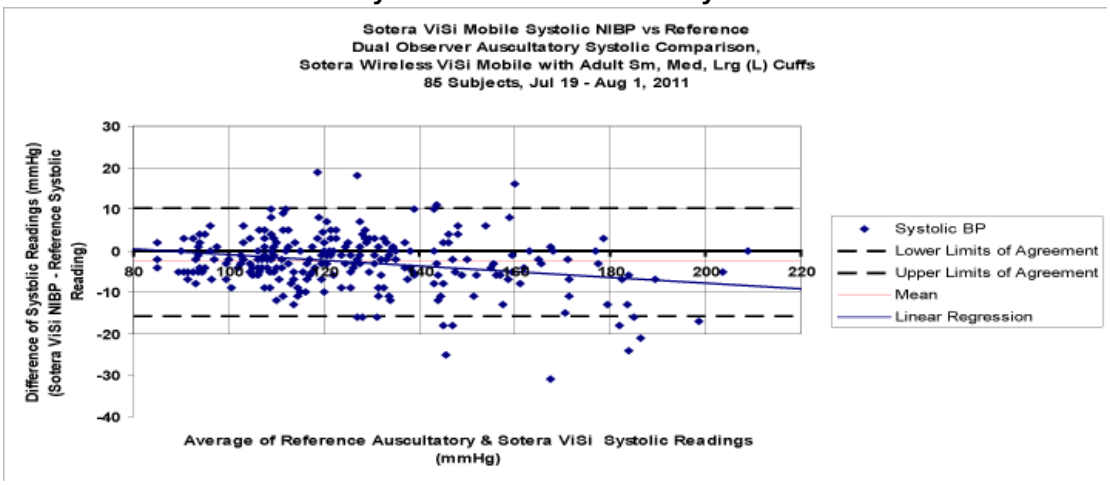
Bland-Altman: ViSi Mobile Pulse Oximetry



9.2.4 Non-Invasive Blood Pressure (NIBP)

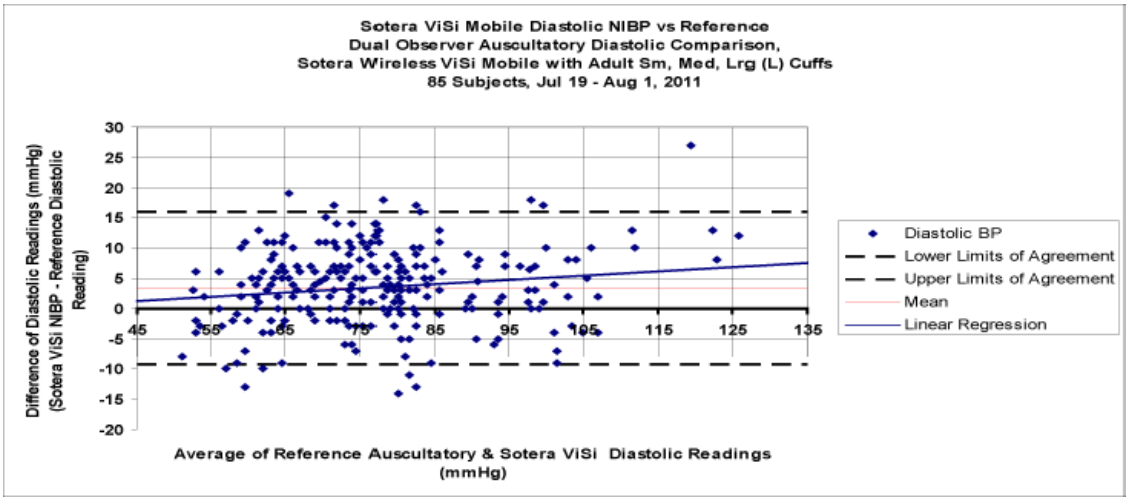
Non-Invasive Blood Pressure (NIBP)	
Normative Reference	ISO 81060-2: Non-invasive Sphygmomanometers - Part 2: Clinical validation of automated measurement type.
Principle of Operation	Oscillometry
Systolic	Range: 60 to 240 mmHg Accuracy: Mean error of less than ± 5 mmHg and a std.dev. of ≤ 8 mmHg Resolution: 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
Pulse Rate	Accuracy (NIBP) <3 BPM
Validation Study	Dual auscultatory observer Reference: ISO 81060-2 First Edition 2009-05-01, Section 5.2.4.1, same arm simultaneous method. Number of subjects: 85 Subject age range: 18-79 years Subject posture during data collection: Seated with feet on ground per ISO 81060-2

Systolic Bland Altman Analysis



Sample Size:	255 data points
Mean:	12.7 mmHg
Standard Deviation:	6.6 mmHg
Linear Regression (Bland-Altman):	Y = -0.06974 x +6.0599
Upper 95% Limits of Agreement (+1.96 SD):	10.3 mmHg
Upper 95% Limits of Agreement (-1.96 SD):	-15.7 mmHg

Diastolic Bland Altman Analysis



Sample Size:	255 data points
Mean:	3.5 mmHg
Standard Deviation:	6.3 mmHg
Linear Regression (Bland-Altman):	Y = -0.05962 x +1.0917
Upper 95% Limits of Agreement (+1.96 SD):	15.9 mmHg
Upper 95% Limits of Agreement (-1.96 SD):	-8.9 mmHg

9.2.5 Temperature

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

9.3 Physical Components

9.3.1 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
Cleaning / Disinfecting	Liquid Ingress Rating	IPX7 During cleaning cycle only, not during monitoring
	Solutions / Compounds	• Isopropyl alcohol (IPA) • Green soap

Wireless Communications / Radio

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

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

Mode Plugs

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

9.3.2 ViSi Mobile Chest Sensor Cable

ViSi Mobile Chest Sensor Cable		
Mechanical	Complies with EC53	
Length	54 cm (21.25 in)	
Weight (5 lead-wire / 3 lead-wire)	72 g / 62 g (2.54 oz. / 2.19 oz.)	
Cleaning / Disinfecting	Liquid Ingress Rating	IPX7 During cleaning cycle only, not during monitoring
	Solutions / Compounds	• Isopropyl alcohol (IPA) • Green soap

9.3.3 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
Cuff Sizes	Small	
	Medium	
	Large	
Cleaning / Disinfecting	Liquid Ingress Rating	IPX0 During cleaning cycle only, not during monitoring
	Solutions / Compounds	• Isopropyl alcohol (IPA) • Green soap

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

9.3.4 ViSi Mobile Thumb Sensor

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

9.3.5 ViSi Mobile Charger

ViSi Mobile Charger		
Physical Characteristics	Dimensions	7.64 cm. H x 12.7 cm. W x 6.35 cm. L (3 in. H x 5 in. W x 2.5 in. L)
	Weight	1.59 kg / 3.5 lbs
AC Mains	Power Supply	D.C. Input to Charger: 15VDC
	AC Line Voltage	90-264 VAC, 47-63 Hz
	Power (while charging)	50 w max
Cleaning / Disinfecting	Liquid Ingress Rating	IPX0 During cleaning cycle only, not during monitoring
	Solutions / Compounds	• Isopropyl alcohol (IPA) • Green soap

9.3.6 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 (4) 500 GB 7200 RPM hard drives in RAID 6 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 lbs (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.

9.3.7 ViSi Mobile Remote Viewer

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

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

9.3.8 Customer Network

Wireless Network	
Wireless Network Standard	IEEE 802.11b
Recommended Channels	1, 6, 11
Network Latency	< 150 ms
Wireless Network Security Support	WPA2-PSK
Minimum Receiver Sensitivity	-65 dBm (edge coverage)
Wireless access point cell overlap	15-20%
Signal-to-Noise Ratio	≥25 dB
Packet loss	<8%
SSID	Dedicated or shared with other medical devices

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

9.4 Alarms / Alerts Annunciation

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

9.4.1 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	1.5Hz	50% ON
Life-Threatening Priority	Red / White	1.5Hz	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		Deferral Delay
	Care Unit	Patient	Patient	Care Unit	Patient	Care Unit[a]	
Critical Low HR	18	18	N/A	N/A	N/A	N/A	N/A
Heart Rate	30	40	140	160	N/A	N/A	60
Pulse Rate	30	40	140	160	30	30	60
BP Systolic	70	90	190	240	N/A	N/A	60
BP Diastolic	40	50	120	150	N/A	N/A	60
Respiration	5	6	35	40	120	30	60
SpO2	N/A	N/A	85	85	30	30	60
Skin Temp	N/A	N/A	N/A	N/A	N/A	N/A	N/A

a. As the vital sign measurement approaches the care unit limit, the annunciation delay will decrease linearly.

No Pulse Detected Alarms	Limit	Delays	
		Annunciation	Deferral
When Thumb Sensor is primary source	No Pulse	30	60
When Cuff Module is primary source	No Pulse	N/A	60

Battery Alarms

	Battery Alarms	Limit	Delays (in seconds)	
			Annunciation	Deferral
Monitor	Monitoring Mode	50ºC (122ºF)	N/A	N/A
	In the Charger	40ºC (104ºF)	N/A	N/A
	Not monitoring / Not in the Charger	40ºC (104ºF)	N/A	N/A
Cuff Module	Connected to the Monitor	50ºC (122ºF)	N/A	N/A
	In the Charger	40ºC (104ºF)	N/A	N/A
	Not monitoring / Not in the Charger	40ºC (104ºF)	N/A	N/A

9.4.2 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	3
Medium	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)	Delays (in seconds)	
		Annunciation	Deferral
ECG Lead Failure	N/A	N/A	120
All ECG Lead Failure	N/A	N/A	120
Chest Sensor Disconnected	N/A	N/A	120
General Fault Detected	N/A	N/A	120
Multiple Connections	N/A	N/A	N/A
Temperature Sensor Fault	N/A	N/A	120
Accelerometer Fault - Chest Module	N/A	N/A	120
Accelerometer Fault - Upper Arm	N/A	N/A	120

Thumb Sensor Alerts	Limit (if applicable)	Delays (in seconds)	
		Annunciation	Deferral
SpO2 Signal Lost	N/A	< 30	120
Thumb Sensor Off	N/A	< 30	120
Thumb Sensor Disconnected	N/A	N/A	N/A
Thumb Sensor Failure	N/A	30	120

Thumb Sensor Alerts	Limit (if applicable)	Delays (in seconds)	
		Annunciation	Deferral
SpO2 Unobtainable	N/A	30	120

Cuff Module Alerts	Limit (if applicable)	Delays (in seconds)	
		Annunciation	Deferral
Low Battery	4% to 10%	N/A	120
Battery Empty	< 4%	N/A	120
Cuff Leak	N/A	N/A	120
Cuff Occluded	N/A	N/A	120
NIBP Unobtainable	N/A	N/A	120
Invalid Software Loaded	N/A	N/A	120
Pressure Accuracy Fault	N/A	N/A	120
General Fault Detected	N/A	N/A	120
Pressure Exceeded	N/A	N/A	120
Multiple Connections	N/A	N/A	N/A

Wrist Monitor Alerts	Limit (if applicable)	Delays (in seconds)	
		Annunciation	Deferral
Low Battery	120 minutes	N/A	N/A
Critical Low Battery	30 minutes	N/A	120
Too Low to Monitor	10 minutes	N/A	N/A
Invalid Plug Connected	N/A	N/A	N/A
Audio System Failure	N/A	N/A	120
Wireless Radio Failure	N/A	N/A	N/A
All Sensors Disconnected	N/A	N/A	N/A
Accelerometer Failure	N/A	N/A	120
Shock Hazard	N/A	N/A	120
Patient Tampering	5 Attempts	N/A	N/A

Motion Alerts	Limit (if applicable)	Delays (in seconds)	
		Annunciation	Deferral
Heart Rate	Presence of motion	N/A	120
Pulse Rate	Presence of motion	N/A	120
Respiration	Presence of motion	N/A	120
SpO2	Presence of motion	N/A	120

9.5 Environmental Conditions

Environmental Conditions for all ViSi Mobile Components (Monitor, Cuff Module, Chest Sensor Cable, Charger, Cuff, Thumb Sensor)		
Condition	**Storage (Packaged / Unpackaged)**	**Operating (Unpackaged)**
Temperature	-20°C to +55°C (50°C for NIBP) -4°F to +131°F (122°F for NIBP)	0°C to +50°C 32°F to +122°F
Humidity	15% to 95% non-condensing (90% for NIBP)	10% to 95% non-condensing (90% for NIBP)
Atmospheric Pressure Range	107 kPa to 50 kPa 803 mmHg to 375 mmHg 1.06 atm to 0.49 atm	107 kPa to 70 kPa 803 mmHg to 525 mmHg 1.06 atm to 0.69 atm

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

9.6 Agency Compliances

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

9.7 Safety and Performance Tests

You must observe any national regulations on the qualification of the testing personnel and suitable measuring and testing facilities. See *User Maintenance on page 109* for a list of required tests.

9.7.1 Electromagnetic Compatibility (EMC) Specifications

Take special precautions regarding electromagnetic compatibility (EMC) when using medical electrical equipment. You must 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 Bio Med department or vendors for assistance in identifying EMC compliance status of other medical devices when using the ViSi Mobile Monitoring System.

Accessories Compliant with EMC Standards

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

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

9.7.2 Electromagnetic Emissions

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

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

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

9.7.3 Electromagnetic Immunity

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

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

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

9.7.4 Recommended Separation Distance

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

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

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

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

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

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

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

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

From Portable and Mobile RF Communication Equipment

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

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

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

Electrosurgery Interference/Defibrillation/Electrostatic Discharge

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

Fast Transients/Bursts

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

9.8 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 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 interfer with the Monitor's wireless communications. During such interference, the Monitor continues to monitor and will alarm locally. If wireless communication is affected when using the Monitor in close proximity with another RF radiating device, move the other device away from the Monitor or discontinue use of the other device.

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

9.8.1 Risk Analysis Summary

- The ViSi Mobile Monitors are the source of all alarms and alerts.
- The ViSi Remote Viewer provides a supplemental alarm notification. When connectivity is present audio alarms are deferred to the ViSi 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 Remote Viewer.

9.8.2 Residual Risks

Loss of network connectivity will result in failure in supplemental alarm notification to the ViSi Appliance and ViSi 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.

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 specified in the ViSi Installation Manual (Hardcopy: 95-10061 / CD: 95-10059).
- Maintain network configuration post installation of the ViSi Mobile System.
- Notify Sotera prior to modifications to the network, including any configurations changes that could potentially compromise the IT Network as verified at the initial installation of the ViSi System. For support contact Sotera Wireless or an authorized Sotera Wireless representative in your area.

Appendix A - Symbols

Alarms / Alerts

Alarm / Alert States

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

Alarm Management

Symbol	Description
	Pause alarm annunciation (visual and audible) for 2 minutes.
	Turn off alarm annunciation (visual and audible).
	Resume alarm annunciation from a paused state.

Symbol	Description
	Turn alarm annunciation back on.
	Acknowledge an alarm/alert that is in progress.

Battery States

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

General Icons

Navigation

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

Vital Signs Menu

Symbol	Description
	Access to the clinical menu.
	Start a manual cuff inflation. Cuff inflations are set up to be taken on an ad hoc basis.
	Start a manual cuff inflation. Cuff inflations are set up to be taken automatically at a selected time interval.
	Stop a cuff inflation currently in progress.

Clinical Menu

Symbol	Description
	Cuff management. Setup the cuff inflation intervals or define as ad-hoc only inflations.
	Initiate the stop monitoring sequence.

Symbol	Description
	Access information regarding the ViSi Mobile Monitor: Monitor Id, MAC address, Serial #, software version installed and battery status.
	Alarm management. Review the patient's current alarm limits, adjust the alarm limits using "Auto Set" or turn off the alarm annunciation.
	QRS beep is turned on.
	QRS beep is turned off.

Other

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

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
CONT	Contents

Symbol	Description
	MRI Unsafe

- Notes -

Appendix B - Model Numbers

Introduction

In the event any component needs to be replaced, contact the Sotera Wireless Inc. Customer Service Department or the Sotera Wireless representative in your area.

If a component needs to be returned, prior to shipping ensure the returned components have been properly disinfected.

ViSi Mobile System Components

Model Number	Description
92-10010	ViSi Mobile Monitor
92-10011	ViSi Mobile Cuff Module
92-10012	ViSi Mobile Chest Sensor (5 lead-wire ECG, AAMI)
92-10014	ViSi Mobile Chest Sensor (3 lead-wire ECG, AAMI)
92-10016	ViSi Mobile Chest Sensor (5 lead-wire ECG, IEC)
92-10018	ViSi Mobile Chest Sensor (3 lead-wire ECG, IEC)
92-10020	ViSi Mobile Thumb Sensor
92-10066	ViSi Mobile Patient Kit (Single-use, adult, S)
92-10067	ViSi Mobile Patient Kit (Single-use, adult, M)
92-10068	ViSi Mobile Patient Kit (Single-use, adult, L)

Accessories

Model Number	Description
92-10023	ViSi Charger

- Notes -

Appendix C - Warranty

Warranty

USA, Canada, Mexico, Puerto Rico

Sotera Wireless Inc. warrants that its products will be free from defects in workmanship and materials for a period of one (1) year from the date of purchase except that disposable or one-time use products are warranted to be free from defects in workmanship and materials up to a date one year from the date of purchase or the date of first use, whichever is sooner. This warranty does not cover consumable items such as, but not limited to, batteries, external cables, sensors, cuffs, hoses, or mounts.

Sotera Wireless Inc. shall not be liable for any incidental, special, or consequential loss,

damage, or expense directly or indirectly arising from the use of its products, liability under this warranty and the buyer's exclusive remedy under this warranty is limited to servicing or replacing at Sotera Wireless Inc. option at the factory or at an authorized Sotera Wireless Inc. Distributor, any product which shall under normal use and service appear to the Company to have been defective in material or workmanship.

No agent, employee, or representative of Sotera Wireless Inc. has any authority to bind

Sotera Wireless Inc. to any affirmation, representation, or warranty concerning its products, and any affirmation, representation or warranty made by any agent, employee, or representative shall not be enforceable by buyer.

This warranty is expressly in lieu of any other express or implied warranties, including any implied warranty or merchantability or fitness, and of any other obligation on the part of the seller.

Damage to any product or parts through misuse, neglect, accident, or by affixing any nonstandard accessory attachments or by any customer modification voids this warranty.

Sotera Wireless Inc. makes no warranty whatever in regard to trade accessories, such being subject to the warranty of their respective manufacturers.

A condition of this warranty is that this equipment or any accessories which are claimed to be defective be returned when authorized by Sotera Wireless, freight prepaid to Sotera Wireless Inc., San Diego, California 92121. Sotera Wireless Inc. shall not have any responsibility in the event of loss or damage in transit.

Calibration may be performed without the need to disassemble the instrument. It is the responsibility of the purchaser to perform calibration as necessary, in accordance with the instructions provided in the technical manual.

Sotera Wireless Responsibility

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

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

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