STASIS MONITORING SYSTEM USER MANUAL

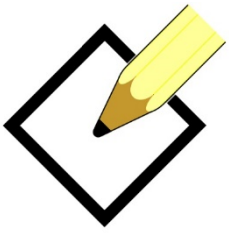
Table of Contents

NOTE: This user's guide is provided as an initial outline for review by Stasis. It is intended to provide a first review for Stasis personnel to confirm that the higher-level information covers needed topics and to guide fulfilling the scope of the project.

I. SYMBOLS USED IN USER MANUAL

Symbol	Description
 WARNING	**A Warning indicates a hazardous situation which, if not avoided, could result in death or serious injury.**

Symbol	Description
 CAUTION	**A Caution indicates a hazardous situation which, if not avoided, could result in minor or moderate injury or could result in property damage. This manual treats violation of HIPAA guidelines as a minor injury warranting a caution alert.**

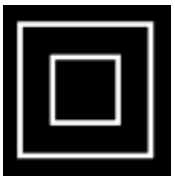
Symbol	Description
 NOTE	**Notes provide additional useful information.**

II. SYMBOLS USED IN DEVICE LABELING

Symbol	Description
 WARNING	**Warnings are identified by the WARNING symbol shown at left. A Warning indicates a hazardous situation which, if not avoided, could result in death or serious injury.**

Symbol	Description
 REFER TO INSTRUCTIONS	**This symbol prompts the user to refer to the user manual before using the Stasis Monitoring System.**

Symbol	Description
 DATE OF MANUFACTURE	**This symbol indicates the year that the Stasis Monitor was manufactured in.**

Symbol	Description
 CLASS II	This symbol indicates that the Stasis Monitor is a Class II device.

Symbol	Description
 TYPE CF	This symbol indicates that the Stasis Monitor is a Type CF device intended for defibrillation-protected direct conductive contact with the heart.

Symbol	Description
 TYPE REF	This symbol precedes the model designation of the Stasis Monitor.

Symbol	Description
 SERIAL NUMBER	This symbol precedes the serial number of the Stasis Monitor.

Symbol	Description
 DC POWER	**This symbol indicates that the Stasis Monitor accepts DC power input.**

III. ACRONYMNS USED

A. SMS – Stasis Monitoring System

B. EWS – Early Warning Score

C. ECG – Electrocardiogram

D. SpO_2 – Peripheral Capillary Oxygen Saturation

E. HR – Heart Rate

F. BPM – Beats per Minute

G. RPM – Respirations per Minute

H. Temp – Skin Temperature

I. BP – Blood Pressure

J. NIBP – Non-Invasive Blood Pressure

K. IBP – Invasive Blood Pressure

L. SYS – Systolic Blood Pressure

M. DIA – Diastolic Blood Pressure

N. VSR – Vital Sign Records

O. UG – User's Guide

P. IFU – Instructions for Use

Q. VAC – Volts, Alternating Current

R. VDC – Volts, Direct Current

S. V/m – Volts per Meter (a measurement of electric field strength)

T. **Vrms** – Volts root mean square (a measurement of electric field strength)

IV. OVERVIEW

A. The Stasis Monitoring System consists of a compact six-parameter vital signs monitor that sits at patient bedside and communicates via Bluetooth with Android tablets running our proprietary application. System uses traditional wired sensor technology to acquire the vital signs. The primary data display and control for the monitoring system is on the Android tablet.

B. The model name of the hardware component of the Stasis Monitoring System is the "Stasis Monitor".

C. The Stasis Monitor is manufactured for Stasis Labs by:

Johari Digital Healthcare Ltd.
G-582-584, EPIP, Boranada
Salawas Road, Basni Silawatan
Rajasthan - 342014, India

 **CAUTION**	All users should read this manual thoroughly. An electronic version of the current copy of this manual may be obtained by emailing: **contact@stasislabs.com**

 **CAUTION**	Review the intended use and warnings and cautions sections in this manual.

V. INTENDED USE

The Stasis Monitoring System is intended for use by clinicians and medically qualified personnel for single or multi-parameter vital signs monitoring of adult patients (21 years of age or older). It is indicated for 3 lead ECG, respiration rate (RESP), heart rate (HR), noninvasive blood pressure (NIBP), noninvasive 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 Stasis Monitoring System includes bedside Patient Monitors that communicate with mobile Tablets through wireless Bluetooth Low Energy (BLE) communication. The Stasis Monitoring System can generate alerts when rate-based cardiac arrhythmias such as asystole are detected, and when physiological vital signs fall outside of selected parameters. The Stasis Monitoring System has a notification system that communicates data and alarms to a Stasis Tablet. It is intended to supplement the primary alarms which originate at the Stasis Monitor device.

 **CAUTION**	Federal Law (USA) restricts this device to sale by or on an order of a physician.

 **CAUTION**	The use of the Stasis Monitoring System is restricted to one patient at a time.

 **NOTE**	Hospital use typically covers such areas as general care floors, operating rooms, special procedural areas, intensive and critical care areas, or other regions within the hospital. Use with any particular patient requires the selection of appropriate sensors as described in this manual.

Essential Performance

For the Stasis Labs Monitoring System, Essential Performance is defined as:

A) The ability to detect 3 lead ECG, respiration rate (RESP), and heart rate (HR) as per IEC 60601-2-27, noninvasive blood pressure (NIBP) as per IEC 80601-2-30, noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) as per ISO 80601- 2-61, and skin temperature (TEMP) as per ISO 80601-2-56.

B) The ability to provide alarms if any of items listed in A above go above or fall below pre-specified limits (as applicable) as per IEC 60601-1-8.

VI. WARNINGS AND CAUTIONS

A. Warnings Summary

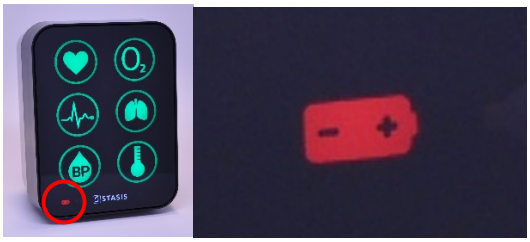
 **WARNING**	Before using the SMS carefully read this user's guide, including all warnings, cautions, and instructions.
 **WARNING**	The SMS is intended for patient assessment. It must be used by healthcare professionals in conjunction with the assessment of clinical signs and symptoms when clinical action, or inaction, is warranted.
 **WARNING**	The use of accessories, sensors, cuffs, and cables other than those specified may result in increased emissions and/or decreased emission immunity and may result in inaccurate measurements.
 **WARNING**	The protection of the Stasis Monitor against the effects of discharge of a cardiac defibrillator depends on using only the accessories described in this user manual.

WARNING

The SMS may only be installed by Stasis-trained personnel.

WARNING

When the Battery level is critically low and has 5 minutes or less of life remaining, the Battery icon will flash red and an audible alarm will sound.



WARNING

To ensure patient safety, do not place the SMS in any position that might cause it to fall on the patient.

WARNING

Ensure that the speaker is clear of any obstructions. Failure to do so could result in an inaudible alarm tone.

WARNING

Do not use the SMS in a MRI suite.

Do not use the SMS to monitor a patient that is being operated on with HF surgical equipment.

Explosion Hazard. Do not use the SMS in the presence of flammable anesthetics or gases.

Vital sign readings may be affected by certain environmental conditions. Refer to the appropriate sections of this manual for specific environmental safety information.

Ensure that cable routing is conducted in a manner which will reduce the possibility of patient entanglement or strangulation.

The conductive parts of the ECG electrodes should not contact other conductive surfaces, or earth ground, at any time.

Do not lift the SMS by sensor/cuff cables or power cord. This will protect the patient from the possibility that such actions could result in the SMS falling on the patient.

 **WARNING**	Do not lift the SMS by sensor/cuff cables or power cord as damaged cabling may cause inaccurate performance or device failure.
 **WARNING**	Do not plug or unplug the AC adapter with wet hands.
 **WARNING**	Do not plug or unplug the AC adapter if the system is wet (as could be the case after cleaning).
 **WARNING**	Do not clean the unit while the power is on and if the AC adapter is connected to the SMS.
 **WARNING**	Do not connect the SMS to an electrical outlet that is controlled by a wall switch as the SMS may be accidentally turned off.
 **WARNING**	Ensure that all sensors/cuffs are connected to the patient properly.

Do not immerse or wet the SpO_2 sensor.

Failure to cover the SMS SpO_2 sensor with opaque light conditions may result in inaccurate measurements.

Inappropriate application or duration of SpO_2 or ECG sensors may result in tissue damage. Inspect the SpO_2 and ECG sensor sites as directed in the SpO_2 and ECG sensor directions for use.

Only use the same type of ECG electrodes for the various sites on the body. Mixing ECG electrode types can adversely affect ECG measurements.

Make certain that the NIBP cuff tube is not bent during inflation and deflation, particularly after a change in patient body position.

Do not wrap the cuff on the following parts of the patient.

- An upper arm on which an SpO_2 sensor, IBP catheter, or other monitor sensor is connected.
- An upper arm on which an intravenous drip or blood transfusion is being performed.
- An upper arm with a shunt for hemodialysis.

 **WARNING**	If the NIBP cuff, SpO_2 sensor or temperature sensor is used on a patient with an infection, it is the responsibility of the healthcare professionals to treat the cuff or sensors as medical waste or consider if appropriate sanitizing cuff or sensors before reuse.
 **WARNING**	Do not use sensors/cuffs prior that appear to be damaged as damaged sensors/duffs may cause inaccurate performance or device failure.
 **WARNING**	Ensure that all sensors/cuffs are connected to the SMS properly.
 **WARNING**	When the SMS monitor alarms or alerts, it is the responsibility of healthcare professionals to review patient condition clinically before conducting interventional measures.
 **WARNING**	It is the responsibility of healthcare professionals to manage the alarm notification settings for their patients.
 **WARNING**	Do not operate the SMS in an environment with high O_2 levels.

 **WARNING**	Impedance pneumography for the determination of Respiration Rate (RESP) is not recommended for use in the presence of mechanically induced high frequency ventilation.
 **WARNING**	The SMS has not been tested for use on neonatal or pediatric patients under the age of 21 years.
 **WARNING**	The SMS has been designed to pair a single monitor to a single tablet during patient monitoring activities. It is not possible to view patient data from more than one SMS on a single tablet.
 **WARNING**	Do not use the same SMS to measure the NIBP of one patient while it is connected simultaneously to another patient.
 **WARNING**	Do not use the SMS 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.
 **WARNING**	Do not use the SMS on a patient on cardio-pulmonary bypass.

 **WARNING**	Do not use the SMS on patient arm where the use of a blood pressure cuff is contraindicated.
 **WARNING**	Do not use the SMS in a MRI Suite.
 **WARNING**	The SMS has been designed to pair a single monitor to a single tablet during patient monitoring activities. It is not possible to view patient data from more than one SMS on a single tablet.
 **WARNING**	The effectiveness of the SMS's blood pressure monitoring has not been established in the presence of any dysrhythmias.
 **WARNING**	Should the SMS monitor lose Bluetooth connection to the SMS tablet, the distributed alarm function will not function. The tablet must not be relied upon to annunciate alarms.
 **WARNING**	When an alarm notification occurs, it is an indicator that the patient needs increased attention. Therefore, it is important for clinical personnel to pay particular attention to the patient. It is the responsibility of the healthcare professional to take appropriate clinical actions, including physically check on the patient if necessary, before enabling the **PAUSE ALARM** function.

 WARNING	If the user is uncertain about the accuracy of any measurement, it is the responsibility of healthcare professionals to check patient vital signs by an alternative means if deemed necessary and make certain that the sensors and/or SMS is functioning properly.
 WARNING	Do not spray, pour, or spill liquids into or onto the Monitor unit, accessories, connectors, buttons, or openings in the housing.
 WARNING	Dispose of all electrical components associated with the SMS in accordance with local requirements and regulations.
 WARNING	Always leave the SMS plugged in to a hospital-grade AC power outlet when possible.

B. Cautions Summary

 CAUTION	All users should read this manual thoroughly. An electronic version of the current copy of this manual may be obtained by emailing: **contact@stasislabs.com**
 CAUTION	Medical personnel using the SMS must be properly trained in the use of the device.

 **CAUTION**	The user is responsible for exercising appropriate protocols to act in accordance with HIPAA regulations with regards to personnel access to the computer operating the SLMS or when sharing patient-specific information.
 **CAUTION**	Federal Law (USA) restricts this device to sale by or on an order of a physician.
 **CAUTION**	Check the wall power source to make certain that it is providing 110VAC power.
 **CAUTION**	If the device has not been used for an extended period of time, verify that it operates normally and safely before use.
 **CAUTION**	Do not subject the SMS unit to mechanical shocks, such as dropping the unit on the floor.
 **CAUTION**	Using the Tablet in high ambient light conditions may affect the ability to read the values correctly.
 **CAUTION**	A displayed NIBP value that is outside of the measurement range of 60-230 mmHg for systolic pressure and 40-130 mmHg for diastolic pressure is not accurate and must be verified.

 **CAUTION**	Only use a GE DURA-CUF NIBP cuff with this device.
 **CAUTION**	Use the appropriate size NIBP cuff to ensure correct measurements. If the NIBP cuff is too large the measured blood pressure value tends to be lower than the actual blood pressure. If the NIBP cuff is too small the measured blood pressure value tends to be higher than the actual blood pressure.
 **CAUTION**	NIBP measurements should be performed with the cuff placed on the upper arm.
 **CAUTION**	Make certain that the part of the cuff is approximately the same elevation as the heart. A difference of 10cm (4in) in height may cause a variation in the measured blood pressure value of up to 7-8mmHg.
 **CAUTION**	If the NIBP cuff is wrapped over thick clothing it could affect the accuracy of the measured blood pressure.
 **CAUTION**	If patient sleeve is rolled up in a manner where it exerts pressure on the arm it could affect the accuracy of the measured blood pressure.

 **CAUTION**	If the patient moves or talks during the blood pressure measurement it could affect the accuracy of the measured blood pressure.
 **CAUTION**	Make certain that the pneumatic connector is locked on the pneumatic nipple on the SMS unit. If the pneumatic connection is not secure it could affect the accuracy of the readings.
 **CAUTION**	Make certain that the cuffing tubing does not have a heavy object resting on it and that it has no kinks, as restrictions in air flow to the cuff can affect the accuracy of the NIBP readings.
 **CAUTION**	Do not use the NIBP cuff if it is damaged or has holes.
 **CAUTION**	If you believe that your SMS is in need of repair, contact your Stasis sales representative for instructions on sending the system to Stasis for diagnosis and repairs.
 **CAUTION**	Installation of unauthorized software will result in the voiding of the SMS service agreement.

CAUTION	The SMS can be sanitized by wiping down with a soap and water solution, 70% isopropyl alcohol, or dilute glutaraldehyde solution.

CAUTION	Do not sterilize by autoclave, irradiation, or gas sterilization methods.

C. Notes Summary

NOTE	Hospital use typically covers such areas as general care floors, operating rooms, special procedural areas, intensive and critical care areas, or other regions within hospital or hospital-type facilities. Hospital-type facilities include physician-office-based facilities, sleep labs, skilled nursing facilities, surgical centers, sub-acute centers, dental clinics, or oral surgeon clinics. Intra-hospital transport includes transport of a patient within the hospital or hospital-type facility. Home Care use is defined as managed/used by a lay person (parent or other similar non-critical care giver) in the home environment. Use with any particular patient requires the selection of appropriate sensors as described in this manual.

NOTE	The Stasis power supply cord has a two-prong US power plug. If the user is using the SMS device in an environment with a different power source or outlet design, the user will need to procure a converter.

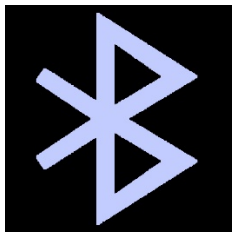
NOTE

Battery power life may be affected by certain operational parameters including, but not limited to:

- The frequency at which audible alarms are sounded.
- The frequency at which NIBP measurements are made.

NOTE

For the Sync to occur successfully between the SMS and the Tablet there must be a valid Bluetooth connection.



NOTE

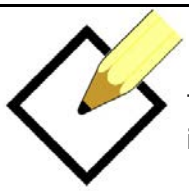
For the Sync to occur successfully between the SMS and the Tablet a patient must have been selected or admitted on the Tablet.

NOTE

Place the SpO_2 sensor on the finger in a manner which results in the molded imprint of the finger and nail is on the same side of the finger as the nail.

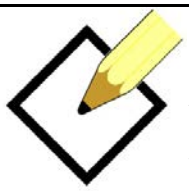
NOTE

If there are no SMS systems within the same Bluetooth range, the screen will prompt the **user to RETRY CONNECTION**.



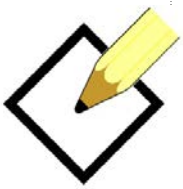
NOTE

The PAUSE ALARM button will only illuminate when an alarm condition exists.



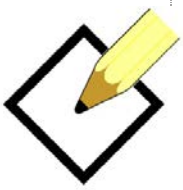
NOTE

Any displayed ECG alarms are based on a rate-based detection algorithms, not a waveform-based analysis



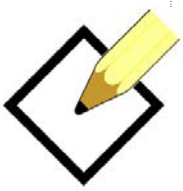
NOTE

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones, WIFI-enabled devices, and land mobile radios; amateur radios; AM and FM radio broadcast; and TV broadcast, and WIFI transmission cannot be predicted theoretically with survey accuracy. To assess 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 SMS is used exceeds the applicable RF compliance level described in this section, the SMS should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the SMS.



NOTE

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



NOTE

The SMS has an IP rating of IP22. This means it is protected from intrusion by a large part of the body such as a hand (but no protection from deliberate access), and from solid objects greater than 50mm in diameter. It is also protected from vertically dripping water when the enclosure is tilted at an angle of up to 15 degrees from its normal position.

VII. USE CONSIDERATIONS

WARNING

Before using the SMS carefully read this user's guide, including all warnings, cautions, and instructions.

WARNING

The SMS is intended for patient monitoring. It must be used by healthcare professionals in conjunction with the assessment of clinical signs and symptoms to determine when clinical action, or inaction, is warranted.

WARNING

The use of accessories, sensors, cuffs, and cables other than those specified may result in increased emissions and/or decreased emission immunity and may result in inaccurate measurements.

WARNING

Do not operate the SMS in an environment with high O_2 levels.

WARNING

It is the responsibility of healthcare professionals to manage the alarm notification settings for their patients.

 **WARNING**	Impedance pneumography for the determination of Respiration Rate (RESP) is not recommended for use in the presence of mechanically induced high frequency ventilation.
 **WARNING**	The SMS has not been tested for use on neonatal or pediatric patients under the age of 21 years.
 **WARNING**	The SMS has been designed to pair a single monitor to a single tablet during patient monitoring activities. It is not possible to view patient data from more than one SMS at a time on a single tablet.
 **WARNING**	Do not use the same SMS to measure the NIBP of one patient while it is connected simultaneously to another patient.
 **WARNING**	Do not use the SMS 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.
 **WARNING**	Do not use the SMS on a patient on cardio-pulmonary bypass.

 WARNING	Do not use the SMS on patient arm where the use of a blood pressure cuff is contraindicated.
 WARNING	Do not use the SMS in a MRI Suite.
 WARNING	The effectiveness of the SMS's blood pressure monitoring has not been established in the presence of any dysrhythmias.
 CAUTION	Medical personnel using the SMS must be properly trained in the use of the device
 CAUTION	The user is responsible for exercising appropriate protocols to act in accordance with HIPAA regulations with regard to personnel access to the computer operating the SLMS or when sharing patient-specific information.

A. INSTALLATION

1. Installation instructions:

a. The Stasis Monitoring System comes in 5 packages:

i. Stand Base and Hooks

ii. Stand Poles

iii. Stasis Monitor

iv. Stasis Sensors

v. Stasis Tablet

b. The first step in installing the Stasis Monitoring 3System is assembling the stand.

i. Remove the stand base, bottom pole, top pole, cable management hooks, and tablet cradle (if provided) from the packaging.

ii. Attach the larger bottom pole to the stand base using the single provided screw and set the stand upright.

iii. Slide the smaller top pole into the bottom pole, with the threaded hole in the top pole towards the top.

iv. Slide the cable management hooks and tablet cradle (if provided) on to the top pole.

v. Attach the monitor bracket to the top pole using the single provided screw.

c. With the stand assembled, attach the Stasis Monitor to the stand using the screw provided in the back of the Stasis Monitor.

d. Connect the 4 sensors to the Stasis Monitor and loop the sensor cables and hose around the cable management hooks.

e. Plug the power supply into a hospital-grade power outlet and connect the barrel connector to the rear of the Stasis Monitor.

f. Place the Stasis Monitoring System in the location where it is to be used. The Stasis Monitoring System is now ready for use.

2. Considerations

Medical personnel using the SMS must be properly trained in the use of the device.

All users should read this manual thoroughly. An electronic version of the current copy of this manual may be obtained by emailing:

contact@stasislabs.com

The user is responsible for exercising appropriate protocols to act in accordance with HIPAA regulations with regard to personnel access to the computer operating the SLMS or when sharing patient-specific information.

LATEX ALLERGIES – No components made with natural rubber latex are used in the components that come in patient tissue contact

a. The operator position for this system is assumed to be adjacent to the Stasis Monitoring System at the patient bedside.

B. Service

1. Troubleshooting and service procedures on the software or hardware components may only be performed by, or under the direct supervision of, Stasis-authorized personnel or agents.

2. Service Contact Information: contact@stasislabs.com

VIII. SYSTEM SET-UP

A. Components

WARNING	Only use the accessories, sensors, cuffs, and cables described below with the SMS.

1. Stasis Monitor

a. Physical Characteristics

i. Size: 13.3cm(T) X 10.3cm(W) X 7.2cm(D)*
[5.38"(T) X 4.07"(W) X 3.88"(D)*]

* D (depth) does not include the protrusion of the sensor connectors in the rear nor the room required for sensor cables.

b. Back Panel

1	Power on/off switch	Rocker switch. Rock to "1" to power on and rock to "0" to power off.
2	NIBP connector	Connects the NIBP cuff to the SMS
3	ECG connector	Connects the ECG leads to the SMS
4	Temperature connector	Connects the temperature sensor to the SMS

5	DC power adaptor plug	Connects the AC adapter to wall power source
6	SpO_2 sensor connector	Connects the SpO_2 sensor to the SMS

c. Front Panel

Vital Signs Indicators

	Heart Rate (HR) (sensor connected when illuminated)
	Peripheral Oxygen Saturation (SpO_2) (sensor connected when illuminated)
	Electrocardiogram (ECG) (electrodes connected when illuminated)
	Respiration Rate (Resp) (sensor connected when illuminated)
	Blood Pressure (BP) (cuff connected when illuminated)
	Temperature (Temp) (sensor connected when illuminated)

System Status Indicators (Next to Stasis Logo)	
	Battery (monitor operating on battery power when illuminated)
	Alarm Audio Paused (audible alarm is disabled when illuminated)
	Bluetooth (Bluetooth connection between monitor and tablet is active when illuminated)

i. Key Features

i-a. SpO_2 (indicated by O_2 symbol) and Heart Rate (indicated by heart symbol) sensor

i-b. ECG (indicated by ECG waveform symbol) and respiration rate (indicated by lung symbol) sensor

i-c. Temperature (indicated by thermometer symbol)

i-d. NIBP Monitoring (indicated by BP symbol)

Motion Stop Function	When body movement is detected, the device stops inflation for 5 seconds
Irregular Pulse Indicator	Helps identify changes in heart rate, rhythm, or pulse which may be caused by heart disease or other serious health issues.
Inflation Pressure Settings	Initial inflation pressure is 140 mmHg, max inflation pressure is 300 mmHg

2. Samsung Galaxy Tab A 8" Tablet Console

a. Specifications:

i. 8" display

ii. Dimensions: 8.20" x 5.43" x 0.29"

iii. Android 5.0 or above

iv. 1.2 GHz quad-core processor

v. 802.11 a/b/g/n and Bluetooth 4.1 capability

vi. 1.5 GB RAM

vii. 16GB memory

b. Power ON/OFF

c. Interactive Touch Screen

i. Vital signs Indicators

3. Accessories

WARNING

The protection of the Stasis Monitor against the effects of discharge of a cardiac defibrillator depends on using only the accessories described in this user manual.

a. Friwo Power Supply

Type: FW8000M/05

Part Number: 1899240

Input Voltage: 100-240 V AC, 50-60 Hz

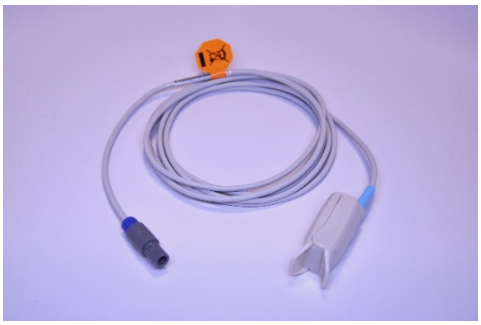
Nominal Output Voltage: 5 V DC

Nominal Output Current: 2200 mA

NOTE

The Stasis power supply cord is intended to be plugged into a standard Type A hospital plug. If the user is using the SMS device in an environment with a different power source or outlet design, the user will need to procure a converter.

b. Unimed SpO_2 Sensor (Model # U410-147)



Model # U410-147

Key Features

Adult Only	Greater than 40 kg

Measurement Range

SpO_2	70% to 100%
Heart Rate	20 to 250 bpm
Perfusion Range	0.3% to 20%

Accuracy

Saturation	
Adult[1]	70-100% +/- 2 digits
Low Perfusion[2]	70-100% +/- 2 digits
Heart Rate	
Adult[1]	20-250 bpm +/- 3 digits
Low Perfusion[2]	20-250 bpm +/- 3 digits

[1] Saturation accuracy may vary on sensor type used. Adult specifications are detailed in the IFU for the particular sensor used.

[2] Specification applies to monitor (SMS) performance.

Data Averaging: Display value is a moving average of the last 5 readings from the pulse oximeter, which are taken at 60 Hz.

Data Update Period: Every 2 seconds

Alarm Condition Delay: 80 ms

Alarm Signal Generation Delay: 10 s

Range of peak wavelengths: 657-663 nm

Maximum optical output power: 2.0 mW

This information about the optical output and wavelength range of the SpO_2 probe can be especially useful to clinicians.

The Unimed U410-147 is the only pulse oximeter probe that is validated and tested for compliance with ISO 80601-2-61 with the SMS. Do not use with any probe cable extenders.

If the signal from the SpO_2 Sensor is not sufficient to derive a reading, the tablet display shows "Pulse Ox Not Connected" in the area where the waveform is typically displayed. This serves as the signal inadequacy indicator.

The SpO_2 waveform is normalized on the tablet display.

The pulse oximeter is calibrated to display functional oxygen saturation.

The accuracy of the pulse oximeter was validated against arterial blood sample references from human subjects measured with a CO-oximeter.

A functional tester cannot be used to assess the accuracy of the pulse oximeter probe or the accuracy of the Stasis Monitor's pulse oximetry.

Do not leave the SpO_2 sensor on a patient for more than 8 hours at a time before inspecting the finger with the sensor for any potential injury.

The SpO_2 sensor and the SMS have been validated and tested for compliance with ISO 80601-2-61.

The responsible organization can verify the functionality (but not the accuracy) of the SpO_2 sensor with a functional tester. A functional tester such as the Pronk Technologies OX-1 OxSim Optical SpO_2 Pulse Oximeter Simulator (any software version) is suitable for this purpose. Refer to the operator's manual of the functional tester for details of how to verify the functionality of the SpO_2 sensor.

SpO_2 measurement can be adversely affected by the presence of dyshaemoglobins, ambient light, electromagnetic interference, electrosurgical units, dysfunctional hemoglobin, presence of certain dyes, and inappropriate positioning of the pulse oximeter probe.

If the Stasis Monitor detects that the SpO2 or pulse rate value is potentially incorrect, the Stasis Tablet will display the message "Reading may be unstable".

The SpO_2 sensor uses silicone for patient-contacting parts, which has no known toxicity effects.

 **WARNING**	This probe is only for use with the SMS. Do not attempt to use this probe with other monitoring systems.

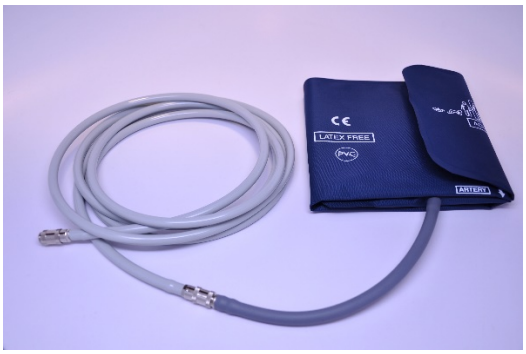
 **WARNING**	The responsible organization and the operator must verify the compatibility of the monitor and probe before use to avoid patient injury.

WARNING	The misapplication of the pulse oximeter probe with excessive pressure for extended periods of time may cause a pressure injury to the patient.

WARNING	The SpO_2 sensor must only be used continuously on a single finger for 8 hours before inspecting the finger. If there is any evidence of pressure injury or other damage to the finger, move the sensor to a different finger.

c. GE DURA-CUF NIBP Cuff, Adult Only

Adult Sizes Available (see GE DURA-CUF catalog, only Adult cuffs can be used)



Measurement Range:

Systolic: 60 – 230 mmHg

Diastolic: 40 – 130 mmHg

Pressure Precision: +/- 3 mmHg

Pressure Display Resolution: 1 mmHg

Pressure Measurement Variability:

Average Deviation: +/- 5 mmHg

Standard Deviation: +/- 8 mmHg

Maximum Inflation Pressure: 275 mmHg

d. NIBP Cuff Extension Tube (pictured above with NIBP cuff)

-NIBP Extension Tube for Edan M3A Vitals Monitor
-3 meters long
-Terminated with female metal bayonet connectors

 **WARNING**	Taking blood pressure measurements too frequently can cause injury to the patient due to blood flow interference. Ensure that circulation is not compromised during repeated blood pressure measurements.

 **WARNING**	Do not apply the blood pressure cuff over a wound, as this may lead to additional patient injury.

 **WARNING**	Do not apply the blood pressure cuff to a limb with intravascular access or an arterio-venous shunt. Inflating the cuff may cause an interruption in blood flow resulting in patient injury.

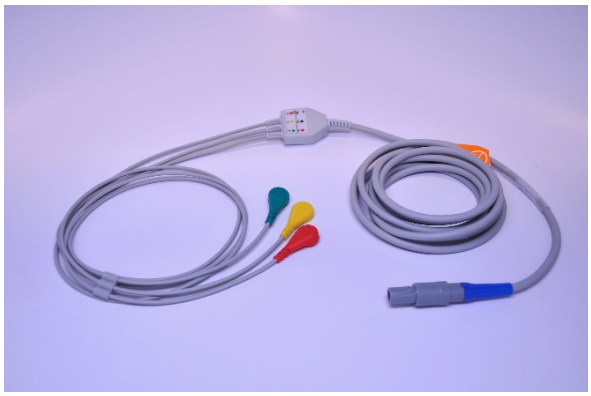
 **WARNING**	Do not apply the blood pressure cuff to a limb on the side of the patient body where a mastectomy was recently conducted.

 **WARNING**	Pressurization of the blood pressure cuff can temporarily cause loss of function of other monitoring equipment that is being used on the same limb as the cuff.

 **WARNING**	Regularly check that the operation of the automated sphygmomanometer does not result in the prolonged impairment of patient blood circulation.

WARNING	If a blood pressure measurement is questionable, retake the measurement. If the result is still questionable, use a different method of measurement.

e. Med-Link EA021S3I ECG Cable



Key Features:

3 Leads

Defibrillation-protected

Heart Rate:

Range: 30 – 200 BPM

Accuracy: +/- 1% or 1 BPM, whichever is greater

Resolution: 1 BPM

Respiration Rate Measurement:

Method: Impedance Pneumography

Range: 7-120 RPM

Resolution: 1 RPM

Accuracy: +/- 2 RPM

ECG and Respiration Rate Measurement Information **All Testing Conducted in Accordance with ANSI/AAMI EC13:2002**	
Available Time Base for ECG Display	25 mm/sec
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	• Pacemaker pulse rejection range:
	  ○ Amplitude: -2 mV to 2 mV
	  ○ Pulse width: 0.1 ms to 2 ms
	• Indicated Heart Rate:
	  ○ Ventricular Pacing:
	  ▪ Case (a): 0 BPM
	  ▪ Case (b): 60 BPM
	  ▪ Case (c): 30 BPM
	  ○ Atrial/Ventricular Pacing:
	  ▪ Case (a): 0 BPM
	  ▪ Case (b): 60 BPM
	  ▪ Case (c): 30 BPM

Pacemaker Pulse Rejection With Overshoot	• Pacemaker pulse rejection range:
	  ○ Amplitude: -2 mV to 2 mV
	  ○ Pulse width: 0.1 ms to 2 ms
	• Overshoot time: 0 ms to 4 ms
	• Indicated Heart Rate:
	  ○ Ventricular Pacing:
	  ▪ Case (a): 0 BPM
	  ▪ Case (b): 60 BPM
	  ▪ Case (c): 30 BPM
	  ○ Atrial/Ventricular Pacing:
	  ▪ Case (a): 0 BPM
	  ▪ Case (b): 60 BPM
	  ▪ Case (c): 30 BPM

Defibrillation Response	• Defibrillation protected • Displays heart rate measurement less than 5 seconds after defibrillation • Displays an ECG waveform less than 5 seconds after defibrillation
T-Wave Rejection	Rejects T-Waves up to 120% of QRS amplitude
Heart Rate Averaging	Measured heart rate is a 15 second moving average
Heart Rate Accuracy and Response to Irregular Rhythm	Waveform A1: 80 BPM Waveform A2: 60 BPM Waveform A3: 120 BPM Waveform A4: 92 BPM
Change in Heart Rate	80 BPM to 120 BPM: Less than 10 seconds 80 BPM to 40 BPM: Less than 10 seconds
Time to Alarm for Cardiac Standstill	Less than 10 seconds

Time to Alarm for Tachycardia	Figure B1: • 1.0 x Gain: 6 seconds • 2.0 x Gain: 8 seconds • 0.5 x Gain: 6 seconds Figure B2: • 1.0 x Gain: 6 seconds • 2.0 x Gain: 8 seconds • 0.5 x Gain: 6 seconds
Input Impedance	>5 Mohms
Respiration Rate Detection Signal Applied to Patient	32.5 kHz sine wave 0.08 V P-P
Lead-Off Detection Current	48.3 nA

Do not use the SMS to monitor a patient that is being operated on with HF surgical equipment.

Pacemaker Patients: Rate meters may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely upon heart rate meter alarm signals. Keep pacemaker patients under close surveillance. See this manual for disclosure of the pacemaker pulse rejection capability of this instrument

Do not use the SMS to monitor a patient that is being operated on with HF surgical equipment.

NOTE	Use the ECG cable only with 3M Red Dot 2560 Monitoring Electrodes.

f. Unimed T2252-AS Temperature Sensor, Adult Only

The sensor must be used with the included adapter (Monoprice part number 7135) as shown in the above image to connect with the Stasis Monitor's compact temperature port.

Key Features:

Skin temperature sensor intended to be attached to an adult patient's skin in the axillary region with medical tape. This is a direct mode thermometer that displays the measured temperature at the axillary site.

Display Range: 30-45 °C

Accuracy Range: 10-50 °C

Resolution: 0.1 °C

Accuracy: +/- 0.2 °C

Recommended minimum measurement time: 5 minutes

Measured time response:

35 to 37 °C: 59 seconds

35 to 33 °C: 32 seconds

NOTE	Do not leave the adapter connected to the Stasis Monitor without the temperature sensor attached to avoid the possibility of accidental impact damage.

IX. SYSTEM USE

A. SMS placement

1. Place the SMS within 1m of the patient at the patient bedside.

 **WARNING**	To ensure patient safety, do not place the SMS in any position that might cause it to fall on the patient.
 **WARNING**	Disconnect all sensors/cuffs from the patient during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns.
 **WARNING**	Explosion Hazard. Do not use the SMS in the presence of flammable anesthetics or gases.
 **WARNING**	Vital sign readings may be affected by certain environmental conditions. Refer to the appropriate sections of this manual for specific environmental safety information.
 **WARNING**	Ensure that the speaker is clear of any obstructions. Failure to do so could result in an inaudible alarm tone.
 **WARNING**	Remove the SMS from the vicinity of the patient if he/she is in the same room as a magnetic resonance imaging (MRI) scanning device. The magnetic field of the MRI may cause the system to fall on the patient.

 WARNING	Ensure that cable routing is conducted in a manner which will reduce the possibility of patient entanglement or strangulation
 WARNING	The conductive parts of the ECG electrodes should not contact other conductive surfaces, or earth ground, at any time.
 WARNING	Do not lift the SMS by sensor/cuff cables or power cord in order to protect the patient from the possibility that such actions could result in the SMS falling on the patient.
 WARNING	Do not lift the SMS by sensor/cuff cables or power cord as damaged cabling may cause inaccurate performance or device failure.
 CAUTION	Do not subject the SMS unit to mechanical shocks, such as dropping the unit on the floor.

B. Connecting the SMS to Power and Charging the Battery.

1. The SMS has an internal battery power source that may be used to power the SMS when AC power is not available. A new, fully-charged monitor may operate on its battery power source for at least 2 hours.

2. The SMS is intended to be plugged in to a power source at all times.

 CAUTION	If the device has not been used for an extended period of time, verify that it operates normally and safely before use.

NOTE

Battery power life may be affected by certain operational parameters including, but not limited to:

- Frequency at which audible alarms are sounded.
- The frequency at which NIBP measurements are made.

3. Charging the SMS Battery

a. Upon initial receipt of the SMS from Stasis, the SMS battery will not be charged adequately to operate for proper operation.

b. The SMS has a battery power indicator on the bottom left to let the user know the battery status.

c. If the monitor is plugged in and fully charged, the battery icon will be off.

d. If the monitor is plugged in and charging, the battery icon will flash white.

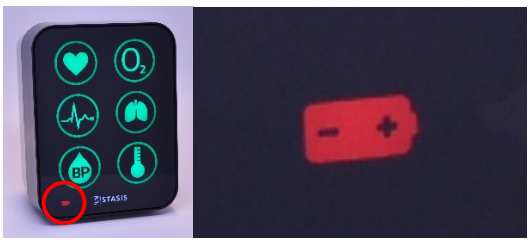
e. If the monitor is unplugged and using battery power, the battery icon will be illuminated in white.

f. If the monitor is unplugged and has a low battery, the battery icon will be illuminated in cyan.

g. If the monitor is unplugged and has a critically low battery the battery icon will flash red.

WARNING

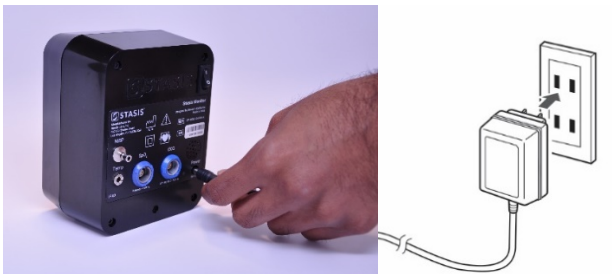
When the Battery level is critically low, and the system is in danger of shutting down, the Battery icon turns red and flashes. An audible alarm will sound as well.



CAUTION

Always leave the SMS connected to a power supply whenever possible. The internal battery is only intended as a backup power source.

h. The SMS AC adapter is designed to convert wall current from a Type A hospital grade wall outlet to 5VDC to charge the system's battery. To operate the system and charge the SMS battery, connect the AC adapter to the DC connector on the SMS and insert the wall plug in to the wall power outlet.



WARNING	Do not plug or unplug the AC adapter with wet hands.

WARNING	Do not plug or unplug the AC adapter if the system is wet (as could be the case after cleaning).

WARNING	Do not clean the unit while the power is on and if the AC adapter is connected to the SMS.

WARNING	Do not connect the SMS to an electrical outlet that is controlled by a wall switch as the SMS may be accidentally turned off.

CAUTION	Check the wall power source to make certain that it is providing 110VAC power.

i. The internal battery takes approximately 50 minutes to charge from 0% to 90%.

C. Power the SMS device on

1. Press the rocker switch on the back from the "OFF" to the "ON" position

D. Power the Tablet on

1. Press, and hold down, the power button on the tablet.

CAUTION	Using the Tablet in high ambient light conditions may affect the ability to read the values correctly.

E. Configuring the Stasis Tablet Application

a. When the user first opens the Stasis Tablet Application, they will be prompted to configure the **HOSPITAL ADMINISTRATOR SETTINGS.**

b. The user will be prompted to enter in Default Alarm Settings.

c. The user will be prompted to either Enable or Disable audio for low-priority technical alarms.

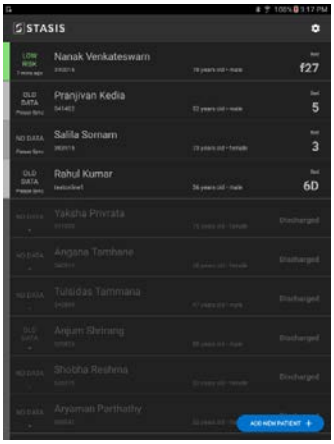
d. The user will be prompted to configure Alarm Pause Times, which will be chosen from when pausing active physiological alarms.

e. The user will be prompted to either allow or disallow the ability to use custom Alarm Settings on each patient. If disallowed, only the hospital-configured Default Alarm Settings will be used.

F.

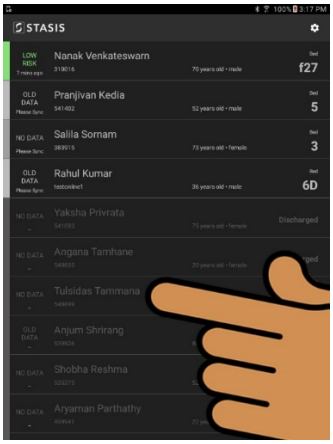
2. Admitting a Patient

a. After the STASIS icon is pressed the PATIENT SELECT / ADD PATIENT screen will illuminate.



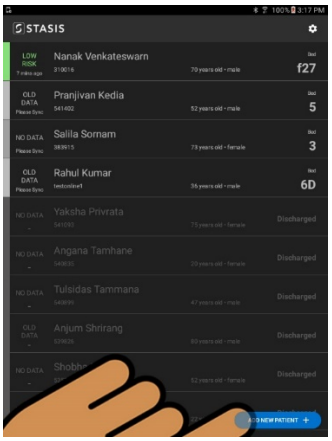
b. Select a patient by

…pressing patient name on the patient list



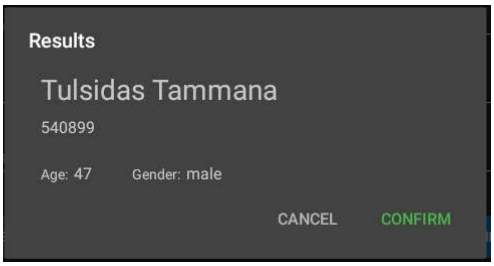
by pressing patient name On the patient list

or



by pressing "Add New Patient" icon

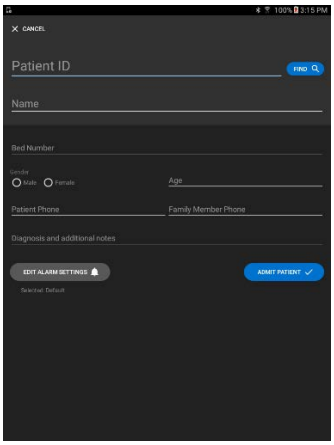
i. If the user chooses patient name from the supplied list, the following window will pop up



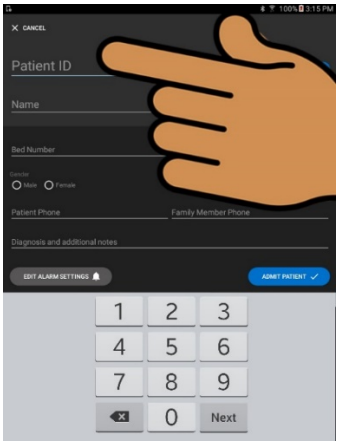
– The user will be prompted to **CONFIRM** or **CANCEL** the choice.

ii. To add a patient press the **ADD A NEW PATIENT** button.

The following window will appear:

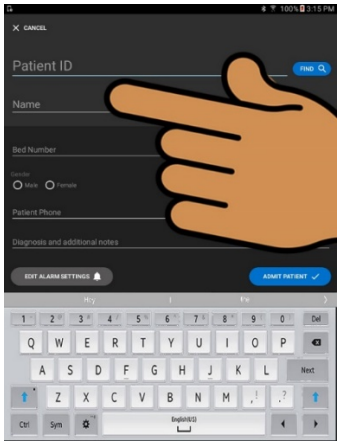


– The user may fill in the required information by selecting the desired field.



the number pad displays when fields requiring numeric values are selected

or



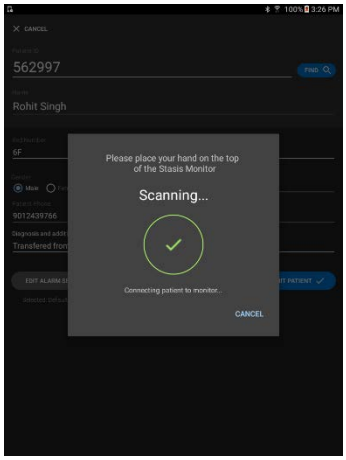
The alpha-numeric keyboard displays when fields requiring alpha and numeric values are selected

iii. When the patient information is entered, and the user pressed the **Admit Patient** button, the user will be prompted to sync with the SMS.

G. Syncing the Tablet to a specific SMS Monitor

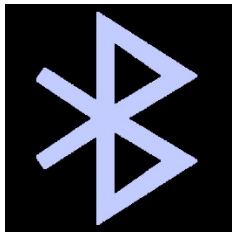
1. Place your hand on the top of the SMS monitor while holding the tablet.

a. As the tablet and the monitor sync, the tablet screen displays the following:



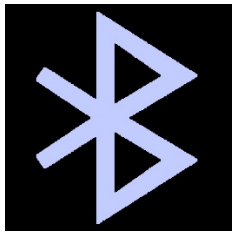
NOTE

For the Sync to occur successfully between the SMS and the Tablet there must be a valid Bluetooth connection. On the Monitor, this is indicated by flashing the Bluetooth icon.



NOTE

For the Sync to occur successfully between the SMS and the Tablet a patient must have been selected or admitted on the Tablet.



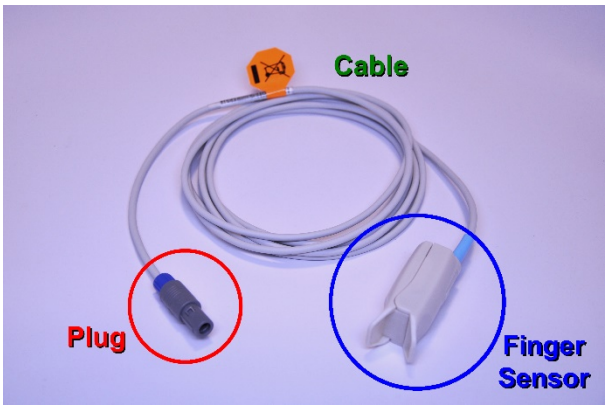
b. If no sensors are connected to the patient, then the vital sign icons will illuminate in white:

Attaching Sensors to and Operating the Monitor

WARNING

Ensure that all sensors/cuffs are connected to the patient properly.

1. Pulse Rate / Oxygen Saturation Monitoring



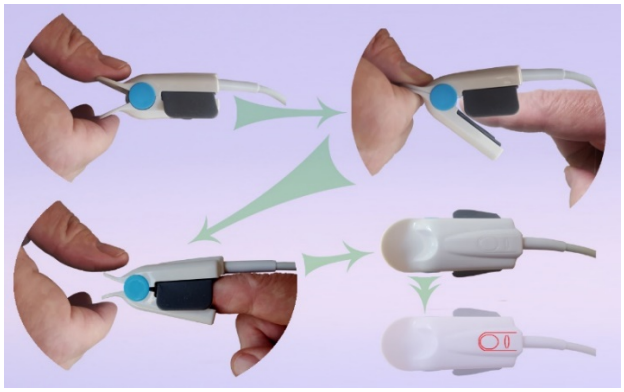
a. Attaching the SpO_2 Sensor to System

i. Insert the grey plug on the end of the SpO_2 sensor into the port marked SpO_2 on the back of the SMS (Note: Despite both having blue keying color, the SpO_2 connector can not plug into ECG connector port due to unique connector keying).

ii. It is necessary to align the two protruding rails on the plug in to the two slots on the port.

iii. When the SpO_2 sensor is connected, the SMS monitor will display the SpO_2 icon in green.

b. Attaching Sensor to Patient



i. Clamp the prongs of the sensor, opening it.

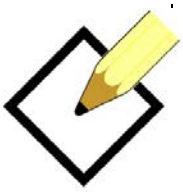
ii. Place the sensor on the finger.

c. When the SpO_2 sensor is connected and a reading is being acquired, SpO_2 and HR icons will flash white. Once a reading is acquired, the SMS will display the SpO_2 and HR icons in green if no alarm condition is active.

Symbol	Description
 Signal Inadequacy Indicator	This symbol indicates a potentially incorrect SpO_2 or pulse rate value. It will appear next to the SpO_2 reading.

 **WARNING**	Do not immerse or wet the SpO_2 sensor.

 **WARNING**	Bright light on the SMS SpO_2 sensor may result in inaccurate measurements.

 **NOTE**	Place the SpO_2 sensor on the finger in a manner which results in the molded imprint of the finger and nail is on the same side of the finger as the nail.

2. ECG / Respiration Rate Monitoring

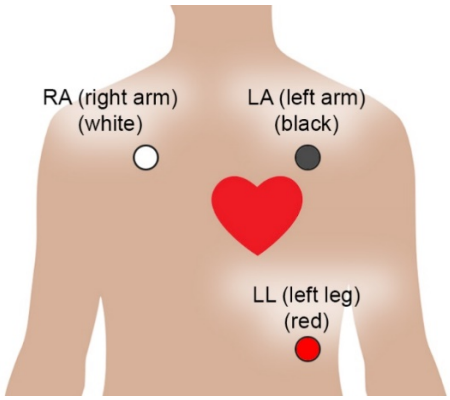
a. Attaching Sensor to System

i. Insert the grey plug on the end of the SpO_2 sensor array into the port marked **ECG** on the back of the SMS (Note: Despite both having blue keying color, the ECG connector **can no**t plug into SpO_2 connector port due to unique connector keying).

ii. It is necessary to align the protruding rail on the plug in to the slot on the port.

b. Attaching Sensor to Patient

i. Place ECG electrodes according to standard clinical practice.



c. When the ECG sensor is connected and a reading is being acquired, ECG, Resp and HR icons will flash white. Once a reading is acquired, the SMS will display the ECG, Resp and HR icons in green if no alarm condition is active.

WARNING	Inappropriate application or duration of SpO_2 or ECG sensors may result in tissue damage. Inspect the SpO_2 and ECG sensor sights as directed in the SpO_2 and ECG sensor directions for use.

WARNING	Only use the same type of ECG electrodes for the various sites on the body. Mixing ECG electrode types can adversely affect ECG measurements.

3. Blood Pressure Monitoring

a. Attaching Sensor to System

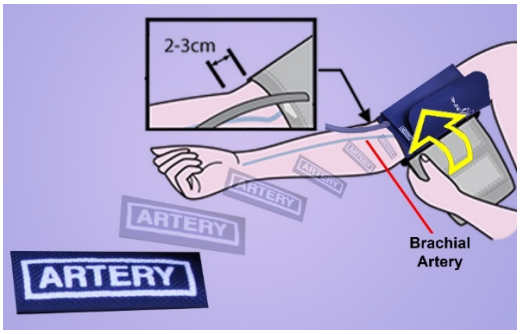
i. Press the pneumatic connector on the end of the cuff on to the nipple-connector on the back of the SMS device.

ii. In order for the connection to lock, it is necessary to pull back on the outer cannula of the pneumatic connector while pressing it on to the nipple.

b. Placing the cuff on the patient.

i. Most measurement errors occur by not taking the time to choose the proper cuff size. Wrap the cuff around patient arm and use the INDEX line to determine if patient arm circumference falls within the RANGE area. Otherwise, choose the appropriate smaller or larger cuff.

ii. Palpate/locate the brachial artery and position the BP cuff so that the **ARTERY** marker and the pneumatic tube points to the brachial artery. Wrap the BP cuff snugly around the arm.



c. When the NIBP cuff is connected and a reading is being acquired, the NIBP icon will flash white. Once a reading is acquired, the SMS will display the NIBP icon in green if no alarm condition is active.

d. When taking blood pressure measurements, ensure that:

i. The patient is comfortably seated

ii. The patient's legs are uncrossed

iii. The patient's feet are flat on the floor

iv. The patient's back and arm are supported

v. The middle of the cuff is at the level of the right atrium of the heart

vi. The patient is relaxed as possible and does not talk during the measurement

vii. 5 minutes elapse with the patient in the correct position before the first measurement is taken

 **WARNING**	The accuracy of the blood pressure readings can be impacted by extremes of temperature, humidity, or altitude.

 **WARNING**	Make certain that the NIBP cuff tube is not bent, compressed, or restricted during inflation and deflation, particularly after a change in patient body position.

 **WARNING**	Do not wrap the cuff on the following parts of the patient. • An upper arm on which an SpO_2 sensor, IBP catheter, or other monitor sensor is connected. • An upper arm on which an intravenous drip or blood transfusion is being performed. • An upper arm with a shunt for hemodialysis.

 **WARNING**	The blood pressure reading may be affected by the measurement site, the position of the patient, patient exercise, or the patient's physiological condition.

 **WARNING**	If the NIBP cuff, SpO2 sensor or temperature sensor is used on a patient with an infection, it is the responsibility of the healthcare professionals to treat the cuff or sensors as medical waste or consider if appropriate sanitizing cuff or sensors before reuse.

 **WARNING**	Do not use sensors/cuffs prior that appear to be damaged as damaged sensors/duffs may cause inaccurate performance or device failure.
 **WARNING**	Ensure that all sensors/cuffs are connected to the SMS properly.
 **CAUTION**	Only use a GE DURA-CUF NIBP cuff on this device.
 **CAUTION**	Use the appropriate size NIBP cuff to ensure correct measurements. If the NIBP cuff is too large the measured blood pressure value tends to be lower than the actual blood pressure. If the NIBP cuff is too small the measured blood pressure value tends to be higher than the actual blood pressure.
 **CAUTION**	NIBP measurements should be performed with the cuff placed on the upper arm.
 **CAUTION**	Make certain that the part of the cuff is approximately the same elevation as the heart (A difference of 10cm (4in) in height may cause a variation in the measured blood pressure value of up to 7-8mmHg.
 **CAUTION**	If the NIBP cuff is wrapped over thick clothing it could affect the accuracy of the measured blood pressure.

If patient sleeve is rolled up in a manner where it exerts pressure on the arm it could affect the accuracy of the measured blood pressure.

If the patient moves or talks during the blood pressure measurement it could affect the accuracy of the measured blood pressure.

Make certain that the pneumatic connector is locked on the pneumatic nipple on the SMS unit. If the pneumatic connection is not secure it could affect the accuracy of the readings.

Make certain that the cuffing tubing does not have a heavy object resting on it and that it has no kinks, as restrictions in air flow to the cuff can affect the accuracy of the NIBP readings.

Do not use the NIBP cuff if it is damaged or has holes.

4. Temperature Monitoring

a. Attaching Temperature Sensor to System

i. Insert the male connector on the Temperature Sensor in to the Temperature port on the SMS monitor.

b. When the temperature sensor is connected and a reading is being acquired, the temperature icon will flash white. Once a reading is acquired, the SMS will display the temperature icon in green if no alarm condition is active.

5. Alarms

WARNING	When the SMS monitor alarms or alerts, it is the responsibility of healthcare professionals to review patient condition clinically before conducting interventional measures.

a. When an alarm condition is active, the relevant icons will change color and/or flash based on the priority of the alarm. Alarm conditions are detailed in **Section IX.**

ALARM: HR limits exceeded

ALARM: SpO_2 limits exceeded

ALARM: Respiration rate limits exceeded

ALARM: Systolic NIBP or Diastolic NIBP limits exceeded

ALARM: Temperature limits exceeded

b. When an alarm condition is active, an audible alarm may sound on the SMS system. Alarm conditions and audible alarms are detailed in **Section IX.**

WARNING	Ensure that the speaker is clear of any obstructions. Failure to do so could result in an inaudible alarm tone.

WARNING	If the Alarms are paused or turned off there is no notification if a clinically significant change in patient vital signs occurs. Observe the patient by other means when alarms are paused or turned off.

	Should the SMS monitor lose Bluetooth connection to the SMS tablet the Alarm function will not function. The tablet must not be relied upon to annunciate alarms.

WARNING	

c. Alarm audio may be paused by the Tablet. If an alarm's audio is currently paused, the Alarm Audio Paused Icon will be displayed in white. Alarm pause functionality is detailed in **Section IX.**

WARNING	If alarms are paused or disabled check the patient frequently to make certain that his/her condition is acceptable.

H. Operating the Tablet

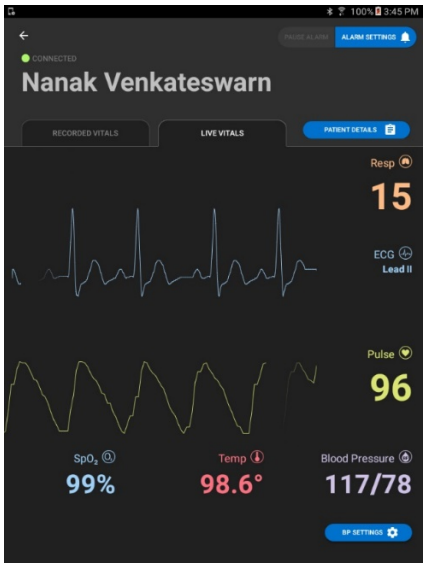
When the Patient Information is input or the Patient is selected from the patient list the **LIVE VITALS** screen will display

WARNING	If the user is uncertain about the accuracy of any measurement, check patient vital signs by an alternative means and make certain that the sensors and/or SMS is functioning properly.

WARNING	The Bluetooth range of the tablet and monitor connection is 20 feet. Attempting to use the tablet outside of this range may result in unreliable operation.

1. The **LIVE VITALS** screen.

If the user wishes to view the live vital sign readings, he/she may proceed.

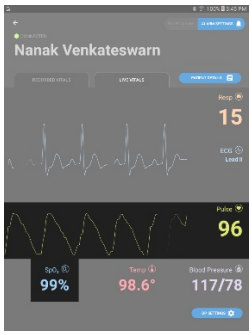


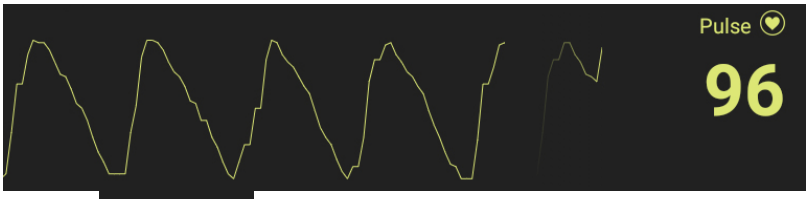
NOTE

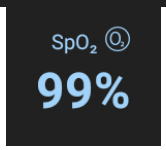
If the SMS which the patient is connected to is not in Bluetooth range, the screen will prompt the user to **RETRY CONNECTION**.

a. ECG Display

b. SpO_2 Display



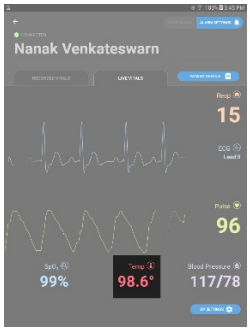


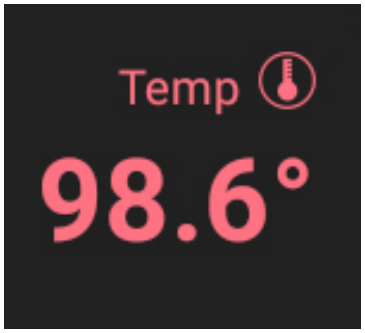


i. The oxygen Saturation level (SpO_2) is displayed numerically below the plethysmograph.

ii. The pulse rate is derived from the SpO_2 sensor. It is displayed to the right of the plethysmograph.

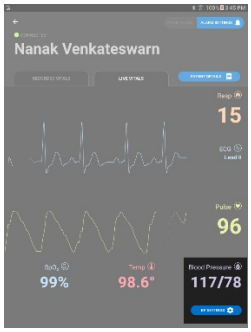
c. Temperature Display



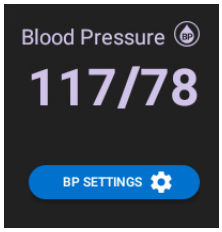


i. Patient temperature is displayed below the plethysmograph.

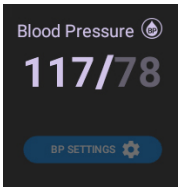
d. Blood Pressure Display.



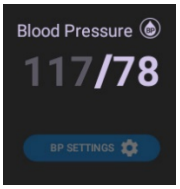
i. The non-invasive blood pressure (NIBP) reading is displayed in the lower right-hand corner of the **LIVE VITALS** screen.



– The display updates the systolic and diastolic readings obtained from the cuff with each reading.

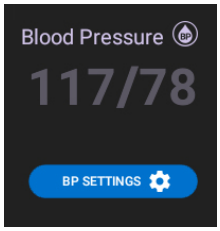


Systolic NIBP reading

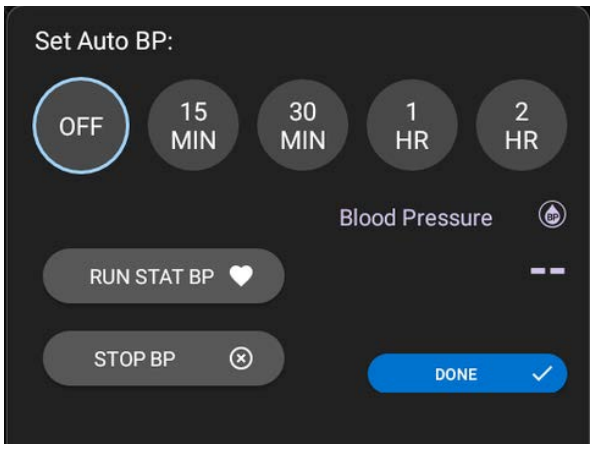


Diastolic NIBP reading

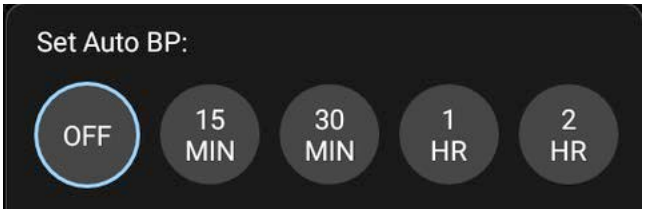
– The user may select several functions for NIBP readings by pressing the **BP SETTINGS** button.



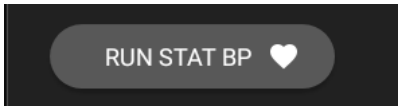
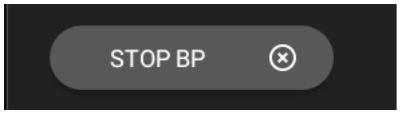
When selected, the **BP SETTINGS** button displays the following window.



From the Blood Pressure Settings window, the user may perform the following functions:



The System automatically obtains NIBP readings at selected intervals. The user may select the interval by pressing one of the above intervals.

	Pressing the **STAT BP** button immediately inflates the blood pressure cuff and initiates and NIBP reading.
	Pressing the **STOP BP** button immediately deflates the blood pressure cuff and cancels the NIBP reading.

2. RECORDED VITALS screen

If the user wishes to view the **RECORDED VITALS** values, he/she may press the **RECORDED VITALS** tab on the **LIVE VITALS SCREEN**

a. The RECORDED VITALS screen will display a historical graph of various vital signs, plus the numeric values of each recorded vital sign at the selected time.

i. The user may select a record by pressing on the graph, revealing the vital sign readings for the selected time.

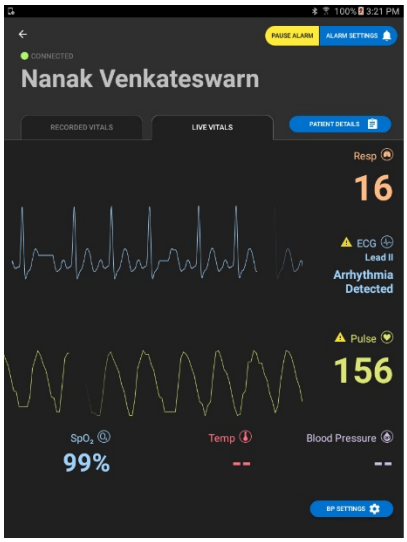
ii. The user may return to the **LIVE VITALS** screen by selecting the **LIVE VITALS** tab from the **RECORDED VITALS** screen.

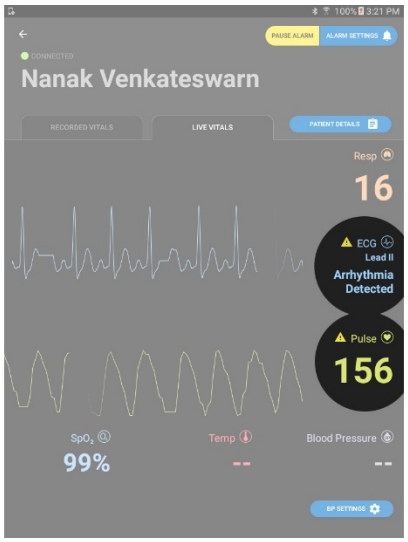
3. Alarms

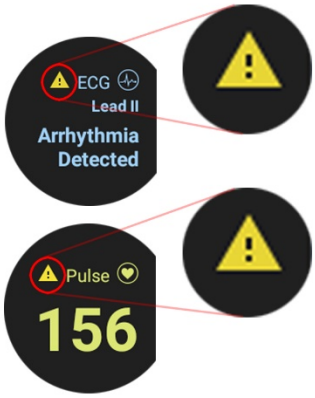
WARNING	When the SMS monitor alarms or alerts, it is the responsibility of healthcare professionals to review patient condition clinically before conducting interventional measures.

a. Alarm Displays on Live Vitals screen

i. If a medium or low priority physiological alarm is active, a yellow CAUTION icon will illuminate next to the specific vital sign that is outside of the **ALARM SETTINGS.**



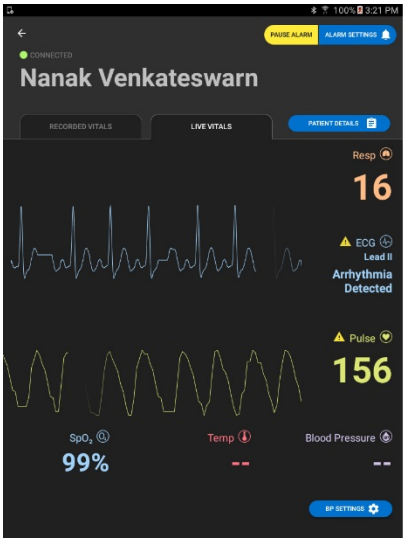


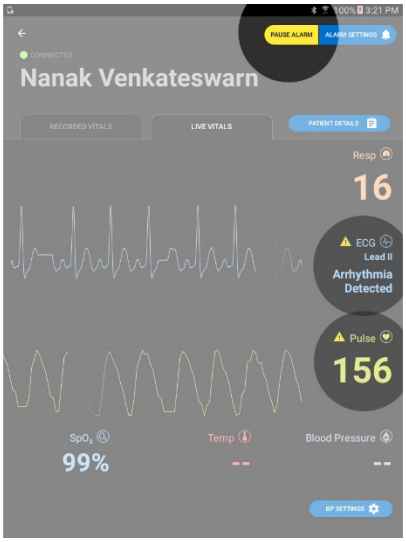


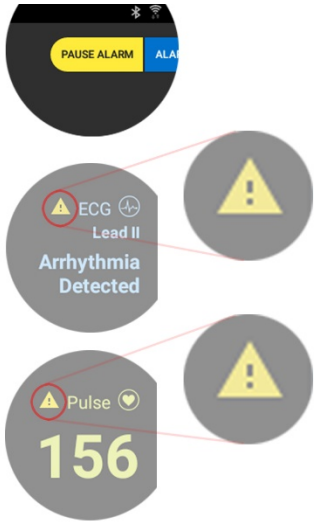
ii. If a high priority physiological alarm is active, a red CAUTION icon will illuminate next to the specific vital sign that is outside of the **ALARM SETTINGS.**

iii. If a low priority technical alarm is active, a blue CAUTION icon will illuminate next to the specific vital sign that is outside of the **ALARM SETTINGS.**

iv. Active alarms may be viewed and paused by pressing the **PAUSE / RESET ALARMS** button at the upper right-hand side of the **LIVE VITALS SCREEN**.

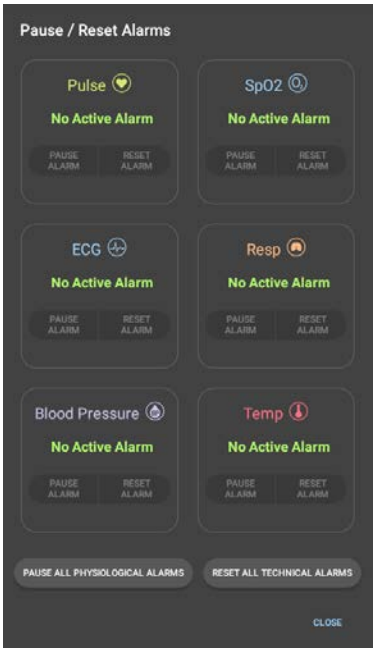






v. The **PAUSE / RESET ALARMS** screen shows a detailed view of each active alarm. If a vital sign has no active alarm, the screen will display "No Active Alarm".

– Active low priority technical alarms are shown with a solid blue CAUTION icon.
– Active low priority physiological alarms are shown with a solid yellow CAUTION icon.
– Active medium priority physiological alarms are shown with a flashing yellow CAUTION icon.
– Active high priority physiological alarms are shown with a flashing red CAUTION icon.



vi. From the **PAUSE / RESET ALARMS** screen, the user can reset any active Probe Off alarm by pressing the **RESET ALARM** button next to the relevant vital sign.

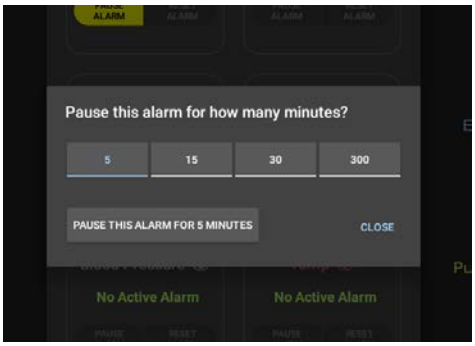
The user can also reset all active Probe Off alarms by pressing the **RESET ALL TECHNICAL ALARMS** button.

vii. From the **PAUSE / RESET ALARMS** screen, the user can pause any active physiological alarm by pressing the **PAUSE ALARM** button next to the relevant vital sign.

The user can also pause all active physiological alarms by pressing the **PAUSE ALL PHYSIOLOGICAL ALARMS** button.

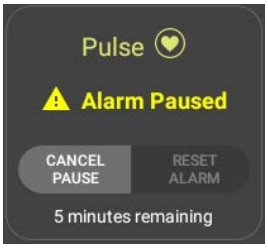
- If any **PAUSE ALARM** button is pressed, a second window appears, prompting the user to specify the alarm pause time.

These pause time options are configured by the user from the **HOSPITAL ADMINISTRATOR SETTINGS** screen.



viii. From the **PAUSE / RESET ALARMS** screen, the user can re-enable a paused physiological alarm by pressing the **CANCEL PAUSE** button next to the relevant vital sign.

- Text indicating the amount of time the alarm will continue to be paused for will appear under the **CANCEL PAUSE** and **RESET ALARM** buttons for the relevant vital sign



WARNING	When an alarm notification occurs it is an indicator that the patient needs increased attention. Therefore, it is important for clinical personnel to pay particular attention to the patient. It is the responsibility of the healthcare professional to take appropriate clinical actions, including physically check on the patient if necessary, before enabling the **PAUSE ALARM** function.

NOTE

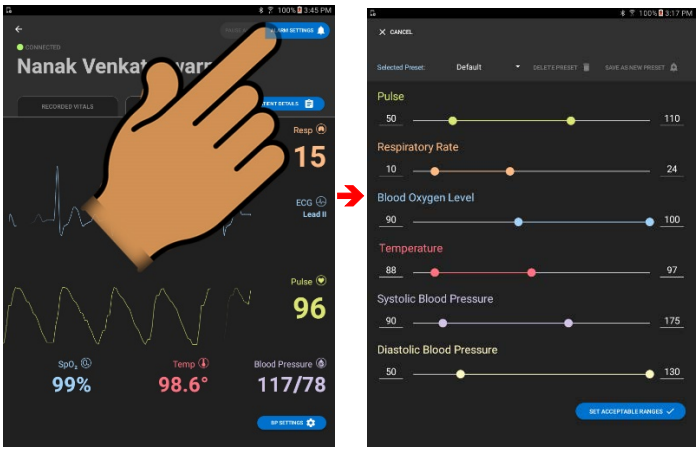
The PAUSE ALARM button will only illuminate when an alarm condition exists.

NOTE

Any displayed ECG alarms are based on a rate-based detection algorithms, not a waveform-based analysis

Accepting / Adjusting Alarm Values

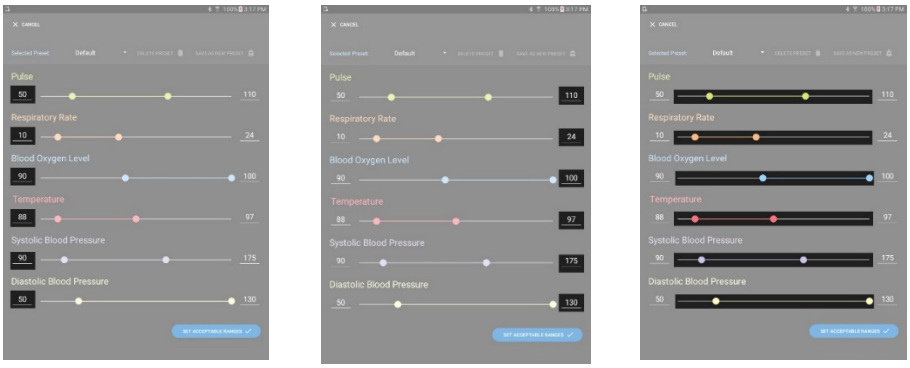
i. Alarm values may be viewed or adjusted by pressing the **ALARM SETTINGS** button on the upper right hand portion of the **LIVE VITALS** screen.



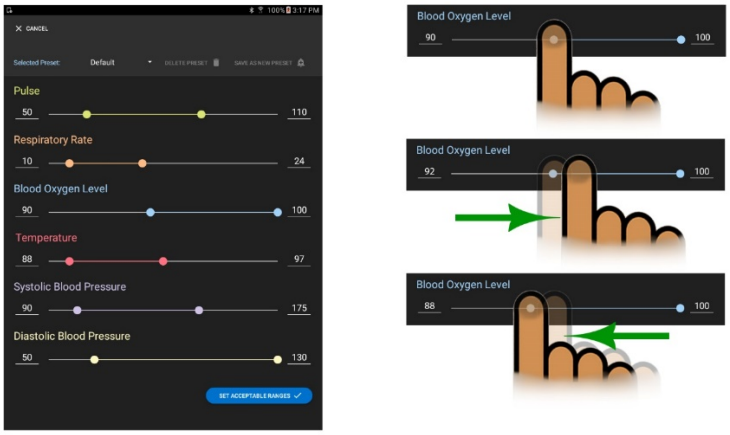
ii. The minimum alarm values will be displayed numerically on the left.

iii. The maximum alarm values will be displayed numerically on the right.

iv. The alarm adjustments sliders are displayed in the middle.

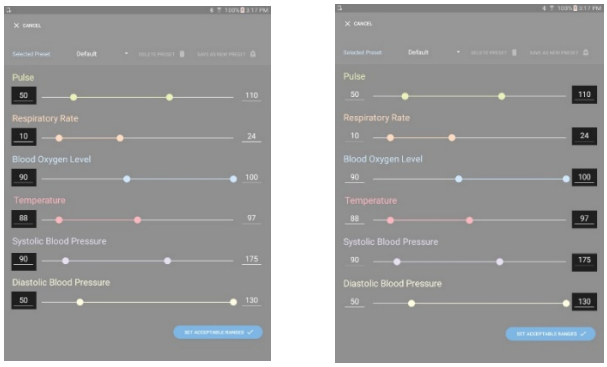


v. The minimum and maximum alarm values may be adjusted by the sliding bars on the **ALARM SETTING** screen



- Pressing a finger on the left-hand circle on the alarm line and moving that ball to the right raises the alarm value.
- Pressing a finger on the right-hand circle on the alarm line and moving that ball to the left lowers the alarm value.

vi. The minimum and maximum alarm values may also be adjusted by selecting the current alarm values, and entering a new value.

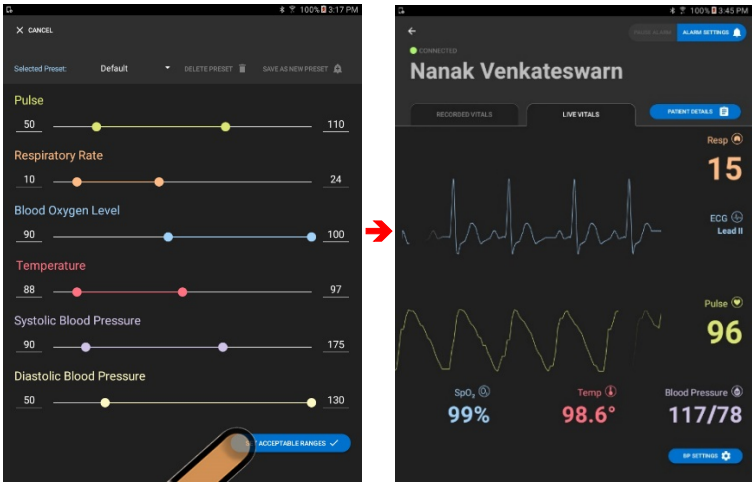


vii. Default Alarm Values

Default alarm values can be viewed in the Alarms section of this document.

viii. If the Alarm Values are acceptable then the user may return to the Live Vitals screen by pressing the **SET ACCEPTABLE RANGES** button on the lower left-hand corner of the **ALARM VALUES** screen.

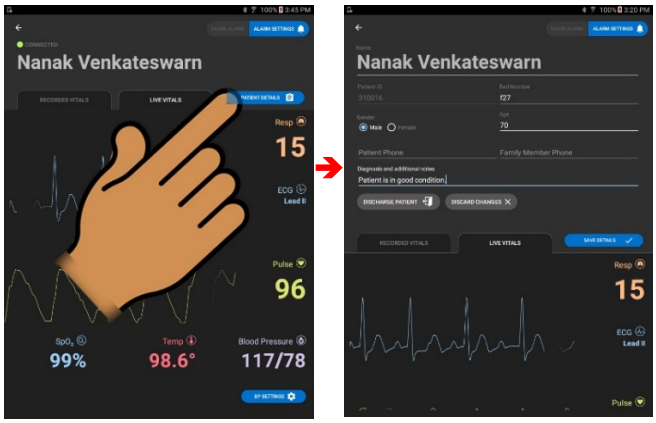
After pressing **SET ACCEPTABLE RANGES** the Tablet will return to the **LIVE VITALS** screen.



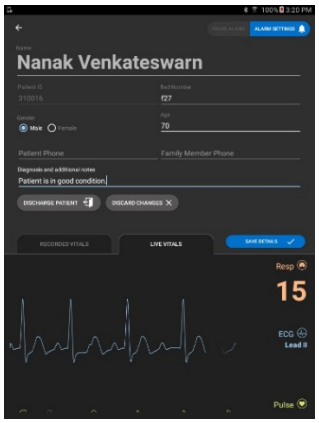
– pressing a finger on the left-hand circle on the alarm line and moving that ball to the right.

4. Patient Details

a. The **PATIENT DETAILS** screen may be accessed by pressing the **PATIENT DETAILS** button on the right-hand side of the **LIVE VITAL SIGNS** or **RECORDED VITALS** screens.



b. PATIENT DETAILS screen



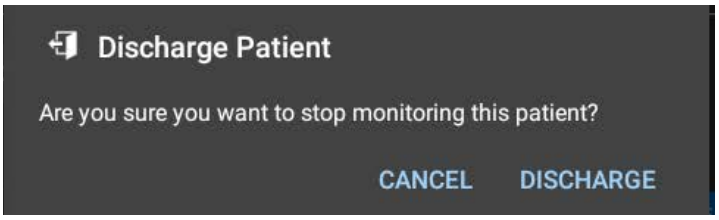
i. In this screen the user may edit the following
- Patient Name
- Patient ID number
- Patient Bed Number
- Patient Age

ii. The user may also add notes by pressing the NOTES field and typing in notes with the screen-provided alpha-numeric keyboard.

iii. The user may also discharge the patient.

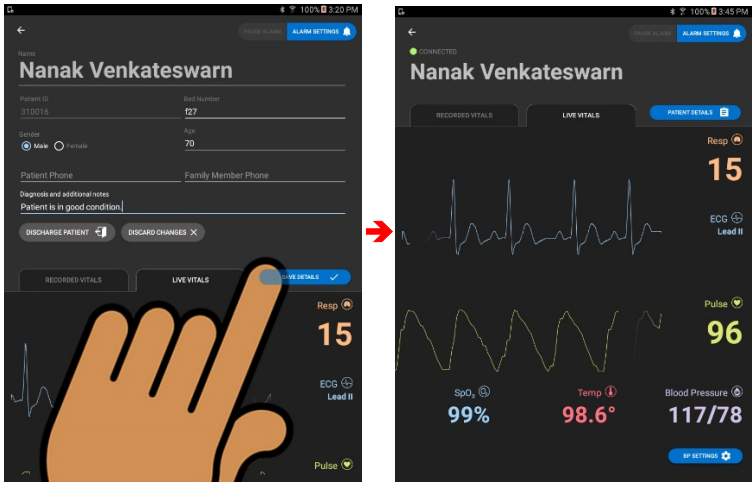
iv. In this screen the user may also discharge the patient by pressing the **DISCHARGE PATIENT** button.

If the user chooses DISCHARGE PATIENT, a window will pop-up asking the user to confirm the order to discharge the patient.



v. In this screen the user may cancel all edits by pressing the **DISCARD CHANGES** button.

vi. In this screen the user may save patient detail edits by pressing the **SAVE DETAILS** button.



– When the **SAVE DETAILS** button is pressed the screen returns to the **LIVE VITALS** or **RECORDED VITALS** screen.

5. Safely Terminating Use

a. To safely terminate use of the SMS, disconnect the sensors from the patient and turn off the monitor using the power switch on the rear of the device.

6. Error, System, and Fault Messages

Message	Potential Causes
The Stasis Tablet Application has encountered a problem that it cannot recover from. Please try restarting the tablet. If this problem persists, contact Stasis.	Nonvolatile memory (local storage) is corrupted. Program memory is corrupted. Tablet BLE module (Android framework) is unresponsive.
Add Patient: Could not add patient. The clinician you entered does not exist. Please select a clinician from the dropdown. Patient Details: Could not save changes. The clinician you entered does not exist. Please select a clinician from the dropdown.	Invalid clinician name entered in the 'Clinician name' field when admitting a patient.
Could not connect to Monitor. Patient was not created.	Monitor BLE connection/write operation failure when admitting a patient.
Patient ID found on patient list.	User enters ID of patient already admitted (i.e. active) when attempting to add a new patient.

Patient could not be admitted because the monitor you're trying to admit to is not compatible with this version of the tablet application. The monitor version is %s and the tablet version is X.	Tablet application and Monitor P1 application on incompatible major/minor software versions.
<Field Name> is a required field.	A field marked as required (in hospital authority settings) is left empty when adding a new patient.
Error accessing patient file. Please try again.	Patient file fails to successfully load from local storage.
Unable not connect to Monitor, please try again.	Unable to establish connection with Monitor when patient file is opened for admitted patient.
Alarm could not be silenced because tablet is disconnected from the monitor.	Connection with Monitor lost when attempting to pause alarms.
Check BP Cuff Placement.	Unrealistic BP values (out of BP board/monitor error checking ranges) detected.
NIBP Failure detected.	Monitor detects error with BP board.
Sorry, no Monitor connection was detected. Your changes will not be saved.	Writing new alarm settings to Monitor after returning from alarm settings view fails.
You cannot name your preset 'Default' or 'Custom', sorry.	User tries to name a new custom preset 'Custom' or 'Default'.
Out of bounds. Enter a value between <min_value> and <max_value>.	User tries to enter an invalid value for alarm settings ranges.

X. ALARMS

WARNING

Do not set the alarm limits to extreme values to prevent the triggering of alarms. This could lead to injury or death to a patient if an alarm does not sound for a dangerous condition.

WARNING

It is the responsibility of the operator to ensure that the alarm pre-set is suitable for each patient.

The functionality of the alarm system is checked every time the Stasis Monitor is turned on. The alarm speaker should beep 3 times every time the Stasis Monitor is turned on using the power switch on the rear of the device. If no audio is heard when the Stasis Monitor is turned on, or the audio sounds muffled or otherwise abnormal, remove the monitor from service immediately and notify Stasis to have the monitor serviced.

After the loss of the external power source the monitor will retain its alarm settings for a minimum of 3 hours.

The volume of the audio alarms is as follows (A-weighted):

Low Priority Alarms: 62.5 dB(A)
Medium Priority Alarms: 62.2 dB(A)
High Priority Alarms: 60.5 dB(A)

Alarm Types:

Type	Priority	Visual Indication	Audible Indication
Asystole (physiological)	High	Red icon, flashing at 2 Hz (250 ms on, 250 ms off)	• 325 Hz, 100ms Beep • Wait 100ms • 325 Hz, 100ms Beep • Wait 100ms • 325 Hz, 100ms Beep • Wait 300ms • 325 Hz, 100ms Beep • Wait 100ms • 325 Hz, 100ms Beep • Wait 10 seconds • 325 Hz, 100ms Beep • Wait 100ms • 325 Hz, 100ms Beep • Wait 100ms • 325 Hz, 100ms Beep • Wait 300ms • 325 Hz, 100ms Beep • Wait 100ms • 325 Hz, 100ms Beep • Wait 10 seconds • Repea
Heart rate, SpO2, respiration rate, NIBP, or temperature alarm limits exceeded (physiological)	Medium	Yellow icon, flashing at 0.625 Hz (800 ms on, 800 ms off)	• 325 Hz, 200ms Beep • Wait 200ms • 325 Hz, 200ms Beep • Wait 200ms • 325 Hz, 200ms Beep • Wait 20 seconds • Repeat
Critical Battery (technical)	High	Red battery icon, flashing at 2 Hz (250 ms on, 250 ms off)	Same as high priority physiological
Low Battery (technical)	Low	Yellow battery icon, constantly on	None
Other Technical Alarms	Low	Cyan icon, constantly on	• 325 Hz, 200ms Beep • Wait 200ms • 325 Hz, 200ms Beep • Wait 20 seconds • Repeat

Types of Technical Alarms:

- NIBP failure detected
- Pulse oximeter off patient
- ECG leads off patient
- Temperature probe off patient
- Pulse oximetry module hardware failure detected
- ECG module hardware failure detected
- NIBP module hardware failure detected

If multiple alarms are active simultaneously, the system will sound the highest-priority active alarm, and display all active alarms.

If the Stasis System detects a module failure, the icon for the associated vital signs will illuminate in cyan and the Stasis logo will illuminate red. In case this occurs, contact Stasis customer support.

Alarm Deactivation:

Default alarm audio pause time: 60 seconds

Audio for all active physiological alarms can be paused for a specified duration with the Stasis Tablet. The physiological alarms to have their audio paused can be specified, or audio of all of the physiological alarms can be paused at once. This audio paused state can be canceled by the Stasis Tablet, and the audio pause state will be canceled automatically if the associated vital sign returns inside the set alarm limits.

The visual indication of the alarm state will not be affected by the alarm audio pause.

Technical alarms can be reset by the Stasis Tablet. The technical alarms to be reset can be specified, or all of the technical alarms can be reset at once. This reset cannot be reversed.

Default Alarm Limits:

	Default Lower	Default Higher	Minimum Allowed	Maximum Allowed
Pulse	**50**	**110**	**30**	**150**
Respiration Rate	**10**	**25**	**6**	**50**
Blood Oxygen Level	**90**	**100**	**82**	**100**
Temperature	**89**	**99**	**88**	**108**
NIBP				
Systolic Blood Pressure	**90**	**180**	**70**	**230**
Diastolic Blood Pressure	**50**	**130**	**30**	**130**

Alarm System Delays:

The following alarms will be activated within the following times after an alarm condition is reached:

High priority alarm signal generation delay: 10 seconds
Medium priority alarm signal generation delay: 10 seconds
Low priority technical alarm signal generation delay: 10 seconds

Alarm System Security:

Hospital administrators are the only users who are authorized to make changes to the alarm presets and alarm delay times. In order to enforce this, an administrator PIN is required to be entered before changes to the restricted alarm settings can be saved.

Description of Alarm Symbols:

Symbol	Description
 **Low-Priority Alarm**	**This symbol indicates a low-priority technical alarm. The symbol appears on the tablet in blue.**

Symbol	Description
 **Medium-Priority Alarm**	**This symbol indicates a medium-priority physiological alarm. The symbol appears on the tablet in yellow.**

Symbol	Description
 **High-Priority Alarm**	**This symbol indicates a high-priority physiological alarm. The symbol appears on the tablet in red.**

Symbol	Description
 **Alarm Audio Pause**	**This symbol indicates that alarm audio is paused. Note that this indicates that an alarm condition is currently active, but the associated alarm audio is currently muted.**

XI. SYSTEM MAINTENANCE

A. The system complies with IEC 60601-1/EN 60601-1 standards.

B. If the Stasis Monitor is in storage, check the battery every 3 months to ensure that it is still able to charge and power the monitor.

C. Repair

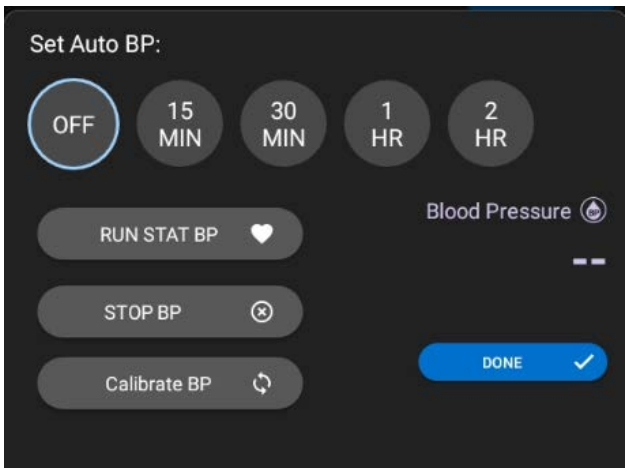
 **CAUTION**	If you believe that your SMS is in need of repair, contact your Stasis sales representative for instructions on sending the system to Stasis for diagnosis and repairs.
 **CAUTION**	Installation of unauthorized software will result in the voiding of the SMS service agreement.
 **WARNING**	The battery can only be replaced by service personnel using a tool.

D. NIBP Calibration Verification Procedure

This mode is restricted to access by the responsible organization and service personnel and is not available in normal use.

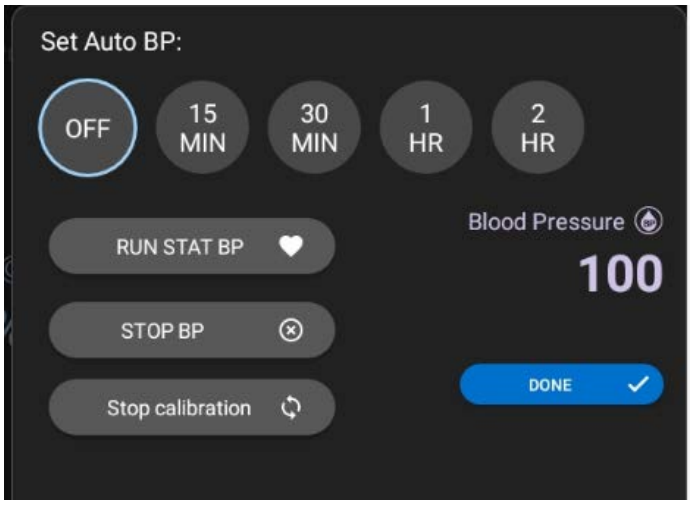
a. Enable the "Show BP calibration button" feature in hospital administrator settings.

b. Go to BP menu and start the Calibration.



c. Set the Cuff pressure to 80, 100, 150,200,250 using a simulator or a manual sphygmomanometer and note down the readings.

d. Stop the calibration after taking the readings.



e. The measured values should be less than or equal to +/- 3mmHg of the actual Cuff pressure

f. If measured values are outside of the set cuff pressures, contact Stasis for monitor refurbishment

E. Cleaning Instructions

1. Stasis Monitor

a. Turn off the SMS before cleaning.

b. Wipe exposed surfaces with a soft cloth or a pad moistened with a mild detergent solution.

The SMS can be sanitized by wiping down with a soap and water solution, 70% isopropyl alcohol, or dilute glutaraldehyde solution.

Do not sterilize by autoclave or gas sterilization methods.

Do not spray, pour, or spill liquids into or onto the unit, accessories, connectors, buttons, or openings in the housing.

2. Reusable SpO_2 Sensor

a. Disconnect the SpO_2 sensor from the SMS before cleaning

b. Clean the inside of the sensor, and the two optical elements, with a cotton swab or equivalent.

c. Moisten cotton swab, or equivalent, with a mild detergent solution or medical alcohol (70% isopropyl alcohol solution).

Do not immerse or wet the SpO_2 sensor.

F. Disposal Instructions

Dispose of all electrical components associated with the SMS in accordance with local requirements and regulations.

XII. OPERATING CONDITIONS

A. The system complies with IEC60601-1/EN 60601-1 standards.

B. Environmental Specifications:

1. Operating

Temperature	10°C - 40°C (50°F - 104°F)
Altitude	-390 m - 3,000 m (-557 ft – 9,843 ft)
Pressure	71 to 106 kPa
Relative Humidity	15% - 95% non-condensing

2. Transport and Storage

Temperature	-20°C - 50°C (-4°F - 122°F)
Altitude	-390 m - 3,000 m (-557 ft – 9,843 ft)
Pressure	71 to 106 kPa
Relative Humidity	15% - 95% non-condensing

C. IT Network Specifications

a. Purpose of SMS Connection to an IT Network

The Stasis System can optionally allow for remote patient monitoring through the Stasis Cloud. The Stasis Cloud allows users to view recorded vital signs information. It does not allow for viewing of live patient information or include any real-time alarm capability.

To use the Stasis Cloud for remote viewing, the Stasis Tablet Application must be connected to a Hospital's IT Network over Wi-Fi, and must authenticate with the Stasis Cloud.

The Stasis System is designed to work stand-alone without the Stasis Cloud. The Stasis System is designed such that network failures, including temporary failures of a hospital's Wi-Fi network, will not disrupt the Stasis Monitor and the Stasis Tablet Application from working normally.

b. Required Characteristics, Configuration, and Technical Specifications of the IT Network

- The Stasis Tablet Application is designed to connect to a network according to the 802.11b standard, which has the marketing name of Wi-Fi.

- The Stasis Tablet Application is designed to be used on a Wi-Fi network secured with WPA2-PSK security.
- Your hospital's IT network must be configured properly to allow the Stasis Tablet Application to communicate with the Stasis Cloud.
- The Stasis Tablet Application will not send any patient information over Wi-Fi unless it is configured to communicate with the Stasis Cloud from the Hospital Administrator Settings screen.

c. Intended Information Flow

Patient vitals data is collected on the Stasis Monitor. This data is transferred wirelessly via Bluetooth Low Energy (BLE) to the Stasis Tablet. The Stasis Tablet then transfers this information via an 802.11 Wi-Fi network to the Stasis Cloud. Operators can then use any internet-connected device to view this recorded patient vitals information via the Stasis App, which receives information from the Stasis Cloud.

d. Potential Hazardous Situations Resulting from the Failure of the IT Network to Provide the Required Characteristics

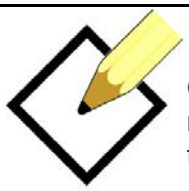
- The Stasis Monitor is the source of all alarms. Failure of the IT network will not result in the Stasis Monitor failing to alarm.
- Failure or misconfiguration of the IT network may result in data not being sent to the Stasis Cloud, which may inconvenience operators.
- Failure or misconfiguration of the IT network may result in previously unidentified risks to patients, operators, or third-parties.
- Hospitals are responsible for identifying, evaluating, and controlling these risks.
- Changes to the IT network, including changes in network configuration, connection or disconnection of additional devices, and upgrades of equipment may result in IT network failures.
- Stasis Labs will work with hospitals during installation and upon IT network changes to ensure the IT network is configured correctly for the Stasis System.

WARNING

Connection to IT networks including other equipment could result in previously unidentified risks to patients, operators, or third parties.

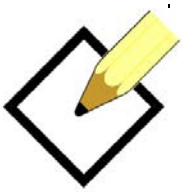
WARNING

The responsible organization should identify, analyze, evaluate, and control any additional risks resulting from the SMS being connection to IT networks including other equipment.



NOTE

Changes to the IT network could introduce new risks that require additional analysis by the responsible organization.



NOTE

Changes to the IT network include:

-Changes in network configuration

-Connection of additional items

-Disconnection of items

-Upgrade of equipment

D. Electrical

The Stasis Monitoring System requires special precautions regarding EMC and must be installed and put into service according to the EMC information provided in this section.

1. Electromagnetic Emissions

a. Complies with IEC 60601-1-2

Table 1 – Guidance and manufacturer's declaration – electromagnetic emissions – for all medical electrical equipment and medical electrical systems

Guidance and manufacturer's declaration – electromagnetic emissions		
The Stasis Monitoring System is intended for use in the electromagnetic environment specified below. The customer or the user of the Stasis Monitoring System should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions EN 55011	Group 1	The Stasis Monitoring System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions EN 55011	Class B	The Stasis Monitoring System is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions EN 61000-3-2	Complies	
Voltage fluctuations / flicker emissions EN 61000-3-3	Complies	

Bluetooth Details:

Frequency of emission: 2402-2480 MHz

Type of modulation: Gaussian frequency shift modulation

Effective radiated power: 8 dBm

2. Electromagnetic Immunity

Table 2 – Guidance and manufacturer's declaration – electromagnetic immunity – for all medical electrical equipment and medical electrical systems

Guidance and manufacturer's declaration – electromagnetic immunity			
The Stasis Monitoring System is intended for use in the electromagnetic environment specified below. The customer or the user of the Stasis Monitoring System should assure that it is used in such an environment.			
Immunity test	Error! Reference source not found. **60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) EN 61000-4-2	± 6kV contact ± 8kV air	± 6kV contact ± 8kV 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 EN 61000-4-4	± 2 kV for power supply lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN 61000-4-5	± 1 kV line(s) to line(s)	± 1 kV line(s) to line(s)	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11	< 5 % U_T (> 95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (> 95 % dip in U_T) for 5 s	< 5 % U_T (> 95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (> 95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Stasis Monitoring System requires continued operation during power mains interruptions, it is recommended that the Stasis Monitoring System be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field EN 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 commercial or hospital environment.
NOTE U_T is the AC mains voltage prior to application of the test level.			

Table 4 – Guidance and manufacturer's declaration – electromagnetic immunity – for all medical electrical equipment and medical electrical systems that are not life-supporting

Guidance and manufacturer's declaration – electromagnetic immunity			
The Stasis Monitoring System is intended for use in the electromagnetic environment specified below. The customer or the user of the Stasis Monitoring System should assure that it is used in such an environment.			
Immunity test	Error! Reference source not found. Error! Reference source not found. **60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of < EUT Name > , including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF EN 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	$d = 1{,}2\sqrt{P}$
Radiated RF EN 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}3\sqrt{P}$ 800 MHz to 2,5 GHz where *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). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a 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 assess 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 < EUT Name > is used exceeds the applicable RF compliance level above, the < EUT Name > should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the < EUT Name > . b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Table 6 – Recommended separation distances between portable and mobile RF communications equipment and the medical electrical equipment and medical electrical systems – for medical electrical equipment and medical electrical systems that are not life-supporting

Recommended separation distances between portable and mobile RF communications equipment and the Stasis Monitoring System			
The Stasis Monitoring System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Stasis Monitoring System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Stasis Monitoring System as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2.3\sqrt{P}$
	3V	**3V/m**	**3V/m**
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Cables Used in System:

Cable	Part Number	Length
SpO2 Cable	U410-147	3 m
ECG Cable	EA021S3I	3 m
Temperature Cable	T2252-AS	3 m
Power Cable	1899240	3 m

The use of cables other than those specified may result in increased emissions or decreased immunity of the ME equipment or ME system.

Do not use the SMS in a MRI suite.

The ME equipment or ME system should not be used adjacent to or stacked with other equipment, and that if adjacent or stacked use is necessary, the ME equipment or ME system should be observed to verify normal operation in the configuration in which it will be used.

Use of accessories, transducers, or cables with ME equipment and ME systems other than those specified may result in increased emissions or decreased immunity of the ME equipment or ME system.

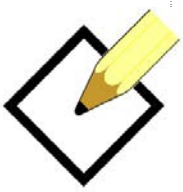
The Stasis Monitor may be interfered with by other equipment, even if that other equipment complies with CISPR EMISSION requirements.

WARNING	

 **WARNING**	Portable and mobile RF communications equipment may affect the function of the Stasis Monitoring System.

 **WARNING**	This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the Stasis Monitoring System or shielding the location.

 **WARNING**	Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones, WIFI-enabled devices, and land mobile radios; amateur radios; AM and FM radio broadcast; and TV broadcast, and WIFI transmission cannot be predicted theoretically with survey accuracy. To assess 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 SMS is used exceeds the applicable RF compliance level described in this section, the SMS should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the SMS.



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

FCC Compliance Statements

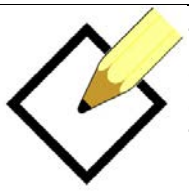
This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

1. This device may not cause harmful interference, and
2. This device must accept any interference received, including interference that may cause undesired operation.

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

This equipment should be installed and operated with minimum distance 20 cm between the radiator and your body.

Part 15B Compliance Statements for Digital Devices:



This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful

interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

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

XIII. TECHNICAL SUPPORT

A. If you believe that your system is malfunctioning, contact Stasis at contact@stasislabs.com for instructions on returning your current system and receiving a replacement.

Manufacturer: Stasis Labs, Inc.

Model: Stasis Monitoring System

Address: 9121 Airdrome St., Los Angeles, CA 90035

XIV. RECORDS

REVISION	SIGNIFICANT CHANGES	DCO#	EFFECTIVE DATE
A	Initial release	0034	1/4/18
B	See redlined	0053	1/17/18