WVSM

WIRELESS VITAL SIGNS MONITOR

NON-INVASIVE BLOOD PRESSURE | PULSE OXIMETRY | ELECTROCARDIOGRAM

Operator's Manual

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare professional.

Athena GTX ® reserves the right to make changes and improvements to this manual, and the products it describes at any time, without notice or obligation.

This device is produced in accordance with one or more of the following US patents: Patent Pending.

Operator's Manual Document Control Number: 600-0001-01 Rev: E, 6 June 2012

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1.0 Safety Information – General

WARNING: Before using the WVSM® device, read and understand this manual in its entirety.

WARNING: The equipment is provided with signal terminals supplied by and to be connected to secondary circuits complying with Class 2 requirements.

WARNING: Be careful not to position the WVSM® device in a manner that would make it difficult to operate or disconnect the device accessories or charging unit.

WARNING: The use of the WVSM® device is restricted to one PATIENT at a time.

WARNING: A safety hazard may exist due to simultaneous use of other PATIENT-connected MEDICAL ELECTRICAL EQUIPMENT, for example, a cardiac pacemaker or other electrical stimulators.

This section describes general safety information about this device. Additional safety information is also provided throughout this manual.

1.1 Contraindications

1. The Pulse-Ox (SpO_2) module does not meet the defibrillation-proof requirement per IEC 60601-1: 1990, clause 17.h.
2. DO NOT attach the NIBP cuff to a limb being used for IV infusions as the cuff inflation can block the infusion, potentially causing harm to the patient.
3. The NIBP should not be used when oscillometric pulses may be altered by other devices or techniques such as External Counterpulsation (ECP) or Intra Aortic Balloon Pump Counterpulsation.

1.2 Warnings

WARNING: DO NOT use the WVSM® device in an explosive atmosphere or in the presence of flammable anesthetics or gases.

WARNING: DO NOT use the WVSM® device or accessories if they are damaged or broken. If damaged, remove immediately from service.

WARNING: Using the WVSM® device outside of specified operating environment may adversely affect its performance.

WARNING: DO NOT use the WVSM® device or accessories in an MRI environment.

WARNING: Pay special attention to the type of electrodes used since some may be subject to large offset potentials due to polarization. Only use electrodes that are constructed of the same materials. Recovery time after application of defibrillator pulses may be especially compromised.

WARNING: DO NOT use the WVSM® device to monitor Pediatrics or Neonates.

WARNING: To avoid the possibility of patient entanglement or strangulation carefully route all patient cables and tubing.

WARNING*:* To avoid risk of electric shock, this equipment must only be connected to a supply main with protective earth/grounding.

WARNING: Use only Athena GTX® approved accessories with the WVSM® device. Improper functioning and/or insufficient protection during defibrillation could result if alternate ECG leads are used.

WARNING: DO NOT allow conductive portions of the ECG electrodes, leads and cables to come into contact with any other conductive parts including earth ground.

WARNING: The WVSM® device can be used during defibrillation. Inaccurate readings may occur during defibrillation and for a short time after defibrillator use.

WARNING: DO NOT sterilize the WVSM® device or its accessories, (by irradiation, steam, ethylene oxide, autoclave or other methods). Cleaning instructions are included in the maintenance section later in this manual.

WARNING: Line isolation monitor transients may resemble actual cardiac waveforms and thus inhibit heart rate alarms. For methods to minimize this problem, see instructions for proper electrode placement and cable arrangement.

WARNING: PACEMAKER PATIENTS. The WVSM® device may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. DO NOT rely entirely upon rate meter alarms. Keep pacemaker patients under close surveillance. See this manual for disclosure of the pacemaker pulse rejection capability of this instrument.

WARNING: An improperly connected electrosurgical unit may cause a patient to receive a burn. The WVSM® device may also incur damage or cause inaccurate readings. Proper instructions should be followed to avoid such consequences.

WARNING: ECG leads may become damaged if used during defibrillation. DO NOT reuse the ECG leads after use with defibrillators unless their functionality is properly verified.

WARNING: The use of accessories and cables other than those specified by Athena GTX® may result in inaccurate readings or damage to the WVSM® device.

WARNING: The use of accessories and cables other than those specified by Athena GTX® may result in increased electromagnetic emissions and/or a decreased immunity of the WVSM® device. See Accessories list later in this manual.

WARNING: Use only approved/recommended power adapters. The charging unit is specified as part of the WVSM system - use only the approved unit as specified in section 18.2.

WARNING: The WVSM® device should not be used adjacent to or stacked with other equipment. If this becomes necessary, the WVSM® device should be observed to verify normal operation.

WARNING: No modification of the WVSM® device or its accessories is allowed.

WARNING: The Pulse-Ox function does not meet defibrillation-proof requirements.

WARNING: The Pulse-Ox function will not work correctly if there is a blood flow restrictor such as a tourniquet or blood pressure cuff. If possible, make sure the Pulse-Ox function is on the opposite arm as the blood pressure cuff.

WARNING: Using the Pulse-Ox function under the minimum amplitude of 0.3% modulation may cause inaccurate results.

WARNING: Certain changes in the blood flow may cause inaccurate readings. Make sure to validate patient condition before changing patient care.

WARNING: Inspect the Pulse-Ox sensor application site at least every 6 to 8 hours to check sensor position and skin integrity.

WARNING: Pulse-Ox function is calibrated to display functional oxygen saturation.

WARNING: Be sure that all blood pressure tubing is not pinched and that flow is not restricted in any way while taking blood pressure measurements. The cuff must be correctly fitted, placed, and checked to be operational. The Patient Sensor Connections section below has guidelines for proper fitting. If the cuff is not fitted properly, or the tubing is pinched, accuracy can be diminished or fail.

WARNING: In radical cases the NIBP system could fail and cause restriction to the patient's limb. Furthermore, frequent measurements could cause poor circulation depending on the patient's condition, frequency, and other physiological variables. Be sure to check the monitored limb for proper circulation on a schedule deemed appropriate by trained personnel.

WARNING: Prolonged over-inflation of the NIBP cuff could cause poor circulation depending on the patient's condition. Be sure to check the monitored limb for proper circulation on a schedule deemed appropriate by trained personnel.

WARNING: Cuff placement should avoid limbs that are being used for intravenous delivery of fluids, SPO_2 monitoring or other possible obstructions.

WARNING: Patient should remain still while blood pressure measurements are being taken. Patient movement may produce inaccurate results.

WARNING: The WVSM® device only displays the last NIBP measurement. If there is a critical change in condition between measurements, alarms will not sound.

WARNING: DO NOT immerse the WVSM® device or any accessories in water, solvents, cleaning solutions or other liquids. Follow the cleaning instructions included in the maintenance section later in this manual.

WARNING: Penetration of water or other liquids into the WVSM® device may result in damage, and the device may not function properly. If this occurs, immediately remove the device from the patient and discontinue use.

WARNING: Patient positioning and patient physiological condition can adversely affect the accuracy of blood pressure measurements. Please follow the guidelines in Patient Sensor Connections to avoid problems.

WARNING: Alarm indications on the PC or PDA are for additional information purposes only and shall not be solely relied upon for receipt of ALARM SIGNALS.

WARNING: Prior to using the WVSM® device to monitor a patient, all alarm limit settings should be reviewed to ensure they are appropriate for the patient being monitored.

WARNING: A HAZARD can exist if different ALARM PRESETS are used for the same or similar equipment in any single area, e.g. an intensive care unit or cardiac operating theatre.

WARNING: Make sure that the AC adapter is unplugged from the AC power source before cleaning.

WARNING: There are no serviceable items in the WVSM® device. DO NOT attempt to disassemble. For repairs or battery replacement contact Athena GTX®.

WARNING: A multiple socket outlet or extension cord may not be connected to the WVSM® device. Risks of connecting the WVSM® device to a multiple socket outlet include excessive patient leakage current and patient electrical shock.

WARNING: A computer not in accordance with IEC 60601-1 must be placed outside the patient environment. System configuration must to be evaluated by the Responsible Organization in accordance with IEC 60601-1. No multiple socket outlet shall be used - risk of excessive patient leakage current.

1.3 Cautions

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare professional.

CAUTION: Use caution when removing disposable ECG electrodes to avoid damaging patient's skin.

CAUTION: Check the skin around the patient's ECG electrodes for signs of irritation.

CAUTION: For best monitoring results minimize patient motion.

CAUTION: Accuracy of Pulse-Ox function may be affected if cable length is increased.

CAUTION: The Pulse-Ox function is intended to determine the percent of arterial oxygen saturation of hemoglobin, which may be affected by any of the following conditions: high levels of dysfunctional hemoglobin (or methemoglobin), excessive ambient light, excessive motion, electrosurgical interference, improperly applied sensor, incorrect sensor type, poor pulse quality, venous pulsations, anemia or low hemoglobin concentrations, cardiogreen or other intravenous dyes, carboxyhemoglobin, methemoglobin, dysfunctional hemoglobin, artificial nails or fingernail polish, or a sensor not at heart level.

CAUTION: Though the Pulse-Ox function attempts to remove motion artifact, occasionally some motion artifact may be interpreted as good pulse quality.

CAUTION: The Pulse-Ox function complies with IEC EN 60601-1-2:2001 for electromagnetic compatibility for medical electrical equipment and/or systems. This standard attempts to reduce the occurrence of an electrical device interfering with typical medical installations.

CAUTION: Portable or mobile RF communications equipment may affect the function of the WVSM® device.

CAUTION: Readings may be affected by the use of an electrosurgical unit (ESU).

CAUTION: The Pulse-Ox function may not work on cold fingers, because of lack of circulation. Warm or rub the finger to increase circulation or reposition sensor.

CAUTION: Setting ALARM LIMITS to extreme values can render the ALARM SYSTEM useless.

CAUTION: Use of the data port / data cable is restricted to use with, and connected to, approved accessories. Unauthorized connection to other equipment via the DATA or AUX ports could result in malfunction of the equipment or damage to WVSM® device or connected equipment.

CAUTION: Inspect the WVSM® device and accessories for damage before cleaning.

CAUTION: Use only approved cleaning solutions.

CAUTION: Refer to Pulse-Ox sensor Accessory instructions for additional or updated information on proper cleaning procedure.

CAUTION: Refer to Cuff Accessory instructions for additional or updated information on proper cleaning procedure.

CAUTION: When disposing of or recycling the WVSM® device follow local government ordinances and recycling instructions.

CAUTION: The WVSM® device contains a lithium ion battery. Potential for fire or burning. DO NOT disassemble, crush, heat, burn or incinerate.

1.4 Adverse Reactions

ADVERSE REACTION: Allergic exanthema (symptomatic eruption) in the area of the cuff may result, including the formation of urticaria (allergic reaction including raised edematous patches of skin or mucous membranes and intense itching) caused by the fabric material of the cuff.

Petechia (a minute reddish or purplish spot containing blood that appears in the skin) formation or Rumple-Leede phenomenon (multiple petechia) on the forearm following the application of the cuff, which may lead to Idiopathic thrombocytopenia (spontaneous persistent decrease in the number of platelets associated with hemorrhagic conditions) or phlebitis (inflammation of a vein) may be observed.

2.0 *Introduction*

2.1 Intended Use

The Wireless Vital Signs Monitor (WVSM®) is intended to be used as an adult patient monitor. It is indicated as a single or multi-parameter vital signs monitor for ECG, noninvasive blood pressure (NIBP) and SpO_2. It may be used in the following locations: Hospitals, healthcare facilities, emergency medical applications, during transport, and other healthcare applications. The monitor uses wireless communications to transmit vital signs data to a handheld device or personal computer.

The monitor is intended to be used by trained healthcare providers.

2.2 Manual Overview

This manual describes how to set up and use the Wireless Vital Signs Monitor (WVSM®). Important safety information regarding the proper use of this device is located throughout this manual.

Before using this device read and understand this manual in its entirety.

The overall system use and operation is described first and detailed instructions for each measurement parameter follows in later sections. Detailed performance specifications, maintenance and troubleshooting guides are also provided.

3.0 Device Overview

The WVSM® device is a small, rugged, highly mobile device designed to monitor patient vital signs (specifically ECG, SpO2, non-invasive blood pressure and heart rate). The WVSM® device can be used as a standalone monitor, with a Personal Data Assistant (PDA) or with a Microsoft Windows XP compatible Personal Computer (PC) with a wireless radio or data cable. The WVSM® PC Management Suite software is capable of monitoring a maximum of 20 WVSMTM devices at one time.

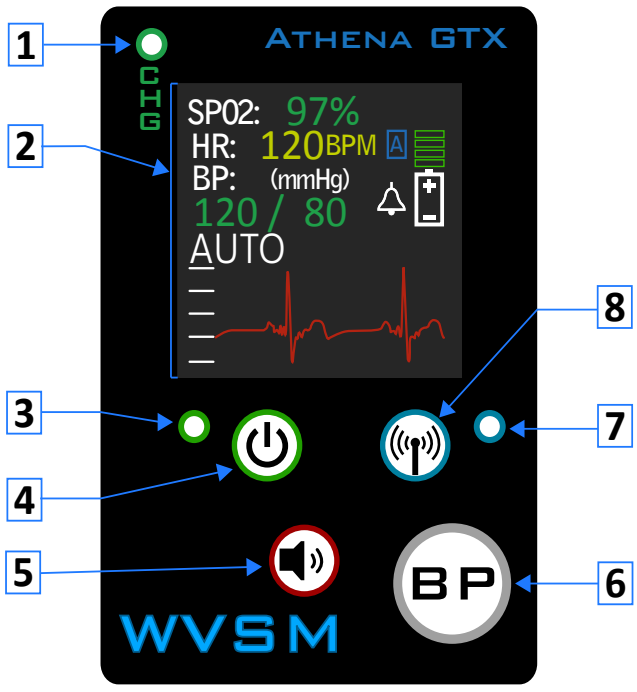
Limitations of Wireless Communications

As with any wireless system the ability to communicate between the WVSM® device and a PC can be greatly affected by distance, interference, attenuating masses, system resources, and topography. Wireless communications may also be adversely affected when multiple PCs are simultaneously uploading historical patient vital signs data.

In normal situations these conditions do not affect the device's ability to function as a standalone patient monitor. A wireless connection is not required for the device to perform its intended function. However, these conditions may temporarily affect the ability of the PC to maintain continuous Wi-Fi communications with the device, and therefore **the PC monitor should not be solely relied upon for patient monitoring. If communications are temporarily interrupted, the system will re-establish communications automatically and repopulate the dropped/missing data.**

3.1 Controls, Indicators and Symbols

3.1.1 Front Panel



1. Charge Status Indicator
2. Display
3. Power On/Off Indicator
4. Power On/Off
5. Alarm Silence
6. Take BP/ BP Mode Selector
7. WiFi On/Off Indicator
8. WiFi On/Off

Figure 1. WVSM™ Front Panel

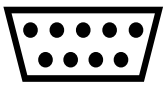
Table 1. Front Panel Functions		
Symbol	**Description**	**Function**
	Charge Status Indicator	Green = Battery charging completed Red = Battery charging Off = Charge fault condition
	Power On/Off Button and Indicator	Press and hold turns unit on. Press and hold again turns unit off. Green = Power On Off = Power Off
	Alarm Silence	Silences audio alarms
	Take BP/BP Mode Selector	Press and release Starts/Stops BP. Press and hold toggles between Normal and Turbo Modes
	WiFi On/Off Button and Indicator	Press and release toggles between WiFi On and Off Blue = WiFi On Off = WiFi Off

3.1.2 Bottom Panel

Figure 2. WVSM™ Bottom Panel

1. *Pulse-Ox Sensor Connection*
2. *ECG Cable Connections*
3. *NIPB Connection*

Table 2. Bottom Panel Sensor Connections

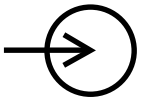
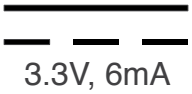
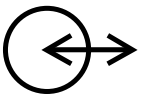
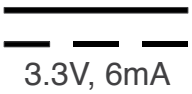
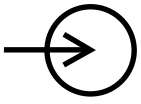
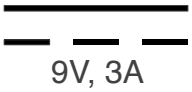
Parameter	Sensor/Connector	Symbol	Defibrillator-Proof
Pulse-Ox	Compatible with Nonin Pulse-Ox sensors only. See list of recommended accessories in this manual.		
ECG	Compatible with 1.5mm safety plug connectors. Use ECG cables provided with the device.		
NIBP	Compatible with SunTech NIBP cuffs. See list of recommended accessories in this manual.	NIBP	

3.1.3 Top Panel

Figure 3. WVSM™ Top Panel

1. AUX Sensor Connection (Future Use)
2. Data Cable Connection
3. AC Adapter/DC Input Port

Table 3. Top Panel Connections

Port	Sensor/Connector	Type	Power
AUX	Compatible with 2.5mm 3 contact plug. For future use sensor input only.		 3.3V, 6mA
DATA	Compatible with 2.5mm 4 contact plug. For use with Athena GTX supplied data cable.		 3.3V, 6mA
DC Input	Compatible with Athena GTX medical grade AC adapter. See list of recommended accessories in this manual.		 9V, 3A

3.1.4 Symbols

Table 4. Symbols Table Labels

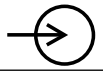
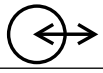
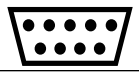
Symbol/ Icon	Description	Function
	Caution, consult accompanying documents	This symbol advises the reader to consult the accompanying documents for important safety-related information such as warnings and precautions that cannot, for a variety of reasons, be presented on the device itself.
	Consult instructions for use	This symbol advises the reader to consult the operating instructions for information needed for the proper use of the device.
REF	Catalog number	Device Part Number. Format: XXX-XXXX-XX.
SN	Serial number	Device Serial Number. Format: XXXX.
	Date of manufacture	This symbol is accompanied by the date that the device was manufactured. Format: MM-YYYY.
IPX2	Water Ingress Rating	Shows the device is protected to a water ingress level of dripping water at an angle of 15°.
	Non-ionizing electromagnetic radiation	Device includes an RF Transmitter (WiFi 802.11b/g).
	DC Voltage	Indicates where DC voltage is used.
Rx Only	Requires a prescription for use	Must be prescribed by a medical professional.
	DO NOT dispose of in the Trash	When disposing of or recycling the WVSM® device, follow local government ordinances and recycling instructions.
	Input	Identifies a connection port as an input only.
	Input / Output	Identifies a connection port as an input and output.
	ECG Connection	Connector identification and location for the ECG cables.
	Pulse Oximeter Connection	Connector identification and location for the Nonin Pulse-Oximeter sensor.
	Type BF applied part	Identifies applied part as Type BF.
	Defibrillation-proof type CF applied part	Identifies applied part as Type CF.

Table 5. Symbols Table Device User Interface		
Symbol	**Description**	**Function**
	Charge Status Indicator	Green = Battery charging completed Red = Battery charging Off = Charge fault condition
	Power On/Off Button and Indicator	Press and hold turns unit on Press and hold again turns unit off Green = Power On Off = Power Off
	Alarm Silence	Silences audio alarms.
	Take BP/BP Mode Selector	Press and release Starts/Stops BP. Press and hold toggles between Normal and Turbo Modes.
	WiFi On/Off Button and Indicator	Press and release toggles between WiFi On and Off. Blue = WiFi On Off = WiFi Off
	Battery Fuel Gauge	Bars show level of charge.
	Alarms Enabled	Audio alarms are active.
	Alarms Silenced	Audio alarms are silenced for 2 minutes.
	BP–Auto Mode	NIBP is in auto mode.
	BP–Manual Mode	NIBP is in manual mode.
	BP–Turbo Mode	NIBP is in turbo mode.
	BP–In Progress	Cuff is in the process of inflating and measuring NIBP.

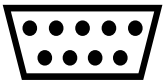
Table 6. Symbols Table Parameters		
Symbol	**Description**	**Function**
	ECG Connection	Connector identification and location for the ECG cables
	Pulse Oximeter Connection	Connector identification and location for the Nonin Pulse-Oximeter sensor
NIBP	Non-Invasive Blood Pressure Connection	Connector identification and location for the SunTech NIBP Cuff
	Type BF applied part	Identifies applied part as Type BF
	Defibrillation-proof type CF applied part	Identifies applied part as Type CF

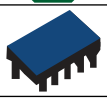
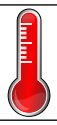
Table 7. Symbols Table PDA Icons		
Symbol/ Icon	**Description**	**Function**
	Patient List Toggle	Toggles between Patient List view and detailed View ECG screens for a selected patient
	History	Enters the View Patient History screen for a selected patient
	Stop BP	Cancels or Stops taking a BP Measurement for a selected patient
	Take BP	Initiated taking a BP for a selected patient
	Device Configuration	Enters the Device Configuration screen for a selected patient

Table 8. Symbols Table PC Icons		
Symbol/ Icon	**Function**	**Description**
	Opens Settings and Options Menu	Allows for adjustment of certain settings such as, Graphing Control, and EtCO2 Dongle Control
	Print Settings and Options	Allows the adjustment of vital signs printing as well as the time interval in which they are to be printed
 	Single View List View	Allows user to toggle the display from single view to list view, and vice versa
	Peek Time Limit	Selects amount of time for display to remain in Peek Mode (briefly viewing another patient) before reverting back to the patient assigned to the main display *Time values are in seconds*
	WVSM Configuration Settings	Opens configuration menu that allows for adjustment of multiple settings including alarms, gain, and BP reading intervals.
	Locate Icon	Used to aid in locating selected WVSM/ patient Causes selected WVSM's display to flash, as well as emit an audible alarm sound.
 	Start/Stop Blood Pressure Reading	Green "BP" button causes selected WVSM to begin a new blood pressure reading Red "BP" button is used to cease a blood pressure reading that is currently in progress
	GCS Icon	Allows for input and recording of patient's Glasgow Coma Scale Score for their selected WVSM
	Respiratory Rate Icon	Allows for input and recording of patient's respiratory rate for their selected WVSM.
	Temperature Icon	Allows for input and recording of temperature for their selected WVSM

3.2 General

3.2.1 Mechanical

The WVSM® device is a small, rugged, highly mobile patient vital signs monitor designed to be used at the point of injury. The overall size is 2.6 inches X 4.0 inches X 5.4 inches and weighs approximately 16 oz.

3.2.2 Electrical

The WVSM® device provides approximately 7 hours of operation using the internal battery. The AC adapter can be used to charge the battery. An indicator light on the front panel is provided to show battery charging status. A battery fuel gage is provided on the display to indicate remaining battery life. The fuel gauge bars are also color coded to help further identify battery life status (Green = Good, Yellow = Recharge Soon and Red = Recharge as soon as possible). The battery icon flashes when the battery falls below 5% (an estimated 20 minutes or less) of charge remaining.

3.2.3 Display

The display uses Organic Light Emitting Diode (OLED) technology. The active area is approximately 1 inch x 1 inch. Vital signs information is displayed, as well as various status, alarm and ECG waveform data.

3.2.4 Outputs

The WVSM® device has one Data output port that is activated when WiFi is turned OFF. The Athena GTX® data cable provided with the device is required to use this output port. It is a serial interface to the WVSM® device. Additional information can be found in the Communications section of this manual.

3.2.5 Accessories

Only approved accessories are authorized for use with the WVSM® device. See the list of approved accessories in the Accessories section of this manual.

4.0 Set Up

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare professional.

WARNING: DO NOT use the WVSM® device to monitor Pediatrics or Neonates.

WARNING: To avoid the possibility of patient entanglement or strangulation carefully route all patient cables and tubing.

WARNING: A multiple socket outlet or extension cord may not be connected to the WVSM® device. Risks of connecting the WVSM® device to a multiple socket outlet include excessive patient leakage current and patient electrical shock.

4.1 Monitor

Ensure that the monitor and accessories are not damaged prior to use. If damage is evident upon initial receipt of equipment contact the shipping company immediately. Retain all packing material and contact Athena GTX® for a return material authorization and instructions.

4.1.1 Sensor Connections

The WVSM® device has three vital signs parameter connections:

[1] NIBP

[2] ECG

[3] Pulse-Ox

They are all located on the bottom panel of the device. The steps for connecting the sensors to the WVSM® device are:

Connect the SunTech blood pressure cuff and the WVSM® device tubing together. Latch the tubing together by rotating the connectors.

Insert the ECG cables into the corresponding color coded connectors. The WVSM® device cables are marked as Right Arm (RA), Left Arm (LA) and Left Leg (LL). The ECG leads are color coded as White (RA), Black (LA) and Red (LL) to ensure cables are properly connected.

Open the rubber boot cover if necessary. Insert the Nonin SpO_2 finger clip sensor plug into the WVSM® device. Ensure the plug is fully installed.

Figure 4. Sensor Connections

4.1.2 Other Cable Connections

On the top panel of the WVSM® device there are three possible cable connections: AUX, DATA and DC Input. The AUX connection is for future use and is not used at this time. The DATA and DC Input connections are optional depending on operational use.

CAUTION: Use of the data port / data cable is restricted to use with, and connected to, approved accessories. Unauthorized connection to other equipment via the DATA or AUX ports could result in malfunction of the equipment or damage to WVSM® device or connected equipment.

An auxiliary output (DATA Port) is provided for "wired" transmission of data via RS232 protocol to a PC or other similar compatible device. All functions available in wireless mode are also available in wired mode except for history retrieval. Display of pacemaker pulses are unaffected by using wired mode. To connect the DATA cable accessory, open the rubber insert to expose the DATA port. Insert the Athena GTX® Data cable. Ensure that it is completely inserted.

To connect the medical grade AC Adapter accessory to the DC input, open the rubber insert cover and insert the AC Adapter plug into the receptacle.

Figure 5. DATA and AC Power Adapter Connections

Figure 5a. Data Cable

Figure 5b. AC Power Adapter

4.2 Configuration of PC & PDA Devices

WARNING: A computer not in accordance with IEC 60601-1 must be placed outside the patient environment. System configuration must be evaluated by the Responsible Organization in accordance with IEC 60601-1. No multiple socket outlet shall be used - risk of excessive patient leakage current.

4.2.1 Software Installation, Communications and Set-Up

For instructions on how to install the WVSM® software to a PC or PDA device, and to establish communications, refer to the Service Manual.

5.0 System Operation

5.1 Overview

The WVSM® device is a multi-parameter patient vital signs monitor (specifically ECG, SpO_2, non-invasive blood pressure (NIBP) and heart rate). The WVSM® device can be used as a standalone device, with a Personal Data Assistant (PDA) or Personal Computer (PC). The WVSM® device measures, stores and transmits patient vital signs data. Data is transmitted via WiFi (802.11b/g) to a PDA or PC running WVSM® device software. (Data can also be transferred via RS232 connection). A PDA or PC is required to adjust alarm presets, adjust configuration presets and use other functions such as viewing data history.

Figure 6. The WVSM® device system

Figure 6a. WVSM™ Device

Figure 6b. PDA and PC

5.2 Power On

To turn the WVSM® device **ON** press and hold the Power button until the Start Up WVSM® screen appears on the display. A menu screen appears. Choose the appropriate Mode Selection:

Table 9. Mode Select Table

Color	Function	Description/Use
Blue	New File	Starts a new patient file. Use when starting monitoring a new patient.
Red	Continue	Continues adding data to the previous patient file. Use this if the monitor is inadvertently turned off.
Gray	Calibrate	Enter the NIBP calibration mode. Use to verify NIBP calibrate and for calibration of the NIBP module.

Figure 7. Power On Display Screens

Figure 7a. Start UP Screen

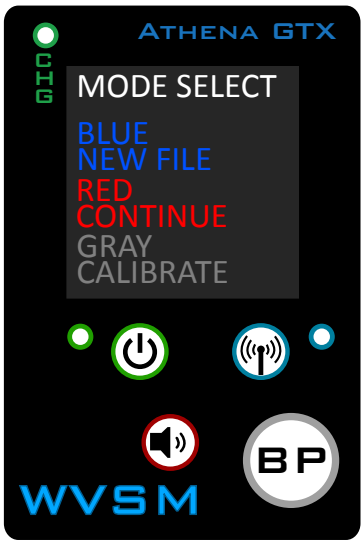


Figure 7b. Menu Screen

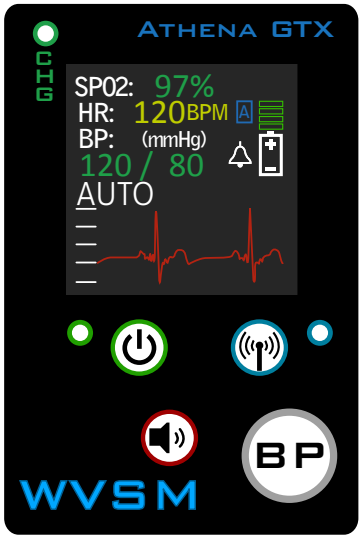


Figure 7c. Vital Signs Display

Choosing the New file or continue will bring up the Vital Signs Display. Calibration is discussed in the Maintenance section of this manual.

5.3 Power Off

To turn the WVSM® device **OFF** press and hold the Power button until the Power Down WVSM® screen appears on the display. The device powers off and remains in "sleep" mode waiting for Power On.

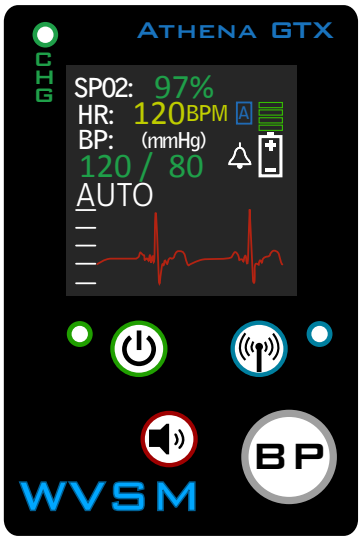


Figure 8a. Vital Signs Display

Figure 8b. Power Down Screen

Figure 8. Power Off Display Screens

5.4 Device

There are several functions that can be accessed directly on the WVSM® device:

- WiFi On/Off
- Power On/Off
- Alarm Silence/Reset
- Start BP
- Stop BP
- Initiate Turbo Mode
- View Vital Signs (SpO_2, HR or PR, NIBP (Systolic/Diastolic), and
- View ECG waveform

These are all accessed or viewed from the front panel of the WVSM® device. The table below describes how to perform each function.

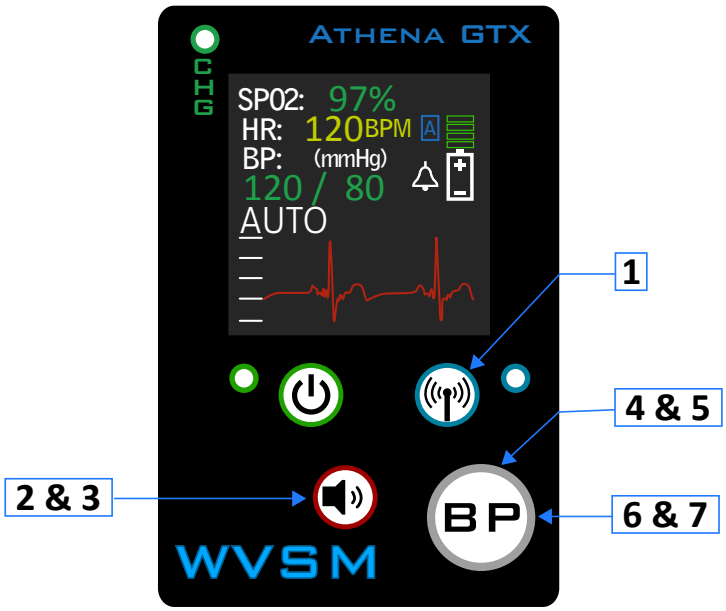


Figure 9. WVSM™ User Interface

Table 10. The WVSM® device User Interface

Item	Function	Description
1	WiFi On/Off	Press and release WiFi Button toggles between WiFi On and Off Blue LED On = WiFi On Blue LED Off = WiFi Off
2	Alarm Silence	Press and release Alarm Silence button to Silence an active audio alarm for two (2) minutes. Icon shows a dashed X.
3	Re-Activate Audible Alarm	Press and release Alarm Silence button if already in Silence mode. Dashed X is removed from Icon
4	Start BP	Press and release BP button to Start BP.
5	Stop BP	Press and release BP button to Stop BP (if BP is taking a reading).
6	Initiate Turbo Mode	Press and hold BP button to enter Turbo Mode. Icon changes from (Auto BP)or (Manual BP) to (Turbo BP)
7	Exit Turbo Mode	Press and hold BP button to exit Turbo Mode (If device is already in Turbo Mode). Icon changes from (Turbo BP) to (Auto BP) or (Manual BP).

5.5 PDA

5.5.1 Power On and Software Start

1. Turn the PDA on by pressing the on/off button.
2. The main menu of the PDA should be visible.
3. Select —> Start —> Programs —> File Explorer —> WVSM® Management Software
4. An alarms warning screen appears – Read the Warning and select OK.
5. The WVSM® program starts and Patient List should be visible if there are WVSM® devices ON and in range. If there are no devices on or in range a message appears on the Patient List Screen “Searching for patients . . .”
6. A Detailed View is shown by selecting a patient and selecting the Patient List Toggle Icon (See Section 5.5.2).

Figure 10. PDA Display Screens

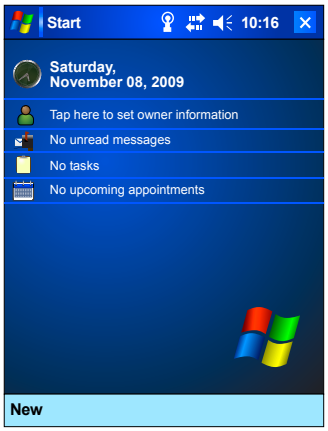


Figure 10a. Main Menu

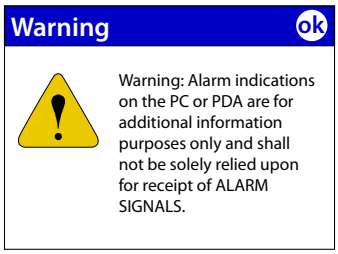


Figure 10b. Warning Screen

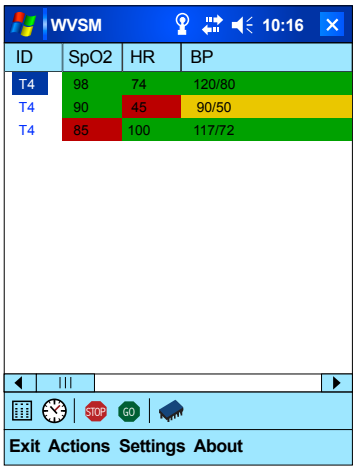


Figure 10c. Patient List

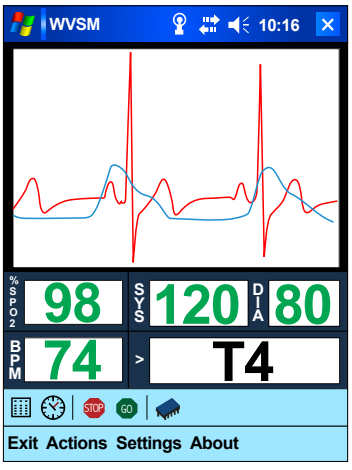
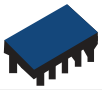


Figure 10c. Detailed View

5.5.2 ICON Functions

Table 11. PDA ICONS		
Symbol/ Icon	**Description**	**Function**
	Patient List Toggle	Toggles between Patient List view and detailed View ECG screens for a selected patient
	History	Enters the View Patient History screen for a selected patient
	Stop BP	Cancels or Stops taking a BP Measurement for a selected patient
	Take BP	Initiated taking a BP for a selected patient
	Device Configuration	Enters the Device Configuration screen for a selected patient

5.5.3 Menu Functions

Table 12. PDA Menu Structure and Functions

Menu Structure	Description/Function
Exit	Opens Exit Menu Selections
Cancel	Cancel the Exit menu
Exit	Exits the WVSM® Software
Actions	Opens Action Menu Selections
Take BP Now	Starts BP measurement for the selected patient
Abort BP	Stops BP measurement for the selected patient
Normal BP	Exits Turbo Mode (If device is currently in Turbo Mode). Icon changes from (Turbo BP) to (Auto BP) or (Manual BP)
Turbo BP	Enters Turbo Mode. Icon changes from (Auto BP) or (Manual BP) to (Turbo BP)
Locate	Initiate Locate function that causes the selected WVSM® to emit both a visual (screen flash) alarm, and an audible (beeping) alarm
View List	Changes from ECG Detailed View to List View screen
View ECG	Changes form List View to ECG detailed View for a selected WVSM®
View History	Changes to the History View mode
Settings	Opens Settings Menu Selections
PDA	Opens PDA Menu Selections
Security	Opens PDA Security Menu Selections
Add New User	Opens a dialog box to add a new user
Delete User	Opens a dialog box to delete current users

Menu Structure		Description/Function
	Change Password	Opens a dialog box to change a user's password
WVSM® Unit		Opens WVSM® Device Menu Selections
Edit Configuration		Opens the Configuration Input Screen
	Device ID	Allows Authorized User to change the Unit ID for the selected WVSM®
	ECG Scale	This controls the scale/gain on the WVSM® unit only and does not affect the scale on the PC software
	Auto BP	When selected, this option causes the selected WVSM® to take an automatic blood pressure reading according to the interval determined in the "Reading Interval" section, at the end of this menu If the box is deselected, the BP button will need to be pressed manually on the WVSM® unit, or within the program toolbar, each time a blood pressure reading is to be taken for the selected WVSM®
	HR From ECG	When selected, this option will cause the selected WVSM® to take and display the Heart Rate (HR) from the ECG leads (as opposed to the Pulse Rate (PR) from the pulse oximetry clip) When deselected, the Pulse Rate (PR) will be derived from the pulse oximetery clip of the selected WVSM®
	ECG High Gain	This switches the hardware gain (prior to the ADC) from 220 and 1000. ECG peak amplitudes of 0.5mV and below should use the High gain setting to improve signal quality and bit resolution through the ADC. For higher amplitude signals the low gain setting must be used to avoid clipping of the waveform.
	Pacemaker Mode	This feature allows the pacemaker pulses to be displayed at the required amplitude. It turns off the software filter increasing the bandwidth of the system. If the software filter needs to be turned off for any specific test, this can be done by selecting Pacemaker Mode
	NIBP Turbo Mode	When selected, this option causes the selected WVSM® to automatically take a blood pressure reading in the following increments: 2min,2min,3min,3min,5min,5min After the last BP reading of the Turbo Mode period is completed, the selected WVSM® will return to its previously selected setting
	Extended Mode	This extends the bandwidth of the hardware filtering by lowering the cutoff of the high pass filter. The bandwidth in this mode is extended to 0.05Hz to 40Hz
	Reading Interval	Allows user to determine the time interval (in minutes) between blood pressure readings for the selected WVSM®
	Set As Boot Up Default	Allows Authorized User to use selected settings as boot up default settings
Alarms		Opens WVSM® Device Alarms Menu Selections
	SpO2 And Pulse	Opens the SpO2 and Pulse alarm limits dialog box for the selected patient. User can adjust alarm limits for the selected patient These alarm limits are for the selected WVSM® ONLY
	Blood Pressure	Opens the NIBP alarm limits dialog box for the selected patient. User can adjust alarm limits for the selected patient These alarm limits are for the selected WVSM® ONLY
About		Opens a dialog box that shows the WVSM® PDA software revision that is in use

5.6 PC

Optimal PC Settings: *Windows XP running in XP Theme, Recommended Display resolution 1280 x 1024 or 1680 x 1050*

5.6.1 Starting PC Software and Connecting to the WVSM® Device

1. Load the software onto a PC (refer to Section 4.3). Place shortcut on desktop. Start the program by clicking the icon. The first screen to appear should be the Alarms Warning Screen. Read the Warning and select OK to continue. The List View should appear. Expand to full screen.

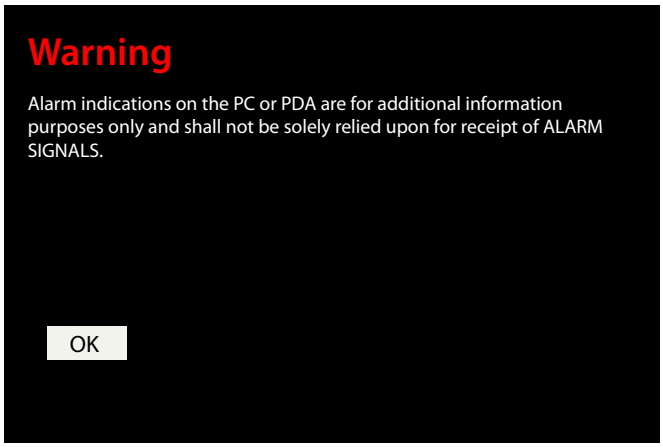


Figure 11. PC Alarms Warning Screen

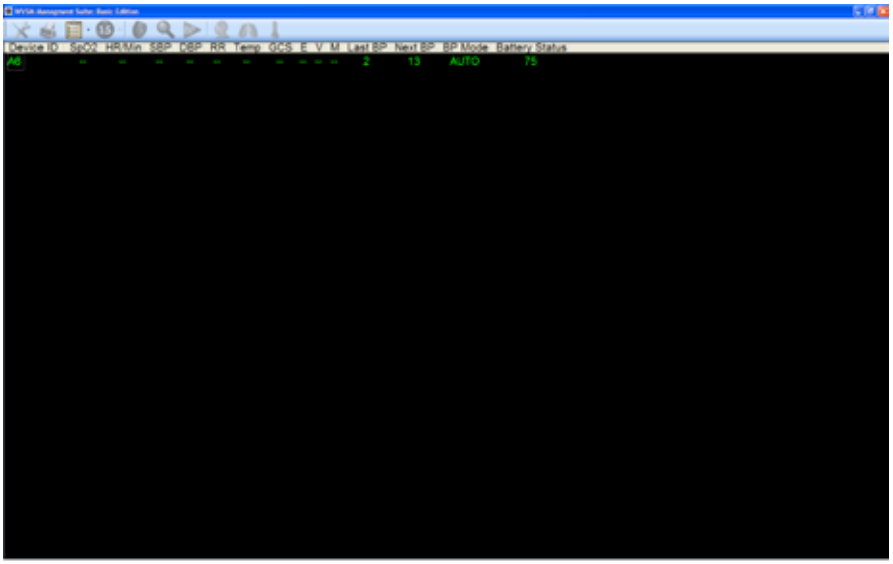


Figure 12. PC Software List View

2. Select the clipboard icon (refer to Section 5.6.2 PC Icon Functions) to open the drop-down menu. Select the person icon to change from List View to Single view:

Once in Single view all the WVSM® devices that are powered on, broadcasting wirelessly, and in range will be listed across the bottom of the display. Select the WVSM® device you wish to set as the primary for the display. A dialogue box will prompt you to assign this patient to the main display. Select "Yes". The screen will then change to Single View for that WVSM® device (See Figure 13). This screen will serve as the preferred starting point for all of the functions described below.

Figure 13. PC Software Single View

The PC single view mode (Figure 13) allows the user to see current vital signs, past vital signs (history), and waveform data. It is arranged in a logical pattern with history data on the left side of the display, current vital signs in the center of the display and waveform data on the right hand side. Icons across the top allow for easy access to configuration menus and data input screens that perform necessary interaction with the WVSM® device. These icons and their functions are explained in detail below.

SpO_2, HR/PR, SYS (Systolic BP), DIA (Diastolic BP), Pleth waveform and ECG waveform data are all monitored via the WVSM® device measurements. MAP (Mean Arterial Pressure) is a calculated parameter displayed in gray, in the PC Software. RR (Respiration Rate), TEMP and GCS (Glasgow Coma Scale Score) are all manually entered data using the PC or PDA software interface. Each entry is stored on the WVSM® device and is part of the history data.

Battery life of the selected WVSM® device is also shown on the PC using a color coded bar and the % of charge remaining. Finally, data from other WVSM® devices listed across the bottom of the display can be viewed temporarily by using the Peek Mode. By selecting the WVSM® device you wish to "Peek", a dialogue box will prompt you to assign this patient to the main display. If you select "No", the screen will then change to temporarily view the data coming from that WVSM® device. The display automatically changes back to the primary patient after the preferred time limit selected in the toolbar.

5.6.2 ECG Waveform Specs and Features

ECG Scale/Gain Adjust: There are two buttons (+ and –) on the upper left side of the ECG display area that control the scale/gain of the ECG signal for the PC software. The scale label (mV/div) will change based on selecting the arrows and will cycle through all the selections:

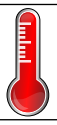
- *Aspect Ratio 0.4s/mV – mV/div varies based on Display Window Size*
- *3mV/div (3.33mm/mV)* *15mV max*
- *2mV/div (5mm/mV)* *10mV max*
- *1mV/div (10mm/mV)* *5mV max*
- *0.4mV/div (25mm/mV)* *2mV max*
- *0.2mV/div (50mm/mV)* *1mV max*
- *0.1mV/div (100mm/mV)* *0.5mV max*

ECG Display Aspect Ratio: Several aspect ratios are available. The software provides an aspect ratio of 0.4s/mV which can be selected in two ways a) 1mV/div and b) 25mm/sec to make the grid represent this ratio or the highest scale setting will automatically adjust the gain setting to match the physical screen display size.

Only one Lead is provided: Lead II is the only ECG lead configuration used by WVSM® device. The only leads that are connected to the Instrumentation amplifier are the LL and RA (Red and White). The LA (Black) is permanently connected as a common mode reference input.

5.6.3 PC Icon Functions

Table 13. PC Icons

Symbol/ Icon	Function	Description
	Opens Settings and Options Menu	Allows for adjustment of certain settings such as, Graphing Control, and EtCO2 Dongle Control.
	Print Settings and Options	Allows the adjustment of vital signs printing as well as the time interval in which they are to be printed.
 	Single View List View	Allows user to toggle the display from single view to list view, and vice versa.
	Peek Time Limit	Selects amount of time for display to remain in Peek Mode (briefly viewing another patient) before reverting back to the patient assigned to the main display. *Time values are in seconds*
	WVSM Configuration Settings	Opens configuration menu that allows for adjustment of multiple settings including alarms, gain, and BP reading intervals.
	Locate Icon	Used to aid in locating selected WVSM/ patient. Causes selected WVSM's display to flash, as well as emit an audible alarm sound.
 	Start/Stop Blood Pressure Reading	Green "BP" button causes selected WVSM to begin a new blood pressure reading. Red "BP" button is used to cease a blood pressure reading that is currently in progress.
	GCS Icon	Allows for input and recording of patient's Glasgow Coma Scale Score for their selected WVSM
	Respiratory Rate Icon	Allows for input and recording of patient's respiratory rate for their selected WVSM.
	Temperature Icon	Allows for input and recording of temperature for their selected WVSM

5.6.4 PC Icon Menu Functions

Table 14. PC Icon Menu Structure and Functions

Menu Structure	Description/Function
Settings and Options Icon Menu	Opened by selecting Settings and Options Icon
Graphing Control	Adjustments to the ECG and Pleth graph displays
Graphing Lines ON	Enables graphing/grid lines on ECG waveform display. Each vertical line represents 0.05 seconds.
Sweep Time (5 second)	The sweep rate has two settings to make it easier to see test signals at 40Hz with reduced display aliasing. Default is 25mm/sec (1sec/div) or 5 seconds total display time. The other is 125mm/sec (0.2sec/div) or one second total display time. Sets time base signal sweep to 5 seconds when checked. If box is unchecked, the sweep time will be set to 1 second.
Set Full Height (50mm)	The max width of the ECG display can be adjusted. Two choices are available 50mm and 30mm. White tick marks on the left side of the display show the max width.
20%, 50%, 80%	This allows for the ECG waveform “0” baseline to be adjusted in the available display window. Choices are 20%, 50% and 80% of full scale. An arrow on the left side of the waveform display shows the current baseline setting.
Username Control	Allows for the login of individual users.
Printer Settings and Options Menu	Opened by selecting the Print Icon
Printing Options	
Print Vitals (text only)	When box is checked, the vitals for the selected WVSM® will print in spreadsheet format, according to the time interval selected below
Printing Time Interval	Used to select the desired time interval between printing of vital signs
Configuration Settings Menu	Opened by selecting the WVSM® Configuration Icon *NOTE: For the saving and alteration of default settings/ alarms contained within this menu, a user authorized to make these changes must login using his/her Username and Password in the Authorization frame at the bottom of this menu.*
Configuration TAB	
Device ID	Allows authorized user to determine or change the ID of the selected WVSM®
ECG Scale	This controls the scale/gain on the WVSM® unit only and does not affect the scale on the PC software. “Auto Scale” performs this task automatically.

Menu Structure	Description/Function
Auto BP	When selected, this option causes the selected WVSM® to take an automatic blood pressure reading according to the interval determined in the “Blood Pressure Interval” section, at the bottom of this menu If the box is deselected, the BP button will need to be pressed manually on the WVSM® unit, or within the program toolbar, each time a blood pressure reading is to be taken for the selected WVSM®
NIBP Turbo Mode	When selected, this option causes the selected WVSM® to automatically take a blood pressure reading in the following increments: 2min,2min,3min,3min,5min,5min After the last BP reading of the Turbo Mode period is completed, the selected WVSM® will return to its previously selected setting
HR from ECG	When selected, this option will cause the selected WVSM® to take and display the Heart Rate (HR) from the ECG leads, as opposed to the Pulse Rate (PR) from the pulse oximetry clip When deselected, the Pulse Rate (PR) will be derived from the pulse oximetery clip of the selected WVSM®.
ECG High Gain	This switches the hardware gain (prior to the ADC) from 220 and 1000. ECG peak amplitudes of 0.5mV and below should use the High gain setting to improve signal quality and bit resolution through the ADC. For higher amplitude signals the low gain setting must be used to avoid clipping of the waveform.
ECG Extended Mode	This extends the bandwidth of the hardware filtering by lowering the cutoff of the high pass filter. The bandwidth in this mode is extended to 0.05Hz to 40Hz.
Pacemaker Enhanced Mode	This feature allows the pacemaker pulses to be displayed at the required amplitude. It turns off the software filter increasing the bandwidth of the system. If the software filter needs to be turned off for any specific test, this can be done by selecting the Pacemaker Enhanced Mode
Blood Pressure Interval	Allows user to determine the time interval (in minutes) between blood pressure readings for the selected WVSM®
Authorization Section	Allows for login of authorized users. Required to make certain changes in default configuration and alarm settings.

Menu Structure	Description/Function
NIBP Alarms Tab	Allows user to configure BP alarm limits
SBP Low Yellow	LOW SYSTOLIC BLOOD PRESSURE value that will be displayed in YELLOW, a low priority alarm
SBP Low Red	LOW SYSTOLC BLOOD PRESSURE value that will be displayed in RED, a high priority alarm
SBP High Yellow	HIGH value at which SYSTOLIC Blood Pressure will be displayed in YELLOW, a low priority alarm
SBP High Red	HIGH value at which SYSTOLIC Blood Pressure will be displayed in RED, a high priority alarm
DBP Low Yellow	LOW value at which DIASTOLIC Blood Pressure will be displayed in YELLOW, a low priority alarm
DBP Low Red	LOW value at which DIASTOLIC Blood Pressure will be displayed in RED, a high priority alarm
DBP High Yellow	HIGH value at which DIASTOLIC Blood Pressure will be displayed in YELLOW, a low priority alarm
DBP High Red	HIGH value at which DIASTOLIC Blood Pressure will be displayed in RED, a high priority alarm
Vital Alarms Tab	Allows user to configure SpO2 and HR/PR alarm limits
PR/HR High Red	HIGH value at which Pulse Rate/Heart Rate will be displayed in RED, a high priority alarm
PR/HR High Yellow	HIGH value at which Pulse Rate/Heart Rate will be displayed in YELLOW, a low priority alarm
PR/HR Low Yellow	LOW value at which Pulse Rate/Heart Rate will be displayed in YELLOW, a low priority alarm
PR/HR Low Red	LOW value at which Pulse Rate/Heart Rate will be displayed in RED, a high priority alarm
SpO_2 Low Yellow	LOW value at which SpO_2 will be displayed in YELLOW, a low priority alarm
SpO_2 Low Red	LOW value at which SpO_2 will be displayed in RED, a high priority alarm

Figure 14a: PC-Standard Settings & Options Menu

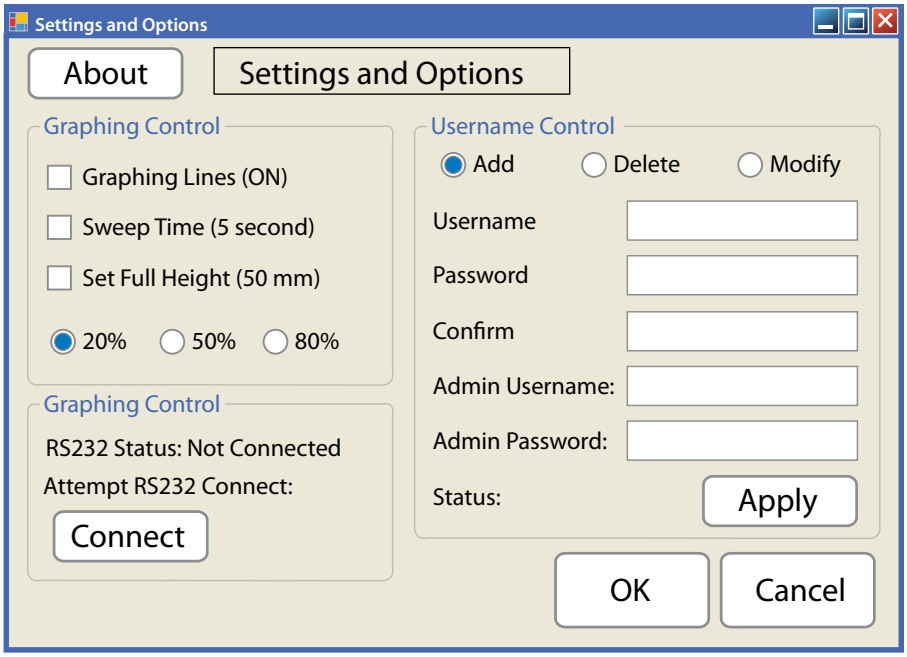


Figure 14b: PC-Touch Settings & Options Menu

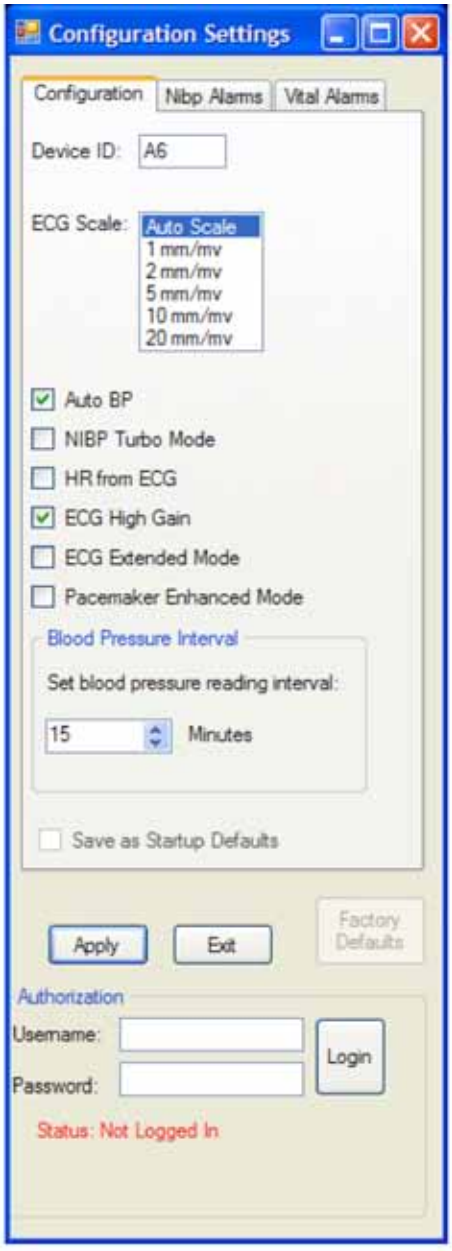


Figure 15a: PC-Standard Configuration Settings Menu

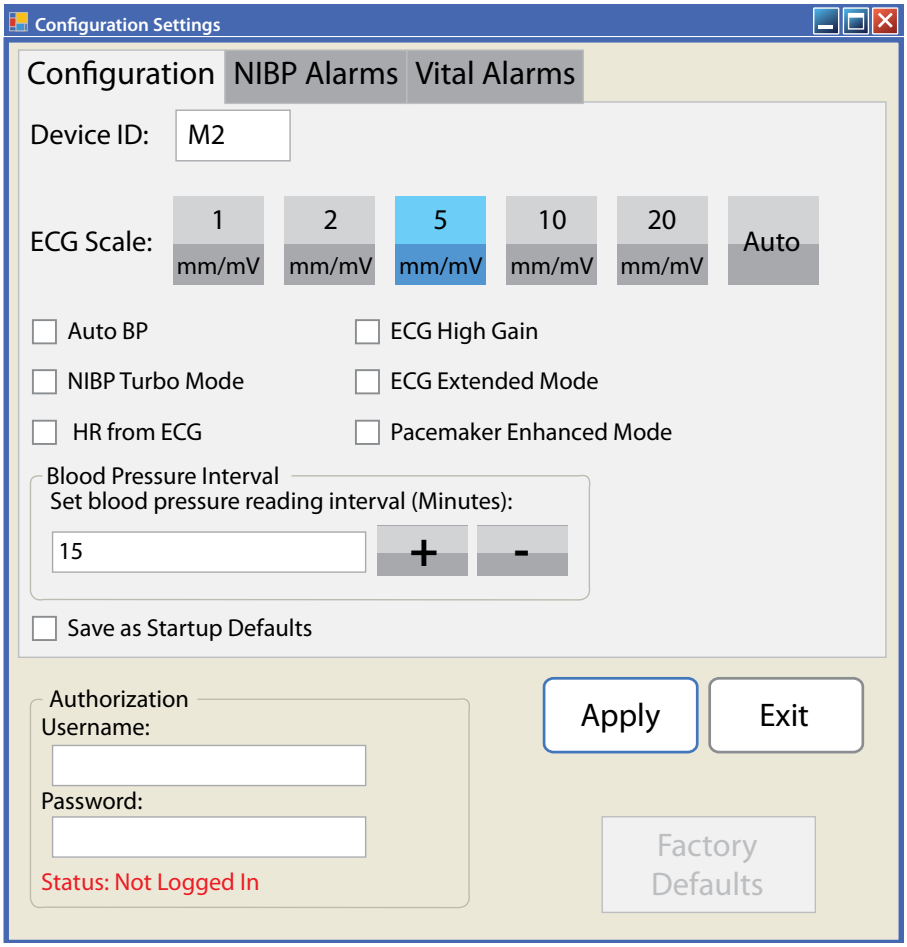


Figure 15b: PC-Touch Configuration Settings Menu

6.0 Alarms

6.1 General

The Wireless Vital Signs Monitor (WVSM®) provides visual and audible alarms to notify the user of a patient's condition, such as a vital sign that is outside of the specified limits. There are two categories of alarms: Physiological and Technical.

WARNING: Alarm indications on the PC or PDA are for additional information purposes only and shall not be solely relied upon for receipt of ALARM SIGNALS.

6.1.1 Physiological Alarms

There are two priority alarm states for physiological alarms, High and Low. With a high priority alarm, the physiological parameter value (i.e., SpO_2, HR, and BP) is displayed in the color Red. With a low priority alarm, the parameter is displayed in Yellow. Normal physiological parameters are displayed in Green.

Any physiological parameter causing a High priority alarm also activates a simulated red indicator light and the audible buzzer. The indicator light and parameter label text (i.e. SPO_2, HR/PR or NIBP) flashes at a frequency of about 2 Hz. The audible alarm operates at a minimum sound pressure level of 54 dB at a distance of 1 meter. The tone produced by the audible alarm is intermittent. The alarm sounds in accordance with the IEC 60601-1-8 high priority alarm 10 pulse burst pattern (3 short pulses, pause, 2 short pulses, pause, 3 short pulses, pause, 2 short pulses, longer pause, and repeat). This burst pattern, indicator light and parameter label flashing continues until the alarm has been cleared by the user.

- *Section 6.4.2 provides details of how the Responsible Organization may permanently change alarm settings.*
- *Section 6.4.3 provides details of how the Operator may temporarily change alarm settings.*

6.1.2 Technical Alarms

There are two technical alarms in the WVSM® device: one for the SpO_2 sensor and one for Power Failure. The SpO_2 OEM III module provides a number of sensor fault conditions to the WVSM® device host. These are displayed on the WVSM® device and PC/PDA as yellow dashed lines (– – – –) for the parameter values (SpO_2 or PR) to indicate that there is a low priority technical alarm condition.

A Power Failure alarm is indicated in stages by the battery fuel gage icon on the WVSM® device and % remaining on the PC/PDA. Color changes are representative of status and an audible alarm is generated before the battery reaches the minimum required for operation. A medium priority audible alarm is used to differentiate this technical alarm from the high priority physiological audible alarm. The alarm sounds in accordance with the IEC 60601-1-8 medium priority alarm 3 pulse burst pattern (3 short pulses, 17 second pause, and repeat). This burst pattern continues until the alarm has been cleared by the user. The alarm sounds when the battery falls below 5% (approximately 20 minutes of power remaining). Color codes for the battery status are as follows (Next Page):

Battery Status Bars: 7 Segments

- *Green 4 – 7 segments on Status bar, 45% to 100% charge remaining*
- *Yellow 2 – 3 segments on Status bar, 20% to 44% charge remaining*
- *Red 1 segment on Status bar, 10% to 19% charge remaining*
- *None 0 segments on Status bar, 0% to 9% charge remaining*
- *None & Battery Icon Flashing Below 5% remaining, audible alarm sounds*

6.2 Visual Indicators & Priorities

6.2.1 The WVSM® Device

The WVSM® device provides visual indicators for all physiological parameters displayed (i.e., SpO_2, HR, and BP). Priority levels for each of the parameters are displayed using a Non-latching (non-permanent, does not require user intervention to change) color coding format shown below.

- Parameters displayed in YELLOW indicate LOW Priority
- Parameters displayed in RED indicate HIGH Priority
- Parameters displayed in GREEN indicate NORMAL

High priority alarms also generate a RED flashing simulated indicator light and flash the parameter label text (i.e. SPO_2, HR/PR or NIBP). This part of the visual alarm is latching (requires user to manually clear) to further assist the responder in determining what caused the alarm condition.

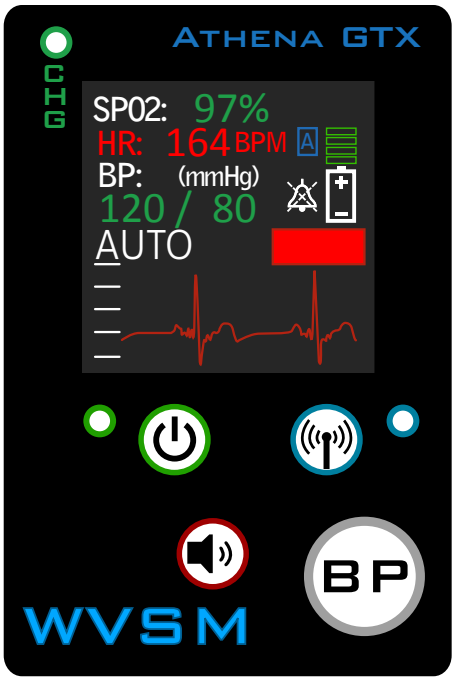


Figure 16. Visual Alarms

6.2.2 PC

WVSM® software running on a PC has the ability to show the visual indicator alarms for the physiological parameters shown on the WVSM® device as well as the manually entered parameters (RR, TEMP, and GCS).

6.2.3 PDA

WVSM® software running on a PDA has the ability to show the visual indicator alarms for the physiological parameters shown on the WVSM® device. The manually entered parameters (RR, TEMP, and GCS) are NOT color coded on the PDA and are only shown in LIST MODE and are highlighted in Blue. Scroll right in list mode to view these parameters.

6.3 Audible Indicators

6.3.1 The WVSM® Device

Any physiological parameter causing a High priority alarm activates the audible buzzer. The audible alarm operates at a minimum sound pressure level of 54 dB at a distance of 1 meter. The tone produced by the audible alarm is intermittent. The alarm sounds in accordance with the IEC 60601-1-8 high priority alarm 10 pulse burst pattern (3 short pulses, pause, 2 short pulses, pause, 3 short pulses, pause, 2 short pulses, longer pause, and repeat). This burst pattern continues until the alarm has been cleared by the user. The audible alarm may be temporarily silenced for a period of two (2) minutes by pressing the alarm button on the front panel of the WVSM® device. Refer to Section 6.6 for details related to silencing the audible alarm.

A Power Failure alarm is indicated by a medium priority audible alarm (used to differentiate this technical alarm from the high priority physiological audible alarm). The alarm sounds in accordance with the IEC 60601-1-8 medium priority alarm 3 pulse burst pattern (3 short pulses, 30 second pause, and repeat). This burst pattern continues until the alarm has been cleared by the user.

6.3.2 PC/PDA

WVSM® software running on a PDA or PC are NOT able to produce audible alarms to avoid multiple alarms and reduce confusion. The primary alarm remains on the WVSM® device.

6.4 Adjusting Alarm Limits and Presets

WARNING: Prior to using the WVSM® device to monitor a patient, all alarm limit settings should be reviewed to ensure they are appropriate for the patient being monitored.

CAUTION: Setting ALARM LIMITS to extreme values can render the ALARM SYSTEM useless.

The Wireless Vital Signs Monitor is configured at the factory with two alarm limit presets in the unit: MANUFACTURER-configured alarm presets and DEFAULT alarm presets. The MANUFACTURER-configured alarm presets cannot be accessed, and are non-adjustable. The DEFAULT alarm presets can be accessed by entering a RESPONSIBLE ORGANIZATION (Administrator) password. The DEFAULT alarm presets are provided so each institution can configure the WVSM® device to meet appropriate institutional guidelines for alarm limit settings. The DEFAULT alarm limit settings will be used on each power up cycle. The DEFAULT alarm presets are set to the MANUFACTURER configured presets at the factory.

Alarm limit settings may also be temporarily adjusted on the WVSM® device for each individual patient. Temporarily adjusting the alarm limits does not require the user to enter a password. Once the WVSM® device is turned off and a new patient is selected, the temporary settings will be lost and all alarm presets will revert to the DEFAULT alarm presets.

Alarm limit settings for SpO_2, HR/PR, SYS and DIA parameters are set for each WVSM® device and are transmitted and used by the PC or PDA. The additional manual input parameters (Temperature, Respiratory Rate and GCS) on the PC are selected on each PC independently, by the user. These parameters do not generate audible alarms. The additional manual input parameters (Temperature, Respiratory Rate and GCS) are also not alarmed on the PDA. Alarm limit settings are not accessible directly on the WVSM® device. All alarm limit settings are changed using a PDA or PC. Refer to the sections below for a detailed explanation on how to change alarm limit settings.

6.4.1 Manufacturer Configured Presets (Factory Default)

The WVSM® device is delivered with factory default alarm settings. The tables below provide a summary of each parameter and the default settings.

Table 15. Manufacturer Configured Presets on the WVSM® device

Parameter	Limit(s)	Value	Priority	Color
PR/HR	High	140 bpm	High	Red
PR/HR	Mod-high	110 bpm	Low	Yellow
PR/HR	Mod-low	60 bpm	Low	Yellow
PR/HR	Low	45 bpm	High	Red
SpO_2	High	NA	NA	NA
SpO_2	Mod-high	NA	NA	NA
SpO_2	Mod-low	90%	Low	Yellow
SpO_2	Low	85%	High	Red
Systolic BP	High	200 mmHg	High	Red
Systolic BP	Mod-high	160 mmHg	Low	Yellow
Systolic BP	Mod-low	90 mmHg	Low	Yellow
Systolic BP	Low	70 mmHg	High	Red
Diastolic BP	High	100 mmHg	High	Red
Diastolic BP	Mod-high	90 mmHg	Low	Yellow
Diastolic BP	Mod-low	50 mmHg	Low	Yellow
Diastolic BP	Low	40 mmHg	High	Red

Table 16. Manufacturer Configured Presets on the PC

Parameter	Limit(s)	Value	Priority	Color
RR	High	24 breaths/min	High	Red
RR	Mod-high	20 breaths/min	Low	Yellow
RR	Mod-low	11 breaths/min	Low	Yellow
RR	Low	8 breaths/min	High	Red
TEMP	High	103.0 °F	High	Red
TEMP	Mod-high	100.8 °F	Low	Yellow
TEMP	Mod-low	97.1 °F	Low	Yellow
TEMP	Low	96.0 °F	High	Red
GCS	Low	8	High	Red
GCS	Mod-Low	14	Low	Yellow

6.4.2 Responsible Organization Presets

WARNING: A HAZARD can exist if different ALARM PRESETS are used for the same or similar equipment in any single area, e.g. an intensive care unit or cardiac operating theatre.

The Responsible Organization can change the DEFAULT ALARM PRESETS for the WVSM® device or PC to coincide with the institution's alarm limit setting guidelines. Once changed, the DEFAULT ALARM PRESETS will remain in effect until these presets are modified again. Each time the WVSM® device is turned on, the unit will revert to these default settings. Changing the DEFAULT ALARM PRESETS requires a Responsible organization (Administrator) password. Passwords can be set to prevent unauthorized changes. Refer to the service manual for details on how to change and save DEFAULT ALARM PRESETS.

6.4.3 Operator Alarm Limit Adjustments

The operator can temporarily change the alarm limit settings for a particular patient. The alarm limit settings will remain active until either the settings are modified again, or if the device is turned off and then turned back on and a new patient file is selected. When a new patient file is selected, the WVSM® device will return to the default alarm presets. The temporary alarm limit settings will remain in effect if the WVSM® device is turned off and then turned back on, and the continue button is pressed.

Note: The % SpO_2 Low Alarm Limit cannot be set below the DEFAULT ALARM PRESETS set by the Responsible Organization.

Temporary alarm limit settings can be changed for the WVSM® device parameters (SpO_2, HR/PR, SYS and DIA) by using the PC or PDA interface and for Manual entered parameters (Temperature, Respiratory Rate and GCS) on the PC.

To **Temporarily** adjust the alarm limit settings for SpO_2, HR/PR, SYS and DIA on the WVSM® device follow the steps outlined on the next page:

[1]Using a PDA select:

a. ***Settings> WVSM® Unit> Alarms> SpO_2 and Pulse or Blood Pressure***

b. Make the appropriate adjustments to the alarm limit settings and press ***OK*** to save.

c. The new alarm limit settings are now in effect and will remain until the settings are modified again, or the unit is turned off and then turned back on and a new patient file is selected.

Figure 17. The WVSM® Device Parameter Alarm Limits Interface Screens on the PDA

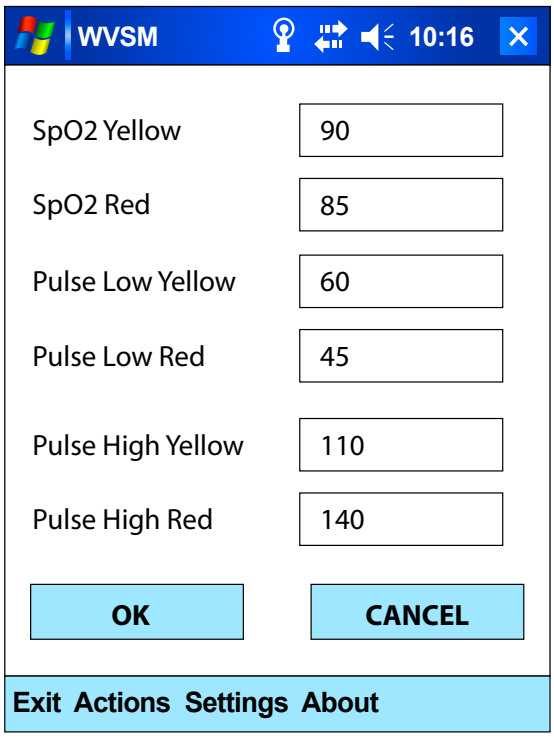


Figure 17a:
SpO2 and Pulse Alarms

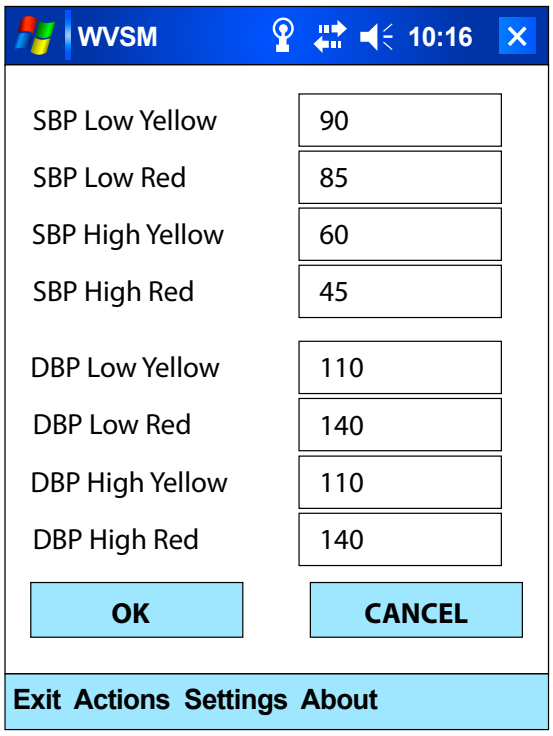


Figure 17b:
NIBP Alarms

[2]Using a PC select:

a. ***WVSM® Configuration Settings Icon NIBP Alarms Tab or Vital Alarms Tab***

b. Make the appropriate adjustments to the alarm limit settings and press ***Apply*** to save.

c. The new alarm limit settings are now in effect and will remain until the settings are modified again, or the unit is turned off and then turned back on and a new patient file is selected.

Figure 18. WVSM® Parameter Alarm Limits Interface Screen on the PC

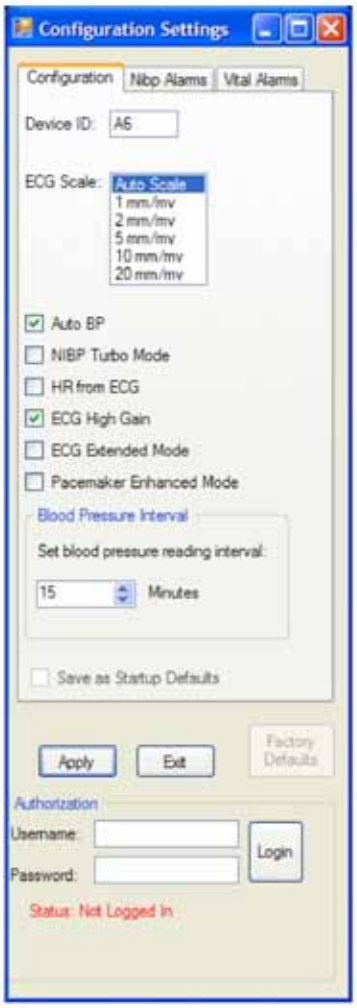


Figure 18a: PC-Standard Configuration

Figure 18b: PC-Standard NIBP Alarms

Figure 18c: PC-Standard Vital Alarms

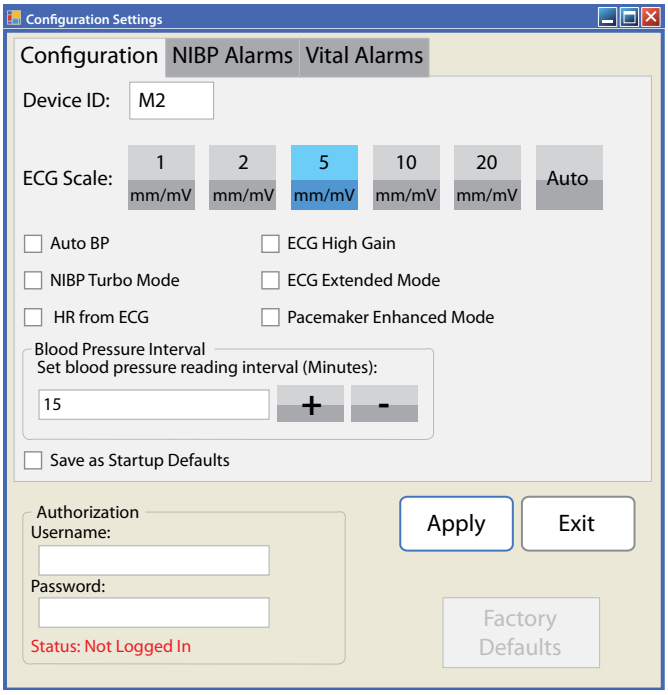


Figure 18d: PC-Touch Configuration

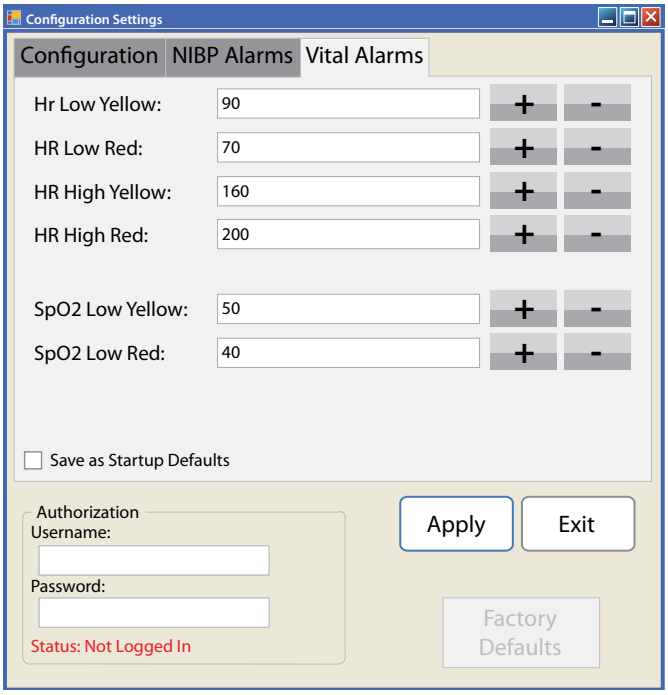


Figure 18f: PC-Touch Vital Alarms

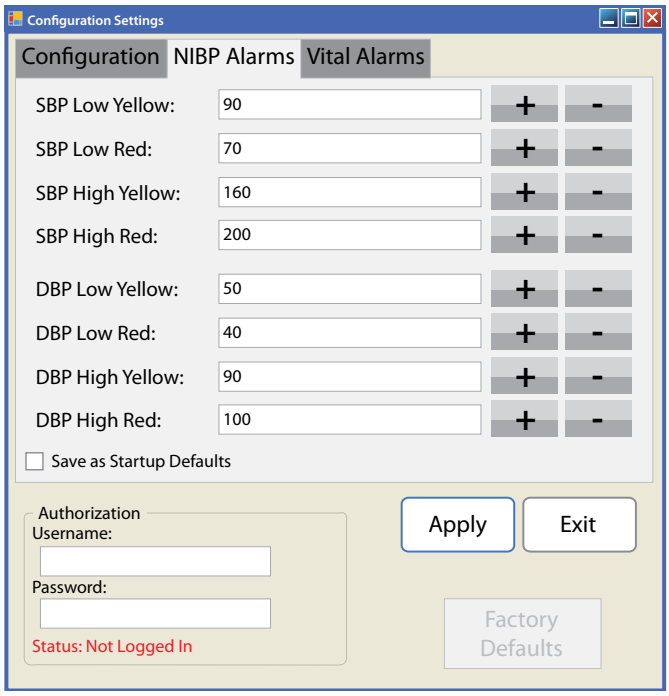


Figure 18e: PC-Touch NIBP Alarms

To **Temporarily** adjust the alarm limit settings for the manually entered parameters (Temperature, Respiratory Rate and GCS) on the PC follow the steps outlined below:

[1] Using a PC select

a. Double click on the Bell icon next to the parameter

b. Make the appropriate adjustments to the alarm limit settings and press ***OK*** to save.

c. The new alarm limit settings are now in effect and will remain until the settings are modified again, or the unit is turned off and then turned back on, and a new patient file is selected.

Figure 19. Manually Entered Parameter Alarm Limits Interface on the PDA

Figure 19a: PC-Standard Respiratory Rate

Figure 19b: PC-Standard Temperature

Figure 19c: PC-Standard Glasgow Coma Score

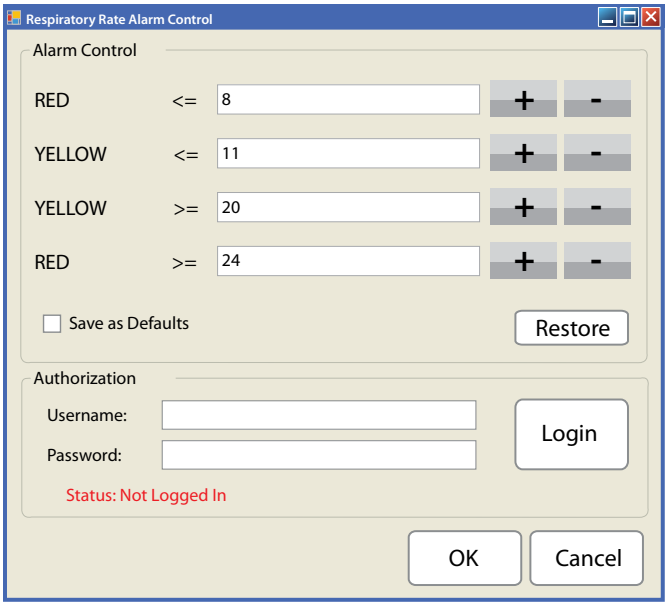


Figure 19d: PC-Touch Respiratory Rate

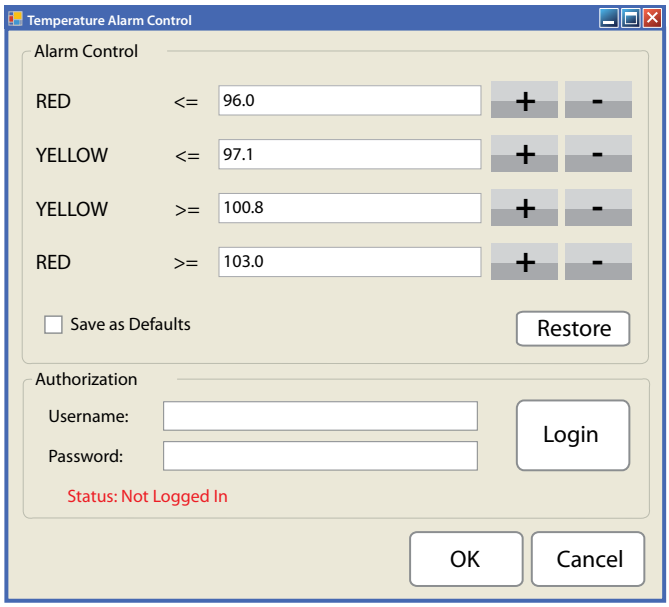


Figure 19e: PC-Touch Temperature

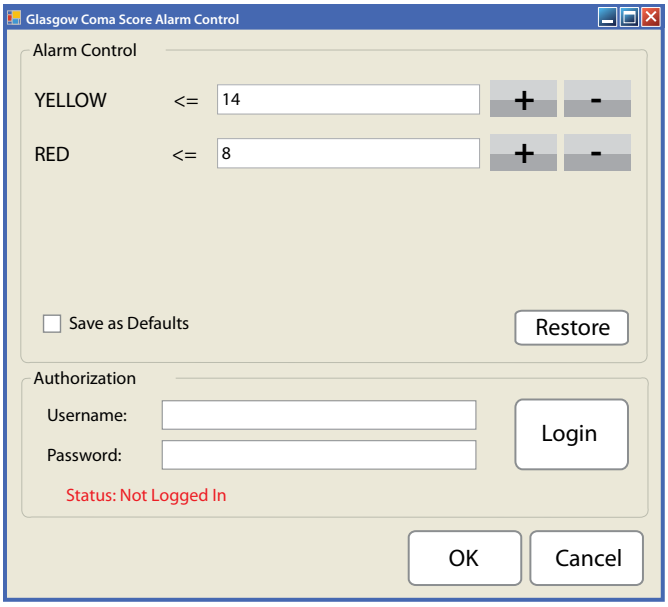


Figure 19f: PC-Touch Glasgow Coma Score

6.5 Alarm Silence

The audible alarm can be temporarily silenced by pressing the alarm button on the front panel of the WVSM® device. This action will silence the audible alarm for a period of two (2) minutes, after these two minutes, the WVSM® device will automatically turn the audible alarm on. This automatic feature is an industry requirement. To determine the status of the alarm, refer to the bell shaped icon shown. When the alarm silence has been activated, the bell icon will have an “X” appear within the body of the icon. (While in alarm silence mode, the WVSM® device continues to monitor patient parameters, and all buttons, functions and features continue to work normally). By pressing the button again, the alarm will be activated and the bell icon will no longer display an “X” within the bell icon. See figure 20.

When the alarm silence mode has been activated, the audible alarm for the parameter that caused the alarm is **silenced**. If a new alarm condition occurs while in the alarm silence mode, the audible alarm will **reactivate.**

Figure 20. Alarm Silence

Figure 20a:
Audio Alarms Active

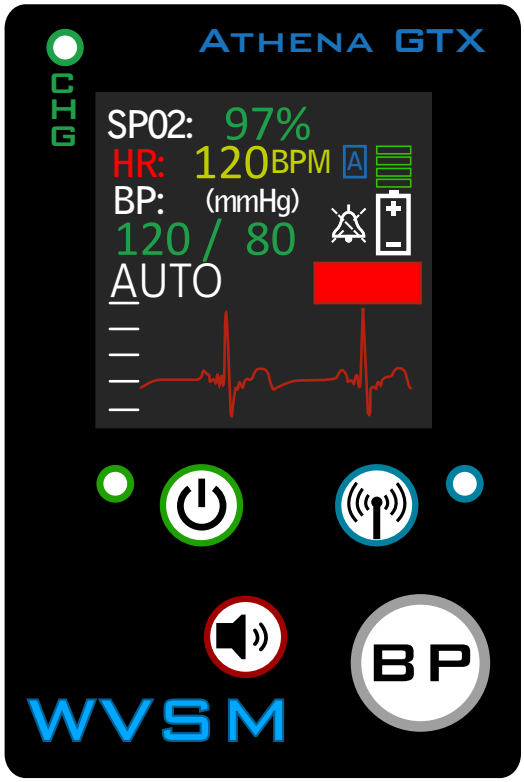


Figure 20b:
Audio Alarms Silenced

6.6 Testing Alarms

To test the Physiological alarm function on the WVSM® device patient simulators are required (ECG, NIBP and/or Pulse-Ox). Follow the below steps to test the alarm function:

1. Connect the simulators to the WVSM® device and start with simulator settings in the normal range.
2. Observe that the parameter values on the WVSM® device are green and no audible alarm is sounding.
3. Change the simulator settings above the Mod-High alarm limit for one of the parameters.
4. Observe the parameter is Yellow.
5. Change the simulator settings above the High alarm limit for the same parameter.
6. Observe the parameter is Red, the parameter label text is Flashing Red, the simulated indicator light is Flashing Red and the high priority alarm is sounding.
7. Repeat this process to test low value alarms.
8. Silence the alarm and return parameter settings to the normal range.
9. Reset the audible and indicator light alarms.
10. Repeat for remaining parameters.

To test the SpO_2 technical alarm functions follow the below steps:

1. Disconnect the SpO_2 sensor.
2. Observe the yellow " - - - - " line for the SpO_2 and PR parameter values.
3. Connect sensor and attach to a simulator or subject.
4. Observe the parameter values displayed.

To test the Power technical alarm function follow the below steps:

1. Allow the battery to run until the battery life is below 5%.
2. Observe color changes on the fuel gauge indicator as the battery is depleted.
3. Observe the battery icon flash and the medium priority alarm sounds when battery life is below 5%.
4. Turn off unit and recharge the battery.

7.0 ECG Monitoring

7.1 General

ECG electrodes are used to monitor the electric activity of the heart which is amplified and visualized using the WVSM® device. Three ECG electrodes are used to obtain an ECG waveform. Each of the three electrode wire leads have two ends; one which is connected to the subject and the other end connects to the corresponding color coded ports on the WVSM® device. The monitor is configured to display and record in a Lead II configuration only. Heart rate can also be obtained from the ECG.

7.2 Safety

WARNING: Use only Athena GTX® approved accessories with the WVSM® device. Improper functioning and/or insufficient protection during defibrillation could result if alternate ECG leads are used.

WARNING: DO NOT allow conductive portions of the ECG electrodes, leads and cables to come into contact with any other conductive parts including earth ground.

WARNING: The WVSM® device can be used during defibrillation. Inaccurate readings may occur during defibrillation and for a short time after defibrillator use.

WARNING: DO NOT immerse the WVSM® device or any accessories in water, solvents, cleaning solutions or other liquids. Follow the cleaning instructions included in the maintenance section later in this manual.

WARNING: DO NOT sterilize the WVSM® device or its accessories (by irradiation, steam, ethylene oxide, autoclave or other methods). Cleaning instructions are included in the maintenance section later in this manual.

WARNING: DO NOT use the WVSM® device or its accessories if they are damaged or broken. If damaged, remove immediately from service.

WARNING: Line isolation monitor transients may resemble actual cardiac waveforms and thus inhibit heart rate alarms. Methods for minimizing this problem: See instructions for proper electrode placement and cable arrangement.

WARNING: PACEMAKER PATIENTS. The WVSM® device may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. DO NOT rely entirely upon rate meter alarms. Keep pacemaker patients under close surveillance. See this manual for disclosure of the pacemaker pulse rejection capability of this instrument.

WARNING: An improperly connected electrosurgical unit may cause a patient to receive a burn. The WVSM® device may also incur damage or cause inaccurate readings. Proper instructions should be followed to avoid such consequences.

WARNING: ECG leads may become damaged if used during defibrillation. DO NOT reuse the ECG leads after use with defibrillators unless their functionality is properly verified.

WARNING: The use of accessories and cables other than those specified by Athena GTX® may result in increased electromagnetic emissions and/or a decreased immunity of the WVSM® device.

See Accessories list later in this manual.

WARNING: The WVSM® device should not be used adjacent to or stacked with other equipment. If this becomes necessary, the WVSM® device should be observed to verify normal operation.

WARNING: The use of accessories and cables other than those specified by Athena GTX® may result in inaccurate readings or damage to the WVSM® device.

WARNING: No modification of the WVSM® device or its accessories is allowed.

WARNING: Pay special attention to the type of electrodes used since some may be subject to large offset potentials due to polarization. Only use electrodes that are constructed of the same materials. Recovery time after application of defibrillator pulses may be especially compromised.

CAUTION: Use caution when removing disposable ECG electrodes to avoid damaging patient's skin.

CAUTION: Check the skin around the patient's ECG electrodes for signs of irritation.

CAUTION: For best monitoring results minimize patient motion.

Patient Sensor Connections

1. Ensure that the ECG leads are connected to the WVSM® device.
2. ECG cables should be attached to the metal snap of the disposable electrodes prior to attaching to the patient.
3. Remove the electrodes from the protective backing and apply each electrode to the patient's body as shown. White (Right Arm), Black (Left Arm), and Red (Left Leg).
4. If possible, choose flat areas and avoid major muscles, fatty areas or bony areas for placement of the ECG electrodes.
5. The site of electrode should be prepared by shaving or clipping any hair and applying isopropyl alcohol, soap and water or skin preparation pads, and dried.

Figure 21. ECG Patient Sensor Connections

7.3 Settings and Mode Selections

7.3.1 HR/PR

Heart Rate (HR) is derived from the R waves obtained from the ECG leads. Pulse Rate (PR) refers to the rate of pulses detected from the pulse oximeter, which is the default setting. To obtain the heart rate from the ECG, perform the following steps:

1. Select a patient
2. Select the Configuration Icon
3. Select the **HR From ECG** check box (a check mark will appear in the box)
4. Save (On the PDA) and Apply (on the PC)

Figure 22. Configuration Interface - HR/PR

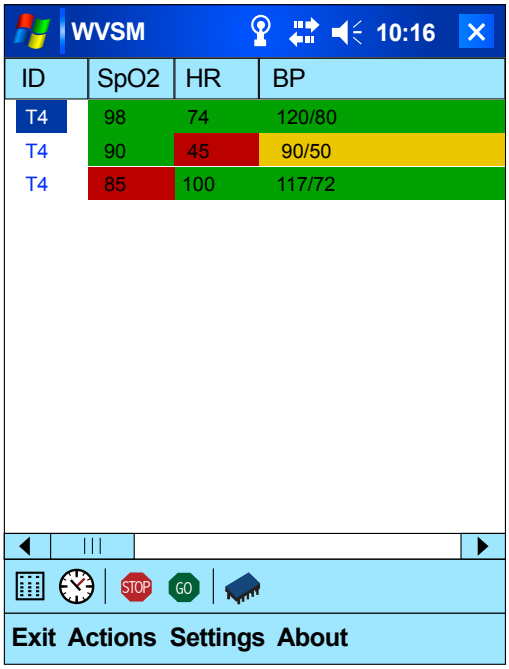


Figure 22a. Patient List

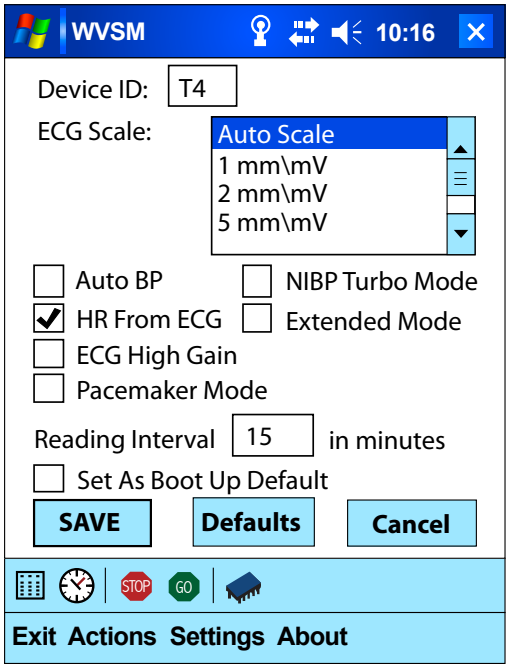


Figure 22b. HR from ECG

7.3.2 HW Gain Setting

The WVSM® device allows having 2 hardware gains of 220 and 1000. For ECG waveforms below 0.5mV the ECG High Gain setting is recommended. The user should select the gain setting that allows for the best display of the ECG waveform. To select the gain setting, perform the following steps:

1. Select a patient
2. Select the Configuration Icon
3. Select the **ECG High Gain** check box to select gain of 1000 (a check mark will appear in the box). If the check box is NOT checked, the hardware is set to the lower 220 gain setting.
4. Save (on the PDA) and Apply (on the PC)

Figure 23. Configuration Interface - HW Gain

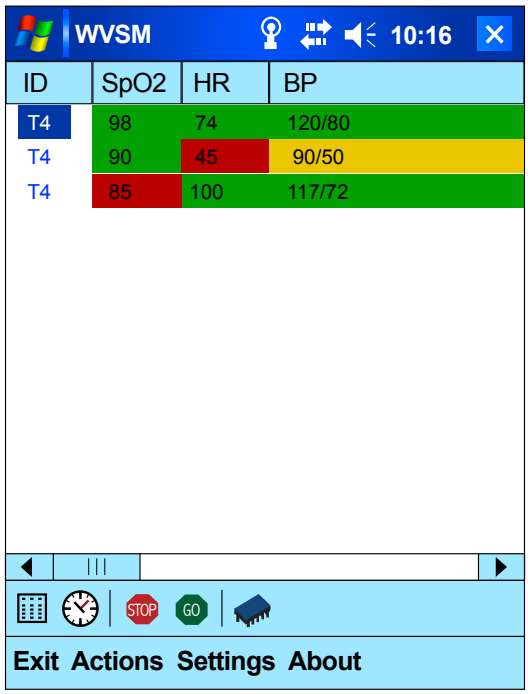


Figure 23a. Patient List

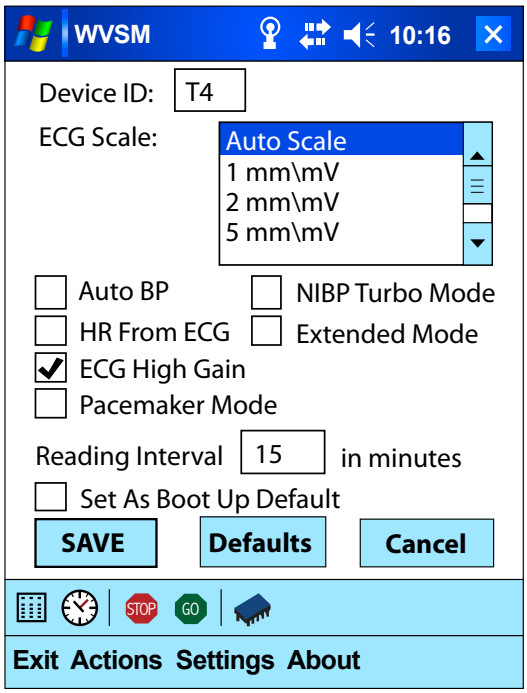


Figure 23b. HW Gain

7.3.3 Extended Mode

The default mode for the WVSM® device is “monitor” mode which corresponds to an ECG signal bandwidth of 0.6Hz to 40Hz. An Extended Mode is provided that expands the lower frequency ability of the monitor to a bandwidth of 0.05Hz to 40Hz. To select the extended mode, perform the following steps:

1. Select a patient
2. Select the Configuration Icon
3. Select the **Extended Mode** check box (a check mark will appear in the box). If the check box is NOT checked, the Device is in Monitor Mode.
4. Save (on the PDA) and Apply (on the PC)

Figure 24. Configuration Interface - Extended Mode

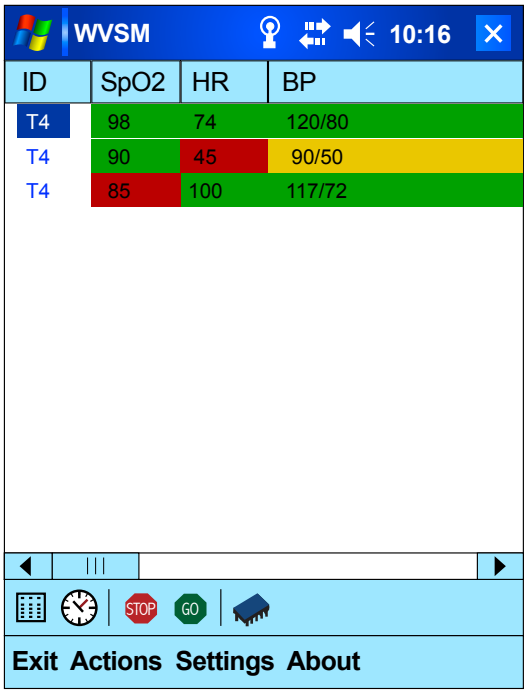


Figure 24a. Patient List

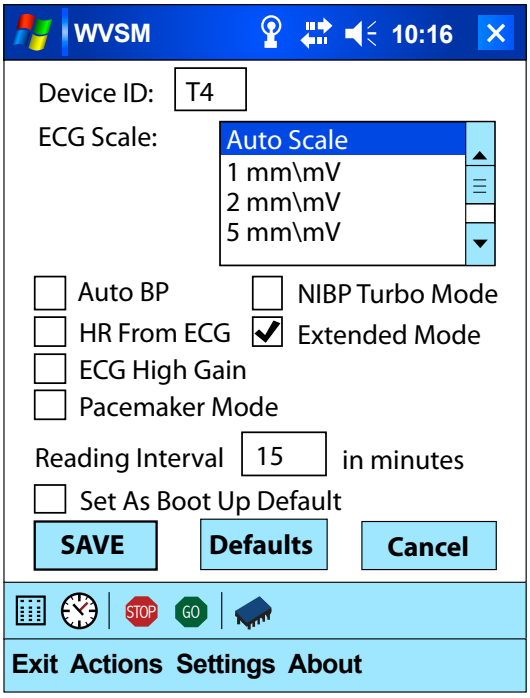


Figure 24b. Extended Mode

7.3.4 Display Scaling

The WVSM® device has an ECG display area that corresponds to a vertical height of 10mm and a horizontal width of 25mm. The horizontal axis is the time scale and cannot be adjusted. The time scale on the device is 1 second. The vertical axis includes 4 equally spaced tic marks (2.5mm each).

Figure 25. The WVSM® Device Display Screen

The WVSM® device allows for selecting different vertical display scaling. The current scale is displayed on the left side of the display just above the ECG waveform. The following choices are available:

- Auto
- 1mm/mV
- 2mm/mV
- 5mm/mV
- 10mm/mV
- 20mm/mV

The default setting for the WVSM® device is AUTO scale. Depending on how large you wish to visualize the graph an appropriate scale can be chosen based on the strength of the ECG signal of the patient. Auto Scale adjusts the display representation of the ECG waveform so that the full vertical axis is utilized each update (every second). Signal strength (mV) cannot be determined using this setting. To determine ECG signal strength one of the alternate settings must be used. To select a display scale, perform the following steps:

1. Select a patient
2. Select the Configuration Icon
3. Select the desired display scale (use the scroll bar as necessary).
4. Save (on the PDA) and Apply (on the PC)

Figure 26. Configuration Interface - ECG Scaling

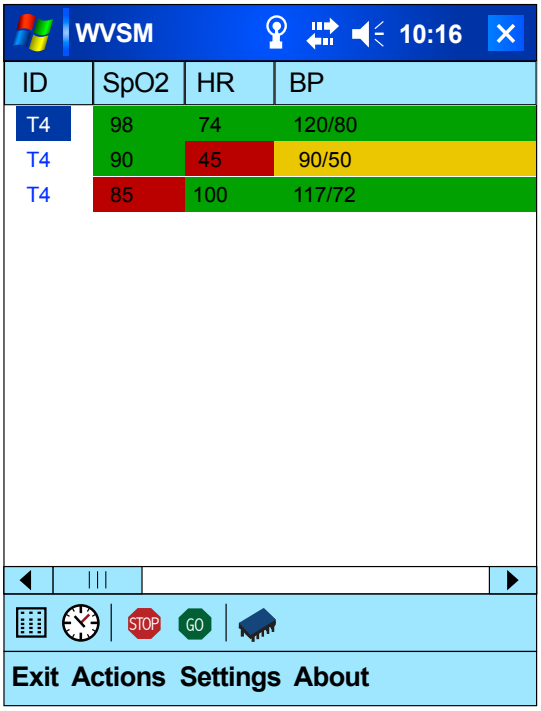


Figure 26a. Patient List

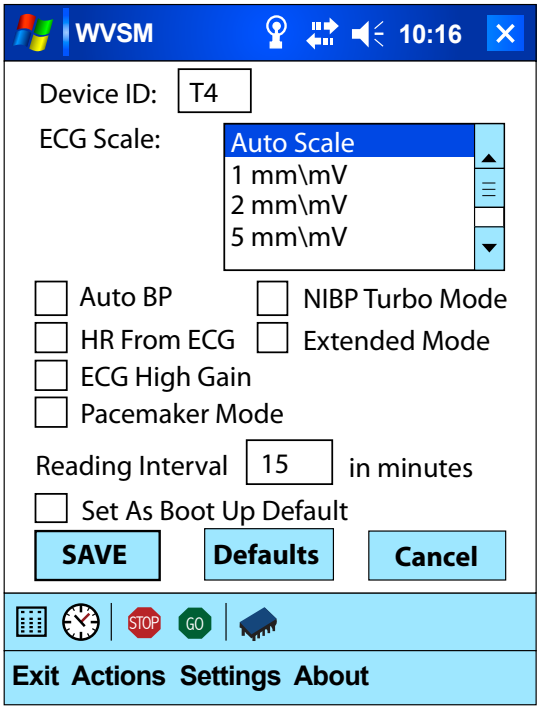


Figure 26b. ECG Scaling

8.0 Pulse-Ox (SpO_2 and Pulse Rate) Monitoring

8.1 General

The Pulse-Ox monitoring device used in the WVSM® device is the NONIN® OEM III. A reusable adult finger clip is provided as a standard accessory, but the WVSM® device is compatible with several NONIN® sensors. See the Accessories Section 18.3 of this manual for more information. The Pulse Ox monitor is able to continuously measure oxygenated and deoxygenated blood through the use of infrared and red LEDs, respectively. The amount of each light absorbed is the concentration of oxygenated or deoxygenated blood. During the continuous measurement, a systolic wave would cause an increase in arterial blood flow, and recording these increases and decreases in blood flow calculates the pulse rate of the patient. Both the SpO_2 and the pulse rate can be measured from this device. The SpO_2 has a range from 0% to 100% and the pulse rate has a range from 30 bpm to 250 bpm. Accuracy is dependent upon sensor type (refer to Section 16.5).

The SpO_2 is the first number displayed on the WVSM® device screen and the pulse rate (PR) or heart rate (HR) is directly below the SpO_2 . Signal inadequacy and sensor faults are displayed using dashed lines (– – – –) for each of these parameters. The colors of these parameters are explained in the Alarms Section of this manual. See the Maintenance Section of this manual for cleaning and maintenance instructions.

Figure 27. The WVSM® Device Display Screen - Pulse-Ox

8.2 Safety

WARNING: DO NOT use the WVSM® device in a explosive atmosphere or in the presence of flammable anesthetics or gases.

WARNING: The Pulse-Ox function does not meet defibrillation-proof requirements.

WARNING: The use of accessories and cables other than those specified by Athena GTX ® may result in inaccurate readings or damage to the WVSM® device.

WARNING: DO NOT use the WVSM® device to monitor Pediatrics or Neonates.

WARNING: The Pulse-Ox function will not work correctly if there is a blood flow restrictor such as a tourniquet or blood pressure cuff. If possible, make sure the Pulse-Ox function is on the opposite arm as the blood pressure cuff.

WARNING: To avoid the possibility of patient entanglement or strangulation, carefully route all patient cables and tubing.

WARNING: Using the Pulse-Ox function under the minimum amplitude of 0.3% modulation may cause inaccurate results.

WARNING: DO NOT use the WVSM® device or accessories if they are damaged or broken. If damaged, remove immediately from service.

WARNING: Before using the Pulse-Ox sensor, read and understand all directions for use, and inspect the device and sensor before use for damage.

WARNING: No modification of the WVSM® device or its accessories is allowed.

WARNING: Certain changes in the blood flow may cause inaccurate readings, make sure to validate patient condition before changing a patient care.

WARNING: Inspect the Pulse-Ox sensor application site at least every 6 to 8 hours to check sensor position and skin integrity.

WARNING: Pulse-Ox function is calibrated to display functional oxygen saturation.

CAUTION: Accuracy of Pulse-Ox function may be affected if cable length is increased.

CAUTION: The Pulse-Ox function is intended to determine the percent of arterial oxygen saturation of hemoglobin, which may be affected by any of the following conditions: high levels of dysfunctional hemoglobin (or methemoglobin), excessive ambient light, excessive motion, electrosurgical interference, improperly applied sensor, incorrect sensor type, poor pulse quality, venous pulsations, anemia or low hemoglobin concentrations, cardiogreen or other intravenous dyes, carboxyhemoglobin, methemoglobin, dysfunctional hemoglobin, artificial nails or fingernail polish, or a sensor not at heart level.

CAUTION: Though the Pulse-Ox function attempts to remove motion artifact, occasionally some motion artifact maybe interpreted as good pulse quality.

CAUTION: The Pulse-Ox function complies with IEC EN 60601-1-2:2001 for electromagnetic compatibility for medical electrical equipment and/or systems. This standard attempts to reduce the occurrence of an electrical device interfering with typical medical installations.

CAUTION: Portable or mobile RF communications equipment may affect the function of the WVSM® device.

CAUTION: Readings may be affected by the use of an electrosurgical unit (ESU).

CAUTION: The Pulse-Ox function may not work on cold fingers, because of lack of circulation. Warm or rub the finger to increase circulation or reposition sensor.

8.3 Patient Sensor Connections

Ensure that the sensor is properly plugged into the WVSM® device. The Pulse-Ox sensor is only to be used on the index, middle or ring finger for patients weighing more than 30 kg (66 lbs). If possible, use the **arm without the blood pressure cuff**, so that signal is not lost while taking a BP. The placement of the clip should be such that the wire is on the dorsal (non palmer) side of the hand, placing the nail of the finger facing the same direction as the depiction of the finger on the device, see figure below. Allow the clip to close around the patient's finger.

Figure 28. The WVSM® device Pulse-Ox Sensor Connections

8.4 Settings and Mode Selections

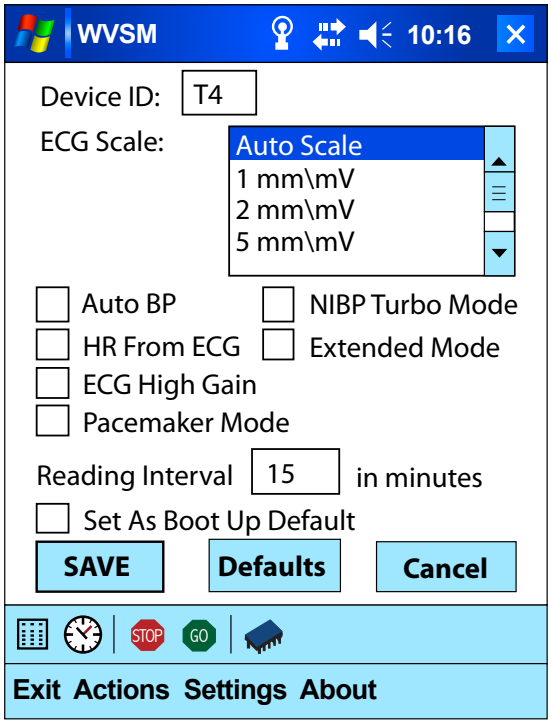
The WVSM® device has the ability to display either the heart rate or pulse rate on the display, by using the accompanying PDA or PC, see below for instructions. Heart Rate (HR) is determined from the ECG signal whereas the Pulse Rate (PR) is determined by the Pulse-Ox monitor signal.

8.4.1 HR/PR

Heart rate is recorded by the number of R waves recognized from the ECG signal. Pulse rate is recorded by the number of arterial blood pressure waves recognized by the Pulse-Ox monitor. Depending upon site of injury, accessibility to vital signs, and/or preference, either of these settings can provide a reading for the rate at which the heart beats. The accuracy of the PR is ± 5 digits or better depending on sensor, motion and perfusion conditions. To change the setting to have heart rate calculated from the Pulse-Ox, perform the following steps:

1. Select Patient
2. Select the Configuration Icon
3. Uncheck **HR From ECG**
4. Save (on the PDA) and Apply (on the PC)

Figure 29. Configuration Interface - HR/PR



9.0 Blood Pressure (NIBP) Monitoring

9.1 General

The NIBP system in the WVSM® device is a SunTech Advantage Mini system that is made to use an oscillometric technique to take the blood pressure measurement. This system uses an electric pump, valve, and sensor closed system to detect oscillations in pressure allowing systolic and diastolic pressure to be measured. The systolic and diastolic measurements will be displayed on the WVSM® device screen with units in millimeters of mercury (mmHg). The coloring of systolic and diastolic text adopts the same meaning as described in the Visual Alarm section.

Blood pressure measurements determined with this device are equivalent to those obtained by a trained observer using the cuff / stethoscope auscultation method, and are within the limits prescribed by the American National Standard Electronic or automated sphygmomanometers. NIBP module performance with common arrhythmias, such as atrial or ventricular premature beats or atrial fibrillation, has been verified by use of a patient simulator to AAMI SP10 performance criteria.

The NIBP system has three modes of operation: auto, manual and turbo. The default mode is Auto; Turbo and Manual modes must be manually set by the user. Specifics of the modes will be given below in the Settings and Mode Selection section.

The recommended SunTech Orbit cuff range is 40-260 mmHg for systolic and 20-200 mmHg for diastolic. The accuracy of the NIBP system is factory tested to read static pressure within +/-3 mmHg. Although SunTech cuffs are recommended for use with the WVSM® device, other types may be used. This is discussed in the Accessories Section of this manual.

9.2 Safety

WARNING: Be sure that all blood pressure tubing is not pinched and that flow is not restricted in any way while taking blood pressure measurements. The cuff must be correctly fitted, placed, and checked to be operational. The Patient Sensor Connections section below has guidelines for proper fitting. If the cuff is not fitted properly, or the tubing is pinched, accuracy can be diminished or fail.

WARNING: In radical cases the NIBP system could fail and cause restriction to the patient's limb. Furthermore, frequent measurements could cause poor circulation depending on the patient's condition, frequency, and other physiological variables. Be sure to check the monitored limb for proper circulation on a schedule deemed appropriate by trained personnel.

WARNING: Prolonged over-inflation of the NIBP cuff could cause poor circulation depending on the patient's condition. Be sure to check the monitored limb for proper circulation on a schedule deemed appropriate by trained personnel.

WARNING: Cuff placement should avoid limbs that are being used for intravenous delivery of fluids, SPO_2 monitoring or other possible obstructions.

WARNING: Patient should remain still while blood pressure measurements are being taken. Patient movement may produce inaccurate results.

WARNING: The WVSM® device only displays the last NIBP measurement. If there is a critical change in condition between measurements, alarms will not sound.

WARNING: Penetration of water or other liquids into the WVSM® device may result in damage, and the device may not function properly. If this occurs, immediately remove from the device from patient and discontinue use.

WARNING: Patient positioning and patient physiological condition can adversely affect the accuracy of blood pressure measurements. Please follow the guidelines in Patient Sensor Connections to avoid problems.

9.3 Patient Sensor Connections

This section has directions specific to the SunTech Orbit brand BP Cuff. These directions may not be sufficient for other BP cuffs.

Choosing the Cuff Size

To determine the correct cuff size for your patient, follow these simple steps:

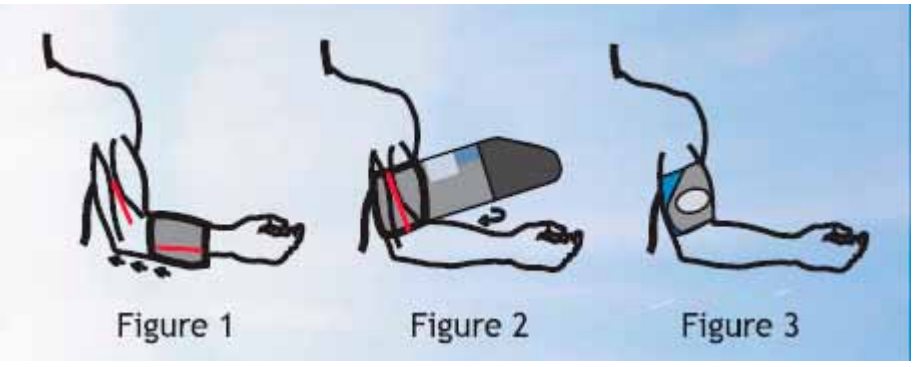
1. Wrap the cuff around the patient's upper arm without sliding the arm through the sleeve.
2. Use the color-coded RANGE indicator on the inside of the cuff and the bold INDEX marker to check that the circumference falls within the cuff range.
3. If the arm is within range, this cuff size is correct for your patient. If the measurement is outside the RANGE indicator, select a new cuff size as indicated by color.

Applying the Cuff

1. To apply the Orbit cuff, slide the sleeve up the patient's arm, ensuring the artery arrow points down the arm. The cuff should be midway between the elbow and shoulder.
2. Be sure the ARTERY indicator is over the patient's brachial artery, between the bicep and tricep muscles (see illustration showing left arm placement).
3. Wrap the cuff snugly around the patient's upper arm.
4. Take the initial BP reading and ensure the system is working.

Refer to Figure 1, 2 and 3 for an illustrated overview.

Figure 30. NIBP Cuff Patient Placement



Prepare the Patient

Preparing the patient is the most important step in obtaining an accurate, reliable blood pressure measurement.

Review the following instructions with your patient:

- Avoid excess movement during readings.
- Relax the instrumented arm, slightly away from the body.
- Avoid hand movement.
- Avoid flexing muscles during reading.
- DO NOT remove the cuff between readings.

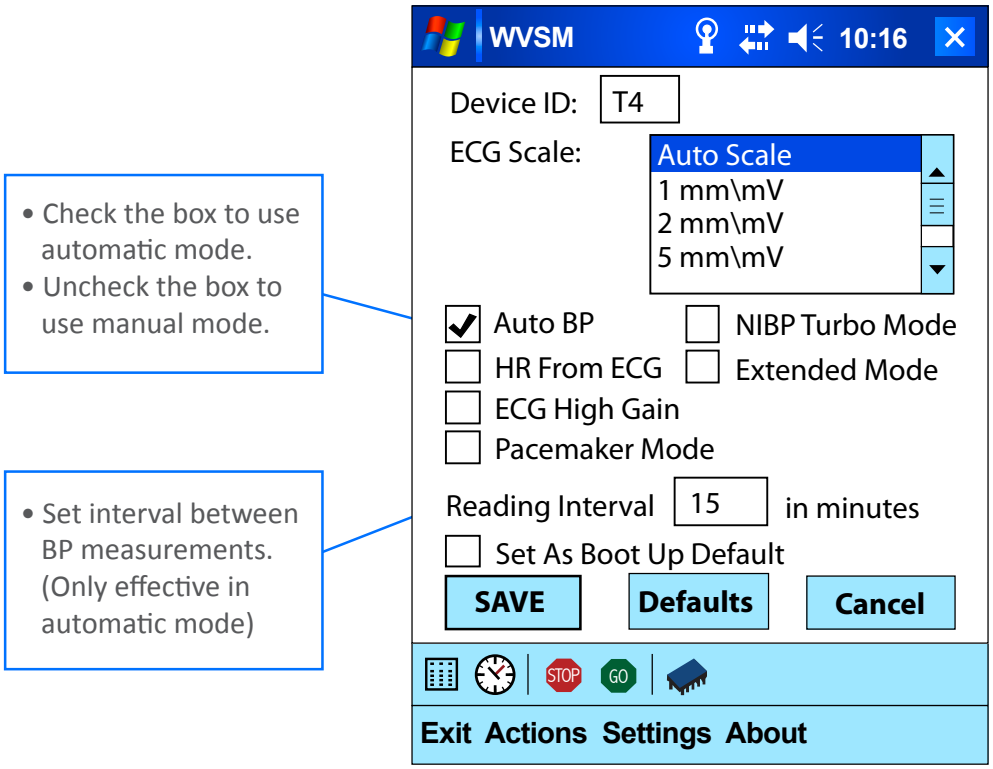
9.4 Settings and Mode Selections

9.4.1 Auto/Manual Mode

Auto mode is set as the system's default mode. This mode will automatically take BP measurements every 15 minutes, and has an initial inflate pressure of 160 mmHg. You can change from the default 15 minute automatic interval to a manual setting where only manual BP measurements are taken by un-checking the Auto BP check box. Within the automatic mode you can adjust the interval of BP measurements via PDA or PC software.

The screen shot below shows the settings available to change.

Figure 31. Configuration Interface - NIBP



9.4.2 Turbo Mode

The turbo mode, which must be turned on manually, will take BP measurements in a sequence of every 2, 2, 3, 3, 5, 5 minutes, and then return to Auto or Manual mode depending upon current settings. The cuff's initial inflation pressure is 160 mmHg in turbo mode.

To put the unit in turbo mode, the user must press and hold the BP button for 2 seconds until the pump starts the first measurement in the sequence.

Frequent measurements (Auto Mode interval set to below 15 minutes) could cause poor circulation depending on the patient's condition, frequency, and other physiological variables. Be sure to check the monitored limb for proper circulation on a schedule deemed appropriate by trained personnel.

9.4.3 Automatic Mode and Interval Adjustment

The WVSM® device comes with automatic mode as the default setting. The configuration settings menu allows the user to view or change the device's current mode and allows them to set the blood pressure reading time interval. This menu can be reached according to the instructions outlined in the Auto/Manual Mode section above.

Frequent measurements (Auto Mode interval set to below 15 minutes) could cause poor circulation depending on the patient's condition, frequency, and other physiological variables. Be sure to check the monitored limb for proper circulation on a schedule deemed appropriate by trained personnel.

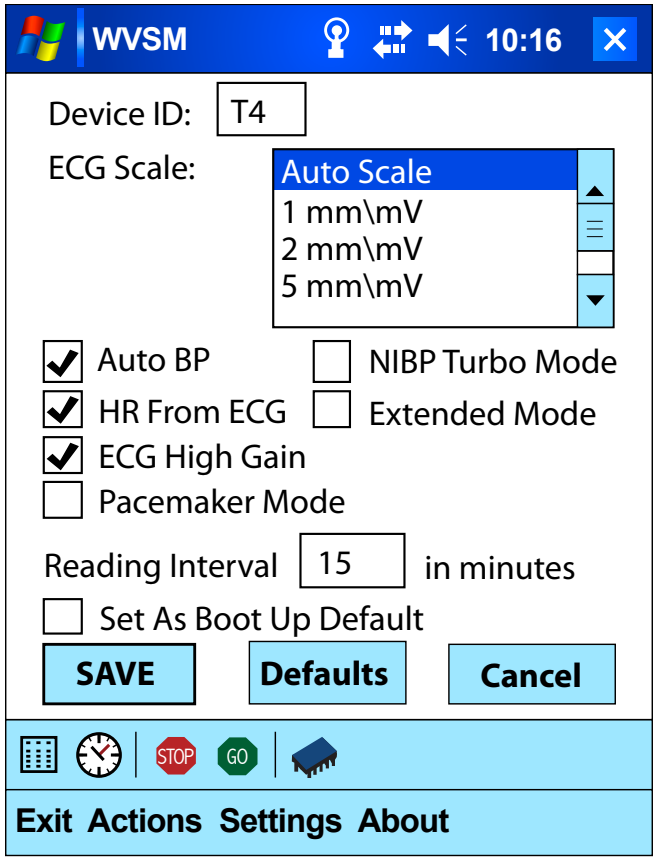
10.0 Configuration Presets & Management

The operator can temporarily change the configuration preset settings for a particular patient. The configuration presets will remain active until either the settings are modified again, or if the device is turned off and then turned back on, and a new patient file is selected. When a new patient file is the selected WVSM® device will return to the default configuration presets. The temporary configuration presets will remain in effect, if the WVSM® device is turned off and then turned back on, and the continue button is pressed. The figure below shows the device configuration screen on the PDA. The following presets are available:

Table 17. Configuration Presets

Configuration Preset	Description
Device ID	WVSM Device ID – Typically a Letter and Number combination to Identify the device on the patient and on the PDA/PC display screen. **Default is WV**
ECG Scale	Scales the ECG waveform on the WVSM Device display. Options are Auto, 1, 2, 5, 10, and 20 mm/mV. **Default is Auto**
HR From ECG	Toggles between displaying the heart rate calculated from the ECG waveform (HR) and the Pulse-Ox (PR). **Default is PR**
ECG High Gain	Toggles between the hardware gain settings of Low (220) and High (1000) to increase signal quality into the ADC for small ECG signals (below 0.5mV amplitude). **Default is Low(220)**
Extended Mode	Toggles between Monitor Mode and Extended Mode for the ECG waveform frequency response bandwidth. **Default is Monitor Mode**
Auto BP	Toggles between Manual Mode and Auto mode for taking NIBP measurements. **Default is Auto**
NIBP Turbo Mode	Indicates the device is in Turbo Mode for NIBP measurements. **Default is Auto**
Reading Interval	Sets the time interval between NIBP measurements in Auto BP Mode. Time interval is Start to Start. **Default is 15 minutes**

Figure 32. The WVSM® Device Configuration Interface Screen



To temporarily change the configuration presets for a patient, perform the following steps:

1. Select a patient
2. Select the Configuration Icon
3. Adjust the settings as necessary
4. Save (on the PDA) and Apply (on the PC)

Note: Only the designated Responsible Organization personnel can change the Default Presets (See the WVSM® device Service Manual)

11.0 Uploading of Historical Patient Data to a personal computer

11.1 General

In order for the WVSM® device to display patient data on a PC the following is required;

1) The PC must be running the WVSM® Management Suite software and

2) Network communications must be established between the WVSM® device and the PC

When a patient wearing the WVSM® device comes into communication range of a PC running the WVSM® Management Suite software, the patient's current vital signs will immediately be displayed on the PC, and any patient history will automatically begin attempting to upload to the PC. The WVSM® device is capable of storing up to 4.5 hours of a patient's vital signs data.

11.2 Viewing Patient Historical Data

The patient's vital signs history is uploaded to the PC with the most recent data first and continuing until all historical data is fully uploaded. Available patient historical data can be reviewed when in Single Patient View by using the appropriate scroll bar.

11.3 Uploading Data of Multiple Patients

The WVSM® Management Suite software has been designed to wirelessly connect and monitor up to twenty patients simultaneously. The Management Suite has also been designed to simultaneously upload stored historical patient data for a maximum of 6 patients (5 automatically selected by the PC + 1 user selectable patient), at a time.

In cases where more than five patients come into communication range, the WVSM® Management Suite software will attempt to automatically select and begin uploading patient data from those devices.

As uploading of historical data from one patient is completed, the software will search for the next available device to begin the uploading process until each patient's historical data has been uploaded to the computer.

11.4 Uploading of Patient Data Using Multiple Computers

In cases where multiple PCs are used to monitor WVSM® devices, uploading of patient data is controlled by the WVSM® Management Suite software. Current patient data is broadcast by each WVSM® in near real time to all PCs within communication range and can be seen on the PC display immediately. Patient historical data can only be transmitted to one PC at a given time.

If for example a single WVSM® device is selected by more than one PC, the device will begin to upload patient history to the PC with which communications was established first. When uploading is completed, it will then begin uploading to next PC and so on. During this process all PCs receive near real time patient vital signs data from the WVSM® device, and the patient's current condition can be monitored. It is only the historical data that is uploaded to each PC on an individual basis. As with any prioritized communications network, the greater the number of users requesting patient historical data, the longer the time required to provide the information to each user. A status indicator can be seen when in the Single Patient View display mode (Refer to Figure 33). The following wording is displayed:

Uploading: The selected WVSM® device is actively uploading patient data to the personal computer.

Queued: The selected WVSM® device is waiting to be selected and to begin uploading patient data to the PC.

Blocked: The selected WVSM® device is currently uploading patient information to another computer. Once the device has fully uploaded all patient data, “Blocked” will no longer be seen indicating the WVSM® device is available to upload patient data.

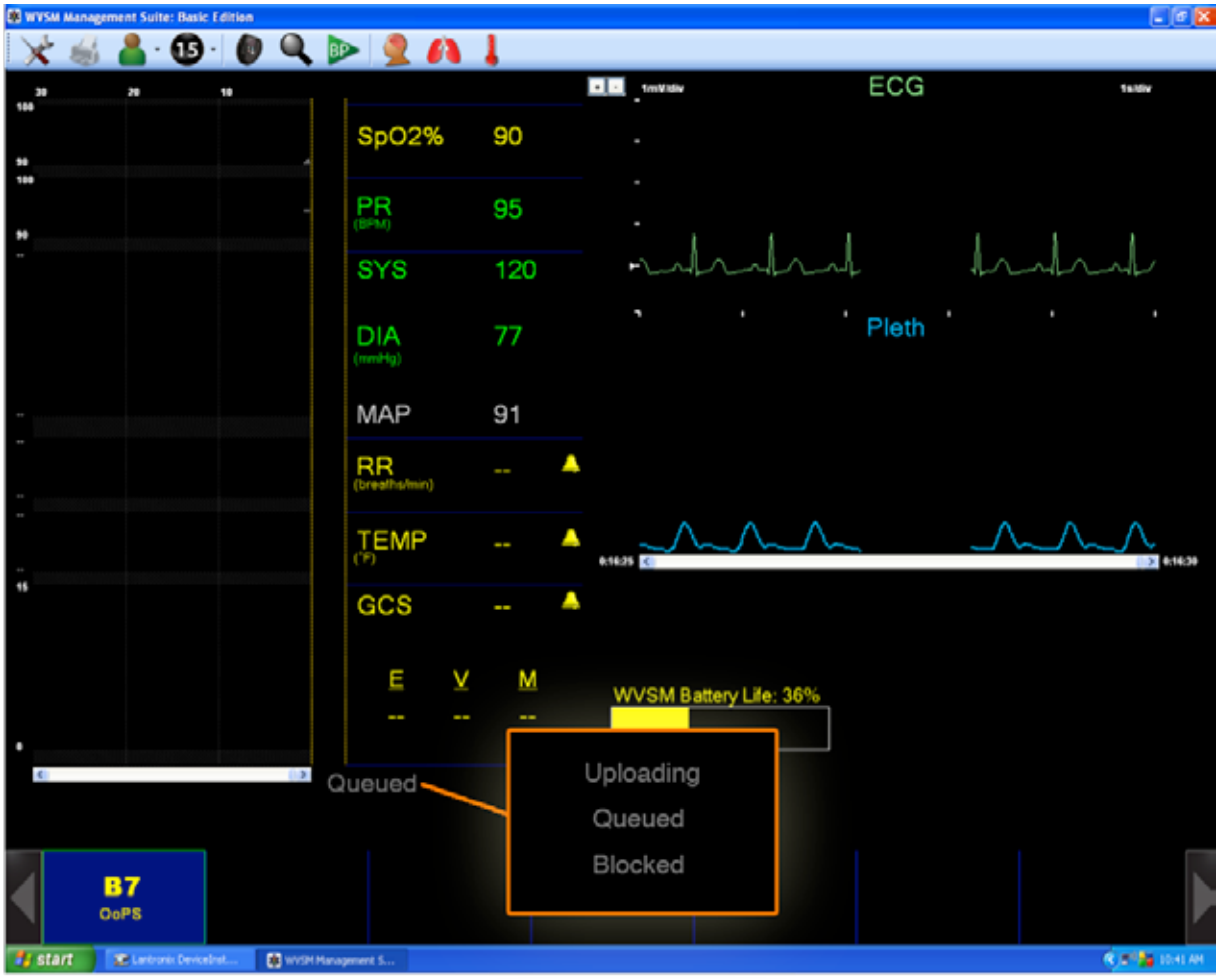


Figure 33. Uploading, Queued & Blocked

11.5 Data File Storage Location

The PC software creates a new file for each patient monitored. These files are saved using the unique ID code that is displayed on the selection band in the Single Patient View screen. The raw binary data is stored in the location c:\ETF DATA\[Unique ID].dat. As a normal part of PC maintenance these files should be periodically deleted or moved to a holding directory to prevent file naming and/or memory storage issues.

12.0 Patient Data History Printing

The patient history can be printed by selecting a patient from the patient list and selecting the Print Icon from the menu toolbar. The printing icon is only available when a patient has been completely uploaded as indicated by the uploading status label. As seen in Figure 34, the printing dialog can print vitals in intervals of 1, 5, and 10 minutes. The data is printed in the format shown in Figure 35, and contains the following information: Unique ID, Device ID, Time, BPM, SpO2, Systolic blood pressure, Diastolic blood pressure, Mean arterial blood pressure, Respiratory rate, Temperature, and Glascow Coma Score. If a value has not been entered or is not valid “NaN” is printed.

Patient data is stored on the WVSM® device in non-volatile memory. This stored information will remain in memory and can be printed until the device is powered OFF/ON and the Blue New File option is chosen from the Mode Select menu. When a new file is selected all previously stored patient data is erased from device memory.

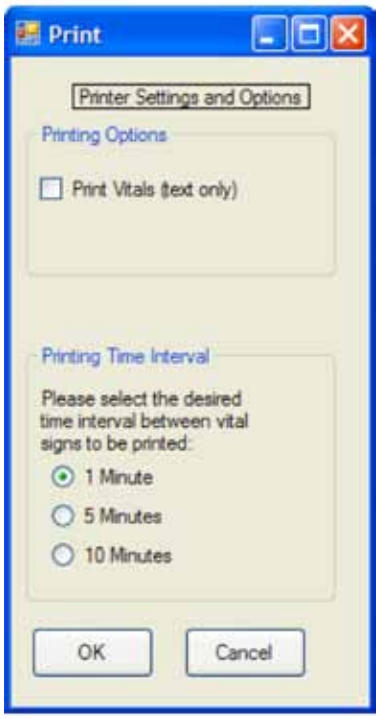


Figure 34. Patient Data History Screenshot

Unique ID:		Device ID:									
Time	BPM	SPO2	SYS	DIA	MAP	RR	TEMP	GCS	E	V	M

Figure 35. Printing Format

13.0 Communications Interface

13.1 General

The communication with the WVSM® device can be accomplished either by WiFi or by RS232. Communicating wirelessly can be done by setting up the proper wireless configuration with the PC or PDA. The default mode for the WVSM® device is to communicate via WiFi. Indication that WiFi is enabled is given by the blue LED on the membrane switch on the front panel of the device. Both RS232 and WiFi connections provide the same data and memory functions.

13.2 Switching from WiFi to RS232

CAUTION: Use of the data port / data cable is restricted to use with, and connected to, approved accessories. Unauthorized connection to other equipment via the DATA port could result in malfunction of the equipment or damage to the WVSM® device or connected equipment.

To communicate via RS232 perform the following steps:

1. Connect the 2.5mm jack end of the serial cable accessory to the data port located on the rear panel of the WVSM® device.
2. Connect the DB9 end of the serial cable accessory to the PC or PDA.
3. Turn off the wireless communications by pressing the blue button on the top panel of the WVSM® device. The blue LED will no longer be illuminated.

13.3 Switching from RS232 to WiFi

To change from RS232 communications to WiFi communications perform the following steps:

1. Turn on the wireless communications by pressing the blue button on the top panel of the WVSM® device. The blue LED will be illuminated.
2. The RS232 cable accessory can now be disconnected if desired, but may remain in place.

14.0 Maintenance

14.1 Cleaning

WARNING: DO NOT sterilize the WVSM® device or its accessories by irradiation, steam, ethylene oxide, autoclave or other methods.

WARNING: DO NOT immerse the WVSM® device or any accessories in water, solvents, cleaning solutions or other liquids.

WARNING: Make sure the AC adapter is unplugged from the AC power source before cleaning.

CAUTION: Use only approved cleaning solutions. See Athena GTX® recommended cleaning solutions below.

CAUTION: Inspect the WVSM® device and accessories for damage before cleaning.

14.1.1 The WVSM® Device

1. Cleaning solutions: Use an approved solution (See Section 16.0)
2. Wipe with damp lint-free cloth in accordance with Athena GTX® recommendations.
3. Wipe off any excess liquid.

14.1.2 Pulse-Ox Sensor

CAUTION: Refer to Pulse-Ox sensor Accessory instructions for additional or updated information on proper cleaning procedure.

For instructions regarding cleaning pulse oximeter sensors, refer to the appropriate pulse oximeter sensor package inserts.

14.1.3 ECG Cables

Single use disposable

14.1.4 NIBP Cuffs

CAUTION: Refer to Cuff Accessory instructions for additional or updated information on proper cleaning procedure.

For instructions regarding cleaning NIBP cuffs, refer to the appropriate cuff package inserts.

14.1.5 Data Cable

1. Cleaning solution: Use an approved solution (See Section 16.0)
2. Wipe with damp lint-free cloth in accordance with Athena GTX® recommendations.
3. Wipe off any excess liquid.

14.2 Recharging the Battery

The WVSM® device contains a rechargeable lithium ion battery capable of multiple charge/discharge cycles. A new WVSM® device under normal use conditions will have a battery life of up to 7 hours. When the WVSM® device can no longer maintain an adequate charge, contact Athena GTX ® for replacement of the battery.

To recharge the WVSM® device battery, perform the following steps:

1. Plug the medical grade power cord accessory (Provided with the WVSM® device) into the power adapter (Also provided with the WVSM® device).
2. Plug the medical grade power cord into an appropriate AC power source.
3. Ensure the WVSM® device is “OFF”. If adapter is plugged in while the WVSM® device is “ON”, the WVSM® device will warn the user of an automatic shutdown.
4. Plug in the power adapter into the rear panel of the WVSM® device. The CHG status light should be “RED”.
5. The battery will charge and automatically terminate. The CHG status light will turn “GREEN” when charging is complete. Charging a fully discharged battery takes approximately 3 hours.
6. If a charging fault occurs the CHG status light will turn “OFF”.

WARNING: Use only approved/recommended power adapters. The charging unit is specified as part of the WVSM system - use only the approved unit as specified in section 18.2.

WARNING*:* To avoid risk of electric shock, this equipment must only be connected to a supply main with protective earth/grounding.

CAUTION: The WVSM® device contains a lithium ion battery. Potential for fire or burning. DO NOT disassemble, crush, heat, burn or incinerate.

CAUTION: The WVSM® device contains no user serviceable parts. DO NOT disassemble. Contact Athena GTX® regarding repair or battery replacement.

Figure 36. WVSM® Battery Recharging

14.3 NIBP Calibration

The NIBP system in the WVSM® device is compliant with international standards of automatic device blood pressure accuracy. The international standard requires static measurements to be within +/-3 mmHg. It is important to have proper test equipment and that it is in good working order while performing calibration. Verify Calibration once every year. See Service Manual for Calibration Procedures.

14.4 Disposal

CAUTION: When disposing of or recycling the WVSM® device follow local government ordinances and recycling instructions.

15.0 Troubleshooting

15.1 The WVSM® Device

1. The WVSM® Device is not turning on:
    b. If the blue WiFi light blinks when power button is pushed the battery needs to be recharged.
    c. If the blue WiFi light does not blink when power button is pushed the battery may have been over discharged. Charging the battery should resolve the problem.
    d. If recharging the battery does not resolve the problem return the unit back to the manufacturer for repair or replacement or call the manufacturer for advice.
2. No/Incorrect ECG waveform
    e. Check for loose connections:
        i. at the WVSM® device ECG connector port
        i. at the ECG adaptor [both ends] (if applicable)
        ii. at the ECG electrode snap interface
    f. Ensure that ECG electrodes are secured on the patient's body
    g. Confirm that the individual ECG electrodes are placed correctly on the patient
    h. Verify that the individual ECG electrodes are plugged into the corresponding ports(RA, LA, LL) on the ECG adaptor
    a. Ensure that ECG electrodes are plugged into the WVSM® device ECG connector port before the WVSM® device is turned on (otherwise, restart the WVSM® device after plugging in the ECG electrodes first)
3. No/Incorrect SpO_2 readings:
    a. Ensure that there is no loose connection (at the WVSM® device connector port and at the finger clip)
    i. Check to see if the NIBP arm cuff is inflating (especially if the SpO_2 finger clip is placed on the same limb as the cuff, the SpO_2 reading may be momentarily interrupted)
    b. Ensure that Pulse-Ox sensor is plugged into the WVSM® device SpO_2 connector port before the WVSM® device is turned on (otherwise, restart the WVSM® device after plugging in the ECG electrodes first).
4. No/Incorrect NIBP readings:
    j. Ensure that the NIBP arm cuff is placed on the patient arm properly (the cuff must be properly placed around the patient's arm and the "artery" arrow indicator must be lined up properly)
    k. Ensure that the patient and his/her arm is immobile during the measurement (motion artifacts can influence the accuracy)
    a. Recharge the battery (there may be insufficient power remaining on the WVSM® device to properly inflate the arm cuff)
5. Pressing "Continue" on Menu screen produces an error message and returns to Menu screen
    a. The WVSM® device has detected an error in the configuration files and cannot continue with the previous patient.
    l. Select "New Patient" to use the monitor.

15.13 Communications

15.13.1 Pocket PC WLAN connection not successful:

1. Turn the WVSM® device(s) on (Otherwise there is no network)
2. Wait a few seconds for the Pocket PC WLAN to find the network and connect (connected = ⇆; not connected = ⇆x)
3. Change to the WVSM® device WLAN connection network (If there are other networks present, the PDA may have connected to the wrong network)
4. Touch the WLAN icon on top ⇆
5. Touch Settings from the Connectivity popup menu
6. Touch Advanced tab at the bottom
7. Touch Network Card near the bottom
8. Touch wvsm network from the list
9. Continue to touch OK buttons until returning to the Home Screen
10. In order to communicate with the WVSM® device, the PDA needs to be setup to operate on the same network. New systems should be set up by the user. Contact your Network or System Administrator if you are unable to do so.

15.13.2 PC WLAN Connection not Successful

1. Check to ensure the wireless device [USB, CF, SD, etc.] is plugged in properly (These devices can get displaced easily).
2. Restart the computer (This action resets the WLAN communication system).

15.13.3 PDA

1. PDA does not allow tapping actions to take place
   a. Non-activity on the PDA screen for a period of time will automatically shut off the back light. Touching the screen will bring the home screen back up.
   b. In some models, the PDA software may also lock out inadvertent taps on the screen. If that should occur, follow the manufacturer's unlocking procedures.
2. PDA will not turn on – Recharge battery with PDA Power Adapter.
3. WVSM® Software is not listed on the PDA (Could be due to PDA losing all power and erasing RAM) – Reload software from SD Card.
4. PDA is non-responsive – Reset PDA.

15.13.4 PC

1. WVSM® software is not responsive – Open Task Manager to see if WVSM® software is non-responsive. If non-responsive, end program and try restarting the WVSM® software.
2. PC is non-responsive – Re-boot the computer.
3. Wireless connection cannot be established – See Wireless connection procedures in this manual.

16.0 Specifications

16.1 General/Mechanical

Title	Specification
Method of Cleaning	See Section 14.0
Approved Cleaning Solutions	**1. Vesphene II SE**, **2. Clorox Disinfectant Wipes** [n-Alkyl (C14,60%; C16,30%; C12,5%; C18,5%) dimethyl benzyl ammonium chloride 0.145%, n-Alkyl (C12,68%; C14,32%) Dimethyl Ethylbenzyl Ammonium Chloride 0.145%], **3. Isopropal Alcohol** 70%, **4. Clorox Bleach Solution** 1.84% Sodium Hypochlorite
Flammable Anesthetics	No
Monitor Size	
Height	2.6 in (6.6 cm)
Width	4.0 in (10.2 cm)
Depth	5.4 in (13.7 cm)
Monitor Weight	Approximately 16 oz (0.45 kg)

16.2 Electrical

Title	Specification
Electrical Shock Protection	Medical Grade Power Adapter
Electrical Shock Protection for Patient Parts	ECG and NIBP: Type CF Pulse-Ox: Type BF
Operational Time	Up to 7 hrs (WiFi On and NIBP taken every 15 min)
Recharge Time	Approximately 3 hrs
Charger	Internal to WVSM – Constant Current + Constant Voltage (8.4 V and 1300 mA)

Battery	
Chemistry	Li-Polymer
Capacity	2800 mAh
Nominal Voltage	7.4 V
Watt Hour Rating	21 Wh
Protection	Overcurrent, Overdischarge, Overcharge Detection
Safety	Cells UL 1642 approved
Power Adapter	SL Power/Ault MW173KB Series
Input	100 – 240 V AC, 50 – 60 Hz, 1.0 A
Output	+9 V DC, 3.0 A
Power	27 Watts
Use	Indoor Use Only
Safety	UL60601-1, IEC/EN60601-1
EMC	EN60601-1-2/EN55024
Input Connector (AC)	IEC320 w/ground C14
Output Connector (DC)	Redel Series 1P, 2 pin, Plastic, Keyed
Case Material	Black Polycarbonate UL-94V0
Reverse Voltage Protection	Yes (Diode internal to WVSM)
Over Current Protection	Yes (Self Resetting Fuse internal to WVSM)

16.3 Environmental

Title	Specification
Operating Temperature	
Discharge	0 to +40°C
Charging	0 to +40°C
Shipping and Storage Temperature	-30 to +70°C
Operating Altitude	0 to 15,000 feet
Shipping and Storage Altitude	0 to 15,000 feet
Operating Relative Humidity	Up to 95% RH non condensing

Shipping and Storage Relative Humidity	Up to 95% RH non condensing
Water Resistance	IPX2
Drop	IEC 60601-1, 1meter onto a 50mm thich hard wood board
Shock	ISO 9919 Transport - peak 1 000 m/s2 (102 g), 6 ms, half-sine, 3 shocks per direction per axis (18 total)
Vibration, Random	ISO 9919 Transport - 10 Hz to 2 000 Hz, resolution: 10 Hz; acceleration amplitude: 10 Hz to 100 Hz: 5.0 (m/s2)2/Hz; 100 Hz to 200 Hz: –7 db per octave; 200 Hz to 2 000 Hz: 1.0 (m/s2)2/Hz; duration: 30 min per perpendicular axis (3 total).
Electromagnetic Compatibility (EMC)	IEC 60601-1-2 Class B and ISO 9919 transport levels for Immunity (20 V/m) during monitor with wireless communications. Charging and Monitoring with data cable immunity level is 3 V/m.

16.4 ECG

Title	Specification
Regulatory Standards	EC-13 (Safety and performance) and 60601-2-25 (Safety)
Connector	1.5mm Safety Plug
Cable Type	EC-53, Individual 3 Leads
ECG Scaling	Auto, 1, 2, 5, 10, 20 mm/mV
(Monitor)	Auto
(PDA)	Aspect Ratio 0.4s/mV – mV/div varies based on Display Window Size
(PC)	3mV/div (3.33mm/mV) 2mV/div (5mm/mV) 1mV/div (10mm/mV) 0.4mV/div (25mm/mV) 0.2mV/div (50mm/mV) 0.1mV/div (100mm/mV)
Display Sweep Speed **(Monitor & PDA)**	25mm/sec
(PC)	1sec/div (25mm/sec), 0.2sec/div (125mm/sec)

Title		Specification
Bandwidth **Monitor (Normal) Mode** **Extended Mode**		 0.67 to 40 Hz 0.05 to 40 Hz
Notch Filters		None
Sample Rate		230 Hz
Input Protection		Protected against Defibrillation. Recovery from Defibrillation < 5 sec
Electrosurgery Interference Suppression (AAMI Specification EC13-2002, 4.1.2.1 a)		None
Respiration, leads-off sensing, and active noise suppression (AAMI Specification EC13-2002, 4.1.2.1 b)		None
Tall T-Wave Rejection (AAMI Specification EC13-2002, 4.1.2.1 c)		Up to 1.2mV
HR Averaging Method (AAMI Specification EC13-2002, 4.1.2.1 d)		Analyzes an array of the last 8 beats. Takes the average of Valid beats in the array. Minimum of 4 valid beats is required. A "Valid" Beat (R-R interval) is within 10% of at least one other beat in the array. Display is updated every second
Response to Irregular Rhythm (AAMI Specification EC13-2002, 4.1.2.1 e)		
Ventricular Bigeminy (VB)		80 bpm
Slow Alternating VB		60 bpm
Rapid Alternating VB		120 bpm
Bidirectional Systole		90 bpm
Response time of heart rate meter to change in heart rate (AAMI Specification EC13-2002, 4.1.2.1 f)		≤ 10 Seconds
Response to Irregular Rhythm (AAMI Specification EC13-2002, 4.1.2.1 g)		
1 mV Ventricular Tachycardia (206 bpm)	**0.5x**	Failure to Alarm
Time to Alarm	**1x**	1x Range 2.2 - 4.3 sec Avg 2.9 sec
	2x	2x Range 2.7 - 3.1 sec Avg 2.9 sec
2 mV Ventricular Tachycardia (195 bpm)	**0.5x**	0.5x Range 6.7 - 18.1 sec Avg 13.8 sec
Time to Alarm	**1x**	1x Range 3.8 - 6.1 sec Avg 4.9 sec
	2x	2x Range 1.5 - 2.9 sec Avg 2.4 sec

Title	Specification
Common Mode Rejection (ANSI/AAMI:EC 13:2002, Sec 4.2.9.10)	< 1mV RTI
Input Impedance	> 2.5M ohms
Input Range (AC)	10 mV peak-to-peak
Input Range (DC)	Up to ±300 mV
Accuracy of Input Signal Reproduction- Impulse Response	ANSI/AAMI:EC 13:2002, Sec 4.2.9.8 c) when in Extended Mode
System Noise	Software filter on, ≤ 30 µV peak-to-valley, RTI
Baseline Recovery (Trace Restore)	Automatic
QRS Detector (ANSI/AAMI:EC 13:2002, Sec 4.2.6.1)	0.5 mV to 5 mV, and 70 ms to 120 ms
HR Range	0 to 250 beats/min
HR Alarm Limits **High** **Low**	 35 to 250 beats/min 30 to 245 beats/min
HR Resolution	1 beat/min
HR Alarm Resolution	1 beat/min
HR Accuracy (30 to 250 beats/min)	±10 % of the input rate or ±5 bpm whichever is greater
HR Display Update Interval at Monitor	1 Second
AAMI HR Response to "Ineffectively Paced QRS Pattern" **(ANSI/AAMI:EC 13:2002, Sec 5.1.4 f), g), h))**	Indicates 30 to 40 bpm for pacemaker pulses with amplitudes from +2mV to +9mV, -2mV to -7mV and pulse widths from 0.1ms to 2ms, with and without overshoot. Overshoot Method A.
Drift Tolerance **(AAMI Specification EC13-2002, 4.2.6.3)**	80 bpm indicated when 0.1 Hz triangular wave of 4 mV p-v amplitude is superimposed on a train of QRS signals of 0.5 mV amplitude, 100 ms duration, and 80 bpm repetition rate
Pacer Pulse Display Indication **(ANSI/AAMI:EC 13:2002, Sec 4.2.9.12 & 4.1.4)**	While in Pacemaker Mode: 0.2 mV RTI for amplitudes (ap) from ±2 mV to ±700 mV and pulse widths (dp) from 0.5 ms to 2 ms

Title	Specification
Pacer Pulse Rejection **(ANSI/AAMI:EC 13:2002, Sec 4.1.4.1 & 4.1.4.2)**	Monitor rejects pacemaker pulses with amplitudes from +2mV to +9mV, -2mV to -7mV and pulse widths from 0.1ms to 2ms. Monitor has been tested using Method A for overshoot conditions.
Pacer Pulse Detector Minimum Slew Rate Detection Threshold **(ANSI/AAMI:EC 13:2002, Sec 4.1.4.3)**	See Pacer Pulse Display Indication. Device does not "detect" pacer pulses or give an indication of detected pulses. Pulses are displayed and rejected as part of the HR calculations.
ECG Trace Duration (Monitor & PDA) **(PC)**	1 second 1 or 5 seconds selectable

16.5 Pulse-Ox

Title	Specification
Input Protection	Type BF
Saturation (% SpO2)	
Displayed Range	0% to 100%
Displayed Resolution	1%
Signal Inadequate Indicator	
WVSM	– – – –
PC & PDA	– –
Pulse Rate	
Displayed Range	0 – 250 bpm
Displayed Resolution	1 bpm
Signal Inadequate Indicator	
WVSM	– – – –
PC & PDA	– –
Display Update Interval at the Monitor	1 Second
Pleth Waveform Display (PC & PDA)	Normalized
Alarm Silence Period	2 minutes

Circuitry		Nonin OEM III Module
Electrosurgery Interference Suppression		None
%SpO2 Alarm Limits		
Upper		NA – High limits are not settable for SpO2
Lower		LOW DEFAULT ALARM PRESET to 95% (User)
		55 to 95% (Responsible Organization)
Pulse Rate Alarm Limits		
Upper		35 to 250 beats/min
Lower		30 to 245 beats/min
%SpO2 Accuracy (Arms*)		70% to 100%
No Motion		
ReUseable:	Finger Clip:	± 2 digits
	Flex:	± 3 digits
	Soft Sensor:	± 2 digits
	8000R:	± 3 digits
	8000Q:	± 4 digits
DISPOSABLE:	6000 Series:	± 2 digits
	7000 Series:	± 3 digits
Motion		
REUSABLE:	Finger Clip:	± 2 digits
	Flex:	± 3 digits
	Soft Sensor:	± 3 digits
Low Perfusion		
	All Sensors:	± 2 digits
Note: * ±1 Arms represents approximately 68% of measurements. Pulse oximeter equipment measurements are statistically distruibuted, only about two-thirds of pulse oximeter equipment measurements can be expected to fall within ± Arms of the value measured by a CO-oximeter.		
%SpO2 Accuracy Below 70%		Values are displayed. Accuracy is Unspecified.

Pulse Rate Accuracy		
No Motion (30 – 250 bpm)		
ReUseable:	Finger Clip:	± 3 digits
	Flex:	± 3 digits
	Soft Sensor:	± 3 digits
	8000R:	± 3 digits
	8000Q:	± 3 digits
DISPOSABLE:	6000 Series:	± 3 digits
	7000 Series:	± 3 digits
Motion (40 – 240 bpm)		
REUSABLE:	Finger Clip:	± 5 digits
	Flex:	± 5 digits
	Soft Sensor:	± 5 digits
Low Perfusion (40 – 240 bpm)		
	All Sensors:	± 3 digits

Sensor Compatibility	
Reusable Group **(See Accessories List Section 18.0)**	**Finger Clip Sensors:** 8000AA-1, 8000AA-3, **Flex Sensors:** 8000J-1, 8000J-3 **Soft Sensors:** 8000SS, 8000SM, 8000SL
Disposable Group **(See Accessories List Section 18.0)**	**Flexi-Form® II (7000 Series) Sensors:** 7000A **6000 Series Sensors:** 6000A
Sensor Lights	For using NONIN PureLight® Sensor
Red Wavelength	660 nanometers @ 0.8 mW maximum average
Infrared Wavelength	910 nanometers @ 1.2 mW maximum average
Note: This information is especially useful for clinicians performing photodynamic therapy	

16.5.1 Testing Summary

SpO_2 accuracy, motion and low perfusion testing was conducted by NONIN® Medical, Incorporated as described below.

SpO_2 Accuracy Testing

SpO_2 accuracy testing is conducted during induced hypoxia studies on healthy, non-smoking, light-to-dark-skinned subjects during motion and no-motion conditions in an independent research laboratory. The measured arterial hemoglobin saturation value (SpO_2) of the sensors is compared to arterial hemoglobin oxygen (SaO2) value, determined from blood samples with a laboratory co-oximeter. The accuracy of the sensors in comparison to the co-oximeter samples measured over the SpO_2 range of 70 – 100%. Accuracy data is calculated using the root-mean-squared (Arms value) for all subjects, per ISO 9919:2005, Standard Specification for Pulse Oximeters for Accuracy.

Pulse Rate Motion Testing

This test measures pulse rate accuracy with motion artifact simulation introduced by a pulse oximeter tester. This test determines whether the oximeter meets the criteria of ISO 9919:2005 for pulse rate during simulated movement, tremor, and spike motions.

Low Perfusion Testing

This test uses an SpO_2 Simulator to provide a simulated pulse rate, with adjustable amplitude settings at various SpO_2 levels. The module must maintain accuracy in accordance with ISO 9919:2005 for pulse rate and SpO_2 at the lowest obtainable pulse amplitude (0.3% modulation).

16.5.2 Equipment Response Time

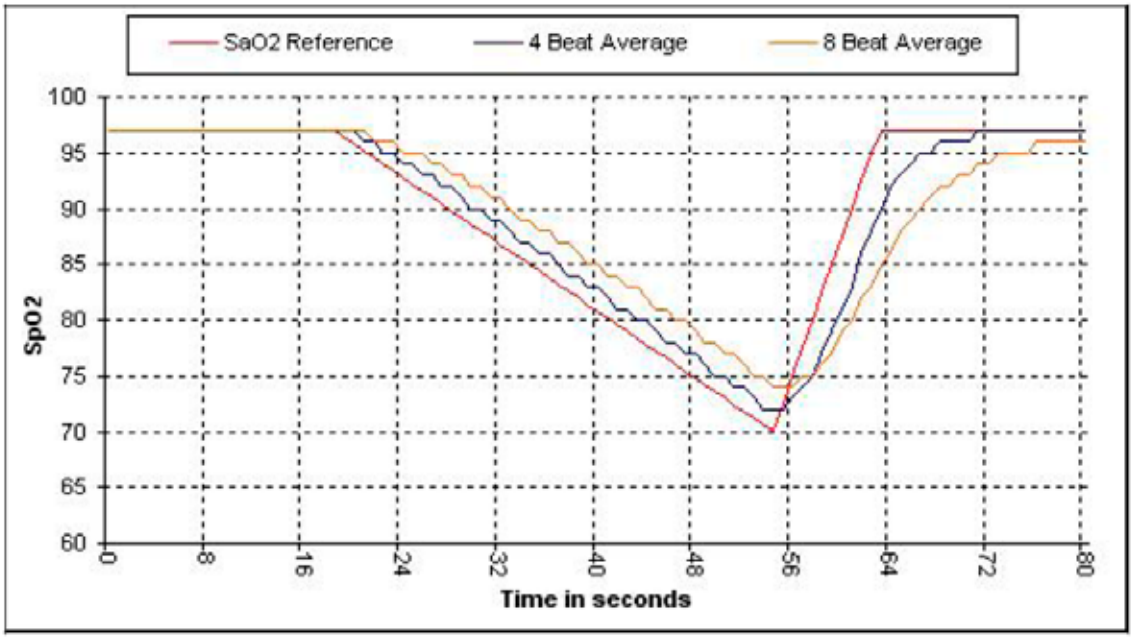
SpO_2 Values	Average	Latency
Standard/Fast Averaged SpO_2	4 beat exponential	2 beats
Extended Averaged SpO_2	8 beat exponential	2 beats

Pulse Rate Values	Average	Latency
Standard/Fast Averaged Pulse Rate	4 beat exponential	2 beats
Extended Averaged Pulse Rate	8 beat exponential	2 beats

Example – SpO_2 Exponential Averaging

SpO_2 decreases 0.75% per second (7.5% over 10 seconds)

Pulse Rate – 75 BPM



Specific to this example:

- The response of the 4-beat average is 1.5 seconds.
- The response of the 8-beat average is 3 seconds.

16.6 NIBP

Title	Specification
Method	Oscillometric. Diastolic values correspond to Phase 5 Korotkoff sounds.
Regulatory Standards	AAMI SP10-1992, EN60601-1, EN60601-2-30, EN1060-1, EN1060-3
Modes	Manual, Auto, Turbo
Input Protection	Protected against Defibrillation, Type CF. Recovery from Defibrillation < 5 sec
Auto Intervals	
Default	15 min
Range	5 to 100 min
Turbo Mode	2, 2, 3, 3, 5, 5 min then return to Auto Setting
Reported Pressures	20 to 260 mmHg
Pressure Resolution	1 mmHg
Systolic Range	40 to 260 mmHg
Alarm Limits Range	
Upper	45 to 260 mmHg
Lower	40 to 255 mmHg
Diastolic Range	20 to 200 mmHg
Alarm Limits Range	
Upper	25 to 200 mmHg
Lower	20 to 195 mmHg
Pulse Rate Range	30 to 220 mmHg
Static Manometer Accuracy	± 3mmHg between 0 mmHg and 300 mmHg for operating conditions between 0°C and 50°C. Possible slight reduction in accuracy for temperatures above50°C up to 60°C.
Atmospheric Pressure Compensation	Yes
Default Inflation Pressure	160 mmHg
Normal Overpressure Limit	300 mmHg
Max Cuff Inflation Time	75 seconds
Maximum Duration of Reading Time	130 seconds
Minimum Time Between Automatic Measurements	1 minute

Allowable Retries	N/A
Electrosurgery Interference Suppression	Yes
Calibration	Verified on a yearly interval

16.7 PDA

WARNING: A computer not in accordance with IEC 60601-1 must be placed outside the patient environment. System configuration must to be evaluated by the Responsible Organization in accordance with IEC 60601-1. No multiple socket outlet shall be used - risk of excessive patient leakage current.

1. PDA: Ensure that a PDA is selected that meets the intended environment (i.e. Hospital/Office, Transport, Helicopter, etc.). The WVSM® device has been tested with the following PDAs.
   h. ASUS MyPal Pocket
2. Wireless Communications: 802.11b/g
3. Operating System: Microsoft Pocket PC version 4.2 or greater
4. Memory 50 MB or greater

16.9 PC

WARNING: A computer not in accordance with IEC 60601-1 must be placed outside the patient environment. System configuration must to be evaluated by the Responsible Organization in accordance with IEC 60601-1. No multiple socket outlet shall be used - risk of excessive patient leakage current.

1. Ensure that a PC is selected that meets the intended environment (i.e. Hospital/Office, Transport, Helicopter, etc.) complying with the safety requirements of IEC 60601-1 or IEC 60950-1 or the equivalent.
2. The WVSM®device has been tested with the following PCs:
   a. DELL
   b. HP
   c. Panasonic Toughbook
3. Wireless Communications: 802.11b/g
4. Processor Speed: 2.0 GHz or greater
5. Operating System: Microsoft Windows XP
6. RAM: 2 GB or more
7. Hard Drive Memory: 100 GB or more

16.10 Data Port

When connecting WVSM® device to other equipment via the data cable ensure the following:

1. Connect to a serial port having the following characteristics:
   k. RS232 Serial Port
   l. DB9 style connector – Male
   a. Note: WVSM® PC SW Auto configures the serial port
2. Potential HAZARDOUS SITUATIONS if characteristics above are not provided:
   m. Data may not be displayed on the other equipment (PC or PDA)
   a. Damage to the WVSM® Data Port or other equipment (PC or PDA) could result
   n. Should not be used with an adapter, gender changer, or extension cables – Data may be corrupted
3. Instructions to RESPONSIBLE ORGANIZATION
   a. Connection of a WVSM® device to a NETWORK/DATA COUPLING that includes other equipment could result in previously unidentified RISKS to PATIENTS, or OPERATORS and RESPONSIBLE ORGANIZATION should identify, analyze, and control such RISKS
   o. Subsequent changes to NETWORK/DATA COUPLING introducing new RISKS and requiring new analysis; and changes to NETWORK/DATA COUPLING include:
      i. Changes in NETWORK/DATA COUPLING configuration
      ii. Connection of additional items to NETWORK/DATA COUPLING
      iii. Disconnecting items from NETWORK/DATA COUPLING
      iv. Update of equipment connected to NETWORK/DATA COUPLING
      v. Upgrade of equipment connected to NETWORK/DATA COUPLING

16.16 Alarms

Title	Specification
Operator Position	
Primary	Patient Environment
Secondary	Outside Patient Environment (Distributed)
Verify Alarm Function	1 Second beep at start-up To verify activation at limits, user must simulate alarm condition.

Alarm Conditions and Priority	
Physiological	High and Low Priority based on Alarm Limits set for each parameter.
%SpO2	
HR/PR	
Systolic BP	
Diastolic BP	
Technical	
SpO2 Sensor	Low Priority when a sensor fault is detected
Battery Power	Medium Priority below 5% remaining
Silence/Reset	2 min Does not affect same or higher priority audible alarm functions
Visual Alarms	
High Priority	Parameter Display is “Red” Simulated Indicator Light & Parameter Label Text “Flashes Red”
Low Priority	Parameter Display is “Yellow”
Normal	Parameter Display is “Green”
Audible Alarms	
High Priority 10 Pulse Burst	200ms on, 125ms off, 200ms on, 125ms off, 200ms on, 450ms off, 200ms on, 125ms off, 200ms on, 600ms off, 200ms on, 125ms off, 200ms on, 125ms off, 200ms on, 450ms off, 200ms on, 125ms off, 200ms on, 3 sec off; Repeat
Medium Priority 3 Pulse Burst	250ms on, 250ms off, 250ms on, 250ms off, 250ms on, 17 sec off; Repeat
Low Priority	None
Find 5 Pulse Burst	500ms on, 1000ms off, 500ms on, 1000ms off, 500ms on, 1000ms off, 500ms on, 1000ms off, 500ms on, 1000ms off
Audible Alarm Volume	Minimum 54 dB @ a distance of 1 meter
Audible Alarm Frequency	1 KHz with harmonics up to 10 KHz
Audible Alarm Location	Monitor

Power Interruption	N/A Default and temporarily changed alarm limit settings are stored in non-volatile RAM - not affected by power interruptions
Distributed Alarm Function	Secondary indication of alarms is provided on the PC/PDA. Primary alarms are on the Monitor.
Alarm Condition Logging	None
Alarm Limits	Settable for each Parameter (See Section 6.0)
Alarm Hold-Off	None
Alarm System Delay at the Monitor	
HR/PR	
ALARM CONDITION DELAY	within 9 sec
ALARM SIGNAL GENERATION DELAY	1 sec
Total ALARM SYSTEM Delay	within 10 sec
SpO2	
ALARM CONDITION DELAY	within 4 sec
ALARM SIGNAL GENERATION DELAY	1 sec
Total ALARM SYSTEM Delay	within 5 sec
NIBP (SYS/DIA) - Aperiodic Measurement	
ALARM CONDITION DELAY	5 to 100 min (Default = 15 min),
Auto Mode	2 to 5 min
Turbo Mode	1 sec
ALARM SIGNAL GENERATION DELAY	2 to 100 min
Total ALARM SYSTEM Delay	
Alarm System Delay at the PC/PDA (added to the Alarm System Delay at the monitor)	< 1 sec (typical)

17.0 EMC Compliance

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this document.

CAUTION: Portable or mobile RF communication equipment may affect the function of the WVSM® device.

17.1 Battery Operated Mode

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The WVSM® is intended for use in the electromagnetic environment specified below. The customer or the user of the WVSM® should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment – Guidance**
RF emissions CISPR 11	Group 1	The WVSM® 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 CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Not applicable (Battery Operated)	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable (Battery Operated)	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The WVSM® is intended for use in the electromagnetic environment specified below. The customer or the user of the WVSM® should assure that it is used in such an environment.			
IMMUNITY Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output Lines	Not connected to mains (battery operated)	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Not connected to mains (battery operated)	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 IEC 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	Not connected to mains (battery operated)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the WVSM® requires continued operation during power mains interruptions, it is recommended that the WVSM® be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the AC mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The WVSM® is intended for use in the electromagnetic environment specified below. The customer or the user of the WVSM® should assure that it is used in such an environment.			
IMMUNITY Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the WVSM®, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	20 V/m 80 MHz to 2,5 GHz	20 V/m	$d = 0.18\sqrt{P}$ 80 MHz to 800 MHz $d = 0.35\sqrt{P}$ 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 WVSM® is used exceeds the applicable RF compliance level above, the WVSM® should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the WVSM®.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the WVSM®

The WVSM® is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the WVSM® can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the WVSM® 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** $d = 0.18\sqrt{P}$	**800 MHz to 2,5 GHz** $d = 0.35\sqrt{P}$ [1]
0.01	0.12	0.018	0.035
0.1	0.38	0.057	0.11
1	1.2	0.18	0.35
10	3.8	0.57	1.1
100	12	1.8	3.5

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.

17.2 Charging Mode

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The WVSM® is intended for use in the electromagnetic environment specified below. The customer or the user of the WVSM® should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment – Guidance**
RF emissions CISPR 11	Group 1	The WVSM® 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 CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	The WVSM® is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The WVSM® is intended for use in the electromagnetic environment specified below. The customer or the user of the WVSM® should assure that it is used in such an environment.			
IMMUNITY Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output Lines	± 2 kV for power supply lines ± 1 kV for input/ output Lines	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	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 IEC 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 WVSM® requires continued operation during power mains interruptions, it is recommended that the WVSM® be powered from an uninterruptible power supply or a battery.

Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the AC mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The WVSM® is intended for use in the electromagnetic environment specified below. The customer or the user of the WVSM® should assure that it is used in such an environment.

IMMUNITY Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the WVSM®, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 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 WVSM® is used exceeds the applicable RF compliance level above, the WVSM® should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the WVSM®.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the WVSM®

The WVSM® is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the WVSM® can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the WVSM® 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** $d = 2.3\sqrt{P}$
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.

17.3 Battery Operating Mode with Data Cable

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The WVSM® is intended for use in the electromagnetic environment specified below. The customer or the user of the WVSM® should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment – Guidance**
RF emissions CISPR 11	Group 1	The WVSM® 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 CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Not applicable (Battery Operated)	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable (Battery Operated)	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The WVSM® is intended for use in the electromagnetic environment specified below. The customer or the user of the WVSM®should assure that it is used in such an environment.			
IMMUNITY Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output Lines	Not connected to mains (battery operated)	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Not connected to mains (battery operated)	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 IEC 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	Not connected to mains (battery operated)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the WVSM® requires continued operation during power mains interruptions, it is recommended that the WVSM® be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the AC mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The WVSM® is intended for use in the electromagnetic environment specified below. The customer or the user of the WVSM® should assure that it is used in such an environment.			
IMMUNITY Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the WVSM®, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 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 WVSM® is used exceeds the applicable RF compliance level above, the WVSM® should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the WVSM®.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the WVSM®

The WVSM® is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the WVSM® can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the WVSM® 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		
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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.

18.0 Accessories

WARNING: The use of accessories and cables other than those specified by Athena GTX ® may result in increased electromagnetic emissions and/or a decreased immunity of the WVSM® device.

WARNING: Use only Athena GTX ® approved accessories with the WVSM® device. Improper functioning and/or insufficient protection during defibrillation could result if alternate ECG leads are used.

18.1 General

The following items are supplied with the WVSM® device:

- Medical Grade Power Adapter: Athena P/N 530-0002-01
- Medical Grade Power Cord: Athena P/N 467-0006-01

18.2 ECG

The following Athena GTX® sensor cables and electrodes are supplied with the WVSM® device:

- ECG leads 1.5mm (Color coded 3 pack): Athena P/N 570-0004-01
- BioDetek ECG electrodes: Athena P/N 570-0006-01

18.3 Pulse-Ox

The following NONIN sensor is supplied with the WVSM® device:

- **8000AA** Adult Articulated Internal Spring Finger Clip, 3 feet / 1 meter cable: Athena P/N 570-0002-01

The following NONIN sensors are compatible with the WVSM® Nonin OEM III module:

- **8000J** Adult Flex, 3 feet / 1 meter cable
- **8000Q** Ear Clip, 3 feet / 1 meter cable
- **8000R** Reflectance, 3 feet / 1 meter cable
- **8000SS** Sensor, Reusable, Soft, Small, 1 Meter
- **8000SM** Sensor, Reusable, Soft, Medium, 1 Meter
- **8000SL** Sensor, Reusable, Soft, Large, 1 Meter
- **7000A** Flexi-Form® II Adult, 3 feet / 11 meter, 10-pack
- **6000A** Sensor, Disposable, Adult, 45cm Cable
- **UNI-RA-0** 7.5” 90-degree Patient Cable
- **UNI EXT-X** Patient Extension Cable (1 or 3 meter)

18.4 NIBP

The following SunTech NIBP cuff is supplied with the WVSM® device:

- Orbit BP Cuff (Adult Plus): Athena P/N 570-0001-03
- The following SunTech NIBP cuffs are compatible with the WVSM® Advantage Mini OEM Module:
- Eclipse D-Ring BP Cuff
- Orbit BP Cuff
- All Purpose BP Cuff
- Extension Hose (Standard Lengths 1.5m and 3m))

18.5 PDA/PC

The following items are compatible with the WVSM® device:

- Athena GTX® Serial Interface Cable: Athena P/N 550-0002-01

19.0 Warranty and Service Information

19.1 Limited Warranty

Athena GTX® guarantees the device will be free from defects in material and workmanship for a period of one (1) year from the date of purchase. Accessories purchased directly from the manufacturer are guaranteed of a period of ninety (90) days. The warranty is considered void if the device or its accessories are modified in any way or if the following are true:

The WVSM® device or Accessory has been damaged due to excessive wear and tear, negligence or misuse,

The WVSM® device has not been operated in accordance with applicable safety and regulatory requirements including use with non-approved and designated accessories, or

The WVSM® device has been serviced by unauthorized service personnel.

This warranty replaces all other oral, and/or written warranties, obligations, and/or liabilities Athena GTX® and distributors of the WVSM® device except those expressly set forth in the product warranty. Athena GTX® and distributors of the WVSM® device make no other representation or warranty of any kind and expressly disclaim any and all representations and warranties, expressed or implied, in fact or in law, including without limitation, any warranty of merchantability or fitness for a particular purpose.

The sole and exclusive remedy for all purchasers/end-users shall be replacement or repair of such products proved to be defective because of workmanship upon inspection by Athena GTX®. Only Athena GTX® shall determine the form of remedy. No warranty claim shall be honored unless received by Athena GTX® within one (1) year (ninety (90) days for accessories) of the date that the WVSM® device or accessories were delivered to the purchaser/end-user. Athena GTX® and distributor shall not be liable for injury, loss or damage, direct or consequential, arising out of the use or inability to use the product.

19.2 Service

Refer to Service Manual

or

Contact below for all service and warranty related inquiries:

Athena GTX ®

3620 SW 61st Street, Suite 395

Des Moines, IA 50321

USA

(515) 288-3360

www.athenagtx.com