

WVSM **WIRELESS VITAL SIGNS MONITOR**

NON-INVASIVE BLOOD PRESSURE | PULSE OXIMETRY | ELECTROCARDIOGRAM

Service 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.

Copyright 2011 Athena GTX®. All rights are reserved. Reproduction or duplication of this manual or any part thereof, in any form, without permission from Athena GTX® is strictly prohibited.

Athena GTX® is a registered trademarks of Athena ISG/GTXtreme, Inc. dba Athena GTX®.

SunTech®, Advantage OEM BP™, Eclipse™, Orbit™ are registered trademarks and/or trademarks of Suntech Medical, Inc.

Nonin®, OEM III®, PureLight® are registered trademarks of Nonin Medical, Inc.

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

Service Manual Document Control Number: 610-0001-01 Rev: C, 6 June 2012

Athena GTX®
3620 SW 61st Street, Suite 395
Des Moines, IA 50321
USA

(515) 288-3360
www.athenagtx.com

Table of Contents

1.0	Safety Information - General.....	7
1.1	Contraindications.....	7
1.2	Warnings.....	8
1.3	Cautions.....	11
2.0	Introduction.....	13
2.1	Intended Use.....	13
2.2	Manual Overview.....	13
3.0	Device Overview.....	14
3.1	Controls, Indicators and Symbols.....	14
3.1.1	Front Panel.....	14
3.1.2	Bottom Panel.....	16
3.1.3	Top Panel.....	17
3.1.4	Symbols.....	18
3.2	General.....	22
3.2.1	Mechanical.....	22
3.2.2	Electrical.....	22
3.2.3	Display.....	22
3.2.4	Outputs.....	22
3.2.5	Accessories.....	22
3.2.6	Pacemaker Rejection Capability.....	23
3.2.7	Functional Testers.....	23
4.0	Set Up.....	24
4.1	Install the WVSM® PC Software.....	24
4.2	Establish Communications to the WVSM® Device.....	24
4.3	Overview of the WVSM® Network.....	30
4.4	Default Network Settings.....	31
4.5	Considerations When Making Network Changes to the WVSM® System.....	32
5.0	Responsible Organization Default Configurations and Alarm Presets.....	34
5.1	Changing the RO Password.....	34
5.1.1	Adding User.....	34

5.1.2	Deleting User	34
5.1.3	Modifying User	35
5.2	WVSM® Default Configuration Settings.....	37
5.2.1	Using a PC	37
5.3	WVSM® Default Alarm Limits.....	38
5.3.1	Using a PC	38
5.4	PC Default Alarm Limits for Manual Parameter Data	40
6.0	Maintenance	42
6.1	Cleaning	42
6.1.1	WVSM® Device	42
6.1.2	Pulse-Ox Sensor	42
6.1.3	ECG Cables	42
6.1.4	NIBP Cuffs	43
6.1.5	Power Adapter and Data Cable	43
6.2	Recharging the Battery.....	44
6.3	NIBP Calibration.....	45
6.3.1	Equipment Needed for Calibration Verification & Full Calibration.....	45
6.3.2	Verification Procedure.....	46
6.3.3	Full Calibration Procedure	47
6.4	Disposal.....	48
7.0	Troubleshooting	49
7.1	WVSM® Device.....	49
7.2	Communications.....	50
7.2.1	PDA WLAN connection not successful:	50
7.2.2	PDA Not Connecting to Active WVSM®s.....	51
7.2.3	PC WLAN Connection not Successful	51
7.3	PDA.....	52
7.4	PC.....	52
8.0	Warranty and Service Information.....	53
8.1	Limited Warranty	53
8.2	Service.....	53

Table of Figures

Figure 1. WVSM® Front Panel.....	14
Figure 2. WVSM® Bottom Panel.....	16
Figure 3. WVSM® Top Panel.....	17
Figure 4. Select Internet Protocol.....	25
Figure 5. Properties Dialog Box.....	26
Figure 6. IP Address Properties.....	27
Figure 7. wvsm Network Properties.....	28
Figure 8. wvsm Connection Setting.....	29
Figure 9. Advanced Network Settings	30
Figure 10. Example of WVSM® Wireless Network	31
Figure 11. Settings and Options Menu	35-36
Figure 12. WVSM® Configuration Menu on the PC	37
Figure 13. WVSM® Alarm Limit Menu on the PC.....	38-39
Figure 14. PC Alarm Limit Dialog Windows for Manually Entered Parameters.....	40-41
Figure 15. WVSM® Battery Recharging.....	44
Figure 16. Calibration Test Set Up.....	45
Figure 17. Calibration Verification Display Screens.....	46
Figure 18. Calibration Screen Shots.....	47
Figure 19. Calibration Screen Shots.....	48

Table of Tables

Table 1. Front Panel Functions.....	15
Table 2. Bottom Panel Sensor Connections.....	16
Table 3. Top Panel Connections.....	17
Table 4. Symbols Table Labels.....	18
Table 5. Symbols Table Device User Interface.....	19
Table 6. Symbols Table Parameters.....	20
Table 7. Symbols Table PDA Icons.....	20
Table 8. Symbols Table PC Icons.....	21

1.0 Safety Information - General

WARNING: Before servicing 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 accessories or charging unit.

WARNING: Do not simultaneously touch parts of non-ME EQUIPMENT in the PATIENT ENVIRONMENT during maintenance, calibration, etc.

WARNING: Assembly of ME SYSTEMS and modifications during actual service life shall be evaluated based on the requirements of IEC 60601-1.

WARNING: The use of the WVSM® 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 and in the Operator's Manual.

1.1 Contraindications

1. Do not use the WVSM® device in an MRI environment.
2. Explosive Hazard: Do not use this device in an explosive atmosphere or in the presence of flammable anesthetics or gases.
3. DO NOT immerse the WVSM® device or any of its accessories in water, solvents, cleaning solutions or other liquids.
4. The Pulse-Ox (SpO₂) module does not meet the defibrillation-proof requirement per IEC 60601-1: 1990, clause 17.h.
5. 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.
6. 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 Warning

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

WARNING: Do not simultaneously touch parts of non-ME EQUIPMENT in the PATIENT ENVIRONMENT during maintenance, calibration, etc.

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 device performance.

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 mains 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 electrodes, leads, and cables to come into contact with any other conductive parts including earth ground.

WARNING: The WVSM® device can be used for 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, or 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. 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 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 it 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.

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 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.

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 the WVSM®'s accuracy can be diminished or can 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, SpO₂ 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® 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 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: Use only approved/recommended power adapters. The charging unit is specified as a part of ME EQUIPMENT or combination is specified as a ME SYSTEM - use only the approved unit as specified in Section 18.2 of the Operators Manual.

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 multiple socket outlets 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.

WARNING: Functional tester cannot be used to assess the accuracy of a pulse oximeter probe.

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, carboxhemoglobin, 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.

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® or connected equipment.

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.

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 SpO₂. 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 service the Wireless Vital Signs Monitor (WVSM®). Important safety information regarding the proper servicing of this device is located throughout this manual.

Before servicing this device read and understand this manual and the Operator's Manual in their entirety.

The WVSM® is NOT field repairable.

The overall system use and operation is described first and detailed instructions for servicing the device follow in later sections.

3.0 Device Overview

WVSM® is a small, rugged, highly mobile device designed to monitor patient vital signs (specifically: ECG, SpO₂, noninvasive blood pressure and heart rate). WVSM® can be used as a standalone device, with a Personal Digital Assistant (PDA) or Personal Computer (PC).

3.1 Controls, Indicators and Symbols

3.1.1 Front Panel

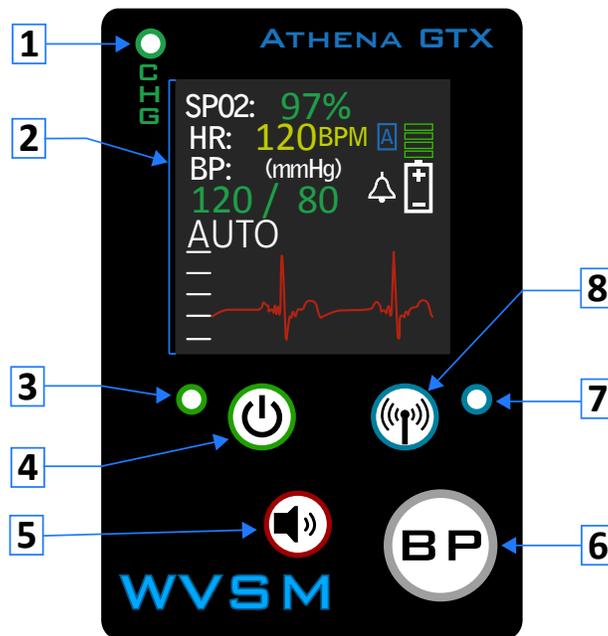


Figure 1. WVSM™ Front Panel

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

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

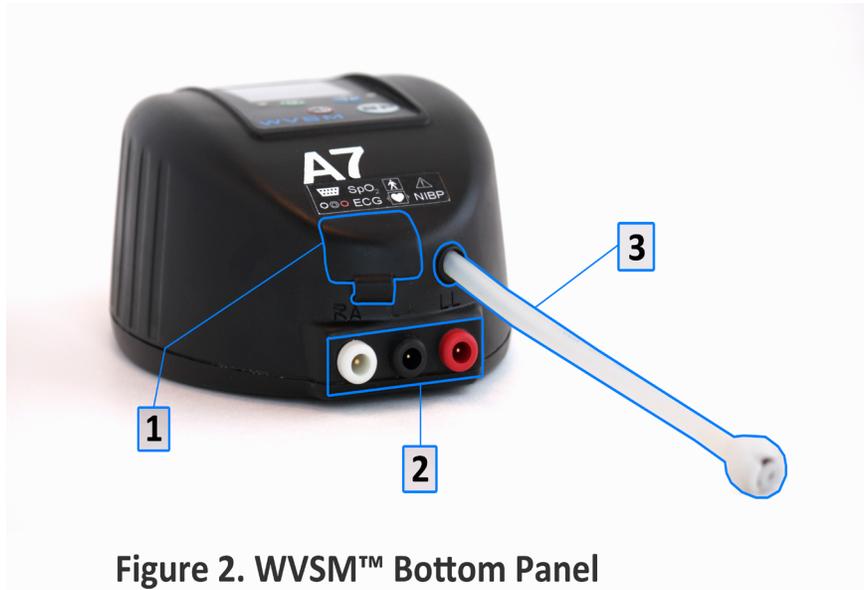
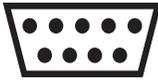


Figure 2. WVSM™ Bottom Panel

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

Table 2. Bottom Panel Sensor Connections

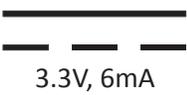
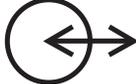
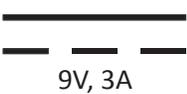
Parameter	Sensor/Connector	Symbol	Defibrillator-Proof
Pulse-Ox	Compatible with Nonin Pulse-Ox sensors only. See list of recommended accessories in this manual.		
ECG	Compatible with 1.5mm safety plug connectors. Use ECG cables provided with the device.		
NIBP	Compatible with SunTech NIBP cuffs. See list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

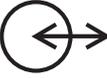
Table 4. Symbols Table Labels		
Symbol/Icon	Description	Function
	Caution, consult accompanying documents	This symbol advises the reader to consult the accompanying documents for important safety-related information such as warnings and precautions that cannot, for a variety of reasons, be presented 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.
	Catalog number	Device Part Number. Format: XXX-XXXX-XX.
	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 WVSM® or the battery pack, 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.

Table 4. Symbols Table Labels

	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 Enable	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.

Table 5. Symbols Table Device User Interface

	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

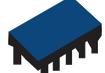
Symbol/Icon	Description	Function
	Patient List Toggle	Toggles between Patient List view and detailed View ECG screens for a selected patient.
	History	Enters the View Patient History screen for a selected patient.
	Stop BP	Cancels or Stops taking a BP Measurement for a selected patient.
	Take BP	Initiated 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. <i>Time values are in seconds</i>
	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® 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® 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 gauge 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 on this display as well as various status, alarm and ECG waveform data.

3.2.4 Outputs

The WVSM® 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®. Additional information can be found in the Communications section of the Operator's manual.

3.2.5 Accessories

Only approved accessories are authorized for use with the WVSM®. See the list of approved accessories in the Accessories section of the Operator's manual.

3.2.6 Pacemaker Rejection Capability

Title	Specification
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.
Pacer Pulse Detection	See Pacer Pulse Display Indication. Device does not “detect” pacer pulses or give an indication of detected pulses. Pulse are displayed and rejected as part of the HR calculations.
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. Pulse are displayed and rejected as part of the HR calculations.

3.2.7 Functional Testers

WARNING: Functional tester cannot be used to assess the accuracy of a pulse oximeter probe.

4.0 Set Up

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.

It is highly recommended the user review all the information within this chapter to gain an understanding of the preferred method for creating a wireless network for the WVSM® patient monitor, the device's factory configured (default) settings, and considerations that should be addressed when making changes to the network system.

4.1 Install the WVSM® PC Software

Athena GTX recommends closing all programs before installing the WVSM PC Software on a computer. Applications that run in the background, such as virus scanning utilities should be disabled during installation.

Before installing the WVSM® PC Software, uninstall any earlier versions that may be on the computer.

The WVSM® PC Software requires Microsoft .NET Framework 3.5 to be installed before continuing with the installation. Microsoft .NET Framework 3.5 has been provided on the installation CD/DVD.

NOTE: PC Software 1.0.8 and above includes two options for installation: one optimized for a standard PC and one optimized for a touchscreen PC. This is selectable during installation.

1. To load the software on a PC, perform the following steps:
2. Place the CD/DVD into the Drive. Allow the computer to recognize the CD/DVD. A dialog window will appear and guide the user through the installation process.
3. If the installation software does not run automatically, from the Windows desk top select My Computer, locate the CD/DVD drive, and run the Install program.
4. Follow the instructions when prompted.
5. Software will be installed in the desired location.

The WVSM® PC Software Management Suite is now installed on the Personal Computer. A Wireless connection must now be established in order to have full functionality of the WVSM® device(s). Proceed to the next section and follow the steps to create the proper system network connections.

For optimal wireless communications performance the computer's wireless radio should be configured to the 802.11g protocol. Refer to the PC manufacturer's documentation for the specifics on how to make the appropriate adjustments.

4.2 Establish Communications to the WVSM® Device

Once the WVSM® PC Software has been installed onto a Personal Computer, the wireless network must be set up so the PC can communicate with the WVSM® patient monitoring device(s). The following is considered a typical network system setup. Using this or a similar setup will allow the Responsible Organization to have potentially 253 unique IP addresses on a specific network reserved for PC's running the WVSM® Software Management Suite.

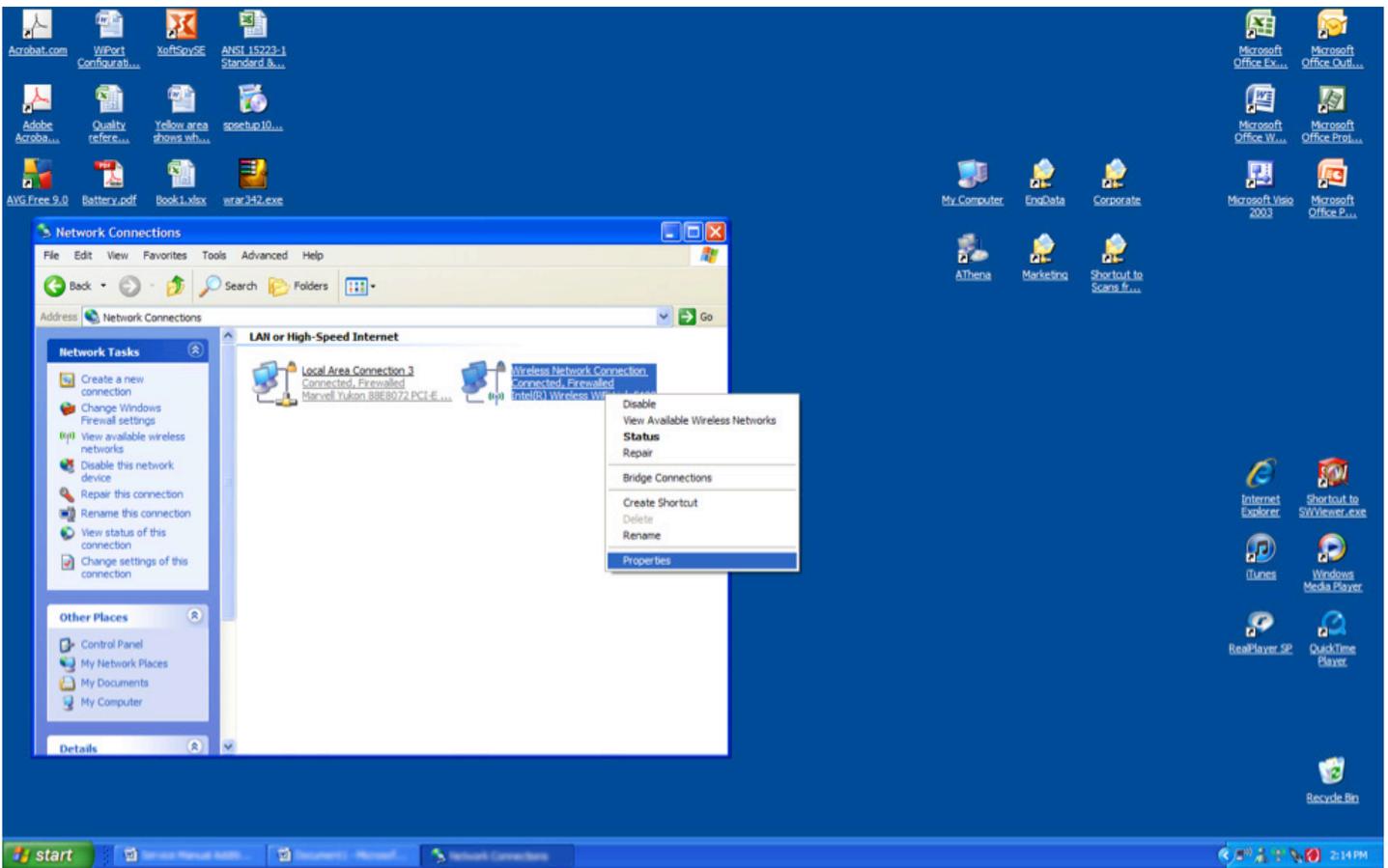
Note: The WVSM® Software Management Suite is capable of connecting to and monitoring a maximum of 20 WVSM® devices.

Perform the following steps to establish wireless communications.

Turn the WVSM® device on and from the *MODE SELECT* screen press the blue Wi-Fi button. Ensure the blue LED is illuminated. When the LED is on, the WVSM® device is broadcasting a wireless signal that can be detected by the PC.

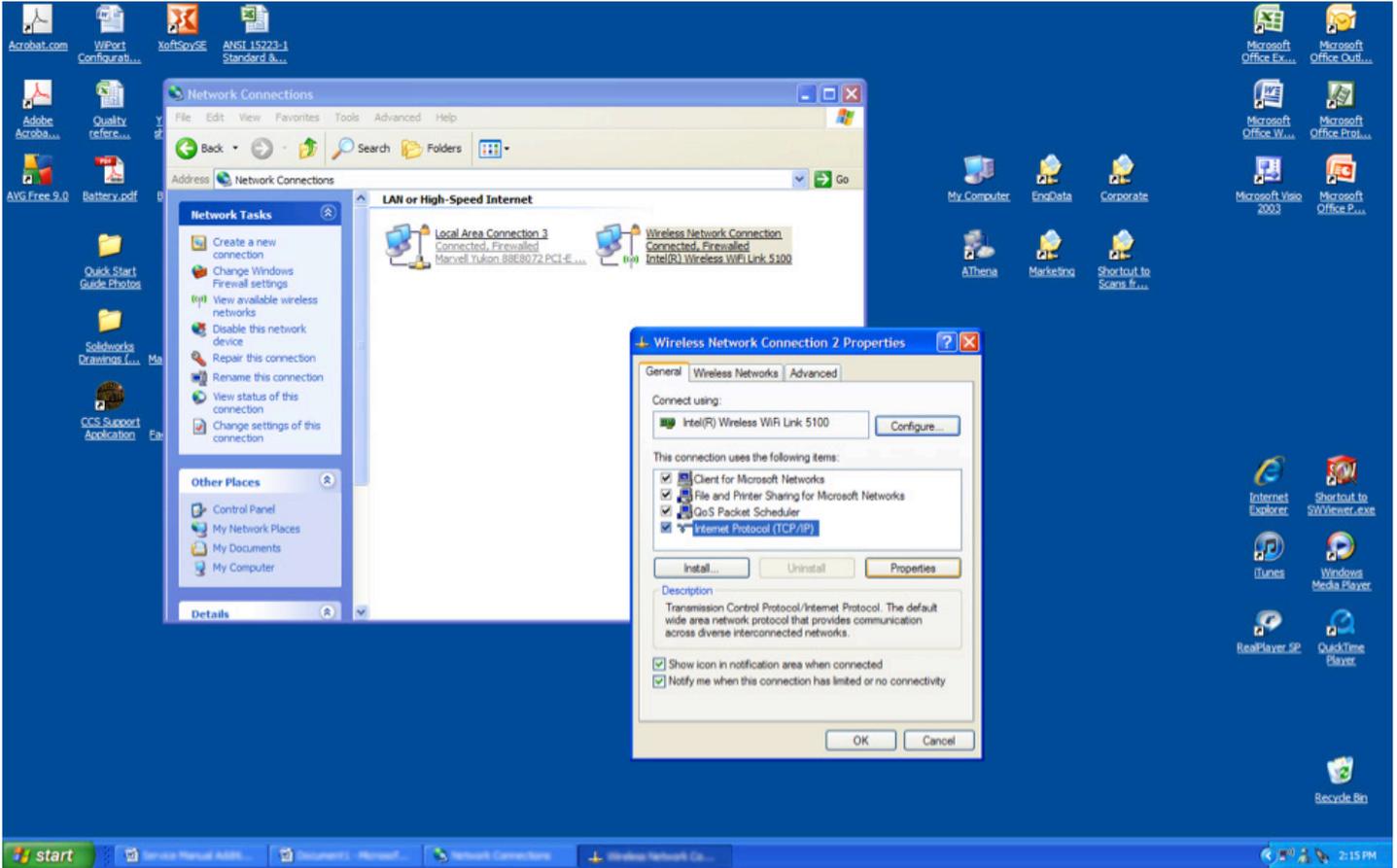
Using the Microsoft Windows XP operating system (OS) select *Start-Control Panel-Network Connections*. Right click the *Wireless Network Connection* icon, and select *Properties*.

Figure 4. Select Internet Protocol



Select *Internet Protocol (TCP/IP)* and select *Properties*.

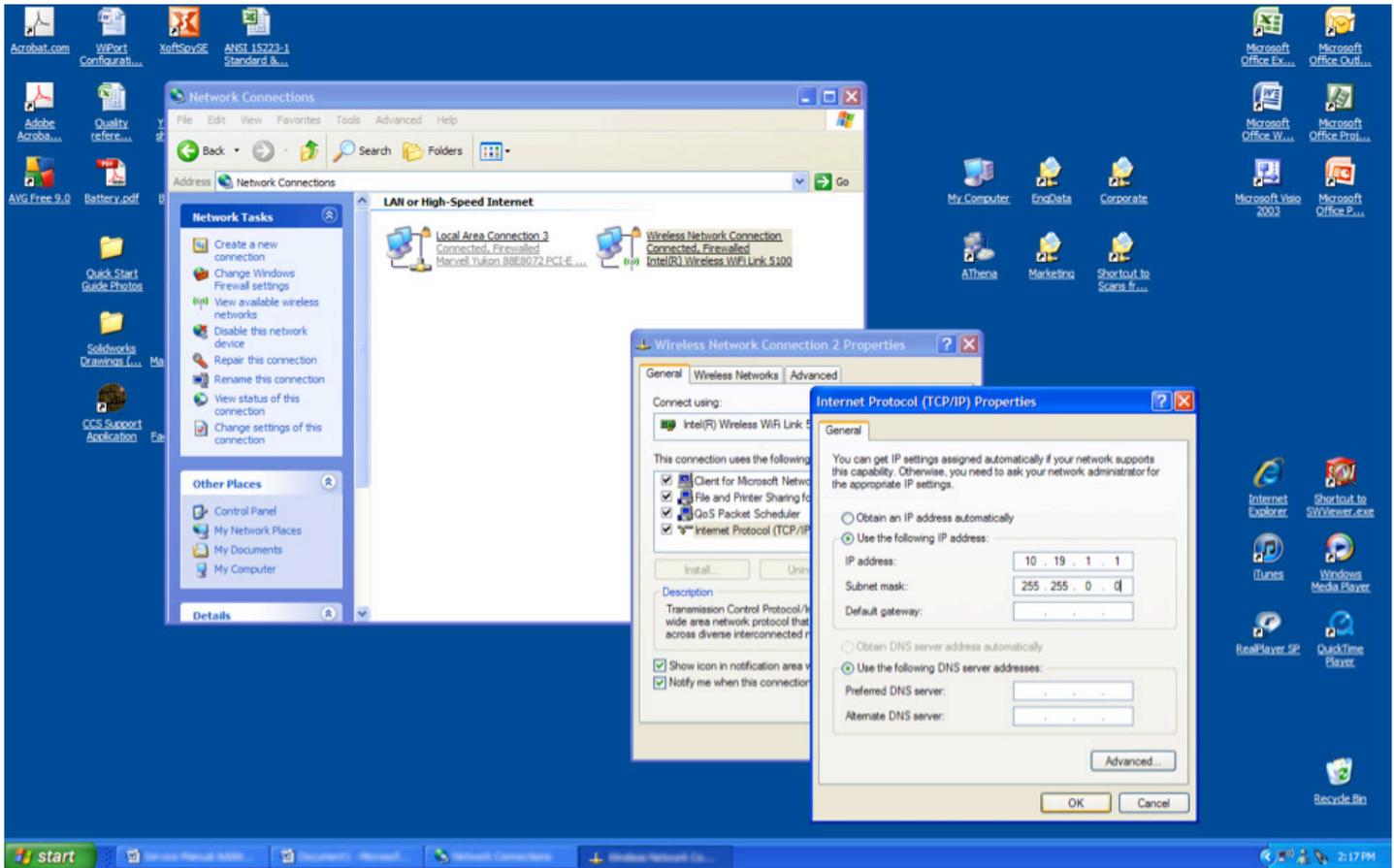
Figure 5. Properties Dialog Box



The *Internet Protocol (TCP/IP) Properties* dialog box will appear.

Select *Use the following IP address* button and enter a unique IP address for the computer.

Figure 6. IP Address Properties



Using the suggested setup, the IP address range of 10.19.1.(1-254) has been reserved for PCs running the WVSM® Software Management Suite. When assigning the IP address for the computer, the Responsible Organization should verify that other devices in the area are not utilizing the same IP address.

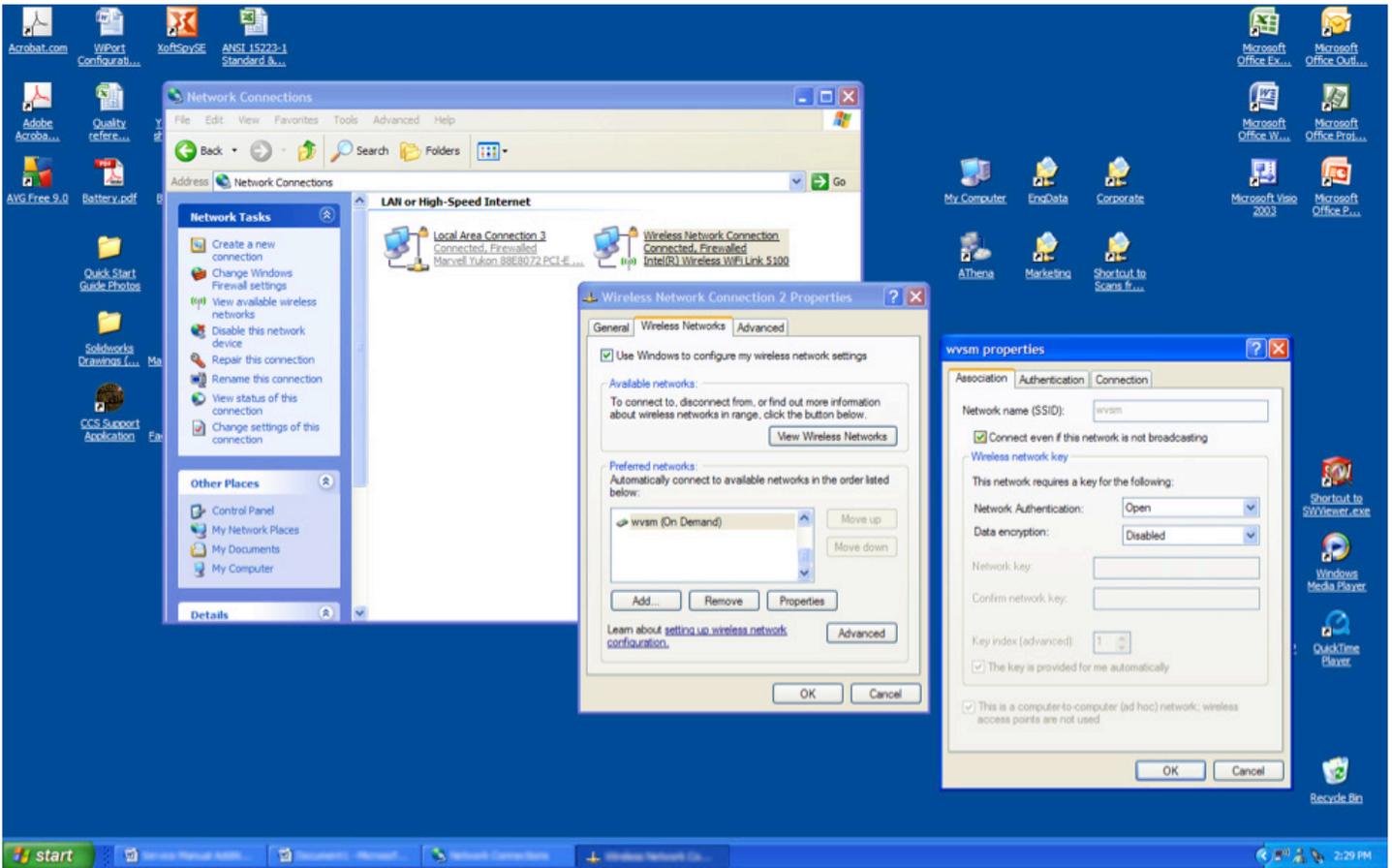
Note: If an IP address conflict occurs (i.e., two or more devices using the same IP address), the network may become unstable and cause communication problems or errors with WVSM® device(s).

Set the Subnet Mask to 255.255.0.0

Confirm the settings and close the dialog box by selecting OK.

Next select the *Wireless Networks* tab. Find and select the network named *wvsm*. Select *Properties*.

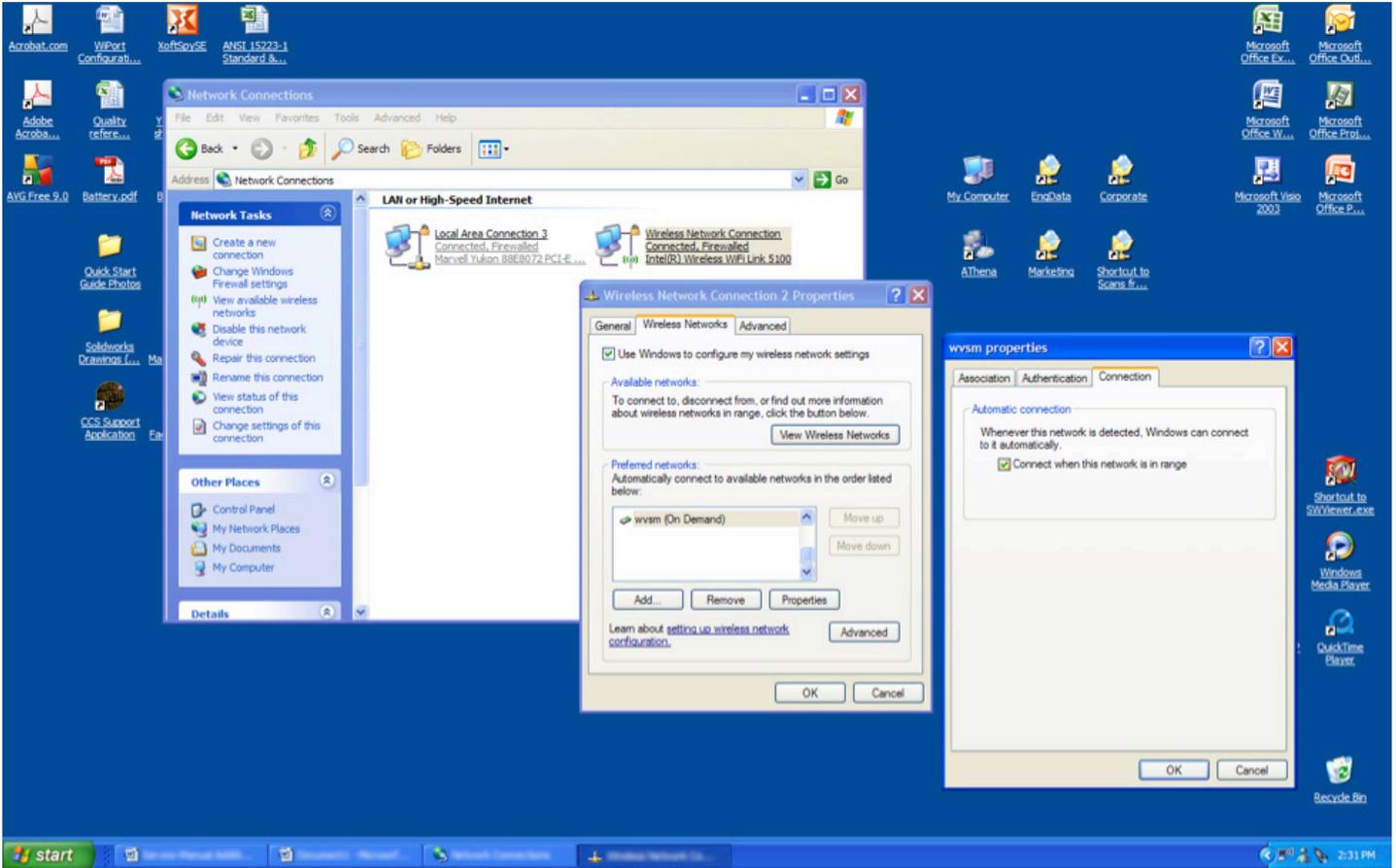
Figure 7. wvsm Network Properties



Check the box *Connect even if this network is not broadcasting.*

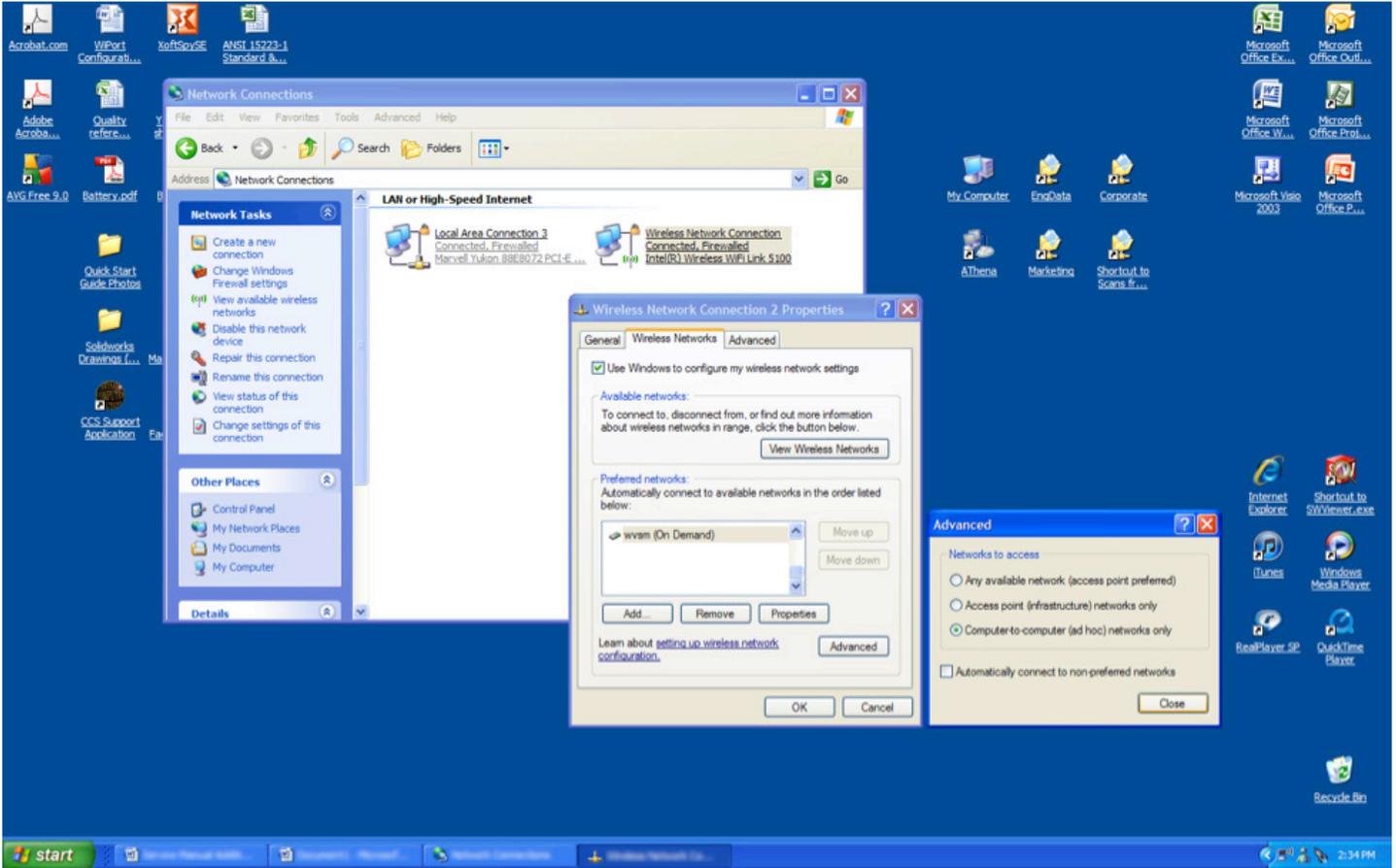
Next select the *Connection* tab, and check the box *Connect when this network is in range*.

Figure 8. wvsm Connection Setting



Next, under the *Wireless Networks* tab select *Advanced* and select *Computer-to-computer (ad hoc) networks only*. Confirm the setting and press *Close*.

Figure 9. Advanced Network Settings



A wireless connection should now be established with the WVSM® device(s), and the system is ready for use. Start the WVSM® PC Software Management Suite and turn on any additional WVSM® devices to monitor patients.

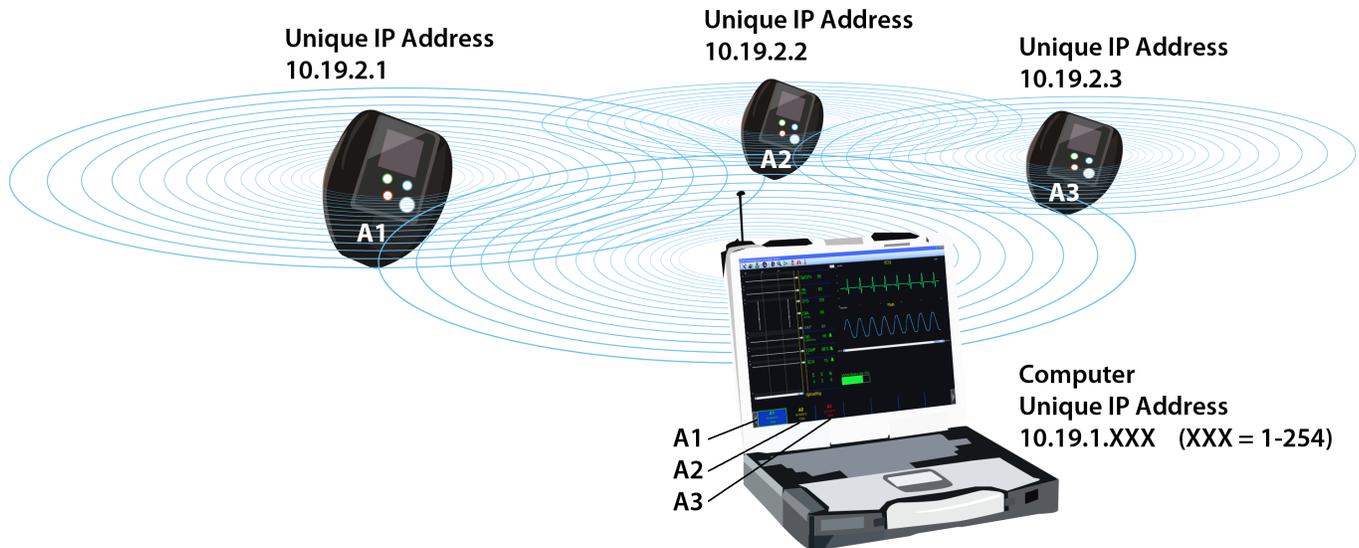
4.3 Overview of the WVSM® Wireless Network

The WVSM® device hardware has been programmed with initial network settings from the factory. These settings are intended to facilitate the creation of a working WVSM® network system. This initial network can be customized by the Responsible Organization’s network administrator.

Each WVSM® device has been assigned a unique IP address in the 10.19.(2-254).(1-254) range. The Subnet mask is set to 255.255.0.0 and the network name (SSID) has been set to “wvsm”, (lower case letters).

In the example network illustrated below, all PCs running the WVSM® Software Management Suite have an IP address in the range of 10.19.1.XXX (Where XXX can be set to 1-254). The example shown demonstrates that multiple devices can be utilizing the network while minimizing the potential for IP address conflicts between devices.

Figure 10. Example of WVSM™ Wireless Network



4.4 Default Network Settings

WVSM® Devices

Each WVSM device comes with a unique IP address in the range of 10.19.(2-254).(1-254). This unique address is included with the documentation provided with each device. The user can change the IP address of the WVSM through a separate utility (Lantronix Device Installer), available on the installation CD.

SSID

The wireless radio in the device has a default SSID set to “wvsm” (lower case letters). If desired, another SSID can be assigned by using the Lantronix Device Installer utility available on the installation CD.

Subnet Mask

If the user intends to use the factory configured IP address range, the subnet mask should be set to 255.255.0.0 **not the windows default 255.255.255.0**. If the user chooses a different configuration scheme, be sure to unmask enough of the range on the PC software to ensure the PC and WVSMs can communicate.

NOTE: Changing the IP address of the WVSM device to a different range requires the PC software to be set to a compatible range to ensure the WVSM device and PC software are able to communicate.

Resetting the WVSM® Device IP Address

The IP address for the WVSM® device can be reset to a default address of 10.19.254.254 as follows:

1. With the device turned off and the charging cable connected, press and hold the ON/OFF and BP buttons simultaneously.
2. The reset address is the same for all WVSMs and should only be used temporarily on one device at a time to prevent IP address conflicts.
3. Performing this operation allows the user to easily identify the Wi-Port using the Lantronix Device Installer software and to set the IP address as desired.

NOTE: Resetting the Wi-Port to default address may prevent the device from being discoverable by the WVSM® PC software.

NOTE: If an IP address conflict occurs the WVSM® device will still be able to perform its monitoring functions, save history and provide alarms, but may not be able to communicate with the PC Software. IP address conflicts may also result in an unstable network.

NOTE: When booting up the PC it may be necessary to direct the PC's network utility to connect to the wireless network labeled "wvsm".

4.5 Considerations When Making Network Changes to the WVSM® System

The following is a list of some of the network configuration concerns that should be considered by the WVSM® network administrator.

1. The Responsible Organization should assure that the WVSM® network administrator customizing the WVSM® Wireless LAN has a thorough understanding of network configuration concerns and practices. The network administrator should also have detailed knowledge of the other wireless networks, communications equipment, medical equipment, and other equipment that may impact WVSM® network configuration choices, network performance, or network security.
2. If resetting the WVSM® Wireless LAN, an SSID (network name) should be selected with a sufficient length and complexity to assure that a network with the same name will be unlikely in the operating environment. Use of the default SSID could, for example, result in a WVSM® network that conflicts with another WVSM® installation that also uses the default SSID.
3. WVSM® was developed and tested in an ad-hoc (also called peer-to-peer) network configuration. The WVSM® ad-hoc network eliminates the need to use a router or access point in the network. All WVSM® devices can wirelessly connect directly to the PC or PDA.
4. If selecting a different wireless network channel, choose one that is least likely to be shared with other networks or wireless equipment. Keep in mind that wireless network channels use frequencies that overlap with neighboring frequencies. To minimize interference with a network on a given channel, choose a WVSM® channel that is 5 or more channels higher or lower than the other network. Network channels 1, 6, and 11 do not use overlapping frequencies, for example.

5. The IP address of each WVSM[®] network device in the network (group of devices with the same SSID) must be unique. The following IP address ranges are reserved for public networks, and are recommended for use with WVSM[®].
- i. 10.0.0.0 to 10.255.255.255 (16,777,216 possible unique IP addresses)
 - ii. 172.16.0.0 to 172.31.255.255 (1,048,576 possible unique IP addresses)
 - iii. 192.168.0.0 to 192.168.255.255 (65,636 possible unique IP addresses)

5.0 Responsible Organization Default Configurations and Alarm Presets

The Responsible Organization (RO) is able to modify the default Preset Configuration and Alarm Limits that are used upon power on and selecting new file on the WVSM® device. The initial User Name and Password have been set at the factory and are as follows:

User Name: admin

Password: nimda

It is strongly encouraged that the User Name and Password be changed by the Responsible Organization before the WVSM® devices are placed into service.

5.1 Changing the RO Password

5.1.1 Adding User

Add a user to the RO assigned username and password, perform the following steps:

1. Open the Setting and Options dialog from the menu toolbar
2. Select the Add option from the Username control as shown in Figure 4.1.1.1
3. Enter in an unused Username and Password in the corresponding input fields to add
4. Repeat the same Password in the Confirm input field
5. Enter in a valid Admin username and password
6. Press Apply to add a new user

5.1.2 Deleting User

To delete a user from the RO assigned username and password, perform the following steps:

1. Open the Setting and Options dialog from the menu toolbar
2. Select the Delete option from the Username control as shown in Figure 4
3. Enter an existing Username the corresponding input fields to remove from active usernames
4. Enter a valid Admin username and password
5. Press Apply to remove user

5.1.3 Modifying User

To modify a user in the RO assigned username and password, perform the following steps:

1. Open the Setting and Options dialog from the menu toolbar
2. Select the Modify option from the Username control as shown in Figure 4.1
3. Enter in an existing Username and Password in the corresponding input fields
4. Enter a new password in the New Password input field
5. Press Apply to modify an existing user's password

Figure 11. Settings and Options Menu

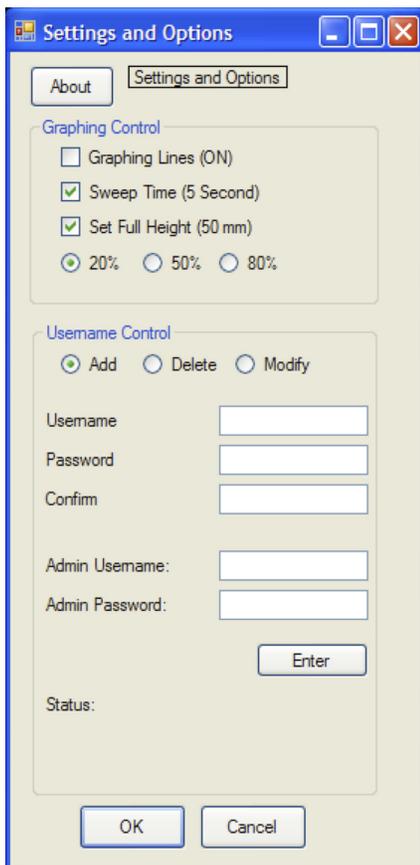


Figure 11a: PC-Standard Add New User

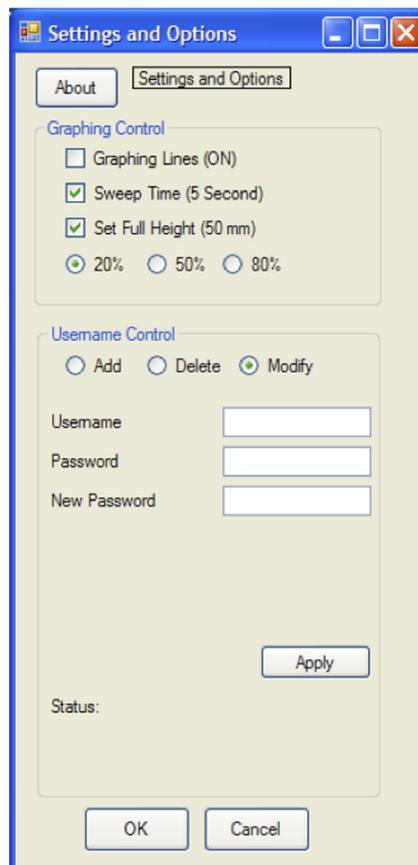


Figure 11b: PC-Standard Delete User

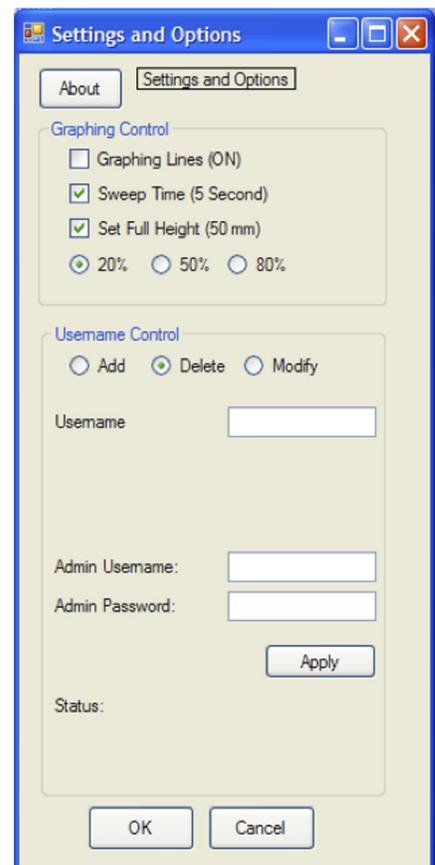


Figure 11c: PC-Standard ModifyUser

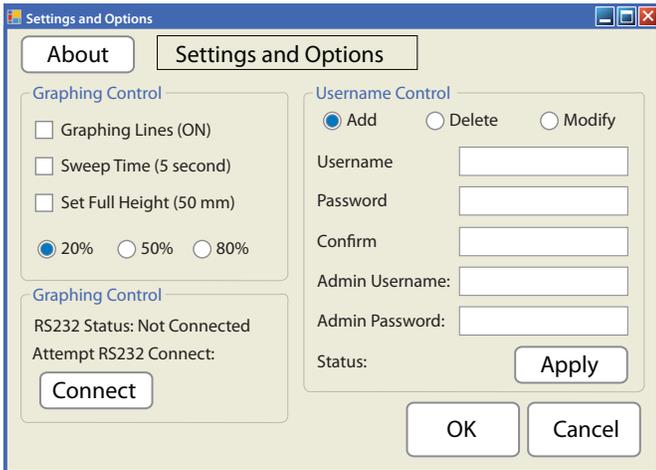


Figure 11d: PC-Touch Add New User

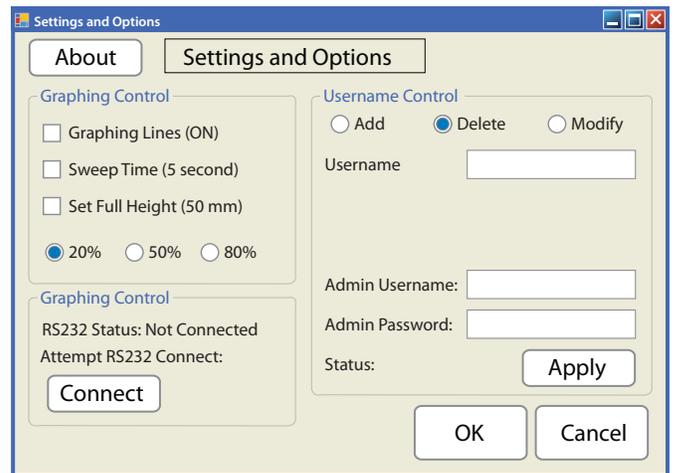


Figure 11e: PC-Touch Delete User

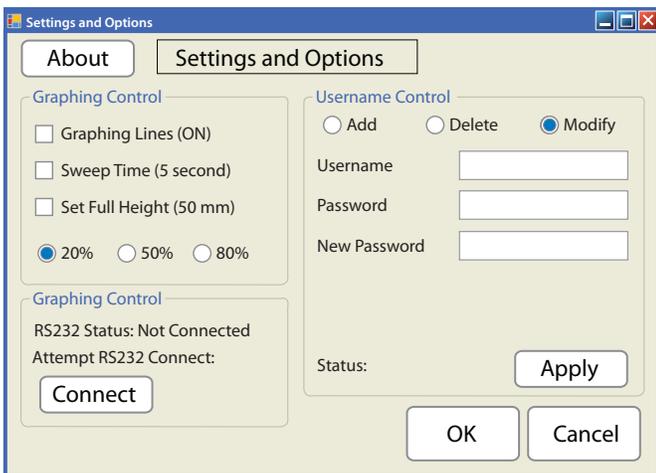


Figure 11f: PC-Touch Modify User

5.2 WVSM® Default Configuration Settings

5.2.1 Using a PC

To set the default configuration presets perform the following steps:

1. Open the WVSM® Configuration Settings Icon
2. Log in by entering the RO assigned username and password and pressing Login
3. Make the appropriate adjustments to the configuration settings
4. Check Save as Start Up Defaults
5. Press Apply to save
 - a. The new default configuration settings are now in effect and will remain until the settings are modified again by the approved RO
6. Close the configuration dialog menu when finished, Exit or the red X

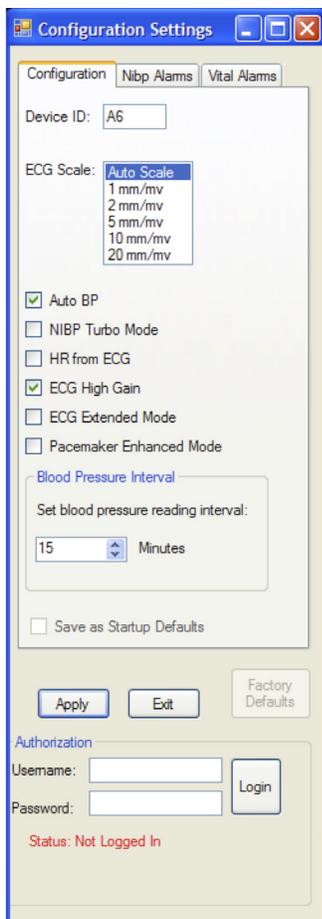


Figure 12a: PC-Standard WVSM Configuration Menu

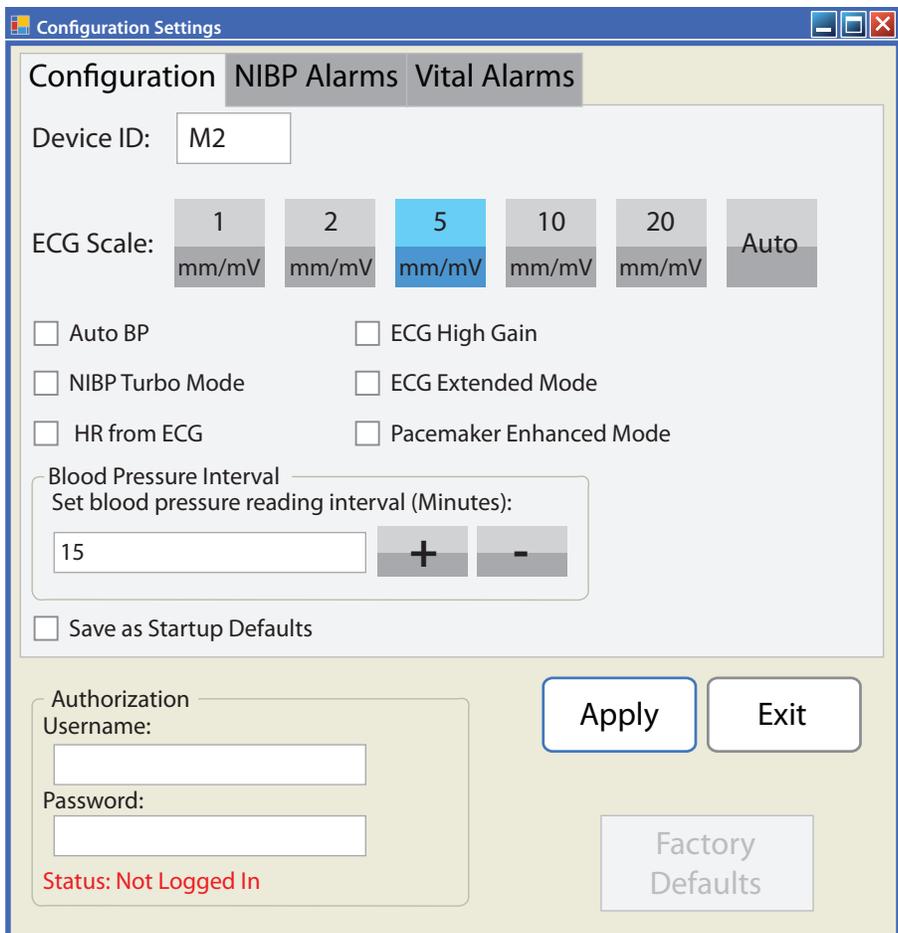


Figure 12b: PC-Touch Configuration Settings Menu

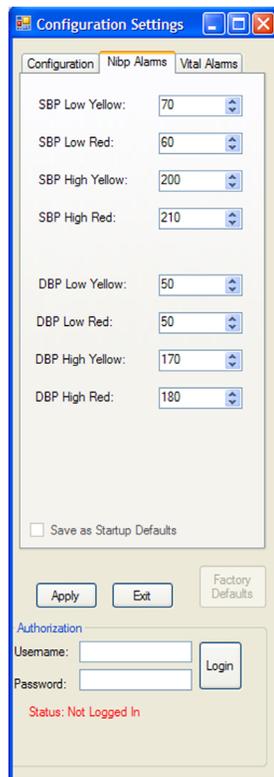
5.3 WVSM® Default Alarm Limits

5.3.1 Using a PC

To set the default alarm limit presets on the WVSM® perform the following steps:

1. Open the WVSM® Configuration Settings Icon
2. Select NIBP Alarms Tab or Vital Alarms Tab
3. Log in by entering the RO assigned username and password and pressing Login
4. Make the appropriate adjustments to the alarm limit settings
5. Check Save as Start Up Defaults
6. Press Apply to save
 - a. The new default alarm limit settings are now in effect and will remain until the settings are modified again by the approved RO
7. Close the alarm limits dialog menu when finished, Exit or the red X

Figure 13. WVSM Alarm Limit Menu on the PC



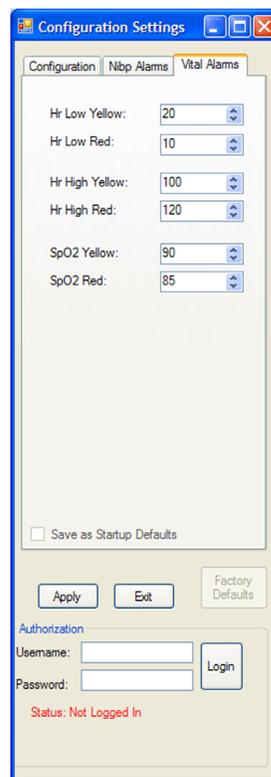
Configuration	Nibp Alarms	Vital Alarms
SBP Low Yellow:	70	
SBP Low Red:	60	
SBP High Yellow:	200	
SBP High Red:	210	
DBP Low Yellow:	50	
DBP Low Red:	50	
DBP High Yellow:	170	
DBP High Red:	180	

Save as Startup Defaults

Apply Exit Factory Defaults

Authorization
 Username: Login
 Password: Login
 Status: Not Logged In

Figure 13a: PC-Standard NIBP Alarms



Configuration	Nibp Alarms	Vital Alarms
Hr Low Yellow:		20
Hr Low Red:		10
Hr High Yellow:		100
Hr High Red:		120
SpO2 Yellow:		90
SpO2 Red:		85

Save as Startup Defaults

Apply Exit Factory Defaults

Authorization
 Username: Login
 Password: Login
 Status: Not Logged In

Figure 13b: PC-Standard Vital Alarms

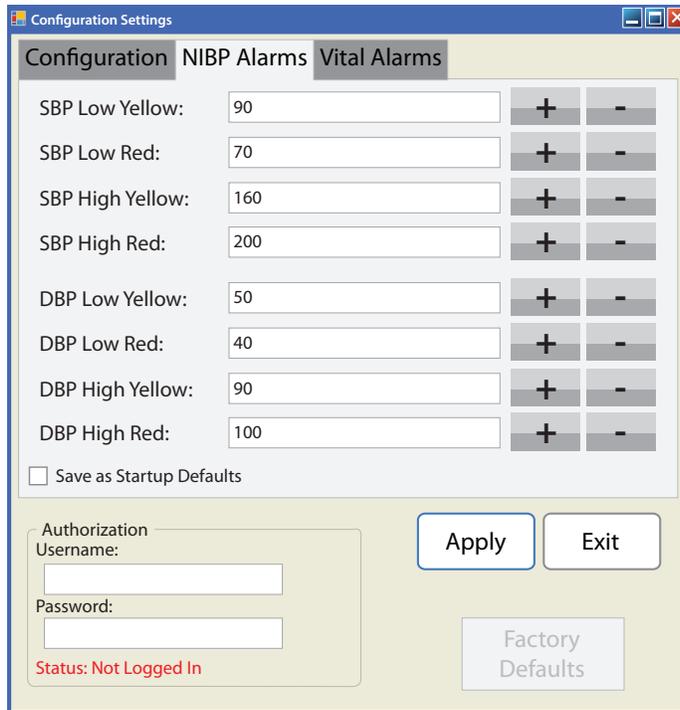


Figure 13c: PC-Touch NIBP Alarms

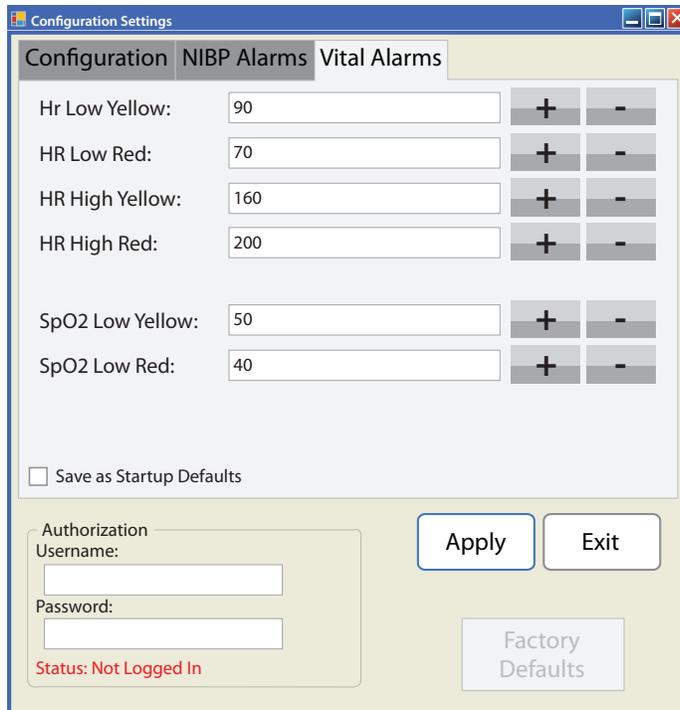


Figure 13c: PC-Touch Vital Alarms

5.4 PC Default Alarm Limits for Manual Parameter Data

To set the default alarm limit presets on the PC for the manually entered parameters, perform the following steps:

1. Double click on the Bell icon next to the parameter
2. Log in by entering the RO assigned username and password and pressing Login
3. Make the appropriate adjustments to the alarm limit settings
4. Check Save as Start Up Defaults
5. Press OK to save
 - a. The new default alarm limit settings are now in effect and will remain until the settings are modified again by the approved RO
6. Close the alarm limits dialog window when finished using the red X

Figure 14. PC Alarm Limit Dialog Windows for Manually Entering Parameters



Respiratory Rate Alarm ...

Alarm Control

RED <= 5

YELLOW <= 11

YELLOW >= 20

RED >= 24

Save as Defaults

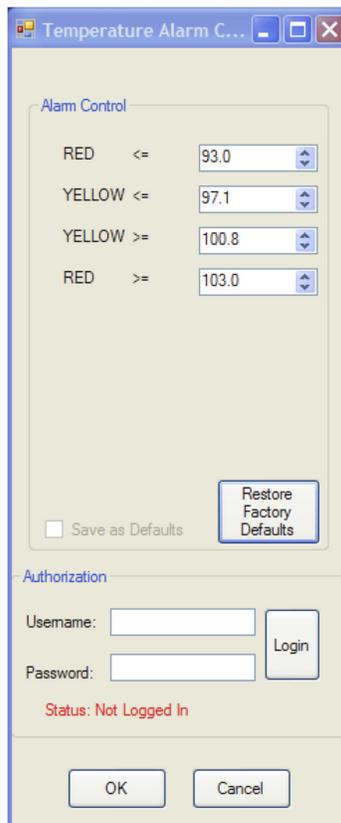
Authorization

Username:

Password:

Status: Not Logged In

Figure 14a: PC-Standard Respiratory Rate



Temperature Alarm C...

Alarm Control

RED <= 93.0

YELLOW <= 97.1

YELLOW >= 100.8

RED >= 103.0

Save as Defaults

Authorization

Username:

Password:

Status: Not Logged In

Figure 14b: PC-Standard Temperature



Glasgow Coma Score ...

Alarm Control

YELLOW <= 14

RED <= 8

Save as Defaults

Authorization

Username:

Password:

Status: Not Logged In

Figure 14c: PC-Standard Glasgow Coma Score

The screenshot shows the 'Respiratory Rate Alarm Control' dialog box. It has a title bar with standard window controls. The main area is divided into two sections: 'Alarm Control' and 'Authorization'.
 In the 'Alarm Control' section, there are four rows of controls:
 - Row 1: 'RED' with a '<=' operator and a text box containing '8'. To the right are '+' and '-' buttons.
 - Row 2: 'YELLOW' with a '<=' operator and a text box containing '11'. To the right are '+' and '-' buttons.
 - Row 3: 'YELLOW' with a '>=' operator and a text box containing '20'. To the right are '+' and '-' buttons.
 - Row 4: 'RED' with a '>=' operator and a text box containing '24'. To the right are '+' and '-' buttons.
 Below these rows is a checkbox labeled 'Save as Defaults' and a 'Restore' button.
 The 'Authorization' section contains:
 - 'Username:' and 'Password:' labels with corresponding text input boxes.
 - A 'Login' button to the right of the password box.
 - A red status message: 'Status: Not Logged In'.
 At the bottom of the dialog are 'OK' and 'Cancel' buttons.

Figure 14d: PC-Touch Respiratory Rate

The screenshot shows the 'Temperature Alarm Control' dialog box. It has a title bar with standard window controls. The main area is divided into two sections: 'Alarm Control' and 'Authorization'.
 In the 'Alarm Control' section, there are four rows of controls:
 - Row 1: 'RED' with a '<=' operator and a text box containing '96.0'. To the right are '+' and '-' buttons.
 - Row 2: 'YELLOW' with a '<=' operator and a text box containing '97.1'. To the right are '+' and '-' buttons.
 - Row 3: 'YELLOW' with a '>=' operator and a text box containing '100.8'. To the right are '+' and '-' buttons.
 - Row 4: 'RED' with a '>=' operator and a text box containing '103.0'. To the right are '+' and '-' buttons.
 Below these rows is a checkbox labeled 'Save as Defaults' and a 'Restore' button.
 The 'Authorization' section contains:
 - 'Username:' and 'Password:' labels with corresponding text input boxes.
 - A 'Login' button to the right of the password box.
 - A red status message: 'Status: Not Logged In'.
 At the bottom of the dialog are 'OK' and 'Cancel' buttons.

Figure 14e: PC-Touch Temperature

The screenshot shows the 'Glasgow Coma Score Alarm Control' dialog box. It has a title bar with standard window controls. The main area is divided into two sections: 'Alarm Control' and 'Authorization'.
 In the 'Alarm Control' section, there are two rows of controls:
 - Row 1: 'YELLOW' with a '<=' operator and a text box containing '14'. To the right are '+' and '-' buttons.
 - Row 2: 'RED' with a '<=' operator and a text box containing '8'. To the right are '+' and '-' buttons.
 Below these rows is a checkbox labeled 'Save as Defaults' and a 'Restore' button.
 The 'Authorization' section contains:
 - 'Username:' and 'Password:' labels with corresponding text input boxes.
 - A 'Login' button to the right of the password box.
 - A red status message: 'Status: Not Logged In'.
 At the bottom of the dialog are 'OK' and 'Cancel' buttons.

Figure 14f: PC-Touch Glasgow Coma Score

6.0 Maintenance

6.1 Cleaning

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

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

WARNING: Make sure that 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® and accessories for damage before cleaning.

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

6.1.1 WVSM® Device

1. Cleaning solutions: Use an approved solution (See Section 5.0)
2. Wipe with damp lint-free cloth in accordance with cleaning solution manufactures' recommendations.
3. Wipe off any excess liquid.

6.1.2 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.

6.1.3 ECG Cables

Single use disposable

6.1.4 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.

6.1.5 Power Adapter and Data Cable

1. Cleaning solution: Use an approved solution (See Section 5.0)
2. Wipe with damp lint-free cloth in accordance with cleaning solution manufactures' recommendations.
3. Wipe off any excess liquid.

6.2 Recharging the Battery

The WVSM® battery is internal to the device and cannot be removed for charging. To recharge the WVSM® battery, perform the following steps:

1. Plug the medical grade power cord accessory (Provided with WVSM®) into the power adapter (Also provided with WVSM®).
2. Plug the medical grade power cord into an appropriate AC power source.
3. Ensure WVSM® is “OFF”. If adapter is plugged in while WVSM® is “ON”, WVSM® will warn the user of an automatic shutdown.
4. Plug the power adapter into the top panel of the WVSM®. 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 a part of ME EQUIPMENT or combination is specified as a ME SYSTEM - use only the approved unit as specified in Section 18.2 of the Operators Manual.

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

WARNING: The WVSM® device contains a lithium ion battery. Potential for fire or burning. Do not disassemble, crush, heat, burn or incinerate.



Figure 15. WVSM™ Battery Recharging

6.3 NIBP Calibration

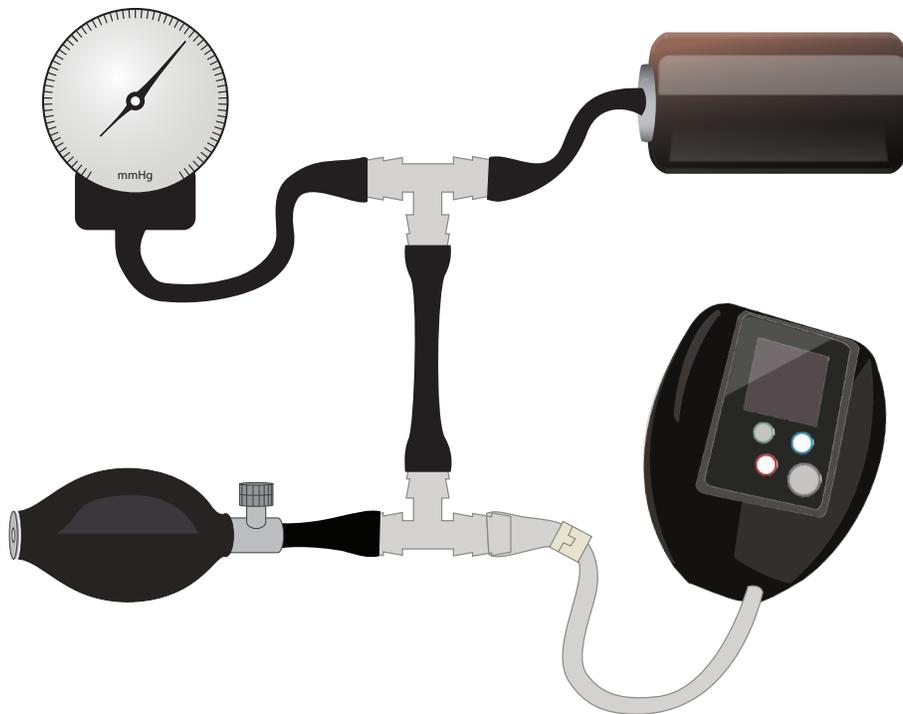
The NIBP system in the WVSM® is compliant with international standards of automatic device blood pressure accuracy. The international standard requires static measurements to be within ± 3 mmHg. It is important to have proper test equipment and that it is in good working order while performing calibration.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

6.3.1 Equipment Needed for Calibration Verification & Full Calibration

- Calibrated Manometer
- Pneumatic “T” Adapters
- Volume (500mL bottle or regular-sized cuff wrapped around a solid object is suggested)
- Hand Bulb
- Connection Tubing

Note: Volume is added to the pneumatic system so that the user has more control of the pressure increments when using the hand bulb. If no volume is added, it is quite easy to cause unwanted overpressure errors using the hand bulb.

Figure 16. Calibration Test Setup



6.3.2 Verification Procedure

The WVSM® device has a calibration mode that allows the user to verify the pressure transducer accuracy. To enter the calibration mode on the WVSM® device, perform the following:

1. Set up the equipment in accordance with Figure 9
2. Press and hold the Power Button on the WVSM® front panel to turn on the device
3. The mode select menu appears on the screen
4. Press the Gray BP button to enter the calibration mode
 - a. The current pressure applied to the NIBP hose connection is displayed in Green in mmHg

Figure 17. Calibration Verification Display Screens

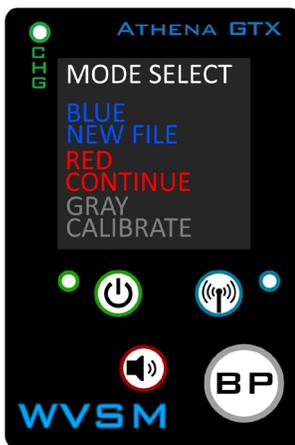


Figure 17a. MODE SELECT screen

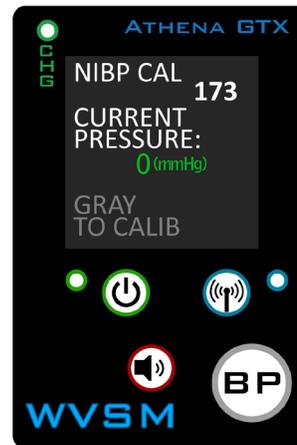


Figure 17 b. NIBP CAL screen

5. Perform transducer pressure verification testing
 - a. Apply various pressures (between 0 mmHg and 280 mmHg) to the Module with the hand bulb. Verify that the Module pressure is equal to the manometer pressure (+/-3mmHg). If the Module pressure does not agree with the manometer pressure (+/-3mmHg), perform the Full Calibration procedure steps below until the Module pressure and the manometer pressures agree within +/- 3mmHg.
6. When finished, Press and hold the Power button to exit the calibration verification mode and turn off the device

6.3.3 Full Calibration Procedure

If the verification procedure above shows that the WVSM® needs to be re-calibrated, perform the following steps:

1. Set up the equipment in accordance with Figure 9.
2. Turn on the WVSM® by pressing and holding the Power button. Figure 10a should appear.

Figure 18. Calibration Screen Shots



Figure 18a. Mode Select

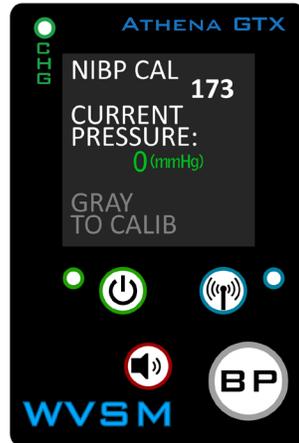


Figure 18b. NIBP CAL. Screen

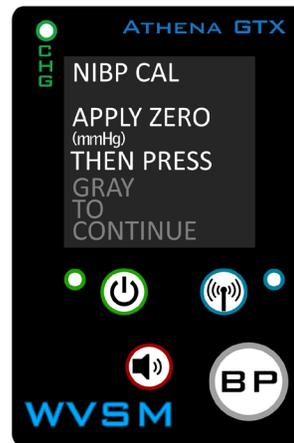


Figure 18c. Apply Zero Screen

3. Press the Gray BP button in Mode Select screen to enter Calibration Mode (Figure 11a)
4. Press Gray BP button in NIBP CAL Screen (Figure 11b)
5. Apply 0 mmHg to the system and Verify that the manometer reads 0 (Figure 11c)
6. Press Gray BP button (Figure 11c)

Figure 19. Calibration Screen Shots

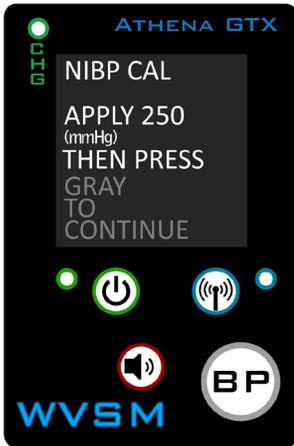


Figure 19a. Apply 250 Screen

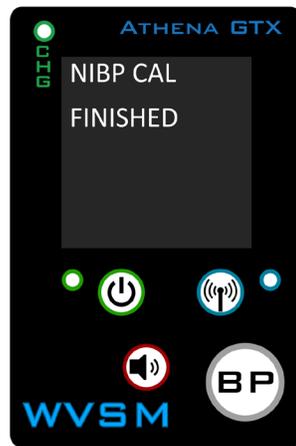


Figure 19b: Finished Screen

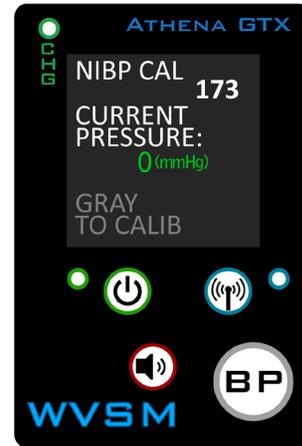


Figure 19c. Current Pressure Screen

7. Figure 12a should appear
8. Close the valve on the hand bulb
9. Pump hand bulb to increase pressure in the system until the manometer reads 250mmHg
10. Press Gray BP button (Figure 12a)
11. Figure 12b should appear
12. Press Gray BP button to finish calibration
13. Figure 12c should appear
14. Calibration is complete
15. Turn off the WVSM® by pressing and holding the Power button
16. Re-Verify the calibration by performing the procedure in paragraph 5.3.2 Verification Procedure above

6.4 Disposal

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

7.0 Troubleshooting

7.1 WVSM® Device

1. WVSM® Unit not turning on:
 - a. If the blue WiFi light blinks when power button is pushed the battery needs to be recharged.
 - b. 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.
 - c. 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:
 - a. Check for loose connections:
 - i. at the WVSM® ECG connector port
 - ii. at the ECG adaptor [both ends] (if applicable)
 - iii. at the ECG electrode snap interface
 - b. Ensure that ECG electrodes are secured on the patient's body.
 - c. Confirm that the individual ECG electrodes are placed correctly on the patient.
 - d. Verify that the individual ECG electrodes are plugged into the corresponding ports (RA, LA, LL) on the ECG adaptor
 - e. Ensure that ECG electrodes are plugged into the WVSM® ECG connector port before the WVSM® unit is turned on (otherwise, restart the WVSM® unit after plugging in the ECG electrodes first)
3. No/Incorrect SpO₂ readings:
 - a. Ensure that there are no loose connections (at the WVSM® connector port and at the finger clip)
 - b. Check to see if the NIBP arm cuff is inflating (especially if the SpO₂ finger clip is placed on the same limb as the cuff, the SpO₂ reading may be momentarily interrupted)
 - c. Ensure that Pulse-Ox sensor is plugged into the WVSM® SpO₂ connector port before the WVSM® unit is turned on (otherwise, restart the WVSM® unit after plugging in the ECG electrodes first).
4. No/Incorrect NIBP readings:
 - a. 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)
 - b. Ensure that the patient and his/her arm is immobile during the measurement (motion artifacts can influence the accuracy)
 - c. Recharge the battery (there may be insufficient power remaining on the WVSM® unit to properly inflate the arm cuff)
5. Pressing "Continue" on Menu screen produces an error message and returns to Menu screen:
 - a. WVSM® has detected an error in the configuration files and cannot continue with the previous

patient

- b. Select “New Patient” to use the monitor.

7.2 Communications

7.2.1 PDA WLAN connection not successful:

1. Turn the WVSM® unit(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® 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®, the PDA needs to be setup to operate on the same network. The units sent by the Athena GTX are already configured properly. New systems should be set up by the user. Contact your Network or System Administrator if you are unable to do so or contact the manufacturer on the help lines established.

7.2.2 PDA Not Connecting to Active WVSM®s

1. Turn on the WVSM® Software while a WVSM® is within wireless range
2. Wait several seconds to ensure no patient is loaded to list
3. Touch Start Menu
4. Touch Settings
5. Touch Connections
6. Touch Connections Icon
7. Touch Advanced Tab
8. Touch Network Card
9. Touch “User specific IP Address”
10. Enter in a unique IP address in the format 192.168.1.0xx where xx is any value not on any other wireless device running the WVSM® software within wireless range
11. Enter “255.255.255.0” in Sub net mask
12. Touch ok to apply changes
13. Restart WVSM® software and ensure WVSM® are able to connect to software

7.2.3 PC WLAN Connection not Successful

1. Check to ensure that the wireless device [USB, CF, SD, etc.] are plugged in properly (These devices can get displaced easily)
2. Restart the computer (This action resets the WLAN communication system)
3. If not connected go to View Wireless Networks from wireless network connections
4. Click Change Advanced Settings
5. Select Internet Protocol from list and click Properties
6. Select “Use the following IP address”
7. Enter “192.168.1.0xx” where xx is any value not on any other wireless device running the WVSM® software within wireless range
8. Enter “255.255.255.0” in Sub net mask
9. Click OK
10. Go to Wireless Networks tab
11. If WVSM® is not in Preferred network list click Add or else select WVSM® and click Properties

12. Enter in or ensure the following settings
13. SSID is “WVSM”
14. Check “Connect even if this network is not broadcasting”
15. Network Authentication is Open
16. Data encryption is Disabled
17. Click Connection tab
18. Check Connect when this network is in range
19. Click OK
20. Remove any other Preferred Networks other than WVSM
21. Click OK
22. Restart computer

7.3 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 black light. Touching the screen will bring the home screen back up.
 - b. In some DELL 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.

7.4 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.
4. Message on software startup say “The WVSM® Management Suite software is already running in the background. Please use the current running software or exit to restart” – If the software is not viewable and does not look to be running, Press ctrl-alt-del to open Task Manager select ETFathenaCSharp from the list and click End Process.
5. Data and waveforms look erratic in WVSM® software – go to C:\ETFDATA clean data files from directory.

8.0 Warranty and Service Information

8.1 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® or Accessory has been damaged due to excessive wear and tear, negligence or misuse,
- The WVSM® has not been operated in accordance with applicable safety and regulatory requirements including use with non-approved and designated accessories, or
- The WVSM® has been serviced by unauthorized service personnel.

This warranty replaces all other oral, and/or written warranties, obligations, and/or liabilities of the manufacturers and distributors of the WVSM® except those expressly set forth in the product warranty. The manufacturers and distributors of the WVSM® 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 the manufacturer. Only the manufacturer shall determine the form of remedy. No warranty claim shall be honored unless received by the manufacturer within one (1) year (ninety (90) days for accessories) of the date that the WVSM® or accessories were delivered to the purchaser/end-user. The manufacturer 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.

8.2 Service

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