AortaScan®

AORTASCAN AMI 9700

Operations & Maintenance Manual

VERATHON®
New World. Real Solutions.

AORTASCAN

AMI 9700

Operations & Maintenance Manual

Effective: November 2, 2015

Caution: Federal (United States) law restricts this device to sale by or on the order of a physician.

CONTACT INFORMATION

To obtain additional information regarding your AortaScan system, please contact Verathon® Customer Care or visit verathon.com/contact-us.

Verathon Inc.
20001 North Creek Parkway
Bothell, WA 98011 U.S.A.
800.331.2313 (US and Canada only)
425.867.1348
Fax: 425.883.2896
verathon.com

EC REP

Verathon Medical (Europe) B.V.
Willem Fenengastraat 13
1096 BL Amsterdam
The Netherlands
Tel: +31 (0) 20 210 30 91
Fax: +31 (0) 20 210 30 92
verathon.com

CE 0123

TABLE OF CONTENTS

IMPORTANT INFORMATION

OVERVIEW

PRODUCT DESCRIPTION

The AortaScan AMI 9700 is a portable ultrasound instrument that provides noninvasive measurements of abdominal aortic diameter. The device consists of an ultrasound probe that scans the patient's aorta, and a compact, battery-operated console that provides measurement-related information.

The AortaScan AMI 9700 can measure diameters ranging between 3 and 12.4 cm with a diameter accuracy of ± (15% + 0.5 cm). This error-range data (Table 1) indicates a range of values obtained by the device relative to follow up and clinical significance, specifically with respect to risk vs. diameter.

Table 1. Expected Aortic Measurement Ranges

ACTUAL AORTIC DIAMETER												
	3.0 cm		3.5 cm		4.0 cm		4.1 cm		5.0 cm		5.3 cm	
Average estimated risk of rupture for actual aortic diameter	0%		0%		0%		1%		11%		11%	
Aortic diameter as reported by the device based on allowable tolerances												
	Min	Max	Min	Max	Min	Max	Min	Max	Min	Max	Min	Max
± 15%	2.55	3.45	2.98	4.03	3.40	4.60	3.49	4.72	4.25	5.75	4.51	6.10
With additional ±0.5 cm	2.05	3.95	2.48	4.53	2.90	5.10	2.99	5.22	3.75	6.25	4.01	6.60
Average estimated risk of rupture for reported aortic diameter	0%	0%	0%	1%	0%	1%	0%	11%	0%	26%	0.5–5.0%	26%

Note: The AortaScan AMI 9700 is not intended to detect, identify, screen for, or diagnose abdominal aortic aneurysms (AAAs).

The AortaScan AMI 9700 is quick and easy to use. When the user releases the scan button, the AortaScan AMI 9700 uses patented VMODE® technology to measure ultrasound reflections on multiple planes inside the body and produces a three-dimensional image within seconds. Based on this image, the AortaScan AMI 9700 calculates and displays the approximate abdominal aortic diameter. A sonographer is not required.

If needed, after a scan has been taken, a unique aiming icon guides the operator to optimal probe placement with a comprehensive, three-dimensional display showing the aorta in two cross-sectional images verifying that a complete scan has been achieved.

AortaScan AMI 9700 measurements can be printed via an onboard thermal printer or transmitted, via a proprietary wireless connection, to a personal computer running HIPAA-compliant ScanPoint® with QuickPrint software. ScanPoint with QuickPrint software enables the user to print detailed reports for medical records or reimbursement, calibrate the instrument (requires a calibration kit), download and install software updates, and archive data on Verathon® servers.

The optional calibration kit, consisting of a spiral-shaped calibration target along with a special calibration container, allows the user to easily calibrate the device at their facility by scanning a known target.

The AortaScan AMI 9700 system also includes a battery charger/wireless hub for the custom, user-replaceable lithium-ion battery that mounts in the console.

The AortaScan AMI 9700 may be mounted on a cart which holds the instrument securely in place and provides a holder for ultrasound gel and other accessories.

NOTICE TO ALL USERS

The AortaScan AMI 9700 should be used only by individuals who have been trained and authorized by a physician or the institution providing patient care. All users must read this entire manual prior to using the AMI 9700. Do not attempt to operate this instrument until you thoroughly understand all instructions and procedures in this manual. Failure to comply with these instructions may compromise the performance of the device and the reliability of its measurements.

For the most current version of this manual, please visit verathon.com.

STATEMENT OF PRESCRIPTION

Caution: Federal (United States) law restricts this device to sale by or on the order of a physician.

STATEMENT OF INTENDED USE

The AortaScan AMI 9700 is an ultrasound device that projects ultrasound energy into the mid-abdomen to obtain an image of the abdominal aorta for aortic diameter measurements.

ESSENTIAL PERFORMANCE

Essential performance is the system performance necessary to achieve freedom from unacceptable risk. The essential performance of the AortaScan AMI 9700 system is to produce ultrasonic output energy, display ultrasonic images, and display numerical values for aortic diameter. The system has a temperature-controlled transducer assembly.

SAFETY INFORMATION

ULTRASOUND ENERGY SAFETY

To date, exposure to pulsed diagnostic ultrasound has not been shown to produce adverse effects. However, ultrasound should be used prudently, and total patient exposure should be kept *as low as reasonably achievable* (ALARA). Following the ALARA principle, ultrasound should only be used by medical professionals when clinically indicated, using the lowest possible exposure times necessary to obtain clinically useful information. For more information on ALARA, please refer to the American Institute of Ultrasound in Medicine publication, *Medical Ultrasound Safety*.

The ultrasound output power of the system is not user adjustable and is limited to the minimum level necessary for effective performance. Data on acoustic output levels can be found in the Product Specifications section of this manual.

CONTRAINDICATIONS

The AortaScan AMI 9700 is not intended for fetal use or for use on pregnant patients.

The AortaScan AMI 9700 is not intended for acute events such as aortic dissection, ulcer, or rupture.

PRECAUTIONS & WARNINGS

Warnings indicate that injury, death, or other serious adverse reactions may result from use or misuse of the device. *Cautions* indicate that use or misuse of the device may cause a problem, such as a malfunction, failure, or damage to the product. Throughout the manual, pay attention to sections labeled *Important*, as these contain reminders or summaries of the following cautions as they apply to a specific component or use situation. Please heed the following warnings and cautions.

PRECAUTIONS

CAUTION

The AortaScan AMI 9700 and related devices may contain mineral oils, batteries, and other environmentally hazardous materials. When the instrument and/or accessories have reached the end of their useful service life, see the section Device Disposal on page 63.

CAUTION

When using the AortaScan AMI 9700 with optional ScanPoint® software, your computer must be minimally certified to EN / IEC / CSA / UL 60950 or 60101-1 standards. This configuration ensures that compliance to the EN/IEC 60601-1-1 system standard is maintained. Anyone connecting additional equipment to the AortaScan AMI 9700 signal input port or signal output port configures a medical system, and is therefore responsible for ensuring that the system complies with EN/IEC 60601-1-1. If you need assistance, contact your biomedical staff, Verathon® representative, or Verathon Customer Care.

CAUTION

Potential Device Interference. Bluetooth and Wireless LAN devices operate within the same radio frequency range and may interfere with one another.

If you are using the AortaScan AMI 9700 Bluetooth link and wireless LAN devices simultaneously, you may experience less-than-optimal network performance or even lose your network connection. If this happens, you may need to move the AortaScan AMI 9700 and ScanPoint® host computer to an area away from the 2.4 GHz wireless LAN devices (40 meters/44 yards, or more).

CAUTION

Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC) and must be installed and operated according to the instructions in this manual. For more information, see the Electromagnetic Compatibility section on page 72.

To maintain electromagnetic interference (EMI) within certified limits, the AortaScan AMI 9700 system must be used with the cables, components, and accessories specified or supplied by Verathon®. For additional information, see the System Components & Accessories and Component Specifications sections. The use of accessories and/or cables other than those specified or supplied may result in increased emissions and/or decreased immunity of the system.

The AortaScan AMI 9700 system should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the system should be observed to verify normal operation in the configuration in which it will be used.

This device can radiate radio frequency energy and is very unlikely to cause harmful interference with other devices in the vicinity. There is no guarantee that interference will not occur in a particular installation. Evidence of interference may include degradation of performance in this device or other devices when operated simultaneously. If this occurs, try to correct the interference by using the following measures:

- Turn devices on and off in the vicinity to determine the source of interference
- Reorient or relocate this device or other devices
- Increase the separation between devices
- Connect the device to an outlet on a circuit different than the other device(s)
- Eliminate or reduce EMI with technical solutions (such as shielding)
- Purchase medical devices that comply with IEC 60601-1-2 EMC Standards

Be aware that portable and mobile radio frequency communications equipment (cellular phones, etc.) may affect medical electrical equipment; take appropriate precautions during operation.

CAUTION

Use of the following cleaning methods or solutions may cause device damage not covered by the AortaScan AMI 9700 warranty.

- Do not immerse the instrument in disinfectant solution.
- Do not use Cidex Plus® to disinfect the instrument. Cidex Plus will damage the plastic enclosure.
- Do not subject any part of the instrument to steam sterilization or ethylene oxide sterilization.

WARNINGS

WARNING

The aortic diameter measurement function provides images that may be used for diagnosis and screening. If clinically indicated, appropriate patients should be referred for additional diagnostic testing.

WARNING

The AortaScan system is designed to detect the fluid (blood) filled region of the abdominal aorta only. The system cannot detect the presence of a blood clot (thrombus) and therefore may provide a false negative result.

WARNING

The AortaScan system is an ultrasound-based device and is subject to all limitations of this method. If clinically indicated, appropriate patients should be referred for a diagnostic standard (confirmatory) test, regardless of test results.

WARNING

Risk of explosion. If you use the AortaScan AMI 9700 in the presence of flammable anesthetics, the hazard of potential explosion exists.

WARNING

Risk of electric shock or burns. Do not use the AortaScan instrument in conjunction with HF surgical equipment.

WARNING

Ensure proper distance from patient. The AMI 9700 battery charger/wireless hub and the computer used to access online ScanPoint® image archives (if used) must be placed outside the patient vicinity (more than 2 m [6 ft] from the patient).

WARNING

Risk of explosion, fire, or serious injury. The AortaScan AMI 9700 is powered by a lithium-ion battery. Failure to note the following when handling the battery may result in serious injury:

- Never short-circuit the battery by either accidentally or intentionally bringing the battery terminals into contact with any other conductive object. This could cause serious injury or fire and could also damage the battery and/or the instrument.
- Never expose the battery to abnormal shock, vibration, or pressure. The battery's internal protective covering could fail, causing it to overheat or ignite, resulting in caustic liquid leakage, explosion, or fire.
- Do not disassemble, heat above 60°C (140°F), or incinerate the battery. Keep battery out of reach of children and in original package until ready to use. Dispose of used batteries promptly according to local recycling or waste regulations.
- If the battery is leaking or its case is cracked, put on protective gloves to handle it, and discard it immediately. Always dispose of used batteries in compliance with all applicable laws and regulations. Put insulating tape, such as cellophane tape, on the electrodes during transportation in order to avoid a possible short circuit, fire, or electrical shock.

WARNING

Do not use the AortaScan AMI 9700 on:

- A patient who has open skin or wounds in the mid-abdominal area.
- A patient with ascites.
- A pregnant patient.

WARNING

Potential patient hazard. To date, exposure to low-power, pulsed diagnostic ultrasound has not been shown to produce adverse effects. However, medical professionals should use ultrasound only when clinically indicated, using the lowest exposure times possible to obtain proper measurements. The ultrasonic output of the AortaScan AMI 9700 is not user adjustable and is limited to the minimum level necessary for effective performance. For more information about the acoustic output levels of this device, see the section Product Specifications on page 68.

WARNING

Ensure that you follow the manufacturer's instructions for handling and disposing of the cleaning and disinfection solutions provided in this manual.

WARNING

Risk of inaccurate measurements/results. When using the instrument, be aware of the following conditions that can decrease the accuracy of exam results:

- In some cases, the normal operating tolerances of the instrument can cause it to report a falsely normal or abnormal measurement. For more information, see Interpret the Aortic Measurement Results on page 51.
- Visual verification that the aorta position is fully within the scan cone on the displayed images is important.
- A thrombus (blood clot) can complicate aortic measurements. A soft, blood-like thrombus may appear as part of the lumen. However, a calcified thrombus may appear as part of the aorta's wall, resulting in a measurement of lumen diameter that is smaller than the aorta diameter. Accordingly, in patients where thrombus is known or suspected, other imaging methods should be used prior to ruling out an aneurysm.
- Use care when scanning patients who have had abdominal surgery. Scar tissue, surgical incisions, sutures, and staples can affect ultrasound transmission and accuracy.
- Ensure that the patient fasts for 12 hours prior to undergoing an aortic diameter measurement in order to minimize the presence of bowel gas, which may obstruct proper measurement.
- Obesity may affect ultrasound aortic diameter measurements. For more information, see Obesity on page 54.

Accuracy is compromised if the user does not obtain an optimal, repeatable image.

WARNING

Cleaning is critical to ensuring the component is ready for disinfection. Failure to properly clean the device could result in a contaminated instrument after completing the disinfection procedure.

WARNING

This product may only be cleaned and disinfected by using the approved processes provided in this manual. Cleaning and disinfection methods listed are recommended by Verathon® based on compatibility with component materials.

WARNING

Availability of cleaning and disinfection products varies by country, and Verathon is unable to test products in every market. For more information, please contact Verathon Customer Care at 1.800.331.2313 or your local representative. For additional contact information, visit verathon.com/contact-us.

INTRODUCTION

COMPONENTS & FEATURES

The AortaScan AMI 9700 is designed for simple, intuitive operation. However, to ensure safe and effective operation, before using the device:

- Familiarize yourself with the contents of this manual.
- Watch the training video provided on the instrument.

The AortaScan AMI 9700 has two main components: the console and the probe. The console and probe are linked by a detachable cable.

Figure 1. AortaScan AMI 9700 System Components

PROBE COMPONENTS

The probe transmits and receives ultrasound waves, automatically moving its internal probe 360° to scan twelve different planes to produce a three-dimensional image of the aorta. The probe is attached to the console by a cable.

Figure 2. Probe Components

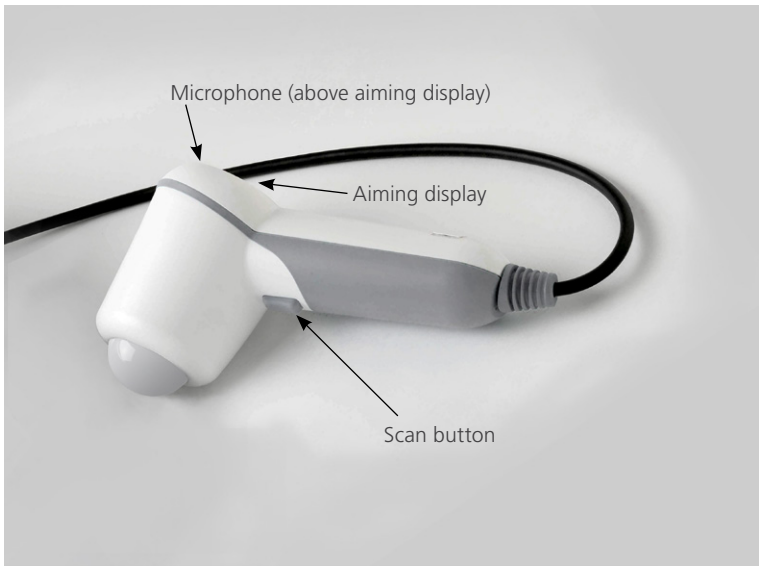


Table 2. Probe Components

PART NAME	PURPOSE
Scan button	When pressed, a scan is performed.
Aiming display	Displays directional arrows to ensure the aorta is centered within the scanning cone.
Microphone	Records voice annotations.

CONSOLE COMPONENTS

The console provides all operating controls for the scanning process by means of five variable-function buttons. The measured aortic diameter and target-shaped aiming icons are clearly displayed on the LCD screen. The console also provides controls for adjusting brightness and volume, turning the power on/off, interfacing with a ScanPoint® host computer (optional), and adjusting user settings and preferences. The console also houses the battery and the printer.

Figure 3. Console Components

Table 3. Console Components

PART NAME	PURPOSE
Main display	Displays the aortic volume measurement, patient type, settings, and instrument status.
Power on/off	Toggles main power on/off.
Volume	Adjusts volume up/down on voice annotation playback, start up sound, and "scan complete" tone.
Brightness	Adjusts display brightness dimmer/brighter.
Five variable function buttons	Provides access to all instrument functions for scanning, recording annotations, printing, connecting to ScanPoint® (optional), accessing the training video, and setting user preferences.
Printer/printer door	Prints the scan results.

BATTERY CHARGER/WIRELESS HUB

The AortaScan AMI 9700 is powered by a lithium-ion battery. The battery charger provided with the AMI 9700 can charge two lithium-ion batteries while simultaneously functioning as the wireless hub linking the AMI 9700 to the ScanPoint® host computer. A battery icon on the instrument display is always present indicating how much power remains and when the battery needs to be changed. The user can change the battery whenever necessary. Removing a discharged battery and replacing it with a fully charged battery will not erase any saved exams or user settings.

To provide power to the batteries, the battery charger/wireless hub must be plugged into a wall outlet by using the power cord provided. Use only the battery charger provided with the AMI 9700. Any other battery charger may damage the battery. The battery charger automatically detects whether a lithium-ion battery is being charged.

To provide wireless communication between the AMI 9700 and the ScanPoint host computer, plug the battery charger/wireless hub USB connector into a USB port on the ScanPoint host computer. The battery charger/wireless hub maintains an operating distance of up to 120 feet (36 meters) between the ScanPoint computer and the AMI 9700, regardless of barriers such as walls, ceilings, or windows.

Note: Use of ScanPoint with QuickPrint software is optional.

Figure 4. Battery Charger/Wireless Hub

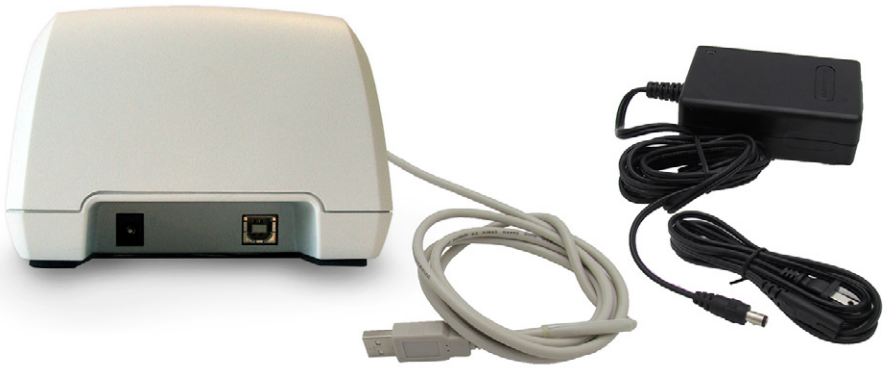


Table 4. Battery Charger/Wireless Hub Components

PART NAME	DESCRIPTION
Battery charger/ wireless hub	Charges the lithium-ion batteries and receives and sends information to/from the AMI 9700 instrument within communication range.
Lithium-ion batteries	When charged, provides power to the AMI 9700 device.
Power cord	Connects the battery charger/wireless hub to the wall outlet.
Wireless hub USB cable	Connects the battery charger/wireless hub to the ScanPoint host computer.

SYSTEM COMPONENTS & ACCESSORIES

Table 5. Components and Accessories

COMPONENTS
AMI 9700 console
AMI 9700 probe
Battery charger/wireless hub with AC power cord
ACCESSORIES
Lithium-ion battery (2 provided)
AortaScan AMI 9700 In-Service CD or USB, containing the Operations & Maintenance Manual
Thermal paper roll for the printer
Ultrasound gel
Mobile cart (Optional)
Universal accessory basket (Optional)
ScanPoint® with QuickPrint software install CD (Optional)
ScanPoint with QuickPrint user's manual (Optional)
Calibration kit (Includes calibration container, calibration target, etc.) (Optional)

To order any of the above parts or accessories, contact your authorized Verathon® sales representative or contact Verathon Customer Care.

ICONS & BUTTONS

The console LCD presents user information and prompts that vary depending on the current device function. The five buttons below the display have variable functions according to device mode. Button functions are indicated by icons in the display footer, immediately above each button.

CONSOLE DISPLAY ICONS

The following icons may appear on the console main display.

ICON	PURPOSE
	A fully charged battery.
	A battery 50% to 75% charged.
	A battery 25% to 50% charged.
	An almost depleted battery. Can power a few more scans.
	A fully discharged battery. Replace immediately.
	Empty exam folder
	Current exam folder
	Saved exam folder
	(Solid arrow) The aorta is contained within the image cone (cone-shaped area in which the probe transmits ultrasound waves), but the presence of bowel gas prevents a proper measurement. You may be able to obtain a more appropriate measurement by moving the probe 1/2 to 1 inch (1 to 2 cm) in the direction indicated by the arrow.
	(Flashing arrow) The aorta is obstructed by bowel gas and the probe needs to be repositioned. The arrow shows the direction to move or tilt the probe to improve the measurement. Try moving the probe 1/2 to 1 inch (1 to 2 cm) in the direction of the arrow.

VARIABLE BUTTON FUNCTIONS

ICON	PURPOSE
	Go to the Home screen.
	View the training video.
	Go to the Settings screen.
	Go to the Review screen. If there are no saved exams, this button is disabled.
	Initiate communication with the ScanPoint® host computer. Saved and annotated exams will be automatically uploaded to the host computer. *Note: ScanPoint software must be previously installed and the computer connected to the wireless hub. Use of the ScanPoint software is optional.*
	Record a voice annotation.
	Play a previously recorded voice annotation. If no voice annotations are recorded, this button is disabled.
	Print exam results from the onboard printer. While printing is in progress, an hourglass icon appears on the display, and most buttons are disabled.
	Move down an item.
	Move up an item.
	Move right an item.
	Delete an exam or cancel the current action.
	Select the highlighted item.
	Stop recording a voice annotation.
	Play video playback.
	Pause video playback.

ICON	PURPOSE
	Add and/or toggle characters, as appropriate.
	Remove and/or toggle characters, as appropriate.
	Select the Axis on which to manually measure the aorta.
	Go to the manual measurement tool and select appropriate cursor while manually measuring the aorta.
	No function.

BUTTON FUNCTIONS FOR EACH DISPLAY SCREEN

The **Power**, **Brightness**, and **Volume** buttons are constant buttons on the body of the console and can be pressed at any time. The five buttons below the LCD have variable functions according to device mode. The Scan button is located on the underside of the probe.

SCREEN/MODE	ACTIVE BUTTONS
Home screen Appears when the instrument is turned on and set to the AortaScan mode.	(1) No function. (2) **Tutorial**: opens Tutorial screen. (3) **Settings**: opens Settings screen. (4) **Review**: opens the Review screen. (5) **ScanPoint®**: transmits saved exams to ScanPoint.
Scan screen Appears when the operator presses and releases the Scan button. As the aortic diameter is calculated, the display refreshes and updates until the scan is complete.	Scan button: Press and release to take a scan. (1) - (4): No function. (5): **Home**: Return to Home screen.
Results screen Appears when a scan is complete. Prominently displays calculated aortic diameter in centimeters, the ultrasound image of the scan, and available memory. An hourglass icon appears when the device is printing.	(1) **Record**: press to record, changes to a stop button during recording. (2) **Print**: print to onboard printer. (3) **Listen**: press to listen to the voice annotations. If no scans are saved, the button is disabled. (4) If in B-mode: **Manual Measure**: allows for a manual measurement of the aorta. (4) If in C-mode: **Review**: opens the Review screen. (5) **Home**: return to Home screen.
Review screen Allows the user to review saved exams. Saved exam folders are on the left side of the screen with the currently selected saved exam being an open folder icon. The ultrasound images associated with selected exam are on the main display.	(1) **Down Arrow**: select the next saved exam. (2) **Print**: print to onboard printer. (3) **Listen**: replay voice annotation for selected exam. (4) **Delete**: delete selected exam. (5) **Home**: return to Home screen.
Tutorial screen View the training modules menu.	(1) **Down Arrow**: skip to next video. (2) **Up Arrow**: select previous video. (3) **Select**: play selected video. (4) No function. (5) **Home**: return to Home screen.

SCREEN/MODE	ACTIVE BUTTONS
Video Viewing screen Plays the selected tutorial video.	(1) No function. (2) **Play**: plays selected video, changes to a pause button when video is playing. (3) **Up Arrow**: return to Tutorial screen. (4) No function. (5) **Home**: return to Home screen.
Settings screen Start screen for editing clinic name, date and time, general preferences, savings preferences, and self test options.	(1) **Down Arrow**: select next setting in list. (2) **Up Arrow**: select previous setting in list. (3) **Select**: proceed to the selected screen. (4) No function. (5) **Home**: return to Home screen.
Name screen Displays alpha numeric characters for entering information.	(1) **Down Arrow**: move to the character below. (2) **Right Arrow**: move to the character to the right. (3) **Plus Sign**: add currently selected character. (4) **Minus Sign**: delete currently selected character. (5) **Settings**: return to main settings screen.
Date and Time screen Allows the user to set the date and time.	(1) **Down Arrow**: move forward to next editable unit. (2) **Up Arrow**: move back to previous editable unit. (3) **Plus Sign**: add/toggle units. (4) **Minus Sign**: decrease/toggle units. (5) **Settings**: save current date/time entries and return to main settings screen.
General Preferences screen List of available settings and their current values.	(1) **Down Arrow**: select next setting in list. (2) **Up Arrow**: select previous setting in list. (3) **Plus Sign**: select next option. (4) **Minus Sign**: select previous option. (5) **Settings**: return to main settings screen.
Self Test screen Displays test progress and results. It begins testing as soon as Self Test option is selected.	(1) - (4) No function. (5) **Settings**: go back to main settings screen.
ScanPoint® screen Displays status information about the ScanPoint communication. *Note: Available only when ScanPoint is installed on instrument.*	(1) - (3) No function. (4) **Cancel**: cancels connection to ScanPoint. (5) No function.

DISPLAY SCREENS

HOME SCREEN

The Home screen appears when the AortaScan is first powered on. It serves as a starting point for all of the main functions of the device.

The Home screen displays:

- In the header: Your clinic's name, the battery status indicator and the current date and time.
- On the left side: A list of saved exam results (10 maximum) saved in chronological order. Yellow folders hold saved exams. Grey folders represent empty spaces still available for saving exam results.

Table 6. Battery Power Level

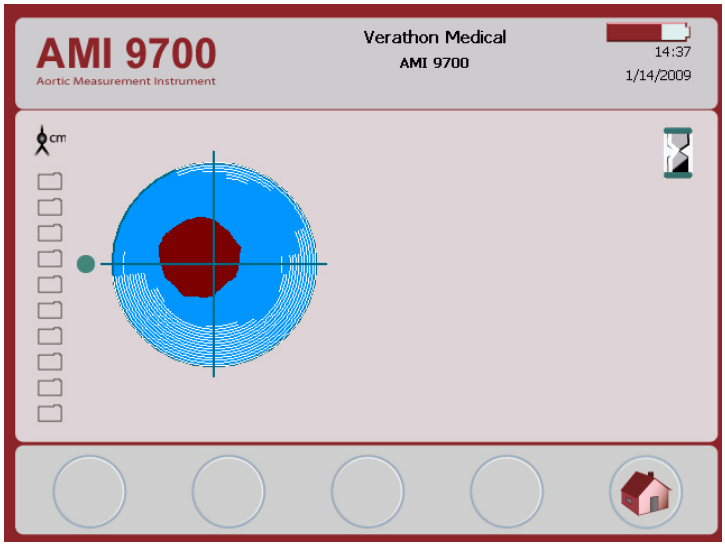
BATTERY ICON	POWER LEVEL
	Indicates a fully charged battery.
	Indicates a battery 50% to 75% charged.
	Indicates a battery 25% to 50% charged.
	Indicates a battery is almost depleted. Can power a few more scans.
	Indicates that a battery should be replaced immediately.

Table 7. Home Screen Button Functions

BUTTON	FUNCTION
	No function.
	View the training video.
	Go to the Settings screen (set the time, date, institution name, and user preferences).
	Review a previously saved exam.
	Initiate communication with the ScanPoint® host computer. Saved and annotated exams will be automatically uploaded to the host computer. *Note: ScanPoint software must be previously installed, and the computer must be connected to the wireless hub. Use of the ScanPoint software is optional.*

SCAN SCREEN

The Scan screen appears after you press the **Scan** button on the probe and displays a progressively updating image of the aorta outline. When the ultrasound measurement is complete, the Results screen opens automatically. Four buttons below the display do not function during the scan.



RESULTS SCREEN

The Results screen appears automatically when an ultrasound scan is complete. The display presents the result of the exam: crosshairs, aorta outline, and the calculated aorta diameter. You may choose to print this result to the onboard printer and/or to record a voice annotation to save the exam. After the annotation is recorded, the Play and Review buttons become active, and the newly recorded exam appears on the main display as an yellow folder icon.

Depending on the Print Report Type selected (see General Preferences Screen), the Results screen will show one of two displays.

Figure 5. B-Mode Report Type

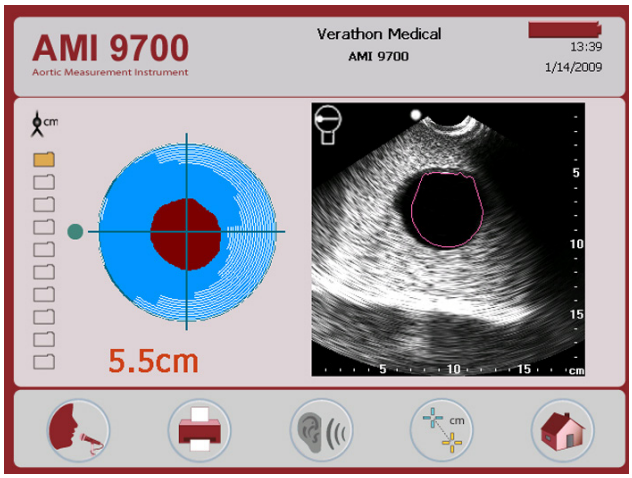


Figure 6. C-Mode Report Type

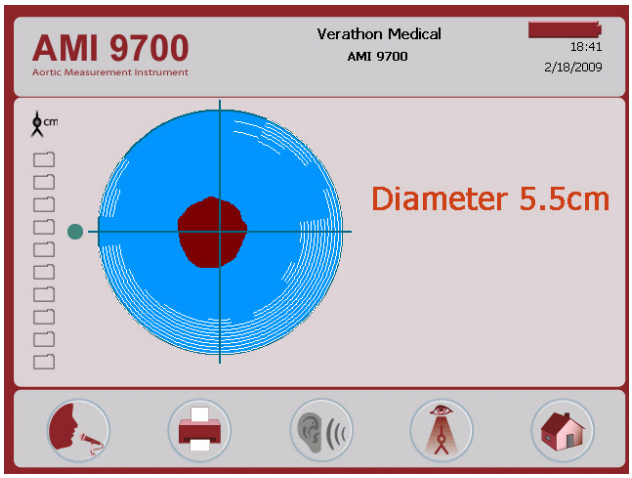


Table 8. Results Screen Button Functions

BUTTON	FUNCTION
	Record a voice annotation (up to 10 seconds long).
	Print exam results to the onboard printer.
	Play a previously recorded voice annotation. If no voice annotations are recorded, this button is disabled.
	B-Mode report type: Manually measure the aortic diameter. C-Mode report type: Review a previously saved exam.
	Return to the Home screen.

TUTORIAL SCREEN

To open the Tutorial screen, press the **Tutorial** button from the Home screen. The Tutorial screen presents a menu of training modules.

Note: When this screen is open, the Scan button on the probe is disabled.

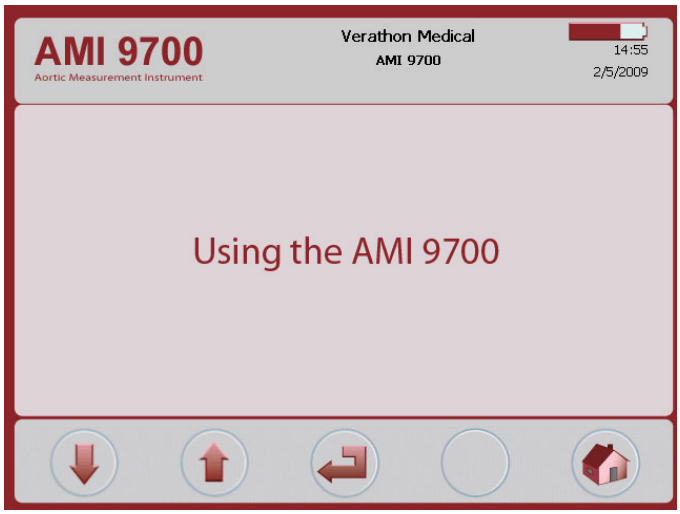


Table 9. Tutorial Screen Button Functions

BUTTON	FUNCTION
	Move down one title or skip back one chapter in the training module.
	Move up one title or skip forward one module.
	Begin module playback. While the module is playing, press to pause. Press again to resume play.
	No function.
	Return to the Home screen.

VIDEO VIEWING SCREEN

The Video Viewing screen is activated by pushing the **Enter** button on the Tutorial screen.

Press the **Play** button to begin the desired tutorial.

Note: When this screen is open, the Scan button on the probe is disabled.

Table 10. Video Viewing Screen Button Functions

BUTTON	FUNCTION
	No function.
	Play or pause video playback.
	Return to the screen showing the list of titles..
	No function.
	Return to the Home screen.

SETTINGS SCREEN

To open the Settings screen, push the **Settings** button on the Home screen. The display presents a list of user-configurable settings: Name, Date & Time, General Preferences, and Self Test.

Note: When this screen is open, the Scan button on the probe is disabled.

Table 11. Settings Screen Button Functions

BUTTON	FUNCTION
	Move down one setting in the list.
	Move up one setting in the list.
	Select the highlighted setting.
	No function.
	Return to the Home screen.

NAME SCREEN

This screen allows you to select the appropriate alpha numeric characters for entering your health care institution's name.

For more information, see Program the Clinic Name on page 37.

Table 12. Name Screen Button Functions

BUTTON	FUNCTION
	Move down in the grid.
	Move right in the grid.
	Add the highlighted character to the name.
	Delete one character from the name.
	Save the current name setting and return to the Settings screen.

DATE & TIME SCREEN

This screen allows you to adjust the date and time.

For more information see Set the Date & Time on page 39.

Note: If the time display is set to show a 24-hour clock, the hour units are 0–23. If the clock is set to show a 12-hour clock, the hour units are 01-12.

Table 13. Date & Time Screen Button Functions

BUTTON	FUNCTION
	Move back one changeable unit.
	Move to the next changeable unit
	Add and/or toggle digits as appropriate. Press and hold the button to move through options more quickly.
	Subtract or toggle digits as appropriate. Press and hold the button to move through options more quickly.
	Save the current date and time settings and return to the Settings screen.

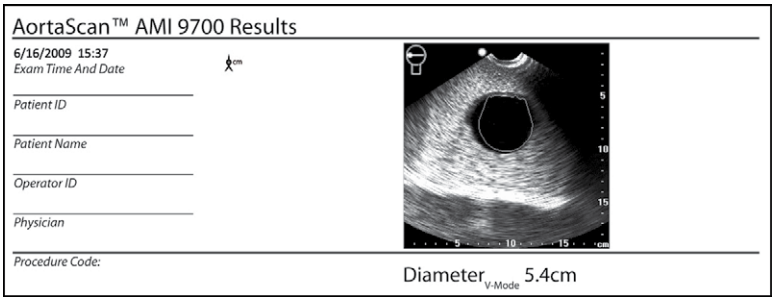
GENERAL PREFERENCES SCREEN

This screen displays a list of available settings and their current values.

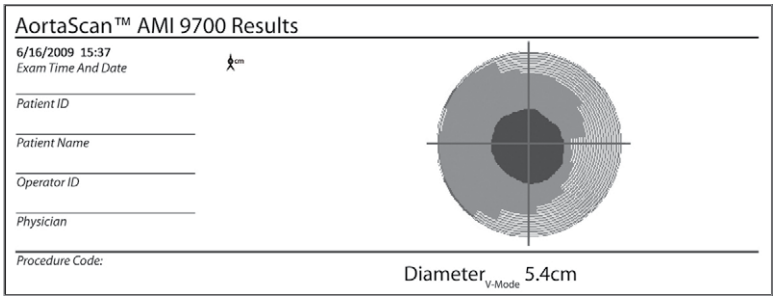
Available settings:

- **Language:** Multiple languages are available. English is the default setting.
- **Date Format:** mm/dd/yyyy; dd.mm.yyyy; yyyy-mm-dd.
- **Time Format:** 12 hour or 24 hour.
- **Calibration Warning:** On (default), Off. When On is selected, a calibration warning will appear in the display header when the device requires calibration.
- **Print Report Type**: Toggle between C-mode images (aorta in crosshairs) and B-mode images (image of aorta and abdominal space below probe).
- **Enable ScanPoint®:** On (default), Off. Select "Off" to disable ScanPoint.

Figure 7. B-Mode and C-Mode Print Reports



B-Mode print report



C-Mode print report

Table 14. General Preferences Screen Button Functions

BUTTON	FUNCTION
	Move down a setting in the list.
	Move up a setting in the list.
	Select the next option. Press and hold to move through options more quickly.
	Select the previous option. Press and hold to move through options more quickly.
	Save the current settings and return to the Setup screen.

SELF TEST SCREEN

When you open the Self Test screen, testing begins automatically. Once testing is complete, data on the screen is printed automatically to the instrument's onboard printer.

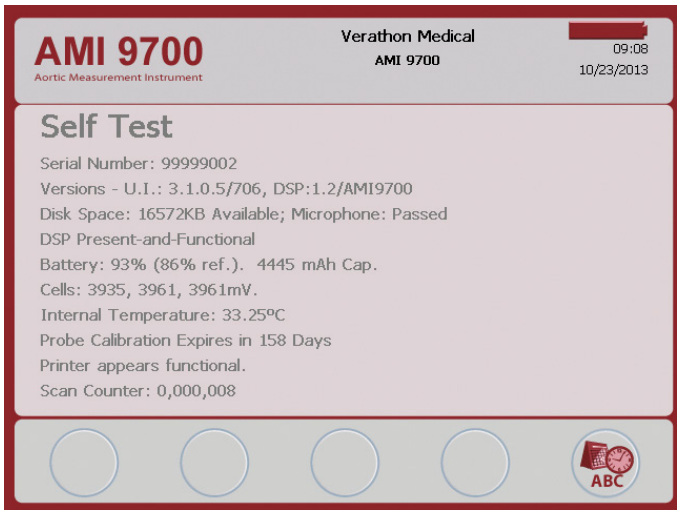


Table 15. Self Test Screen Button Functions

BUTTON	FUNCTION
	No function.
	No function.
	No function.
	No function.
	Return to the Settings screen.

SCAN COUNTER FEATURE ON THE SELF TEST SCREEN

The AortaScan AMI 9700 is equipped with a scan counter feature. It counts all scan button pushes captured by the console. It is designed to enable clinical users or service technicians to determine the number of scans the device has performed over its lifetime. It counts all scans taken with the instrument, including air scans and practice scans. The counter advances automatically after each scan.

Please note that the scan counter feature is available only with software version 3.1.0.0 or higher. Some AortaScan consoles cannot be upgraded to run software version 3.0 or higher. Software updates may be performed by either logging on to ScanPoint®, or by contacting Verathon® Customer Care.

The scan counter may be monitored as a part of a regular device maintenance program. The number of scans appears as a value on the self test screen and the self test printout.

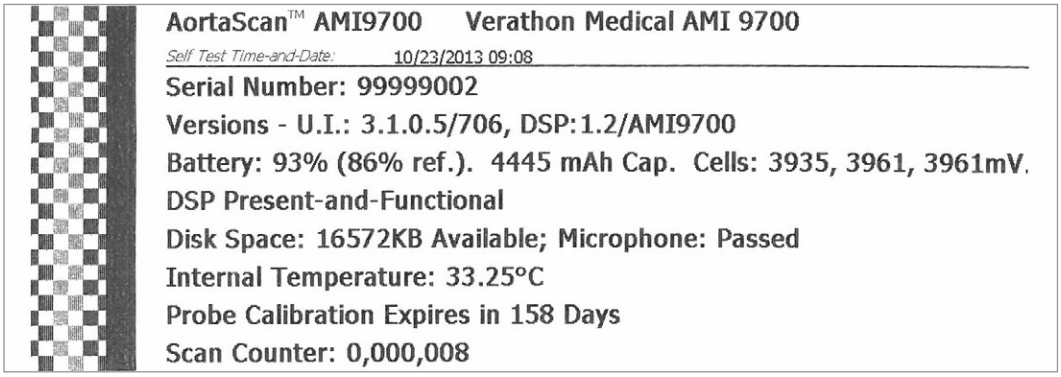
To ensure reliability, a backup copy of the scan count is stored in device memory. If both the scan counter and its backup copy are corrupted, the scan counter will automatically reset to a zero value.

The scan counter feature is designed so that the value cannot be manually reset or modified by the clinical user or service partner.

PRINTING THE SCAN COUNT FROM THE SELF TEST SCREEN

Once the self-test screen is accessed, data on the screen are printed automatically using the instrument's onboard printer.

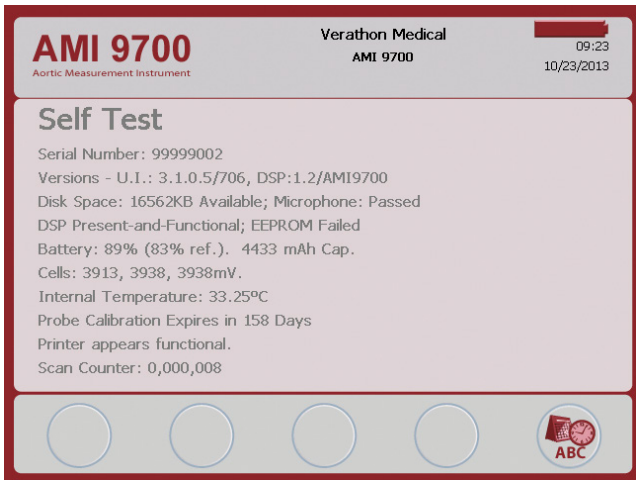
Figure 8. Printout of Self Test Screen

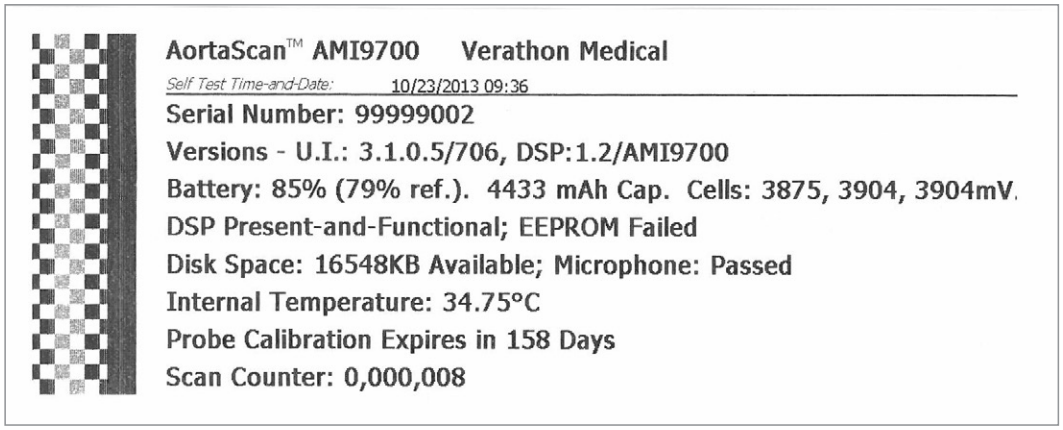


TROUBLESHOOTING

The scan counter feature is designed for redundancy, so the scan value is stored in multiple locations in the instrument's internal memory. If one of the storage locations fails, the text "EEPROM Failed" will be added to the DSP status line. In the event of an EEPROM failure, the counter will continue to work but will not have a backup copy stored in the instrument.

Figure 9. Self Test Screen and Printout when EEPROM Has Failed





SCANPOINT SCREEN

Note: This screen is only available if the optional ScanPoint® software is installed on a PC.

Press the **ScanPoint** button on the Home screen. The ScanPoint screen displays information about the status of the link between the AortaScan instrument and the ScanPoint host computer.

Figure 10. ScanPoint Screen (Searching)

Figure 11. ScanPoint Screen (Connected)

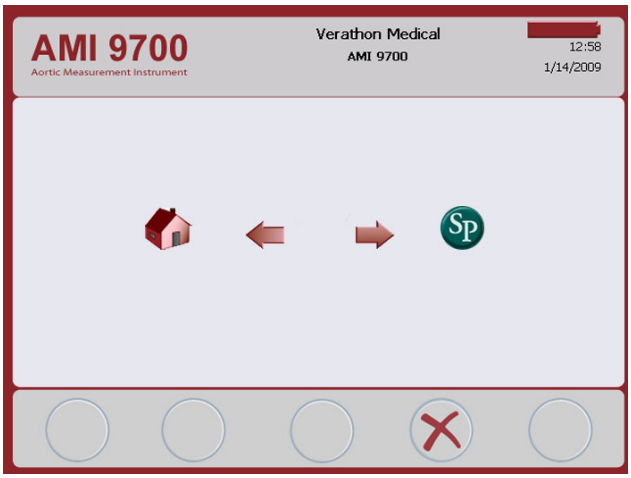


Table 16. ScanPoint Screen Button Functions

BUTTON	FUNCTION
	No function.
	No function.
	No function.
	Cancels the current action and ends communication with ScanPoint®.
	No function.

SLEEP MODE

To conserve battery power, the AortaScan AMI 9700 goes into sleep mode by shutting itself down automatically when not in use.

After four minutes of idle time, a sleep mode alert message displays for 15 seconds. While the message is displayed, press any button to keep the console awake and dismiss the message. After 15 seconds, the console goes to sleep. To wake the instrument from sleep, simply press the Power button.

SETTING UP

To help you get up and running as quickly as possible, the next few pages explain how to:

1. Perform the Initial Inspection
2. Set Up the Battery
3. Attach the Probe to the Console
4. Program the Clinic Name
5. Set the Date & Time
6. Load the Thermal Paper
7. Attach the Instrument to a Medical Cart (Optional)
8. Install ScanPoint with QuickPrint (Optional)
9. Watch the Training Video

PROCEDURE 1. PERFORM THE INITIAL INSPECTION

When you receive the AortaScan AMI 9700 system, Verathon® recommends that an operator familiar with the instrument perform a full visual inspection of the system for any obvious physical damage that may have occurred during shipment.

1. Carefully open the top flaps of the shipping box. Do not insert anything sharp through the top of the box.
2. Remove the contents and verify that you have received the appropriate components for your system.
3. Inspect the components for damage.
4. If any of the components are missing or damaged, notify the carrier and Verathon Customer Care or your local representative.

PROCEDURE 2. SET UP THE BATTERY

WARNING

Risk of explosion, fire, or serious injury. The AortaScan AMI 9700 is powered by a lithium-ion battery. Failure to note the following when handling the battery may result in serious injury:

- Never short-circuit the battery by either accidentally or intentionally bringing the battery terminals into contact with any other conductive object. This could cause serious injury or fire and could also damage the battery and/or the instrument.
- Never expose the battery to abnormal shock, vibration, or pressure. The battery's internal protective covering could fail, causing it to overheat or ignite, resulting in caustic liquid leakage, explosion, or fire.
- Do not disassemble, heat above 60°C (140°F), or incinerate the battery. Keep battery out of reach of children and in original package until ready to use. Dispose of used batteries promptly according to local recycling or waste regulations.
- If the battery is leaking or its case is cracked, put on protective gloves to handle it, and discard it immediately. Always dispose of used batteries in compliance with all applicable laws and regulations. Put insulating tape, such as cellophane tape, on the electrodes during transportation in order to avoid a possible short circuit, fire, or electrical shock.

WARNING

Ensure proper distance from patient. The AMI 9700 battery charger/wireless hub and the computer used to access online ScanPoint® image archives (if used) must be placed outside the patient vicinity (more than 2 m [6 ft] from the patient).

Two lithium-ion batteries are included with the AortaScan AMI 9700. One battery can be recharged in the battery charger/wireless hub while the other is installed in the AortaScan instrument. This ensures there is no instrument downtime. The charger will bring the batteries to a full charge within 6 hours or less. Before using the AortaScan AMI 9700 for the first time, you need to charge both batteries.

The console draws very little power when it is turned off. However, if you do not plan to use the instrument for several weeks, you should remove the battery to prevent it from discharging. When batteries are not in use, they should be stored in the battery charger so they remain fully charged.

CHARGE THE BATTERIES

1. Plug the battery charger/wireless hub unit into a standard wall outlet.
2. Insert the battery into the recess in the battery charger.

   Note: Fully charging the battery may take up to 6 hours. Batteries may be stored in the charger. There is no danger of overcharging the batteries.

3. Check the colored indicator lights on the battery charger to determine battery status:

   Solid green: Battery fully charged.

   Amber: Battery charging.

   The battery status indicator remains in the top right corner of the screen and indicates the charge level of the battery.

Table 17. Battery Power Level

BATTERY ICON	POWER LEVEL
	Indicates a fully charged battery.
	Indicates a battery 50% to 75% charged.
	Indicates a battery 25% to 50% charged.
	Indicates a battery is almost depleted. Can power a few more scans.
	Indicates that a battery should be replaced immediately.

INSERT A BATTERY INTO THE INSTRUMENT

4. To insert the charged battery into the battery well in the console, slide it under the ledge and push down gently until the battery clicks into place.

   Note: The battery is designed to prevent incorrect installation. If the battery does not slide into the battery well easily, remove the battery and try again. Do not force the battery into position.

PROCEDURE 3. ATTACH THE PROBE TO THE CONSOLE

1. Locate the cable port on the back of the console.

2. Align the silver arrow on the probe cable connector to the top of the cable port.

3. Gently push the connector ring into the port, until the cable clicks into place and is secure.

The cable can remain attached to the console in between uses.

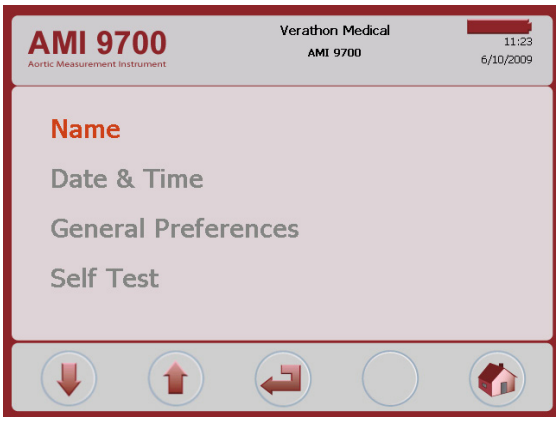
Note: To remove the cable, pull the connector ring back until the cable disconnects. Do not pull on the cable.

PROCEDURE 4. PROGRAM THE CLINIC NAME

You can customize your AortaScan AMI 9700 by entering your facility's name. This information will subsequently be included on the console display and all printouts of exam results.

1. Turn the AortaScan AMI 9700 on by pressing the **Power** button on the front of the console.
2. When the Home screen appears, press the **Settings** button to open the Settings screen.

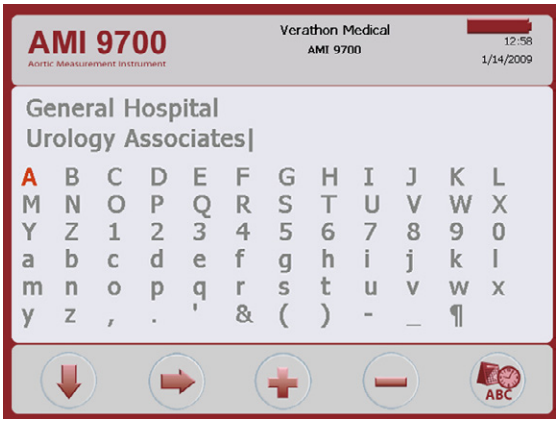
3. On the Settings screen, push either the **Up Arrow** button or **Down Arrow** button until "Name" is highlighted. Press the **Enter** button to open the Name screen.



4. On the Name screen, use the **Right Arrow** button and **Down Arrow** button to move to the desired character. When the desired character is highlighted, press the **Plus** button to add it to your text. Use the **Minus** button to delete characters.

   To add a space between words, select the blank space below the letter x.

   To add a second line of text use the ¶ character

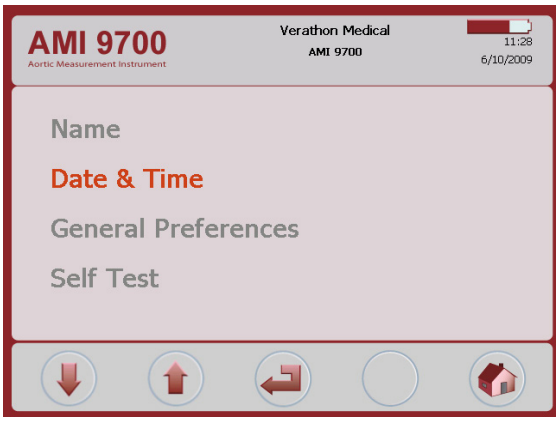


5. When finished, press the **Settings** button to return to the Settings screen. From the Settings screen, press the **Home** button to return to the Home screen. The facility name will now appear in the display header.

   Note for extended-Latin and/or non-Latin characters: Extended Latin characters (tilde, umlaut, accents, circumflex, etc.) and/or non-Latin characters can be entered only by using ScanPoint® with QuickPrint software. To enter a name that uses extended or non-Latin characters, please refer to the instructions in the ScanPoint with QuickPrint User's Manual.

PROCEDURE 5. SET THE DATE & TIME

1. Turn on the device by pressing the **Power** button .
2. From the Home screen, press the **Settings** button to open the Settings screen.
3. On the Settings screen, push either the **Up Arrow** button or **Down Arrow** button buttons until "Date & Time" is highlighted. Press the **Enter** button to open the Date and Time screen.



4. On the Date and Time screen, use the **Up Arrow** button and **Down Arrow** button to move to the desired unit (hours, minutes, month, day, year). When the desired unit is highlighted, press the **Plus** button to increase values and the **Minus** button to decrease values.

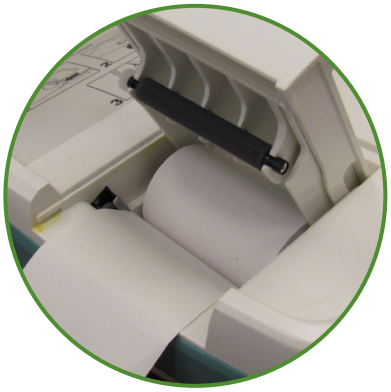
   Note: If the time display is set to show a 24-hour clock, the hour units are 0–23. If the clock is set to show a 12-hour clock, the hour units are 1-12.

5. When the time and date are set correctly, press the **Settings** button to return to the Settings screen. From the Settings screen, push the **Home** button to return to the Home screen.

PROCEDURE 6. LOAD THE THERMAL PAPER

If paper appears to be stuck in the printer, see the procedure Clear a Paper Jam on page 66.

1. Locate the paper compartment door on the base of the console, behind the display.
2. Slide the door to the right, then lift up.
3. If there is an empty paper roll, remove it.
4. In the paper well, insert the end of a new paper roll with the thermal side down.



5. Extend the end of the paper past the side of the unit.
6. Snap the door completely closed, then slide the door back into the console.
7. Tear off any paper extending from the back of the console.

PROCEDURE 7. ATTACH THE INSTRUMENT TO A MEDICAL CART (OPTIONAL)

The AortaScan AMI 9700 is completely portable and can be easily moved and positioned for convenient use. Installing the AMI 9700 on the optional mobile cart will allow you to move the AortaScan along with related accessories to the patient examining area or bedside, as necessary.

Figure 12. Assembled Medical Cart

Figure 13. Medical Cart Assembly

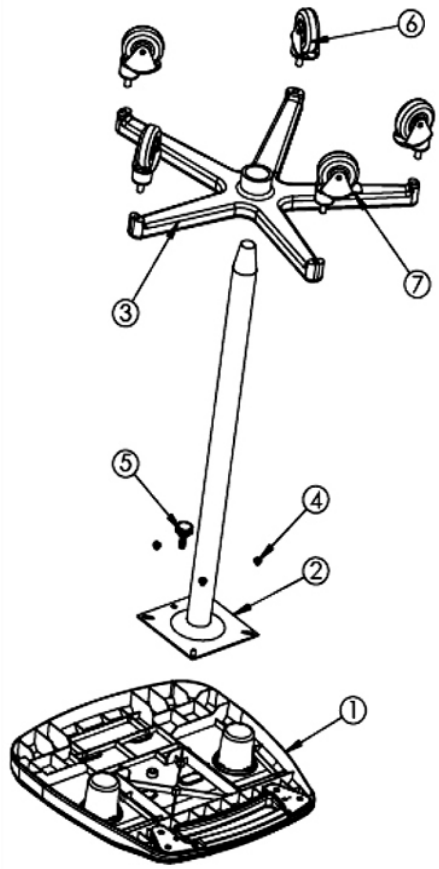


Table 18. Medical Cart Parts List

ITEM	QTY	PART
1	1	Medical tray
2	1	Post
3	1	Medical cart base
4	4	Screw PH W Lock 25-20 x 1/2
5	1	Fluted knob 3/8-16 x 1.00
6	3	Caster, 3 inch
7	2	Caster, 3 inch with brake
—	2	Loctite® 680 retaining compound (not pictured)

ASSEMBLE THE MEDICAL CART

1. Insert the five casters into the medical cart base, positioning the brake casters on opposite ends of the base.
2. Insert the post into the square relief on the underside of the medical tray.
3. Insert the four screws through the bracket on the top of the post into the molded inserts in the medical tray and tighten securely.
4. If you want to permanently attach the post to the wheeled base, refer to Step 6 through Step 11.

   If you want the ability to disassemble the medical cart at a later date, place the tray assembly with the post into the wheeled medical cart base.
5. Place the AortaScan into the foot prints on the medical tray.

   If you want to secure the instrument to the medical cart, refer to Step 13 through Step 15.

PERMANENTLY ATTACH THE POST TO THE WHEELED BASE (OPTIONAL)

6. Place medical cart base on level ground.
7. Open the two tubes of Loctite 680 by snapping off the tips of the tubes.
8. Apply the Loctite 680 all around the tapered portion of the post. Use all of the contents of both tubes. Complete coverage of the tapered portion is not necessary as the Loctite will spread upon insertion into the base.
9. Slide the post into the hole in the base with a twisting motion and press down firmly.
10. Wipe off excess Loctite with paper towel and discard towel as waste.
11. Allow post and base to sit undisturbed for 3 hours.

ATTACH THE ACCESSORY BASKET (OPTIONAL)

A universal accessory basket is available for the medical cart to provide additional storage capacity.

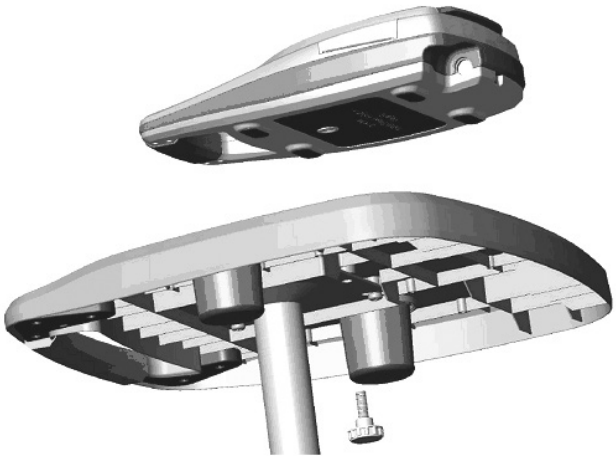
12. Follow the manufacturer's instructions for attaching the accessory basket to the pole.

Figure 14. Universal Accessory Basket

ATTACH THE INSTRUMENT TO THE MEDICAL CART (OPTIONAL)

13. Place the AMI 9700 atop the cart, aligning the rubber pads on the bottom of the device to the corresponding indentations on the tray.
14. On the bottom of the tray, insert the fluted knob into the mounting hole in the center.
15. Screw the fluted knob into the mounting hole until the device is secure on the tray.

Figure 15. Attach the AMI 9700 to the Medical Cart



PROCEDURE 8. INSTALL SCANPOINT WITH QUICKPRINT (OPTIONAL)

The optional ScanPoint® with QuickPrint software is designed to work seamlessly with your AortaScan devices. The AMI 9700 automatically downloads exam data to the ScanPoint host computer via a wireless connection enabled by the battery charger/wireless hub, allowing further viewing, analysis, archiving, and report generation.

To install ScanPoint with QuickPrint software, insert the ScanPoint with QuickPrint install CD into your computer's CD drive and follow the onscreen prompts. Please refer to the separate manual provided with ScanPoint with QuickPrint software for complete installation and operating instructions.

PROCEDURE 9. WATCH THE TRAINING VIDEO

The training video provides an overview of how to perform an ultrasound scan of the aorta using the AortaScan AMI 9700. The video:

- Is approximately 5 minutes long.
- Is available at the Verathon® Web site: http://verathon.com.
- Is available for review anytime on the instrument by pushing the **Tutorial** button from the Home screen.

USING THE DEVICE

WARNING

The aortic diameter measurement function provides images that may be used for diagnosis and screening. If clinically indicated, appropriate patients should be referred for additional diagnostic testing.

WARNING

The AortaScan system is designed to detect the fluid (blood) filled region of the abdominal aorta only. The system cannot detect the presence of a blood clot (thrombus) and therefore may provide a false negative result.

WARNING

The AortaScan system is an ultrasound-based device and is subject to all limitations of this method. If clinically indicated, appropriate patients should be referred for a diagnostic standard (confirmatory) test, regardless of test results.

WARNING

Risk of inaccurate measurements/results. When using the instrument, be aware of the following conditions that can decrease the accuracy of exam results:

- In some cases, the normal operating tolerances of the instrument can cause it to report a falsely normal or abnormal measurement. For more information, see Interpret the Aortic Measurement Results on page 51.
- Visual verification that the aorta position is fully within the scan cone on the displayed images is important.
- A thrombus (blood clot) can complicate aortic measurements. A soft, blood-like thrombus may appear as part of the lumen. However, a calcified thrombus may appear as part of the aorta's wall, resulting in a measurement of lumen diameter that is smaller than the aorta diameter. Accordingly, in patients where thrombus is known or suspected, other imaging methods should be used prior to ruling out an aneurysm.
- Use care when scanning patients who have had abdominal surgery. Scar tissue, surgical incisions, sutures, and staples can affect ultrasound transmission and accuracy.
- Ensure that the patient fasts for 12 hours prior to undergoing an aortic diameter measurement in order to minimize the presence of bowel gas, which may obstruct proper measurement.
- Obesity may affect ultrasound aortic diameter measurements. For more information, see Obesity on page 54.

Accuracy is compromised if the user does not obtain an optimal, repeatable image.

WARNING

Risk of explosion. If you use the AortaScan AMI 9700 in the presence of flammable anesthetics, the hazard of potential explosion exists.

WARNING

Do not use the AortaScan AMI 9700 on:

- A patient who has open skin or wounds in the mid-abdominal area.
- A patient with ascites.
- A pregnant patient.

The AortaScan AMI 9700 provides the capability to measure abdominal aortic diameter noninvasively using 3D ultrasound. AortaScan ultrasound may be preferred as the initial imaging modality for measuring abdominal aortic diameter due to its portability, availability, lack of ionizing radiation, and cost when compared to other alternatives like CT, CTA, MRI, MRA, or standard ultrasound performed by trained sonographers.

The AortaScan AMI 9700 can measure diameters ranging between 3.0 and 12.4 cm with a diameter accuracy of ± (15% + 0.5 cm). For details about the normal variability of scan results, and the effect of that variability on potential rupture risk, refer to Table 19 on page 51.

Note: The AortaScan AMI 9700 is not intended for screening or diagnosis of abdominal aortic aneurysms (AAAs), or for use on acute events such as aortic dissection, ulcer, or rupture.

In B-mode report type, the scan output provides two images: an aiming display on the left and a results display on the right. The AMI 9700 also displays the calculated diameter of the aorta in centimeters (cm) below the aiming display.

Figure 16. B-Mode Report Type

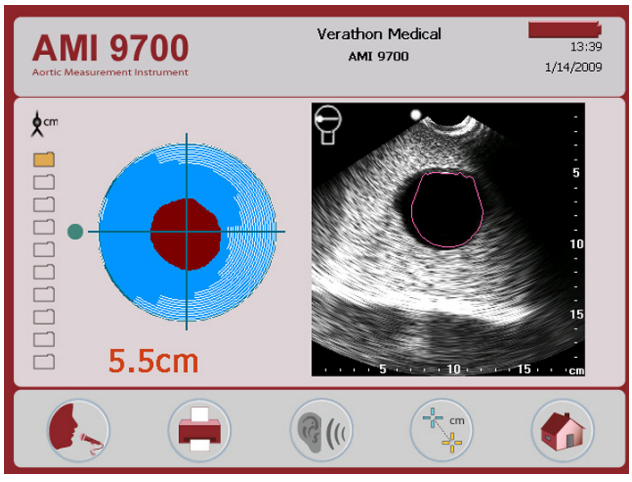
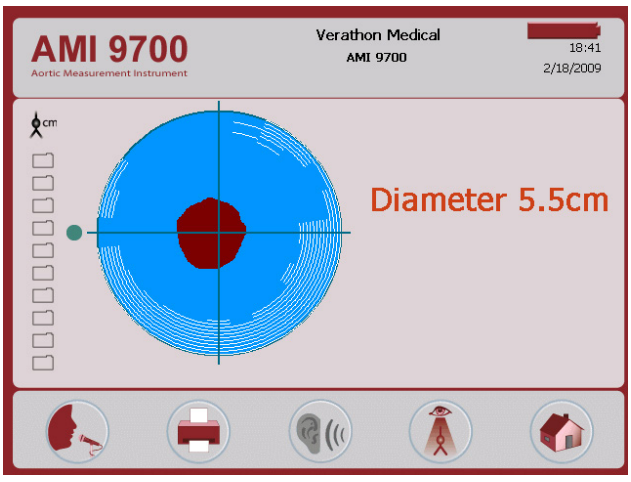


Figure 17. C-Mode Report Type



AIMING DISPLAY

The aiming display illustrates the location of the aorta relative to the ultrasound probe. The center of the two axes represents the center of the probe. The aorta is shown in red. The white lines represent areas of high reflection, most likely caused by bowel gas.

When aiming, the goal is to angle the probe so the aorta in red is not intersecting any white lines (bowel gas) on the aiming display. Arrows will appear, which indicate the direction the probe needs to move in order to produce a better scan.

RESULTS DISPLAY

The Results display provides an image of the cross section of the abdominal space below the probe. Both axes of the image are in centimeters. The abdominal aorta is seen as a dark circular shadow with a red outline amidst the black and white "speckling" of the ultrasound image.

PROCEDURE 1. PREPARE FOR THE EXAM

1. Ensure you are familiar with the parts and functions of the instrument. For more information, see the Introduction chapter on page 8.
2. Check the instrument battery icon to ensure the battery has sufficient power.

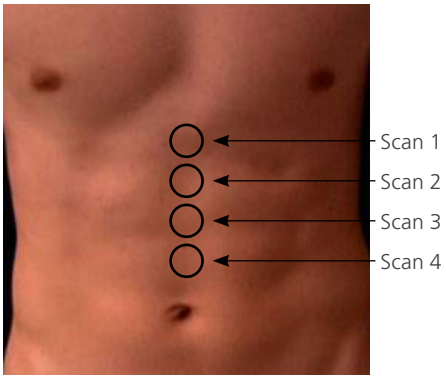
   If the battery icon is ¼ full or less, replace the battery with a freshly charged battery before proceeding. Ensure the instrument is off before you replace the battery. Place the discharged battery in the battery charger to recharge.
3. Ensure that the instrument has been properly cleaned according to the instructions in the chapter Cleaning & Maintenance on page 55.
4. Be aware of the following conditions that may affect ultrasound transmission and the accuracy of the exam:
   - Bowel gas is a common problem for abdominal ultrasound measurement and results in unreadable exams. To avoid bowel gas obstruction of the ultrasound, have patients fast for 12 hours prior to the exam. When aiming, position the probe so that the image of the aorta on the aiming display does not intersect with bowel gas.
   - Previous abdominal surgery. Scar tissue, surgical incisions, sutures, and staples can affect ultrasound transmission and reflection.

   Do not use the AMI 9700 on:
   - Patients with ascites.
   - Patients with open skin or wounds in the mid-abdominal region.
   - Pregnant patients.

PROCEDURE 2. MEASURE ABDOMINAL AORTIC DIAMETER

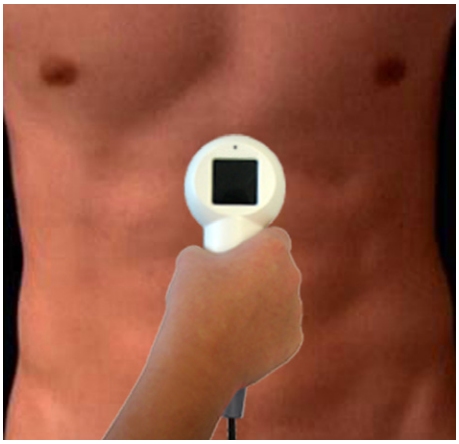
1. Turn on the instrument by pressing the **Power** button .
2. With the patient in the supine position, identify four equally spaced scan locations between the xiphoid process and the umbilicus.

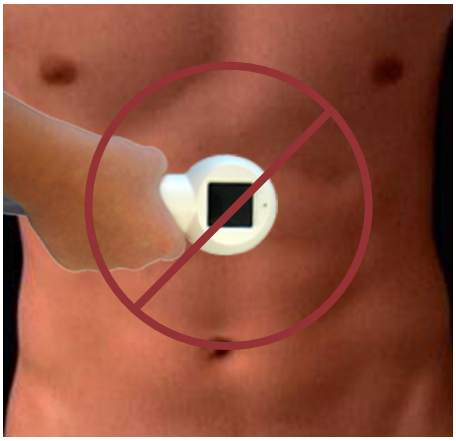
Figure 18. Four Scan Locations for Measuring



3. Place an ample amount of ultrasound gel on the patient's abdomen in the selected scan locations.
4. Standing at the patient's right side, place the probe on the gel at the first position.
5. Hold the probe with the long axis aligned with the midline of the abdomen. Do not hold the probe with the handle pointing to either side of the patient.

Figure 19. Correct and Incorrect Orientation of the Probe





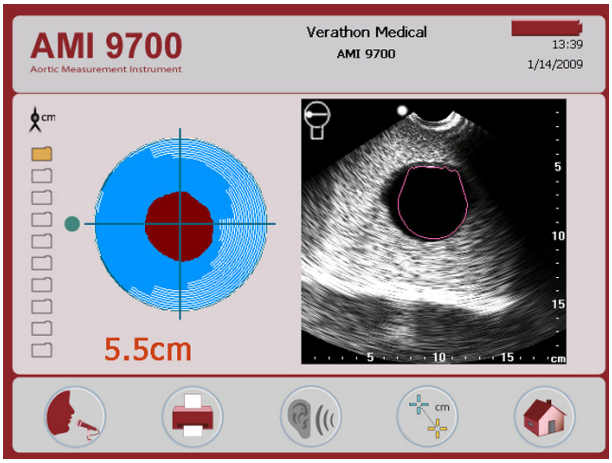
6. Press and release the **Scan** button on the underside of the probe. When you hear the tone, the scan is complete.

   Note: Do not move the probe while the scan is in progress as that will decrease the accuracy of the measurement.

7. Save the exam results by creating a voice annotation. See Save, Review, & Print Exam Results.

8. Perform three more measurements and save and annotate the result of each exam. For more information, see Save, Review, & Print Exam Results on page 50.

Figure 20. Results Screen



9. If you would like to perform another exam, press the **Home** button, and then repeat this procedure.

   If you would like to measure abdominal aortic diameter manually, complete the procedure Measure Aortic Diameter Manually (Optional) on page 49.

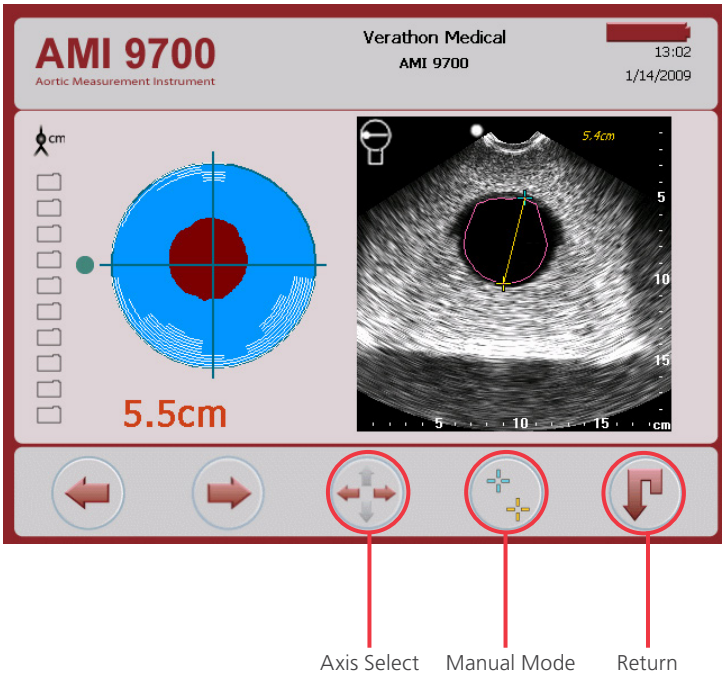
10. Once you have completed the exam, wipe the gel off the patient and probe.

    For ScanPoint® subscribers, logging onto ScanPoint automatically transfers and saves your annotated exams to your ScanPoint host computer.

PROCEDURE 3. MEASURE AORTIC DIAMETER MANUALLY (OPTIONAL)

To measure abdominal aortic diameter manually, you must perform a scan in B-mode. For information about setting the instrument in B-mode, see General Preferences Screen on page 26.

1. After completing the scan, press the **Manual Mode** button . The Manual Measurement Mode screen opens.



2. By using the following button controls, move one cursor to the right edge of the aorta and move the other cursor to the opposite edge of the aorta:
   - Press the **Axis Select** button to swap between the Up and Down arrows or the Left and Right arrows.
   - Use the **Manual Mode** button in order to swap between cursors on the results display.
   - When you are finished moving the cursors, press the **Return** button .

   This records the measurement and exits Manual Measurement Mode. The manual measurement is displayed on the Review screen. Record a voice annotation in order to save the manual measurement result.

PROCEDURE 4. SAVE, REVIEW, & PRINT EXAM RESULTS

IMPORTANT

In order to save the scan, you must record an annotation. If you do not record an annotation, the scan result will be lost, and the next scan you perform will overwrite the non-annotated scan.

The AMI 9700 instrument does not automatically save each scan. It is recommended that you add a voice annotation or write down the diameter calculated for each location.

SAVE/ANNOTATE AN EXAM

1. On the console, press and release the **Record** button.
2. Hold the probe approximately six inches (15 cm) from your mouth, and then record the patient information by speaking clearly into the probe microphone located just above the aiming display on the probe.
3. When you are finished recording, press the **Stop** button. An hourglass icon appears to indicate that the scan is being saved.
4. Press the **Listen** button. The voice annotation plays.

   If you are not satisfied with the recording, press the **Record** button again to record a new annotation.

   Note: You can make a new recording only if the instrument still displays the aortic diameter for that particular scan.

If desired, the instrument is ready to perform another scan.

REVIEW AN EXAM

5. On the console, press the **Review** button.

   On the Review Screen, two types of diameter measurements may be displayed:

   - $\text{Diameter}_{\text{V-MODE}}$ – Diameter measured automatically by AMI 9700
   - $\text{Diameter}_{\text{Manual}}$ – Diameter measured manually in Manual Measurement Mode. See Measure Aortic Diameter Manually (Optional) for further details.

   Note: You must record a voice annotation in order to review the results.

PRINT AN EXAM

6. If you are printing exam results immediately after the measurement is taken, on the Results screen, press the **Print** button.
7. If you are printing saved exam results, press the **Review** button, select the saved exam that you want to print, then press the **Print** button.

PROCEDURE 5. INTERPRET THE AORTIC MEASUREMENT RESULTS

WARNING

The aortic diameter measurement function provides images that may be used for diagnosis and screening. If clinically indicated, appropriate patients should be referred for additional diagnostic testing.

WARNING

The AortaScan system is designed to detect the fluid (blood) filled region of the abdominal aorta only. The system cannot detect the presence of a blood clot (thrombus) and therefore may provide a false negative result.

WARNING

The AortaScan system is an ultrasound-based device and is subject to all limitations of this method. If clinically indicated, appropriate patients should be referred for a diagnostic standard (confirmatory) test, regardless of test results.

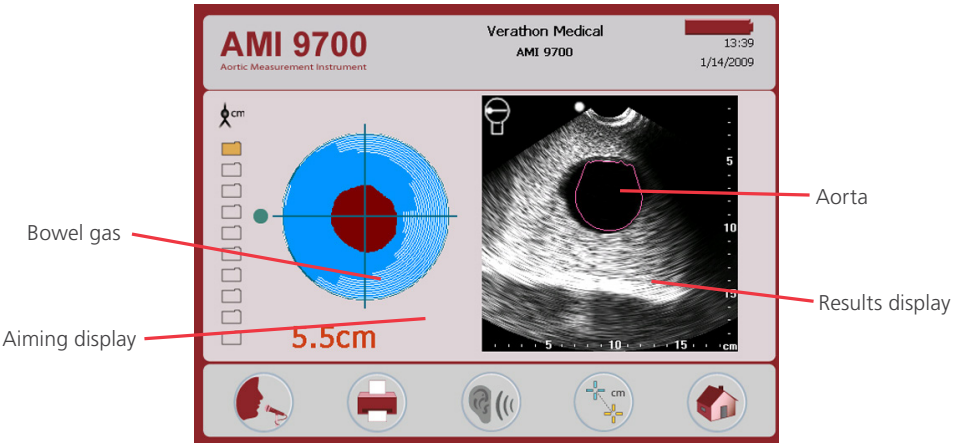
The AortaScan AMI 9700 can measure diameters ranging between 3 and 12.4 cm with a diameter accuracy of ± (15% + 0.5 cm). This error-range data (Table 19) indicates a range of values obtained by the device relative to follow up and clinical significance, specifically with respect to risk vs. diameter.

Table 19. Expected Aortic Measurement Ranges

ACTUAL AORTIC DIAMETER												
	3.0 cm		3.5 cm		4.0 cm		4.1 cm		5.0 cm		5.3 cm	
Average estimated risk of rupture for actual aortic diameter	0%		0%		0%		1%		11%		11%	
Aortic diameter as reported by the device based on allowable tolerances												
	Min	Max	Min	Max	Min	Max	Min	Max	Min	Max	Min	Max
± 15%	2.55	3.45	2.98	4.03	3.40	4.60	3.49	4.72	4.25	5.75	4.51	6.10
With additional ±0.5 cm	2.05	3.95	2.48	4.53	2.90	5.10	2.99	5.22	3.75	6.25	4.01	6.60
Average estimated risk of rupture for reported aortic diameter	0%	0%	0%	1%	0%	1%	0%	11%	0%	26%	0.5–5.0%	26%

An unobstructed scan has been achieved when the probe displays eight solid green arrows.

When the scan is complete, the AortaScan AMI 9700 shows the aortic diameter and two displays on the console screen.



The aiming display on the left side of the screen shows the location of the aorta relative to the probe, as viewed looking from the probe into the body. The aorta is shown in red and bowel gas is shown as white lines. The green dot on the left side is the reference mark correlating the aiming display with the results display on the right side of the screen.

The results display is a cross-section of the abdomen below the probe. The abdominal aorta is shown as a dark circular shadow with a red outline. The white dot on the image is a reference mark correlating the results display with the aiming display.

MEASURING AORTIC DIAMETERS < 3 CM

The AortaScan AMI 9700 can detect aortas with diameters between 3 cm and 12.4 cm. Diameters less than 3 cm occur in patients who have normal-sized aortas.

The round shadow at 6 cm depth in the results display is the patient's abdominal aorta. Patients with aortas less than 3 cm in diameter will show no red outline around the aorta in the results display, as the diameter cannot be measured automatically. However, because of the potential variability between actual and measured diameters, the absence of a red outline around the aorta cannot be relied upon to identify an abdominal aorta less than 3 cm in diameter. The diameter can also be estimated using Manual Measurement Mode.

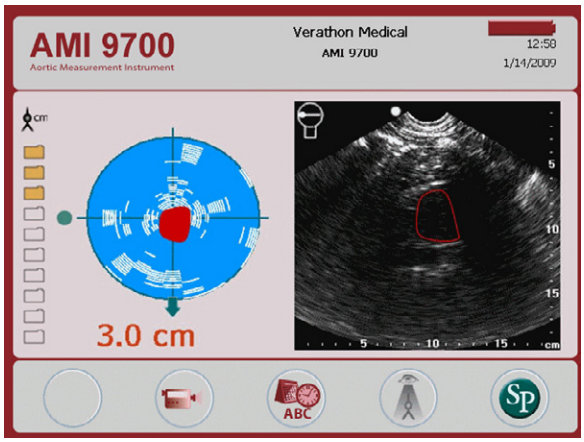
The "speckled" look to the Results display indicates the ultrasound signal was not blocked by bowel gas. The clearly visible aorta and the lack of any arrows telling the user to re-aim the probe mean the user can feel confident that the lack of diameter information is due to a small aorta and not due to the presence of bowel gas. In this case, the aortic diameter measurement is valid.

PARTIAL GAS OBSTRUCTION

In some cases, gas or air bubbles may be present but do not block the aorta entirely. In this case, diameter measurements are still calculated, but they are not typical.

A green arrow on the console and a solid green arrow on the probe indicate the abdominal aorta can be detected, but the presence of bowel gas prevents a proper measurement.

Figure 21. Partial Gas Obstruction



Moving the probe 1/2 to 1 inch (1 to 3 cm) in the direction of the arrow has a high probability of obtaining a successful scan.

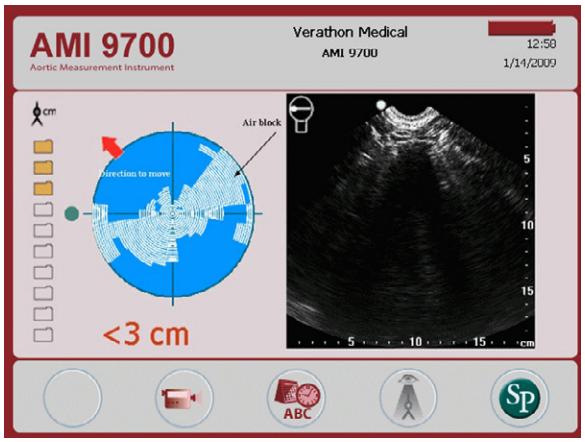
In this case, the probe should be repositioned and the patient rescanned. Gently but firmly work the probe into the tissues of the abdomen with a side-to-side rocking motion to try and displace any bowel gas obscuring the aorta. Do not move the probe while the scan is in progress as that will decrease the accuracy of the measurement.

SUBSTANTIAL GAS OBSTRUCTION

A substantial amount of gas in the abdomen can block ultrasound from reaching the aorta and results in an unreadable or inappropriate scan.

A red arrow on the console and a flashing green arrow on the probe indicate bowel gas has substantially obscured the aorta. No diameter measurement can be calculated and the results display shows a diameter of < 3 cm, meaning the aorta was not detected.

Figure 22. Substantial Gas Obstruction



Although moving the probe 1/2 to 1 inch (1 to 3 cm) in the direction of the arrow has a low probability of providing a successful scan, an additional scan should be attempted. In this case, the probe should be repositioned and the patient rescanned. Gently but firmly work the probe into the tissues of the abdomen with a side-to-side rocking motion to try and displace any bowel gas obscuring the aorta. Do not move the probe while the scan is in progress as that will decrease the accuracy of the measurement.

If rescanning is not successful, the exam should be postponed and rescheduled. Have the patient fast for 12 hours prior to the exam.

OBESITY

Attenuation of the ultrasound signal by excess abdominal fat can result in a poor ultrasound image, which affects the quality of the diameter measurement.

With obese patients, try pressing the probe firmly into the abdomen to reduce the distance to the aorta as much as possible, while attempting to minimize patient discomfort.

In rare cases, it is possible for a patient's abdomen to be too thick for the ultrasound to reach the aorta. If a patient has an extra-thick abdomen where the distance from the probe face to the aorta is greater than 18 cm (7 in), the AortaScan AMI 9700 will not detect the aorta appropriately. In these cases, alternative imaging methods should be used.

CLEANING & MAINTENANCE

Routine cleaning and maintenance will help ensure safe and effective operation of the AortaScan AMI 9700. For more information, please contact your authorized AortaScan Service Center, your local AortaScan distributor, or Verathon® Customer Care.

CLEANING & DISINFECTING

Clean and disinfect the instrument before use and between patient exams.

WARNING

This product may only be cleaned and disinfected by using the approved processes provided in this manual. Cleaning and disinfection methods listed are recommended by Verathon based on compatibility with component materials.

WARNING

Availability of cleaning and disinfection products varies by country, and Verathon is unable to test products in every market. For more information, please contact Verathon Customer Care at 1.800.331.2313 or your local representative. For additional contact information, visit verathon.com/contact-us.

WARNING

Ensure that you follow the manufacturer's instructions for handling and disposing of the cleaning and disinfection solutions provided in this manual.

PROCEDURE 1. CLEAN THE INSTRUMENT

WARNING

Cleaning is critical to ensuring the component is ready for disinfection. Failure to properly clean the device could result in a contaminated instrument after completing the disinfection procedure.

Cleaning is the removal of all visible soil or contaminants from the exterior surfaces of the device. The device must be cleaned after every use, and cleaning is an essential step before disinfection.

1. Wipe the ultrasound gel completely off the probe.
2. Use a moistened, soft cloth to remove particulate matter or body fluids that remain on the instrument.
3. Do not re-use cloths or wipes.
4. Allow the device to air dry, or towel dry with a clean dry cloth. Next, you must disinfect the instrument.

PROCEDURE 2. DISINFECT THE INSTRUMENT

IMPORTANT

Failure to heed the following may cause device damage not covered by the warranty:

- Do not immerse the instrument in the disinfectant solution.
- Do not subject any part of the instrument to steam, ethylene oxide, radiation, or similar methods of sterilization or autoclaving.
- Do not use CidexPlus® to disinfect the instrument. CidexPlus will damage the plastic enclosure.

Disinfectants and cleaning methods listed are based on compatibility with product materials, not biological effectiveness. Refer to the instructions from the manufacturer of the disinfectant for guidance on biological effectiveness of the disinfectant.

The following liquid disinfectants and wipes are compatible with the materials used in the instrument:

- A-456® II Disinfectant
- Accel® TB Wipes
- Cavicide®
- CaviWipes®
- Chloro-Sol Spray®
- Clorox® Germicidal Wipes
- Sani-Cloth® Bleach Wipes
- Sani-Cloth® Germicidal Wipes
- Sani-Cloth® Plus Germicidal Wipes
- Sporicidin® Disinfecting Towelettes
- T-Spray II®

The level of disinfection required for a device is based on the type of tissue it contacts during use. Based on the intended use of the AortaScan AMI 9700, low-level disinfection is the minimum level required.

1. Ensure the instrument has been properly cleaned according to the procedure Clean the Instrument on page 55.
2. Ensure the disinfectant has not expired.
3. If using a liquid disinfectant, prepare the disinfection solution according to the manufacturer's label instructions, ensuring that you are using the proper concentration.
4. Apply the solution to a soft cloth or wipe.

   Note: Do not spray or apply liquid disinfectants directly to the surface of the device, and do not soak the device in liquids.
5. Wipe the surfaces of the device and allow the surface to remain wet for the required contact duration. Follow the manufacturer's instructions for the appropriate disinfection level contact duration.
6. Do not re-use cloths or wipes.
7. If rinsing or removal of the disinfectant solution from the device is required by the disinfectant manufacturer's instructions, wipe with a clean soft cloth dampened in sterile water. Verathon® recommends wiping the device three separate times to remove all residual disinfectant.
8. Allow the device to air dry, or towel dry the device with a clean, dry cloth.

REGULAR INSPECTIONS

Verathon® recommends that the AortaScan AMI 9700 be certified by an authorized Service Center once a year. Certification service includes comprehensive inspection and testing of the instrument to ensure proper performance in clinical use. For more information, please contact your authorized Verathon Service Center, your local Verathon distributor, or Verathon Customer Care.

Note: ScanPoint® Online customers can maintain device certification via the Internet by accessing their ScanPoint account. For more information about using ScanPoint Online, please refer to the ScanPoint with QuickPrint user's manual.

WEEKLY INSPECTIONS

Once a week, you should inspect the probe and cable for physical faults or cracks. Cracks that allow the ingress of fluid may affect the performance of the instrument. Any apparent cracks or faults in the console, probe, or the cable that links the console and the probe, must be referred to your authorized AortaScan Service Center, your local Verathon distributor, your local Verathon representative, or Verathon Customer Care.

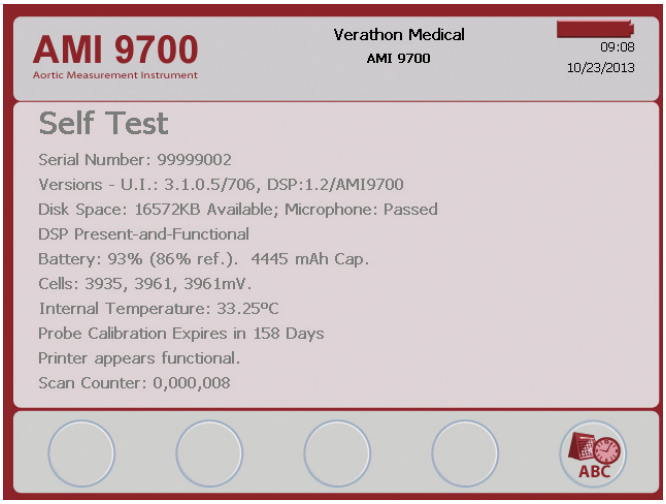
MAINTENANCE

PROCEDURE 1. RUN A SELF TEST

The AMI 9700 can perform a number of self-diagnostic tests. To access the Self Test utility:

1. From the Home screen, press the **Settings** button.
2. When the Settings screen opens, press the **Up Arrow** button or **Down Arrow** button buttons until **Self Test** is highlighted in red, then press the **Enter** button. The Self Test screen opens and testing begins automatically. The display provides status and results, and when the test in complete, the printer prints the results.

   Note: Make sure the printer is loaded with paper. See Load the Thermal Paper.

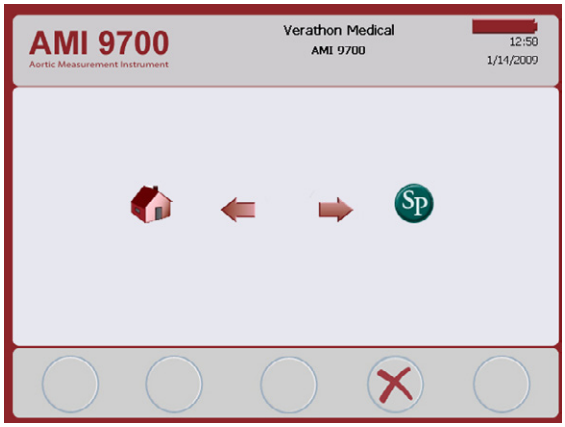


3. If the screen indicates any failed tests or abnormal results, contact your authorized AortaScan representative, or contact the Verathon Customer Care Department.
4. When the test is complete, press the **Settings** button to return to the Settings screen, then press the **Home** button to return to the Home screen.

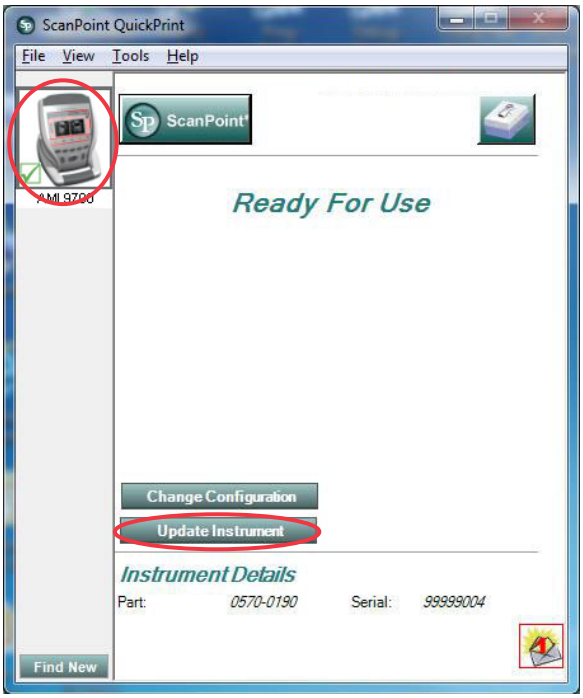
PROCEDURE 2. UPDATE THE SOFTWARE

1. On the instrument, on the Home screen, press the **ScanPoint** button .
2. On the computer, double-click the ScanPoint with QuickPrint icon. ScanPoint® opens.

3. On the computer, in the ScanPoint QuickPrint window, click **Find New**. QuickPrint establishes a connection with the instrument, and an icon for the device appears in the left pane.



4. Select the 9000 Series device, verify that the serial number matches the device you are updating, and then click the **Update Instrument** button.



5. If any updates are available, the device downloads and installs them. The console displays a progress bar and automatically restarts when the installation is complete.

   If no updates are available, nothing happens.

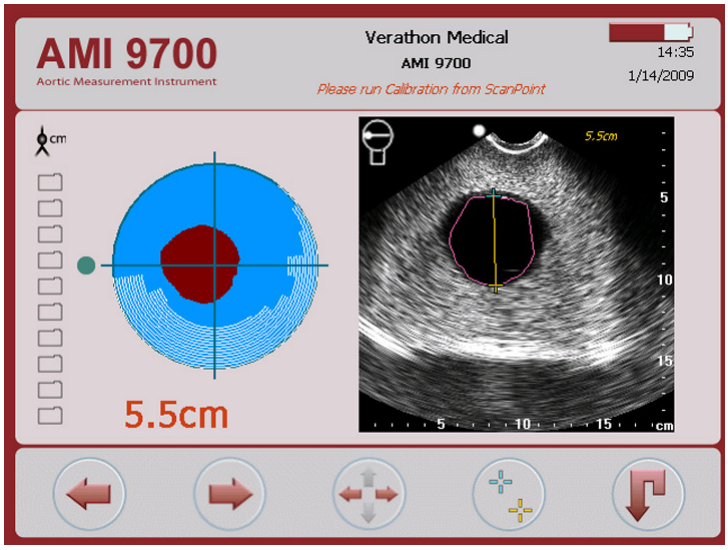
6. If you would like to view the current software version and verify that the newest software is installed, complete the procedure Run a Self Test. The results screen displays the software version.

PROCEDURE 3. CALIBRATE THE PROBE USING THE SCANPOINT SYSTEM

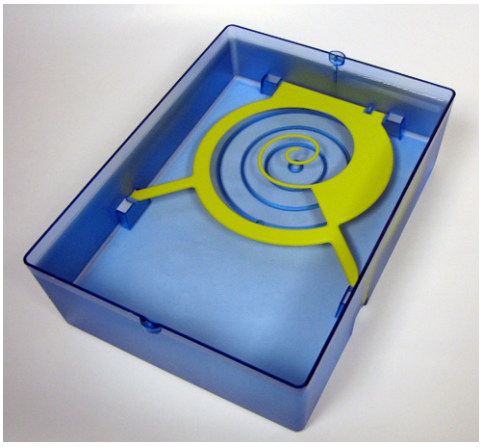
If you do not have ScanPoint® with QuickPrint software, you must send your instrument to an authorized Verathon® service center for calibration. Contact Verathon Customer Care for more information.

At minimum, the AMI 9700 must be calibrated every 12 months in order to ensure appropriate results. Calibrating ensures proper alignment of the instrument's internal coordinate system. If calibration is not performed by the prescribed date, the instrument can still be used to take scans but measurements may be compromised. When calibration is required, a warning appears in the display header.

Figure 23. Calibration Warning

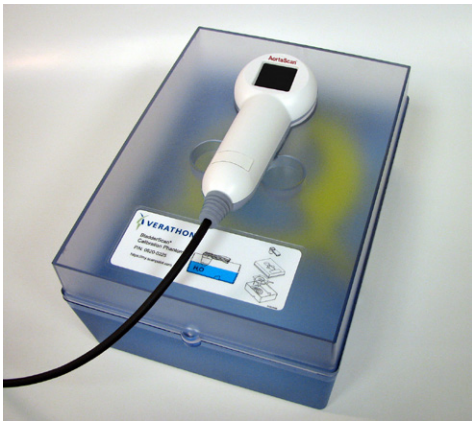


1. Within 10 feet of the Battery Charger/Wireless Hub, place the calibration tank on a flat, nonreflective surface, and then remove the lid.
2. Pour clean, room-temperature water into the container, filling to the indicator mark. Ensure that there is a minimal amount of bubbles in the water.
3. Using the notches to position the spiral-shaped target correctly, place the target in the container.



4. Replace the lid onto the calibration container.

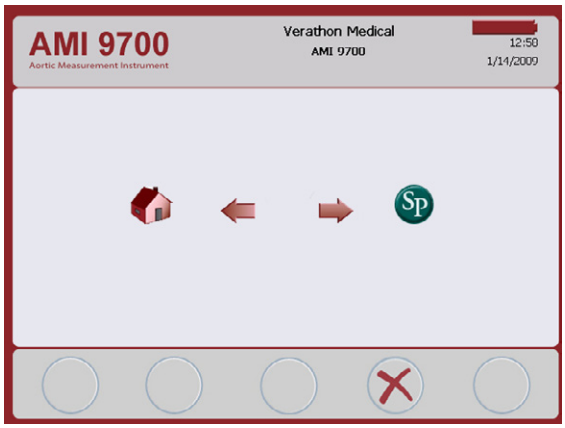
5. Place the probe into the cutout in the lid. Ensure that the tip of the probe is submerged in the water.



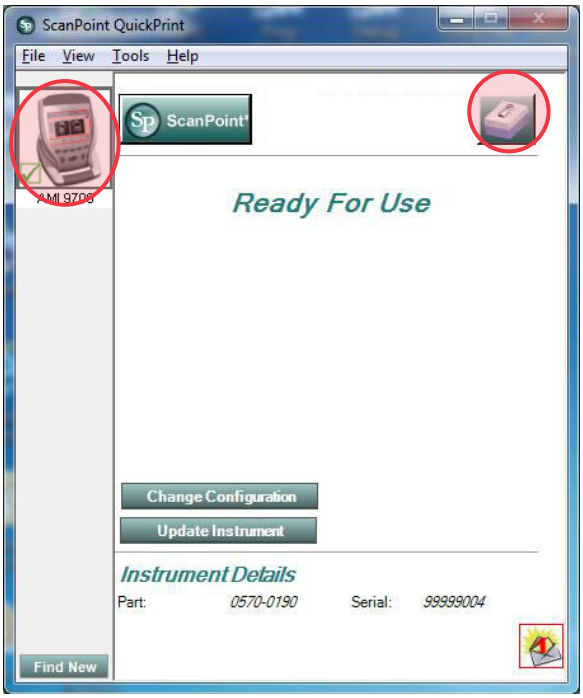
6. On the computer, double-click the ScanPoint with QuickPrint icon. ScanPoint® opens.

7. On the console, on the Home screen, press the **ScanPoint** button  .

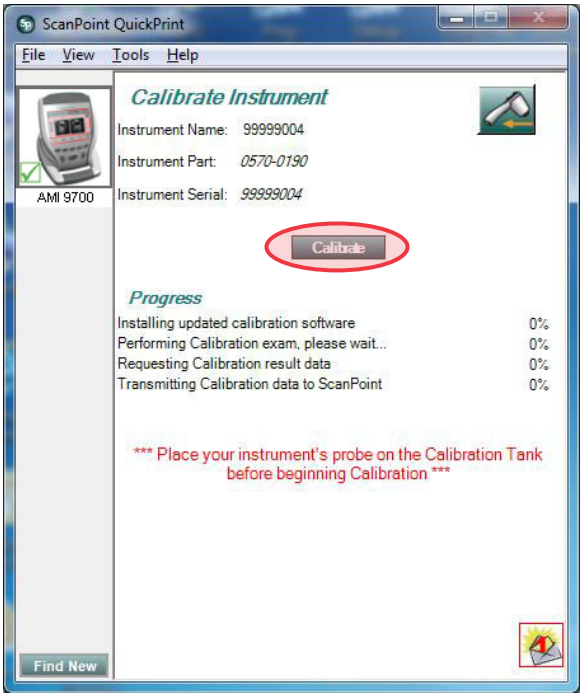
8. On the computer, in the ScanPoint QuickPrint window, click **Find New**. QuickPrint establishes a connection with the instrument, and an icon for the device appears in the left pane. On the console, two arrows appear, confirming that the console is connected to ScanPoint.



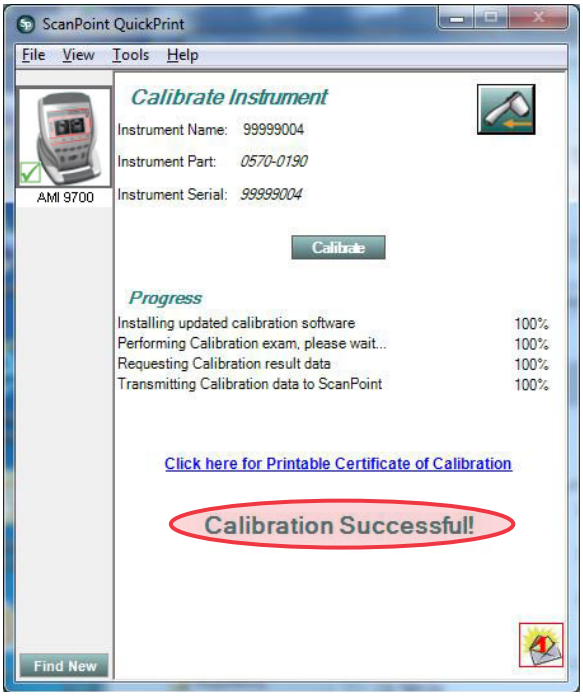
9. Select the 9000 Series device, verify that the serial number matches the device you are calibrating, and then click the calibration tank icon.



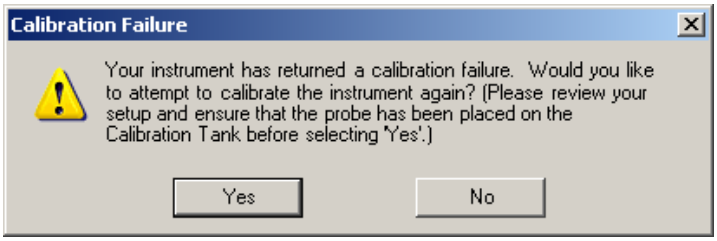
10. Click the **Calibrate** button. ScanPoint® begins to scan and analyze the data in order to ensure that it meets the calibration parameters. If necessary, the instrument automatically rescans the phantom.



11. If calibration is successful, a "Calibration Successful" message is displayed on the computer.



If calibration fails, a Calibration Failure message appears. Ensure that the calibration chamber has sufficient water and that the probe is seated properly in the calibration lid, and then on the Calibration Failure message, click **Yes**. ScanPoint® restarts the calibration.



12. On the console, click the **Exit** button . This terminates the calibration procedure and ends communication with ScanPoint QuickPrint.

13. Remove the probe from the calibration lid, and then dry it with a clean, soft cloth.

DEVICE DISPOSAL

The AortaScan AMI 9700 and related devices may contain mineral oils, batteries, and other environmentally hazardous materials. When the AortaScan AMI 9700 has reached the end of its useful service life, return the device, battery charger/wireless hub, and related accessories to a Verathon® Service Center for proper disposal. Alternatively, follow your local protocols for hazardous waste disposal.

TROUBLESHOOTING

HELP RESOURCES

Verathon® provides several customer service resources, described in the table below.

RESOURCE	DESCRIPTION
In-service CD or USB	The CD or USB flash drive included with your system that provides instructions for using the instrument.
Video tutorial	The video tutorial explains how to take aortic diameter measurements. The tutorial is installed on the instrument.
Phone support	Please refer to the list of Customer Care resources available at verathon.com/contact-us

DEVICE REPAIR

The AortaScan AMI 9700 console, probe, and battery charger/wireless hub are completely sealed. There are no user-serviceable components. Verathon does not make available any type of circuit diagrams, component parts lists, descriptions, or other information that would be required for repairing the device and related accessories.

Premium Warranty customers have access to a loaner unit and free shipping options that vary according to the service plan.

If you have any questions, contact your local Verathon representative or Verathon Customer Care.

TROUBLESHOOTING PROCEDURES

PROCEDURE 1. TROUBLESHOOT SCANPOINT CONNECTION

Complete this procedure if the console cannot connect to ScanPoint®.

1. In ScanPoint, retry the connection by clicking the **Find New** button. Repeat this step up to 3 times.

   If the console does not connect, continue to the next step.

2. Turn the console off, turn the console on, and then press the **ScanPoint** button. On the PC, in ScanPoint, click **Find New**.

   If the console does not connect, continue to the next step.

3. On the PC, click **Find New**. While the device is attempting to connect to ScanPoint, remove the battery.

4. Reinsert the battery, allow the device to power on, and then press the **ScanPoint** button.

5. On the PC, click **Find New**.

   If the console does not connect, contact Verathon® Customer Care.

PROCEDURE 2. TROUBLESHOOT POWER ISSUES

If the instrument does not turn on, this is usually due to a dead or discharged battery and can be remedied by replacing the dead battery with a charged battery.

When the battery charge is too low to allow normal operation (but not too low to permit operation of the internal circuitry) the device displays the following message:

Battery charge level is too low for instrument operation. Recharge before next use.

In this case, the battery must be recharged or replaced with a charged one.

You may find that you need to exchange the battery more often over time due to normal loss of battery capacity. For this reason, Verathon® recommends replacing the existing batteries with new batteries every two years.

If the instrument has stopped responding even with a new battery, perform a full reset by removing and reinserting the battery. If the instrument still does not respond, contact Verathon Customer Care.

PROCEDURE 3. INSTRUMENT TOO HOT

The AMI 9700 displays the message "Too hot" if the print head overheats. In this case, turn off the AMI 9700 immediately. This condition may be the result of a paper jam.

PROCEDURE 4. CLEAR A PAPER JAM

Complete this procedure if the paper will not advance through the printer.

1. Open the printer door on the back of the console and clear the paper jam.
2. Ensure that the thermal paper is loaded correctly according to the instructions in the procedure Load the Thermal Paper on page 40.

WARRANTY

Verathon® warrants the AortaScan AMI 9700 against defects in material and workmanship as long as it is covered by the Premium Warranty.

Verathon's policy is to honor product warranties and to perform services only on products purchased from an authorized Verathon entity. If you purchase a Verathon product or system components from unauthorized entities or if the original factory serial number has been removed, defaced, altered, or if the product is past its expiration date, your Verathon warranty will be invalidated. Purchasing Verathon products from unauthorized entities could result in receipt of products or system components that are counterfeit, used, expired, defective, or not intended for use in your region.

Pursuant to this warranty, a service center authorized by Verathon will repair or replace units that prove to be defective during the warranty period.

This warranty does not apply if the unit was misused or modified by anyone other than an authorized service center.

The unit must be used in accordance with the instructions contained in this manual. Consumable items are not covered in this warranty and should be used in conformance with Verathon product specifications, as provided in the Product Specifications chapter.

For further details, consult your Premium Warranty. Warranty conditions may differ in some countries outside the United States. Contact your local distributor for warranty terms.

DISCLAIMER OF ADDITIONAL WARRANTIES

There are no understandings, agreements, representations of warranties expressed or implied (including warranties of merchantability or fitness for a particular purpose) other than those set forth in the preceding Warranty section. The contents of this manual do not constitute a warranty.

Some states disallow certain limitations on applied warranties. The purchaser, user, and patient should consult state law if there is a question regarding this disclaimer. This information, descriptions, recommendations, and safety notations in this manual are based upon Verathon experience and judgment with the AortaScan AMI 9700 as of December 2013. The contents of this manual should not be considered to be all-inclusive, or to cover all contingencies.

The physician who directs the use of the AortaScan AMI 9700 at the institution where it is in use is responsible for keeping current with clinical research in aortic diameter measurements.

Please direct any questions or problems concerning aortic diameter measurement, using the instrument, or the interpretation of data to the responsible physician.

PRODUCT SPECIFICATIONS

COMPONENT SPECIFICATIONS

CONSOLE & PROBE SPECIFICATIONS

Table 20. General Specifications

ITEM	SPECIFICATION
Input	Lithium-ion battery.
Output	No load to full load at rated voltage. Refer to unit label.
Insulation	The power supply is Class I with basic insulation to each terminal.
Transient overvoltage	Category II
Weight	5.2 lb (2.36 kg) (with battery)
Display	13.36 cm W x 10.13 cm H (5.26 in W x 3.99 in H) (640 x 480 pixels, 120 dpi)
Integrated printer	Thermal printer

Table 21. Ultrasound Acoustic Output Parameters

Values in this table are the maximum readings obtained from three test results.

ACOUSTIC OUTPUT			MI	$I_{SPTA.3}$ (mW/cm²)	$I_{SPPA.3}$ (W/cm²)
Global Maximum Value			0.519*	0.632	9.35
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	0.684		
	W_o	(mW)		1.55	1.44
	f_c	(MHz)	1.74	1.74, 2.63†	1.74
	z_{sp}	(cm)	1.90		1.90
	Beam dimensions	x_{-6} (cm)			0.321
		y_{-6} (cm)			0.334
	PD	(µsec)	2.93		2.93
	PRF	(Hz)	400		400
	EDS	Az. (cm)		7.40, 7.38†	
		Ele. (cm)		7.40, 7.38†	
TIS/TIB/TIC range			0.0-1.0*		

* *Both MI and TI values are below 1.0.*

† *Each scan point along the scan line consists of two transmit pulses. The first pulse is 1 cycle at 2.95 MHz and the second pulse is 5 cycles at 1.74 MHz. Data for each pulse is provided and separated by a comma.*

Table 22. Accuracy Specifications

SPECIFICATION	DESCRIPTION
Aorta diameter range	3–12.4 cm
Diameter accuracy	± (15% + 0.5 cm) on a Verathon® tissue-equivalent phantom

The accuracy specifications assume the instrument is being used according to the instructions provided by Verathon while scanning a tissue-equivalent phantom.

Table 23. Operating & Storage Conditions

SPECIFICATION	DESCRIPTION
Operating Conditions	
Use	Indoor
Ambient temperature range	10–40°C (50–104°F)
Atmospheric pressure range	700 hPa–1060 hPa
Relative humidity	30–75% non-condensing
Water resistance	Rated at IPX1 (indicates DRIP-PROOF, a higher than ORDINARY level of protection from drips, leaks, and spills)
Storage Conditions	
Storage	Indoor
Ambient temperature range	-20–60°C (-4–140°F)
Atmospheric pressure range	500 hPa–1060 hPa
Relative humidity	20–95% non-condensing

BATTERY SPECIFICATIONS

The AortaScan AMI 9700 is provided with two lithium-ion batteries. A battery icon on the instrument display is always present, indicating how much power remains and when the battery needs to be changed. You can change the battery whenever necessary.

Removing a discharged battery and replacing it with a fresh battery should not erase any saved exams or user settings. In the event any user settings change, reset them using the instructions in the Setting Up chapter.

Use only the battery charger provided with the AMI 9700. Any other battery charger may damage the battery.

Table 24. Battery Specifications

CONDITION	DESCRIPTION
Battery type	Lithium-ion
Battery life	A fully charged battery can provide approximately 30 exams within a 24-hour period.
Charging time	Charging time offline will take no more than six hours from an empty battery to a full charge.
Rated capacity	4800–5200 mAh
Normal voltage	11.1 V
Max charging voltage	12.6 V
Max weight	350 g
Width	3.11 in (79 mm)
Length	4.65 in (118 mm)
Thickness	0.91 in (23 mm)

BATTERY CHARGER/WIRELESS HUB SPECIFICATIONS

The battery charger/wireless hub is powered from a standard wall outlet (adaptable to international power standards). The battery charger/wireless hub can charge two batteries simultaneously.

Table 25. Battery Charger/Wireless Hub Specifications

SPECIFICATION	DESCRIPTION
Operating Conditions	
Use	Indoor
Ambient temperature range	5–40°C (41–104°F)
Atmospheric pressure range	700 hPa–106 hPa
Relative humidity	30–75% non-condensing
Water resistance	Rated at IPX 0 (ordinary equipment without protection against ingress of water)
Computer connection	USB 2.0
Charger	Powered by a desktop DC power supply.
Input voltage	100–240 V AC RMS
Input frequency	50–60 Hz
Input current	1 A max
Input connection	2 wire IEC 60320 C7
Output	9 V at 1 A
Insulation	Class II with double insulation
Fuses	250 V AC, 2 A, quick acting
Testing	CSA 60950-1-03/UL 60950-1
Storage Conditions	
Storage	Indoor
Ambient temperature range	20–60°C (4–140°F)
Atmospheric pressure range	500 hPa–1060 hPa
Relative humidity	20–95% non-condensing

BLUETOOTH WIRELESS TECHNOLOGY

The Bluetooth® technology used in the AortaScan AMI 9700 is compliant with:

- Bluetooth Specification as defined and approved by The Bluetooth Special Interests Group.
- Logo certification with Bluetooth wireless technology as defined by The Bluetooth Special Interest Group.

ELECTROMAGNETIC COMPATIBILITY

The AortaScan AMI 9700 system is designed to be in compliance with IEC 60601-1-2:2007, which contains electromagnetic compatibility (EMC) requirements for medical electrical equipment. The limits for emissions and immunity specified in this standard are designed to provide reasonable protection against harmful interference in a typical medical installation.

The AortaScan AMI 9700 system complies with the applicable essential performance requirements specified in IEC 60601-1 and IEC 60601-2-37. Results of immunity testing show that the essential performance of the system is not affected under the test conditions described in the following tables. For more information about the essential performance of the AortaScan AMI 9700 system, see Essential Performance on page 2.

ELECTROMAGNETIC EMISSIONS

Table 26. Guidance and Manufacturer's Declaration—Electromagnetic Emissions

The AortaScan AMI 9700 system is intended for use in the electromagnetic environment specified below. The customer or the user of the AortaScan AMI 9700 system should assure that it is used in such an environment.

EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT – GUIDANCE
RF emissions CISPR 11	Group 1	The AortaScan AMI 9700 system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The AortaScan AMI 9700 system is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

ELECTROMAGNETIC IMMUNITY

Table 27. Guidance and Manufacturer's Declaration—Electromagnetic Immunity

The AortaScan AMI 9700 system is intended for use in the electromagnetic environment specified below. The customer or the user of the AortaScan AMI 9700 system should assure that it is used in such an environment.

IMMUNITY TESTS	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT – GUIDANCE
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	In compliance	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	In compliance	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	In compliance	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	In compliance	Mains power quality should be that of a typical commercial or hospital environment. If the user of the AortaScan AMI 9700 system requires continued operation during power mains interruptions, it is recommended that the AortaScan AMI 9700 system be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	In compliance	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the AortaScan AMI 9700 system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance d (m)** $d=1.2\sqrt{P}$

Table 27. Guidance and Manufacturer's Declaration—Electromagnetic Immunity

The AortaScan AMI 9700 system is intended for use in the electromagnetic environment specified below. The customer or the user of the AortaScan AMI 9700 system should assure that it is used in such an environment.

IMMUNITY TESTS	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT – GUIDANCE
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: U_T is the AC mains voltage prior to application of the test level.

At 80 MHz and 800 MHz, the higher frequency range applies.

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 AortaScan AMI 9700 system is used exceeds the applicable RF compliance level above, the AortaScan AMI 9700 system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the AortaScan AMI 9700 system.

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

RECOMMENDED SEPARATION DISTANCES

Table 28. Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the AortaScan AMI 9700 System

The AortaScan AMI 9700 system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the AortaScan AMI 9700 system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the AortaScan AMI 9700 system as recommended below, according to the maximum output power of the communications equipment.

RATED MAXIMUM OUTPUT POWER OF TRANSMITTER (W)	SEPARATION DISTANCE ACCORDING TO FREQUENCY OF TRANSMITTER (m)		
	150 kHz to 80 MHz $d=1.2\sqrt{P}$	80 MHz to 800 MHz $d=1.2\sqrt{P}$	800 MHz to 2.5 GHz $d=2.3\sqrt{P}$
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: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

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

ACCESSORY CONFORMANCE TO STANDARDS

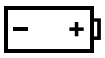
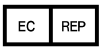
To maintain electromagnetic interference (EMI) within certified limits, the system must be used with the cables, components, and accessories specified or supplied by Verathon®. For additional information, see the System Components & Accessories and Component Specifications sections. The use of accessories or cables other than those specified or supplied may result in increased emissions or decreased immunity of the system.

Table 29. EMC Standards for Accessories

ACCESSORY	MAX LENGTH
AC power cord	2 m (6.6 ft)
USB cable	1.9 m (6.2 ft)
Desktop power supply	—

SYMBOL DIRECTORY

SYMBOL	MEANING
	Warnings & Cautions
	Warning or Caution—Consult accompanying documents. Read instructions before connecting or operating.
	Risk of electric shock
	Flammable material
	Non-ionizing, electromagnetic radiation
	Product Use & Specifications
	Refer to the operations & maintenance manual
	Manufacturer
	Date of manufacture
	Use-by date
	Catalog (part) number
	Serial number
	Batch code
	Temperature limitation
	Statement of prescription
	Shipping & Disposal
	Lithium-ion battery in package
	Fragile item, handle carefully

SYMBOL	MEANING
	Electrical & Power
	Class II equipment
	Type BF applied part
	Energy Efficiency Level V
	Battery operated
	Connector polarity mark—positive
	Connect to power supply
LPS	Limited power source
	USB
	Standards & Certifications
	CE—Marked in accordance with the Medical Device Directive (MDD)
	CSA—Canadian Standards Association mark of certification to applicable standards for electromedical equipment
	FCC—Tested to Federal Communications Commission requirements
	EC REP— Authorized Representative in the European Community
	WEEE—Subject to waste electrical and electronic equipment regulations
	TUV—Safety approval mark for components or subassemblies
	GS—German safety approval showing conformity with the German Equipment Safety Law
	UL—Underwriters Laboratories Certification mark for electrical shock, fire, and mechanical hazards only
	UL—Underwriters Laboratories Recognized Component certification mark

GLOSSARY

TERM	DEFINITION
A	Ampere
C	Celsius
cm	Centimeter
CSA	Canadian Standards Association
DC	Direct current
EMC	Electromagnetic compatibility
EMI	Electromagnetic interference
Essential performance	The system performance necessary to achieve freedom from unacceptable risk
ESD	Electrostatic discharge
F	Fahrenheit
g	Gram
GHz	Gigahertz
HIPAA	Health Insurance Portability and Accountability Act
hPa	Hectopascal
Hz	Hertz
IEC	International Electrotechnical Commission
Image cone	Cone-shaped area in which the probe transmits ultrasound waves
in	Inch
ISM	Industrial, scientific, and medical
ISPPA	Spatial-peak, pulse-average intensity
ISPTA	Spatial-peak, temporal-average intensity
LAN	Local area network
LCD	Liquid crystal display
m	Meter
mAh	Milliampere-hour
MDD	Medical Device Directive
MHz	Megahertz
MI	Mechanical index
mm	Millimeter
RF	Radio frequency
RMS	Root mean square
UL	Underwriters Laboratories
V	Volt
VAC	Volt alternating current
W	Watt
WEEE	Waste electrical and electronic equipment


VERATHON®
New World. Real Solutions.