December 1st 2015

# Urgent - Field Safety Notice

**Subject: Important Safety Information for Verathon BladderScan® BVI 9600 and AortaScan® AMI 9700**

To our Valued BladderScan and AortaScan Customers,

Verathon Incorporated, manufacturer of portable ultrasound instruments, is revising the Instructions For Use for BladderScan® BVI 9600 and AortaScan® AMI 9700.

Our records indicate your facility may have received one or more of the products affected by this notice. Serial numbers of BladderScan and AortaScan instruments are located on the back of the console; please identify the relevant serial numbers on your devices and follow the instructions below as applicable.

This Field Safety Notice is being conducted with the knowledge of the applicable Regulatory Authorities.

Thank you for your immediate attention to this matter. Verathon is committed to providing products of the highest quality and we regret any inconvenience this revision may cause. We encourage you to contact us if you need assistance or further information.

verathon.com



CORPORATE HEADQUARTERS
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<Insert Mail Date>

# Urgent - Field Safety Notice

BLADDERSCAN® BVI 9600 WITH AORTASCAN® MODE & AORTASCAN® AMI 9700
Usage for abdominal aorta diameter measurement

The purpose of this Field Safety Notice is to advise you that Verathon Incorporated is issuing a Voluntary Correction regarding all BladderScan® BVI 9600 and AortaScan® AMI 9700 devices. Both the BladderScan® BVI 9600 with AortaScan mode and AortaScan® AMI 9700 portable ultrasound instruments are indicated for obtaining an image of the abdominal aorta for aortic diameter measurement.

**Serious injuries and/or deaths could occur due to the failure mode associated with this voluntary correction. We have no reports of deaths but we do have one (1) report of serious injury.**

As part of this Field Safety Notice, Verathon is providing you with an updated Operations and Maintenance Manual for each of your BVI 9600 and AMI 9700 units. The updated Operations and Maintenance Manuals clarify that these devices should not be used for the screening, detection, or diagnosis of abdominal aortic aneurysms (AAAs), despite the inclusion of statements regarding use of these devices as screening tools in the current Operations and Maintenance Manuals. In September 2014, Verathon provided you with an Important Safety Information letter outlining important safety information regarding the intended use of the BladderScan® BVI 9600 and AortaScan® AMI 9700 devices, including the potential variance in reported abdominal aorta diameter. Since then, Verathon has taken another look at the Operations and Maintenance Manuals and determined that they needed further clarification regarding the appropriate use of the BVI 9600 and AMI 9700 devices for abdominal aorta diameter measurement. This Field Safety Notice is intended to provide you with updated Operations and Maintenance Manuals that confirm the device's intended use and indications for use and includes revised warning information as specified in the September 2014 communication.

**Product and Distribution Information:**

| Affected Devices | | |
|---|---|---|
| **Model** | BladderScan® BVI 9600 in AortaScan Mode | AortaScan® AMI 9700 |
| **Description** | Portable Ultrasound Instrument | Portable Ultrasound Instrument |
| **Part Numbers** | 0270-0452 | 0270-0639 |
| **Serial Number Ranges** | All Serial Numbers | All Serial Numbers |



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**Reason for the Field Safety Notice:**

Customers may be using the BladderScan® BVI 9600 with AortaScan mode or AortaScan® AMI 9700 as a screening or diagnostic tool to detect abdominal aortic aneurysms (AAAs). The devices are not indicated for that purpose and due to the design characteristics described in this section, relying on the devices for an AAA-detection function poses a potential risk to patients' health, as described in the next section.

Due to the design characteristics of both the BladderScan® BVI 9600 and AortaScan® AMI 9700, the abdominal aortic measurement reported by the device may be significantly smaller (or larger) than the actual diameter of the abdominal aorta. The devices can measure abdominal aortic diameters ranging from 3 to 12.4 cm with a diameter accuracy of ± 15% ± 0.5 cm. As shown in *Table 19* of the AMI 9700 Operations and Maintenance Manual and *Table 23* of the BVI 9600 Operations and Maintenance Manual, this measurement variance may result in reported measurements that vary by more than one centimeter from the actual diameter of the patient's abdominal aorta. For example, a true abdominal aortic diameter of 5.3 cm may be reported to be as low as 4.01 cm or as large as 6.60 cm. In another example, a true abdominal aortic diameter of 3.5 cm may be reported to be as low as 2.48 cm or as large as 4.53 cm.

Verathon has received forty (40) reports in the United States of instances in which a patient's abdominal aortic diameter was initially measured to be 3.0 centimeters (cm) or less using a BVI 9600 or AMI 9700, but was later determined by additional screening to be greater than 3.0 cm. There have been no reported deaths and only one (1) report of a patient requiring medical intervention. In that instance, the patient presented at an emergency room and required surgery to treat an 8.6 cm AAA with dissection despite an earlier abdominal aortic diameter measurement of less than 3.0 cm obtained using a BladderScan® BVI 9600 device in AortaScan mode.

**Note**: this Field Safety Notice does not affect BladderScan® BVI 9600 when used to obtain an image of the bladder for measuring bladder volume.

**Risk to Health:**

Relying on BladderScan® BVI 9600 with AortaScan mode and the AortaScan® AMI 9700 as the sole method for measuring abdominal aortic diameter for the purpose of detecting the presence or absence of AAAs could result in the failure to identify an AAA, which could impact whether the patient receives proper medical monitoring and/or treatment. As stated in the current Operations and Maintenance Manual, these devices should not be relied upon as the sole source of identification of a "normal" abdominal aorta (less than 3.0 cm diameter) or "potentially abnormal" abdominal aorta (equal to or greater than 3.0 cm in diameter, which the United States Preventive Services Task Force (USPSTF) defines as an AAA), even in clinically suitable subjects.

Because of this variation in measurement and the serious health risks associated with undetected AAAs, Verathon is reminding you that, if clinically indicated, appropriate patients should be referred for a diagnostic standard test for either screening for or diagnosis of an AAA, regardless of test results obtained with BladderScan® BVI 9600 or AortaScan® AMI 9700 devices. Thus, the device should not be relied upon for the single (one-time) AAA screening using ultrasound that is recommended by the USPSTF for men ages 65 to 75 who have ever smoked, nor for the screening that the USPSTF recommends offering to men ages 65 to 75 who have never smoked. Relying on the BladderScan® BVI 9600 or AortaScan® AMI 9700 for the recommended one-time screening without performing confirmatory testing risks false negatives in these higher-risk groups, even when the device is functioning as intended.



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**How to Recognize that the Device May Provide an Inaccurate Measurement:**

All BladderScan® BVI 9600 and AortaScan® AMI 9700 units are designed with the ±15% ± 0.5 cm measurement allowance. Healthcare professionals should consider clinical factors when assessing whether a BladderScan or AortaScan measurement might be inaccurate.

**Actions to be Taken by the Customer/Distributor:**

Verathon has revised its Operations and Maintenance Manual to more clearly reflect the indication for use for the BladderScan® BVI 9600 and AortaScan® AMI 9700 (that is, measurement of the abdominal aortic diameter) and to more prominently explain the anticipated variance in diameter measurements.

Because of the potential variation in measurement and the serious health risks associated with undetected AAAs, Verathon is reminding you that, if clinically indicated, appropriate patients should be referred for a diagnostic standard test for either screening for or diagnosis of an AAA, regardless of test results obtained with BladderScan® BVI 9600 or AortaScan® AMI 9700 devices.

Enclosed with this letter, please find the revised Operations and Maintenance Manual for each of your BladderScan® BVI 9600 and AortaScan® AMI 9700 devices, provided by Verathon at no cost to you. Please destroy all existing Operations and Maintenance Manuals and replace them with these updated versions. You do not need to return your AortaScan or BladderScan devices to Verathon.

Also enclosed with this letter is a reply form titled "Field Safety Notice Reply Form: RESPONSE REQUIRED". Please complete the information on this form and email the completed form within 10 business days to:

**E-mail:**
verathon3108@stericycle.commailto:customerservice@verathon.com?subject=GlideScope%20Reusable%20Safety%20Notice%20and%20Recallmailto:customerservice@verathon.com?subject=GlideScope%20Reusable%20Safety%20Notice%20and%20Recall

Should you have any questions about this Field Safety Notice or the revised Operations and Maintenance Manual, please contact your Verathon representative or email: verathon3108@stericycle.com

Encl: (1) Operations and Maintenance Manual(s); Quick Reference Card(s)

(2) Field Safety Notice Reply Form: RESPONSE REQUIRED



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If you/your facility received a BladderScan® BVI 9600, portable ultrasound instrument, or an AortaScan® AMI 9700, portable ultrasound instrument, please fill out and return this **Field Safety Notice Reply Form**.

For users of BladderScan® BVI 9600 and AortaScan® AMI 9700, Verathon is implementing a Field Safety Notice regarding updates to the following Operations and Maintenance Manuals (OMM):

- BladderScan® BVI 9600 Operations and Maintenance Manuals: 0900-4413-03-60
- AortaScan® AMI 9700 Operations and Maintenance Manual: 0900-4411-03-60

| FIELD SAFETY NOTICE REPLY FORM: RESPONSE REQUIRED | | |
|---|---|---|
| Affected Devices | | |
| **Model** | BladderScan® BVI 9600 in AortaScan Mode | AortaScan® AMI 9700 |
| **Part Number** | 0270-0452 | 0270-0639 |
| **Serial Number Ranges** | All serial numbers | All serial numbers |

I have ensured that this Field Safety Notice was distributed to users, including applicable physicians and nurses, throughout the facility.

☐ YES ☐NO If NO, please explain: _____

I destroyed the facility's existing Operations and Maintenance Manual(s) and replaced these Manual(s) with the updated Manual(s) provided with this Field Safety Notice.

☐ YES ☐NO If NO, please explain: _____

The following BladderScan® BVI 9600 or AortaScan® AMI 9700 device(s) are still in use at our facility, as per the provided list – please record Serial Number(s):

| BladderScan® BVI 9600 | AortaScan® AMI 9700 |
|---|---|
| Ex. A7000000 | |
| | |

The following BladderScan® BVI 9600 or AortaScan® AMI 9700 device(s) are no longer in use at our facility, as per the provided list – please record Serial Number(s):

| BladderScan® BVI 9600 | AortaScan® AMI 9700 |
|---|---|
| Ex. A7000000 | |
| | |

| | |
|---|---|
| Business Name: | |
| Address, City, State/Prov., Post Code: | |
| Signature: | Phone: |
| Printed Name: | Date: |

Please e-mail the completed form to: **E-mail:** verathon3108@stericycle.com



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mailto:customerservice@verathon.com?subject=GlideScope%20Reusable%20Safety%20Notice%20and%20Recallmailto:customerservice@verathon.com?subject=GlideScope%20Reusable%20Safety%20Notice%20and%20Recall



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