October 02, 2020

Field Safety Notice
MEDICAL DEVICE RECALL
BLADDERSCAN® PRIME PLUS™ PROBE HANDLE

«ContactName»
«CustomerName»
«Address1»
«City», «State» «ZipCode»

Dear «CustomerName»:

The purpose of this letter is to advise you that Verathon Incorporated is conducting a voluntary recall for select BladderScan® Prime Plus™ (referred to as "Prime Plus") probes. This voluntary recall notification relates to the handle of the Prime Plus probe. On May 27, 2020, a Verathon supplier initiated an unauthorized manufacturing change. This manufacturing change caused the Prime Plus probe handle plastic to be exposed to excessive heat during the molding process. This created the potential for the handle to become brittle and crack. No other plastic molded part of the BladderScan® Prime Plus™ were impacted by this unauthorized manufacturing change. Only the Prime Plus probe handle is affected by this recall notification,

Our records indicate that your facility has received one or more of the devices affected by this notice. At this time we require customers to respond to this recall by completing the attached Recall Response Form and returning it to Verathon by email to CSNotifications@verathon.com.

Please follow the instructions under *'Actions to be Taken by the Customer/Distributor'* beginning on page 3 of this letter and **return the Recall Response Form on page 5**.

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

As with any concerns with Verathon products, please report suspected malfunctions or adverse events related to any BladderScan device to Verathon Customer Care at (800) 331-2313 or email us at CSNotifications@verathon.com.

Sincerely,

xxx

Verathon Inc. Global Headquarters
20001 North Creek Parkway, Bothell, WA 98011, USA
Toll-free: +1 800 331 2313 Main: +1 425 867 1348

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

verathon.com

Field Safety Notice

MEDICAL DEVICE RECALL

Affected products: BladderScan® Prime Plus Probe Handle
(Serviced or Distributed between June 9, 2020, and July 22, 2020)

The BladderScan Prime Plus system is an ultrasound device intended to be used for measuring the urine volume in the bladder noninvasively. Only BladderScan Prime Plus probes that were serviced or distributed between June 9, 2020, and July 22, 2020, and are listed in the Recall Response Form, are within scope of this recall.

Devices that are not listed in the Recall Response Form are not impacted by this voluntary recall.

Reason for the Voluntary Recall:

Verathon Incorporated has become aware that because of an unauthorized change in the molding process by a Verathon supplier, BladderScan Prime Plus probe handles may crack shortly after assembly. During the date range of service or distribution listed above, Verathon discovered through its final visual inspection and prior to packaging for shipment, that probes began experiencing cracking of the probe handle. Verathon's investigation determined that the probe handle may crack in three primary locations: 1) observed along the threads where the probe handle attaches to the base; 2) vertically through the set screw feature, and 3) with the internal molded-in screw bosses which connect the handle to the probe cap (see Figure 1). Verathon has received a total of six (6) customer complaints regarding cracked probe handles for probes serviced or distributed between June 9, 2020, and July 22, 2020. These were reported as out of box failures.

Figure 1: Example of cracked probe handle

Verathon Inc. Global Headquarters
20001 North Creek Parkway, Bothell, WA 98011, USA
Toll-free: +1 800 331 2313 Main: +1 425 867 1348

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

verathon.com

Verathon and the supplier's investigation into the unauthorized manufacturing change determined root cause of probe handle cracking to be the degradation of plastic material. This degradation was caused by increased residence time in the molding process. Residence time is the time that plastic resin is heated before being injected into the mold.

This Field Safety Notification is being conducted to inform the small number of customers who purchased or serviced devices between June 9, 2020, and July 22, 2020 who might observe cracking of Prime Plus probe handle plastics.

Risk to Health:

Verathon is not aware of any instances of patient or user injury attributed to this issue. There is an improbably/remote possibility that a cracked probe handle will cause any adverse health consequence. The cracked probe handle might impair or otherwise impact functionality of the BladderScan Prime Plus, requiring backup equipment. Cracks that allow the ingress of fluid into the probe may affect the performance of the instrument.

Actions to Be Taken by the Customer/Distributor:

Our records indicate that your facility has received one or more BladderScan Prime Plus probes impacted by this recall.

Please take the following actions:

1. Check the list of Serial Numbers that are provided within the Recall Response Form.

Verathon Inc. Global Headquarters
20001 North Creek Parkway, Bothell, WA 98011, USA
Toll-free: +1 800 331 2313 Main: +1 425 867 1348

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

verathon.com

2. Perform a visual inspection of the probe handle for cracks or damage.

3. Based on the visual inspection of your device(s), please do one of the following:

   - If your BladderScan Prime Plus probe handle plastics have no visible cracks or damage and / or you do not wish for units to be serviced, complete the attached Recall Response Form by indicating "no" or "0" in the text box and return the form to Verathon by email to CSNotifications@verathon.com.

Or

   - If your BladderScan Prime Plus probe handle plastics have visible cracks and you wish for these units to be serviced, complete attached Recall Response Form by indicating by number the count of probe handle plastics that require repair in the text box and return the form by email to CSNotifications@verathon.com. Verathon Customer Care will contact you to arrange for repair of the probe handle plastics. This replacement will be at no charge to you.

Verathon offers live Customer Care agent support Monday through Friday from 6:00 am to 4:00 pm Pacific Time for the United States at (800) 331-2313. You may also email us at CSNotifications@verathon.com, and we will respond promptly.

Action to Be Taken by Verathon:

As a corrective action, Verathon has issued a Supplier Corrective Action to the supplier. The supplier returned to the validated, approved manufacturing process on 11 August 2020.

Verathon is voluntarily undertaking this recall to replace the impacted Prime Plus probe handle plastics.

Should you have any questions about this Field Safety Notice, please contact your Verathon representative or Verathon Customer Care at CSNotifications@verathon.com.

Verathon Inc. Global Headquarters
20001 North Creek Parkway, Bothell, WA 98011, USA
Toll-free: +1 800 331 2313 Main: +1 425 867 1348

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

verathon.com

Recall Response Form: Response Required

Please complete this form

Our records indicate that your facility has received one or more BladderScan® Prime Plus Probes.

Please fill out and return this **Recall Response Form**.

RECALL RESPONSE FORM: RESPONSE REQUIRED
Affected Products: BladderScan® Prime Plus Probe (Serviced or Distributed between June 9, 2020 and July 22, 2020)

(Please indicate a number in the box below)

My facility has checked our Prime Plus devices listed in the BladderScan Prime Plus Probe Serial Numbers table below and request that _____ units be serviced.

If no cracking is observed and / or you do not wish units to be serviced, indicate "no" or "0" in the box above.
If a number other than 0 is listed, Verathon will contact you to schedule service.
If a device is not listed in the table below, it not in scope. Please contact Customer Care for support.

BladderScan Prime Plus Probe Serial Numbers			

Please sign, date, and print your name and title below. Thank you!

Customer Information	
Business Name: **«CompanyName»**	
Address: **«Address1»**	
City, State/Prov. Post Code: **«City», «State» «ZipCode»**	
Signature:	Phone:
Printed Name:	Date:

Please email the completed form to:
CSNotifications@verathon.com

Verathon Inc. Global Headquarters
20001 North Creek Parkway, Bothell, WA 98011, USA
Toll-free: +1 800 331 2313 Main: +1 425 867 1348

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

verathon.com