# URGENT MEDICAL DEVICE CORRECTION

GE Healthcare
3000 N. Grandview Blvd. - W440
Waukesha, WI 53188, USA

<Date of Letter Deployment>

GEHC Ref# 12283

To: Director of Breast Imaging
Director of Radiology
Director of Biomedical Engineering

RE: **Senographe Pristina with Serena – Potential slippage of the biopsy positioner when the gantry is rotated during a biopsy procedure.**

***This document contains important information for your product. Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.***

**Safety Issue**

If the Senographe Pristina gantry is rotated and the biopsy positioner is attached, the angulation angle may unexpectedly change during a motorized angulation motion, due to insufficient brake performance. This issue could result in injury to the patient's breast. No injuries have been reported due to this issue.

**Safety Instructions**

The following uses of Senographe Pristina System are unaffected by this issue; you may continue to use your system for the following:

- 2D acquisitions in screening and diagnostic modes,
- Digital Breast Tomosynthesis (3D acquisitions), and
- SenoBright HD, Contrast Enhanced Spectral Mammography (CESM).

When using the Pristina Serena for biopsy procedure:

- You may continue to perform biopsy procedures when the Senographe Pristina gantry is **not** rotated in vertical or horizontal biopsy approaches. See Figure #1 and #2.
- **Do Not Use** your Pristina Serena system to perform biopsy procedures at **any** gantry rotation other than 0°. See Figure #3 & Figure #4.

**Figure #1 – Acceptable Gantry Position for Biopsy Procedure:** Senographe Pristina gantry rotation angle is 0°. Vertical approach setup.

**Figure #2 – Acceptable Gantry Position for Biopsy Procedure:** Senographe Pristina gantry rotation angle is 0°. Horizontal approach setup.

**Figure #3 – <u>Do Not Use Gantry Rotation for Biopsy Procedure</u>:** Senographe Pristina gantry rotated at 90° position.

**Figure #4 – <u>Do Not Use Gantry Rotation for Biopsy Procedure</u>:** Senographe Pristina gantry at **<u>ANY</u>** rotation different from 0°.

**Note:** If you regularly perform biopsy procedures with gantry rotation different from 0° and have questions about alternative clinical approaches, please contact your local Clinical Representative.

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|---|---|
| **Affected Product Details** | All Senographe Pristina systems that are equipped to receive a biopsy device.<br>All Serena systems. See attached Appendix for a list of serial numbers. |
| **Product Correction** | GE Healthcare will correct all affected products at no cost to you. A GE Healthcare representative will contact you to arrange for the correction. |
| **Contact Information** | If you have any questions or concerns regarding this notification, please contact GE Healthcare Service at 1-800-437-1171 or your local Service Representative. |

Please be assured that maintaining a high level of safety and quality is our highest priority. If you have any questions. Please contact us immediately per the contact information above.

Sincerely,

[redacted]

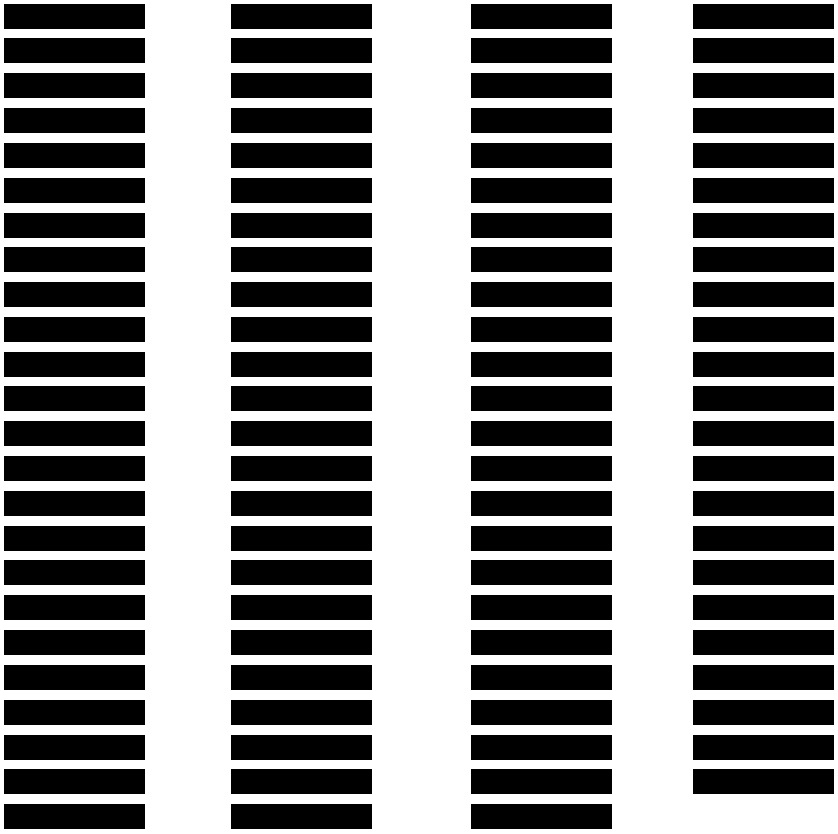
James W. Dennison
Vice President - Quality Assurance
GE Healthcare

[redacted]

Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare

## Appendix

**List of Affected Serial numbers**



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**MEDICAL DEVICE NOTIFICATION ACKNOWLEDGEMENT**
**RESPONSE REQUIRED**

**Please complete this form and return it to GE Healthcare promptly upon receipt and no later than 30 days from receipt. This will confirm receipt and understanding of the Medical Device Correction Notice and required actions to be taken GEHC Ref# 12283.**

Customer/Consignee Name: _____

Street Address: _____

City/State/ZIP/Country: _____

mail Address: _____

Phone Number: _____

**If you are using a Biopsy device with any other or additional Pristina systems in your facility, please provide the system**

**ID number.** _____

☐ We acknowledge receipt and understanding of the accompanying Medical Device Notification, and that we have taken and will take appropriate actions in accordance with that Notification.

**Please provide the name of the individual with responsibility who has completed this form.**

Signature: _____

Printed Name: _____

Title: _____

Date (DD/MM/YYYY): _____

**Please return completed form scanning or taking a photo of the completed form e-mailing to:**
Recall12283@ge.com
**You may obtain this e-mail address through the QR code below:**