URGENT FIELD SAFETY NOTICE

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.

Affected Product Details	All Senographe Pristina systems that are equipped to receive a biopsy device. 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 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,

James W. Dennison
Vice President - Quality Assurance
GE Healthcare

Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare

Appendix

List of Affected Serial numbers

716784BU4	718602BU6	732448BU6	737211BU3
716785BU1	722648BU3	732449BU4	738021BU5
716786BU9	722649BU1	732450BU2	738023BU1
716787BU7	722653BU3	732727BU3	738192BU4
716788BU5	722654BU1	732728BU1	738356BU5
718583BU8	722655BU8	733031BU9	738357BU3
718584BU6	722656BU6	733600BU1	738358BU1
718585BU3	722657BU4	733706BU6	738557BU8
718586BU1	730124BU5	733707BU4	738573BU5
718587BU9	730125BU2	733903BU9	738574BU3
718588BU7	730126BU0	733904BU7	738586BU7
718589BU5	730292BU0	734169BU6	738587BU5
718590BU3	730293BU8	734170BU4	738695BU6
718591BU1	730663BU2	734192BU8	738696BU4
718592BU9	730664BU0	734206BU6	738712BU9
718593BU7	730665BU7	734840BU2	738792BU1
718594BU5	732049BU2	735432BU7	738793BU9
718595BU2	732050BU0	735558BU9	738794BU7
718596BU0	732113BU6	735779BU1	738795BU4
718597BU8	732303BU3	736006BU8	738864BU8
718598BU6	732304BU1	736007BU6	739150BU1
718599BU4	732305BU8	736008BU4	739178BU2
718600BU0	732362BU9	736366BU6	739721BU9
718601BU8	732363BU7	736588BU5	

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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: