URGENT FIELD SAFETY NOTICE

GE HealthCare

Date of Letter Deployment

GE HealthCare Ref. # 79072

To: Head of Ultrasound Department
Head of Obstetrics and Gynecology Department
Hospital Administrator / Risk Managers
Biomedical Engineering

RE: **Double image artifact with IC9-RS intracavitary probes**

Safety Issue

GE HealthCare has become aware of an issue with certain IC9-RS ultrasound probes (see Affected Products List) that can result in a double image artifact creating a ghost image with realistic features. An unrecognized artifact may lead to misdiagnosis.

Actions to be taken by Customer/ User

1. Ensure all potential users in your facility are made aware of this correction notification and the recommended actions.
2. You can continue to use your ultrasound system with all other probes.
3. Upon receipt of the letter, verify if your IC9-RS probe is functioning correctly prior to use by performing the Double Image artifact test described below. (Testing must be repeated monthly)
4. If a double image artifact is seen, **do not use the probe** and contact a GE HealthCare representative to get a replacement probe.
5. Complete and return the attached acknowledgement form to Recall.79072@ge.com. Please retain this document for your records.

Double Image artifact test:

Settings:

1. Operate the probe clean and dry in air
2. Use standard IC9-RS probe settings on the console, Gynecology, Routine HI
3. Set field of view to Max Angle (Angle 185°)
4. Set image gain to 5 dB
5. Ensure Time Gain Compensation (TGC) sliders in center position

Testing:

1. Run the edge of a smooth, metal reflector (paperclip, metal pen, flat side of tweezers or similar) along the probe lens starting at the edge of the field of view and running it along the full curvature of the probe (Figure 1).
2. The metal reflector will produce strong echoes localized at the point of contact.
3. To enhance the echoes, apply a smear of water on the metal reflector only.

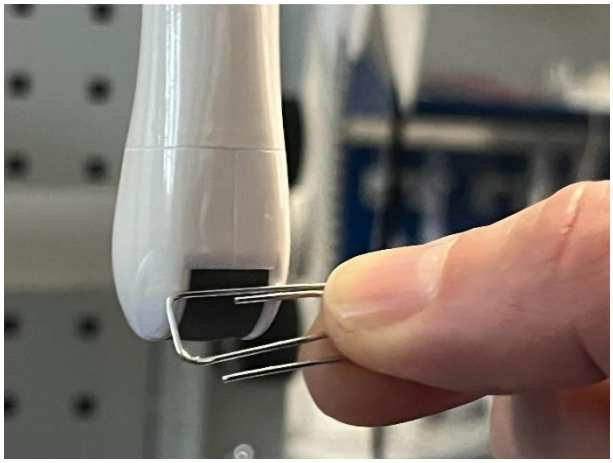

Figure 1: Double image test procedure. Place metal reflector (paperclip shown) at the edge of the field of view. Run reflector along the full curvature of the transducer.

If an additional echo is seen in the sector opposite of the point of contact, the probe is producing a double image artifact. Double image artifacts are only visible towards the edges of the field of view. See test images below from a normal IC9-RS probe (Figure 2) and a malfunctioning IC9-RS probe producing double image artifact (Figure 3).

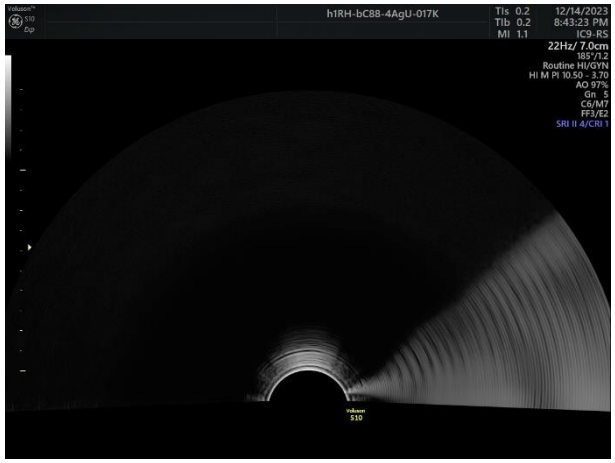

Figure 2. Test image from a normal IC9-RS probe. No artifact visible.

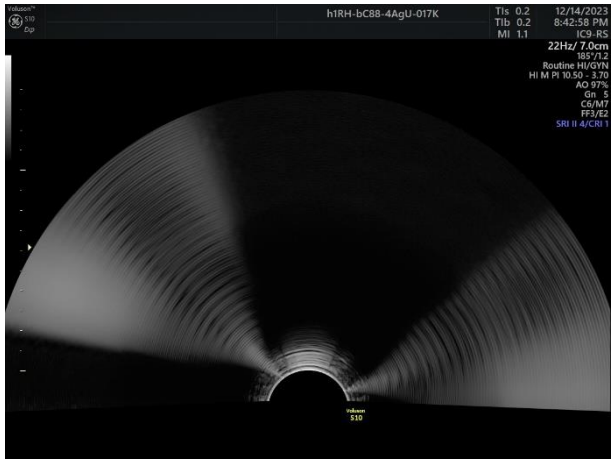

Figure 3. Test image from a malfunctioning IC9-RS probe showing double image artifact in the opposite sector.

Affected Product Details

IC9-RS probes with a serial number included in Appendix A are affected by this issue. The serial number (SN) can be found on the rating plate as shown in Figure 4

Figure 4. Rating plate example – displaying probe type (IC9-RS) and serial number (SN).

Intended Use

GE HealthCare ultrasound imaging systems are intended for use by a qualified physician or sonographer for ultrasound evaluation in the following clinical application: Image Acquisition for diagnostic purposes including measurements on acquired image.

For the IC9-RS probe the clinical applications are for use in obstetrics, gynecology (including transvaginal), and in transrectal applications.

Product Correction	GE HealthCare will correct all affected products at no cost to you. A GE HealthCare representative will contact you about the correction method and schedule.
Contact Information	If you have any questions or concerns regarding this notification, please contact your local GE HealthCare Representative.

GE HealthCare confirms that this notice has been notified to the appropriate Regulatory Agency.

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

Sincerely,

Laila Gurney
Chief Quality & Regulatory Officer
GE HealthCare

Scott Kelley
Chief Medical Officer
GE HealthCare

GE HealthCare Ref. # 79072

MEDICAL DEVICE NOTIFICATION ACKNOWLEDGEMENT
RESPONSE REQUIRED

Please complete this form and return it to GE HealthCare promptly upon receipt of this letter and no later than 30 days from receipt. This will confirm receipt and understanding of the Medical Device Correction Notice.

There are two options for your convenience:

1) Electronic response form (this page)

   OR

2) Manual filled and scanned response form (next page)

Please scan the QR code or follow the link below to complete the workflow.

https://app.sc.ge.com/esurveys/takesurvey/18446744073711057248

Alternatively, if the workflow on the previous page is not possible, 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.

*Customer/Consignee Name: _____

Street Address: _____

City/State/ZIP/Country: _____

*Customer Email Address: _____

*Customer Phone Number: _____

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

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

Signature: _____

*Printed Name: _____

*Title: _____

*Date (DD/MM/YYYY): _____

*Indicates Mandatory Fields

Please return completed form by scanning or taking a photo of the completed form and email to:
Recall.79072@ge.com

Appendix A: IC9-RS Probe Affected Serial Number (SN) List

The probe SN's listed below, including IC9-RS SN's within the list ranges, are affected by this recall. Identify affected IC9-RS probes based on the digits before "WX".		
933456WX6 - 933497WX0	1078278WX7 - 1078408WX0	1194104WX4 - 1194363WX6
937959WX5 - 937966WX0	1078424WX7 - 1078477WX5	1200537WX7 - 1200696WX1
947802WX5	1083711WX0 - 1083866WX2	1203801WX4 - 1203825WX3
947865WX2	1086779WX4 - 1087024WX4	1204031WX7 - 1204320WX4
960937WX1	1087884WX1 - 1088007WX8	1204903WX7 - 1205016WX7
961364WX7	1089738WX7 - 1089921WX9	1209200WX3 - 1209411WX6
962632WX6 - 962686WX2	1093974WX2 - 1094093WX0	1213742WX8 - 1214337WX6
965260WX3 - 965325WX4	1097933WX4 - 1098182WX7	1222421WX8 - 1222575WX1
965754WX5 - 965779WX2	1101411WX5 - 1101636WX7	1226148WX3 - 1226245WX7
967707WX1 - 967846WX7	1102408WX0 - 1102526WX9	1226408WX1 - 1226499WX0
990730WX4 - 990759WX3	1108310WX2 - 1108479WX5	1227585WX5 - 1227599WX6
990791WX6	1111842WX9 - 1111969WX0	1229676WX0 - 1229875WX8
990796WX5	1116814WX3 - 1117060WX2	1231604WX8 - 1231683WX2
1007170WX2	1117096WX6 - 1117155WX0	1232379WX6 - 1232511WX4
1012616WX7	1117178WX2 - 1117253WX3	1237164WX7 - 1237299WX1
1017062WX9	1122988WX7 - 1123555WX3	1239964WX8 - 1240113WX9
1017149WX4	1131085WX1 - 1131340WX0	1240384WX6 - 1240581WX7
1017164WX3	1132783WX0 - 1132816WX8	1244712WX4 - 1244885WX8
1025152WX8	1135895WX9 - 1136402WX3	1245442WX7 - 1245529WX1
1025302WX9 - 1025312WX8	1143145WX9 - 1143366WX1	1250184WX7 - 1250361WX1
1025367WX2 - 1025674WX1	1147961WX5 - 1147977WX1	1254993WX7 - 1255138WX8
1035096WX5 - 1035250WX8	1148772WX5 - 1148922WX6	1255255WX0 - 1255410WX1
1037703WX4	1154390WX7 - 1154603WX3	1259954WX4 - 1260153WX0
1045752WX1 - 1045814WX9	1158828WX2 - 1159381WX1	1260775WX0 - 1260796WX6
1049144WX7 - 1049340WX1	1162024WX2 - 1162047WX3	1263031WX5 - 1263162WX8
1052548WX3	1164476WX2 - 1164581WX9	1264956WX2 - 1265071WX9
1056701WX4 - 1056771WX7	1165240WX1 - 1165427WX4	1268755WX4
1056903WX6 - 1057301WX2	1168344WX8 - 1168605WX2	1269477WX4 - 1269776WX9
1060771WX1 - 1060884WX2	1177226WX6 - 1177345WX4	1273875WX3 - 1274090WX8
1066742WX6 - 1066853WX1	1179023WX5 - 1179184WX5	1278241WX3 - 1278318WX9
1066894WX5 - 1067071WX9	1184045WX1 - 1184166WX5	1278415WX3 - 1278556WX4
1073037WX2 - 1073146WX1	1188481WX4 - 1188572WX0	1279311WX3 - 1279371WX7
1075082WX6 - 1075211WX1	1191001WX5 - 1191131WX0	
1078125WX0 - 1078251WX4	1193932WX9 - 1194071WX5	