



# URGENT FIELD SAFETY NOTICE

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

15 September 2021

GE Healthcare Ref# 60982

To: Director of Clinical/Radiology  
Risk Manager/Hospital Administrator

RE: **Sagittal VIBRANT with NoSlabWrap factor greater than 1.0. SIGNA Premier, SIGNA Pioneer, SIGNA Architect, Discovery MR750w 3.0T, Discovery MR750 3.0T, SIGNA Voyager, Optima MR450w 1.5T, SIGNA Artist, SIGNA Creator, SIGNA Explorer, 1.5T Signa HDxt (HD29)**

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

### Safety Issue

GE Healthcare has recently become aware of an issue on the affected products listed below, which impacts breast imaging when running the Sagittal VIBRANT application with ASSET. The issue arises when the NoSlabWrap factor is set to a value larger than the default value of 1.0.

In this scenario, some slices may be missing which can lead to a gap of anatomy in the 3D Volume images.

There have been no injuries reported to GE Healthcare as a result of this issue.

### Actions to be taken by Customer / User

You can continue to use your device.

- 1.) Please ensure users prescribing Sagittal VIBRANT application with ASSET ensure the **NoSlabWrap factor is set to 1.0**. (See Figure 1 for reference to 3D Sag VIBRANT No Slab Wrap factor setting location)

**Figure 1 – User Interface showing A) Imaging Options for selecting 3D VIBRANT with ASSET and B) location for No Slab Wrap factor**



- 2.) Re-review any exams previously conducted with Sagittal VIBRANT series with ASSET where the NoSlabWrap factor was set to greater than 1.0.
- 3.) Complete and return the attached response form to **Recall.60982@ge.com**

**Affected  
Product  
Details**

The following MR systems with the software versions listed below are potentially affected:

| <b>Product Name</b>    | <b>Affected Software Version - Global excluding China</b> | <b>Affected Software Version - China Only</b> | <b>GTIN</b>  |
|------------------------|---|---|--|
| SIGNA™ Premier         | RX29.1  | RX27.3  | 00195278010797<br>00840682135269   |
| SIGNA™ Architect       | DV29.1  | DV28.4 (F), DV27.3 (T)                        | 00840682147095<br>00195278023643<br>00840682122702<br>00840682123440                                     |
| SIGNA™ Pioneer         | PX29.1  | PX25.4 (T), PX28.3                            | 00195278005502<br>00840682104401<br>00840682145770   |
| Discovery™ MR750w 3.0T | DV29.1  | N/A   | 00840682103817<br>00195278229519   |
| Discovery™ MR750 3.0T  | DV29.1  | N/A   | 00840682115872<br>00195278229519   |
| SIGNA™ Artist          | DV29.1  | N/A   | 00195278117021<br>00195278210036<br>00195278126443<br>00840682146104<br>00840682123457<br>00840682123129 |
| SIGNA™ Voyager         | VX29.1  | PX26.4  | 00840682108607<br>00195278124609   |
| SIGNA™ Creator         | SV29.1  | SV25.4  | 00840682113786   |
| SIGNA™ Explorer        | SV29.1  | SV25.4  | 00840682113762   |
| Optima™ MR450w 1.5T    | DV29.1  | N/A   | 00840682115971<br>00195278229519   |
| 1.5T SIGNA™ HDxt       | HD29.1  | HD16.2  | 00840682115964<br>00840682144261<br>00195278416339   |

**Intended Use:**

GE Healthcare Whole-Body MR scanners are used to produce images of the inside of the human body that help aid the diagnosis of disease. In a clinical setting, Magnetic Resonance imaging (MRI) can be used to distinguish diseased or compromised tissue from normal tissue.

MRI technology is routinely used to help the diagnosis in diseases such as oncology, stroke, heart and peripheral vascular disease, pediatric diseases, etc. MRI technology in general, however, is not limited to specific diseases, stage and condition of diseases, or clinical forms.

MRI technology is intended to be used by the healthcare professionals (clinicians and trained technologists) following good clinical practice. It can be used in broad patient population including adults, children and infants, following good clinical practice.

**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.

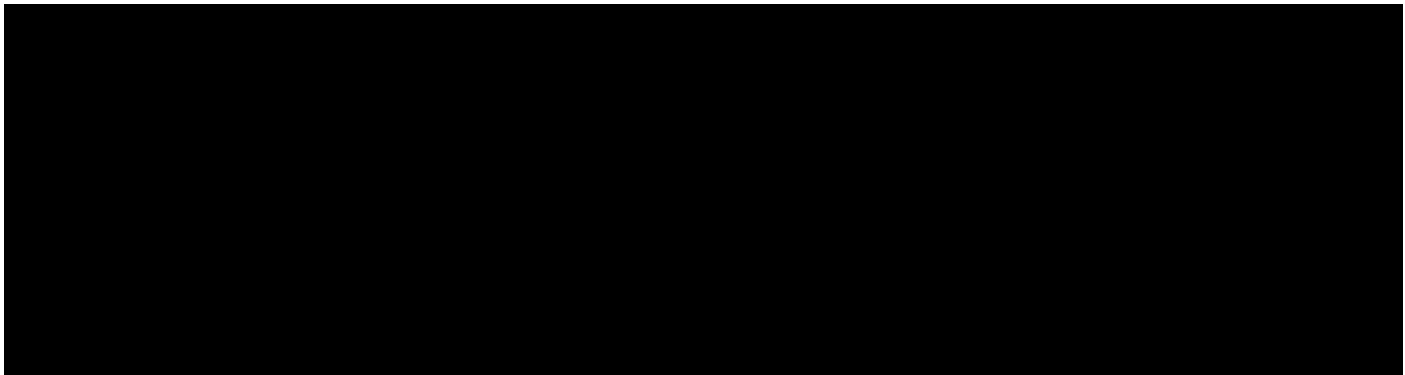
To make users aware of this issue, GE Healthcare recommends you post this letter in your facility on or near the MR operator console until GE Healthcare corrects your affected product.

**Contact  
Information**

If you have any questions or concerns regarding this notification, please contact GE Healthcare Service or your local Service 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 immediately per the contact information above.





**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.**

Customer/Consignee Name: \_\_\_\_\_

Street Address: \_\_\_\_\_

City/State/ZIP/Country: \_\_\_\_\_

Email Address: \_\_\_\_\_

Phone Number: \_\_\_\_\_

System ID \_\_\_\_\_

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): \_\_\_\_\_

**Please return completed form by scanning or taking a photo of the completed form and email to: Recall.60982@ge.com**

