GE Healthcare
Healthcare Systems
9900 Innovation Drive
Wauwatosa, WI 53226
USA

<Date of Letter Deployment>

To: Hospital Administrators / Risk Managers
Radiology Department Managers
Radiologists

RE: Revised URGENT MEDICAL DEVICE CORRECTION for 3.0T 6 Channel Flex Coil Fails Surface Coil Temperature Test.
GEHC Ref#60888

GE Healthcare is revising the recently distributed URGENT MEDICAL DEVICE CORRECTION (Ref#60888) to provide an important clarification:

- Previously the letter only listed MR750W Surgical Suite Scanners. Because 3.0T 6 Channel Flex Coils are used with the MR750, MR750W, and 3.0T HDxT (including HD23), these devices have been added to the letter.

- There are no other changes to the letter.

A copy of the revised URGENT MEDICAL DEVICE CORRECTION is attached.

Sincerely,

[redacted]

James W. Dennison
Vice President - Quality & Regulatory
GE Healthcare

[redacted]

Jeff Hersh, M.D.
Chief Medical Officer
GE Healthcare

URGENT MEDICAL DEVICE CORRECTION

GE Healthcare
9900 Innovation Drive
Wauwatosa, WI 53226
USA

<Date of Letter Deployment>

GEHC Ref# 60888

To: Hospital Administrators / Risk Managers
Radiology Department Managers
Radiologists

RE: 3.0T 6 Channel Flex Coil Fails Surface Coil Temperature Test

GE Healthcare has recently become aware of a potential safety issue with the 3.0T 6 Channel Flex Coil used with the 3.0T MR750, MR750W, and HDxT (including HD23) Systems. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue

Coil overheating can occur when the device is used in Mode 2 setup. This could lead to a serious patient thermal injury. There have been no injuries reported as a result of this issue.

Safety Instructions

The issue is observed during the Mode 2 setup, as described in the "6-Channel Flex coil" section of the Surgical Suite operator manual (excerpts provided below).

To prevent this issue:

1. Discontinue placing coil cables exiting toward the patient's feet.
2. Discontinue use of Mode 2.

You can continue use of Mode 1.

Coil placement on patient

Two coil segments are supplied. One coil segment is to be positioned under the anatomy (bottom) and the other segment on top of the anatomy.
Position the coil during surgical preparation, before the sterile drapes are installed. To position the coil on the patient, use the following steps.

1. Place the bottom coil segment between the patient and the skull clamp.
   - The coil can be left on during surgery or it can be re-positioned prior to imaging.
   - The bottom coil should always be placed with the coil cable exiting toward the magnet (Figure 3-51).

Figure 3-51: Base of 6-Channel Flex coil between patient and skull clamp

2. After the patient is transferred to the MR for imaging, place the second half of the coil above the patient anatomy, over the sterile drapes.
   - The top coil can be placed with the coil cable exiting toward the magnet or toward the patient's feet.

Securing coil cables
Once the coils are positioned on the patient, the coil cables must be secured within the cable clamp assemblies. The routing of the coil cables vary depending on how the top coil is

positioned on the patient. There are two possible positioning modes:

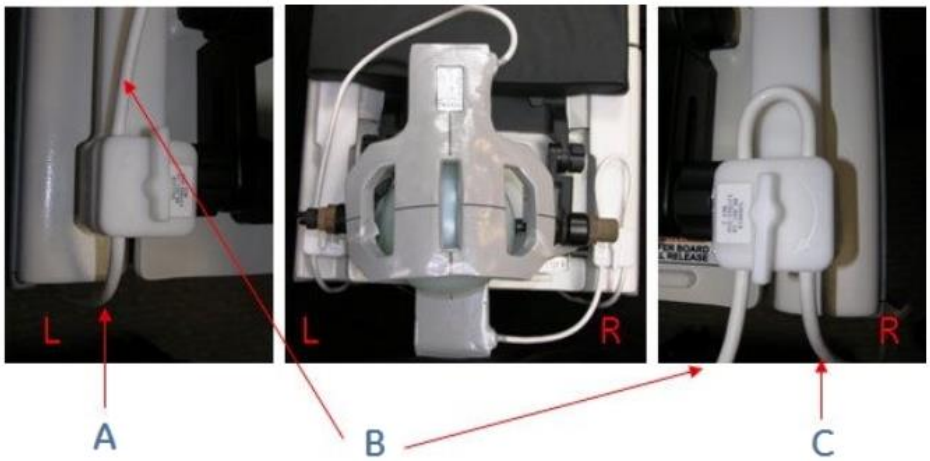
- Mode 1 – the top coil cable exits toward the magnet
- Mode 2 – the top coil cable exits toward the patient's feet

Always place the bottom coil with the coil cable exiting toward the magnet.

To secure the coil cables:

- Mode 1 – Place the coil cables into the grooves within the cable clamp as shown in Figure 3-53 and Figure 3-54. Turn the locking lever on the cable clamp ¼ turn in the direction of the arrow to lock the cables firmly in place.
- Mode 2 – Place the coil cables into the grooves within the cable clamp as shown in Figure 3-53 and Figure 3-55. Turn the locking lever on the cable clamp ¼ turn in the direction of the arrow to lock the cables firmly in place.

Figure 3-55: Mode 2 – top coil with coil cable exiting toward patient's feet: left cable to MRI (A), to coil (B), and right cable to MRI (C).



Affected Product Details	All 3.0T GE MR Systems with 3.0T GE 6-Channel Phased Array Flex Coil, M0050SS.
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 & Regulatory
GE Healthcare

[redacted]

Jeff Hersh, M.D.
Chief Medical Officer
GE Healthcare