



IMPORTANT PRODUCT INFORMATION

GE Healthcare

3000 N. Grandview Blvd. - W444
Waukesha, WI 53188, USA

<Date of Letter Deployment>

GEHC Ref# 67933

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

RE: **1.5T Express Head Neck Array Coil Surface Temperature**

Please ensure that all potential users in your facility are made aware of this notification and the recommended actions.

- Issue** GE Healthcare has become aware of a condition in the system software that could potentially lead to the 1.5T Express 16ch Head Neck Array Coil surface temperature exceeding regulatory limits, as defined by IEC60601-1, in the absence of appropriate patient padding as directed by the Operator Manual.
- Instructions** Observe existing Operator Manual instructions and warnings ensuring non-conductive padding is placed between the surface coil and the patient when using the coil configuration with the Adapter Block.
- Affected Product Details** The following products are affected, when used with the 1.5T Express 16ch Head Neck Array Coil with Adapter Block (see Figure 1 for configuration with adapter block).
- SIGNA Explorer 1.5T
 - Optima MR360 1.5T

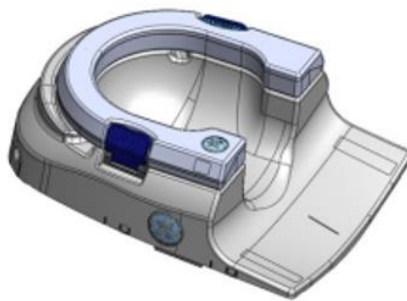


Figure 1. 1.5T Express 16ch Head Neck Array Coil configuration with adapter block

- 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.

8001243002

SaudiArabiaServiceCenter@ge.com

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,

A handwritten signature in dark blue ink, appearing to read "Laila Gurney", followed by a long horizontal flourish.

Laila Gurney
Senior Executive, Global Regulatory and Quality
GE Healthcare

A handwritten signature in dark blue ink, appearing to read "Jeff Hersh", with a stylized, overlapping structure.

Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare