

IMPORTANT PRODUCT INFORMATION

GE Healthcare

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

<Date of Letter Deployment>

GEHC Ref# 17124

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

RE: Regulatory non-conformance with certain Proteus XR/a Fixed RAD systems

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 that when using the Proteus XR/a radiographic system, the user

may not hear the tone for short exposures. This issue could result in an incorrect radiation

exposure indication display/output.

Instructions You can continue to use your Proteus XR/a system by monitoring the exposure indicator light for

short exposures to ensure the exposure occurred.

Affected Proteus XR/a fixed RAD systems (console part number 5441870) and (console spare part numbers

Product 5462233, 5462233-R, 5761170, 5462233-H) shipped from Jan 2017 to July 2019.

Details

Product GE Healthcare will correct all affected products at no cost to you. A GE Healthcare representative

Correction will contact you to arrange for the correction.

Contact If you have any questions or concerns regarding this notification, please contact GE Healthcare

Information 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,



James W. Dennison
Vice President - Quality Assurance
GE Healthcare



Jeff Hersh, PhD MD Chief Medical Officer GE Healthcare