IMPORTANT – ELECTRONIC PRODUCT RADIATION WARNING

To: GE Healthcare customer

Re: Leakage radiation from Sytec6000/8000, Lemage, ProSeed and ProSpeed families of Computed Tomography systems

During internal testing, GE Healthcare has recently determined that the collimator used on our Sytec6000/8000, Lemage, ProSeed and ProSpeed families of Computed Tomography systems does not comply with the specific requirements in United States Title 21 of the Code of Federal Regulations, and IEC 60601-1-3, related to leakage radiation from the diagnostic source assembly, which includes the collimator. Your system(s) has been identified as containing one of these collimators. Please see the attached listing of all affected product names.

The excess leakage radiation is the result of some scatter radiation, internal to the collimator, being able to exit the collimator adjacent to the collimator's aperture control mechanism. The primary beam is not affected. This leakage effect is most pronounced for the thinnest collimator aperture and almost non-existent for the widest aperture setting. For the thinnest collimator setting, this excess leakage radiation represents a small fraction of the dose a patient would normally receive without leakage at this collimation, and is within normally expected variations of dose published in your system's user manual. The incremental exposure is less than 6% at the thinnest collimation. Note that thin collimations have the smallest primary beam dose to which the leakage increment is referenced.

This excess leakage radiation also contributes to the normal scatter radiation within the exam room and would be of concern to someone standing in the exam room during a patient scan (the patient effect is discussed above). The scatter plots provided with your system's user manual were determined using conditions at the widest aperture (which result in the highest scatter values) and remain valid. Additionally, at the time of installation, or subsequently your facility may have measured the in-room scatter, which would have been correctly characterized and would have taken this effect into account. GE Healthcare has not been made aware of any customer sites with concerns regarding levels of scatter radiation.

The system is currently operating no differently than when it was originally installed at your site, at which time it was placed into your facility's radiation monitoring program. No further actions other than following the requirements of your facility's existing radiation monitoring program, are recommended by GE Healthcare. Investigation and quantification of the effects has not identified any information that necessitates the need for you to stop using your system.

Please ensure that all potential users in your facility are made aware of this notification and the information contained herein.

GE Healthcare

GE Healthcare will, without charge, repair and bring the product into compliance with the applicable Federal and International standard in accordance with a plan to be approved by the Secretary of Health and Human Services, the details of which will be included in a subsequent communication to you via our field service organization. The current plan is for affected units to be modified by means of a visit to each customer site by a GE Healthcare field service representative who will perform the corrective action. This procedure will take approximately 3 hours, and will be performed to minimize disruption, wherever possible.

Please be assured that maintaining a high level of safety and quality is our highest priority. For further information, please contact your local service manager or appropriate number below.

Sincerely,

[redacted]

[redacted]
Vice President & General Manager
Computed Tomography & Advantage Workstation

[redacted]

[redacted]
Regulatory Affairs Manager
Molecular Imaging and Computed Tomography

United States / Canada	1-800-437-1171
Latin America	Local GE Healthcare Service Representative
Australia/New Zealand	1-800-659-465
SEA	Local GE Healthcare Service Representative
China	800-810-8188
India	1-800-114567
Korea	1544-6119
Japan	0120-055-919
Europe	Local GE Healthcare Service Representative
Great Britain	[redacted] +44 (0)7825273426 Compliance Manager 352 Buckingham Avenue Slough SL1 4ER United Kingdom

Products Affected

Lemage Family
Lemage Supreme
Lemage SX
Lemage SX/E
Lemage

Sytec Family
Sytec8000
Sytec6000

ProSeed Family
ProSeed SA Libra
ProSeed
ProSeed Accell
ProSeed EF
ProSeed Accell EI

ProSpeed Family
ProSpeed Advantage
ProSpeed
ProSpeed S Fast
ProSpeed SX Power
ProSpeed SX Advantage
ProSpeed VX
ProSpeed S
ProSpeed SX
ProSpeed Plus