GE Healthcare
Healthcare Systems
3000 N. Grandview Blvd.
Waukesha, WI 53188
United States

# IMPORTANT PRODUCT INFORMATION

Date: March 12, 2010

To: Chief of Radiology, Emergency Medicine Physicians, Neurologists, Neurosurgeons, Radiologic Technologists, Medical Physicists, Radiation Safety Officers

RE: **Computed Tomography Protocols and Dose**

GE Healthcare has recently become aware of radiation overexposures during perfusion CT imaging to aid in the diagnosis and treatment of stroke. The US Food & Drug Administration issued an initial public notice on these incidents on October 8, 2009 at the following link:

http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm185898.htm

**Issue**

Over an 18-month period, 260 patients at a particular facility received radiation doses that were approximately eight times the expected level. Instead of receiving the expected dose of 0.5 Gy (maximum) to the head, these patients received between 3 and 4 Gy. In some cases, this excessive dose resulted in hair loss and erythema. Since the FDA's initial notice, at least one other US facility has publicly reported a similar incident. At that site, during an 11-month period, 10 patients received three to four times the expected dose during CT head perfusion scans.

In all cases, a non-GE (user-defined) protocol was created using CT scan acquisition parameters that were not optimized, which resulted in more radiation dose than was intended. GE Healthcare is not aware of any CT equipment malfunctions that relate to these incidents.

**Affected Product**

All GE Healthcare CT scanners.

**Instructions**

CT users are advised to review all CT protocols in use and compare them to the GE-recommended protocols that are permanently available on the scanner. In addition, users should monitor dose-related information both before and after a CT scan.

In its notice, the FDA recommended that every facility performing CT imaging:

- Review its CT protocols and be aware of the dose indices normally displayed on the control panel. These indices include the volume computed tomography dose index (abbreviated $CTDI_{vol}$, in units of "milligray" or "mGy") and the dose-length product (DLP, in units of "milligray-centimeter" or "mGy-cm").

- For each protocol selected, and before scanning the patient, carefully monitor the dose indices displayed on the control panel. To prevent accidental overexposure, make sure that the values displayed reasonably correspond to the doses normally associated with the protocol. Confirm this again after the patient has been scanned.

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.
Information on GE-provided protocols can be obtained through our Training-in-Partnership applications team at **1-800-682-5327** (USA and Canada) or from your local GE Healthcare Applications Specialist.

Thank you,

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