FDA Issues Large Recall of GE MRI Scanners

The U.S. Food and Drug Administration (FDA) has ordered a recall of thousands of MRI scanners manufactured by GE Healthcare to correct a problem that could “result in life-threatening injuries” if magnet shutdown modules are disconnected, according to an FDA notice. The FDA announced that it has ordered a class I device recall of all GE MRI scanners using superconducting magnets. The recall covers some 33 brand names of scanners and thousands of systems distributed throughout the world, manufactured from 1985 to today.

The notice describes the problem as pertaining to the systems’ magnet rundown units (MRUs), which are designed to initiate a controlled quench and turn off the magnetic field in the event of certain problems with the scanner, such as a ferromagnetic object introduced into the MRI suite. Such shutdowns are only intended for extreme emergencies and can put an MRI magnet out of commission for a week or more and cost up to $30,000 to replace lost helium. “Maintaining a high level of safety and quality is GE Healthcare’s highest priority,” said a GE spokesperson. “GE Healthcare will be deploying service engineers to address any customer concerns as quickly as possible.”

Anthem Sends Emails, Notices About Massive Data Breach

Letters are in the process of reaching 78.8 million people affected by the massive security breach, an Anthem official said recently (those who provided their email address have already received notice). The infiltration also affected many former Anthem members, dating back to 2004. It impacted affiliated plans and people in independent Blue Cross and Blue Shield plans who received care in areas serviced by Anthem.

The breach has triggered investigations by regulators. Anthem’s response to the breach has been praised by the White House and the FBI. These efforts include setting up an informational website, as well as a hotline to help consumers. “With tens of millions of people who need to be notified, we are working as quickly as possible to provide personal notification,” said Anthem Blue Cross spokesman Darrel Ng. Working with different regulators in different states along with the large scope of the attack complicated the process of notifying the people affected, he said. “In the interim, any Anthem member can already access credit monitoring and identity theft repair services.

Did You Know?

New criteria developed by the American College of Radiology for lung screening with low-dose computed tomography (LDCT) reduced the false positive rate by 75% compared with previous guidelines.

Did You Know?

Patients suffering from chronic plantar fasciitis now have a new weapon against this painful foot ailment. Researchers utilized ultrasound imaging and energy to penetrate, emulsify and remove diseased plantar fasciitis tissue.
Applying CAD Twice To DBT Improves Performance At Lower Dose

Researchers from the University of Michigan have developed a new double-barreled approach to computer-aided detection (CAD) that uses two separate CAD algorithms on digital breast tomosynthesis (DBT) exams. They believe the technique enables a high level of sensitivity with lower radiation dose. The technique applies independent CAD algorithms to analyze microcalcifications in mammography images: first to data acquired with a modified low-dose DBT protocol, and then to a planar projection image derived from the DBT data. With their approach, the researchers achieved a high level of sensitivity while cutting radiation dose in half -- to the level of a conventional full-field digital mammography exam, according to researcher Ravi Samala, PhD. "There is potential to combine these two systems to increase overall sensitivity," Samala said.

The group started with a prototype DBT system (GEN2, GE Healthcare) that was used to obtain two-view (craniocaudal and mediolateral oblique) images in 154 breasts. Images were then processed to simulate two types of DBT acquisitions, a normal protocol and a low-dose protocol. The researchers concluded that joint CAD on low-dose DBT and PPJ images provided a statistically significant improvement over a single CAD protocol at a low dose, while providing comparable performance at half the radiation dose to a dual-CAD protocol at a normal dose.

Regarding study drawbacks, Samala said that noise remains a major factor degrading microcalcification detection. More effective regularization methods need to be developed for reconstructing DBT images.

Coding and Compliance Tips by Lori Shore, CPC, RCC

CMS Makes Claims-Based PQRS Reporting More Complex

The Centers for Medicare and Medicaid Services (CMS) has increased the complexity for successfully reporting the Physician Quality Reporting System (PQRS) in 2015 to avoid a 2% reduction to Medicare reimbursements in 2017. In previous years, eligible professionals were only required to successfully report on 3 measures. In 2015 the bar has been raised to 9 measures in 3 domains. In addition, if the reporting eligible professional reports at least one face-to-face encounter, he/she must also report on a cross-cutting measure. If 9 measures do not exist for any given individual provider using claims-based reporting, the eligible professional will be subject to the Measure Applicability Validation (MAV) process. This process looks at all measures available in your reporting method to make sure that all measures that could be reported were reported successfully for 50% of Medicare Part B patients.

What are domains? Domains are basically categories by which the measures have been divided. Examples of some domains are: Effective Clinical Care, Patient Safety, Communication and Care Coordination.

What are cross-cutting measures? Cross-cutting measures are 19 measures of which any provider reporting Evaluation and Management (E/M) services must report at least one. These measures cover screening questions, medication reconciliations, immunization status and pain measurements.

Both the American College of Radiology (ACR) and CMS have suggested measures for radiology but since subspecialties exist within practices, not all measures apply across the board.