

#### Siemens' SAFIRE Iterative Reconstruction Protocol Cleared by FDA

Raw data and model-based iterative reconstruction algorithm enables CT dose reduction of up to 60%

**Malvern, Pa., November 23, 2011 – Siemens Healthcare has announced that its computed tomography (CT) iterative reconstruction algorithm SAFIRE – Sinogram Affirmed Iterative Reconstruction – has been cleared for domestic sale by the U.S. Food and Drug Administration (FDA). This new generation of image reconstruction software and hardware, developed within Siemens Healthcare's initiative Agenda 2013, allows for a robust reduction of radiation dose<sup>1</sup> in CT examinations. Additionally, the use of projection raw data during the iterative image improvement process enables a reduction of subtle image artifacts and therefore a further improvement in general image quality.**

SAFIRE helps users reduce dose by up to 60% compared to previous filtered back projection techniques, as documented in the FDA clearance letter.<sup>2</sup>

"From a clinical perspective, SAFIRE helps to significantly reduce radiation exposure across the whole portfolio of clinical applications and continues to demonstrate Siemens' commitment to deliver the best possible patient care at the lowest possible radiation dose," said Elliot Fishman, MD, CT section chief of radiology at Johns Hopkins Medical Institutions in Baltimore, and a member of the SIERRA (Siemens Radiation Reduction Alliance) dose expert panel.

SAFIRE's extremely fast reconstruction speed of 20 images per second enables reconstruction of a typical high-resolution thorax examination of 30 cm in just 15 seconds. With this as-yet-unmatched reconstruction performance, SAFIRE can be applied routinely in clinical practice. SAFIRE ties into the Siemens Healthcare global initiative Agenda 2013, which among other measures focuses on driving the development of next-generation healthcare IT.

“Siemens once again demonstrates its commitment to radiation dose reduction in computed tomography,” said Stefan Ulzheimer, PhD, Director of Global Scientific Marketing, Siemens Healthcare Computed Tomography. “Independent scientific validation of our products has always been a cornerstone of our development process. We are extremely excited that the FDA now recognizes these efforts and, to our knowledge, for the first time has allowed a quantitative dose reduction claim for an iterative reconstruction technique in the industry.”

SAFIRE completes the availability of Siemens unmatched CT dose reduction portfolio in the U.S. Over the past 38 years, Siemens pioneered many dose reduction technologies – many of which remain unique. These exclusive features include CARE kV, the first automated organ-sensitive voltage setting; CARE Child, making 70kV tube voltage available for the first time in the industry; X-CARE, organ-based dose modulation; and the SOMATOM® Definition Flash, which enables consistent imaging of the coronary arteries with a radiation dose below 1 mSv.

Unveiled last November at RSNA '10 as a work-in-progress, SAFIRE is available for Siemens SOMATOM Definition Flash and SOMATOM Definition AS CT systems and will be available on the Definition DS in mid-2012. In the meantime, Siemens' current iterative reconstruction method, IRIS (Iterative Reconstruction in Image Space), will remain available for SOMATOM Definition dual-source systems and additionally, due to the overwhelming response to IRIS in the Siemens CT install base, for SOMATOM Emotion 16 (2007) and SOMATOM Sensation 40, 64 and Open CT systems.

<sup>1</sup> Depending on the clinical task, patient size, anatomical location, and clinical practice, the use of SAFIRE can help to reduce radiation dose while maintaining pixel noise, low contrast detectability and high contrast resolution. Phantom measurements showed that high contrast resolution and pixel noise are equivalent between full dose WFBP images and reduced dose SAFIRE images. Additionally, SAFIRE can reduce spiral artifacts by using iterations going back and forth between image space and raw data space. A consultation with a radiologist and a physicist should be made to determine the appropriate dose to obtain diagnostic image quality for the particular clinical task.

<sup>2</sup> A Model Observer evaluation showed that equivalent low contrast detectability can be achieved with 54% to 60% less dose using SAFIRE at highest noise reduction strength for thin (0.6 mm) reconstruction slices in simulated body and head phantoms for low contrast objects with different contrasts.

Launched by **Siemens Healthcare Sector** in November 2011, Agenda 2013 is a two-year global initiative to further strengthen the Healthcare Sector's innovative power and competitiveness. Specific measures will be implemented in four fields of action: Innovation, Competitiveness, Regional Footprint, and People Development.

The **Siemens Healthcare Sector** is one of the world's largest suppliers to the healthcare industry and a trendsetter in medical imaging, laboratory diagnostics, medical information technology and hearing aids. Siemens offers its customers products and solutions for the entire range of patient care from a single source – from prevention and early detection to diagnosis, and on to treatment and aftercare. By optimizing clinical workflows for the most common diseases, Siemens also makes healthcare faster, better and more cost-effective. Siemens Healthcare employs some 51,000 employees worldwide and operates around the world. In fiscal year 2011 (to September 30), the Sector posted revenue of 12.5 billion euros and profit of around 1.3 billion euros. For further information please visit: [www.siemens.com/healthcare](http://www.siemens.com/healthcare).

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