GE Healthcare Announces the First U.S. FDA 510(k) Cleared Deep Learning Based CT Image Reconstruction Technology

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WAUKESHA, Wis., April 18, 2019 – GE Healthcare has received 510(k) clearance from the U.S. Food and Drug Administration of its Deep Learning Image Reconstruction engine on its new Revolution Apex CT device and as an upgrade to its Revolution CT system in the United States.

> **"We are proud to usher in the next generation of image reconstruction," said Mike Barber, President and CEO of MICT, GE Healthcare. "Our Deep Learning Image Reconstruction engine combines the ground truth image quality of filtered back projection (FBP) with the low dose capabilities of iterative reconstruction to produce TrueFidelityTM CT Images. These images offer outstanding image quality and restore noise texture to improve radiologists' confidence in diagnosing a wide range of clinical cases."**

Deep Learning Image Reconstruction (DLIR) is the next generation image reconstruction option that uses a dedicated Deep Neural Network (DNN) to generate TrueFidelity CT Images. These TrueFidelity CT Images have the potential to improve reading confidence in a wide range of clinical applications such as head, whole body and cardiovascular, for patients of all ages.

Compared to current iterative reconstruction technology, TrueFidelity CT Images can elevate every image to a powerful first impression with impressive image quality performance[1], and preferred image sharpness and noise texture[2], without compromising dose performance.

"Physicians that have reviewed our new TrueFidelity CT Images consistently say they are among the best CT images they have ever seen, and our 510(k)-reader study also demonstrated this improvement," said Scott Schubert, General Manager of Global Premium CT, GE Healthcare. "Revolution Apex delivers CT technology innovations including the Quantix™ 160 x-ray tube and Deep Learning Image Reconstruction, and we are pleased to bring these innovations as optional upgrades to our Revolution CT users as well."

The FDA also granted 510(k) clearance to three additional GE Healthcare CT applications recently introduced at RSNA 2018: Bone VCAR, Thoracic VCAR with GSI Pulmonary Perfusion, and SnapShot Freeze 2.

Both Bone VCAR and SnapShot Freeze 2 are Edison applications. Edison is a platform that helps accelerate the development and adoption of AI technology and empower providers to deliver faster, more precise care.

Bone VCAR uses a deep-learning algorithm to automatically identify and label the vertebrae for faster spine assessment and improve reporting efficiency. SnapShot Freeze 2 is an intelligent motion correction algorithm that takes cardiac imaging to the next level by expanding the breadth of intelligent motion correction applications, further enhancing clinical performance and introducing whole heart motion correction.

Thoracic VCAR with GSI Pulmonary Perfusion provides automated segmentation and measurements for assessment and follow-up of thoracic diseases. It also now includes dedicated GSI Pulmonary Perfusion, a one-click protocol to assist in the identification of variations of relative perfusion distribution in the lungs. Thoracic diseases that may be associated with changes in perfusion include pulmonary embolism or chronic obstructive pulmonary disease (COPD).

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About GE Healthcare:

GE Healthcare is the $19 billion healthcare business of GE (NYSE: GE). As a leading provider of medical imaging, monitoring, biomanufacturing, and cell and gene therapy technologies, GE Healthcare enables precision health in diagnostics, therapeutics and monitoring through intelligent devices, data analytics, applications and services. With over 100 years of experience in the healthcare industry and more than 50,000 employees globally, the company helps improve outcomes more efficiently for Follow us on Facebook, LinkedIn, Twitter and The Pulse for the latest news, or visit our website www.gehealthcare.com for more information.

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[1] Image quality comparisons between DLIR and ASiR-V, were evaluated by phantom tests of MTF, SSP, axial NPS, standard deviation of image noise, CT Number accuracy, CNR, and artefact analysis. Additionally, LCD was demonstrated in phantom testing using a model observer with the head and body MITA CT IQ Phantoms (CT191, CT189 The Phantom Laboratory). DLIR and ASiR-V reconstructions were performed using the same raw data.

[2] As demonstrated in a clinical evaluation consisting of 60 cases and 9 physicians, where each case was reconstructed with both DLIR and ASiR-V and evaluated by 3 of the physicians. In 100% of the reads, DLIR's image sharpness was rated the same as or better than ASiR -V's. In 91% of the reads, DLIR's noise texture was rated better than ASiR -V's. This rating was based on each individual reader's preference.