

Press Information

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Philips receives FDA 510(k) clearance for IQon Spectral CT

First spectral detector computed tomography (CT) provides clinicians with on-demand data analysis, enabling more confident diagnosis.

Andover, MA – Reinforcing its commitment to enabling confident diagnosis through innovation, <u>Royal Philips</u> (NYSE: PHG AEX: PHIA) today announced 510(k) clearance from the U.S. Food and Drug Administration (FDA) for its <u>IQon Spectral CT</u>, presenting an entirely new approach to spectral imaging. This first-of-its kind technology adds a new dimension to Computed Tomography (CT) imaging, delivering anatomical information and offering the ability to characterize structures based on their material content within a single scan. The enhanced image quality may help improve confidence in diagnoses and deliver operational efficiency.

Due to its accessibility, speed and accuracy, CT imaging is widely used in the diagnosis of many different diseases and injuries. The additional level of spectral information in the CT exam helps clinicians identify the composition of materials in the body for further diagnostic interrogation.

"The IQon Spectral CT represents our commitment to leading a new, higher standard for medical imaging that is driven by clinical insights and focused on the patient experience," said Gene Saragnese, CEO Imaging Systems, Philips Healthcare. "Delivering an additional level of spectral information without impacting clinician workflow is vital for confident diagnoses that can significantly add value to help improve patient care."

Philips IQon Spectral CT was developed in close collaboration with clinicians and is designed to overcome some of their most immediate challenges, including workflow and image management issues. The technology can discriminate between X-ray photons of multiple high and low energies – similar to the principal behind a prism splitting white light into the rainbow of colors. Through the Spectral CT scan, clinicians can access the conventional grey-scale anatomical images, along with the spectral information within the same scan. As a result, Philips IQon Spectral CT enables real-time, retrospective data analysis, without disrupting a clinician's workflow and takes the guesswork out of multi-energy acquisitions, making it easy to use and allowing for routine spectral use.

"Spectral imaging has the potential to change the way clinicians practice radiology in the future," said Jacob Sosna, President of the Israeli Radiology Society and Chairman of the Department of Radiology at Hadassah Hebrew University Medical Center, who collaborated with Philips on the development the product. "A recent study¹ with Philips IQon Spectral CT revealed enhanced diagnosis in up to 70 percent of cases. Using the prospective approach, we would only have access to spectral information in 20 or 25 percent, at maximum."

¹ Gabbai, M, et al. "The Clinical Impact of Retrospective Analysis in Spectral Detector Dual Energy Body CT." Radiological Society of North America 2013 Scientific Assembly and Annual Meeting, December 1 - December 6, 2013, Chicago IL. <u>http://archive.rsna.org/2013/13018312.html</u> Accessed June 24, 2014.





The IQon Spectral CT system is currently available for ordering in 36 countries. Philips will be showcasing the IQon Spectral CT at booth #6742 at the upcoming <u>Radiological Society of North</u> <u>America Annual Meeting</u> (RSNA), on November 30th through December 5th in Chicago, where visitors will be able to experience this new solution for themselves. For more information on Philips' presence at #RSNA14, visit www.philips.com/rsna and follow @PhilipsHealth.

For more information on Philips innovative imaging systems that focus on the health continuum from prevention, screening and diagnosis, to treatment, recovery and wellness, visit <u>www.philips.com/healthcare</u>.

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About Royal Philips:

Royal Philips (NYSE: PHG, AEX: PHIA) is a diversified health and well-being company, focused on improving people's lives through meaningful innovation in the areas of Healthcare, Consumer Lifestyle and Lighting. Headquartered in the Netherlands, Philips posted 2013 sales of EUR 23.3 billion and employs approximately 115,000 employees with sales and services in more than 100 countries. The company is a leader in cardiac care, acute care and home healthcare, energy efficient lighting solutions and new lighting applications, as well as male shaving and grooming and oral healthcare. News from Philips is located at www.philips.com/newscenter.