
US FDA Approves World's First Photon-Counting CT System



On September 30, the US FDA approved the Siemens Naeotom Alpha, the world's first photon-counting computed tomography (CT) scanner through the 510(k) premarket clearance pathway. 510(k) clearance establishes that a medical device is equivalent to a legally marketed predicate device. FDA and CT experts consider this a revolutionary shift in CT scanner technology.

Dr Laurel Burk, assistant director of the Diagnostic X-ray Systems Team in the FDA's Center for Devices and Radiological Health, said: 'Computed tomography is an important medical imaging tool that can aid in diagnosing disease, trauma or abnormality; planning and guiding interventional or therapeutic procedures; and monitoring the effectiveness of certain therapies,... Today's action represents the first major new technology for computed tomography imaging in nearly a decade and underscores the FDA's efforts to encourage innovation in areas of scientific and diagnostic progress.'

Current systems use detectors that measure the total energy in the many X-rays that passes through a patient's body. This two-step conversion process converts X-ray photons into visible light via a scintillator layer in the detector. Photodiode light sensors then convert visible light into a digital signal. This intermediate step causes X-ray energy information to be lost. In contrast, the approved device uses photon-counting detectors which measure each X-ray. Counting each X-ray photon provides more detailed information.

CT experts say the photon counting system includes the following benefits:

- No electric noise, which permits lower radiation dose scans.
- Smaller detector pixels improve spatial resolution.
- No down-weighting of lower energy photons, which enhances image contrast.
- Intrinsic spectral imaging is built into each scan.
- Direct digital photon detection allows photon-counting detectors to differentiate the energy of each photon to enable dual-energy, spectral imaging.

Spectral imaging allows material decomposition based on the chemical elements that make up various materials in the scan. This enables automated removal of metal blooming artefacts and clear imaging inside calcified arteries. Furthermore, multiple contrast agents can be used concurrently to image with each individual contrast or combine them for much higher soft tissue (MRI-like) resolution.

GE Healthcare, Samsung, and Philips Healthcare are developing their own versions of the technology.

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