Press release: December 16, 2019

FDA approves diffusion-weighted images for Elekta Unity, expanding options for assessment during therapy

Elekta Unity MR-Linac cleared for diffusion-weighted images to assess tumor response paving the way toward a new era of personalized radiotherapy

STOCKHOLM – Elekta (EKTA-B.ST) today announced that it has received 510(k) premarket notification from the U.S. Food and Drug Administration for the use of diffusion-weighted MR images (DWI) obtained with Elekta Unity to be interpreted by a trained physician. This expands the clinical utility of Elekta Unity to include biologic assessment of tumor response during therapy, allowing treatment adaptation based not just on gross anatomic changes but also on early biologic changes at the cellular level. Elekta Unity, the world's first high-field MR-Linac, received initial 510(k) clearance in December 2018 and CE mark in June 2018.

DWI creates a map of the diffusion of water molecules at the cellular level and can be processed to generate the apparent diffusion coefficient, or ADC. A growing body of evidence shows that ADC changes within a tumor can provide important insights into an individual's tumor response that would previously have been unavailable during radiation treatment. These insights can support further personalization of the radiation therapy regimen by allowing more tailored dose adaptation. The acquisition of DWI is critically dependent on the high quality of the 1.5 Tesla MR scanner integrated into Elekta Unity and can occur while the patient is undergoing their treatment with little or no overhead.

"One of the goals for Elekta Unity was to develop an MR-guided radiation therapy system that not only treats patients with unparalleled anatomic personalization but could also incorporate the individuals' response to their treatment.," said Richard Hausmann, President and CEO, Elekta. "This new functionality has excited early adopters of Unity. It allows us to assess biologic changes within the tumor, which may occur earlier than anatomic changes. This will improve clinicians' ability to deliver the right dose to the right part of the tumor based on this new biological marker.

As a result of this 510(k) clearance, the Indication of Use Statement for Elekta Unity has been updated to include the following language: When interpreted by a trained physician magnetic resonance images acquired before, during, and after the radiotherapy treatment yield information that can be useful in diagnosis and may assist therapy planning, patient positioning and treatment delivery related to radiation oncology.

In addition to the comprehensive MRI sequences cleared with the initial release, Elekta Unity now has the ability to generate images using the following techniques, before, during or after treatment for off-line review:

- Single-shot EPI diffusion imaging (DWI) with three diffusion directions and up to 16 b-values.
- Diffusion imaging processing with automatic generation of the ADC and/or eADC maps.

To learn more, visit elekta.com/Unity.

Elekta Unity is CE-marked and 510(k) cleared. Not available in all markets.

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About Elekta Unity
Elekta Unity combines a state-of-the-art 1.5T MRI scanner and a best-in-class 7MV linear accelerator, giving it the ability to reshape the radiation dose based on daily changes in shape, size and position of tumor and surrounding healthy anatomy. This groundbreaking technology enables accurate dose delivery with real-time visualization and characterization of the tumor so that doctors can better target cancers and minimize risk to surrounding tissue.

About Elekta
For almost five decades, Elekta has been a leader in precision radiation medicine. Our nearly 4,000 employees worldwide are committed to ensuring everyone in the world with cancer has access to – and benefits from – more precise, personalized radiotherapy treatments. Headquartered in Stockholm, Sweden, Elekta is listed on NASDAQ Stockholm Exchange.
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