Coral Gables, FL, USA | February 12th, 2024

PRESS RELEASE

ThinkQA Secondary Dose Check is FDA 510(k) Cleared for conventional and online Adaptive RadioTherapy

DOSIsoft, leading provider of patient-specific imaging and dosimetry software solutions for Radiation Oncology and Nuclear Medicine, is pleased to share that it has obtained 510(k) clearance from the US Food and Drug Administration (FDA) on January 18th, 2024, for the commercialization of ThinkQA (Edition 2) Secondary Dose Check. This advanced Patient Quality Assurance (QA) for External Beam Radiation Therapy (EBRT) tool offers reliable, automated, and 3D independent calculation-based dose verification, specifically crafted for both offline and online adaptive workflows.

This new technology breakthrough fulfils all key requirements, ensuring a streamlined workflow, safe patient treatments and compliance with AAPM recommendations – contributing significantly to the confidence of US medical physicists in the modern RT treatment modalities.

Compliant with AAPM Task Group 219 guidelines[1] to facilitate the fulfillment of QA requirements

Detecting errors before the actual radiation treatment commences is a crucial aspect of the verification process for comprehensive Patient Quality Assurance. This holds particularly true for the new adaptive radiotherapy. In order to assist physicists in meeting the QA regulatory standards for the latest radiotherapy equipment and practices, ThinkQA Secondary Dose Check incorporates in its product R&D the specific recommendations outlined in AAPM Task Group 219 Report:

- Fast, simple and automated system to be used **for each plan**
- **Fully independent** algorithm and implementation: ThinkQA Secondary Dose Check uses an advanced model-based independent 3D dose calculation engine, a specifically adapted Collapsed Cone Convolution (CCC) algorithm – is compatible with both conventional and adaptive RT workflows
- **3D dose distribution comparison** providing analysis with respect to specific automatic volumes (High dose, High gradient, Mean dose and Low dose) as well as 3D Gamma Passing Rates (GPR) for High Dose / High Gradient regions and PTVs
- **Flexibility to define tolerance limits** and action levels, such as the proposed 90% 3% - 2mm

"Speed, accuracy & simplicity" confirmed key benefits for routine TPS plan verification

CE marked and commercialized since April, 2023, the new software product has been considered as ***"an ideal solution for dose verification in the online adaptive workflow…"*** by the Hôpital Riviera-Chablais (Rennaz, Switzerland)[2], *"**Having a secondary dose calculation solution that is precise, fast and easy to use in the Elekta Unity online adaptive workflow has been extremely beneficial for department productivity and for our patients***." highlighted by Suisse clinic's physicists.

Automatically managing adapt-to-position and adapt-to-shape plans, ThinkQA Secondary Dose Check can swiftly verify, **within a few minutes**, the consistency of the TPS-calculated dose distribution with plan parameters. It confirms the plan's acceptability for each patient and each day.

(1) Reference: OI: 10.1002/mp.15069 Report of AAPM Task Group 219 on independent calculation-based dose/MU verification for IMRT Medical Physics. 2021;48:e808–e829.

(2) Based on customer testimonial in Elekta Focus Magazine, December 2023

With its user-friendly web platform and dashboard, the qualified professional users can visualize 3D dose distribution comparisons and key dosimetric indicators offered by ThinkQA Secondary Dose Check. These include whole matrix differential and cumulative DVH (Dose Volume Histograms) and Gamma Index Agreements (GAI) on automatic or target volumes. This enables the evaluation of potential dose calculation errors in the TPS plan.

Adding significant value to patient treatment safety within the U.S. adaptive radiotherapy market

FDA clearance paves the way for entry into the American market, enabling US clinics and hospitals to benefit from ThinkQA Secondary Dose Check - a valuable technological solution. This tool is designed with the flexibility to facilitate straightforward commissioning and seamless integration into diverse medical and IT environments.

Supporting multiple treatment techniques & energies (3D-CRT, IMRT, VMAT and FF & FFF beams) used in External Beam Radiation Therapy (EBRT) departments, ThinkQA Secondary Dose Check can be installed through a ready-to-use Elekta beam model template to ensure a perfect match with Elekta conventional Linacs for online and offline adaptive workflows.

Also customized for US clinics equipped with Elekta Unity MR-Linac, the solution is designed with careful consideration of the cryostat transmission and magnetic field effects on the dose. Utilizing gold standard beam model data for Elekta Unity, it provides a rapid secondary dose check outcome within the Elekta Unity planning workflow.

"*Combining **dose computation accuracy**, **relevant dose comparison metrics**, and **ergonomic web design**, ThinkQA Secondary Dose Check simplifies and automates routine TPS plan verification.*" concluded by Jean-Elie KAFROUNI, CEO in DOSIsoft Americas, *"We are confident that ThinkQA Secondary Dose Check can meet the reporting and reimbursement needs of US Radiation Oncology departments, ensure compliance in plan quality, and instill confidence in patient safety by seamlessly integrating essential Patient QA."*

About ThinkQA

ThinkQA (Edition 2) Secondary Dose Check is CE marked as a class I medical device in Europe, under the new European Medical Device Regulation (EU) 2017/745. ThinkQA (Edition 2) is FDA 510(k) cleared as class II Medical Charged-Particle Radiation Therapy System. In line with other DOSIsoft Patient-QA solutions - EPIbeam for pretreatment verification and EPIgray for in vivo dosimetry - ThinkQA Secondary Dose Check is seamlessly integrated into the Elekta ONE Smart Workflows, exclusively distributed by Elekta. For more information, visit www.elekta.com.

About DOSIsoft

Founded in 2002, DOSIsoft designs, develops & delivers patient-specific imaging & dosimetry software solutions in Radiation Oncology & Nuclear Medicine to improve cancer patient safety & treatment quality. More than 20 years of innovation and R&D investments have led to world leading software used in over 600 hospital centers in 60 countries. Spin-off between Gustave Roussy and Institut Curie, DOSIsoft constantly innovates in partnership with the major cancer institutes and research centers in the world. www.dosisoft.com

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