

DOSIsoft PLANET[®] Onco Dose receives FDA 510(k) Clearance for Molecular Imaging & Molecular Radiotherapy Dosimetry

DOSIsoft, leading provider of advanced software solutions for Radiation Oncology and Nuclear Medicine, is pleased to announce it has received on March 7th, 2019, from the US Food and Drug Administration (FDA), the 510(k) clearance to market **PLANET[®] Onco Dose** software, for its **Oncology** and **Yttrium-90 microsphere SIRT 3D Dosimetry** components.

An integrated imaging and dosimetry platform dedicated to Molecular Imaging & Molecular Radiotherapy Dosimetry

PLANET[®] Onco Dose is a comprehensive software platform dedicated to medical diagnosis aid, therapy response assessment aid, contouring for radiotherapy and internal dosimetry computation, using molecular imaging modalities.

PLANET[®] Onco Dose is a modular software suite composed of two main elements:

- **PLANET[®] Onco**: The Oncology module with core System features, comprehensive reviewing of multimodal molecular image series (CT, MRI, PET, SPECT), fusion and registration, automatic and semi-automatic contouring of regions of interest, tumor segmentation, quantification, tumoral activity monitoring, therapy response assessment;
- **PLANET[®] Dose**: The Dosimetry module including 3D personalized voxel-based internal dosimetry computation dedicated to Molecular Radiotherapy (MRT)

PLANET[®] Onco provides advanced tools to display, co-register (including deformable registration), compute Standardized Uptake Value and import / export results (contours and quantification results) to / from Treatment Planning Systems and PACS devices for assessment, treatment planning and response of patients undergoing a course of oncology treatments.

A Personalized 3D Dosimetry solution for ⁹⁰Yttrium-based Selective Internal Radiation Therapy (SIRT)

Leveraging its long-term experience, DOSIsoft has transferred its External Radiation Therapy advanced software technology to Nuclear Medicine and Molecular Radiotherapy. CE marked since March 2016, PLANET[®] Onco Dose is the first fully integrated imaging and personalized 3D dosimetry platform for radionuclide-based therapies.

PLANET[®] Onco Dose is intended to assist the user in the diagnosis, quantification and verification of radiation doses received by tissues as a result of administering permanent Yttrium-90 (90Y) microsphere implants, as well as in therapy response follow-up.

PLANET[®] Onco Dose provides tools for post-treatment absorbed dose calculation and evaluation on PET and SPECT images. The following functions are available to allow dose calculations for patients after they have received a treatment using permanent Yttrium-90 microspheres:

- 3D liver-lung shunt assessment;
- Voxel-based Dosimetry based on 90Y-microspheres-PET (or SPECT Bremsstrahlung) series;
- Dose computation models: Local Deposition Method and Voxel S Value Dose Kernel Convolution approach;
- Analysis down to any liver sub region: healthy liver, lobes, tumors, toxicity regions, ...
- Advanced and interactive dosimetry quantification (profile, dose-volume histograms, statistics, ...);
- Ability to scale to known activity;
- Compatible with PET images acquired with another radioisotope (correction of branching ratio and decay parameters).

"The current 510(k) FDA clearance of PLANET[®] Onco Dose is a great achievement and recognition of our technology and solution. We are very proud to bring this breakthrough innovation to the US medical care teams. We believe they can benefit from its full advanced functionalities in order to better and more precisely perform patient-specific 3D imaging and dosimetry for ⁹⁰Yttrium SIRT cancer therapies. As a dosimetry expert company well-established in Europe, we will be bringing more innovation to the US centers with software versions supporting other radionuclide-based therapies in the near future."
comments Jean-Elie KAFROUNI, CEO of DOSIsoft Inc.

About DOSIsoft - Founded in 2002, DOSIsoft develops cutting-edge software solutions for Radiation Oncology and Nuclear Medicine. 16 years of innovation and R&D investments have led to world leading software solutions used successfully in over 200 hospital centers in 26 countries around the world. Spin-off between Gustave Roussy and Institut Curie, DOSIsoft constantly innovates in partnership with the major cancer institutes and research centers in the world.

DOSIsoft will participate in the Annual Meeting of SNMMI from June 22nd to 25th, 2018 in Anaheim, CA, US. Come visit us at booth #423.