

OLEA MEDICAL S.A.S
93 avenue des sorbiers
ZI Athelia IV
13600 LA CIOTAT – France

FIELD SAFETY CORRECTIVE ACTION

TO :
Hospital Administrator
Vigilance Contact Person
Head of Radiology Department
Director of IT Department

La Ciotat, April 18th 2019

Reference : VIG-OM 19/01

RE : Update of Olea Sphere V3.0 IFU

This notification is intended to alert our users to the optimal usage of our Olea Sphere V3.0 software.

Given the relative novelty of SMS/multi-band type of acquisition and the lack of consensus in the current state of the art about this type of acquisition, Olea Medical inform its users that the produced images with this type of acquisition can be loaded and visualized with Olea Sphere V3.0 software, but Olea Medical do not recommend to use Olea Sphere V3.0 software to derive quantitative parameters (e.g.ADC) and let alone use these quantitative parameters to identify, delineate abnormalities and estimate volumes of interest.

Consequence

The SMS/multi-band type of acquisition could potentially lead to errors for the estimation of the quantitative parameters like ADC, this could potentially impact the interpretation of these parameters.

No incidents were reported regarding the estimation of quantitative parameters.

Corrective action implemented by Olea Medical:

Olea Medical provides you the updated user guide containing information about SMS/multi-band acquisition:

- Warning for modules **Diffusion Weighted Imaging (DWI)** and **Analysis**
- Note for modules **Diffusion Tensor Imaging (DTI)** and **IntraVoxel Incoherent Motion (IVIM)**

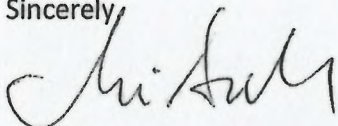
We thank you in advance for performing following actions:

- To communicate to us by return the reply slip below completed (mail or e-mail) to following addresses:
 - Oana de Clock-Mitulescu, OLEA MEDICAL S.A.S; 93 avenue des Sorbiers ; ZI Athelia IV ; 13600 LA CIOTAT – France
 - oana.declock-mitulescu@olea-medical.com
- Upon receipt of the user manual to read with attention the updated sections of the IFU regarding the modules referenced above
- To share this information with your institution Health professional users of Olea Sphere V3.0 software
- To maintain this notification in your records as Olea medical notified to concerned Competent Authorities

We remain committed in continuous improvement of our products and services to enable you to take care of your patients safely and effectively.

Feel free to contact Olea medical for any questions,

Sincerely,



Oana DE CLOCK-MITULESCU
Vigilance contact person
Quality & Regulatory Affairs Director



Reply slip

Name of the person who received the mail:

Name of the person to whom to send the user manual:

E-mail address of the person to whom the user manual should be addressed:

Date:

Signature: