SonaFuse-ProFuse\textsuperscript{FP} Software

Allows users to import segmented and annotated DICOM MRI images from the Eigen Profuse Radiology Software directly into the Sonablate\textsuperscript{®} 500 System. These images can then be fused with live transrectal ultrasound data acquired with the Sonablate\textsuperscript{®} probe. The combined modalities enable advanced HIFU planning including the concentration of ablative energy to previously annotated regions of interest. SonaFuse-ProFuse\textsuperscript{FP} software requires DICOM images exported from Profuse Radiology Fusion Software.

SonaCare Medical collaborates with leading fusion software developers to provide an integrated MRI / ultrasound image fusion treatment planning solution. SCM is working on similar packages to integrate with other fusion software packages.
**Sonablate® 500**

**Sonablate-ProFuseFP Software**
One (1) Sonablate-ProFuseFP

Uniquely created to allow the import of ProFuse segmented and annotated DICOM Radiology images directly into the Sonablate® 500 System and fuse them with live transrectal ultrasound acquired with the Sonablate® probe. The combined modalities enable advanced HIFU planning including the concentration of ablative energy to previously annotated regions of interest. Sonablate-ProFuseFP software requires DICOM images exported from Profuse Radiology Fusion Software.

**Profuse Radiology Fusion Software by Eigen**
Two (2) copies/licenses of ProFuse Radiology Software

ProFuse Radiology is a universal DICOM viewer for images generated via magnetic resonance and permits retrieval and annotation of MR images. ProFuse is especially useful for the offline annotation of regions of interest.

ProFuse Radiology is a software application to be used for 2D and 3D prostate visualization, mapping and annotation. The annotated DICOM images can be exported and used in Artemis Biopsy system and/or Sonablate-ProFuseFP.

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FOR DISTRIBUTION OUTSIDE OF THE UNITED STATES

SonaCare Medical, LLC, with its subsidiary Focus Surgery, Inc., designs and manufactures high intensity focused ultrasound (HIFU) medical devices, including the following: Sonablate® 450 which is investigational in the U.S. and being studied in a pivotal FDA clinical trial as a possible treatment for recurrent prostate cancer in patients treated previously with external beam radiation therapy; Sonablate® 500 which has CE Marking and is, or has been, approved for use to treat prostate cancer in more than 30 countries outside the U.S.; and Sonatherm® laparoscopic HIFU surgical ablation system which is 510(k) cleared in the U.S. The FDA has made no decision as to the safety or efficacy of Sonablate® 450 or 500.

In the event Sonablate® 450 is approved by the FDA for use in the U.S., there is no assurance that instructions for use or the specifications of the device will be the same for treatment approved or authorized in other countries outside of the U.S.