

The DVS[®] (Dose Verification System) is intended for use in radiation therapy to verify treatment planning and radiation dose to tissue and organs in or near the irradiated areas of a patient. The implantable DVS radiation dosimeter contains a ferrite core and is encapsulated in a hermetically sealed glass capsule. The following information is provided to healthcare professionals to determine the compatibility of the DVS radiation dosimeter with other therapies. For additional information or questions about DVS, refer to the prescribing information or contact Sixel Technologies[®], Inc.:

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Microwave mediated therapy should not be used for patients with a DVS Dosimeter.

Do not allow patients with a DVS Dosimeter to receive the following treatments: shortwave diathermy, microwave diathermy, or therapeutic ultrasound. These could result in serious injury.

In clinical studies of the DVS Dosimeter, some subjects received mammograms subsequent to completion of radiotherapy. There were no specific reports of adverse events associated with mammography. However, the dosimeter contains a glass capsule so patient monitoring during mammography is important. There were also no indications of difficulty or inability to successfully analyze mammogram images. As necessary, use digitized images and computer aided detection to increase sensitivity.

The presence of DVS Dosimeters causes MR image artifacts. If an MRI scan is required in the area in which dosimeters will be implanted, it is recommended that the scan be performed prior to dosimeter implantation. A post-implantation waiting period of 3-6 weeks is recommended to allow tissue healing to occur. If the area of interest cannot be visualized after application of clinical MR sequences that reduce artifact size, the removal of dosimeters may be required.

There are three considerations with regard to implantable devices and MR imaging: localized heating, movement due to interaction with the magnetic field, and image distortion or flare.

Non-Clinical Phantom Testing to ASTM Standards

Non-clinical 1.5 T testing has demonstrated that the DVS Dosimeter (device size: 2.1 mm diameter by 20 mm length) is MR Conditional. It can be scanned safely under the following conditions:

- Static magnetic field of 1.5 Tesla or less
- Spatial gradient field of 250 Gauss/cm or less
- Maximum whole-body-averaged specific absorption rate (SAR) of 3.5 W/kg for 15 minutes of scanning

In non-clinical testing, the DVS Dosimeter produced a temperature rise of less than 1.8°C at a maximum whole body averaged specific absorption rate (SAR) of 3.5 W/kg for 15 minutes of MR scanning in a 1.5 Tesla MR system: Symphony Siemens Medical Solutions.

Non-clinical 3.0T testing has demonstrated that the DVS Dosimeter (device size: 2.1 mm diameter by 20 mm length) is MR Conditional. It can be scanned safely under the following conditions:

- Static magnetic field of 3.0 Tesla or less
- Spatial gradient field of 400 Gauss/cm or less
- Maximum whole-body-averaged specific absorption rate (SAR) of 4.0 W/kg for 15 minutes of scanning

In non-clinical testing, the DVS Dosimeter produced a temperature rise of less than 0.1°C above the background rise at a local specific absorption rate (SAR) of 6.0 W/kg for 15 minutes of MR scanning in a 3.0 Tesla MR system: Magnetron Trio, A TIM System, Siemens Medical Solutions.

MR image quality will be compromised if the area of interest is in the exact same area or relatively close to the position of the DVS Dosimeter. Testing based on ASTM standard F2119-01 using non-clinical sequences produced artifacts (Long axis of device parallel to static field—1.5T: T1 weighted spin echo, 16.6 cm²; gradient echo, 31.1 cm²; 3.0T: T1 weighted spin echo, 21.0 cm²; gradient echo, 44.0 cm²). Therefore, it will be necessary to optimize MR imaging parameters for the presence of this metallic implant.

Clinical Applications

The presence of the DVS Dosimeter during MRI poses essentially no additional risk to the patient. MR conditions for safe scanning of patients with the dosimeter are met by operating the MR system with static field 3.0 T or less in either normal operating mode or first level controlled operating mode as defined in IEC 60601-2-33. This covers all operation of the MR system that does not require approval from a regulatory board. Optimization of clinical sequences for visualization may be required.

The following table provides guidance on the interactions of an implanted DVS Dosimeter with various imaging and therapeutic modalities:

Imaging/Therapeutic Modality	Compatible	Potential Issues	Resolution
X-Ray Photography (10-100kV)	Yes The dosimeter is radio-opaque and will appear on X-Ray images.	1. Dosimeter obstructs region of interest. 2. For fluoroscopic procedures, dosimeter will accumulate dose – reducing total dose range.	1. Use alternate X-Ray views. 2. Complete anticipated fluoroscopic procedures prior to implantation if possible.
Computed Tomography (CT)	Yes The dosimeter is radio-opaque and will appear on CT images.	The dosimeter contains metal components and can cause streak artifacts in transverse CT images.	Use metal artifact reduction (MAR) software to remove/reduce artifacts if necessary.
Mammography	Yes The dosimeter is radio-opaque and will appear on mammograms.	Dosimeter may obstruct region of interest.	Use additional views during screening, use digitized scans and computer aided detection to increase sensitivity, and/or use ultrasound.
Nuclear Imaging (PET and Bone Scan)	Yes	The dosimeter could cause some attenuation of “hot-spots” in the nuclear image.	Use artifact reduction algorithms or tomography if a region of interest is obstructed by the dosimeter.
Magnetic Resonance Imaging (MRI)	MR Conditional	The dosimeter will cause a “flare” or image artifact in the MRI image.	Perform any necessary MR imaging prior to implantation. Subsequent imaging may require removal of the DVS Dosimeters.
Ultrasound	Yes	Dosimeter obstructs region of interest.	Use additional views during screening.
Shortwave or Microwave Diathermy	No	Heating of metal may cause tissue damage and loss of functionality.	Contraindicated
Therapeutic Ultrasound	No	Heating of metal or mechanical stress may cause tissue damage and loss of functionality.	Contraindicated