Elcam MEDICAL
Where everything connects

MRI Safety of the Sense – IT™ (DIPT) Transducer

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Introduction

Magnetic resonance imaging (MRI) is widely used in hospitals for medical diagnosis, staging of disease and follow-up without exposure to ionizing radiation.

MRI is in general a safe technique but patients are reviewed for contraindications related to devices and implants that are attached to the patient prior to MRI scanning. According ASTM F2503 (recognized by the FDA) medical devices and implants are labeled as MR Safe, MR Conditional or MR Unsafe.

- MR-Safe — an item that poses no known hazards in all MRI environments. MR-Safe item is non-magnetic, non-electrically conductive, and non-RF reactive, eliminating all of the primary potential threats during an MRI procedure. An item may be determined to be MR Safe by providing a scientifically based rationale rather than test data.
- MR-Conditional — an item that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use. Field conditions that define the MR environment and additional conditions, including specific configurations of the item (e.g., the routing of cables connected to the item), may be required
- MR-Unsafe — an item that is known to pose hazards in all MRI environments. MR-Unsafe items include ferromagnetic items such as pair of scissors. The FDA suggests assuming that any object without a MR label is Unsafe.

MRI Safety of Elcam's Sense-IT™ Transducer

Elcam Medical's Disposable integrated pressure transducer (DIPT) – the **Sense-IT™ Transducer**- is the first and only fully integrated pressure transducer. This integration provides reliability and robustness no other transducer can provide, along with the space saving and ease of use so much needed in Intensive Care Units and Operating Rooms.

Non-clinical testing* conducted by a well-established US laboratory determined that the **Elcam Sense-IT™ (DIPT) Transducer is MR Conditional:** A patient with this device can be scanned safely in an MR system providing that the cable is not used** inside the bore of the MR system and not in direct contact with the patient (at least 1-cm of air or insulation) during the MR procedure.

This MR Conditional rating has been achieved under the following test conditions:
- Testing conducted under a static magnetic field of 1.5 and 3-Tesla
- Maximum spatial gradient magnetic field of 4,000-Gauss/cm (extrapolated) or less

The Image artifacts caused by the device were very small and extend approximately 20mm from the device.

Elcam further examined the MRI influence on the functionality of the Sense-IT™.

Linearity and Zero offset tests conducted before and after the MRI exposure revealed the same measurements, and it was therefore concluded that MRI exposure has no influence on the functionality of the Sense-IT™ Transducer.

For further information and documentation please contact Elcam Medical

* The testing were conducted according to ASTM standards – F2052 (Induced Displacement Force), F2119 (Evaluation of MR Image Artifacts from Passive Implants), F2182 (Induced Heating) and F2213 (Induced Torque).

** The Sense-IT™ Transducer (DIPT) should not be connected to the monitoring equipment or to the extension cable during the MRI procedure.

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