RECOMMENDED MRI LABELING BASED ON THE TEST RESULTS

MRI Safety Information

Non-clinical testing demonstrated that the WT-A543 UHF RFID Tag for Linens is MR Conditional. This device can be scanned safely under the following conditions:

- Static magnetic field of 1.5-Tesla and 3-Tesla, only
- Maximum spatial gradient magnetic field of 4,000-gauss/cm (40-T/m)(extrapolated)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the First Level Controlled Operating Mode

Under the scan conditions defined, the WT-A543 UHF RFID Tag for Linens is expected to produce a maximum temperature rise of 3.0˚C after 15-minutes of continuous scanning (i.e., per pulse sequence).

In non-clinical testing, the image artifact caused by the WT-A543 UHF RFID Tag for Linens extends approximately 2-mm from this device when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

Important Note: Because the Fujitsu WT-A543 UHF Linen Tag uses the same RFID Tag components as other families of products, which have no additional metallic or conducting materials, the findings of the MRI tests pertain to the following:
Fujitsu WT-A54x UHF RFID Linen Tag
Fujitsu WT-A53x UHF RFID Linen Tag
Fujitsu WT-A52x UHF RFID Linen Tag

Disclaimer
The recommended labeling information is provided as an example of proper labeling for this product based on the latest information from the Food and Drug Administration and the American Society for Testing and Materials (ASTM) International, Designation: F2503-13. Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. The issued labeling may be modified by the manufacturer, as needed. The manufacturer of this product is ultimately responsible and liable for damages involved in the use of the MRI-related labeling. The author or Shellock R & D Services, Inc. shall not be held liable for the product labeling or damages related to the use of this labeling.