FLOTEC

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MRI Compatibility of Flotec Aluminum and Brass Regulators

Flotec Aluminum and Brass Regulator are rated as MRI Conditional.

Magnetic attraction is a critical factor in devices rated for use in or around MRI (Magnetic Resonance Imaging) equipment. All MRI equipment have powerful magnets that are capable of pulling magnetic material violently. Multiple injuries and fatalities have been reported due to negligence in acting according to procedure. All due caution is to be taken when designing and using medical devices that are to be used in or around MRI equipment.

Flotec uses ASTM F2503-13 (Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment) to rate our devices. Flotec manufactures a number of devices that are rated ***MR Conditional.*** MR Conditional, according to ASTM F2503-13, is an item with demonstrated safety in the MR environment within defined conditions. Each relevant device is marked with the MR conditional symbol (see figure A.) with the conditions defined within the Instructions for Use.

Figure A.

Flotec devices were tested for compliance by: *Emanuel Kanal, MD, FACR, Director of MR Services, UPMC Presbyterian*

Methods:

The Flotec oxygen regulator submitted for testing was tested for deflection. The oxygen regulator was also tested for torque and artifact generation potential. All testing was performed in a GE Signa® LX 3.0T MR System. Specifications: multi-coil super conducting, actively shielded magnet housed in a 94cm bore; gradient amplitude - 40mT/m and slew rate - 150T/m/s; 8.2.5 M4 software. Using gauss line plots and visual inspection, the location of where the spatial magnetic field gradients were the greatest was determined. This location was marked by color-coded tape.

Using established guidelines*, an apparatus was constructed to hold the implants for testing. This apparatus consisted of a plastic protractor with a string to hold the implants and a plastic level glued to the top of the protractor. The protractor assembly was attached to a slide mechanism on a plastic rod that was attached to a flat piece of Plexiglas. The protractor was placed far enough away from the rod to allow for free movement of the implants. Using the scanner alignment lights, isocenter in the coronal plane was marked on the rod.

The oxygen regulator was tested with a hand held magnet prior to measurements. No gross ferromagnetic attraction was noted with the oxygen regulator when exposed to the relatively weak hand magnet, and we proceeded with the formal phase of the testing. The oxygen regulator was weighed on a top loading balance, XL-5K, Denver Instrument Company. The string used to hold the oxygen regulator was weighed using a top loading balance, XL-300, Denver Instrument Company.

All sources of forced air movement were shut off. This included the patient fan inside the bore of the magnet, as well as the gradient cooling fan. The apparatus was aligned in the direction of the main magnetic field and centered in the sagittal plane using the scanner alignment lights. The device was attached to the string and placed at isocenter in the vertical axis as determined by the MR scanner alignment lights. The protractor was leveled horizontally. A landmark was then established. The apparatus was advanced to the location of the maximum gradient change marked previously. The table location, as indicated by the LED display, was documented. After steadying the implant, with the string at 90 degrees, the device was released to move freely and the deflection angle was recorded. Three separate measurements were taken and recorded.

Torque was measured on this single device by positioning it perpendicular to the orientation of the MR scanner's magnetic field/magnetic lines of force while on a sheet of plate glass at magnet isocenter and grossly observing for any rotational realignment forces attempting to reestablish a parallel orientation.

Flow measurements were examined on the Flotec oxygen regulator, S/N 421763 model in two separate locations: 1) Location #1 just inside the magnet bore opening, and 2) Location #2 at the entrance to the magnet room (approximately 33 feet away from the magnet bore opening). Measurements were taken with an attached Sherwood MR compatible post valve (tested by our facility at 3 Tesla) in the "On", or fully opened, position. Flows were set at the oxygen flow rate control unit at the side wall of the MR scanner and measurements called off by a second individual blinded to the flow settings at the wall unit control location. Flow measurements were made using a standard flow meter positioned >10 feet from the magnet bore entry location. Of that which was set on the single oxygen regulator so tested (Flotec oxygen regulator, S/N 421763) setting

To test for possible artifacts within MR images obtained while this oxygen regulator was in use, two separate scans were performed to determine if the presence of the oxygen regulator in the magnetic field created any degradation in the MR images. The GEMS nickel doped spherical phantom, in the loader, was scanned, using gradient echo sequences with an echo time of 20 milliseconds, flip angle of 45 degrees, repetition time of 200 milliseconds, 24cm x 24cm field of view, 5mm slice thickness with a 1mm gap. This sequence was performed twice; once with the post valve/oxygen regulator located at the bore entry location and then again with these devices removed from the bore/bore entry position.

**Standard Test Method for Measurement of Magnetically Induced Displacement Force on Passive Implants in the Magnetic Resonance Environment, 6. Apparatus*

Results:

The Flotec Oxygen Regulator S/N 421763 demonstrated 21 degrees of deflection on the deflection angle test; this is below the 45- degree threshold necessary for claims of MR safety/compatibility. Torque test was grossly negative for this model/device. No significant artifacts were observed in the image with this oxygen regulator/attached post valve positioned at the magnet bore entry location. Signal to noise measurements of the phantom with the above-noted post valve still attached to the Flotec Oxygen Regulator, S/N 421763 at the bore entry location, were comparable (150.6 for the baseline and 152.6 with the devices at the bore entry location) and well within one standard deviation of noise measurements (noise measurements were 23.18 for the baseline and 22.8 with the post valve/oxygen regulator at the bore entry location). Flow rates measured at increments of <=1 l/m throughout the range of 0 to 6 l/m at both locations #1 and #2 measured consistently within roughly 0.5 l/m of that set on the wall control unit. Thus, no alteration of flow rate/function was identified or observed for this oxygen regulator S/N 421763 that appeared in any way dependent upon or modified by the presence or absence of the static magnetic field and static spatial magnetic field gradients of the 3T MR scanner.

Conclusions:

It is my opinion that the present submitted Flotec Oxygen Regulator S/N 421763 model tested does meet the criteria for both MR safety as well as MR compatibility at 3 Tesla when used up to and including at the magnet bore entry position of this system on which it has been tested.

Please note that grossly detectable Lenz's Law related forces when torqued at bore entry and even greater such detectable forces at magnet isocenter are expected and predictable for metallic objects of this mass/geometry, and should not be misconstrued as affecting present definitions of product labeling.

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