MRI Conditional Claim for 3M Radiolucent Snap Style Electrodes (2244, 2570, 2660 and 2670)

MRI labeling requirements have changed in recent years with the definition of MR Safe becoming more restrictive (ASTM F2503). 3M believes that since electrodes are conductive and can possibly pose a risk to the patient in an MR environment that an MR conditional claim is more appropriate than MR Safe. According to this new guidance MR Conditional devices can be safely scanned in a MR environment as long as the conditions on the MR environment are met.

The 3M™ Red Dot™ monitoring electrodes model numbers 2244, 2570, 2660 and 2670 have been demonstrated to be MR Conditional.

See reverse side for information needed by radiology to safely scan patients wearing the 2244, 2570, 2660 or 2670 electrodes.

It is important to note that this MR Conditional claim applies only to the electrodes and not any monitors, cables or leadwires which may be attached to the electrode.
MRI Information

MR Conditional

The (2244, 2570, 2660 or 2670) Cardiac Monitoring Electrode was determined to be MR-Conditional.

Non-clinical testing demonstrated that the (2244, 2570, 2660 or 2670) Cardiac Monitoring Electrode is MR Conditional. A patient with this device can be scanned safely immediately after placement under the following conditions:

Static Magnetic Field

- Static magnetic field of 3-Tesla or less
- Maximum spatial gradient magnetic field of 720-Gauss/cm or less

MRI-Related Heating

In non-clinical testing, the (2244, 2570, 2660 or 2670) Cardiac Monitoring Electrode produced the following temperature rise during MRI performed for 15-min of scanning (i.e., per pulse sequence) in the 3-Tesla (3-Tesla/128-MHz, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MR system: Highest temperature change +1.5°C

Therefore, the MRI-related heating experiments for the (2244, 2570, 2660 or 2670) Cardiac Monitoring Electrode at 3-Tesla using a transmit/receive RF body coil at an MR system reported whole body averaged SAR of 2.9 -W/kg (i.e., associated with a calorimetry measured whole body averaged value of 2.7-W/kg) indicated that the greatest amount of heating that occurred in association with these specific conditions was equal to or less than +1.5°C.

Artifact Information

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the (2244, 2570, 2660 or 2670) Cardiac Monitoring Electrode. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary. The maximum artifact size (i.e., as seen on the gradient echo pulse sequence) extends approximately 2-mm relative to the size and shape of the (2244, 2570, 2660 or 2670) Cardiac Monitoring Electrode.

<table>
<thead>
<tr>
<th>Pulse Sequence</th>
<th>T1-SE</th>
<th>T1-SE</th>
<th>GRE</th>
<th>GRE</th>
</tr>
</thead>
<tbody>
<tr>
<td>2244 Signal Void Size</td>
<td>1,349-mm²</td>
<td>115-mm²</td>
<td>1,634-mm²</td>
<td>246-mm²</td>
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<tr>
<td>2570 Signal Void Size</td>
<td>1,483-mm²</td>
<td>130-mm²</td>
<td>1,822-mm²</td>
<td>273-mm²</td>
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<tr>
<td>2660 Signal Void Size</td>
<td>1,103-mm²</td>
<td>103-mm²</td>
<td>1,270-mm²</td>
<td>134-mm²</td>
</tr>
<tr>
<td>2670 Signal Void Size</td>
<td>1,096-mm²</td>
<td>88-mm²</td>
<td>1,401-mm²</td>
<td>92-mm²</td>
</tr>
</tbody>
</table>

| Plane Orientation | Parallel | Perpendicular | Parallel | Perpendicular |

Important Note: This ECG Electrode that underwent MRI testing was not connected to an electrocardiograph (ECG) lead and/or an MR conditional monitoring system. Therefore, the safety of using this ECG Electrode attached to an ECG lead and/or MR conditional monitoring system is unknown. Furthermore, an MR conditional monitoring system typically requires use only with ECG electrodes specifically designed and tested with that specific equipment. It is unknown if this ECG Electrode is acceptable for use with an MR conditional ECG monitoring system designed to be used to monitor a patient undergoing an MRI procedure.