

	<p>Non-clinical testing, MRI simulations, and <i>in vivo</i> modeling demonstrated that every version of the Orthodonture Product Family is MR Conditional. A patient with the Orthodonture Product Family may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.</p>
<p>MR Conditional</p>	
<p>Parameter</p>	<p>Condition</p>
<p>Nominal Values of Static Magnetic Field (T)</p>	<p>1.5-T or 3.0-T</p>
<p>Maximum Spatial Field Gradient (T/m and gauss/cm)</p>	<p>20-T/m (2,0000-gauss/cm)</p>
<p>Type of RF Excitation</p>	<p>Circularly Polarized (CP) (i.e., quadrature-transmission)</p>
<p>Transmit RF Coil Information</p>	<p>There are no transmit RF coil restrictions.</p> <p>Accordingly, the following may be used: body transmit RF coil and all other RF coil combinations (i.e., body RF coil combined with any receive-only RF coil, transmit/receive head RF coil, transmit/receive knee RF coil, etc.)</p>
<p>Operating Mode of MR System</p>	<p>Normal Operating Mode</p>
<p>Maximum Whole Body Averaged SAR</p>	<p>2-W/kg (Normal Operating Mode)</p>
<p>Maximum Head SAR</p>	<p>3.2-W/kg (Normal Operating Mode)</p>
<p>Limits on Scan Duration</p>	<p>Whole body averaged SAR of 2-W/kg for 60 minutes of continuous RF exposure (i.e., per pulse sequence or back-to-back sequences/series without breaks)</p>
<p>MR Image Artifact</p>	<p>The presence of this device produces an imaging artifact. Therefore, carefully select pulse sequence parameters if the device is located in the area of interest.</p>