

**MR Conditional**

Non-clinical testing, MRI simulations, and *in vivo* modeling demonstrated that every version of the **Orthodonture Product Family**, is MR Conditional. A patient with the **Orthodonture Product Family** may be scanned safely in an MR system under the following conditions:

- Static magnetic field of 1.5-Tesla or 3-Tesla, only
- Maximum spatial gradient magnetic field of 2,000-Gauss/cm (20-T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode

Under the scan conditions defined, the Orthodonture Product Family is expected to produce a maximum temperature rise of 3.4 °C after 15-minutes of continuous scanning (i.e., per pulse sequence).

In non-clinical testing, the image artifact caused by the Orthodonture Product Family extends approximately 175-mm from this device when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.