

MR SAFETY INFORMATION - MR CONDITIONAL

Non-clinical testing has demonstrated that the Synergy Disc is MR Conditional. A patient with the Synergy Disc can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5-Tesla (1.5 T) or 3-Tesla (3 T).
- Maximum spatial field gradient of 5,730 G/cm (57.3 T/m).
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2W/kg (Normal operating mode) at 1.5T and 3T for a maximum scan time of 15 minutes.

Under the scan conditions defined above, Synergy Disc is expected to produce a maximum temperature rise of less than or equal to 4 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by Synergy Disc device extends approximately 1.7 cm from the Synergy Disc when imaged with a spin echo pulse sequence and a 3T MRI system.

- There are no positional requirements for safe use in the MR environment.
- There are not any restrictions on the coil type used.

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