Mona Lisa

Declaration of the Manufacturer

Mona Lisa NV
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Belgium

Non-clinical testing according to the ASTM standards has demonstrated the Mona Lisa intrauterine devices are MR conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 Tesla and 3 Tesla, with
- Maximum spatial field gradient of 12,700 G/cm (127 T/m)
- Theoretically estimated maximum whole body averaged (WBA) specific absorption rate (SAR) of < 2 W/kg (Normal Operating Mode)

Under the scan conditions defined above, the Mona Lisa intrauterine device is expected to produce a maximum temperature rise of less than:

- 1.7°C (2 W/kg, 1.5 Tesla) RF-related temperature increase with a background temperature increase of ≈ 1.4°C (2 W/kg, 1.5 Tesla)
- 1.2°C (2 W/kg, 3 Tesla) RF-related temperature increase with a background temperature increase of ≈ 0.8°C (2 W/kg, 3 Tesla)

after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 1.99 mm from the Mona Lisa intrauterine device when imaged with a gradient echo pulse sequence and a 3 Tesla MR system.

In non-clinical testing, the magnetically induced displacement force and magnetically induced torque were tested and no clinically significant displacement or torque was measured.

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