

Kind attention to:
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Villanova di San Daniele, February 21, 2020

Declaration on MRI Compatibility (Physica ZUK)

MR Test performed on LimaCorporate Physica ZUK Knee System

There are inherent risks associated with the use of metallic implants in the MR environment, including component migration, heat induction and signal interference or distortion near the component(s).

Heat induction of metallic implants is a risk related to the component geometry and material, as well as the MR power, duration and pulse sequence.

Since MR equipment is not standardized, the severity and likelihood of occurrence are unknown for these implants.

Nowadays, the Physica ZUK Knee System IFU reports that its *“components have not been evaluated for safety and compatibility in the MR environment”*.

LimaCorporate performed tests to evaluate displacement force, torque, heating and artifacts produced by the interaction between the MRI and the Physica ZUK Knee System.

Physica ZUK Knee System (typical value 30 x 70 x 80 mm) has resulted to be **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 7,200 G/cm (72 T/m)
- Maximum force product of 132 T²/m (132,000,000 G²/cm)
- 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 Physica ZUK Knee System (typical value 30 x 70 x 80 mm) is expected to produce a maximum temperature rise of less than:

- 1.6°C (2 W/kg, 1.5 Tesla) RF-related temperature increase with a background temperature increase of ≈0.8°C (2 W/kg, 1.5 Tesla)
- 3.7°C (2 W/kg, 3 Tesla) RF-related temperature increase with a background temperature increase of ≈1.4°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 53.0 mm from the Physica ZUK Knee System when imaged with a gradient echo pulse sequence and a 3 Tesla MR system.

Given the above conclusion on MRI compatibility of the Physica ZUK Knee System, the IFU of the system will be updated accordingly.

Best regards,

Roberto Gabetta
Regulatory Manager

