

Magnetic Resonance Imaging with the BONEBRIDGE BCI 601¹



The BONEBRIDGE is MR Conditional up to 1.5 Tesla. This means that the BONEBRIDGE has been tested and is approved for MRI testing up to 1.5 Tesla. All MRI testing (including tests regarding force, torque, heating, device malfunction, image artifacts and unintended output) has successfully been passed. The implant magnet does not have to be removed before the MR imaging is carried out. This is possible due to the patented BCI 601 holding magnet that is basically force/torque-neutral in the MRI.

The following conditions shall be observed:

- The audio processor shall not be worn during an MRI examination, however, it is still possible that audible interference can occur.
- An artifact of approx. 15 cm around the implant will be present on the images.
- MRI examination within magnetic fields greater than 1.5 Tesla will damage the implant and must be avoided.

Specific Data

- Non-clinical testing has demonstrated the BCI601 is MR Conditional.
- It can be scanned safely under the following conditions:
 - » static magnetic field of 1.5 Tesla or less, with
 - » spatial gradient field of 118 T/m or less
 - » spatial gradient field product of 141 T²/m or less
 - » maximum whole body averaged (WBA) specific absorption rate (SAR) of < 2.3 W/kg at 1.5 Tesla, for 15 minutes of continuous MR scanning.
- In non-clinical testing the "BONEBRIDGE hearing implant" produced a temperature rise of 2.0 °C (with a background temperature increase of ≈ 1.6 °C) at a maximum whole body averaged specific absorption rate (SAR) of ≈ 2.3 W/kg assessed by calorimetry for 15 mins. of continuous MR scanning with body coil in a 1.5 Tesla Intera, Philips Medical System (PMS) (Software: Release 12.6.1.3, 2010-12-02) MR Scanner.
- Gradient magnetic fields: stimulation level parameter PNS = 47 % (1.5 T Intera, Philips Medical Systems (PMS)) was used during RF heating tests. No tests have been performed regarding possible nerve or other tissue stimulation.
- The "BONEBRIDGE hearing implant" has not been tested in simultaneous combination with other devices.
- MR image quality is compromised. Worst-case image artifacts are expected to affect the image in a surrounding area with a radius of 15 cm measured from the geometrical center of the implant. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this implant.

- MR imaging up to 1.5 Tesla
- Force-free, patented magnet technology
- No magnet removal necessary

¹ Please note that this material is for information only. For further clarification the "Instructions For Use" for the respective BCI 601 device should be consulted.

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