

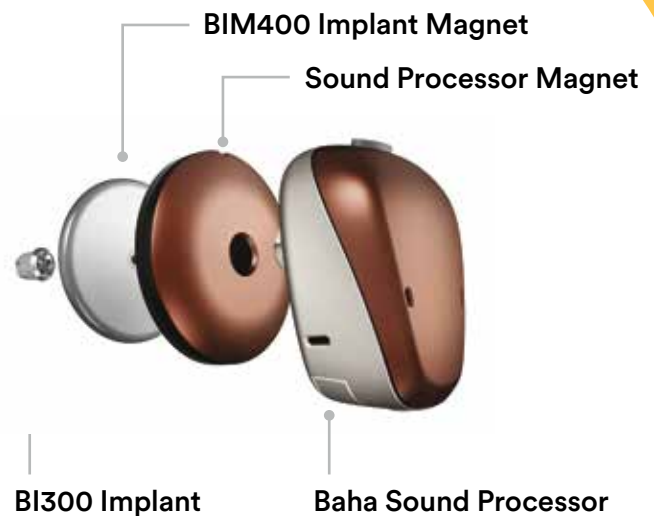

Cochlear™ Baha® Attract System

Radiographer's Instructions for MRI

The Cochlear™ Baha® Attract System is a magnetic bone conduction implant system. The system includes an osseointegrated BI300 Implant and a BIM400 Implant magnet that are implanted beneath the skin. A Baha Sound Processor and a Sound Processor (SP) Magnet are worn on the head (see Fig. 1).

These guidelines are intended for radiologists performing MRI scans on a patient with the Cochlear Baha Attract System. Please read this information carefully. **For more information, contact Cochlear.**

Figure 1



MRI Safety Information

The sound processor and Sound Processor Magnet must be removed before entering a room where an MRI scanner is located.



Non-clinical testing has demonstrated that the BIM400 Implant Magnet, in combination with a BI300 Implant, is MR Conditional.

It can be scanned safely under the following conditions. Scanning under other conditions may result in severe patient injury or device malfunction.

- Static magnetic field of 1.5 Tesla only
- Maximum spatial gradient field of 26600 Gauss/cm (266 T/m)
- Maximum switched gradient slew rate per axis of 200 mT/m/ms
- Maximum switched gradient amplitude per axis of 45 mT/m
- Maximum MR System reported whole body averaged specific absorption rate (SAR) of 2.0 W/kg (Normal Operating Mode)

Additional instructions essential to safe use in the MR environment:

Under the scan conditions defined above, the BIM400 Implant Magnet is expected to produce a maximum temperature rise of 2.1 °C after 15 minutes of continuous scanning.

In non-clinical testing, the BIM400 Implant Magnet produced a temperature rise of less than 2.1 °C (extrapolated) at a maximum whole body averaged specific absorption rate (SAR) of 2.0 W/kg (extrapolated) assessed by calorimetry for 15 minutes of MR scanning in a 1.5 Tesla Intera, Philips Medical Systems (Software: 12.6.1.3, 2010-12-02) MR Scanner.

In non-clinical gradient-induced heating testing, the BIM400 Implant Magnet produced a temperature rise (extrapolated) of less than 4.5 °C at a time rate of change of the theoretical maximum worst-case gradient magnetic field dB/dt (extrapolated) of 200 T/s during 30 min. of continuous exposure in a test laboratory system (Pulsed Magnetic Field Generator) equivalent with a gradient system of a 1.5 Tesla MR system.

Note:

MR System manufacturers may claim that scanning patients with implanted devices is generally contraindicated. This is a general precautionary claim due to the fact that MR System manufacturers are unable to ensure safety for all types of implantable devices. Cochlear has performed specific testing for the above implants and established the necessary SAR safety limits as outlined. Recently available MR Systems are able to monitor SAR levels. The MR System manufacturer should be able to provide advice on how to maintain SAR levels with their system.

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Not everyone with hearing loss is a candidate for a Baha System. All surgical procedures include an element of risk, and it is impossible to guarantee success. For complete information regarding the risks and benefits of a Baha procedure, please refer to the Instructions for use for the Baha implant available at www.Cochlear.com/US/BahaIndications

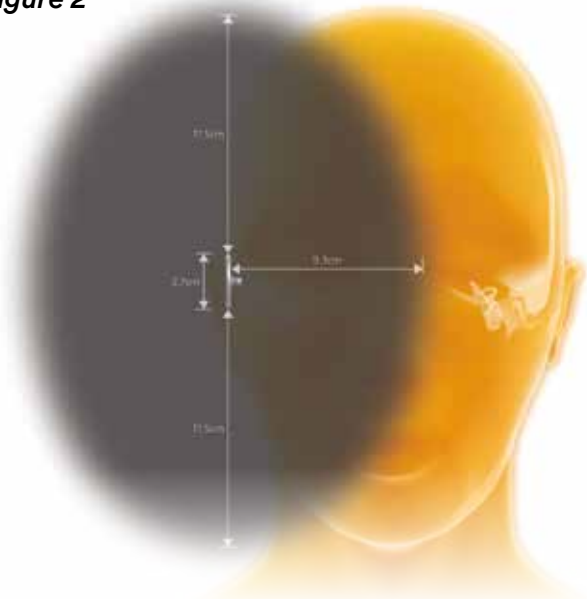
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In non-clinical testing with the implant magnet in place, the image artifact caused by the device extends approximately 11.5 cm (4.5 in.) from the BIM400 Implant Magnet when imaged with a gradient echo pulse sequence and a 1.5 Tesla MRI system (see Fig. 2). The artefact is reduced to 1.2 cm from the implant when the implant magnet is removed.

Figure 2



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