

MRI Checklist

This checklist provides practical steps to perform safe MRI examinations for patients with an Oticon Medical cochlear implant. Please refer to the 'Neuro Zti Instructions for Use', section 'MRI Safety Information' for further details.

 Prior to scanning a patient, ensure you always use the latest version available at www.oticonmedical.com/mri If the instructions herein are not followed, injury to the patient and/or damage to the implant may occur.

If the patient has an additional implant (such as a pacemaker), ensure the MRI safety guidelines for that device are followed. For further questions, please contact Oticon Medical at mri.ci@oticonmedical.com

Magnetic Resonance Imaging (MRI) safety statement

All external components of the Oticon Medical cochlear implant system (BTE, antenna, accessories...) are MR unsafe and need to be removed prior to MR imaging.	
The implanted components of the Oticon Medical cochlear implant system (Neuro Zti implants) are MR conditional.	

Before the MRI examination, check the MRI eligibility

Step 1: Check the patient's data information

Most of the information can be found on the Patient ID card, otherwise contact the ENT physician.

- Verify if the patient is unilaterally or bilaterally implanted:

- Unilateral Bilateral

- Verify the last cochlear implant surgery:

- <2 weeks 2 to 4 weeks >4 weeks

 **No MRI examination allowed.**
A minimum waiting time of 2 weeks will allow for wound swelling to reduce.

MRI may be possible. Wound break-down may occur during this period. Please consult with the ENT physician for an assessment.

MRI allowed.

- Verify the patient's model(s) of implant(s):

- Neuro Zti or Digisonic SP Other OM implants Other manufacturers

Use following steps to determine scan conditions.

Not compatible.

 Please contact the manufacturer of the other device to verify the MRI constraints.

- Step 2: Determine the static magnetic field strength needed

- 1.5 Tesla 3 Tesla

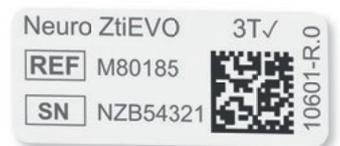
Compatible with Neuro Zti and Digisonic SP implants, subject to conditions, outlined in Step 5 and Step 6.

Unilateral implant: Ensure the 3T✓ symbol is present on the Patient ID card as shown in Figure 1.

Bilateral implant: Ensure the 3T✓ symbol is present on the Patient ID card for **both** implants as shown in Figure 1.

 All other OM implants are MRI contraindicated.

Figure 1:



 Digisonic SP not compatible with 3 Tesla.

 If the 3T✓ symbol is missing, magnet removal is required for 3 Tesla MRI examinations. If the 3T✓ symbol is present, 3 Tesla MRI examination is possible following the conditions outlined in steps 3, 5 and 6.

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If the patient is eligible for the MRI:

Step 3: Inform the patient of the potential side effects

-  Might experience pain/discomfort, localised heating or auditory sensations during the MRI scan.
-  With the Neuro Zti implant: Even if extremely unlikely, magnet dislodgement may occur and the magnet will need to be replaced.
-  Demagnetisation of the implant magnet may occur due to the static magnetic field: 2% with one and 3% with ten 3 Tesla MRI scans.

Step 4: Manage the magnet removal for the Neuro Zti implant (if required)

For patients who are not able to undergo 3 Tesla MRI (see Steps 1 and 2 above), or to reduce artefact size (see Step 7).

1. Request to order one dummy magnet (M80179) or 2 dummy magnets (bilateral patients).
2. Request to order a Neuro Zti magnet extractor (M80177) and a new magnet (M80178) or two magnets for replacement in the case of bilateral patients.
3. Schedule the pre-MRI surgery with the cochlear implant surgeon to remove the magnet*.
4. Schedule the post-MRI surgery with the cochlear implant surgeon to insert a new magnet*.

MRI examination

Step 5: Prepare the patient

- Ensure the magnet has been carefully removed – if required.
- Remove all external components before entering the MRI room.

Determine the anatomic area which requires a scan:

Head

-  Transmit head coils not allowed.

-  Correctly position the patient in the MRI scanner. For all MRI examinations which require placement of the head in the centre of the tunnel, position the patient in a supine position (Figure 2).

Body

-  • Body coil can be used in Transmit/Receive mode.
- Transmit/Receive knee coils can be used.
- Receive-only coils can be used.

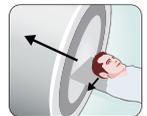


Figure 2

Step 6: Ensure the MRI machine is correctly set-up (Neuro Zti only)

MRI Field Strength	1.5 Tesla	3 Tesla
Maximum Spatial Field Gradient	20 T/m	15 T/m
Maximum switched gradient slew rate per axis	200 T/m/s	
Continuous MR scanning time	60 min	
Maximum temperature rises under conditions specified above	2.8° C	4.0° C

MRI Field Strength	Maximum average Head SAR	Maximum average Whole-Body SAR	
		Distance (in B0 axis) between top of the head and centre of MR scanner ≤ 30 cm	Distance (in B0 axis) between top of the head and centre of MR scanner > 30 cm
 1.5 Tesla	3.2 W/kg	2.0 W/kg	2.0 W/kg
3 Tesla	1.0 W/kg	0.6 W/kg	2.0 W/kg

Step 7: Perform the MRI examination (you should expect to see artefacts, for example with spin echo, as below):



After the MRI examination

Step 8: Patient follow-up

After leaving the MRI room, schedule the post-MRI surgery to replace the Neuro Zti magnet if the magnet has been removed (refer to Step 4 above). If the MRI examination was performed with the magnet(s) in place, put the sound processor on the patient's head and ensure the device and coil are correctly placed. Turn on the sound processor.

-  If the patient feels discomfort or a change in sound perception, contact the ENT physician as soon as possible.