Cochlear Implants

MED-EL

Medical Procedures

for MED-EL CI Systems

AW33290 8.0 (English US)

This manual provides important instructions and safety information for MED-EL CI System users who have to undergo a medical procedure (e.g. MRI).

The authorization of any medical procedure remains a medical decision balancing the risk of damage against the benefit provided.

As a CI user, you might have questions about undergoing further medical procedures. Your medical team may also want more information about any special considerations for implant users. This guidance provides information that will help prevent damage to your CI and injury to yourself. Please share this information with your healthcare provider.

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Interference with other equipment, robustness of the device in special medical or diagnostic environments

- Generally, remove your external components (e.g. audio processor and accessories) from your head when undergoing medical treatment where an electrical current is passed through your body, or at least carefully observe the correct functioning of your entire MED-EL Implant System during the initial stages of the treatment.
- Instruments used in electrosurgery can produce high-frequency voltages which may induce currents in the electrodes of implantable devices. Such currents may damage the implant and/or the surrounding tissue. Monopolar electrosurgical instruments must not be used in the head and neck region. If bipolar electrosurgical instruments are used, the tips of the cautery must be kept at least 5 mm away from the reference electrodes on the stimulator housing and any contacts of the active electrode.
- Any necessary ionizing radiation therapy should be carefully considered and the risk of damage to the MED-EL implant has to be carefully weighed against the medical benefit of such therapy.
- Electroshock or electroconvulsive therapy in the head and neck region must not be used. Such therapy may damage the implant and/or the surrounding tissue.
- Neurostimulation or diathermy must not be carried out in the area of the implant since it could lead to current induction at the electrodes. This may damage the implant and/or the surrounding tissue. This applies also to iontophoresis and any current inducing medical and/or cosmetic treatment.
- Diagnostic ultrasound does not cause any damage to the implant.
- Ultrasonic therapy must not be used in the area of the implant, as the implant may inadvertently concentrate the ultrasound field and cause harm.
- MED-EL Cochlear Implants are robust against 240 Gy ionizing radiation dose under 6 MV photon beam (pulsed radiation from a linear accelerator) with a field size FS = 30 cm × 30 cm, source to surface distance SSD = 100 cm, depth = 0.8 cm in a 30 cm × 30 cm × 15 cm perspex phantom. MED-EL external components need to be taken off during irradiation. Therapeutic ionizing radiation in general may damage electronic components of your MED-EL Cochlear Implant System and such damage may not be immediately detected. In order to minimize the risk of tissue necrosis due to local overdose, during radiotherapeutic treatments, the implant should not be placed in the direct radiotherapeutic beam.
- Other treatments: The effects of a number of treatments are unknown, e.g. electrical examinations in the dental area. Please contact your clinic.

Magnetic Resonance Imaging (MRI) Safety Information

	The external components of the MED-EL Cochlear Implant System (audio processor and accessories) are MR Unsafe and need to be removed prior to scanning.	
	The implant components of the MED-EL Cochlear Implant System are MR Conditional.	

Patients implanted with a MED-EL Cochlear Implant may be safely scanned with an MRI system without surgical removal of the internal magnet when adhering to the conditions for safe scanning listed below. The implant has a specially designed magnet which allows safe MRI scanning with the magnet in place, and there is no need to remove the implant magnet. The implant magnet can be surgically removed if needed to avoid imaging artifacts. The physician/MRI operator should always be informed that a patient is a MED-EL Cochlear Implant user and that the conditions for safe scanning below must be followed.

Hydrogen/proton imaging only.

Non-clinical testing has demonstrated that the MED-EL Cochlear Implants Mi1250 SYNCHRONY 2 and Mi1250 SYNCHRONY 2 PIN are MR Conditional.

A patient with any of these implants can be safely scanned in a MR system under following conditions:

- Static magnetic field of 1.5 T or 3 T
- Maximum spatial field gradient of 30 T/m (3,000 G/cm)
- For 1.5 T scans only sequences in "Normal Operating Mode" (see Table 1)
- For 3 T scans the SAR limit must not exceed the SAR values for specific anatomic regions (see Table 1)

MRI field strengths	Average head SAR	Average whole-body SAR	
		Landmark location <35 cm from the top of the head	Landmark location ≥35 cm from the top of the head
1.5 T	3.2 W/kg	2.0 W/kg	2.0 W/kg
3 T	1.6 W/kg	1.0 W/kg	2.0 W/kg

Table 1: Anatomical region and scanner strength dependent maximum Specific Absorption Rates (SAR)

For 3 T head examinations and for 3 T examinations of the body that are less than 35 cm from the top of the head, the MRI system must have the ability to set a reduced maximum specific absorption rate (SAR) or to display the estimated maximum SAR value.

For 1.5 T scans under the conditions listed above, the implant is expected to produce a maximum temperature rise of less than 2 °C during 15 minutes of continuous MR scanning.

For 3 T scans under the conditions listed above, the implant is expected to produce a maximum temperature rise of less than 3 °C during 15 minutes of continuous MR scanning.

- Before patients enter any MRI room, all external components of the implant system (audio processor and accessories) must be removed from the head. No supportive head bandage over the implant is required.
- The patient should be lying on the stretcher without inclining the head sideways (ear towards shoulder) by more than approximately ±30 degrees.
- Head transmit coils and whole-body multichannel transmit coils with more than two channels must not be used in case of a 3 T MR System.
- The implant must not be damaged mechanically, electrically or in any other way.
- In case of additional implants, e.g. a hearing implant in the other ear: MRI safety guidelines for this additional implant must be met.
- The above instructions should also be followed if areas of the body other than the head are to be examined (e.g. knee, etc.).
- For scans requiring a head coil, the head coil will maintain the correct head orientation. For scans without a head coil, appropriate padding that will prevent the head from tilting more than 30 degrees must be used.

Additional information:

- The patient should keep the head away from the scanner wall near the entrance of the scanner to reduce the likelihood of discomfort.
- Upon entry in the MRI scanner tube the patient might perceive a clicking sound.
- Testing has demonstrated that migration or magnet displacement will not occur when scanned under these conditions.
- During the scan the patient might perceive auditory sensations (temporarily) such as clicking or beeping as well as non-auditory sensations such as prickling, stinging or pain (slight). This is possible even if all protocols are followed.
  - Adequate counselling of the patient is advised prior to performing the MRI.
  - In case of well-acceptable mild sensations, the MRI can be continued.
  - The likelihood and intensity of auditory and non-auditory sensations can be reduced by selecting sequences with a lower Specific Absorption Rate (SAR) and slower gradient slew rates.
- The magnet can be surgically replaced with the Non-Magnetic Spacer to reduce image artefacts. If the magnet is not removed, image artifacts are to be expected. The artifacts extend approximately 10 cm (3.9″) in radius around the device in a Spin Echo scan (refer to Figure 1 and Figure 2).
  - Further information on magnet exchange is available within the Instruction for Use of the Magnet Replacement Kit as well as the S-Vector Magnet Replacement Kit.

– The exchange of the magnet with the Non-Magnetic Spacer and vice versa has been tested for at least five repetitions.

If the conditions for safe scanning listed above are not followed, injury to the patient and/or damage to the implant may result!

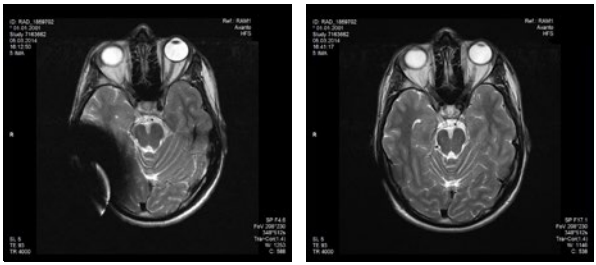

Figure 1: Image artifacts of a spin echo sequence in axial view arising in a 1.5 T scanner. The left picture shows the artifacts obtained with the implant magnet in place, whereas the right picture illustrates the image artifacts when the implant magnet is replaced with the Non-Magnetic Spacer.

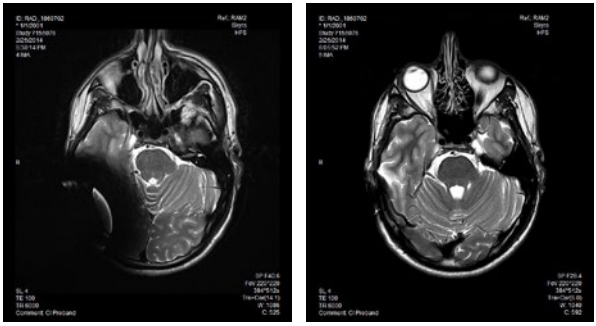

Figure 2: Image artifacts of a spin echo sequence in axial view arising in a 3 T scanner. The left picture shows the artifacts obtained with the implant magnet in place, whereas the right picture illustrates the image artifacts when the implant magnet is replaced with the Non-Magnetic Spacer.

Interference with other equipment, robustness of the device in special medical or diagnostic environments

- Generally, remove your external components (e.g. audio processor and accessories) from your head when undergoing medical treatment where an electrical current is passed through your body, or at least carefully observe the correct functioning of your entire MED-EL Implant System during the initial stages of the treatment.
- Instruments used in electrosurgery can produce high-frequency voltages which may induce currents in the electrodes of implantable devices. Such currents may damage the implant and/or the surrounding tissue. Monopolar electrosurgical instruments must not be used in the head and neck region. If bipolar electrosurgical instruments are used, the tips of the cautery must be kept at least 5 mm away from the reference electrodes on the stimulator housing and any contacts of the active electrode.
- Any necessary ionizing radiation therapy should be carefully considered and the risk of damage to the MED-EL implant has to be carefully weighed against the medical benefit of such therapy.
- Electroshock or electroconvulsive therapy in the head and neck region must not be used. Such therapy may damage the implant and/or the surrounding tissue.
- Neurostimulation or diathermy must not be carried out in the area of the implant since it could lead to current induction at the electrodes. This may damage the implant and/or the surrounding tissue. This applies also to iontophoresis and any current inducing medical and/or cosmetic treatment.
- Diagnostic ultrasound does not cause any damage to the implant.
- Ultrasonic therapy must not be used in the area of the implant, as the implant may inadvertently concentrate the ultrasound field and cause harm.
- MED-EL Cochlear Implants are robust against 240 Gy ionizing radiation dose under 6 MV photon beam (pulsed radiation from a linear accelerator) with a field size FS = 30 cm × 30 cm, source to surface distance SSD = 100 cm, depth = 0.8 cm in a 30 cm × 30 cm × 15 cm perspex phantom. MED-EL external components need to be taken off during irradiation. Therapeutic ionizing radiation in general may damage electronic components of your MED-EL Cochlear Implant System and such damage may not be immediately detected. In order to minimize the risk of tissue necrosis due to local overdose, during radiotherapeutic treatments, the implant should not be placed in the direct radiotherapeutic beam.
- Other treatments: The effects of a number of treatments are unknown, e.g. electrical examinations in the dental area. Please contact your clinic.

Magnetic Resonance Imaging (MRI) Safety Information

	The external components of the MED-EL Cochlear Implant System (audio processor and accessories) are MR Unsafe and need to be removed prior to scanning.	
	The implant components of the MED-EL Cochlear Implant System are MR Conditional.	

Patients implanted with a MED-EL Cochlear Implant may be safely scanned with an MRI system without surgical removal of the internal magnet when adhering to the conditions for safe scanning listed below. The implant has a specially designed magnet which allows safe MRI scanning with the magnet in place, and there is no need to remove the implant magnet. The implant magnet can be surgically removed if needed to avoid imaging artifacts. The physician/MRI operator should always be informed that a patient is a MED-EL Cochlear Implant user and that the conditions for safe scanning below must be followed.

Hydrogen/proton imaging only.

Non-clinical testing has demonstrated that the MED-EL Cochlear Implants Mi1200 SYNCHRONY and Mi1200 SYNCHRONY PIN are MR Conditional.

A patient with any of these implants can be safely scanned in a MR system under following conditions:

- Static magnetic field of 1.5 T or 3 T
- Maximum spatial field gradient of 30 T/m (3,000 G/cm)
- For 1.5 T scans only sequences in "Normal Operating Mode" (see Table 1)
- For 3 T scans the SAR limit must not exceed the SAR values for specific anatomic regions (see Table 1)

MRI field strengths	Average head SAR	Average whole-body SAR	
		Landmark location <35 cm from the top of the head	Landmark location ≥35 cm from the top of the head
1.5 T	3.2 W/kg	2.0 W/kg	2.0 W/kg
3 T	1.6 W/kg	1.0 W/kg	2.0 W/kg

Table 1: Anatomical region and scanner strength dependent maximum Specific Absorption Rates (SAR)

For 3 T head examinations and for 3 T examinations of the body that are less than 35 cm from the top of the head, the MRI system must have the ability to set a reduced maximum specific absorption rate (SAR) or to display the estimated maximum SAR value.

For 1.5 T scans under the conditions listed above, the implant is expected to produce a maximum temperature rise of less than 2 °C during 15 minutes of continuous MR scanning.

For 3 T scans under the conditions listed above, the implant is expected to produce a maximum temperature rise of less than 3 °C during 15 minutes of continuous MR scanning.

- Before patients enter any MRI room, all external components of the implant system (audio processor and accessories) must be removed from the head. No supportive head bandage over the implant is required.
- The patient should be lying on the stretcher without inclining the head sideways (ear towards shoulder) by more than approximately ±30 degrees.
- Head transmit coils and whole-body multichannel transmit coils with more than two channels must not be used in case of a 3 T MR System.
- The implant must not be damaged mechanically, electrically or in any other way.
- In case of additional implants, e.g. a hearing implant in the other ear: MRI safety guidelines for this additional implant must be met.
- The above instructions should also be followed if areas of the body other than the head are to be examined (e.g. knee, etc.).
- For scans requiring a head coil, the head coil will maintain the correct head orientation. For scans without a head coil, appropriate padding that will prevent the head from tilting more than 30 degrees must be used.

Additional information:

- The patient should keep the head away from the scanner wall near the entrance of the scanner to reduce the likelihood of discomfort.
- Upon entry in the MRI scanner tube the patient might perceive a clicking sound.
- Testing has demonstrated that migration or magnet displacement will not occur when scanned under these conditions.
- During the scan the patient might perceive auditory sensations (temporarily) such as clicking or beeping as well as non-auditory sensations such as prickling, stinging or pain (slight). This is possible even if all protocols are followed.
  - Adequate counselling of the patient is advised prior to performing the MRI.
  - In case of well-acceptable mild sensations, the MRI can be continued.
  - The likelihood and intensity of auditory and non-auditory sensations can be reduced by selecting sequences with a lower Specific Absorption Rate (SAR) and slower gradient slew rates.
- The magnet can be surgically replaced with the Non-Magnetic Spacer to reduce image artefacts. If the magnet is not removed, image artifacts are to be expected. The artifacts extend approximately 10 cm (3.9") in radius around the device in a Spin Echo scan (refer to Figure 1 and Figure 2).
  - Further information on magnet exchange is available within the Instruction for Use of the Magnet Replacement Kit

– The exchange of the magnet with the Non-Magnetic Spacer and vice versa has been tested for at least five repetitions.

If the conditions for safe scanning listed above are not followed, injury to the patient and/or damage to the implant may result!

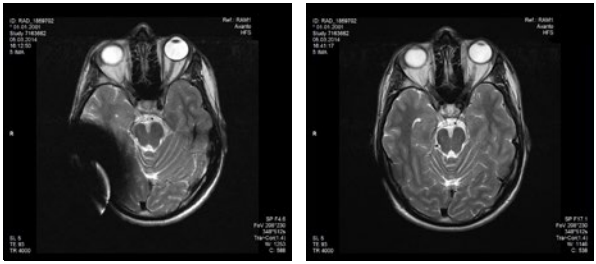

Figure 1: Image artifacts of a spin echo sequence in axial view arising in a 1.5 T scanner. The left picture shows the artifacts obtained with the implant magnet in place, whereas the right picture illustrates the image artifacts when the implant magnet is replaced with the Non-Magnetic Spacer.

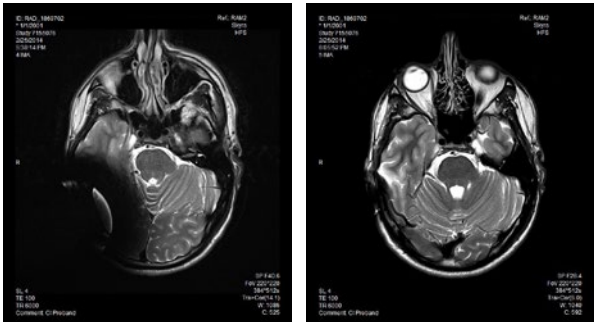

Figure 2: Image artifacts of a spin echo sequence in axial view arising in a 3 T scanner. The left picture shows the artifacts obtained with the implant magnet in place, whereas the right picture illustrates the image artifacts when the implant magnet is replaced with the Non-Magnetic Spacer.

Interference with other equipment, robustness of the device in special medical or diagnostic environments

- Generally, remove your external components (e.g. audio processor and accessories) from your head when undergoing medical treatment where an electrical current is passed through your body, or at least carefully observe the correct functioning of your entire MED-EL Implant System during the initial stages of the treatment.
- Instruments used in electrosurgery can produce high-frequency voltages which may induce currents in the electrodes of implantable devices. Such currents may damage the implant and/or the surrounding tissue. Monopolar electrosurgical instruments must not be used in the head and neck region. If bipolar electrosurgical instruments are used, the tips of the cautery must be kept at least 5 mm away from the reference electrodes on the stimulator housing and any contacts of the active electrode.
- Any necessary ionizing radiation therapy should be carefully considered and the risk of damage to the MED-EL implant has to be carefully weighed against the medical benefit of such therapy.
- Electroshock or electroconvulsive therapy in the head and neck region must not be used. Such therapy may damage the implant and/or the surrounding tissue.
- Neurostimulation or diathermy must not be carried out in the area of the implant since it could lead to current induction at the electrodes. This may damage the implant and/or the surrounding tissue. This applies also to iontophoresis and any current inducing medical and/or cosmetic treatment.
- Diagnostic ultrasound does not cause any damage to the implant.
- Ultrasonic therapy must not be used in the area of the implant, as the implant may inadvertently concentrate the ultrasound field and cause harm.
- MED-EL Cochlear Implants are robust against 240 Gy ionizing radiation dose under 6 MV photon beam (pulsed radiation from a linear accelerator) with a field size FS = 30 cm × 30 cm, source to surface distance SSD = 100 cm, depth = 0.8 cm in a 30 cm × 30 cm × 15 cm perspex phantom. MED-EL external components need to be taken off during irradiation. Therapeutic ionizing radiation in general may damage electronic components of your MED-EL Cochlear Implant System and such damage may not be immediately detected. In order to minimize the risk of tissue necrosis due to local overdose, during radiotherapeutic treatments, the implant should not be placed in the direct radiotherapeutic beam.
- Other treatments: The effects of a number of treatments are unknown, e.g. electrical examinations in the dental area. Please contact your clinic.

Magnetic Resonance Imaging (MRI) Safety Information

	The external components of the MED-EL Cochlear Implant System (audio processor and accessories) are MR Unsafe and need to be removed prior to scanning.	
	The implant components of the MED-EL Cochlear Implant System are MR Conditional.	

Hydrogen/proton imaging only.

Non-clinical testing has demonstrated that MED-EL Cochlear Implants Mi1000 MED-EL CONCERT and Mi1000 MED-EL CONCERT PIN are MR Conditional.

A patient with any of these implants can be safely scanned in a MR system under following conditions:

0.2 or 1.5 Tesla:

Conditions:
- Static magnetic field of 0.2 T or 1.5 T
- Spatial field gradient of up to 30 T/m (3,000 G/cm)
- Only sequences in Normal Operating Mode with a maximum whole-body averaged Specific Absorption Rate (SAR) of 2 W/kg and a maximum head averaged SAR of 3.2 W/kg
- Implantation performed at least 6 months ago
- **Before patients enter any MRI room, all external components of the implant system (audio processor and accessories) must be removed**
- The implant is not damaged mechanically, electrically or in any other way

Additional MRI safety information for 0.2 or 1.5 Tesla scanning:
- Large image artifacts are to be expected. The size and shape of the image artifacts depend on the MRI sequence. The artifacts extend approximately 10 cm (3.9 in.) in radius around the device in a Spin Echo scan (refer to Figure 2).
- A supportive head bandage must be placed over the implant before entering the scanner room. This may be an elastic bandage wrapped tightly around the head at least three times (refer to Figure 1). The bandage needs to fit tightly but should not cause pain.
- In 1.5 T MRI systems, the patient should be lying in the scanner in a supine, prone or side position with the head kept straight. The patient should be advised to not tilt their head to either side otherwise possible demagnetization of the implant magnet may be possible.

- During the scan (temporarily) patients might perceive auditory sensations such as clicking or beeping as well as non-auditory sensations such as prickling, stinging or pain (slight). Adequate counselling of the patient is advised prior to performing the MRI. The likelihood and intensity of auditory and non-auditory sensations can be reduced by selecting sequences with a lower Specific Absorption Rate (SAR) and slower gradient slew rates.
- In rare cases temporary pain or discomfort may occur in the implant area during MRI even if all protocols and bandaging instructions are followed.
- The above instructions should also be followed if areas of the body other than the head are to be examined (e.g. knee, etc.).
- In non-clinical testing and electromagnetic in-vivo computer simulations, the implant produced a maximum temperature rise <2 °C during 15 minutes of continuous MR scanning in the Normal Operating Mode at a maximum whole-body averaged SAR of 2.0 W/kg and a maximum head averaged SAR of 3.2 W/kg.

To reduce the likelihood and degree of patient discomfort, the patient should keep their head away from the scanner wall near the entrance of the scanner.

If the conditions for safe scanning listed above are not followed, injury to the patient and/or damage to the implant may result!

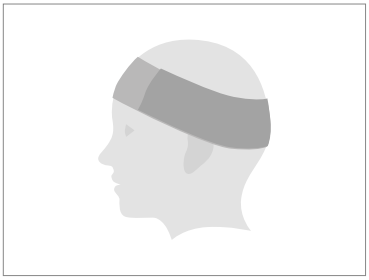

Figure 1: Head bandage to support fixation of the implant

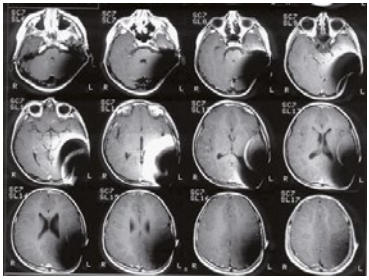

Figure 2: MR images obtained with a 1.5 T scanner (8-year-old child)

Interference with other equipment, robustness of the device in special medical or diagnostic environments

- Generally, remove your external components (e.g. audio processor and accessories) from your head when undergoing medical treatment where an electrical current is passed through your body, or at least carefully observe the correct functioning of your entire MED-EL Implant System during the initial stages of the treatment.
- Instruments used in electrosurgery can produce high-frequency voltages which may induce currents in the electrodes of implantable devices. Such currents may damage the implant and/or the surrounding tissue. Monopolar electrosurgical instruments must not be used in the head and neck region. If bipolar electrosurgical instruments are used, the tips of the cautery must be kept at least 5 mm away from the reference electrodes on the stimulator housing and any contacts of the active electrode.
- Any necessary ionizing radiation therapy should be carefully considered and the risk of damage to the MED-EL implant has to be carefully weighed against the medical benefit of such therapy.
- Electroshock or electroconvulsive therapy in the head and neck region must not be used. Such therapy may damage the implant and/or the surrounding tissue.
- Neurostimulation or diathermy must not be carried out in the area of the implant since it could lead to current induction at the electrodes. This may damage the implant and/or the surrounding tissue. This applies also to iontophoresis and any current inducing medical and/or cosmetic treatment.
- Diagnostic ultrasound does not cause any damage to the implant.
- Ultrasonic therapy must not be used in the area of the implant, as the implant may inadvertently concentrate the ultrasound field and cause harm.
- MED-EL Cochlear Implants are robust against 240 Gy ionizing radiation dose under 6 MV photon beam (pulsed radiation from a linear accelerator) with a field size FS = 30 cm × 30 cm, source to surface distance SSD = 100 cm, depth = 0.8 cm in a 30 cm × 30 cm × 15 cm perspex phantom. MED-EL external components need to be taken off during irradiation. Therapeutic ionizing radiation in general may damage electronic components of your MED-EL Cochlear Implant System and such damage may not be immediately detected. In order to minimize the risk of tissue necrosis due to local overdose, during radiotherapeutic treatments, the implant should not be placed in the direct radiotherapeutic beam.
- Other treatments: The effects of a number of treatments are unknown, e.g. electrical examinations in the dental area. Please contact your clinic.

Magnetic Resonance Imaging (MRI) Safety Information

	The external components of the MED-EL Cochlear Implant System (audio processor and accessories) are MR Unsafe and need to be removed prior to scanning.	
	The implant components of the MED-EL Cochlear Implant System are MR Conditional.	

Hydrogen/proton imaging only.

Non-clinical testing has demonstrated that MED-EL Cochlear Implant SONATA is MR Conditional.

A patient with any of these implants can be safely scanned in a MR system under following conditions:

0.2 or 1.5 Tesla:

Conditions:
- Static magnetic field of 0.2 T or 1.5 T
- Spatial field gradient of up to 30 T/m (3,000 G/cm)
- Only sequences in Normal Operating Mode with a maximum whole-body averaged Specific Absorption Rate (SAR) of 2 W/kg and a maximum head averaged SAR of 3.2 W/kg
- Implantation performed at least 6 months ago
- **Before patients enter any MRI room, all external components of the implant system (audio processor and accessories) must be removed**
- The implant is not damaged mechanically, electrically or in any other way

Additional MRI safety information for 0.2 or 1.5 Tesla scanning:
- Large image artifacts are to be expected. The size and shape of the image artifacts depend on the MRI sequence. The artifacts extend approximately 10 cm (3.9 in.) in radius around the device in a Spin Echo scan (refer to Figure 2).
- A supportive head bandage must be placed over the implant before entering the scanner room. This may be an elastic bandage wrapped tightly around the head at least three times (refer to Figure 1). The bandage needs to fit tightly but should not cause pain.
- In 1.5 T MRI systems, the patient should be lying in the scanner in a supine, prone or side position with the head kept straight. The patient should be advised to not tilt their head to either side otherwise possible demagnetization of the implant magnet may be possible.

- During the scan (temporarily) patients might perceive auditory sensations such as clicking or beeping as well as non-auditory sensations such as prickling, stinging or pain (slight). Adequate counselling of the patient is advised prior to performing the MRI. The likelihood and intensity of auditory and non-auditory sensations can be reduced by selecting sequences with a lower Specific Absorption Rate (SAR) and slower gradient slew rates.
- In rare cases temporary pain or discomfort may occur in the implant area during MRI even if all protocols and bandaging instructions are followed.
- The above instructions should also be followed if areas of the body other than the head are to be examined (e.g. knee, etc.).
- In non-clinical testing and electromagnetic in-vivo computer simulations, the implant produced a maximum temperature rise <2 °C during 15 minutes of continuous MR scanning in the Normal Operating Mode at a maximum whole-body averaged SAR of 2.0 W/kg and a maximum head averaged SAR of 3.2 W/kg.

To reduce the likelihood and degree of patient discomfort, the patient should keep their head away from the scanner wall near the entrance of the scanner.

If the conditions for safe scanning listed above are not followed, injury to the patient and/or damage to the implant may result!

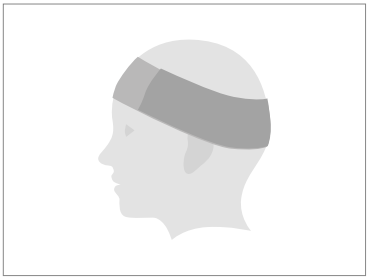

Figure 1: Head bandage to support fixation of the implant

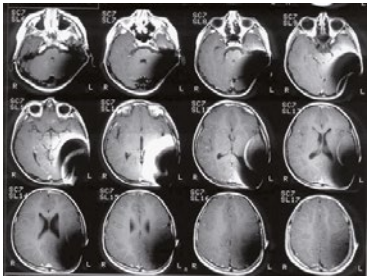

Figure 2: MR images obtained with a 1.5 T scanner (8-year-old child)

Interference with other equipment, robustness of the device in special medical or diagnostic environments

- Generally, remove your external components (e.g. audio processor and accessories) from your head when undergoing medical treatment where an electrical current is passed through your body, or at least carefully observe the correct functioning of your entire MED-EL Implant System during the initial stages of the treatment.
- Instruments used in electrosurgery can produce high-frequency voltages which may induce currents in the electrodes of implantable devices. Such currents may damage the implant and/or the surrounding tissue. Monopolar electrosurgical instruments must not be used in the head and neck region. If bipolar electrosurgical instruments must be used, the tips of the cautery must be kept at least 3 cm away from the stimulator and all areas of the electrodes.
- Any necessary ionizing radiation therapy should be carefully considered and the risk of damage to the MED-EL implant has to be carefully weighed against the medical benefit of such therapy.
- Electroshock or electroconvulsive therapy in the head and neck region must not be used. Such therapy may damage the implant and/or the surrounding tissue.
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- Other treatments: The effects of a number of treatments are unknown, e.g. electrical examinations in the dental area. Please contact your clinic.

Magnetic Resonance Imaging (MRI) Safety Information

	The external components of the MED-EL Cochlear Implant System (audio processor and accessories) are MR Unsafe and need to be removed prior to scanning.	
	The implant components of the MED-EL Cochlear Implant System are MR Conditional.	

Hydrogen/proton imaging only.

Non-clinical testing has demonstrated that MED-EL Cochlear Implant PULSAR is MR Conditional.

A patient with any of these implants can be safely scanned in a MR system under following conditions:

0.2 or 1.5 Tesla:

Conditions:

- **Bone thickness underneath the implant magnet of at least 0.4 mm. Bone thickness must be determined using CT images.**
- Static magnetic field of 0.2 T or 1.5 T
- Spatial field gradient of up to 30 T/m (3,000 G/cm)
- Only sequences in Normal Operating Mode with a maximum whole-body averaged Specific Absorption Rate (SAR) of 2 W/kg and a maximum head averaged SAR of 3.2 W/kg
- Implantation performed at least 6 months ago
- **Before patients enter any MRI room, all external components of the implant system (audio processor and accessories) must be removed**
- The implant is not damaged mechanically, electrically or in any other way

Additional MRI safety information for 0.2 or 1.5 Tesla scanning:

- Large image artifacts are to be expected. The size and shape of the image artifacts depend on the MRI sequence. The artifacts extend approximately 10 cm (3.9 in.) in radius around the device in a Spin Echo scan (refer to Figure 2).
- A supportive head bandage must be placed over the implant before entering the scanner room. This may be an elastic bandage wrapped tightly around the head at least three times (refer to Figure 1). The bandage needs to fit tightly but should not cause pain.

- In 1.5 T MRI systems, the patient should be lying in the scanner in a supine, prone or side position with the head kept straight. The patient should be advised to not tilt their head to either side otherwise possible demagnetization of the implant magnet may be possible.
- During the scan (temporarily) patients might perceive auditory sensations such as clicking or beeping as well as non-auditory sensations such as prickling, stinging or pain (slight). Adequate counselling of the patient is advised prior to performing the MRI. The likelihood and intensity of auditory and non-auditory sensations can be reduced by selecting sequences with a lower Specific Absorption Rate (SAR) and slower gradient slew rates.
- In rare cases temporary pain or discomfort may occur in the implant area during MRI even if all protocols and bandaging instructions are followed.
- The above instructions should also be followed if areas of the body other than the head are to be examined (e.g. knee, etc.).
- In non-clinical testing and electromagnetic in-vivo computer simulations, the implant produced a maximum temperature rise <2 °C during 15 minutes of continuous MR scanning in the Normal Operating Mode at a maximum whole-body averaged SAR of 2.0 W/kg and a maximum head averaged SAR of 3.2 W/kg.

To reduce the likelihood and degree of patient discomfort, the patient should keep their head away from the scanner wall near the entrance of the scanner.

If the conditions for safe scanning listed above are not followed, injury to the patient and/or damage to the implant may result!

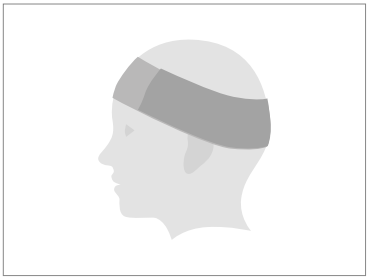

Figure 1: Head bandage to support fixation of the implant

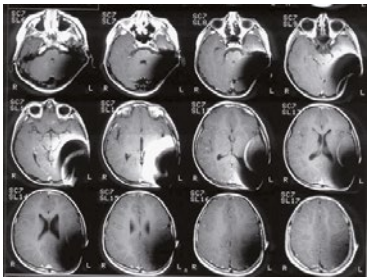

Figure 2: MR images obtained with a 1.5 T scanner (8-year-old child)

Interference with other equipment, robustness of the device in special medical or diagnostic environments

- Generally, remove your external components (e.g. audio processor and accessories) from your head when undergoing medical treatment where an electrical current is passed through your body, or at least carefully observe the correct functioning of your entire MED-EL Implant System during the initial stages of the treatment.
- Instruments used in electrosurgery can produce high-frequency voltages which may induce currents in the electrodes of implantable devices. Such currents may damage the implant and/or the surrounding tissue. Monopolar electrosurgical instruments must not be used in the head and neck region. If bipolar electrosurgical instruments must be used, the tips of the cautery must be kept at least 3 cm away from the stimulator and all areas of the electrodes.
- Any necessary ionizing radiation therapy should be carefully considered and the risk of damage to the MED-EL implant has to be carefully weighed against the medical benefit of such therapy.
- Electroshock or electroconvulsive therapy in the head and neck region must not be used. Such therapy may damage the implant and/or the surrounding tissue.
- Neurostimulation or diathermy must not be carried out in the area of the implant since it could lead to current induction at the electrodes. This may damage the implant and/or the surrounding tissue. This applies also to iontophoresis and any current inducing medical and/or cosmetic treatment.
- Diagnostic ultrasound does not cause any damage to the implant.
- Ultrasonic therapy must not be used in the area of the implant, as the implant may inadvertently concentrate the ultrasound field and cause harm.
- MED-EL Cochlear Implants are robust against 240 Gy ionizing radiation dose under 6 MV photon beam (pulsed radiation from a linear accelerator) with a field size FS = 30 cm × 30 cm, source to surface distance SSD = 100 cm, depth = 0.8 cm in a 30 cm × 30 cm × 15 cm perspex phantom. MED-EL external components need to be taken off during irradiation. Therapeutic ionizing radiation in general may damage electronic components of your MED-EL Cochlear Implant System and such damage may not be immediately detected. In order to minimize the risk of tissue necrosis due to local overdose, during radiotherapeutic treatments, the implant should not be placed in the direct radiotherapeutic beam.
- Other treatments: The effects of a number of treatments are unknown, e.g. electrical examinations in the dental area. Please contact your clinic.

Magnetic Resonance Imaging (MRI) Safety Information

	The external components of the MED-EL Cochlear Implant System (audio processor and accessories) are MR Unsafe and need to be removed prior to scanning.	
	The implant components of the MED-EL Cochlear Implant System are MR Conditional.	

Hydrogen/proton imaging only.

Non-clinical testing has demonstrated that MED-EL Cochlear Implant C40+ is MR Conditional.

A patient with any of these implants can be safely scanned in a MR system under following conditions:

0.2 or 1.5 Tesla:

Conditions:

- **Bone thickness underneath the implant magnet of at least 0.4 mm. Bone thickness must be determined using CT images.**
- Static magnetic field of 0.2 T or 1.5 T
- Spatial field gradient of up to 30 T/m (3,000 G/cm)
- Only sequences in Normal Operating Mode with a maximum whole-body averaged Specific Absorption Rate (SAR) of 2 W/kg and a maximum head averaged SAR of 3.2 W/kg
- Implantation performed at least 6 months ago
- **Before patients enter any MRI room, all external components of the implant system (audio processor and accessories) must be removed**
- The implant is not damaged mechanically, electrically or in any other way

Additional MRI safety information for 0.2 or 1.5 Tesla scanning:

- Large image artifacts are to be expected. The size and shape of the image artifacts depend on the MRI sequence. The artifacts extend approximately 10 cm (3.9 in.) in radius around the device in a Spin Echo scan (refer to Figure 2).
- A supportive head bandage must be placed over the implant before entering the scanner room. This may be an elastic bandage wrapped tightly around the head at least three times (refer to Figure 1). The bandage needs to fit tightly but should not cause pain.

- In 1.5 T MRI systems, the patient should be lying in the scanner in a supine, prone or side position with the head kept straight. The patient should be advised to not tilt their head to either side otherwise possible demagnetization of the implant magnet may be possible.
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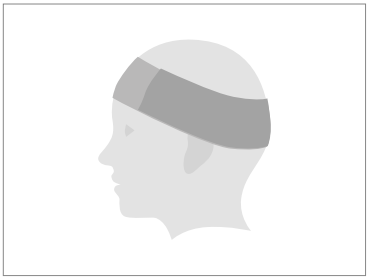

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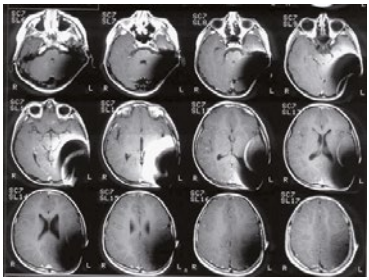

Figure 2: MR images obtained with a 1.5 T scanner (8-year-old child)

Symbols

MR Conditional

MR Unsafe

Manufacturer

Prescription only (USA)

Help & Contact

Please visit us at http://www.medel.com/us/isi-cochlear-implant-systems/

Help and assistance are always available from your local office.

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