Cochlear Implants

MED EL

OPUS 2

User Manual

AW5473_5.0 (English US)

1. Table of Contents

2. Introduction

This user manual provides information and instructions regarding the MAESTRO Cochlear Implant System with the OPUS 2 audio processor. It includes descriptions of available parts, wearing configurations, and accessories for the OPUS 2, as well as instructions for troubleshooting and proper care of the external cochlear implant equipment.

Your MED-EL Cochlear Implant System consists of the Mi1000 MED-EL CONCERT (hereafter referred to as MED-EL CONCERT), PULSARCI^{100}, SONATATI^{100} or C40+ implants, the external OPUS 2 audio processor (including FineTuner), the D Coil or the COMT+/COMT+ P coil, the external components and accessories, and any external hardware and software used by your audiologist.

We recommend that you read this manual in its entirety.

Information particularly relevant for parents of implanted children is added, wherever necessary, in this font and with this symbol.

The adjustment to a cochlear implant and adequate fitting of the device are gradual processes that occur over time. It is important to remember that your ability to hear with your new MAESTRO Cochlear Implant System may take a little time while you become accustomed to this new method of hearing.

The audio processor can be activated for the first time after the surgical incision has completely healed and any remaining swelling has gone away. The implant cannot provide any sound information until the audio processor has been programmed by your audiologist, turned on, and the coil placed on the head over the implant.

After your initial fitting, you will need to return to your CI center on a regular basis for reprogramming. Frequent reprogramming may be required during the first year of implant use. This is normal and necessary, and it reflects a learning process that occurs as you become more and more accustomed to stimulation through the implant. As more time passes, you will likely find that you may require fewer and fewer sessions. Most patients continue to need occasional adjustments for as long as they use their implant.

Please contact your CI center or MED-EL with any additional questions you may have.

3. Intended use – Indications – Contra-Indications

INTENDED USE

The OPUS 2 audio processor is part of the MAESTRO Cochlear Implant System. The MAESTRO Cochlear Implant System is intended to evoke auditory sensation via electrical stimulation of the auditory pathways for severely to profoundly hearing impaired individuals who obtain little or no benefit from acoustic amplification in the best aided condition.

INDICATIONS

The OPUS 2 audio processor is an external component of the MAESTRO Cochlear Implant System and is indicated for use on patients who have been implanted with MED-EL CONCERT, PULSARCI^{100}, SONATATI^{100} or C40+ cochlear implants. The MAESTRO Cochlear Implant System is indicated for:

- Adults eighteen (18) years of age or older who have bilateral, sensorineural hearing impairment and obtain limited benefit from appropriately fitted binaural hearing aids. These individuals typically demonstrate bilateral severe to profound sensorineural hearing loss determined by a pure tone average of 70 dB or greater at 500 Hz, 1000 Hz, and 2000 Hz. Limited benefit from amplification is defined by test scores of 40% correct or less in best aided listening condition on CD recorded tests of open-set sentence recognition (Hearing In Noise Test [HINT] sentences).
- Children aged twelve (12) months to seventeen (17) years eleven (11) months must demonstrate a profound, bilateral sensorineural hearing loss with thresholds of 90 dB or greater at 1000 Hz. In younger children, little or no benefit is defined by lack of progress in the development of simple auditory skills in conjunction with appropriate amplification and participation in intensive aural habilitation over a three (3) to six (6) month period. In older children, lack of aid benefit is defined as < 20% correct on the Multi-syllabic Lexical Neighbourhood Test (MLNT) or Lexical Neighbourhood Test (LNT), depending upon the child's cognitive ability and linguistic skills. A three (3) to six (6) month hearing aid trial is required for children without previous experience with hearing aids. Radiological evidence of cochlear ossification may justify a shorter trial with amplification.

As the OPUS 2 is a component of the MAESTRO Cochlear Implant System, all indications stated for the Cochlear Implant System are applicable.

To obtain optimal benefit from the cochlear implant, candidates shall be sufficiently motivated and shall understand the importance of returning to the CI center for regular audio processor programming, assessment sessions and training.

CONTRA-INDICATIONS

A patient must not receive an OPUS 2 audio processor if the individual is known to be intolerant of the materials used in the OPUS 2 control unit, battery pack, earhook, FM Battery Pack Cover or FineTuner. For details please refer to Chapter 10, Technical data.

As the OPUS 2 is a component of the MAESTRO Cochlear Implant System, all contra-indications stated for the Cochlear Implant System are applicable.

The FineTuner is not intended to be used in environments where RF transmissions are prohibited.

NOTE:
Indications/contra-indications for the Cochlear Implant System are shipped to your clinic together with the implant. If you want to review this document, please contact MED-EL.

4. Getting started

THE PARTS OF THE SYSTEM

The MAESTRO Cochlear Implant System is an active medical device that has internal (implanted) and external parts. The internal part of the device is surgically implanted behind the ear in the skull, while the external components are worn behind the ear or on the body.

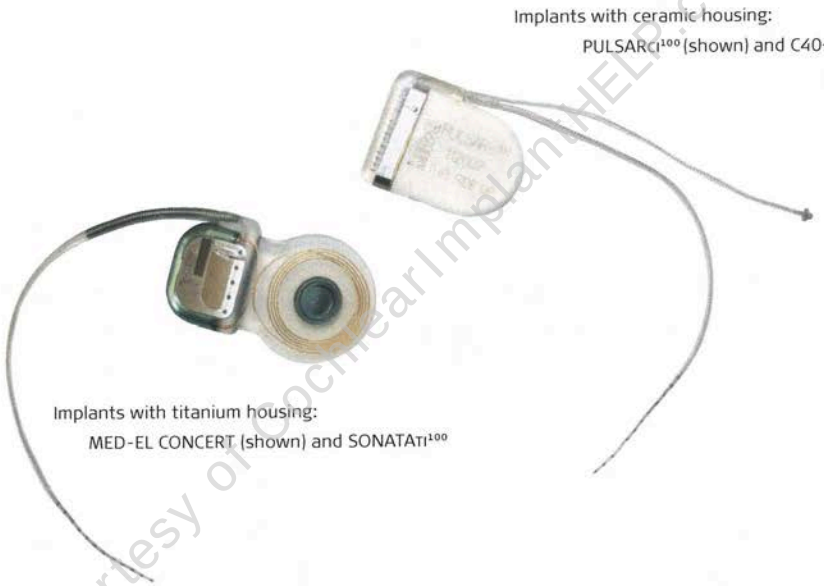


Fig. 1 The MED-EL cochlear implants

The external parts include the OPUS 2 audio processor and the audio processor accessories. In its basic configuration, the OPUS 2 audio processor consists of the control unit with the earhook attached, the battery pack frame and cover, the connecting piece, the coil and the coil cable. A device called a FineTuner facilitates access to various audio processor functions.

The coil is held in place by magnetic attraction to the implant.

The audio processor uses batteries that provide sufficient power for both the external and the implanted electronics. The implanted part does not contain batteries.

Fig. 2 Your OPUS 2 audio processor

5. OPUS 2 audio processor

CONTROL UNIT

Switching your processor ON and OFF

The battery pack lock functions as an ON/OFF switch.

You may select the following positions:
Battery pack lock open: OFF
Battery pack lock closed: ON

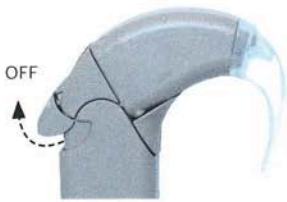


Fig. 3 The OPUS 2 audio processor in position OFF

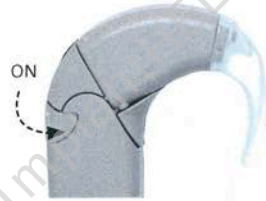


Fig. 4 The OPUS 2 audio processor in position ON

After switching on the OPUS 2 audio processor, the red indicator light in the earhook will blink up to four times indicating the activated program (i.e. number of blink signals corresponds to the number of activated program). During this time the audio processor is already working.

In position OFF, the audio processor is turned off. No current is drawn in this position. Make sure to open the battery pack lock of your audio processor when not in use, as this prolongs the lifetime of the batteries (see also Chapter 8, Care and maintenance).

The OPUS 2 audio processor has an integrated telephone coil (telecoil). The telecoil picks up magnetic sound signals coming from telephone receivers or loop systems, which are installed in some public buildings, and converts them into electrical signals. When you switch on the audio processor, the microphone is active even if you had the telecoil selected before you switched off the audio processor. When the telecoil is active, you may hear buzzing sounds when operating a FineTuner key. The buzzing is normal and indicates that a command is being sent. To reduce interference with various electronic and electrical equipment when the telecoil is active, we recommend you reduce audio sensitivity (see Chapter 5, OPUS 2 audio processor, FineTuner, FineTuner controls).

FINETUNER

Your audiologist will program your OPUS 2 audio processor to your needs. The FineTuner is an accessory device to help you optimally use your audio processor in changing daily listening situations.

Your OPUS 2 audio processor has only an ON/OFF switch, all other functions are accessed with a separate device, the FineTuner, which transmits commands to your OPUS 2 audio processor via a radio frequency (RF) link. Its ergonomic design and larger size keys facilitate changing the settings of your OPUS 2 audio processor.

Keeping the FineTuner out of the reach of children prevents them from inadvertently changing the settings of their OPUS 2.

The FineTuner is not necessary for the function of your audio processor. When switched on, the OPUS 2 audio processor activates the same program, volume and audio sensitivity setting it had when it was switched off.

The FineTuner is configured for its designated target OPUS 2 audio processor, i.e. only the target OPUS 2 audio processor will execute the desired command when a certain key is pressed on the FineTuner. The typical maximum operating distance between the FineTuner and the OPUS 2 audio processor is approximately 80 cm (2.62 ft.). This range could be decreased close to electronic and electrical equipment even if this equipment complies with all applicable electromagnetic emission requirements.

How to configure your FineTuner

The FineTuner is configured for your audio processor and cannot be used by another cochlear implant user. Your audiologist or clinical staff will configure the FineTuner to your needs. Sometimes it may be necessary that you synchronize your FineTuner and audio processor (e.g. if you purchase a backup FineTuner). Switch off your OPUS 2 audio processor and place the coil of the OPUS 2 audio processor system on the keyboard of the FineTuner (approximately over key MT). Then switch on your OPUS 2 audio processor. The audio processor and the FineTuner will be synchronized automatically. Successful synchronization is indicated by a short blinking signal of the two amber indicator lights on your FineTuner.

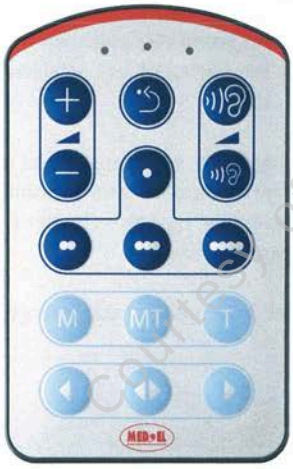
For bilaterally implanted users

If you want to use your FineTuner for both audio processor systems, your audiologist or clinical engineer has received the MAESTRO software manual with detailed programming information and will assign two audio processors to your dataset. Once your OPUS 2 audio processors are programmed correctly, the synchronization procedure described above should be performed with both audio processors.

FineTuner controls

The keyboard has 15 keys (see Fig. 5)

- Volume keys: Two keys to increase ⊕ or decrease ⊖ overall loudness. Loudness is increased or decreased continuously.
- Sensitivity keys: Two keys to increase or decrease the audio sensitivity. Audio sensitivity is increased or decreased continuously.
- Default key: This key sets overall volume and audio sensitivity to predefined values determined by your audiologist or clinical staff.
- Program Selection keys: Four keys to access four different programs.
- Input Selection keys: Three keys to select the microphone M, the telecoil T or the microphone and the telecoil (mix) MT as the signal source.
- Processor Selection keys (for bilateral patients only): The Processor Selection keys allow selecting the left, right or both processors. These buttons are also required in programming mode, e.g. to activate or deactivate the keyboard lock (see Chapter 5, OPUS 2 audio processor, FineTuner, FineTuner functions – Automatic keyboard lock).



All FineTuner controls can be selectively disabled by your audiologist or clinical staff by disabling the respective command in the control unit. Your FineTuner will still be able to transmit all commands, but your control unit will not execute disabled commands.

Fig. 5 FineTuner

FineTuner functions

Automatic keyboard lock: To avoid unintentional operation of a key, the FineTuner features an optional automatic keyboard lock. This function electronically locks the keyboard if no key is pressed for more than 10 seconds.

To activate the keyboard lock feature of your FineTuner, press the key for more than 5 seconds to enter the program mode (the red and both amber indicator lights on your FineTuner will both start blinking alternately indicating that you have successfully entered the FineTuner's program mode) and then the key to activate the automatic keyboard lock (the FineTuner will confirm successful activation of the automatic keyboard lock by a short blinking signal of the two amber indicator lights).

To deactivate the automatic keyboard lock, press the key twice to unlock the keyboard for 10 seconds, then hold it down for more than 5 seconds to enter the program mode. Press the key to deactivate the keyboard lock. As above the FineTuner will confirm successful deactivation of the automatic keyboard lock by a short blinking signal of the two amber indicator lights.

To activate a certain function while the keyboard lock is active, press the desired function key twice. The first click temporarily unlocks the keyboard, the second click executes the command. After 10 seconds without pressing another key, the keyboard lock is active again.

Battery low warning: The processor features an optical warning signal, which appears as a red indicator light flashing 3 times on the FineTuner. The signal is generated after pressing a key if the voltage level of the FineTuner reaches a critical lower limit (see also Chapter 8, Care and maintenance, Batteries, Changing the battery of your FineTuner).

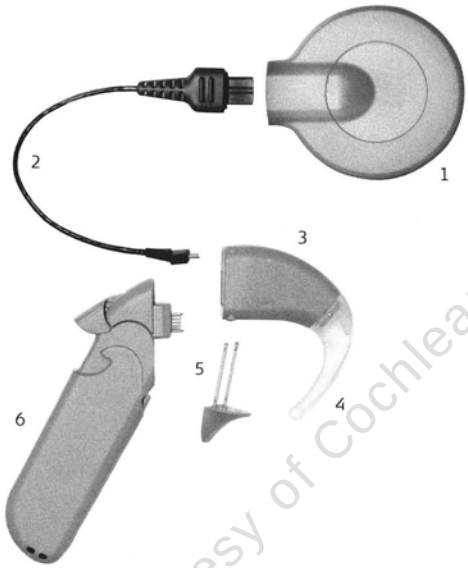
Transmitter time-out: The FineTuner stops transmitting after 3 seconds to save energy, even if the key is still pressed.

Your FineTuner does not have an ON/OFF switch.

Three indicator lights with different colors (2 amber, 1 red) indicate various conditions of the FineTuner. For a detailed description of their function see Chapter 9, Troubleshooting. The FineTuner does not affect connected Assistive Listening Devices (ALD's).

BATTERY PACK

The OPUS 2 battery pack consists of the battery pack frame holding 3 hearing aid batteries, and the battery pack cover. The battery pack cover slides over the battery pack frame and is held in place by the battery pack lock which also functions as the ON/OFF switch of the control unit (see Fig. 3+4). This configuration allows the entire audio processor to be worn at the ear and is the most common configuration for older children and adults.



1 Coil
2 Coil cable
3 Control unit
4 Earhook
5 Connecting piece
6 Battery pack

Fig. 6 How to assemble the control unit and battery pack

How to assemble your control unit and battery pack

1. Connect the coil cable to the coil. There is a guide pin on the coil end of the cable. This guide pin is thicker than the two remaining pins, so there is only one correct way to insert the cable into the coil (see Fig. 6).
2. Connect the opposite end of the cable into the control unit (see Fig. 13).
3. Add the battery pack frame with the cutout area positioned to accommodate the coil cable plug.
4. Insert the pins of the connecting piece into the small holes at the bottom of the control unit.

   If this configuration is used with children:

   For young children, it is mandatory to use the safety lock to prevent them from disassembling the audio processor (see Chapter 5, OPUS 2 audio processor, Safety lock).

   NOTE:
   It is not possible to attach or remove the connecting piece if the battery pack cover is not removed from the battery pack frame.

5. Add fresh batteries.
6. Add the battery pack cover and close the battery pack lock to switch the processor on.
7. The red indicator light in the earhook will blink up to four times indicating the activated program.
8. Position the audio processor on the ear and the coil over the implant.
9. Choose the desired program, volume and sensitivity settings with the FineTuner.

Only parents/adults are allowed to disassemble the device to change defective parts. Parents/adults must check the device frequently for damage or missing parts.

For more wearing options see Chapter 5, OPUS 2 audio processor, Additional wearing options.

An ear-mold may help keep the processor in position on the ear. Contact your CI center or audiologist for assistance.

COIL

The coil connects the OPUS 2 audio processor with the implant. It sends both energy and the coded acoustic signal through the skin to the implant. A small magnet is located in the center of the coil to hold it in place on the head over the implant package. The magnet strength can be adjusted by your audiologist or clinical staff to meet your individual needs.

If you notice any signs of skin irritation around the coil, contact your clinic or CI center.

MED-EL offers different types of coils.

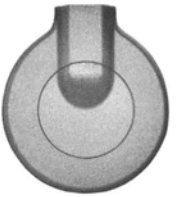


Fig. 7 D Coil

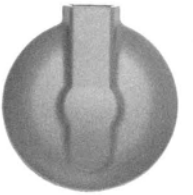


Fig. 8 COMT+/COMT+ P coil

D COIL

The D Coil allows changing the magnet in the center of the coil to adjust the magnet strength to your needs. The magnet is attached to the coil cover. To open the coil cover, turn it to either side until it disengages and lift it off.

To insert a new magnet, place the coil cover including the magnet over the recess in the coil as shown in Fig. 9. It should glide into the recess easily. Now turn the cover until it engages. You will feel a slight resistance when the cover snaps in place.

Fig. 9 Removing/inserting the magnet

Four magnet strengths are available. Magnet strength is indicated by the number of white circles on the magnet.

Fig. 10 Magnet strength

The serial number of the coil is indicated in the magnet compartment.

Fig. 11 Serial number of D Coil

IMPORTANT

MED-EL strongly recommends that you do not change the magnet yourself, but have your audiologist or clinical staff do it.

COMT+/COMT+ P COIL

The COMT+/COMT+ P coil is also available in four magnet strengths. However, since the magnet is fixed to the coil, the entire coil must be replaced to change magnet strength. For some types of the COMT+/COMT+ P coil, however, it is possible to add small magnetic disks to increase magnetic attraction. The serial number is on the outside of the coil.

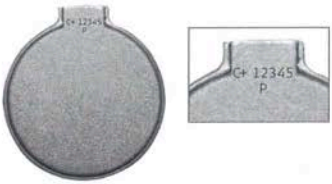


Fig. 12 Serial number of COMT+/COMT+ P coil

IMPORTANT

For users of a COMT+/COMT+ P coil:

When operating the cochlear implants MED-EL CONCERT, PULSARCI^{100} or SONATATI^{100} with an OPUS 2 audio processor, we recommend using a COMT+ coil with the suffix "P" in its serial number. Using the MED-EL OPUS 2 audio processor with a COMT+ coil without the suffix "P" could, under extreme environmental conditions (i.e. when exceeding the specified operational temperature range of the OPUS 2 audio processor, e.g. in winter), cause the cochlear implants MED-EL CONCERT, PULSARCI^{100} or SONATATI^{100} to switch off. In this case, the implant will stop stimulation, wrong stimulation or over-stimulation is impossible. As soon as the operational temperature is reached again, the implant will resume proper stimulation. This does not apply to the D Coil.

It is easiest to observe children when playing or in everyday situations to determine whether the coil is properly attracted to the implant. If the coil falls off too easily, your child may develop an aversion to wearing the coil. During the first months after surgery, you should regularly check the skin under the coil for irritation. As the child grows, skin thickness will increase and the magnetic attraction force may have to be adjusted by increasing the magnetic strength.

COIL CABLE

The coil and audio processor are connected by the coil cable. You have to unplug the cable for maintenance purposes or if you want to replace the cable. It is not necessary to disconnect the cable when changing the batteries.

Although the cable is designed for maximum durability and flexibility, this part of the MAESTRO Cochlear Implant System is most likely to wear out.

If a cable fails, order a new one immediately.

IMPORTANT
Do not use the cable with devices other than the OPUS 2 audio processor.

The coil cable is available in different versions: for connection to the D Coil and for connection to the COMT+/COMT+ P coil. All coil cables for connection to the D Coil feature a red arrow on the cable plug connecting to the control unit. Coil cables for connection to the COMT+/COMT+ P coil are available with and without the red arrow on the cable plug.

How to replace the coil cable

Fig. 13 Connecting the coil cable

1. Open the battery pack lock and remove the battery pack cover.
2. Pull the connecting piece straight down until you feel a slight mechanical click. The connecting piece need not be removed completely but you may do so if you wish.
3. Disassemble the battery pack frame from the control unit.
4. Disconnect the coil cable from the control unit and the coil.
5. Connect the new coil cable to the coil.
6. Connect the opposite end of the new coil cable into the control unit. Make sure that the cable plug is correctly positioned. The slanting edge should face up. If your coil cable features a red arrow, the arrow should face up.
7. Reassemble the battery pack frame and the control unit. The coil cable plug rests in the small cutout section of the angled section of the battery pack.
8. Push the connecting piece back in place.
9. Slide the battery pack cover back on and close the battery pack lock. The audio processor is now active.

IMPORTANT

To prolong your cable's life, we recommend the following:

- Do not bend the cable.
- When unplugging the cable, pull on the plug and not on the cable itself.
- Do not lift the audio processor by the cable.
- Do not use excessive force when unplugging the cable.

CONNECTING ASSISTIVE LISTENING DEVICES

The additional components required for the connection of Assistive Listening Devices (FM Battery Pack Cover and Adapter Cable) are included in the FM Extension Kit which may be purchased separately.

A special battery pack cover is provided to connect your OPUS 2 audio processor to external, battery-powered audio devices, such as portable CD players, MP3 players, AM-FM radios, etc. The FM Battery Pack Cover is slightly longer than the standard cover to accommodate the integrated FM connector.

To assemble the FM Battery Pack Cover, proceed as follows:

- Open the battery pack lock.
- Remove the battery pack cover.
- Slide on the FM Battery Pack Cover.
- Close the battery pack lock.

Connect the three-pin connector of the Adapter Cable (grey end) to the openings at the bottom of the FM Battery Pack Cover. Mind the orientation of the three pins and do not use excessive force when connecting the cable.

Connect the audio phone plug (yellow or red end) to the audio output of the battery-powered device.

Fig. 14 Connecting the FM cable and FM receiver

Direct-link FM systems (e.g. Phonic Ear/Oticon Lexis) may be connected to the FM Battery Pack Cover without an Adapter Cable.

NOTE:
Due to the increased power demand of modern direct link assistive listening devices it is recommended to use high power zinc air batteries when connecting a direct link assistive listening device to the OPUS 2.

IMPORTANT
The provided cable is intended for the connection of battery-powered audio devices, such as portable CD players, MP3 players, AM-FM radios, etc. For connection of FM or infrared systems, use the respective manufacturers' adapter cables.

WARNING
Do not use cables longer than 1 m (3.28 ft.) as these cables may result in increased electromagnetic emissions or decreased electromagnetic immunity of your audio processor system.
Cables from MED-EL are available for unilateral and bilateral implant use and for Mix and Ext mode. For more information, please contact your local MED-EL office.

Mix mode:
When connected to an external device, the OPUS 2 microphone remains active. You will hear inputs from the external device and the audio processor. Use this mode when you want to continue hearing both the external device and the sounds around you (for example, both music and someone talking to you).
Mix cables are indicated by a yellow 3.5 mm plug.

Ext mode:
When connected to an external device, the OPUS 2 microphone is deactivated. You will hear input from the external device only.
Ext cables are indicated by a red 3.5 mm plug.

ADDITIONAL WEARING OPTIONS

BabyBTE™/ActiveWear

MED-EL's signature wearing option for infants and young children is the BabyBTE™. The BabyBTE™ has the advantage of allowing a young child to begin using the same ear-level audio processor that he or she will use for the long term, while still accommodating a baby's small ear and activity level. For this wearing option, the entire BTE processor is placed on the clothing, and only the coil is placed over the implant on the head.

This configuration is also referred to as ActiveWear for users who participate in sports or other activities where a very secure placement is desired. For activities that require wearing a helmet, using this configuration allows the microphone of the audio processor to be positioned outside the helmet, with only the coil and cable fitting underneath.

When using the BabyBTE™ or the ActiveWear configuration, it is important to be aware of the position of the microphone; it should be positioned in such a way that the majority of sound will be directed at the microphone port (i.e. facing forward). The microphone should not be covered or positioned where jewellery and/or clothing could obstruct input to the microphone.

1 Coil
2 Coil cable
3 Safety lock
4 Control unit
5 Microphone cover
6 Connecting piece
7 Fixation bar
8 Straight Battery Pack

Fig. 15 How to assemble the BabyBTE™/ActiveWear

How to assemble your BabyBTE™/ActiveWear configuration

The additional components required for the BabyBTE™ assembly and the ActiveWear configuration (Straight Battery Pack, 28 cm coil cable, microphone cover, connecting piece, safety bar, screw-on fixation bar and fixation clip) are included in the BabyBTET™/ ActiveWear Extension Kit which may be purchased separately.

Fig. 16 OPUS 2 BabyBTE™/ActiveWear

1. Exchange the earhook with the microphone cover: Remove the earhook fixation pin (when used) and pull off the earhook as shown in Fig. 19 + 20.
2. Attach the microphone cover to the control unit as shown in Fig. 20. You will hear or feel a soft click when the microphone cover is attached properly.
3. Attach the screw-on fixation bar or the fixation clip to the Straight Battery Pack.
4. Connect the 28 cm coil cable to the coil.
5. Connect the opposite end of the cable to the control unit.
6. Connect the Straight Battery Pack to the control unit.
7. Insert the pins of the connecting piece for safety lock into the small holes at the bottom of the audio processor. Secure the assembly by attaching the safety lock as shown in Fig. 21.

   For young children, it is mandatory to use the safety lock to prevent them from disassembling the audio processor (see Chapter 5, OPUS 2 audio processor, Safety lock).

8. To insert batteries, open the battery pack lid of the Straight Battery Pack by pushing the lever at the back of the device as shown in Fig. 24 and hold it in this position. Now push the battery pack lid backwards about 3 mm, then remove it by pushing it to the front.
9. Add fresh batteries.

10. To close the battery pack lid, put it on the housing so that it overhangs the back of the Straight Battery Pack by about 3 mm. Gently push the battery pack lid onto the housing. When the battery pack lid is positioned correctly, it can be pushed forward, where it snaps in place easily. Never put the battery pack lid on the very back of the housing, pushing it forward by force. This could damage the Straight Battery Pack. Do not use excessive force when closing the battery pack.
11. Switch on the audio processor at the back of the Straight Battery Pack.
12. The red indicator light behind the microphone cover will blink up to four times indicating the activated program.
13. Attach the audio processor to the clothing so that the microphone is generally pointing in the desired direction, and then place the coil over the implant.
14. Choose the desired program, volume and sensitivity settings with the FineTuner.

Children's Battery Pack

The control unit is worn at the ear, which provides optimal microphone placement and easy visibility of the red indicator light in the earhook. A cable allows the battery pack to be attached directly to clothing. This cable is hard-wired into the battery pack and cannot be disconnected or replaced. If the cable is damaged, the entire battery pack should be replaced.

The additional components required for the Children's Battery Pack assembly (Children's Battery Pack, children's connecting piece, safety lock, screw-on fixation bar and fixation clip) are included in the Children's Extension Kit which may be purchased separately.

Fig. 17 How to assemble the Children's Battery Pack

How to assemble your Children's Battery Pack

1. If you were using the BabyBTE™ assembly before, exchange the microphone cover with the regular earhook. Carefully pull off the microphone cover and attach the earhook to the control unit as shown in Fig. 20. You will hear or feel a soft click when the earhook is attached properly. It is recommended to insert the earhook pin. The earhook pin will make it difficult for children to remove the earhook.
2. Attach the screw-on fixation bar or the fixation clip to the Children's Battery Pack.
3. Connect the coil cable to the coil.
4. Connect the opposite end of the cable to the control unit.
5. Connect the cable of the Children's Battery Pack to the control unit.
6. Insert the pins of the children's connecting piece for safety lock into the small holes at the bottom of the audio processor: Secure the assembly by attaching the safety lock (see Fig. 21).

For young children, it is mandatory to use the safety lock to prevent them from disassembling the audio processor (see Chapter 5, OPUS 2 audio processor, Safety lock).

7. To insert batteries open the battery pack lid of the Children's Battery Pack by pushing the lever at the back of the device as shown in Fig. 24 and hold it in this position. Now push the battery pack lid backwards about 3 mm, then remove it by pushing it to the front.
8. Add fresh batteries.
9. To close the battery pack lid, put it on the housing so that it overhangs the back of the Children's Battery Pack by about 3 mm. Gently push the battery pack lid onto the housing. When the battery pack lid is positioned correctly, it can be pushed forward, where it snaps in place easily. Never put the battery pack lid on the very back of the housing, pushing it forward by force. This could damage the Children's Battery Pack. Do not use excessive force when closing the battery pack.
10. Switch on the audio processor at the back of the Children's Battery Pack.
11. The red indicator light in the earhook will blink up to four times indicating the activated program.
12. Attach the Children's Battery Pack to the clothes, put the control unit on the ear and place the coil over the implant.
13. Choose the desired program, volume and sensitivity settings with the FineTuner.

An ear-mold may help keep the processor in position on the ear. Contact your CI center or audiologist for assistance.

Fig. 18 OPUS 2 Children's Battery Pack

Locking lever

The Children's Battery Pack, in contrast to the other battery pack versions, is provided with a locking lever. With this lever, the battery door can be opened only by using a ballpoint or other pointed object. Thus, a small child is not able to open the battery pack lid to take out the batteries and possibly swallow them.

EARHOOK/MICROPHONE COVER

How to remove the earhook pin

Your OPUS 2 audio processor is shipped with a pin securing the earhook to the control unit. This configuration is recommended when the user is a young child.

To remove the earhook pin, push the pin through the holes (see Fig. 19) using the supplied tool, then grab it and pull it out completely.

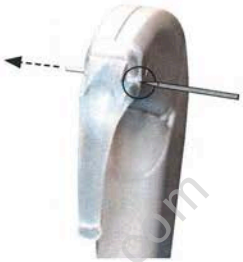


Fig. 19 How to remove the earhook pin

How to remove the earhook or microphone cover

To exchange the earhook or replace it with the microphone cover, gently push the earhook downwards (a,b) to remove it from the control unit. Attach the new earhook or microphone cover over the rib in the lower part of the control unit and push it gently upwards (c,d) until it snaps in place (see Fig. 20). To remove the microphone cover from the control unit, push against the top rib of the cover (e,f).

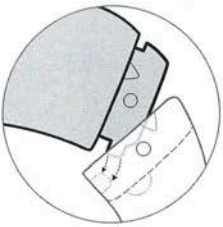


Fig. 20 How to remove the earhook or microphone cover

Make sure to insert the earhook pin when attaching the earhook to prevent children from removing the earhook. Keep the supplied pin removal tool away from children.

SAFETY LOCK

The safety lock prevents small children from disassembling their audio processor, therefore it is mandatory to use it for children. After attaching the safety lock, check that the safety lock is positioned properly.

Insert the connecting piece for safety lock (with long pins) and place the safety lock on the protruding pins. The coil cable plug rests in the cutout section. Slide the black lever into the shown direction using a pointed object (e.g. ballpoint) to secure the safety lock. To open the safety lock, move the black lever in the other direction.

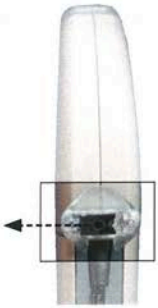


Fig. 21 Safety lock

6. Special considerations for young children

The OPUS 2 audio processor has several features that are particularly designed for young children. Among them:

- Locked earhook: The earhook is secured to the control unit with a small pin.
- Safety lock to prevent small children from disassembling the audio processor, therefore it is mandatory to use it for children.
- Wearing configurations for small ears that remove the audio processor from the head and place it securely on the clothing.
- Deactivation of certain FineTuner controls: To prevent accidental program, volume or sensitivity changes, it is possible to deactivate these FineTuner controls. Please contact your CI center for assistance.
- Only parents/adults are allowed to disassemble the device to change defective parts. Parents/adults should check the device frequently for damage or missing parts.

7. General precautions and warnings

This section contains information on the safe use of your Cochlear Implant System. Please read this information carefully. Your CI center or nearest MED-EL office will assist you with any additional questions.

Before you undergo medical treatments or examinations, always inform your doctor that you have a cochlear implant.

Expected performance with the cochlear implant cannot be predicted accurately. Past experience with the MAESTRO Cochlear Implant System may provide some general guidelines. Duration of deafness, age at implantation, primary communication mode, communicative ability and the patient's auditory environment all have an impact on the success with the cochlear implant, as do other factors, some of which may be unknown.

Do not use the MAESTRO Cochlear Implant System with any device other than those listed in this manual or approved by MED-EL. If you have problems with any component of the system, refer to Chapter 9, Troubleshooting.

IMPORTANT

If you ever experience uncomfortable hearing sensations, we strongly recommend that you no longer wear your external system components. Please contact your clinic or CI center immediately.

If your child refuses to wear the system or indicates uncomfortable hearing sensations, remove the system immediately and have your child's system checked at your clinic or CI center.

GENERAL PRECAUTIONS FOR YOUR COCHLEAR IMPLANT SYSTEM

The OPUS 2 audio processor and other parts of the system contain sophisticated electronic components, which need special precautions regarding electromagnetic compatibility (EMC). When activating your OPUS 2 audio processor always follow the guidelines outlined in this section and Chapter 10, Technical data, Guidance and manufacturer's declaration.

The electronics are durable but must be treated with care.

- Never open the housing of your OPUS 2 audio processor. Unauthorized opening invalidates the warranty. To change the batteries or clean the battery contacts, remove only the battery pack cover as described in Chapter 8, Care and maintenance.
- Before switching on the OPUS 2 audio processor, check the external parts of the MAESTRO Cochlear Implant System for proper mechanical condition, e.g. for loose or broken parts. In case of problems, the audio processor may/should not be switched on. Read Chapter 9, Troubleshooting or contact your CI center or MED-EL.

IMPORTANT

If you plan to enter an environment that could potentially adversely affect the operation of your Cochlear Implant System (e.g. an area that is protected by a warning notice preventing entry by patients fitted with a pacemaker) it is advisable to first contact your clinic or MED-EL.

Everyday Life

The implant package and the electrodes are located directly under the skin. In order to avoid damage to the implant you/your child should not unnecessarily move and extensively scratch the skin above the implant site and should also avoid mechanical pressure on the site. When brushing or styling the hair at the site of implantation, you should be careful not to harm the skin (at the site of the implant there may be a slight bulge).

For the external components, please observe the following:

- Your OPUS 2 audio processor, FineTuner and coil do not require regular maintenance by clinic personnel or other experts.
- The defined operating temperature range is between +10 °C and +45 °C (+50 °F and +113 °F) for the OPUS 2 audio processor and the FineTuner. Normally, when the OPUS 2 audio processor is worn on the body, natural body heat helps maintain this temperature range.
- Do not leave the audio processor or FineTuner in direct sunlight (particularly inside a car).
- If you ever experience loud or uncomfortable sounds, please remove your coil immediately: this will stop stimulation at once.
- Do not use the audio processor or FineTuner of another cochlear implant user. Your audio processor and FineTuner have been adjusted to your individual needs. Using another audio processor or FineTuner may cause painful or uncomfortable stimulation.
- Avoid getting your audio processor or FineTuner wet as this may impair its function. Always remove and switch off the external parts of your implant system and keep them in a dry place before bathing, showering or engaging in other water-related activities.
- If the external parts become wet, switch off your audio processor as quickly as possible, remove the batteries from the battery pack, unplug the battery pack from the control unit, and gently wipe all external parts dry, using a soft, absorbent cloth. Then store the audio processor for at least 12 hours in the supplied drying kit to allow moisture inside the audio processor to dry. If in doubt, extend the drying period to a day or longer. If the FineTuner becomes wet, wipe it off with a dry tissue.
- You also have to take care of the external components of your/your child's Cochlear Implant System. They should not be dropped or subjected to dangerous areas (machines or high voltage) which could result in damage to the components.
- Do not use the OPUS 2 audio processor and the FineTuner in environments where radio frequency (RF) transmissions are prohibited.
- Do not try to shape the earhook by hot air.

Children shall be instructed not to swallow or put any components of their Cochlear Implant System into their mouths and not to play with any components. For young children, it is mandatory to use the safety lock to prevent them from disassembling the audio processor (see Chapter 5, OPUS 2 audio processor, Safety lock).

Technology in everyday life

Metal detectors and anti-theft systems

Metal detectors, some anti-theft security systems and other RF transmitters may produce a buzzing sound heard by the implant user, when you are near or walking through the magnetic field emitted by these systems. To avoid the buzzing sound, switch your OPUS 2 audio processor off when walking through metal detectors and anti-theft systems. Please note that your FineTuner will not be able to communicate with your processor until the processor is switched back on. In rare cases, a cochlear implant may trigger a security system alarm, so make sure that you always carry your MED-EL ID card with you in order to identify yourself as a cochlear implant user.

Air travel

During takeoff and landing, airlines request that computers, cell phones and other electronic devices be switched off to avoid interference with the airplane's communication instruments. This does not apply to your OPUS 2. US aviation law states that medical devices such as pacemakers and hearing aids are exempt from this law [US Federal Aviation Regulation 91.21].

If you decide to remove or to turn off your audio processor at any time during a flight, tell your airline attendant that you are a cochlear implant user and that you may require special instructions while your processor is OFF.

Interference with reception of TV

In rare cases, your audio processor may interfere with reception when using certain TV sets (sets with an indoor antenna). You can reduce the amount of interference by moving away from the TV set and turning the antenna.

Mobile phones

Mobile phones and other portable and mobile RF communications equipment may interfere (perceived as a buzzing sound) with the external parts of your Cochlear Implant System if they are used within a distance of less than 3 meters (9.84 ft.).

TV, radio, FM systems, etc.

The audio processor should never be connected directly to any equipment connected to an electrical outlet of any kind, including a power strip. Galvanic isolation systems, such as an infrared system or FM system, should always be used if you want to connect to a device that plugs into an electrical outlet. Battery operated devices can be directly connected to the audio processor. Special cables may be needed (e.g. for connection to FM systems). For further information please contact MED-EL.

Electrostatic discharge (ESD)

Electronic devices are influenced by electrostatic discharge (ESD). Although the MAESTRO Cochlear Implant System has several internal safety features designed to reduce ESD, there is a small risk that the external or internal equipment can be damaged if the static discharge flows through the external equipment. Switching off your audio processor will not prevent damage from occurring. In rare cases, the user may experience uncomfortably loud hearing sensations, however, the most likely occurrence in case of an ESD event is a short interruption of stimulation or a controlled audio processor shutdown.

Following the listed guidelines can reduce the probability of electrostatic discharge:

- If you believe that you or your child is statically charged, discharge by touching a radiator, a water tap, or any grounded metal object.
- Do not allow another person to touch the external parts of your implant system unless both you and the other person are "discharged".
- You should always discharge before taking off or putting on the OPUS 2 audio processor. To do this, use this two step approach:
  (A) When removing another person's audio processor:
  Step 1: Touch the person's body
  Step 2: Touch the processor
  (B) When picking up the audio processor from a table or other surface:
  Step 1: Touch the table
  Step 2: Pick up the processor
- You or your child should always be "discharged" when leaving the car. Touching the car door is a good way to discharge. The audio processor or cables should neither touch the car door nor other parts of the car body.
- Use an antistatic spray for upholstery, TV or computer screens to reduce static build-up. These sprays are also available for carpets or clothing.
- Always remove your audio processor before dressing and undressing, especially if garments include synthetic fibers. Generally, cotton and natural fibers are less likely to cause ESD problems. Fabric softeners might also help reduce static electricity. When getting dressed, put your OPUS 2 audio processor on last, and remove it first when undressing.
- Always remove the OPUS 2 audio processor and coil before touching plastic play equipment (e.g. children's slides). Switching off the audio processor may not be enough to prevent ESD damage. Completely remove the audio processor from the body. Afterwards, do not touch the site of the implant. Make sure that you or your child "discharge" before touching the audio processor. If you have any doubt about a particular material, it is best to be cautious by removing the OPUS 2.

- Always remove the OPUS 2 audio processor and coil when experimenting with static electricity and "high" voltage. Van de Graaff generators, as found in school science departments or science museums, should never be used by cochlear implant users because they produce very high levels of static electricity.
- When working at a computer, make sure the computer is grounded and use an anti-static mat under your work area to reduce static build-up. Never directly touch the screen of a computer or TV. The risk of problems from computer screens is very small but may be further reduced by attaching an anti-static screen to the computer.
- If your audio processor stops working and you suspect an ESD is the cause, switch off the audio processor, wait for a few minutes and switch it on again.

Sports and play

It is important to protect the implant from sources of direct impact. Accidents like falling out of a chair or bumping into furniture with your head could damage the implant. As with any child, parents should take measures to prevent these accidents by using child seats and child locks where appropriate and by supervising outside play.

Avoid contact sports that might result in severe blows to the head or continuous pressure on the implant, since this could damage the implant. Other physical activity is generally allowed. Make sure that you wear the OPUS 2 securely (see Chapter 5, OPUS 2 audio processor, Additional wearing options) to protect it from physical damage. Sports that require a helmet are okay as long as they do not exceed the given capabilities of the user. Use a helmet whenever necessary to protect the implant site from any blows. Your/your child's helmet should be high quality and may need to be modified to meet your individual needs. For specific questions about contact sports, contact your CI center. Most water sports should not cause any problem as long as the external parts of the implant system are removed. If headgear or face mask are worn, care must be taken to ensure that the strap is not too tight over the site of the implant. In any case you should consult an experienced physician about possibilities and personal restrictions when performing water sports, especially in the case of SCUBA diving. The implant is robust against pressure changes which occur during SCUBA diving to depths up to 50 m (165 ft).

If you have any concerns or questions, ask your physician for advice about performing sports and limitations caused by your/your child's health status.

PRECAUTIONS FOR MEDICAL PROCEDURES

Neurostimulation or diathermy

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.

Electrosurgery and other treatment with electrical current

Monopolar electrosurgical instruments must not be used in the head and neck area. Instruments used in electrosurgery can produce high-frequency voltages which may induce currents in the electrodes of the cochlear implant. Such currents may damage the implant and/or the surrounding tissue. In general remove your OPUS 2 audio processor from your head any time a medical treatment is given in which an electrical current is passed through your body, or at least carefully observe the correct functioning of your entire Cochlear Implant System during the initial stages of the treatment.

Ultrasound

Therapeutic ultrasound treatment should not be applied close to the cochlear implant as the implant may inadvertently concentrate the ultrasound field and cause harm.

Electroconvulsive therapy

Electroshock or electroconvulsive therapy should not be used in patients with cochlear implants. Such therapy may damage the implant and/or the surrounding tissue.

Therapy using ionizing radiation

The MED-EL PULSAR, SONATA, CONCERT and CONCERT PIN Cochlear Implants are robust against 240 Gray 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 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 radio-therapeutic beam.

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 implanted components of the MED-EL cochlear implant system are **MR Conditional**.	

MED-EL PULSAR, SONATA, CONCERT & CONCERT PIN

Non-clinical testing has demonstrated that the MED-EL PULSAR, SONATA, CONCERT and CONCERT PIN cochlear implants are MR Conditional. They can be safely scanned under the 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 gradient field of up to 8 T/m (800 G/cm).
- Sequences in Normal Operating Mode only 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 T 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 radius around the device in a Spin Echo scan (refer to Figure B).
- 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 A). The bandage needs to fit tightly but should not cause pain.

- Head orientation: In case of 1.5 T systems, the longitudinal axis of the head must be parallel to the main magnetic field of the scanner. For example this is the case when the patient is in a supine position with the head kept straight. The patient should not turn or bend his/her head to the side; otherwise partial demagnetization of the implant magnet is possible.
- During the scan, patients might perceive auditory sensations such as clicking or beeping. Adequate counseling of the patient is advised prior to performing the MRI. The likelihood and intensity of auditory sensations can be reduced by selecting sequences with lower specific absorption rate (SAR) and slower gradient slew rates.
- The above instructions should also be followed if areas of the body other than the head are to be examined (e.g. knee, etc.). When lower extremities are to be examined, it is recommended that the patient's legs are positioned in the scanner first to minimize any risk of weakening the implant magnet.
- 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.

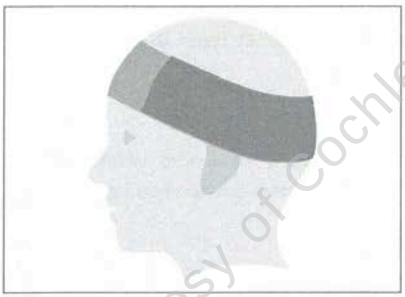


Fig. A Head bandage to support fixation of the implant.

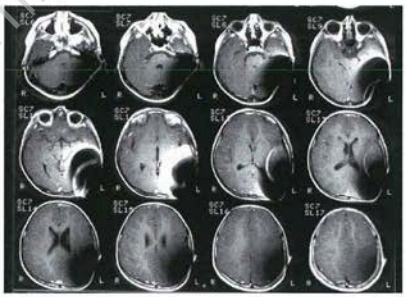


Fig. B MR images obtained with a 1.5 T scanner (8 year old child).

Non-clinical testing has demonstrated that the MED-EL C40+ cochlear implant is MR Conditional and can be safely scanned under the following conditions:

MED-EL C40+

0.2 Tesla

Only 0.2 T MRI scanners should be used on patients who have MED-EL C40+ implants. There is no need to remove your implant's internal magnet, but you should always remove your OPUS 2 audio processor before undergoing a MRI scan. Most 0.2 T MRI machines are "open MRI". Unlike other tube-like MRI scanners, the open MRI machines have a clear, unobstructed space on one or more sides allowing patients to see and talk to imaging personnel and loved ones during the exam. If you have difficulty locating 0.2 T MRI scanners, MED-EL can provide a list of scanners and their locations.

Please have your radiologist contact MED-EL Corporation for details on the appropriate scanning techniques with MED-EL C40+ implants before scheduling your exam. The following is a list of some of the most important information that your radiologist should know before s/he begins your scan:

CAUTION:

MED-EL must be consulted prior to conducting a 0.2 T MRI examination on any patient with a MED-EL C40+ Implant.

- Do not, under any circumstances, scan a MED-EL C40+ patient with field strengths greater than 0.2 T.
- When scanning at 0.2 T, confirm that the patient is positioned so that the magnetic field of the internal magnet is in the same orientation as the magnetic field of the scanner. This is necessary to minimize torque on the internal magnet and induced voltage in the receiver.
- Straight orientation of the head is acceptable for bilaterally implanted patients.
- Please note that there exist many types of 0.2 T MRI scanners. In some, the head coil used for head imaging is attached to the MRI bed. Further counseling and recommendations will be provided to the cochlear implant professional and radiologist in the event of head imaging.

MED-EL has prepared a MRI Examination Request Form containing precise information on device parameters (magnetic field strengths) and guidelines for a MRI examination under safe conditions. The MRI Examination Request Form must be completed by the requesting physician in cooperation with the applicable radiology department and reviewed and approved by MED-EL prior to performing the MRI examination with a MED-EL C40+ implant for safety reasons and to avoid loss of warranty coverage. External equipment should not enter or be in close proximity to the MRI machine.

Other treatments

The effects of a number of treatments are unknown, e.g. radioactive radiation (cobalt, linear accelerator) or electrical examinations in the dental area. Please contact your clinic.

Ear infections

Infections in the implanted ear must be treated promptly by a physician who will prescribe antibiotics as necessary. Prophylactic use of antibiotics is recommended for all patients unless medically contraindicated. The surgeon should prescribe adequate dosing for each patient's condition. Please inform your CI center of such infections.

Electrical lice combs

Cochlear implant users should not use these devices.

Meningitis vaccine and prevention

Bacterial meningitis is rare but has the potential to be serious. The risk of contracting meningitis after your CI surgery can be reduced by the meningitis vaccine, by using antibiotics before and after CI surgery and by using the surgical technique recommended by MED-EL. As with all cochlear implant surgery, preventative antibiotic usage is recommended for all patients unless medically contraindicated. Talk to your surgeon about this. Your surgeon should prescribe adequate antibiotic dosing for you or your child and should check your or your child's immunization status before your implant surgery. The correct vaccinations and vaccination booster schedules are available at the cdc.gov website.

8. Care and maintenance

MAINTENANCE

Your OPUS 2 audio processor is designed for durability and reliability. When handled with sufficient care, it will function for a long time. The battery pack and particularly its cover may wear out due to frequent opening and closing and therefore have to be replaced more frequently.

Do not clean the external parts in or under water. Use a damp cloth to gently clean the audio processor. Do not use aggressive cleaning agents. Prevent water from running into the audio processor via the connectors, controls, or the battery pack.

Protect your OPUS 2 audio processor from water (see also Chapter 7, General precautions and warnings).

Do not try to repair electronic parts of your OPUS 2 audio processor and do not try to open the control unit.

Do not touch the battery contacts. If the contacts need to be cleaned, use a cotton swab and a small amount of cleaning alcohol. Gently wipe dry after cleaning.

If you do not use your audio processor for an extended period of time, you should remove the batteries and store them separately. Cover the air openings on the top with adhesive tape when storing the batteries to avoid self-discharge. Also remove the batteries when drying the audio processor in the enclosed drying kit.

Handle your FineTuner with care. Avoid getting the FineTuner wet. Do not clean the FineTuner in or under water. Use a damp cloth to gently clean the FineTuner. Do not use aggressive cleaning agents.

BATTERIES

In its current version, the OPUS 2 audio processor requires three 675 zinc air batteries. These batteries supply the external and internal components with energy.
If you want to get more information on batteries, please contact your local MED-EL representative or CI center.

The battery pack cover has two air holes on each side of the bottom end. Do not cover these holes as this may shorten battery life. If the holes are contaminated, remove the battery pack cover and carefully clean the holes with the enclosed cleaning brush.

NOTE:
Due to the increased power demand of modern direct link assistive listening devices it is recommended to use high power zinc air batteries when connecting a direct link assistive listening device to the OPUS 2.

IMPORTANT
Always remove used batteries immediately to avoid leaking and possibly damaging the device.

Dispose of used batteries according to local regulations. Generally, batteries are collected separately and not discarded with the household garbage.

To prevent children from swallowing or choking on batteries, always keep new and used batteries out of the reach of children. Children should be instructed not to swallow or put any components of their Cochlear Implant System into their mouths and not to play with any components. For young children, it is mandatory to use the safety lock to prevent them from disassembling the audio processor (see Chapter 5, OPUS 2 audio processor, Safety lock).

Changing the batteries of your OPUS 2 audio processor

When the red indicator light in the earhook blinks continuously (⌐¬⌐¬⌐¬), the battery set must be replaced (see also Chapter 9, Troubleshooting).

To change the batteries, proceed as follows

1. Remove the coil from your head and switch off the OPUS 2 audio processor before replacing the batteries.
2. Open the battery pack lock (a) and remove the battery pack cover (b).
3. Replace the used battery set (c) by removing the three batteries with the coil magnet or by gently shaking them into your hand. Try not to touch the battery contacts.
4. Before inserting the new battery set, make sure that the battery contacts are clean and dry. The foil covering the zinc air batteries must be removed before use. Check for correct polarity when inserting the new batteries. The positive pole (+) must face outward, i.e. the "+" sign is still visible when the batteries are inserted.
5. Slide the cover over the battery pack frame (d) and close the battery pack lock.

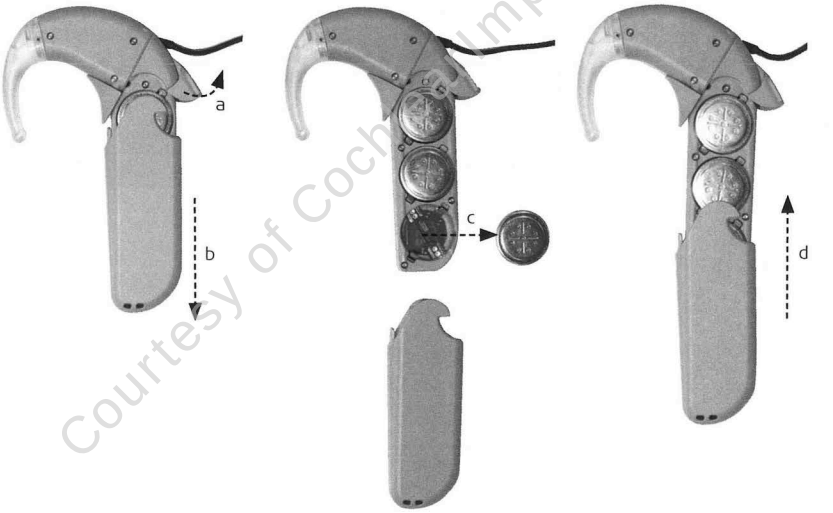


Fig. 22 Changing the batteries of your audio processor

Changing the battery of your FineTuner

When your FineTuner generates an optical battery low warning signal (see also Chapter 5, OPUS 2 audio processor, FineTuner, FineTuner functions), it is recommended to replace the battery of your FineTuner.

To change the battery, proceed as follows:

1. Open the lid on the back of the FineTuner with a small screwdriver.
2. Replace the used button battery (type CR2025) by removing it with the coil magnet or by gently shaking it into your hand. Try not to touch the battery contacts.
3. Insert the new battery with the "+" sign facing up.
4. Close the lid by carefully inserting it on the right side, then sliding it in place and tightening the screw.

Fig. 23 Changing the battery of your FineTuner

Changing the batteries of your BabyBTE™/ActiveWear and Children's Battery Pack

When changing the batteries for the BabyBTE™/ActiveWear and Children's Battery Pack options, proceed as described for the OPUS 2 audio processor. The only difference will be how to remove and attach the battery pack cover:

1. To open the battery pack, push the lever at the back of the BabyBTE™/ActiveWear and hold it in this position (a). Use a pointed object to open the locking lever at the back of the Children's Battery Pack. Now push the lid on the battery pack backwards about 3 mm (b) and remove it by pushing it to the front (c).
2. To close the battery pack, put the lid on the housing so that it overhangs the back of the audio processor by about 3 mm (d). Gently push the lid onto the housing. When the lid is positioned correctly, it can be pushed forward (e), where it snaps in place easily. Never put the lid on the very back of the housing pushing it forward by force. This could damage the battery pack. Do not use excessive force when closing the battery pack.

Fig. 24 Changing the batteries of your BabyBTE/ActiveWear and Children's Battery Pack

WEEKLY MAINTENANCE OF YOUR OPUS 2 AUDIO PROCESSOR

Thoroughly wipe the external parts of your OPUS 2 audio processor with a tissue and let them dry completely.

Drying your OPUS 2 audio processor

The audio processor system includes a drying kit (electrical drying kit or drying box with drying capsules). For detailed information, please read the respective drying kit user manual.

Remove the batteries from your OPUS 2 audio processor and, if possible, cover the removed batteries with the stickers they were originally packed with. The audio processor need not be completely disassembled.

We recommend that you dry your OPUS 2 audio processor once a day (preferably overnight), although how often you will need to dry your equipment depends on the humidity in your environment. Excessive perspiration or high humidity in the air will require more frequent use of the drying kit.

Never swallow any drying capsules which may be included in the drying kit!

9. Troubleshooting

Once you are familiar with your Cochlear Implant System, you will not find it difficult to handle minor technical problems which are similar to those encountered in other electronic devices. Functional problems are most frequently related to batteries or cables.

Using cables or plugs not recommended or delivered by MED-EL may damage your Cochlear Implant System or cause uncomfortable stimulation and may void the warranty. If you have any questions or problems, please get in touch with your CI center or nearest MED-EL office.

Switching the audio processor on or off can cause a soft sound. You can remove the coil before operating the switch if this bothers you.

IMPORTANT

If this troubleshooting does not eliminate the problem and you do not hear sound with your Cochlear Implant System, please contact your clinic or CI center immediately.

SPEECH PROCESSOR TEST DEVICE

Fig. 25 Speech Processor Test Device

For your convenience you have been provided with a small grey Speech Processor Test Device.

The Speech Processor Test Device is a simple, optional troubleshooting tool for MED-EL audio processors intended to be used by cochlear implant users or other persons interacting with cochlear implant patients (parents, audiologists, teachers, etc.).

The Speech Processor Test Device is not necessary for the function of your audio processor, it is just intended to help detect most common functional audio processor problems like defective coil cables, defective audio processor microphones, weak batteries or other minor defects that might cause improper functioning of the audio processor.

If you suspect a malfunction of your audio processor, contact your CI center or MED-EL or try the following procedure:

Switch on the OPUS 2 audio processor and make sure that it is supplied with batteries. Place the coil underneath the Speech Processor Test Device (see Fig. 25). The coil will position itself correctly due to magnetic attraction.

When speaking into the microphone, the red light on the Speech Processor Test Device should flicker in the rhythm of your voice. If the red light does not light or is on constantly, try the following steps:

- Adjust the volume setting. By using the appropriate loudness setting, you should be able to recognize the flickering of the LED in the rhythm of your voice.
- Change the batteries.
- Replace the existing cable with a substitute cable.

We recommend you try these steps independent of the use of your Speech Processor Test Device. If these measures are not successful, immediately contact your CI center or MED-EL. Do not try to open the audio processor or to disassemble the coil as this will cause damage to the device and immediately voids any warranty.

The Speech Processor Test Device should be handled with care to achieve maximum lifetime and ensure proper function. Do not expose your Speech Processor Test Device to conditions other than those suitable for your OPUS 2 audio processor (see also Chapter 7, General precautions and warnings).

FINETUNER

The FineTuner transmits commands to the OPUS 2 audio processor via a radio frequency (RF) link. If the OPUS 2 does not respond to FineTuner commands, the below describes potential reasons for this occurring and provides information to assist you in solving the problem:

- The OPUS 2 is out of the FineTuner's operating distance. To overcome this you should move the FineTuner closer to the OPUS 2.
- The FineTuner keyboard lock is active. In this case follow the instructions for the unlocking function as described in Chapter 5, OPUS 2 audio processor, FineTuner, FineTuner functions.
- Interference from other electronic or electrical equipment is present that blocks the transmission. To eliminate this interference you need to move the FineTuner closer to the OPUS 2 and/or go to a different location.
- The OPUS 2 and the FineTuner are not synchronized. In this case you need to refer to the section described in Chapter 5, OPUS 2 audio processor, FineTuner, How to configure your FineTuner.
- In the case of a suspected malfunction of the FineTuner you need to remove the battery and re-insert it after a few minutes as described in Chapter 8, Care and maintenance, Batteries, Changing the battery of your FineTuner.
- The FineTuner battery is low. In this case you need to replace the battery as described in Chapter 8, Care and maintenance, Batteries, Changing the battery of your FineTuner.
- The desired command in the OPUS 2 has been disabled by your audiologist during fitting. To enable this command you will need to contact your clinic, CI center or MED-EL.
- The red indicator light in the OPUS 2 has been disabled by your audiologist during fitting. To enable the red indicator light you will need to contact your clinic, CI center or MED-EL.

Additional troubleshooting information

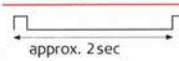
- If you or your child have used the T (telecoil) or MT (microphone and telecoil) settings and are unable to return to the M (microphone) signal source input with the FineTuner, you need to switch the audio processor off and on. When the audio processor is switched on again it will automatically start with the M (microphone) setting activated.
- If you or your child have lost the FineTuner please contact your clinic, CI center or MED-EL immediately and ask for a replacement.

OPUS 2 RED INDICATOR LIGHT

The red indicator light on the front of the audio processor flashes with different patterns to indicate different conditions. If the indicator light begins flashing, use the following tables to determine the cause.

Your audiologist can deactivate the blinking signals permanently (except error and program change patterns) if you prefer this.

Error patterns

Blinking pattern	Meaning	Action to take	Remarks
 approx. 2 sec	Electronic problem or temporary processor disturbance	Switch processor off. Switch processor back on.	If the blinking persists, the audio processor must be replaced.
 approx. 2 sec	Selected position is not programmed, or there has been a program failure	Select another position.	If the blinking persists, the processor should be reprogrammed by the clinic.
 approx. 2 sec	Electronic problem or program failure	Switch processor off. Switch processor back on.	If the blinking persists, the processor must be reprogrammed.
 approx. 2 sec	Electronic problem or temporary processor disturbance	Switch processor off. Switch processor back on.	

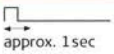
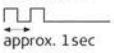
Warning patterns

Blinking pattern	Meaning	Action to take	Remarks
 approx. 1 sec	Batteries empty	Switch processor off. Change the batteries. Switch processor back on.	If the processor is not switched off, the red indicator light will continue to blink.
	Maximum or minimum value of volume or audio sensitivity range reached	Stop pushing button(s) on FineTuner.	

Confirmation pattern

Blinking pattern	Meaning	Action to take	Remarks
Brief flash of red indicator light	FineTuner command received and accepted	None	IMPORTANT: Pressing the Default key on your FineTuner only affects volume and audio sensitivity. The program position does not change.

Program change pattern

Blinking pattern	Meaning	Action to take	Remarks
 approx. 1 sec  approx. 1 sec  approx. 1 sec  approx. 1 sec	Program 1 to 4 selected	None	The red indicator light will blink depending on the selected program position. IMPORTANT: These blinking patterns start like the battery empty pattern.

Status pattern

Blinking pattern	Meaning	Action to take	Remarks
 approx. 3.5 sec	The processor is initialised and working	None	A clicking sound may be perceived with active telecoil whenever the indicator light blinks.

PRIVATE ALERT

The private alert feature allows adding an acoustic warning signal to the audio signal. This added signal is audible only to the user of the audio processor and can be adjusted in 8 loudness steps. Your audiologist will set the loudness accordingly.

Battery low warning signal

If the battery voltage falls below a certain level, four short warning beeps will be generated approximately every 14 seconds. You are still able to hear, but should change the batteries of the OPUS 2 audio processor as soon as possible.

End of range reached warning signal

If a maximum or minimum value of volume or audio sensitivity has been reached, a continuous beeping signal is audible for the user as long as the key of the FineTuner is pressed.

Confirmation signal

If a command from the FineTuner has been executed successfully by the OPUS 2 audio processor, a confirmation beep is audible for the user of the audio processor.

The two warning signals and the confirmation signal may be deactivated permanently by your audiologist if your prefer this.

FINETUNER INDICATOR FUNCTIONS

Three indicator lights with different colors (left and right: amber; center: red [warnings]) indicate various conditions of the FineTuner.

Keyboard locked

If you press a key while the keyboard is locked, the red indicator light comes on. For power saving reasons the red indicator light goes off after 5 seconds even if the key is still pressed.

Transmitting

If a key is accepted and the FineTuner transmits commands to the audio processor, the left or right or both indicator lights (depending on the current side selected) blink synchronously to the transmitted signals. To save energy, the FineTuner stops transmitting (and the indicator light blinking) after 3 seconds even if the key is still pressed.

Switch to side

If the FineTuner is programmed for two different audio processors (i.e. in case of bilateral users), the left indicator light illuminates when pressing , the right indicator light illuminates when pressing and both indicator lights illuminate when pressing . To save energy, any indicator light goes off after 5 seconds even if the key is still pressed (if is pressed for more than 5 seconds, the FineTuner enters the program mode, see below).

Low battery

The FineTuner checks the battery status after each transmission to the audio processor. If a low battery status is detected, the red indicator light (center) blinks in a regular pattern (⌐¬⌐¬⌐¬ - red indicator light on your FineTuner goes on 3 times).

Configuration successful

If configuration of your FineTuner (see Chapter 5, OPUS 2 audio processor, FineTuner, How to configure your FineTuner) was successful, or if the automatic keyboard lock feature was successfully activated/deactivated, both amber indicator lights will illuminate for approximately one second.

Program mode

If is pressed for more than 5 seconds (when unlocked; see Chapter 5, OPUS 2 audio processor, FineTuner, FineTuner functions for locking/unlocking instructions), the FineTuner enters the program mode. The three indicator lights start flashing. When the red indicator light is on, the two amber indicator lights are off and vice versa. Flashing stops and the program mode is left after 5 seconds or earlier when a correct key is pressed.

10. Technical data

AUDIO PROCESSOR

Dimensions of OPUS 2 audio processor (mm) [1]

Weight [1]

12.4 g (0.437 oz) (including batteries)

Power supply

3 hearing aid batteries type 675 zinc air (1.4 V)

Hardware

- Fully digital signal processing
- Various parameters programmable
- 4 programs selectable
- Up to 12 band pass filters; filter characteristics programmable
- Non-linear amplification programmable
- Frequency range: up to 10,000 Hz
- Audio processor self test: checksum on programs, continuous parity check
- Automatic Gain Control (AGC) configurable
- FineTuner commands can selectively be disabled

[1] typical value

COIL

The coil connects the OPUS 2 audio processor with the implant. It sends both energy and the coded acoustic signal through the skin to the implant. A small magnet is located in the center of the coil to hold it in place on the head over the implant package. The magnet strength can be adjusted by your audiologist or clinical staff to meet your individual needs.

If you notice any signs of skin irritation around the coil, contact your clinic or CI center.

MED-EL offers different types of coils.

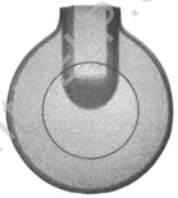


Fig. 7 D Coil

Fig. 8 COMT+/COMT+ P coil

FINETUNER

Dimensions [1]

Length: 85.5 mm (3.336 in.)
Width: 54 mm (2.126 in.)
Height: 6.3 mm (0.248 in.)
Weight: 33 g (1.164 oz) (incl. battery)

Controls/Indicators

- Default key
- Volume keys
- Sensitivity keys
- Program selection keys
- Input selection keys
- Processor selection keys
- Indicator lights: 1 red LED for alarm and 2 amber LEDs for indicator functions

Power supply

- One lithium/manganese dioxide battery type CR2025 (3 V)
- Typically, battery life is expected to be more than 6 months

Classification

- 47 CFR Part 15 Low Power Transmitter below 1705 kHz – US
- Short Range Device (SRD) according to ERC/REC 70-03 Annex 9 (band aa) and Annex 12 (band b) – EU
- Equipment class 3 – EU

Materials

Mixture of polycarbonate and acrylonitrile-butadiene-styrol polymer (PCABS)

Temperature and humidity range

Operating temperature range: 10 °C (50 °F) to 45 °C (113 °F)
Storage temperature range: –20 °C (–4 °F) to 60 °C (140 °F)
Relative humidity range: 10 % to 90 % (at or above 31 °C/ 88 °F)
10 % to 93 % (below 31 °C/88 °F)

Radio frequency (RF) link

Carrier frequency: 9.07 kHz (±0.7 %)
Type of modulation: phase shift keying (PSK)
Maximum RF output power: 11.7 dBµA/m @ 10 m
Maximum operating distance: ~ 1.15 m (3.77 ft.)

[1] typical value

Applicable in Canada only:
This Category II radiocommunication device complies with Industry Canada Standard RSS-310.

Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Ce dispositif de radiocommunication de catégorie II respecte la norme CNR-310 d'Industrie Canada.

L'utilisation de ce dispositif est autorisée seulement aux deux conditions suivantes : (1) il ne doit pas produire de brouillage, et (2) l'utilisateur du dispositif doit être prêt à accepter tout brouillage radioélectrique reçu, même si ce brouillage est susceptible de compromettre le fonctionnement du dispositif.

Applicable in the USA only:
This device complies with Part 15 of the FCC Rules.
Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Warning: Changes or modifications made to this equipment not expressly approved by MED-EL may void the FCC authorization to operate this equipment.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

SYMBOLS

CE 0123

The OPUS 2 audio processor and the FineTuner are in compliance with EU Directive 90/385/EEC (Active Implantable Medical Devices/AIMD).

CE mark applied in 2006

The OPUS 2 audio processor and the FineTuner (RF link) comprise "Class 2" radio equipment under the R&TTE directive.

Hereby MED-EL declares that the OPUS 2 audio processor and the FineTuner (RF link) are in compliance with the essential requirements and other relevant provisions of EU Directive 1999/5/EC (Radio Equipment and Telecommunications Terminal Equipment/R&TTE). The Declaration of Conformity can be obtainted directly from MED-EL Worldwide Headquarters (for address see Chapter 11, Appendices).

MR unsafe

Caution, consult accompanying documents (manual)

Type BF
(IEC 60601-1 / EN 60601-1)

Non-ionizing radiation (FineTuner)

Applicable in Bulgaria only:
The OPUS 2 audio processor and the FineTuner (RF link) are in accordance with the Ordinance for essential requirements and conformity assessment of radio equipment and telecommunications terminal equipment.

Fragile; handle with care

Relative humidity

Temperature limit

The OPUS 2 audio processor, the FineTuner and the Speech Processor Test Device are in compliance with EU Directive 2002/96/EC (Waste Electrical and Electronic Equipment/WEEE).

The WEEE logo () on the product or in this user manual indicates that this product must not be disposed of or dumped with your other household waste. You are liable to dispose of all external components of your MAESTRO Cochlear Implant System by returning them to your local MED-EL subsidiary or distributor. Isolated collection and proper recovery of your electronic and electrical waste equipment at the time of disposal will allow us to help conserve natural resources. Moreover, proper recycling of the electronic and electrical waste equipment will ensure safety of human health and environment.

Applicable in Europe only:
The OPUS 2 audio processor and the FineTuner (RF link) may be operated in:

AT	BA	BE	BG	CH	CY
CZ	DE	DK	EE	ES	FI
FR	GB	GR	HR	HU	IE
IS	IT	LI	LT	LU	LV
MK	MT	NL	NO	PL	PT
RO	SE	SI	SK	TR	YU

SPEECH PROCESSOR TEST DEVICE

The Speech Processor Test Device is in compliance with EU Directive 2004/108/EC (Electromagnetic Compatibility/EMC).

CE mark applied in 2005

GUIDANCE AND MANUFACTURER'S DECLARATION

Tables according to IEC 60601-1-2 for OPUS 2

Electromagnetic emissions – for all equipment and systems

The OPUS 2 is intended for use in the electromagnetic environment specified below. The customer or the user of the OPUS 2 should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The OPUS 2 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The OPUS 2 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Electromagnetic immunity – for all equipment and systems

The OPUS 2 is intended for use in the electromagnetic environment specified below. The customer or the user of the OPUS 2 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	< 5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 sec	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the OPUS 2 requires continued operation during power mains interruptions, it is recommended that the OPUS 2 be powered from an uninterrupted power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE U_T is the a.c. mains voltage prior to application of the test level.

Electromagnetic immunity – for equipment and systems that are not life-supporting

The OPUS 2 is intended for use in the electromagnetic environment specified below. The customer or the user of the OPUS 2 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the OPUS 2, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1.17 * \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.17 * \sqrt{P}$ 80 MHz to 800 MHz $d = 2.33 * \sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a: Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the OPUS 2 is used exceeds the applicable RF compliance level above, the OPUS 2 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the OPUS 2.
b: Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the OPUS 2 – for equipment and systems that are not life-supporting

The OPUS 2 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the OPUS 2 can help prevent electromagnetic interference (resulting in the perception of a "buzzing sound") by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the OPUS 2 as recommended below according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.17 * \sqrt{P}$	80 MHz to 800 MHz $d = 1.17 * \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.33 * \sqrt{P}$
0.01	0.12 (0.39 ft.)	0.12 (0.39 ft.)	0.23 (0.75 ft.)
0.1	0.37 (1.21 ft.)	0.37 (1.21 ft.)	0.74 (2.43 ft.)
1	1.17 (3.84 ft.)	1.17 (3.84 ft.)	2.33 (7.64 ft.)
10	3.70 (12.14 ft.)	3.70 (12.14 ft.)	7.39 (24.25 ft.)
100	11.70 (38.39 ft.)	11.70 (38.39 ft.)	23.30 (76.44 ft.)

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

11. Appendices

WARRANTY, GUARANTEE AND REGISTRATION CARD

Our warranty is in agreement with statutory warranty claims.

MED-EL grants a three-year guarantee for the OPUS 2 audio processor system.

This warranty exclusively covers product failures; it shall not apply to any MED-EL product subjected to physical or electrical abuse or misuse, or operated in any manner inconsistent with the applicable MED-EL instructions.

Statutory warranty claims shall not be granted unless the registration card is completed and returned to MED-EL within 30 days of the initial fitting for newly purchased systems. The warranty period for the OPUS 2 audio processor system begins with the date of first audio processor fitting.

The implant itself is covered by a 10-year warranty. MED-EL shall provide a new implant free of charge if the implant fails due to a mechanical or electrical defect caused by MED-EL. The warranty period for the implant begins with the date of implant surgery and depends on the completion and return of the registration form within 30 days.

Guarantees exceeding statutory warranty periods shall not be granted unless the registration form is completed and sent to MED-EL.

Please ensure that you and your clinic complete both the registration card and registration form (CI patient card), and return them to MED-EL via registered mail.

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